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# Proceedings of the WORKSHOP ON MEASUREMENT QUALITY ASSURANCE FOR IONIZING RADIATION

Held at  
National Institute of Standards and Technology  
Gaithersburg, Maryland  
March 16-18, 1993

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## FOREWORD

The Workshop on Measurement Quality Assurance for Ionizing Radiation was held at the National Institute of Standards and Technology Administration Building in Gaithersburg, Maryland. This workshop is a sequel to a previous workshop, "Workshop on Radiation Survey Instruments and Calibrations," held in 1984 and organized under the auspices of the National Bureau of Standards. This workshop was held to review the status of secondary level calibration accreditation programs, review related measurement accreditation programs, document lessons learned, and to present changes in programs due to new national priorities involving radioactivity measurements.

This document is a compilation of 45 out of the 63 papers/posters that were presented at the Workshop on Measurement Quality Assurance for Ionizing Radiation. Minor editing has been done to correct errors in punctuation, use of acronyms, consistency, and spelling. Each paper was edited as a separate item and then all papers were formatted to give the document a uniform appearance. The author assumed responsibility for the overall quality of the paper and graphics.

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The following individuals organized the meeting and developed the meeting program:

Elmer Eisenhower (Health Physics Society)  
Tom Heaton (U.S. Federal Drug Administration [CDRH])  
Ken Swinth (Pacific Northwest Laboratory)  
Mary Rosenfeld (American Association of Physicists in Medicine)  
Pam Dukes (Conference of Radiation Control Program Directors)  
Marshall Cleland (Council on Ionizing Radiation Measurements and Standards)  
Col. Dave Case (U.S. Air Force)  
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R. Tom Bell (U.S. Department of Energy, EH)  
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Donald O. Nellis (NRC)

We wish to express appreciation for our sponsors:

American Association of Physicists in Medicine  
Conference of Radiation Control Program Directors  
Council on Ionizing Radiation Measurements and Standards  
Health Physics Society  
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## QUALITY ASSURANCE AND THE COMPETITIVE EDGE

Curt Reimann<sup>(1)</sup>

In Katherine Gebbie's opening remarks, she mentioned that the subject of competitiveness has really "heated up." It simmered all through the 1980's. From the point of view of the National Institute of Standards and Technology (NIST), "competitiveness" really reached the boiling point during the past few years. Much of it was associated with the changing of our name from the National Bureau of Standards (NBS) to NIST. One piece of the whole competitiveness puzzle is the area of quality and the whole set of issues (including quality assurance) that are built around it. For the last five years, the Malcolm Baldrige National Quality Award has been in the eye of that storm. We are fortunate that the Baldrige Award has become a Presidential Award, beginning with President Reagan in 1988. President Bush continued that tradition, and there are encouraging signs that the Clinton Administration will follow suit.

Today, I'd like to paint a panoramic picture of what we are trying to achieve for our country with the award. I think you will see that what is going on here today—particularly the customer orientation that Katherine and Ken Inn projected about the role of NIST and wanting to make a difference in the outcomes of your programs—will be seen to fit with what we are trying to do in the larger sense.

First, the Baldrige Award program is trying to strategically create a value system to instill real meaning to the underlying concepts of quality. We are trying to have this tied to a diagnostic tool so that we can obtain feedback for the applicants. This feedback is a very important part of the overall process and serves as a vehicle for cooperation to bring people together (just as you are here today). For example, today we have two classes meeting down the hall where our examiners/evaluators for 1993 are receiving three days of training to prepare for the 1993 award cycle. Finally, everything we do is a dynamic process subject to annual review and improvement.

The award criteria are built upon a set of core values. The first of these values is customer-driven quality. Katherine was talking about making a difference in measurement. Perhaps the NBS or NIST of 50 years ago would have been very content with getting the right answer in a calibration or a basic standard and might not have worried too much about how those measurements were used. I would not say that NBS was detached from the field, but I think its responsibilities were defined in a more

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<sup>(1)</sup> Malcolm Baldrige National Quality Award, Office of Quality Programs, National Institute of Standards and Technology.

narrow sense. I think now we are taking a much harder look at making a difference in measurement. A lot of emphasis at NIST (and NBS) actually derives from some of the early work of the radiation community. That group's concern with measurement assurance was some of the best and earliest work here that reflected this new customer orientation. Interestingly, we have had three people from the radiation area working in very important parts of the Baldrige Award program—beginning with Bert Coursey and, currently, Jackie Calhoun and Wayne Cassatt. From this linkage with the radiation area, we have adopted a lot of that philosophy and, hopefully, are getting that philosophy out to other institutions in the United States. From the basic core values, you can see we are not just talking about quality assurance. We are talking about productivity, employee involvement, development of people, and cycle time or responsiveness. We are really talking about productivity-related issues, as well as quality. This is not quality defined as the "high-priced spread," so to speak; it is the quality of total operations, which is reflective of delivering customer value and of the effectiveness of the delivering organization.

We have worked with the private sector (the Baldrige Award program is funded heavily by the private sector) to develop a new framework for defining all the interrelationships for an organization to serve the customer well and in a very productive way. This framework is now widely used, not only in the United States, but around the world. We distribute approximately 200,000 copies of the award criteria per year. The criteria have given a new, more technical life to the very elusive and sometimes arbitrary subject of quality. You can see that we are really focusing on the dual goals of serving the customer well and serving the customer in a way that is productive to the delivering organization.

One of the building blocks is what we call management of process quality. The role of measurement and measurement assurance occurs not only in the design and introduction of quality products and services, but also in the management of the processes. As most of you know, measurements have become more process-oriented and prevention-based, rather than after-the-fact and inspection-based. The quality assessment function within the management of the process quality category of the award criteria would look at the adequacy and the appropriateness of the measurements used throughout the whole productive enterprise. We feel that measurement quality assurance is really built into the basic set of criteria. Everywhere we go, we find that the more technically oriented companies are doing more in the area of measurement quality assurance. They are also being driven in the direction of more productive measurements; in other words, the cost of measurement is also an issue. We expect this to be a very big consideration as we hope to extend the award program to health care. Health care measurement (many of you are involved in aspects of this) is a major part of the cost (some say \$50 or \$60 billion, or more, of the total cost) of the health care enterprise. The productivity of those measurements is a consideration as well as their accuracy. As time goes on, I think we will see this clash between a greater need for accuracy and reliability on one hand, and the cost factors on the other. We are trying to develop frameworks for tying all these concepts together, nationally. I would consider that this is probably our most important work. The giving of awards is nice—with all the pomp and circumstance—but actually, in terms of daily working tools, we feel this is the more significant direction.

I would like to say a word or two about the award evaluation process. We develop consensus criteria in meetings very much like this one. We focus on the values, processes, and systems needed to execute a good review of applicants for the award. We have a four-stage review process. It is a peer review, which, at the time it was invented five years ago, was unlike any review in the world. A company that "survives" all the way from the beginning of the evaluation process down to a site visit

and judges' review receives about 500 hours of evaluation, ending with a feedback report. So you can see that it is a very comprehensive, careful review with multiple input. All applicants for the award receive feedback reports, which is a very elaborate and detailed information transfer process. This is an area of continuous improvement opportunities for the Baldrige program to provide detailed, as well as timely, feedback.

To date, the award winners have given more than 10,000 presentations around the country at their own expense, and they have reached literally hundreds of thousands of organizations. Their activities have triggered networks and actions around virtually all of the states.

At the risk of belaboring a point, I would say again that we are really talking about two thrusts in the Baldrige Award criteria: 1) delivering customer value and 2) improving the productivity and overall effectiveness of the organization. This is what the competitive pressures are all about. You can always deliver on one if you spend enough. You can always improve your productivity if you do not care about the quality of your output. The challenge for any organization is to be able to blend those two, and the great organizations around the world are finding new and better ways of doing just that. A lot of those lessons have been taught to us by the Japanese.

The five-year-old Baldrige Award program illustrates that, through cooperative government/industry joint partnerships, we can create a meaningful basis for progress, cooperation, and sharing. More of that is occurring now than ever before. We have had about 600 people serve on our boards. Those people, in turn, have given about 10,000 or more presentations around the country. With very little federal expenditure, the Award Program has had an enormous impact by a "multiplier effect," which I think is consistent with the kind of multiplier effects that are tied up with meetings like this. There are grass-roots networks, state programs, community programs, and programs of trade and professional associations now focusing on quality. There is now a lot of interest in other sectors, such as health care and education. (In fact, right after this meeting I am going to another meeting at the National Education Association, where people are talking about business-education cooperation, based in part on quality-related management strategies.) There have been numerous Baldrige-like awards (probably several score of them), at company, state, and local levels. Several international awards have been set up. For example, the Quality Awards in the European community, South America, Australia, and Mexico are just a few recent instances of new awards built very tightly around what we have done here. With a great deal of academic interest and a lot of spin-off training, we are trying to create a common language for communicating and cooperating in the area of quality management.

We receive many inquiries for a comparison of the award and the International Organization for Standardization (ISO) standards. We try to point out that the award emphasizes customer-driven, market-oriented quality. Much more than in the past, it means tracing what customers actually do with products and services, and whether the products and services are actually solving their problems. The award provides a more comprehensive view of the customer relationship. It is very sensitive to looking for the existence of continuous improvement in all operations of the company. There is a lot of discussion these days about organizational learning. We believe that we are working on an organizational learning model of how you collect information and subsequently use that information to improve processes on a continuous basis. Because the criteria are oriented toward results and productivity, there are many results indicators (including those in the area of public responsibility, such as environmental concerns, health, and safety). We are trying to link processes and results by key indicators and analysis. We are trying to work collectively with industry to look at mechanisms

for analyzing and using data rapidly to improve processes. The Baldrige Award emphasizes stretch standards and stretch goals. One of our award winners has improved defect levels 150-fold since winning the award a few years ago and is continuing to eliminate defects. Admittedly, defect elimination is only one part of the overall quality equation. We are trying to create a device for internal self-assessment, because we feel that not everyone wants to compete for awards, nor is everybody eligible to compete. If they use a particular framework that others are using, they can do a self-assessment and share information and drive improvement that way.

We see that there is a major challenge of management in a world where there are standards like ISO standards and award criteria that drive improvement. The challenge is really to understand the content of each and to avoid too much emphasis on documentation, and locking in traditional practices and structures, and blending in terms of using standards to meet near-term commitments to customers and using award criteria to drive longer-term improvement. Right now there is probably a lot of confusion over these two systems because they are both very visible, nationally. Since they both relate to quality and quality improvement, quality assessment, and quality assurance, there is a tendency to compare and confuse them. I think that over the next few years we will see that situation clarified. In any case, a number of companies have embarked on an effort to achieve a better integration.

I will close by showing a picture of the award itself. It is a Steuben crystal statue 14 inches tall. It contains a gold medallion with the Baldrige Award logo and the Presidential Seal. The Baldrige Award might look good some day on your boss's desk! I commend your interest in it. On that note, I will close. Thank you for inviting me to your important meeting.

*Note: The award criteria and materials on the award winners are available from the Office of Quality Programs, (301) 975-2036.*

# **FUNDAMENTALS OF MQA**

Session Chair  
**Kenneth Inn, NIST**

Tuesday  
March 16, 1993

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# CIRMS ROLE IN COORDINATING MQA PROGRAMS

Marshall R. Cleland<sup>(1)</sup>

*Abstract* - This paper presents the purposes, functions, and expected benefits of the Council on Ionizing Radiation Measurements and Standards (CIRMS), a new association of ionizing radiation measurers and users. The initial activities are reported, including the program of the inaugural meeting. The organizational structure, members of the executive committee, and chairmen of the standing committees are also given. Governmental and professional organizations, industrial corporations, and interested individuals may join. Broad participation in CIRMS will support the principles of measurement quality assurance for ionizing radiation.

## INTRODUCTION

CIRMS is a new voice in the diverse community of ionizing radiation measurers and users. It will focus attention on current issues and support the objectives of measurement quality assurance (MQA) in this field. The Council will function through an annual meeting, through the activities of various committees and subcommittees, and through the sponsorship of seminars and workshops for the advancement of ionizing radiation measurements and standards.

## PURPOSES AND FUNCTIONS

- Provide a forum for discussing common national ionizing radiation measurement and standards problems.
- Study and gather information on the present and future needs of the ionizing radiation measurement community.
- Define and prioritize needed work in ionizing radiation measurements and standards, and recommend actions to be taken.

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<sup>(1)</sup> Radiation Dynamics, Inc., Edgewood, New York 11717.

- Provide information and data useful to the Ionizing Radiation Division of the National Institute of Standards and Technology (NIST) in pursuing its lead role as the U.S. national laboratory for ionizing radiation physical standards.
- Provide information and data useful to secondary standards laboratories and radiation measurers in pursuing improvement of the national support system for radiation measurement.
- Disseminate information concerning, and enhance the technical basis for, the development of national and international written standards for ionizing radiation measurement.
- Hold or sponsor meetings, seminars, and workshops to advance ionizing radiation measurements and standards.

### **EXPECTED BENEFITS**

- Creation of opportunities for long-range planning, and development of consensus views on ionizing radiation measurements and standards.
- Improvement of communication and coordination within the ionizing radiation community on issues of measurements, standards, and MQA.
- Identification and prioritization of the most important work needed in ionizing radiation measurements and standards.
- Development of a partnership between the ionizing radiation community and NIST on questions of national standards, transfer standards, MQA, calibrations, and traceability.
- Improved dissemination of information on the written standards for ionizing radiation measurement.

### **FORMATION OF CIRMS**

The need for this new organization can be traced to the congressional Cannon Report of 1981, which recommended a system of secondary laboratories. NIST's ability to interact with these secondary laboratories was diminished by the major restructuring and reduction in staff of its Ionizing Radiation Division in 1988. Letters were written to NIST by the U.S. Council for Energy Awareness (USCEA), Health Physics Society (HPS), and American Association of Physicists in Medicine (AAPM) in 1989 expressing concern over NIST's support for ionizing radiation programs.

In response, NIST offered to work in collaboration with other groups in the community of ionizing radiation measurers and users on joint studies to evaluate priorities. However, the difficulties of working one-on-one with many different organizations led in 1990 to the idea of forming a council, which would include the whole national radiation measurement system: users, research organizations, secondary and tertiary laboratories, and NIST. An example of how useful this can be is the Council on Optical Radiation Measurements (CORM), which was formed for analogous purposes 20 years ago and now has 500 members serving the optical radiation community.



## **INITIAL ACTIVITIES**

An organizational meeting, held at NIST on February 26, 1991, was attended by representatives from 18 groups: professional societies, federal agencies, and industrial associations. The purposes, functions, and need for CIRMS were discussed, and a decision to proceed was made by a consensus of the participants.

The organizing committee held further meetings and proposed a slate of officers on June 17, 1991. Ballots were mailed to the participants of the organizational meeting and the officers were elected on February 10, 1992. The officers met with the organizing committee at NIST on March 31, 1992, and accepted their positions. An executive committee was formed consisting of the officers and representatives from NIST and from an industrial association. Invitations to join CIRMS were sent to organizations, corporations, and individuals starting in April 1992.

The inaugural meeting of CIRMS was held at NIST on October 22-23, 1992, with 64 participants. The proposed bylaws and committee structure were approved. The chairmen and initial members of the standing committees were selected. Formal presentations on various topics of interest were given by invited speakers. The diversity of the ionizing radiation community is indicated by the titles of these presentations, which are listed below in the program of the meeting.

### **PROGRAM OF THE INAUGURAL MEETING, OCTOBER 22-23, 1992**

- Welcoming Remarks Katharine B. Gebbie
  
- The Objectives of CIRMS Randall S. Caswell
  
- Commonality of Measurement and Standards Problems Bert M. Coursey
  
- Bringing Diverse Uses and Common Interests Together Peter R. Almond
  
- CIRMS Functions and Bylaws Elmer H. Eisenhower
  
- CIRMS Committee Structure R. Thomas Bell
  
- Committee Membership and Future CIRMS Activities Marshall R. Cleland
  
- After-Dinner Address:  
"Living with Radiation" Eric J. Hall

## PRESENTATIONS ON IONIZING RADIATION APPLICATIONS AND ISSUES

### "The Diversity of Ionizing Radiation Measurement Needs"

- Radiation Oncology Peter R. Almond
- Diagnostic Radiology H. Thompson Heaton
- Industrial Radiation Processing Harry Farrar
- Industrial Radiography Harold Berger
- Nuclear Energy Radioactivity Felix M. Killar
- Nuclear Power Materials Dosimetry Charles Z. Serpan
- Defense Eric E. Kearsley
- Radon Carl V. Gogolak
- Environmental Radioactivity Kenneth G. W. Inn
- Health Physics R. Thomas Bell
- Nuclear Medicine William C. Eckelman

CIRMS was incorporated in Maryland on January 5, 1993, as a non-profit, educational and scientific organization. The first meetings of the CIRMS committees were held at NIST on March 15, 1993. Attendance was curtailed by the "Blizzard of '93," but substantial progress was made in defining goals and preparing agendas for future activities.

### ORGANIZATION OF CIRMS

The mailing address for communications about membership and council activities is given below, along with the registered address of the corporation:

Mailing Address  
CIRMS Secretariat  
P.O. Box 3418  
Gaithersburg, MD 20885

Registered Address  
CIRMS, Inc.  
18924 Falling Star Road  
Germantown, MD 20874

The present officers and members of the executive committee are listed below:

- President Marshall R. Cleland  
Radiation Dynamics, Inc.
- 1st Vice President Peter R. Almond  
University of Louisville

- 2nd Vice President R. Thomas Bell  
U.S. Department of Energy
- Secretary-Treasurer Elmer H. Eisenhower  
NIST (retired)
- Executive Committee Anthony J. Berejka  
RadTech International North America
- Executive Committee Randall S. Caswell  
NIST

The activities of the council are conducted by the following standing committees and subcommittees:

- Science and Technology Committee  
Chairman: H. William Koch, American Institute of Physics (retired)  
Functions: Studying and gathering information on present and future needs; defining and prioritizing needed work and recommending actions; providing information and data useful to NIST, and to secondary standards laboratories and radiation measurers.
- Medical Subcommittee  
Chairman: H. Thompson Heaton, Center for Devices and Radiological Health, U.S. Food and Drug Administration  
Interests: Radiation Oncology, Radiology, and Nuclear Medicine.
- Public/Environmental Radiation Protection Subcommittee  
Chairman: Carl B. Gogolak, Environmental Measurements Laboratory, U.S. Department of Energy  
Interests: Nuclear Energy, Defense, Environment and Radon.
- Occupational Radiation Protection Subcommittee  
Chairman: Kenneth L. Swinth, Battelle Pacific Northwest Laboratories  
Interests: Personnel Monitoring, Bioassay, and Instrumentation.
- Radiation Effects on Materials Subcommittee  
Chairman: Walter J. Chappas, University of Maryland  
Interests: Nuclear Power, Radiation Processing, Medical Device Sterilization, and Radiation Hardness.
- Program Committee  
Chairman: Anthony J. Berejka, RadTech International North America  
Functions: Holding and sponsoring meetings, seminars, and workshops, including the annual meeting.

- Communications Committee  
 Chairman: William H. Casson, Oak Ridge National Laboratory  
 Functions: Disseminating information concerning the development of national and international written standards, and publicizing the existence and activities of CIRMS.
  
- Membership Committee  
 Chairman: R. Thomas Bell, U.S. Department of Energy  
 Functions: Processing of applications for membership, and recommending new members to the executive committee.
  
- Finance Committee  
 Chairman: Elmer H. Eisenhower, NIST (retired)  
 Functions: Establishing and maintaining suitable procedures for collecting and disbursing monies, formulating the annual budget, recommending dues and assessments, and rendering an annual accounting.
  
- Nominating Committee  
 Chairman: The Immediate Past President

To date, the CIRMS membership includes 11 governmental and professional organizations, 10 industrial corporations, and 13 individuals. The roster is expected to increase as the existence and activities of the Council become better known.

#### **ANNUAL MEETING**

One of the principal activities of CIRMS is a formal annual meeting, which will be held in the fall of each year. The meeting program includes technical presentations and reports of committee activities. The dates and location of the next annual meeting are November 9-10, 1993, at the NIST offices in Gaithersburg, Maryland 20899, USA. The committees and subcommittees will meet on November 8.

#### **SUMMATION**

The purpose and functions of CIRMS have been defined, and the organizational activities have been completed. The officers have been elected and installed. The members of the executive committee and the standing committees have been chosen, and they have already begun working. More participants will be needed to accomplish the many tasks that will be undertaken in the future.

The purposes and expected benefits of CIRMS are sufficient reasons for its formation. Active support from the broad community of ionizing radiation measurers and users will ensure further advances in the quality and effectiveness of this important field of science and technology.

# NIST COMMITMENT TO NATIONAL MQA PROGRAMS

Randall S. Caswell<sup>(1)</sup>

*Abstract* - The program of the Ionizing Radiation Division, Physics Laboratory is discussed, especially relating to standards, calibrations, and measurement quality assurance (MQA). The NIST program is "vertically integrated," meaning that activities extend from fundamental research to measurement research to supplying services and data. Typical methods NIST uses to assure the quality of the national standards are presented. Some of the programs in x-ray, gamma-ray, electron, neutron, and radioactivity research which support MQA are presented. Examples are given of MQA activities.

## INTRODUCTION

The primary responsibility within NIST for MQA for ionizing radiations rests with the Ionizing Radiation Division, which is part of the Physics Laboratory, one of eight major Operating Units of NIST. In order to carry out its service missions, such as instrument calibration and measurement quality assurance, the Division is "vertically integrated." Vertical integration means activities stretch from fundamental research to measurement research to supplying services such as radioactivity standard sources (Standard Reference Materials or SRMs), evaluated data, calibrations, and MQA testing. All of these kinds of activities are located within the Division.

To carry out its mission, the Ionizing Radiation Division is organized into four groups, shown in the middle row of boxes in Figure 1. The Office of Radiation Measurements has the chief responsibility for outreach to the radiation community, and also provides MQA to a system of "reference laboratories" in various sectors, such as the federal government, state governments, industry, and the medical or health care industry. The major project of the Office of Radiation Measurements is MQA, as shown in the bottom row of boxes, where major projects are indicated. In the Division are three technical groups: Radiation Interactions and Dosimetry is responsible for research, measurements, and standards for x-rays, gamma-rays, and electrons. Neutron Interactions and Dosimetry is similarly responsible for neutrons, and Radioactivity for radionuclide metrology.

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<sup>(1)</sup> National Institute of Standards and Technology, Technology Administration, Department of Commerce, Gaithersburg, Maryland 20899. (Contribution of NIST. Not subject to copyright.)

## CUSTOMERS

The Ionizing Radiation Division serves a diverse community of radiation users and measurers. As indicated in Table 1, the fields of diagnostic radiology and nuclear medicine are ubiquitous, and about 15% of us may expect to receive radiation therapy during our lifetime. Over one million radiation workers are badged for radiation protection. Public concerns focus on radon in homes and buildings and on environmental radioactivity, especially when it is found in food and water.

Industrial applications of radiation, shown in Table 2, include industrial radiation processing for sterilization of medical supplies, improvement of the properties of plastics, and curing of wire insulation and organic coatings; nuclear electric power provides 22% of U.S. electricity and represents a large capital investment. Smaller industrial applications include industrial radiography and the field of radiation effects on electronic devices, important for space and military applications.

Fundamental scientific research (see Table 3) in long-term support of measurements and standards programs is carried out on the physics of radiation interactions, especially at the nanometer level, and on resonance ionization spectroscopy for atom counting which, has important potential applications in environmental radioactivity assessment. Fundamental neutron physics is carried out at the Cold Neutron Source of the NIST nuclear reactor and includes neutron lifetime measurement, neutron interferometry for testing the bases of quantum theory, and experiments with polarized neutrons.

## MEASUREMENT QUALITY ASSURANCE

The Office of Radiation Measurements, as indicated in Figure 1, has a major responsibility for MQA, especially for the creation of a national system of secondary, or reference, laboratories located where needed in both the governmental and private sectors (Inn et al. 1993). How the reference laboratory system works is indicated in Figure 2. A reference laboratory is accredited, not by the NIST Ionizing Radiation Division, but by other organizations such as the Conference of Radiation Control Program Directors (CRCPD), the Health Physics Society, the American Association of Physicists in Medicine (AAPM), or the National Voluntary Laboratory Accreditation Program (NVLAP), which operates out of NIST. The accrediting organization makes a decision whether or not to accredit a given reference laboratory based on a number of criteria, such as the technical qualifications of personnel, adequate equipment for the laboratory's job, an in-house quality control system, and, finally, satisfactory performance on MQA testing by NIST. The user's motivation for calibration or MQA testing is shown as the "driving force," which may be regulatory requirements, codes of good practice, assurance of legally defensible measurements, or simply a desire for high confidence in measurement.

A rough picture of the developing system of reference laboratories located in the state, federal, medical, and industrial sectors is shown in Figure 3. A summary of the current status of the national system of reference laboratories is presented in Table 4. The AAPM and CRCPD systems of laboratories have been well established for many years, whereas accreditation of the survey instrument laboratories by the Health Physics Society and of the federal laboratories by NVLAP is just getting underway. New programs for reference laboratories are underway for bioassay, high-level dosimetry, environmental radioactivity, and commercial radioactivity standards. The Accredited Dosimetry Calibration Laboratories of the AAPM are shown in Figure 4.

A different approach to measurement quality assurance is represented by the collaborative programs of the U.S. Council for Energy Awareness (USCEA) with the National Institute of Standards and

Technology (Gray, Golas, and Calhoun 1990). These programs are carried out by Research Associates from USCEA who are located at NIST and work closely with the NIST Radioactivity Group. The two traceability programs are Radiochemistry for the Nuclear Power Industry (see Figure 5) and for Radiopharmaceutical Manufacturers. As indicated in Figure 5, the driving force for the Radiochemistry program is regulatory requirements of the Nuclear Regulatory Commission. The program is primarily for electric power utilities and the laboratories that provide them with services, but commercial calibration source suppliers also participate. Some results from the Radiopharmaceutical program are shown in Figure 6. Largely as a result of this program, the vast majority of the proficiency test results are within 10% (the FDA requirement) of the NIST value.

Another NIST service for the radiation community is the calibration of neutron sources for neutron emission rate (McGarry and Boswell 1988). The most popular source is the  $^{252}\text{Cf}$  spontaneous fission neutron source. Some of these sources are very intense, producing more than  $10^9$  neutrons/s in a capsule the size of a pencil eraser (the actual source material is much smaller). Consequently, special facilities are required for source handling. Figure 7 shows the 1.27-meter diameter manganous sulfate bath in which sources are calibrated by activation of  $^{55}\text{Mn}$ , located behind a shielding window equipped with a remote handling arm.

## STANDARDS AND RESEARCH ACTIVITIES

### Methods for Assuring Quality of NIST Standards

The MQA services provided by NIST are of little value unless they are backed up by reliable, state-of-the-art standards, and transfer instruments or methods. How does NIST assure the quality of NIST standards? Four methods are indicated in Table 5. Intercomparisons with other national standards laboratories and leading research laboratories assure that we are all on the same international measurement scale. If the intercomparisons show disagreement, they show areas where more study is needed. Many of these intercomparisons are organized by the Consultative Committee for Measurement Standards of Ionizing Radiations (CCEMRI, from its French name), which meets at the International Bureau of Weights and Measures (Bureau International des Poids et Mesures or BIPM) in Sèvres, a suburb of Paris (see, for example, Caswell and Lewis 1992). Others are organized by the International Committee for Radionuclide Metrology (ICRM).

A second method for assuring the validity of national standards is to measure the value of the standard by several independent physical methods. For example, absorbed dose can be measured by calorimetry, ionization chamber methods, and Fricke (ferrous sulfate) dosimetry. This is perhaps the best way to gain information on systematic errors. If all methods agree, we assume the standard is fine. If methods disagree, we know where to look for problems.

A vigorous program of measurement research is necessary for developing new standards and transfer instruments and to have a deep understanding of the whole measurement process. Fundamental research helps in two ways: 1) to accomplish the goal of the fundamental research, measurement techniques of unprecedented accuracy are frequently needed—and developed and 2) fundamental research is a source of new ideas for primary standards. For example, many of our standards defined on an atomic basis have come from fundamental research. We shall now cite a few examples of the research carried out in the NIST Ionizing Radiation Division, which we expect to lead to better standards and transfer instruments on a shorter or longer time scale.

## X-Ray, Gamma-Ray, and Electron Research

The simplest way in principle of measuring absorbed dose to a material is through the temperature rise, i.e., a calorimeter. Protocols for radiation therapy with  $^{60}\text{Co}$  gamma-rays and high-energy x-rays call for the determination of the absorbed dose to water, from which the dose to the human body is determined by calculation. The usual method used for determining the absorbed dose to water has been by measuring ionization to air in an ionization chamber and correcting to water, a less direct method than the calorimeter. When calorimetric measurements were attempted, a graphite calorimeter was usually used. The graphite calorimeter, of course, has the problem of the correction from absorbed dose in graphite to absorbed dose to water. Steve Domen of NIST solved this problem by inventing the water calorimeter, shown in Figure 8. It would never have occurred to me that you could make a calorimeter out of water. The first water calorimeters did have a serious problem of calorimetric defect—excess heat produced by chemical reactions in the water. This was resolved by several workers by purifying the water to eliminate the reactions (Domen 1988). The water calorimeter is now taking its place as a primary standard for high-energy x-rays and gamma-rays.

A new idea coming out of NIST measurement research is the Laser Telemetering Dosimetry System, an R&D 100 Award winner by William McLaughlin and Marlon Walker. The experimental arrangement is shown in Figure 9. The key detector is the radiochromic dye film sensor located in the field of the radiation source. As the film is irradiated, it darkens with nanosecond time resolution, the increase in optical density being used as a measure of the radiation field. The dye film is interrogated with a He-Ne laser; the transmitted light impinging on a photodiode followed by appropriate electronics and a computer. This device has many possible applications for quick, easy, and inexpensive measurement of radiation fields in remote locations or which vary rapidly with time (Walker and McLaughlin 1990).

For many years NIST has calibrated beta-ray ophthalmic applicators used for radiation therapy of eye diseases. The usual calibration has been carried out with an extrapolation ionization chamber, the result being given in terms of absorbed dose rate averaged over an effective area for the applicator. However, the application of the laser-scanning microdensitometer (Soares 1992) to read the energy absorbed in a radiochromic dye film placed on the face of the applicator and backed by a tissue-equivalent plastic phantom has made it possible to provide the customer with much more detailed information about the applicator, as shown in Figure 10. In the lower part of the figure is an isodose plot for the applicator, giving information about the uniformity and location of the radiation dose from the applicator. The top part of Figure 10 shows a three-dimensional plot of the same information, the absorbed dose rate being given on the vertical axis. These plots are now routinely supplied with the calibration report for the applicator.

An advanced method of dosimetry now being pursued vigorously at NIST is Electron Paramagnetic Resonance (EPR) Dosimetry, also known as Electron Spin Resonance (ESR) dosimetry. This method, while not extremely sensitive, has the advantage of being suitable for post-irradiation dosimetry. Applications include radiation sterilization and processing, detecting irradiated foods, evaluating absorbed dose from irradiation accidents using bone samples or tooth enamel from the victims (Chernobyl), and measurements of bone biopsy samples in radiation beam therapy or radiopharmaceutical therapy. Figure 11 shows a typical EPR spectrometer (Kojima et al. 1993), the sample being placed in the microwave cavity in the field of a strong magnet. Figure 12 shows the typical signals received from a bone sample and an alanine sample, alanine being widely used for EPR dosimetry.



To carry out these NIST research programs, we need a wide variety of x-ray, gamma-ray, electron, and neutron sources, as well as many kinds of radioactive sources in solid, liquid, and gaseous forms. For the x-ray and electron program, an important new source is the Medical-Industrial Radiation Facility (MIRF), now being installed in the Radiation Physics Building. The basic accelerator is shown in Figure 13. It is an electron linear accelerator, push-button operable from 7 to 32 MeV in steps of 3 MeV. It will be used for dosimetry research in support of radiation therapy of cancer and industrial radiation processing, and also for development of new radiation processing technologies.

## Neutron Research

Neutron measurements are particularly important for all forms of nuclear power and for worker protection. One of the approaches to neutron standardization is through creation of well-characterized standard neutron fields in which instruments or foils can be placed for calibration. One of these fields, the  $^{252}\text{Cf}$  standard neutron field, is shown in Figure 14. The tiny neutron source is a small right circular cylinder located just above the small sphere located at the bottom of the figure. On either side of the source are located two NIST fission ionization chambers which are detectors used in many experiments. Use of two detectors at  $180^\circ$  to each other makes the experiments less sensitive to actual source position. Neutron cross-sections for fissionable isotopes are often measured in this way. In the particular experiment shown, the sphere is filled with water, with the source placed at the center, and benchmark measurements are made to check computer codes used to assure the safety of large containers used to store aqueous solutions of fissionable isotopes (Gilliam et al. 1990). Other NIST standard neutron fields include pure  $^{235}\text{U}$  and  $^{252}\text{Cf}$  fission neutron fields and thermal neutron fields located in the thermal column of the NIST reactor, reactor-filtered neutron beams at 2, 24.5, and 144 keV, calibrated cold neutron beams, a  $\text{D}_2\text{O}$ -moderated  $^{252}\text{Cf}$  neutron source, the Materials Dosimetry Reference Facility located at the University of Michigan reactor, and monoenergetic neutron beams at 0.1-1 MeV, 2-5 MeV, and 12-18 MeV can be made available from the NIST 3-MeV positive-ion Van de Graaff accelerator.

An example of advancing the state-of-the-art of precision neutron measurement comes from a fundamental neutron physics experiment being carried out on the Cold Neutron Research Facility. The experiment is a highly-accurate measurement of the neutron lifetime (Byrne et al. 1990). One of the most difficult quantities to measure in this experiment is the neutron fluence rate (often called flux) in a cold neutron beam. Figure 15 shows an apparatus designed for one of several independent methods of measuring the neutron fluence rate—in this case, by defined solid angle counting with four solid-state detectors viewing a boron foil of known boron content. The accuracy sought in fluence rate is 0.1 percent, an accuracy almost never achieved in neutron fluence measurement.

A novel new neutron personnel dosimeter is the bubble dosimeter, shown in Figure 16. The dosimeter is made of a supersaturated tissue-equivalent gel. When a single neutron interacts with a hydrogen atom in the gel, creating a recoil proton, a bubble is produced, such as are shown in the figure. The dose can be read visually, by counting the number of bubbles, or by detecting the audible "pop" made when a bubble is formed and recording that on an appropriate electronic scaler. The NIST role has been to test these instruments in both monoenergetic and distributed neutron sources (Perks et al. 1988). The bubble dosimeter at the present state of technology is a rather special purpose dosimeter for short-term measurements but lacking good long-term stability.

## Radioactivity Research

We have previously mentioned the standardization of radioactive sources and MQA testing for the radiochemistry departments of nuclear power plants and for radiopharmaceutical manufacturers, which are done in collaboration with research associates from the USCEA. Quite a different problem is the standardization of radon measurements, important for quality control of the many small companies that provide radon measurements for homes and buildings. The primary standard for radon, an alpha-particle emitting colorless noble gas, is a pulse ionization chamber (Collé, Hutchinson, and Unterweger 1989), four of which are shown at the bottom of Figure 17. Each radon alpha decay produces a large pulse that can be counted and discriminated from other events. The gas handling system is used in conjunction with the pulse ionization chambers to prepare gas samples of known activity. Gas samples can be used for measurement traceability and for MQA testing. For example, in Figure 18 is shown the results of a measurement intercomparison carried out in 1990 between many of the leading radon measurement laboratories in the world. These are difficult measurements, but the spread of values is under 8%.

Radioactivity research and development activities sometimes are called on to address some very practical problems. For example, the military services needed a calibration source for large-area alpha survey meters. NIST developed the calibration device shown in Figure 19, which is supplied with both  $^{239}\text{Pu}$  and  $^{238}\text{Pu}$  sources (Unterweger, Hutchinson, and Hodge 1993). The calibration accuracy is in the range of 2-4%.

## REMARKS

We believe that most critical dosimetry MQA needs are being met by NIST, but there are some new areas where the programs need to grow. We are looking to the Council on Ionizing Radiation Measurements and Standards (CIRMS), discussed in another paper at this meeting, for guidance on program direction and priorities. NIST is convinced that a strong research program is necessary to back up our calibration, standard reference material, and measurement quality assurance programs. We expect a steady expansion of MQA efforts, especially in the area of radioactivity. Information on radiation user needs and problems is most welcome.

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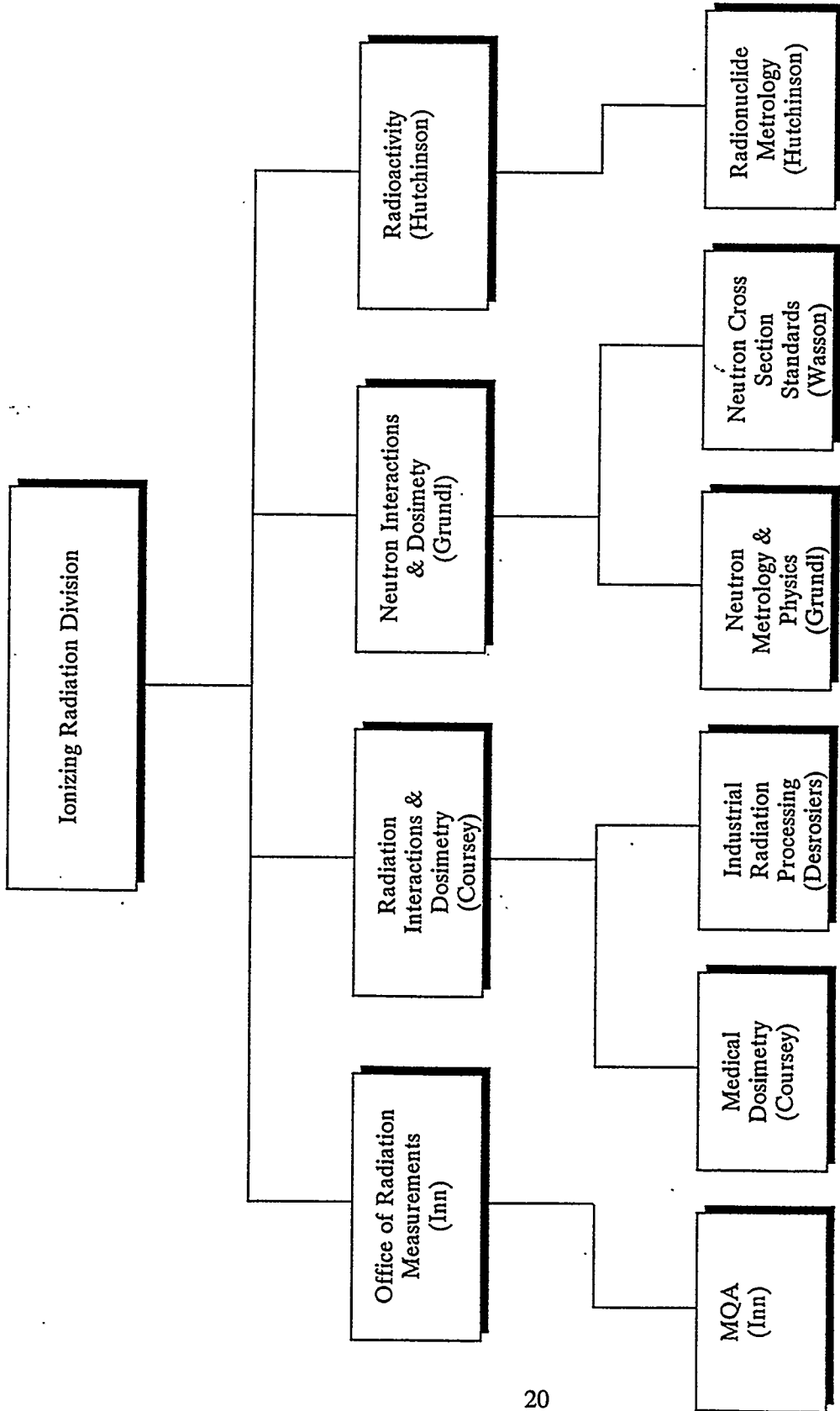


Figure 1 - Organization of the NIST Ionizing Radiation Division. Groups are shown in the middle row, and major projects in the bottom row.

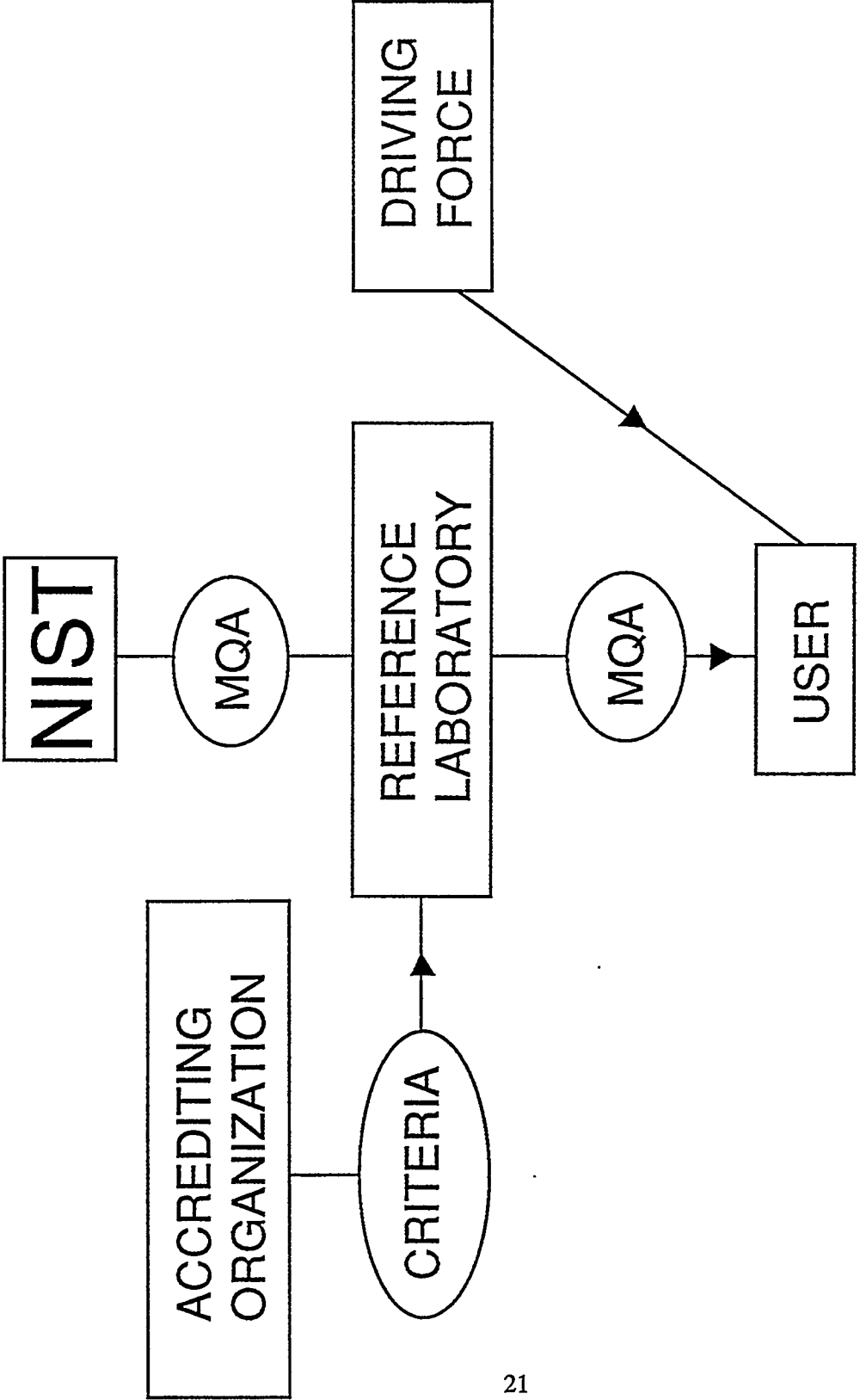


Figure 2 - Usual Structure for Measurement Quality Assurance. (See text for discussion of how this system works.)

# ASSURING RADIATION MEASUREMENT QUALITY

We Help the Nation Achieve Quality Control for Health and Safety, Industrial Productivity, and Defense and Aerospace

## NATIONAL MEASUREMENT SUPPORT SYSTEM

- Approximately a quarter million ionizing radiation sources and detectors require calibration or measurement standards in this country.
- There are 100,000 dental, 135,000 diagnostic, and 5,600 industrial x-ray facilities in the U.S.

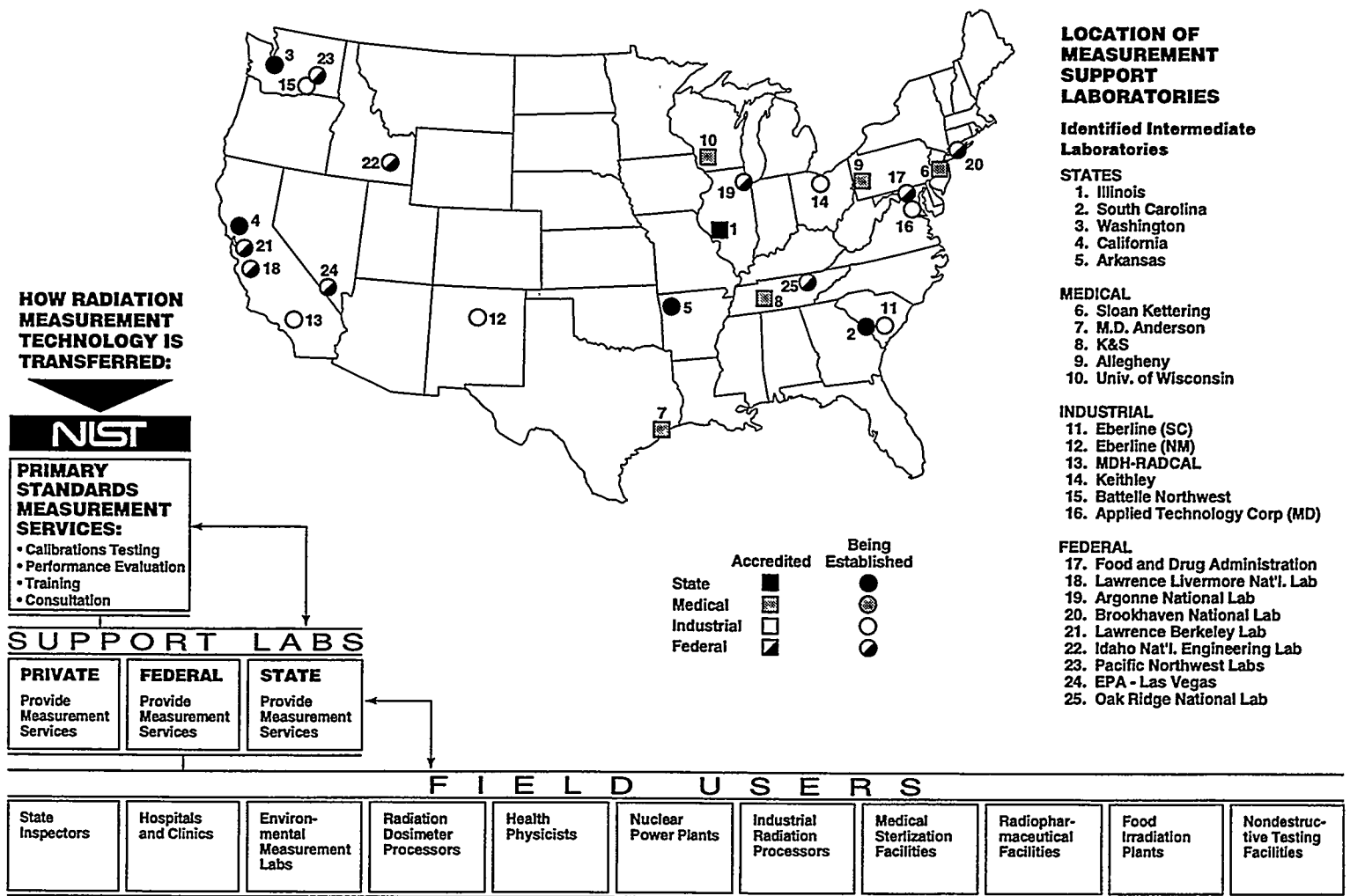
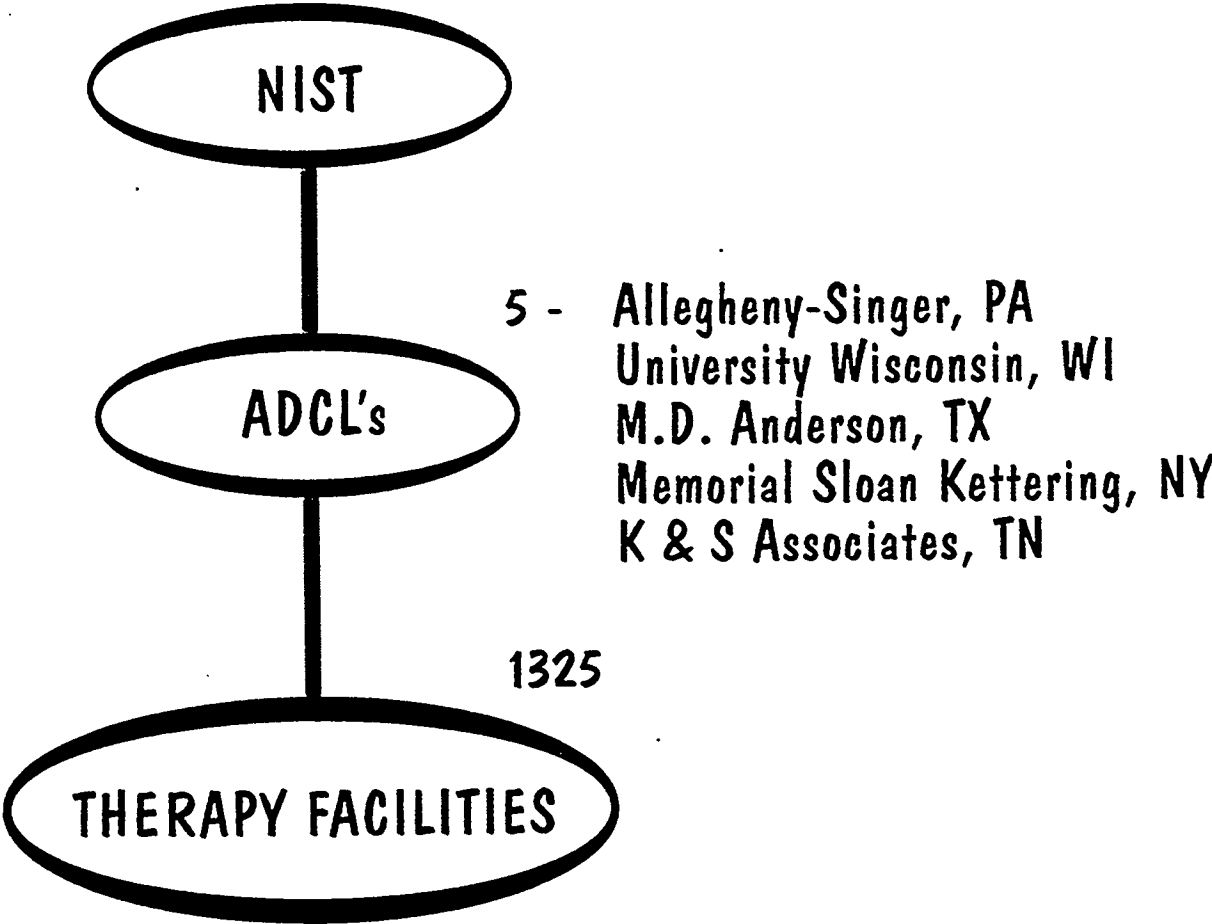


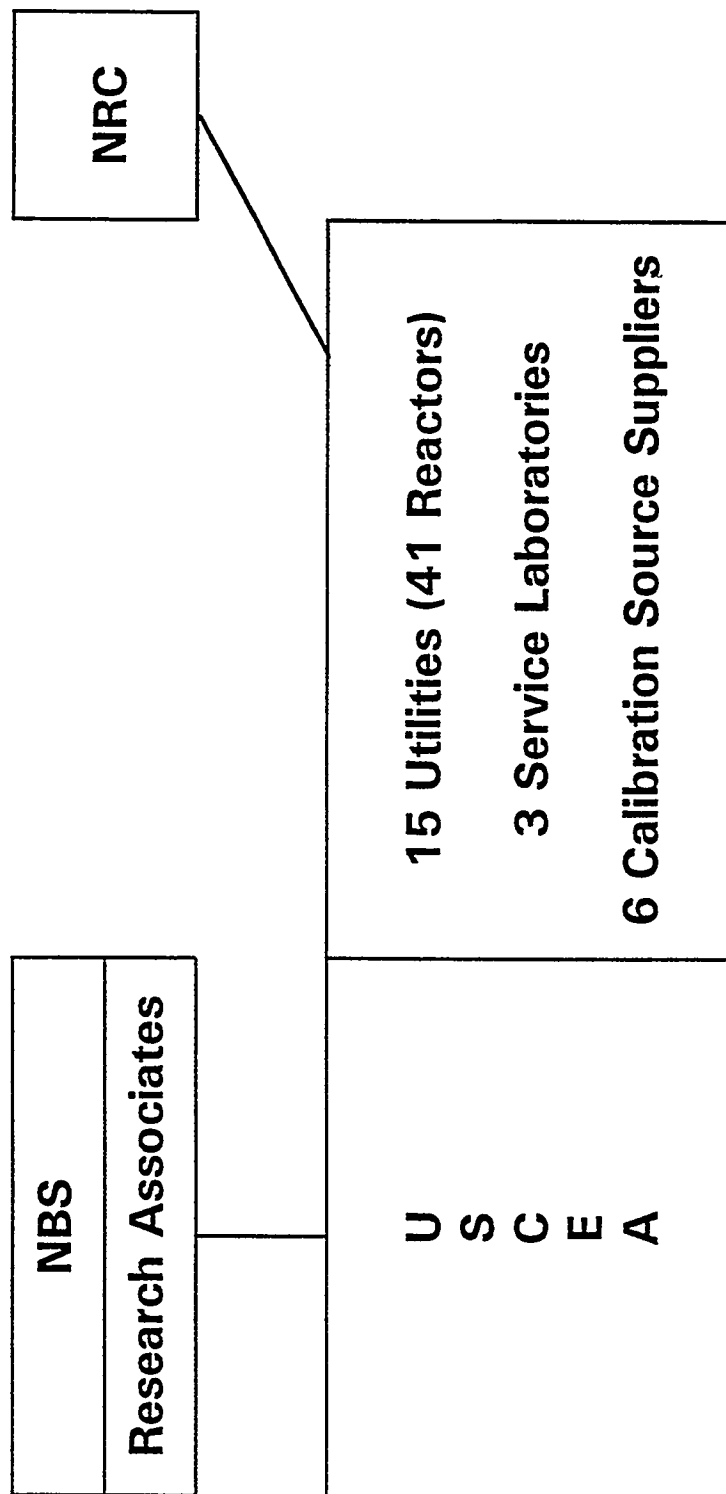
Figure 3 - System of Reference Laboratories in the United States (not current). Also called the National Measurement Support System.

**American Association of Physicists in Medicine (AAPM)  
Accredited Dosimetry Calibration Laboratories (ADCL's)**



*Figure 4 - Accredited Dosimetry Calibration Laboratory System of the American Association of Physicists in Medicine.*

# RADIOCHEMISTRY MEASUREMENT ASSURANCE PROGRAM FOR THE NUCLEAR POWER INDUSTRY



*Figure 5 - Radiochemistry Measurement Assurance Program for the Nuclear Power Industry, a Collaboration Between the NIST Radioactivity Group and the USCEA.*



June 1 1975 through January 1 1993

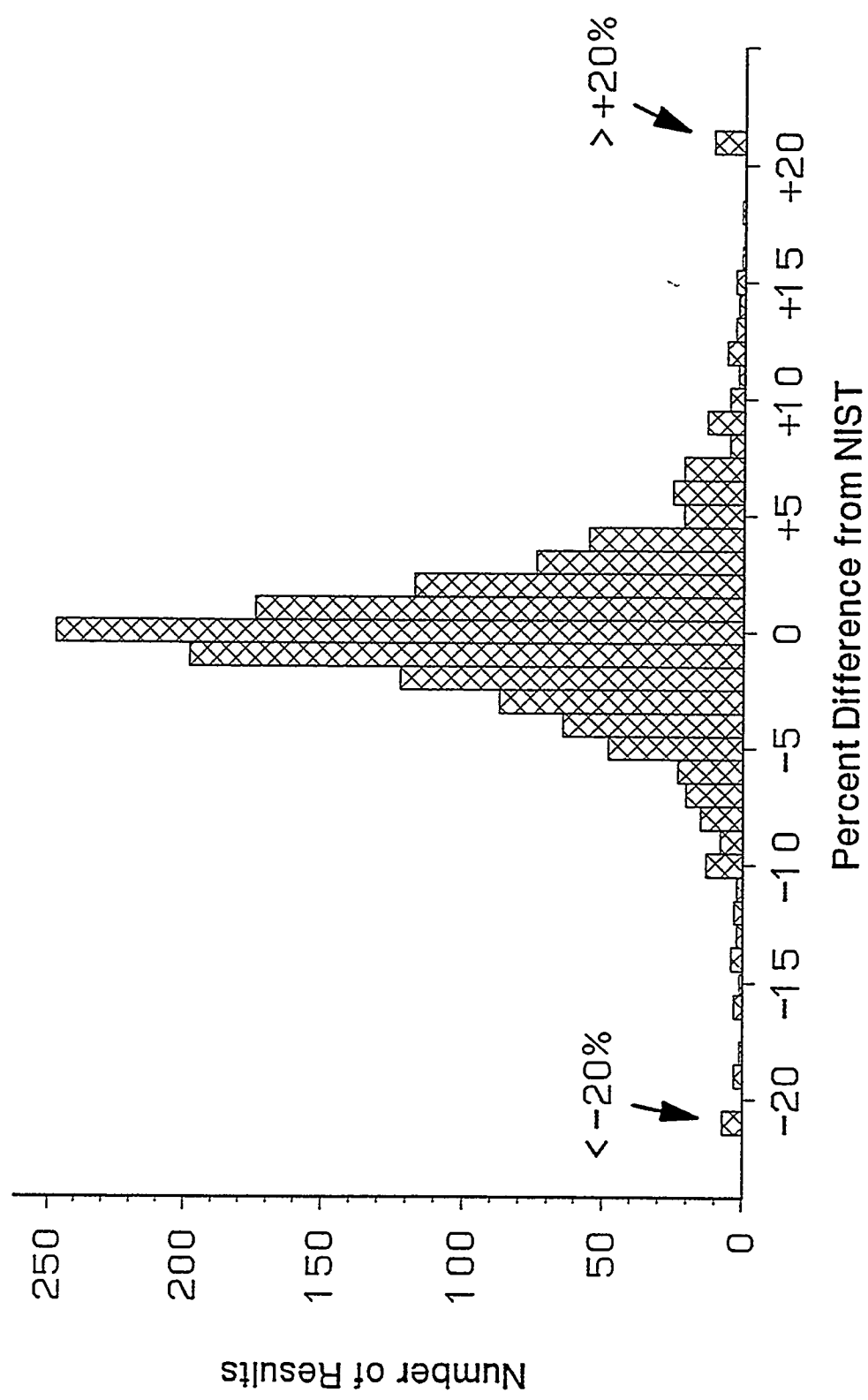
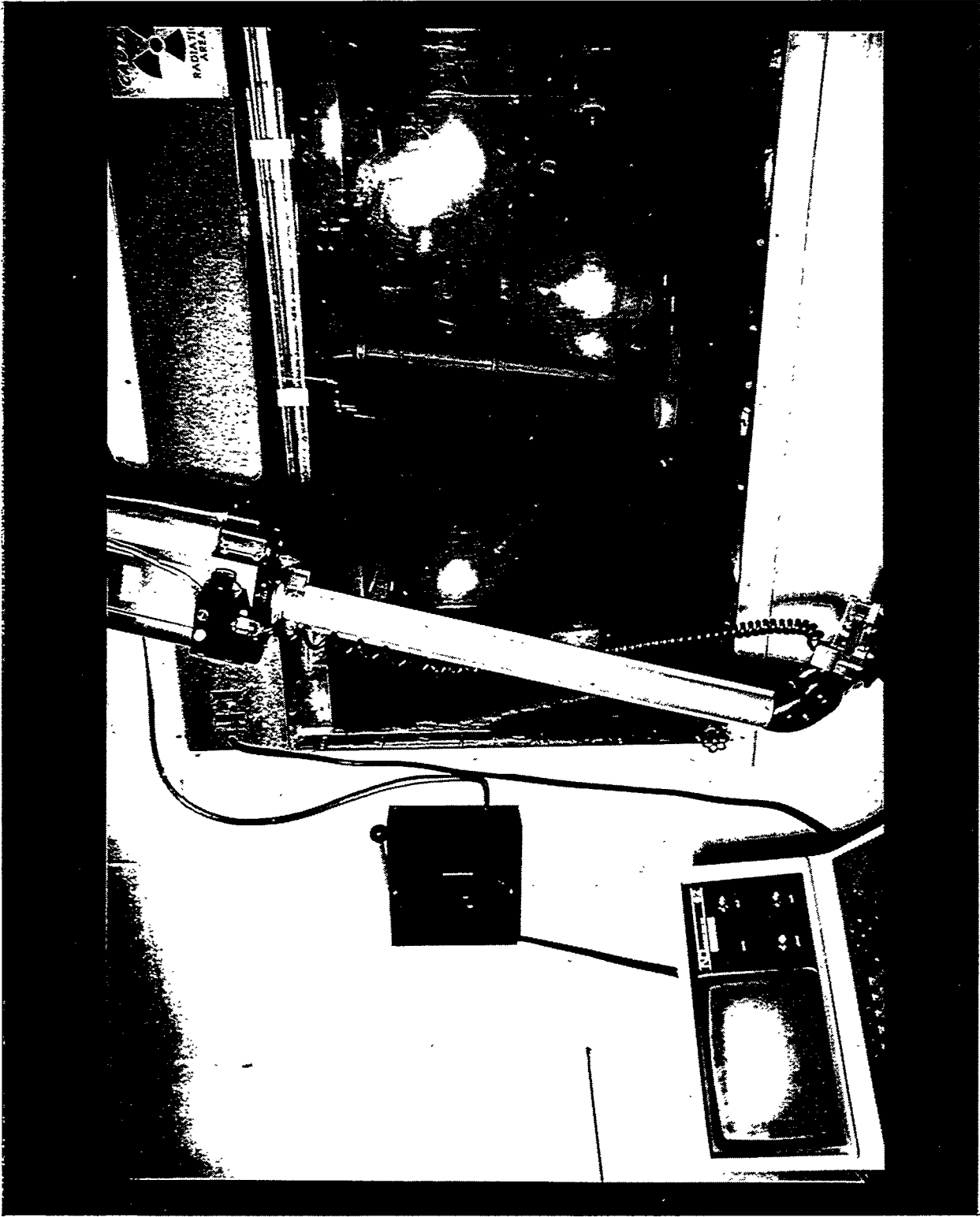


Figure 6 - Results of the Radiopharmaceutical Measurement Quality Assurance Program, Jointly Sponsored by the NIST Radioactivity Group and USCEA.



*Figure 7 - Manganous Sulfate Bath for Neutron Source Calibration, Shown Behind Shielding Window and Showing Master-Slave Arm Used for Source Handling.*

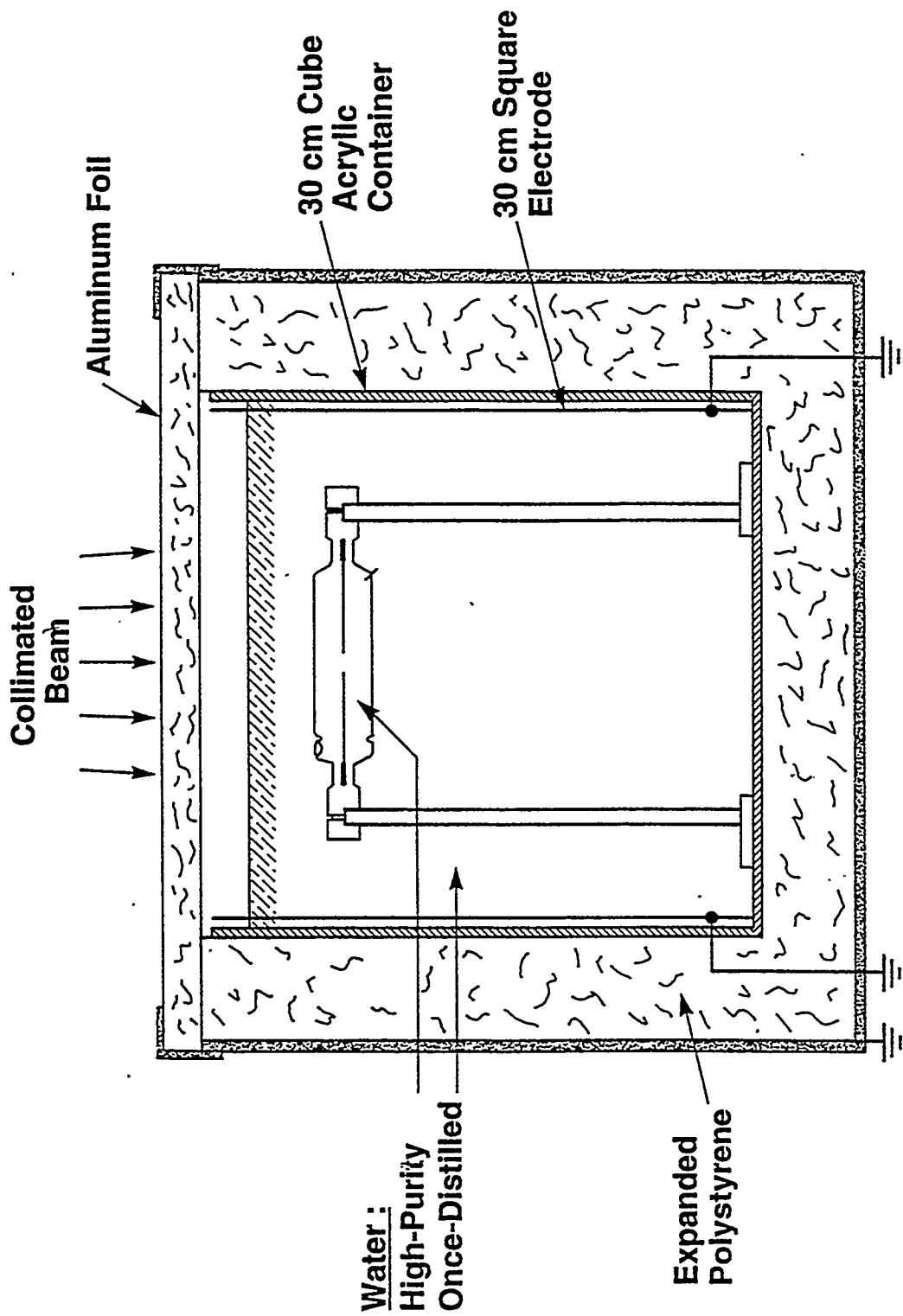


Figure 8 - Water Calorimeter, a Proposed NIST Measurement Standard for Absorbed Dose for  $^{60}\text{Co}$  Gamma-Ray Beams and Megavoltage X-Rays.

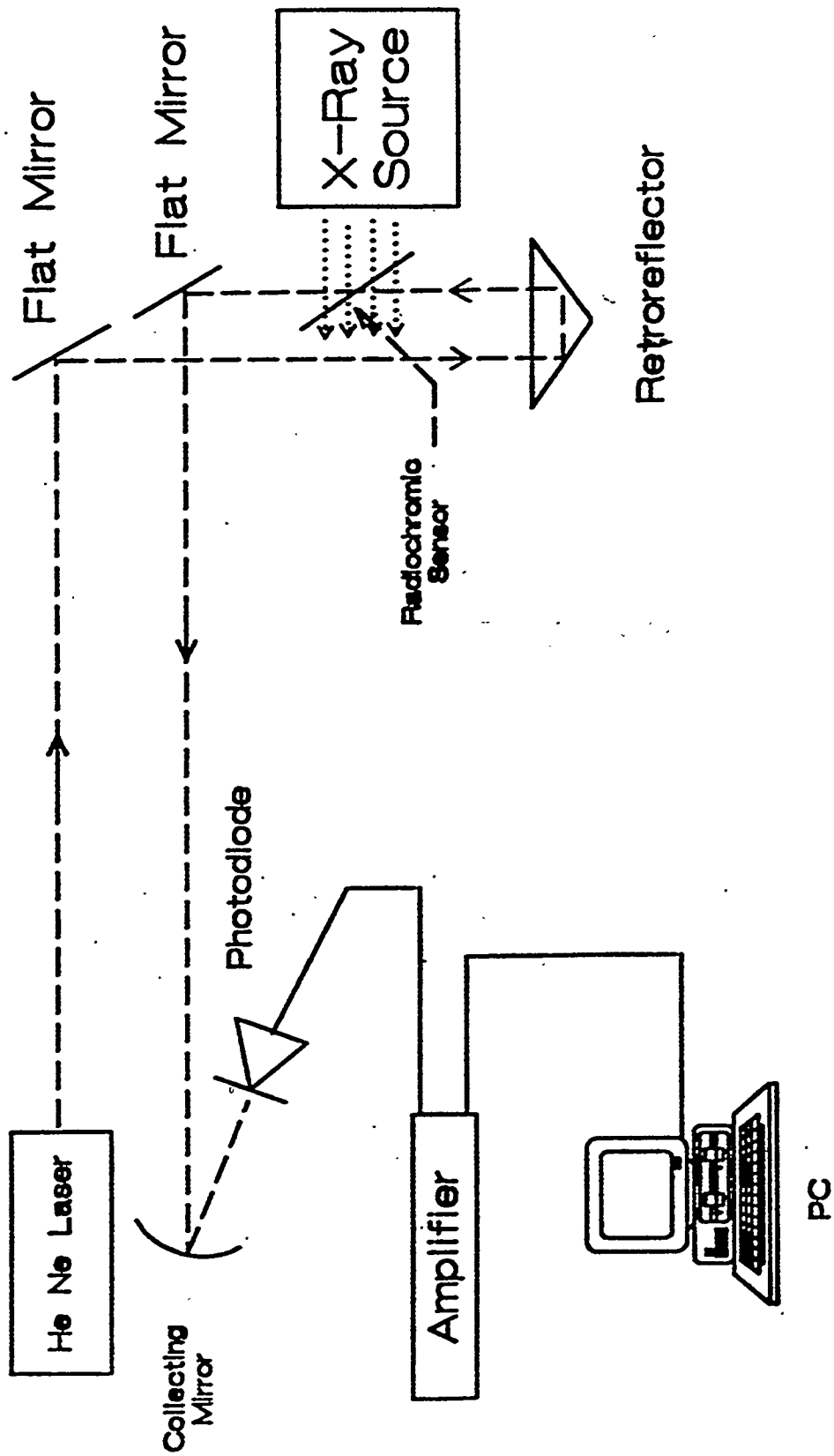


Figure 9 - Laser-Telemetering Dosimetry System.

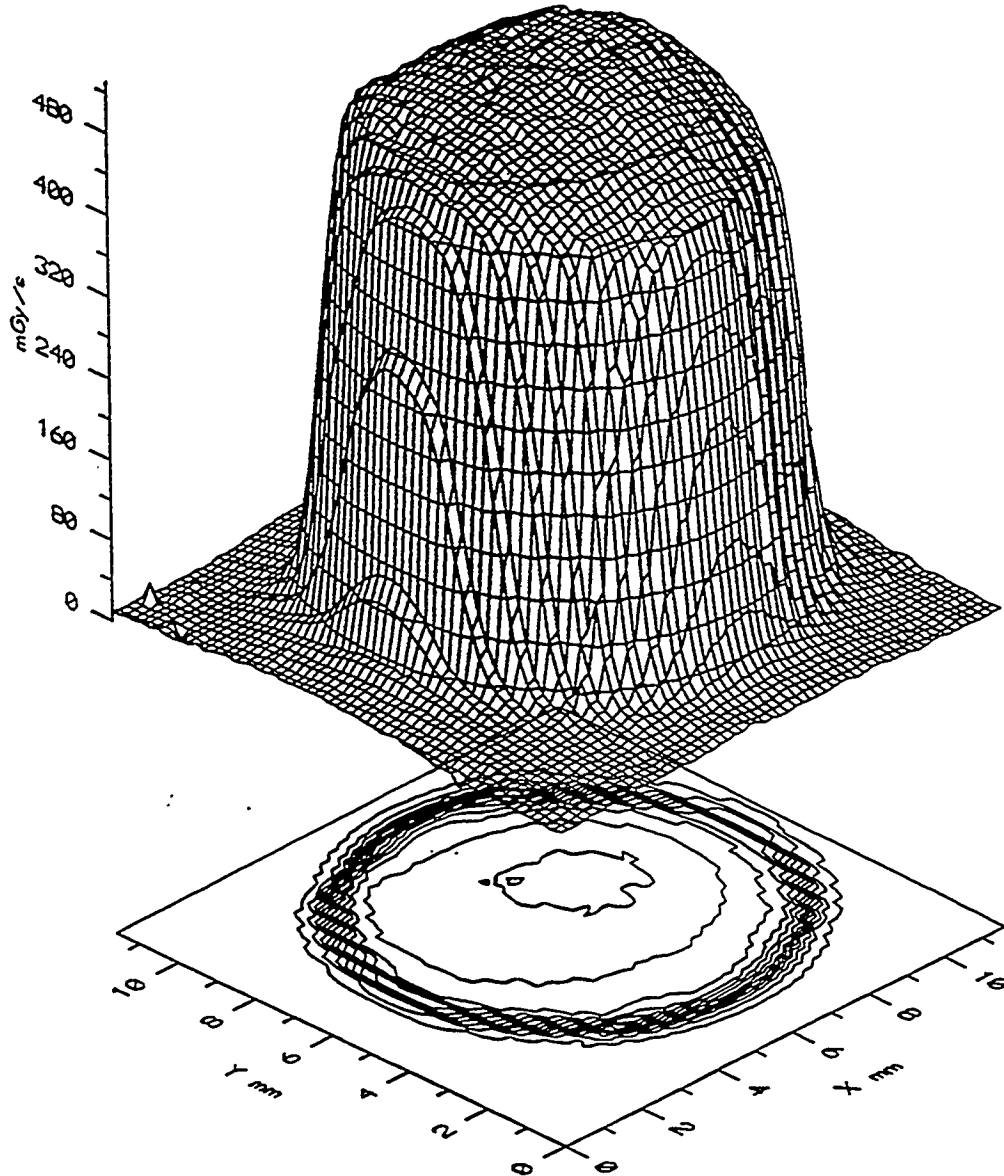


Figure 10 - Isodose Plot and Three-Dimensional Dose Plot for  $^{90}\text{Sr}$ - $^{90}\text{Y}$  Ophthalmic Applicator.

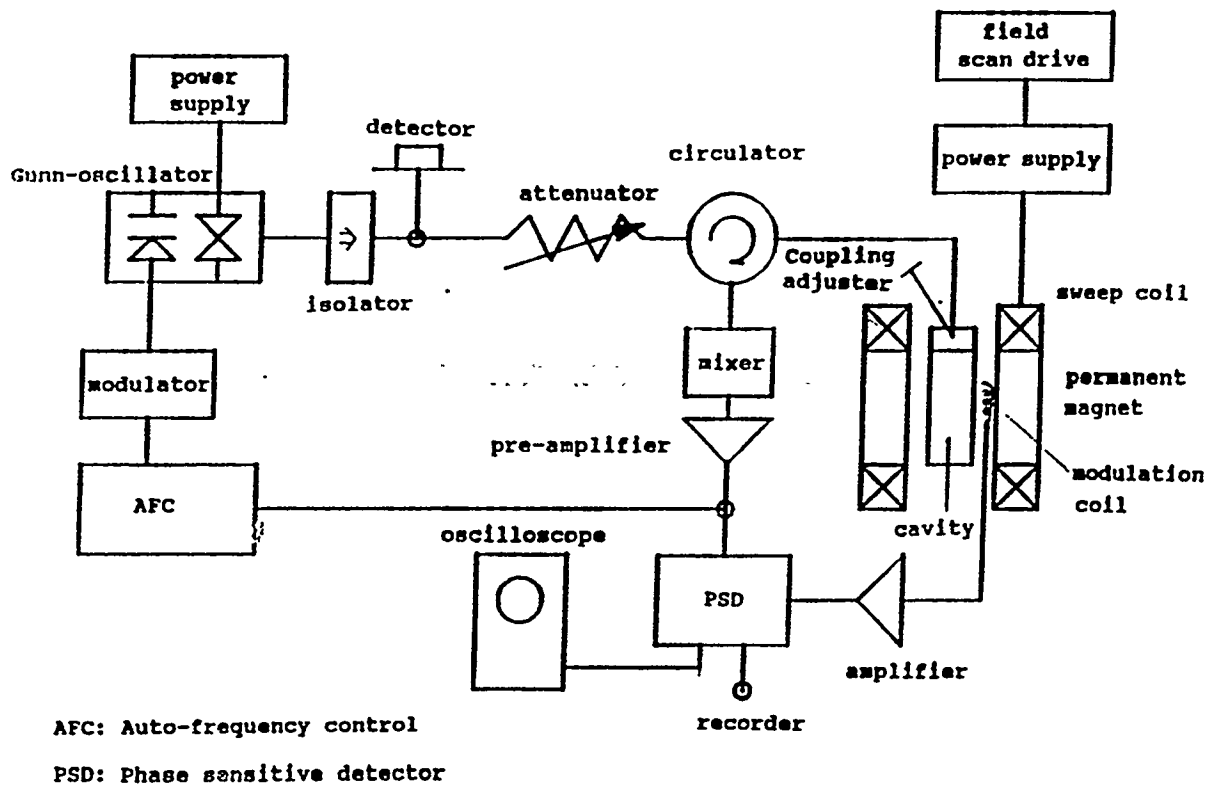


Figure 11 - Block Diagram of a Portable ESR Spectrometer (Kojima et al. 1993).

# Electron Spin Resonance Dosimetry

in vivo dosimeters  
Hydroxyapatite (bone)

external dosimeters  
Alanine (crystalline pellets)

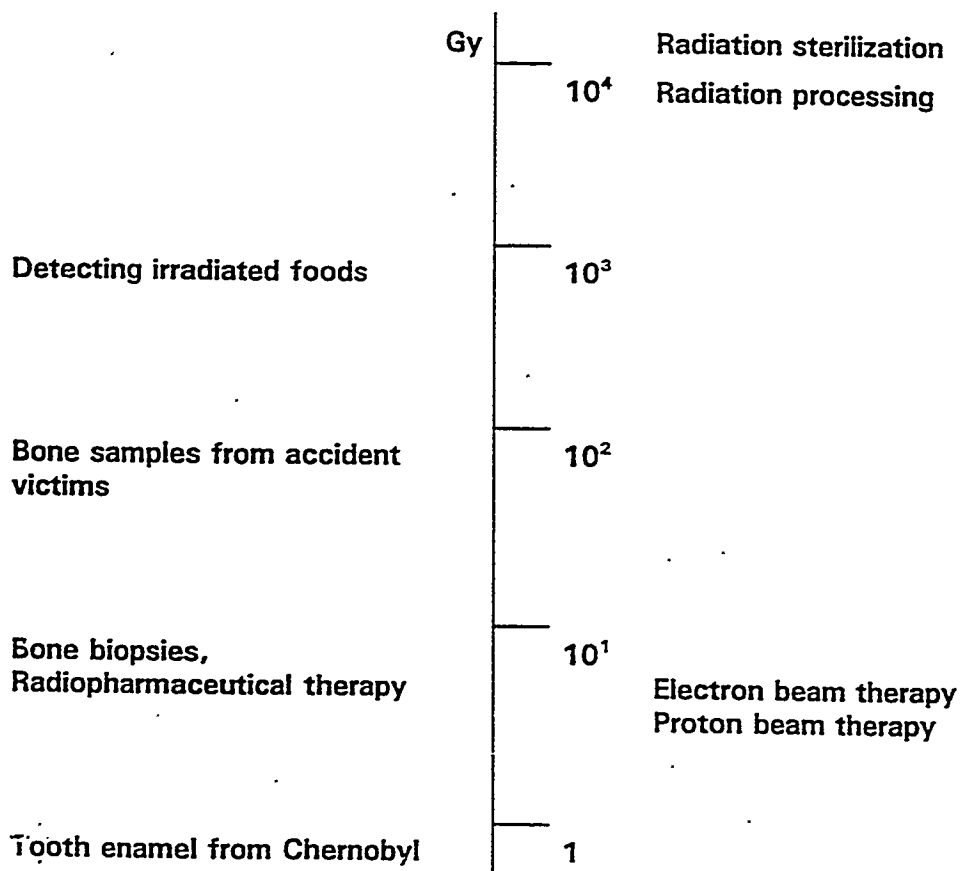
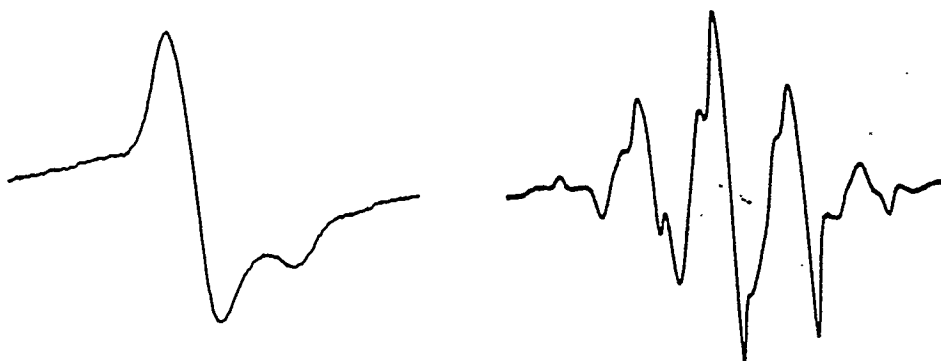


Figure 12 - Electron Spin Resonance Dosimetry (also known as Electron Paramagnetic Resonance Dosimetry), Shown for In Vivo Dosimetry in Bone and for Alanine Crystals.

# MIRF

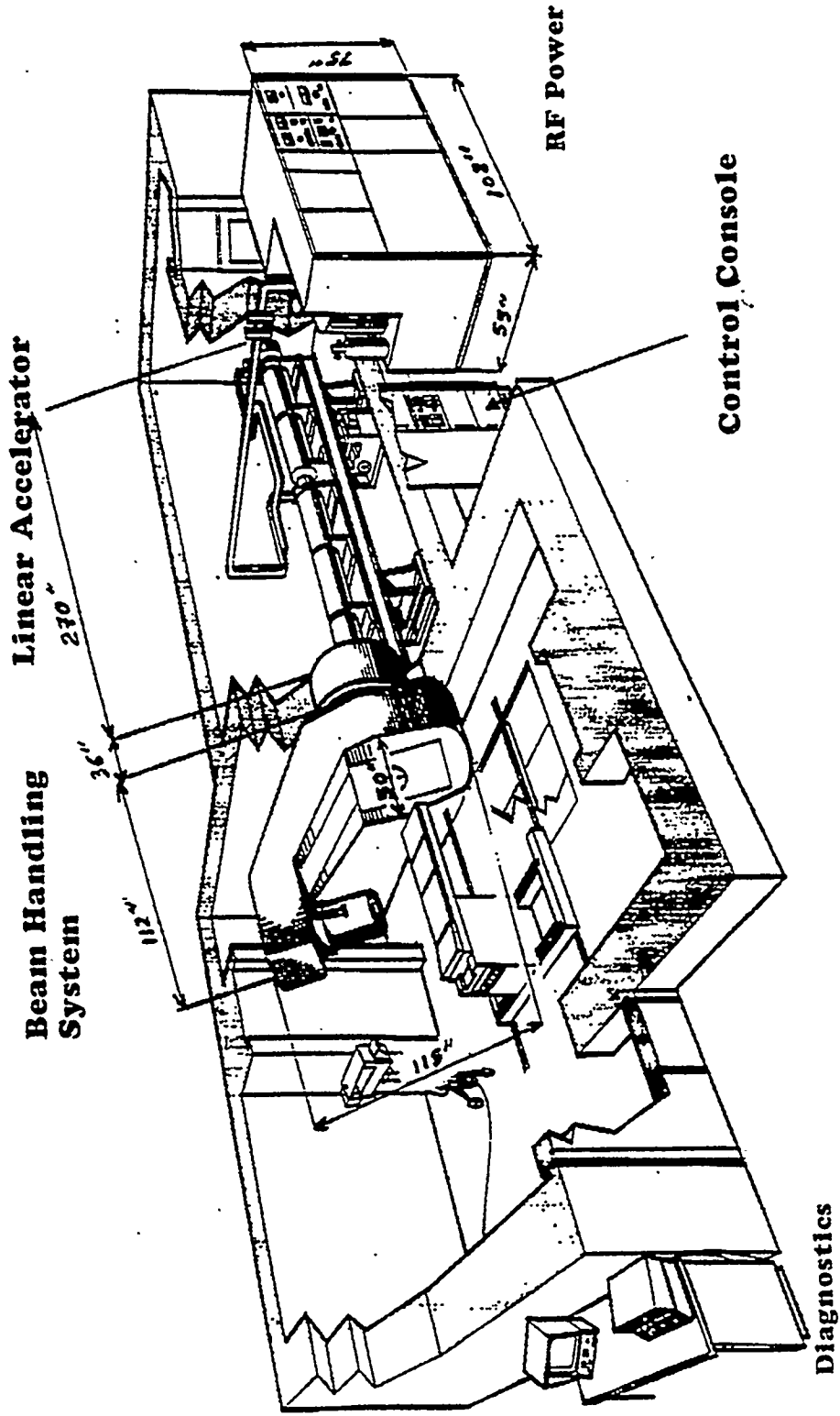
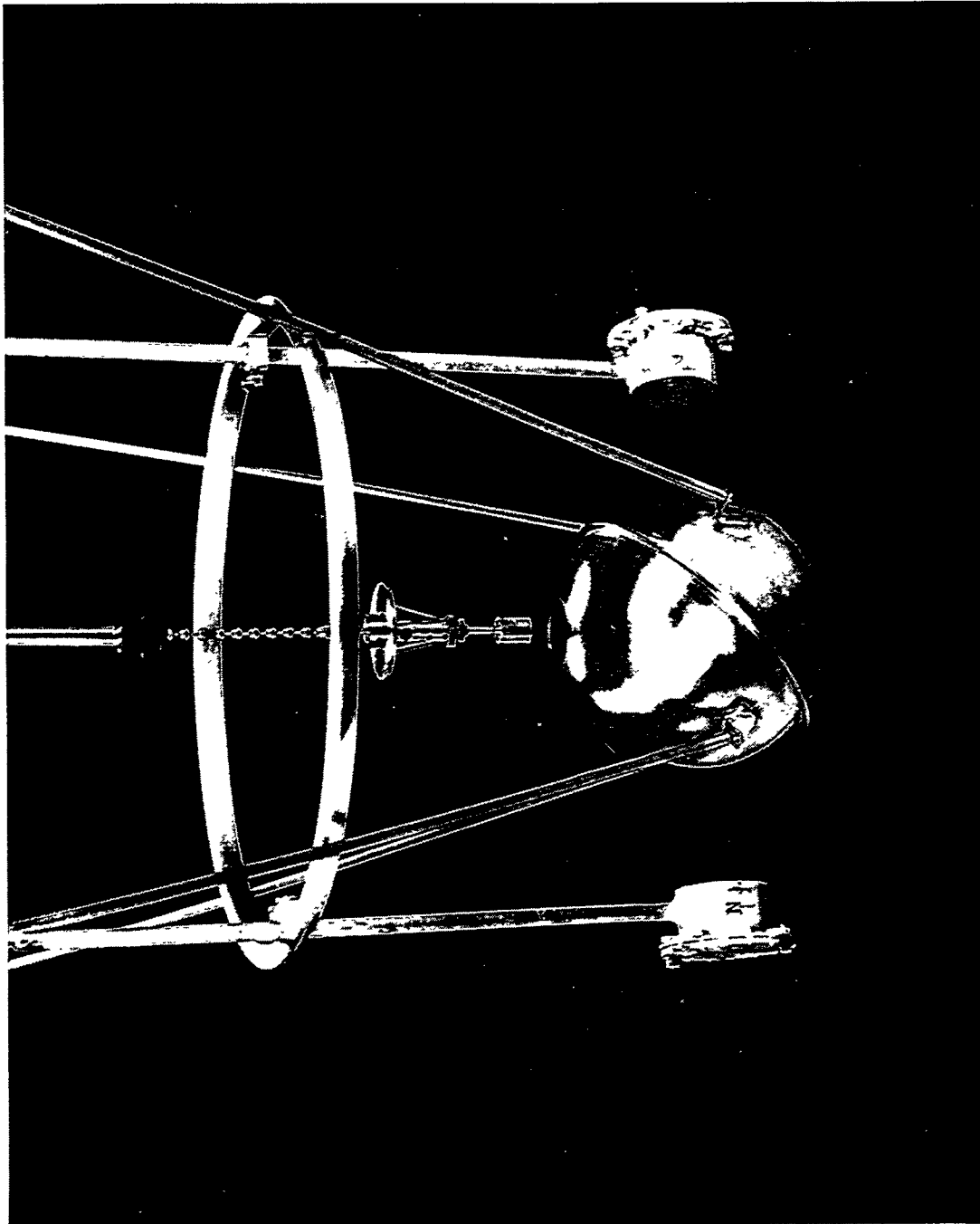
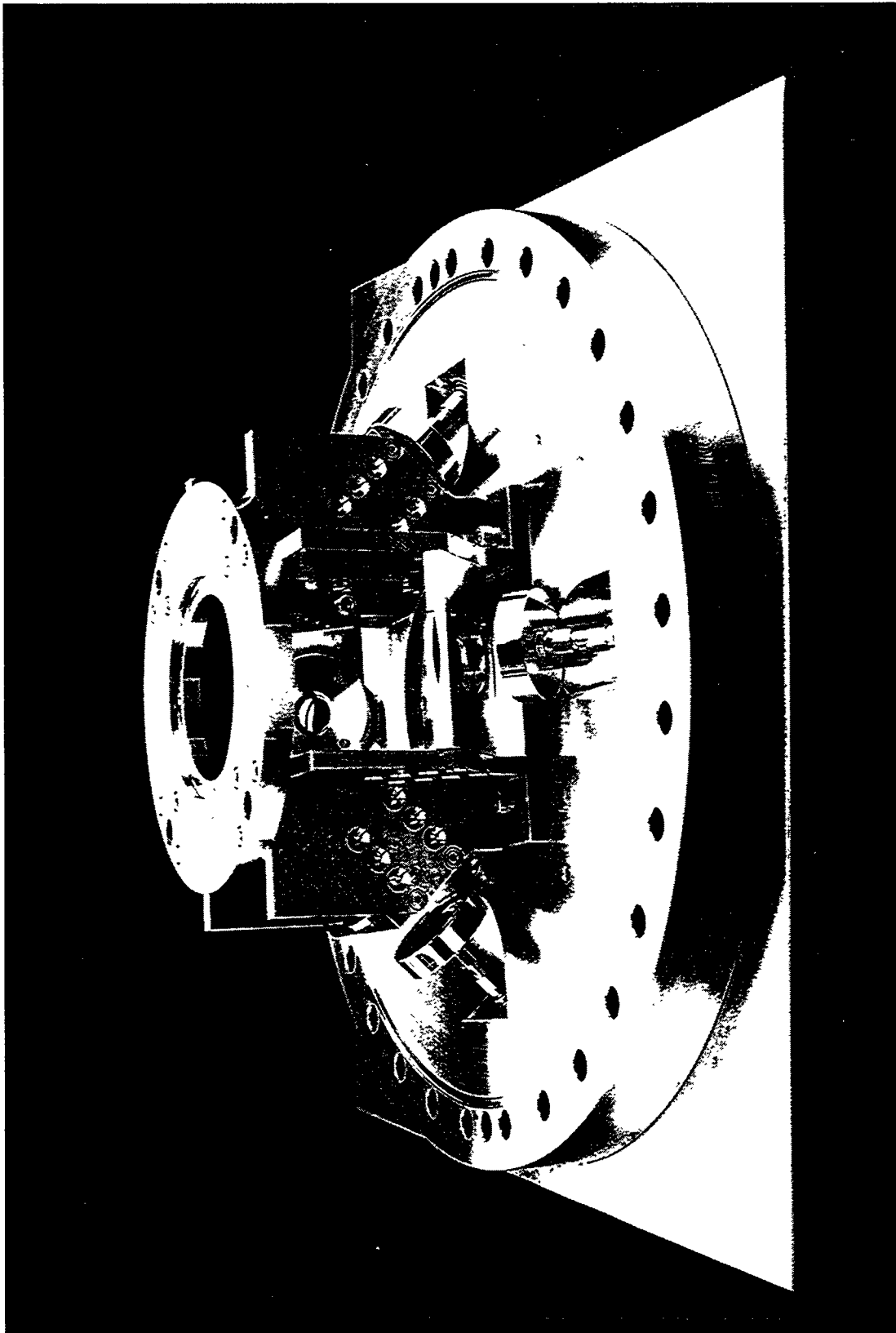


Figure 13 - Layout Diagram for the Sagittaire Linear Accelerator Being Used for the NIST Medical-Industrial Radiation Facility (MIRF).  
Layout at MIRF is Modified, and Will Have a Horizontal Beam Only.

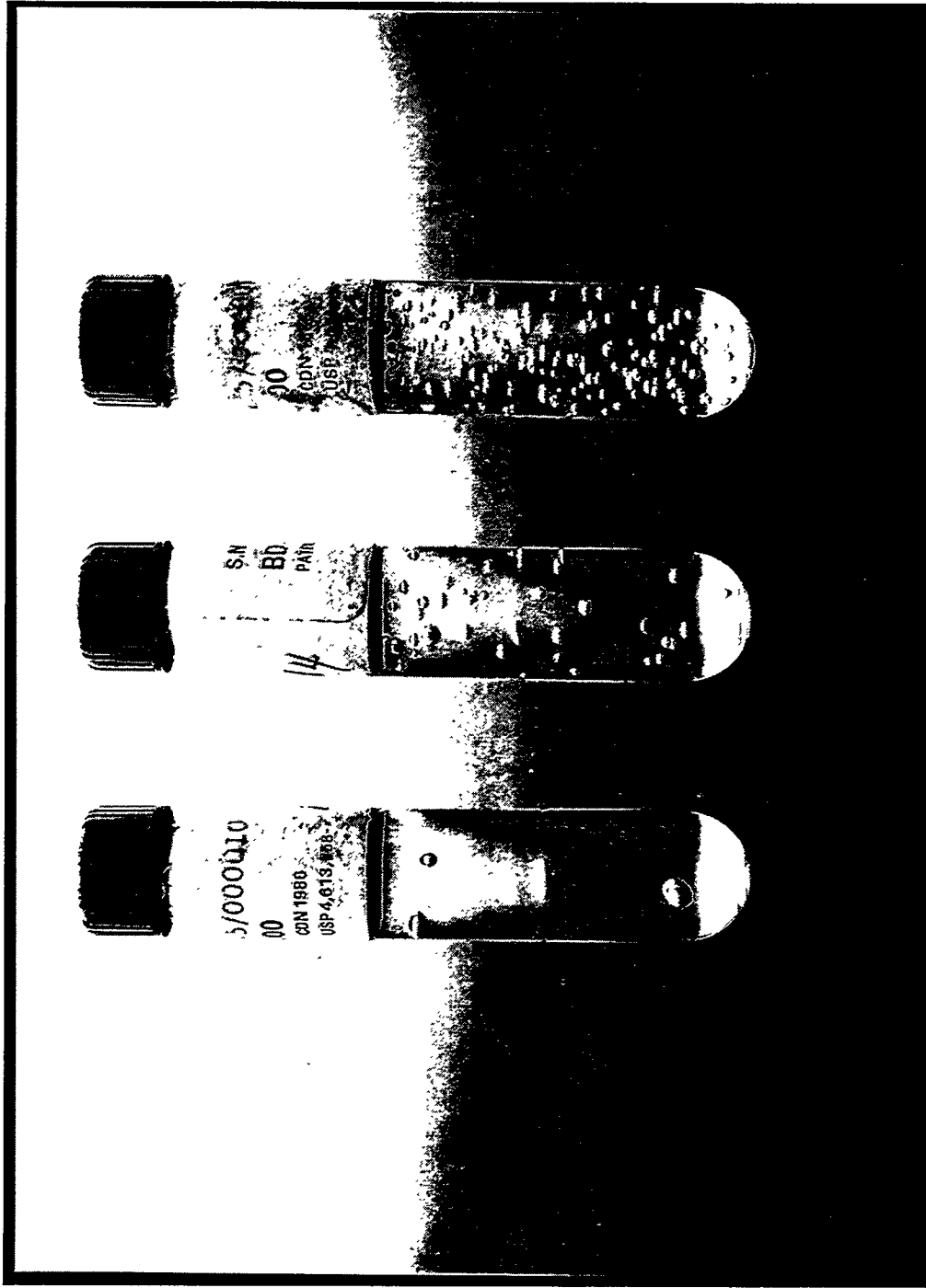




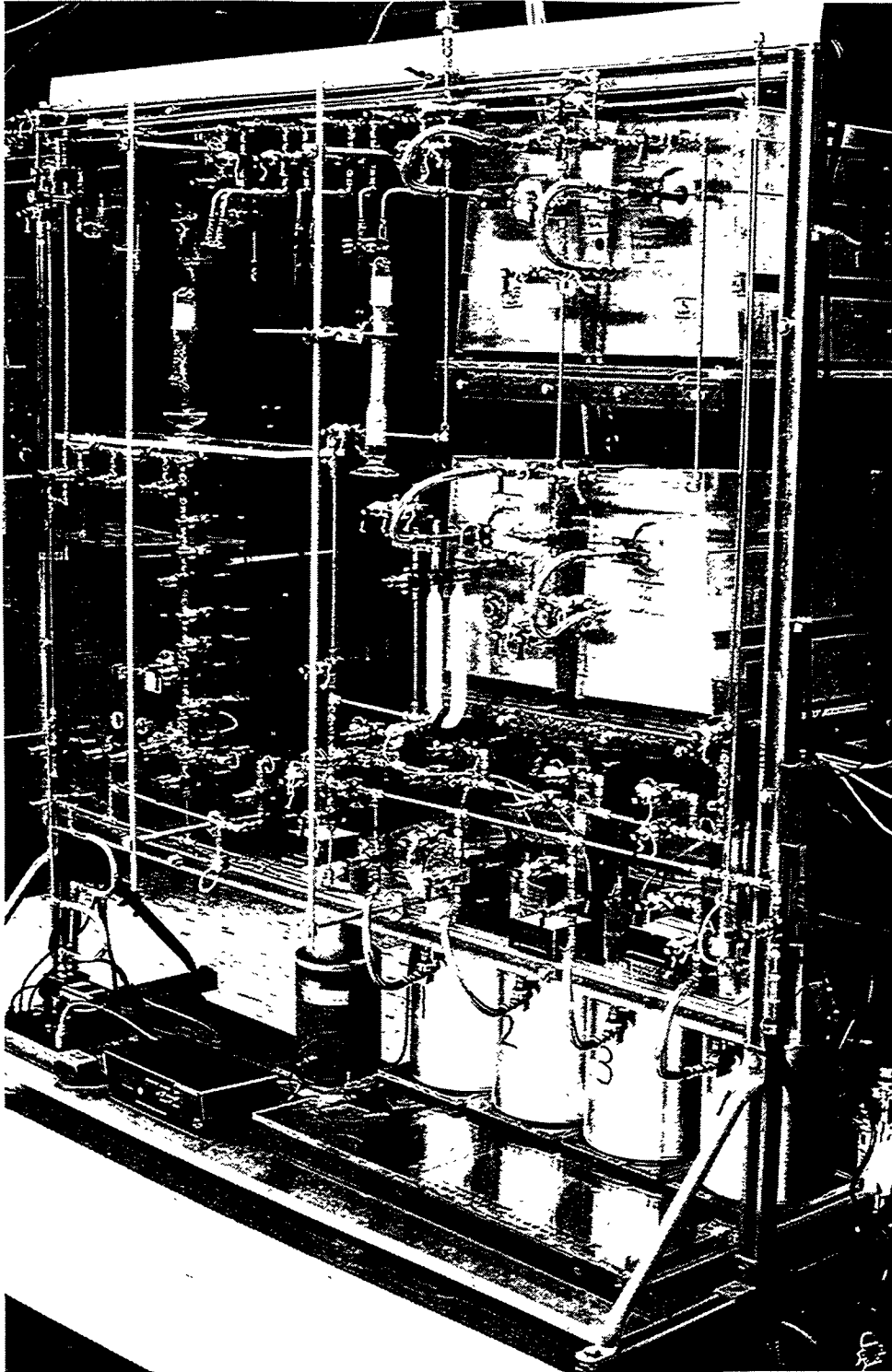
*Figure 14 - Low-Scatter  $^{252}\text{Cf}$  Irradiation Facility Shown with Source, Paired Fission Ionization Chamber Detectors, and Moderating Sphere, which is Filled with Water in the Particular Experiment Shown.*



*Figure 15 - Neutron Fluence-Measuring Apparatus, Using Boron Film and Known Solid Angle Alpha-Particle Semiconductor Detectors.*



*Figure 16 - Neutron-Sensitive Bubble Detectors, Showing Three Levels of Exposure.*



*Figure 17 - Gas-Handling Apparatus for Radon Measurements. Showing the Four Pulse-Ionization Detectors (near bottom) which Serve as Primary Standards.*

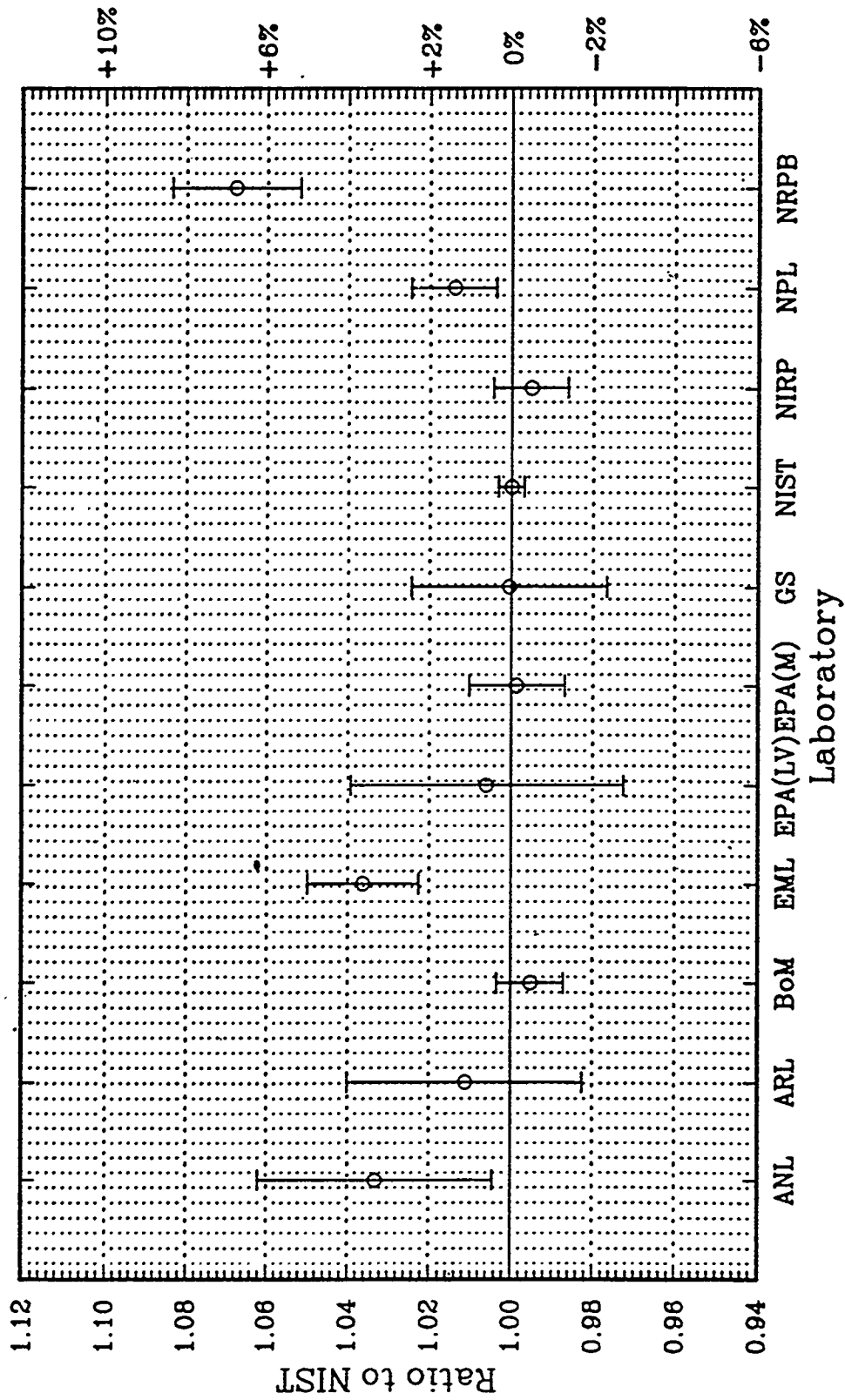
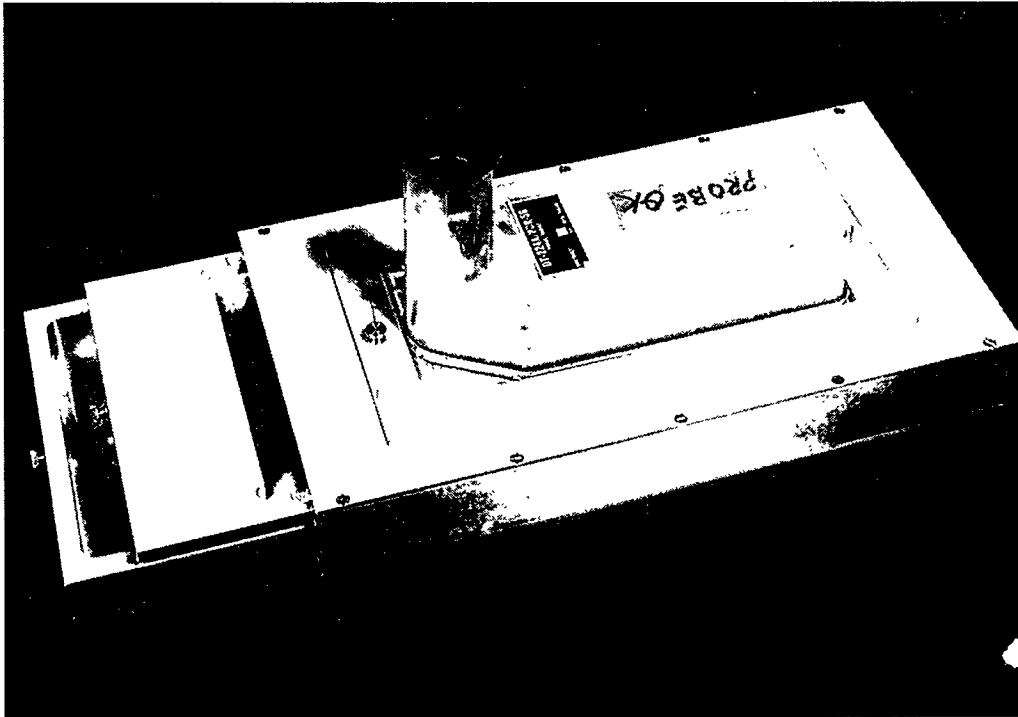


Figure 18 - Results of International Radon Intercomparison Sponsored by NIST Among Major Laboratories.



*Figure 19 - NIST-Developed Calibration Source for Large-Area Alpha Survey Meters.*

*Table 1 - Safety, Health, and Environment*

Diagnostic Radiology	125 million people receive 200 million x-ray examinations/year; 200 million dental x-rays/year; Imaging equipment 2.5 B\$/year
Radiation Therapy	1 person in 4 gets cancer, 60% treated with radiation therapy; Accuracy: 5% dose to tumor, 3% physical dosimetry; 600,000 patients per year; 10 B\$ at 1325 facilities
Nuclear Medicine	1 person in 4 entering hospital has radionuclides used as part of the diagnostic procedure
Occupational Radiation Protection	1.3 million radiation workers badged
Public	Radon Environmental radioactivity (esp. food, water)

*Table 2 - Industry*

Industrial Radiation Processing	5 B\$/y
Nuclear Electric Power	22% of U.S. electricity (30 B\$/y) Replacement cost of 108 reactors ~500 B\$
Industrial Radiography	0.5 B\$/y
Radiation Effects on Electronic Devices	~1 B\$/y

*Table 3 - Science*

- Physics of radiation interactions at the nanometer level
- Resonance ionization spectroscopy—atom counting
- Fundamental neutron physics

**Table 4 - Office of Radiation Measurements National Measurement Support System for Ionizing Radiation**

Radiation Therapy	5 laboratories [AAPM]
States	Illinois, South Carolina, California, (Arkansas) [CRCPD]
Personnel Radiation Dosimetry	1 testing lab, PNL, 89 processors [NVLAP] 1 testing lab, RESL, ~ 12 processors [DOELAP]
Survey Instrument Calibration	Eberline, New Mexico [HPS]
Federal Laboratories	CDRH, (ORNL), (PNL), (Navy SC) [NVLAP]
Under Development	Bioassay High-level dosimetry Environmental radioactivity Radioactivity standards

Brackets [ ] indicate accrediting organization.  
 Parentheses ( ) indicate "in progress."

**Table 5 - Assurance of NIST Standards**

- Intercomparisons with other National Standards Laboratories and Leading Laboratories
- Comparisons of Independent Standardization Methods
- Measurement Research
- Fundamental Research



# **STANDARDS FOR MQA PROGRAMS**

Session Chair

James Little, Eberline

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## FOREIGN CRITERIA AND PROGRAMS

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### INTRODUCTION

The concept of measurement quality assurance (MQA) as embodied in National Institute of Standards and Technology (NIST) programs is not generally used within European programs for testing or accreditation. Although the essential elements of quality control and quality assurance are in the European programs, the concept of testing the capability of the laboratory itself, in terms of its performance for the designated measurements, may not be included. Rather, the European programs use the concept of periodic calibration of laboratory reference standards against the next highest level of standards. Thus, they embody the concept of measurement traceability to appropriate primary standards.

Within Europe a series of calibration accreditation programs has been established in the various countries tied together through a multilateral agreement. The radiation measurement programs are based on the International Organization for Standardization (ISO) 9000 series of standards. The guideline document "General Requirements for the Competence of Calibration and Testing Laboratories" (ISO/IEC 1982), which expands upon and interprets statements made in the ISO 9000 series, provides definitive criteria for an accreditation program. This guide and additional derivative guidance along with selected consensus standards form the basis for the European programs.

The purpose of this paper is to outline the overall operation of European Accreditation Programs in the radiation calibration and measurement areas. The operation of the radiation measurement programs of the National Measurement Accreditation Service (NAMAS) in the United Kingdom (U.K.) is described in detail along with other European programs. The manner in which these programs relate to individual dosimetry service programs is also described.

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## **ISO STANDARDS**

### **ISO 9000 Series Standards**

The ISO 9000 series of standards (ISO 1987a, ISO 1987b, ISO 1987c, ISO 1987d, ISO 1987e) constitute worldwide guidelines for developing a documented quality system. The standards provide the framework for a quality-management system but do not provide the appropriate level of detail for operation of quality programs. They will not guarantee quality but simply document the process; separate processes (e.g., accreditation) must examine the technical basis for the quality system. Table 1 lists the five ISO 9000 series standards and their titles.

The ISO 9000 series standards have technical equivalents in several of the other countries. Table 2 shows how some of these various standards interrelate. The heart of these standards is documentation and data collection. The standards require compliance through development of a documented and functioning system. As with most quality assurance activities, the key to successful compliance with the standards is to document what you do, do what you document, and demonstrate that you are doing it.

### **Guideline Documents**

Since the standards are very general in nature, additional guidance is required to provide further information in specific technical areas. Consequently, several guideline documents or guides have been developed to support these documents. Guideline documents exist for software and for services and, most importantly for this paper, for calibration and testing laboratories. The ISO/IEC Guide 25, "General Requirements for the Competence of Calibration and Testing Laboratories," (ISO/IEC 1982) is the critical guidance document for the development of calibration accreditation programs.

The ISO/IEC Guide 25 provides specific recommendations for the quality system for calibration and testing laboratories. It includes the general requirements needed in most laboratories; specific technical requirements must be derived from other sources, such as technical standards. Table 3 shows the contents of the standard. The guide provides the information in a manner to facilitate the accreditation and bilateral or multilateral recognition of the competence of the laboratory. ISO/IEC Guides 54 (ISO/IEC 1988a) and 55 (ISO/IEC 1988b) provide additional guidance on the accreditation process. ISO/IEC Guide 25 provides the common elements for a calibration program and parallels the general criteria in the Federal program calibration accreditation effort as described in NIST Special Publication 812 (Eisenhower 1991). The guideline document for the Health Physics Society Calibration Accreditation Program is being revised to include the specific guidance and format of ISO/IEC 25.

### **Radiation Protection Standards**

The ISO has several committees and subcommittees involved in the preparation of technical standards, in addition to efforts on quality assurance standards. For the purposes of this paper, the important committees are ISO Technical Committee 85, "Nuclear Energy," and Subcommittee 2, "Radiation Protection." Of particular interest within this subcommittee is Working Group 2, which deals with "Reference Radiations." An abbreviated coding is used to identify the various committees or working groups, for example, ISO/TC85/SC2/WG2 (which stands for ISO, Technical Committee 85, Subcommittee 2, Working Group 2).

The efforts of Working Group 2 have resulted in several standards that are widely used to define reference radiation fields to be used for calibrations. Table 4 lists the numbers and titles of several of the standards that are completed and in general use. These standards define the characteristics, and the methods of production, of reference radiation fields for calibrations using photons, X-rays, beta, and neutron radiations; the standards also define acceptable parameters for the calibration of surface contamination monitors. Compliance with these standards will provide a commonality of radiation fields among all users, while establishing essential guidance upon which the radiation industry can develop a measurement system that will be comparable from facility to facility and nation to nation.

This series of standards has been complemented by supporting standards which specify the dosimetry of the reference fields. Working Group 2 has recently started preparing a third series of standards that will deal with the calibration of individual dosimeters and dose or dose-rate meters and with the determination of their response a function of radiation energy. The standards will also make recommendations on the phantoms to be used when irradiating individual dosimeters; it will specify conversion factors from free-field quantities, such as air kerma to the ICRU dose equivalent quantities, and will provide advice on the limits of acceptable uncertainty.

### **WESTERN EUROPEAN CALIBRATION COOPERATION (WECC)**

The WECC is a collaboration of the national calibration laboratory accreditation bodies operating in Europe. The WECC, founded in 1975, is active to this day. Its purpose is to build up and maintain mutual confidence between accreditation bodies to help them reach mutual agreement on the equivalence of operations directly overseen by the accreditation bodies themselves and mutual recognition of the certificates issued by the accredited laboratories. In general, this effort supports the removal of technical barriers to trade that might relate to calibration and maintains open channels of communication between accreditation bodies to assist in establishing a common high level of measuring capability. In addition to the exchange of technical information, the WECC promotes participation in inter-laboratory comparisons and exchange of experts for assessments and surveillance visits. The experienced members of the WECC have signed an agreement stating that they will recognize the operation of other services as equivalent to their own. Table 5 lists the countries and the services that have signed this agreement. The WECC has also established mutual recognition with countries outside of Europe.

### **EUROPEAN ACCREDITATION**

Within Europe the accreditation activities follow the guidance of WECC and the ISO/IEC Guide 25. The signatories of the multilateral agreement noted in Table 5 are the major countries in Europe with accreditation programs. NAMAS, the largest accreditation system in Europe, along with its predecessor organizations, has been involved in accreditation for 25 years. There are now approximately 1200 laboratories accredited under NAMAS. Of course, most of these laboratories are not accredited in the area of radiation measurements.

#### **Accreditation in the United Kingdom**

NAMAS (the U.K. accreditation program) has a series of accreditation documents that parallel the requirements of other accreditation programs. The primary documents, NAMAS Accreditation Standard (NAMAS 1989a) and NAMAS Regulation (NAMAS 1989b), include requirements falling under headings that parallel the requirements listed for ISO/IEC Guide 25, as shown in Table 3.

Other general documents provide guidance on statistics, preparation of quality manuals, etc. In addition, specific publications interpret specific requirements in the areas of radiation calibration and testing, as noted in Tables 6 and 7. The specific guidance draws heavily on the requirements for reference radiation fields, as developed in the ISO series of standards and listed in Table 4. In fact, U.K. organizations assisted in the development and evaluation of many of the techniques or standards documented in the ISO series. For example, the ISO Series 1 Beta Reference Radiations were originally developed by Owen of National Physical Laboratory (NPL) (Owen 1972). Other European organizations were also involved in development and evaluation of criteria. The ISO X-filtered radiations were specified following an intercomparison exercise between laboratories in England, France, and Germany, while the fluorescent X-radiations were developed jointly by France and England.

The NAMAS information sheets for specific radiations draw directly on the ISO reference radiation standards (Table 4) for radiation types. They provide requirements for monitoring (e.g., transmission chambers) of intensity and quality (e.g., half-value layers, first and second). The information sheets provide conversion factors for ambient dose equivalent and directional dose equivalent based on the calibration quantities (air kerma, absorbed-dose-to-air, fluence) and the radiation energy. Typically, the calibrations must be traceable to the NPL. However, calibration may be through another national standardizing laboratory or through a NAMAS laboratory, with approval of NAMAS. The recalibration interval is specified according to the radiation type. For the photon radiations, the permitted recalibration period for the ionization chamber is four years; for the beta-ray source calibrations, the period is dependent upon the radionuclide. For neutron reference radiations, the transfer instrument has to be recalibrated at intervals not exceeding four years. A requirement for accuracy is not provided; the best measurement capability for accredited radiations is stated in the schedule (scope of accreditation) for accreditation, along with the range of radiation intensities. For surface-contamination sources, the reference sources are taken from the ISO standard (ISO 1988) with three additional radionuclides ( $^{238}\text{Pu}$ ,  $^{137}\text{Cs}$ ,  $^{60}\text{Co}$ ). Sources must be calibrated every two half-lives or, at a maximum, every five years. Sources must be  $100\text{ cm}^2$  and are calibrated in terms of surface-emission rate. Guidance is provided on converting the surface-emission rate calibration to measurements of the surface activity for the contaminant.

The NAMAS accreditation process is identified as a four-stage process as noted below:

- Stage 1. Review the NAMAS accreditation documents and requirements.
- Stage 2. Prepare the quality manual to NAMAS specifications; submit it and the complete working procedures to NAMAS; and apply for accreditation, including the payment of the application fees. The application will list the radiations, quantities, range, uncertainties, and types of instrument to be calibrated for which the accreditation is being sought. At this point NAMAS will appoint a technical officer and assessor.
- Stage 3. The technical officer and assessor conduct a pre-assessment visit to the laboratory to identify any deficiencies or omissions in the quality system and activities.
- Stage 4. Following the notification of the fees, a visit for the full assessment of the laboratory will be conducted. Following the clearing of any non-compliance items, the fees will be paid and the accreditation granted.

Accreditation is for an agreed schedule or scope and includes a certificate and the right to use the NAMAS logo. Maintaining accreditation involves regular surveillance visits and may involve participation in proficiency tests and calibration of audit samples.

It should be stressed that the NAMAS scheme is a voluntary one and that within the U.K. there is no legal obligation for a calibration laboratory to obtain their accreditation. However, the NAMAS documents on personal dosimetry are prepared by the Radiological Working Group of the NAMAS Health and Hygiene Technical Committee in collaboration with the Health and Safety Executive (HSE) to provide guidance to laboratories providing personal dosimetry services. The statutory approval of such services is vested in the HSE, who may supplement their approval criteria with the NAMAS guidance documents. The HSE also requires that services seeking formal approval comply with criteria contained in Guidance Notes published by the HSE (HSE 1991a, HSE 1991b). Their General Guidance Note is based on a working draft produced by the NAMAS Radiological Working Group. As part of the approval system, Dosimetry Services is required to participate in performance testing, and the initial and periodic testing has to be carried out at a NAMAS-accredited laboratory.

At the present time, this performance testing is restricted to irradiation doses from photon radiation. An initial study on the performance testing for neutron dosimeters has been undertaken by the NPL, who irradiated the dosimeters using  $^{241}\text{Am-Be}$  and  $^{252}\text{Cf}$  sources. The results of this trial test will assist the HSE in formulating the performance-testing policy for service providing legal neutron dose evaluations.

The requirements of the U.K. legislation on the calibration and type testing of radiation-monitoring equipment are given in Regulation 24 of "The Ionizing Radiations Regulations 1985" (HSE 1985a). These regulations require employers to provide equipment that is suitable for carrying out adequate monitoring of their designated, controlled, and supervised areas. Such equipment must have had its performance established by tests before it is put into use for the first time; it must be properly maintained; and it must be thoroughly examined and tested at least once in every 14 months. The pre-use testing and the periodic testing have to be carried out by, or under the immediate supervision of, an appointed qualified person. More specific practical guidance on this testing is contained in the HSE document "Approved Code of Practice, The Protection of Persons Against Ionizing Radiation Arising from Any Work Activity" (HSE, 1985b). The qualified person will decide the extent of pre-use testing required on an individual instrument by using information available as a result of type testing carried out to accepted standards by, or under the control of, a qualified person or carried out in a NAMAS-accredited laboratory. Detailed information on type testing of monitoring equipment is given in the many International Electrotechnical Commission (IEC) standards. The type tests require access to specialized facilities and will normally be performed in a laboratory with secondary standard, or similar, status, for example, a NAMAS-accredited laboratory.

The HSE provides procedures that are appropriate for the pre-use and periodic testing of individual dose-rate and contamination-monitoring equipment. Details are given on linearity, energy response, polar response, and overload testing.

It is important to note that within the U.K. there is common legislation on personal dosimetry and instrument calibration for all fields, including the medical, university, nuclear energy, and industrial areas. Representatives of organizations in all these areas also participate voluntarily in a working group called the Ionizing Radiation Metrology Forum run by the NPL. This group organizes intercomparison exercises on the calibration of dose-rate instruments and surface-contamination

monitors. The group also provides a forum for discussion of any problems that may arise from the legislation.

For external radiation monitoring, the ICRU 39 (ICRU 1985) quantities for ambient and directional dose are used, and after December 1993 the personal control doses will be reported in terms of the ICRU 47 (ICRU 1992) personal dose equivalents,  $H_p(10)$  and  $H_p(0.07)$ .

### **Accreditation in France**

At the present time in France, there are no nationally accepted procedures for calibrating monitoring instruments or personal dosimeters. There is, however, widespread use of the ISO reference radiations for calibrating monitoring instruments and personal dosimeters.

The French National Bureau of Metrology has issued draft documentation that deals with the structure of the methodology and accreditation of calibration laboratories. The accreditation will be based upon the quality assurance requirements of ISO/IEC Document 25.

The National Bureau of Metrology draft documents are general documents that do not specify the accreditation requirements specific to radiological calibration.

### **Accreditation in Germany**

#### **Dosimetry Services**

In Germany no national accreditation procedure exists; instead the German Laender (Federal State) stipulates the service that is responsible for each Land (Federal State). Presently, there are six such dosimetry services.

The Verification Ordinance, 12 August 1988 (Eichordnung von 12 August 1988, 1988), specifies the mandatory type tests of dosimetry systems for photon radiation using thermoluminescent or thermally stimulated exoelectron emission (TSEE) detectors or films. Regular comparison measurements using a special procedure to assure the quality of the routine operation of the dosimetry services are prescribed. Further requirements regarding the operation of the services have been prescribed in the Anforderungen an die nach Landesrecht Zuständige Meßstelle (requirements for dosimetry services) (1979).

Details of the requirements for the type tests have been laid down by the Physikalisch-Technische Bundesanstalt (PTB); the most important performance characteristics to be tested are:

- a. photon energy response
- b. photon angular response
- c. non-linearity of response
- d. temperature and humidity response.

The services must use approved systems, but they also have to participate successfully in a yearly comparison measurement program involving irradiation at the PTB of 10 dosimeters for each dosimetry system in use. The official of a verification office will, without prior notice, give the service these 10 irradiated dosimeters and require the service to immediately evaluate the doses using



their documented procedures. The evaluated dose results are given to the PTB for comparison with the acceptable level of errors.

The dosimetry guideline is being revised to include criteria for beta particle and neutron dosimetry, but this will not require legal type-testing. Each service will also be required to have access to at least gamma and beta radiation sources, X-ray and neutron irradiation facilities, and their associated calibration equipment. Examples of typical annual comparison measurements are given by Böhm and Buchholz (1986).

### Calibration of Radiation-Monitoring Equipment

Germany's requirements for instrument calibrations are less well documented than those for personal dosimetry.

Germany does have a legal requirement for the PTB to type-test each design of instrument. For example, a photon-dose-rate instrument may not be used for measurements unless the energy response varies less than  $\pm 30\%$  over the energy range of 10 to 1300 keV, and the angular response variation is less than  $\pm 20\%$ , and the linearity is within  $\pm 20\%$  over the instrument's range.

Along with other Commission of the European Communities (CEC) countries, Germany now uses only SI units, and the instruments' indications are in units of sieverts. However, at the present time the ICRU 39 operational dose equivalent qualities are not used, and the quality used for measurement of photon radiation is the "photon dose equivalent." The photon dose equivalent is obtained from exposure in Roentgens, R, simply by applying a conversion coefficient of 0.01 Sv/R. Thus, instruments that meet the PTB photon energy response requirements are unlikely to be suitable for measurements of the ambient dose equivalent within the U.K.

## COMPARISON OF NATIONAL PROGRAMS

### Personal Dosimetry Accreditation

Only the accreditation schemes in use in the United States (U.S.), the U.K., and Germany are compared because published reports from these countries are the most readily available. There are significant differences among these three national programs, although the associated quality assurance programs of each one, including the recent French proposals, seem to be consistent with the requirements of ISO/IEC Guide 25. Information on these programs can be found in recent publications (Ambrosi 1992, Böhm 1992, McDonald 1992).

The U.K. is the only country of the three that has a single common legal approval system for the whole country. The U.S. has the U.S. Department of Energy Laboratory Accreditation Program (DOELAP) and the National Voluntary Laboratory Accreditation Program (NVLAP) requirements, while in Germany there is no national accreditation program.

There are also significant differences among the three countries in the performance testing of approved dosimetry services. All three countries require that individual dosimetry services, as well as the laboratories responsible for the performance-testing irradiations, use radiation fields with dose rates or doses that have been measured by methods traceable to national/primary standards. In Germany this traceability is obviously more direct since the performance irradiations are undertaken at the PTB.

However, the U.S. irradiation laboratories (performance-testing laboratories) are subject to external audits and reviews while the U.K. irradiation laboratories have to be NAMAS-accredited. Germany's performance testing allows the dosimetry services no prior warning of test irradiations while the U.S. and U.K. testing programs do. (In the latter two, each service must select and send dosimeters to an irradiation laboratory for the test irradiations.)

The dosimeter irradiations performed in each country are also different. In the U.K. the present legally required testing only requires irradiation of the dosimeters free-in-air with the single-photon radiation from  $^{137}\text{Cs}$ . This contrasts with the U.S. dosimeter processor accreditation program requirements by which dosimeters are irradiated on a phantom with a combination of low- and high-energy photons as well as with beta and neutron radiations. These programs operated by the DOE and the NVLAP use radiations and doses described in their respective standards (DOE 1986, ANSI 1983). In Germany the dosimeters are irradiated free-in-air at photon energies from 20 keV to 3 MeV, sometimes with irradiations at several energies. The dosimeters can also be irradiated at different angles, up to  $\pm 45^\circ$ , relative to the reference direction. Performance testing of neutron dosimeters is at present only undertaken within the U.S., although both Germany and the U.K. intend to introduce such testing in the near future.

### **Instrument Testing and Calibration**

The differences among the national calibration and test requirements of the U.S., the U.K., and Germany for instruments are even greater than those for personal dosimetry accreditation.

Only the U.K. has common legal requirements for the type testing, pre-use testing, and routine testing of all radiation equipment that is used for monitoring each controlled or supervised area. The U.K. legislation also requires that such testing be undertaken or supervised by an appointed qualified person and that the calibrations shall be traceable to national/primary standards.

Germany permits the use of radiation-monitoring equipment only if it has passed its type test at the PTB. Information on German national requirements for the pre-use and routine calibration of monitoring instruments is not available. The U.S. does not have a type testing program or requirements for pre-use testing or routine testing. The U.S. does have voluntary programs for the accreditation of calibration laboratories for protection level instruments. The programs are operated by the Council of Radiation Control Program Directors (CRCPD) for the state programs, by the Health Physics Society (HPS) for commercial-sector programs and by NVLAP for government-controlled programs. Only the NVLAP program operates under published criteria (Eisenhower 1991). The other programs operate with criteria developed and maintained by the respective groups, the HPS and the CRCPD. These programs accredit laboratories for the establishment of reference radiation fields for calibration and for the proper quality control and use of these fields. ANSI standard N323 (ANSI 1978) describes the use of these fields for the calibration of protection-level instruments and is a required standard within the DOE.

### **SUMMARY AND OBSERVATIONS**

In developing a calibration or testing program, there are obviously advantages to be gained by studying and learning from the experiences and techniques used in other countries. This paper is a continuing part of that process. Participation in intercomparisons is also valuable in identifying both

when existing procedures are acceptable and when they require changing. Consideration should thus be given to forging closer ties between European and U.S. intercomparison exercises.

European countries have the advantage of a long-established intercomparison program for dosimeters and monitoring equipment. The use within Europe of the ISO radiations, however, has diminished the need for such intercomparisons because the use of well-defined irradiation conditions removes a major variable and allows more direct comparison of measurements made at different laboratories.

Of great concern is the fragmented approach in all countries to the adoption of the SI units and the dose-equivalent quantities recommended in ICRU Reports 39 and 47. This cannot help promote international trade because manufacturers have to supply different versions of the same instrument to countries that use different measurement quantities and units. There is also an increased danger that the manufacturer may supply an instrument having the incorrect detector configuration. As long as this situation continues, it is particularly important that pre-use testing of radiation monitors include energy- and angular-response testing.

On the positive side, it is encouraging to note a more common approach to the adoption of quality assurance programs and procedures, with the basic recommendations listed in the IEC/ISO guideline document, IEC/ISO 25, being used in many countries.

The recent European Economic Community unification and the consequent freedom of movement of workers within the community should stimulate the need for unification of accreditation and calibration schemes throughout Europe. In the U.S. there may be similar advantages in combining the DOELAP and NVLAP accreditation schemes. In the long term, unification and multi-lateral recognition of the calibration and accreditation programs throughout the world will enhance world-wide trade.

There appears to be considerable scope for a more unified and internationally standardized approach to calibration programs for both personal dosimeters and monitoring equipment. One very significant step would be the adoption of the ISO reference radiations in the U.S. In Europe these radiations are widely used, and they are also specified in all the IEC standards on radiation-monitoring equipment and dosimeters.

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**Table 1 - International Organization for Standardization (ISO)  
Standards of the 9000 Series (1987)**

Number	Title
ISO 9000	Quality Management and Quality Assurance Standards - Guidelines for Selection and Use
ISO 9001	Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation and Servicing
ISO 9002	Quality Systems - Model for Quality Assurance in Production and Installation
ISO 9003	Quality Systems - Model for Quality Assurance in Final Inspection and Test
ISO 9004	Quality Management and Quality System Elements - Guidelines

**Table 2 - National Equivalents to ISO 9000**

International	United States	European	British
ISO 9000	ANSI/ASQC Q90	EN 29000	BS 5750: Part 0; Section 0.1
ISO 9001	ANSI/ASQC Q91	EN 29001	BS 5750: Part 1
ISO 9002	ANSI/ASQC Q92	EN 29002	BS 5750: Part 2
ISO 9003	ANSI/ASQC Q93	EN 29003	BS 5750: Part 3
ISO 9004	ANSI/ASQC Q94	EN 29004	BS 5750: Part 0; Section 0.2

*Table 3 - Major Sections of ISO/IEC Guide 25*

<b>Section Number</b>	<b>Title</b>
1	Scope
2	References
3	Definitions
4	Organization and Management
5	Quality System, Audit and Review
6	Personnel
7	Accommodation and Environment
8	Equipment and Reference Materials
9	Measurement Traceability and Calibration
10	Calibration and Test Methods
11	Handling of Calibration and Test Items
12	Records
13	Certificates and Reports
14	Sub-contracting of Calibration or Testing
15	Outside Support Services and Supplies
16	Complaints



*Table 4 - ISO Reference Radiation Standards*

Number	Title
ISO 4037, Part 1	X and Y Reference Radiations for Calibrating Dosimeters and Dose Ratemeters and for Determining Their Response as a Function of Photon Energy, Characteristics of the Radiations, and Their Methods of Production
ISO 6980	Reference Beta Radiations for Calibrating Dosimeters and Dose Ratemeters and for Determining Their Response as a Function of Beta Energy
ISO 8529	Reference Neutron Radiations for Calibrating Neutron-Measuring Devices Used for Radiation Protection Purposes and for Determining Their Response as a Function of Neutron Energy
ISO 8769	Reference Sources for the Calibration of Surface- Contamination Monitors - Beta-Emitters (maximum beta energy greater than 0.15 MeV) and Alpha-Emitters

*Table 5 - Signatories of the Multi-Lateral Agreement Between European Calibration Services*

Country	Name of Service
Denmark	Danish Accreditation Scheme
Finland	Center for Metrology and Accreditation
France	Bureau National de Metrologic, BNM (Reseau National d'Essais, RNE)
Germany	Physikalisch-Technische Bundesanstalt, PTB (Deutscher Akkreditierungs Rat, DAR)
Italy	Servizio di Taratura in Italia, SIT
The Netherlands	Nederlandse Kalibratie Organisatie, NKO
Sweden	Swedish Board for Technical Accreditation, SWEDAC
Switzerland	Swiss Calibration Service, SCS
United Kingdom	National Measurement Accreditation Service, NAMAS

*Table 6 - NAMAS Information Sheets in the Area of Radiation Calibration*

Calibration of Radiological Protection Level Instruments: X, $\gamma$ , and $\beta$ rays Information Sheet B0811
Calibration of Radiological Protection Level Instruments: Neutrons Information Sheet B0813
The Calibration of Radiological Protection Level Instruments: Surface-Contamination Measuring Instruments and Sources for their Calibration. Information Sheet B0824.
The Expression of Uncertainty in Radiological Measurements: Information Sheet B0825
Supplementary Criteria for Laboratory Accreditation: Calibration of Radionuclide Sources Activity, Particle or Photon Emission Rate, Exposure Rate or Air Kerma Rate. Publication B0814

*Table 7 - NAMAS Documents Applicable to Testing Laboratories*

The Assessment of Whole Body Dose by the Determination of Tritium in Urine, Publication NIS 59
Use of Film Dosimeters for Beta, Gamma, X- and Thermal Neutron Radiations, Publication NIS 61
Use of Thermoluminescent Dosimeters for Beta, Gamma, X- and Thermal Neutron Radiations, Publication NIS 65

# **PERSPECTIVES AND POLICIES**

Session Chair  
Tom Heaton, FDA

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# **QUALITY ASSURANCE PROGRAMS DEVELOPED AND IMPLEMENTED BY THE U.S. DEPARTMENT OF ENERGY'S ANALYTICAL SERVICES PROGRAM FOR ENVIRONMENTAL RESTORATION AND WASTE MANAGEMENT ACTIVITIES**

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## **INTRODUCTION**

The U.S. Department of Energy's (DOE's) Office of Environmental Restoration and Waste Management (EM) has been tasked with addressing environmental contamination and waste problems facing the Department. A key element of any environmental restoration or waste management program is environmental data. An effective and efficient sampling and analysis program is required to generate credible environmental data. The bases for DOE's EM Analytical Services Program (ASP) are contained in the charter and commitments in Secretary of Energy Notice SEN-13-89, EM program policies and requirements, and commitments to Congress and the Office of Inspector General (IG).

The Congressional commitment by DOE to develop and implement an ASP was in response to concerns raised by the Chairman of the Congressional Environment, Energy, and Natural Resources Subcommittee, and the Chairman of the Congressional Oversight and Investigations Subcommittee of the Committee on Energy and Commerce, regarding the production of analytical data. The development and implementation of an ASP also satisfies the IG's audit report recommendations on environmental analytical support, including development and implementation of a national strategy for acquisition of quality sampling and analytical services. These recommendations were endorsed in Departmental positions, which further emphasize the importance of the ASP to EM's programs.

In September 1990, EM formed the Laboratory Management Division (LMD) in the Office of Technology Development to provide the programmatic direction needed to establish and operate an

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EM-wide ASP program. In January 1992, LMD issued the "Analytical Services Program Five-Year Plan." This document described LMD's strategy to ensure the production of timely, cost-effective, and credible environmental data.

This presentation describes the overall LMD Analytical Services Program and, specifically, the various QA programs.

## **ANALYTICAL SERVICES PROGRAM**

The LMD Analytical Services Program is divided into three core areas: Resource Management, Analytical Support, and Quality Assurance (QA). The program currently is focusing on the following selected items, which are divided among the sections:

- Assess radiochemical, chemical, and physical sampling needs, and current analytical community capabilities and capacities.
- Develop a strategic plan to meet EM's future analytical support needs.
- Develop sample and information management systems for EM's environmental sampling and analytical data.
- Develop a compendium of field and laboratory analytical procedures, as well as sampling procedures, for use by waste management operations and environmental restoration program/project participants.
- Develop QA requirements and supporting documents.
- Provide oversight procedures to assure production of credible data by analytical laboratories and field operations (performance evaluation samples and other audit/assessment programs).
- Provide and implement the Data Quality Objective (DQO) process to optimize EM sampling and analysis programs.

## **QUALITY ASSURANCE PROGRAM**

The QA program is responsible for all QA aspects of hazardous, radioactive, and mixed waste sampling, and analysis as well as for assuring compliance with DOE Orders, e.g., 5700.6C, and regulatory requirements programs. The major functions include management and coordination of:

- Quality Assurance Guidance Supplements: developing and overseeing the implementation of QA requirements for environmental sampling and analysis.
- Performance Evaluation (PE) Program: developing and managing a program for assessing laboratories that perform EM's analyses.
- Audit Program: developing and implementing management and technical system audits of sample collection, analytical measurements, and data analyses.

- Data Quality Objectives: implementing the DQO process to optimize environmental sampling and analysis.

There are six QA guidance supplements being developed in LMD to address the following general issues:

- Implementation of DOE QA Order 5700.6C, specifically in areas of environmental sampling and analysis.
- Definition of the expectations for elements of the sampling and analysis programs.
- Definition of required participation in external performance evaluation sample programs.
- Harmonize interagency and DOE field office QA activities and assure consistency across the DOE complex.

The six supplements are Sampling Aspects; Laboratory Aspects; Management Assessment; Integrated Performance Evaluation Program (IPEP); Field Assessment; and Laboratory Assessment. Figure 1 shows the relationship between the supplements and the ten criteria of DOE Order 5700.6C.

#### **INTEGRATED PERFORMANCE EVALUATION PROGRAM**

The IPEP's purpose is to monitor and improve the quality of environmental data obtained from laboratories. The program applies to all private sector, government, and government-owned, contractor-operated analytical laboratories supporting EM activities. The program integrates and coordinates participation in various PE programs to ensure regulatory compliance and reduce program redundancy. A function of the IPEP is to develop PE materials specifically required for EM sampling and analysis programs.

The elements of the IPEP program include:

- developing questionnaires to determine current use and program need for performance evaluation materials
- establishing a DOE laboratory performance evaluation database
- distributing radiochemistry PE samples (participating in the QA program of the DOE's Environmental Monitoring Laboratory)
- initiating a mixed waste performance evaluation sample program
- implementing a performance assessment program (scoring) for DOE laboratory participants.

## **AUDIT PROGRAMS**

In any environmental sampling and analysis program, there is a need to periodically review various technical and managerial activities to assure that the processes and procedures that are in place are working. Specifically, the LMD audit program:

- Reviews and evaluates the management structures associated with planning and implementing field and laboratory activities
- Reviews technical procedures to determine if they were developed properly and are being implemented properly
- Reviews the results of the sampling and analysis data gathering to assess data quality characteristics and their appropriateness for use.

## **DATA QUALITY OBJECTIVES**

The DQO process is a Total Quality Management tool developed by the U.S. Environmental Protection Agency (EPA) to facilitate the planning of data collection activities. Use of this tool allows planners to focus their efforts by specifying the use of the data, decision criteria with respect to the data, and a measure of the acceptable probability for making a wrong decision based on the data collected. It is a sequential process that guides the user through consideration of the factors that increase or decrease the certainty of data and how this affects decisions that are based on the analytical data. The principles of the process are directly applicable to both large and small data-gathering operations. DQOs are specifications that are developed during study design that define the level of data quality necessary to support a decision. They are quantitative expressions (with associated precision and bias) that are required to demonstrate that the desired result identified during the planning process has been achieved. The quality specifications reflect regulatory requirements, input requirements for statistical analysis, resource constraints, and so on, and are used to plan for the uncertainty that arises from any measurement process. DQOs may be different for different decisions within the context of the same study, but can be generated so that relevant data can be collected once to support many or all of the required decisions.

Key elements of the DQO process include:

- problems/concerns that require resolution
- data requirements that are developed to address the problems/concerns
- tolerances for drawing the wrong conclusions
- a decision rule that results in a quantified action plan
- optimized design for cost-effective implementation.

The DQO process results in consensus among the concerned parties with respect to the optimized design. Concerned parties (the stakeholders) may include regulators, state and local personnel, Indian tribes, and others who are involved in the process. The process encourages structured communication



about requirements among these parties during the planning process (i.e., before resources are expended in sampling and analysis). The structure of the DQO process provides a convenient way to document activities and decisions and to present the plans in a logical manner to a wider audience.

The DQO process consists of seven key steps:

1. Statement of the problem to be resolved, including any resource, time, or other practical limits and evaluation of existing knowledge about the problem and identification of available resources.
2. Identification of the decision, using environmental data and any actions that will result. Focus is placed on actions that result from the use of the data so that data needs that are exploratory can be eliminated.
3. Identification of the inputs, the list of environmental variables or characteristics to be measured, criteria for action, and additional information needs. Focus is placed on characteristics that require measurement in order to develop the study design.
4. Definition of the boundaries of the study, the population for which the decision will be made, includes the area and time period. People and objects that may be affected as well as the boundaries of the environmental media are included.
5. The decision rule is developed. It is a statement that defines how the environmental data will be used to make the decision and integrates the inputs from previous steps into a single action statement that includes quantitative criteria.
6. The limits on uncertainty are specified which provide the acceptable probability of a false negative or false positive error. Estimates of economic health, and ecological consequences of an error in the required decision, as well as political and social consequences, are put forward.
7. Optimization of the design, including the lowest cost that will meet the criteria defined by the DQOs. Statistical techniques are used to balance design criteria to maintain the limits on uncertainty with the lowest expenditure of resources.

The decision to be made, or the question to be answered, is defined in the first two steps. Available data are examined and the need for further information is determined in the next three steps. Uncertainty constraints are developed, and the sampling and analytical requirements for data collection activities are specified in the last two steps. Study optimization evaluates error rates and costs to select the most cost-effective design that meets the user-defined confidence limits.

## CONCLUSION

This paper describes the DOE's analytical services program for QA, which was developed and are being implemented by the Laboratory Management Division of the Office of Special Programs for Environmental Restoration and Waste Management programs. This program satisfies the DOE program requirements for the production of analytical data of known quality.

*Figure 1 - Environmental Sampling and Analysis (ESAA) Guidance*

	Ten Criteria of DOE Order 5700.6C	Samp Aspect	Lab Aspect	Mgmt Assess	IPEP	Field Assess	Lab Assess
1.	Program	X	X		X		
2.	Personnel Training & Qualification		X	X		X	
3.	Quality Improvement	X	X	X	X	X	X
4.	Documents & Records	X	X		X		
5.	Work Processes	X	X		X		
6.	Design	(Nothing unique to ESAAs)					
7.	Procurement	X	X		X	X	X
8.	Inspection, etc.	X	X		X	X	X
9.	Management Assessment			X			
10.	Independent Assessment				X	X	X

# NVLAP ACTIVITIES AT DEPARTMENT OF DEFENSE CALIBRATION LABORATORIES

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*Abstract* - There are 367 active radiological instrument calibration laboratories within the U.S. Department of Defense (DoD). Each of the four services in DoD manages, operates, and certifies the technical proficiency and competency of those laboratories under their cognizance. Each service has designated secondary calibration laboratories to trace all calibration source standards to the National Institute of Standards and Technology. Individual service radiological calibration programs and capabilities, present and future, are described, as well as the measurement quality assurance (MQA) processes for their traceability. National Voluntary Laboratory Accreditation Program (NVLAP) programs for dosimetry systems are briefly summarized. Planned NVLAP accreditation of secondary laboratories is discussed in the context of current technical challenges and future efforts.

## INTRODUCTION

Within DoD, four services, the Navy, Army, Air Force, and Marine Corps, individually manage and operate their own radiological calibration programs. Each service has made some degree of commitment to becoming involved in seeking accreditation of one or more of its calibration laboratories under the NVLAP. The purpose for such accreditation is to establish a few laboratory centers which can be certified as having credible traceability of all their radiation source standards to the National Institute of Standards and Technology (NIST) and also to carry the chain of standards traceability in a reliable fashion down to each of their subordinate field calibration laboratories. This chain of traceability is vitally important considering that each service has a separate worldwide and sometimes diverse complex of calibration laboratories which must suit specific service missions, customer needs, and technical emphasis, and also serve key operational centers to which they are proximally located. DoD participates in two main NVLAP activities: dosimetry system and secondary radiological calibration laboratory accreditation programs. In the first activity, DoD laboratory centers which process dosimetry have become technically mature under NVLAP. This activity is driven by the Code of Federal Regulations (CFR 1992) which require certification once

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every two years under NVLAP (ANSI 1982). The second activity, NVLAP accreditation of calibration laboratories, is somewhat in its early stages. This NVLAP program, however, is not governed as a mandatory certification under Federal Regulations and, therefore, does not have quite the impetus for implementation as there was historically for the dosimetry NVLAP. That is not to say there are no incentives for accrediting calibration laboratories. Each of these laboratories, which must be licensed by the U.S. Nuclear Regulatory Commission (NRC) for the use of its source standards, needs to conform to "good practice" guidelines under various NRC regulatory guides and standards (NRC 1981, 1985, 1987; ANSI 1978).

The guides, based on health physics operational requirements, specify that sources used to calibrate instruments should be traceable to national standards to within  $\pm 5\%$ . It is this required tolerance which gives rise to the need for MQA through a NVLAP program.

The purpose of this paper is to describe the DoD laboratories involved in NVLAP activities as well as the various processes for maintaining MQA throughout the complex of service laboratories. Dosimetry system accreditation will be briefly summarized. Most of the discussion will concentrate on radiological calibration laboratories, the quality processes now in effect for each service calibration program, the challenges presented by the NVLAP accreditation process, and future radiological functions which might benefit from an MQA program.

## **DESCRIPTION OF THE VARIOUS DOD PROGRAMS**

The various DoD programs are described in the following.

### **NVLAP Dosimetry Laboratories**

Each service has its own centralized laboratory for processing personnel dosimeters and maintaining historical dose records, except for the U.S. Marine Corps, which obtains its dosimetry from the Navy. In addition, the Navy operates another separate dosimetry system to support the Naval Nuclear Propulsion Program under its strict guidelines. That system, thought to be the largest completely decentralized dosimetry program in the world, provides on-site and work-site processing of personnel dosimeters in the field. Table 1 shows where each service dosimeter processor is located, the equipment used, number of organizations monitored, the current transaction rate per year, and the frequency for reading personnel dosimeters. For the second Navy system, the location named is the organization responsible for the NVLAP accreditation. Each location for the centralized processors currently carries NVLAP certification and has successfully maintained it since 1986. The Navy's decentralized system has also been continuously accredited under NVLAP from 1989 onward. The accreditation categories for each dosimetry system are given in Table 1.

Each centralized processor's dosimetry system is operated under locally established and approved procedures. They specify how often the readers are to be properly adjusted and calibrated and what measures are to be taken if dosimeters, which are given known exposures and randomly seeded within processing runs, identify out-of-tolerance conditions. Individual dosimeters are checked for proper sensitivity to and registration of radiation before they are sent back to various customers. Multiple processing frequencies, where shown, are structured to require personnel with a potential for higher exposure to get their dosimeters evaluated more often, and likewise for lower exposure potentials less often. The Navy's decentralized dosimetry system, however, is treated differently, but also subjected to stringent controls. Each processor must have its dosimeters checked for proper sensitivity at least

every 6 months and dosimetry readers calibrated at least every year. Calibration standards are replaced at every fifty uses. Additionally, and most importantly, each processor receives inspection each year from an independent organization of examiners or the program office to demonstrate the proficiency of personnel operating the dosimetry equipment. Also, the dosimetry equipment is subjected to a performance test each year to prove whether it meets specified criteria or needs correction of its out-of-tolerance condition (USN 1988). All corrections are followed up by retests. Personnel dosimeters are processed daily if used in shipyard work, up to monthly if used in shipboard activities, or the same day after leaving a high-radiation area. The unique and all-encompassing quality assurance test process for this dosimetry system is depicted in Figure 1. Tight control of 160 processors to a single calibration reference at the Naval Shipyard, Puget Sound, Washington, and yearly internal performance testing keep this system well within NVLAP tolerances. It is also an excellent example of a proven and successful MQA process.

In general, the services have maintained mature and smooth operating dosimetry programs which have benefitted from NVLAP accreditation. The long-term success of these NVLAP programs owes to the early 1980's participation of the services in the University of Michigan pilot program for dosimetry processor accreditation (Plato and Hudson 1980). The early collaboration of both processor and test organizations allowed organizations to make the proper corrections and refinements to their dosimetry equipment. In turn, the testing organization was able to identify and amend unrealistic performance criteria before the NVLAP was established. This joint effort contributed to the high degree of acceptance of the dosimetry NVLAP even before mandatory certification became a requirement by federal law (CFR 1992).

### **DoD Calibration Laboratories**

Each service within DoD has its own radiological instrument calibration program, supporting management structure, operating directives and policies, technical procedures, and inspection and audit process for maintaining MQA and traceability to NIST. Table 2 describes the relative sizes of various service radiological calibration programs in terms of calibration transactions performed per year and also the size of the instrument inventory supported. It also breaks out the number of instruments identified in the operational category, which are employed in daily, routine health physics applications. The rest of the inventories fall under warfare preparedness and contingency planning. The calibration frequencies for the instruments reflect the ranges of the above applications.

### **U.S. Navy Program**

The Navy's radiological instrument calibration program is managed by Naval Sea Systems Command in Washington, D.C. while its operation has been delegated by NAVSEA authority to the Naval Electronic System Engineering Center (NAVELEXCEN), Charleston, South Carolina. The latter organization has the responsibility for the secondary calibration laboratory, and its basic function is to hold NIST-traceable calibration source standards for the Navy and ensure that all other radiological calibration laboratories within the Navy trace their measurements to these sources. NAVEXCEN Charleston also manages the operation and inspection of all subordinate laboratories listed in Table 3. There are 30 laboratories within NAVEXCEN's area of responsibility, 16 laboratories on board tenders or repair ships, 10 within the continental United States, and 4 outside the continental United States. The secondary calibration laboratory at Charleston carries a high-intensity, open-range capability for gamma radiation; an open-air range for neutrons; and large-area sources for alpha radiation.

The 30 calibration laboratories listed in Table 3 presently trace their calibration sources to those described for the Charleston laboratory. Each of these laboratories has similar capabilities, depending on whether a tender or a shore organization is performing calibrations. The shipboard laboratories, stationed throughout the world and deployable to other locations to support military forces in international conflicts, do not use open-range sources. To fit the confines of the ship, box calibrators for gamma and neutron sources are required. The shore laboratories, however, having greater space allocations, calibrate with open-air ranges where possible. NAVELEXCEN Charleston plans to become accredited as a secondary laboratory under NVLAP within the next few years. In the upgrade of its capabilities, it will phase in a multisource, uncollided beam Cs-137 gamma calibrator, in place of the current AN/UDM-1A, and also an open-range Co-60 source. The large-area alpha sources in the AN/UDM-7 series will be replaced with large-area electroplated Amersham-type sources. Also, a 320-kVp x-ray range will be added to its capability. The same gamma calibrators will eventually be installed at all shore laboratories, replacing all AN/UDM-1A calibrators.

The Navy's structure for maintaining MQA throughout its laboratory organizations is summarized in Figure 2. There are four management directives (USN 1989a, 1989b, 1992a, 1992b) which cover all aspects of the operation and control of the calibration program. The administrative and operational directive (USN 1989a) establishes calibration priorities and frequencies. Table 2 indicates that equipments used for operational health physics applications form a significant part of the Navy inventory. For the Navy, the operational applications for reactor, medical, radiation safety, radiography, and nuclear weapons functions are the highest priority and require 6-month calibration periods (3 months for radiography) for its needs. Emergency response, training, and warfare preparedness are the lowest priority categories and have longer instrument calibration periods. A local field office structure, which reports through NAVELEXCEN Charleston, is required to oversee the operation of local calibration laboratories. These responsibilities include seeing that a weekly quality assurance sample of instruments is drawn and inspected for proper calibration and completion of repairs and documentation, reviewing personnel training requirements and competencies for laboratory work, performing monthly on-site surveillances to ensure that equipment calibrations are performed according to calibration directives, conducting twice-a-year formal reviews to observe and test for strict word-for-word adherence to formally published instrument calibration procedures (USN 1992b), and preparing for once every 12 to 18 months audits of the entire program by NAVELEXCEN Charleston.

The audit program (USN 1989b) certifies the fitness of the laboratory to deliver NIST-traceable calibrations for the instruments used by various Navy customers. It covers factors from laboratory environmental control, radiological safety, work space and support equipment standards, ability to follow calibration procedures, and utilization and currentness of technical publications and management directives to the retention of calibration certificates. Each laboratory is given a certification, an interim certification, or decertification, depending on the number and severity of findings. Remedial actions are required if a less than full certification is received and another audit visit is scheduled. Laboratories unable to receive full certification are given a limited remedial period for correcting deficiencies or are not permitted to operate. This audit program is also supplemented throughout the year by inspections from the Nuclear Propulsion Program if calibrations at a given laboratory are performed for its application. The Office of the Chief of Naval Operations through the Radiological Affairs Safety Office (RASO) in Yorktown, Virginia, holds the Navy's NRC master material license and directs once every 3 years inspections of all calibration laboratories for compliance with NRC requirements which prescribe the safe and proper control and handling of radioactive materials.

The secondary laboratory at Charleston maintains the update and control of all radiological instrument calibration procedures which are distributed to all concerned (USN 1992b). It also operates under its own policy directives and procedures (USN 1992a) for the traceability of all laboratory sources to NIST. This directive covers personnel training of the technical team which visits each laboratory once every 3 years, or sooner if there is technical assistance required in repairing a calibrator. The directive instructs how to analyze the field calibration data, what verification methods to use, and what data to report to the calibration laboratories. There is no formal program in place yet to independently audit this function in the Navy's calibration program. NVLAP certification is proposed to supplement the audit of this program.

### **U.S. Army Program**

The Test, Measurement, and Diagnostic Equipment (TMDE) Activity, which resides at Redstone Arsenal, Alabama, both manages and operates the Army's radiological instrument calibration program. TMDE's responsibility for source traceability is identical to that for the Navy's laboratory at Charleston. It serves as a secondary calibration laboratory for the Army's basic radiation source standards. TMDE Activity formulates and distributes policy for the operation and management of subordinate calibration laboratories, as listed in Table 4. However, the inspection function for all laboratories, including the secondary laboratory, is handled through an independent organization at TMDE called the Inspection and Policy Compliance Division. There are 203 radiological calibration laboratories which trace their calibration sources to standards held at TMDE Activity. They have all been categorized as to level 1, 2, or 3 laboratories and have stratified levels of accuracy in their calibration capability. Level 3 laboratories have the same source capabilities as level 2, but mostly check and calibrate instruments to a 30% tolerance level and refer instruments to the next level laboratory if they require a tighter degree of tolerance. Out of the eight level 1 laboratories, two are outside the continental United States and six are within. All ten level 2 laboratories are within the continental United States. Table 4 also describes the degree of planned consolidation of Army calibration activities over the next few years.

In addition, the dosimetry processing function, now at the U.S. Army Ionizing Radiation Dosimetry Center (USAIRDC), Lexington, Kentucky, will move to be combined with the TMDE function at Redstone Arsenal, Alabama. The current capability at Redstone's secondary calibration laboratory includes a high-intensity, open-air gamma source, the AN/UDM-1A, small-area alpha standards, AN/UDM-6, a beta source calibrator for low-range survey meters, and 320- and 50-kVp x-ray machines. Its planned capability as a secondary laboratory, when its new laboratory is constructed and all organizational consolidations are completed, will propose the following capabilities for NVLAP certification: Shepherd series 81 with open-air Cs-137 and Co-60 calibration ranges; a Cs-137 box calibrator; both large- and small-area, electroplated Amersham-type alpha source sets; the beta calibrator with standard (Sr-90, Pr-147, and Tl-204) sources and beam flatteners; the 320- and 50-kVp x-ray machines; and an open-range PuBe neutron source.

Level 1 laboratories differ from level 2 and 3 laboratories in that they have high-intensity gamma capability and the others use AN/UDM-2 source sets instead. This means that the need for instrument calibrations using a high-intensity gamma range calibration would have to be fulfilled at the level 1 hierarchy. In Table 2, it can be seen that, unlike the Navy's mission, which is heavily influenced by operational health physics requirements, the Army's mission is geared to servicing instruments for contingency and warfare preparedness applications.

The Army organizational structure for maintaining MQA is given in Figure 3. There are four main Army directives (USA 1989, 1990, 1991, 1992) which set policies for the management and operation of Army radiological calibration laboratories. The overall policy directive (USA 1989) establishes TMDE at Redstone Arsenal, Alabama, as the responsible agent for the Army's radiological calibration program and empowers it to set requirements and distribute procedures for the operation of calibration laboratories at subordinate organizations. Calibration frequencies for instrument calibrations are influenced by the use category of the instrument (USA 1992). Instruments are categorized into the following uses: active, radiographic, or medical; "REACT" for emergency teams; and warfare contingency. The category "active" means that the instrument is in daily use around ionizing radiation sources. Instruments in the first category grouping are calibrated every 90 to 120 days, depending on instrument performance data; those in the second category every 90 days, and those in the last every 5 years. Calibration procedures and methodologies along with calibration intervals are contained in published references (USA 1991, 1992). The calibration protocol requires adjustment only if the measured value exceeds the specified tolerance. Otherwise, no adjustments are made. This method is contrasted with the Navy and Air Force practices to adjust instruments to the optimum set points any time a user submits an instrument for calibration.

The published methodologies also describe a QA program wherein TMDE Activity analyzes calibration frequency data, fields questions and problems from the users and laboratories, and examines the findings of technical audits and inspections for abnormal behavior trends. From this field link, TMDE Activity is able to modify policies and procedures to implement needed improvements and refinements. TMDE Activity personnel within the secondary calibration laboratory check the source standards at each calibration activity (including their own) every 18 to 24 months to ensure its sources are kept traceable to NIST. Under procedures and check lists for quality assurance tests (USA 1990), the TMDE independent compliance team mentioned earlier inspects each laboratory every 18 to 24 months. Its findings, if serious enough, can be reported through the U.S. Army Inspector General for resolution. The report from this team decides the suitability of the laboratory for continued calibration of instruments. In addition, because the calibration sources of all levels of laboratories are licensed radioactive material, the Army Environmental Hygiene Agency (AEHA) conducts NRC compliance inspections once every 3 years to ensure laboratories are handling and transporting sources correctly and safely.

### **U.S. Air Force Program**

The Aerospace Guidance and Metrology Center (AGMC) at Newark Air Force Base (AFB), Ohio, manages and operates the Air Force's radiological instrument program. AGMC is responsible for maintaining basic radiological source standards traceable to NIST and acting as the secondary calibration laboratory to which all other Air Force radiological calibration laboratories trace their source standards. The AGMC, like the Army's TMDE Activity, formulates and distributes policy to the operation and management of subordinate laboratories listed in Table 5. The inspection and audit function for all laboratories, including the secondary one at AGMC, belongs to a separate AGMC organization responsible for laboratory compliance. There are 128 radiological calibration laboratories within the Air Force, 8 depot level laboratories, and 120 Precision Measurement Equipment Laboratories (PMEL). They trace their source standards to AGMC. Locations for the major depots are listed in Table 5. Six depots are within the continental United States; two are outside. The 120 PMELs are spread through various field units. Depots at Patrick AFB and Brooks AFB are special cases in that Patrick AFB only has a high-intensity gamma capability to support the work of the space program and Brooks AFB has expanded capabilities in support of special medical



health physics consultation functions. Given the level of health physics expertise at Brooks AFB and the variety of capabilities for its mission (see Table 5), Brooks AFB also plans to become accredited as a secondary calibration laboratory. The current capability at AGMC includes two open-air ranges: one for a high-intensity Cs-137 gamma source and medium intensity neutrons from PuBe. Also, there are large-area and small-area alpha source standards, the AN/UDM-7 and CS-1, respectively. A box calibrator for checking pocket dosimeters with a Cs-137 source rounds out AGMC's capability. In AGMC's future plans as an accredited secondary calibration laboratory, a 320-kVp x-ray machine and electroplated Amersham-type large-area alpha source (to replace the AN/UDM-7) will enhance its current capability. In its special consultation support within the Air Force, Brooks AFB will bring two x-ray machines, 160 and 420 kVp, a beta source calibrator, and three neutron sources in a low scatter facility (one PuBe and two Cf-252), along with its regular depot capability, into its intended scope of NVLAP accreditation. In addition to high-intensity gamma capability, depots are given low-intensity bench-top gamma capability (D0062) and small-area alpha source sets (AN/UDM-6). PMELs only have bench-top gamma and small-area alpha source capabilities. From Table 2, it can be noted that, even though the total Air Force inventory of instruments calibrated is appreciably smaller than the Navy's or the Army's, there is sizable support required for operational health physics instruments.

The Air Force organizational structure for maintaining MQA is shown in Figure 4. Four main policy directives (USAF 1992a, 1992b, 1992c, 1992d) control the management and operation of the Air Force radiological instrument program. Unlike the other services discussed thus far, these directives apply to all test and monitoring equipment calibration throughout the Air Force, and radiological equipment is only one small part in these directives. As can be seen in Figure 4, the management, operational, and independent inspection and audit processes are the same for the Air Force as they were for the Army. Within the directives, however, there are some programmatic differences. The overall policy directive (USAF 1992b), establishes AGMC as the secondary radiation laboratory through which all subordinate calibration laboratories derive their radiation source standards. This directive also specifies the general standards for calibrating radiological instruments, the documentation for calibration certificates, the performance data to be collected, and the locations of both Air Force and other services' calibration laboratories. It includes the requirements for an independent audit of all calibration laboratories once every 2 years. During this audit, the greater of 15 or 1% of all instruments on the "ready" shelf are sampled for conformance to technical and documentation requirements. A failure rate of greater than approximately 15% is a major deficiency for the laboratory. This team is also empowered to decertify and close laboratories found to be in non-compliance with Air Force calibration policies. On-site QA is also in effect between audits. Quality Visual Inspections (QVIs) are performed on 1% of outgoing equipment each month. Also, each technician is subjected to two Over the Shoulder (OTS) inspections each year to monitor his proficiency in complying with Air Force Calibration Procedures (USAF 1992c). There are inspection checklists for each outgoing instrument. Reports are maintained on the above activities for supervisory review. If QVI and OTS results show a pattern of unacceptable work, technicians are temporarily removed from calibration work and given retraining to restore the proper level of proficiency. Another directive (USAF 1992a) specifies the calibration frequencies for the instruments and the end-use application. For example, radiography survey meters are calibrated every 3 months, instruments supporting use of byproduct material and academic programs are calibrated every 6 months, and instruments involving medical and laboratory safety are calibrated every 12 months. All other instruments maintained for war reserve and mobilization are calibrated every 18 months. There is also a directive (USAF 1992d) which is a compilation of the procedures and methods for the AGMC secondary calibration laboratory to follow in demonstrating traceability of all laboratory

source standards to NIST. Source traceability measurements are performed at least once every 3 years. In addition, as in the other services, the NRC master material license granted to the Air Force gives the Brooks AFB the responsibility for conducting compliance inspections every 3 years at calibration laboratories to ensure the safe use and handling of radioactive material.

### **U.S. Marine Corps Program**

The Office of the Commandant of the Marine Corps is the centralized management organization for the Marine Corps' radiological instrument program. By a broad policy directive, each of the Marine Corps' three laboratories, located as shown in Table 6, manage their own operations. Depending on whether the radiological instruments are Navy or Army in their design and application, the calibration laboratories will follow either Navy or Army calibration procedures (USA 1992, USN 1992b). The Marine Corps laboratories fall under the jurisdiction of the Navy's NRC master material license and, as such, must meet the  $\pm 5\%$  source traceability criteria found in regulatory guides applicable to the use of byproduct material. The RASO conducts license compliance visits at each Marine Corps laboratory once every 3 years. The alpha source standard at each laboratory in Table 6 traces to NIST via the Navy's secondary calibration laboratory at Charleston, South Carolina. As regards the high-intensity gamma calibrators, the Office of the Commandant of the Marine Corps plans within the next 2 years to set up the Barstow, California, laboratory as the secondary laboratory to be accredited under NVLAP, and also establish an audit program to inspect the laboratories for proficiency and competence to perform instrument calibrations.

### **SUMMARY**

With the exception of the Marine Corps, each service has its own elaborate MQA process, which tracks radiation calibration source standards from the lowest level laboratory to NIST. The Army and Air Force programs rely on independent inspection and audit processes to demonstrate performance and conformance to program policy, directives, and procedures. The Navy, on the other hand, concentrates inspections and audits at the lowest laboratory level, where there is strong interaction with customers receiving the calibration program's benefits. This emphasis is evident in an extensive field office organization which reports to the management of the secondary calibration laboratory at Charleston, South Carolina (USN 1989a). Customer involvement in the audit process adds an extra dimension to management's judgment of program quality. However, this attribute should complement the independent audit process, which evaluates every step in the NIST traceability hierarchy.

### **CHALLENGES IN MEASUREMENT QUALITY ASSURANCE**

Since the introduction of the NVLAP requirements for accrediting secondary calibration laboratories (NIST 1990), there has not been a great deal of energy exerted within individual services to press on with laboratory certification. At the moment, there appears to be a level of frustration with the documentation requirements which must be met before an on-site visit is granted and proficiency testing is started. Most prospective laboratories have voiced the opinion that there is no incentive to become certified under NVLAP. As long as each service provides calibration only for its own internal customers, the certification is merely a prestige. With the pressures of reducing the defense budget, some consider the cost of accreditation too high. On the other hand, it is known only too well that NVLAP did enhance the performance and quality of personnel dosimetry processing within DoD. So long as such participation became a mandatory NRC requirement and applicable across both federal and private sector lines, all dosimeter processors within DoD became willing and eager

to embrace the program. There is some thought that, if secondary laboratory accreditation is made an NRC requirement, most, if not all, DoD laboratories will aggressively pursue bringing their organization up to technical performance standards and quickly seek NVLAP accreditation. There is one impediment here that the private sector will need to back the concept of required NVLAP certification. Some laboratories find the technical criteria a worthwhile aspiration and, given the time and resources available, will become accredited, even if not required by law. In time, however, the expectation is that all DoD secondary calibration laboratories will meet the call for technical excellence which NVLAP accreditation represents.

Another area of great consternation is the development of the quality manual described in the recommended program standard (ISO 1990). The emphasis on producing a quality manual to describe the quality program as a stand-alone entity is going against the grain of what is being introduced today in the precepts of total quality management. There is a definite clash of cultures here, which is confusing laboratory organizations seeking accreditation. Quality, as it is being described today, is process oriented and also something that must be integrated into our work processes in order to be effective. The task of producing the quality manual is being viewed as requiring the extraction of the requirements from the process rather than showing how they are integrated. The topical requirements, which are listed in the NVLAP accreditation handbook (NIST 1990) and its related standard (ISO 1990), are reasonably sound and really need to be addressed in the calibration laboratories' management and operational processes. A mere semantical change might help erase the frustration. Rather than call it a quality manual, rename it as follows: *Operational and Administrative Processes for the Technical Management of a Secondary Calibration Laboratory*. This will do two things: it will orient laboratories to think of their work in terms of processes and also allow the quality requirements of the NVLAP technical standards to be built into the processes. The small change in philosophy of concentrating on what should be in the process rather than how the requirements should be described should go a long way in giving initiative and enthusiasm to organizations becoming NVLAP accredited.

To boost enthusiasm for secondary laboratory accreditations, it might be helpful to step back and follow the paradigm of the dosimetry NVLAP. Some thought that instituting a pilot program where there is a trial period of performance and proficiency testing would be enlightening to those laboratories unsure and somewhat apprehensive about meeting the certification standard on their first try. Certainly, the trial, no-fault, non-attribution performance period opened a dialogue between the test administrators and tested organizations to learn, not only how the quality requirements were to be met, but perhaps that some of the test requirements had to be refined or modified based on knowledge of collective laboratory experiences. If secondary laboratory accreditation moves toward becoming a legal requirement for the calibration of instruments used in NRC-licensed programs, a pilot program will be a great incentive to the program participants, especially if one is started now. A pilot program would also allow the opportunity for some "give and take" on the implementation of quality requirements in laboratory processes.

## **FUTURE NVLAP EFFORTS**

There are still other processes within the practice of health physics which lend themselves to certification. Examples of areas where proficiency testing would benefit and enhance performance consistency are:

- biodosimetry/bioassay programs
- counting laboratories
- extremity monitoring
- radiological instrument testing
- brachytherapy
- medical accelerator treatment.

Should some of these areas above be considered, it might be necessary to merge similar certification programs which fall under the Health Physics Society (HPS) or the American Association of Physicists in Medicine (AAPM), or enter into joint programs with these organizations. Also, if there is a movement to add more radiological processes/programs to NVLAP, a general NVLAP handbook for health physics programs should be developed so that, as individual parts are possibly adopted, they will be add-on rather than stand-alone programs. It would then allow the experiences drawn from the other parts to influence positively the implementation efforts of new programs.

Under consideration is NVLAP accreditation for the gamma and neutron sources at Naval Surface Warfare Center (NAVSWC), where instruments continue to be calibrated to characterize the output signatures for various weapon systems under the DoD Intrinsic Radiation (INRAD) Program. With the passage of Public Law 102-578, the DoD will most likely be asked to collaborate with the Department of Veterans Affairs in undertaking a health effects study of those veterans who were engaged in weapons maintenance and handling and exposed to measurable levels of neutrons by today's standards. Because neutron dosimetry was insensitive or unavailable in the pre-1970's, measurable doses to this population are not known. NAVSWC's dose equivalent measurement capability can be used to remeasure the old systems in configurations in which workers serviced them. These measurements can then be used to reconstruct the personnel doses for the health effects study. Also foreseen are the possibilities of joint programs involving the U.S. Department of Energy (DOE). Public Law 102-484 and currently proposed legislation have identified civilians engaged in the same type of work for medical follow-up. It would enhance the credibility of such studies to know that the reconstructions trace back to NVLAP-accredited source standards and methodologies.

## **ACKNOWLEDGEMENTS**

I express my sincere appreciation to all of those who briefed me on their radiological programs at the various service organizations I visited in preparation for this paper. I am also grateful to my colleagues at Defense Nuclear Agency and JAYCOR for the helpful discussions and support in the production of this report.

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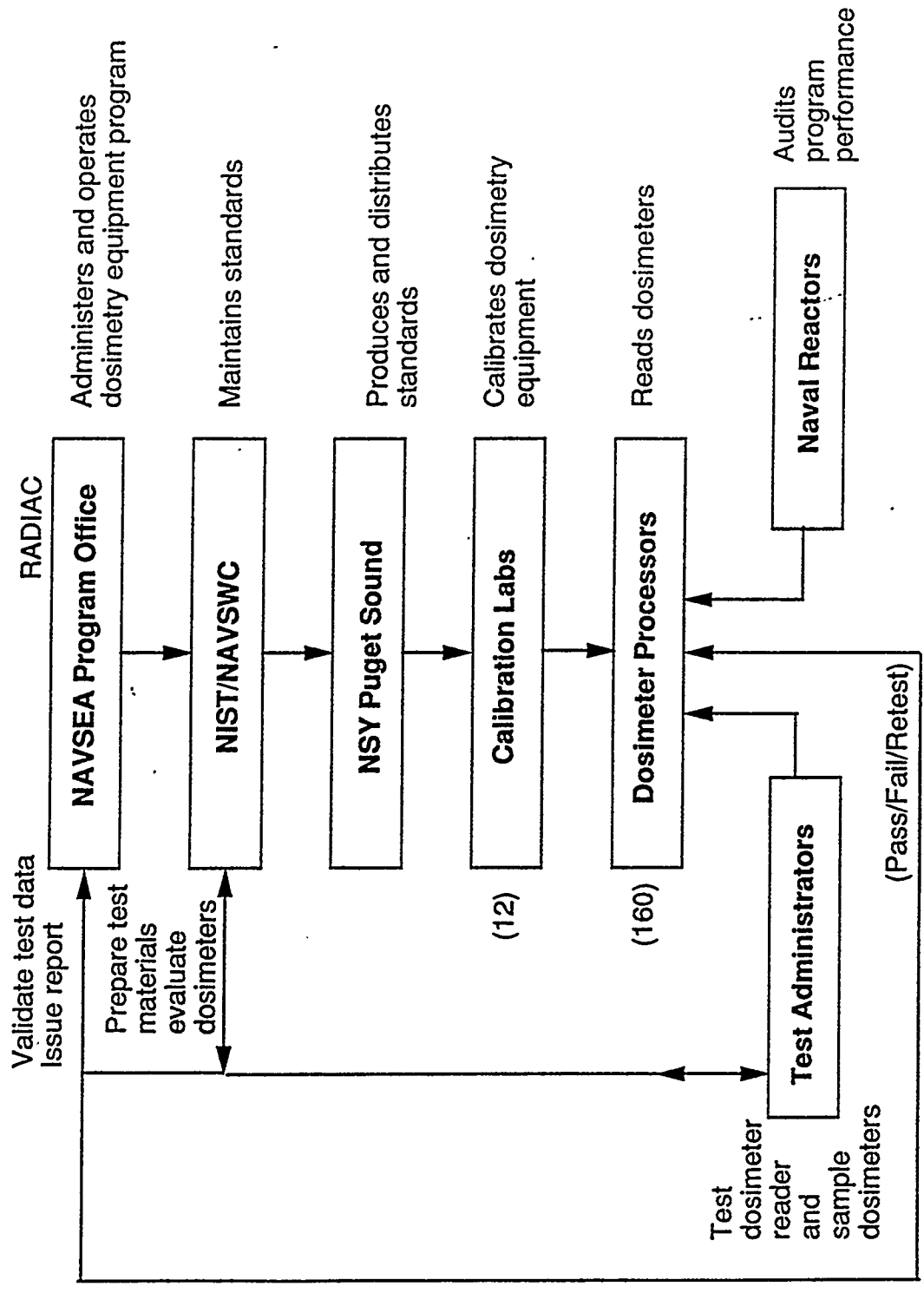


Figure 1 - Description of Quality Assurance Program for the U.S. Navy Calcium Fluoride Thermoluminescent Dosimetry System

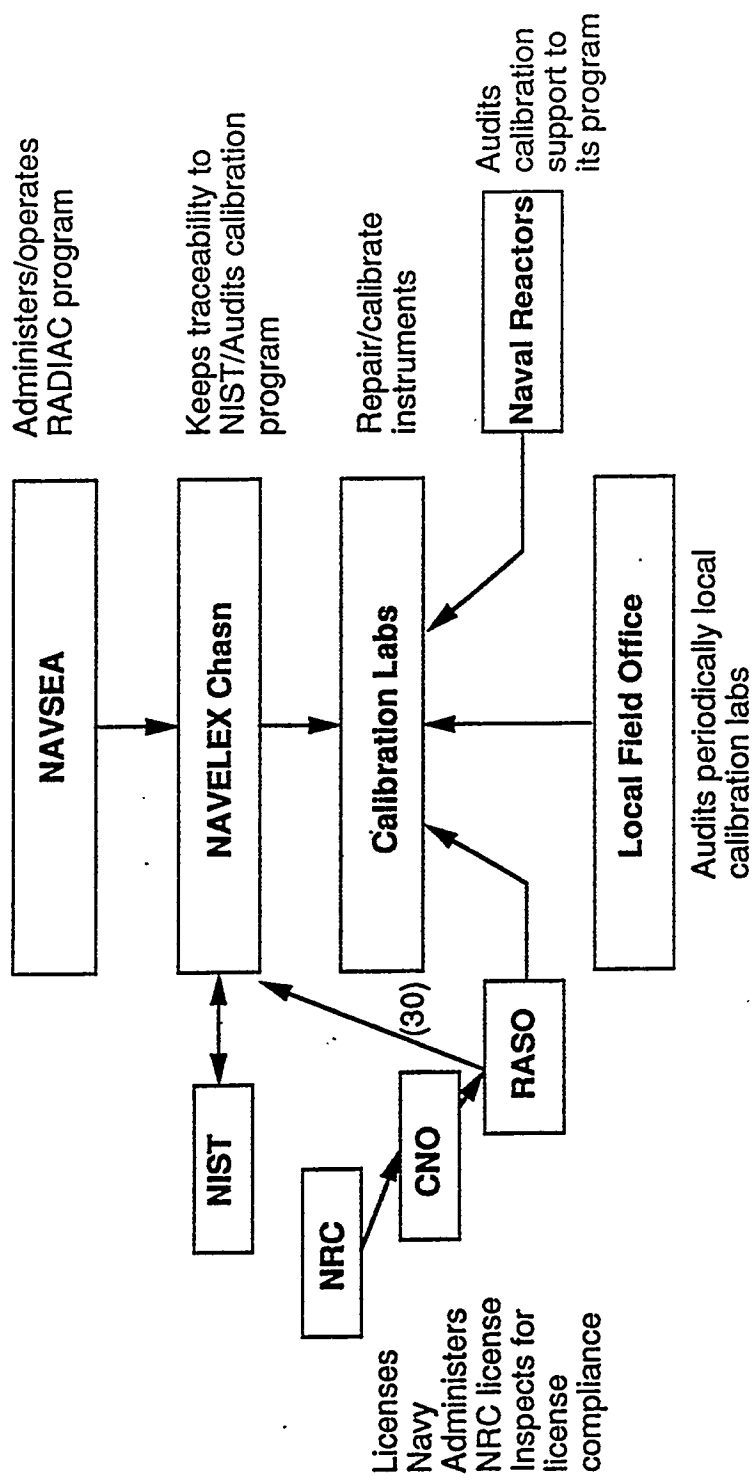


Figure 2 - Description of the Quality Assurance Accountability Process for U.S. Navy Radiological Calibration Labs



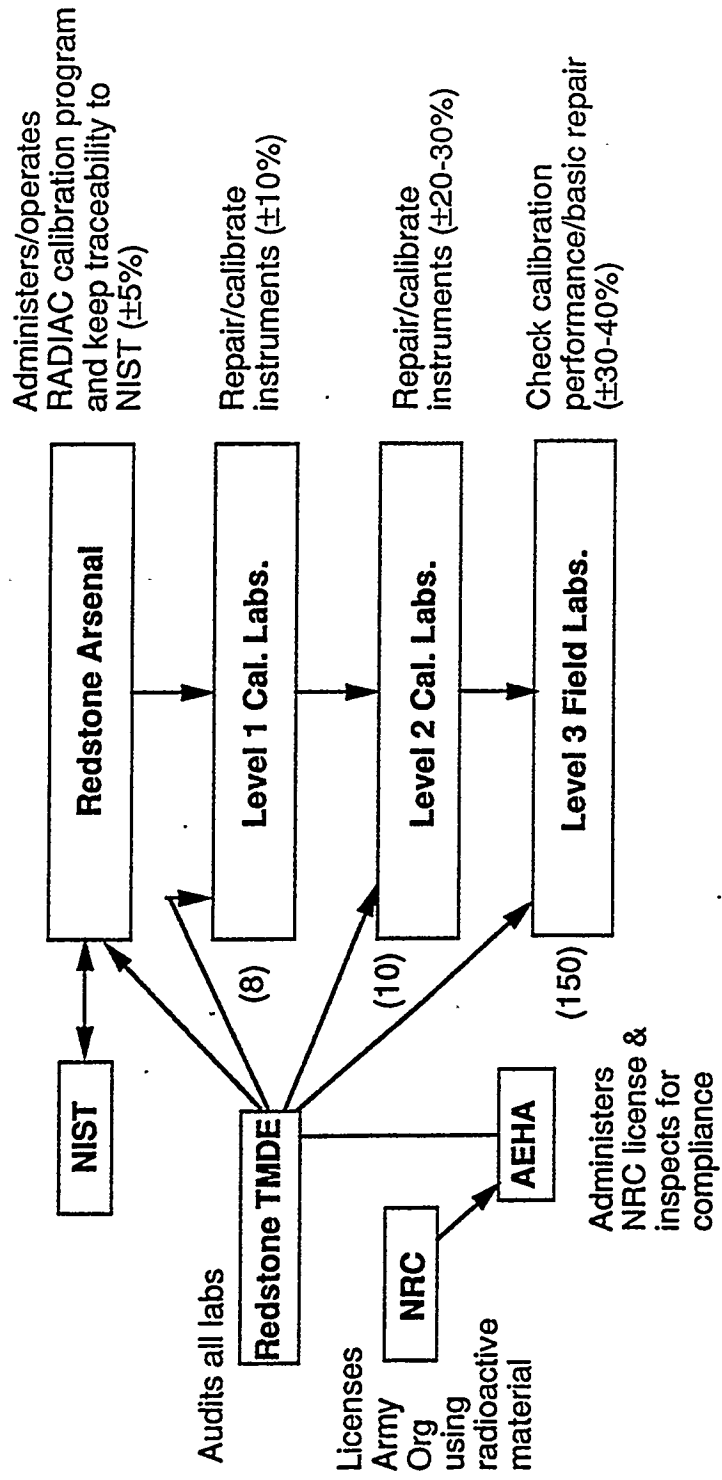


Figure 3 - Description of the Quality Assurance Accountability Process for U.S. Army Radiological Calibration Labs

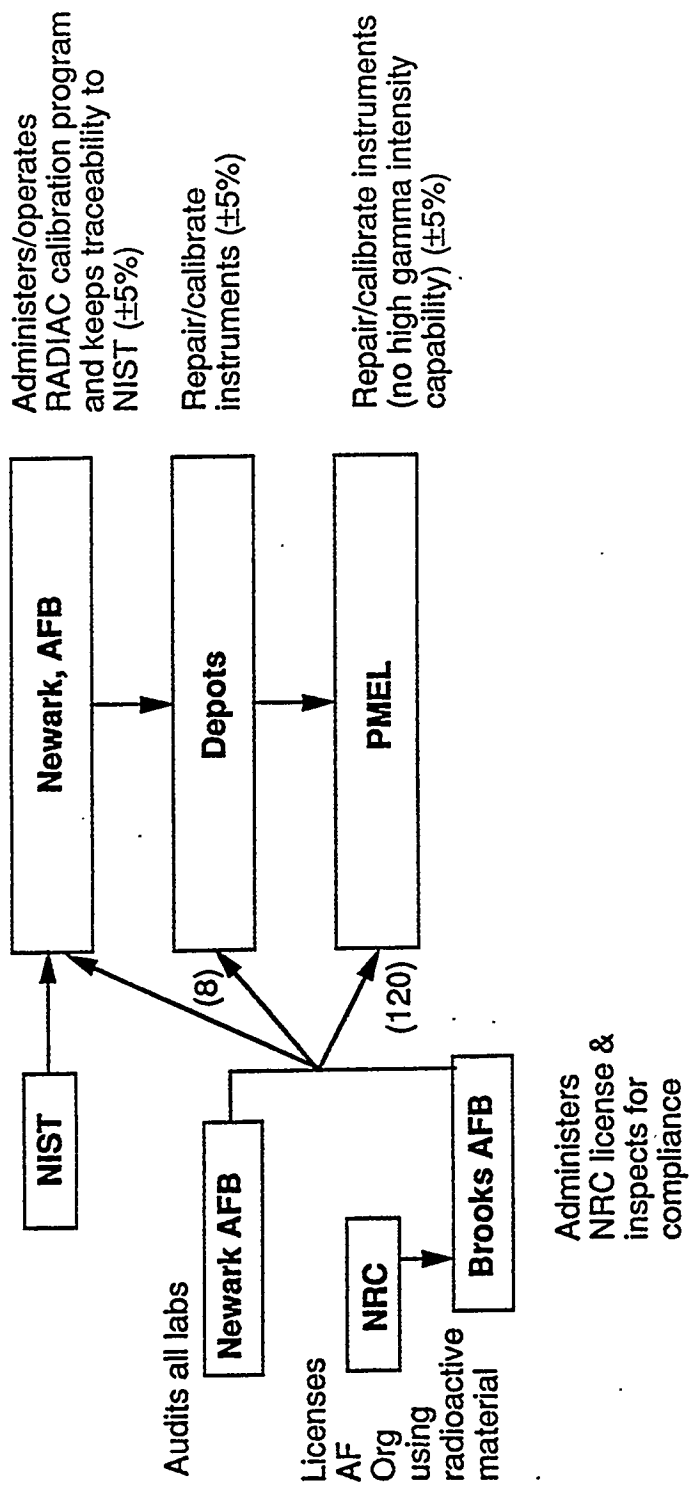


Figure 4 - Description of the Quality Assurance Accountability Process for U.S. Air Force Radiological Calibration Labs

*Table 1 - Department of Defense (DoD) Dosimeter Processors Accredited under NVLAP*

Service	Location	Dosimetry System	Number of Orgs. Monitored	Transactions per year	Processing Frequency	NVLAP Category
Navy*	NEHC Bethesda, MD	Harshaw 8000/8001/8002	415	395K	6-8 wks	All
Navy	Puget Sound NSY/Decentralized	Harshaw design DT-526-CP-1112	160	2.7M	daily/mo	II, IV
Army	USAIRDC Lexington, KY	Panasonic 710/UD802AS/UD874A-T	776	30K	wk/mo/qty	All
Air Force	Armstrong Lab Brooks AFB, TX	Panasonic 716/UD802AT/ISA Model 820	250	250K	mo/qty	All

\*Includes Marine Corps Activities.

*Table 2 - Individual Service Radiological Instrument Support*

Service	Calibration Transactions per year	RADIAC Inventory (total/operational)	Calibration Frequency
Navy	250,000	130,000/60,000	3 mo/6 mo/12 mo
Army	31,000	81,500/3,800	90 d/120 d/5 yr
Air Force	38,000	30,000/8,000	3 mo/6 mo/12 mo/18 mo
Marine Corps	12,000	12,000/60	3 mo/6 mo/12 mo

*Table 3 - U.S. Navy Radiological Instrument Calibration Laboratories and Their Capabilities*

Secondary Calibration Lab	Current Capability	Capability Planned	Calibration Labs Traceable to Chasn	Capability
<p>Naval Electronics Systems Engineering Center, Charleston, SC</p>	<p>AN/UDM-1A (Gamma ~120 Ci <sup>137</sup>Cs)</p> <p>AN/UDM-7 Series (Alpha ~810 ug <sup>239</sup>Pu)</p> <p>Fast Neutron Range (~5 Ci PuBe)</p>	<p>Shepherd Series 81 (~138 Ci <sup>137</sup>Cs)</p> <p>Shepherd Series (~300 Ci <sup>60</sup>Co)</p> <p>Amersham <sup>238</sup>Pu (Alpha)</p> <p>Fast Neutron Range (~5 Ci PuBe)</p> <p>320 kVp x-ray</p>	<p>6 Destroyer Tenders 10 Submarine Tenders</p> <p>Calibration Labs at Portsmouth, NH Groton, CT Portsmouth, VA Charleston, SC Mayport, FL Rota, Spain Bremerton, WA Vallejo, CA Pearl Harbor, HI Yokosuka, Japan Guam, MI San Diego, CA Yorktown, VA Idaho Falls, ID</p> <p>(30 Labs)</p>	<p>TS-1216 (Gamma) (20 Ci <sup>137</sup>Cs) AN/UDM-10 (Neutron) (100m Ci AmBe) AN/UDM-7 Series (Alpha)</p> <p>AN/UDM 1A or Shepherd Series 81 (Gamma)</p> <p>AN/UDM-7 Series (Alpha)</p> <p>Fast Neutron Range (Neutron) or AN/UDM-5 (Neutron) 5 Ci PuBe or AN/UDM-10 (Neutron)</p>

Table 4 - U.S. Army Radiological Instrument Calibration Laboratories and Their Capabilities

Secondary Calibration Lab	Current Capability	Planned Capability	Level 1 Labs	Capability	Level 2 Labs***	Capability
Redstone Arsenal, Huntsville, AL	AN/UDM-1A (Gamma) (~120 Ci <sup>137</sup> Cs) AN/UDM-6 (Alpha) (~4 ug <sup>239</sup> Pu) AN/UDM-2 (Beta) (~185 m Ci <sup>90</sup> Sr) 320 kVp x-ray 50 kVp x-ray	Shepherd 81 Quad (Gamma) (~200 Ci <sup>60</sup> Co) (~100 Ci <sup>137</sup> Cs) Shepherd 89 Box (~400 Ci <sup>137</sup> Cs) Amersham <sup>238</sup> Pu, <sup>239</sup> Pu, <sup>241</sup> Am (Alpha) (~8u Ci each) (Large and Small area) 320 kVp x-ray 50 kVp x-ray Neutron source**** Beta Calibrator ( <sup>90</sup> Sr/ <sup>Y</sup> , <sup>147</sup> Pr, <sup>204</sup> Tl) (~50m Ci)	Sacramento, CA* White Sands, NM Seneca, NY** Aberdeen, MD Lexington, KY* Redstone Arsenal, AL Pirmasens, GE Camp Carroll, KO (* Labs)	AN/UDM-1A AN/UDM-6 (±10%)	Tobyhanna, PA Letterkenny, PA Anniston, AL Tooele, UT** Sacramento, CA White Sands, NM Seneca, NY Lexington, KY Aberdeen, MD Redstone Arsenal, AL (10 Labs)	AN/UDM-2 AN/UDM-6 (±20-30%)

1. \*Labs to be merged with Redstone Arsenal, Alabama
2. \*\*Labs expected to be closed in the future
3. \*\*\*Level 3 Field Calibration @ ~185 locations
4. \*\*\*\*Neutron calibration capabilities using PuBe currently at Sacramento, California

Table 5 - U.S. Air Force Radiological Instrument Calibration Laboratories and Their Capabilities

Secondary Calibration Lab	Current Capability	Planned Capability	Depot Labs	Capability	PMEL	Capability
Newark AFB, OH	Shepherd Series 81 (~130 Ci <sup>137</sup> Cs) Fast Neutron Range (~16 Ci PuBe) Eberline CS-1 (Alpha) (~2u Ci <sup>239</sup> Pu) AN/UDM-7 Series (Alpha) (~810 ug <sup>239</sup> Pu) Dosimeter Calibrator (Gamma) (~20 Ci <sup>137</sup> Cs)	Shepherd Series 81 (~130 Ci <sup>137</sup> Cs) Shepherd Series 81 (~1000 Ci <sup>60</sup> Co) Fast Neutron Range (~16 Ci PuBe) Amersham (Alpha) ( <sup>238</sup> Pu) Eberline CS-1 320 kVp x-ray Dosimeter Calibrator (~20 Ci <sup>137</sup> Cs)	Kelly AFB, TX Hill AFB, VT McClelland AFB, CA Ramstein AFB, GE Kadena AB, Japan Newark AFB, OH Brooks AFB, TX* Patrick AFB, FL**  (8 Labs)	Shepherd Series 81 (~130 Ci <sup>137</sup> Cs) D0062 (~120 m Ci <sup>137</sup> Cs) AN/UDM-6 Alpha (4 ug <sup>239</sup> Pu) AN/UDM-7 Alpha (~±5%)	(120 Labs)	D0062 AN/UDM-6 (~±5%)
Brooks AFB, TX		Shepherd Series 81 (~130 Ci/ ~130 m Ci <sup>137</sup> Cs) 420 kVp x-rays 160 kVp x-rays Beta Calibrator (~50 m Ci <sup>90</sup> Sr/ ~2 m Ci <sup>90</sup> Sr/ ~14 m Ci <sup>204</sup> Tl/ ~2 m Ci <sup>147</sup> Pr) Neutron Ranges (~5 Ci PuBe/2.2 and 0.1 mg <sup>252</sup> Cf)				

\*Planned to become accredited as a secondary calibration lab for health physics instrumentation

\*\*Shepherd Series 81 only

**Table 6 - U.S. Marine Corps Radiological Instrument Calibration Laboratories and their Capabilities**

Secondary Calibration Lab	Planned Capability	Calibration Labs (stand alone)	Capability	Planned Capability
(None now) Marine Corps Logistic Base, Barstow, CA (planned)	Shepherd Series 81 (Gamma) (~ 130 Ci <sup>137</sup> Cs)	Barstow, CA Albany, GA Okinawa, Japan	AN/UDM-1A (Gamma) (~ 120 Ci <sup>137</sup> Cs)  AN/UDM-7 Series (Alpha) (~ 810 ug <sup>239</sup> Pu)*  Shepherd Series 81 (Gamma) (~ 130 Ci <sup>137</sup> Cs)	Shepherd Series 81 (Gamma)  AN/UDM-7 Series *

\*Available from Naval Electronics Systems Engineering Center, Charleston, the U.S. Navy's Secondary Calibration Lab.

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# QUALITY ASSURANCE MEASUREMENT FOR EMERGENCY MANAGEMENT

Michel S. Pawlowski<sup>(1)</sup>

*Abstract* - Under the Federal Civil Defense Act of 1950, as amended, the Federal Emergency Management Agency (FEMA) is charged with maintenance of a nationwide inventory of 4.3 million radiological instruments procured and granted by the federal government to state and local governments. These instruments are used by trained state Radiological Response Team Members, first responders, and critical workers to support the population from a national security or large-scale peacetime radiological disaster, e.g., Chernobyl, Three Mile Island, Satellite Reentry, etc. The inventory is maintained through a network of 100% federally funded state maintenance and calibration facilities, with overall technical guidance and standardization provided by the FEMA Radiological Instrumentation Test Facility. The system used to support maintenance and standardized calibration of the inventory consists of CDV-794 Radiation Calibrator (High Range), CDV-765 Model 2 Gamma Transfer Standard, CDV-790 Model 1 Calibrator (Low Range), and Dosimeter Transfer Standards. Past studies have indicated the "Readiness" and "Reliability" of the inventory to meet mission requirements based upon a standardized system of maintenance and calibration. FEMA has just initiated a new instrument Readiness and Reliability study with the State of Ohio Radiological Instrument Maintenance and Calibration Program to provide data to reassess the capability of the current inventory to support all types of peacetime and national security missions.

## INTRODUCTION

Under the Federal Civil Defense Act of 1950, as amended, the Federal Emergency Management Agency (FEMA) is charged with developing plans and procedures for protection of the public and providing radiological instruments to support the population from a national security or large-scale peacetime radiological disaster, e.g., Chernobyl, Three Mile Island, Satellite Reentry, etc. The need for specialized radiological instruments for civil defense/emergency management was recognized in the early 1950's. The federal government procured and granted a sizeable inventory of radiological instruments to state and local governments in the 1960's. Even though the majority of these instruments were

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manufactured in the 1960's, these instruments are still operational and, in some cases, due to retrofit procedures developed by FEMA and standardized maintenance and calibration procedures, these instruments perform and are in better operational condition to support mission requirements than when they were originally procured and delivered to the government. Today, the nationwide inventory of civil defense/emergency management radiological instruments consists of over 4.3 million radiological instruments, a national treasure and an essential resource for national preparedness. FEMA is considered to be the largest user of radiological instruments and provides a system to the states for standardized maintenance and calibration of the nationwide instrumentation inventory.

## MAIN TEXT

The national inventory of radiological instruments is currently maintained through a 100% federally-funded program administered by FEMA and funded through a Comprehensive Cooperative Agreement executed between FEMA and 48 individual States or territories. Today, approximately 117 full-time state personnel annually inspect and calibrate one-quarter of the instruments in the national inventory. One of our state shops, the State of California Radiation Instrument Calibration Laboratory, is a Regional Calibration Laboratory accredited by the Conference of Radiation Control Program Directors (CRCPD). The instruments are processed in specially equipped state shop facilities. Overall program direction is provided by the FEMA Radiological Instrumentation Branch, with technical management provided by the staff of the FEMA Radiological Instrumentation Test Facility (RITF) located at Berryville, Virginia. The RITF is responsible for: R&D, dosimeter repair for FEMA and DoD, standardization, quality assurance (QA), technical support, overall support to DoD for special programs and/or initiatives dealing with radiological instrumentation. The FEMA instrumentation program is a cooperative joint effort with participation from other federal and state agencies, wherein FEMA has overall responsibility for instrumentation support from the cradle to the grave.

Since 1965, FEMA's RITF has conducted instrument performance testing and provided guidance to state personnel for standardization of a nationwide radiological instrumentation maintenance and calibration program. The FEMA RITF is currently in the process of completing the necessary documentation for application to become certified as a Secondary Calibration Laboratory For Ionizing Radiation under the National Institute of Standards and Technology (NIST) National Voluntary Laboratory Accreditation Program (NVLAP).

The nationwide inventory of CD instruments consists approximately of 600,000 survey instruments and 2.8 million dosimeters. The survey instruments are composed basically of two types:

- CDV-715 (0-500 R/h) High-Range, Gamma Detection and Measurement Ionization Chamber Type Instrument
- CDV-700 (0-50 mR/h) Low-Range, Beta Detection and Gamma Detection and Measurement Geiger Müller Type Instrument.

The dosimeters primarily consist of self-indicating, quartz-fiber electrostatic dosimeters. The four ranges of dosimeters used for gamma radiation detection vary accordingly: CDV-138 (0-200 mR), CDV-730 (0-20 R), CDV-740 (0-100 R), and CDV-742 (0-200 R).

The nationwide inventory of instruments are used by trained State Radiological Response Team members, first responders, and critical workers.

We use the standard roentgen for instrument calibration. The system used to support maintenance and standardized calibration of the inventory in each of the state shop facilities consists of the following equipment: CDV-794 Radiation Calibrator, CDV-765 Model 2 Gamma Transfer Standard, CDV-790 Model 1 Calibrator, and Dosimeter Transfer Standards.

### **CDV-794 Radiation Calibrator (High-Range)**

This device is used for calibration of the CDV-715 High-Range Gamma Survey Instrument and dosimeters. There is one or more in each of the state shop facilities. The CDV-794 calibrator contains approximately 130 curies of  $^{137}\text{Cs}$ - $^{137}\text{Ba}$  in a sealed source. The gamma radiation from this source is collimated into a lead-lined box containing the instrument in a fixed geometry. Four discrete gamma exposure rates are produced in the calibrator: 0.4; 4.0; 40; and 400 R/h. Overall precision and accuracy for this system which serves as the primary secondary standard for all FEMA gamma calibration is within  $\pm 4\%$  of the NIST values for the roentgen.

### **CDV-765 Model 2 Gamma Transfer Standard**

The CDV-765 Model 2 was designed by Oak Ridge National Laboratory to transfer the RITF roentgen, traceable to the NIST for the CDV-715 rate meter. The CDV-765 Transfer Standard provides calibrated exposure rates from the CDV-794 calibrator and various other gamma radiation sources used in the FEMA maintenance and calibration program in the field (at each state shop facility location) against the primary gamma standard located at the FEMA RITF. This ensures that the calibration of instruments is standardized throughout the CD/Emergency Management system. The CDV-765 Model 2 is a special electrometer that has been designed to measure the current from an ion chamber. Previous test data obtained shows that the true roentgen is probably being provided to the 48 state shop facility locations via the CDV-765 Transfer Standard with an accuracy of better than  $\pm 6\%$ . This is based upon a variation of 2% between standards and  $\pm 4\%$  for the precision and accuracy of the primary field. CDV-715 instruments can be calibrated to within  $\pm 14\%$  of the true exposure rate at one point on each detection range.

The CDV-765 Transfer Standards are returned to the FEMA RITF by the states annually for recalibration. The CDV-794 calibrators in the field are recalibrated using the CDV-765 Transfer Standard annually.

### **CDV-790 Model 1 Calibrator**

The CDV-790 Model No. 1 Calibrator was developed for calibration of the CDV-700 GM-type instrument and designed to be operated from a workbench and provide ease as well as speed in calibrating instruments with minimum gamma exposure to operating personnel. The CDV-700 survey instrument is widely used to measure low intensities of gamma radiation and detect the presence of beta radiation. In order to obtain correct readings of radiation intensity, the survey meter must be calibrated against a standard radioactive source whose output is known. The calibration set point is approximately 45 mR/h from a  $^{137}\text{Cs}$  radioactive source. An additional seven (7) points are obtained by observing the instrument's meter response at different ranges while positioning the various attenuator slides of the calibrator in the gamma beam. A slide positioning mechanism is located which allows three (3) circular disk-shaped, tungsten alloy attenuators to be positioned axially over a 2.5-inch hole which contains a pinned 16-mCi  $^{137}\text{Cs}$  source providing a collimated gamma radiation beam. These attenuators are 2.5 inches in diameter and were machined to a thickness that will provide a  $2/3$ , a  $1/2$  and a  $1/10$  value

attenuation disk for  $^{137}\text{Cs}$  gamma radiation. Each attenuator is on a separate guide so that any or all of the attenuators can be moved in or out of the gamma radiation beam in multiple configurations as follows: 1.5; 2.25; 3.0; 4.5; 15.0; 22.5; 30.0; and 45.0 mR/h. The calibrator output exposure rates are known to be within  $\pm 5\%$  of the NIST roentgen at a predetermined point. The output ranges are provided by the FEMA RITF.

### Dosimeter Transfer Standards

States must use the dosimeter Transfer Standards and fixtures provided with the CDV-765 Transfer Standard to obtain the times required for mid-scale exposure of dosimeters to be calibrated. Dosimeters are calibrated mid-scale since dosimeters are not completely linear. FEMA specifications require that dosimeters should respond to within  $\pm 10\%$  of true dose. FEMA realizes that the CDV-794 is a box calibrator and absolutely precise Transfer of Calibration may not be possible due to geometry (positioning) and radiation scatter components. Therefore, FEMA allows a deviation of  $\pm 15\%$  from true exposure as related to the FEMA RITF's free air gamma range which is within  $\pm 2\%$  of the NIST Roentgen. We do know however, that most states maintain their inventory of dosimeters within  $\pm 10\%$ .

Dosimeters which do not meet the  $\pm 15\%$  criteria are returned to the FEMA RITF for repair or refurbishment. The FEMA RITF has a process to adjust the accuracy of dosimeters to within  $\pm 10\%$  tolerance.

Table 1 provides the recommended limits for the crucial tests affecting all dosimeters.

In order for FEMA to determine whether our instruments meet their mission requirement for today, we periodically gather data and reassess the "mission readiness and reliability" for the inventory. FEMA conducted a nationwide Readiness and Reliability study of Instrumentation in the field in 1977 primarily centered around the high-range survey instruments. In 1991, FEMA conducted a limited analysis of state dosimetry calibration. The results of these studies reaffirmed the "Readiness" and "Reliability" of the inventory at that point in time. During the years between 1977 and 1991, we conducted regular on-site quality control inspection visits to individual state shop facilities. We have just initiated an Instrument Readiness and Reliability Study with the State of Ohio Radiological Instrumentation Maintenance and Calibration Program (RERP) to provide us with data to reassess the existing capability of the instrument inventory to support all types of peacetime (Radiological Emergency Response Program) and national security missions. Instruments used to support the RERP in Ohio are exchanged on a semiannual basis. The non-RERP instruments are exchanged on a 4-year cycle. Data gathered will be analyzed by the RITF to determine how well these instruments hold calibration, and if there is a statistically significant difference in those instruments calibrated annually, versus those calibrated on the 4-year cycle. The Ohio study is intended to include a statistical sampling of instruments on a nationwide basis. A follow-up report will be provided based upon the Ohio study. The Ohio study will include all the instruments in the inventory with the following minimum evaluation criteria: radiation response, months since last calibrated, operator test, and storage/operational environment.

The FEMA radiological instrument program is one of continuous reassessment of requirements and needs at the state and local level of government. It is FEMA's long-term objective to have sufficient instrumentation available to every state and local jurisdiction with standardized calibration to support development and maintenance of a multi-hazard radiological instrumentation response capability.

*Table 1 - Required Calibration Dose and Accuracy Limits for Dosimeters*

<b>Model Number</b>	<b>Required Dose</b>	<b>Accuracy Limits + 15% True Dose</b>
FEMA-200 mR	100 mR	85 - 115 mR
CDV-138	100 mR	85 - 115 mR
CDV-730	10 R	8.5 - 11.5 R
CDV-740	50 R	42.5 - 57.6 R
FEMA-200 R	100 R	85 - 115 R
CDV-742	100 R	85 - 115 R

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## CURRENT NRC ACTIVITIES RELATED TO MQA

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The U.S. Nuclear Regulatory Commission's (NRC's) interest in measurement quality assurance (MQA) goes back to before 1963, when the Atomic Energy Commission (AEC) published a notice in the Federal Register concerning the need for establishing a Film Dosimetry Calibration Laboratory, and also provided a set of minimum performance criteria to be used by the laboratory in evaluating film dosimetry services used by licensees. The proposed laboratory was not established, but in 1967 the AEC contracted with Battelle's Pacific Northwest Laboratory (PNL) to evaluate film dosimeter performance criteria and provide a basis for establishing a Film Dosimetry Calibration Laboratory if the study showed that it was needed. Excessive bias and variance were found among all classes of processors: commercial, government, and military. Although the study indicated a need for common performance criteria, no definitive standard was promulgated. Then, in 1973, the Conference of Radiation Control Program Directors (CRCPD), concerned with the state of dosimetry processing and the lack of adequate standards, recommended that the National Bureau of Standards (NBS) direct a performance testing program for personnel dosimetry processing services. Later, in 1976, NRC asked PNL to conduct a study to evaluate the four existing performance standards for personnel dosimetry processing. One result of this study was that the HPSSC standard, which later became ANSI N13.11, was recommended as the standard for use in a national dosimetry processing program. The rest is common knowledge. With the support of numerous other federal agencies and the CRCPD, NRC published a regulation, effective in 1988, that required all processors of personnel dosimeters be accredited under the National Voluntary Laboratory Accreditation Program (NVLAP), operated by the NBS, which is now called the National Institute of Standards and Technology (NIST). At present, there are 75 dosimetry processing laboratories accredited under NVLAP.

In addition to the dosimetry accreditation program discussed above, which is involved with whole body dosimeters, the Commission directed that extremity dosimeters were to be included in the program as soon as a satisfactory performance standard became available. The NRC contracted with PNL to evaluate the appropriateness of the draft standard for extremity dosimetry (ANSI P/N 13.32) and, to date, PNL has conducted three separate evaluations of the standard and recommended several changes.

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It is expected that the final version of the standard will be approved shortly and that extremity dosimetry processing will be added to NVLAP.

Another MQA area of interest to NRC involves performance requirements for health physics survey instruments and performance criteria for bioassay measurements. In 1981, NRC and the U.S. Department of Energy (DOE) jointly funded technical assistance contracts at PNL to test draft standard ANSI P/N 42.17A (health physics instruments), and draft standard ANSI P/N 13.30 (bioassay). Tests were performed against the draft standard ANSI P/N 42.17A over a period of four years, using currently available survey instruments. A number of changes were made in the standard as a result of these tests. The testing also revealed a large variability in the performance of similar instruments from different manufacturers and variability was also observed between same manufacturer/same model instruments. The final version of ANSI N42.17A was published in 1989. The NRC position on the implementation was to let the industry implement the standard voluntarily and, at some later time, consider whether a regulatory requirement was in order. At the present time, it appears that the standard is not being implemented by the industry. NRC currently has a contractor evaluating available information on survey instrument use. In general, NRC justifies imposing regulatory requirements on the basis of safety issues and, to date, no definite conclusions have been reached on whether to require licensees to use instruments that comply with the ANSI N42.17A standard.

In regard to the bioassay performance standard (ANSI P/N 13.30), one of the studies completed by PNL (NUREG/CR-5516), indicated that the test criterion for the minimum detectable amount (MDA) was the one that was most commonly failed, and it recommended some additional procedures to be followed by bioassay laboratories in order to pass this particular test criterion. Another of the studies completed by PNL (NUREG/CR-5396) evaluated the cost involved in requiring bioassay service laboratories to meet the criteria of the draft standard. NRC is presently evaluating other methods for calibrating in vivo bioassay systems and has recently entered into a contract with Lawrence Livermore National Laboratory (LLNL). The method under investigation by LLNL involves a Monte Carlo technique to calculate doses. This method uses magnetic resonance imaging (MRI) to create a library of body types and sizes. In addition to providing information on various body types, the images produced by MRI are capable of estimating the water and fat content of the tissues. The Monte Carlo code can then be run using the MRI data to define a radiation transport medium, with various tissues and organs being selected as those containing radioactive material. This process can then be used to calibrate an in vivo system for a particular subject. It is hoped that this effort will be completed and the results published in 1994.

NRC also has an interest in the current generation of electronic personnel dosimeters (EPDs), which provide visual readouts, provide audio and visual alarms, have software to process the stored data, and, in some cases, come equipped with remote readout capabilities. These dosimeters have undergone some testing under NVLAP and DOELAP and, while some have been reported to be susceptible to RF fields and to be non-linear in high-dose rate fields, a number of licensees are currently using them. NRC is currently examining the use of EPDs as possible replacements for film badges and thermoluminescent dosimeters (TLDs) for personnel monitoring. At present, there is no performance standard for EPDs, although it is intended that the requirements will be included in the next revision of ANSI N13.27, which is expected to begin shortly. In the meantime, NRC is considering contractor support to identify performance requirements and such other criteria that may be needed for evaluation, along with such quality control (QC) and quality assurance (QA) requirements needed to ensure reproducibility under a variety of conditions for the current generation of EPDs.



Another area that is related to the use of survey instruments is their use in performing monitoring to permit unrestricted release of facilities upon completion of decommissioning. NRC decommissioning regulations specify that licenses can be terminated only after "the terminal radiation survey and associated documentation demonstrates that the facility and site are suitable for unrestricted release." NRC is currently in the process of evaluating the establishment of radiological criteria needed for decommissioning NRC-licensed facilities to permit unrestricted release. A major issue associated with the development of these criteria is the ability of current survey meters and other related instrumentation to measure the low levels of radioactivity to be specified in the release criteria. NRC is currently using contract support to evaluate existing instrumentation and develop MDAs for various classes of survey and environmental instrumentation. An expected outcome of this work will be the establishment of QA and QC procedures for the decommissioning measurements and traceability of the measurements to national standards.

The last MQA activity to be discussed involves environmental monitoring of aquatic and terrestrial samples in the vicinity of nuclear power plants. Each of the five NRC regions operates a mobile laboratory that monitors plants in their region for use of proper monitoring procedures, for sources used in monitoring, and for proper recording of results. Traceability to NIST is maintained through DOE's Radiological and Environmental Sciences Laboratory (RESL). (A paper on this subject was presented at the Wednesday afternoon session.)

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## OVERVIEW OF THE EPA QUALITY SYSTEM FOR ENVIRONMENTAL PROGRAMS

Gary L. Johnson<sup>(1)</sup>

*Abstract* - Formalized quality assurance program requirements for the U.S. Environmental Protection Agency (EPA) have been established for more than a decade. During this period, the environmental issues and concerns addressed by the EPA have changed. Many issues, such as ozone depletion and global climate warming, have become international concerns among the world environmental community. Other issues, such as hazardous waste cleanup and clean air, remain a focus of national environmental concerns. As the environmental issues of the 1980's evolved, the traditional quality assurance (QA) program was transformed through the use of quality management principles into a Quality System to help managers meet the needs of the 1990's and beyond.

Since 1984, the EPA has incorporated fundamental concepts of quality management into integral elements of how the Agency conducts environmental programs. This includes a reliance on customer-supplier partnerships as the basis to define the measures of success for determining quality in environmental programs. The Quality System is structured to provide the necessary management and technical processes to effectively plan, implement, and assess the results of work performed in environmental programs.

EPA is revitalizing its Quality System through two initiatives: the use of a new national consensus QA standard for environmental programs, ANSI/ASQC E4, and the development of a new series of requirements and guidance documents to implement the quality management "tools" now available. It is expected that new standards will increase consistency across EPA Quality Systems and between EPA and the regulated community. The new QA documents will provide current, focused guidance on implementing the various elements of the EPA Quality System.

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## QUALITY MANAGEMENT AND THE EPA MISSION

In recent years, there have been increasing successes by businesses and industry in the use of quality management principles to achieve more effective operations. The EPA is one of several federal agencies successfully applying these same principles to government operations and activities. This paper describes the EPA Quality System for environmental data collection and evaluation that is based on these principles, and provides an overview of the Quality System "tools" used to plan, implement, and assess the effectiveness of that system.

EPA is a large government agency, employing more than 18,000 people nationwide. The Agency's mission is to protect human health and the environment. This mission is accomplished through implementation of laws such as the Clean Air Act, Clean Water Act, Resource Conservation and Recovery Act (RCRA), and Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), by 50 headquarters offices, regional offices, and research laboratories. Because of EPA's authority to regulate many activities that may affect health and the environment, EPA decisions have a wide impact in terms of both quality of life and costs imposed on regulated parties. It is therefore of utmost importance that EPA serve its constituents in the most effective way, and ensure that technical and regulatory decisions are developed with quality as a first priority.

In 1984, EPA began to utilize quality management principles as the foundation for the Agency's mandatory quality assurance (QA) program. Quality management, in the context of its use by EPA, may be defined as follows:

*Quality Management is that aspect of the overall management systems of an organization that determines and implements policy regarding the Quality System, including strategic planning, allocation of resources, and the planning, implementation, and assessment of programs by the organization.<sup>(1)</sup>*

EPA has drawn from many sources of well-known principles of quality management to provide the basis for a Quality System for environmental programs. These principles include:

- a focus on meeting customer requirements
- long-term commitment to the quality management process
- management involvement in leading Total Quality Management (TQM) efforts
- effective communications across all levels of the organization
- use of quality goals and measures of effectiveness
- employee involvement and recognition
- training and education for all employees.

The goal of the Quality System is to provide the necessary framework embodying these principles to enable the mission of the organization to be conducted successfully. For EPA, a critical part of its operations involve the collection and evaluation of environmental data for use in making decisions involving rulemaking, regulatory actions, and research.

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<sup>(1)</sup> ANSI/ASQC E4-19xx, "Quality Systems Requirements for Environmental Programs," American Society of Quality Control (DRAFT).

## THE IMPORTANCE OF ENVIRONMENTAL DATA COLLECTION ACTIVITIES

Since 1984, EPA has been applying quality management principles to the collection, analysis, and use of environmental data. Environmental data help form the basis for nearly all policy, technical, and regulatory actions at EPA. Therefore, it is vital that the collected data are of the type, quantity, and quality needed to make decisions with the desired degree of confidence; that is, to assure management that the data do not lead to an incorrect decision and that the data can withstand scientific and litigative scrutiny. The quality of environmental data may be affected by any aspect of data collection, including sampling, analysis, validation of results, and evaluation of the complete measurement system, that may, in turn, impact the decision-making process adversely. The EPA commitment to quality is embodied in EPA Order 5360.1, "Program and Policy Requirements to Implement the Mandatory Quality Assurance Program," which requires all EPA organizations collecting environmental data to implement an effective Quality System.

The cost of incorrect decisions may be high for both EPA and the parties it regulates. Incorrect decisions could lead to inadequate health protection on one hand, or an inefficient expenditure of resources on the other. For example, EPA uses air monitoring data to determine if an area is in compliance with the air quality standard for ozone, a hazardous pollutant. Error in the data could cause the decision to be incorrect in one of two ways. EPA could determine that the location was out of compliance with the ozone standard when it was actually in compliance; or EPA could determine that the location was in compliance when it had actually exceeded the standard. In the first case, EPA might require the facility owner to install more efficient and more costly pollution control devices or require a state to reduce new industry starts when there was no real need for these actions. In the second case, no action would be taken when, in fact, the protective air standard had been exceeded and a health threat could exist. The impacts of either decision are significant. This example illustrates the critical role of environmental data in EPA decision making and the importance of ensuring that the data are of the quality needed and specified for the decision to be made.

## THE COMPLEXITY OF REGULATORY DECISION MAKING

In addition to the importance of environmental data to EPA decision making, there is another reason why application of quality management to environmental data collection is so vital: the complexity and variability of the decision-making process in a regulatory agency. The ozone example above involves a fairly straightforward compliance decision, but most EPA technical and regulatory decisions are more complex and are not generally amenable to a standard or repetitive problem-solving approach. Some of the many variables affecting the decision-making process are discussed below:

- Uncertain Targets: Unlike the compliance example, the end-product or specific definition of the decision to be made is often not obvious at first, and considerable effort may be required to define the decision in a way that directly addresses the problem at hand. For example, at a hazardous waste site, how will it be determined that clean-up efforts have been successful and that the site is "clean"? Will the decision be based on the concentration of one chemical or ten chemicals, will chemical concentrations be measured in soil or in water or in both, at what location(s) on or near the site will measurements be taken, how will data from various chemicals be combined, etc.

- Sequencing of Issues: Each decision or action may be comprised of multiple questions and sub-decisions to be answered that rely largely on data; the proper sequencing of these decisions can be crucial to arriving at the correct decision in a timely way.
- Multiple Organizations and Jurisdictions: For each decision or related set of decisions, there may be a different group of participants cutting across several organizational boundaries. These individuals may have varying technical backgrounds and approaches to problem solving or may have different goals.
- Variation in Data Types: Each problem requires various types of environmental data that need to be combined in different ways for decision making. For example, at a hazardous waste site, measurements of several chemicals in water, soil, and air may need to be combined with data on health effects of each compound, their ability to migrate in each medium, and the characteristics of the nearby population. The most meaningful way to incorporate all of this information must be determined.
- Statistical Variability: With all data collection, there is uncontrollable variability inherent in the environment and in the environmental measurements (which is controllable to some extent); this means that decisions based on data are probabilistic in nature, that an element of risk always remains, and that the objective of the decision-making activity is to minimize that risk to acceptable levels.

There is a distinction between this type of problem-solving activity and a manufacturing or continuous service operation. For every environmental data operation that is not a straightforward compliance determination, the specific end-product (decision or action) and the means to attain it with a defined degree of confidence have to be specified at the outset. Each new environmental problem presents different pollutants and health threats, different media that may be affected (air, surface or ground water, soil), and different regulatory goals to be met. The integration of these factors is unique for each new data operation. The problem-solving process often is akin to creating a new blueprint for each situation rather than finding new ways to refine and improve an existing blueprint.

## **EPA QUALITY MANAGEMENT PROCESS**

Because the content of each decision-making activity is so variable, a consistent structure and process are crucial to ensure that all critical planning steps are addressed and that the focus of each data operation is on the needs of the data user or customer. The ultimate quality of any product or service is determined largely by whether or not the needs and expectations of the customer have been satisfied. Moreover, it was necessary to create and adapt several quality management tools in order to be able to apply the desired quality management principles to the Agency's environmental programs.

Quality management must be embedded in the organization so that the many sources of variability do not lead to inconsistent or inadequate environmental data collection activities. Consequently, the overall focus of quality management efforts at EPA is on the institutionalization of a quality consciousness in the planning, implementation, and review of data collection efforts. That is, everyone must have an awareness that quality must be a principal consideration in the planning, implementation, and assessment of every program. Through a two-tiered quality management structure, as shown in Table 1, EPA is addressing both the organizational and project decision-making aspects of the Agency's environmental

data collection activities using a variety of specialized "tools" to achieve this awareness and to ensure that Agency projects meet the needs and expectations of their customers.

### **EPA Quality Management Process Tools**

There are eight specific tools or components used in EPA's two-tiered process for quality management, as given by Table 2. These elements reflect such basic principles as management direction and involvement, open and effective communication, a focus on customer requirements, use of quality goals and measures to assess progress, and employee involvement. Three of the tools deal with functions that are common to all activities and operations conducted by the organization: human resources, Quality Management Plans, and Management Systems Reviews. The other tools apply to project-specific activities that are planned, implemented, and assessed under the umbrella of the Quality System structure defined by the organization.

### **Quality Management at the Organizational Level**

An important way that institutionalization of the quality management process at the organizational level is being achieved is through ongoing human resources development: training, communications, and recognition. For the Quality System to be successfully implemented, it is critical that each person understand the quality management fundamentals and his/her role in making things work right the first time. To help convey this message, EPA provides:

- training for employees in the principles and application of quality management
- training in setting quality goals for data collection and decision-making operations
- direct implementation support for quality management activities in EPA organizations
- extensive communications focused on quality awareness including a monthly newsletter, written guidance, monthly conference calls, and an annual national conference
- an annual Quality Manager of the Year Award, for which EPA employees nominate a peer for recognition of his/her contribution to quality improvement.

These efforts help to create a positive climate in which all employees understand the importance of quality management and proactive problem solving in environmental data operations, understand their role in the overall scheme, and have access to the tools and skills needed to carry out their responsibilities.

Communication and training are integrated with the other components of the EPA Quality System to enable planning, implementation, review, and follow-up action on two levels: the individual EPA organization and the specific data operation/decision-making activity within an organization. At the organizational level, the Quality Management Plan (formerly called the Quality Assurance Program Plan) defines a framework for line management to set organizational goals and creates a quality management system tailored to the particular mission of the organization. The Management Systems Review provides a process for assessing the effectiveness of the organization's approach to quality management. At the project level, the Data Quality Objectives process provides a structure and a systematic approach for defining quality goals for data collection operations. Technical Assessments and the Data Quality

Assessment (DQA) process may be used to determine if the planned technical and quality goals have been met.

Implementation of the quality management process is decentralized to provide greater flexibility to line management in tailoring a process that best fits the particular EPA organization and mission. EPA's Quality Assurance Management Staff (QAMS) provides guidance and oversight of quality management activities throughout the agency, but the primary responsibility for implementation of the process rests with each organization's line management. The EPA Quality System has been designed to be responsive to the needs of EPA headquarters offices, regional offices, and research laboratories. The system must be flexible because each organization has a different mission with widely varying activities and data collection needs. For example, the data collection programs of an office conducting research in atmospheric transport of pollutants will differ greatly from those of an office studying contamination of ground water from solid waste landfills.

In addition to being responsible for implementation of their organization's quality program, line managers have an important role in the institutionalization of the quality management process. These managers are likely to be career government employees who represent a longer-term presence at the Agency, in contrast to the more frequent changes in politically appointed managers at the highest levels. The acceptance and active endorsement by the career managers of quality management principles is essential to its acceptance and effectiveness over the long term. The "buy-in" of quality management principles by the career managers bolsters senior management support for the Quality System and provides organizational continuity that might otherwise be reduced by the periodic turnover in senior management.

At the level of the individual EPA organization, the Quality System is documented by the Quality Management Plan (QMP). The QMP is the blueprint for an organization's quality management process for data collection operations. The QMP identifies the mission and customers of the organization, documents specific roles and responsibilities of top management and employees, outlines the structure for effective communications, and defines how measures of effectiveness will be established. The QMP is an organization's commitment to quality management principles, tailored by top management to meet the organization's needs. The QMP also identifies training needs and environmental data operations for which quality goals will be developed over the next year. The process of developing and annually updating the QMP provides an opportunity for management and staff to clarify roles and responsibilities, address problem areas, and acknowledge successes so that they may be fostered and rewarded.

Effective implementation of the activities documented in the QMP relies on ongoing communications and a consistent emphasis on quality from the organization's top management. To assess the effectiveness of the organization's implementation of the quality management process outlined in the QMP, managers may use the Management Systems Review (MSR). MSRs examine the structure and process of the organization's quality management activities as applied to a particular environmental data collection activity. The review focuses on specific issues identified by program management. Through the MSR, management may identify and highlight those areas where significant achievements have been made, and target areas where additional work or corrective action is needed. MSRs may be conducted by the organization itself or by QAMS at the organization's request. This type of review is particularly effective at addressing quality issues that cross organizational boundaries, when multiple organizations such as the EPA regional offices participate in the data collection.



For example, QAMS conducted a study of the Superfund hazardous waste clean-up program at the request of top management in that office. The review identified significant strengths in the Regional Quality Systems being applied to the Remedial Investigation/Feasibility Study process, as well as areas where improvements were needed. With this information, senior management was better equipped to take effective and appropriate action. Another MSR for the pilot study of the "National Survey of Pesticides in Ground Water" provided management with important information which enabled them to develop a more comprehensive and effective quality management program for the full national survey.

Taken together, the thoughtful planning involved in development and implementation of the QMP and the assessment of effectiveness achieved with the MSR provide a comprehensive system for planning, implementing, and evaluating the effectiveness of quality management activities at the level of the EPA organization.

### **Quality Management at the Project Level**

With the organizational framework and process in place, attention can be focused on quality management at the next level; that of the environmental data collection activity.

EPA has developed a process that can be used to determine customer requirements for a particular data operation and articulate those requirements in a way that can be used as a basis for planning and designing the data collection program. The Data Quality Objectives (DQO) process results in a statement of quality standards or goals for environmental data used in decision making. Critical to the success of this process is communication between the data provider and the data user or customer. The DQO process provides a systematic way to approach complex technical problems, define the action that will be based on data, specify what inputs are needed and how data should be applied to provide the necessary inputs to the decision(s), and define the acceptable level of error that can be tolerated in these inputs. The data user must specify a level of error that he or she will find acceptable when relying on the data to make a decision. This specified level, along with other technical constraints, represents the customer requirements. Subsequently, the data collection activity is designed to attain these requirements, and the most cost-effective data collection design that meets specifications is chosen for implementation. Thus, the DQO process provides a helpful planning tool for the project decision maker to use in striking a balance between risk in decision making and the resources available for data collection.

The quality standards, goals, and performance specifications derived through the DQO process, and the QA/QC activities necessary to achieve them, are incorporated into a specific Quality Assurance Project Plan (QAPP) for the data collection activity. The QAPP serves as the blueprint for implementing the data collection activity in order to achieve the technical and quality goals of the operation. General guidance for preparing QAPPs is available; however, individual organizations have substantial flexibility to tailor the QAPP requirements to their particular mission or needs. As a result, QAPP requirements vary among the EPA program offices, regions, and ORD laboratories. The QAPP provides the necessary link between the required data quality constraints and the sampling and analysis activities to be conducted. To assure that the data collection effort will produce results meeting the DQOs, the QAPP is the focus of rigorous review before the data collection begins. Experience has shown that when well-thought-out and focused QAPPs are implemented properly, the resultant data are cost-effective and timely, and meet quality performance expectations.

One of the keys to successful implementation of the approved QAPP is the development and use of Standard Operating Procedures (SOPs). Standardization of methods and protocols has been shown to

reduce error and costs of rework. EPA strongly encourages organizations to develop and implement SOPs for their unique Quality System procedures. Moreover, communications among users is also encouraged to reduce duplication of SOPs. Many functions are common across organizational boundaries and need not be duplicated.

During implementation of a data collection program or afterwards, technical assessments may be used to check progress against data quality constraints and other QA/QC specifications. EPA uses several types of technical assessments to evaluate the effectiveness of the QAPP implementation, including Surveillance, the Technical Systems Audit (TSA), and the Performance Evaluation (PE).

Surveillance is an important technical assessment tool involving the first-hand observation of the implementation of planned procedures. Surveillance determines whether or not the critical steps in the measurement process are being executed in the correct manner and sequence.

The TSA is a qualitative assessment of the total measurement system being employed to collect the data. The objective of the TSA is to assess all facilities and equipment used, and to examine and document data validation procedures, maintenance records, calibration procedures and records, and QC procedures. The approved QAPP provides the "measure of success" for the TSA. This means that the QAPP provides the criteria by which the measurement system used for data collection is evaluated qualitatively.

The PE is a quantitative evaluation of the effectiveness of the measurement system in meeting specified standards for precision and accuracy (or bias). The expected performance goals are defined in the QAPP and are derived from the DQOs. The PE will determine if the measurement system is operating within the established control limits necessary to achieve the DQOs for the data collection effort.

The Data Quality Assessment (DQA) process allows the data user to determine if data quality is adequate for the intended use; that is, were the data obtained within the limits given by the DQOs. The DQA process is a systematic, statistically-based evaluation of the data and the overall measurement process that may be employed without DQOs having been specified at the beginning. Its results may be used to set limits on the use of the data if the original criteria were not met completely. The results of TSAs and PEs are often important inputs to the DQA process. Experience has shown that even when measurement systems perform as expected, unexpected factors can influence the usability of data, and the quantitative assessment of the usefulness of the data for their intended purpose provides a measure of assurance for the decision maker.

Thus, the EPA Quality System incorporates several helpful tools to enable users to conduct the needed planning, implementation, and review functions for ensuring the quality of specific environmental data collection activities conducted by EPA.

## **NEW INITIATIVES AND DOCUMENTS**

Later this year, the American Society for Quality Control (ASQC) will publish the first American National Standard for environmental programs, ANSI/ASQC E4, "Quality Systems Requirements for Environmental Programs." It is EPA's intention to adopt this standard as the basis for its internal Quality System. Already there is substantial consistency between the EPA Quality System and E4, and it is expected that the adoption of E4 will have little impact on the Agency's existing programs.

The availability of an American National Standard provides a reference basis for a new array of requirements and guidance documents describing the quality management "tools" discussed in this paper. These documents will include "requirements documents" that will undergo internal consensus approval and be issued as official EPA policy, and "guidance documents" that will be issued through regular reporting mechanisms following internal peer review. The requirements documents will define the minimum criteria for various activities and will define WHAT must be done. The guidance documents, on the other hand, are non-mandatory and will offer suggestions on HOW certain activities may be accomplished. During the next 18-24 months, QAMS expects to issue requirements and guidance documents for QMPs, QA PPs, MSRs, DQOs, DQAs, and many other QA and QC activities.

## CONCLUSION

The organizational level and technical/project level of EPA's quality management process, combined with communication and training efforts, form an integrated Quality System in which each component supports and adds to all others. The stage is set on the organizational level for successful implementation of program-level activities. At the project level, the Quality System results in well-planned and executed data collection activities that meet data quality goals. This two-tiered approach to quality management has been successful in EPA's highly decentralized operations. It supplies EPA employees at all levels with the training and tools that they need to create the larger framework for quality management and then carry out the specific goals for program activities. The process provides implementation support through outreach and training. It also provides mechanisms to determine if the organizational system is working as intended and that program data quality objectives have been attained. These checks provide an opportunity for follow-up actions.

EPA has been implementing this quality management-based program since 1984. During this period, we have repeatedly confirmed the importance of applying quality management principles in a regulatory agency where the quality of operations relies heavily on the reliability and appropriate use of scientific data. Quality management efforts are needed to provide a consistent structure and process to complex and variable decision-making activities with many technical inputs, to promote a focus on customer requirements in these activities, to limit the probability of making an incorrect regulatory or compliance decision, and to encourage open communications and contribution by all employees.

EPA's Quality System is evolving and will continue to evolve as we learn to use the fundamental principles of quality management more effectively. The quality of our decisions reflects the quality of the data used to make them. As a government agency and a steward of the public's trust and funds, our continued commitment to quality must be an integral part of how EPA operates, both now and in the future.

**Table 1 - Quality Management Process Structure**

<p><b>ORGANIZATIONAL LEVEL</b></p> <p><i>Management functions common to all activities of the organization</i></p> <p><b>TECHNICAL/PROJECT LEVEL</b></p> <p><i>Technical and management functions unique to a specific project or activity</i></p>
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**Table 2 - Quality Management Tools**

<p><u>Organizational Level</u></p> <ul style="list-style-type: none"><li>• <i>Human Resources Development – Training, Communication, Recognition</i></li><li>• <i>Quality Management Plans</i></li><li>• <i>Management Systems Reviews</i></li></ul> <p><u>Technical/Project Level</u></p> <ul style="list-style-type: none"><li>• <i>Data Quality Objectives Process</i></li><li>• <i>Quality Assurance Project Plans</i></li><li>• <i>Standard Operating Procedures</i></li><li>• <i>Technical Assessments</i></li><li>• <i>Data Quality Assessment Process</i></li></ul>
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## MQA - CRCPD'S PERSPECTIVE

Pamela M. Dukes<sup>(1)</sup>

*Abstract* - The Conference of Radiation Control Program Directors, or CRCPD, was formed by state radiation control programs, and exists to serve the needs of and provide a resource to these programs. One of the fundamental requirements of a radiation control program is the ability to accurately and reliably make radiation measurements. The CRCPD has a continuing commitment to promoting measurement quality assurance (MQA) in several areas, including having an accreditation program for calibration laboratories. As the needs of radiation control programs in the area of MQA increase, the CRCPD will also increase its activities in this area.

The Conference of Radiation Control Program Directors, or CRCPD, was established in 1968 by state radiation control programs in the United States. The CRCPD is composed of radiation control program directors and staff, and other individuals who have an interest in the activities and goals of the organization. The primary purpose of the CRCPD is to provide coordination of, and guidance to, state and local governments on issues concerning radiation protection. The CRCPD also serves as a resource for technological information for radiation control programs.

The broad objectives of the CRCPD include promoting radiological health in all aspects, promoting uniformity of radiation control laws and regulations, encouraging and supporting programs that contribute to radiation control, assisting the membership in their technical work and development, and exercising leadership with radiation control professionals and consumers in radiation control development and action.

Obviously, one of the fundamental requirements of any radiation control program that protects the public from unnecessary or excessive radiation exposure is the ability to accurately and reliably make radiation measurements. The measurements that are made by the radiation control programs have the potential for seriously impacting the work of major industries, health care facilities, and academic institutions. Therefore, it is imperative that state and local health physicists be able to make radiation measurements with properly calibrated instruments, and maintain a certain level of MQA.

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The CRCPD has a continuing commitment to promoting MQA on a nationwide basis. To fulfill this commitment, the Conference provides guidance and support for the MQA process at several levels. Training courses are offered to state and local inspectors in special sessions and as part of an annual conference on radiation control. The Conference has also established a Committee on Ionizing Measurements that supports and promotes MQA. This Committee publishes a document entitled "Ionizing Radiation Measurement Criteria for Regulatory Purposes," which guides regulatory staff in selecting appropriate instruments for the type and energy range of radiation to be measured. Calibration, traceability, measurement precision, accuracy, and uncertainty are also discussed in detail to assist the inspectors in establishing and improving quality assurance for their measurements.

The major focus of the Conference on MQA, however, has been on the establishment of an accreditation program for state calibration laboratories. Several state calibration laboratories were developed in the late 1970s and early 1980s. The Conference then began an accreditation program similar to other accrediting bodies, such as the Health Physics Society and the American Association of Physicists in Medicine. The laboratory accreditation program is currently an active program, and will continue to ensure that state and local radiation control programs have access to laboratories offering traceable instrument calibrations.

The future direction of the Conference with respect to MQA will probably prove to be quite interesting. As regulatory responsibility in the area of radiation control increases, the needs of the states in ensuring MQA will also increase. The Conference is considering establishing an accreditation program for state and local environmental laboratories. Other future activities that the Conference will be involved in include greater interaction with the National Institute of Standards and Technology (NIST) for the exchange of technological information between NIST and Conference members, promoting the establishment of a national standard for the calibration of instruments used in mammographic energy ranges, promoting the use of National Voluntary Laboratory Accreditation Program approved dosimetry processors, and promoting greater use of the national standards and references available through NIST. Through these efforts, the CRCPD hopes to improve the level of MQA currently existing in state and local radiation control programs.

# **COMPLETE MQA PROGRAMS**

Session Chair  
Elmer Eisenhower, HPS

Wednesday  
March 17, 1993

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# HISTORY, ORGANIZATION, AND OVERSIGHT OF THE ACCREDITED DOSIMETRY CALIBRATION LABORATORIES BY THE AAPM

Martin Rozenfeld<sup>(1)</sup>

*Abstract* - For more than 20 years, the American Association of Physicists in Medicine (AAPM) has operated an accreditation program for secondary standards laboratories that calibrate radiation measuring instruments. Except for one short period, that program has been able to provide the facilities to satisfy the national need for accurate calibrations of such instruments. That exception, in 1981, due to the combination of the U.S. Nuclear Regulatory Commission (NRC) requiring instrument calibrations by users of cobalt-60 teletherapy units and the withdrawal of one of the three laboratories accredited at that time. However, after successful operation as a Task Group of the Radiation Therapy Committee (RTC) of the AAPM for two decades, a reorganization of this structure is now under serious consideration by the administration of the AAPM.

## HISTORY

The idea of establishing secondary standards laboratories in this country for the calibration of radiation measuring instruments was first presented by Bob Loevinger, then head of the Dosimetry Section of the National Bureau of Standards (NBS), at an AAPM meeting in December 1968. His major problem was that the NBS could not provide any financial support, and yet it wanted to have some influence on the operation of the laboratories. The AAPM offered to help establish such laboratories and provide the necessary oversight after his negotiations with several other organizations were unsuccessful.

The project was assigned to Task Group No. 3 of the RTC of the AAPM. Requests were distributed to interested parties to submit proposals for the establishment of such laboratories. By July 1970, 34 individuals and institutions had expressed interest; however, only 8 complete proposals were submitted. These ranged from a few with dedicated equipment and previous experience in performing calibrations of in-house instruments to those proposing intercomparison of instruments at local chapter

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meetings. The type of laboratory finally chosen was that modeled after the two labs that had been performing in-house calibrations at the Memorial Sloan Kettering Institute in New York and the M. D. Anderson Hospital in Houston. These were the first two laboratories given provisional accreditation by the AAPM in December 1970. These labs did not need financial support, since they already had the needed facilities and equipment. The NBS involvement would be through a membership or consultant position on the Task Group. Provisional accreditation is offered to all new laboratories, with an upgrade to full accreditation after a year of successful operation.

Task Group No. 3 was also given the responsibility for soliciting new laboratories, accrediting them, and maintaining oversight to ensure acceptable performance. The original concept was to have laboratories in each region of the country, so they were called Regional Calibration Laboratories. However, it was soon found that there was not enough work to support a lab in each region. The distance of the labs from most of their customers was no hardship, since no more effort was required to ship an instrument across the country than across a state.

As early as 1971, a suggestion was made that the Task Group organize an intercomparison between the labs and the NBS. This would be in addition to requiring routine recalibration of their internal secondary standards at the NBS.

In early 1972, Victoreen Instrument Company proposed that their production calibration facility be accredited. There was interest in having them as one of the accredited labs, since most of the instruments used in Radiation Therapy in the U.S. at that time were manufactured by Victoreen. However, that proposal was rejected after a site visit found that their production facility did not meet our minimum requirements. Victoreen then built a separate dedicated facility in their plant and it was finally accredited in 1976.

In 1978 a subgroup generated the first draft of a document that is now called "Guidelines for Accreditation of Dosimetry Calibration Laboratories." This document spells out such things as the procedures for applying for accreditation, the acceptance criteria, the minimum equipment and calibration procedures, as well as accuracy and documentation requirements. In 1979, a memorandum of understanding between the NBS and the AAPM was approved. This memorandum enumerates the duties and responsibilities of the respective parties relative to the operation and oversight of the accredited laboratories.

### **Shortage of Calibration Facilities**

At about that same time, a radiation incident occurred with a cobalt-60 teletherapy unit in Columbus, Ohio. In that incident, 400 patients were overexposed because the teletherapy unit was not calibrated for several years and the correction for radioactive decay was incorrectly determined. In response to that incident, the NRC issued the rule (Federal Register 1979) requiring all teletherapy units under their jurisdiction to be calibrated yearly with an instrument that had been calibrated within the previous 2 years. The NRC also required that the instrument be calibrated by the NBS or a laboratory accredited by the AAPM. This ruling gave the accredited laboratories official government recognition, but also significantly increased the inquiries for calibrations at the accredited laboratories. Radiation therapy facilities without cobalt-60 teletherapy units also began to adopt the 2-year schedule for recalibrating their instruments.

During this same period, the customer service at the Victoreen laboratory deteriorated after the laboratory director was transferred out of state. Victoreen officials decided to withdraw from the accreditation program in June 1982, rather than recruit a replacement with adequate training and experience to act as the laboratory director, as required by the "Guidelines." Because of the increase in inquiries and the loss of one lab, the waiting time for new calibrations at the two remaining labs increased to over 1 year, and a number of institutions found that they could not meet the new NRC requirements.

Several steps were taken to alleviate that situation. The NRC was petitioned to allow for an extension of time between recalibration of instruments, and additional laboratories were solicited to apply for accreditation. The NRC then published a rule (Federal Register 1982) allowing a period of 4 years between recalibration of instruments, provided an intercomparison with a calibrated instrument was made after 2 years at a meeting sponsored by a professional organization, such as a chapter of the AAPM, the Radiological Physics Center (RPC), or a Regional Center for Radiological Physics. By mid-1982, one additional laboratory was accredited to calibrate with cobalt-60 and the long waiting time was quickly being eliminated.

After the experience of suddenly not having the calibration facilities to meet this important national need, it was decided to accredit two more laboratories, for a total of five. It was estimated that four laboratories should be able to provide the calibrations projected to be required for the foreseeable future with minimal waiting time. A fifth laboratory was included to ensure that there would not be a repeat of the serious shortage of calibration facilities if one were to withdraw in the future. Rather than open the accreditation to all those applying that met the criteria, it was decided to limit the total number to five to prevent excessive competition and thereby further reduce the probability of future withdrawals.

### **Laboratory Suspension**

The accreditation of the Allegheny laboratory was suspended in 1989, when its director relocated to California and a younger, less experienced individual, unknown to the Task Group, was appointed as a replacement. The previous director wanted to establish a laboratory at his new facility and apply for the open accreditation. However, Allegheny was given the opportunity to document the training and experience of their new appointee and meet all the other criteria for accreditation. After a year of correspondence, interviews and another site visit, the accreditation of the Allegheny laboratory was reinstated. During that year the remaining four laboratories were able to provide the necessary calibrations with no increase in waiting time.

At our annual meetings, each lab reports on the number of calibrations performed, the waiting and turnaround time, and an estimate of their work load as a fraction of full capacity with their present staff. Thus, on a yearly basis, we are able to monitor the national need for instrument calibrations for Radiation Therapy and the adequacy of the available facilities.

Figure 1 is a stacked bar graph which shows the complete history of the number of cobalt-60 calibrations performed by the accredited labs from the inception of this program through last year's reporting period. The reduction in calibrations due to the withdrawal of Victoreen is clearly seen, as well as the general increase with a small 2-year cyclic variation. Apparently the increase in cobalt-60 calibrations, despite the reduction in the number of cobalt-60 teletherapy units in use, is due to the

general adoption of the 2-year rule and the need for such calibrations to determine  $N_{\text{gas}}$ , which is the basis for calibration of high-energy photon and electron beams.

Figure 2 presents the same information for orthovoltage x-ray calibrations for the same time period. Figures 1 and 2 also show that the reduction to four labs in 1989 did not lead to a reduction in calibrations. However, it is uncertain how long it would take to recover if, for some reason, the K. & S. laboratory were to cease operations, since that lab performs more calibrations than all the others combined. Finally, Figure 3 shows the same data for calibrations with cesium-137 beams. Such calibrations are used mostly in health physics applications.

### **Brachytherapy Calibrations**

K. & S. was the first laboratory accredited to calibrate low-dose-rate brachytherapy sources and chambers in 1986. To formalize those requirements, the document "Guidelines for Accreditation of Dosimetry Calibration Laboratories (for Brachytherapy Calibrations)" was prepared by Task Group 22 of the RTC, based on the general outline of the "Guidelines" for external beam calibrations. That Task Group was asked to help prepare the document for brachytherapy calibrations since their members had expertise in that field. In 1990, the Wisconsin laboratory was also accredited for the calibration of low-dose-rate brachytherapy sources and chambers. So far, the number of such calibrations has been quite low, with only 56 low-dose-rate sources and 23 re-entrant chambers calibrated last year.

Since the inception of the program, the basic objective of the laboratories has been to transfer the National Radiation Standards to the end user. However, recently a need arose for calibrations for which there is no national standard, due to the increasing use of high-dose-rate (HDR) remote afterloading brachytherapy equipment employing high-activity iridium-192 sources. Fortunately individuals closely associated with the Wisconsin lab developed a method (Goetsch et al. 1991) for calibrating such sources based on an interpolation between an orthovoltage and a cesium-137 beam calibration. After more than a year of discussion, that method was finally accepted as an interim procedure that the Wisconsin lab could offer as an accredited activity. Within another year, the K. & S. laboratory was also accredited to offer HDR calibrations based on the same interpolation procedure for which they determined all the necessary corrections independently. The two labs agreed within a few tenths of a percent in a blind intercomparison of their HDR calibrations.

During the 4 years that the K. & S. lab was the only one accredited for brachytherapy, they could only intercompare with the National Institute of Standards and Technology (NIST). However, since NIST no longer calibrates radium-226 sources, no intercomparison for those sources could be performed. Last year we arranged for an intercomparison with such sources at the RPC in Houston, but then K. & S. decided to dispose of their radium sources with the imminent closing of the last facility willing to accept such sources. Thus, there is no longer any accredited facility that will calibrate radium-226 sources.

### **ORGANIZATION**

Since its inception, Task Group No. 3 of the RTC of the AAPM has had the responsibility for accrediting and overseeing the operations of the laboratories. The voting members of the Task Group include the directors of the accredited laboratories, a representative from NIST, and several other AAPM members interested in metrology. All actions taken by the Task Group are in the form of

recommendations to the parent committee, which then reports to the Science Council. Finally, major decisions, such as accreditation of laboratories, are also reviewed by the AAPM Board and the letter conferring official accreditation is sent by the AAPM President.

The Task Group operates without a budget. Meetings are held at national AAPM and American Society for Therapeutic Radiology and Oncology meetings. All work on the Task Group is done on a voluntary basis, and the laboratories are not charged any fees or assessments. The only additional expenses to the labs for accreditation are for the travel of the site-visit team and NIST's charge for the round-robin intercomparison. There is an initial site visit upon application for accreditation and another every 5 years for each lab. To keep these costs to a minimum, the intercomparison with NIST is held every second year, with an intercomparison between the labs alone on alternate years.

Although this organization has functioned well, it has been criticized because it was felt that the AAPM could not exercise adequate oversight since the laboratory directors make up a majority of the Task Group membership. In response to that criticism, we have pointed out that 1) it is important for the laboratory directors to have a meaningful say in the operation of the Task Group to obtain their full cooperation and support; 2) there are too few independent AAPM members with knowledge and experience in metrology to appoint a clear independent majority. Even if that were possible, it would make our present 3-hour meetings still longer; and 3) the Task Group chairman, who is independent of the labs, could refer any questionable decisions to the RTC for their review.

So far these arguments have succeeded in thwarting any attempts to alter the present organization. However, other concerns have recently been raised, and serious consideration is being given to revamp the structure of this oversight group. These concerns are that 1) the AAPM could become financially liable in case of a lawsuit involving an accredited laboratory; 2) there is a potential conflict of interest when a director votes on accreditation of his/her or another laboratory; 3) Task Group No. 3 is permanent, while all other task groups in the AAPM have limited lifetimes; and 4) the term of other committee and task group members is 3 years, once renewable, while the term on Task Group No. 3 is indeterminate. Various suggestions have been offered to accommodate the needs of this oversight activity within the organizational structure of the AAPM. Unfortunately, none of them satisfy all the concerns listed above, especially the concern over potential liability.

## **OVERSIGHT**

Generally, the round-robin intercomparisons with NIST and those among the laboratories have produced results within our accuracy goals. In those few exceptions when those goals were not met, the cause could be traced to a failure of internal redundant checks or the inadequacy of earlier intercomparisons.

A 2% error in the x-ray calibrations at the Wisconsin lab in 1986 was traced to a loss of redundancy in the use of the x-ray monitor chamber, combined with a change in sensitivity of the transfer chamber to x-rays but not to cobalt-60. A 4.3% error was discovered at the first intercomparison arranged between the K. & S. lab and the RPC for radium-226. That error was caused by a misinterpretation of the corrections described on the 40-year-old NBS certificate.

These two items were enumerated because they demonstrate the importance of adequate internal redundancy within each laboratory and prompt and routine intercomparisons between laboratories.

## OTHER TASK GROUP ACTIVITIES

The Task Group has become involved in several other activities as problems have arisen in its normal operation. When K. & S. was accredited, they had one of their transfer chambers calibrated at the NBS over a wide range of half-value layers. There was a significant jump on a plot of the calibration factor of the chamber versus the first half-value layer. The cause of the jump was found to be a significant change in beam quality at two adjacent half-value layers produced by different voltages and filtration. To solve this problem, in 1983 the NBS modified their x-ray beam qualities and divided them into three families with low, medium, and high filtration. The calibration factors for ionization chambers would then fall on a smooth curve when plotted against first half-value layer, provided that the points were chosen from the same family.

With the official acceptance of the TG-21 protocol (Task Group 21, 1983), the calibration factor  $N_x$  provided by the laboratories had to be converted to the factor  $N_{gas}$  in order to determine the absorbed dose. This conversion depends on the physical dimensions and materials of the chamber and buildup cap. Manufacturers frequently give nominal values for dimensions and sometimes change materials without changing model numbers. To provide the laboratories' customers with accurate values of the conversion factors for a large number of commercial chambers, several members of Task Group No. 3 (Gastorf, Humphries, and Rozenfeld 1986) calculated these factors based on measured dimensions and materials provided by the manufacturers for different models and years of construction.

For several years, there has been disagreement amongst the laboratories on the proper method for calibrating parallel-plate chambers in a cobalt-60 beam. Some preferred to calibrate them in air with buildup material, while others preferred to embed the chamber in a phantom. We referred this problem to our parent committee and they established Task Group No. 39 to address this subject. The final version of their report is now under review by the RTC. That report provides for three different methods to perform the calibration, each yielding the same result. Those methods are limited to five commercial chambers for which data is available to allow the accurate calculation of  $N_{gas}$  from  $N_x$ .

The "Guidelines" specify 0.5% as the accuracy goal of the laboratories in terms of deviation from the national standard for reference class instruments on cobalt-60. However, we had never made an analysis of the total uncertainty of the calibrations at the laboratories until the question was raised by the Diagnostic X-ray Imaging Committee of the AAPM. An investigation (Ibbott et al. 1991) of the Type A and Type B uncertainties at the laboratories gave an overall uncertainty of 1.5% for cable-connected instruments at the 2-standard deviation level when combined with the uncertainty of the NIST calibrations.

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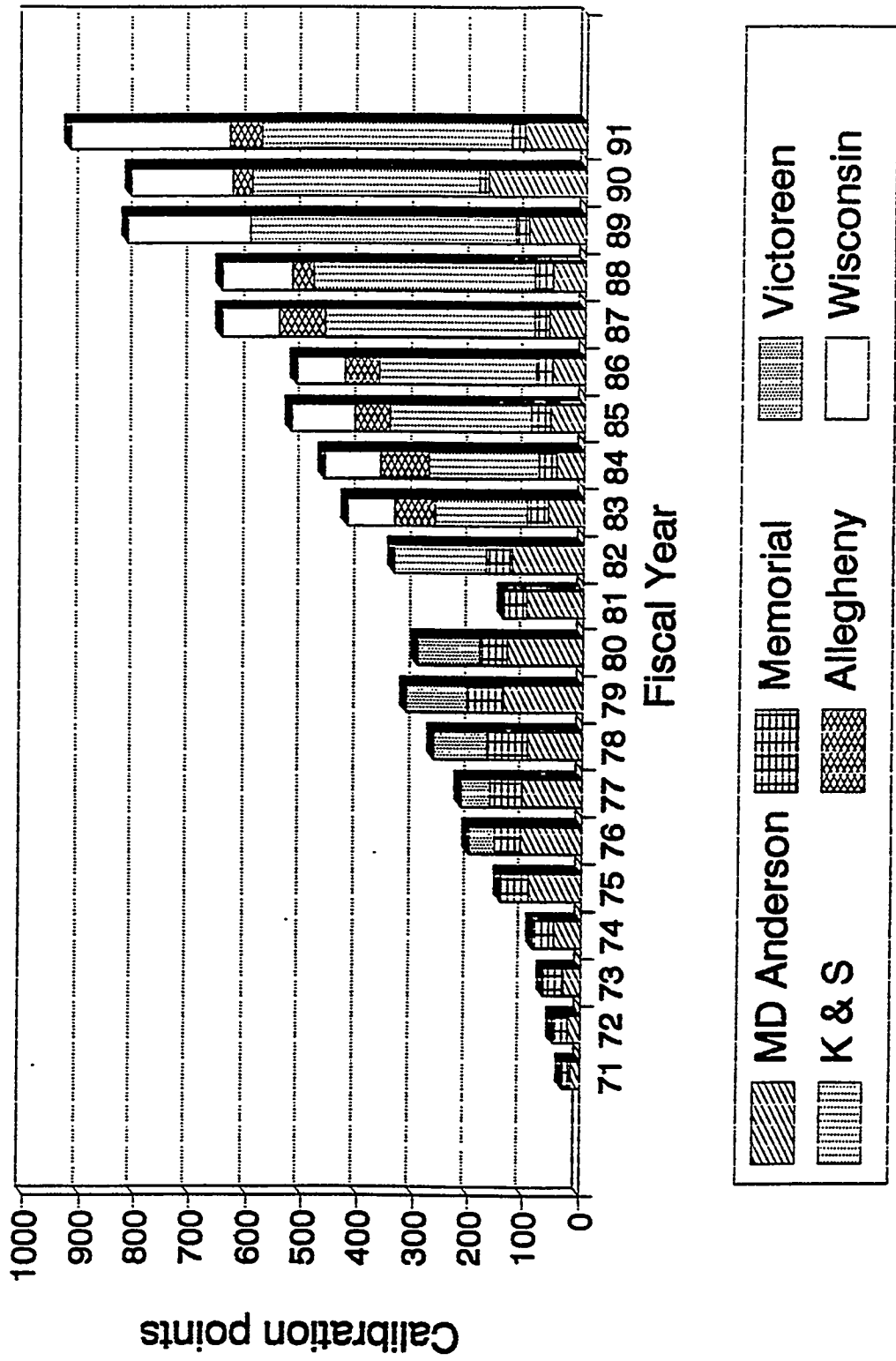


Figure 1 - Yearly Cobalt-60 Calibrations by the Accredited Laboratories



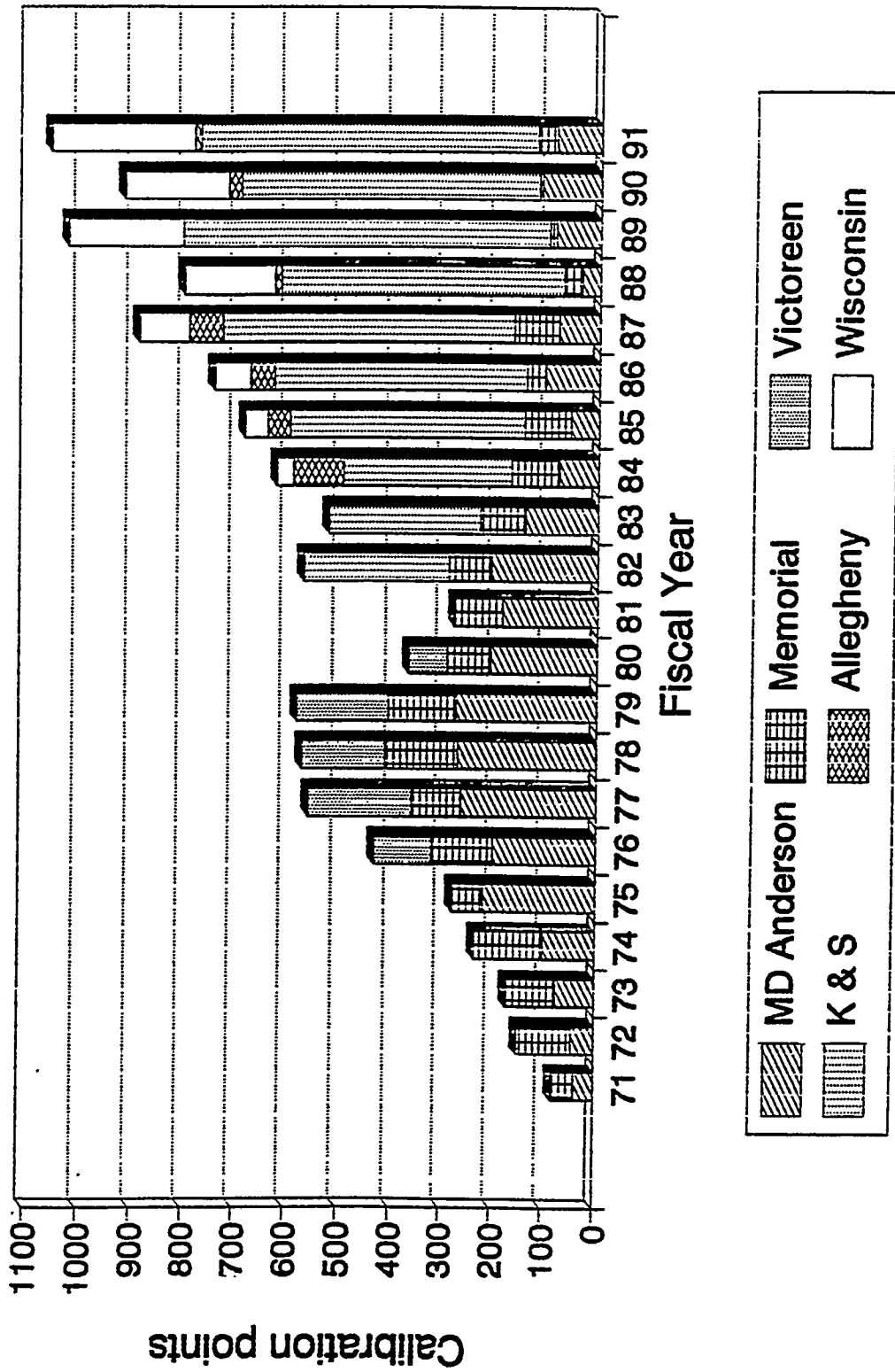


Figure 2 - Yearly X-ray Calibrations by the Accredited Laboratories

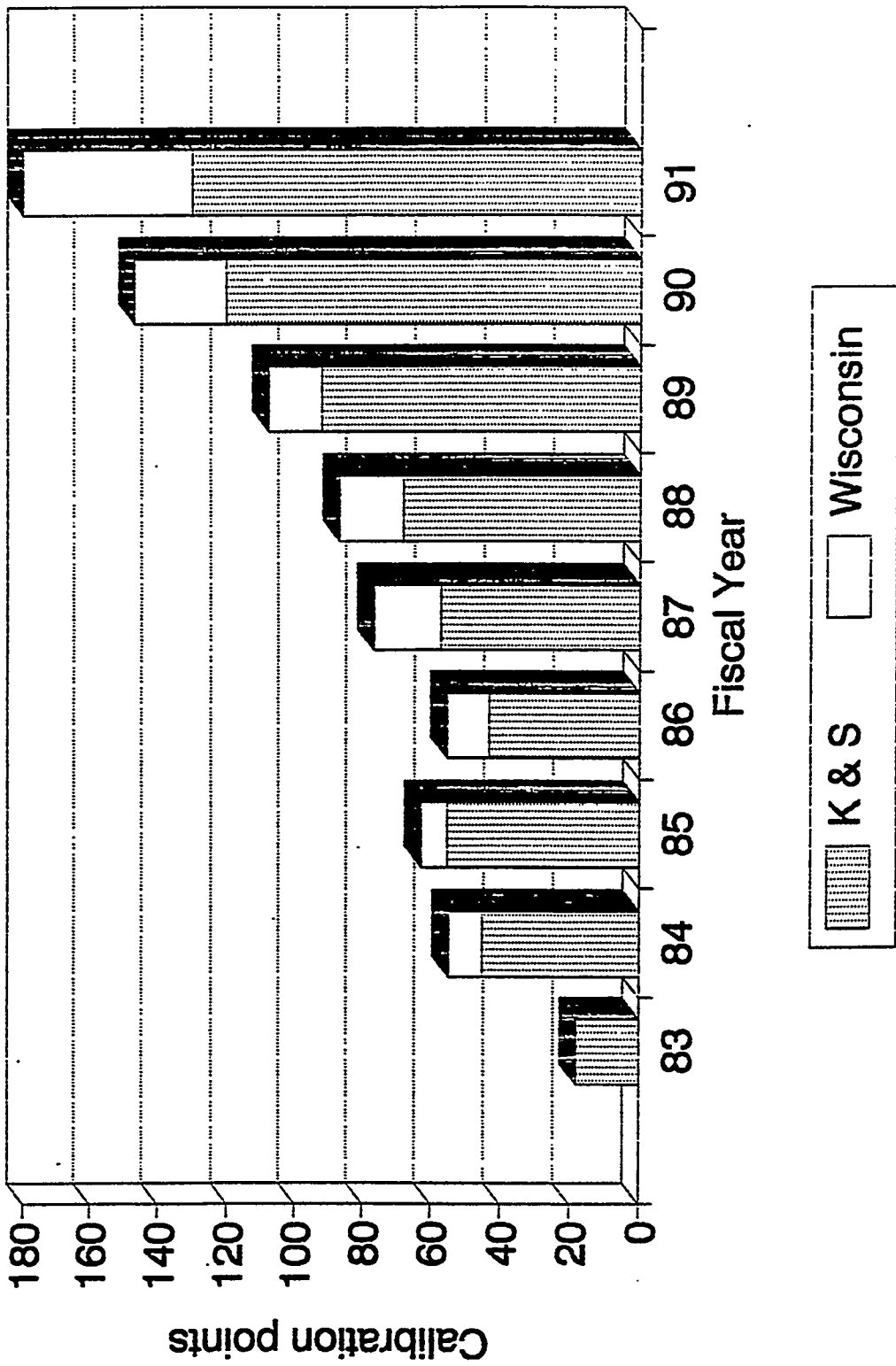


Figure 3 - Yearly Cesium Beam Calibrations by the Accredited Laboratories

## CRCPD'S LABORATORY ACCREDITATION PROGRAM

Pamela M. Dukes<sup>(1)</sup>

*Abstract* - The Conference of Radiation Control Program Directors, or CRCPD, first became involved in a calibration laboratory accreditation program about 17 years ago. Since that time, the CRCPD has formed a Committee on Ionizing Measurements which writes criteria for the accreditation of laboratories, and performs the accreditation review process. To become accredited, a laboratory must agree to an administrative review, and an onsite review, and participate in measurement quality assurance (MQA) testing with the National Institute of Standards and Technology (NIST). The CRCPD currently has four accredited laboratories. All the laboratories are working with the Conference in promoting the improvement of MQA in radiation control programs.

The CRCPD first became involved in a laboratory accreditation program about 17 years ago. A CRCPD task force on radiation measurements, under contract to the National Bureau of Standards (NBS), met in 1975 to review the needs of the states in the area of radiation measurements. The task force was to determine the different areas where radiation control programs needed assistance, and identify for NBS the kinds of technical assistance that would be required. A questionnaire was sent to the state radiation control programs to assess their needs. The results of the questionnaires were completed in April 1976, and showed that most states responding felt that their radiation measurements needed to be better. They needed to be more accurate, there needed to be more uniformity among the states, their measurements needed to be defensible, and there was a definite need for calibrations that were traceable to the NBS.

In 1979, the Task Force on Ionizing Measurements wrote a report to the U.S. Senate Committee on Commerce, Science, and Transportation concerning radiation measurements. As a result of that report, Congress provided funding to NBS to establish state regional calibration laboratories. Several states showed interest in hosting a regional calibration lab, and so labs were established in Illinois, Washington, and South Carolina. A lab was eventually established in California, and one is currently under development in Arkansas. The states provide a facility and staff for the laboratories and,

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initially, the equipment was provided by NBS. The labs were provided with an x-ray machine to calibrate diagnostic x-ray instruments and a gamma source to calibrate survey meters.

The Task Force on Ionizing Measurements became the Committee on Ionizing Measurements, and began writing criteria to accredit the state labs. The state labs may be accredited to calibrate instruments over a range of ionizing radiation types, energies, and intensities. The accreditation provides verification that a laboratory's measurement process is under statistical control and produces results that are consistent with the physical measurement standards maintained by NIST (formerly the NBS). This consistency is demonstrated by participation in MQA testing provided periodically by NIST. Participation in MQA services is required for accreditation under the criteria. The extent of participation depends on the scope of calibrations for which the laboratory desires accreditation.

To become accredited, a laboratory undergoes an evaluation of their resources and procedures, including an onsite assessment. They must also successfully complete a proficiency test through NIST. This process is repeated for each accreditation renewal. Initially, laboratories are accredited for a period of 1 year. After the initial accreditation, and 1-year review, the accreditation is renewed for a 3-year period. The Conference only accredits state-owned laboratories in radiation control programs, universities, or other state agencies.

The laboratory management must agree to the following basic conditions in order to receive accreditation:

1. To be evaluated and audited initially on a periodic basis.
2. To offer, with highest priority, its services to state and local radiation control programs in the host and other states.
3. To claim or imply accreditation only for procedures listed within the Scope of Accreditation.
4. To meet and maintain compliance with the accreditation criteria/
5. To participate in proficiency testing that may be required for achieving and maintaining accreditation.

The criteria used to evaluate laboratories address a laboratory's organizational structure and staff, physical aspects, calibration equipment and facilities, operational procedures, traceability and accuracy, records and reports, and general procedures. These criteria were prepared by the Conference Committee on Ionizing Measurements, in cooperation with NIST, and were approved by the Executive Board of the CRCPD.

Visits to the laboratory's facilities are conducted prior to initial accreditation, and thereafter on a regular basis prior to accreditation renewal. The onsite assessment team consists of four persons: a member of the CRCPD Committee on Ionizing Measurements, a representative of NIST, a representative of the U.S. Food and Drug Administration's Center for Devices and Radiological Health, and a member at large appointed by the CRCPD. The laboratory must demonstrate its operational procedures, and allow review of any records or documents required by the criteria. In addition, to scheduled onsite assessments, monitoring visits may be made to ensure that a laboratory

continues to comply with the accreditation criteria. Monitoring visits may be conducted randomly or in response to perceived problems.

Another important component of accreditation is proficiency testing. Laboratories are required to participate in proficiency testing to gain and continue accreditation. To determine calibration proficiency, NIST sends a well-characterized instrument to the participating laboratory for calibration. The calibration factors determined by the lab are sent to NIST, where the data are analyzed to determine if the lab's results are within acceptable limits of uncertainty. Generally, the proficiency testing is completed on an annual basis.

The assessment team uses three sources of information to determine if a lab should be accredited. These are written materials provided by the lab, results of proficiency testing, and results of onsite visits to the lab. The assessment team reviews all these and makes a recommendation to the Conference Executive Board to grant or deny accreditation.

The Conference currently has four accredited laboratories, located in Illinois, South Carolina, Washington, and California. The only other lab that is expected, at this time, to be accredited by the Conference is located in Arkansas.

The currently accredited labs are working, with the help of the CRCPD Committee on Ionizing Measurements, on promoting the use of the state labs by the radiation control programs. The focus for the future is on improving MQA in radiation control programs by encouraging the use of the CRCPD-accredited regional calibration laboratories.

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## HPS INSTRUMENT CALIBRATION LABORATORY ACCREDITATION PROGRAM

F. X. Massé<sup>(1)</sup>  
E. H. Eisenhower<sup>(2)</sup>  
K. L. Swinth<sup>(3)</sup>

*Abstract* - The purpose of this paper is to provide an accurate overview of the development and structure of the program established by the Health Physics Society (HPS) for accrediting instrument calibration laboratories relative to their ability to accurately calibrate portable health physics instrumentation. The purpose of the program is to provide radiation protection professionals more meaningful direct and indirect access to the National Institute of Standards and Technology (NIST) national standards, thus introducing a means for improving the uniformity, accuracy, and quality of ionizing radiation field measurements. The process is designed to recognize and document the continuing capability of each accredited laboratory to accurately perform instrument calibration. There is no intent to monitor the laboratory to the extent that each calibration can be guaranteed by the program; this responsibility rests solely with the accredited laboratory.

### OVERVIEW OF THE ACCREDITATION PROGRAM

Over the past several years, the Health Physics Society (HPS) has developed a program for accrediting instrument calibration laboratories relative to their ability to accurately calibrate portable ionizing radiation detecting equipment. The program activities and responsibilities were deliberately and carefully divided among several groups to maintain independent checks and balances, to eliminate bias, and to achieve confidentiality throughout the process. The initial structure and basic organization of the program was formulated by an ad hoc committee, which reported to the HPS Board of Directors, who formally adopted the program concept. This led to the appointment of an HPS Standing Committee for the Accreditation of Instrument Calibration Laboratories (which was

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(1) Massachusetts Institute of Technology.

(2) National Institute of Standards and Technology.

(3) Pacific Northwest Laboratory. PNL-SA-15929A. Work supported by the U.S. Department of Energy under Contract DE-AC06-76RLO 1830.

later renamed the Policy Committee). This committee was initially responsible for drafting the basic policies and procedures of the program, including the general criteria for accrediting laboratories, all of which were ratified by the HPS Board, thus initiating the establishment of the program.

This Policy Committee has continuing responsibility to establish and amend as necessary, program operational procedures and specific criteria related to type of calibration. It is also responsible for extending the accreditation process to new areas of calibration.

Also included in the approved structure is the appointment by the Board of a second committee, which is now entitled the Laboratory Accreditation Assessment Committee. This committee is responsible for carrying out the policies and procedures, review of applications, accreditation review, and onsite assessment, and ultimately accrediting successful candidate laboratories. The identity of each applicant rests with this committee, which must mask all information to maintain confidentiality during the approval process in order to preserve the confidentiality of the applicants until accreditation is granted. Similarly, the Committee must permanently protect the confidentiality of proprietary information submitted by the applicants. The Policy Committee provides independent oversight to assure that accreditations are granted in accordance with established policy and procedures.

The program also includes the eventual establishment of an Advisory Group, which will consist of representatives of accredited labs. This group will assemble, as necessary, to review the ongoing program and consider problems as they may arise, acting as a resource to both the accredited and applicant laboratories, as well as the other two committees, as the procedures and criteria are modified or expanded.

A paid Technical Director was added to the program structure when it became apparent that the duties and responsibilities had expanded beyond what may reasonably be expected from the usual HPS volunteer committee appointee. This part-time position provides the necessary individual to serve as a central point of contact for the program, and provide single overall direction and coordination. The Director expedites the work of the two committees with technical support and assistance such as screening of applications, selection and training of volunteers who will perform onsite assessments, ensuring the timeliness of proficiency tests and other steps in the evaluation process, and maintaining the records of the overall program.

An ongoing relationship with NIST is a vital part of this program. NIST appoints a representative who serves as a member of the Assessment Committee, and consistency with NIST is maintained through periodic calibration intercomparison between NIST and accredited secondary laboratories.

A two-level accredited laboratory structure consisting of secondary and tertiary laboratories was adopted in this program. Secondary labs are to have a broad spectrum of calibration capabilities, both in terms of type of radiation and range of dose rates. Reference instrument calibration intercomparison is performed with NIST initially and annually thereafter, and all accreditation review functions are conducted through the Assessment Committee. Secondary labs must also possess a depth of expertise and experience that enable them to adequately service tertiary labs.

Tertiary labs conduct their reference instrument calibration intercomparison with established secondary labs, and may have more limited capabilities in terms of calibration range and sources. Accreditation review functions for tertiary labs may be shared by the secondary lab and the Assessment Committee, to the satisfaction of the Assessment Committee.



Final approval in both categories rests with the Assessment Committee. All accredited secondary labs are obliged to provide calibration and accreditation assistance to tertiary labs. This tier system is designed to provide expanded access to accredited calibration labs with proven calibration ability for as many end users as possible.

An impasse or negative action from the Assessment Committee may be appealed directly to the Policy Committee by the dissatisfied applicant with the understanding that, in so doing, confidentiality is forfeited. The Policy Committee may then review all submitted materials and test data with the Assessment Committee in an effort to resolve the dispute.

Accreditation at either level is granted for a three-year period subject to renewal through repeat of the application process at that time and subject to a record of continuing satisfaction of the annual calibration intercomparison. An accredited lab may voluntarily withdraw its accreditation at will. If the Assessment Committee discovers violations of the basic conditions for accreditation at any time through its monitoring efforts, it may revoke accreditation on 30-day notice, subject to appeal to the full Policy Committee.

The program is funded through fees from applicant laboratories. The fees are established to cover all program expenses on a break-even basis. Secondary lab services to tertiary labs are expected to be provided at a reasonable cost commensurate with the HPS pricing policy for the secondary lab fees.

The question of legal liability exposure for the Health Physics Society in the conduct of such a program was subject to much investigation and debate at the time the program was organized. The Executive Secretary investigated this issue thoroughly with the appropriate legal consultants and reported to the Board that the use of the word "accreditation" was key to the issue, that the adopted wording clearly implied that the Society was accrediting laboratories based on their demonstrated abilities and was not assuming liability for individual calibration procedures. All documentation for the program has clearly emphasized this point.

Application forms may be obtained from and completed applications forwarded to the HPS Secretariat. All actions of both committees are routinely reported to the HPS Board, which is ultimately responsible for all actions of the Society.

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**SECONDARY CALIBRATION LABORATORY FOR IONIZING  
RADIATION LABORATORY ACCREDITATION PROGRAM  
NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY  
NATIONAL VOLUNTARY LABORATORY ACCREDITATION  
PROGRAM**

Paul R. Martin<sup>(1)</sup>

*Abstract* - This paper presents an overview of the procedures and requirements for accreditation under the Secondary Calibration Laboratory for Ionizing Radiation Program (SCLIR LAP). The requirements for a quality system, proficiency testing and the onsite assessment are discussed. The purpose of the accreditation program is to establish a network of secondary calibration laboratories that can provide calibrations traceable to the primary national standards.

## **INTRODUCTION**

The National Voluntary Laboratory Accreditation Program (NVLAP) is administered by the National Institute of Standards and Technology (NIST). NVLAP follows the procedures contained in the U.S. Code of Federal Regulations, Title 15, Part 7, when establishing a laboratory accreditation program and accrediting laboratories which participate in that program. NVLAP is moving towards the adoption of the ISO Guide 25 in its requirements for evaluation of laboratory competence.

NVLAP currently has eleven laboratory accreditation programs (LAPs) including the Ionizing Radiation Dosimetry Program, formally the Personnel Radiation Dosimetry Program. The SCLIR LAP was established in response to a request from representatives of federally owned laboratories engaged in the calibration of devices or instruments for measuring ionizing radiation.

## **CRITERIA FOR ACCREDITATION**

The criteria for this program is contained in the NVLAP Program Handbook and NIST Special Publication 812 "Criteria For the Operation of Federally Owned Secondary Calibration Laboratories

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<sup>(1)</sup> National Institute of Standards and Technology.

for Ionizing Radiation." The technical criteria in NIST SP-812 were developed by a group of 26 representatives of federally owned calibration laboratories.

## **NVLAP ACCREDITATION**

Accreditation by NVLAP signifies formal recognition of a testing laboratory's competence to perform calibrations or specific test methods in specified fields of calibration or testing. It means that NVLAP has evaluated the laboratory's quality system, staff, facilities and equipment, calibration procedures, test methods and procedures for calibrations, records, and test reports. The laboratory must also demonstrate its competence through proficiency testing, which in this program involves the comparison of calibrations performed by the laboratory and the primary standard calibration performed by the NIST Ionizing Radiation Division.

## **SCOPE OF THE PROGRAM**

Accreditation is available to any organization that can demonstrate the competence to perform the calibration services covered by the program. A laboratory may be accredited to calibrate specific instruments or sources of its choice in any one or more of the areas listed below.

### **Survey Instruments**

- Gamma ray
- X-ray
- Beta particle
- Neutron
- Alpha particle

### **Diagnostic Instruments**

- X-ray

### **Reference Class Instruments**

- Gamma ray
- X-ray

### **Irradiation of Personnel Dosimeters**

- Gamma ray
- X-ray
- Neutron
- Beta particle

### **Source Calibrations**

- Gamma ray

## **ACCREDITATION PROCESS**

The accreditation process is divided into two stages. Stage I is a preliminary technical evaluation of the laboratory and includes a thorough review of the quality manual. To initiate this evaluation, a laboratory must submit an application with the stage one fee of \$2120, currently, and three copies of its quality manual. The application requires a description of the laboratory facilities and proposed scope of accreditation. An Application Package containing the necessary forms, a Program Handbook, program criteria document, and fee information is sent to a laboratory upon request.

Stage II is the full evaluation of the laboratory which includes proficiency testing, an onsite assessment, deficiency resolution, and a technical review by a panel of technical experts. Figure 1 is a flow diagram of the Secondary Calibration Laboratory for Ionizing Radiation LAP accreditation process.

## **QUALITY SYSTEM**

The Quality System is defined as the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. Quality Systems are developed by the laboratory for the type of calibration or testing service performed, by tailoring the generic guidelines for a Quality System. The NVLAP requirements for a Quality System are contained in ISO Guide 25 and the NVLAP procedures in the U.S. Code of Federal Regulations, Title 15, Part 7, Section 7.33. ISO Guide 25 is an international guide for the evaluation of the competence of laboratories.

The Quality System includes the following major components: the organization and management, including a corporate quality policy, Technical and Quality Managers, personnel training and quality audits; the facilities and equipment used in performing the specific calibration or testing functions; the calibration of test equipment, reference materials, and measurement traceability to the national standards; the laboratory operating procedures for performing the calibrations and maintaining quality control; and the records and calibration certificates documenting these functions.

There must be a documented procedure for identifying items that have been received by the laboratory for calibration. This identification can be used for tracking the item from receipt until it is returned to the client with the calibration report. The reports and records that a laboratory maintains for a specific instrument calibration should be retained for at least 5 years. The test reports must contain the necessary information to verify the calibration of the instrument, and to recreate the calibration of the instrument if needed.

The Quality Manual is used to document the Quality System. It is generally one manual that describes the Quality System. It contains references to other supporting documents such as calibration records, equipment inventory and status, operating procedures for performing the specific calibration or test, proficiency testing, quality control functions, and statistical methods for controlling the quality of the laboratory function. The requirements for the Quality Manual are contained in the Program Handbook, Section 6.4, and in the ISO Guide 25, Section 5.2.

## **PROFICIENCY TESTING**

In order to be eligible for accreditation, each laboratory must demonstrate the calibration of an instrument by proficiency testing. The proficiency test requirements for the SCLIR LAP are contained in Appendix A of NIST SP-812. Proficiency testing is performed once prior to accreditation and then annually thereafter. If the laboratory has requested accreditation for more than one instrument category and the same radiation type, proficiency testing will only be required for the higher accuracy category. The laboratory must perform a calibration at the accuracy and uncertainty level specified for each category in NIST SP-812, in order to receive that uncertainty limit on their scope of accreditation.

The laboratory is required to perform an uncertainty error analysis for the calibration procedures for which they are seeking accreditation by NVLAP.

## **ONSITE ASSESSMENT**

Before initial accreditation and periodically (every 2 years) thereafter, an onsite assessment of each laboratory is conducted to determine compliance with the NVLAP criteria. The assessment is

conducted by two assessors selected on the basis of their expertise in the appropriate field(s) of calibration. One assessor is a NIST employee from the Ionizing Radiation Division, the other is a NVLAP peer assessor. An assessment normally takes 2 to 3 days depending on the extent of the laboratory's calibration services. During the assessment, the assessor will examine the quality system, calibration records, test procedures, personnel competency records, calibration reports and other quality assurance procedures. The assessor will examine equipment and facilities, and will ask to have selected procedures demonstrated.

Assessors use checklists, based on the specific criteria, during the assessment to ensure that each laboratory receives an assessment comparable to that received by others. Onsite assessments are conducted every two years, but the accreditation is renewed annually. Monitoring visits may occur between scheduled onsite assessments.

## **DEFICIENCY NOTIFICATION AND RESOLUTION**

A deficiency is the failure of a laboratory to meet a NVLAP criterion. Deficiencies may be determined during onsite assessments, monitoring visits, proficiency testing or technical review for initial accreditation. Laboratories are informed of deficiencies either during an onsite assessment or through other correspondence and are given an opportunity to resolve the deficiency.

## **CONCLUSION**

The review of the Quality Manual, proficiency testing and error analysis, and the onsite assessment, together form the basis for determination of competence leading to accreditation of laboratories that calibrate ionizing radiation measurement instruments. Laboratories accredited under this program will be at the level of a secondary standard calibration laboratory.

## **REFERENCES**

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FLOW CHART FOR: SECONDARY CALIBRATION LABORATORY FOR IONIZING RADIATION LAP

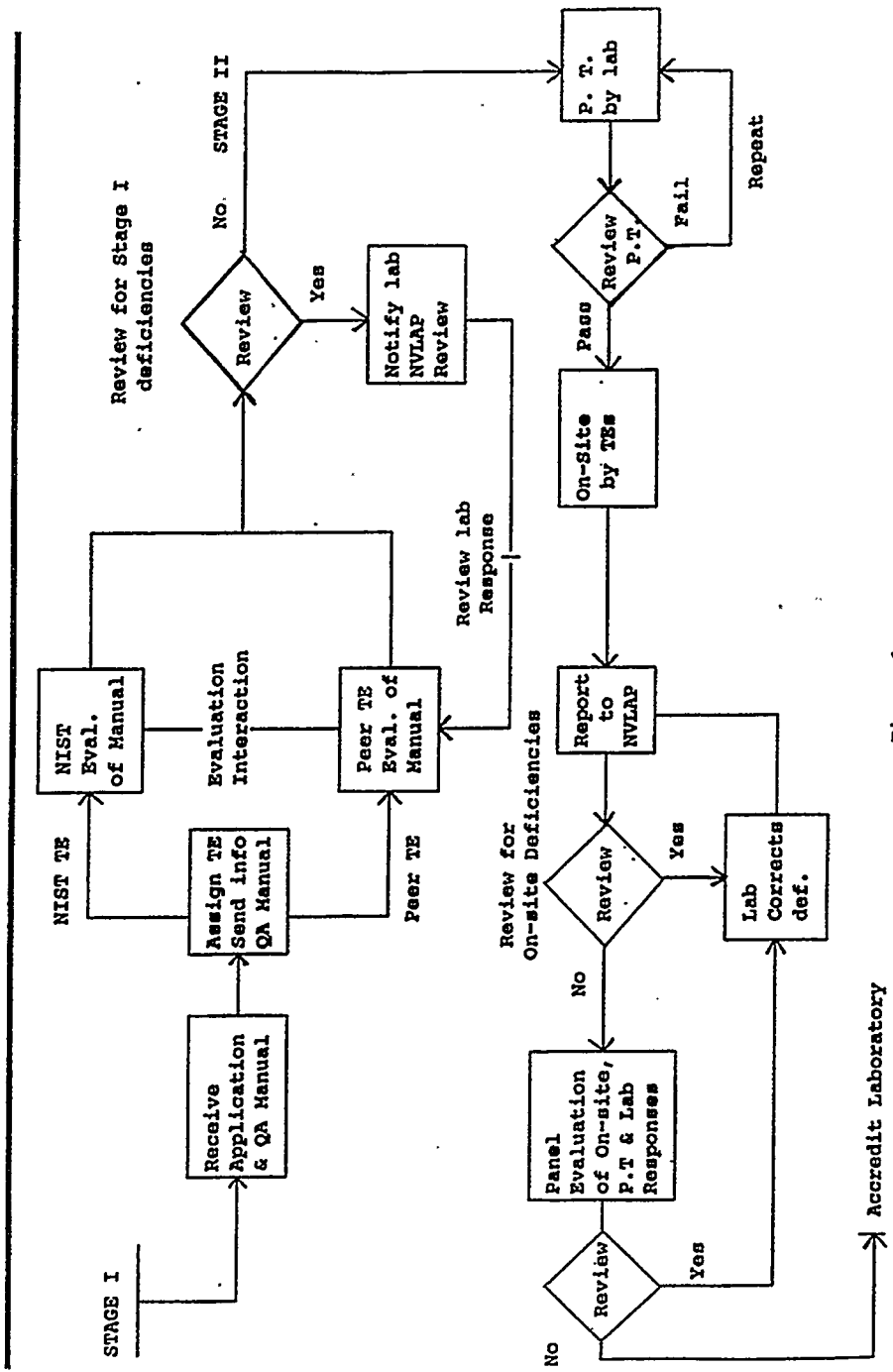


Figure 1.

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# NVLAP CALIBRATION LABORATORY PROGRAM

James L. Cigler<sup>(1)</sup>

*Abstract* - This paper presents an overview of the progress up to April 1993 in the development of the Calibration Laboratories Accreditation Program within the framework of the National Voluntary Laboratory Accreditation Program (NVLAP) at the National Institute of Standards and Technology (NIST).

## NVLAP FOCUS

NVLAP was established in 1976 as a result of the need to accredit testing laboratories in fields of testing such as acoustics, asbestos fiber, carpet, and many others. Laboratories engaged in product testing, according to well-defined standards (such as MIL-STD-462 for Electromagnetic Compatibility), are evaluated for compliance with NVLAP quality assurance requirements and performance of proficiency testing on sample products provided to the laboratories under assessment.

As of April 1992, over 1000 laboratories have been successfully accredited in eleven different areas or fields of testing. They can be found listed, along with their areas of proficiency, in the NVLAP 1993 Directory of accredited laboratories.

NVLAP is now in the process of adding two new programs: fasteners and metals and calibration laboratories.

## ESTABLISHMENT OF NEW NVLAP PROGRAMS

**Fasteners and Metals:** Public Law 101-592, The Fastener Quality Act, requires that fasteners (screws, nuts, bolts, etc.) manufactured or imported into this country be tested for compliance with manufacturing specifications. In addition, the legislation requires that testing laboratories must be accredited under a Fasteners and Metals Accreditation Program administered by NVLAP. To this end, NVLAP is developing the Fasteners and Metals Program. Some of you may have attended the public workshop on the Fasteners and Metals Program, which was held at NIST on February 17, 1993.

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<sup>(1)</sup> National Institute of Standards and Technology, National Voluntary Laboratory Accreditation Program.

Calibration Laboratories: The National Conference of Standards Laboratories (NCSL) Total Quality Management (TQM) Subcommittee petitioned NIST to develop a Calibration Laboratory Program under NVLAP. As is the legal requirement in 15 CFR Part 7 (NVLAP Procedures) regarding NVLAP's response to a request for an additional service, a notice was placed in the Federal Register soliciting comments from the public and private sector on the petition.

The responses obtained in this manner were overwhelmingly in favor of establishing the Calibration Laboratory Program. The positive responses were divided between a desire to obtain international recognition of laboratory competence through the use of International Organization for Standardization (ISO) Guide 25 as the basis for accreditation, the desire to satisfy government audit requirements through the recognition and use of nationally accredited laboratories, and a desire on the part of laboratory management to be recognized as competent by the national laboratory. The negative responses were focused on a fear of exorbitant cost associated with the program, and the establishment of a bureaucratic government laboratory accreditation program which could add to the number of required audits.

After careful deliberation, the Director of NIST published a notice of intent to develop the NVLAP Calibration Laboratory Accreditation Program in the Federal Register on May 18, 1992.

### **NVLAP CALIBRATION LABORATORY PROGRAM MATRIX**

Figure 1 shows the matrix organization which exists within NVLAP for the development and ultimate operation of the Calibration Laboratory Program. Program Management responsibilities are assigned to me by the NVLAP Chief, Mr. Albert D. Tholen. The NVLAP operation is accountable to the NIST Director's office through the Office of Standards Services and the Director of Technology Services. The Calibration Laboratory Program is divided into eight fields of calibration, which include Dimensional, Electromagnetic-DC/Low Frequency, Electromagnetic-RF/Microwave, Mechanical, Thermodynamic, Ionizing Radiation, Optical Radiation, and Time and Frequency. There are many parameters which are normally encountered within those eight fields. In the case of NIST Calibration services, this list represents those fields of calibration and associated parameters which are found in NIST Special Publication SP 250, NIST Calibration Services Users Guide. The eight fields of calibration are aligned under four Measurement Laboratories or Operating Units (OUs): the Manufacturing Engineering Laboratory (MEL), Electronics and Electrical Engineering Laboratory (E&EEL), Chemical Science and Technology Laboratory (CS&TL), and the Physics Laboratory. My staff and I, cut horizontally across OU lines and enjoy the support of NIST scientists in the development of technical criteria for the program, as a source of potential assessors in the future and as a technical training resource, including workshop and seminar presentations.

Currently, the main thrust of our collective efforts is in development of technical criteria to be included in a Calibration Program Technical Guide. This will be a companion document used with the draft Calibration Laboratories Program Handbook which is nearing finalization. The Technical Guide will address areas of commonality within the eight fields of calibration as well as areas of uniqueness which will require the assessor's consideration during the actual assessment. The Technical Guide will also serve as a valuable source of information for prospective laboratories seeking accreditation.

The Calibration Laboratory Program, when fully implemented, will offer accreditation to laboratories engaged in any or all parameters under the eight fields of calibration. In addition, as a result of the

realization that many laboratories desire accreditation for calibration of test equipment (i.e. voltmeters, oscilloscopes, torque machines) for which NIST does not offer a calibration service, the program will have provisions for accommodating those needs.

## **ADOPTION OF ISO GUIDE 25**

The Calibration Laboratory Program, like all other existing NVLAP programs, is embracing the use of ISO Guide 25 as the foundation for the Program Handbook. I am working closely with the NCSL TQM Committee to tailor ISO Guide 25 to the needs of U.S. Government and private industry. It should be noted that, with very minor exceptions, nothing is being tailored out of the basic ISO Guide 25 requirements. Rather, an attempt is being made to add requirements which satisfy government audit requirements (for example, MIL-STD-45662A for the Department of Defense). This is being accomplished through the NCSL TQM Committee in the form of a proposed U.S. Standard currently titled "General Requirements for Calibration Laboratories and Measuring and Test Equipment." When completed, it will serve as this country's interpretation and implementation of ISO Guide 25 in determining the competence of calibration laboratories as part of the NVLAP accreditation process.

NVLAP's goal is to determine that a Calibration Laboratory complies with the quality requirements of ISO Guide 25 and that it is technically competent to perform the calibration operations for which it is accredited. Technical Experts (TEs), or assessors, are used in a team approach to review quality documentation and for onsite visits to the laboratory to witness calibrations, interview management and staff, and to oversee proficiency testing, if required. The laboratory is evaluated in relation to the capabilities (parameters, uncertainties, type of equipment), for which it has requested accreditation.

NVLAP focuses on the ability of the laboratory to provide quality measurements with documented traceability to national, international, or intrinsic standards, using well-defined procedures and techniques to ascertain measurement uncertainty. Proficiency testing, which requires the laboratory to measure an artifact of NIST choosing, is used where it is determined necessary. Other ways of determining competence is reviewing of Measurement Assurance Program (MAP) results, reviewing of correlation or round robin interlaboratory measurements, reviewing of measurement process control documentation, observation of calibration(s) during onsite assessments, and the optional sampling of the product from the completed shelf of the laboratory. This may involve observation of a successful recalibration in the laboratory, or removal and performance of correlation measurements at NIST, or a NIST-empowered laboratory. It is anticipated that this approach will be helpful in assessing laboratory competence in areas involving calibration of types of measuring and test equipment not calibrated as a NIST service.

## **ACCREDITATION DOCUMENTS**

The successful accreditation of a calibration laboratory will result in the issuance of two NVLAP documents. The first, referred to as the Certificate of Accreditation, will indicate that the laboratory has been accredited as a Calibration Laboratory under one or more of the eight fields of calibration. The second document, referred to as the Scope of Accreditation, will list the specific parameter(s), range(s), uncertainty(ies), and perhaps the type of equipment for which the laboratory has been accredited. There will also be a provision for adding any other qualifying remarks which are appropriate.

## **CALIBRATION PROGRAM DEVELOPMENTS**

Currently, I am in the process of separating the NVLAP Calibration Laboratories Program Handbook from the technical criteria which is being developed for inclusion into the Technical Guide. In addition to information related to the process for requesting NVLAP accreditation and the duties and responsibilities of both NVLAP and the accredited laboratory, the Program Handbook contains the tailored ISO Guide 25 requirements and NVLAP general operating procedures, policy guides, assessor checklists, and definitions related to the Calibration Laboratory Program.

Some recent additions to the Program Handbook is adoption of ISO/TAG 4/WG 3: June 1992, "Guide to the Expression of Uncertainty in Measurement," as the approved method for determining and reporting measurement uncertainties. This approach has been adopted within NIST for calibration and research measurements, and will be fully implemented by January 1994. I am also referencing the NCSL Recommended Practice #7, "Recommended Practice Laboratory Design," as the basis for desired environment and facilities requirements. This document is in final draft form at the present time.

The Program Handbook was reviewed in detail and comments were solicited from those in attendance at a public workshop at NIST, Boulder, Colorado, May 18, 1993. The intention is to make final changes prior to publishing the document.

Much work is being done at the present time on development of general and specific criteria under the eight fields of calibration for inclusion in the Technical Guide. NIST OUs are working on the parametric requirements related to our SP 250 calibration services. I have also asked them to include, where appropriate, devices which are multi-parametered, such as LCR (inductance, capacitance, resistance) meters, which cover groups of NIST-calibrated parameters. At the same time, I am meeting with representatives from other government laboratories and private industry through the NCSL TQM Committee to get inputs from other perspectives, especially in the areas of types of measuring and test equipment for which laboratories may seek accreditation.

The program will rely heavily on the quality of technical criteria in the Technical Guide and the qualifications of NVLAP TEs, which means that considerable help is required from the NIST OUs, other government laboratories and private industry.

## **POSITIVE BY-PRODUCTS**

There are positive by-products which exist for both NIST and potential accredited laboratories. Since the technical competency requirements can be satisfied by documented successful participation in MAPs and other NIST-based correlation programs, NIST can look forward to a program-driven expansion of its customer base in those areas. Along related lines, the customer(s) can look forward to a measurement technology transfer through the process of expanded participation in national measurement correlation schemes. I also mentioned earlier that we are working closely with the NCSL TQM Committee to ease the current burden of multiple government audits through the use of laboratory accreditation.

ISO Guide 25 focuses on TQM. It is obvious, in visiting laboratories, that many are working on generating quality manuals, or incorporating already existing quality documents into a format suitable for use in seeking accreditation. This documentation of the quality process within the laboratory is

extremely important and critical to the success of efforts to acquire, train, and promote future metrologists. NVLAP is a resource of ISO Guide 25 information and expertise, and we are very anxious to help laboratories become accredited.

As a separate, but very important side issue, successful accreditation to the basic requirements of ISO Guide 25 by NVLAP accreditation results in the satisfaction of ISO 9002 Quality Assurance requirements for the accredited laboratory. A distinction must be kept in mind that this does not imply compliance with ISO 9002 requirements for the parent organization if the calibration laboratory is operated as a functional unit under a larger organization.

NVLAP is also interested in helping laboratories improve their international status through recognition of NVLAP by the international community. I have had extensive discussions with the National Measurement Accreditation Service (NAMAS) in the UK, and I will be travelling there in the very near future to further discuss areas of agreement. At the same time NVLAP takes an active interest in the activities of the now-forming North American Calibration Commission (NACC), the Western European Laboratory Accreditation Commission (WELAC), and the International Laboratory Accreditation Committee (ILAC).

## SUMMARY

In summary, NVLAP is working energetically to develop the Calibration Laboratory Accreditation Program under the mandate of the NIST Director. There are very positive by-products associated with laboratory accreditation. For example, NIST stands to expand its customer base in the areas of MAPs and correlation measurements. Customer laboratories can benefit from a measurement technology transfer as part of the accreditation process. Documentation of the quality process is critical to perpetuating expertise within the metrology community. Also, a positive impact can be made in reducing international trade barriers through the recognition of calibration laboratories and acceptance of measurement data. Finally, there is a great potential to ease the existing burden due to the government audit process.

There is much work to be done in a relatively short time. NVLAP recognizes that many foreign countries have conducted calibration laboratory accreditation programs for many years and are now looking for the U.S. to follow suit. In addition to, the public workshop for final review of the Program Handbook (on May 18, 1993 at NIST Boulder), I intend to have draft technical criteria ready for review at a second public workshop, as yet unscheduled, at NIST Gaithersburg by mid-summer 1993. Hopefully, this will lead to publishing the Technical Guide by the end of August 1993. Assessor recruitment and training is to commence within the next month, and I expect to have a pool of potential NVLAP assessors available by the end of September 1993. Assessors will be contracted for by NVLAP and their labor and related travel and per diem expenses will be totally reimbursed by NVLAP. As has been the case with the ongoing NVLAP testing programs, there will be no staff of full-time assessors.

I anticipate announcement of the NVLAP Calibration Laboratories accreditation service in October of 1993 via a Federal Register notice. Applications will be accepted from any laboratory desiring accreditation. Fees are now being determined and will be based on the number of fields of calibration, parameters, and/or types of measuring and test equipment for which accreditation is desired. The month of November will be used to process applications, relate necessary fees, and

determine which laboratories wish to continue with the process. I hope to have an assessment team or teams in a limited number of laboratories by the end of December 1993.

This is a very optimistic schedule, but one which I believe with the continued support of NIST, other government, and private industry laboratories.

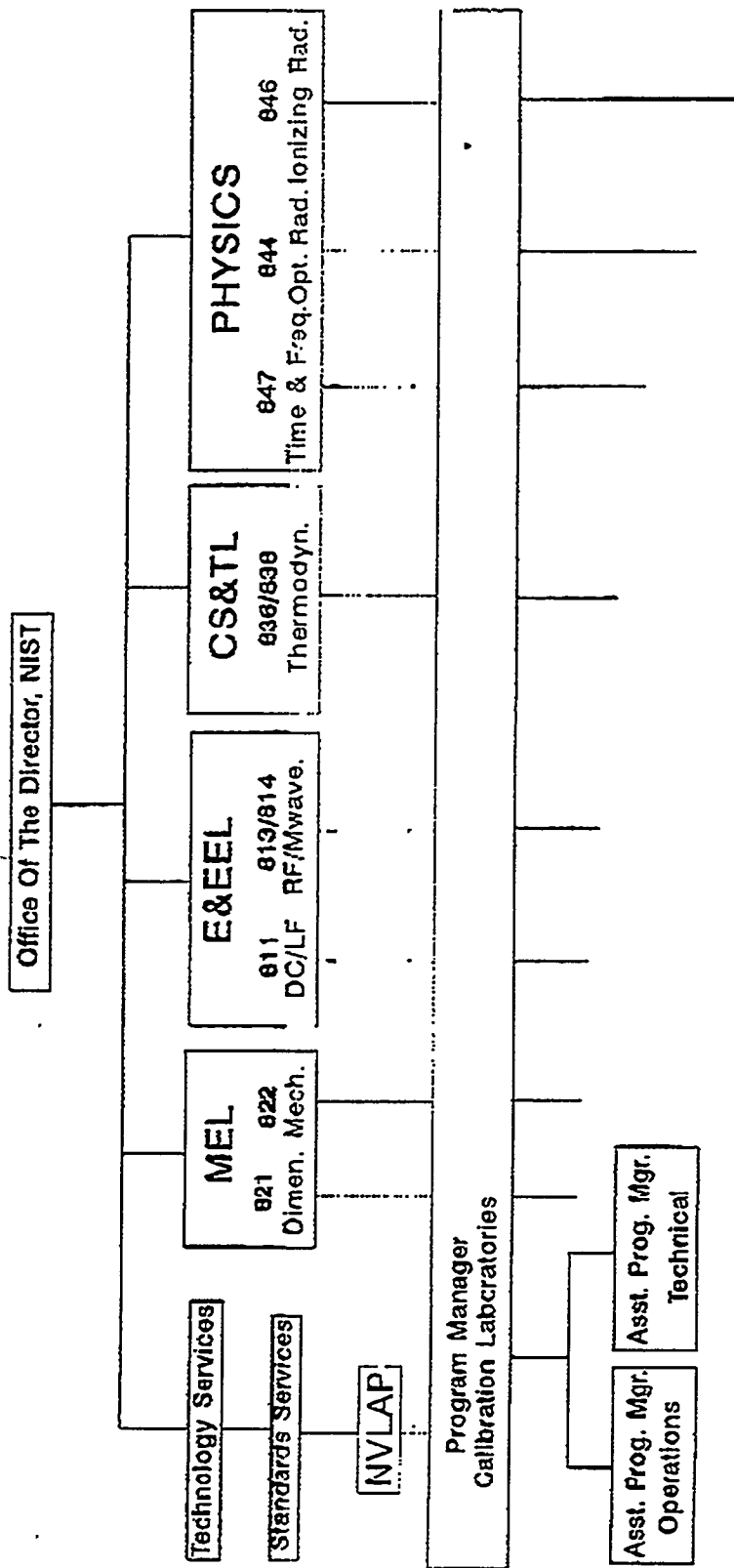


Figure 1 - NVLAP Calibration Laboratory Program Matrix

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# **FUTURE MQA PROGRAMS**

Session Chair  
Pamela Dukes, Bureau of  
Radiological Health SC/CRCPD

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## MEASUREMENT QUALITY ASSURANCE FOR RADIOASSAY LABORATORIES

D. E. McCurdy<sup>(1)</sup>

### INTRODUCTION

Until recently, the quality of U.S. radioassay laboratory services has been evaluated by a limited number of governmental measurement assurance programs (MAPs). The major programs have been limited to the U.S. Department of Energy (DOE), the U.S. Environmental Protection Agency (EPA) and the U.S. Nuclear Regulatory Commission (NRC). In 1988, an industry MAP was established for the nuclear power utility industry through the U.S. Council for Energy Awareness/National Institute of Standards and Technology (USCEA/NIST). This program functions as both a MAP for utility laboratories and/or their commercial contractor laboratories, and as a traceability program for the U.S. radioactive source manufacturers and the utility laboratories. Each of these generic MAPs has been initiated and is maintained to serve the specific needs of the sponsoring agency or organization. As a result, there is diversification in their approach, scope, requirements, and degree of traceability to NIST.

In 1987, a writing committee was formed under the American National Standards Institute (ANSI) N42.2 committee to develop a standard to serve as the basis document for the creation of a national measurement quality assurance (MQA) program for radioassay laboratories in the U.S. The standard is entitled, "Measurement Quality Assurance For Radioassay Laboratories." The document was developed to serve as a guide for MQA programs maintained for the specialized sectors of the radioassay community, such as bioassay, routine environmental monitoring, environmental restoration and waste management, radiopharmaceuticals, and nuclear facilities. It was the intent of the writing committee to develop a guidance document that could be utilized to establish a laboratory's specific data quality objectives (DQOs) that govern the operational requirements of the radioassay process, including mandated protocols and recommendations.

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This presentation has been developed to provide the conference participants with an overview of the current version (revision 11, dated August 14, 1992) of the standard and its status as related to the ANSI review process.

## **COMMITTEE MEMBERSHIP**

Since the standard was to be a consensus document, every effort has been made to have representation from all facets of the nuclear industry. The writing committee is comprised of 13 technical experts and representatives from the commercial laboratories, State government laboratories, DOE, EPA, NIST and the nuclear power industry. Additional review and guidance have been provided by the ANSI membership, NRC, the U.S. Food and Drug Administration, and individual technical experts.

## **PURPOSE**

The standard has been developed for laboratories or programs required to have an MQA program to ensure that DQOs are achieved. The purpose of the standard is to provide, as a minimum, the following:

- guidance for a national program for testing, accrediting, and monitoring of all types of radioassay laboratories
- guidance for the minimum requirements necessary to maintain a viable service laboratory, as provided in the body of the standard and the various appendices
- criteria for the establishment of monitoring and reference laboratories
- operational and quality assurance for service, monitoring, and reference laboratories
- guidance for NIST and an accrediting organization to implement the standard.

## **SCOPE**

The scope of the standard has been limited to the generic framework of a national MQA program, the elements thereof, and specific operational guidance or requirements for the individual radioassay laboratories. The major areas emphasized include:

- the operational framework of a national MQA program
- the roles of the accrediting organization, NIST, and the reference, monitoring and service laboratories
- the protocol for the preparation and distribution of test media by the monitoring or reference laboratories
- the bases for calculating the required accuracy and precision parameters of radioassay measurements of environmental media for service, monitoring, and reference laboratories
- the protocol for the evaluation and reporting of test results

- the protocol for the assessment and evaluation of test results and reporting assessment findings by the accrediting organization
- requirements and guidance for the proper operation of a radioassay laboratory
- guidance for determining the *a priori* decision-level concentration and minimum detectable concentration for each radionuclide
- the requirements for reporting radioassay results to the customer by service laboratories
- eleven key elements of a viable quality assurance program applicable to the service monitoring, and reference laboratories
- the quality assurance and quality control programs for the service, monitoring, and reference laboratories.

This standard requires that the service laboratory and its client establish precision, bias, detection levels, and other quality performance specifications within a pre-processing agreement or contract. A client may be viewed as being either external (for a commercial laboratory) or internal (for work performed within the same company or government agency). The quality performance specifications shall be related to the DQOs requiring the radioassays. For radioassays requiring an MQA program, this standard requires the use of a third-party monitoring laboratory to evaluate the service laboratory's ongoing capability to meet pre-established, contractual performance specifications. If agreed upon by the client and service laboratory, the service laboratory's internal quality assurance (QA) program may function as a monitoring laboratory as long as the requirements for the monitoring laboratory as established in this standard, are met.

#### **NATIONAL PERFORMANCE TESTING PROGRAM**

The organizational structure of the national MQA program recommended by the standard has been graphically illustrated in Figure 1. The basic concepts and foundation of the national MQA program have been formulated to facilitate the application of the MQA program concept to an individual government agency, such as DOE, NRC, or EPA. There are five entities comprising the MQA program: NIST, an accrediting organization, and three distinct functioning radioassay laboratory types. The laboratory types include:

- Reference laboratory - a laboratory authorized to prepare testing media and be responsible for evaluating the accuracy and precision of the service and monitoring laboratories
- Monitoring laboratory - an accredited laboratory that prepares and distributes test materials to a service laboratory for the purpose of monitoring day-to-day operation of the service laboratory
- Service laboratory - a laboratory, either internal to an agency (or company) or commercially contracted, that performs radioassay measurements to provide analytical results, exclusive of the purpose of monitoring or testing.

The standard describes, in detail, the functions, responsibilities and inter-relationships of these five organizations. The role of NIST shall be greatly expanded to include traceability of all radioassay laboratories and involvement with the accrediting organization in the assessment process.

## QUALITY ASSURANCE

The standard writing committee reviewed the primary recommendations and requirements of the major QA standards, guidelines, and regulations, such as 10 CFR 50 Appendix B, ASME/ANSI NQA-1, EPA/QAMS, ASTM C0009, and NRC Regulatory Guide 4.15. The standard outlines 11 key elements of a quality assurance program applicable to all types of radioassay laboratories. Each element has been described, and specific guidance and requirements summarized within the document. The 11 key elements are:

- organization
- design control
- procurement control
- instructions and procedures
- document control
- identification and control
- validation and verification
- instrument control
- corrective actions
- QA records
- assessments.

Guidance and requirements have been provided for sample process quality control applicable to all radioassay laboratories. Each laboratory shall have written quality control procedures to verify that the quality of measurements complies with specified performance requirements. The quality control procedures shall require the following:

- use of traceable reference standards
- performance checks of measurement systems
- intralaboratory analyses (e.g., known quantities, replicates and blanks)
- participation in at least one interlaboratory intercomparison program through an accredited monitoring laboratory, as defined in this standard

- computational checks
- review of procedures, specifications, and operating logs
- observation of operations and evaluation of quality control data
- documentation of conformance to the performance criteria of this standard
- a method for evaluating quality control data to ensure the long-term consistency of analytical results.

A section has been written to cover the proper use of reagent blanks, replicates, matrix spikes, and traceable reference material.

The standard requires the preparation and submittal of a QA report to the customer or client on an annual basis. The minimum content of the QA report has been specified within the standard.

### **SUPPORTING INFORMATION AND GUIDANCE**

Several appendices have been included with the standard to provide additional background material and operational guidance for the service laboratory. One appendix provides an overview of the current MQA programs conducted by international and governmental agencies, and private radioassay laboratories. MQA programs conducted by the International Atomic Energy Agency, the World Health Organization, DOE, EPA, and two nuclear power facilities have been summarized.

Another appendix contains the guidance and requirements for the proper operation of a service laboratory. The subject areas covered include:

- service laboratory operational criteria
- facility criteria
- general laboratory area
- waste management plan
- staff qualifications
- nuclear instrumentation-calibration and instrument quality control
- laboratory performance criteria
- detection limits concepts
- reporting results by the service laboratory

- record retention by the service laboratory
- test selection.

#### **STATUS OF ANSI N42.2 STANDARD**

During October 1992, the draft revision 11, dated August 14, 1992, was submitted for review and comment to the ANSI N42.2 Radioactivity Measurements subcommittee, the main committee of N42, and various interested technical experts. Comments from the reviewers have been received and are being addressed by the standard's writing committee chairman. Two sections of the draft standard have been rewritten to be consistent with ANSI N13.30, "Performance Criteria For Radiobioassay." The proposed responses to the reviewers' comments shall be evaluated by the writing committee prior to August 1993. The writing committee shall finalize the standard during a meeting scheduled in October 1993. The standard shall be redistributed for final comment by the first calendar quarter of 1994.



RELATIONSHIP BETWEEN NIST, ACCREDITING ORGANIZATION, REFERENCE, MONITORING, AND SERVICE LABORATORIES

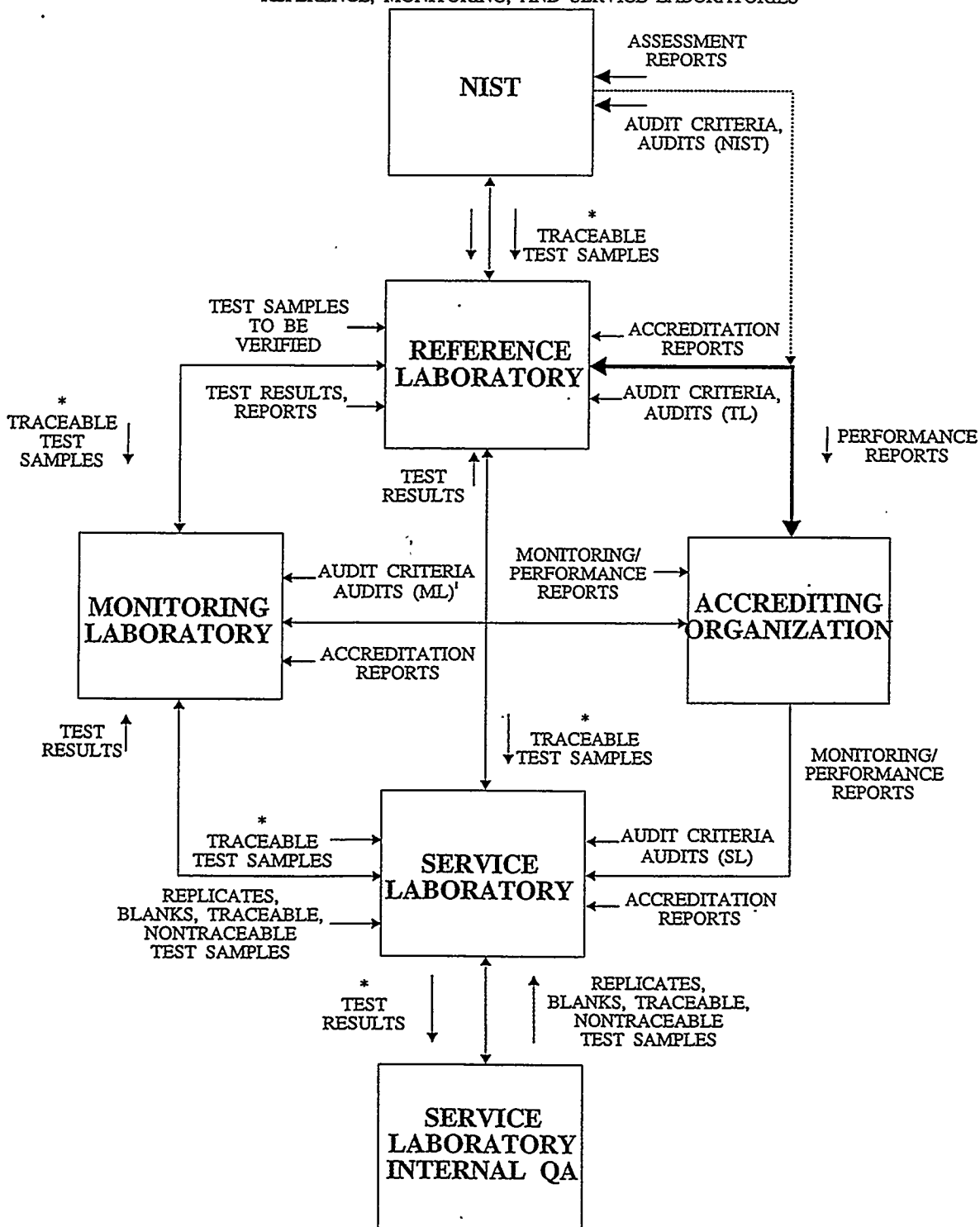


Figure 1 - National Performance Testing Program

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# HIGH-DOSE SECONDARY CALIBRATION LABORATORY ACCREDITATION PROGRAM

J. C. Humphreys<sup>(1)</sup>

*Abstract* - There is a need for high-dose secondary calibration laboratories to serve the multi-billion dollar radiation processing industry. This need is driven by the desires of industry for less costly calibrations and faster calibration-cycle response time. Services needed include calibration irradiations of routine processing dosimeters and the supply of reference standard transfer dosimeters for irradiation in the production processing facility. In order to provide measurement quality assurance and to demonstrate consistency with national standards, the high-dose secondary laboratories would be accredited by means of an expansion of an existing National Voluntary Laboratory Accreditation Program. A laboratory performance criteria document is under development to implement the new program.

## INTRODUCTION

The multi-billion dollar radiation processing industry uses high doses of ionizing radiation to produce a variety of products and services, including sterilization of medical devices and supplies (such as disposable syringes, operating room drapes and gowns); modification of polymers (wire and cable insulation, rubber tires, and auto parts); and treatment of foods (extension of shelf life for fruits, control of salmonella in chicken). Dosimetry is the principal means of measurement quality assurance (MQA) for processors to assure that the product received the appropriate radiation dose, i.e., a dose adequate to produce the desired effect without causing product degradation. Proper calibration of the dosimetry systems is essential to the MQA programs of the processors.

## NEED FOR ACCREDITATION PROGRAM

Most current dosimeter calibrations for the radiation processing industry are performed by the National Institute of Standards and Technology (NIST). Some calibrations are performed by the University of Maryland Dosimetry Laboratory; however, they are not recognized as an official secondary calibration laboratory since an accreditation program for high-dose applications does not presently exist. Due to the cost and occasionally long turn around time for these services, a number

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<sup>(1)</sup> National Institute of Standards and Technology, Gaithersburg, Maryland 20899.

of facilities in the industry have expressed interest in becoming accredited high-dose secondary calibration laboratories.

### **TYPES OF PROCESSING FACILITIES**

The radiation processing industry uses a variety of ionizing radiation sources for their material processing facilities. The majority of facilities use  $^{60}\text{Co}$  gamma ray sources in large plaque arrays containing millions of curies. Dosimetry is performed by placing routine passive dosimeters on or within the product units that are cycled through the shielded irradiation vault. The process usually requires several hours to complete.

Electron beams are becoming increasingly popular as radiation sources for processing. The very high dose rates available provide very short irradiation times (seconds instead of hours) and, thus, higher throughput of product. The energies of the electrons utilized range from about 200 keV for the curing of surface coatings to about 10 MeV for bulk products. The routine dosimeters are usually placed on the surface of the product.

High-energy x-rays (bremsstrahlung), generated by new high-power electron accelerators, are starting to be used for radiation processing. The energies of the x-rays are limited to a maximum of 5 MeV to avoid any possible activation of the product. These x-rays combine the penetration characteristics of  $^{60}\text{Co}$  gamma rays with the convenience of a machine source that can be turned on and off when desired. Dosimeters are used in a manner similar to that for gamma facilities.

### **CALIBRATION SERVICES REQUIRED**

The calibration services that should be available from the secondary calibration laboratory include the irradiation of customer dosimeters to absorbed doses of about 100 Gy to 1 MGy (10 krad to 100 Mrad) in a reasonable time. Generally, this would be done with a well-characterized, calibrated  $^{60}\text{Co}$  facility that provides a minimum dose rate of about 4 kGy/h. The laboratory should be able to supply high-quality, reference-class transfer dosimeters to customers for irradiation at the customer's facility. These reference dosimeters would be used either to go through the production irradiator side-by-side with routine dosimeters, or to calibrate the dose rate of the customer's in-house calibration source. If the secondary laboratory has an electron accelerator, it could also be used as a calibration source after appropriate calibration. All the radiation facilities employed by the secondary laboratory for calibrations must be shown to be consistent with and traceable to national standards by means of proficiency tests and appropriate measurement intercomparisons.

### **ACCREDITATION PROGRAM DOCUMENT REQUIREMENTS**

There is currently an accreditation program called Secondary Calibration Laboratories for Ionizing Radiation (SCLIR), administered by the National Voluntary Laboratory Accreditation Program (NVLAP) at NIST (Eisenhower 1991). This program is concerned with MQA procedures at dose levels appropriate to personnel dosimetry and radiation therapy. NVLAP has expressed willingness to expand that program to include high-dose secondary calibration laboratories. As part of that expansion process, it was recognized that a laboratory performance criteria document appropriate to those high-dose areas is required. Additionally, an associated accreditation checklist for the assessors will be needed.

## LABORATORY PERFORMANCE CRITERIA DOCUMENT

The performance criteria document is being developed as an American Society for Testing and Materials (ASTM) standard within Subcommittee E10.01 on *Dosimetry for Radiation Processing*.

The criteria are based generally on ISO/IEC Guide 25, *General Requirements for the Competence of Calibration and Testing Laboratories* (ISO/IEC Guide 25 1990).

The criteria document will include:

- Part A. Section on general criteria that is very close to ISO/IEC Guide 25, retaining that text pertaining to calibration activities while deleting that material pertaining to testing laboratories
- Part B. Section making the material of Part A specific to ionizing radiation applications
- Part C. Section on specific performance requirements for a secondary calibration laboratory for dose levels appropriate to radiation processing.

Part A will contain general criteria sections, including scope; references; definitions; organization and management; quality system, audit, and review; personnel; accommodation and environment; equipment and reference materials; measurement traceability and calibration; calibration methods; handling of calibration items; records; certificates and reports; sub-contracting of calibration; outside support services and supplies; and complaints.

Part B will set out the specific requirements for a laboratory dealing with ionizing radiation. It will amplify and interpret the general requirements of Part A. It can also be used as a guide for radiation calibration laboratories in developing and implementing their quality systems.

Part C will provide the specific performance requirements for the secondary calibration laboratory, such as level of agreement with national standards of the dose rates in their calibrated radiation fields; types of radiation sources available; types of radiation measurement instruments available; types of associated electronic measurement and test equipment available; and physical arrangements in radiation areas to minimize scattering effects and changes in energy spectra.

## ACCREDITATION PROCESS

Accreditation of a secondary calibration laboratory under NVLAP consists initially of the laboratory submitting its Quality Manual (including all quality control [QC] and MQA procedures) to the assessors for evaluation. If the Manual is found to have significant deficiencies, the laboratory is asked to make appropriate modifications. If the Manual is found to be satisfactory, the next step is for proficiency tests to be performed for all types of radiation calibration categories for which the laboratory requested accreditation. This may involve the use of new transfer instruments such as calorimeters for high-power electron and x-ray beams. Once these tests are successfully completed, an onsite assessment is performed by a team of NVLAP selected and trained Technical Experts. The assessors observe the laboratory personnel performing routine calibrations and examine equipment performance and all aspects of the laboratory operations. Any deficiencies observed are pointed out and discussed with the laboratory staff. After completion of the onsite visit, a report of the

assessment results is written. Any deficiencies must be corrected to the satisfaction of the Technical Expert team. After all aspects of the laboratory performance are found to be satisfactory, the laboratory is granted official NVLAP accreditation.

After being accredited by NVLAP, the laboratory can show that a strong MQA program is in place and prove traceability of their dosimetry systems to federal regulatory agencies (such as the U.S. Food and Drug Administration) and to any potential customers of their services. An accredited laboratory that is part of a large company can provide calibration services to its own internal company facilities. This can save them money and provide faster turnaround.

## **CONCLUSIONS**

The ASTM draft laboratory performance criteria should be ready for ballot by the end of 1993 and should gain final approval within a year after that. The assessor check list will be developed within NVLAP in parallel with the ASTM document. NVLAP should be able to offer accreditation of laboratories in the program as soon as the performance criteria standard receives final approval.

Benefits to the radiation processing community (Inn et al. 1993) for the operation of the high-dose secondary calibration laboratory program include:

- Assurance of product quality
- Demonstrated integrity of calibration services
- Satisfaction of regulatory requirements
- Defense of litigation
- Public assurance
- Cost effectiveness and competitive operations
- Consistent technical assessments
- Reduced number of audits.

In addition, the processing community has the opportunity to provide real and substantial input into the development of the ASTM performance criteria document. This is valuable in that the document is a consensus of the views of the entire community as well as helping in the development of internal MQA programs for the processors.

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# INTERCOMPARISON OF HIGH-ENERGY NEUTRON PERSONNEL DOSIMETERS

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R. M. Loesch<sup>(2)</sup>

**Abstract** - An intercomparison of high-energy neutron personnel dosimeters was performed to evaluate the uniformity of the response characteristics of typical neutron dosimeters presently in use at U.S. Department of Energy (DOE) accelerator facilities. It was necessary to perform an intercomparison because there are no national or international standards for high-energy neutron dosimetry. The testing that is currently underway for the U.S. Department of Energy Laboratory Accreditation Program (DOELAP) is limited to the use of neutron sources that range in energy from about 1 keV to 2 MeV. Therefore, the high-energy neutron dosimeters currently in use at DOE accelerator facilities are not being tested effectively. This intercomparison employed neutrons produced by the  $^9\text{Be}(p,n)^9\text{B}$  interaction at the University of Washington cyclotron, using 50-MeV protons. The resulting neutron energy spectrum extended to a maximum of approximately 50 MeV, with a mean energy of about 20 MeV. Intercomparison results for currently used dosimeters, including Nuclear Type A (NTA) film, thermoluminescent dosimeter (TLD)-albedo, and track-etch dosimeters (TEDs), indicated a wide variation in response to identical doses of high-energy neutrons. Results of this study will be discussed along with a description of plans for future work.

## INTRODUCTION

The DOE currently administers 12 laboratories that are associated with accelerator-based research. The accelerators at these laboratories produce radiations with energies from a few MeV to the TeV range. The new Superconducting Super Collider will extend this range to even higher energies. Particle beam currents vary from picoamperes to kiloamperes, and particle types include electrons and

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<sup>(1)</sup> Pacific Northwest Laboratory, Richland, Washington 99352. PNL-SA-22048. Work supported by the U.S. Department of Energy under contract DE-AC06-76RLO 1830.

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protons as well as heavy nuclei up to, and including, uranium (Coulson et al. 1989) The high-energy neutrons produced by these accelerators present a radiation protection problem because they can penetrate thick shields. In addition, high-energy neutrons have a large relative biological effectiveness (McCall et al. 1988).

DOELAP has demonstrated that the performance of personnel dosimetry systems in use at DOE facilities is adequate to meet the requirements set forth in DOE Orders (McDonald et al. 1992). The neutron sources used for DOELAP proficiency testing are unmoderated and D<sub>2</sub>O-moderated <sup>252</sup>Cf. The unmoderated <sup>252</sup>Cf source has a mean energy of about 2.3 MeV, with a high-energy tail extending to approximately 10 MeV. However, this source is not appropriate for testing personnel dosimeters that are expected to measure neutrons with energies of several hundred MeV.

There are no national or international standards describing reference radiations for high-energy neutron dosimetry. The National Institute of Standards and Technology (NIST) does not have a high-energy neutron standard. Therefore, it is not possible to perform a proficiency test for this type of radiation. In order to assess the degree of uniformity and reproducibility that now exists in DOE neutron personnel dosimetry, an intercomparison feasibility study was undertaken.

## MATERIALS AND METHODS

Dosimeters for this study were submitted by several DOE accelerator laboratories, including Lawrence Berkeley National Laboratory (LBL), Stanford Linear Accelerator Center (SLAC), Brookhaven National Laboratory (BNL), and Pacific Northwest Laboratory (PNL). Several types of neutron personnel dosimeters were sent by some of the participants, including CR-39 and Lexan polycarbonate TEDs, NTA film, and TLD-albedo dosimeters. The dosimeters were exposed five at a time on a standard DOELAP irradiation phantom constructed of polymethylmethacrylate (PMMA) and measuring 40 x 40 x 15 cm. Dosimeters from different facilities were exposed at the same time on the same phantom.

Reports by McCaslin et al. (1977) and Hoefert (1983) indicated that most of the neutron dose equivalent produced in the vicinity of high-energy accelerators is due to neutrons with energies between about 0.1 and 20 MeV. This is because the neutrons must pass through heavy shields, and this absorption and scattering produces large quantities of lower-energy neutrons. In addition, the quality factor is at a maximum for neutrons of approximately 0.5 MeV and decreases for higher-energy neutrons. These factors combine to maximize the dose equivalent for neutrons below about 20 MeV.

The neutron field used for this study was produced at the University of Washington Hospital Cyclotron Facility. This cyclotron is used for cancer radiation therapy; therefore, its neutron beam is well controlled, collimated, and monitored for the purpose of administering precise doses of fast neutrons to cancer patients. Neutrons are produced by bombarding a beryllium target with protons. The 50 MeV-protons produce neutrons with a maximum energy slightly above 50 MeV, due to the positive Q value of the reaction <sup>9</sup>Be(p,n)<sup>9</sup>B. The mean energy of the spectrum is approximately 20 MeV (ICRU 1989).

Dosimeters were taped to the front surface of the PMMA phantom and were covered by a 1-cm-thick PMMA plate, which was used to establish transient charged particle equilibrium. A tissue-equivalent plastic ionization chamber was used to measure absorbed dose, and dose equivalent was subsequently



calculated using values of the quality factor from Publication 21 of the International Commission on Radiation Protection (ICRP 1069).

The dosimeters were given two different exposure of 3.25 and 6 rem. All dosimeters were then returned to the participants. The dosimeters were read out and the measured dose equivalent values were recorded. Ratios of the measured values of dose equivalent divided by the given dose equivalent were then calculated.

## RESULTS AND DISCUSSION

The results of the two sets of exposures are shown in Figures 1 and 2. It can be seen that the ratios of reported-to-given values of dose equivalent differ from unity by almost a factor of three, in some cases. The error bars on individual data points indicate the range of values for replicate dosimeters.

Some dosimeter types indicated dose equivalent values that were close to the value delivered. However, it is not obvious why certain dosimeters performed well and other performed poorly. All of these dosimeters have a response that varies strongly with the neutron energy. TLD-albedo dosimeters respond well to lower-energy neutrons, whereas NTA film and TEDs respond well to higher-energy neutrons and have a low-energy cutoff in their response of about 100 keV.

Dosimeters were also calibrated using different neutron sources. Some were calibrated using unmoderated  $^{252}\text{Cf}$  and others were calibrated with either Am-Be or Pu-Be neutron sources. Because dosimeter response is energy dependent, the calibration source used can also make a large difference in the dose equivalent value.

The results of this intercomparison can be summarized in the following way. First, it was demonstrated that an intercomparison of neutron personnel dosimeters could be performed and that useful information would result from such a project. This study showed a wide variation in the readings of the dosimeters, which may have been due to the energy response of the dosimeters, the calibration methodology, or some combination of these items. This study only made use of dosimeters from a few DOE facilities; therefore, it would be useful to extend the study to give a more complete indication of the uniformity of high-energy neutron personnel dosimetry in DOE facilities.

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Dose: 3.245 rem, QF=6.123

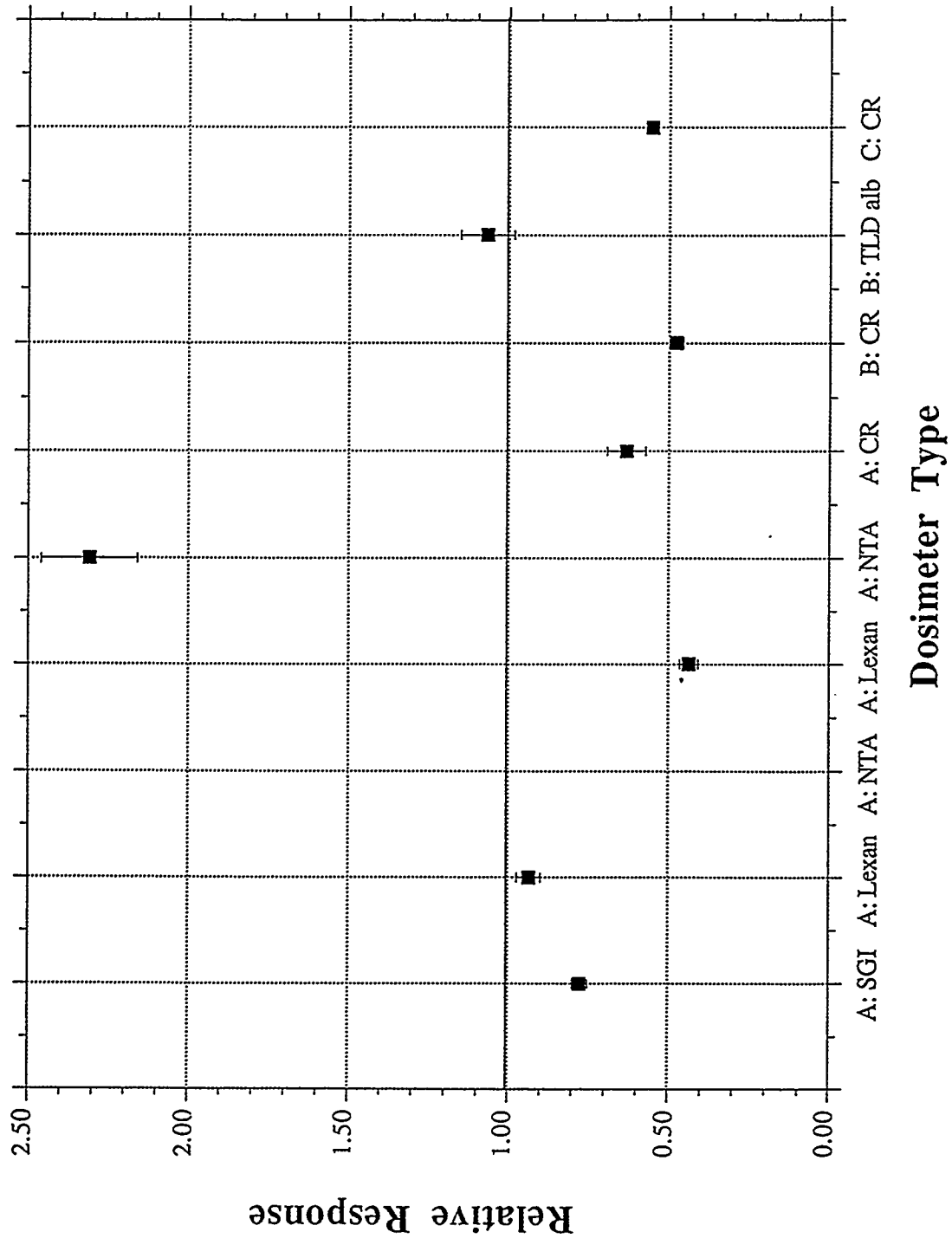


Figure 1 - Dosimeter Responses Relative to the Mean for a Dose Equivalent of 3.245 Rem

Dose: 6.01 rem, QF=6.123

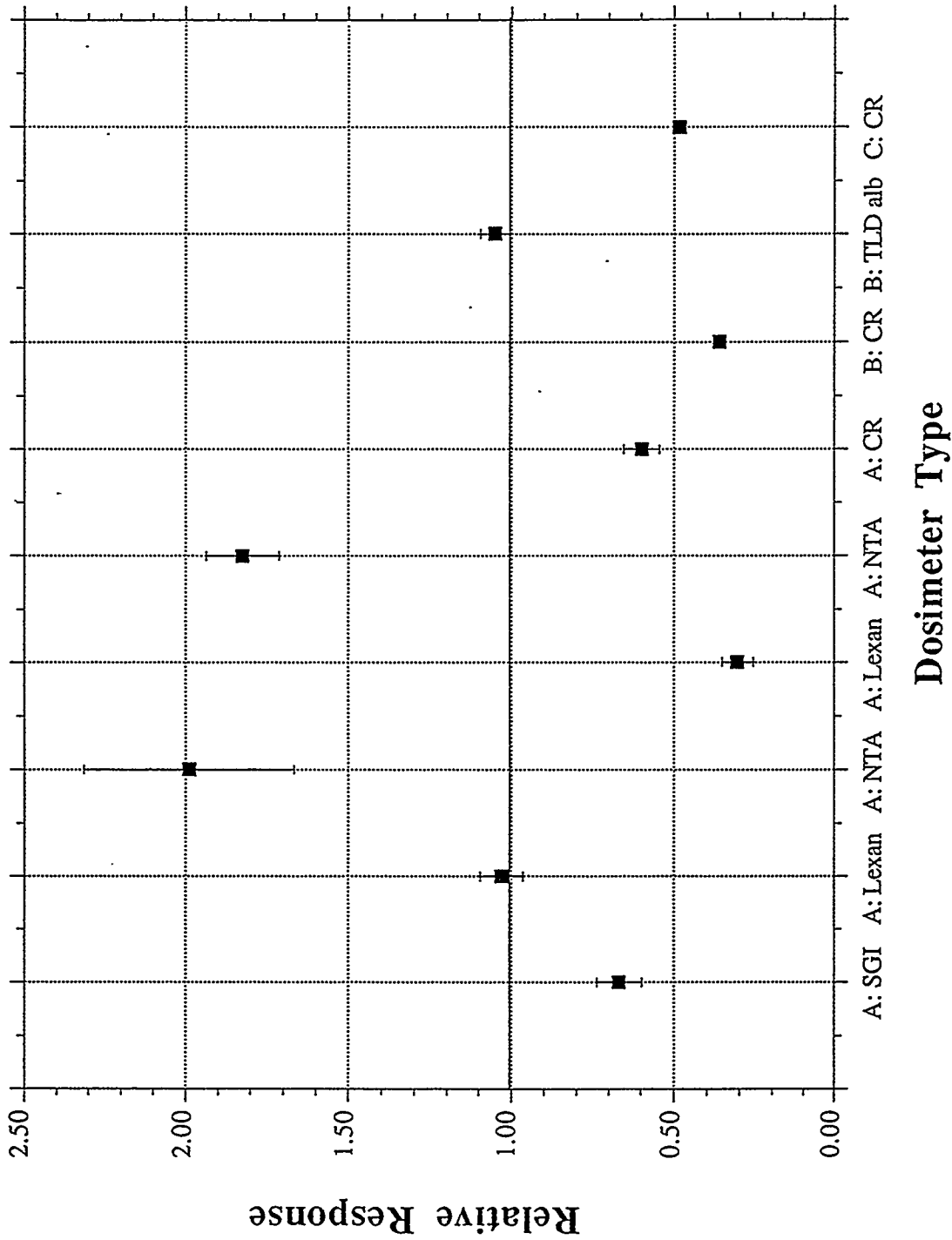


Figure 2 - Dosimeter Responses Relative to the Mean for a Dose Equivalent of 6.01 Rem

# **QA/QC PROGRAMS - RADIOACTIVITY**

Session Chair  
Don Nellis, NRC

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# QUALITY ASSURANCE FOR RADON EXPOSURE CHAMBERS AT THE NATIONAL AIR AND RADIATION ENVIRONMENTAL LABORATORY, MONTGOMERY, ALABAMA

Mark O. Semler<sup>(1)</sup>  
Edwin L. Sensintaffar<sup>(1)</sup>

*Abstract* - The Office of Radiation and Indoor Air, U.S. Environmental Protection Agency (EPA), operates six radon exposure chambers in its two laboratories, the National Air and Radiation Environmental Laboratory (NAREL) in Montgomery, Alabama, and the Las Vegas Facility, Las Vegas, Nevada. These radon exposure chambers are used to calibrate and test portable radon measuring instruments, test commercial suppliers of radon measurement services through the Radon Measurement Proficiency Program, and expose passive measurement devices to known radon concentrations as part of a quality assurance plan for federal and state studies measuring indoor radon concentrations. Both laboratories participate in national and international intercomparisons for the measurement of radon and are presently working with the National Institute of Standards and Technology (NIST) to receive a certificate of traceability for radon measurements. NAREL has developed an estimate of the total error in its calibration of each chamber's continuous monitors as part of an internal quality assurance program. This paper discusses the continuous monitors and their calibration for the three chambers located in Montgomery, Alabama, as well as the results of our intercomparisons and total error analysis.

## INTRODUCTION

The EPA, through its laboratories in Montgomery, Alabama, and Las Vegas, Nevada, has been involved in assessment of exposures to indoor radon and radon decay products since the formation of EPA in 1970. NAREL in Montgomery functioned as the measurement support laboratory for radon studies in homes located in the phosphate mining areas of southern Florida during the 1970's. In 1984, when two locations in New Jersey were found to have radium waste material buried under many homes, NAREL sent a field team to perform door-to-door radon measurements in the affected area. NAREL also provided field teams for door-to-door radon measurements in the Reading Prong

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area of Pennsylvania when a house in that area was found to have a significantly elevated level of indoor radon in 1985.

In 1978, NAREL built a 3.6 m<sup>3</sup> radon exposure chamber, 1.2 m by 1.2 m by 2.5 m, based on a design suggested by Thomas (Thomas 1975) to allow testing and calibration of portable radon measuring instruments and passive measuring devices. A laminar flow of radon-laden air is passed through the chamber and exhausted to the atmosphere. We added control of temperature and humidity to this chamber in 1982.

EPA began a program of testing companies providing commercial measurement of indoor radon concentrations in 1986. To accommodate the increased need for exposing measurement devices to known radon concentrations, NAREL designed and built a 40 m<sup>3</sup> walk-in chamber. Control of environmental parameters and air flow are handled by an industrial heating, ventilation, and air conditioning (HVAC) controller<sup>(1)</sup>. Radon and radon-decay-product concentrations were initially monitored using commercially available instruments interfaced to two IBM PC/XT<sup>®</sup>-compatible personal computers. Environmental conditions within the chamber were also monitored using these computers. The radiological monitoring systems were subsequently updated using discrete components and custom software from a commercial vendor.

In 1990, NAREL built a second walk-in chamber that was essentially the same as the first one. At this time we also connected the monitoring computers for all three chambers to a local area network and stored the monitoring data on a central file server. The monitoring data is merged with daily grab calibration data to generate reports on the conditions of the chambers during testing and to determine the cumulative exposure for the period.

## **RADON MONITORING SYSTEMS**

Each of the three chambers is monitored continuously by two independent measurement systems for radiological and environmental conditions. Radon gas concentration is measured using a zinc sulfide scintillation cell with a nominal volume of 1.4 L mounted on a 12.7-cm (5-in.) photomultiplier tube. Chamber air is pulled through a 0.8-micrometer membrane filter and the scintillation cell at 1 liter per minute and exhausted back into the chamber.

The output of the photomultiplier is connected through a standard nuclear instrumentation preamplifier and amplifier to an analog-to-digital converter and multichannel buffer (MCB)<sup>(2)</sup>. The MCB plugs into a personal computer expansion slot and is controlled by custom software. The radon concentration can be measured for a period of 15 minutes to 1 hour. Data for each period are stored on a central file server. This system has previously been described in greater detail (Sensintaffar, Van Cleef, and Windham 1988).

The continuous radon monitors are calibrated against zinc sulfide scintillation-cell-grab samples. Data from the two continuous monitors are compared to the measured radon concentration for the hour a

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<sup>(1)</sup> Model DMS 35, Robertshaw Controls Company, Richmond, Virginia.

<sup>(2)</sup> Model 916-2k, EG&G ORTEC, Oak Ridge, Tennessee.



grab sample was taken, and a calibration factor for each continuous monitor computed. If the calculated calibration factor is within  $\pm 2$ -sigma of the mean for previous calibrations, it is included in a database for calibration factors. If it is outside of  $\pm 2$ -sigma, it is stored in a separate database. The calibration factor database is examined periodically to look for slow, long-term trends that may indicate system drift or problems with either the electronics or air flow systems. Rejected calibration data are examined periodically to resolve the cause of each rejected data point. Examples of information in the calibration database and a printout of the analysis of calibration factors are shown in Figures 1 and 2.

## CALIBRATION OF SCINTILLATION CELLS

NAREL calibrates its scintillation cells using a modification of the method described by Lucas (Lucas and Markun 1988; Sensintaffar and Windham 1990). Dry nitrogen is flowed slowly through an emanation flask containing a radium-226 solution, and emanated radon-222 is collected in an 18-liter SARAN bag. Total volume is measured with a calibrated dry gas meter placed upstream of the emanation flask. The collection bag is allowed to stand for 1 hour to allow thorough mixing of the radon. Scintillation cells are then filled from the bag using a vacuum transfer manifold. The filled cells are assayed 4 hours after filling on one of eight photomultiplier scaler systems controlled by a personal computer. The length of the count is adjusted to allow collection of a nominal 100,000 counts.

Prior to a calibration run, each cell is evacuated to less than 1 torr and stored for 24 hours to test for leakage. The residual vacuum is measured and must be less than 100 torr ( $\sim 25$  in. Hg) for the cell to remain in service. Each cell is also background counted and must have a background count rate of less than 2.0 counts per minute. Typical backgrounds are less than 1.0 count per minute. Cells are thoroughly purged with dry nitrogen after a calibration run and stored for four or more days to allow complete decay of the short-lived decay products. They are again background counted and returned to service.

Three radium-226 solutions from NIST are used to calibrate the cells. Cells are calibrated twice yearly using a different solution, so each cell is calibrated with each of the three solutions every 1.5 years. Each cell is tested against its calibration history; and must be within  $\pm 5\%$  of the mean, or it is removed from service and recalibrated. Since NAREL began using the modified Lucas method of calibration, the standard deviation of cell calibration factors has averaged  $\pm 3.6\%$  in 14 calibration runs.

## CALIBRATION OF SCINTILLATION CELL DETECTION SYSTEMS

Scintillation cells are presently assayed using a counter<sup>(1)</sup> with internal high voltage and an HPIL<sup>(2)</sup> interface connected to a 5-cm photomultiplier tube in a light-tight enclosure<sup>(3)</sup>. Eight scalers are connected to a personal computer which controls data acquisition and calculations. These systems are adjusted before each calibration run and weekly during extended chamber operations,

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(1) Model 2200-12, Ludlum Measurements, Inc., Sweetwater, Texas.

(2) Hewlett-Packard Company, Corvallis Workstation Operation, Corvallis, Oregon.

(3) Model 182, Ludlum Measurements, Inc., Sweetwater, Texas.

using a sealed scintillation cell containing approximately 1.5 Bq of radium-226. This cell is counted for 23 minutes, yielding a nominal 10,120 counts. The actual count must be within  $\pm 2\%$ , or the system is adjusted and the cell recounted. By adjusting all scalers to this nominal count, any scintillation cell can then be assayed on any scaler.

## **ANALYSIS OF ERROR**

Recently errors associated with the calibration of our scintillation cells and the continuous monitors were analyzed in detail by Dr. Karen Stevenson (Stevenson 1990). Dr. Stevenson analyzed all potential sources of random and systematic error and evaluated the magnitude of each error at the 3-sigma level. These errors were combined quadratically with the 2-sigma counting error for calibration runs to derive an overall estimate of the total error in the calibration of our cells. Table 1 lists the major sources of these errors and their estimated magnitudes. A similar evaluation was then made for calibration of the continuous monitors. These estimates are shown in Table 2. From these tables it is apparent that the total error for the calibration of our cells is  $\pm 5.0\%$ , and that the total error for the calibration factors of the chamber continuous radon monitors is  $\pm 11\%$  at  $148 \text{ Bq}\cdot\text{m}^{-3}$  ( $4 \text{ pCi/L}$ ).

## **INTERCOMPARISONS**

NAREL has participated in radon measurement intercomparisons with the U.S. Department of Energy, Environmental Measurements Laboratory, since 1981. Figure 3 shows the ratios of our performance versus the EML reference values from pulse ion chamber measurements for these intercomparisons. Excluding the two earliest runs, when we were developing our calibration techniques, we have an average performance ratio of 0.99 and a standard deviation of 3.5%.

NAREL has also participated in intercomparisons sponsored by NIST. In June 1987, we analyzed radon concentrations in two glass bulbs. Our values were within  $\pm 1\%$  of NIST for each bulb, and the average of the two was 0.1% low. In July 1990, for a measurement intercomparison of five bulbs, our average was within 0.5% of NIST.

## **NIST CERTIFICATION OF TRACEABILITY**

NAREL and the Las Vegas Facility are presently working with NIST through an interagency agreement to receive a certificate of traceability for the measurement of radon gas. NIST is testing the measurement proficiency of each lab using NIST-supplied radon samples, and it is evaluating each lab's estimate of the random and systematic measurement errors associated with the calibration of cells. NIST will also measure a sample of radon gas from each lab's calibration facility. Work towards this certification should be completed by the end of Fiscal Year 1993.

## **SUMMARY**

Because of the need to maintain a very high level of quality and accuracy in the measurement of radon gas concentrations, NAREL has dedicated significant effort to calibrating our systems and understanding the errors associated with these measurements. We have participated in many measurement intercomparisons and are now working closely with NIST to receive a certificate of traceability. The results of our intercomparisons have been quite good. Use of a highly reliable calibration procedure with multiple standard sources has improved the calibration of our scintillation

cells and significantly reduced variability between calibration runs. NAREL is continuing to look at ways to improve our measurements program and would welcome comments or suggestions.

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DATE	TIME	B_SC <sup>(a)</sup>	CAL_1 <sup>(b)</sup>	RN_1 <sup>(c)</sup>
10/24/92	11:41	5.620	0.758	7.3900
10/25/92	17:33	4.500	0.712	6.3200
10/26/92	14:42	5.100	0.723	7.0500
:	:	:	:	:
11/17/92	13:29	25.90	0.728	35.600
11/18/92	14:31	24.70	0.702	35.200
11/19/92	15:37	25.80	0.731	35.300
11/20/92	09:29	26.70	0.738	36.200
11/21/92	14:34	26.00	0.760	34.200
11/22/92	10:50	26.90	0.737	36.500
:	:	:	:	:
01/28/93	11:35	25.70	0.710	36.200
01/29/93	15:37	23.60	0.688	34.400
01/30/93	10:25	26.10	0.735	35.500
01/31/93	09:34	27.00	0.740	36.500
02/02/93	13:48	87.60	0.712	123.00
02/03/93	15:25	89.80	0.730	123.00
:	:	:	:	:
02/24/93	16:28	24.40	0.728	33.500

- <sup>a</sup> Chamber radon concentration as measured by a scintillation cell grab.
- <sup>b</sup> Continuous monitor calibration factor.
- <sup>c</sup> Continuous monitor counts per minute for period of grab sample.

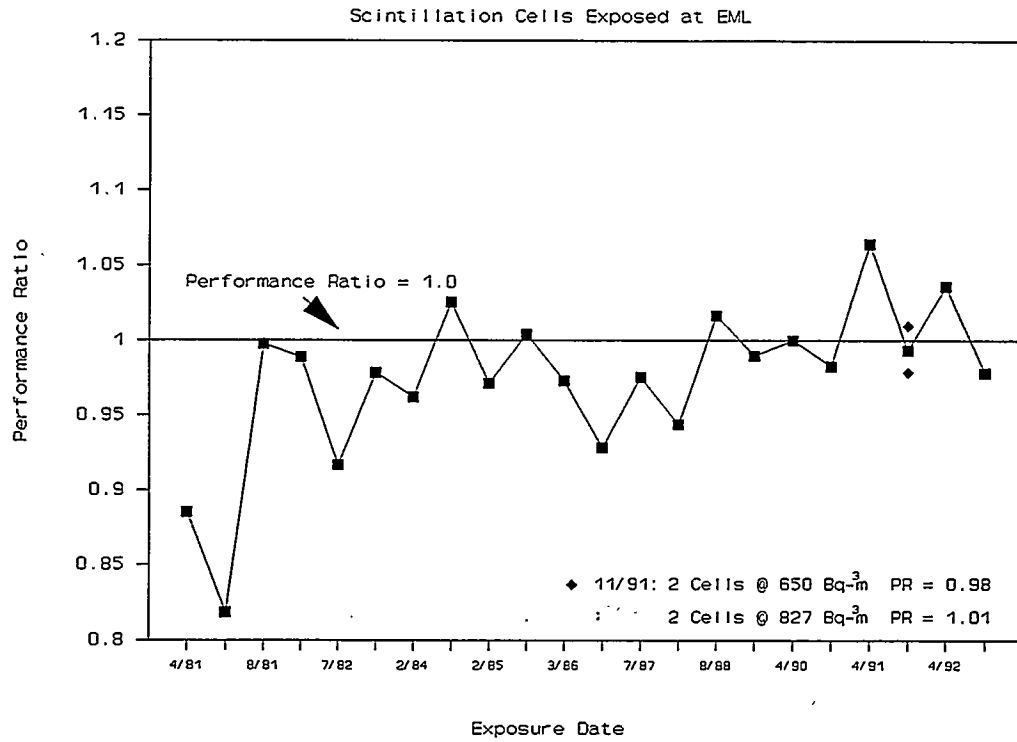
**Figure 1 - Example of Data in Chamber B, System 1 Calibration Database**

CHAMBER B						
= SCINTILLATION DATE	CELL = TIME	= RADON	== SYSTEM RN CPM	1 == CAL F	== SYSTEM RN CPM	2 == CAL F
←----->						
10/24/92	11:41	5.600	7.39	0.758	7.62	0.735
10/25/92	17:33	4.500	6.32	0.712	6.45	0.698
10/26/92	14:42	5.100	7.05	0.723	7.12	0.716
:	:	:	:	:	:	:
11/17/92	13:29	25.900	35.60	0.728	35.50	0.730
11/18/92	14:31	24.700	35.20	0.702	34.90	0.708
11/19/92	15:37	25.800	35.30	0.731	34.90	0.739
11/20/92	9:29	26.700	36.22	0.738	35.90	0.744
11/21/92	14:34	26.000	34.20	0.760	36.10	0.720
11/22/92	10:50	26.900	36.50	0.737	38.00	0.708
:	:	:	:	:	:	:
1/28/93	11:35	25.700	36.22	0.710	36.50	0.704
1/29/93	15:37	23.600	34.40	0.688	(a)	
1/30/93	10:25	26.100	35.50	0.735	36.30	0.719
1/31/93	9:34	27.000	36.50	0.740	37.70	0.716
2/ 2/93	13:48	87.600	123.00	0.712	123.00	0.712
2/ 3/93	15:25	89.800	123.00	0.730	126.00	0.713
:	:	:	:	:	:	:
2/24/93	16:28	24.400	33.50	0.728	34.20	0.713
			Average	0.727		0.718
			Std Dev	0.022		0.024
			% Std	3.018%		3.417%

<sup>a</sup> Calibration data for System 2 was rejected on this day.

**Figure 2 - Sample Printout of Calibration Data for Continuous Monitors on Radon Chamber B**

# NAREL Radon Intercomparison Performance



**Figure 3 - NAREL's Performance in the International Radon Measurement Intercomparisons Sponsored by EML**

*Table 1 - Summary of Random and Systematic Errors for the Calibration of NAREL's Zinc Sulfide Scintillation Cells*

Description of Error	Error <sup>(a)</sup>	Total Error
NIST Ra-226 Solution Random & Systematic	1.2%	1.2%
Cell Calibration - Random Errors Counting Error (> 100,000 cts) Dry Gas Measurement	0.8% <sup>(b)</sup> 0.8%	1.6%
Cell Calibration - Systematic Error Mixing of Gases in Bag Scaler Calibration Equilibrium, Ra-226/Rn-226 Emanation from Solution Equilibrium, Rn-222/Decay Products Decay Correction	0.05% 1.5% 0.1% 1.0% 1.0% 1.0%	4.55%
Total Error (Combined in Quadrature)		4.97%

<sup>a</sup> All errors are at a 99.7% (3-sigma) level of confidence unless otherwise indicated.

<sup>b</sup> A 2-sigma level of confidence.

**Table 2 - Summary of Random and Systematic Errors for Calibration of NAREL's Radon Chamber Continuous Monitors**

Description of Error	Error <sup>(a)</sup>	Total Error
Scintillation Cell Calibration Random & Systematic	4.97%	4.97%
Grab Cell - Random Error Counting Error	6.3% <sup>(b)</sup>	6.3%
Grab Cell - Systematic Errors Scaler Calibration Equilibrium, Rn-222/Decay Products Decay Correction	1.5% 1.0% 1.0%	3.5%
Continuous Monitors - Random Error Counting Error	6.5% <sup>(c)</sup>	6.5%
Continuous Monitors - Systematic Error Drift of PMT's	1.0%	1.0%
<b>Total Error (Combined in Quadrature)</b>		<b>11.0%</b>

<sup>a</sup> All errors are at a 99.7% (3-sigma) level of confidence unless otherwise indicated.

<sup>b</sup> Assumes ~1000 counts total for a radon concentration of 148 Bq-m<sup>-3</sup> (4 pCi/L); 2-sigma level of confidence.

<sup>c</sup> For a radon concentration of 148 Bq-m<sup>-3</sup> and a 1-h counting time; 2-sigma level of confidence.



# ENVIRONMENTAL RADIOACTIVITY INTERCOMPARISON PROGRAM AND RADIOACTIVE STANDARDS PROGRAM

George Dilbeck<sup>(1)</sup>

*Abstract* - The Environmental Radioactivity Intercomparison Program described herein provides quality assurance support for laboratories involved in analyzing public drinking water under the Safe Drinking Water Act (SDWA) Regulations, and to the environmental radiation monitoring activities of various agencies. More than 300 federal and state nuclear facilities and private laboratories participate in some phase of the program.

This presentation describes the Intercomparison Program studies and matrices involved, summarizes the precision and accuracy requirements of various radioactive analytes, and describes the traceability determinations involved with radioactive calibration standards distributed to the participants. A summary of program participants, sample and report distributions, and additional responsibilities of our program are discussed.

## INTRODUCTION

Environmental measurements of radiation are made daily by many federal, state, local, and private agencies. The data from these measurements are used for a wide variety of purposes including assessment of health effects, the establishment of standards and guides, and enforcement activities. It is imperative that the precision and accuracy of the data be assured so that decisions concerning environmental quality or impact are based on data of known reliability.

An agency-wide quality assurance program has been implemented within the U.S. Environmental Protection Agency (EPA) to attain this goal. Radiation quality control responsibilities have been assigned to the Nuclear Radiation Assessment Division of the EPA at the Environmental Monitoring Systems Laboratory - Las Vegas (EMSL-LV) in Las Vegas, Nevada. A program has been instituted to encourage the development and implementation of quality control procedures for sample collection, laboratory analysis, and data handling and reporting.

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A major objective of this program is to assist laboratories involved in environmental radiation measurements to develop and maintain both intralaboratory and interlaboratory quality control programs. In part, this is accomplished through an extensive laboratory intercomparison studies program involving environmental media (water, milk, and air) and a variety of radionuclides with activities at or near environmental levels.

EMSL-LV maintains a comprehensive radionuclide standards and reference materials inventory. These materials are available for distribution only to the radioanalytical laboratories throughout the country that participate in the EPA's national quality assurance program administered by EMSL-LV.

To assure the integrity of its standards and reference materials, EMSL-LV conducts ongoing traceability studies (direct and indirect) with the National Institute of Standards and Technology (NIST), often using the nuclides prepared for dilution.

## **MAIN TEXT**

Simulated environmental samples containing known amounts of one or more radionuclides are prepared and are periodically distributed to laboratories upon request. Tables 1 and 2 list summaries of the EMSL-LV Intercomparison Studies Program. These laboratories perform the required analyses and return their data to the Nuclear Radiation Assessment Division for statistical analysis and comparison with known values as well as with analytical values obtained by other participating laboratories.

Each laboratory making environmental radiation measurements should have an internal quality control program in operation to ensure that all instrumentation is calibrated and functioning, and that analytical procedures are being carried out properly. Such a program includes continual monitoring of instrumentation, the plotting of instrument control charts, frequent analysis of replicate samples to check precision, and the regular measurement of samples to which known amounts of activity have been added to check the accuracy of the systems.

Participation in a laboratory intercomparison study does not automatically assure the precision and accuracy of the data of a laboratory and should not be considered as a substitute for a continuous quality control program within a laboratory. Intercomparison data may be useful for documenting precision and accuracy and for helping to indicate instrumental or procedural problems. Participation in intercomparison studies is useful in augmenting the quality control program of a laboratory by serving as a check on its internal quality control program.

Each participating laboratory is expected to perform three independent determinations for each radionuclide included in a study. Analytical results can be reported by mail or FAX, as specified on the form provided with the sample to be analyzed (samples which require special dilution and/or processing are accompanied by an instruction sheet attached to the results report form). It is highly recommended and encouraged that results be transmitted using the computer phone-in program.

After receipt of analytical results from the participating laboratories, the data are analyzed. This analysis includes determination of the laboratory standard deviation, and calculation of the normalized range, the normalized deviation, the sample standard deviation, and the grand average of all laboratories. The analytical precision values, used as a basis for specific nuclides, are summarized in Table 3.

A report is then generated containing data reported by participating laboratories, which are listed according to their identity code. Each participating laboratory receives a copy of the report along with local, state, and federal regulating agencies.

The radionuclides used in preparing standard solutions are obtained from the NIST and other reliable commercial sources. The uncertainty in the known activity of those supplied radionuclide solutions ranges from 0.5 to 5%. The activity of radionuclide impurities, excluding daughters, is documented and typically is less than 1% of the activity of the principal radionuclide at the time of sample preparation.

Upon receipt of a radionuclide solution by EMSL-LV, the radionuclide is diluted on a weight basis with deionized water containing appropriate stable carriers and preservatives (generally dilute acids). The diluted radionuclide is calibrated, checked for impurities, and aliquoted into 5-mL glass ampules, which are then flame-sealed and added to the inventory of standard radionuclide solutions. The concentration of the dilutions is compared to the value of the supplier, corrected for the dilution weights and radioactive decay. These values and comparisons can be found in Table 4.

Radionuclide requests are received from user laboratories, and standard solutions (5-mL ampules), containing from 1 to 200 nanocuries per gram concentration (depending upon the radionuclide), are shipped from the inventory of those solutions. These calibrated materials are shipped, at no cost, within 2 weeks after receipt of requests, provided that they are in stock. Accompanying the shipment of each standard solution and reference material is a certificate listing pertinent information concerning the sample with the value of the activity.

To further ensure the precision and accuracy of the prepared standard solutions, the Nuclear Radiation Assessment Division participates in ongoing traceability studies with NIST. Tables 5 and 6 list the results of the EPA's traceability program with NIST. Shown in each category of direct and indirect traceability are nuclides and the ratios of the activity measured by EPA to the activity measured by NIST. In the section on direct traceability, each nuclide is a sample of a radioactive solution taken from the EPA radionuclide inventory and sent to NIST for periodic analysis.

## **RESULTS**

Table 7 summarizes the level of interaction between EMSL-LV and the various participants involved in our program. Participants include local, state, and federal laboratories, in addition to private and commercial analytical laboratories and nuclear power facilities. Numerous foreign laboratories also take part in our program. Distribution of samples, reports, and calibrated radioactive standards are also mentioned in this table.

Additional responsibilities of the Nuclear Radiation Assessment Division include, but are not limited to, method research and development, collaborative studies, and technical assistance to participating laboratories. EMSL-LV also has the responsibility for the primacy Safe Drinking Water Laboratory audits and evaluations, along with their recommendations for certification (or certification downgrade) to the corresponding EPA Regional Certification Authority.

*Table 1 - Summary of Laboratory Intercomparison Studies for Water\**

Sample	Analysis
Gamma	Co-60, Zn-65, Ru-106, Cs-134, Cs-137, Ba-133
Iodine-131	I-131
Gross Alpha, Gross Beta	Gross Alpha, Gross Beta
Tritium	H-3
Radium	Ra-226, Ra-228
Plutonium	Pu-239
Strontium	Sr-89, Sr-90
Uranium	Total Uranium
Performance Evaluation (Blind)	Part A - Gross Alpha, Ra-226, Ra-228, Uranium Part B - Gross Beta, Sr-89, Sr-90, Co-60, Cs-134, Cs-137

\* Laboratories are required to have the necessary NRC and/or state license(s) before receiving these samples.

*Table 2 - Summary of Laboratory Intercomparison Studies for Other Matrices\**

Sample	Analysis
Milk	Sr-89, Sr-90, I-131, Cs-137, Potassium
Air Filter	Gross Alpha, Gross Beta, Sr-90, Cs-137

\* Laboratories are required to have the necessary NRC and/or state license(s) before receiving these samples.

*Table 3 - Laboratory Precision: One Standard Deviation Value*

Analysis	Active Level (pCi)	One Standard Deviation for Single Determination (pCi or %)
Gross Alpha	≤20	5
	>20	25%
Gross Beta	≤50	5
	>50	10
	>100	15%
Gamma Emitter	5 - 100	5
	>100	5%
Sr-89, Sr-90	5 - 100	5
	>100	5%
I-131	≤55	6
	>55	10%
Uranium	≤35	3
	>35	10%
Ra-226	≥0.1	15%
Ra-228	≥0.1	25%
Pu-239	≥0.1	10%
Potassium	≥0.1	5%
Tritium	<4000	170 x (known) <sup>0.0933</sup>
	≥4000	10%
Warning Limits	Control Limits	
Known ± $\frac{2\sigma}{\sqrt{3}}$	Known ± $\frac{3\sigma}{\sqrt{3}}$	

*Table 4 - EMSL-LV Traceability to Radionuclide Suppliers, December 1991 to Present*

Nuclide	Expd (nCi/g)	EMSL-Val (Nci/g)	% Diff	EMSL Expd
I-131	236.91	237.30	0.16	1.002
Sr-89	48.01	47.80	-0.44	0.996
Ru-106	111.50	110.90	-0.54	0.995
I-131	159.80	163.60	2.38	1.024
Th-230	NA	167.00	NA	NA
AM-241	6.02	6.03	0.17	1.002
Sr-89	51.77	51.22	-1.06	0.989
I-131	146.00	146.90	0.62	1.006
Y-88	72.30	72.90	0.83	1.008
H-3	21.80	21.95	0.69	1.007
I-131	216.30	218.20	0.88	1.009
Zn-65	73.14	74.74	2.19	1.022
Ba-133	31.18	30.95	-0.74	0.993
Am-241	5.96	5.96	0.00	1.000
Sr-90	5.11	5.04	-1.37	0.986
Sr-85	100.80	99.20	-1.59	0.984
Co-57	46.20	47.00	1.73	1.017
Eu-152	214.50	214.50	0.00	1.000
Cs-137	13.50	14.05	4.07	1.041

*Table 5 - Direct Traceability Samples Submitted to NIST by EMSL-LV,  
January 1974 to September 1991*

Nuclide	EMSL-LV Value		Nuclide	EMSL-LV Value	
	NIST Value			NIST Value	
H-3	0.995 0.973	1.025	Zn-65	0.994	1.022
Co-57	0.994		Y-88	1.018	
Co-58	0.987	0.987	Zr-95	0.997	
Co-60	0.996	1.006	Ru-106	0.979	
Sr-89	0.956 0.981 1.002	0.977 0.989 1.005	Cd-109	1.026	1.027
Sr-90	0.997 1.007 0.999	1.006 1.024	Ag-110m	1.008	
I-131	0.977 0.988	0.981 0.994	Sb-125	1.015	
Ra-226	0.993 1.002	1.009 1.002	Ba-133	0.989	0.977
Ra-228	1.021		Cs-134	0.986 0.967	0.988 0.966
Na-22	1.007		Cs-137	0.984 0.970	0.990
Cr-51	0.985	1.000	Ce-144	0.972	
Mn-54	0.997	1.009	Hg-203	0.995	
Am-241	0.944 0.999	0.995 1.002	Th-230	0.956	0.964
			U-232	0.941	
			U-238	0.989	0.988

*Table 6 - Indirect Traceability Samples Submitted to EMSL-LV by NIST,  
January 1974 to September 1991*

Nuclide	EMSL-LV Value NIST Value		Nuclide	EMSL-LV Value NIST Value	
C-14	0.969 1.004	0.986	Sr-89	0.997	
Cr-51	0.974 1.016	1.015	Sr-90	1.008	1.014
Ni-63	0.989 1.043	1.006	Cd-109	0.970	
Cs-134	0.996	1.013	Ag-110m	1.018	
Cs-137	0.981	1.000	Ba-133	0.985	
Am-241	0.955 0.994	0.990	Ba-140	0.979	
Ca-45	1.049		Ce-141	1.080	
Sc-46	0.995		Pm-147	1.008	
Fe-59	0.996		Eu-152	0.959 0.993	0.991
Co-57	1.026	1.027	Hg-203	1.017	1.024
Co-58	0.960		Pb-203	1.171	
Co-60	1.001		Ra-226	0.999	
Zn-65	1.014	1.018	Th-228	0.970	
Se-75	0.919	1.023	Pu-238	1.000	1.000
Ru-103	1.012	1.013	Pu-239	0.986	



*Table 7 - Intercomparison Studies Program Summary*

Category	Number
Federal Laboratories	36
State Laboratories	80
Nuclear Power Facilities	31
Commercial Laboratories	135
Foreign Laboratories	35
Intercomparison Studies*	28
Intercomparison Samples Distributed*	4927
Intercomparison Reports Distributed*	6788
Radioactive Standards Distributed*	1981

\*Fiscal Year 1992.

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# NUCLEAR REACTOR EFFLUENT MONITORING

J. L. Minns<sup>(1)</sup>

T. H. Essig<sup>(1)</sup>

**Abstract** - Radiological environmental monitoring and effluent monitoring at nuclear power plants is important both for normal operations, as well as in the event of an accident. During normal operations, environmental monitoring verifies the effectiveness of in-plant measures for controlling the release of radioactive materials in the plant. Following an accident, it would be an additional mechanism for estimating doses to members of the general public. This paper identifies the U.S. Nuclear Regulatory Commission (NRC) regulatory basis for requiring radiological environmental and effluent monitoring, licensee conditions for effluent and environmental monitoring, NRC independent oversight activities, and NRC's program results.

## REGULATORY BASIS FOR REQUIRING MONITORING

The principal regulatory basis for requiring environmental monitoring and effluent monitoring at nuclear power plants during the operational stage is contained in General Design Criteria 64 of Appendix A of Title 10 of CFR Part 50, and Section IV.B of Appendix I of 10 CFR 50. For example, Section IV.B states that:

The licensee shall establish an appropriate surveillance and monitoring program to:

1. Provide data on quantities of radioactive material released in liquid and gaseous effluents...;
2. Provide data on measurable levels of radiation and radioactive materials in the environment to evaluate the relationship between quantities of radioactive materials released in effluents and resultant radiation doses to individuals from principle [*sic*] pathways of exposure; and ....

Results from the environmental and effluent monitoring programs are reviewed, and if the data indicate that the relationship between the quantities of effluents and doses to individuals is significantly different than that assumed in the licensing calculations, then the NRC may modify the

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allowable quantities in the Technical Specifications for the nuclear power plant (Section IV.C of Appendix I of 10 CFR 50, Ref. 2).

The NRC, through the use of regulations and license conditions, requires licensees to develop programs and procedures to monitor and to minimize releases to unrestricted areas. Results of these programs are submitted to the NRC periodically for review. The NRC also sponsors programs that are independent from, but supplemental to, the monitoring programs conducted by the licensees. These programs provide a means of verifying licensee performance and assuring that releases to the environment and associated population are maintained as low as reasonably achievable (ALARA). The independent programs consist of the following elements:

- Radiological environmental monitoring
- Thermoluminescence dosimetry

Through the five regional offices, the NRC contracts with 34 states to carry out independent environmental monitoring. The purpose of these contracts is to provide independent measurements of the concentration of radioactive material and radiation levels in the environs of NRC-licensed facilities. These programs provide independent duplication of certain parts of the licensees' environmental monitoring efforts. The results of the states' monitoring program are also used to check the accuracy of licensees' monitoring programs and to aid in verifying the ability of the licensee to measure radioactivity in environmental media. The state provides the NRC with an annual report of all offsite analyses with comparisons to similar analysis by the respective licensee. In the future, results of the state's monitoring program will be available for distribution annually.

The NRC has contracted the U.S. Department of Energy, Idaho Operations Office (DOE/ID) Radiological and Environmental Sciences Laboratory (RESL) to provide the regions with a much broader base of radioisotopic measurement capability traceable to the National Institute of Standards and Technology (NIST). With RESL's support, the regional laboratories determine if licensee measurements are accurate and make independent radiological assessments of situations to provide or justify the basis for NRC action. It is through this program that the regions maintain their credibility with the licensee. RESL also provides analytical sample measurement expertise for samples requiring lengthy chemical separation or alpha spectroscopy that is beyond the capabilities of the regions. RESL has also provides analysis for state contractors when evaluation of unique samples is required.

NRC regional inspection activities relating to environmental areas are as follows. Approximately once per year the licensee's radioanalytical laboratory programs are inspected. The scope of the inspection encompasses organization, procedures records, quality control, laboratory facilities and confirmatory measurements. NRC conducts this inspection with the use of a mobile laboratory. Effluent stream samples are split with the licensee and analyzed in their laboratory and in the NRC mobile laboratory. A high level of quality control is maintained over the NRC mobile laboratory with traceability to NIST. Split sample results are intercompared and applied to an agreement/disagreement criteria. The purpose of this type of inspection is to assure that licensees are making valid radioanalytical measurements. Details of this inspection activity are discussed in NRC Inspection Procedure 84725.

The NRC also operates mobile laboratories which are used during plant inspections to confirm, using split samples, the accuracy of the licensee's radiological monitoring program. The mobile labs are deployed to licensee facilities every other year. The mobile labs also provide prompt and accurate

assessments during accidents situations. Licensees are also required to participate in an interlaboratory comparisons program which provides an independent check of the accuracy and the precision of the measurement of radioactive material in environmental samples.

The NRC is also able to utilize a state-of-the-art aerial radiation surveillance program operated under the DOE by EG&G/Las Vegas. The Aerial Measuring System (AMS) consists of rotary and fixed wing aircraft-equipped gamma ray and neutron detectors. In the East, the AMS is based at Andrews Air Force Base, Maryland, and in the West at Las Vegas, Nevada. The AMS program is directed toward obtaining surveys of gamma data (gross and spectral) that can be used to assess changes in environmental levels of radiation from nuclear tests and operation of nuclear facilities. Preoperational surveys are made at all nuclear power reactor sites, and these surveys are periodically updated at 3- to 5-year intervals for most facilities. A periodic update survey to measure environmental buildup of long-lived radionuclides is made for all nuclear facilities in order to determine the baseline for post-nuclear incident restoration.

The NRC has contracted with Brookhaven National Laboratory (BNL) to compile information obtained from the licensee in the semiannual report for all reactor facilities. The information presents principal radionuclides released in power plant effluents for all light-water reactors. This report is published annually as NUREG/CR-2907 and is widely distributed.

In response to the concerns expressed about the magnitude of the collective dose received by the general population residing near commercial power plants, the NRC contracted with Pacific Northwest Laboratory (PNL) to undertake a series of studies to estimate radiation dose commitments to the population produced by radionuclides releases from commercial light-water power reactors. Fifty-year dose commitments for a 1-year exposure from both liquid and atmosphere releases is calculated for four population groups (infant, child, teenagers, and adult) residing between 2 and 80 km from each of 71 sites. Data from NUREG/CR-2907 are used to carry out the calculation. This report is published annually as NUREG/CR-2850.

EG&G/Idaho, under contract to the NRC, supports licensing activities by providing technical reviews of licensees' revision to Offsite Dose Calculations Manual (ODCM) upon request from the Commission. These NRC-conducted programs, along with the licensees to provide monitoring of releases, yield accurate information for assessing the effect of nuclear power plants on the population and environment.

After the TMI accident, the NRC determined that relying solely on licensee estimates of population exposure during an accident situation was unacceptable. The NRC decided to develop its own program to provide the data needed to independently assess the radiological impacts of an accident. The Direct Radiation Monitoring Network is operated by the NRC through the Facilities Radiological Protection Branch in Region 1, which has implementation responsibility. All data processing and reporting of results is handled by the TLD Laboratory in Region 1. At most sites, deployment and collection of TLDs is performed by state personnel under contract with the NRC. The network provides continuous measurements of the ambient radiation levels around NRC-licensed power reactor facilities. The network also provides the NRC a means of identifying any deficiencies in the licensees' monitoring program. Results of this program are published quarterly in NUREG-0837.

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## USCEA/NIST MEASUREMENT ASSURANCE PROGRAMS FOR THE RADIOPHARMACEUTICAL AND NUCLEAR POWER INDUSTRIES

Daniel B. Golas<sup>(1)</sup>

*Abstract* - In cooperation with the U.S. Council for Energy Awareness (USCEA), the National Institute of Standards and Technology (NIST) supervises and administers two measurement assurance programs for radioactivity measurement traceability. One, in existence since the mid 1970s, provides traceability to suppliers of radiochemicals and radiopharmaceuticals, dose calibrators, and nuclear pharmacy services. The second program, begun in 1987, provides traceability to the nuclear power industry for utilities, source suppliers, and service laboratories. Each program is described, and the results of measurements of samples of known, but undisclosed activity, prepared at NIST and measured by the participants are presented.

NIST has more than 100 Cooperative Research and Development Agreements (CRADAs) in which individual companies work directly with NIST researchers to achieve joint goals. NIST collaborates on two such programs with the USCEA: one is a measurement assurance program for the radiopharmaceutical industry; and one is a measurement assurance program for the nuclear power industry.

The USCEA is the commercial nuclear power industry's national communications and information association. Its main function is to disseminate information on nuclear power to the public using print and TV advertisements, and through several publications. USCEA represents a broad spectrum of nearly 400 companies in the U.S. and overseas (USCEA 1990). USCEA is involved with these measurement assurance programs only as a service to their members. The companies that were interested in starting these measurement assurance programs already belonged to USCEA, and this provided a common infrastructure already in place to hire people to work at NIST to provide the services that they desired.

The companies that started these programs did so because the programs that already existed did not fully meet their needs. There are several advantages that these programs have that others do not. First, they provide the participants with a direct link of their measurements to the national standards. Second, the participants can receive the kind of radionuclides that they want, at the activity levels that

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<sup>(1)</sup> U.S. Council for Energy Awareness, Washington, D.C.

they want, in the mixtures that they want, with the interferences that they want, and in the form that they want. Third, the participants find the program cost effective because the cost of the program is offset by savings on customer complaints due to improved measurement accuracy, as in the radiopharmaceutical program, or the need to perform fewer audits on source suppliers, as in the power plant program. Finally, the participants have a ready access to an independent third party if a measurement dispute occurs between participants or between a participant and a customer or regulator.

The remainder of this paper will briefly describe both measurement assurance programs, concentrating on four areas: 1) the participants in each program; 2) the standards and other services they receive; 3) how the programs are supported financially; and finally, 4) a summary of the results of the participants measurements compared to the NIST values. Previous publications (Golas and Calhoun 1983; Hoppes 1990; Gray, Golas, and Calhoun 1990) can provide more detail on certain aspects of each program.

The radiopharmaceutical Measurement Assurance Program (MAP) began in the mid 1970s. The current participants are shown in Figure 1. Together, the participants represent the entire spectrum of the radiopharmaceutical industry from bulk radiochemical suppliers, to radiopharmaceutical manufacturers, to a radiopharmacy that provides unit doses of radiopharmaceuticals in the form of filled syringes and capsules to hospitals for individual diagnostic tests and treatments. The Food and Drug Administration also participates through an interagency agreement with NIST.

Figure 2 shows the distribution schedule for 1993. Ten different Standard Reference Materials (SRMs) are produced yearly, one per month, except for May and November. During these two months, known as "open months," participants can elect to submit samples to NIST for verification. This allows participants to get traceability on radionuclides that are important to them but are not on the schedule during the year, or to perform a test on some measurement problem that they may have had. Except for  $^{99m}\text{Tc}$ , each monthly distribution consists of a high-level and a low-level SRM. The high levels are in the 0.1 to 10 GBq (multi-millicurie) range of activity while the low levels are usually from 5 to 800 MBq (one to several hundred microcuries). All the standards are in the form of 5 milliliters of solution in standard NIST glass ampoules except for  $^{133}\text{Xe}$ , which is provided in a 5-mL Pyrex<sup>®(1)</sup> ampoule. The lack of availability of high-level standards was one of the original reasons for beginning the program. The other major reasons were that some standards that were needed by the industry were not available in the form they required and some decay data were not well known. This was a source of problems many years ago because if one company or supplier based an activity value on a measurement of a gamma ray with a poorly known probability per decay, and someone else used another method of calibration such as an ionization chamber, the activities sometimes did not agree. Because some of these companies purchased large quantities of radioactive material from each other, the economic consequence of being different from each other by a few percent was one of the major incentives for starting this program.

The SRMs are supplied to the participants with the NIST-measured activity undisclosed, or as "blinds." The participants make their measurements on the sources and report their results on a questionnaire supplied with the source. After the questionnaire is received and analyzed, NIST issues

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(1) The mention of commercial products does not imply recommendation or endorsement by NIST, nor does it imply that the products identified are necessarily the best available for the purpose.



a report which compares the participant's measurement with the NIST value, providing traceability for the measurement. Usually, one beta-emitting SRM is issued every year, but this year it was replaced by  $^{153}\text{Sm}$ . Also,  $^{57}\text{Co}$  was substituted for  $^{51}\text{Cr}$  which has been prepared in July during the last several years.

The low-level standards are also available for sale to the general public, and the sale of these help to support the operation of the program. The SRMs provided to the public are not available as "blinds." The participants that created and support the program believe that allowing non-participants to receive the SRMs as blinds would remove the incentive to belong to the program. This would result in the program collapsing from lack of support, with the result that the SRMs might not be available at all since NIST would have no resources available to prepare the radiopharmaceutical SRMs.

Figure 3 is a diagram of how the radiopharmaceutical program operates. First, the participants meet at an annual steering committee meeting to decide on the 10 standards that are to be prepared the following year. The participants decide on which high- and low-level SRMs they want to receive and they pay USCEA for these along with a participation fee, currently \$2,000. The \$2,000 participation fee covers the cost of the two "open months," which are provided to the participants at no additional charge. Participants must also pay to belong to USCEA. USCEA charges a membership fee which is different for each company, based on a formula that takes into account the company's income related to the nuclear industry. This charge is separate from these measurement assurance programs and is charged whether or not they belong to one of these programs. The minimum membership fee is \$500 and increases from there. USCEA uses the money collected from the participants to pay NIST for the SRMs provided to the participants and for supplies and raw materials needed to prepare the standards. This last category currently costs approximately \$10,000 per year. Payment for the SRMs provided to the participants is done quarterly. The research associates are employees of USCEA and are paid as any other USCEA employee. USCEA employs two research associates, one for each of the measurement assurance programs. However, all the work for both programs is done cooperatively, so the costs are averaged between both programs. As previously mentioned, the low-level SRMs are advertised for sale to the general public to help support the program. The current price for these is \$378 each. From the sale of each one of these, \$115 is kept by NIST and the rest is returned to USCEA, also quarterly. The other arrows on the diagram indicate that the research associates help NIST personnel with some of their needs in the production of other SRMs, and NIST personnel assist the research associates with the preparation of the radiopharmaceutical SRMs, as well as the sources for the power plant program. All parties are in agreement that the contributions of each balance out.

The newest USCEA measurement assurance program was set up with the nuclear power industry in 1987. The reasons for setting up this program were similar to those of the other program, namely that other programs that existed at the time didn't fully meet their needs. This program was modelled after the radiopharmaceutical program but has several differences. The first difference is that there are different categories of participants rather than just one: source suppliers, service laboratories, and utility participants. Each participant pays the same amount each year, currently \$8,500 but depending on the category, receives different benefits. Currently, there are 25 participants. Most, if not all, of the domestic source suppliers are members, only a small sample of service laboratories, and approximately one-quarter of the utilities that operate nuclear power plants, representing approximately one-third of all the commercial nuclear power plants currently in operation. A list of current participants is shown in Figure 4.

All of the participants receive six sources per year that are prepared by the research associates in cooperation with NIST. The distribution schedule for 1993 is shown in Figure 5. In addition to the samples prepared at NIST, there are "open months" similar to the case for the radiopharmaceutical program. In this program the companies pay for what are known as "credits" that the participants may use for having their own sources verified. Each credit is worth \$1,000, which is the same as the cost of the "open months" for the radiopharmaceutical participants. However, in this case the samples that are submitted to NIST for verification are measured by NIST personnel instead of the research associates, and depending on the category of the participant, they may send in different numbers of sources each year. The source suppliers may have up to twelve credits worth of calibrations performed, service laboratories may have up to three credits worth of calibrations performed, and utilities get one credit, or may instead receive up to \$1,000 worth of other NIST SRMs sent to them at no charge during the year or receive extra samples of the six sources prepared at NIST. Incidentally, if a participant submits a sample that requires a greater amount of time to calibrate, such as mixed gamma sources or beta calibrations, the participant is usually charged more than one credit for the measurement.

The six sources per year prepared for this program are distributed approximately one every other month. In general, these sources are at lower activity levels than the radiopharmaceutical SRMs, but higher than those available in some other cross-check programs, so that the uncertainties due to background corrections will be minimized. The sources are supplied as a solution in our standard 5-mL ampoules, as simulated 47-mm-diameter filters for gamma-ray measurements, as rectangular paper filters when the filters must be dissolved for analysis, and as 33-mL double-stopcock glass spheres for gases. The gas sources are purchased from another supplier and calibrated at NIST. As in the radiopharmaceutical program, the participants decide on the sources that they want prepared at an annual steering committee meeting. At the beginning of the program, the sources were prepared as single radionuclides with no interferences so that the participants could use them to check their calibrations and measurement techniques. In subsequent years, the matrices have become more complex with mixtures of multiple radionuclides, often with interferences added, and sometimes without the radionuclides in the mixtures revealed so that the participants must also identify the radionuclides as well as report on the quantities measured. In 1993 we are returning somewhat to more single radionuclides and simpler mixtures to allow the participants that were not in the program the first two or three years to use the sources to also calibrate their measuring systems.

Figure 6 is a diagram of how this program operates. In general, it is much the same as the radiopharmaceutical program, but simpler. First, there are no SRMs available for sale to the public, so the box that was at the bottom of Figure 3 is not there. Consideration was given to offering these sources as SRMs when the program was first set up, but several source suppliers thought that this would put NIST in direct competition with them and they did not want that. Because there are no SRMs for sale, there is no arrow for money to be returned to USCEA. Consequently, the participants pay more for the sources and calibrations that they do receive. More money is also paid to NIST because NIST does more work for the many calibrations that are performed for the source suppliers and service laboratories. Last fall a review of the program was made by representatives of the steering committee. After looking over the amount of work that was being performed, they recommended to the steering committee that the addition of a technician was appropriate to help in the production of the sources and assist NIST personnel in making measurements on the submitted samples. The technician is supported one-half by USCEA and one-half by NIST. USCEA employs the technician, the same as the research associates. NIST supports their half by charging less for the credits provided to the source suppliers and service laboratories up to an amount equal to one-half of

the technician's salary. The steering committee has also paid additional money to NIST over the past few years to have special calibrations made that probably would not have been done without outside support. Because of this additional support, NIST has developed new calibrations for  $^{141}\text{Ce}$  and  $^{144}\text{Ce}$ , and calibrations for both a mixed gas and solid Marinelli beaker geometries.

A closer look at the benefits received by each category of participant reveals that the utility participants subsidize the majority of the open month "credits" used by source suppliers. The service laboratories are roughly in balance and get back what they put in. The participants set the program up this way from the start. One of the reasons advanced for creating this program was that if the utilities were confident that the source suppliers were making sources that were traceable to NIST then they would have to perform fewer or no audits on the source suppliers and everyone would save money and time.

Figure 7 is a histogram of the results received from the radiopharmaceutical participants since the beginning of the program. The histogram represents 1410 results submitted from June 1975 through January 1993. Approximately 84% of the results are within  $\pm 5\%$  of NIST, and about 96% are with  $\pm 10\%$  of NIST. Of the 1.3% that are greater than  $\pm 20\%$  of NIST, most of these are results from the earlier years. It is likely that measurements have improved over the years, but it is also possible that companies that made poor measurements just stopped submitting results. Because the people that receive these SRMs know that they are making their measurements in order to become traceable to NIST, one could assume, certainly not "incorrectly," that these results represent "best efforts." It can only be guessed how well others not in the program routinely do. It is reassuring to see that the values are centered around the NIST value, proving that no matter what the different participants use to calibrate their measuring equipment, on the whole they agree with NIST.

The histogram from the nuclear power program, Figure 8, shows the results categorized by the type of participant. There are a total of 1388 results for sources distributed from June 1987 through October 1992: 1061 from utility participants; 230 from source suppliers; and 97 from service labs. The results are only for the distributed samples and not from sources submitted to NIST for verification from the source suppliers and service laboratories. The histogram shows a wider dispersion from NIST than the radiopharmaceutical results, but this should not be surprising. In almost all cases, the sources measured by the power plant participants were more complex, often with intentional interferences included to make the measurements difficult. In many cases, the samples required chemical processing before measurements could be performed, unlike the radiopharmaceutical SRMs. In spite of all this, the results still fall around the NIST value.

As well as providing calibrated sources and SRMs to the participants in these programs, another task is to assist any participant with any problems they may have encountered in measuring these sources. This is done directly, if someone calls with a problem, but participants can also obtain useful information from the summaries that are issued after everyone has submitted his result. The summary for the radiopharmaceutical program is fairly simple. For each radionuclide distributed, a list is generated which shows all deviations from the NIST value for each participant, and the type of detector used to make the measurement. An average difference of the results from the NIST value is also generated so individual participants can compare their difference from everyone else. The results are reported with the companies unidentified. The summary provides only a few details for this program, because it would be easy to identify a company after a while if too much of the measurement technique was described.

For the power plant program, the summary provides more detail. For each result, the difference from the NIST value, the type of detector used, a short description of how the source was measured is provided as shown in Figure 9. Again the participants are not identified. The sample number of the source is shown, but this is randomly assigned to each participant before the sources are shipped. The reason the sample number is provided is so that multiple results for one source can be identified. Some participants submit individual questionnaires for several different detectors or geometries for one source so that they can obtain traceability for particular geometries or measuring equipment. Also included is a graph of the participant's results compared to the other results submitted, as shown in Figure 10. The vertical line above and below the participant's value indicates the one sigma uncertainty on the participant's result as reported on the questionnaire. The long, horizontal dashed lines mark the NIST combined standard uncertainty.

In conclusion, this has been a summary of both USCEA/NIST measurement assurance programs: who the participants are; how the programs are structured; how the programs are financed; and how well the participants are making their measurements. The programs fill a need in each industry and the participants find the programs useful, necessary, and cost effective. They also have an opportunity each year at the annual steering committee meeting to change their programs to adapt to any changes that are taking place to meet new demands or regulations.

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**PARTICIPANTS IN THE NIST/USCEA  
RADIOACTIVITY MEASUREMENTS  
ASSURANCE PROGRAM FOR THE  
RADIOPHARMACEUTICAL INDUSTRY**

**Bristol-Meyers Squibb Company**

**Cintichem, Incorporated**

**DuPont Merck Pharmaceuticals Company**

**Hybritech, Incorporated**

**Mallinckrodt Medical, Incorporated**

**Medi+Physics, Incorporated**

**Nordion International, Incorporated**

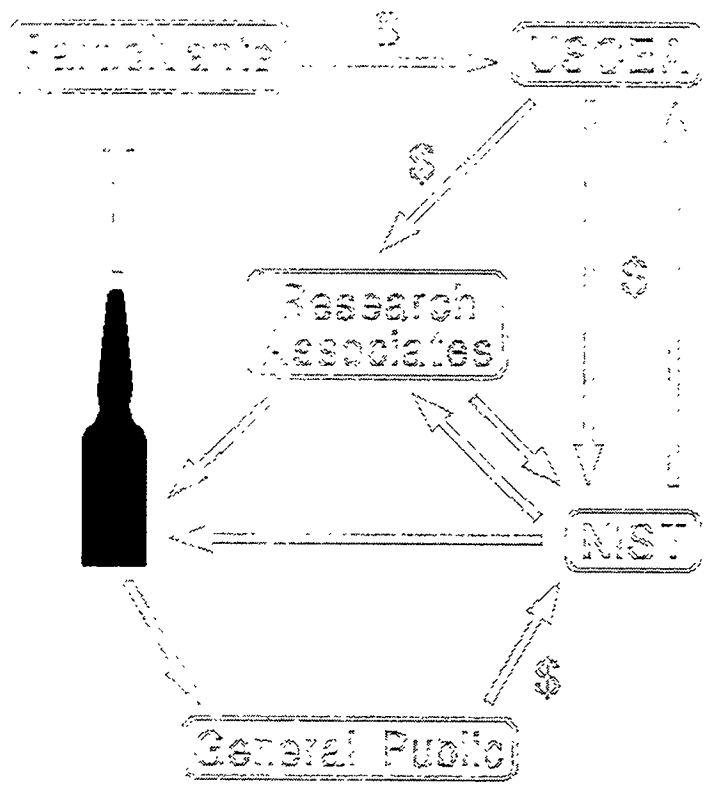
**Syncor International Corporation**

*Figure 1*

# 1993 DISTRIBUTION SCHEDULE FOR THE NIST/USCEA RADIOPHARMACEUTICAL PROGRAM

<u>Month</u>	<u>Radionuclide</u>	<u>High Level</u>	<u>Low Level</u>
January	$^{131}\text{I}$	750 MBq (20 mCi)	25 MBq (700 $\mu\text{Ci}$ )
February	$^{99}\text{Mo}$	3 GBq (80 mCi)	75 MBq (2 mCi)
March	$^{133}\text{Xe}$	7.5 GBq (200 mCi)	750 MBq (20 mCi)
April	$^{67}\text{Ga}$	375 MBq (10 mCi)	20 MBq (500 $\mu\text{Ci}$ )
May	OPEN	n/a	n/a
June	$^{201}\text{Tl}$	225 MBq (6 mCi)	35 MBq (900 $\mu\text{Ci}$ )
July	$^{57}\text{Co}$	75 MBq (2 mCi)	10 MBq (250 $\mu\text{Ci}$ )
August	$^{111}\text{In}$	375 MBq (10 mCi)	20 MBq (500 $\mu\text{Ci}$ )
September	$^{99\text{m}}\text{Tc}$	7.5 GBq (200 mCi)	n/a
October	$^{153}\text{Sm}$	375 MBq (10 mCi)	20 MBq (500 $\mu\text{Ci}$ )
November	OPEN	n/a	n/a
December	$^{125}\text{I}$	750 MBq (20 mCi)	6 MBq (150 $\mu\text{Ci}$ )

*Figure 2*



*Figure 3 - Diagram of Radiopharmaceutical Program Operation*

**PARTICIPANTS IN THE NIST/USCEA  
RADIOACTIVITY MEASUREMENTS ASSURANCE  
PROGRAM FOR THE NUCLEAR POWER INDUSTRY**

**SOURCE SUPPLIERS**

**Amersham Corporation  
Arlington Heights, Illinois**

**Analytics, Incorporated  
Atlanta, Georgia**

**Isotope Products Laboratories  
Burbank, California**

**North American Scientific  
North Hollywood, California**

**The Source  
Santa Fe, New Mexico**

**TMA/Eberline  
Albuquerque, New Mexico**

**SERVICE LABORATORIES**

**Atlan-Tech, Incorporated  
Roswell, Georgia**

**Battelle, Pacific Northwest Laboratories  
Richland, Washington**

**Institute of Nuclear Energy Research  
Lung-tan, Taiwan**

**Sciencetech, Incorporated  
Gaithersburg, Maryland**

**UTILITIES**

**American Electric Power Service Co.  
Bridgman, Michigan**

**Babcock & Wilcox  
Lynchburg, Virginia**

**Baltimore Gas and Electric Company  
Lusby, Maryland**

**Commonwealth Edison Company  
Maywood, Illinois**

**Connecticut Yankee  
East Hampton, Connecticut**

**Houston Lighting & Power Company  
Houston, Texas**

**New York Power Authority  
White Plains, New York**

**Northeast Nuclear Energy Company  
Waterford, Connecticut**

**Omaha Public Power District  
Fort Calhoun, Nebraska**

**Pacific Gas & Electric Company  
San Ramon, California**

**Pennsylvania Power & Light  
Berwick, Pennsylvania**

**Portland General Electric  
Rainier, Oregon**

**Public Service Electric & Gas  
Hancocks Bridge, New Jersey**

**Rochester Gas & Electric Company  
Ontario, New York**

**Yankee Atomic Electric Company  
Bolton, Massachusetts**

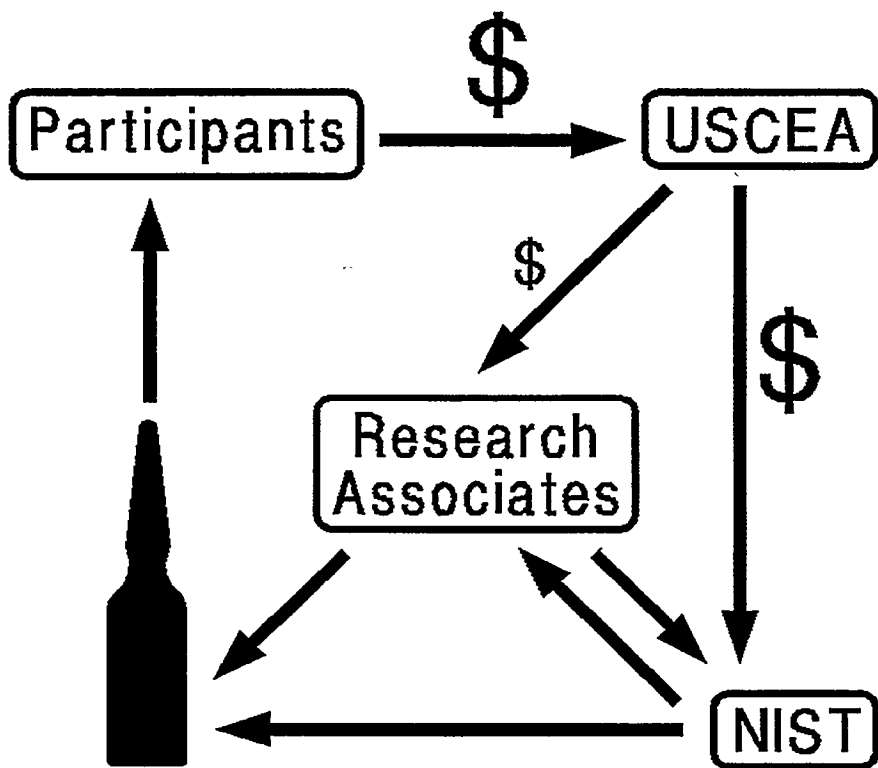
*Figure 4*



# 1993 DISTRIBUTION SCHEDULE FOR THE NIST/USCEA POWER PLANT PROGRAM

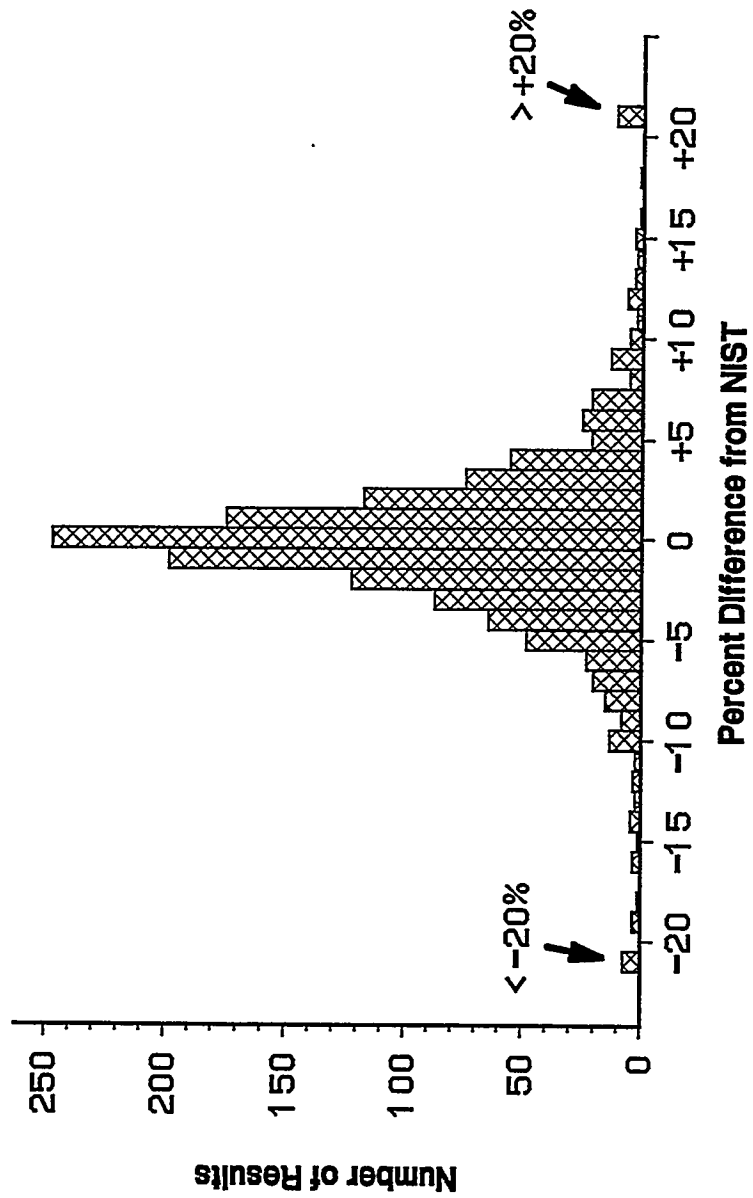
<u>MONTH</u>	<u>RADIONUCLIDE(S)</u>	<u>SOURCE DESCRIPTION</u>
February	$^{131}\text{I}$	37 kBq or 3700 kBq in 5 mL of solution
April	$^{60}\text{Co}$ , $^{65}\text{Zn}$ , $^{134}\text{Cs}$ , $^{137}\text{Cs}$	100-200 Bq each, on an air filter
June	$^{230}\text{Th}$	Less than 200 Bq in 5 mL of solution
August	$^{110\text{m}}\text{Ag}$	$5000 \text{ } \mu\text{s}^{-1}\text{g}^{-1}$ in 5 mL of solution
October	$^{85}\text{Kr}$ , $^{127}\text{Xe}$ , $^{133}\text{Xe}$	1 MBq, 100 kBq, and 200 kBq, respectively, in a 33 mL double-stopcock borosilicate-glass sphere
December	$^{55}\text{Fe}$	37 kBq in 5 mL of solution

*Figure 5*



*Figure 6 - Diagram of Program Operation*

**Radl pharmaceutical Program Results**  
June 1 975 through January 1 993



*Figure 7 - Histogram of the Results Received from the Radl pharmaceutical Participants*

**Power Plant Program Results**  
 June 1987 through October 1992

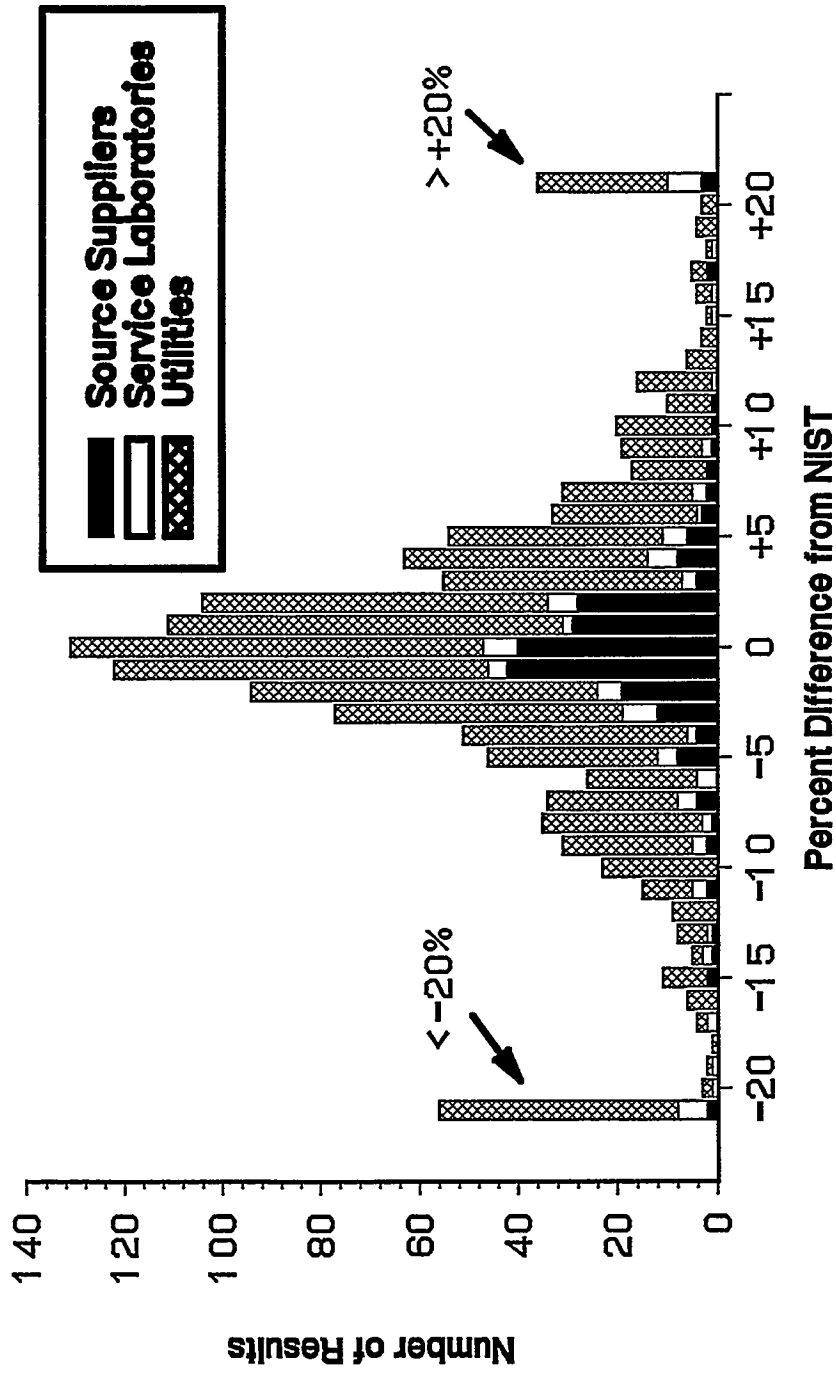


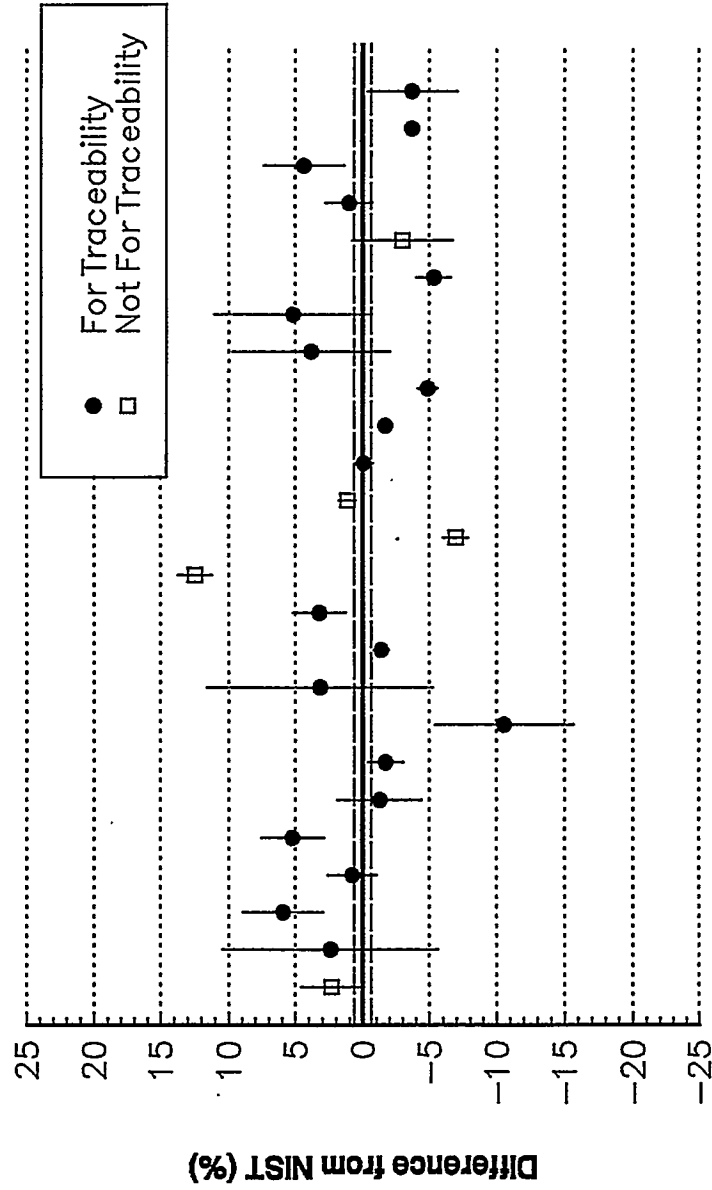
Figure 8 - Histogram from the Nuclear Power Program

ZN-65 June 1992 (8731)			Results by Date (As of 5/19/93)	
Sample	% Difference	Detector Used	Summary of Source Preparation Technique Used	
* 1	2.31	Ge(Li) detector	Counted three times "as is" for 1000 seconds each 4 cm from detector.	
2	2.39	High purity Ge detector	Counted "as is" for 30 minutes.	
6	5.92	Ge(Li) detector	Counted "as is" 2 cm from Ge(Li) crystal.	
9	0.77	Ge(Li) and HPGe detectors	Counted "as is" six times: two shelf positions on three detectors.	
10	5.22	High purity Ge detector	Sample measured "as is" in 47 mm filter geometry for 600 seconds.	
11	-1.29	Intrin. Ge closed-end coaxial	Filter was counted "as is" on four detectors at approximately 6 cm from detector for approximately 3000 seconds each.	
13	-1.73	High purity Ge detector	Sample measured "as is" at distances from 50 to 100 mm from detector. Counting times $\geq 54,000$ seconds.	
14	-10.56	Germanium detector	Counted "as is" four times, 2,000 seconds at 10 cm and 10,000 seconds at 20 cm on two detectors.	
15	3.16	High purity Ge detector	Sample was placed in planchet and counted "as is" 2000 seconds each at an elevated geometry on three different detectors.	
20	-1.39	Intrin. Ge closed-end coaxial	Counted "as is" 11 times, 900 seconds each measurement, 43 mm from detector.	
21	3.21	High purity Ge detector	Filter was counted "as is" one time each on five detectors at 2.91" from detector, 10,800 to 60,000 second counts.	
* 22	1.13	Intrinsic Ge detector	Placed in 2" stainless steel planchet and counted "as is" on shelf #2.	
* 22	-6.96	Intrinsic Ge detector	Placed in 2" stainless steel planchet and counted "as is" on shelf #2.	
* 22	12.46	Intrinsic Ge detector	Placed in 2" stainless steel planchet and counted "as is" on shelf #2.	
23	-0.08	High purity Ge detector	Counted "as is" 20 times on two detectors for 2000 seconds each.	
24	-1.70	Low-energy Ge detector	Sample measured "as is" in petri dish placed about 1.5" above detector end cap. 14,400-second count time.	
25	-4.88	Intrin. Ge closed-end coaxial	Counted "as is" 11 times, 900 seconds each measurement 43 mm from detector.	
27	5.16	Reversed electrode Ge detector	Filter was placed in a petri dish and counted three times "as is" at approximately 13 cm above detector end cap.	
27	3.82	Reversed electrode Ge detector	Filter was placed in a petri dish and counted three times "as is" at approximately 13 cm above detector end cap.	
28	-5.34	High Purity Ge detector	Sample measured "as is" in planchet. Counted at 3, 6, and 10 cm.	

NOTE: \* means that the result was not counted for traceability.

Figure 9 - USCEA/NIST Radioactivity Measurements Assurance Program for the Nuclear Power Industry

**Zn-65: June 1992**  
Mixed  $\gamma$  Filters



**Vertical Lines Represent Participant's 68% Confidence Interval**

*Figure 10 - Graph of Participant's Results Compared to the Other Results Submitted*

# **QA/QC PROGRAMS - DOSIMETRY**

Session Chair  
**Marty Rozenfeld**  
St. James Hospital and Health Center

Thursday  
March 18, 1993

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# A QUALITY AUDIT PROGRAM FOR EXTERNAL BEAM RADIOTHERAPY

William F. Hanson<sup>(1)</sup>  
Marilyn Stovall<sup>(1)</sup>

*Abstract* - For more than 25 years, the University of Texas M. D. Anderson Cancer Center has had a quality audit program using mailed dosimeters to verify radiation therapy machine output. Two programs, one compulsory and one voluntary, presently monitor therapy beams at more than 1000 megavoltage-therapy facilities. A successful program requires two major components: a high-precision thermoluminescent dosimeter (TLD) system and dedicated staff that interact closely with the users to resolve discrepancies. The TLD system, the logistics used, and the human interaction of these programs are described. Examples show that the programs can identify major discrepancies, exceeding 5%, as well as discrepancies as small as 3%.

## INTRODUCTION

The University of Texas M.D. Anderson Cancer Center has two highly successful, mailed quality audit programs for external beam radiation therapy using TLDs. Together, the programs annually monitor approximately 10,000 beams at more than 1000 institutions throughout the United States, Canada, and a few other countries. Originally, the programs were designed to yield a check of beam calibration for photons only. The programs were expanded in the early 1980s to include calibration checks and spot checks of radiation energy for electron therapy beams. The first program, now called Radiation Dosimetry Services (RDS), is a voluntary for-fee service with TLDs mailed at the frequency specified by the institution, typically monthly, quarterly, semiannually, or annually. The second program is through the Radiological Physics Center (RPC), a National Cancer Institute (NCI) grant-supported program. This program is compulsory for all megavoltage facilities that participate in NCI-funded cooperative clinical trials involving radiation therapy. Since one program is voluntary and the other compulsory, the experiences of each differ.

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## ANECDOTAL CASES

Table 1 presents a series of typical cases where the TLD program identified a dosimetry problem; the institution corrected the problem and the TLD results improved. The programs originally were designed to identify major dosimetry problems, i.e., discrepancies exceeding 5%. Cases 1 through 4 illustrate that the programs have been effective in identifying these problems. Furthermore, cases 5 and 6 show that the TLD programs have also flagged discrepancies of 3% or less, which motivated the local physicist to identify minor dosimetry problems. Cases 5 and 6 are from the voluntary program, where the physicist welcomed an opportunity to resolve the problem. Data in Figure 1 are for a participant in the compulsory program; this is an unusual situation, presently under investigation. The TLD/INST ratio has varied from 0.96 to 1.08. Twice during the last several years, the results were outside our criteria; however, repeat TLD results were within the criteria. This situation was ultimately flagged when the physicist returned the TLDs unirradiated along with a nasty note. After investigation, the RPC physicist discovered that the institution's physicist calibrated his beam either at d-max or at depth (5 cm) in polystyrene. Whenever he calibrated at d-max, the TLD results were within 2%; when he calibrated at depth, the results varied considerably and changed dramatically following the RPC dosimetry review visit in 1989. Following several phone calls, the physicist at the institution is now willing to help us resolve the discrepancy.

In order for the quality audit program to distinguish minor problems, the TLD system must have high accuracy and high precision. In addition, a program must have a high sensitivity provided by the management of the program. Therefore, in addition to the high-quality technical system, human interaction gives our programs a sensitivity that we believe is unparalleled. This presentation will describe briefly the physical aspects of the TLD system and then discuss the most significant component, the human element.

## DOSIMETERS

We have chosen lithium fluoride (LiF) TLDs in throw-away powder form. A large crystal (approximately 4 kg) of LiF doped with magnesium and titanium (TLD 100) is grown by Harshaw/Bicron, crushed, annealed, and homogenized before shipment to the Radiation Detection Company. The Radiation Detection Company dispenses the powder into capsules containing approximately 30 mg of powder each.

In the past, approximately 100,000 capsules have been made from a single LiF crystal. The most recent crystal is larger and the amount in each capsule is smaller, so we anticipate having 200,000 capsules from the present batch. There are two major reasons that we use powder: better precision and simpler bookkeeping. With the high level of quality control at Harshaw and the Radiation Detection Company, we are assured of a precision of  $\pm 1\%$  (1 standard deviation for a single capsule irradiated with a known quantity of cobalt-60) for the entire batch of 100,000 to 200,000 samples without a sophisticated bookkeeping system.

## IRRADIATION PHANTOMS

The choice of irradiation phantom is not as simple as the choice of dosimeter. Table 2 lists the criteria for a phantom for a mailable quality audit program. Three types of phantoms have been used for mailed TLD systems. The International Atomic Energy Agency (IAEA) has chosen a water phantom and mails only a small TLD holder to be set in a pail of water (Svensson et al. 1990). Each

participant provides the pail; therefore, cost to the IAEA is minimal for constructing the phantom and shipping the TLD holder. From 1974 to 1986, most of the Centers for Radiological Physics (CRPs) used plastic full-scatter phantoms with the TLD located at depth in the plastic (Samulski et al. 1981). This phantom is expensive to build and to mail; however, it is probably the best for reproducibility of set-up. For the RPC and RDS system, we have chosen a compromise; these phantoms are discussed by Kirby et al. (1986). For photons an acrylic miniphantom block contains TLDs located in the center of the block with full build-up thickness on all sides. The block is placed on a "scatter free" platform as shown in Figure 2. For electrons the phantom is an acrylic cube approximately 9 cm on a side. TLDs are placed near d-max to check output and in the fall-off region to verify radiation energy, as illustrated in Figure 3. Our system allows precise positioning of the TLD and easy set-up by the user. For redundancy, three dosimeters are placed at each depth of measurement and a "reading" is the average of the three dosimeters.

## READER SYSTEM

Our experience is that the simplest reader system is the best, and we presently use the Teledyne Model 7300 reader. To improve precision, we dispense approximately 20 mg of powder and mass the powder using a Mettler microbalance. The reader and balance are interfaced to a computer; the glow curve is displayed on the computer screen and integrated using our own software. Bar coding helps manage the paper work associated with receipt of dosimeters, reading of the samples, and progress of reports.

## COMMISSIONING

At the present time, a single batch of TLD powder lasts 18 to 30 months. Table 3 lists the steps required to commission a batch prior to use. In chronological order, we first verify that the batch has acceptable uniformity of response. At least 100 capsules are chosen randomly from various packets of dosimeters, irradiated to the same cobalt-60 dose, and read in several reading sessions. One standard deviation of 1% or better is considered acceptable. We then check the linearity of response over the range of dose from 100 to 500 cGy. Typically we find supralinearity of response, with approximately an 8% change in relative sensitivity, from which a linearity correction is derived. Fading of response with time is also a consideration. We apply a two-step correction factor, assuming that the TLDs fade 0.1% per day for the first 50 days and do not fade thereafter. Data confirming the applicability of this assumption are shown in Figure 4 for Batch B/90. We are presently considering a non-linear fit to the fading data. To minimize the magnitude of the corrections, we ask institutions to irradiate near 3 Gy and we use standards irradiated within a few days of the irradiation of the mailed TLD.

The most difficult characteristic to determine is the energy dependence. This correction accounts not only for the energy response of the TLD but also for the different scattering conditions of the various blocks. Figure 5 shows data for TLD Batch 6/88 for photons from cobalt-60 to 25-MV x-rays. We use block-specific corrections, so the correction factors take on a step function shape as shown. Similar data are collected for electrons. The energy correction factors are based on measurements at depth in a water phantom, using a cylindrical ion chamber and calculations recommended by the AAPM Task Group 21 calibration protocol (AAPM 1983), normalized to unity at cobalt-60 energy.

Characteristics of a new batch of TLDs are similar to previous batches. Comparison across batches provides additional assurance that commissioning procedures are correct and shows the value of having long experience with the same type of TLD.

## PRECISION

Our TLD system is based on calibration with a cobalt-60 beam. All calculations are based on the AAPM TG-21 calibration protocol (AAPM 1983), using ion chambers with calibrations directly traceable to National Institute of Standards and Technology. We therefore consider the accuracy of the system to be in compliance with national standards. Thus, we will consider here only the precision, or reproducibility, of the TLD system. In a recent publication, Kirby et al. (1992) discuss the theoretical precision of the TLD system in detail. As suggested earlier, 1 standard deviation of a single reading is typically  $\pm 1\%$ . Theory predicts that combining errors for linearity, fading, and energy dependence yields a variance of approximately 3% for a single dosimeter, which results in an uncertainty of 5% at a confidence level in excess of 90% for a single data point (three dosimeters).

The above theoretical assessment of precision is verified by our experience. Since 1984, approximately 4% of all photon checks and 7% of all electron checks are outside our  $\pm 5\%$  criteria. Some of these checks (1%-2%) represent real discrepancies in calibration or set-up, with the remainder apparently due to statistical variations. In addition, ion chamber measurements by the RPC at the participating institutions have a standard deviation of the ratio RPC/INST of 1.8% for photons and 2.2% for electrons. The standard deviation of the TLD/INST over the same period of time is 2.7% for photons and 3.0% for electrons. This 1% increase in uncertainty is also consistent with the theoretical estimate of precision.

The effort required to maintain the precision of the TLD system is illustrated by the fact that approximately one-third of our TLD are used in quality control of the system.

## LOGISTICS

Communication with users is paramount to the success of a mailed quality audit program and it is the human factor that makes our programs effective. Our for-fee program (RDS) requires that primary communication be with a physicist rather than a machine technician, therapist, or radiation oncologist. This assures that the physicist is in charge of irradiation of dosimeters, receives the reports, and resolves discrepancies.

The instructions and forms to be completed by the user must be short, simple, and concise. The RDS program limits the instruction to one page each for electrons and photons, while the RPC combines instructions for both photons and electrons into a two-page instruction sheet. We have found a diagram to be particularly helpful, such as seen in Figures 2 and 3.

We recommend the following for irradiation of the dosimeters:

- TLD set-up should closely simulate patient set-up.
- Irradiation time should be similar to times used clinically. (We use 300 cGy.)

- TLDs should be irradiated by the physicist in collaboration with the therapist and/or radiation oncologist who normally treat the patient. It is particularly important for a consultant physicist to ensure that the oncologist and therapist are using the calibration information in a manner consistent with the measurements.
- TLDs should be irradiated using the output used clinically. (This is a corollary to the preceding comment.)

The data sheet completed by the user also should be short and concise. Information should include:

- Institution, therapy-beam identification, and name of the person irradiating the TLDs, including his telephone number.
- Identification of the phantom blocks.
- TLD irradiation condition: field size, distance to platform, monitor (time) setting.
- Dose to the reference point. It should be clear that this does not relate to the dose given to the TLDs but rather to the absorbed dose at the institution's standard reference point (e.g., dose at d-max for standard SSD). One or two redundant questions are helpful to identify potential misunderstandings.
- Information concerning the calibration protocol used.

The report issued to the physicist includes the following:

- Date of irradiation.
- Identification of institution, therapy unit/beam, and person irradiating the TLDs.
- Distance to the reference point.
- Institution's stated dose and dose measured by TLD.
- Ratio of absorbed dose determined by TLD and that stated by the institution, expressed as TLD/INST.
- Date TLD read.
- Signature of the reviewing physicist.

The report also includes the following qualifying statements which state the intent of the program, the precision of the program, and the criterion for a satisfactory check.

**THIS INFORMATION SHOULD BE USED ONLY AS A CHECK OF MACHINE OPERATION AND NOT AS A MACHINE CALIBRATION, nor as an alternative to frequent calibrations by a qualified physicist.**

The variance of the dose determined by a single TLD is less than 3%. The average of readings for three dosimeters, therefore, has an uncertainty of 5% at a confidence level in excess of 90%. This analysis does not include uncertainties in the institution's irradiation technique. A typical therapy unit may have increased uncertainty.

Agreement within 5% is considered a satisfactory check.

## **RESOLUTION OF DISCREPANCIES**

The TLD results are processed by a computer and a calculation sheet is generated, as well as the report to the user. Each calculation sheet and report is reviewed by a dosimetrist and/or a physicist. The review verifies that the TLD was set properly and that we interpreted the institution's data correctly in our calculations. The TLD history for the therapy unit is also printed on our calculation sheet so that our reviewer can look for changes in the results or identify trends.

Interaction with the institution's physicist is necessary to resolve discrepancies. If the TLD results disagree with the institution's stated dose by more than 5%, we contact the institution by phone immediately. We also contact the institution by telephone if there appears to be a trend developing or if there are questions regarding irradiation set-up or the institution's data. During the telephone conversation, we discuss the set-up, the possibility of extraneous radiation to the TLD, whether the physicist measured the machine output prior to irradiation of the TLD, the details of his calibration procedures (phantom, distance, chamber, etc.), and the actual numbers used in the calculation of dose. Frequently, the origin of the discrepancy is discovered in this telephone conversation. Regardless of whether we believe the discrepancy has been resolved, a repeat TLD is sent to verify the findings of the telephone conversation. Frequently, we provide the repeat TLD free of charge to the institution.

It is this follow-up phase that is the principal difference between the RDS (voluntary) program and the RPC (compulsory) program. Those institutions who subscribe to the program on a voluntary basis tend to be more willing to search for the problem during the telephone conversation. If the RDS dosimetrists cannot resolve the discrepancy, the problem is turned over to an experienced physicist for further investigation. In a very few cases, intractable discrepancies have been resolved by one of our physicists visiting the institution, with an ion chamber and water phantom in order to verify the machine calibration.

The RPC (compulsory) program finds it more often must perform on-site reviews of institutions to resolve discrepancies. Five to eight institutions are visited per year as a result of unresolved TLD discrepancies. Approximately 50% of the time, the ion chamber verifies the TLD results. The remainder of the time, the ion chamber measurements have no apparent relation to the TLD results. However, of 93 institutions visited for an intractable TLD problem, only one institution has had a repeat of the TLD discrepancy. This suggests that the institutions have changed their TLD irradiation or dose calibration procedures without informing us.

We believe strongly that it is this follow-up procedure that gives our quality audit programs their good track record.

## CONCLUSIONS

The University of Texas M. D. Anderson Cancer Center in Houston, Texas, has two quality audit programs to verify calibration of photon and electron radiotherapy beams using mailed TLDs. These two programs presently monitor therapy units at more than 1000 megavoltage-therapy facilities in the U.S., Canada, and a few facilities elsewhere in the world. These programs require a high-precision mailed TLD system using powdered LiF in acrylic phantoms. The variance of a single dosimeter is less than 3%, and a single data point (three TLDs) has a precision of  $\pm 5\%$  at a greater than 90% confidence level.

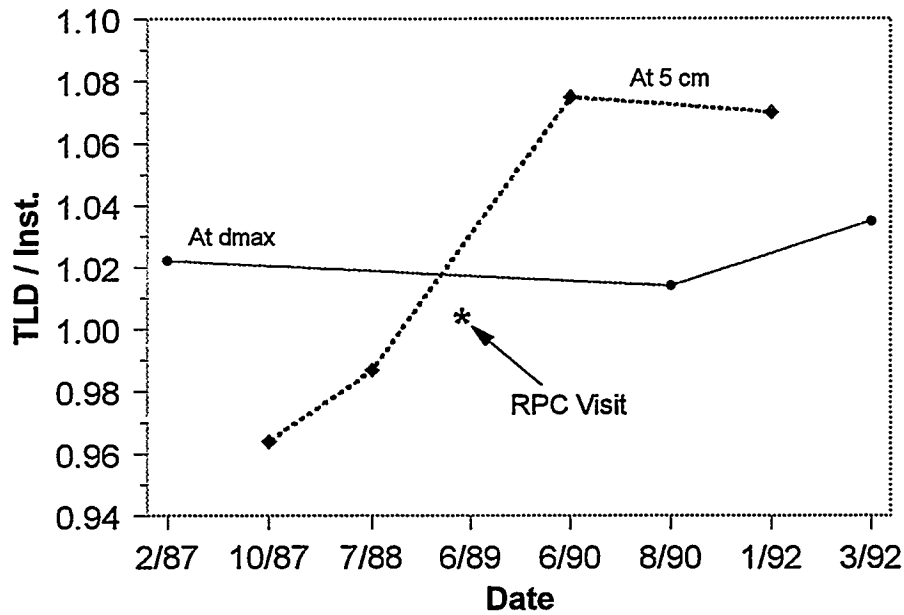
In addition to the high precision of the physical system, an extensive follow-up program by telephone to resolve discrepancies is in place. Examples show that the program can detect major discrepancies ( $> \pm 5\%$ ); it may also suggest discrepancies as low as 3%. Collaboration with the local physicist helps him to find and resolve discrepancies.

Our programs are unique, both in volume and longevity. The large volume helps to maintain the precision and to keep cost at a reasonable level. A long history obviously gives the benefit of experience, but also allows us to compare present results with previous data. We are always alert to ways to improve our programs; however, the impact and appropriateness of even minor changes are carefully considered before they are implemented.

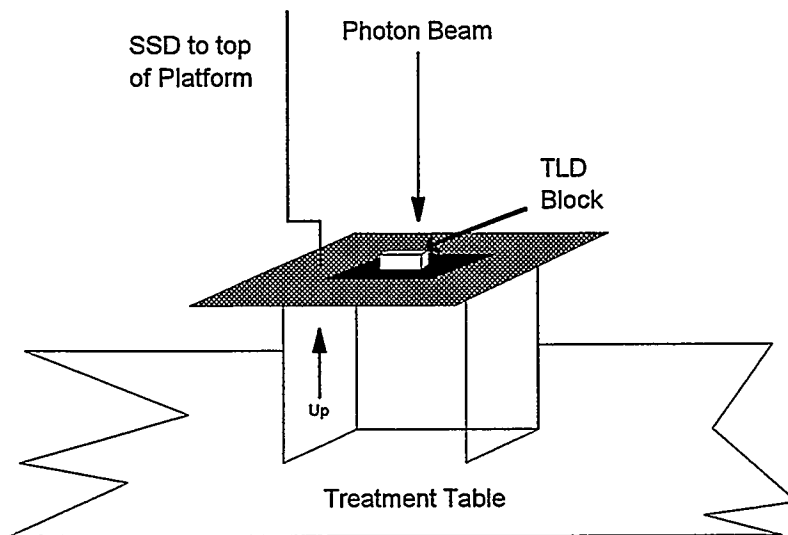
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## Consistency of TLD - Inst #1

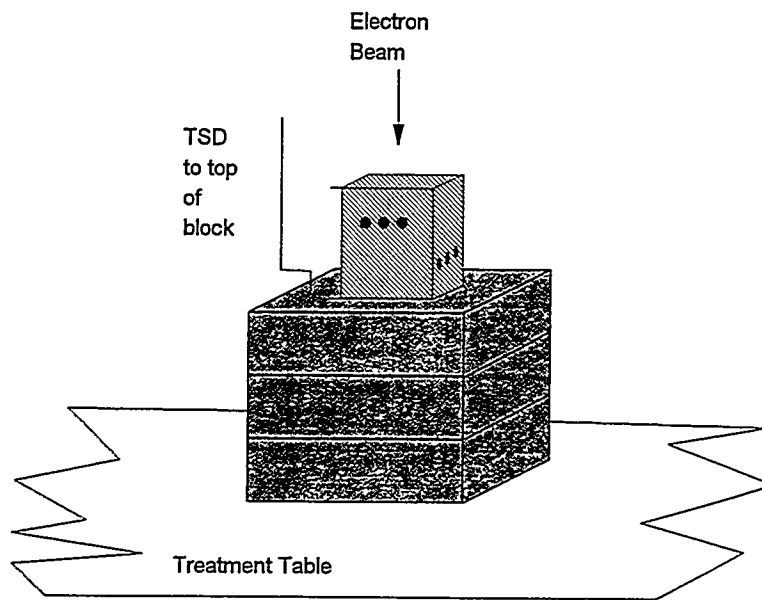


*Figure 1 - Results of six mailed TLDs over a 5-year period on a 6-MV x-ray beam. The results of ion chamber measurements by the RPC on this beam in 1989 are also included. The results appeared to have wide variations until the trend was identified. The institution calibrated the beam either by measurements at  $d$ -max or a 5-cm depth in a polystyrene phantom. The disparity between the two is presently under investigation.*

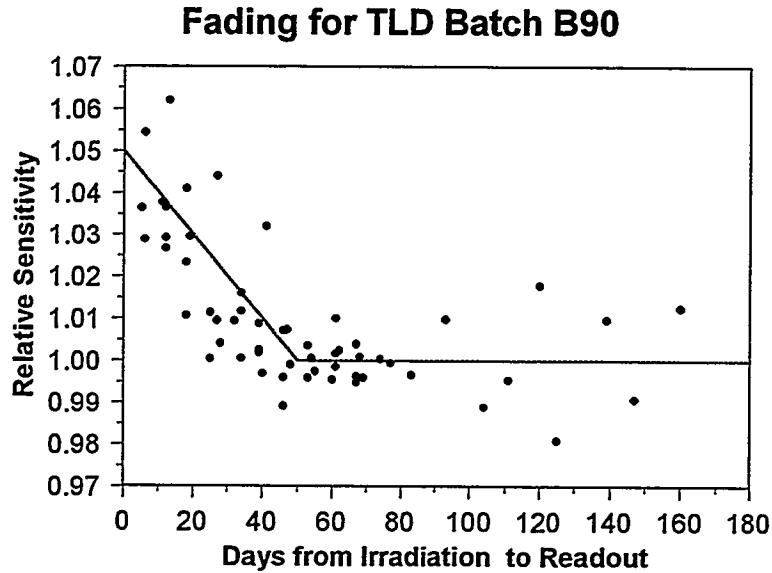


*Figure 2 - Schematic diagram of the photon irradiation geometry for the TLDs. The TLD block is energy dependent and just large enough to assure full build-up in all directions. The platform is of 1/8" acrylic and therefore nearly scatter-free.*





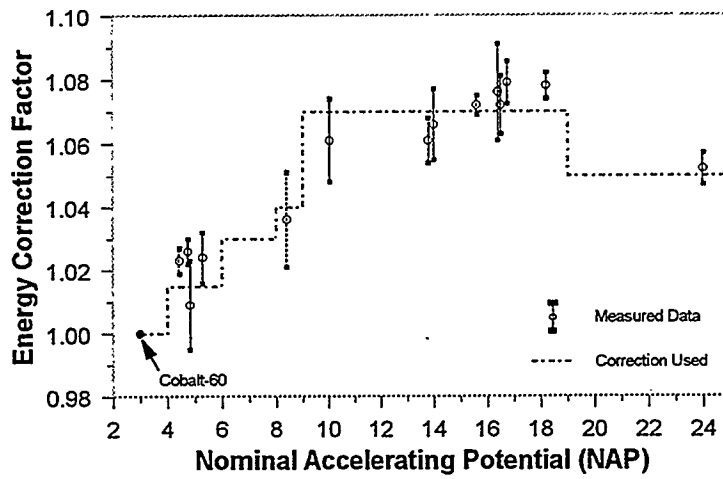
**Figure 3 - Schematic Diagram of the electron irradiation geometry. The block holding the TLDs is shown partially withdrawn to demonstrate the location of the two sets of TLDs, one near  $d$ -max and one in the fall-off region.**



**Figure 4 - Fading characteristics of the TLDs. Data points are represented, as well as the theoretical curve (solid line). Our TLDs fade approximately 0.1% per day for the first 50 days.**

# Energy Dependence

TLD Batch 6/88



*Figure 5 - Dependence of the TLD system on the photon energy. Various irradiation blocks are used over a range of energies. The correction factor used is specific to the block and is indicated by the dashed line.*

*Table 1 - Typical Discrepancies Identified by the Mailed TLD Programs and Subsequently Resolved by the Institution.*

Case No.	Initial TLD/Inst	Problem Corrected	Final TLD/Inst
1	1.17	Physicist trained chief tech to do daily output checks on 20-MV x-ray beam. Tech set up 100-cm SSD, not 100-cm SAD. Calibration depth = 7 cm.	~1.00
2	1.06	On first check, physicist was filling water tank to wrong mark on the water phantom.	1.00
3	0.90 on 7e <sup>-</sup> 0.94 on 11e <sup>-</sup>	For electrons, institution calibrated with a horizontal beam; TLDs were irradiated with a vertical beam. Severe angular dependence of output was discovered.	
4	1.06 to 1.07	Institution's constancy check meter had failed to detect change in machine output.	1.01
5	1.03 to 1.04	After TLD/Inst. was near 1.00 for 2 years, it jumped to 1.03 and 1.04 for 2 TLDs. Physicist discovered his correction for solid water was multiplied, not divided.	1.00
6	1.03	After TLD/Inst. was near 1.00 for 2 years, it jumped to 1.03. Physicist "corrected a problem with the timer error."	~1.00

*Table 2 - Criteria in the Choice of a Mailable Phantom.*

Criteria	Preferred Phantom
Minimum cost	Water
Easily mailable	Water or plastic
Ease of use	Plastic
Reliable set-up	Plastic

*Table 3 - Commissioning of a TLD Batch*

Calibrate with cobalt-60 as "standard."

Check response for:

- Uniformity across batch
- Linearity
- Fading with time
- Energy dependence

# MAMMOGRAPHY ACCREDITATION PROGRAM

Pamela Wilcox<sup>(1)</sup>

## BACKGROUND

In the mid-1980's, the movement toward the use of dedicated mammography equipment provided significant improvement in breast cancer detection. However, several studies demonstrated that this change was not sufficient to ensure optimal image quality at a low radiation dose. In particular, the 1985 Nationwide Evaluation of X-ray Trends (Reuter 1987) identified the wide variations in image quality and radiation dose, even from dedicated units.

During this time period, the American Cancer Society (ACS) launched its Breast Cancer Awareness Screening Campaign. However, there were concerns about the ability of radiology to respond to the increased demand for optimal screening examinations that would result from the ACS program. To respond to these concerns, the ACS and the American College of Radiology (ACR) established a joint committee on mammography screening in 1986. After much discussion, it was decided to use the ACR Diagnostic Practice Accreditation Program as a model for the development of a mammography accreditation program. However, some constraints were required in order to make the program meet the needs of the ACS. This voluntary, peer review program had to be timely and cost effective. It was determined that the best way to address these needs would be to conduct the program by mail. Finally, by placing emphasis on the educational nature of the program, it would provide an even greater opportunity for improving mammographic quality.

The result of this effort was that, almost six years ago, in May 1987, the pilot study for the ACR Mammography Accreditation Program (MAP) began, and in August of that year, the first applications were received. In November 1987, the first 3-year accreditation certificates were awarded.

## GROWTH

Since that time, the program has grown rapidly, from an average of 50 new applications per month in 1988 to over 350 per month in 1992. It has now leveled off to an average of 150 as we reach saturation. Table 1 lists the top ten states in the accreditation program, based upon the number of units that have applied from that state. It is apparent from this list that the highest level of activity

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(1) American College of Radiology.

comes from states with legislation, such as Michigan, or with very active ACS Breast Cancer Screening Programs, such as California, and other states where accreditation is tied to reimbursement. In states where there has been a high degree of media interest, such as New York and Illinois, there is a proportional level of participation in the MAP.

It is interesting to note the contrast between the states that are ranked highest by volume and the states that are ranked highest in relation to the percentage of total units accredited. For example, California is number one by volume, but it is in the bottom third of the states by percentage of units accredited, with only 49%.

Table 2 illustrates the distribution of applications for accreditation broken out by type of facility. Over the course of the past 4 years, 86% of the applications have been from hospitals and private radiology offices, with the remaining 14% distributed among the other categories. The College is currently modifying the application database to further expand the categories to differentiate between such facilities as free-standing breast cancer screening centers and primary care offices.

## **COMPONENTS AND CRITERIA**

The ACR MAP incorporates four phases: the site survey questionnaire, clinical image evaluation, dose and phantom image evaluation, and processor quality control (QC). The first phase of the process requires submission of detailed information regarding the practice attributes and the equipment specifications. The comprehensive site survey questionnaire includes data on practice settings, staff qualifications, CME in mammography, technical specifications of equipment, QC procedures, quality assurance mechanisms, patient education patient assessment, and follow-up mechanisms.

The physicians interpreting mammograms must be board-certified in diagnostic radiology by the American Board of Radiology (ABR) or the American Osteopathic Board of Radiology, or have two months of training in reading mammograms, with instruction in medical radiation physics, radiation effects, and radiation protection. The physician must interpret or review a minimum of 480 mammograms per year. Furthermore, the physician must also have 40 hours of CME credit, specifically in mammography, prior to accreditation, and must participate in at least 15 hours of training every 3 years thereafter.

A medical physicist is qualified to practice diagnostic radiological physics in mammography if he/she is certified by the ABR in Diagnostic Radiological Physics or Radiological Physics, or is certified by another certifying body recognized by the ACR in an equivalent specialty area. However, until January 1, 1996, the following alternative interim criteria will also be deemed to qualify an individual for the practice of diagnostic radiological physics in mammography. Until January 1, 1996, a medical physicist will be considered qualified to practice diagnostic radiological physics in mammography if he/she meets all of the criteria below:

- Holds a Master of Science, a Master of Arts, or a higher degree in an appropriate field from an accredited institution. Appropriate fields include physics, applied physics, radiological physics, biophysics, health physics engineering, and public health when the Bachelor's degree is in a physics science.
- Has had training in biological sciences.

- Has had at least 1 year of training in medical physics in the area of diagnostic radiological physics.
- Has had at least 2 years of experience in conducting mammography equipment performance evaluations.

In addition to either set of qualifications listed above, any individual practicing diagnostic radiological physics in mammography shall have received at least 15 hours of documented continuing medical education, specifically in mammography physics, in the last 3-year period.

The radiologic technologists performing the mammographic examination must be either certified by the American Registry of Radiologic Technologists (ARRT) or licensed by the state. In addition, the technologist must have special training in mammography. The Committee on Mammography Accreditation also strongly recommends that all technologists obtain ongoing continuing education in mammography.

The program requires that facilities have their equipment calibrated at least annually by a medical physicist. A copy of the physicist annual testing and calibration report must be submitted with the application and annually during the 3-year interval between accreditations. It is recommended that this physicist be certified by the ABR in radiologic physics or diagnostic radiologic physics.

The criterion for equipment requires that the mammography unit be specifically designed for mammography, with an appropriate device for compression and a removable grid. Focal spot size should be 0.6 mm or less, with 0.3 being the preferred size for film/screen mammography. The focal-object distance should be 50 cm or more.

A documented QC program must be in place which follows the procedures and testing frequencies described in the ACR Mammography Quality Control Manuals (McLelland et al. 1990). A copy of the QC log for one month must be submitted with the application.

The second phase involves a quantitative assessment of image quality and mean glandular breast dose through the use of a specially designed breast phantom which simulates a 4.5-cm compressed breast. To receive accreditation, the phantom image must demonstrate the four largest fibers, the three largest speck groups, and the three largest masses in the RMI-156 mammographic phantom. Each phantom image is scored independently by three medical physicists. At the time this phantom exposure is made, a dosimeter is placed directly on the phantom to obtain a correlation of dose and image quality. The mean glandular dose must be less than 400 mrad for Xerox and 300 mrad for film/screen. Each of these criteria has equal weight in the evaluation; thus, failure on one item equals failure to receive accreditation.

Clinical image evaluation is assessed in the third phase of the accreditation process. This evaluation is carried out by two radiologists involved in active mammographic practice. The facility must submit two sets of original patient images: one from normal fatty breasts and one from normal dense breasts. Each set of films is analyzed with regard to positioning, compression, exposure level, resolution, contrast, noise, exam identification, and artifacts. As part of the educational focus, reviewers frequently make suggestions for improving the quality of the clinical images even if the images pass the evaluation.

Finally, the facility must submit one month's data for the processor QC evaluation. After the initial data was assessed from the accreditation program, it became apparent that processor variability has a very significant impact on image quality. Therefore, in June 1990, processor QC was added as the fourth component in the MAP. These data must reflect monitoring of developer temperature, film speed, contrast, and base plus fog for every day that mammographic images are developed. The resultant measurements must demonstrate adequate processor QC.

If a given unit meets all of the criteria, accreditation is granted for 3 years. However, to ensure that image quality is maintained over the course of the accreditation, each facility is required to submit an annual update regarding their status. Included in this update should be any changes in staff or equipment as well as copies of their equipment, and processor QC logs for one month and the physicists' annual report. If there are significant changes, additional testing may be required.

Further validation checks have been instituted in the form of on-site visits and random film checks. On-site surveys are performed in approximately 24 sites per year across the country. The survey team consists of a radiologist who is a clinical image reviewer, a physicist who is a phantom image reviewer, and a staff person from ACR headquarters. Random film checks require that the facility submit a set of clinical images and a phantom image from a date that we designate, as well as current processor QC data.

## **RESULTS OF THE PROGRAM**

Since the program's inception through March, 10,037 of the estimated 11,000 to 12,000 mammographic units in the United States have applied for accreditation. Of that number, 7,530 units have completed the evaluation process and a total (including initial and re-application) of 6,520 units have passed.

On the initial attempt, 5,196 units (69%) passed the accreditation. Of the 2,334 units that initially did not meet the criteria, 1,966 have re-applied. After correcting the indicated deficiencies, 1,324 units have completed and passed that process. It is interesting to note that, over the course of the accreditation program, the initial failure rate has remained constant at between 29% and 32%. Table 3 reflects the distribution of the failures for the initial evaluation. Remember that processor evaluation only became a part of the assessment in June 1990, so it is difficult to assess the real impact of processor QC on the failure rate.

As indicated in Table 3, dose has not been a significant cause of failure. Even if the accreditation program was to revise its dose criteria to reflect those defined in the current HCFA regulations, the overall failure rate would only increase by 1%. A film/screen non-grid dose limit of 100 mrad would cause an additional 25 failures. A dose limit of 300 mrad for film/screen grid would add another 24 units. Table 4 illustrates the distribution of measured dose broken out by type of image receptor. Table 5 takes the category of image receptor and shows the phantom image scores for each test object. It is apparent that there is still a wide variability in dose and image quality within these more finite groups.

## **OUTGROWTHS**

Additional analysis of the data available in the accreditation program related to specific equipment may provide clues to improve image quality, while providing a tighter range of patient dose.



Although not originally set up as a research project, the accreditation program now has outcome data on over 7,500 units providing the most extensive database on mammography currently available in the U.S. Through a cooperative agreement with the center for Disease Control (CDC), a major initiative is underway to use these data to guide technical advancement in mammographic equipment as well as to assess educational needs and opportunities for personnel involved in breast cancer detection. This cooperative agreement was established to address activities in mammography QC. Listed below are some of the activities being assessed as a part of this agreement:

- Standardized equipment specifications
- Standardized technique factors
- Dedicated processors
- Routine continuous QC programs
- Phantom and clinical image correlation research
- Outcome database
- Professional

The increased focus on early breast cancer detection in the U.S. and the tremendous response to the MAP brought attention to other related areas that need to be addressed. In fact, the criteria established in the MAP were incorporated into standards for the performance of screening mammography that were passed at the September 1990 annual meeting of the ACR Council.

Until recently, there has been a lack of information on how to perform QC testing in mammography. In November 1990, the ACR, with support from the ACS, published Mammography Quality Control Manuals for the radiologist, the technologist, and the physicist. They were updated and revised in August 1992. These manuals provide a step-by-step procedure with indicated frequencies and performance criteria. They have been distributed to all facilities that have participated in the MAP. They are also available for purchase and are being used as the basis for the professional educational modules being developed through the CDC/ACR cooperative agreement. Effective January 1, 1992, compliance with the tests and frequencies described in these manuals will become a criterion of the MAP.

Another area of concern has been the lack of standardized terminology and reporting systems in mammography. This lack of consistency sometimes makes reports confusing to the referring physician and makes data collection difficult. By standardizing these procedures, we can begin to collect better national statistics on breast cancer incidence and early detection. The College has a committee that has been working on this effort with participation from the National Cancer Institute, CDC, Center for Devices and Radiological Health, American College of Surgeons, American Medical Association, and American College of Pathologists. This document has just been completed and is available for distribution.

## CONCLUSION

Despite its voluntary nature, the ACR MAP has participation from almost 90% of all the mammography units in the country. The media and women recognize it as a means of obtaining a quality mammogram. However, more remains to be done if we are to have a real impact on breast cancer detection. The accreditation program, itself, must undergo continuous assessment to ensure that it responds to improvements in technology. In fact, ongoing data analysis will provide

information regarding trends and opportunities to further the quest for quality. Much has been accomplished over the past 6 years, but even more remains to be done.

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*Table 1 - Top 10 States Applying for Accreditation*

State	Applied	Accredited
California	850	557
New York	589	401
Pennsylvania	533	379
Florida	491	305
Texas	469	249
Ohio	448	300
Michigan	433	309
Illinois	397	271
New Jersey	280	182
Massachusetts	268	208

*Table 2 - Application Rate by Type of Facility*

	Percent Applications
Hospital	43%
Private Office	33%
Multispeciality Clinic	14%
Mobile Unit	4%
Multiple Settings	1%
Other	5%

*Table 3 - Analysis of Failures*

<b>Cause of Failure</b>	
Clinical images	1289
Phantom image	396
Dose	53
Clinical and phantom image	209
Clinical images and dose	29
Clinical images and processor	111
Phantom and processor	16
Phantom and dose	7
All	10

*Table 4 - Average Glandular Dose by Type of Image Receptor*

<b>Image Receptor</b>	<b>Mean</b>	<b>Median</b>	<b>Range</b>
Film/screen, non-grid	76	62	12 - 225
Film/screen, grid	129	122	15 - 599
Xerox	290	278	56 - 890

*Table 5 - Average Phantom Image Scores by Type of Image Receptor*

Unit and Object	Mean	Median	Range
Film/screen, non-grid			
Fibers	4.00	4.0	2.2 - 5.0
Specks	2.95	3.0	2.0 - 4.2
Masses	3.53	3.7	1.3 - 4.3
Film/screen, grid			
Fibers	4.40	4.3	0.8 - 6.0
Specks	3.34	3.3	2.0 - 5.3
Masses	3.71	3.8	1.0 - 4.8
Xerox			
Fibers	4.59	4.7	3.5 - 5.8
Specks	3.19	3.2	2.0 - 4.8
Masses			

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# INSTRUMENT PERFORMANCE EVALUATION

K. L. Swinth<sup>(1)</sup>

*Abstract* - Deficiencies exist in both the performance and the quality of health physics instruments. In the early 1980s, recognizing the implications of such deficiencies for the protection of workers and the public, the U.S. Department of Energy (DOE) and the U.S. Nuclear Regulatory Commission (NRC) encouraged the development of a performance standard and established a program to test a series of instruments against criteria in the standard. The purpose of the testing was to establish the practicality of the criteria in the standard, to determine the performance of a cross-section of available instruments, and to establish a testing capability. Over 100 instruments were tested, resulting in a practical standard and an understanding of the deficiencies in available instruments. In parallel with the instrument testing, a value-impact study clearly established the benefits of implementing a formal testing program. An ad hoc committee also met several times to establish recommendations for the voluntary implementation of a testing program based on the studies and the performance standard. For several reasons, a formal program did not materialize. Ongoing tests and studies have supported the development of specific instruments and have helped specific clients understand the performance of their instruments. The purpose of this presentation is to trace the history of instrument testing to date and suggest the benefits of a centralized formal program.

## INTRODUCTION

Radiation protection instruments play a central role in the protection of the workers and the public. Instruments are needed for more than just quantitating the amount of radiation: they are necessary to detect the mere presence of radiation. Our natural senses provide us with semi-quantitative information about a number of hazards, such as sound level, hydrogen sulfide concentration, and light intensity. Unfortunately, the natural senses do not provide information about ionizing radiation. To control radiation exposures proactively requires the use of instruments; they are an essential part of the safety equipment in our industry.

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Passive dosimeters are used as the legal record of radiation exposures, but they provide only retrospective information. Dosimeters are of questionable value for control of exposures, particularly as we restrict exposures to progressively lower levels. Thus, we can expect to see the role of instruments in radiation protection increase. In fact, instruments, in the form of electronic dosimeters, are beginning to supplant passive dosimeters, and it is predicted that this trend will continue (Swinth 1988).

Electronic dosimeters are subject to all of the deficiencies of common radiation detection instruments, plus deficiencies introduced by the microprocessors and their software. As with passive dosimeters, instruments do not respond to radiation in the same manner as the biological systems that we are trying to protect. The instrument measures a physical quantity that we relate to the expected biological response. Moreover, the instrument's radiation response can be affected by the environment in which it is used. Finally, instruments must be designed in a manner that will make them acceptable to the users and rugged enough to operate reliably in typical operating environments.

In selecting instruments for use in a facility, several factors must be considered:

- Environmental conditions (temperature, humidity, radiofrequency interference, etc.)
- Radiation environment (radiation type, intensities, energies, etc.)
- Electronic and mechanical performance (stability, response time, ruggedness, etc.)
- User acceptability
- Calibration and serviceability
- Field testing and procedures
- Cost
- Regulatory requirements.

Unfortunately, the needed specifications for instruments are often not available and, when available, are often not in a format that facilitates comparison with requirements or with other instruments. The specifications are also needed in a format that facilitates acceptance testing.

Testing standards and testing programs are designed to provide the required performance information. The standards provide testing methods (commonality of testing) and performance criteria (specifications). Independent testing using appropriate standards provides uniformity of testing and consistent presentation of results. The purpose of this paper is to review the need for instrument performance testing and developments in this area over the past decade.

In the following sections, the history of instrument testing is examined: from the identification of the need for testing in the late 1970s, through the development of a testing standard, and finally to the present status of a proposed formal testing program and the review of ongoing testing activities.

## **IDENTIFICATION OF NEED FOR TESTING**

The need for formalized testing was initially identified in early acceptance-testing programs at Hanford (Selby 1985). During the purchasing of a "cutie pie" (a model of portable survey instrument [dose rate meter]), out of 500 instruments approximately one third were rejected due to various problems. In another example, during the purchase of 170 beta-gamma air monitors, it was discovered that most of the monitors had various degrees of air in-leakage. Thus, one would not know whether the sampled air came through the sampling tube, through the instrument, through a



leaking fitting, etc. In addition, approximately 50% of these instruments required electronic repairs (Selby 1985). In another case, it was found that less than half of the portable survey instruments at Three Mile Island (TMI) Unit 2 were operational at the time of the March 1979 accident. In at least two instances, individuals failed to leave high radiation areas in the TMI auxiliary building when their radiation survey instruments failed or deflected full scale. In one of these instances, the failure resulted in a whole-body exposure in excess of regulatory limits (Federline and Alexander 1985). In 1983, two overexposures were reported from a radiography source containing 11 Ci of  $^{60}\text{Co}$ . When the source was examined, the survey meter indicated zero in a high-intensity radiation field (Federline and Alexander 1985).

Total instrument failure, particularly an under-response "fall-back" in a high-intensity field, is the most serious consequence of poor instrument design and construction. Other instrument limitations, such as energy dependence, temperature variations, and susceptibility to interference, can cause erroneous readings. Most of these conditions will not lead to serious overexposures and generally will not result in exposures exceeding regulatory limits. However, such failures can cause workers to exceed control limits, which are becoming more restrictive, and cause a general suspicion of the instrument's performance. Agreement between the dose of record from the personal dosimeter and the instruments used for active control of worker exposure will become more important as the limits are lowered.

An important concern in evaluating the performance of instruments is to determine the actual limitations or operational envelope of the instrument. Often, the purchaser of an instrument will spend a considerable amount of time in an informal survey process to evaluate an instrument's performance through the experience of other instrument users. This is not fair to the vendor or to the purchasers because the performance of instruments should be based on factual data and not on experiences related by various workers (Bellian 1971). The limitations of instruments and needs in health physics instrumentation are generally recognized and have been documented in earlier reports (Swinth, Tanner, and Fleming 1985; Selby, Swinth, and Kenoyer 1985).

England, Germany, and France have active testing programs for instruments. More information on these programs can be found in Merwin, Swinth, and Herrington (1986). The performance-testing programs are based on the recognition that radiation protection instruments are safety-related equipment and their performance must be adequate for the measurements that are required. These countries use testing as the basis for selecting and procuring instruments and, in some cases, require certification of instruments.

Several important points can be noted from the foreign testing programs:

- The testing programs do not rely on pass/fail criteria based on international standards.
- There is a consensus that instruments have improved as a result of testing, but quantitative evidence is generally lacking.
- Instruments with unacceptable or poor performance will be directly or indirectly eliminated from the marketplace by the testing programs.
- A regulatory basis for testing exists in several countries.

## DEVELOPMENT AND VERIFICATION OF ANSI N42.17

Although specific deficiencies with instruments are generally corrected following their identification, there is no mechanism to ensure that the knowledge will be transferred to other models of functionally similar instruments. In addition, a formal mechanism to identify expected performance or to establish a performance envelope for instruments does not exist in the U.S.

The concerns related to inadequate instrument performance led the American National Standards Institute (ANSI) to develop a performance standard, ANSI N42.17A, that set forth performance requirements and evaluation procedures for several parameters (criteria) affecting instrument performance (ANSI 1989a). It is necessary to specify both the performance under the interfering condition and the method of testing because variable test conditions will provide different results. For example, fast temperature excursions will not affect performance in the same manner as slow excursions, which permit the entire instrument to equilibrate at each test temperature. The standard was drafted in 1981 by a task group that included manufacturers and users of such instruments, as well as representatives from the regulatory bodies. After several revisions based on comments from a broad spectrum of reviewers, ANSI N42.17A was published in 1989.

The interest of the DOE and the NRC in adequate worker protection resulted in a jointly sponsored study, initiated in 1981, to evaluate draft ANSI N42.17A by testing the response of health-physics instrumentation against the radiological, electrical, mechanical, general, and environmental performance criteria in the draft standard. Drafts of this standard were also evaluated by the Pacific Northwest Laboratory (Swinth and Kenoyer 1985a,b; Kenoyer et al. 1986) to determine the applicability and practicality of the proposed standard and to test a cross section of currently available commercial instruments for conformance to the proposed standard. Test results were presented and discussed at the 1984 workshop, which was a predecessor to this workshop (Swinth and Kenoyer 1985b). The testing helped to identify specific weaknesses in the drafts of the standard and led to several changes in the standard so that, when published, the standard represented the needs of users and the capabilities of available instruments without being overly restrictive. Similar standards have been written for air monitoring equipment (ANSI 1989b) and for an extended range of environmental conditions for survey instruments (ANSI 1989c).

During the development of ANSI N42.17A, the performance requirements were divided into five broad categories. The first category, general characteristics, included general features of the instrument, such as scale markings, units of readout, and status indicators — items that can generally be assessed by inspection of the instrument. The second category contains the electronic and mechanical requirements (response time, stability, etc.) that could influence instrument readings. In the third category, radiation response, requirements for the response to the quantity of interest are provided. This includes the coefficient of variation, response change with changing radiation energy, and change with angle of incident radiation. The fourth category, interfering response, includes the field conditions that may interfere with the instrument's response; the presence of magnetic fields or radiofrequency fields. The last category, environmental factors, includes temperature, humidity, mechanical shock, and ambient pressure. The standard includes 37 specific test criteria. Eleven selected tests are summarized in Table 1 by failure rate. Out of 101 instruments representing 46 models in 26 tests, the overall failure rate, by model, was 25%. This represents data from 479 tests (every test was not applicable to a specific model, nor was every model tested on all applicable tests). Similar results have been obtained for the testing of air monitoring instruments (Kenoyer, Hickey, and Swinth 1993).

The testing indicated that all of the tests are practical; instruments can be designed to meet the various performance criteria. Specific instrument designs had difficulty meeting certain criteria and during the evaluation of the draft ANSI N42.17A, selected criteria were changed to ensure that they were not unnecessarily restrictive and that they represented practical performance requirements. For example, the requirement for a precision of 2.5% in the initial drafts of the standard was found to be too restrictive and in later drafts of the standard was changed to 10%. Instruments using Geiger-Müller (GM) detectors showed poor energy response, but Barclay (1986) has shown that GM detectors can be designed with adequate compensation to meet both the energy and angular response criteria. Poor precision with GM detector-based instruments occurs because of low sensitivity (i.e., cpm/mR) of the detector and can be improved by the selection of the detectors. Alpha survey instruments using air-proportional counters as detectors are sensitive to high humidity and to changes in atmospheric pressure. This sensitivity may not be correctable, but other probes (e.g., scintillation) are available that are not easily influenced by environmental differences. Most of the problems identified are design-related and can be corrected. For application as safety-related instrumentation, such corrections should be incorporated into the instruments. More details on the evaluation of the standard can be found in reports by Swinth and Kenoyer (1985a,b) and Kenoyer et al. (1986).

### VALUE-IMPACT STUDY

In 1985, a study was performed (Merwin, Swinth, and Herrington 1986) to examine what the impact would be if the NRC implemented a U.S. instrument-testing program based on ANSI N42.17A. The costs and benefits of three potential NRC actions that would encourage industry-wide acceptance of ANSI N42.17A were examined. The study indicated that all of the actions would result in substantial benefits to the health of workers and to the nuclear industry. Although the estimated annual costs were wide-ranging (\$700,000 to \$9,700,000), it was shown that a positive net benefit from each alternative method of implementing the standard was highly probable. Also, other users (DOE facilities, foreign users, etc.) would benefit from NRC implementation of the standard, with no corresponding increase in the costs to the nuclear industry.

Although the estimated net benefits from the key methods of implementation were about equal, the authors recommend that the NRC amend 10 CFR 20 to require that licensees purchase survey instruments that have been successfully type tested against ANSI Standard N42.17A. The instruments should be tested against all testing parameters, although instruments would be acceptable for use if they did not pass against parameters that are not applicable to the intended uses of the instrument. The following considerations support the above recommendation and summarize the conclusions of the study:

- Testing each instrument would not be cost effective and would be inconsistent with ANSI N42.17A recommendations.
- A voluntary program without publication of test results would not generate sufficient action by industry.
- Amending 10 CFR 20 is more desirable than creating a regulatory guide because it would ensure sufficient action by the licensees.
- The regulation should not allow limited testing, since the cost of testing against the basic parameters is not significantly lower than the cost of testing against all parameters.

- Acceptance tests on instruments should be performed to assure that the manufacturer's quality control program is maintaining the performance demonstrated in the type tests.
- A grace period of three years should be allowed before the regulation takes effect.
- The regulation should amend the current 10 CFR 20 requirement that adequate surveys be performed.
- Alternatively, NRC-sponsored publication of test results without additional intervention by the NRC would be highly beneficial. This alternative assumes that the tests will be performed and paid for by the vendors.<sup>(1)</sup>

#### **AD HOC COMMITTEE ON IMPLEMENTATION**

In fiscal years 1985 and 1986, an ad hoc committee of the "Joint Planning Committee for Radiation Survey Instruments and Calibrations" met to consider methods of implementing an instrument testing program within the U.S. The committee was established under the auspices of the National Institute of Standards and Technology (NIST). The committee consisted of ten members representing three vendors, government agencies (U.S. Department of Defense [DOD], NRC, DOE), the states (Committee of Radiation Control Program Directors [CRCPD]), and users.

Due to the regulatory climate at the time, the committee focused on the development of a voluntary program. Among considerations favoring a voluntary program were the following:

- A voluntary program with test results available to the public showed a projected cost benefit in the value-impact study (Merwin, Swinth, and Herrington 1986). While not as great as that for a regulation, the cost benefit is greater than that for provision of a certificate based on a type test.
- A voluntary program can be put into operation much faster than a regulation.
- The present version of the ANSI N42.17A standard does not include methodology for their implementation. This methodology would be very difficult to include in a regulation.
- A voluntary program can respond more rapidly to the future needs and changes in the industry.

Based on a voluntary testing effort, the committee developed several recommendations to guide the development of a program. The committee considered several factors, including testing as a function of use, the cost of testing, and the need for retesting. The committee also recommended that an overview committee be established to guide program development by granting approval of testing facilities, resolving disputes, developing priorities for testing, acting as a repository for acceptance-testing information and, finally, developing recommendations to assure continuing performance of tested instruments.

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<sup>(1)</sup> This option would be optimal if the costs of poor instrument performance were significantly overestimated, if instrument testing would not be as effective in reducing these costs as projected, or if the current political climate encourages voluntary action.

Features of the recommended program include:

1. Instrument models used in radiation protection programs shall be type-tested by an approved laboratory.
2. An acceptance test shall be performed at accredited (at least tertiary) facilities.
3. A period of five years shall be permitted between the initiation of the program and the requirement that all new instruments be tested.
4. "Grandfathering" of instruments shall not be permitted. Instruments in use at the time of program initiation would be retired at the end of an eight-year period or tested and upgraded to meet the required performance.
5. Test data shall be the property of the customer. When the test is purchased by the manufacturers, they will be encouraged to make available the test results with their comments. The overview committee will maintain a list of tested instruments.
6. The overview committee will review and accredit all testing laboratories. Due to the amount of radiation testing involved, testing laboratories shall maintain secondary accreditation as an instrument-calibration laboratory through an approved program.
7. Where possible, acceptance-testing and calibration will be done by a laboratory with accreditation by the Health Physics Society (HPS).
8. The type-testing of instruments shall not be performed in a laboratory that is controlled or operated by a manufacturer.
9. A manufacturer with an accredited calibration facility can perform the acceptance-testing of the instrument.
10. Upon initiation of the program, testing priority will be on a first-come, first-served basis. The manufacturer is expected to pay for all type-testing costs, including any necessary retests. The customer is expected to contract for and pay for acceptance-testing costs. The understanding is that the user will bear all these costs through increased instrument prices and operational costs. The manufacturer should establish a quality control (QC) program to ensure that the instruments will perform as demonstrated during the type-testing. Without such cooperation from the manufacturers, the program will not be successful.
11. If an instrument fails a follow-on test (see Section 4), if a user identifies a change in performance of the instrument, or if acceptance-testing indicates a recurring deficiency, the overview committee shall notify the manufacturer and request that the problem be corrected. If the problem could impact the health and safety of radiation workers, the manufacturer shall send a notification to all customers explaining needed upgrades or limitations on instrument performance.

It may appear unusual to permit a manufacturer to perform the acceptance tests (item 9) but not the type tests (item 8). Independent type-testing was preferred because the method of testing and the

presentation of test results can obscure the actual performance of the instrument (Bellian 1971). Independent testing will remove any question about test results. The testing laboratory data can be used to establish specific test geometries and procedures that will assure that performance of an instrument will meet basic type-testing standards. Thus, it appears reasonable to permit manufacturers to use such procedures and to certify the performance of the specific instrument.

Although a considerable amount of effort went into defining the elements of a program, a testing effort was not established. Without some direct motivation (regulation, recognized liability, or outside support and publication of results), a program will not be established. The costs to the vendor preclude any simple voluntary implementation, even though provision of tested, quality products should be the responsibility of the manufacturer.

## **CURRENT TESTING EFFORTS**

Although a formal testing effort has not been established, the instrument performance criteria in ANSI N42.17 standards and the evaluation of instruments created a heightened concern over the performance of instruments. This concern has led to the testing of instruments for specific applications and to some formal tests by vendors. Prototype tests have been performed on pocket alarming dosimeters and on air monitors for vendors, and formal tests have been performed on pocket alarming dosimeters.

Tests of various models of instruments (both prototypes and commercial models) have been performed for DOE laboratories and the DOD to determine the performance characteristics of alpha survey meters, air monitors, hand and shoe counters, pocket alarming dosimeters, and various dose rate meters. These evaluations have been useful in defining the operational characteristics of the instruments and models tested. The tests have often been complemented by subjective field evaluations. Unfortunately, the tests have not been published in the open literature, and thus the current tests do not serve the general community.

The formal testing has led to improvements in instrument performance, but it has also shown that important deficiencies continue to exist in commercial instruments. Some of these deficiencies have been introduced by new technology. The advent of "smart" instruments has led to new problems introduced through the control software. New technology in the form of large-area silicon detectors has led to serious radiofrequency susceptibility, and incorrect application of active air flow monitors has caused serious errors in calculated air concentrations. Some of these deficiencies are beyond the criteria established in the ANSI N42.17 standards and should be considered in future drafts.

Reductions in the influences of common deficiencies (angular dependence, temperature response, and energy response) that limit overall instrument accuracy (Swinth and Hickey 1988; Swinth et al. 1986; Swinth, Roberson, and MacLellan 1988) have not been observed in our testing. Improvements in these areas would improve the overall accuracy of health physics measurements.

## **CONCLUSIONS AND RECOMMENDATIONS**

The ANSI N42.17 standards, draft laboratory procedures, and quality control requirements exist for a formal instrument testing program. The draft implementation guidance, along with the other documentation, can form the basis for a program standard and handbook. The DOE suggests a formal program in its Radiological Control Manual and does note the need for evaluation of

instruments prior to use (DOE 1992). Although several DOE facilities perform some version of instrument evaluation, establishment of a centralized formal program would improve the availability of data. The need for a formal testing program has been demonstrated, and most of the elements have been developed.

Due to the recognized need for tests and evaluation, informal testing has taken place and testing is encouraged by the DOE. It appears that, without direction (requirements) from the policy-making organizations, a uniform program will not be developed. The benefits of a properly structured program include:

- Uniform requirements for instrument performance
- Transfer of knowledge among users
- Improved measurement accuracy
- Elimination of duplication of effort
- Improved product quality and reliability.

Most of the drawbacks to such a program focus on the costs and the potential for restricting access to the market for the smaller manufacturers. Responsibility for tested, quality products should be the responsibility of the manufacturers. Unfortunately, our experience has been that the products are not improving significantly and new technology continues to introduce new problems that are not recognized without testing.

#### **ACKNOWLEDGEMENTS**

The author would like to acknowledge several colleagues who have participated in and promoted the development of the standard, the testing of instruments, and the development of criteria for a program. Although it is impossible to list individual colleagues without the danger of omitting important contributors, J. M. Selby, E. J. Vallario, and R. E. Alexander deserve special acknowledgement for recognizing the need for instrument testing and initiating the standard preparation and testing. Colleagues including J. L. Kenoyer, D. R. Sisk, E. E. Hickey, and G. A. Stoetzel have participated in the testing, while E. H. Eisenhower and S. E. Merwin have assisted with program development. I would also like to acknowledge the assistance of J. A. Heath and D. J. Hanley in the preparation and editing of the manuscript.

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**Table 1 - Pass/fail performance for selected tests on health physics instruments evaluated against ANSI N42.17A requirements.**

Test	Allowable <sup>a</sup> Variation, %	Number of Failures/Number of Models Tested, by Instrument Category		
		Ion Chamber	Geiger- Müller	Alpha
Stability	±6	0/6	1/20	0/7
Accuracy	±15	1/6 <sup>b</sup>	3/11 <sup>b</sup>	NA <sup>c</sup>
Energy Response	±20	1/7 <sup>b</sup>	9/14 <sup>b</sup>	NA
Angular Variation	±20	1/3 <sup>b</sup>	9/11 <sup>b</sup>	NA
Temperature	±15	3/7	0/12	4/6
Humidity	±15	1/5	2/14	2/4
Mechanical Shock	±15	0/3	0/8	0/6
Vibration	±15	1/4	0/7	2/6
Ambient Pressure	±15	0/6	0/4	6/7
Radiofrequency Susceptibility	±15	2/7	2/5	0/5
Microwave Susceptibility	±15	4/5	3/7	2/3

<sup>a</sup> Variation in reading due to changes in test parameter permitted by ANSI N42.17A test requirements.  
<sup>b</sup> For photon radiation.  
<sup>c</sup> NA = not applicable.

# CALIBRATION SERVICES FOR MEDICAL APPLICATIONS OF RADIATION

L. A. DeWerd, Ph.D.<sup>(1)</sup>

**Abstract** - Calibration services for the medical community applications of radiation involve measuring radiation precisely and having traceability to the National Institute of Standards and Technology (NIST). Radiation therapy applications involve the use of ionization chambers and electrometers for external beams and well-type ionization chamber systems as well as radioactive sources for brachytherapy. Diagnostic x-ray applications involve ionization chamber systems and devices to measure other parameters of the x-ray machine, such as non-invasive kVp meters. Calibration laboratories have been established to provide radiation calibration services while maintaining traceability to NIST. New radiation applications of the medical community spur investigation to provide the future calibration needs.

## INTRODUCTION

Generally, the medical applications of radiation necessitate calibrations for the disciplines of radiation therapy, diagnostic x-ray, and nuclear medicine. Radiation therapy and diagnostic x-ray are the disciplines requiring the most calibration services and are the subject of this paper.

The calibration services for radiation therapy can be divided into those for external radiation beams and brachytherapy applications. External beams necessitate the calibration of ionization chambers, generally farmer-type or parallel plate chambers and electrometers. These systems are then applied to measure the radiation dose which is used for the calculations involved in the American Association of Physicists in Medicine (AAPM) protocol developed by Task Group 21 (known as the TG21 megavoltage protocol) (Task Group 21, 1983). With the increase in use of electron beams in radiation therapy, the uncertainties in the calibration of parallel plate chambers for electron beams resulted in organizing another task group to resolve this issue (Attix 1990; Rogers 1992). For the application of external beams, ionization chambers are calibrated for the following radiation qualities: Co-60, Cs-137, and various x-ray qualities, depending on the therapy application. The calibration services for the brachytherapy division of radiation therapy applications can be artificially divided,

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based on the activity of the radioactive source that is to be used. The low dose rate (LDR) applications generally involve activities less than 3.7 GBq (100 mCi), whereas the high dose rate (HDR) applications involve greater activities. The HDR area uses Ir-192 as the nuclide of choice. This application requires the calibration of ionization chambers, including well-type ionization chambers, and electrometers. The LDR application involves the calibration of radioactive sources, such as Cs-137, I-125, and Ir-192, as well as the calibration of well-type ionization chambers, either sealed or communicating with the atmosphere.

The diagnostic x-ray applications usually involve energies represented by 20 kVp to 150 kVp (HVL of 0.15 mm Al to 10 mm Al). The calibration services needed in diagnostic x-rays involve calibration of ionization chambers and electrometers, or more likely, ionization chambers and electrometers linked together as a system. The diagnostic x-ray application requires some beams that are not provided by NIST. For example, the HVL of 2.89 mm Al at 80 kVp and the HVL of 7.0 mm Al (120 kVp) beam. After accurately matching the NIST x-ray beams with the University of Wisconsin Accredited Dosimetry Calibration Laboratory (UW ADCL) constant potential x-ray machine, the 80 kVp and 120 kVp beams were established by an interpolative technique. Table 1 shows the beam qualities offered by the UW ADCL; these beams match closely those of NIST. Other ADCLs offer similar x-ray beams. The S-beams are also useful for the diagnostic area. In addition, the diagnostic x-ray application involves the need to measure the kVp of the x-ray beam. This is a service no longer provided by NIST, but is being investigated for what type of traceability can be provided.

The needs of the medical physics community can be provided by the beams indicated above. In addition, with a low activity Cs-137 source, survey meters for health physics applications can also be calibrated. The UW ADCL maintains at least two NIST-calibrated standard chambers to provide maximum traceability for Co-60 and Cs-137. The x-ray range utilizes two different types of standard chambers: one for "hard" x-ray beams ( $kVp > 80$ ,  $HVL > 2.9$  mm Al), and one for "soft" x-ray beams ( $20 < kVp < 80$ ). Both of these standards have backup chambers. Further information is given in the paper "QA Experience at the University of Wisconsin Accredited Dosimetry Calibration Laboratory," which is a part of these proceedings.

## **THE NEED OF ACCURACY FOR MEDICAL CALIBRATIONS**

There are different accuracy levels needed for each of the medical applications of radiation. Each of these levels is based upon different considerations, one of which is radiation safety to the patient. In radiation therapy, too high a dose can cause harm to the patient; too low a dose may not destroy the tumor. In diagnostic x-ray, the contrast and density of the image is greatly affected by the radiation exposure. In addition, excess radiation to perform a diagnostic exam is frowned upon, although it is not as severe a problem as it is for radiation therapy. Diagnostic exposure meters do not need to perform with the same accuracy and precision of systems used for therapeutic dose measurements. Table 2 shows the operating accuracy limits for the medical applications. Note that, for diagnostic x-ray ionization chamber systems, a recent task group report has suggested an accuracy of  $\pm 3\%$  (Wagner et al. 1992). In all cases, the medical physics community operates on the AAPM recommendation that dosimetry instrumentation be recalibrated every 2 years.

## **CALIBRATION LABORATORY PROCEDURES AND ACCURACY**

Generalized protocols for calibration have been developed by Task Group 3 (TG3) of the AAPM to maintain consistency in calibration for the medical applications of radiation. The individual laboratory protocols are checked by an on-site review team of TG3. Each ADCL has their own set of protocols and procedures consistent with AAPM guidelines. As an example, those used by the UW ADCL are outlined below.

Each UW ADCL x-ray beam quality was carefully matched to available NIST beams using a standard aluminum filter set (obtained from NIST) for HVL measurement. The UW ADCL constant potential machine has been calibrated for kVp using an intrinsic germanium detector used to determine the spectra and, thus, the kVp. Once the NIST-matched beams were developed, our standard chambers were sent to NIST for calibration. Beam qualities are periodically checked for HVL and kVp accuracy.

In-beam transmission monitors are employed to normalize exposure, both for the standard chamber and for the chamber to be calibrated. This results in the calibration factor being easily transferred from the standard chamber to the customer chamber, with air density and timing errors being canceled.

Brachytherapy calibration procedures differ, depending if the item being calibrated is a well-type ionization chamber or a radioactive source. If it is a well-type ionization chamber, a standard NIST-calibrated radioactive source of the appropriate type, Cs-137, I-125, or Ir-192, is inserted in the well-type chamber to determine a correction factor. The radioactive source is first checked in the UW ADCL "calibrated standard" well-type ionization chamber. If a radioactive source is submitted, it is first determined if the source is similar to a NIST-calibrated source at the UW ADCL. If it is, the NIST-calibrated source is first placed in the standard well-type ionization chamber and then the submitted source of similar make and activity is measured in the standard well-type ionization chamber. If the source is different than the standard NIST source, the submitted radioactive source is measured in air with an ionization chamber at a distance. For HDR applications, the method outlined by Goetsch et al. (1991) is used.

The UW ADCL has established a calibration classification scheme for accuracy of the calibration factors; it is shown in Table 3. Other laboratories have established similar levels.

The ADCLs generally agree with NIST when they intercompare ionization chambers. The requirements are to be in agreement to  $\pm 0.5\%$  for Co-60 beams and  $\pm 1\%$  for x-ray points. Table 4 shows the 1990 agreement for various beams.

## **ADDITIONAL CALIBRATION NEEDS OF THE MEDICAL COMMUNITY**

Some calibration needs of the medical community are in the process of being met by NIST so that the secondary laboratories can provide the calibration services. For example, NIST has completed a study on Sr-90 and I-125 calibrations. In other areas, NIST is investigating the methodology further to establish a standard. For example, NIST is investigating the methodology involved in HDR Ir-192 calibrations; an interim technique was developed by the UW ADCL (Goetsch et al. 1991). Other calibration procedures for medical applications of radiation, such as a calibration for Pd-103, are still too much in their infancy for time to be spent developing a standard.

A calibration that the UW has provided for the diagnostic x-ray community for the past 12 years is that of kVp calibrations. NIST provided a calibration of voltage dividers but stopped in 1988. The UW calibration laboratory has continued to provide calibrations based on a 5-year-old calibration of its voltage divider and old calibrations of Wisconsin kVp cassettes. The two techniques have remained consistent so there is confidence that nothing has changed, or that both have changed in the same manner; however, there is no way to check this at present. Calibrations for kVp are very important for diagnostic x-ray applications, since kVp affects the contrast of the image, especially in mammographic applications. Part of the confusion in this area is the definition of kVp. Calibration of any device requires precise definitions of the quantity being measured so devices can be calibrated versus a standard. NIST is studying this problem. In the interim, intercomparisons with CDRH and our own in-house intercomparisons have provided some assurance that the kVp calibrations have some degree of accuracy.

Other needs in the medical community periodically arise that do not affect NIST, but rather affect methodology of the secondary laboratories concerned with providing calibration service to the medical community. Two examples of this are the calibration of parallel plate chambers for application to the measurement of electron beams, and the uncertainties involved in the transfer of calibrations from NIST through the secondary laboratories. Both of these issues were addressed by TG3 in commissioning study groups. Reports of these issues will be forthcoming in the near future.

## CONCLUSION

The procedures used by the secondary laboratories in cooperation with NIST have provided for the calibration needs of the medical community in the application of radiation. The major needs have been addressed in this paper and outlined as to their implementation. In addition, procedures are in place to address the future needs of the medical community for calibration. All of these methods provide confidence in the transfer of calibration values from NIST to the medical physics community.

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*Table 1 - UW ADCL X-Ray Beam Qualities*

Beam Code	HVL (mm AL)	HC
UW40-L	0.49	60
UW50-L	0.75	61
UW80-L	2.81	58
UW100-L <sup>a</sup>	2.81	59
UW20-M	0.155	81
UW30-M	0.36	68
UW40-M	0.73	69
UW50-M	1.03	66
UW60-M	1.69	67
UW80-M <sup>b</sup>	2.89	66
UW100-M	4.99	71
UW120-M <sup>b</sup>	7.00	77
UW150-M1	0.3	86
UW200-M1	5.0	93
UW250-M1	8.6	95
UW75-S	1.86	62
UW60-S	2.79	77

All beams are matched as closely as possible to available NIST beam qualities.

<sup>a</sup> A UW100-L comparable beam quality is currently unavailable from NIST.

<sup>b</sup> UW80-M and UW120-M beams are not offered by NIST and are interpolated from existing NIST M series beams.

*Table 2 - Accuracy Needs of Calibrations for the Medical Community*

Division	Working Accuracy
External Beam Radiation Therapy	±2%
Brachytherapy	±5%
Diagnostic X-ray	±5%

**Table 3 - UW ADCL classification scheme for the accuracy of the air-kerma or exposure calibration factors for reference and field class instruments. Classes I, II, and III apply to radiation therapy services; Class IV apply to general diagnostic x-ray calibrations**

Class	Cobalt-60	Cesium-137	X-rays
I	±0.5%	±0.5%	±1.0%
II	±0.5%	±0.5%	±2.0%
III	±1.0%	±1.0%	±2.0%
IV	N/A	N/A	±5.0%
UW ADCL Brachytherapy classification scheme.			
	Class	Accuracy	
	I	±2.0%	
	II	±3.0%	
	III	±5.0%	

**Table 4 - 1990 Measurement Quality Assurance Test; ADCLs compared to NIST**

NIST Beam	HVL (mm Al)	Percent Difference from Code				
		NIST by ADCL Number				
		1	2	3	4	5
M50	1.02	0.4		1.1		
M60	1.68	0.5		0.5	-0.1	-0.1
M100	5.0	0.2		0.2	0.1	-0.2
M150	10.2	0.4		0.3	<0.1	-0.2
M200	14.9	0.6		0.4	-0.4	-0.3
M250	18.5	0.6			-0.1	-0.2
Cs-137	N/A	-0.2			0.1	
Co-60	N/A	-0.2	-0.2	0.3	-0.4	0.0



# **LABORATORY PROCEDURES FOR QA/QC**

Session Chair  
Tom Bell, DOE

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# DEVELOPMENT OF A QUALITY ASSURANCE PROGRAM FOR IONIZING RADIATION SECONDARY CALIBRATION LABORATORIES

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Alford R. Taylor, Jr.<sup>(1)</sup>

**Abstract** - For calibration laboratories, routine calibrations of instruments meeting stated accuracy goals are important. One method of achieving the accuracy goals is to establish and follow a quality assurance program designed to monitor all aspects of the calibration program and to provide the appropriate feedback mechanism if adjustments are needed. In the United States there are a number of organizations with laboratory accreditation programs. All existing accreditation programs require that the laboratory implement a quality assurance program with essentially the same elements in all of these programs. Collectively, these elements have been designated as a Measurement Quality Assurance (MQA) program. This paper will briefly discuss the interrelationship of the elements of an MQA program. Using the Center for Devices and Radiological Health (CDRH) X-ray Calibration Laboratory (XCL) as an example, it will focus on setting up a quality control program for the equipment in a Secondary Calibration Laboratory.

## INTRODUCTION

In today's world, most organizations are concerned with producing a quality product. One method of achieving this goal is to institute a quality assurance system to control factors which affect the quality of the product. The International Organization for Standardization (ISO) 9000 series<sup>1,2,3,4,5</sup> of standards describe the elements of a generic quality assurance system. They are widely used throughout the world. For specific industries, the general concepts are often incorporated into programs tailored for that industry. For example, for medical device manufacturers there are Good Manufacturing Practices,<sup>6</sup> for diagnostic radiologic facilities there are recommendations for quality assurance programs,<sup>7</sup> and for users of medical byproduct materials<sup>8</sup> and therapeutic radiation machines<sup>9</sup> there are requirements for implementing a Quality Management Program.

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For laboratories calibrating ionizing radiation instruments, the objective of the quality assurance system is to ensure that all factors which can affect the final quality of the product—a calibrated instrument in this case—have adequate controls. In 1980, the National Institute of Standards and Technology (NIST) was asked to examine the entire measurement system for ionizing radiation with the goal of determining how the system could be improved. This study<sup>10</sup> resulted in a quality assurance system which Eisenhower<sup>11</sup> later called MQA. The elements in the program were a forerunner of recent ISO standards and guides dealing with quality assurance systems that focus on measuring equipment<sup>12,13</sup> and testing (and calibration) laboratories.<sup>14</sup>

This paper is organized into three parts. The first part focuses on the interrelationship between MQA programs, quality assurance systems, and various different laboratory accreditation programs for ionizing radiation calibrations. The second part outlines the common elements of these accreditation programs, with emphasis on their application in an x-ray calibration laboratory. The final part discusses some specific quality control techniques, with specific examples taken from the CDRH XCL.

### MQA AND QUALITY ASSURANCE SYSTEMS

Laboratories calibrating ionizing radiation instruments are fortunate in that various organizations which accredit these laboratories have built into their accreditation criteria the basic elements of a quality assurance system. If the laboratory follows all of the procedures agreed to in the accreditation process, then the basic elements the laboratory needs for ensuring quality will be in place.

Accreditation criteria for laboratories calibrating ionizing radiation measuring instruments have been developed by NIST's National Voluntary Laboratory Accreditation Program (NVLAP),<sup>(2)</sup> the Conference of Radiation Control Program Directors,<sup>(3)</sup> the American Association of Physicists in Medicine (AAPM),<sup>(4)</sup> and the Health Physics Society.<sup>(5)</sup> Laboratories which are accredited by one of these organizations will be designated as Secondary Calibration Laboratories (SCLs).

The accreditation criteria for each organization were developed so that the accuracy requirements appropriate for the intended use of the instruments would be met. For example, the general NVLAP criteria for SCL accreditation are contained in one of their Program Handbooks<sup>15</sup> and the operational criteria are in NIST Special Publication 812.<sup>16</sup> The corresponding accreditation information for the other organizations can be obtained directly from the organization.

ISO 9000 and its derivative standards are widely regarded as the definitive delineation of an infrastructure to assure the quality of products and services. The elements of this infrastructure have been assimilated into the most recent revision of ISO Guide 25, which is being adopted by NVLAP

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(4) Contact: Dr. M. Rozenfield, Chairman AAPM TG3, St. James Hospital, Radiation Oncology, 1423 Chicago Road, Chicago Heights, Illinois 60411.

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for all their calibration laboratory accreditation programs and by the Health Physics Society accreditation program. However, having an infrastructure does not guarantee high quality. Quality experts point to the need for a closed-loop process of continuous improvement in quality.

Any closed-loop process, or control system, has the following basic three elements: 1) a controlled parameter; 2) a means of measuring the controlled parameter; and 3) a feedback mechanism for modifying system operation to adjust the parameter value in the desired direction. For example, consider a system wherein a microprocessor controls x-ray generator voltage within desired limits. The controlled parameter is voltage; the means of measuring it are voltage sensors analyzed by the microprocessor; and the feedback mechanism is the signal the microprocessor sends to the control circuits of the generator to raise or lower the voltage.

The quality assurance system implemented by the calibration laboratory is an application of this quality control model. The controlled parameter is quality. Quality must be defined, characterized, and quantified in terms that permit routine measurement. In other words, the performance of the calibration system and its various components must be routinely measured and analyzed to assess conformance to the specified quality ideals. The feedback mechanism is the set of procedures that the management institutes to correct performance shortcomings, e.g., additional resources, and better training, administrative practices, and procedures.

The ISO standards, accreditation criteria manuals, and laboratory Quality Manuals tend to consider performance, procedures, and responsibilities in isolation, rather than in the context of a dynamic closed-loop process. Other important aspects of quality, such as consideration of the cost of quality, a focus on customer involvement and empowerment and recognition of employees, are not addressed at all. Thus, quality practices and procedures are necessary elements of an MQA program, but they alone do not inherently assure the quality of the product. Quality assurance requires the active and continuing participation of management to adjust the outcome of the calibration process in the desired direction to optimize and maintain the calibration accuracy goals stated in the Quality Manual.

## **MQA PROGRAMS AND LABORATORY ACCREDITATION**

The MQA programs incorporated into the accreditation criteria of these four programs have the following elements designed to assure the traceability of routine calibrations to the national standards:

- 1) fully documented administrative and calibration procedures
- 2) properly calibrated laboratory instruments
- 3) periodic proficiency testing conducted by NIST
- 4) quality control procedures for critical elements of the calibration system
- 5) comprehensive uncertainty analysis for the entire calibration process
- 6) independent evaluation and audits of laboratory procedures.

Each of these six elements is discussed separately in the following paragraphs. For each element, application of the element to an x-ray calibration facility is described, with particular consideration given to opportunities for influencing quality through a closed-loop process.

## Documented Procedures

The first element requires documented procedures for policy issues, calibration procedures, and quality assurance procedures. Quality assurance procedures include personnel training, complaint handling, document control, feedback procedures, and management policies. These documented procedures can also be used as training tools for new employees, to answer questions on specific details on various procedures for present employees, to provide a "paper trail" on the evolution of procedures within the lab, to provide on-site assessors with information they need in evaluating the capabilities of the lab, and to provide management with pertinent information on how proper quality assurance procedures will be implemented within the calibration laboratory. For an SCL, items which should be included in the documentation include:

- Management Policies
  - organizational structure
  - support
- Administrative Policies
  - Quality Manual update procedures
  - Quality Assurance/Quality Control (QA/QC) update procedures
  - software update procedures
  - process validation
  - feedback procedures to ensure quality
  - acceptance testing of equipment
  - personnel training
  - complaint handling
  - error notification
  - audit procedures
- Standard Operating Procedures (SOP)
  - precalibration SOP for each accreditation class or instrument type
  - radiation calibration SOP for each accreditation class or instrument type
  - in-house calibration equipment calibration
  - routine QC
- Facilities
  - specifications, model numbers, serial numbers for commercial equipment, etc.
  - as-built documentation for custom equipment
  - minimal equipment requirements
  - environmental conditions in the laboratory.

## Calibration of Equipment

In the second element, calibration of equipment relates measured output under specified conditions to similar measurements made under reference conditions using a reference standard. For SCLs, the

reference standard used in the calibration should be to the appropriate national standard maintained by NIST. The calibration of equipment should occur when equipment is new or repaired, and thereafter on a periodic basis. Measurements of a test object under specified conditions in conjunction with routine calibrations serve as a reference point for a quality control program to indicate how a piece of equipment has drifted from its initial operating characteristics. This drift (as well as the uncertainty in the initial calibrations) can be incorporated into the uncertainty analysis for the laboratory's entire calibration process.

### **Proficiency Testing**

The third element, proficiency testing, indicates how well the laboratory can perform a specific calibration on the particular transfer standard used in the test. If the transfer standard is calibrated against the appropriate national standard, it can be used to tell how calibrations done at the laboratory compare to the national standard. Proficiency testing exercises the entire calibration system (including the operator) of the laboratory. Compared to simply a calibration certificate from NIST, a proficiency test done by NIST is a much more meaningful method of verifying traceability to the national standards. The agreement in characterization of the transfer standard between NIST and the calibration laboratory provides demonstrated traceability to the national standards at a quantifiable level for that transfer standard.

Using documented procedures with equipment which has been shown to be operating within expected limits through periodic QA/QC procedures provides assurance that routine calibrations should achieve the same degree of "traceability" to the national standards as achieved in the proficiency test with the same equipment and personnel. The one obvious exception to this is an undetected "blunder" made by the calibrator and not detected in the calibration report review. Thus, it must be realized that the accrediting organization cannot guarantee the accuracy of all calibrations done at the laboratory. It can only state that the calibration laboratory has demonstrated that it is capable of calibrating instruments to within a certain consistency of the national standards.

### **Quality Control**

The in-house QC procedures provide the link between routine calibrations done at the laboratory and the degree of agreement demonstrated during the proficiency test. The in-house QC programs should be easily performed. They should be designed to monitor one or more operating characteristics of laboratory equipment used for calibrating instruments. QC procedures are not calibrations but rather indicators of the constancy of the equipment. They are used to indicate where the equipment is operating within expected statistical limits or within predefined tolerance limits. The concept of redundancy is central to these QC measures. The idea is to use additional tests to permit cross-checking of results, and to use additional analysis of results to assure consistency of calibration to calibration over time.

### **Uncertainty Analysis**

To estimate the overall uncertainty of routine calibrations based solely on the results of proficiency testing is a multi-year process. Proficiency tests are really a snapshot in time of the laboratory capabilities to calibrate a particular instrument under specific conditions. To convert this snapshot into a movie, it is necessary to use transfer standards which experimentally test all conditions in the laboratory over a long period of time. To make sure that the transfer standard itself is not a

perturbing factor, it is necessary to use transfer standards comparable to the instruments routinely calibrated at the laboratory. Finally, the sample size of proficiency tests must be large enough to derive a meaningful estimate of the accuracy of the laboratory's calibration process. Proficiency testing provides the accrediting organization with a tool for determining the ability of the SCL to perform proper calibrations under the test conditions.

However, proficiency testing is not a practical tool for the initial estimation of the overall uncertainty. An alternative method is to do an analytic uncertainty analysis. The ISO has recently issued a guide<sup>17</sup> for expressing uncertainty in measurements (or calibrations). The approach in the ISO Guide estimates uncertainty in each component, either using statistical methods (Type A uncertainties) or some other methods (Type B uncertainties). In the ISO approach, it is desirable to model the entire calibration process. The analytic uncertainty analysis provides an estimate of the uncertainty for routine calibration situations where there is no proficiency test (or an insufficient number of proficiency tests). There are two drawbacks to this approach: 1) using an incorrect model of the calibration process will lead to errors in the uncertainty estimate, and 2) one may not have sufficient data or measurements to estimate the expected variability in a particular component of the measurement model.

If one of the parameters in the uncertainty analysis has an associated QC program, the statistical spread in the QC data can be used to estimate the Type A variance for that parameter. If the parameter cannot be estimated by replicate measurements, then some other procedure must be used to estimate the Type B variance. This might simply be a "guesstimate" of the expected spread in the parameter. For example, a laser spot 2 mm in diameter is used to position the reference ion chamber at its geometric center. The user decides that there is equal probability that the true geometric center is uniformly distributed (variance equals 0.577 times the limit) over the diameter of the laser spot. The Type B standard deviation is then 1.2 mm. The combined uncertainty estimate should be equal to or larger than the proficiency test results if all the factors influencing the calibration were properly modeled and estimated.

## **Audits**

The last element provides a formal mechanism for periodically reviewing all the elements in the laboratory's QA program. This audit should be done by personnel not directly connected with the operations or management of the calibration laboratory. All of the accreditation criteria specify an audit or on-site review by a team of technical experts supplied by the accrediting organization. In addition to these audits, the calibration laboratory should arrange for independent audits on at least an annual basis.

The management of the laboratory should use the results of this audit (and the results of all the other MQA processes described above) in a feedback procedure to correct any deficiencies which affect the quality of the calibration. As discussed earlier, to assure the quality of the product (i.e., calibrations), management must be actively involved in implementing all required actions to optimize and maintain the calibration accuracy goals. Understanding any deficiencies reported in the audit report and taking actions to correct these deficiencies is a key role for management to play in the QA program.



## TYPES OF QUALITY CONTROL PROGRAMS FOR CALIBRATION LABORATORIES

As an example of how an SCL can develop an appropriate set of QC programs to monitor the performance of the calibration laboratory, the remainder of this paper will focus on the QC element of the MQA program. Typically, a QC program for the SCLs consists of a series of procedures and routine checks designed to monitor the constancy of equipment used in the calibration process. Four common types of procedures to monitor this constancy are:

- 1) automatic control tests to make sure measured values are within predetermined tolerance limits
- 2) periodic statistical quality control tests with optional predetermined larger tolerance or action limits
- 3) data trends
- 4) operational tests.

Automatic tests can be built into automated calibration procedures in order to monitor the equipment performance during actual calibrations. Periodic QC tests indicate whether test parameters used to indicate the equipment's performance are within normal statistical limits (i.e., control limits). When there are not enough data to determine meaningful statistical control limits, one can still plot the data and look for trends. For example, operational tests to monitor some function of the equipment can be used to verify that the result is within acceptable limits, but the results are not plotted on a control chart.

Each of these procedures can have tolerance limits. These are chosen to ensure that the routine calibrations are within the stated uncertainty. These tolerance limits are treated as "maximum" intervals in the uncertainty analysis and the corresponding variance for that parameter in the measurement model is estimated from this interval. The tolerance limit is typically larger than the statistical control limit.

### Automatic Tests

For SCLs using computers to control the calibration equipment and gather and analyze the calibration data, the most monitored procedures are the automatic control tests. These will detect unacceptable changes which may occur in the time between scheduled QC procedures. The automatic control tests are implemented every time an instrument is calibrated in each reference radiation field. If measured parameters are outside the predetermined tolerance limits, the computer program will either repeat the measurement after making appropriate adjustments; or ask the operator to verify the data and to re-enter correct values. The calibration should not continue until the data are within the appropriate limits. In some defined situations, the operator may be allowed to override the computer control.

### Periodic Quality Control Tests

Periodic QC procedures are designed to monitor two laboratory conditions that result in problems:

- 1) Short-term variations in individual measurements (or sets of measurements) of the test parameter which are outside statistical limits based on the previous history. This indicates that the deviant results are not conforming to the appropriate sample population, i.e., something in the calibration equipment has changed.

- 2) Long-term drifts in measured test parameter values which are within calculated statistical limits. Even though the statistical test may not show results outside of control limits, if corrections are not made, a significant error in the calibration could be introduced.

As an example of these two conditions, consider the measurements of output of a gamma-ray source. Short-term replicate measurements of the source output will be governed by the sampling statistics of the measuring equipment. A long-term "drift" is the radioactive decay of the source. If the short-term replicate measurements are in statistical control, then long-term effects due to source decay can be corrected back to some reference time.

Statistical QC tests are one way to determine the constancy of the laboratory equipment over time. They are a way to anticipate the need for recalibration of individual laboratory instruments if significant drifts appear in the data. There are many procedures for determining statistical control limits and plotting the corresponding control charts, depending on sample size, comparison against a standard or previous data, sampling from a known sample distribution, etc.

For the equipment used in the calibration laboratory, normally there is very little performance variation. Hence the control limits are very tight, e.g., typically a few tenths of a percent. If the QC test measurement on a particular day is only slightly outside the statistical control limit, there is no practical effect on determining the test instrument's correction factor. Thus a second set of limits is established, which, if exceeded, will cause an unacceptable error in the correction factor. These are termed "action limits" or "tolerance limits." If they are exceeded, the cause must be determined before any more calibrations are done.

### **Data Trends**

In some cases, it is not possible for the sample to have enough data points to determine statistically valid control limits. Typically, about 25 observations need to be made before "constant" control limits are achieved. In these cases, the data are merely plotted on a chart and one tries to determine if there are obvious trends in the charts as a function of time. Some anomalies in the trend charts may be explained by physical reasons, e.g., the reference ion chamber was damaged and repaired, resulting in a change of the calibration factor.

### **Operational Tests**

These are very similar to the automatic tests except that these tests are done manually and often there are no numerical tolerance limits. Three examples of operational tests include: 1) observing by visual inspection that operating the shutter moves it to the appropriate microswitch, 2) observing that the warning lights are on when appropriate fault conditions are simulated, and 3) verifying that a computer code gives the expected results for a set of test cases.

## **SETTING UP APPROPRIATE QUALITY CONTROL PROGRAMS**

The first consideration in determining what QC procedures the SCL should develop is to look at the entire calibration process and decide which pieces of equipment or operations significantly affect the accuracy of the calibration. If one has already modeled the entire calibration process in preparation for the uncertainty analysis, it is a simple matter to determine the overall uncertainty for various limits on the performance of the calibration equipment. Once the critical equipment and operations

used in the calibration process have been identified, appropriate QC programs should be developed to periodically monitor some easily measured parameter representative of its performance.

As an example of setting up a complete QC program for an SCL, the procedures developed for the CDRH XCL will be used. Figure 1 shows the main components for x-ray instrument calibrations at the CDRH XCL. This calibration system has been described elsewhere<sup>18</sup> and <sup>(6)(7)</sup> and will only be summarized here. The x-ray generator is operated at a specified x-ray tube current and voltage; a shutter is opened for a preset time, and the actual elapsed time is measured; a filter wheel containing filters for various beam qualities is positioned; the beam is collimated by one of two collimators; the reference ion chamber is positioned in the beam and its output is measured on a precision electrometer; the measured ion chamber current is corrected for the actual air density inside the ion chamber; the test instrument is positioned, and its reading is compared to the reference value; the computer controls the operations of the calibration and performs the required calculations; the calibration report is generated by the computer and the data is stored for future reference; and there are interlocks with alarms to shut down the x-ray generator if unsafe conditions exist in the radiation room.

For the CDRH XCL, the following is a list of critical components of the calibration system or operations performed during the calibration. Each component is listed under the type of QC procedure used to monitor its constancy:

- Computer automatically monitors/calculates/sets/monitors for each beam:
  - x-ray tube kV
  - x-ray tube current
  - x-ray tube yield
  - value of electrometer zero
  - ion chamber leakage current
  - coefficient of variation of radiation measurements
  
- Statistical QC measurements, results plotted on control charts:
  - picoampere source
  - electrometer
  - barometer
  - thermometer
  - hygrometer
  - correction factors of in-house test instrument
  - x-ray generator high voltage
  - beam quality (HVL)
  - ratio of two large-volume, spherical ion chambers

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<sup>(6)</sup> See the article "Services of the CDRH X-ray Calibration Laboratory and Their Traceability to the National Standards" by H. T. Heaton and F. Cerra, published in these proceedings.

<sup>(7)</sup> See the article "Characterization of X-ray Fields at the Center for Devices and Radiological Health" by F. Cerra, published in these proceedings.

- QC measurements, results within predetermined tolerance limits:
  - filter wheel positioning
  - positioning reference ion chamber
  - positioning test instrument
  - chronometer
  - elapsed time
  
- Trends:
  - NIST calibration factor of reference ion chamber intercomparison of calibration factor of reference ion chamber measured at two CDRH x-ray sets
  
- Operational checks:
  - shutter operation
  - computer hardware
  - computer interface hardware
  - computer program
  - interlocks
  - warning lights
  - area radiation detectors.

The reference ion chambers are periodically intercompared to reduce the chance of introducing biases which may take several proficiency test cycles to verify. Their calibration factors are monitored on a trend chart. Since there are only a few cycles of calibration factors for any individual reference ion chamber, one can only look for trends in the reported calibration factors.

## CONTROL CHARTS

There are many methods of calculating control limits and plotting the results on control charts, depending on exactly what feature is to be monitored and the sampling method used for the monitoring, e.g., see the American Society for Testing and Materials (ASTM) report, STP 15D,<sup>19</sup> or MIL-HDBK-683.<sup>20</sup> On control charts, the abscissa is the sequence number of the sample (or day of sample) and the ordinate is the value of the statistical parameter being monitored, e.g., the observed value, the average value of the sample, its standard deviation. The ASTM procedures calculate statistical control limits such that 99% of the results should lie between the upper and lower limits under the assumption that the data are normally distributed.

Methods for determining control limits are based on how the data are sampled and tested: 1) controls with no standard given, 2) controls with respect to a given standard, and 3) individual measurements. In the first two methods, one determines the average value and standard deviation, or ranges of a finite random sample from the population being monitored. These statistical parameters are used to determine if the results for the given sample are within statistical limits for a number of situations such as large and small sample size, samples of the same (or different) size, results compared against a standard or compared to previous results. In the last method, the individual results (rather than averages) are used to determine the control limits.

For many components of the calibration system, there are multiple factors which affect the value of the parameter being sampled. In these cases the day-to-day variation of the average value is often greater than expected based on the standard deviations of the corresponding measurements taken over a short time interval; i.e., the statistical variations in data sets can result from short-term or long-term processes as discussed in the last section. The type of variation depends explicitly on the nature of the process controlling the random variation. For measurements used to monitor the control limits of the calibration equipment, the short-term standard deviation of a set of replicate measurements is usually much less than the corresponding long-term standard deviation. For this reason, the Method of Moving Ranges (as discussed in ASTM report, STP 15D) was used for generating control charts for the calibration equipment in the CDRH XCL.

The mean moving range procedure is based on the measurement value of the current point,  $x_i$ , and on the measurement value of the preceding point,  $x_{i-1}$ . For  $n$  points, the mean value is

$$\bar{x} = \frac{1}{n} \sum_{i=1}^n x_i$$

and the mean range is

$$\bar{R} = \frac{1}{n-1} \sum_{i=2}^n |x_i - x_{i-1}|$$

This control limit procedure is called "mean moving range" because the mean value of  $R$  (and  $x$ ) changes as the number of observations "moves" (i.e.,  $n$  increases).

The control limits on the mean value of the raw data points are

$$\text{upper: } \bar{x} + 2.66 \bar{R}$$

$$\text{lower: } \bar{x} - 2.66 \bar{R}$$

and the control limits on the range are

$$\text{upper: } 3.27 \bar{R}$$

$$\text{lower: } 0$$

Control charts show trends in the observed test points as a function of time. They also show individual results outside of expected statistical limits. For many applications, there are processes occurring which are not due to random sampling on a short-term basis but rather depend on physical conditions, e.g., the change in the output resistance of a picoampere source with ambient room temperature.

## EXAMPLES OF QUALITY CONTROL PROCEDURES

The remainder of this paper will deal with three specific examples of QC procedures taken from the CDRH XCL. The actual QC procedure for each of the critical pieces of calibration equipment may have several different test procedures designed to monitor different aspects of its performance. At present there are 138 different control charts used to monitor the calibration equipment at the XCL. These are given in more detail in the CDRH Quality Manual for Quality Control and Uncertainty Analysis.<sup>21</sup>

### Example 1) Large Volume Ion Chamber Ratio

To verify compliance with the TV and cabinet x-ray performance standards, it is necessary to calibrate survey instruments at exposure rates as low as 0.5 mR/h. This low exposure rate is achieved by using both a low tube current and a large source-detector distance (750 cm). The reference field for these low exposure rates is determined as follows. First, for large x-ray tube currents, the exposure rate is measured at both the normal 100 cm distance and at 750 cm. The ratio of these exposure rates is independent of the tube current needed to produce a particular exposure rate. Thus, by measuring the exposure rate at 100 cm and using this ratio, the reference field can be accurately determined at the 750-cm position for any tube current.

The exposure rate at any distance depends on the inverse square of the source-detector distance and attenuation in the air path. The actual attenuation in the 650-cm air path depends on the actual air density and the spectrum-averaged value of the mass-attenuation coefficient for air, which can be considered constant, with small changes in the spectrum due to air density variations. Hence, the product of air attenuation and the measured ratio should be stated for air density at reference temperature and pressure conditions, i.e., 22°C and 760-mm Hg.

When survey instruments are calibrated, the air attenuation factor is adjusted for the actual temperature and pressure at the time of the calibration. Thus, for a given tube current, the exposure rate at 750 cm is based on the adjusted ratio and the exposure rate measured at the 100-cm position. When an x-ray tube is replaced, the new physical dimensions may be different, causing a change in the nominal 750-cm, source-detector distance. This changes the value of the ratio, but will have virtually no change on the spectrum-averaged value of the mass attenuation coefficient for air.

Figure 2 shows the control chart for data points for the large volume ion chamber ratio. In Figure 2, it is clear that the ratio changed when the x-ray tube was replaced. This was due to an increase of 12 cm in the larger distance. Normally, one would begin a new control chart at this point, since one is now sampling from a different sample population. To show this change, all of the data points are being retained.

Figure 3 shows the associated control chart for the range and is included to show that there are control charts both for the mean value (Figure 2) and for the standard deviation estimator, the range in this case.

Figure 4 shows the results for the measured mass-attenuation coefficient. Here it can be seen that statistical control is maintained even for the new distance. The change in the ratio is solely due to the larger source-to-survey instrument distance.

### Example 2) Electrometer

The QC program for the electrometer consists of several components: 1) stability of its internal voltage source, 2) stability of measured  $6.00 \times 10^{-11}$  setting on the picoampere source times a normalization constant, 3) stability of measured  $0.60 \times 10^{-11}$  setting on the picoampere source times a normalization constant, 4) "correction" factor for the electrometer coulomb range assuming the output of the picoampere source is calibrated, and 5) "correction" factor for the electrometer's coulomb range assuming that the electrometer's voltage source and value of standard air capacitor are correct. Since the picoampere source, reference voltage source, and air capacitor are not independently calibrated before this procedure is performed, this is not a calibration of the electrometer, but rather a check on its constancy for a specific set of test conditions.

Figure 5 shows the control chart for the "capacitor correction factor" method of the electrometer's coulomb range. There is some indication that the first three data points on this control chart may be drawn from a different sample than the remaining data points, or if they are all from the same sample, that there may be a slow downward drift. However, the control limits are only a few tenths of a percent. Even if there is a drift or change, it will have no practical effect on x-ray instrument calibrations as long as QC measurements continue within the current control limits. The data point above the upper control limit is real. Examining the data after the fact showed that there was unaccounted leakage on the air capacitor.

### Example 3) In-house Test Instrument

As part of the monthly QC program, the  $6 \text{ cm}^3$  probe of a dedicated x-ray monitor is calibrated in the M20, M30, L80, L100, and M100 beams. Contrary to the normal calibration procedure, no adjustments are made to this instrument. The ratio of the measured reference field and the observed instrument reading, e.g., the correction factor, shows the constancy of the entire reference field measuring system and the in-house test instrument. Control charts for the correction factors for each beam and the corresponding beam yield are plotted on control charts. Other tests done during the monthly QC program include: the temperature sensor probe is compared against a reference thermometer, the pressure probe is compared against a reference aneroid barometer, the position of the instrument table is verified, and readings of two separate metering circuits are compared for both the tube mA and kV settings.

Figure 6 shows the data control chart for measured L100 beam correction factors and Figure 7 shows the corresponding control chart for the yield for this beam. As in the case of the large volume ion chamber ratio, it is clear in Figure 7 that the tube yield changed when the x-ray tube was changed, but from Figure 6 it can be seen that this had no effect on the L100 correction factor.

## CONCLUSIONS

This paper reviewed the main elements in an MQA program, their interrelationship to each other, and the overall role of MQA programs in various calibration laboratory accreditation programs. The paper then focused on the elements of QC programs a typical Secondary Calibration Laboratory would include to monitor the consistency of its routine calibrations as compared to the results obtained in a performance test with the NIST. Finally, some specific examples were given of QC programs and the use of control charts taken from the CDRH XCL.

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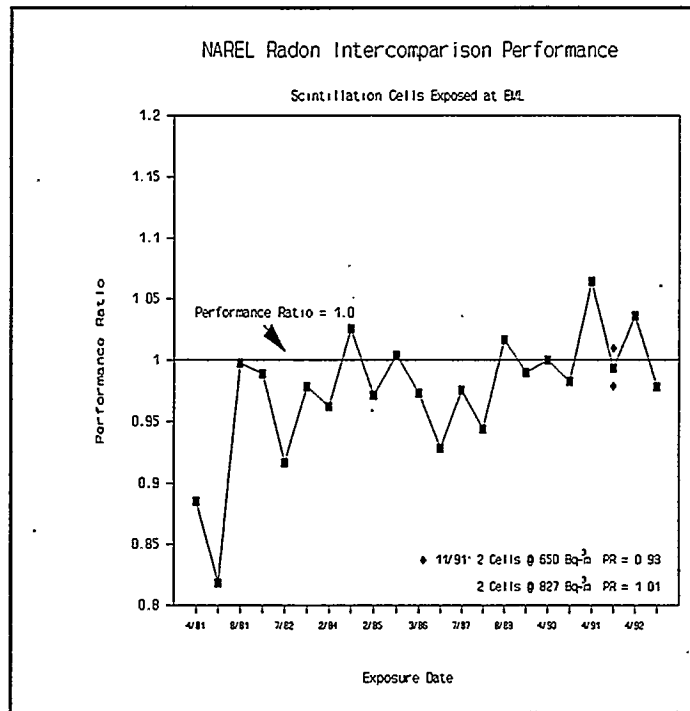


Figure 1 - Overview of Equipment Used for X-ray Calibration at the CDRH XCL

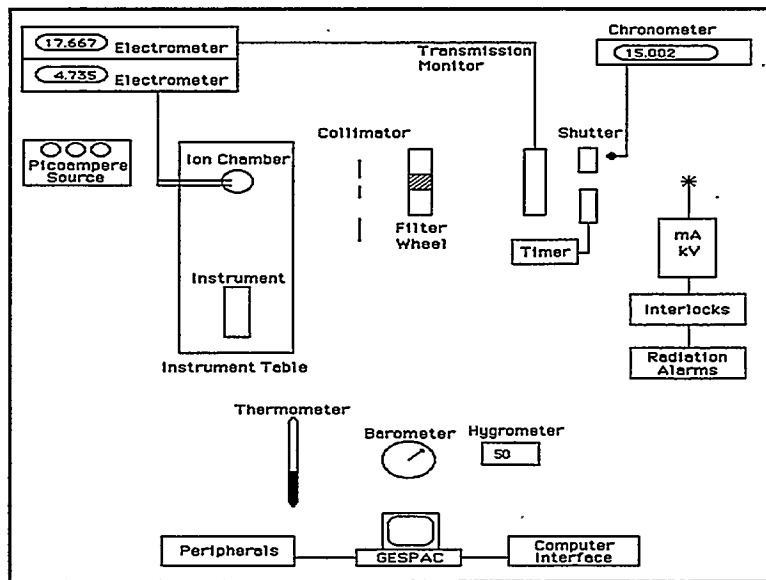
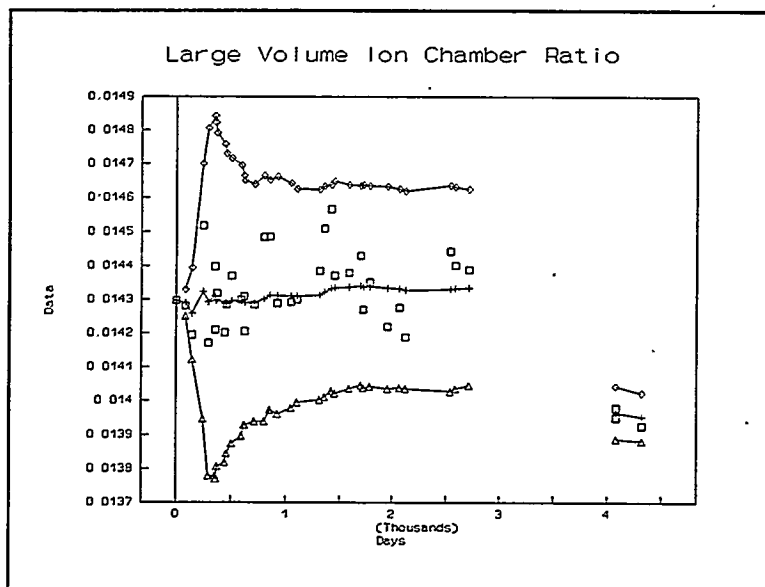
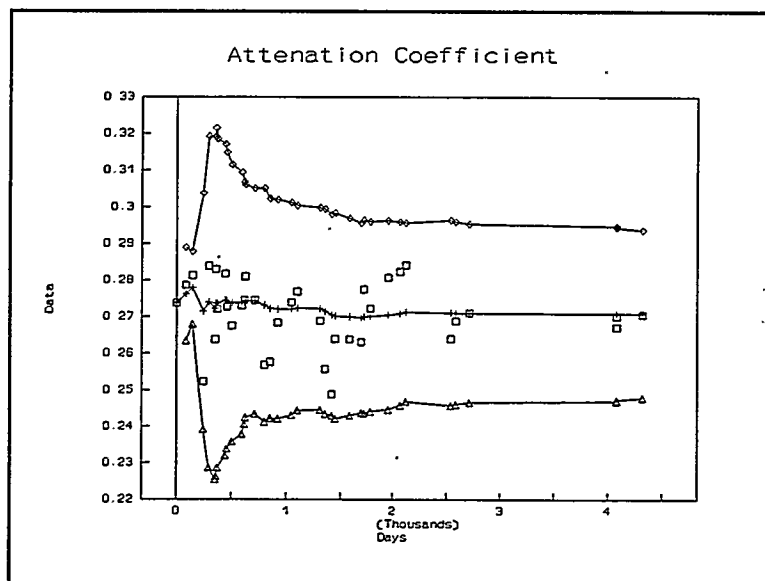


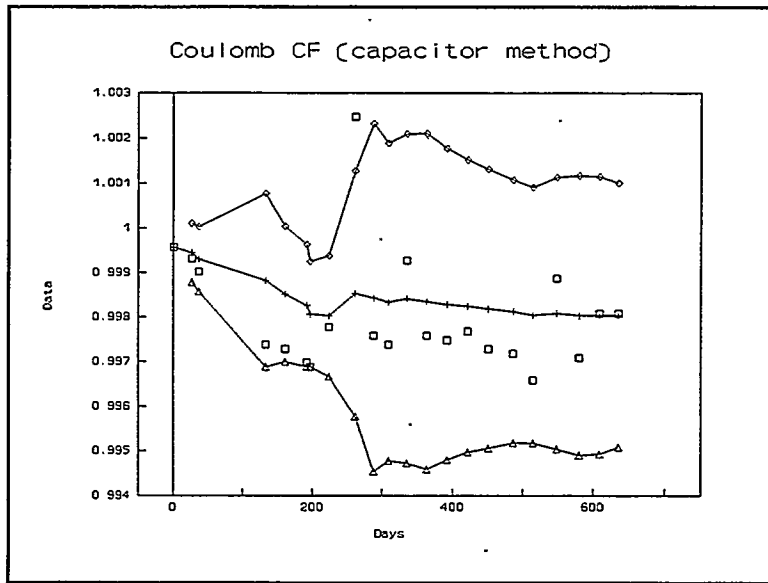
Figure 2 - Data Control Chart for Large Volume Ion Chamber Ration Measurements



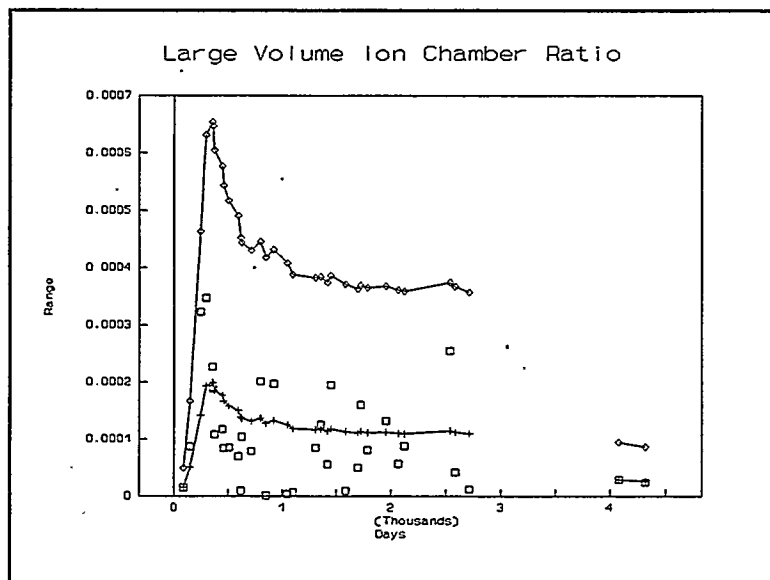
*Figure 3 - Data Control Chart for Spectrum Averaged Mass-Attenuation Coefficient for Air*



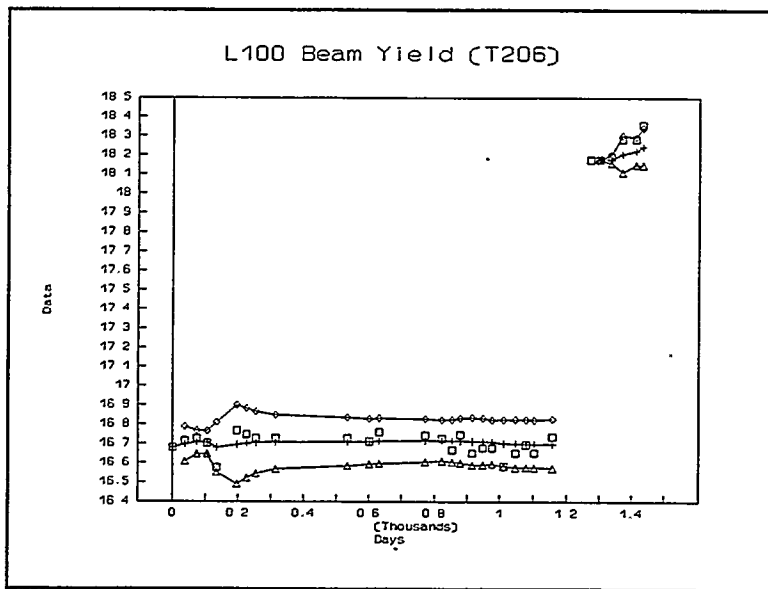
*Figure 4 - Data Control Chart for "Capacitor Correction Factor" Method of Electrometer's Coulomb Range.*



*Figure 5 - Range Control Chart for Large Volume Ion Chamber Ratio Measurements*



*Figure 6 - Data Control Chart for L100 Yield Measurements*



*Figure 7 - Date Control Chart for L100 Correction Factor*

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# QUALITY ASSURANCE PROGRAMS AT THE PNL CALIBRATIONS LABORATORY

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## INTRODUCTION

The calibrations laboratory at Pacific Northwest Laboratory (PNL) serves as a radiological standardization facility for personnel and environmental dosimetry and radiological survey instruments. As part of this function, the calibrations laboratory must maintain radiological reference fields with calibrations traceable to the National Institute of Standards and Technology (NIST). This task is accomplished by a combination of 1) sources or reference instruments calibrated at or by NIST, 2) measurement quality assurance (MQA) interactions with NIST, and 3) rigorous internal annual and quarterly calibration verifications. This paper describes a representative sample of the facilities, sources, and actions used to maintain accurate and traceable fields.

## LABORATORY GOALS

The goal of the calibrations laboratory is to maintain an array of photon (high and low energy), beta, and neutron reference fields (see Table 1) traceable to NIST. These fields are used primarily to calibrate instruments and dosimeters used at the U.S. Department of Energy's (DOE's) Hanford Site. Traceability to NIST is required for instrument calibration per DOE Order 5480.6. Dosimeter standardization to NIST-traceable radiological reference fields is necessary to ensure accurate analysis and performance in periodic U.S. Department of Energy Laboratory Accreditation Program (DOELAP) proficiency testing for personnel dosimetry programs.

PNL also uses the NIST-traceable fields to support additional functions outside the Hanford Site. The calibrations laboratory provides traceable x-ray and neutron reference fields to support the DOELAP proficiency testing program of the Radiological Engineering and Standards Laboratory (RESL). The calibrations laboratory also serves as the sole proficiency testing laboratory for the external dosimetry

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National Voluntary Laboratory Accreditation Program (NVLAP). This program accredits external dosimetry programs for facilities licensed by individual states or by the U.S. Nuclear Regulatory Commission. PNL provides these radiological reference fields, as well as irradiations using these reference fields, for instrument and/or dosimeter calibrations. In addition, PNL provides characterizations for various nuclear utilities, universities, and dosimeter/instrument vendors and providers.

## **METHODS AND PRACTICES**

To establish accurate radiological reference fields, PNL uses 1) calibration instrumentation or sources that have, themselves, been calibrated at NIST, or 2) instrumentation considered to be of "reference class." Instruments used for calibration are selected for their reliability and reproducibility. Following initial establishment of reference fields, periodic constancy verifications are performed to ensure that no unexpected changes have occurred. Traceability to NIST is reaffirmed, typically on a two-year basis, using MQA interactions. These interactions involve an exchange of instruments or other devices to perform equivalent calibrations of similar reference fields within each facility for comparison. In addition to routine calibrations and intercomparisons, process quality control activities are applied. To monitor the irradiation of dosimeters, PNL uses "quality control chambers," which are air ionization chambers mounted either within phantoms or in air at a nearby position to verify the delivered exposure.

Recognizing a need for more than technical verification, PNL also applies a philosophy of administrative quality assurance. Procedures govern the performance of routine practices, and personnel training is conducted to ensure the safe and effective operation of radiation-generating devices. In addition, technicians undergo apprenticeships in performing irradiation and calibration activities. Audits and assessments are performed periodically by various sponsors, including NVLAP and DOELAP, as well as by PNL's own internal quality assurance organization. Records are maintained in a well-organized format; a records inventory and disposition system (RIDS) is used for long-term retention in a safe environment. Current efforts within the calibrations laboratory are focussed on establishing a well-structured and comprehensive program for performing self-assessments. This program, when initiated, will be used to identify beneficial programmatic needs and improvements, to review proper performance of procedures, and to ensure that records and personnel training are current and complete.

## **RADIOLOGICAL REFERENCE FIELDS**

This section contains examples of how each characteristic radiological reference field is maintained to be accurate and traceable to NIST.

### **Gamma ( $^{137}\text{Cs}$ ) Reference Field**

As its primary  $^{137}\text{Cs}$  reference field, the calibrations laboratory maintains a Shepherd Model 81 irradiator equipped with a 100-Ci source. This device is situated near one end of an elongated facility that is 3.7-m wide, 6.4-m long, and 4-m high. Its placement facilitates a collimated field that is uninterrupted for approximately 5 m, producing a beam that is relatively low in scattered photons. A plastic filter, 1-cm thick, is placed at the collimator opening to further reduce low-energy photons and Compton electrons scattered by the collimator.



The Shepherd reference field was initially calibrated using a NIST-traceable Capintec PM-30 air ionization chamber. This chamber has demonstrated excellent stability and reproducibility over time, and its energy dependency is relatively minor, varying only about 5% in the energy range of 35 keV to 1350 keV. In addition, it is manufactured with accurate reproducibility, which is evidenced by the similarity in correction factors among the several PM-30 ionization chambers used at the calibrations laboratory.

Approximately every two years, MQA interactions are performed with NIST. These are typically performed by making calibration measurements of NIST ionization chambers using the PNL sources. Before and after the PNL calibrations, NIST calibrates the chambers using the National Standard  $^{137}\text{Cs}$  source. Comparing the results of the NIST and PNL calibrations provides an indication of how accurately the PNL source is calibrated and used. PNL maintains an informal action level of  $\pm 2\%$ . When agreement is outside this informal action level, investigative measures are initiated to identify anomalies.

The history of these MQA intercomparisons is shown in Figure 1. The various intercomparisons performed since 1984 have used Keithley, Shonka, Exradin, and RADCAL detection systems from NIST, and have involved two different PNL "primary reference"  $^{137}\text{Cs}$  gamma sources. It can be seen from this figure that these intercomparisons have verified traceability.

On a quarterly basis, the  $^{137}\text{Cs}$  reference field is verified through internal constancy checks, again using the PM-30 ionization chamber. The results of these measurements are compared to the decayed exposure rates to ensure that no unexpected changes have occurred (see Figure 2).

### **X-Ray Reference Field**

The calibrations laboratory uses two Philips Model 324 x-ray machines. One of these systems is configured to reproduce the NIST-referenced, filtered techniques (e.g., M30, S60, and H150), and the other is configured to produce K-fluorescence (characteristic) x-rays. These techniques are used to support algorithm development and testing for onsite dosimetry, in addition to providing all of the x-ray techniques within both the NVLAP and DOELAP proficiency testing programs. Future plans include developing specific International Standards Organization (ISO) techniques that are consistent with those developed by NIST.

The x-ray facility is adjacent to the Shepherd irradiation facility, beneath a former reactor-containment room that is heavily shielded. The facility is 4.7-m wide, 12.6-m long, and 4-m high. The x-ray systems are near one end of the long dimension, allowing an irradiation range of approximately 8 m. The K-fluorescence x-ray beam, which is produced at an angle of  $90^\circ$  to the primary beam, is surrounded by a lead shield to prevent scattered photons from the primary beam from contaminating the useful field. Because of this enclosure, the calibration/irradiation range is limited to approximately 1.5 m.

Each x-ray system is equipped with a transmission chamber. Calibration of each x-ray technique is accomplished by calibrating the transmission chamber for the applicable filter pack. The primary reference standard for filtered x-ray techniques with average energy greater than approximately 35 keV is, again, the NIST-traceable PM-30 ionization chamber. Filtered x-ray techniques with average energy less than 35 keV (with half-value layers ranging from about 0.07 to 3.5 mm of aluminum) are calibrated with a NIST-traceable Victoreen Model 415A air ionization chamber. This

chamber, like the PM-30 chamber, has been shown to be extremely stable, with minimal (approximately 5%) variance over the applicable range of x-ray energies.

K-fluorescence techniques are not as directly traceable because NIST does not maintain these techniques. Original reference calibration factors for K-fluorescence were obtained for both the PM-30 and 415A ionization chambers through the National Radiological Protection Board in the United Kingdom. Long-term stability has been assured by constancy verifications using the same instruments that are used to calibrate the beams.

Internal calibrations for commonly used x-ray techniques (e.g., DOELAP and NVLAP techniques) are performed quarterly. The applicable reference chamber is used to establish a new correction factor for the bremsstrahlung and K-fluorescence transmission chambers. The new factors are compared to the old values to screen for any major changes or anomalies involving the system. Agreement of the values is consistently within  $\pm 2\%$ , and typically within  $\pm 1\%$ , as shown in Figure 3 for the M30 and M150 techniques.

As with  $^{137}\text{Cs}$  and  $^{60}\text{Co}$  gamma sources, MQA intercomparisons with NIST are performed for x-rays approximately every two years. Typical interactions involve a subset of several bremsstrahlung (filtered) x-ray techniques, which are performed identically to those for high-energy photons, as described above. Agreement with NIST has been maintained consistently within  $\pm 5\%$ , as shown in Figure 4 for the M30 and M150 techniques.

#### **Beta Reference Field**

Beta sources within the calibrations laboratory are used primarily for dosimetry testing and/or characterization. The isotopic point sources used most frequently include  $^{90}\text{Sr}/^{90}\text{Y}$  (760-keV average energy) and  $^{204}\text{Tl}$  (250-keV average energy), although planar (distributed) sources of these isotopes, depleted uranium, and a  $^{147}\text{Pm}$  (75-keV average energy) source are available. Of highest order within the traceability hierarchy is an Amersham-Buechler beta set, including irradiation jig. This system is directly traceable to the Physikalisch Technische Bundesanstalt (PTB), Germany's national physical standards organization. The system includes two  $^{90}\text{Sr}/^{90}\text{Y}$  sources with activities of 74 and 1850 MBq, an 18.5-MBq  $^{204}\text{Tl}$  source, and a 518-MBq  $^{147}\text{Pm}$  source. Other sources that will fit within the irradiation jig have been procured from U.S. manufacturers. One, a  $^{90}\text{Sr}/^{90}\text{Y}$  source, has encapsulation modified from that of the PTB system to meet specifications of ANSI N13.11, *American National Standard for Dosimetry - Personnel Dosimetry Performance - Criteria for Testing*. Another source,  $^{204}\text{Tl}$ , has a much higher activity than its PTB counterpart.

As stated above, traceability to the PTB has been supplied for the Amersham-Buechler sources. In turn, these sources have been used to establish a PTW extrapolation chamber as an internal reference standard. The extrapolation chamber is then used to calibrate other non-PTB beta sources within the calibrations laboratory. The two non-PTB sources procured to fit within the PTB jig have also been calibrated by NIST personnel within PNL's calibrations laboratory.

Approximately every two years, traceability to NIST is confirmed through an intercomparison using a NIST-owned transfer standard. In the past, NIST has used a PTW Model 2047, large-volume, thin-window transmission chamber, which is described in detail in NBS Special Publication 250-21, *Calibration of Beta-Particle Radiation Instrumentation and Sources*. The intercomparisons have

focused on PTB sources to maintain as much continuity of encapsulation and activity parameters as possible. Agreement between PNL and NIST has typically been maintained within  $\pm 5\%$ .

Established absorbed-dose rates from the various sources are decayed to each date of use; however, these values are verified periodically for constancy. Annually, the extrapolation chamber is verified to be in proper working order, using the PTB standards, and then used to reassess each of the routinely used non-PTB sources. On a quarterly basis, thermoluminescent dosimeter (TLD) measurements are performed which assist in verifying constancy and provide a parameter for trending. Figure 5 indicates the traceability and intercomparison pathway for the various commonly used PNL beta sources.

### **Neutron Reference Field**

Neutron capabilities within the calibrations laboratory include two  $^{252}\text{Cf}$  spontaneous-fission sources. These sources may be used either in unmoderated conditions, producing a spectrum of approximately 2.2-MeV average energy, or within a  $\text{D}_2\text{O}$  moderating sphere (30 cm in diameter and covered with 0.051 cm of cadmium), producing a softer spectrum of approximately 0.5 MeV. The sources are used near the center of a "low scatter facility" that is 10-m wide, 16.4-m long, and 9-m high. The sources are positioned for irradiation through the use of a pneumatic air-transfer system with minimal transit time from storage to exposure.

Each neutron source was submitted to NIST for initial calibration prior to receipt at PNL. Calibrations consist of determining the neutron emission rate using the Manganous Sulfate Bath Method, from which the bare and moderated free-field-dose-equivalent rates are determined using relationships defined in NBS Special Publication 633, *Calibration Techniques for Neutron Personnel Dosimetry*.

During the past several years, several joint efforts have been made by NIST and PNL to establish a suitable MQA method for neutron reference fields. These efforts have involved various measurement devices and outcomes, as indicated in Table 2. Although nominal agreement is somewhat poorer than is typically observed for beta and photon fields, the results are encouraging. With the experience gained from these prior attempts, a successful method of intercomparison may be forthcoming.

Inhouse constancy verifications have been performed periodically for the neutron sources, using a "SNOOPY" neutron detector. This device is a neutron survey instrument that uses a  $\text{BF}_3$  tube to detect thermal neutrons. The detector is surrounded by a cylindrical moderator, as opposed to the spherical moderator used by several other systems. The detector, which has not been used outside the calibrations laboratory, has an established history of accurate performance. Consistent internal agreement within  $\pm 2\%$  has been demonstrated against decayed dose-equivalent rates.

### **QUALITY CONTROL**

In addition to the periodical measurements performed to demonstrate the traceability and constancy of radiological reference fields, systems are established to assess the quality of each dosimeter irradiation. These systems are composed of air ionization chambers placed at key locations within the phantoms, or near the source, to monitor delivered quantities. The use of such devices can provide several key benefits:

- ensuring that the exposure or dose equivalent quantity is correct
- verifying phantom positioning when the device is placed inside the phantom
- verifying the selection of the appropriate source or x-ray technique when there is a multitude of possibilities
- verifying the proper use of flattening filters in the case of beta source irradiations
- accessing exposure time if linked to a backup or recording system, when inadvertent source returns or irradiation-system shutdowns occur.

When not used to detect or recover from anomalies, devices for monitoring quality control provide a means to trend the performance of irradiation systems. Although the monitoring measurements are somewhat less accurate than measurements performed for annual or quarterly constancy verifications, the quantity of the monitoring measurements has the potential for detecting long-term, as well as short-term, biases that may not otherwise be readily observable.

Each type of monitored radiological reference field is configured with a chamber of appropriate sensitivity that is capable of measuring at least some component of the field. Photon irradiations are monitored with air ionization chambers similar to those used for annual calibrations and quarterly constancy checks. Chambers are placed in fixed positions either within the phantom (if used) or in another jig near irradiated dosimeters. Beta irradiations are monitored using a small extrapolation chamber with a thin entrance window suitable for beta particle use. This chamber, which is used in a fixed-volume mode, is mounted within the dosimeter irradiation phantom to ensure reproducible positioning. For neutron irradiations, a tissue-equivalent ionization chamber monitors the photon component yielded by  $^{252}\text{Cf}$  sources. This particular chamber is mounted adjacent to the source, but away from the dosimeter or phantom positions. In most cases, these quality control monitors are capable of verifying each irradiation to within  $\pm 3\%$ . Although the precision level decreases slightly for low-activity sources, the monitors are still extremely useful in measuring irradiation quantity and quality.

## SUMMARY

MQA interactions with NIST are now, and will continue to be, a vital element in maintaining high-quality radiological reference fields at PNL. The interaction process for photon fields has a well-established history. Although the interaction process for beta source measurements is effective, it is somewhat tedious and easily affected by slight differences in measurement techniques between the facilities. NIST is currently investigating methods to improve this interaction. The area currently in most need of development appears to be neutron measurement interaction. The calibration and periodic reassessment of neutron sources at NIST, using the Magnanous Sulfate Bath Method, is valid; however, this method is extremely time-consuming, it requires the ordeal of radioactive shipments, and it does not evaluate free-field dose equivalents within the field environment. In addition, this method cannot be used to assess the effects of moderator usage, which are of prime importance, particularly if subtle differences exist between NIST and field moderator assemblies, as is the case for the PNL  $\text{D}_2\text{O}$ -filled sphere. The most comprehensive assessment requires the simultaneous application of field measurements that, in theory, assess the source, its placement within the facility, the effects of moderation, and the procedure for use. Efforts to identify a suitable

interaction method have been on-going but have left NIST and PNL in a quandary due to differences in outcome.

The use of constancy verifications lends confidence to each traceable radiological reference field and reduces the need for frequent NIST interactions. The use of quality control chambers or other suitable monitoring devices facilitates a high degree of confidence on a daily basis and provides valuable information for long-term trending of each reference field. These devices can also be used to detect potentially interfering radiations from adjoining facilities.

Implementing these practices, in addition to having a comprehensive procedural basis, adequate personnel training, periodic self-assessments, and an open policy for receiving external assessments, provides consistency in calibration techniques and results, and demonstrates a commitment to maintaining a high-quality program.

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# Measurement Quality Assurance Cs-137 Gamma

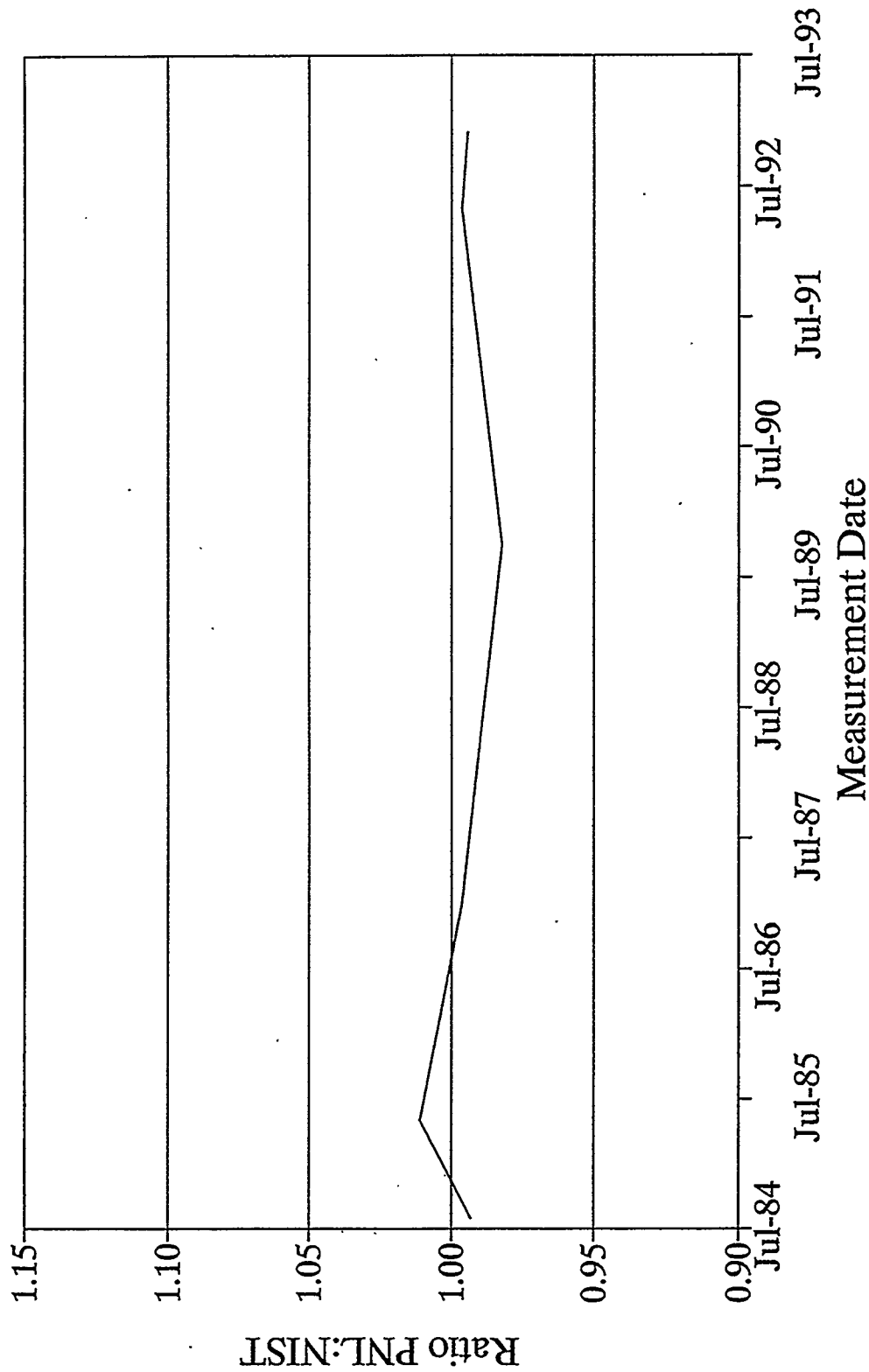


Figure 1 - Comparison of PNL and NIST MQA Results for <sup>137</sup>Cs Gamma Sources

# Periodic Constancy Verification Shepherd Cs-137 Irradiator

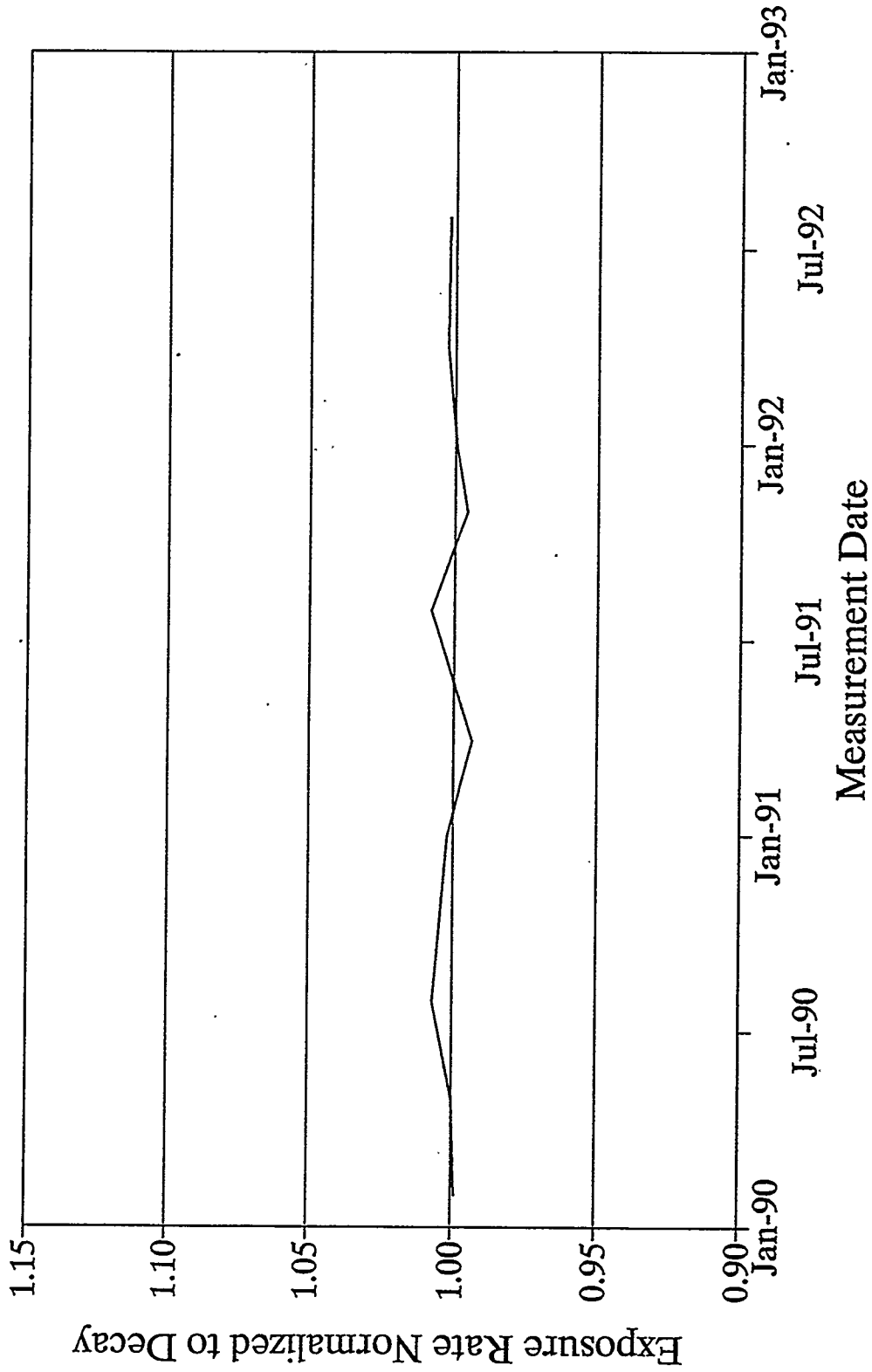


Figure 2 - Constancy Verification Results for Shepherd <sup>137</sup>Cs Gamma Irradiator

# Periodic Constancy Verification

## M30 and M150 X-rays

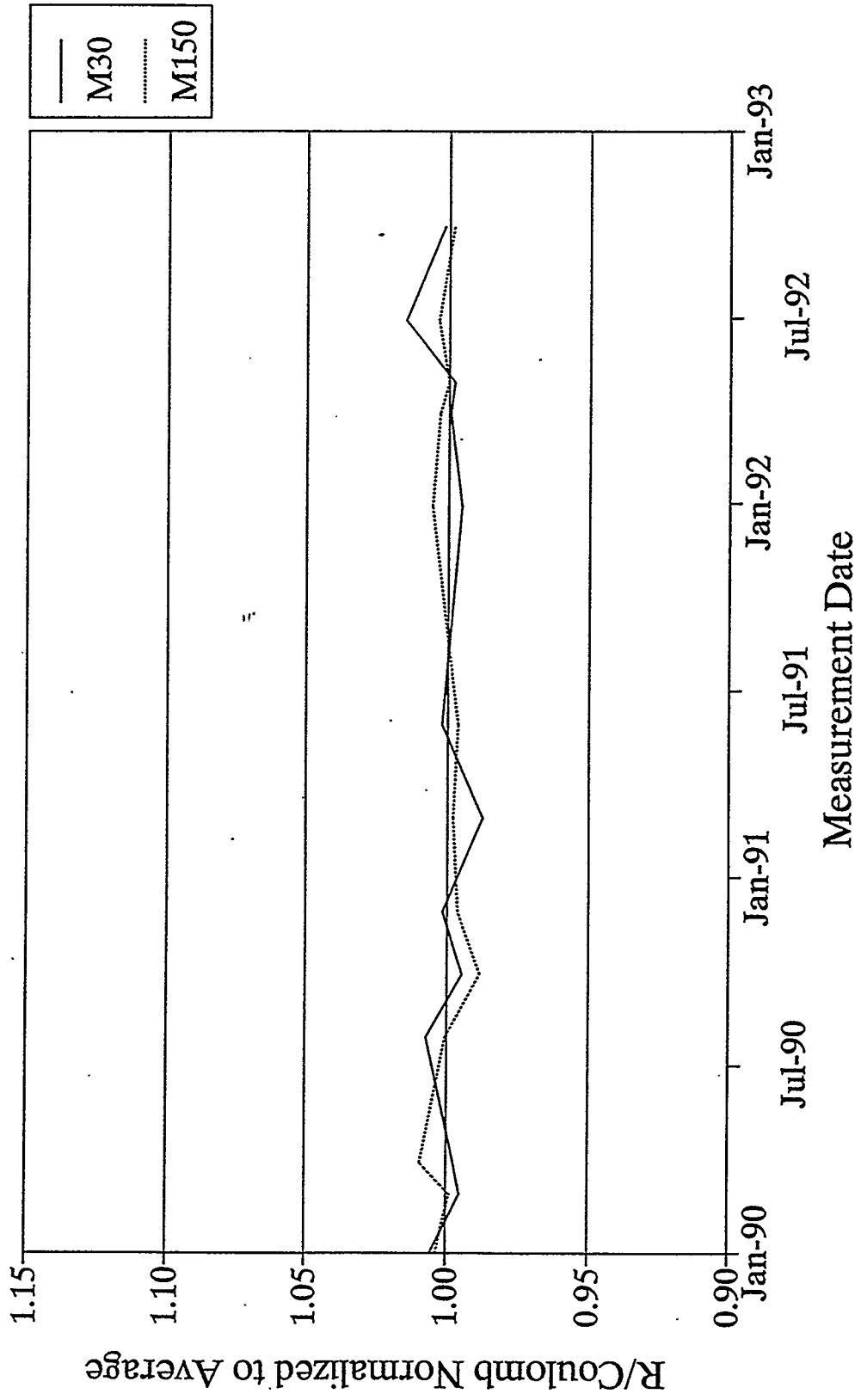


Figure 3 - Verification Results for M30 and M150 Bremsstrahlung X-Ray Techniques



# Measurement Quality Assurance

## M30 and M150 X-rays

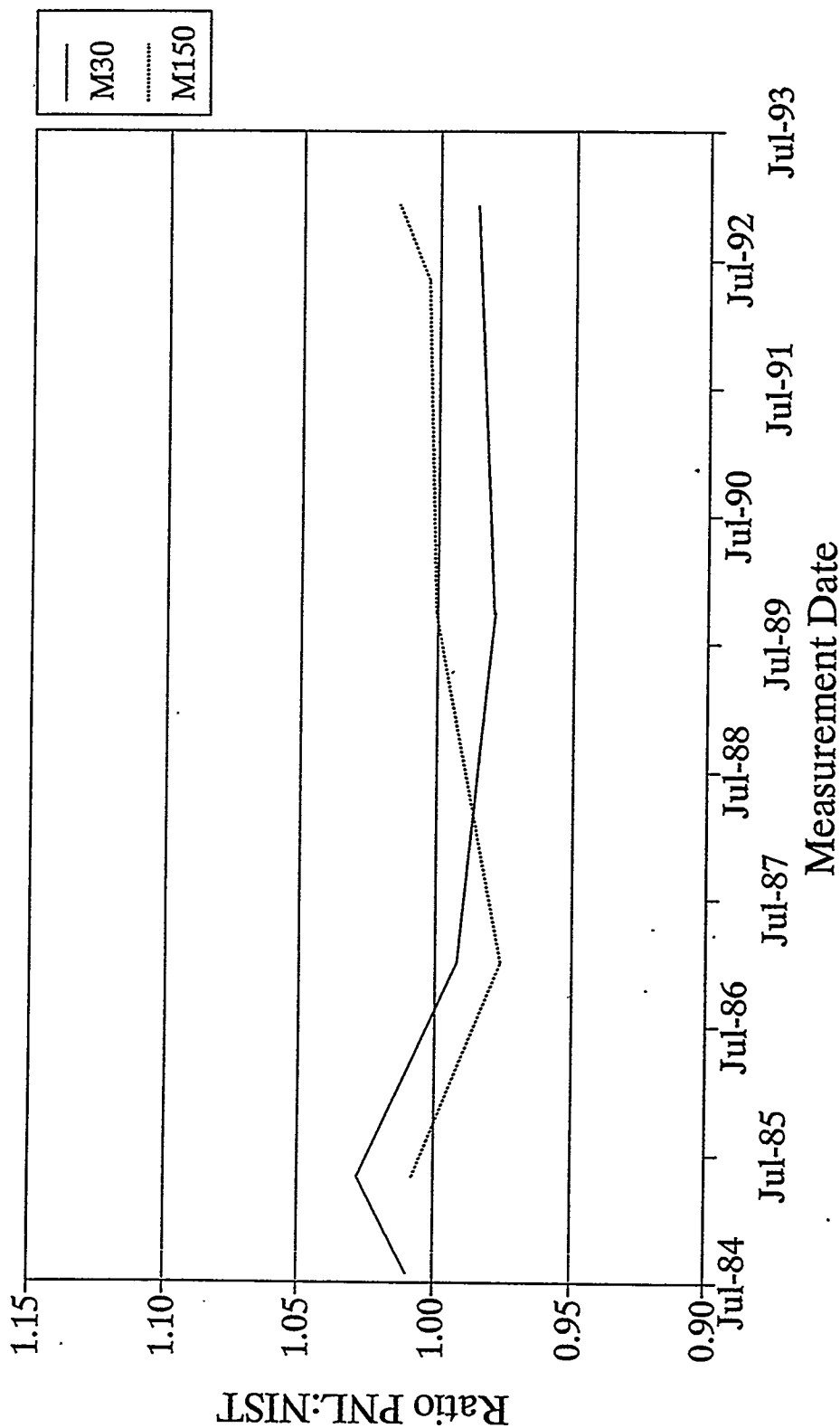
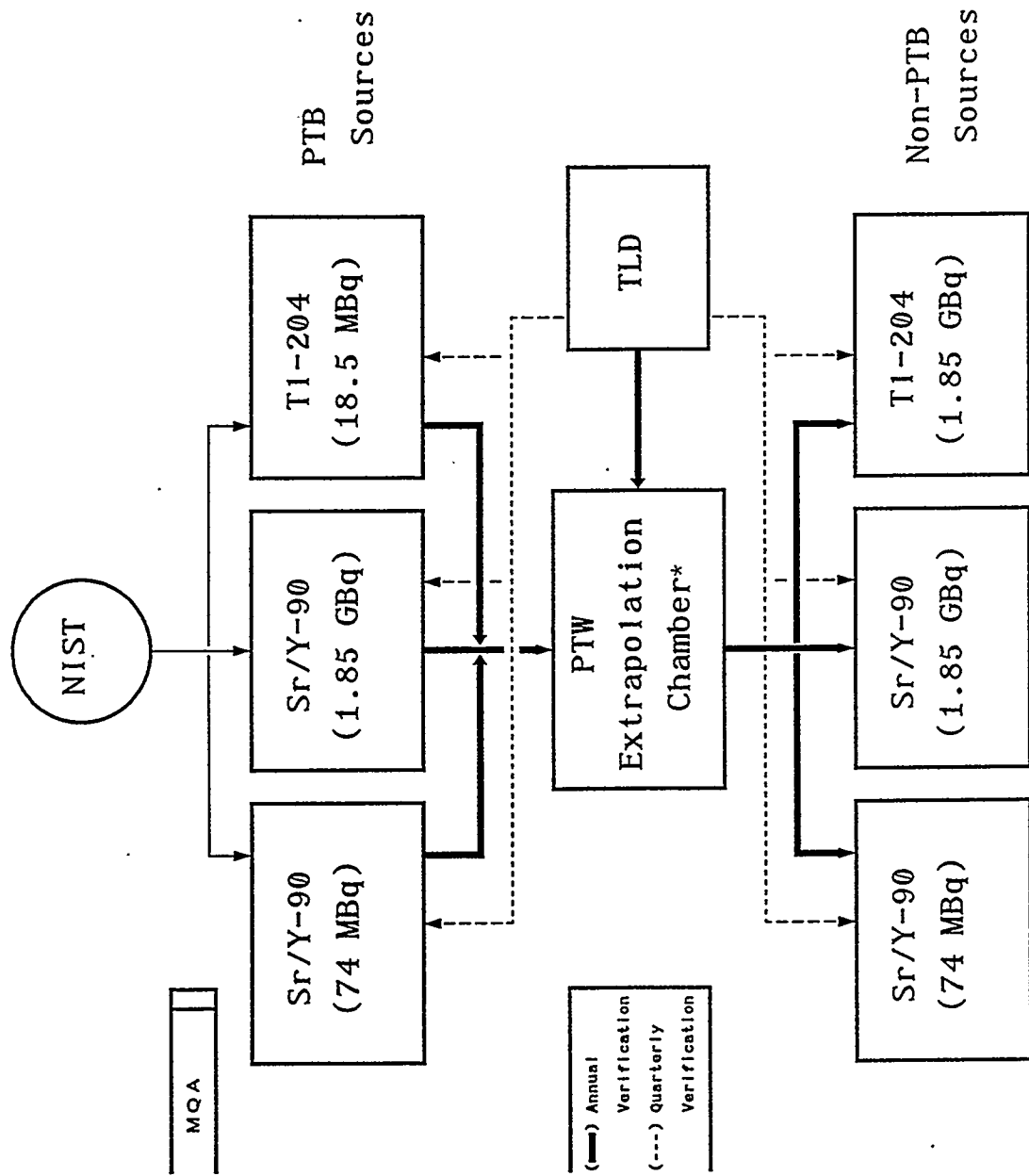


Figure 4 - Comparison of PNL and NIST MQA Results for M30 and M150 Bremsstrahlung X-Ray Techniques



\*PNL-owned.

Figure 5 - Pathway for Maintaining and Verifying the Traceability of Beta Radiation Fields

**Table 1 - Reference Fields Maintained at the PNL Calibrations Laboratory**

Radiation Category	Capabilities Maintained
High-energy photons	$^{137}\text{Cs}$
	$^{60}\text{Co}$
Low-energy photons	Bremsstrahlung (filtered) x-rays
	K-fluorescence x-rays
	$^{241}\text{Am}$
Beta particles	$^{90}\text{Sr}/^{90}\text{Y}$
	$^{204}\text{Tl}$
	Depleted uranium
Neutrons	$\text{D}_2\text{O}$ -moderated $^{252}\text{Cf}$
	Unmoderated $^{252}\text{Cf}$

**Table 2 - PNL Neutron MQA History with NIST**

$^{252}\text{Cf}$ Neutron MQA		
Method	Ratio of PNL to NIST	
	<u>Moderated</u>	<u>Unmoderated</u>
TLD <sup>(a)</sup>	1.18	0.95
CR-39	1.01	1.03
TEPC <sup>(b)</sup>	1.13	1.09
TEIC/GM <sup>(c)</sup>	1.13	1.01

- (a) Thermoluminescent dosimeter. TLD irradiations are performed using the phantom.
- (b) Tissue equivalent proportional counter.
- (c) Tissue equivalent ion chamber Geiger-Müller detector.

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# DATA QUALITY OBJECTIVES

Fred Haeberer<sup>(1)</sup>

*Abstract* - The U.S. Environmental Protection Agency (EPA) spends about \$500 million annually in collecting environmental data for scientific research and regulatory decision making. In addition, the regulated community may spend as much as ten times more each year in responding to EPA compliance requirements. Among the EPA and the regulated community there are several important common concerns: both want to make informed decisions using the right type, quality, and quantity of data. Collecting new data is very resource intensive to all parties. Neither EPA nor the regulated community can afford to collect more or "better" data than are really needed; the Data Quality Objectives (DQO) process is a systematic planning tool for ensuring that the right data will be collected for arriving at a decision within the desired confidence constraints. Using the DQO process to plan environmental data collections can help improve their effectiveness and efficiency, and enhance the defensibility of the decisions for which the data are used.

## INTRODUCTION

Management of environmental data quality is crucial to making correct decisions about Superfund remedial activities. Decision errors regarding hazardous waste site remediation can be classified as either "false positive" or "false negative." When the data erroneously fail to support the true hypothesis that a site does not pose unacceptable risk, then a "false positive" decision can result. This could cause the needless expenditure of millions of dollars in the remediation of a site that does not really require cleanup. Conversely, when the environmental data erroneously support the false hypothesis that a site does not pose unacceptable risk, then a "false negative" decision may result. As a consequence, the site probably would not be remediated. This is clearly the more serious situation in terms of protecting human health, inasmuch as it would leave a potentially serious health threat unresolved.

The traditional focus of environmental data quality has been on laboratory activities. Laboratory measurement (analytical) methods have undergone intense scrutiny to assure that the data are of the quality claimed and can be used in decision making. Millions of dollars of research money have been spent to develop new and/or improved analytical procedures with greater precision and reduced bias

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(i.e., improved accuracy) to produce data that are perceived to be more defensible for remedy selection decisions, litigation or negotiation with potentially responsible parties (PRPs), and cost-recovery actions. There has been a false sense of security in the quality of these data, largely because, until recently, a similar effort had not been made to assure that the samples collected were of the type and quality needed. Sadly, if "bad" samples are collected, even the most precise and accurate analytical methods cannot rectify their quality. For example, a soil sample improperly collected or composited may not represent accurately the actual distribution of contaminants in the area of interest. Similarly, the improper collection of soil samples could result in the loss of volatile constituents critical for risk or exposure determination. Even more seriously, the analytical processes may unwittingly mask the sampling error from being detected and result in the use of poor quality data.

A study of the Superfund remedial investigation/feasibility study (RI/FS) process identified the importance of sampling design and field sampling as activities which contribute significantly to total data error. It emphasized the need for adequate attention to planning, design, implementation, and assessment of environmental data collection programs. This study showed that focused planning, prior to the initiation of any sampling, could improve the current RI/FS process by quantitatively establishing where and how many samples should be collected, thereby reducing the need for unplanned follow-up sampling episodes. In this way, RI/FS time and costs could be reduced and, at the same time, the site decision error rates could be managed at levels acceptable to the data user. This approach considers the activities associated with field sampling and laboratory analysis as components, each contributing its own error portion to the environmental data collection process. It makes the data user aware early in the planning process of the uncertainties associated with the resulting data and provides design opportunities for addressing both sampling and analytical error concerns.

## **THE DATA QUALITY OBJECTIVES PROCESS**

Effective field sampling is achieved by defining what is to be accomplished, planning how to arrive at the defined goal, documenting the required actions, carrying out the documented plan, and assessing the effectiveness or quality of the obtained results. Unfortunately, the data user or decision maker may not understand his/her data quality needs and may consequently be unable to effectively communicate those needs to the technical staff. Conversely, the technical staff may not be able to relate the user's acceptable decision error rates to the data collection design needed to meet the concomitant quality requirements. An effective planning effort is needed to draw the data user and the technical staff into productive communication to bridge the gap in their understanding of the issues. In this way, planning results acceptable to all participants may be achieved. The EPA has developed the Data Quality Objectives (DQO) process to accomplish this vital task. The quality of the information exchanged through this planning process in defining the data user's acceptable decision error rates (i.e., the uncertainty acceptable in the environmental data used in the decision making-process) will directly determine the effectiveness of the data collection design. A responsive data collection design can only be established after the decision, its needed inputs, and the decision error rates acceptable to the data user, have been adequately defined.

The DQO process is a course of action for planning environmental data collection operations that helps the data user(s) decide what data quality (and quantity) will be adequate for decision making and directs the development of a statistical design to collect the data that will meet those needs. The DQO process emphasizes decision making and focuses on quantifying the levels of uncertainty acceptable in data used in decisions. The DQO process provides a logical structure that focuses data collection

planning on the intended use of the data. There are seven steps to the DQO process (see Table 1). The output from each step is used in developing a statistical data collection design.

The DQO process should be used at the planning stage of a data collection operation, before any samples are taken. The outputs of the DQO process provide the information needed by the planning team responsible for the project and form the inputs to the data collection planning process. Only with this type of effective communication of the data user's requirements can the data collection planning team hope to provide a design that will meet the user's needs. In general, EPA's policy is to use the DQO process to plan all data collection efforts that will require or result in a substantial commitment of resources.

## **APPLYING THE DQO PROCESS**

As an example for applying the DQO process and illustrating the outputs that may be expected, a hypothetical, yet plausible, scenario is examined. The example scenario consists of a former wood-preserving plant and storage facility where timbers were treated with creosote and stored prior to their use as telephone and electric power poles, etc. Data available from preliminary investigations and site visits suggest that the site is contaminated with residues and possible spills of the creosote used at the site. While many different compounds may be found in the creosote deposited on the surface soil, the most toxic ones are the polynuclear aromatic hydrocarbon (PAH) constituents. A limited number of soil and ground water samples have been taken at the preliminary assessment/site investigation (PA/SI) stage of the Superfund process. While the water samples indicated that no detectable amounts of PAHs were contained in the sampled ground water, PAHs have been deposited throughout the 18-acre site. Concentration ranging from "not detected" to 83 mg/Kg of total PAHs were found in the soil of the treated timber storage area (14 acres). Soil samples taken in the immediate proximity of where the creosote treatment was carried out resulted in significantly higher yields of PAHs (up to 140 mg/Kg). The site has been scheduled for remediation due to the potential for it contaminating the underlying aquifer, the drinking water source for a nearby residential area. Future land use plans for the site call for single-family residential housing situated on half-acre lots. Working with toxicologists and risk assessors, the Regional Project Manager (RPM) decided that remedial action should be taken if any area of the site presents an increased cancer risk greater than 1 in 10,000. This risk level is approximately equal to 50 mg PAH per kilogram of soil.

Not all of the available information pertaining to the former creosoting site has been presented in the above description. This is also frequently the case in actual applications of the DQO process to real situations. The clear site picture, with all the information needed for developing an effective data collection plan, only emerges through the iterative process that has to be invoked for answering the sometime difficult questions which lead to the formation of DQOs.

### **Stating the Problem**

The planning team is established during the first step of the DQO process. It usually consists of senior program staff (the decision maker/data user, i.e., the EPA Remedial Project Manager [RPM] and/or the state equivalent); technical experts (field and laboratory personnel, engineers); and needed specialists (risk assessor, hydrogeologist, statistician). It is important that all of these people, including managers, participate (or, at a minimum, are kept informed) from the beginning of the DQO process so that it can proceed efficiently. The planning team reviews all available data in order to describe the problem and develop a conceptual site model (if this has not already been done). The

sampling and analysis budget and relevant deadlines are specified. The site manager identifies the scoping team, including representatives from all data users, relevant technical experts, and a design statistician.

In applying this step to the hypothetical creosoting site scenario outlined above, one learns that the site appears to be contaminated with creosote. Polynuclear aromatic hydrocarbons represent the most toxic compounds found in creosote and in the soil of the site. While the ground water at the site is still uncontaminated, there is a strong potential for it becoming polluted as the PAHs leach through the soil. This would endanger the drinking water source of a nearby residential community with the potential of exposing the inhabitants to elevated (unacceptable) cancer risks. The proposed analytical budget is \$100,000. Because of the potential for contaminating the underlying aquifer and the proximity of a residential area, the site has been placed on a priority track, and any needed remediation must commence within one year.

### **Identifying the Decision**

The planning team identifies the site decisions that will be based on analysis of collected data (e.g., whether the site poses an unacceptable threat to human health or the environment), as well as the actions that could result from these decisions (e.g., whether or not cleanup will be required).

The decision(s) to be made for the example scenario focus on remediation actions. The site has already been placed on the National Priority List (NPL) for site remediation due to the underlying aquifer that serves as drinking water source for a nearby residential area. New/additional data will have to be collected quickly to establish what portions of the site are sufficiently contaminated to pose an unacceptable risk ("the decision"). The action that accompanies unacceptable risk is to remove the contaminated soil.

### **Identifying the Inputs to the Decision**

In this step the planning team identifies the specific variables (e.g., the analytes of concern) that will be measured, along with any other information needed to make the decision. Action levels, such as ARARs (Applicable or Relevant and Appropriate Standards, Limitations, Criteria, and Requirements), or target risk levels, which determine whether clean-up activities must be initiated, are also identified in this step.

For the example scenario, toxicology and risk assessment personnel have communicated that the PAHs are the analytes of concern even though the creosote "fingerprint" consists of many other compounds. Decisions on whether site sections are sufficiently contaminated to require soil removal will be based on total PAH concentrations ("the input to the decision"). Furthermore, the project manager working with risk personnel concluded that the target risk level ("the action level") for PAHs in the soil of the example site would be 50 mg/Kg and that contaminated soils with concentrations greater than this should be removed.

### **Defining the Boundaries**

The planning team identifies the spatial and temporal boundaries of the various media needing to be addressed at the site (i.e., the area/volume and time period to which the decision applies). Additionally, the site manager needs to identify whether a single decision will be made about the



entire site or whether the decision will be applied to defined sections (units) of the site. The latter case is most frequently appropriate for remediation of soil contamination where it may be most cost effective to selectively remove only those areas that exceed the action level.

The limited number of samples selected on- and off-site during the preliminary assessment/site investigation phase indicate that soil contamination is confined to the site. Six soil samples collected from just off-site yielded "not detected" results. However, the depth of the soil contamination has not been established except to say it has evidently not reached the aquifer. From the engineer participating in the DQO process it was learned that soil can be removed in 6-inch (15-cm) increments with a high level of control. It was further learned that while half-acre lots (about 45 m x 45 m) were used in developing the target risk levels (i.e., used as exposure units), contaminated soil layers can be efficiently removed from subsections as small as 10 feet by 10 feet (3 m x 3 m). The cost of disposing of PAH-contaminated soil at a licensed Resource Conservation and Recovery Act (RCRA) disposal facility is approximately \$5000 per ton. The analytical costs for determining total PAH in soil by gas chromatography with flame ionization detection is about \$200 per sample and analysis by gas chromatography/mass spectrometry costs about \$400 per sample. This information is useful for developing both data collection and remediation design alternatives so that the lowest cost option meeting all DQOs may be selected for implementation.

### **Developing a Decision Rule**

In this step the planning team develops a statement, known as the decision rule, of how data and the action level will be used in the decision process. This rule should include how data will be summarized and compared to the "assumed" action level for the analyte of concern at the site. As stated earlier, the action level may be based on an ARAR or a target risk level. The decision rule is frequently framed as an "If ---, then ---" statement.

Earlier it was pointed out that the target risk level of PAHs in soil is 50 mg/Kg and that it is EPA policy to clean up to this level. Clearly then, the decision rule must focus on "removal of soil with a concentration exceeding 50 mg/Kg." In defining the boundaries of the study, it was pointed out that clean-up decisions could be made about areas ranging from as large as half-acre home sites to as small as 3 m x 3 m plots. It was also established that 15-cm layers of soil can be efficiently removed. If remedial decisions are to be based on the average PAH concentration of each 3 m x 3 m plot, and only one composited sample was to be collected per plot, a total of 4,050 samples would be generated by the 18-acre site. At \$200 per sample for analysis, the 4,050 samples would generate an analytical bill of \$810,000, clearly exceeding the analytical budget. However, if 15 m x 15 m (50 ft x 50 ft) plots are used, then each half-acre exposure unit would generate only 9 samples composited from each plot for a total of 162 from the entire site. Consequently, the planning team has decided to take a tiered approach for determining which sections will have soil removed from them. Initially composited samples will be collected from the top 15-cm portion of the 162 15-m x 15-m sections that comprise the site. Any plots found to exceed the 50 mg/Kg action limit will be broken down into 25 3-m x 3-m plots and resampled at the surface, at 15 cm and at 30 cm. The samples from 15 cm and 30 cm will be analyzed only in those cases where the surface samples is found to exceed the 50 mg/Kg action level. The soil would be removed only from those plots determined to exceed the action level to the depth of the sample exceeding 50 mg/kg. A 3 m x 3 m x 15 cm (10 ft x 10 ft x 0.5 ft) volume of soil is approximately equal to 50 cubic feet. Each cubic foot of soil nominally weighs 100 pounds. At a cost of \$5000 per ton for the disposal of soil at a RCRA disposal facility, the total cost for the disposal of one 15-cm deep layer of soil from a 3 m x 3 m area would be on the

order of \$25,000. These figures are purposefully presented in "mixed units" to make the point that while a 3 m x 3 m sampling area might seem excessively expensive in terms of analytical costs, the disposal costs of large amounts of soil warrant carefully defining the exact location of the polluted areas so that disposal costs can be minimized.

### **Specifying Acceptable Limits on Uncertainty**

In order to enable the statistician to establish the level of uncertainty acceptable in the data, the decision maker must specify the decision error rates acceptable to him/her under various site conditions. These rates are the probabilities acceptable to the data user of the analytical results, causing the wrong decision to be made. To accomplish this, the data user needs first to be educated regarding the error bounds associated with the environmental data he/she uses and that "true" concentrations of pollutants in various media/matrices cannot be determined with absolute confidence. The data user may want to be more conservative in accepting false negative decision errors than in accepting false positive ones. This is illustrated in Figure 1.

The levels of uncertainty acceptable to the data user are best established by couching data uncertainty in terms of their actual application. In the creosote site example it would perhaps be of limited value to ask the decision maker about the level of uncertainty he/she can tolerate in the data used to make the decision/action regarding soil removal. However, if the decision maker is asked about his/her tolerance for making decision errors at different average concentrations of PAHs in the soil of the site, a more focused answer can be expected. To expedite this process the EPA has adopted the use of the quantitative performance curve depicted in Figure 1. The quantitative performance curve graphs the true concentrations of the analyte of concern on the abscissa while the probability of taking action is graphed on the ordinate. The depicted concentration range must include the action level and should extend several times beyond this point. In the example the decision maker has concluded that below 25 mg/Kg a 5% error rate is acceptable at this site. In other words, the decision maker can accept a 1 in 20 chance of mistakenly removing the soil from areas with PAH concentrations up to 25 mg/Kg. In the range from 25 mg/Kg to 50 mg/Kg the decision maker is willing to accept a 30% false positive decision error rate. The range between 50 mg/Kg and 100 mg/Kg the decision maker regards as an area of indifference, where neither false positive nor false negative decision errors are of concern. From 100 mg/Kg to 150 mg/Kg, the decision maker wants to limit the false negative decision errors to 20%. From 150 mg/Kg to 200 mg/Kg the decision maker wants only a 10% false negative rate, and above 200 mg/Kg, only a 5% error rate is acceptable.

### **Optimizing the Design**

A knowledgeable environmental statistician should, through iteration with the data user, be able to tailor the data collection design and the assumptions underpinning it so that the decision maker's uncertainty constraints can be met by several design options. Subsequently, the scoping team, along with the statistician, identifies the design option best suited to the needs of the site (i.e., that option meeting all DQOs and budgetary constraints) and selects the most cost-effective one. The selected design is incorporated in the Sampling and Analysis Plan (SAP) along with the quality assurance/quality control procedures needed for establishing the effectiveness of the design.

The acceptable decision error rates communicated by the decision maker's consideration of the quantitative performance specification graph provide the primary input needed by the statistical design team for developing sample collection and analysis options. The points defining the acceptable error

rates also define the power curve describing the acceptable data uncertainty. Since the decision whether or not to take action (i.e., sample 3 m x 3 m subplots, remove soil) will be based on PAH concentrations averaged over each area. The statistical design staff will determine how many samples are to be taken in each area, how samples from within areas are to be composited, and how many analyses are to be performed.

The selected design option that results from the DQO process is incorporated into the sampling and analysis plan and/or into the quality assurance project plan (along with the appropriate quality control operations) for implementation in the field and laboratory. Adequate oversight of sampling and analysis activities will help ensure that the design is implemented as intended. The resulting environmental data set should be subjected to Data Quality Assessment, the statistical evaluation to establish quantitatively how well the data user's needs are being met. The DQO process is the first of the three quality assurance operations focusing on planning, implementation oversight, and review/assessment of results, that are recognized by EPA's agency-wide QA program, as needed, for ensuring that the correct type, quality, and quantity of data will be collected for meeting the decision error rates acceptable to the data user.

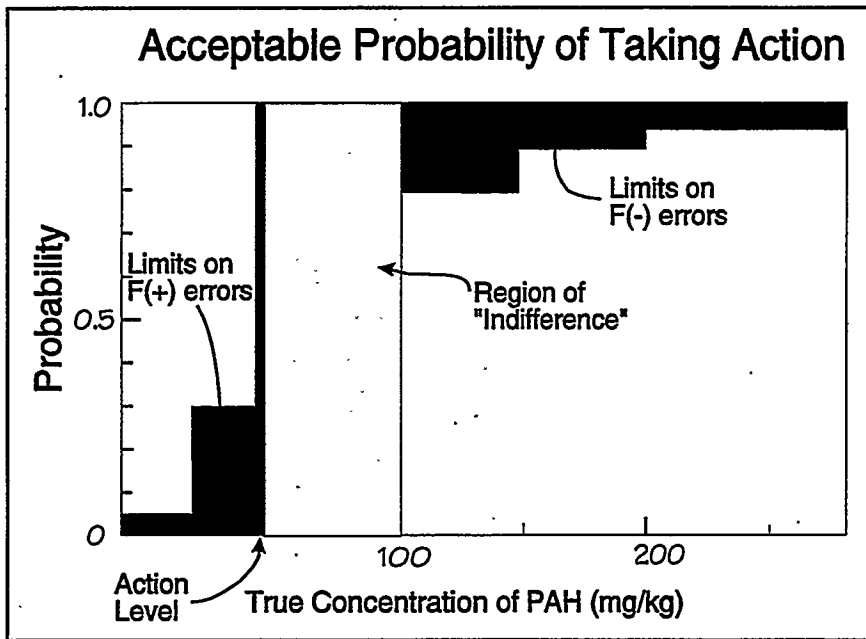


FIGURE I. Quantitative Performance Graph

*Figure 1 - Quantitative Performance Graph*

*Table 1 - Data Quality Objectives Process*

Data Quality Objective Process	
1.	State the problem to be resolved.
2.	Identify the decision to be made.
3.	Identify the inputs needed for the decision.
4.	Define the boundaries of the study.
5.	Develop a Decision Rule.
6.	Specify acceptable limits on uncertainty.
7.	Optimize the design for obtaining the data.

# **IN-HOUSE CONTROLS OF REFERENCE DOSIMETRY LABORATORIES**

Session Chair  
Mike Schaeffer, DNA

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# CHARACTERIZATION OF X-RAY FIELDS AT THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

F. Cerra<sup>(1)</sup>

*Abstract* - This talk summarizes the process undertaken by the Center for Devices and Radiological Health (CDRH) for establishing reference x-ray fields in its accredited calibration laboratory. The main considerations and their effects on the calibration parameters are discussed. The characterization of fields may be broken down into two parts: 1) the initial setup of the calibration beam spectra and 2) the ongoing measurements and controls which ensure consistency of the reference fields. The methods employed by CDRH for both these stages and underlying considerations are presented. Uncertainties associated with the various parameters are discussed. Finally, the laboratory's performance, as evidenced by ongoing measurement quality assurance results, is reported.

## BACKGROUND

The Center for Devices and Radiological Health (CDRH) operates a calibration facility established for providing adequate traceability of ionizing radiation measurements for regulatory purposes. Although calibrations have been provided since 1966, the present facility has been in operation since 1976 and has been accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) since December 1992, under the new Secondary Calibration Laboratory for Ionizing Radiation (SCLIR) program.

The CDRH calibration program, which has been described previously (Ohlhaber 1982; 1985), is concerned with providing traceable calibrations for measurements of x-ray fields of the type encountered in medical diagnostic radiology. In addition, instruments used to evaluate leakage levels from cabinet x-ray systems and consumer products are also calibrated. Since legal action against a manufacturer may ensue based on these measurements, the calibrations performed at this lab must be defensible in a court of law.

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## **CDRH REFERENCE FIELDS**

CDRH has chosen the following National Institute of Standards and Technology (NIST) beams for its calibrations: M20, M30, M50, M100, L80, L100, H50. The first six beams span the range of energies typical of medical diagnostic spectra, and the last is meant to simulate hardened x-rays from electronic products, filtering out of enclosures intended to contain the radiation (i.e., leakage from baggage inspection units, industrial cabinet x-ray units, television sets, Cathode Ray Tubes). The characterization of these beams consists of two major parts. First, the energy spectrum, or beam quality, has to be matched with that of the national standard laboratory. Second, the exposure rate has to be measured accurately so that it can be used as the calibration reference. The first step is accomplished during the initial setup of the beams, while the second is accomplished during each routine calibration performed at the lab. An ongoing quality control program is also in place, which ensures that the initial parameters are maintained and that the exposure rate measurements remain consistent.

## **BEAM QUALITY CHARACTERIZATION**

The "beam quality" is a set of descriptors of the effective distribution of photon energies in a beam. CDRH uses the constant potential kilovoltage (kVcp), half-value-layer (HVL) and homogeneity coefficient (HC) to characterize beam quality. The method is as follows. For a given kVcp setting of the x-ray generator, an attenuation curve for aluminum is obtained. From this curve, the HVL and HC can be determined and plotted as a function of Al filtration. (A typical set of curves is illustrated in Figure 1). The filtration needed for a beam is determined from the HVL curve and matched almost exactly in a filter pack. The actual HVL and HC for the beam are determined by using the respective curves and the actual filtration thickness. Without exception, the HC falls within the allowed 7% of the NIST value for each beam, with the kVcp and HVL matched exactly (within measurement uncertainty). A discussion of the parameters and considerations affecting beam quality follows.

### **Kilovoltage Characterization**

Although the NVLAP accreditation criteria do not specify tolerance limits for kilovoltage analogous to the limits on HVL ( $\pm 5\%$ ) and HC ( $\pm 7\%$ ), it is desirable to approximate the NIST kilovoltages. In any case, the kilovoltage needs to be reproducible. The effects on the beam quality and overall calibration accuracy due to changes in kilovoltage, as measured at the CDRH lab, are summarized in Table 1.

The characterization of kilovoltage at CDRH starts with the x-ray generator specifications and their verification. The output must be constant potential with no significant ripple. There must be good line regulation, adequate resolution of voltage setting, and little drift. There should be a voltage divider and measuring circuit providing a constant, reproducible readout of the actual voltage being applied to the x-ray tube during instrument exposures.

Given adequate capabilities of the generator, the voltage divider and measuring circuit should then be calibrated. At CDRH this is done by spectrometric verification of the cut-off energy, partly because of difficulties in obtaining traceable high voltage dividers.



Finally, there must be a routine quality control program to ensure consistent kilovoltage settings. At CDRH the kV is known within  $\pm 500$  V and reproducible within  $\pm 50$  V. The ripple is  $< 0.1\%$  rms; the line regulation is  $\pm 100$  V for a 10% line fluctuation; the resolution of the voltage setting is 10 V; and the voltage drift is  $< 100$  V in one hour (although the kVcp is always maintained within  $\pm 50$  V while a calibration is in progress).

### **Scatter Contribution**

Two effects of scattered photons must be considered when determining the HVL of a beam. First, the contribution to the HVL measurement error, and second, the effect on the actual beam quality "seen" by the ionization chambers. The first effect is due to the scatter from the filtration used in the attenuation measurements. This skews the attenuation curve, causing the beam to appear "harder" than it really is. This effect may be reduced by using narrow beam geometry when performing the measurements. At CDRH the beam is collimated to a diameter of approximately 2.5 cm at 100 cm from the focal spot. The collimator and filters are placed at half the distance between the detector and x-ray source.

The second effect is due to scatter from the added filtration, the shutter assembly, the collimators, various objects in the room, and the air path. When performing routine calibrations, the beam collimation is constrained by the size of the detectors calibrated. The calibration geometry, therefore, is not as optimal as the geometry of the HVL measurement. Scattered photons, which were excluded by limiting the beam to a 2.5-cm diameter, now contribute up to 7% of the exposure rate. Most of this contribution comes from photons scattered in the added filtration. Room scatter at the CDRH lab contributes only 0.2% to the reference field exposure rate. By limiting the scatter to only small angles ( $\sim 10^\circ$ ), the energy spectrum is not affected significantly. This is due to the fact that, at these angles, the energy loss of a photon is minimal. However, the spectrum is not completely unaffected. Although photons in the energy spectrum incident on the filters are almost equally susceptible to being Compton-scattered at small angles, the photoelectric effect is dominant at low energies. The result is that the proportion of scattered photons contributing to the emergent beam is higher for the high energy end of the spectrum. Since the maximum contribution of scattered photons to the exposure rate is 7%, the energy distribution of these photons is not considered to affect the HVL of the beam significantly.

### **Energy Response of the Detector**

The response of the ionization chamber used in the attenuation measurements is handled in the following manner. For each point in the measured attenuation curve the apparent HVL is obtained from the curve. A correction factor is then obtained, by interpolation, from a plot of the chamber's calibration factors versus HVL. After each point is corrected in this manner and the attenuation curve re-plotted, the procedure is repeated. The new correction factors are then applied to the original data points. After several iterations the attenuation data converges. The resulting curve is then used to determine the beam quality.

### **Purity and Thickness Measurement of Filters**

The purity of all the aluminum filters used for the attenuation measurements as well as in the filter packs is better than 99.9%; therefore no significant errors are introduced by impurities (HVL errors

of 7% could occur if type 1100 Al alloy, which is 99% pure, were used instead (Wagner, Archer, and Cerra 1990)).

The effects of the attenuator thickness uncertainty are given in Table 2. In the worst case, the M20 beam, the HVL changes by 210% per mm of aluminum filtration added (slope at the beam added filtration). Using a Mitutoyo<sup>(1)</sup> dial gauge having a resolution of 0.001 mm, the thickness of each filter was measured in several places and averaged. The resulting thicknesses are believed accurate well within  $\pm 0.005$  mm, contributing less than 1% to the HVL uncertainty. For higher energy beams the error is much smaller.

### **Environmental Conditions and Air Path**

The air path between the source and detector is essentially part of the added beam filtration. As such, it must remain equal at the time of instrument calibrations as at the time of the HVL characterization. For this reason the beam quality is measured at all calibration positions. The density and mass attenuation coefficient of the air path, however, change depending on atmospheric conditions. The temperature and relative humidity, although controlled, do vary with cycling of the heating and air conditioning system, and the barometric pressure ranges over a variation of up to 5% through the year.

The effects of distance and environmental conditions on the M20 beam quality, the most sensitive, are given in Table 3. As can be seen, distance has an important effect. The barometric pressure also has a significant effect, while temperature is not as important because it can easily be maintained within  $\pm 2^\circ\text{C}$ . The relative humidity is not a consideration at the photon energies in question because as the air becomes more moist, its mass-energy absorption coefficient increases; but the density of the air decreases at almost exactly the same rate, so that the two cancel out. (The effects of temperature, pressure, and humidity on the ionization current will be discussed later.)

### **Data Collection Methodology**

Meticulous attention in the collection of data cannot be overlooked. It is not unusual for repeated HVL measurements to yield slightly different results. When a degree of accuracy befitting a standards laboratory is desired, even small effects must be taken into consideration. Systematic errors should be virtually eliminated, and random errors should be minimized by a good experimental design. Since accumulation of one attenuation curve takes approximately 20 minutes, small drifts in parameters are likely. Typically, two ion chamber readings, integrated for about 20 seconds each, are taken and averaged for each data point. Examples of actions taken follow: 1) environmental conditions are monitored continuously, and corrections made where appropriate; 2) the kilovoltage and current through the x-ray tube are monitored for stability; 3) the exposure rate and integrating time are chosen so that resolution is not lost over the desired range of attenuation; 4) multiple readings are taken and averaged, but not so many as to compromise constancy by taking too much time; 5) all the thicknesses of aluminum to be added are decided upon and prepared beforehand, so that data accumulation may proceed at a steady pace; and 6) as the attenuating material is

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<sup>(1)</sup> The mention of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by the Department of Health and Human Services (DHHS).

incrementally added to the beam, every other thickness value is skipped, then the missing points are filled in (in reverse order) as aluminum thicknesses are systematically removed.

### **Quality Control**

After an accurate determination of the filter pack for each beam, the HVL must be monitored so that changes which may come about will be detected before significant errors arise. This is done at CDRH by periodic ionization measurements with and without one HVL thickness of aluminum added. The ratio of the two measurements, corrected for the ionization chamber energy response, should be 0.5-plus or -minus accepted tolerance limits. Other quality control (QC) procedures which will detect a change in beam quality are those which monitor the calibration of kilovoltage and the x-ray yield per tube current.

### **EXPOSURE RATE CHARACTERIZATION**

Routine instrument calibrations at CDRH are performed by measuring the exposure rate of the reference field using a reference ion chamber, then substituting the test instrument in the reference field and repeating the measurement. Each measurement typically consists of several 15-to-30-second integrated exposures of the respective ion chambers. The ratio of reference to test instrument response, after appropriate corrections are made for environmental conditions, is the correction factor for that beam quality. An alternative to this substitution method, which is being considered, would be to monitor the radiation field concurrently with the test instrument exposure. Following is a discussion of the most important elements for the characterization of fields using the substitution method of calibration.

#### **Reference Ion Chamber**

An obvious consideration is the calibration of the reference ion chamber and how well it applies to the field in question. Some important elements regarding the reference ion chamber are the 1) energy dependence, 2) rate dependence, 3) environmental factors, and 4) effective point of measurement. Since the CDRH reference beam qualities are well matched to the NIST beam qualities, and the reference chambers are chosen for optimal response in the region of interest, little error is introduced due to the energy dependence of the reference chambers. Rate dependence effects are also minimal because the calibration exposure rates are too low for ion recombination to be significant.

The environmental conditions are controlled and monitored continuously. Gas law corrections are automatically made for temperature and barometric pressure for each exposure. The effect of relative humidity is limited to changes in the average energy required for the liberation of one ion pair (the energy absorbed per unit volume is not affected significantly, as already seen in the discussion of effects of humidity on beam quality). No corrections are made for relative humidity, as these are considered extremely small. However, if uncontrolled, the relative humidity could reach a level where leakage current becomes a problem, resulting in shutdown of the facility.

An unexpectedly significant effect has been observed for the effective point of measurement of a beryllium window chamber designed for mammography. This instrument is being considered by CDRH as a replacement for the Victoreen 415A as one of the reference chambers. The chamber in question has a considerable lucite backing. Changes in calibration distance produced changes in response which were dependent on energy, leading to the conclusion that backscatter was contributing

significantly to the ionization rate. In a collaborative effort with NIST, which is yet unpublished, this was treated as a shift in the effective point of measurement and characterized as a function of energy.

### **Electrical Charge Measurement System**

The ionization current is collected and measured using one of two methods: 1) a Keithley 617 electrometer operating in the charge mode or 2) a Keithley 616 electrometer measuring the voltage across a standard air capacitor on which the charge is collected. The second method will be phased out. Important considerations pertaining to the charge measurement are the 1) calibration of electrometers and standard capacitors, 2) electronic noise and leakage current, and 3) consistency of performance from day to day.

Each electrometer and standard capacitor is calibrated using NIST-traceable standards prior to installation. Subsequently, quality control procedures are in place which will detect small changes in the calibration not attributable to acceptable statistical fluctuations. If such a change is detected the equipment is re-calibrated. These QC procedures also ensure consistency of measurements from day to day.

Tolerance limits are imposed on the "dark" current so that accuracy is not compromised if conditions of unusually high electronic noise or leakage current exist. The background current is automatically tested against the tolerance limit prior to each reference ion chamber measurement of the exposure rate. The tolerance limit is proportional to the expected ionization current for that specific measurement, and the measurement is not allowed if the tolerance limit is exceeded. This method is preferred over background subtraction because of possible instability of the background current over the duration of a typical exposure.

### **Stability, Uniformity, and Duration of the X-ray Field**

It is imperative, using the substitution method, that the reference field remain stable during the time required to make a reference measurement and a subsequent test instrument measurement. Some of the capabilities of the constant potential generator have already been shown in the discussion of beam quality characterization. In addition, there is regulation of the filament supply within better than 1%. Whenever a set of reference chamber exposures is made and averaged, the standard deviation is automatically calculated and compared to a tolerance limit equal to 1%. If this limit is exceeded the measurement is not accepted. The deviations of test instrument readings are also monitored and flagged if they exceed limits appropriate for the instrument type.

The uniformity of the field is also important. The x-ray tube, is a stationary-anode, water-cooled, industrial tube, generally operated below 3 mA. The anode angle is 22 degrees and the heel effect is considerable: about 0.5% per cm exposure rate gradient in the vertical direction, measured at 1 meter from the focal spot (the distance where all diagnostic instruments are calibrated). The effects of this are kept to a minimum by a very precise positioning system, which places the geometric center of the probes at the reference point in the beam.

Finally, the duration of each exposure must be known with a high degree of accuracy. This is accomplished through a pneumatic shutter. The shutter moves at a speed which introduces little non-uniformity in the spatial delivery of dose, and is accurately timed through position sensors. This allows the kilovoltage to be applied to the tube for the whole duration of one energy point calibration.

This enables accurate setting of kV before starting the exposures, eliminates ramping up and down of the kV, and provides accurate exposure timing.

### **Characterization of Protection-Level Fields Using a Ratio Method**

Protection-level x-ray calibrations of survey meters present two special problems. The first problem is achieving the low exposure rates required, and the second is accurately measuring these rates. The constant potential generator allows microamp current settings while still maintaining an acceptable degree of regulation of the filament supply. However, to achieve the desired exposure rates a longer distance from the source, 7.6 m, is also required.

The reference chamber for these calibrations is the Exradin A6. Although this is a large-volume chamber (800 cc), exposure rates near 0.5 mR/hr (4.4  $\mu$ Gy/hr) do not produce enough current for a high degree of measurement accuracy. This problem is overcome by using two A6 chambers, one at 1 m and one at 7.6 m. At high tube currents both chambers yield accurate measurements. The ratio of exposure rates at the two distances is thus obtained at a high mA setting. After lowering the tube current to the desired level, the substitution method of calibration is used, except that the reference chamber is placed at 1 m and the test chamber is then substituted at 7.6 m. The previously obtained ratio is used to determine the correct exposure rate at 7.6 m.

### **CONCLUSION**

This has been a summary of x-ray field characterization at CDRH. The description given is not complete; there are numerous additional procedures and QC checks. Some considerations of the test instrument response under actual field conditions (e.g., at the exposure rates encountered in diagnostic radiology) have not been described in this talk.

The procedures described are proven procedures. The best method of evaluating a lab's performance is through NIST proficiency testing. The CDRH proficiency test results since 1984 are summarized in Tables 4 and 5. Excluding the H50 survey meter calibrations, the mean  $\pm 3s$  is  $1.004 \pm 0.027$ . This means that, at the 99% confidence level, the total calibration uncertainty is about 3%. The NIST calibration factors of a typical reference chamber, over a period of time, have a similar spread, indicating that a large portion of the error is due to some instability in the reference chamber.

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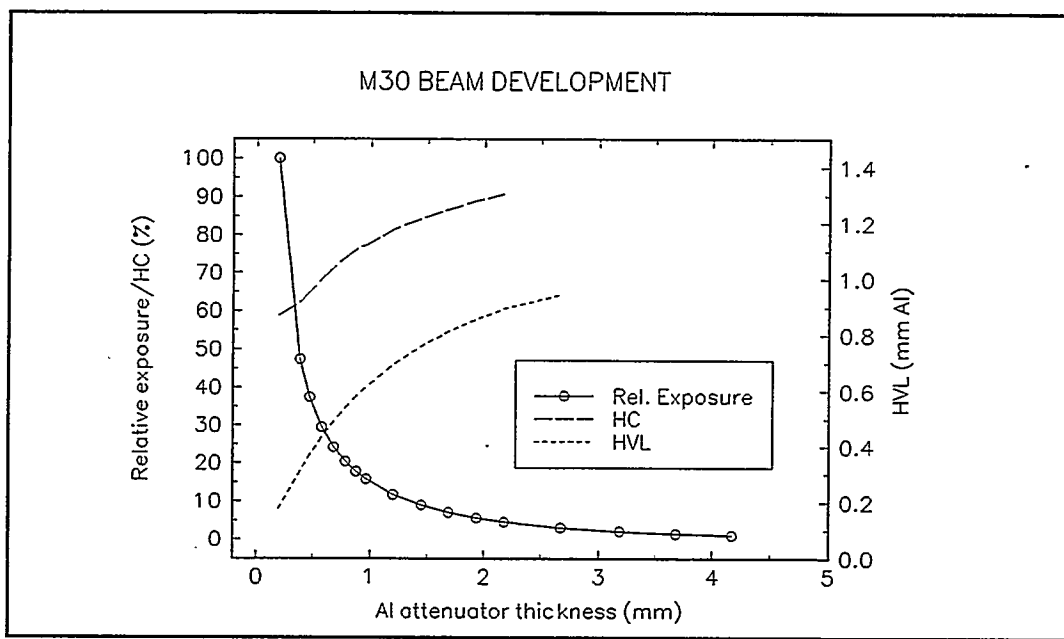


Figure 1 - Attenuation Curve and Resulting HVL, HC Curves for the M30 Beam

Table 1 - The Effects of a Shift in Kilovoltage

Beam	HVL Change per kV (%)	Exp. Rate Change per kV (%)	Error in Measured Exp. Rate per kV (%)	Error in Cal. of MDH 10X5-6 I.C. per kV (%)
M20	5.7	18	.05	~ 1.2
M30	2.8	7.8	.03	~ .6
M50	1.4	3.9	.02	
S75	.8	2.2	.01	
L100	.7	1.8	.02	
M100	.6	2.3	.03	

*Table 2 - The Effects of Attenuator Thickness Uncertainty on HVL*

Beam	HVL Change per mm (%)	Beam	HVL Change per mm (%)
M20	210	L80	44
M30	180	L100	37
M50	56		
M100	10	H50	2

*Table 3 - The Effects of Air Path on HVL (M20 Beam @ 100 cm)*

distance	-9% @ 50 cm +18% @ 200 cm
barometric pressure	~0.6% per in Hg (34 mb)
temperature	~0.7% per 10°C
relative humidity	~0

*Table 4 - Proficiency Test Results: T206 Facility*

Beam	CF(CDRH)/CF(NIST)				
	1984	1986	1988	1990	1992
M20			1.012		0.997
M30	0.983	1.006	1.020	1.014	
M50	0.993	1.011	1.018		
L80		1.020 <sup>(1)</sup>	1.006	1.010	
L100		1.014	1.009		
M100	1.001	1.008	0.999	1.003	1.008
H50 <sup>(2)</sup>			1.026		1.022

(1) S75 beam

(2) Beam for survey meter calibration only

*Table 5 - Proficiency Test Results: T208 Facility*

Beam	CF(CDRH)/CF(NIST)				
	1984	1986	1988	1990	1992
M20			0.999		1.002
M30	0.988	1.015	1.008	1.002	
M50	0.993	1.011	1.007		
L80		1.010 <sup>(1)</sup>	0.997	0.997	
L100		1.004	1.000		
M100	0.990	0.998	0.992	0.998	1.007
M150	1.006		0.994		

(1) S75 beam



# MEASUREMENT QUALITY ASSURANCE FOR BETA PARTICLE CALIBRATIONS AT NIST

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*Abstract* - Standardized beta-particle fields have been established in an international standard and have been adopted for use in several U.S. dosimeter and instrument testing standards. Calibration methods and measurement quality assurance procedures employed at the National Institute of Standards and Technology (NIST) for beta-particle calibrations in these reference fields are discussed. The calibration facility including the NIST-automated extrapolation ionization chamber is described, and some sample results of calibrations are shown. Methods for establishing and maintaining traceability to NIST of secondary laboratories are discussed. Currently, there are problems in finding a good method for routine testing of traceability to NIST. Some examples of past testing methods are given and solutions to this problem are proposed.

## INTRODUCTION

Because of their limited penetrating power, beta particles exhibit strong gradients of energy and angular distribution as functions of spacial position. This makes it necessary for reference fields to be rigorously defined so as to be reproducible between laboratories. Use of these reference fields by secondary laboratories performing accreditation testing necessitates traceability of beta-particle calibrations to national standards.

Reference beta-particle fields have been defined by the International Organization for Standardization (ISO 1984). The reference fields are divided into two types: Series 1 and Series 2. Series 1 reference fields are designed to be uniform over large areas and are suitable for instrument calibration and irradiation of arrays of passive dosimeters. Three sources are included in this series:  $^{90}\text{Sr} + ^{90}\text{Y}$  ( $E_{\text{max}} = 2.274 \text{ MeV}$ ),  $^{204}\text{Tl}$  ( $E_{\text{max}} = 0.763 \text{ MeV}$ ), and  $^{147}\text{Pm}$  ( $E_{\text{max}} = 0.225 \text{ MeV}$ ). A uniformity of  $\pm 5\%$  over a 15-cm diameter is specified for the two higher-energy sources;  $\pm 10\%$  over the same area is specified for the low-energy source. To achieve the necessary uniformity, the sources are used with precisely-defined field flattening filters. Typically, absorbed-dose rates from Series 1

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sources are less than 10  $\mu\text{Gy/s}$ . When higher dose rates are needed, the Series 1 sources, as well as  $^{14}\text{C}$  ( $E_{\text{max}}=0.156\text{ MeV}$ ) and  $^{106}\text{Ru} + ^{106}\text{Rh}$  ( $E_{\text{max}}=3.54\text{ MeV}$ ), may be used without flattening filters. There are requirements on all sources of the maximum energy of the beta-particle spectrum at the calibration distance ( $E_{\text{res}}$ ). This requirement limits encapsulation thickness and distances at which the sources can be used. Specified values for  $E_{\text{res}}$  are given in Table 1; methods for determining this quantity are given in the ISO Standard 6980 (ISO 1984).

The ISO Series 1 reference fields were implemented at National Institute of Standards and Technology (NIST) in the early 1980's (Pruitt, Soares and Ehrlich 1988). Some of the ISO reference beta-particle fields have as well been adopted in the U.S. for accreditation testing. The  $^{90}\text{Sr} + ^{90}\text{Y}$  field was chosen for personnel dosimeter testing in the American National Standards Institute (ANSI) Standard N13.11, "Personnel Dosimetry Performance - Criteria for Testing" (ANSI 1983). This reference field, as well as the  $^{204}\text{Tl}$  field was adopted for personnel dosimetry testing by the U.S. Department of Energy (DOE 1986). In addition to the ISO criteria, DOE added additional criteria concerning ratios of dose rates; these are shown in Table 1. The addition of the  $^{204}\text{Tl}$  source as well as the DOE criteria have been proposed for inclusion in the revision of ANSI N13.11 (ANSI 1993).

Performance testing of personnel dosimetry processors with these standards is carried out by secondary testing laboratories. It is important that the irradiations performed in the fields employed by the secondary laboratories be traceable to NIST. In addition, the quality of measurements at NIST must be assured. The steps in this process are shown schematically in Figure 1. The horizontal line represents the NIST internal quality assurance procedures. The procedures for establishing traceability to NIST of secondary calibration laboratories is represented by the slanted line. Finally, the vertical line represents routine measurement quality assurance procedures necessary to maintain secondary laboratory traceability. Each of these is discussed in the following sections.

## INTERNAL QUALITY CONTROL AT NIST

### Measurement Procedure

A service (Simmons 1991) for the calibration of protection-level beta-particle sources and instrumentation was established at NIST in 1985. Sources accepted for calibration include ISO 6980 Series 1 sources, as well as suitably active small-area sources and large-area plaque sources including, but not restricted to, ISO 6980 Series 2 sources. Ionization chambers accepted for calibration are thin-windowed fixed-gap parallel-plate ionization chambers and thin-windowed extrapolation chambers. Beta-particle sources are calibrated in terms of absorbed-dose rate to tissue at either the surface, the chamber window-thickness depth ( $2.6\text{ mg/cm}^2$ ), or  $7\text{ mg/cm}^2$ . Absorbed-dose rate to tissue is determined from current measurements with the NIST-automated extrapolation chamber at a range of air gaps. The absorbed-dose rate to tissue in Gy/s is given by

$$\dot{D}(z) = \frac{(\bar{W}/e) S_{\text{air}}^{\text{tissue}}}{\rho_0 A} \left( \frac{\Delta I_c}{\Delta d} \right)$$

where  $\dot{D}(z)$  is the absorbed-dose rate to tissue at depth  $z$ ,  $(\bar{W}/e)$  is the average energy required to produce an ion pair in dry air ( $33.97\text{ J/C}$ ),  $S_{\text{air}}^{\text{tissue}}$  is the ratio of the average mass stopping power of tissue to air,  $\rho_0$  is the density of dry air at the reference conditions of  $22^\circ\text{C}$  and  $760\text{ Torr}$  ( $1.197\text{ kg/m}^3$ ),  $A$  is the area of the collecting electrode ( $7.083 \times 10^{-4}\text{ m}^2$ ), and  $(\Delta I_c/\Delta d)$  is the fitted slope of the corrected current versus air gap function in  $\text{A/m}$ . For all sources calibrated, a stopping power

ratio of 1.12 is employed (ISO 1993). The effect of direct beam charge collection is removed by averaging measurements made at both positive and negative polarities. A constant potential gradient of 10 V/mm is employed for all air gaps to avoid deformation of the thin entrance window by attraction to the collecting electrode. For sources measured off contact, a range of air gaps from 0.5 to 2.5 mm will yield a linear function of corrected current versus air gap. For contact measurements, smaller air gaps are necessary to yield a linear function. For depleted uranium slab sources, for example, a range of 0.3 to 1.1 mm has been used successfully.

At NIST, signal current is measured by a negative-feedback amplifier with a capacitive feedback element (Lamperti, Loftus, and Loevinger 1988). This is accomplished by voltage measurements with an electrometer in the feedback mode for known periods of time. The corrected signal at each polarity,  $I_c^{+,-}$ , is given by

$$I_c^{+,-} = \left[ \left( \frac{V^{+,-} C}{t} \right) \Pi_c \Pi_k \right] - I_B^{+,-}$$

where  $V^{+,-}$  is the voltage measured at each polarity,  $C$  is the external feedback capacitance (101.19 pF),  $t$  is the integration time,  $\Pi_c$  is the product of various chamber signal correction factors,  $\Pi_k$  is the product of various source output correction factors, and  $I_B^{+,-}$  is the current measured in the absence of a source (background or leakage signal). For the NIST extrapolation chamber, the last term is less than  $\pm 2$  fA, so it can be neglected for signal currents above about 1 pA. The correction factors employed at NIST are described in Table 2, along with the sources that they should be employed with. Details on their determination and calculation are given elsewhere (Pruitt, Soares, and Ehrlich 1988).

When absorbed-dose rate at depths other than the extrapolation chamber window-thickness depth are desired, a transmission factor must be employed to account for the difference in depth. The transmission factor,  $T(z)$ , is defined as the ratio of the absorbed dose rate at depth  $z$  that at the surface. Values for some transmission factors are given in the latest revision of ISO 6980 (ISO 1993).

Thin-windowed, fixed-gap parallel plate ionization chambers are calibrated in terms of absorbed-dose rate to tissue at  $7 \text{ mg/cm}^2$  per unit of corrected ionization current. Measurements are made in well-characterized NIST beams of known absorbed-dose rate. Ionization currents are corrected to reference temperature and pressure only.

Thin-windowed extrapolation chambers are also accepted for calibration. A calibration of an extrapolation chamber alone can really only tell two things. The first is the accuracy of the air gap setting as indicated on the micrometer barrel. The correction is a constant independent of air gap and is determined from the x-intercept of the fitted corrected current versus nominal air gap function; it is normally in the range of less than  $\pm 70 \mu\text{m}$ . The offset value determined in this way is slightly dependent upon the beta-particle source used. The second thing that can be learned from a calibration is the area of the collecting electrode, which is inversely proportional to the absorbed-dose rate as determined from the slope of the fitted corrected current versus nominal air gap function. Thus, if the current induced in the air gap volume is measured carefully and accurately, and the proper corrections are applied to the measured currents, absorbed-dose rate can be accurately inferred.

The level of precision in an extrapolation chamber measurement is a function of source strength and the background or leakage signal in the extrapolation chamber. Typical values for leakage currents are  $< \pm 2$  fA for high-quality instruments. Thus, with care, signals of a few fA can be measured with satisfactory precision (standard deviation less than 5%) at this leakage level. A signal level of 2 fA/mm corresponds to an absorbed-dose rate of about  $0.09 \mu\text{Gy/s}$  ( $33 \text{ mrad/hr}$ ). To achieve adequate precision at these levels requires fairly long signal integration times, interleaved background signal measurements for background subtraction, and a large number of replicates. In this laboratory, 3 min runs are used, with 30 measurements of both background and source-induced currents per polarity and air gap. With the NIST-automated extrapolation chamber, this procedure takes about 30 hours for 5 air gaps.

Results of some recent source and extrapolation chamber calibrations are shown in Figures 2 to 4. In Figure 2, corrected current versus nominal air gap curves are shown for the NIST extrapolation chamber and a customer extrapolation chamber. The source used is the NIST Series 2  $^{90}\text{Sr}+^{90}\text{Y}$  source measured at a 50-cm distance from the source to the chamber entrance window (SSD). The figure shows that the measured slopes,  $453.1 \pm 0.2$  fA/mm for the NIST chamber and  $452.6 \pm 0.3$  fA/mm for the customer chamber, are very similar, but that the intercepts are somewhat different, being  $-61.4 \pm 0.7 \mu\text{m}$  for the NIST chamber and  $+13.5 \pm 1.0 \mu\text{m}$  for the customer chamber. The uncertainties shown represent one standard deviation. To remove the effect of the different intercepts, the same data are plotted in Figure 3, but with the air gaps corrected for the x-axis intercept position. Also, to bring out more detail, current per unit corrected air gap rather than current is plotted on the y-axis; in this representation, the fitted slope is a constant. The error bars (too small to be seen in Figure 2) are  $\pm 1$  standard deviation of the 30 replicates performed at each air gap using a 20-s integration time. The difference between the two slopes is about 0.1%. In Figure 4, similar results are shown of measurements with a customer Series 1  $^{204}\text{Tl}$  source. Measurements with three extrapolation chambers are shown, again with standard deviations from 30 replicates, but this time with integration times of 3 min each due to the low signal levels. Agreement among the three measurements is about 0.5%.

### Quality Assurance

Routine measurement quality is assured by repeated measurements of the NIST Series 1 sources. Each time a customer source is calibrated, at least one NIST source is calibrated as well, as a check on the measurement system performance. A similar procedure is followed when a customer ionization chamber is calibrated. The measurement system is considered in control if the NIST source calibration is within 1% of the average of previous measurements for  $^{90}\text{Sr}+^{90}\text{Y}$  and  $^{204}\text{Tl}$  or within 3% for  $^{147}\text{Pm}$  and contact sources.

When the NIST facility was being developed, Series 1 sources calibrated by the Physikalisch-Technische Bundesanstalt (PTB) were obtained. The NIST calibration of these sources is within 2% of the PTB values for  $^{90}\text{Sr}+^{90}\text{Y}$  and  $^{204}\text{Tl}$  and within 5% for  $^{147}\text{Pm}$ . This comparison established traceability of the NIST measurements to another national standards laboratory. In setting up the measurement system, accuracy of measurement was ascertained for 1) voltage measurement by the electrometer, 2) temperature, 3) pressure, 4) relative humidity, and 5) time. In addition, the value of the feedback capacitor was determined. Periodically, the accuracy of these parameters is reascertained.

A major factor in continued high-quality measurement has been the complete automation of the NIST extrapolation chamber current measuring system, completed in 1991 (Pruitt 1991). Under computer control is the reading of the temperature, pressure and relative humidity, reading of the electrometer voltage, grounding and ungrounding of the electrometer, opening and closing of the shutter, setting of the extrapolation chamber high voltage, and setting of the air gap. The control program also contains all the information necessary to calculate the corrections needed for the extrapolation chamber signal currents and the source output. With the controls and readout fully automated, it is possible to set up lengthy integration times with many replicates; this makes it feasible to measure very low signal levels with reasonable accuracy. Automation minimizes mistakes in reading and instrument settings that are possible with normal human control.

## **ESTABLISHING TRACEABILITY TO NIST**

When a secondary calibration laboratory is accredited it is necessary that traceability of the laboratory's calibrations to national standards be established. One mechanism for this establishment is for the laboratory's sources and extrapolation chamber to be calibrated by NIST. For a laboratory located at relatively high altitude, where low air density effects low energy source ( $^{147}\text{Pm}$ ) output, the best solution is for the source calibration to be performed at the laboratory site. For higher energy sources, calibrations at NIST are preferred, since direct comparisons with national standards are possible. The secondary laboratory's extrapolation chamber also needs to be calibrated at NIST, subject to the caveats discussed above. These calibrations need to be coupled with accuracy checks of the secondary laboratory's temperature, pressure, humidity and current measurement systems. It is also desirable for there to be an on-site laboratory assessment by NIST personnel as part of the accreditation procedure. These steps allow the establishment of traceability to NIST of beta-particle calibrations and irradiations performed by the secondary laboratory.

## **MAINTAINING TRACEABILITY TO NIST**

Secondary laboratory measurement quality is maintained by good quality control procedures. In addition, periodic external checks are necessary. These usually take the form of irradiation or calibration of mailed test devices for comparison to values obtained at NIST. The most desirable form of such a test is the comparison of calibrations of an unknown source. Calibration of an unknown source tests the entire measurement system, and for this reason, passing such a test is considered to best demonstration of traceability. Criteria for passing such a test is a difference of less than 5% (Eisenhower 1991) from the source output specified by NIST. To date, there have been no such tests carried out; however, such tests are planned for the future.

A second, less desirable form of test is comparison of calibrations of a suitable transfer instrument. For this purpose, a thin-windowed parallel-plate ionization chamber was procured and calibrated by NIST. Several mailings of this device have occurred since 1985; the results have proven that this device is not suitable for this purpose. The main problems with the instrument have been a lack of reproducibility of the calibrations at NIST with the low-level Series 1 sources, mainly due to very high and unstable leakage currents which are not independent of polarity. For this reason, this device will no longer be employed for measurement assurance studies.

A third form of measurement assurance is irradiation of NIST-supplied calibrated passive devices by the secondary laboratory with return to NIST for evaluation. Such tests have proven useful in the past for photons, but up to now they have not been employed by NIST for beta particles. A

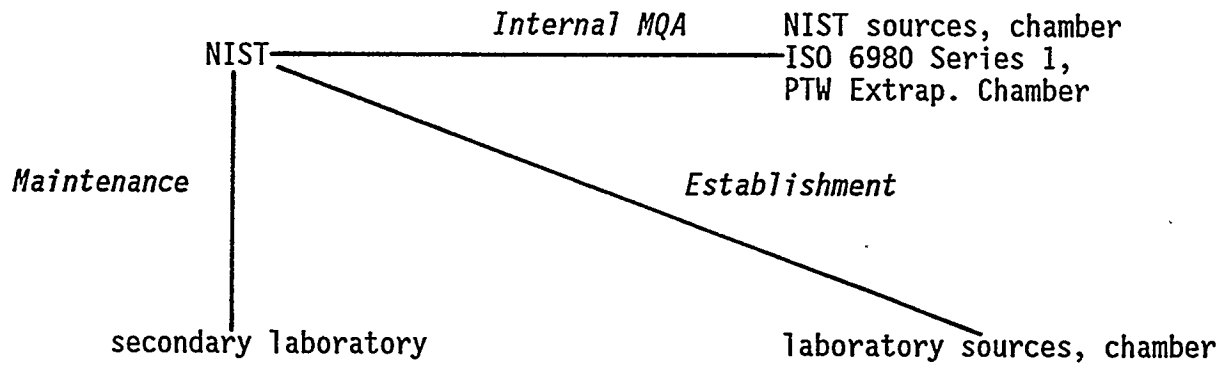
promising development has been the electret ionization chamber (Kotrappa, Soares, and Hobbs 1993) which is capable of measuring absorbed dose to beta particles at the 0.3 mSv level with uncertainties of less than 5% at the 95% confidence level. Problems with transit doses can be avoided since the device can be rendered inactive during shipment by removing the collecting volume from the electret. Readout is very simple and non-destructive; readout devices are sufficiently inexpensive so that one could be included with the dosimeters and used by the secondary laboratory to read devices before and after irradiation. Blindness would be maintained since the calibration factors for the particular devices employed would be known only by NIST. Such a system has been obtained by NIST and will be tested in the coming year as a possible alternative to shipment of active devices.

## CONCLUSIONS

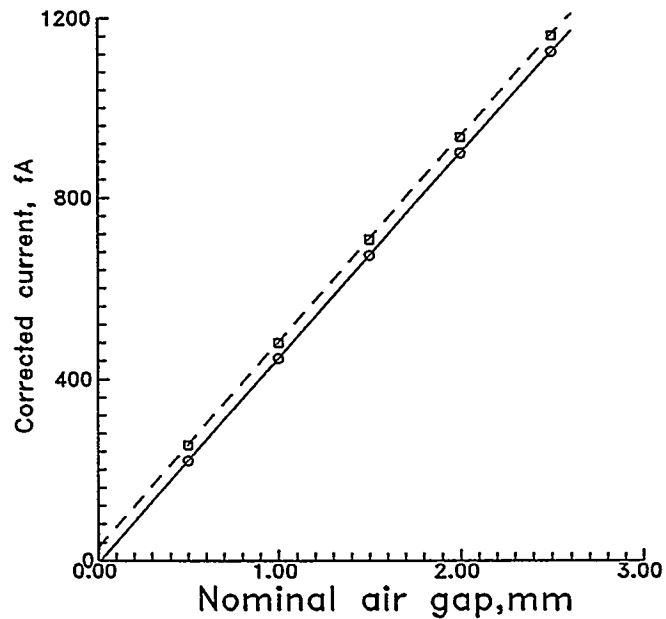
Internal measurement quality assurance at NIST is well established for beta-particle dosimetry calibrations through quality control procedures followed for every customer calibration. Traceability to another national standards laboratory (PTB) has been established. Procedures for establishing traceability to NIST for secondary laboratories doing beta-particle source and instrument calibrations and dosimeter irradiations, are well understood and are being followed. Where challenges presently lie are in procedures for maintaining traceability to NIST through routine measurement quality assurance tests. Several alternatives were discussed and possible solutions outlined. The challenge for the future will be the successful implementation of a good measurement quality assurance test with the required accuracy and sensitivity for establishing traceability of secondary laboratories to NIST at the necessary level of 5% for beta particle fields.

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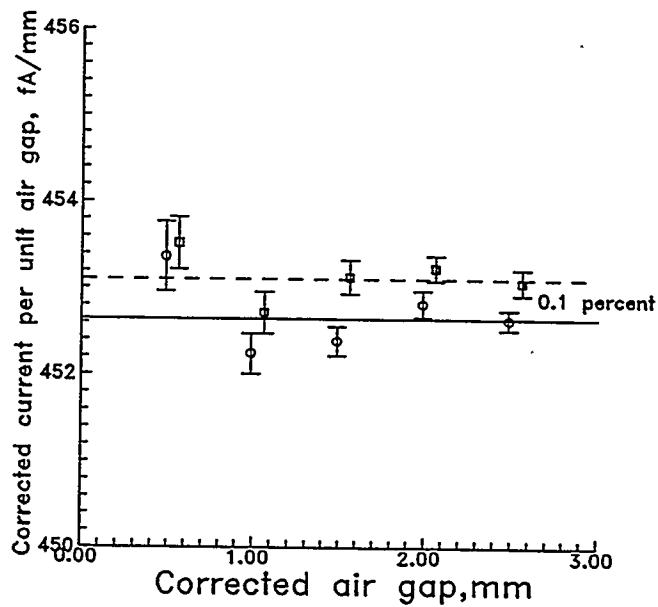


**Figure 1 - Schematic Diagram of Measurement Quality Assurance Procedures for Beta-Particle Calibrations**

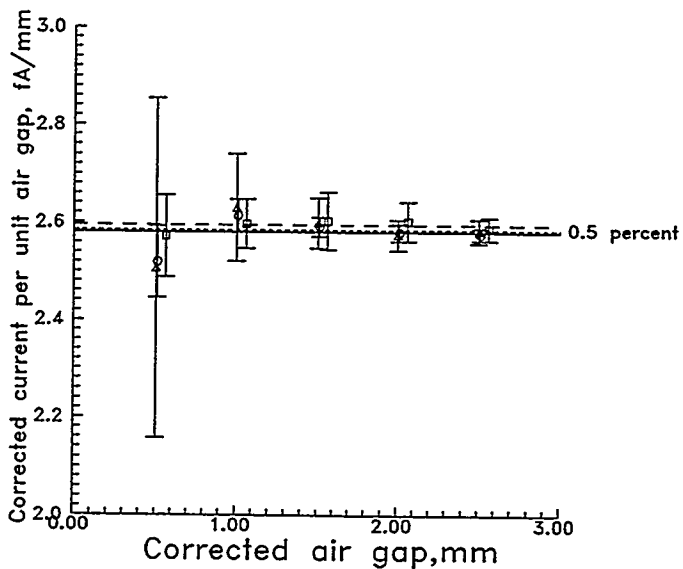


**Figure 2 - Sample Extrapolation Chamber Calibration Data. Squares: NIST Chamber. Circles: Customer Chamber. Lines: Linear Least-Squares Fits to the Data.**





*Figure 3 - The Same Data as in Figure 2, but Corrected for X-Intercepts and Expressed as Current Per Unit Corrected Air Gap*



*Figure 4 - Calibrations of a Customer <sup>204</sup>Tl Source With Three Different Extrapolation Chambers. Squares: NIST Chamber. Circles and Triangles: Customer Chambers*

**Table 1 - Beta-Particle Source Specifications**

Source	ISO 6980	DOELAP (DOE/EH-0027)
$^{14}\text{C}$	$E_{\text{res}} > 0.09 \text{ MeV}$	not used
$^{147}\text{Pm}$	$E_{\text{res}} > 0.13 \text{ MeV}$ $\pm 10\%$ uniform over 15 cm (Series 1 only)	not used
$^{204}\text{Tl}$	$E_{\text{res}} > 0.53 \text{ MeV}$ $\pm 5\%$ uniform over 15 cm (Series 1 only)	$D^a(100 \text{ mg/cm}^2)$ ----- = $0.80 \pm 0.05$ $D(7 \text{ mg/cm}^2)$
$^{90}\text{Sr} + ^{90}\text{Y}$	$E_{\text{res}} > 1.80 \text{ MeV}$ $\pm 5\%$ uniform over 15 cm (Series 1 only)	$D(100 \text{ mg/cm}^2)$ ----- = $1.01 \pm 0.03$ $D(7 \text{ mg/cm}^2)$  $D(1000 \text{ mg/cm}^2)$ ----- $< 0.01$ $D(7 \text{ mg/cm}^2)$
$^{106}\text{Ru} + ^{106}\text{Rh}$	$E_{\text{res}} > 2.80 \text{ MeV}$	not used

<sup>a</sup>D refers to dose or dose rate at the depth indicated.

**Table 2 - Correction Factors Applied to Measurements with the Extrapolation Chamber**

1. Extrapolation Chamber Signal

		<u>Applied to:</u>
$c_{T,p}$	ambient conditions different from STP	All sources
$c_{\text{recom}}$	incomplete ion collection in the collecting volume	All sources
$c_{\text{div}}$	decreasing electron flux with increasing air gap	Non contact
$c_{\text{atten}}$	attenuation in the chamber air gap	Series 1 only
$c_{\text{back}}$	difference in backscatter between tissue and PMMA	All sources
$c_{\text{side}}$	for scatter from the chamber sides	Series 1 only
$c_{\text{phot}}$	photon production in intervening material	Series 1 only

2. Source Output Corrections

$k_{\text{dec}}$	source decay from reference date	All sources
$k_{\text{mass}}$	absorption in beam path different from that at STP	Series 1 only
$k_{\text{hum}}$	humidity	Series 1 only

# **IN-HOUSE CONTROLS OF RADIOACTIVITY LABORATORIES**

Session Chair  
Don Brogan, EML

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# PRIMARY CALIBRATIONS OF RADIONUCLIDE SOLUTIONS AND SOURCES FOR THE EML QUALITY ASSESSMENT PROGRAM

I. M. Fisenne<sup>(1)</sup>

*Abstract* - The quality assurance procedures established for the operation of the U.S. Department of Energy's Environmental Measurements Laboratory (DOE-EML's) Quality Assessment Program (QAP) are essentially the same as those that are in effect for any EML program involving radiometric measurements. All these programs have at their core the use of radionuclide standards for their instrument calibration. This paper focuses on EML's approach to the acquisition, calibration and application of a wide range of radionuclide sources that are required to meet its programmatic needs.

## INTRODUCTION

The DOE-EML administers the QAP for the DOE Office of Environment, Safety, and Health (EH) and the DOE's Office of Environmental Restoration and Waste Management (EM). This program provides an independent vehicle for the evaluation of the quality of near environmental-level radiometric measurements required by DOE and its contractor facilities. To serve this need across the DOE complex, five environmental matrices are considered of fundamental importance: aerosol samples, tissue, soil, vegetation, and water. The variety of specific radionuclide analyses and the large number of facilities required (by DOE Order 5400.1 and EM memorandum) to participate in QAP present a formidable task in order to develop sufficient materials, on a semiannual basis, to meet the needs of the program. From the outset, QAP has been committed to the use of natural matrix materials as the best means of testing the analytical competence of the participants. In the late 1950s, EML (at that time called the Health and Safety Laboratory, HASL) pioneered the development of natural matrix materials for its internal quality assurance/quality control (QA/QC), radiochemical methods development, training and analyst qualification programs for the measurement of <sup>90</sup>Sr from global fallout.

EML's procedures for sample collection, preparation, analyses, sample distribution, and data reports for QAP have been described previously (Sanderson and Feiner 1983; Sanderson 1992).

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Realistically, only the soil, tissue, and vegetation matrices could be prepared in quantity for use in QAP. Since the inception of the QAP, aerosol or air filter samples and water samples have been prepared from mixtures of calibrated radionuclide solutions. The challenge has been to obtain the solutions as the National Institute of Standards and Technology (NIST) Standard Reference Materials (SRM) solutions or to calibrate solutions at EML which would be considered traceable to NIST. Unfortunately, a number of radionuclide solutions required by EML have either been available sporadically, or totally unavailable, as NIST SRMs. It is particularly true of the short-lived radionuclides, those with half-lives of one year or less. Both NIST SRM solutions and sources are initially expensive, and the cost of recalibration by NIST is often equal to, or more than, the original purchase price. Since EML solutions and sources are recalibrated at least once a year, the cost of NIST recertification would be prohibitive. EML's strategy to provide the necessary radionuclide solutions for its programmatic research, instrument calibration and development, and internal QA/QC programs and QAP has emerged over several decades. The basic elements of this strategy and their application to radionuclide solution calibrations are the focal points of this paper.

### **PRIMARY CALIBRATION PROGRAM**

The necessity for the capability of performing primary calibrations of radionuclide solutions, other than uranium, has its roots in the advent of global fallout. The principal purpose of such a program was to provide standardized solutions for use in secondary calibrations of nuclear detection instruments. Many fission products were identified and measured, and standards were required for quantification. The fallout fission products studied were generally  $\beta$  emitters separated, purified, and measured with Geiger-Mueller tube counters. (Gamma spectrometry was in its infancy.) A sensitive technique, the Harley-Hallden method for the identification of  $\beta$ -emitters (Harley and Hallden 1955), had been developed so that the purity of a sample or solution could be ascertained. The problem of certified radionuclide solutions remained. Availability of uncalibrated, individual fission product solutions was great but the number of certified solutions was small. To meet the needs of the monitoring, analytical and instrument development programs at HASL, a scientist was trained at Los Alamos Scientific Laboratory in the art of primary calibration of  $\beta$ -emitting radionuclide solutions.

EML has maintained, expanded, and improved its capability in primary calibrations over the years for the same reasons of availability as mentioned above, as well as internal and contractor QA/QC programs, research and development programs, and also because of the increased economic and possible societal costs of bad measurements. Flawed data must be discarded, contracts may be revoked, and research opportunities may be missed due to improper calibration of detection devices. Lastly, EML is among the few laboratories in the U.S. to have a primary calibration capability. Through its ongoing program, EML provides a service to the standards user community of "checking the checkers," an essential feature of our traceability to NIST.

### **PERSONNEL AND RESPONSIBILITIES**

The quality of standard radionuclide solutions and sources is dependent not only on the starting material, preparation technique, and radiation detection equipment, but also on the knowledge and skill of the personnel performing the calibrations. Mentoring or one-on-one job training is the norm in the scientific community for the important task of radionuclide calibration. The personnel performing calibrations must be knowledgeable in chemistry, radiation physics, electronics, and statistics.

The characteristics of the radionuclide, half-life, type, and energy of the emissions, decay schemes, parent-progeny relationships, and type of equilibrium must be understood to select the method of calibration. Knowledge of the physical and chemical properties of an element is mandatory to properly store radionuclide solutions and prepare sources for measurement. In a few cases, a parent radionuclide must be separated from its progeny prior to calibration.

The response of the detection system must be checked with a known source prior to performing the actual calibrations. Failure to obtain the expected response terminates the process until it is brought back in control. Most often the corrective actions can be taken by the scientist performing the calibration based on personal experience.

The measurement of replicate sources, calculations, and application of appropriate correction factors and statistical evaluation completes the process. The final value must be within the accepted range established for the particular calibration method. Lastly, the data are reviewed by a knowledgeable colleague as an independent quality check.

## **ALPHA METROLOGY**

Primary calibrations of  $\alpha$ -emitting radionuclide solutions and sources are performed at EML with a  $2\pi$  windowless (internal) flow through proportional detection system, with methane (99.99% chemically pure) as the counting gas. Any source to be measured must be on a conducting material. In practice, all sources measured at EML in this system are on metal backings, usually platinum, stainless steel, or aluminum. A detailed description of our measurement practices are documented in EML's Procedures Manual (Fisenne 1992a).

### **Traceability to NIST**

Each day the detection system is used, its operating characteristics are checked with an NIST SRM  $U_3O_8$  source. The NIST-certified value is given in terms of  $\alpha$  particles  $s^{-1}$  in a  $2\pi$  configuration. This means that the  $\alpha$ -backscatter factor is part of the certified value and no correction needs to be made for this source characteristic. The EML value obtained must agree with the NIST-certified value (within the error of the measurement) before other sources are measured. Failure to obtain a flat or a long voltage plateau or failure to agree with the certified source value are immediate indicators of problems in the detection system which must be remedied before proceeding with additional measurements.

As a further check, when NIST  $\alpha$ -emitting SRM sources are purchased, they are treated as unknowns and measured as described above. The value obtained at EML is then compared with the certified value. A few of these comparisons are shown in Table 1.

### **EML Source Preparation**

Electrodeposited sources of  $\alpha$ -emitting radionuclides are prepared on 17-mm diameter virgin platinum discs. These sources, once calibrated, are used as standards to determine the detection efficiencies of  $\alpha$ -scintillation counters and solid-state  $\alpha$ -spectrometry systems. In general, the activity of these sources is 15-20 Bq ( $\sim 450$  pCi or 1000 dpm). The procedure for obtaining a "working standard" source is to measure the NIST SRM  $U_3O_8$  source and background as described in HASL-300, obtain a voltage plateau for the source to be calibrated, and measure the source at the proper plateau voltage

for 2000 s. The net count rate of the source is converted to an activity unit using the detection efficiency of 52%. The Poisson error term associated with this activity is calculated and attached to the activity value.

The calibration of an  $\alpha$ -emitting solution differs from that for electrodeposited sources only in the method of source preparation. The EML source preparation techniques are described in detail in HASL-300 (Fisenne 1992a). The activity and Poisson counting error are calculated for each source and corrected for the aliquot weight to obtain the activity  $g^{-1}$  of solution. A Gaussian mean and standard deviation (SD) are calculated for triplicate source mounts. The Gaussian SD is usually  $<1\%$ . The dilutions of the calibrated solution may then be prepared by weight for use in various EML programs.

Traceability to NIST for this process was established by preparation and measurement of an  $\alpha$ -emitting radionuclide solution at EML with subsequent certification by NIST. The results are shown in Table 2.

### Applications

Disposable scintillation detectors were developed for  $\alpha$  measurements of air dust samples and chemical precipitates (Hallden and Harley 1960). Perhaps their largest application has been in the determination of  $^{222}Rn$  and  $^{220}Rn$  progeny concentrations from air filter samples. Routine applications include the measurement of health physics smear samples, determination of the  $\alpha$ -nuclide concentrations of low-level solutions and measurement of total  $\alpha$  activity of radiochemically separated samples, and investigations of materials for commercial uses.

The detection efficiencies of the EML  $\alpha$ -scintillation counters are determined by measuring electrodeposited "working standard" sources prepared at EML. Measurements with single emitter sources with energies ranging from 3 to 6 MeV show that the detector response is independent of the energy of the  $\alpha$  particle. Sources of  $^{226}Ra$  and  $^{228}Th$  in equilibrium with their short-lived progeny were measured in the  $2\pi$  proportional counter and then mounted and measured in the  $\alpha$ -scintillation detection systems. After applying the detection efficiency obtained from the "working standards," the values obtained by  $\alpha$ -scintillation counting agreed with those of the  $2\pi$  proportional counter within the error of the measurements. This implies that the detection efficiencies of the  $\alpha$ -scintillation counters are independent of the energy of the emitter up to 9 MeV.

Background count rates are determined for the materials commonly used in EML programs. These include platinum discs and cellulose, polystyrene, polypropylene, and glass fiber filters. The background count rates are determined for measurement intervals of  $6 \times 10^4$  s (1000 min) or more. The average detection efficiency determined from measurements of a "working standard" source electrodeposited on platinum is 51%. The source is measured twice weekly for a 100-min counting interval. QC charts are maintained for the background count rates and the detection efficiencies of the  $\alpha$ -scintillation counters. The means and SDs of each type of measurement are calculated on a monthly basis.

The EML solid-state  $\alpha$ -spectrometry systems are used primarily to determine the concentrations of radionuclides in chemically separated samples. The systems are also used to determine the radiopurity of  $\alpha$ -emitter solutions and sources. Virtually all radiochemical analyses for  $\alpha$ -emitting radionuclides are performed with an isotopic tracer. For the transuranic nuclide determinations, the



following tracers are used at EML:  $^{236}\text{Pu}$ ,  $^{242}\text{Pu}$ , and  $^{243}\text{Am}$ . Tracers used in the determination of naturally-occurring radionuclides are  $^{208}\text{Po}$ ,  $^{209}\text{Po}$ ,  $^{229}\text{Th}$  and  $^{232}\text{U}$ .

The solid-state  $\alpha$ -spectrometry systems used at EML are divided into two groups of four detectors, one group is devoted to transuranic measurements, and the other to natural radionuclide measurements. Four vacuum chambers are served by a single beltless vacuum pump. The interior diameters of the vacuum chambers allow samples to be placed as far as 5 cm from the detector. The sample holder, which may be moved vertically, has been modified at EML to an open-drawer slide arrangement. The drawer is locked in place and the slide, with a 2.54-cm diameter by 2-mm deep indentation to accommodate the sample mount, is removable. The sample is placed on a mount, the mount is placed in the indentation, and the slide is then replaced in the open-drawer arrangement. This sample holder arrangement eliminates problems of source to detector geometry. The two kinds of solid-state detectors in use at EML will be discussed below. Voltage to the detectors is supplied by individual regulated power supplies. Each detector has a charge sensitive preamplifier and a linear amplifier. Signals from the detectors are directed through a router into a 4096 multichannel analyzer. One analyzer serves four detectors with data collection divided into four 1024 channel segments. A hard copy of the data is obtained with a high-speed printer. All  $\alpha$ -spectrometry data are reduced "by hand," ensuring immediate and individual review of the spectra. Therefore, difficulties with the spectrometry systems or the samples are quickly noted and remedied.

The solid-state  $\alpha$  detectors are operated at about 10 keV per channel, covering an energy range of about 3-13 MeV. By this practice, all  $\alpha$  emitters present in a sample can be identified from their energies. (Virtually all  $\alpha$  emitters, both natural and artificial, are within this energy range.)

Because EML is primarily involved in the measurement of low-level environmental samples, the most common measurement period by  $\alpha$ -spectrometry is  $3 \times 10^5$  s (5000 min). The solid-state detectors in use at EML for transuranic measurements of electrodeposited samples are conventional 300-mm<sup>2</sup> active area, silicon-surface barrier detectors. Our experience at EML is that the so-called "ruggedized" detectors provide no advantage in terms of decontamination. The resolution of the detectors, as measured routinely with EML-prepared "working standard" sources, is 30-35 keV full width at half the maximum height of the counts in a peak (FWHM). The background count rates in the energy regions of interest are generally 1 to 2 counts in  $3 \times 10^5$  s for a (virgin) platinum disc. The systems are calibrated with "mixed  $\alpha$  standards" electrodeposited on 17-mm platinum discs. The emitter mixtures of the standards are either  $^{238,239,242}\text{Pu}$ ,  $^{244}\text{Cm}$  or  $^{241,243}\text{Am}$ ,  $^{242}\text{Pu}$ ,  $^{244}\text{Cm}$ , covering an energy range of 4.9-5.8 MeV and containing the nuclides of interest in various programs. The standard and sample measurements are performed at a distance of 1 mm from the lip of the detector housing. At this distance, the average detection efficiency is ~25%.

The solid-state detectors in use at EML for naturally-occurring radionuclide measurements are conventional 500-mm<sup>2</sup> active area, silicon-surface barrier detectors. The resolution of the detectors, as measured routinely with EML-prepared "working standard" sources, is 40-45 keV (FWHM). The systems are calibrated with "mixed  $\alpha$  standards" prepared by microprecipitation with  $\text{NdF}_3$  (Hindman 1983; Sill and Williams 1981) on polypropylene filters. The background count rates determined with "blank" microprecipitates in the energy regions of interest are generally 1 to 2 counts in  $3 \times 10^5$  s. The emitter mixture of the standards is  $^{238,239,242}\text{Pu}$ ,  $^{244}\text{Cm}$ . The standard and sample measurements are performed at a distance of 1 mm from the lip of the detector housing. At this distance, the average detection efficiency is 40%.

The detection efficiencies and resolution obtained with microprecipitated standards were checked against those obtained with electrodeposited standards and no differences were found.

The multichannel analyzers used for  $\alpha$ -spectrometry measurements are thoroughly tested by EML's Instrumentation Division to ensure stability over long-measurement periods, 3 to  $6 \times 10^5$  s (5000-10,000 min). The stability of the systems is aided by placing them in a temperature-controlled room. It is important to note that the room temperature needs to be stable. It is fluctuations in temperature that cause the detector response to shift or drift.

The detection efficiencies of the transuranic  $\alpha$ -spectrometry systems are determined by measuring electrodeposited "working mixed standard" sources prepared at EML. The sources are traceable to the NIST through the process described above.

The detection efficiencies of the naturally-occurring radionuclide  $\alpha$ -spectrometry systems are determined by measuring microprecipitated "working mixed standards" prepared at EML. The activity of the standards is determined by  $\alpha$ -scintillation counting on systems calibrated with sources traceable to NIST through the process described earlier.

Measurements with single emitter sources with energies ranging from 3-6 MeV have shown that the energy and detection efficiency responses of silicon-surface barrier detectors are constant. Sources of  $^{228}\text{Th}$  in equilibrium with its short-lived progeny were measured, and the activities of the individual progeny were the same within the error of the measurements. This provided empirical information that the energy response and detection efficiencies of the detectors are constant up to 9 MeV.

It is the practice at EML to measure the background count rate of the detectors each weekend and during the week if time permits. Typical background count rates for the detectors were given above. The background count rates of the systems invariably increase with time due to recoil atoms depositing on the face of the solid-state detectors. It has been our experience that the background count rates become unacceptable after two years of use. The only effective method found to reduce the background count rates is to place the detectors in a high vacuum provided by a liquid nitrogen-cooled diffusion pumping system over a weekend.

Each "working mixed standard" source has a total activity of about 15 Bq. The standards source is measured for  $3 \times 10^3$  s (50 min) before and after each sample measurement. The standard source measurements provide three important pieces of information: the detection efficiency, the detector resolution, and the energy calibration. Deviations from normal operating conditions in any or all of these characteristics are immediately investigated. These quality control records are very important in establishing the norm for each detector system.

## BETA METROLOGY

Primary calibrations of emitting radionuclide solutions are performed at EML with gas flow  $4\pi\beta$  proportional and  $4\pi\beta$  proportional- $4\pi\gamma$  coincidence detection systems (Fisenne 1992b). The commercially obtained aluminum proportional counters have a stainless steel wire anode in each half-cylinder. The total interior volume is  $50 \text{ cm}^3$ . The source mount is an aluminum washer with a 1.8-cm diameter center hole and four 0.3-cm holes in the rim to allow gas flow between the halves with the source mount in place. The counting gas is 99.99% chemically pure methane, and the flow through the chamber is monitored with a bubbler. An EML-designed and -built emitter follower

preamplifier is connected directly to the anodes. Signals from each half of the chamber are summed prior to further amplification. The amplifier is arranged to deliver triggered pulses to an electronic scaler. High voltage is supplied by a 0-5000-V regulated power supply. The chambers exhibit rather long (600 V) and flat ( $<0.5\%$  per 100 V) counting plateau. The  $4\pi$  detection system is unshielded and has a background rate of  $0.7 \text{ counts s}^{-1}$  at 3500 V, the usual operating voltage.

In the  $4\pi\beta$ - $4\pi\gamma$ -coincidence detection system, the chamber is mounted between two  $7.6 \times 12.7$  cm NaI(Tl) crystals. The entire detection assembly is lead shielded. The upper crystal is pneumatically raised and lowered to permit access to the chamber. The signals from the two crystals are summed, amplified, processed through a single channel analyzer, and simultaneously recorded into a scaler and a multichannel analyzer. High voltage to the crystals is supplied by a single 0-1500-V regulated power supply. As described above, the signals from the chamber are summed and amplified, but then split into the variable coincidence gate and a scaler. The output signals from the variable coincidence gate unit are fed into a third scaler. The three scalers are controlled by a master timer. A detailed discussion of the  $4\pi$ -coincidence method can be found in the National Council on Radiation Protection and Measurements Report No. 58 (1985).

### Traceability to NIST

Traceability to NIST is difficult since SRM solutions are not available for some radionuclides at the time of programmatic need. Our approach over the years has simply been to recalibrate NIST SRM solutions or solutions obtained from commercial vendors who are traceable to NIST using EML source preparation techniques and detection systems. Except for discrepancies caused by differences in the use of decay scheme parameters, EML's results are in agreement with the certified values within the error of the measurements. Some examples of these comparisons are shown in Table 3.

The consistency of the measurement method over time has been documented over a 30 year period. These results for a  $^{137}\text{Cs}$  solution are shown in Figure 1.

### EML Source Preparation

Two kinds of supporting films for the source mounts are used in these proportional counters. The first type of film support is prepared from clear vinyl ink (Flat Vinyl Ink 3900-99-Clear, obtained from: Colonial Printing Ink, Co., 180-T East Union Ave., East Rutherford, New Jersey 07073) and is used with pure beta emitters with a maximum energy  $>0.25$  MeV. It has been established experimentally, using NIST and commercial vendor-certified standard solutions of  $^{45}\text{Ca}$ , that the detection efficiency of this emitter is 100% for the source mounts described by Hallden and Fisenne (1963) and in HASL-300.

The second kind of source mount is a  $2\text{-}\mu\text{m}$  thick film of polycarbonate that is glued to the aluminum washer (KIMFOIL; obtained from: Kimberly-Clark Corp., Schweitzer Division, Lee, Massachusetts 01238). These mounts are used for measurements by  $4\pi\beta$ - $4\pi\gamma$  coincidence counting, which will correct for the absorption within the film. The remainder of the source preparation procedure is the same as described for  $4\pi$  measurements. (Note: The thin vinyl films will only tolerate an HCl solution of  $<1 \text{ N}$ . The polycarbonate will withstand HCl concentrations of up to  $6 \text{ N}$ . In addition, the polycarbonate source mounts can be dried gently under a heat lamp.)

The primary radionuclide solution should be essentially carrier-free. The primary radionuclide solution to be calibrated is diluted to a concentration on the order of  $1700 \text{ Bq g}^{-1}$ . The calibration is performed with triplicate source measurements. The voltage plateau for each source is determined in order to select the proper counting voltage. The activity and Poisson counting error are calculated for each source and corrected for the aliquot weight to obtain the activity  $\text{g}^{-1}$ . Other corrections appropriate to the particular radionuclide being calibrated are made for the  $4\pi\beta$ - $4\pi\gamma$  coincidence measurements. A Gaussian mean and SD are calculated for the triplication. Appropriate dilutions are prepared for distribution within EML for various programs.

### **Application**

Essentially all routine  $\beta$  measurements at EML are performed with scintillation counters. The largest application has been the determination of  $^{90}\text{Sr}$  by measurement of  $^{90}\text{Y}$ . These measurements are performed in the low-level scintillation counters (Harley et al. 1962).

### **Description of the Detection Systems**

There are 21 low-level scintillation detection systems presently in use at EML, primarily for the measurement of  $^{90}\text{Y}$ . These EML counters are designed to accept a sample mounted on a 2.54-cm diameter ring and disc assembly.

A 0.25-mm thick x 2.4-cm diameter plastic scintillation phosphor is placed directly on the sample. Using this arrangement leads to reduced background count rate and high detection efficiency. The background count rate depends on the type of filter and precipitate being measured. The detection efficiency depends on the energy of the emitter and the thickness of the precipitate.

To obtain very low background count rates on the order of  $0.004 \text{ counts s}^{-1}$  ( $0.25 \text{ counts min}^{-1}$ ), the 2.54-cm diameter photomultiplier tube (PMT) and sample are fitted into the well of a hollow anode Geiger tube operated in the anticoincidence mode. The PMT and Geiger tubes are housed in a spherical, mercury-filled shield.

An emitter follower is built into the housing of the PMT probe. Amplification and high voltage to the PMT and Geiger tubes are supplied by individual EML-built control units. Data from the units are acquired on five EML programmable data logging units interfaced to a personal computer. The calculations are automated.

### **Calibration of the Detection Systems**

The low-level scintillation counters are checked weekly with sources containing 200 mg of KCl. The detection efficiencies of the 21 counters for these check sources range from 32-36%. The background is also measured weekly with yttrium oxalate blanks yielding rates of  $0.004$ - $0.007 \text{ counts s}^{-1}$  ( $0.25$ - $0.4 \text{ counts min}^{-1}$ ). The counters are standardized monthly with  $^{90}\text{Y}$  oxalate and the detection efficiencies range from 40 to 45%.

## SUMMARY

This paper does not purport to cover all of the myriad aspects involved in carrying out internal and external QA/QC programs. Rather, it is a synopsis of EML's radionuclide calibration program and its applications in radiometrology programs.

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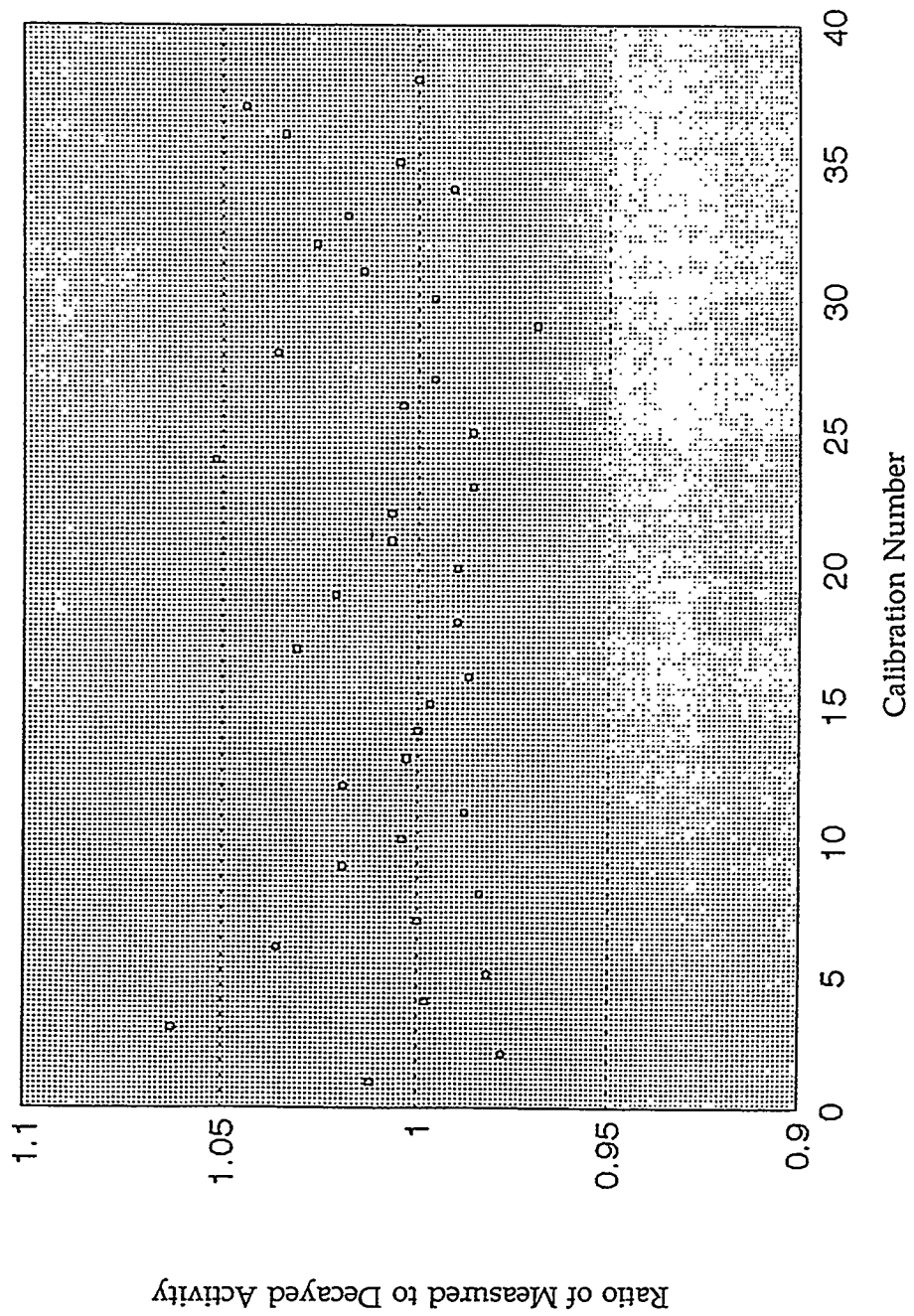


Figure 1 -  $^{137}\text{Cs}$  Calibrations of a Master Solution at EML (1962-1992)

*Table 1 - NIST Alpha Particle Standards Measured at EML*

NIST Standard	Certified Value	EML Value	EML/NIST
U #0-298	$18.7 \pm 2\% \propto \text{s}^{-1}$	$18.7 \pm 0.5\% \propto \text{s}^{-1}$	1.000
U #238-3	$20.6 \pm 2\% \propto \text{s}^{-1}$	$21.1 \pm 0.5\% \propto \text{s}^{-1}$	1.024
Am #4904-C	$6.39 \pm 2\% \propto \text{s}^{-1}$	$6.38 \pm 0.9\% \propto \text{s}^{-1}$	0.998
Gd #4907-8	$49.1 \pm 1.7\% \text{ nts}$	$48.9 \pm 0.4\% \text{ nts}$	0.996

$\propto \text{s}^{-1}$  = alpha particles per second

nts = nuclear transformations per second

*Table 2 - EML  $^{238}\text{Pu}$  Solution Certified by NIST*

EML Value	NIST Certified Value
$1806 \pm 1.07\% \propto \text{s}^{-1}$	$1815 \pm 0.96\% \propto \text{s}^{-1} \text{ g}^{-1}$
EML/NIST - $0.995 \pm 0.014$	

*Table 3 - NIST Beta-Emitting Solutions Measured at EML ( $\text{Bq g}^{-1}$ )*

SRM Number	EML Value	NIST Value	EML/NIST
$^{89}\text{Sr}$ 4945-C	$19170 \pm 1.1\%$	$19200 \pm 2.6\%$	0.988
$^{90}\text{Sr}$ 4919-C	$222 \pm 2.0\%$	$224 \pm 2.0\%$	0.991
$^{137}\text{Cs}$ 4233	$732100 \pm 1.3\%$	$743200 \pm 1.4\%$	0.985

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# EVALUATION OF CONTROLS FOR THE ASSURANCE OF QUALITY DATA IN A RADIOCHEMISTRY LABORATORY

J. S. Morton<sup>(1)</sup>

**Abstract** - The paper describes the controls implemented by the U.S. Department of Energy (DOE) at the Radiological and Environmental Sciences Laboratory (RESL) to secure data quality. A description of the analytical instrumentation and methodology employed by RESL is provided. The results of the intercomparison program with the National Institute of Standards and Technology (NIST) are provided to demonstrate traceability to a primary source. A description of the methods and techniques used to ensure quality control on a daily basis is given. The techniques used to evaluate the sources of uncertainty are reviewed and specific examples cited. The intercomparison programs operated by RESL are discussed.

RESL is one of the three federally owned and staffed laboratories operated by DOE. RESL, located at the Idaho National Engineering Laboratory (INEL), fifty miles west of Idaho Falls, Idaho, was created as the Health Services Laboratory as part of the Atomic Energy Commission (AEC). During the reorganization of the AEC, a legislative mandate appointed RESL as the reference laboratory for the newly created U.S. Nuclear Regulatory Commission (NRC) in the Confirmatory Measurements Program. At that time, RESL established a traceability program with the National Bureau of Standards (NBS)/NIST in gamma-, alpha-, and beta-emitting nuclides. The traceability program also provides for the preparation of standards at RESL for analysis by NIST. This aspect of the program has been in place for about 15 years. The term "traceable" is defined by this program as producing a result that is within 5% of the value postulated by NIST as the true value of some common source. The program evaluates the analytical capability in the Uci - Pci /unit range and not at environmental levels. RESL has operated its own intercomparison program for about 10 years. On a quarterly basis, standards are provided to the participants of the program. The program was established to provide a means of support for the NRC regional mobile laboratories. Because these laboratories usually have limited analytical capability, the gamma-emitting standards are prepared in a variety of matrices that include water, vegetation, air filters, or charcoal cartridges.

The Radiological and Environmental Sciences Laboratory serves as the Performance Testing Laboratory for the U.S. Department of Energy's Laboratory Accreditation Program (DOELAP).

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RESL also provides technical support for the Analytical Services Program operated by the Office of Technology in the DOE. While the Analytical Services Program is not an accreditation program, it does provide the external assessment and performance evaluation testing that an accrediting organization would incorporate.

Quality assurance (QA) is defined in almost as many ways as there are quality assurance officers. John Taylor has described quality assurance as a system of activities that assures the producer or user of a product or a service that defined standards of quality are met at a stated level of confidence. Quality control (QC) differs in that it is an overall system of activities that controls the quality of a product or service so that it meets the needs of the users. From this definition, we can interpret quality control to consist of the internal, day-to-day operation, which could include QC check samples, spikes, blanks, etc. to control and assess the quality of the measurements. Quality assurance is the management system that ensures an effective quality control system is in place and functioning properly.

The purpose of a laboratory quality assurance program is to prevent, detect, and correct problems in the measurement process, while establishing the desired statistical control through quality control samples. The aim of the quality assessment, which may be defined to include both quality assurance and quality control programs, is to control analytical measurement errors at levels acceptable to laboratory standards/controls and to the data user. Once this initial goal is satisfied, then the assurance that the analytical results are of an acceptable quality increases in probability.

For better or worse, most data is evaluated on the basis of its uncertainty when compared with the user-defined requirements. The uncertainty associated with each link in the collection-analysis-reporting chain should determine the uncertainty in the final result. However, as is too often the case, the only uncertainty associated with the sample is that reported by the analyst. Laboratory quality assessment measures, at most, can only account for errors that occur after sample collection. If the analytical process produces results that are excessively variable due to some analytical unknown, or the associated uncertainty exceeds the user's requirements, then the data may be of such a low quality as to be essentially useless. If the uncertainty of the results satisfies both the internal and external requirements, then the data should be considered to be of adequate quality. In some cases, this may produce a result and uncertainty for two different sample/analytical processes that are identical, thus proving that the phrase quality data may be a relative term.

The time allowed does not provide for even an adequate summary of all the criteria that should be incorporated in a comprehensive quality assurance program. With that boundary condition established, I will address a few areas that are of concern to an analytical chemistry laboratory performing analyses for radioactive constituents at concentrations found in the typical environment.

In 1967, Pontius and Cameron published NBS Monograph 103, "Realistic Uncertainties and the Mass Measurement Process." This monograph was the first publication that addressed the measurement as a process that could be held in a state of statistical control. Their work was based on the lectures of Walter Shewhart. Control charts in all their forms have evolved to be one of the most basic tools for quality assurance in use today. Most, if not all, types of control charts can be placed in one of two categories: a "property" chart or a "precision" chart. The precision chart consists of plotting the standard deviation, evaluated at various times. The obvious problem with the precision chart lies in the requirement of plotting the standard deviation. This requirement limits their use in analytical chemistry because of the time-consuming techniques necessary to produce the desired result. A

property chart which plots the selected property of a single measurement, is more susceptible to the unpredictable blunder. A blunder may be defined as simply a mistake that occurs on occasion to produce erroneous results. Examples of blunders include measuring the wrong check source, making a transcription error, misreading the scale, or applying the wrong decay time to the check source.

The most common format of all control charts include a center line that establishes the best estimate of the selected property. A property chart contains a plot of the data points for the selected property verses time. To assist the user in visualizing the response of a system for the selected property, the control chart will indicate, in some manner, limits within which the measured value or selected property may be expected to lie with some established probability. These limits establish a boundary, which, if exceeded, must produce some action on the part of the analyst to assess why the limits were exceeded. These then can be labeled as the upper- and lower-action limits or control limits. Most of the current references establish three-sigma as the bounds within which virtually all values should lie when produced by a system in statistical control. A second set of limiting values may be plotted to serve as warning limits. This set of limiting values is usually at the two-sigma value within which most (95%) of the values should lie. Only a few measurements should lie between these two limits. It should be remembered that when establishing the control limits, the population standard deviation, sigma, is an unknown quantity, but is estimated based on a limited data set.

The procedure in use at RESL establishes the central line from the mean of a number of measured values and the experimentally estimated standard deviation to define the warning and action limits. When using a reference material, such as a Standard Reference Material (SRM) for the control sample, the certified value may then be used as the center line. Even so, that value must be evaluated by the laboratory's statistics of measurement used to define the control limits to show that it does not differ significantly from the measured value. It is suggested that 15 independent measurements be performed to obtain the initial estimates of these statistics. The measurements must be truly independent, meaning that the interval between measurements is long enough to eliminate artifacts of successive measurements, i.e., removing the source and replacing it on the detector, using the same working solvents, using the same detector to verify the value for a standard reference material. The monitoring of the data output to assure quality using the necessary techniques of measurement is the main objective of quality assurance. The incorporation of these techniques and their results should provide confidence to the analyst and user that statistical control has been realized and is being sustained. They should also provide realistic estimates of the accuracy of the resultant data.

The time-honored method used to evaluate precision is repetitive measurement. For some types of rad analytical procedures, repetitive measurements are less restrictive than others. For instance, repetitive measurement by gammaspectroscopy is certainly less restrictive than say, sample decomposition, separation, and concentration for the identification of strontium. Another approach may be the analyses of an appropriate number of duplicate measurements, the examination for beta particles only. This could offer the possibility of evaluating the precision that is required and should therefore minimize questions regarding the suitability of the quality assurance samples.

Realizing that few if any analytical facilities have the time necessary to do repetitive measurements on all but a select few of the samples analyzed, the above requirements must be satisfied in a timely fashion. This is typically accomplished using internal test samples. These test samples may consist of internal reference materials, spiked samples, split samples, and surrogates. These internal test samples can be included with the batch of true samples or analyzed as a group themselves to evaluate the precision of the measurement process. If the concentration of the internal standard is known to

the required, accuracy then bias may be evaluated. Ideally, these test samples should originate from an organization (Laboratory Quality Branch) that is external to the group performing the actual analyses.

Measurement bias may be the result of the analyst, or the instrumentation or the procedure, or may be a combination of some or all of the above. Internal studies used to investigate such a bias may include the use of independent techniques to measure the samples, or the interchange of analysts and/or instrumentation. If the appropriate quality assurance procedures were followed when the calibrations were performed, then the measurement process should be independent of who performed them and the instrumentation used. If this is found not to be the case, the calibration procedure should be examined for any inadequacy. The procedure should then be evaluated for technique dependent steps. The use of control charts, when evaluating the analysts and the instrumentation, should identify the problem. When the data are not sufficient to produce statistical judgements, then only large differences are significant. Usually these cases involve small differences in precision; therefore, statistical evaluations should be based on a relatively large database.

Unfortunately, one of the most driving reasons for evidence of quality in the measurement process by external means may be how it is perceived by regulators and compliance requirements. From the quality assessment point of view, this is not true. In many cases, this approach can reduce the effort required for internal evaluation. Further evidence of quality in the measurement process may be gained by several procedures. The internal evaluation of precision and an independent assessment of bias may be confirmed by these external procedures. These could include participation in round robin studies conducted by the various standards committees, exchange of standards and well-characterized samples with other analytical facilities, participation in external performance evaluation programs, and the analysis of standard reference materials from NIST. If one so chooses, or it is necessary from contractual obligation, the collaborative tests provide a means to compare performance with other facilities performing comparable types of analyses. If the standard or round robin sample is sufficiently well characterized to a specified accuracy, bias can be minimized. The exchange of samples with other analytical facilities or with other groups within the same lab can only provide some degree of evidence of agreement or disagreement. The obvious problem with the exchange of samples is the inherent lack of characterization.

If the results are not in the range of agreement specified, where does the problem reside—in the sample inhomogeneity or in the procedure? It should go without saying, then, that the use of appropriate reference materials to evaluate the data quality is the procedure of choice.

The NIST Technical Note 1297, Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results, states: "In general, the result of a measurement is only an approximation of the value of the specific quantity subject to measurement, and thus the result is complete only when accompanied by a quantitative statement of its uncertainty." The publication goes on to define the random and systematic uncertainty by defining an alternative nomenclature, a "component of uncertainty arising from a random effect" and a "component of uncertainty arising from a systematic effect" where a random effect is one that gives rise to a possible random error in the current measurement process, and a systematic effect is one that gives rise to a possible systematic error in the current measurement process. The random uncertainty can be evaluated by the statistical analysis of a series of observations. The evaluation of uncertainty by means other than the statistical analysis of a series of observations can be the systematic uncertainty. This type B is usually based on scientific judgement using all relevant information available which may include:

- previous measurement data
- experience with, or general knowledge of, the behavior and property of relevant materials and instruments
- manufacturer's specifications
- data provided in calibration and other reports
- uncertainties assigned to reference data taken from handbooks.

Examples of the uncertainty evaluation and quantitative propagation may be found in the Technical Procedures Manual, Analytical Chemistry Branch, RESL.

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# THE ROLE OF THE EPA RADIATION QUALITY ASSURANCE PROGRAM IN THE MEASUREMENT QUALITY ASSURANCE ACCREDITATION PROGRAM FOR RADIOASSAY LABORATORIES

Terence M. Grady<sup>(1)</sup>

*Abstract* - As the nature and extent of radiological contamination becomes better documented and more public, radioanalytical laboratories are faced with a constantly expanding variety of new and difficult analytical requirements. Concurrent with those requirements is the responsibility to provide customers, regulatory officials, or the public with defensible data produced in an environment of verifiable, controlled quality. To meet that need, a quality assurance accreditation program for radioassay laboratories has been proposed by the American National Standards Institute (ANSI). The standard will provide the organizational framework and functional requirements needed to assure the quality of laboratory outputs. Under the proposed program, the U.S. Environmental Protection Agency's (EPA's) Laboratory Intercomparison Program plays a key role as a reference laboratory. The current and proposed roles of the EPA Intercomparison Program are discussed, as are the functional relationships between EPA, the accrediting organization, and the service and monitoring laboratories.

## INTRODUCTION

As a means of assuring consistent, reliable data from commercial and government laboratories, ANSI has prepared and recommended a Standard (N42.2) for creating a measurement quality assurance program for radio-analysis laboratories. The accreditation is structured within a framework that ensures independent verification of performance requirements from the service or production laboratory level through the monitoring and reference laboratories to the accrediting organization and the National Institute of Standards and Technology (NIST). The national performance testing program will rely on key elements such as traceability, performance evaluations, on-site assessments, intercomparisons, and strong internal quality control programs of its participants.

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The EPA, at the Environmental Monitoring Systems Laboratory-Las Vegas (EMSL-LV), currently operates the Radiation Quality Assurance Program. This program will play a key role as a reference laboratory in the implementation of the proposed radioassay laboratory accreditation program. The Radiation Quality Assurance Program has for many years conducted laboratory performance evaluations, provided standard reference materials, and supplied technical support to federal, state and commercial laboratories. In addition to this quality assurance assistance, EMSL-LV performs on-site evaluations of principal state laboratories on a three-year rotational basis.

The EMSL-LV Radioactive Standards Distribution Program maintains a comprehensive radionuclide and standard reference material inventory, which is available for distribution to program participants. To assure the integrity of its standards and reference material, EMSL-LV conducts ongoing traceability studies (direct and indirect) with NIST.

## **ROLES AND RESPONSIBILITIES OF EMSL-LV AS A REFERENCE LABORATORY**

A reference laboratory is primarily responsible for defining the measurement traceability of service and monitoring laboratories for each test category or specific radionuclide. This is made possible by preparing testing media, in the form of applicable sample matrices containing known amounts of radioactive material, providing those materials to monitoring and service laboratories, evaluating the results, and reporting those results to the accreditation authority and the laboratories involved.

A service laboratory is defined as a laboratory that performs radioassay measurements for the purpose of providing analytical results. A service laboratory may be internal to an Agency or company or may be commercially contracted. Service laboratories could be described as production laboratories. A monitoring laboratory is an accredited laboratory that prepares and distributes test samples used to monitor the day-to-day operations of the service laboratories that support its programs.

The largest portion of the EMSL-LV effort is dedicated to the conduct of the Intercomparison Studies Program, in which any laboratory performing environmental radioactivity analyses may participate. In this program, EMSL-LV designs, prepares, verifies, and distributes samples of known radionuclide content. These samples are prepared in water or milk, or as air filters. Participants perform three analyses and report results in writing or by modem. Known study sample concentrations are available immediately after the reporting deadline via modem. Data are analyzed by calculating the normalized range, normalized deviation, sample standard deviation, and grand average of all laboratories. Anonymously coded reports are provided to participating laboratories and to EPA regional or state officials.

Under the proposed accreditation program, reference laboratories such as EMSL-LV are also required to develop measurement methods and instrumentation to serve as secondary methods or references where standard reference material data are not appropriate, evaluate the performance evaluation samples prepared and used by monitoring laboratories to evaluate service laboratories, provide quality assurance consultation to monitoring and service laboratories, and provide training where necessary.

## **FUNCTIONAL INTERACTIONS**

The proposed accreditation program relies heavily on maintaining functional relationships between NIST, the accrediting organization, and the reference, monitoring, and service laboratories. It is envisioned that the accreditation program would require one or two national reference laboratories.



The role of the reference laboratories, including EMSL-LV, would lie at the core of the proposed program. This section describes the relationships that would be maintained between the EMSL-LV and other program participants. At each level, through the exchange of test samples, test results, performance monitoring reports, or accreditation reports and certificates, measurement traceability will be maintained and thoroughly documented.

### **Relationship with NIST**

The EMSL-LV would interact with NIST for the primary purpose of establishing traceability of its measurements to the national physical standard (Figure 1). Traceability would be established using one of two approaches: first, traceable blind samples may be prepared by NIST and provided to the EMSL-LV laboratory for analysis or, alternatively, the EMSL-LV could assay its own test material and send an aliquot to NIST for confirmational analysis. The results of NIST and EMSL-LV would be compared to acceptance criteria and performance reports, then forwarded to the accrediting organization.

### **Relationship with the Accrediting Organization**

The relationship of the reference laboratories with the accrediting organization would be based on exchange of information such as performance reports, accreditation reports, and accreditation certificates. While the accrediting body would not prepare and provide performance evaluation materials, it would participate in yearly on-site assessments of laboratories at all levels. Assessment criteria and checklists, developed by NIST, the accrediting body, as well as reference, service, and monitoring laboratories, would be agreed upon in advance. After the assessment, the teams would provide reports to the EMSL-LV and the other reference laboratory and provide documentation to the accrediting organization.

The EMSL-LV laboratory would be required under the program to submit a yearly report to the accrediting organization detailing the results of NIST traceability checks, sample verification analyses, and intercomparisons. Accreditation reports and certificates would then be issued by the accrediting organization based on the results of yearly on-site assessments and the EMSL-LV reference laboratory's annual reports.

### **Relationship with Monitoring and Service Laboratories**

Unlike the relationship between reference laboratories and NIST, the interchange between reference laboratories and monitoring and service laboratories is characterized primarily by exchange of test samples and test results. The EMSL-LV would have the responsibility of supplying traceable test samples to both service and monitoring laboratories for the purposes of documenting laboratory performance and establishing traceability, within specified accuracies, to the national radioactivity measurement systems. Part of traceability determination would be testing the ability of monitoring laboratories to prepare and verify performance evaluation materials with which service laboratories would be tested. The EMSL-LV would be responsible for determining if the monitoring laboratories are traceable and would report its findings to the accrediting organization.

## CONCLUSION

If the national measurement quality assurance program for radioassay laboratories is adopted by agencies such as the EPA or DOE, much of the existing Radiation Quality Assurance Program would remain intact with few changes. Additional responsibilities would, however, be placed on the core organizations, the reference, monitoring, and service laboratories. As a reference laboratory, EMSL-LV would strengthen its interactions with NIST and outside organizations which may serve as accrediting bodies.

The existing Intercomparison Studies Program now includes laboratories that would be considered monitoring or service laboratories under the proposed accreditation program. The current EMSL-LV program would require modification to permit verification of performance evaluation materials from monitoring laboratories and NIST, and to allow preparation of a wider variety of sample matrix/radionuclide combinations. Concurrent with the expansion of Intercomparison Studies would be demand for a more extensive inventory of traceable radionuclide standards and reference materials and an even higher level of quality assurance support for monitoring and service laboratories.

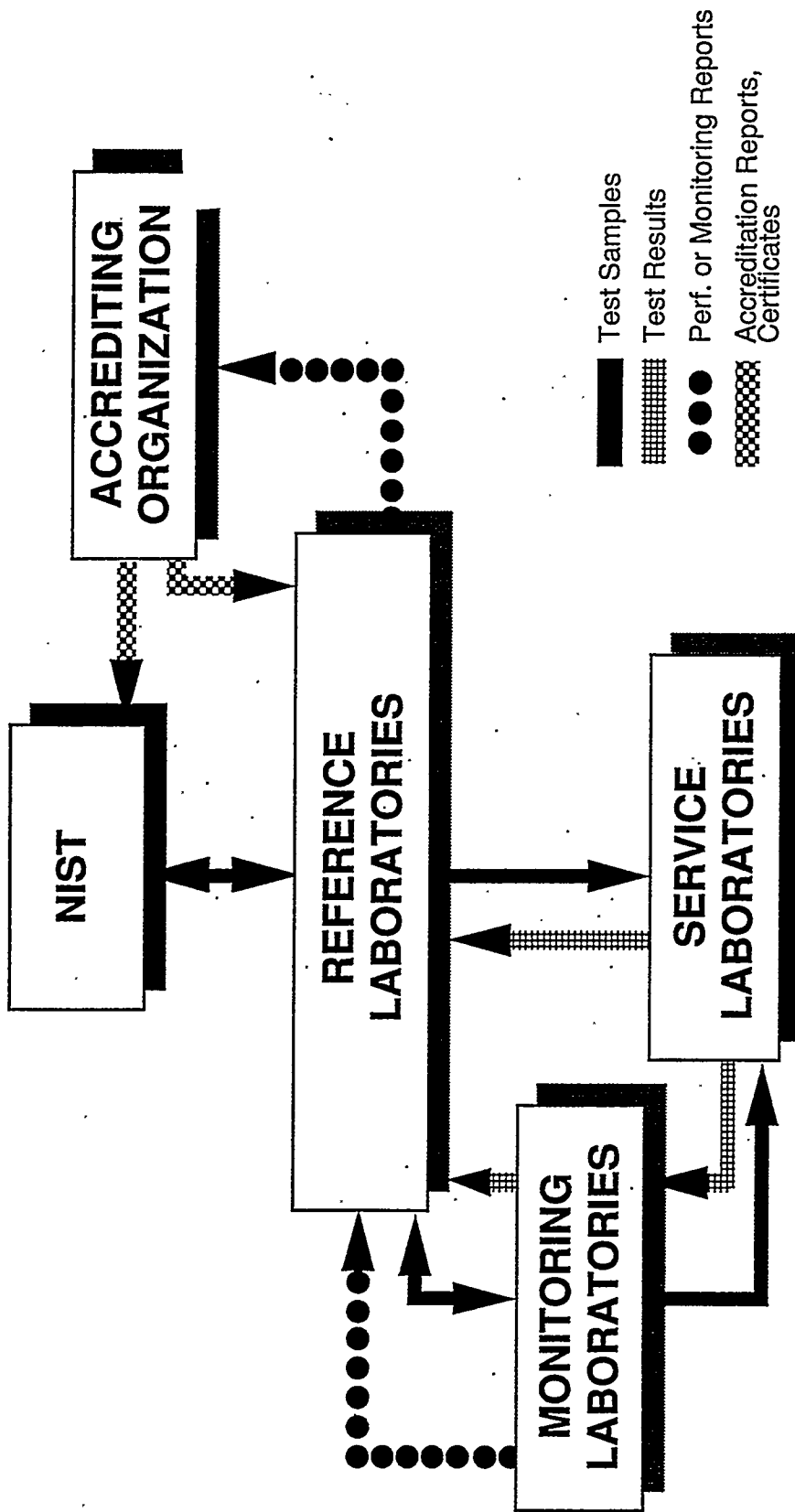


Figure 1 - Functional Relationships of EMSL-LV as a Reference Laboratory

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# STREAMLINING AND AUTOMATION OF RADIOANALYTICAL METHODS AT A COMMERCIAL LABORATORY

James T. Harvey<sup>(1)</sup>  
James W. Dillard<sup>(1)</sup>

*Abstract* - Through the careful planning and design of laboratory facilities and incorporation of modern instrumentation and robotics systems, properly trained and competent laboratory associates can efficiently and safely handle radioactive and mixed waste samples. This paper addresses the potential improvements radiochemistry and mixed waste laboratories can achieve utilizing robotics for automated sample analysis. Several examples of automated systems for sample preparation and analysis will be discussed.

## INTRODUCTION

The purpose of an automated method in a commercial laboratory is to increase the number of samples that can be prepared and analyzed during a given time period. In addition to the increased sample capacity, the system must be able to provide results equivalent to or superior to those obtained via manual analysis. Specifically, the automated system must perform the following:

- Improve the productivity of lab personnel involved in the analysis by allowing them to increase the number of samples they can process in a given time period.
- Minimize head-count increases for a given increase in productivity.
- Generate consistent, high-quality results and reports that are equivalent to or superior to those results obtained by the manual analysis techniques.
- Improve documentation and generate a defensible audit trail by using the automated system to generate hard-copy and electronic sample results.
- Reduce the need for skilled labor in the preparation and analysis of samples.

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<sup>(1)</sup> IT Corporation, Knoxville, Tennessee.

- Decrease the time from sample receipt to reporting of the results.
- Allow laboratory to better handle peak sample loads.
- Reduce cost associated with a given method.
- Improve motivation, reduce turnover, and enhance effectiveness of valuable laboratory personnel.

The process of sample analysis should be diagrammed and divided into tasks. Laboratory robotics systems can perform such tasks as blending, aliquoting by weight or volume, sample microwave dissolution, sonication, extraction, concentration by evaporation, volume dilution, gel permeation chromatography, ion exchange chromatography, liquid-liquid extraction, and many other applications.

There are at least three robotics system types currently available for automated laboratory analysis. There are stand alone dedicated workstations that perform a single or limited number of tasks. Another robotics system utilizes a robotic "arm" to move samples or fractions between stand-alone work stations and analysis instrumentation. Systems with a highly maneuverable "arm" and "hand" may directly interact with a sample or fractions through several tasks. Some robotics utilize a linear track while others use a circular configuration. The laboratory space needs may drastically change depending on the robotics system selected for a task or operation. Special services, power supplies, exhaust systems, and utilities may be required.

For prescribed methods that emphasize repetition of tasks, robotics can improve safety by reducing human exposure to reagent chemicals, radiation, and unknown sample hazards. Quality can be improved through removal of human operator effect on precision and accuracy of task performance. Automation/robotics assures laboratory system-wide method standardization and uniform quality assurance documentation of process performance. Increases in productivity are assured, especially for labor-intensive laboratory operations or tasks.

Because initial capital investment may be high, careful cost/benefit analysis is advised. Tasks that are repetitive, are of high value (revenue) or cost, and are in demand should be considered first for robotics development. Some tasks, however, simply may not be able to justify the cost of development if they are technically difficult to implement or cannot be reliably performed by robotics.

Robotics systems of analysis must be compatible with the laboratory instruments and information systems with which they must interact. Workstations and analysis instruments within a given robotics setup may process samples or fractions at different rates. The central controlling computer must optimize the entire process by communication and control of the robot and peripherals. This also includes communication with a Laboratory Information Management System (LIMS) to assure an efficient, totally automated operation.

## DISCUSSION

A number of examples can be cited to illustrate the gains in productivity and quality, which robotic application of a given method can yield. Unfortunately, because robotics in the radiochemistry laboratory is a fairly recent concept, most of the examples available are from the hazardous chemical

or pharmaceutical industry. While not directly applicable, they do indicate the relative improvements that can be achieved.

The first success story to examine was reported in 1991 (Zenie 1991). Bristol-Meyers Squibb anticipated increasing needs for analytical assays to support their drug development programs. They organized for automation, established talent and equipment, and developed methods to apply robotic technology to the various drug testing procedures. The results were impressive as shown below:

	1985	1986	1987	1988
Laboratory Staff	79	87	105	110
Total Routine Assays	35,177	51,702	85,476	101,256
Assays per Person	445	594	814	921

During the period shown, staff actually increased an average of 12% per year, while the number of assays increased an average of 42% per year. In order to conduct the number of assays done in 1988 at the pre-automation productivity of 1985, Squibb management estimated the laboratory staff in 1988 would have totaled 225 people. Additionally, expansion of space and equipment additions would have been required.

Another example of robotic improvements was reported by Shell Development Company (Taylor, Smith, and Kamla 1990). The particular method automated by Shell involved an analysis of UV-active components in hydrocarbon streams. Converting to the robotic method improved the turnaround time by a factor of five, reduced the cost by a factor of almost four, and increased the precision by a factor of better than three. This information is summarized below:

	Manual	Robotic
Time	3 Hours	30 Minutes
Cost	\$250	\$70
Precision	1%	0.3%
Turnaround	2 Months	2 Weeks

A third example pertaining to the analysis of atrazine and alachlor by a USDA method has been reported by Koskinen et al. (Zymark Corporation 1990). They experienced improved precision and recovery with a substantial reduction in cost per test. The following summarizes their results:

Method	% Recovery	# Samples/wk	# Analyst Reg.
Manual	79 ±17%	80	2
Robotic	89 ±2%	240	1

The last non-radiological example that demonstrates the improvements in precision that can be obtained by an automated system pertains to biological oxygen demand (BOD) testing. The following table (Zymark Corporation 1991) clearly shows an increase in overall precision for a test where each set of standards were run four times each, twice per week, over a 10-week period.

Glucose/Glutamic Acid BOD Standard (ppm)		
	Manual	Automated
Mean	183	209
SD	25.2	13.9
% RSD	13.7	6.7

IT Corporation has begun a robotics/automation program in its radiochemical laboratories in order to achieve the goals outlined in the Introduction above. One of the labor-intensive tasks in a radiochemistry laboratory is the dissolution of soil and sediment samples prior to analysis. This process involves reacting the sample with concentrated acids such as hydrofluoric acid, nitric acid, and hydrochloric acid. The silicate matrix of the soil must be destroyed to release potential contaminants. The acids are added in a prescribed order with heating to dryness over low heat. The process per batch may take 2 or 3 days with periodic attention from laboratory personnel on a 24-hour basis.

A stand-alone robotics system was acquired to automate the soil dissolution process. The system has a multiple sample reaction vessel carousel that is manipulated by the computer controller. Acid additions are by computer-controlled syringe pumps. Heating is accomplished by the use of an open-vessel microwave unit. The robotics "arm" can remove and return reaction vessels from the carousel, the acid addition station, and the microwave heating unit. The advantage of the open-vessel system is that 1) reagents can be added automatically at any time during the dissolution process, 2) volatile dissolution products can be removed or refluxed by selection of the microwave power levels, 3) excess pressure and rupture of the reaction vessel is not possible, 4) the system easily adapts to existing hot plate methods, and 5) dissolution time is significantly reduced due to the efficient heating of focused microwave energy.

Teflon<sup>®</sup> reaction vessels were selected for the soil dissolution because of the necessity of using hydrofluoric acid. One limitation when using Teflon<sup>®</sup> on a hot plate is that operating temperatures should not exceed 200°C. It is also difficult to bring the sample to dryness in Teflon<sup>®</sup> vessels because of their insulating properties. The entire system is computer controlled. After selecting



preprogrammed sequences and loading the carousel with samples, the operator may initiate the process and leave the unit unattended.

The unit is designed for bench-top operation. Venting of digestion fumes is accomplished by flexible ducting to existing fume hood systems. Unit cooling is by a recirculated water reservoir. Uninterruptible power is recommended because the unit does not retain step sequence after power failure.

Soil samples that conventionally take 2 or 3 days to digest have been processed by microwave dissolution in less than 2 hours per sample, with average tracer recoveries and relative standard deviations for uranium dramatically improved, as shown below.

<b>Uranium Tracer Recoveries</b>		
	<b>Hot Plate</b>	<b>PROLABO</b>
<b>X</b>	43%	75%
<b>% RSD</b>	26%	9%

Laboratory control samples and blanks for the batch were within acceptable limits. It should be noted that if a given method is not very good to start with, robotics likely will not improve it.

## **CONCLUSION**

It is clear that there is tremendous potential for productivity and quality improvements through the implementation of robotics and automation in the radiochemistry laboratory. The goal of providing cost-effective, high-quality data for the environmental clean-up activities under way in the United States must include the implementation of robotics and automation if these environmental restoration activities are to be successful and performed on time within budget.

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# POSTER SESSIONS

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## THE QUALITY ASSURANCE PROGRAM AT K & S

T. W. Slowey<sup>(1)</sup>

L. G. Bryson<sup>(2)</sup>

*Abstract* - K & S operates the largest and one of the most comprehensive Accredited Dosimetry Calibration Laboratories (ADCLs) in the American Association of Physicists in Medicine (AAPM) secondary laboratory system. It offers calibrations covering energies from Grenz-Ray (0.03-mm Al) to cesium-137 and cobalt-60, brachytherapy source and well chamber calibrations for low-activity sources, and, recently, high-dose-rate iridium-192. The present Quality Assurance (QA) program at K & S began with the AAPM Guidelines for Accreditation (Task Group #22 and #3, 1989) and grew over the past 10 years to include all aspects of providing a private, self-supporting calibration service from a free-standing independent facility. Some aspects of the QA program were prompted by the requirements of the nuclear power industry while other parts were from national consensus standards or the experiences of staff. Redundancy and teamwork are the most important characteristics of this QA program. K & S has participated in a National Institute of Standards and Technology (NIST) measurement quality assurance (MQA) program since 1982, and, in recent years, an ADCL intralaboratory intercomparison was conducted by Task Group 3 of the Radiation Therapy Committee of the AAPM. One measure of the credibility of a QA program is consistent performance on the MQA program and the ADCL intercomparisons over the past 10 years. An equally important measure of the ability of a program to assure quality results is the frequency of reported errors.

### INTRODUCTION

The calibration laboratory at K & S provides a broad range of calibration services for both in-air type and re-entrant ionization chambers and the calibration of sealed sources. The primary focus of this description of the program will be limited to the calibration of in-air type chambers with only a few references to the QA program for brachytherapy. The brachytherapy part of the K & S QA program, however, is very similar in scope, control techniques, and program content.

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## HISTORY

The laboratory at K & S was accredited by the AAPM in September 1982, after satisfying the requirements of the AAPM Guidelines and successfully completing a site visit and an initial proficiency test with the National Bureau of Standards (NBS). The Guidelines required the use of a written laboratory protocol which described all aspects of the operation of the laboratory. The protocol began as a collection of statements and procedures which described the facility, the equipment, the personnel, and the methods which would be used to calibrate dosimetry instruments within the required accuracy goals. After inquiries from several nuclear power facilities regarding compliance with the QA<sup>(1)</sup> requirements of the U.S. Nuclear Regulatory Commission (NRC) (NRC 1992), we began to investigate the feasibility of organizing a QA program around these regulations and other quality control standards. Although the regulatory criteria for QA programs required by these agencies was apparently directed at material suppliers, most of the basic components were usable as a supplier of services. The basic protocol was then reorganized to accommodate the specific needs of this industry. The suggestions, comments, and requirements of numerous audits by nuclear power QA managers, DoD contractors, and independent auditors over the years have been incorporated into the program.

## REDUNDANCY

The QA program at K & S has as an underlying theme: the concept of redundancy. The AAPM Guidelines suggest the use of redundancy in measurements. The concept of redundancy, however, was proposed earlier (Rozenfeld and Jette 1984) for use as a tool in detecting changes in instrument sensitivity between periodic calibrations. This concept suggests that, with any given assumption of the individual failure rates of the components of a system of independent, redundant observations (or predictions as in decay), the probability of a failure in one component going undetected is significantly reduced with an increase in the number of components or a decrease in the interval between observations. It seems intuitively obvious that if we make more independent measurements of a physical property more often and compare the results, the possibility of missing a mistake is reduced. Yet, as Rozenfeld and Jette point out, many times independent measurements are made without taking advantage of the use of these data in a system of redundant intercomparisons. If the desired result is to maximize the benefit derived from each required measurement and to produce results having the highest level of confidence, the highest quality, then establishing a measurement process with as many redundant systems as possible is the answer. This concept has been extensively used in the K & S QA program with redundancy in local standards, procedures to achieve redundancy in measurements, redundancy in historical data control, redundancy in personnel, and redundancy in the QA review of the calibration report.

### Redundancy in Standards

Dual local standards (each calibrated by NIST) provides the security and convenience of having more than one choice for direct traceability in the event of an accident or failure. Coupling these two components with a third, cobalt-60 or cesium-137 unit for isotope decay, creates a three-component

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(1) Terms such as quality, quality control, quality assurance, and quality management are defined in one or more of the references (ISO 1986).

redundant system which offers the reassurance of significantly reducing the probability of an error in one or the other of the standards going undetected. If an error is detected, the third component allows the capability of determining which component is defective. A weekly intercomparison interval of these three components provides a frequency which is slightly shorter than the normal calibration cycle of 7 working days. This results in a system of the highest confidence level. In the precision calibration business, high confidence in the local primary standards is the first step toward producing quality results.

### **Redundancy in Measurements**

Redundancy in measurements is achieved through the duplication of each of the primary measurements in a separate system and in the careful recording of data which will allow an independent calculation to verify the initial results. The steps in each primary measurement have been formulated to provide at least one other redundant method of calculating independent results.

### **Redundancy in Historical Data**

Access to historical calibration data is an extremely valuable tool in the review and assessment of the calibration data. The reports of calibrations for the current and previous 2 years are maintained in alphabetical order by customer name for ready access by the calibration review team. Log books extending back to the beginning are readily available in the calibration supervisor's office. A redundant file is available at the calibration bench which contains copies of calibration results filed by instrument manufacturer and model. Each file on a frequently calibrated chamber contains an energy response curve for reference by the review team as part of the QA protocol. This particular system is being automated through the use of an integrated report writing and multiple database system.

### **Redundancy in QA Review**

Much of the literature on QA programs propose methods of quality control which involve sampling the results of a process and inferring the quality of a batch or lot. The K & S program, however, requires that every calibration receive a complete QA review by at least two members of the staff in addition to the person performing the calibration. The calibration technician, the laboratory director (or one of the associate directors) and the QA manager sign off on the logged data entries as well as the final report. The objective here is to get three differing points of view for the review of the raw data, the calculation of the factors, and the formal report. These three redundant checks not only result in a very high level of confidence in the final results, but they also allow each individual in the process to take pride in the product of their labors.

## **COMPONENTS OF THE QUALITY ASSURANCE PROGRAM**

The major components of the QA program are: Quality Policy, Traceability Through MQA and ADCL Intercomparisons, Standards Control, Calibration Unit Control, Uncertainty Assessment, Calibration Procedures to Achieve Redundancy, Instrument Flow Control, Records/Document Control and Security, QA Review Process, Annual QA Audits, and QA System Performance Analysis.

## Quality Policy

An overall quality policy is an essential component of the management of a QA program. The policy should identify the personnel, the resources, and the extent and direction of the program. The K & S quality policy is as follows:

1. All calibration laboratory personnel are considered part of the Quality Team. All operations will be conducted in accordance with the policies and procedures contained in the K & S QA program. Quality results depend on quality teamwork.
2. The QA program extends to all laboratory operations which are covered by the protocol.
3. The QA program will be revised and expanded to the extent necessary to assure the highest confidence in the quality of all laboratory operations.

## Traceability Through NIST MQA and ADCL Intercomparisons

At the heart of the service provided by the ADCL secondary system approved by the AAPM is that the ADCL provide direct traceability. This requires the use of a calibration instrument which was calibrated by NIST. Although the AAPM Guidelines only require one of the two mandatory systems be calibrated by NIST, we have found that it is more practical from an operational point of view to have at least two instruments with the same NIST energies. We refer to this system as a redundant standard system. It not only allows the flexibility of choosing either standard for a precision calibration of a customer's instrument, but also prevents the possibility of a shutdown due to a failure of either standard. Each standard instrument received its initial traceability from NIST. This traceability is renewed on a biannual basis through participation in a NIST MQA program. Every other year an ADCL intercomparison provides interim confirmation that the instruments remain in good agreement with the national dosimetry standard. Figure 1 shows the 2-year ADCL Traceability Cycle using the redundant standard concept. The three-component system was established shortly after the initial NIST calibration using the cobalt unit. The local redundant intercomparisons are performed on a weekly basis.

The traceability of the low-dose-rate brachytherapy program is also established initially with a NIST-calibrated source of each isotope offered by the laboratory. Cesium-137 is the only long-lived, low-activity source currently offered by the ADCLs, while iodine-125 seeds and iridium-192 seeds in ribbons are the short-lived isotopes. Redundancy is achieved in the long-lived standards through the use of four NIST-calibrated cesium sources. The redundancy in the short-lived sources, however, is achieved through the use of redundant measuring systems with the cesium sources used for system constancy and locally calibrated working standards of each isotope used for setup constancy. The uncertainty involved in transferring the calibration to a new working standard is included in the total uncertainty for well chamber calibrations. Periodically, K & S sends an iridium source to be calibrated by NIST to confirm the long-term stability of the redundant systems. One intercomparison has been conducted with NIST participation since the program was initiated in 1987-1988 with good agreement between the laboratories and the Radiological Physics Center (RPC) in Houston.

A NIST standard for high-dose-rate iridium-192 is pending. Currently, an interpolative interim standard approved by the AAPM is being used by the ADCL's offering this service.



## Local Standards Quality Assurance

As pointed out above, one of the most important and unique aspects of the ADCL secondary system is its emphasis on redundancy and frequent local intercomparisons. Using cobalt decay and two of the local standard chambers produces a three-component redundant system as shown in Figure 2. In order to prevent the possibility of a change in the energy response of the chambers used for x-ray calibrations, the calibration factors for the transmission monitor on the most stable x-ray techniques are tracked on a monthly basis. This provides a fourth component in the redundant system. Examples of the routine system of the Shonka chambers and the PRM chambers are shown in Figures 3 and 4, and Figures 5 and 6, respectively. Any significant unexplained shift in the factor outside the normal range for one of the chambers would be cause for recalibration with one of the other standards. Two of these four-component systems are used in the QA program. One consists of a set of Exradin Shonka chambers models A2, A3, and A4, and the other consists of two PRM LE-0.8 beryllium window low-energy chambers.

## Calibration Unit Control

The K & S facility was designed with the concept that the calibration procedures and chamber setup methods for each calibration unit would be as consistent as possible. The calibration facility has a Picker cobalt-60 unit, a Picker cesium-137 unit, a GE Maximar 250 III orthovoltage unit (60-300 kVp), a GE Maximar 100 unit (10-100 kVp), a Fisher 125 kVp (35-130 kVp) diagnostic unit, a Universal Grenz Ray unit (2-22 kVp), and the most recent addition is a Picker VTX-650, 600-mA, 150-kVp diagnostic unit. All calibration units (including the cobalt-60 unit and the cesium-137 unit) have been fitted with a custom-designed, dual-chamber, full-beam transmission monitor and a consolidated calibration stand, which permits the same calibration jig to be used on all units. Each unit has been fitted with at least two orthogonal lasers which locate the reference point on each unit. Thus a chamber set up on the cobalt unit for calibration and atmospheric communication tests will be in correct position on any of the other units. A dual-channel electronic thermometer with remote readout is used on each unit to measure the temperature at the transmission monitor and at the chamber position. A redundant thermometer is attached to the standard barometer in the calibration room with its reading being recorded with each calibration. Every physical aspect of the calibration laboratory layout and calibration unit location and capabilities have been formulated to reduce the possibility of errors in the setup and use of each unit. Any questionable results at one energy may be easily checked on a higher or lower technique on the same or a nearby unit.

Measurements of the physical characteristics of each calibration beam are made periodically and recorded in an ADCL Techniques Database on a desktop computer. A sample of the information stored in the database for each combination of energy, field size, and distance is shown in Figure 7. This database is used by the calibration technician to set up the beam on each unit using a computer at the calibration console. Records are also maintained on the previous monitor calibrations for technique tracking purposes. This information is also available on a printed current technique list or on computer for use by the QA review team to verify that the appropriate parameters were used in the calibration.

## Uncertainty Assessment

Uncertainty assessment is a very important part of the K & S QA program. A statement of uncertainty represents to the consumer of the services of a secondary calibration laboratory a promise

of a high level of quality in the reported results. If quality were defined relative to calibration services, it would necessarily include the closeness of the results to the national dosimetry standard, and uncertainty is an estimate of that closeness. The method of uncertainty assessment used at K & S is the method adopted by a subcommittee of Task Group 3 (Ibbott et al, 1991) which follows the method published by NIST (NBS 250-16 [NBS 1988]). Figure 8 describes the basic format used in the assessment. Since uncertainty depends on the physical factors of the calibration, the standard used and the instrument being calibrated, it must be assessed for each group of calibrations offered by the ADCL. Although this method has not been formally adopted by Task Group 3, it has been in use at K & S for several years as a method of estimating the "Accuracy" of the calibration results as recommended in the AAPM Guidelines for accreditation.

### **Calibration Procedures to Achieve Redundancy**

The calibration procedures of the K & S program have been formulated to achieve a balance between efficiency and redundancy. For example, a chamber submitted with an electrometer would be calibrated as follows:

- A. The electrometer is bench calibrated using the standard capacitor and a precision voltage source.
- B. The chamber is calibrated into one of the laboratory precision electrometers using a charge mode and a rate mode.
- C. The chamber and electrometer are calibrated as a system, and the calibration factor thus derived is compared against the product of the individual factors. The system test also provides an intercomparison between the laboratory electrometer and the standard capacitors and voltage source.
- D. Through the use of an independent, solid-state beam timer, the calibration factors are calculated on the basis of isotope decay and compared to results from above.
- E. At least once a week (perhaps during the same calibration, the standard barometer is compared to the station pressure reported by the National Oceanic and Atmospheric Administration (NOAA).
- F. Dual thermometers provide redundant temperature readout.
- G. A redundant calibration of the full-beam transmission monitors for x-ray calibrations are routine procedure (before and after).

Every effort is made to obtain the greatest use of all physical measurements to enhance the overall quality of the results.

### **Instrument Flow Control**

Instrument flow is described in the chart of Figure 9. After checking for shipping damage, the instruments are logged in and inventoried and assigned a test number. Precalibration tests are conducted to ensure proper operation prior to calibration. The QA program includes procedures for each phase of the process including receipt, inspection, handling, precalibration testing, calibration, data recording, verification, comparison to typical performance, previous history review, report preparation, formal report review, packaging, and shipping.

## **The Quality Team**

The Quality Team is currently made up of seven individuals covering the basic functions of the calibration process which includes scheduling, materials management, instrument evaluation, data measurement and report processing. Figure 10 is a chart showing the relationship between the members of the team with an indication of the responsibilities of each member. The associate director performs the annual QA audit since he is not involved with the laboratory on a daily basis.

## **Records/Document Control and Security**

Figure 11 indicates the document system which is being implemented at K & S. Data from the customer, such as shipping address, billing address, and person to contact, are combined with past test numbers and equipment lists to provide a resource for current as well as historical data. The ADCL Techniques Database contains a compilation of all the measured beam data for all the current and previous energies offered by the laboratory. This database is used to set up each technique at the point of calibration and to verify log entries during the QA review process. The Chambers Database, Electrometer Database, and the Other Database (digital meter calibration, etc.) are being established to provide quick access to historical data and to generate energy response curves to replace the existing hand-filing system. Each of these databases will be used to generate the formal report currently generated on a word processor.

## **QA Review Process**

As noted above, the QA program requires that each calibration will be audited by the secretary entering the report on the word processor, by the calibration technician, by the QA manager, and by the director. The review process begins with a completed preliminary data report submitted to the QA manager. Copies of the report are passed to the secretary for entry into the word processor to save time while the review is conducted. The report is verified against the data entered in the calibration log with check calculations of the factor and a check of the files for previous history. The QA manager also verifies that the calibrations performed match the order. Each calibration entry on the form and each page in the respective log book are initialed and dated. Next, the director spot-checks the various calculations, compares the results to previous data on the particular chamber type, prepares a graph if appropriate, and discusses any technical issues for clarification prior to initialing and dating the log entries. The formal report is then reviewed first by the secretary for typographical errors, then by the QA manager, by the calibration technician, and finally by the director for accuracy against the preliminary data.

## **Annual QA Audits**

An annual audit of the QA program is conducted by the associate director. All aspects of the protocol and the procedures are evaluated from the point of view of someone who is not otherwise involved with the day-to-day activities of the laboratory. Calibration support activities, such as local standard intercomparisons, calibration procedures, history file maintenance, calibration QA audits, instrument handling procedures, packaging and shipping standards, procurement of calibration services from other facilities, and supplier qualification, are addressed in the QA audit. Interviews are conducted with each member of the program and a written report is filed with the QA manager.

## QA System Performance Analysis

The performance of the QA system is evaluated on an annual basis after the annual QA audit by the associate director and is based in part on the following:

1. The results of the annual QA audit.
2. The results of the NIST MQA or the intercomparison between the ADCLs.
3. The evaluation of any reported errors.
4. The results of discussions with customers who have recently used the service.

Performance on the NIST MQA has been consistent over the years since 1982 as shown in Figure 12.

Two errors have been reported over the years since 1982. One error involved the use of a calibration factor for an energy other than on the one used in the calibration. This error occurred during the first year of operation. The second error occurred some years ago and involved the use of a large-volume chamber with its cobalt build-up cap on an x-ray energy. The cap was black and fit so tightly that the seam was invisible. Both errors were thoroughly investigated and resulted in many QA procedures which are still in place today.

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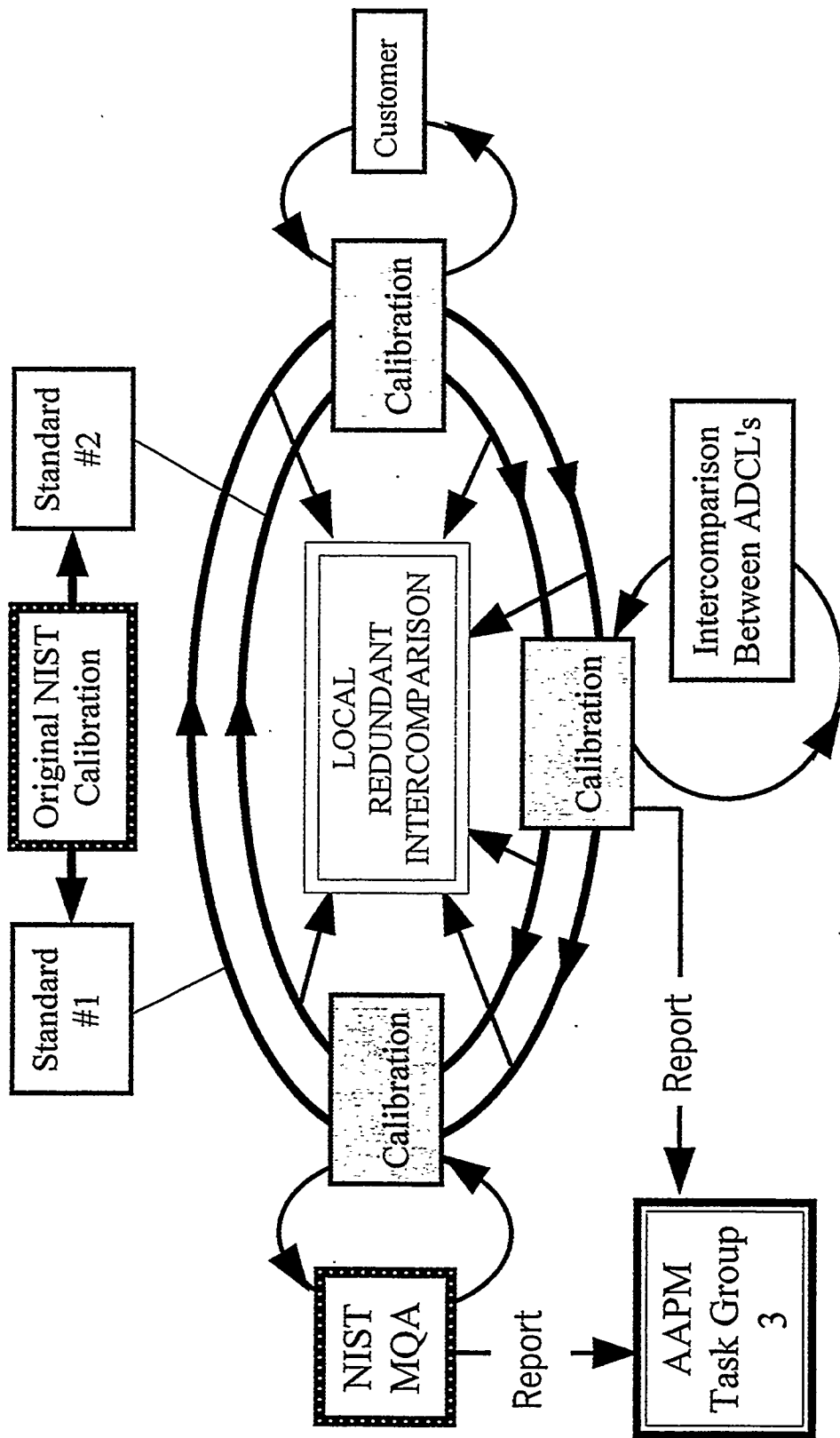


Figure 1 - Two-Year ADCL Traceability Cycle

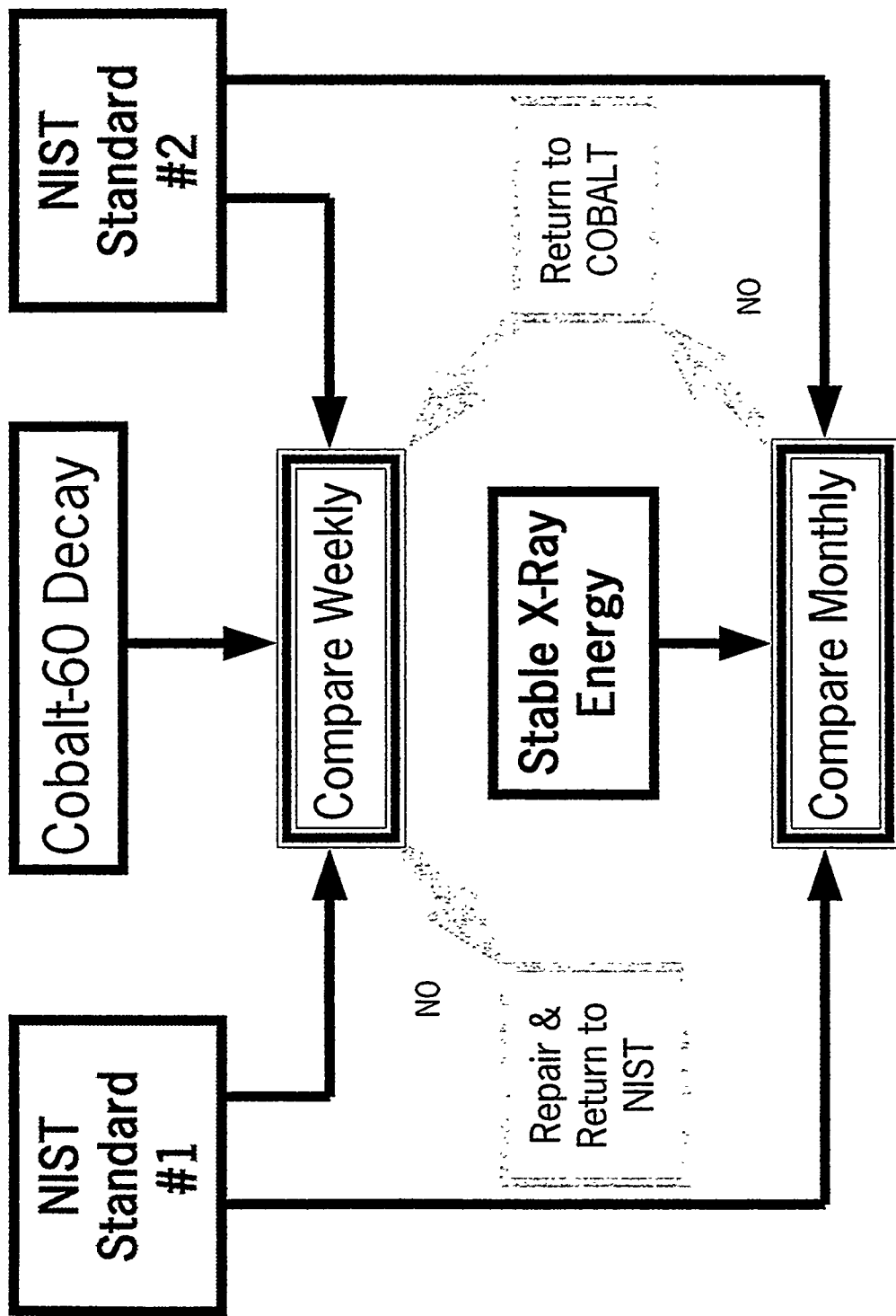


Figure 2 - Local Redundant Intercomparisons

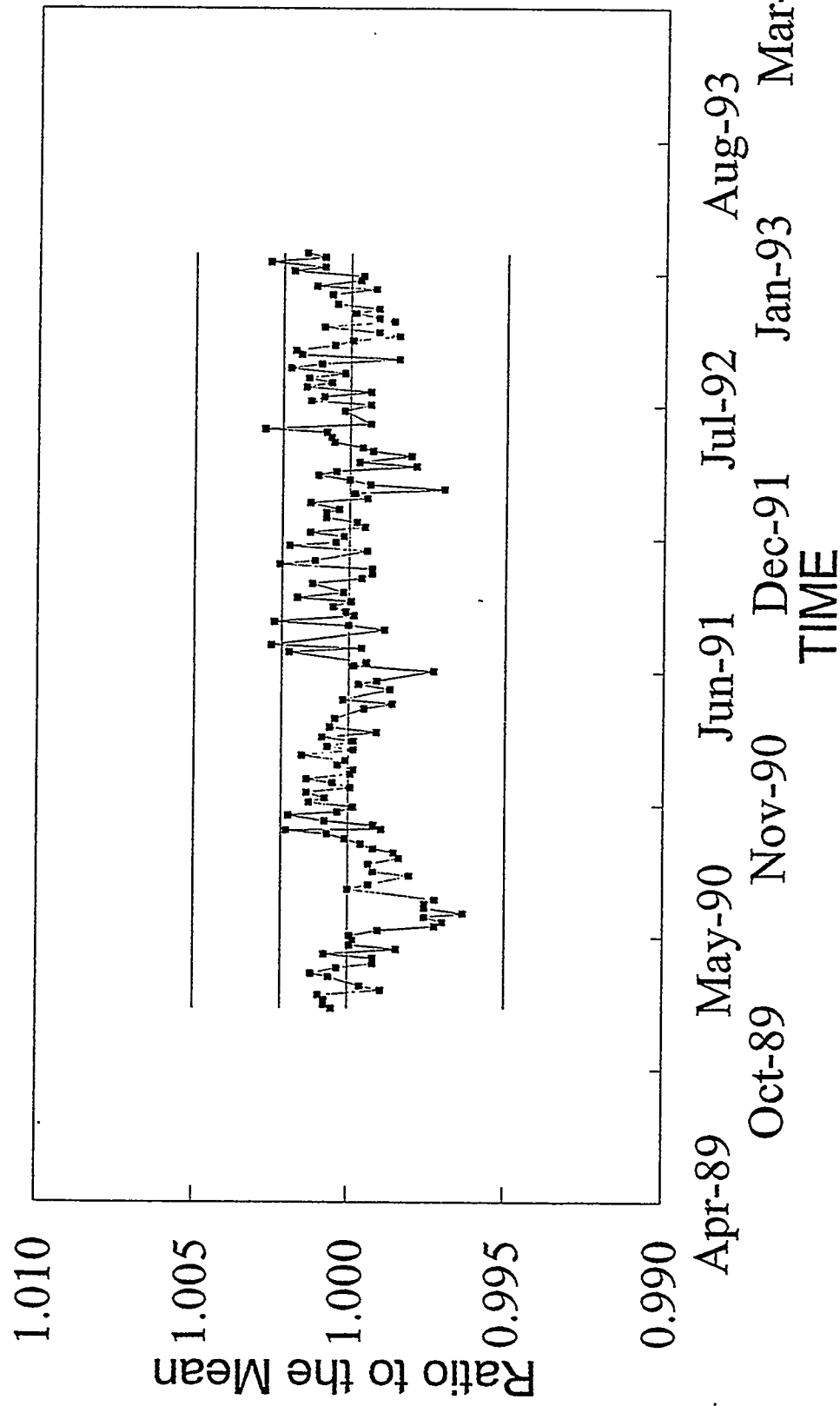


Figure 3 - Cobalt-60 Intercomparison Shonka Chambers



2.97 mm Aluminum HVL

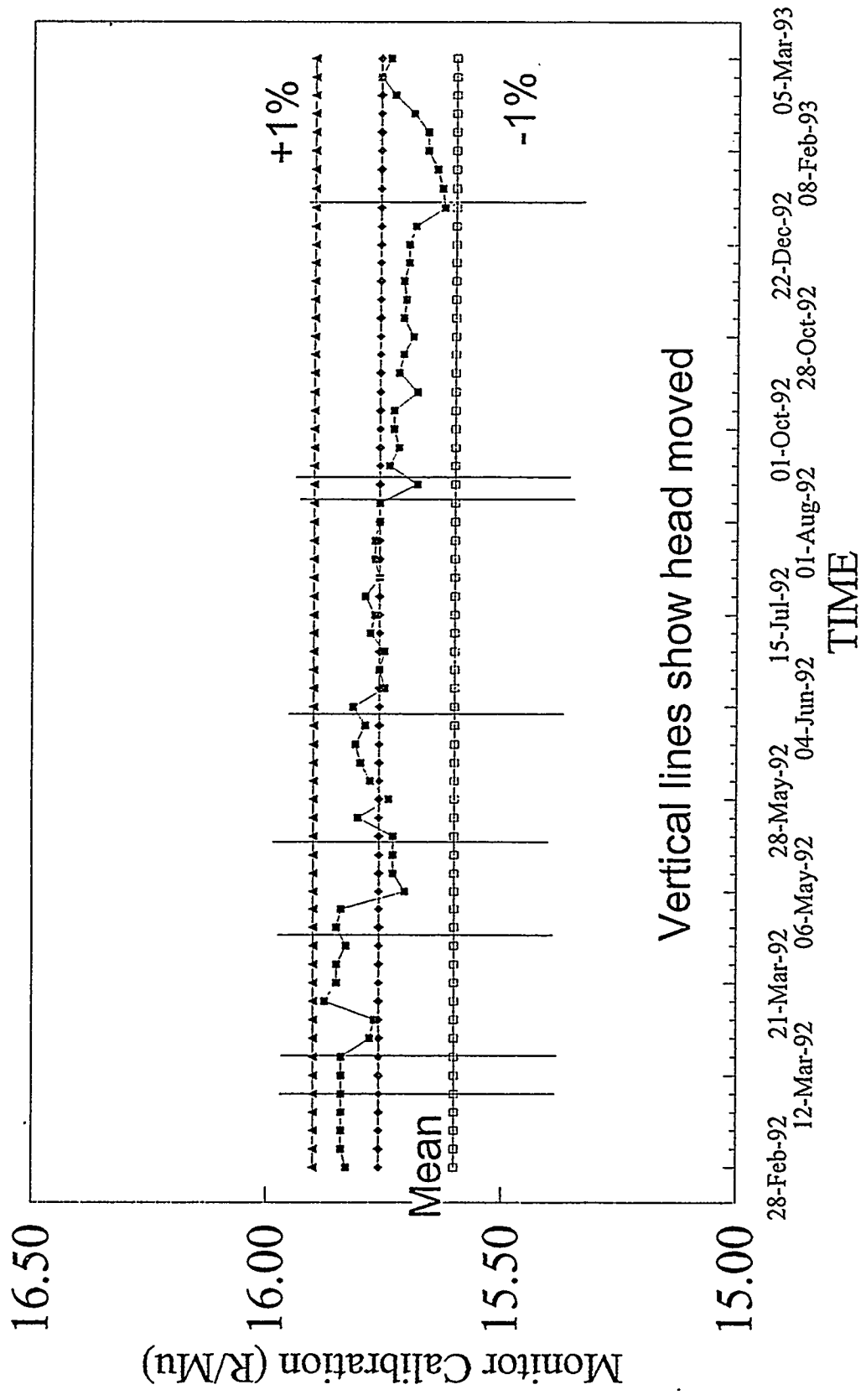


Figure 4 - Shonka X-Ray Intercomparison

# PRM LE-0.8

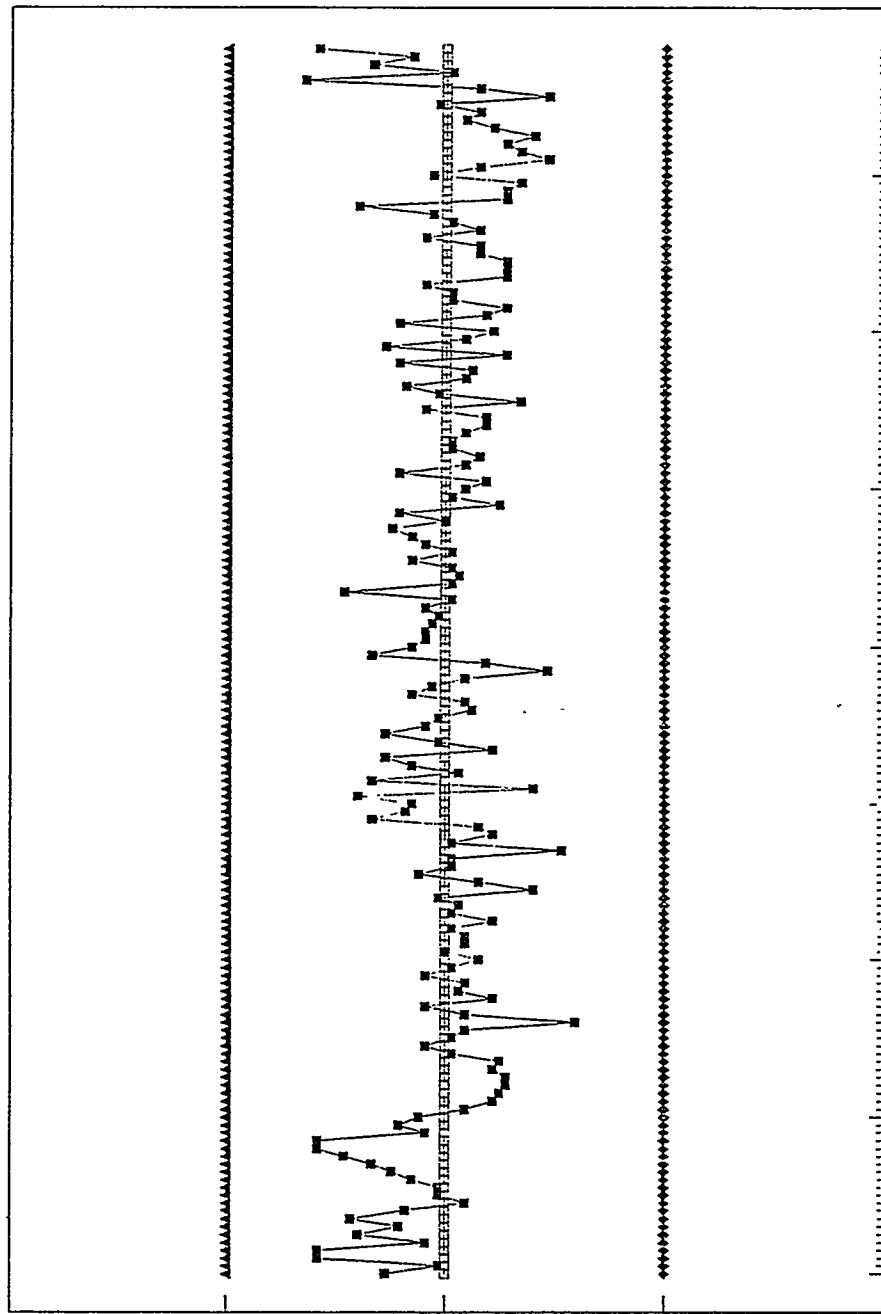
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1.005

1.000

0.995

0.990

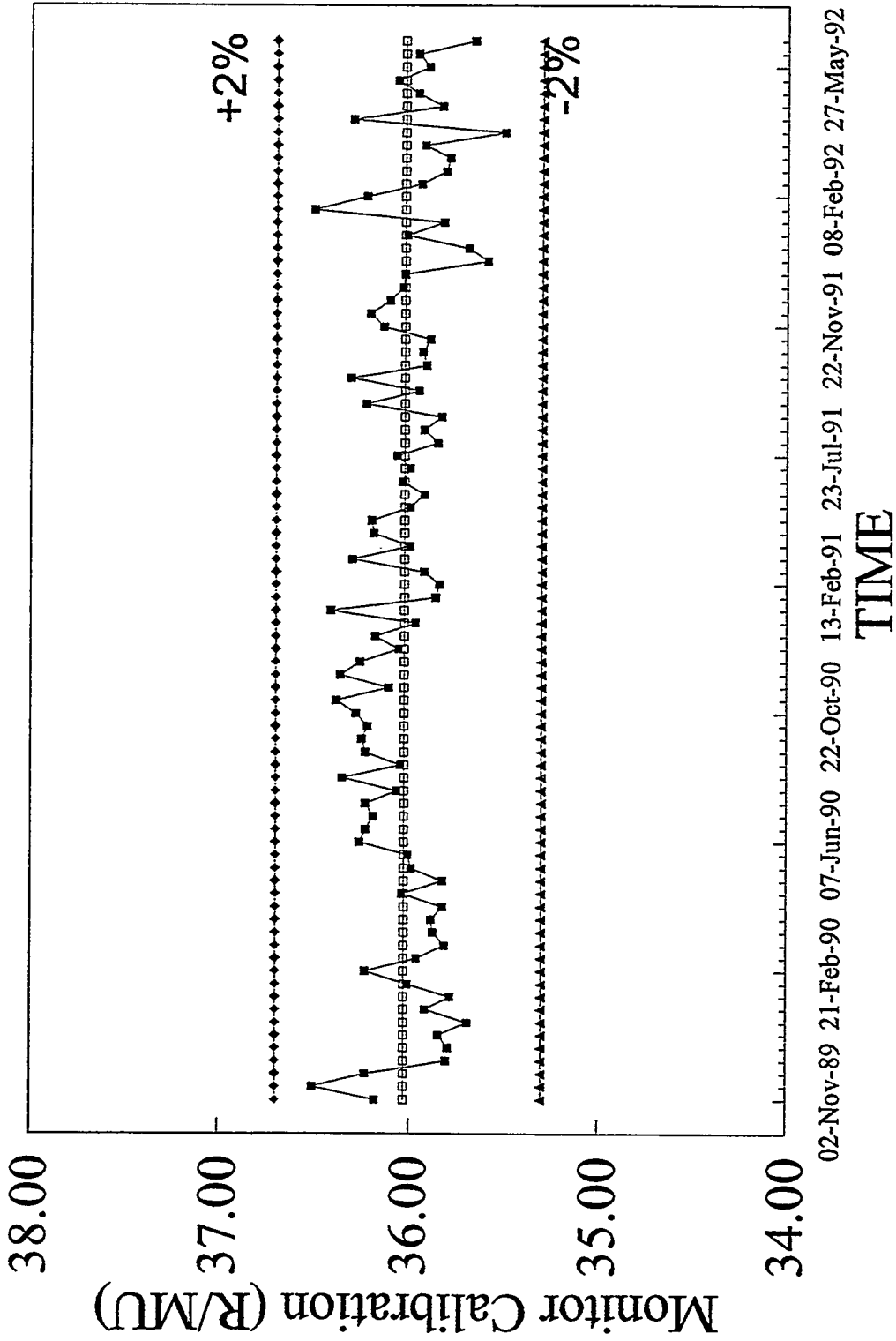


02-Nov-89 03-May-90 11-Oct-90 28-Feb-91 28-Aug-91 23-Jan-92 11-Jun-92 12-Nov-92

TIME

Figure 5 - Cobalt-60 Intercomparison PRM LE-0.8

**X-RAY INTERCOMPARISON  
PRM LE-0.8 - 0.34mm Aluminum HVL**



*Figure 6 - Low-Energy Chamber Intercomparison*

CODE: T24  
 UNIT: 250MAX  
 STATUS: AC

REPORT =====

HVL: 1.05Cu

H.C.: 0.60

kVp: 205 kVp

R/min: 12.7 R/mil

SCD (cm): 45cm

Gy/R: 8.7643E-03

TECHNIQUE =====

Est. KeV: 81.0

ma: 5ma

SETTING:

FIELD: 10cm dia

Filter: 0.5Cu+1Al

R/MU: 15.6

AVG.R/MU: 15.578

AVG.R/min: 12.463

STANDARDS =====

	MFGR/MODEL	SERIAL	FACTOR 1	FACTOR 2	UNCERT
C1M:	PRM LE-8	C1S: 8829	CF1L:	CF1M:	C1U:
C2M:	EXRADIN A2	C2S: 139	CF2L:	CF2M:	C2U:
C3M:	EXRADIN A3	C3S: 137	CF3L:	CF3M:	C3U:
C4M:	EXRADIN A4	C4S: 147	CF4L:	CF4M:	C4U:
C5M:	PRM LE-8	C5S: 8828	CF5L:	CF5M:	C5U:

HISTORY =====

NOTES:

D01:	1/9/93	SET01:	32	RMU01:	15.59	RM01:	12.6
D02:	2/8/93	SET02:	33	RMU02:	15.54	RM02:	12.35
D03:		SET03:		RMU03:		RM03:	
D04:		SET04:		RMU04:		RM04:	
D05:		SET05:		RMU05:		RM05:	
D06:		SET06:		RMU06:		RM06:	
D07:		SET07:		RMU07:		RM07:	
D08:	10/23/92	SET08:	33	RMU08:	15.57	RM08:	
D09:	1/12/00	SET09:	32	RMU09:	15.6	RM09:	12.5
D10:	12/22/92	SET10:	32	RMU10:	15.59	RM10:	12.4

Figure 7 - ADCL Technique Database

DATE: 10/18/90

CODE: Cs02 BEAM: NEL Cesium RATE: 7.800E-03R/min DIST: 150cm  
FIELD: 35cm Gy/R: 8.7780E-03 EXP: 6.84684E-05Gy/min MONITOR (Y/N): y i

=====  
STD.CHAMBER STDCMFGR: Exradin STDCMOD: A4 STDCSN: 147  
STDCVOL: 30ml

STD.ELECT STDEMFGR: PRM STDEMOD: SH-1 STDESN: 8603  
=====

CHAMBER TYPE: spherical CATAGORY: >5cm

CUST.CHAM CUSCMFGR: Exradin CUSCMOD: A6 CUSCSN:  
CUSCVOL: 800ml

CUST.ELECT CUSEMFGR: CUSEMOD: CUSESIN:  
=====

TABLE I

TABLE II

	TYTPE A		TYPE B		TYPE A		TYPE B	
1. CHARGE	C1A:	0.109	C1B:	0.033	C2A:	0.046	C2B:	0.033
2. TIMING	T1A:	0%	T1B:	N/A	T2A:	0%	T2B:	N/A
3. AIR DENSITY	A1A:	0.077	A1B:	N/A	A2A:	0.077	A2B:	N/A
4. RECOMBINATION	R1A:	0%	R1B:	0.067	R2A:	N/A	R2B:	0.067
5. DISTANCE	D1A:	0%	D1B:	0	D2A:	0%	D2B:	0.223
6. BEAM UNIFORM.	B1A:	0%	B1B:	0.038	B2A:	0%	B2B:	0.067

=====  
QUADSUM1: 0.157582 QUADSUM2: 0.134581  
CALIBRATION NIST: 0.5 EXPCAL: 0.524244218  
OVERALL: 1.082486028

NOTES

- N1: C1A=WORST OF 5 R/MU, SIG/3=.327/3
- N2: C2A=WORST OF 3 CALS, 0.1/3
- N3: A1A=.2DEG, 2mm: .23/3
- N4: C2B= ELECT=0.1/3
- N5: R1B=WORST CASE=0.2/3
- N6: A2A=A1A
- N7: D1B=0:difference in table II
- N8: D2B=5mm in 150cm, .668/3
- N9: B1B= .038 (A4)
- N10: B2B=N-3, p232 worst=0.2;0.2/3
- N11:
- N12:

Figure 8 - Uncertainty

INSTRUMENT AND RECORDS  
FLOW CHART

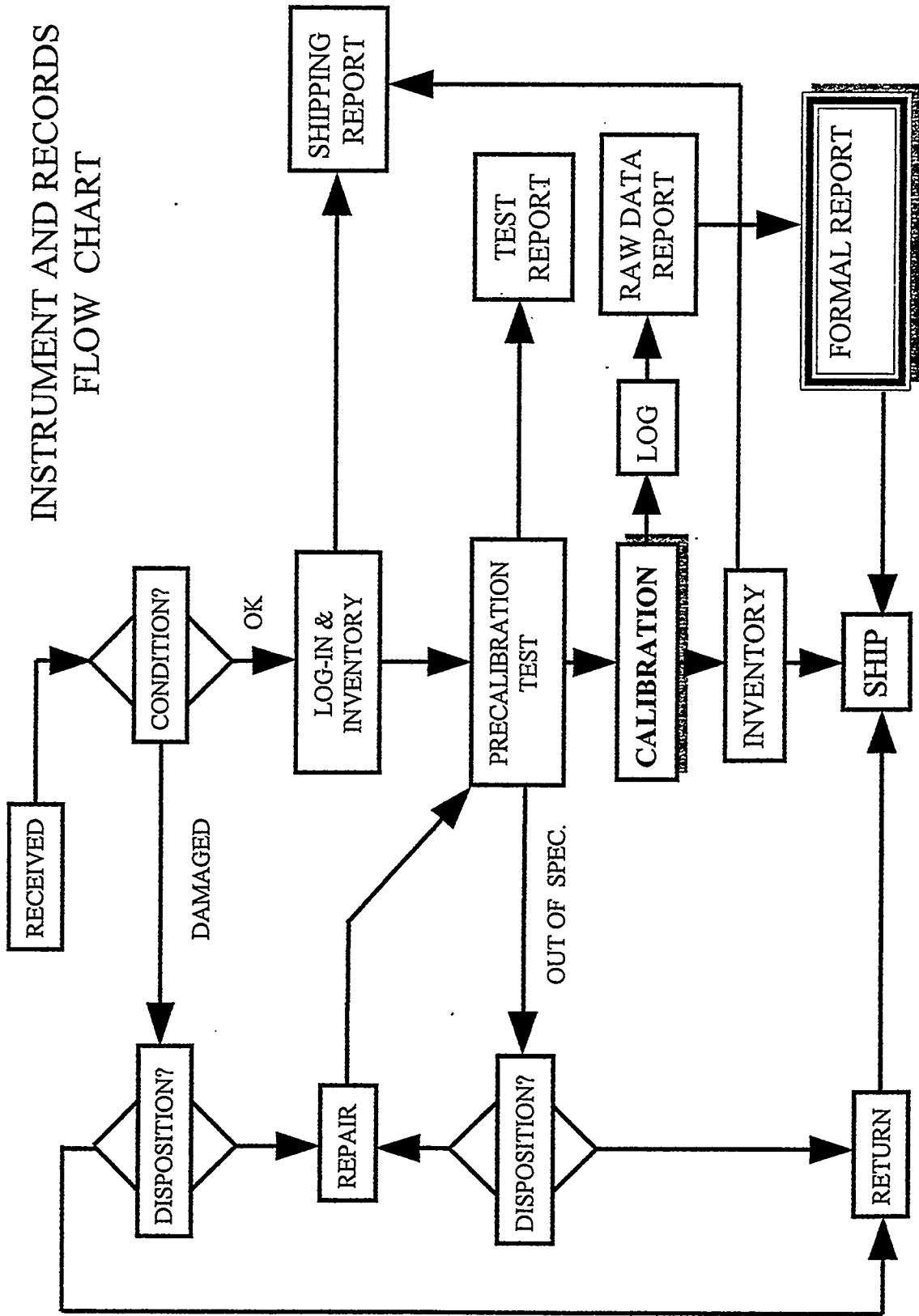


Figure 9 - Instrument and Records Flowchart

# The Quality Assurance Team

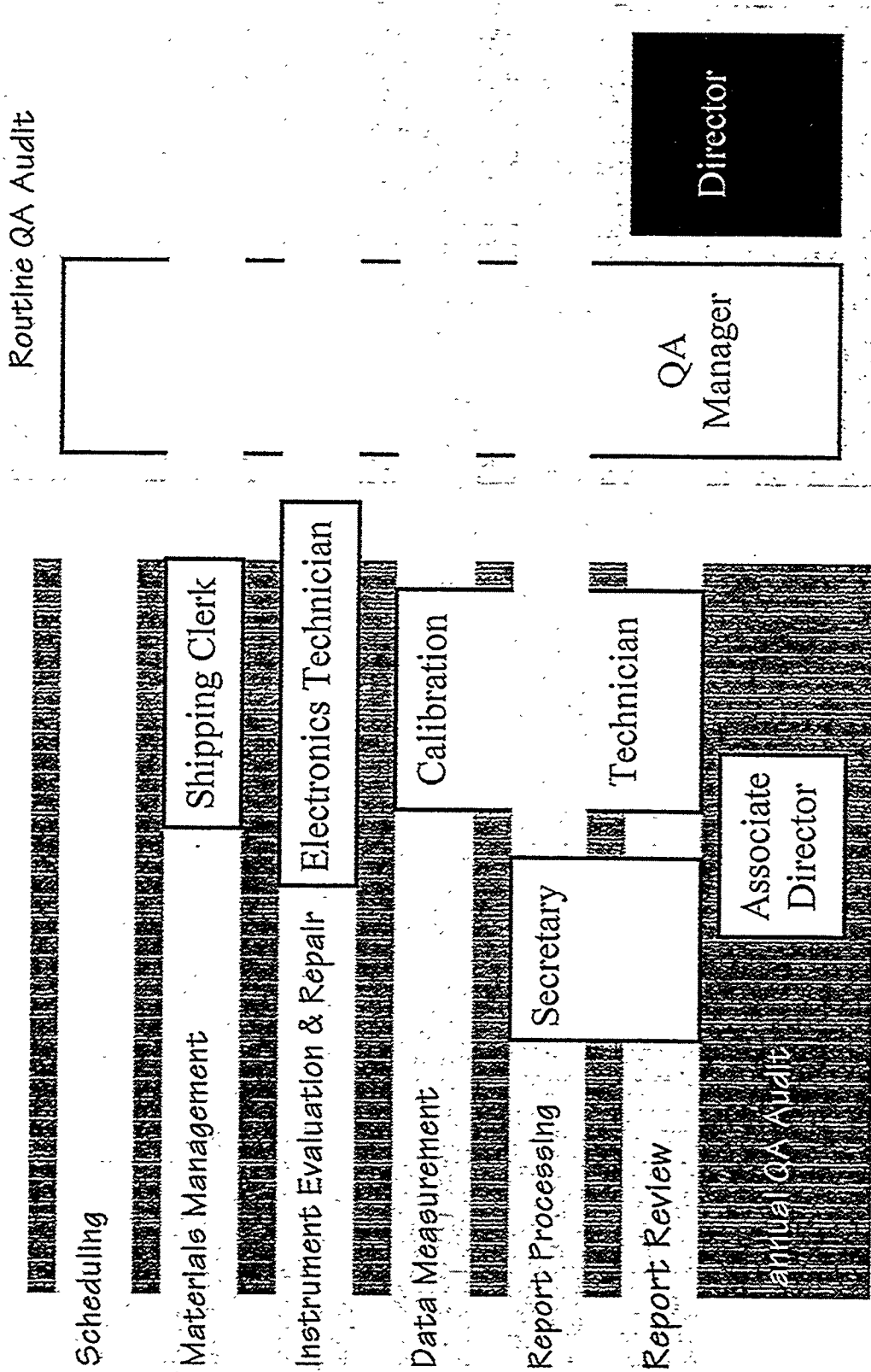


Figure 10 - The Quality Assurance Team

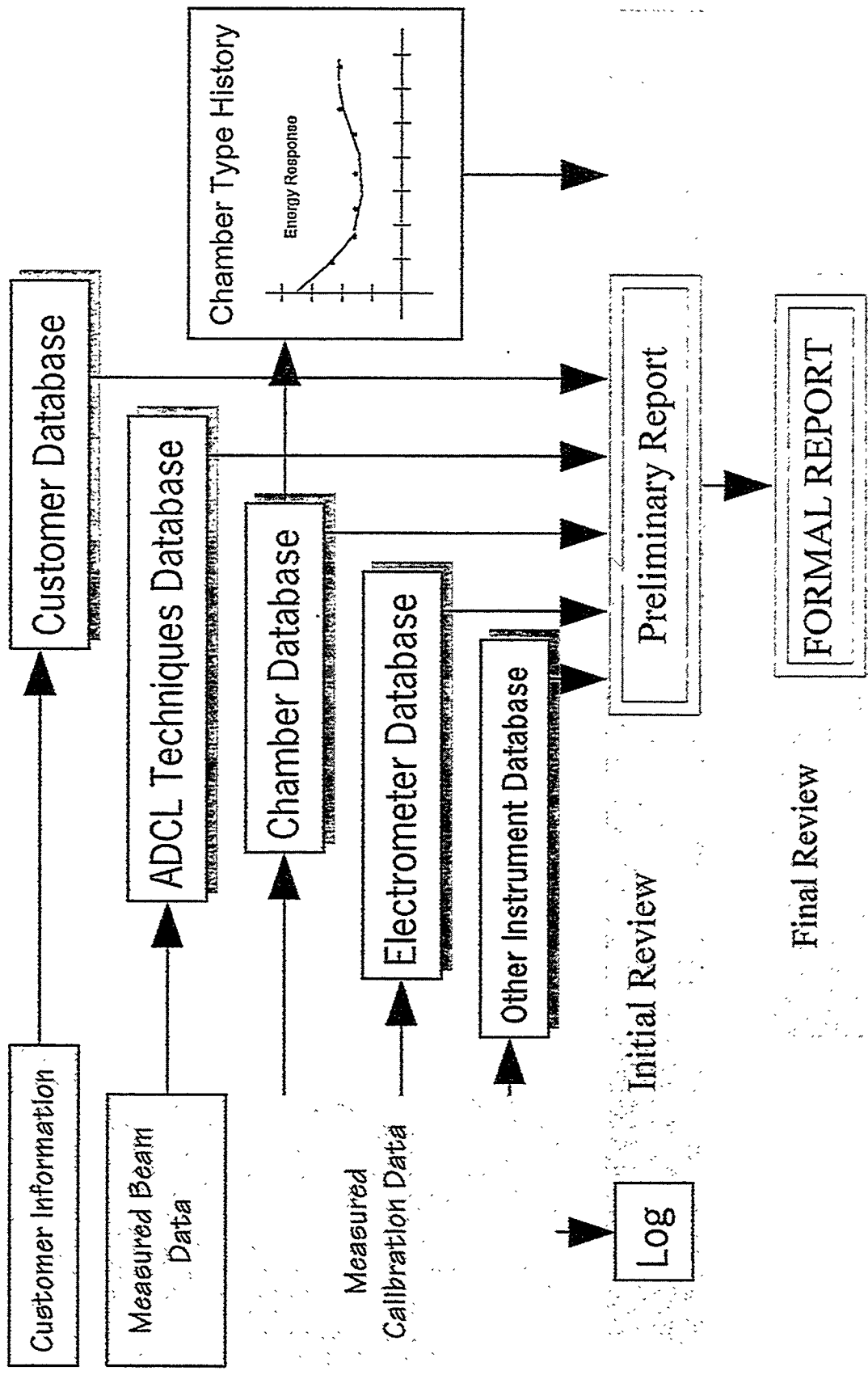


Figure 11- Data Management System



PERCENT DEVIATION

NIST BEAM CODE	HVL	1982		1983		1985		1986-1987		1989-1990		1990-- Supplement	AVERAGE#PTS	
		Cham #1	Cham #2	Cham #1	Cham #2	Cham #1	Cham #2	Cham #1	Cham #2	Cham #1	Cham #2			
L10 (L-B)	0.029mmAL									1.1			1.10	1
L15 (L-C)	0.050mmAL									1.4			1.40	1
L20 (L-D)	0.071mmAL									0.6			0.60	1
L30 (L-G)	0.22mmAL									0.9			0.90	1
L40	0.49mmAL									1.2			1.20	1
L50 (L-I)	0.75mmAL									1.3			1.30	1
L80	1.83mmAL									-0.1			-0.10	1
L100(L-M)	2.8mmAL												ERR	0
M20	0.152mmAL									1.2			1.20	1
M30 (L-G)	0.36mmAL									0.4		-0.24	0.08	2
M40	0.73mmAL									0.9		0.13	0.52	2
M50 (L-I)	1.02mmAL	1.14	0.9	0.3	0.5	0	-0.5	0	0.4	0.6	0.4	0.4	0.37	10
M60 (MFB)	1.68mmAL	-1.04	0.1	0.4	-0.4	-0.7	0.1	0.4	0.5	0.6	0.5	0.33	-0.03	9
60(MFC)	2.79mmAL	-0.54											-0.54	1
75(MFE)	3.39mmAL	-0.75											-0.75	1
M100(MFG)	5.00mmAL	-0.63	0.1	0.2	0	-0.9	0	0.5	0.2	0.2	0.2		-0.07	8
M150(MFI)	10.2mmAL	-0.22	0.2	0.3	0.1	-0.7	0.5	0.3	0.4	0.4	0.4		0.11	8
200(MFK)	13.2mmAL	0.34												
M200	14.9mmAL		0.1	0.4	0.4	-0.4	0.4	0.6	0.6	0.6	0.6		0.30	7
250(MFM)	15.8mmAL	0.23											0.23	1
M250(MFO)	18.5mmAL	0.63	-0.1	0.4	0.2	0	0.3	0.5	0.6	0.6	0.6		0.32	8
M300	22mmAL							0.3	0.3	0.3	0.3		0.30	1
Cesium 137	32mmAL								-0.1	-0.2	-0.2		-0.17	3
Cobalt 60	46mmAL	-0.2	0.6	0	-0.2	-0.3	-0.4	-0.2	-0.2	-0.2	-0.2		-0.11	8

Figure 12 - NIST MOA

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# NEW INSTRUMENT CALIBRATION FACILITY FOR THE DOE SAVANNAH RIVER SITE

W. H. Wilkie<sup>(1)</sup>  
E. J. Polz<sup>(1)</sup>

**Abstract** - A new laboratory facility is being designed, constructed, and equipped at the Savannah River Site (SRS) as a fiscal year 1992 line item project. This facility will provide space and equipment for test, evaluation, repair, maintenance, and calibration of radiation monitoring instrumentation. The project will replace an obsolete facility and will allow implementation of program upgrades necessary to meet ANSI N323 requirements and National Voluntary Laboratory Accreditation Program (NVLAP) criteria for accreditation of federally owned secondary calibration laboratories. An outline of the project is presented including description, scope, cost, management organization, chronology, and current status. Selected design criteria and their impacts on the project are discussed. The upgraded SRS calibration program is described, and important features of the new facility and equipment that will accommodate this program are listed. The floor plan for the facility is shown, and equipment summaries and functional descriptions for each area are provided.

## PROJECT DESCRIPTION

### Design Strategy and Facility Classification

The Health Protection (HP) Instrument Calibration Facility Project will build and equip a single-story structure having an approximate floor area of 26,000 square feet. The facility is being designed as a "green field" project in an undeveloped section of the Site with no constraints imposed by existing structures or unusual topography or geological conditions. The design is being prepared by Ebasco through a Project Engineering Services Contract (PESC). The design will meet (or will provide the capability for the program to meet) the applicable requirements of the partial list of key codes and standards shown in Table 1.

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<sup>(1)</sup> Westinghouse Savannah River Company (WSRC), Health Protection Department, 735-A Savannah River Site, Aiken, South Carolina 29808.

A lump sum fixed price contract will be issued for constructing and equipping the facility as a "turn key" product. The project is a 1992 line item with a total estimated cost (TEC) of \$20,600,000. An estimated total project cost of \$24,400,000 consists of the TEC plus \$3,800,000 from the Site operating budget used to fund supporting activities not covered by project TEC. Table 2 lists cost details for the project.

A Hazards Assessment Document (HAD) prepared in accordance with U.S. Department of Energy (DOE) requirements (DOE 5480.23 as supplemented by DOE-STD-027-92) has resulted in a determination that the overall hazard classification for the facility is GENERAL USE NON-NUCLEAR. An analysis of the radioactive source inventory in accordance with DOE-STD-027-92 found that the facility will be below the threshold of a Category 3 hazard which supports the conclusions of the HAD. Therefore, a Safety Analysis Report will not be required.

The new facility will provide all the laboratories, offices, shops, testing and calibration equipment, furniture, and support space needed for the SRS instrument program. It will support routine repair, maintenance, and calibration activities for portable instruments. The facility will provide extensive capabilities for instrument testing and evaluation in accordance with ANSI N323 Section 3 and ANSI N42.17A for new instruments as well as for instruments in service. In addition, the facility will be equipped to provide the capability for performing specialized tests in support of the external dosimetry program and for testing and evaluating fixed radiation monitoring equipment.

### **Chronology**

Major milestones for the project are listed in Table 3. Although this list indicates a long time line between project inception and completion, it should be emphasized that the schedule is very aggressive with a few brief periods of low activity for reviews and procurement actions.

### **Project Management**

Management of major projects within DOE is very involved and, in addition to specific annual Congressional budget authorization, requires multiple justifications, independent reviews, funding approvals, etc. Figure 1 diagrams the interactions of the key organizations. A project team responsible for the day-to-day work on the project has a membership drawn from the organizations depending on the current project activities. This team meets weekly or as required and conducts project business using a consensus management style. This approach is working well and is proving to be very effective in ensuring that all applicable requirements are met while avoiding big surprises that frequently have plagued projects not coordinated in this manner. The team approach is believed to be especially prudent in view of the rapidly evolving mission objectives and project management requirements within the DOE complex.

### **CURRENT PROGRAM DESCRIPTION AND PROJECT JUSTIFICATION**

The Calibration Group of the HP Technology Section is responsible for providing and maintaining an inventory of portable radiation monitoring instruments for supporting SRS operations. This involves procuring, testing, evaluating, and approving new portable instruments for SRS use and for calibrating, maintaining, and repairing this equipment. The group also is responsible for providing technical advice and approval for installed radiation monitoring instruments used in radiation protection applications, e.g., equipment for monitoring area radiation, laundry contamination, and

breathing air. The current inventory of portable equipment includes approximately 4,000 radiation and contamination monitoring instruments and 5,500 direct-reading quartz fiber and electronic dosimeters. Approximately 15,000 survey instrument calibrations and 11,000 test cycles for direct reading dosimeters are performed per year. The demand for calibrated instruments has continued to climb steadily even as the DOE mission for SRS has been shifting away from nuclear material production in response to world politics.

The current facility for the calibration program was constructed in 1952 and is no longer adequate to meet DOE technical and program requirements. It was determined that expansion and renovation of the existing calibration facility would not be cost effective because:

- It is located in a congested and highly developed part of the site.
- Asbestos in wall panels and floor tiles mandates expensive construction techniques for protecting health.
- Compliance with the access requirements related to safeguards and security and radiation protection would significantly complicate the expansion and renovation work.
- The present program could not be effectively managed with concurrent construction for renovation and expansion.

Therefore, the new facility is being designed to meet present needs and to provide the capability for future expansion should this be required to support the evolving DOE mission objectives for the SRS.

## **FLOOR PLAN AND SELECTED ROOM DESCRIPTIONS**

### **Floor Layout**

The floor plan shown in Figure 2 is intended to support efficient operation by grouping areas requiring heavy staff interaction, frequent instrument movement between rooms, or centralized equipment control and monitoring. An additional design objective is to minimize construction costs, e.g., by grouping together the rooms requiring poured concrete shielding, simplifying the building footprint, and locating the equipment rooms (electrical, mechanical, telecommunications) to ensure convenient access and maintainability. For as low as reasonably achievable (ALARA) reasons, the administrative and personnel service areas were placed to maximize distances from the production support areas containing gamma and neutron irradiators. Figure 3 shows the location of the various categories of space and lists percentages of the total floor area.

### **Control Room**

The operating stations for the Low Scatter, X-ray Beam, and the Gamma Beam Rooms will be located in the Control Room. An additional operating station will be provided for video process and surveillance functions. Normal access to the above mentioned rooms will be through the Control Room as an additional safety feature.

## **Low Scatter Room**

One of the most notable features of the facility is the Low Scatter Room which will provide the capability for performing primary instrument calibrations and dosimeter testing. The room geometry is 40 ft x 40 ft x 40 ft with a single irradiation position located at the geometric center of the room. An aluminum grating working level will be provided slightly below the mid-height of the room. Parametric studies were performed to see if the addition of boron in the concrete would be practical for reducing the fluence rate of low-energy neutrons back into the room. It was determined that the addition of 0.1% boron by weight into the concrete would reduce the low-energy scatter in the room by a factor of approximately 16.

## **Well Room**

Four well-type irradiators will be located in this room. The room is an elongated rectangle with concrete partitions between the wells along the narrow axis of the room to minimize cross talk (radiation interference).

## **Performance and Environmental Testing Laboratory**

The Performance and Environmental Testing Laboratory (PETL) will be used both for evaluating new equipment and for conducting routine periodic testing as specified in ANSI N323 and detailed ANSI N42.17A. Large radiation monitoring systems will be brought into the PETL through a roll-up door opening onto a covered loading area.

## **ADDITIONAL FEATURES**

### **Video Systems**

Extensive use will be made of video equipment in the facility. Color cameras for safety surveillance and high-resolution black and white cameras for monitoring processes will be provided. To prevent confusion during video switching all cameras will be equipped with character generators giving the camera ID, which will be displayed on any monitor switched to that camera. Facility lighting is being designed to minimize glare from instrument meter faces.

The process monitoring cameras for the Well Room will have pan, tilt, and zoom capability and will be mounted on a ceiling-mounted positioning track which will allow positioning to minimize parallax distortion when viewing instrument faces. The process monitoring cameras for the X-ray, Gamma Beam, and Low Scatter Rooms will be rigidly mounted to the instrument positioning tracks and will travel with the instruments during repositioning. Each room will have a portable monitor for use in setting up the cameras for test viewing.

The surveillance cameras with remote pan tilt and zoom capability are an additional safety feature for the rooms in which a potential for significant radiation exposure of personnel exists. Facility operating procedures will require a search of the areas both in person and by using the video surveillance systems prior to activation of the irradiation equipment.

Each surveillance and process camera shall first feed and be controlled from the operating console for that room. The video signal also will feed a video workstation in the Control Room and can be

monitored or recorded at any time. Controls for the remotely controllable cameras also will be provided at the video workstation. However, control must first be turned over from the equipment control station by a technician to prevent interfering with any tests in progress. A 19-inch monitor will be provided in the overhead of the Control Room to provide viewing of the rooms and processes by visitors and interested parties without entering the rooms.

### Computer Network

A network of IBM-compatible computers will be used for maintenance, repair, test, process tracking, and calibration data collection. Workstations will be set up with bar code reading equipment to scan in the ID of equipment and access appropriate information to lead the technicians through the various procedures required in the facility. On-screen procedures will prompt for the appropriate data entry. Error checking will give immediate feedback of incorrect data entry. All data will be collected from workstations over the network to update the master databases on the network server located in the Records Room. Local printers will provide a hard-copy calibration certificate for review and signature of calibration technicians and for printing calibration labels for the instrument.

### Shielding

A design objective is to provide shielding that reduces dose rates to facility staff to below 0.25 mrem/h to the extent practicable and further reduces dose rates within ALARA considerations. Extensive parametric shielding studies were performed, and alternative designs were evaluated against an ALARA criterion of \$15,000 per annual person-rem saved. Also, it was necessary for the shielding to be sufficient to minimize radiation interference with a whole body counting facility to be constructed nearby. The most difficult problems related to the shielding specifications were calculating neutron and gamma dose rates at the entrances of labyrinths and optimizing the designs to minimize loss of floor space while allowing convenient movement of staff and equipment through passageways and labyrinths.

### Radiation Sources

The facility will have the capability for calibrating beta, gamma, neutron, and X exposure (or dose) rate instruments and for alpha and beta/gamma count rate instruments within wide ranges of radiation intensities including:

<u>Radiation</u>	<u>Approximate Calibration Range</u>
gamma ( $^{60}\text{Co}$ and $^{137}\text{Cs}$ )	up to 20,000 R/h
neutron ( $^{252}\text{Cf}$ )	up to 100 rem/h unmoderated
neutron ( $^{252}\text{Cf}$ )	up to 20 rem/h moderated with a 30 cm $\text{D}_2\text{O}$ sphere

Overload testing with gamma radiation will be possible at higher exposure rates of up to 200,000 R/h when uniformity of the radiation field across the detector volumes is not a critical consideration.

All of the high activity  $^{60}\text{Co}$ ,  $^{137}\text{Cs}$ , and  $^{252}\text{Cf}$  sources will meet the DOT "Special Form" requirements (49 CFR 173.469) in order to minimize leakage risks.

## **Irradiation Equipment**

Various types of irradiation equipment are being specified for the facility. Count rate type instruments will be calibrated using small plated sources. The irradiation systems for the facility are listed in Table 4 along with descriptions and expected primary uses. All irradiation equipment for the facility will incorporate instrument positioning fixtures that will provide reproducible geometry during calibration and/or testing. Design considerations for the major equipment include:

- fail-safe design to low-exposure conditions on error, loss of power, or manual trip of conveniently located scram buttons
- computer-controlled operation of major equipment with consideration for a consistent graphical operating interface to ease training on equipment operation
- precise positioning of the sources or the instruments using two independent systems for redundancy
- integration of computer control, calibration data collection, and environmental condition monitoring
- video monitoring of process functions with recording capability
- ease of maintenance including source removal to safe locations to facilitate equipment maintenance
- source selection to provide a wide range of dose rates
- provisions for remotely changing instrument ranges where practical.

## **Truck Loading/Unloading Facilities**

A grade-level loading area will be equipped with a hydraulic platform which can conveniently be adjusted to match the height of the bed of any size truck. Hydraulic loading equipment is believed to be cost effective and will eliminate the need for a below-grade ramp with the accompanying problems due to drainage, trash accumulation, and safety.

## **SUMMARY**

The project to build and equip a new instrument calibration facility at SRS is on schedule and under budget due to management support at all organizational levels and to the efforts of a multidisciplined project team. The facility is expected to be capable of meeting future radiation monitoring instrument needs for the SRS regardless of how the DOE mission evolves, whether it be production support, waste management, decommissioning, environmental restoration, or a combination of activities.

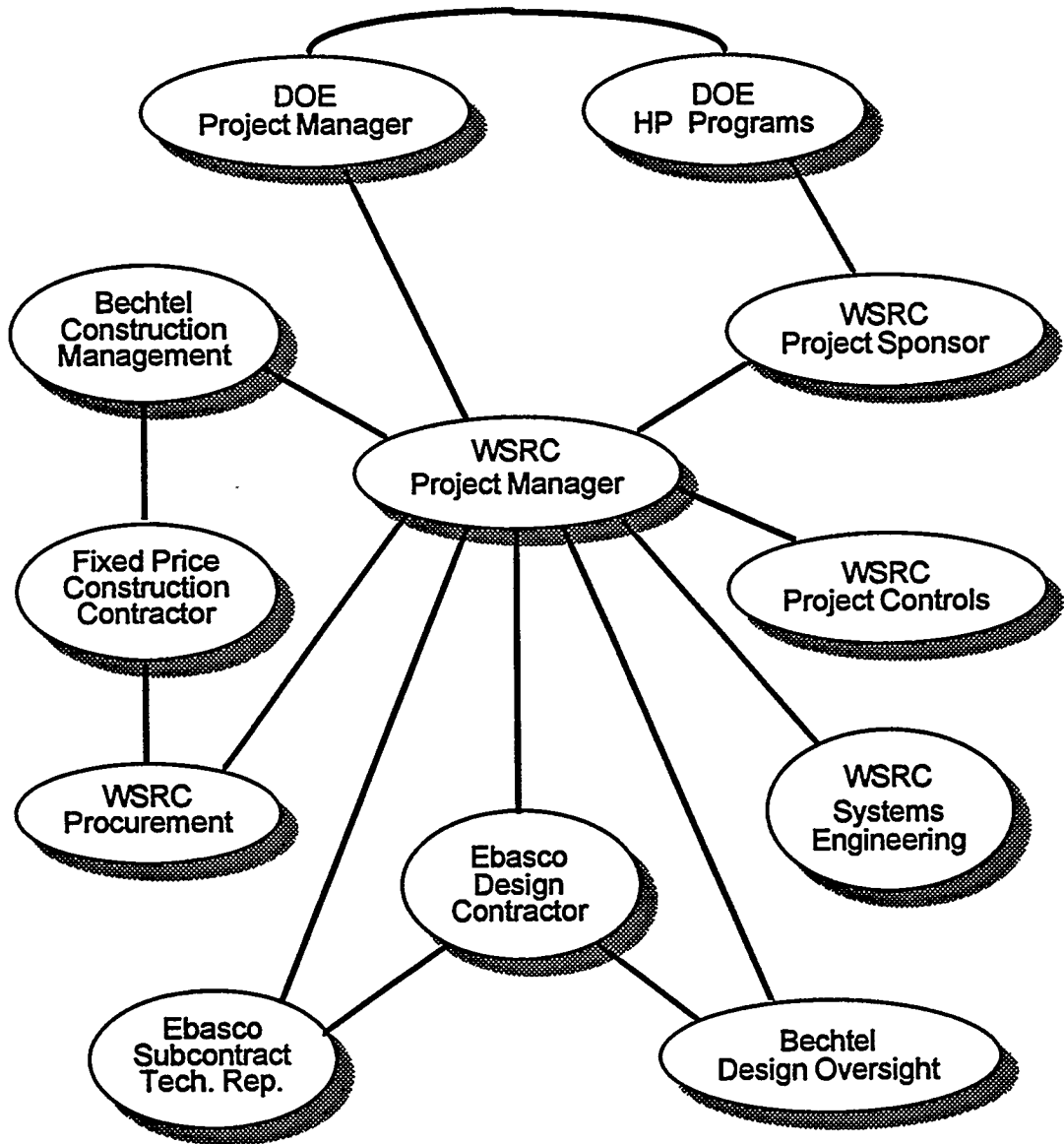


## REFERENCES

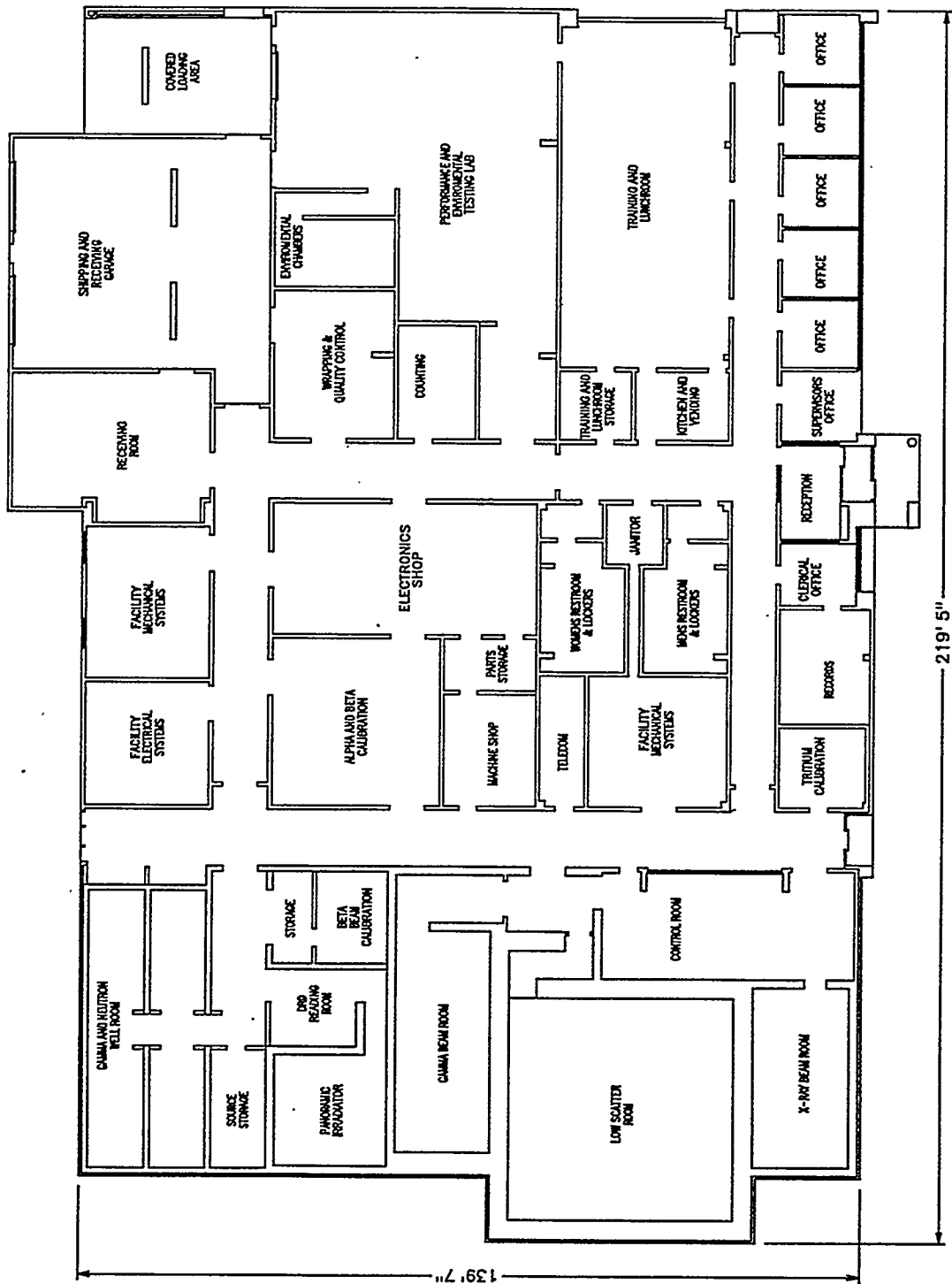
49 CFR 173.469. "Tests for Special Form Radioactive Materials." U.S. Code of Federal Regulations.

U.S. Department of Energy (DOE). 1992. "Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports." DOE-STD-1027-92, Washington, D.C.

U.S. Department of Energy (DOE). 1992. "Nuclear Safety Analysis Reports." DOE Order 5480.23, Washington, D.C.



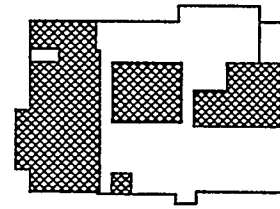
*Figure 1 - Project Interface Plan*



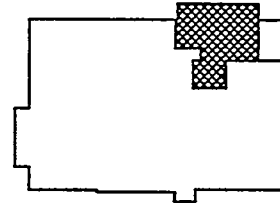
HP Instrument Calibration Facility

Figure 2 - Architectural Floor Plan

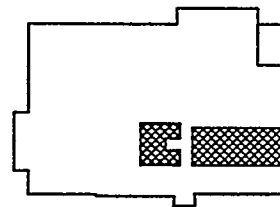
**PROCESS AREAS**  
(calibration, testing, maintenance, repair)  
47 percent of total area



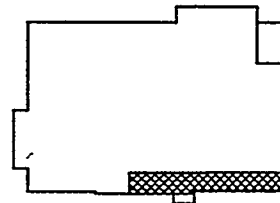
**SHIPPING & RECEIVING AREAS**  
12 percent of total area



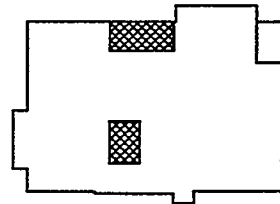
**PERSONNEL SERVICES AREAS**  
(eating, training, toilets)  
11 percent of total area



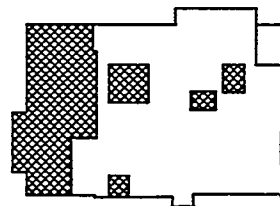
**ADMINISTRATIVE AREAS**  
7 percent of total area



**BUILDING SERVICES AREAS**  
7 percent of total area



**RADIOLOGICALLY CONTROLLED AREAS**  
31 percent of total area



*Figure 3 - Area Footprints*

*Table 1 - List of Key Codes and Standards*

DOE Documents

5400.5	<u>Radiation Protection for the Public and the Environment, 2/8/90</u>
5480.4	<u>Environmental Protection, Safety and Health Protection Standards, 5/16/89</u>
5480.7	<u>Fire Protection, 11/16/87</u>
5480.11	<u>Radiation Protection or Occupational Workers, 12/21/88</u>
6430.1A	<u>General Design Criteria, 4/6/89</u>
N 5480.6	<u>Radiological Control Manual, 6/92</u>

ANSI Standards

ANSI N42.17A	<u>Performance Specifications or Health Protection Instrumentation - Portable Instrumentation or Use in Normal Environmental Conditions, 1989</u>
ANSI N323	<u>Radiation Protection Instrumentation Test &amp; Calibration, 1978</u>
ANSI N543	<u>General Safety Standard or Installations Using Nonmedical X-ray and Sealed Gamma-Ray Sources, 1974</u>

NIST Documents

Criteria for the Operation Federally-owned Secondary Calibration Laboratories (Ionizing Radiation), 1990

NVLAP Program Handbook, Secondary Calibration Laboratory or Ionizing Radiation - Requirements or Accreditation

*Table 2 - Project Cost Details (dollars in \$000)*

SUMMARY

Total Estimated Cost (TEC) .....	20,600
Other Project Costs (OPC) .....	3,800
Total Project Cost (TPC) .....	24,400

ITEM COST

Engineering, design, and inspection .....	2,775
Construction management .....	532
Construction costs      13,302	
Improvements to land (grading, landscaping, drainage diversion, paving, parking, lighting) .....	619
Calibration building, 26,350 sq. ft. ....	7,901
Utilities (power, water, sewer, etc.) .....	324
Special equipment (irradiator, computer, safety systems, and instrumentation) .....	4,458
Standard equipment (office furniture, etc.) .....	577
Contingency at approximately 20% .....	<u>3,414</u>
TOTAL .....	20,600

PROJECT SPENDOUT

Fiscal Year	TEC	OPC	TPC
1992	332	498	830
1993	3,600	312	3,912
1994	8,100	468	8,568
1995	7,700	814	8,514
1996	868	1,648	2,516
Totals	20,600	3,800	24,400

*Table 3 - Chronology*

<u>Milestone</u>	<u>Date</u>
Need for new facility identified . . . . .	1/89
Functional Performance Requirements document issued . . . . .	2/90
Functional Design Criteria document issued . . . . .	5/90
Conceptual Design Report submitted to DOE . . . . .	5/90
Project Validation hearing . . . . .	6/90
Project Authorization issued . . . . .	3/92
Title I design (30% level) complete . . . . .	8/92
Procurement of lump sum contractor initiated . . . . .	7/93
Title II design (90% level) complete . . . . .	6/93
Construction start . . . . .	2/94
Title III design (100% level) complete . . . . .	10/95
Project complete . . . . .	10/95
Approval to commence operations . . . . .	3/96

Table 4 - Major Irradiation Equipment

LABORATORY	EQUIPMENT	PRIMARY USES
Low Scatter	Free-air, low scatter, irradiator system with four positioning tracks.  $^{60}\text{Co}$ 20 Ci $^{137}\text{Cs}$ 100 Ci $^{137}\text{Cs}$ 2.2 Ci $^{137}\text{Cs}$ 0.05 Ci $^{252}\text{Cf}$ 4 mg $^{252}\text{Cf}$ 0.3 mg $^{252}\text{Cf}$ 0.03 mg	Primary calibrations of transfer instruments and general testing: Cf-252 sources may be used bare or with moderation by a 30 cm diameter $\text{D}_2\text{O}$ sphere.
Gamma Beam	Beam type irradiator system with a single positioning track.  $^{60}\text{Co}$ 6,000 Ci $^{60}\text{Co}$ 75 Ci $^{60}\text{Co}$ 1 Ci $^{137}\text{Cs}$ 5,000 Ci $^{137}\text{Cs}$ 62 Ci $^{137}\text{Cs}$ 1 Ci	Primary and high range calibrations; overload response testing.
X-ray Beam	320 kV constant potential X-ray generator and a single positioning track	Low energy calibration and testing; dosimeter irradiation.
Beta Beam	Beta beam irradiator system and a single positioning track.  $^{90}\text{Sr/Y}$ 50 mCi $^{90}\text{Sr/Y}$ 2 mCi $^{209}\text{Tl}$ 0.5 mCi $^{147}\text{Pm}$ 14 mCi	Free field beta calibration and testing.
Well Irradiator	Four independent well-irradiator systems with single sources:  $^{137}\text{Cs}$ 20 Ci $^{137}\text{Cs}$ 20 Ci $^{137}\text{Cs}$ 0.5 Ci $^{252}\text{Cs}$ 0.01 mg	Production calibration of gamma and neutron instruments.
Panoramic Irradiator	A single source:  $^{137}\text{Cs}$ 1.2 Ci	Dosimeter irradiation and testing.



# QA EXPERIENCE AT THE UNIVERSITY OF WISCONSIN ACCREDITED DOSIMETRY CALIBRATION LABORATORY

L. A. DeWerd, Ph.D.  
J. A. Micka, B.S.<sup>(1)</sup>

*Abstract* - The University of Wisconsin Accredited Dosimetry Calibration Laboratory (UW ADCL) employs procedure manuals as part of its Quality Assurance (QA) program. One of these manuals covers the QA procedures and results for all of the UW ADCL measurement equipment. The QA procedures are divided into two main areas: QA for laboratory equipment and QA for external chambers sent for calibration. All internal laboratory equipment is checked and recalibrated on an annual basis, after establishing its consistency on a 6-month basis. QA for external instruments involves checking past calibration history as well as comparing to a range of calibration values for specific instrument models. Generally, we find that a chamber will have a variation of less than 0.5% from previous Co-60 calibration factors, and falls within two standard deviations of previous calibrations. If x-ray calibrations are also performed, the energy response of the chamber is plotted and compared to previous instruments of the same model. These procedures give us confidence in the transfer of calibration values from National Institute of Standards and Technology (NIST).

## INTRODUCTION

The UW ADCL is a secondary calibration laboratory accredited by the American Association of Physicists in Medicine. The laboratory calibrates medical equipment used in the radiation environment; in particular, a large part of the calibrations performed are for radiation therapy and diagnostic x-ray applications. As a secondary laboratory, the UW ADCL has taken great pains to match the x-ray beam qualities established by NIST. Prior to obtaining our constant potential x-ray unit, we had a full-wave, rectified x-ray machine. Our procedure to match NIST x-ray beam qualities

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for that machine is given in the paper by Goetsch, Kamande, and Attix (1985). In 1986 we obtained a constant potential x-ray generator similar to that at NIST. Accurate matching of the NIST x-ray beams using the constant potential machine was straightforward, and performed with a higher degree of precision.

The UW ADCL uses four procedure manuals that outline the operation of the laboratory. These manuals are required reading for any laboratory personnel and are limited in distribution. There is only one "official" copy which is kept in the Director's Office. Any changes must be initialed and approved by the Director before it is officially instituted. A general manual outlines all QA procedures and another entitled "Catalog of Standards & History" includes the calibration history for all of the UW ADCL equipment. All internal laboratory equipment is checked and recalibrated on an annual basis, after establishing its consistency on a 6-month basis. Data for these QA checks are maintained in this "Catalog of Standards & History" manual in addition to outside intercomparisons or calibrations; an example of such an outside activity would be the calibration or re-calibration of an ionization chamber by NIST.

The UW ADCL also includes QA procedures on equipment sent to the laboratory for calibration. For example, data are kept on types of ionization chambers. After calibration, a chamber can be compared with previous values for that model and type. Instruments that do not fall within acceptable ranges are investigated and recalibrated for verification. Also, contact with the user is made to determine instrument repair history and its possible impact on the calibration.

#### **MAINTENANCE OF STANDARD BEAMS**

In order to best serve the needs of the medical physics community, the UW ADCL established a Co-60 calibration range, a Cs-137 calibration range (including 1.3 Ci, 130 Ci, and 800 Ci sources), and an orthovoltage x-ray calibration range with 17 NIST matched beam qualities (see Table 1). All calibration ranges were developed to provide a flat, uniform field approximately 10 cm in diameter at an SSD of 100 cm. The Co-60 and Cs-137 ranges each have at least two NIST-calibrated standard chambers to provide maximum traceability. The x-ray range utilizes two different types of standard chambers: one for "hard" x-ray beams ( $kVp > 80$ , half-value layer (HVL)  $> 2.9$ -mm Al), and one for "soft" x-ray beams ( $20 < kVp < 80$ ). Both of these standards have backups for internal quality control purposes.

Each x-ray beam quality was carefully matched to available NIST beams using a standard aluminum filter set (obtained from NIST) for HVL measurement. The UW ADCL constant potential machine has been calibrated for kVp using an intrinsic Ge detector used to determine the spectra and, thus, the kVp. Once the NIST-matched beams were developed, our standard chambers were sent to NIST for calibration. Beam qualities are periodically checked for HVL and kVp accuracy.

All of the above-mentioned calibration ranges employ in-beam transmission monitors to normalize exposure. These monitors were carefully designed and manufactured in-house to minimize attenuation of the calibration beams, and to provide long-term stability. Use of air-vented transmission monitors allows the calibration of numerous chambers in one cycle, since air density, timing, and geometry changes are constantly monitored. Upon initial calibration of the beam during the daily cycle, the standard chamber charge readings are divided by the transmission monitor readings to produce a "standard ratio." Customer calibrations throughout the remainder of the cycle are normalized to the monitor chamber readings in the same manner. As a result, the calibration factor is easily transferred

from the standard chamber to the customer chamber, and air density and timing errors cancel out. At the end of the calibration cycle, the standard chamber is repeated, and the "standard ratio" is determined once again to make sure nothing has changed during the calibration cycle.

We have produced decay tables for our radioactive sources listing the decay-corrected values for each day. The appropriate value from the table is then used to compare with daily exposure measurements to provide verification of the constancy of our radiation source. For the x-ray machine, the exposure and air kerma rates are measured after the beam qualities are created and matched to NIST beams. A table listing these rates for each beam quality is posted in the control room, and daily exposure measurements are compared to those in this table. If the daily exposure measurements differ significantly from the tabulated predicted values, the calibration cycle is suspended until the discrepancy is resolved.

## **CALIBRATION QA OF UW ADCL EQUIPMENT**

The UW ADCL maintains a number of standard ionization chambers traceable to NIST at various beam energies. In addition to ionization chambers, the laboratory has other equipment (to measure temperature, pressure, voltage, capacitance, etc.) that has been calibrated and is traceable to NIST. The following discussion is oriented toward ionization chambers, but the same procedures are used for all laboratory calibration equipment.

Upon receipt of a new ionization chamber, the UW ADCL will intercompare it with previously calibrated NIST chambers to determine an interim calibration factor. The chamber is monitored and recalibrated over a period of 6 months to ensure stability. The chamber is then sent to NIST for calibration. Upon return, the chamber is again intercompared with other NIST chambers that are calibrated for that energy. This provides two checks for us: first the stability of our chamber calibration factors, and secondly, that the new chamber sent to NIST has not changed in transit. Periodically thereafter, chambers are intercompared with other NIST chambers. This is performed on a 6-month basis until we have established their characteristics and stability. Thereafter, it is performed on a yearly basis. Many times this is done during a calibration procedure of chambers sent in for calibration. It is always done using at least two NIST-calibrated chambers at one time. The value is then recorded on a history sheet such as the one shown in Table 2. Note that the first date of October 1984 includes a number of NIST points for this chamber. Thereafter, Center for Devices and Radiological Health (CDRH) and local intercomparisons are listed; in the interest of brevity, only three dates are included for this table in this publication. Note that this chamber has remained within  $\pm 1.0\%$  throughout its lifetime for the x-ray points.

## **QA OF CHAMBERS SENT FOR CALIBRATION**

QA is also provided on chambers sent for calibration. This involves checking on past calibrations of that chamber as well as checking for a range of calibration values for that type of chamber. Figure 1A shows a scatter plot of the  $N_x$  values with calibrated chamber and Figure 1B shows a bar graph of the frequency of  $N_x$  calibration factors for Capintec PR-06C chambers. Generally, we find that a chamber will have a variation of less than 0.5% of its previous  $N_x$  value for re-calibration at the Co-60 factor. In most cases, it is generally within  $\pm 0.2\%$ . If a Co-60 point and x-ray points are done, the energy response of  $N_x$  for the chamber is compared with previous chambers to show that it falls within two standard deviations. An example of a Capintec PR-06C chamber calibration at Co-60

and several x-ray points is plotted on Figure 2. The displayed error bars in Figure 2 show the 2-sigma standard deviation, and the plot shows an acceptable energy response for this chamber.

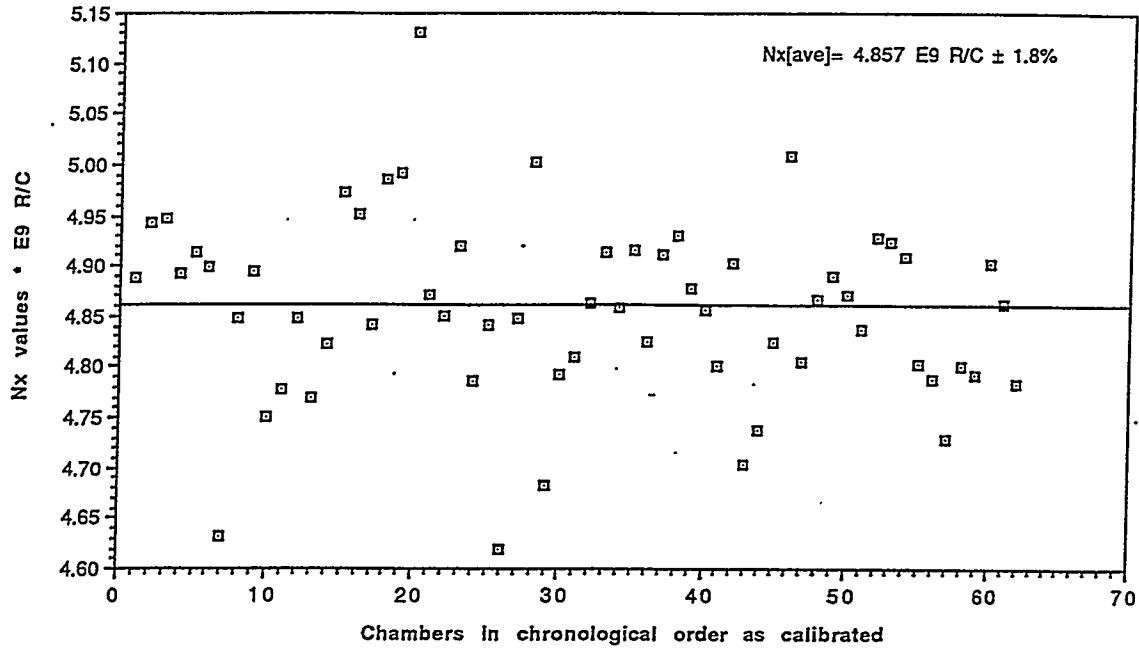
These QA procedures give us confidence in the calibration done on the submitted chambers. If a factor seems to be out of tolerance levels, e.g., its value of  $N_x$  has changed by more than 0.5% or it is outside of 2 standard deviations for a point, we will repeat the point for verification. This repeated point usually has an  $N_x$  value that agrees to within  $\pm 0.2\%$  of the prior calibration done at the UW ADCL. Generally, for chambers with an  $N_x$  value that has changed by an amount greater than 0.5%, we find that the thimble has been replaced or there is some other physical reason for the observed deviation.

## CONCLUSION

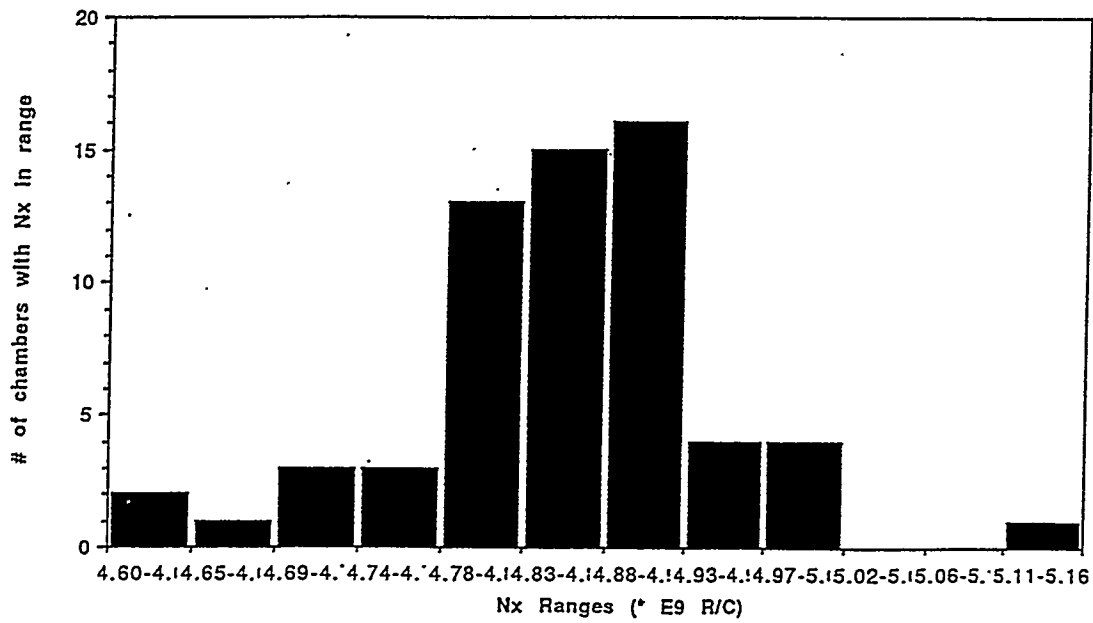
The QA procedures for the UW ADCL provide a means to control exposure and air kerma calibrations of ionization chambers. Numerous instrument problems and discrepancies have been resolved as a result of strict adherence to the QA plan. Through identification of these problems and direct contact with the physicist using the instruments, significant errors in clinical dose measurements have been averted. These procedures provide confidence in the transfer of calibration values from NIST to the medical physics community.

## REFERENCES

Goestch, S. J., J. Kamande, and F. H. Attix. 1985. "Method for Matching NBS X-ray Beam Qualities with a Half or Full Wave Rectified Generator." *Medical Physics* 12:249-251.



*Figure 1a -  $N_x$  Values for 62 Capintec Pr-06Cs at UW ADCL*



*Figure 1b - Distribution of Capintec PR-06C  $N_x$  Values Around Average of  $4.857 * E9$  r/C for 62 Chambers at UW ADCL*

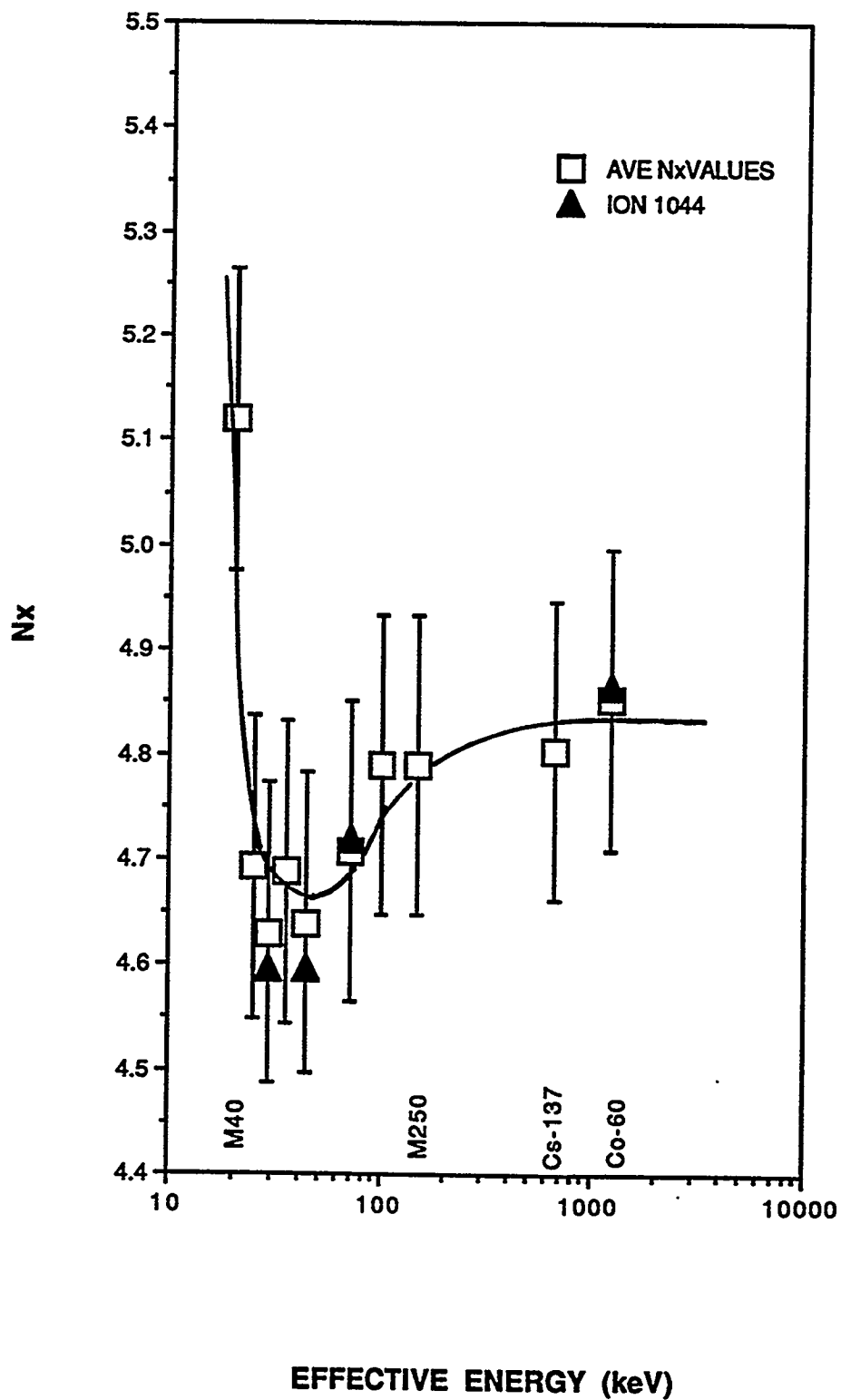


Figure 2 - Energy Plot for a PR-06C Chamber, Showing Average and Two Standard Deviations of all PR-06C Chambers

*Table 1 - Comparison of UW ADCL and NIST Beams*

NIST BEAM QUALITIES			UW ADCL BEAM QUALITIES		
BEAM CODE	HVL (mm Al)	HC	BEAM CODE	HVL (mm Al)	HC
L40	0.49	57	UW40-L	0.49	60
L50	0.75	58	UW50-L	0.75	61
L80	1.83	58	UW80-L	1.83	58
L100 <sup>1</sup>	2.8	59	UW100-L	2.81	59
M20	0.152	79	UW20-M	0.155	81
M30	0.36	64	UW20-M	0.36	68
M40	0.73	66	UW40-M	0.73	69
M50	1.02	66	UW50-M	1.03	66
M60	1.68	68	UW60-M	1.69	67
			UW80-M <sup>2</sup>	2.89	66
M100	5.0	72	UW100-M	4.99	71
			UW120-M <sup>2</sup>	7.00	77
M150	10.2	87	UW150-M	10.3	86
M200	14.9	95	UW200-M	15.0	93
M250	18.5	98	UW250-M	18.6	95
S75	1.86	63	UW75-S	1.86	62
S60	2.8	75	UW60-S	2.79	77

*All beams are matched as closely as possible to available NIST beam qualities.*

<sup>1</sup> A UW100-L comparable beam quality is currently unavailable from NIST.

<sup>2</sup> UW80-M and UW120-M beams are not offered by NIST and are interpolated from existing NIST M series beams.

Table 2 - UW ADCL Standard Chamber Calibration History.

Keithley Model 96035, Serial No. 18691						
Purchased 1984						
Date	Beam	Loc.	Cal. Fact. (R/C)	Comments	Compared to:	Δ%
10/84	L100	NIST	2.474 E 8	(Corrected for 1986 change in definition of R)		
10/84	L50	NIST	2.479			
10/84	M30	NIST	2.455			
10/84	L30	NIST	2.501			
1/85	M100	CDR H	2.454			
1/85	L100	CDR H	2.475		2.474	+0.04
1/85	L80	CDR H	2.505			
1/85	M50	CDR H	2.484			
1/85	M30	CDR H	2.412		2.455	-1.75
12/91	M50	UW	2.488	CDRH:	2.484	+0.16
12/91	M40	UW	2.472	UW-Interpolation:	2.468	+0.16
12/91	M30	UW	2.461	NIST:	2.455	+0.24
12/91	M20	UW	2.536			
12/91	L80	UW	2.503	CDRH:	2.505	-0.08
12/91	L50	UW	2.460	NIST:	2.479	-0.77
12/91	L40	UW	2.475	UW- Interpolation:	2.490	-0.60

\* Note: Chamber was replaced in 1991 by PRM LE 0.8 (s/n 8835) which is the new soft x-ray standard chamber. The 96035 chamber is now used as a backup and for internal quality control.



# SERVICES OF THE CDRH X-RAY CALIBRATION LABORATORY AND THEIR TRACEABILITY TO NATIONAL STANDARDS

F. Cerra<sup>(1)</sup>  
H. T. Heaton<sup>(1)</sup>

## POSTER SUMMARY

The X-ray Calibration Laboratory (XCL) of the Center for Devices and Radiological Health (CDRH) provides calibration services for the Food and Drug Administration (FDA). The instruments calibrated are used by FDA and contract state inspectors to verify compliance with federal x-ray performance standards and for national surveys of x-ray trends (Table 1). In order to provide traceability of measurements, the CDRH XCL is accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) for reference, diagnostic, and x-ray survey instrument calibrations (Table 2). In addition to these accredited services, the CDRH XCL also calibrates non-invasive kVp meters in single- and three-phase x-ray beams, and thermoluminescent dosimeter (TLD) chips used to measure CT beam profiles (Table 3). The poster illustrates these services (Figures 2,3,4,7,8,9,10) and shows the traceability links back to the National Standards (Table 4, Figures 1,5,6).

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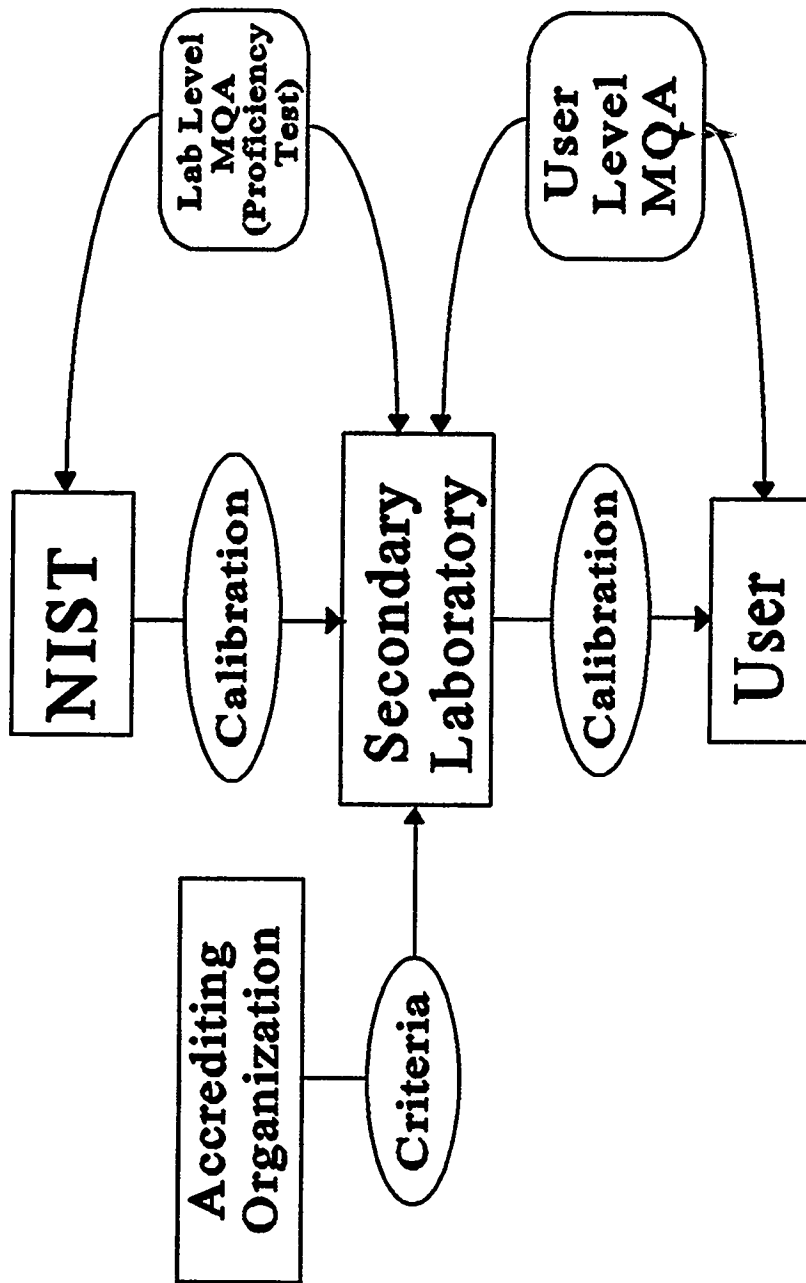
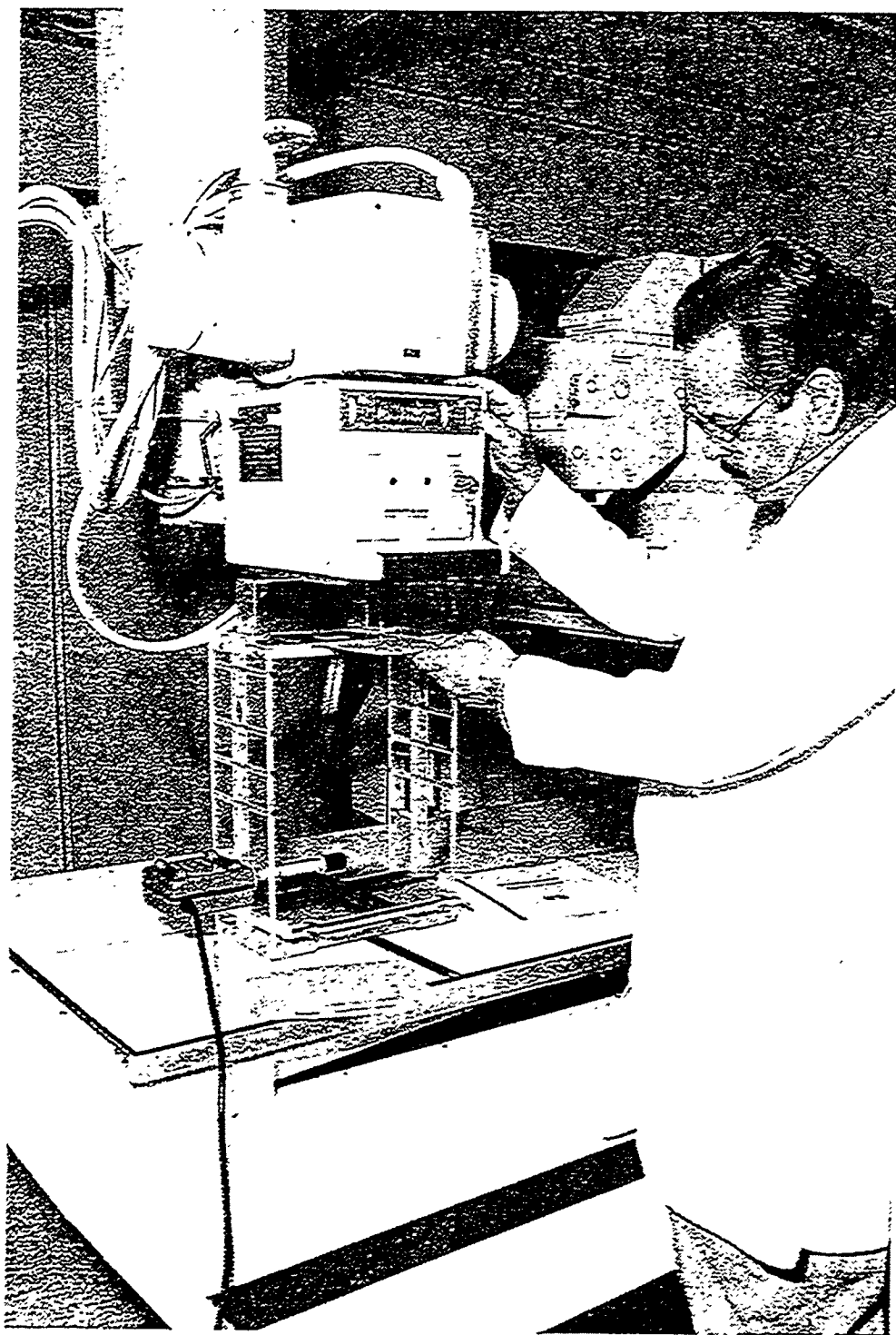
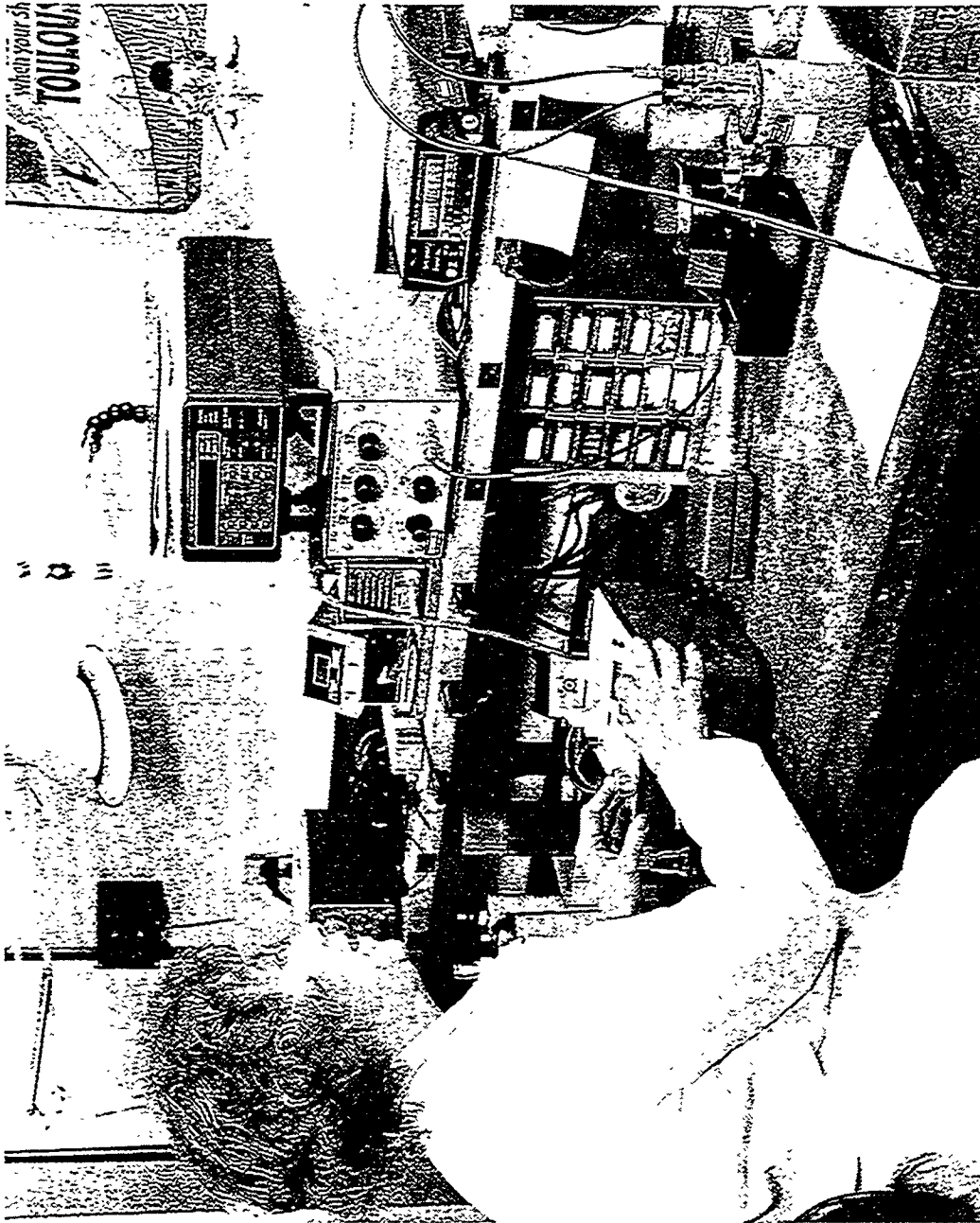


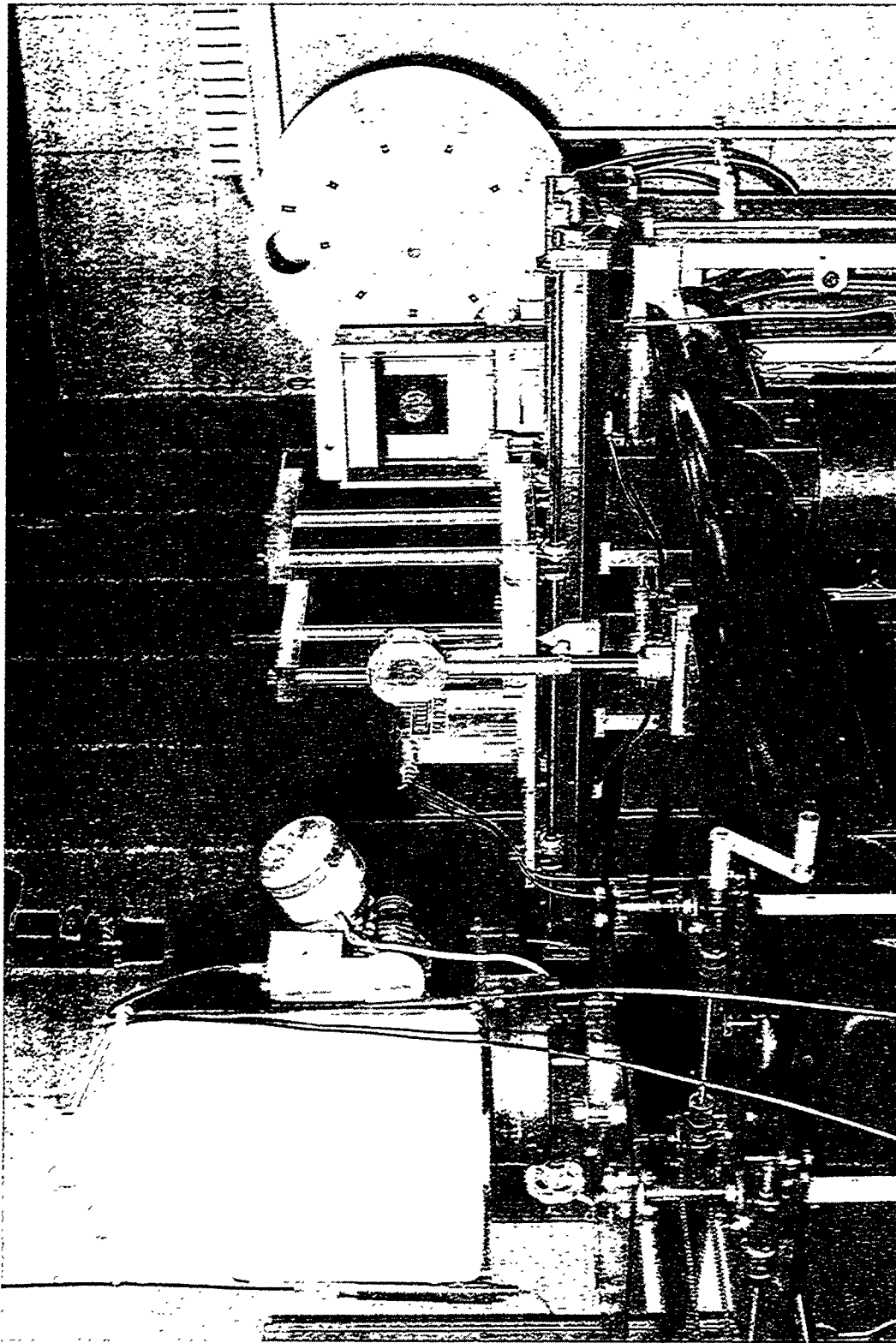
Figure 1 - Traceability of Accredited Services



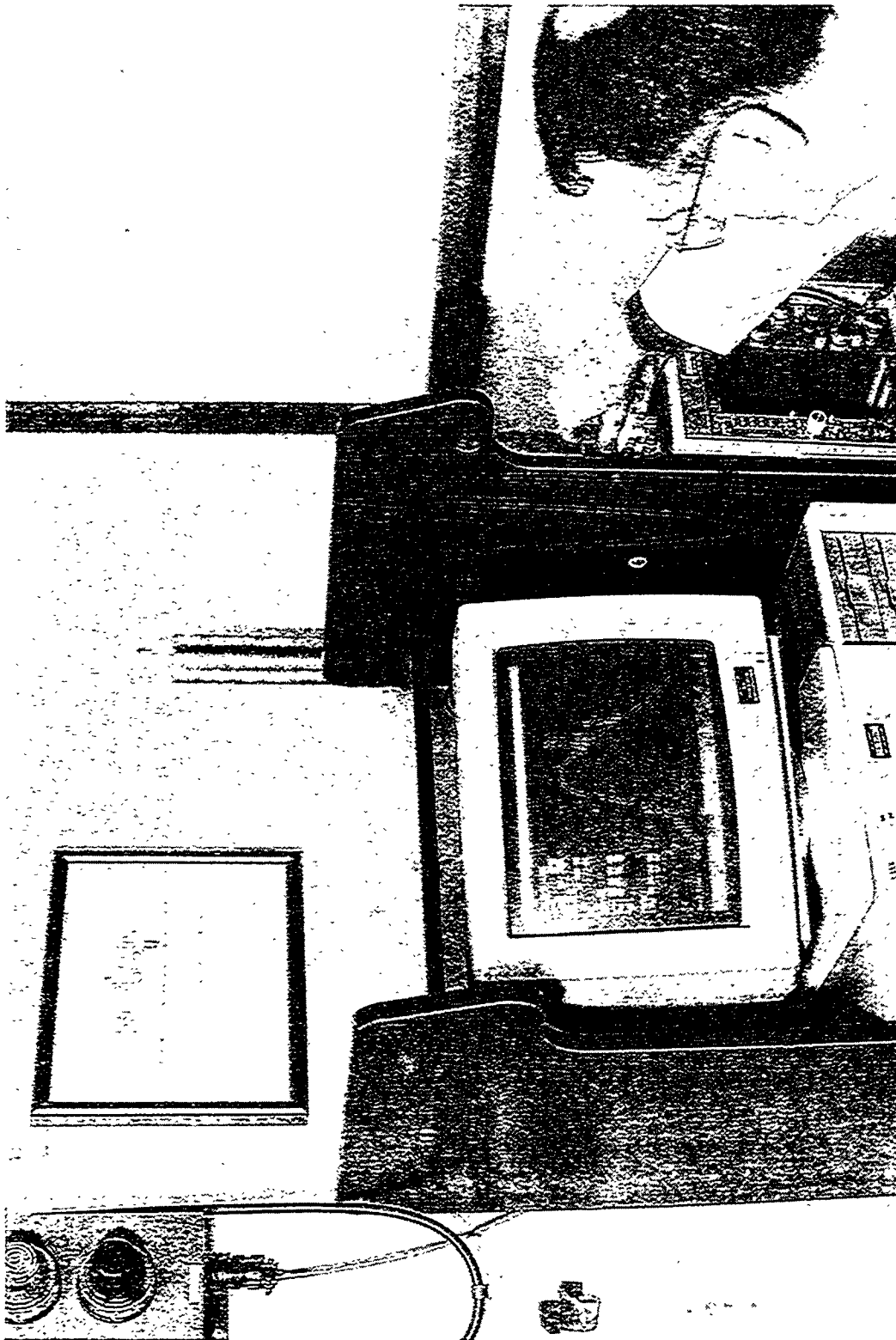
*Figure 2 - Setup for routine compliance testing of diagnostic x-ray systems. The compliance test stand ensures a consistent geometry for measurements. FDA compliance measurements must be made with instruments calibrated at the CDRH X-ray Calibration Laboratory using existing accredited procedures.*



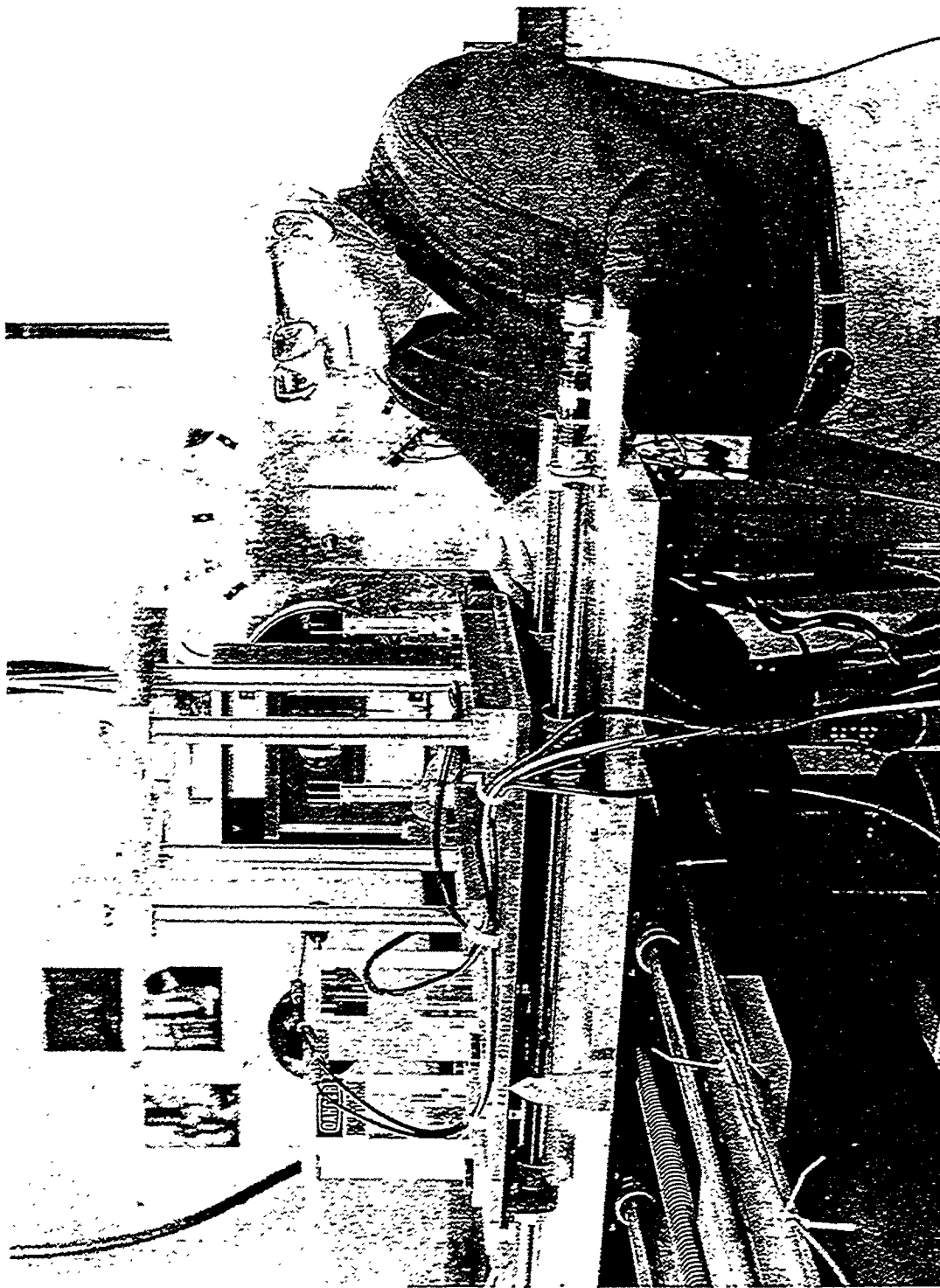
**Figure 3 - Pre-irradiation testing of diagnostic level x-ray meters. This test is used to evaluate the instrument's electronics prior to calibration in an x-ray field. The test is particularly important because it demonstrates the instrument's response linearity as a function of rate (the probes, on the other hand, are type-tested for ion recombination characteristics).**



*Figure 4 - A high-purity germanium detector is positioned for spectral verification of kilovoltage in one of the x-ray calibration rooms. Corrections are made for detector efficiency and k-escape in the Ge crystal. Usable count rates are achieved by pinhole collimation of the beams.*



*Figure 5 - Spectra of the reference x-ray beams are being accumulated for analysis. A high purity germanium spectrometer is used for this purpose. The spectrometer is also used for calibration of the kilovoltage applied to the x-ray tube. The spectrometer is calibrated using gamma rays of known energies, and verified by the fluorescent x-rays from the target material.*

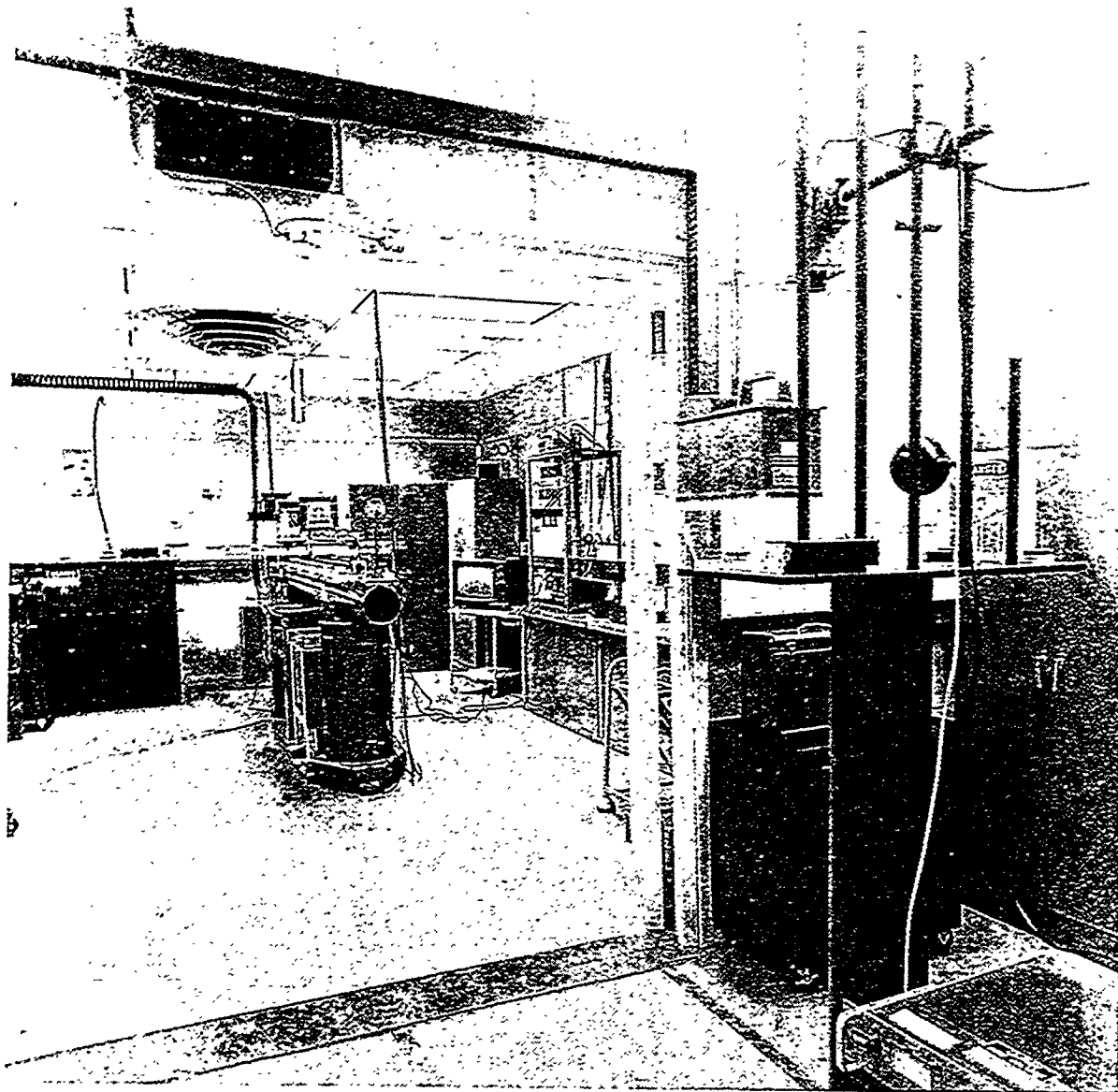


*Figure 6 - Diagnostic probes are being mounted on an automatic positioning system for calibration. This system alternately positions the reference instrument and test instrument to the same spot in the reference field. As the field from the constant-potential unit is very stable, two probes are typically calibrated for each measurement of the reference field.*

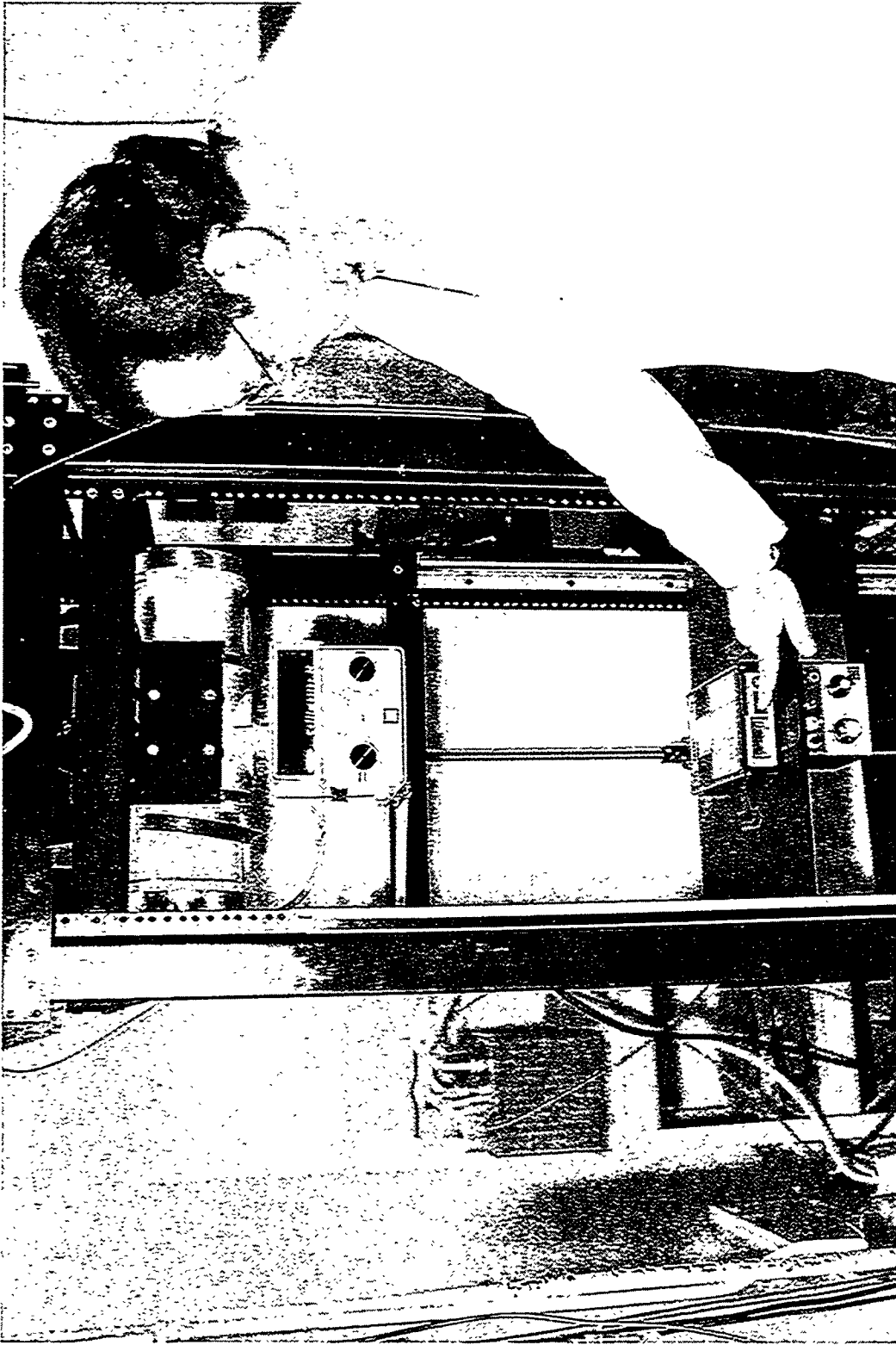


*Figure 7 - The x-ray calibration console for NVLAP-accredited calibrations. The generator controls are on the left side; readouts of the diagnostic instruments can be seen on the TV monitors; readouts of environmental monitors are on the near right; interlock indicators are on the far right. Ion chambers are usually calibrated for five beam qualities at a nominal 20 mR/s (0.18 mGy/s).*

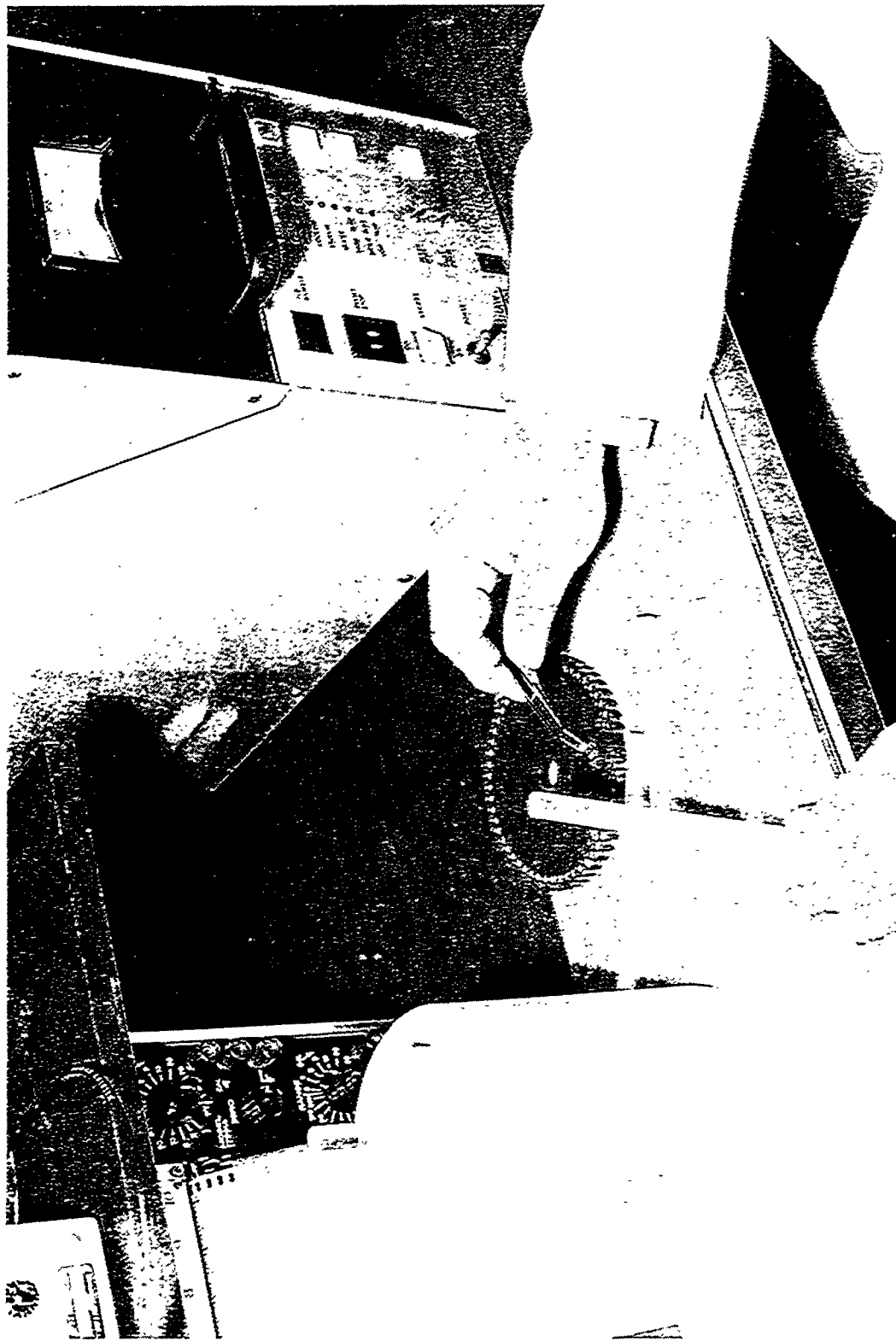




*Figure 8 - Survey meters are calibrated to low intensity fields at a nominal distance of 7.6 m from the x-ray source. The outputs of reference ion chambers at 1 and 7.6 meters are compared at high exposure rates. When the rate is lowered to protection levels, the chamber at 1 m is used to determine the reference field at 7.6 m. This provides a strong reference signal for rates as low as 0.5 mR/hr (4.4  $\mu$ Gy/hr).*



*Figure 9 - Single phase setup for non-invasive kVp meter calibrations. Calibrations are performed at a nominal 60 cm SDD and 2.7 mm AL-equivalent filtration. The reference voltage divider banks can be seen on the left side. Traceability is achieved through NBS-measured divider ratios, and endpoints of measured spectra.*



*Figure 10 - Thermoluminescent dosimeters being loaded into a phantom insert for analyzing beam profiles in Computed Tomography. A CDRH "head" phantom is shown on the left. The TLD lab utilizes a Harshaw Atlas reader (shown on the right).*

**Table 1 - FDA's X-ray Measurement Requirements for Which Instrument Traceability is Provided by the CDRH X-ray Calibration Laboratory**

<p><b>Testing for compliance with mandatory performance standards (21 CFR 1020)</b></p> <p>(1) television receivers          (2) cold cathode discharge tubes          (3) diagnostic x-ray systems              - radiography              - fluoroscopy              - computed tomography          (4) cabinet x-ray systems</p>
<p><b>Nationwide Evaluation of X-ray Trends Program (NEXT)</b></p>

**Table 2 - CDRH's NVLAP-Accredited Services**

<p><b>(1) Calibrations of instruments for diagnostic levels</b></p> <ul style="list-style-type: none"> <li>• beam codes: M20, M30, M50, M100, L80, L100</li> <li>• exposure rate: 2 to 100 mR/s (18 to 880 <math>\mu</math>Gy/s)</li> <li>• uncertainty in reference field: <math>\pm 3\%</math></li> </ul>
<p><b>(2) Calibrations of survey meters</b></p> <ul style="list-style-type: none"> <li>• beam code: H50</li> <li>• exposure rate: 0.5 mR/hr to 14 R/hr                                (4.4 <math>\mu</math>Gy/hr to 123 mGy/hr)</li> <li>• uncertainty in reference field: <math>\pm 5\%</math></li> </ul>
<p><b>(3) Calibrations of reference-quality instruments</b></p> <ul style="list-style-type: none"> <li>• same parameters as for diagnostic levels</li> </ul>

*Table 3 - Non-Accredited Services*

<p><b>(1) Calibrations of non-invasive kVp meters</b></p> <ul style="list-style-type: none"><li>• single-phase generator: 50 to 150 kVp</li><li>• 3-phase, 12-pulse gen.: 50 to 150 kVp</li></ul>
<p><b>(2) TLD irradiations in x-ray reference fields</b></p>

*Table 4 - Traceability Mechanisms*

<p><b>Traceability of accredited services</b></p> <ol style="list-style-type: none"><li>(1) primary calibration of reference instruments</li><li>(2) accreditation criteria</li><li>(3) MQA proficiency testing</li></ol>
<p><b>Traceability of kVp meter calibrations</b></p> <ol style="list-style-type: none"><li>(1) comparison to calibrated, invasive voltage divider</li><li>(2) monitoring of divider accuracy by spectrometric verification of cutoff energy</li></ol>
<p><b>Traceability of TLD irradiations</b></p> <p>TLD's irradiated in same reference fields as accredited services with various types of backscatter conditions or "free-in-air," depending on application</p>

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# U.S. ARMY PRIMARY RADIATION STANDARDS COMPLEX

Steven C. Rogers<sup>(1)</sup>

*Abstract* - This paper describes the U.S. Army Primary Radiation Standards Complex (PRSC) to be constructed at Redstone Arsenal, Alabama. The missions of the organizations to be located in the PRSC are described. The health physics review of the facility design is discussed. The radiation sources to be available in the PRSC and the resulting measurement capabilities of the Army Primary Standards Laboratory Nucleonics section are specified. Influence of the National Voluntary Laboratory Accreditation Program (NVLAP) accreditation criteria on facility design and source selection is illustrated.

## INTRODUCTION

As a result of the Base Realignment and Closure Report of the Defense Secretary's Commission, the U.S. Army Test, Measurement, and Diagnostic Equipment Activity (USATA) decided in 1989 to relocate the U.S. Army Ionizing Radiation Dosimetry Center (AIRDC), currently located at Lexington-Blue Grass Army Depot, Lexington, Kentucky, to USATA Headquarters at Redstone Arsenal, Alabama. The AIRDC would at that point be collocated with the U.S. Army Primary Standards Laboratory Directorate (USAPSLD) Radiation Standards and Dosimetry Laboratory (RSDL). Since existing facilities at USATA Headquarters were incapable of accommodating both organizations, the decision was made to construct a new facility, the Primary Radiation Standards Complex (PRSC), now scheduled for completion in the 1st quarter of fiscal year 1995.

## DESCRIPTION OF THE PRSC

The PRSC is designed to accommodate the RSDL's three sections, Nucleonics, Photonics, and Radiation Safety; the AIRDC and its components, the Low-Level Radioactive Material Counting Laboratory and the Dosimetry Record Repository; and a data repository computer system to support organizational missions. The PRSC is a two-story structure of approximately 32,000 square feet. It will contain work areas and office space for the accommodated organizations. The lower story is

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composed of two wings: one will house the RSDL Nucleonics section and the other, the AIRDC. The upper story is located directly above the AIRDC wing and will house the RSDL Photonics section as well as the mainframe computer system. Radiation Safety section offices will be located in the AIRDC wing.

## **ORGANIZATION MISSIONS**

The RSDL Nucleonics and Photonics sections are the Army's primary level calibration laboratories, secondary only to the National Institute of Standards and Technology (NIST). The Nucleonics section is responsible for the NIST traceability for the Army RADIAC (Radioactivity Detection, Identification, and Computation) calibration program. The Nucleonics section also performs special calibrations of Army calibration sources and survey instrumentation. Similarly, the Photonics section is responsible for providing NIST traceability in the fields of lasers, fiber optics, radiometrics, and photometrics. The Radiation Safety section is responsible for oversight of the USATA radiation safety program, including review of standard operating procedures, implementation of new regulations, approval of users of radiation sources, and conduct of training. The AIRDC mission is threefold: first and foremost, to provide radiation dosimetry to all Army personnel who are occupationally exposed to ionizing radiation; to generate and maintain a repository of the worldwide automated dosimetry program (Dosimetry Record Repository); and to provide a radioactive source leak test analysis service (Low-Level Radioactive Material Counting Laboratory).

## **HEALTH PHYSICS REVIEW OF FACILITY DESIGN**

The Nucleonics section wing is composed of calibration ranges which will house (individually) high-activity cesium-137 ( $^{137}\text{Cs}$ ) sources, low-activity  $^{137}\text{Cs}$  and cobalt-60 ( $^{60}\text{Co}$ ) sources, and a high-energy, x-ray generator; alpha, beta, and low-energy x-ray calibration chambers; a preparation/repair area; and radioactive material and waste storage areas. The entire wing is considered a radiation control area. When a package containing a radioactive source arrives, the package is inspected for damage, surveyed, wipe tested, and processed in, then secured in the radioactive material storage area until required repair or calibration is performed. Each calibration range and chamber, as well as the preparation/repair area, will be equipped with cameras and monitor systems which will give the technician and health physics personnel the means of monitoring the range/chamber/area at any time. The sources to be placed in the calibration ranges will be equipped with photoelectric and door interlock systems for safety enhancement—they will cause the sources to return to the shielded position if the range door is opened during operation.

The walls of the calibration ranges will be composed of reinforced concrete. The wall between each range and its associated control room (located in front of the range, where remote control of the automated calibrator is effected) will be 8-inches thick and includes a leaded glass window to enable the range to be monitored. The rear wall of each range, which is the wall toward which the primary radiation beam is directed, will be 3-feet thick. The side walls separating the high-energy x-ray range from adjoining calibration chambers and the low-activity gamma range will be 2-feet thick. The wall between the low-activity gamma range and the high-activity  $^{137}\text{Cs}$  range will be 2 1/2-feet thick, and the remaining side wall between the high-activity  $^{137}\text{Cs}$  and the exterior will be 3-feet thick. For the sources projected to be installed in the ranges, these thicknesses are sufficient to limit exposure rates to the control room and "crosstalk" radiation between ranges to insignificant amounts. Maximum exposure rates beyond the rear walls and the high-activity  $^{137}\text{Cs}$  side wall are expected to be less than



1.5 mR/h for x-ray and 0.5 mR/h for  $^{137}\text{Cs}$ . Skyshine is not expected to be a factor in the facility because of the 18-inch thickness of the concrete roof.

The Low-Level Radioactive Material Counting Laboratory, located in the AIRDC wing, will generate radioactive waste either as solid radioactive laboratory waste or liquid scintillation vials as a result of its mission. The solid waste will be collected and stored in the radioactive waste storage area until disposal occurs. The vials will be crushed and consolidated in waste containers, and the liquid collected and solidified. This waste will be similarly stored until disposal.

The counting laboratory will be under negative pressure to ensure that potential airborne contamination will not be released into other work areas. The laboratory will be vented through the roof. A fume hood will be installed to store low-level liquid and gaseous radioactive materials and to assist in removing airborne contamination. An underground liquid radioactive waste holding tank will be adjacent to the outside wall of the laboratory. It will be double-walled stainless steel, with a monitoring system utilizing a Geiger-Mueller (GM) tube between the double walls to evaluate the exposure rate of the liquid. A fluid level indicator will alarm if there is an overflow. The contents of the tank will be drained into barrels for solidification, storage, and eventual disposal. The monitoring system readout will be located in the counting laboratory. Also, all counting room sinks will be equipped with diverter valves between the sinks and the tank.

The AIRDC itself will not generate radioactive waste. A thermoluminescent dosimeter (TLD) irradiator, used for determination of relative element sensitivity (badge calibration), will be installed in the AIRDC wing. Exposure levels at the surface of the irradiator are less than 2 mR/h. As a precaution, a detector and monitoring system will be located nearby.

The Radiation Safety office will contain a consolidated monitoring station, which will include a digital exposure rate readout bank which will connect the office with detectors mounted in each area of the facility. The office will also have the capability of monitoring each of the cameras mounted in the calibration ranges and chambers and the preparation/repair area.

## **RADIATION SOURCES AND MEASUREMENT CAPABILITIES**

The calibration ranges and chambers in the Nucleonics wing will contain sources which are expected to greatly increase the laboratory's measurement capabilities. The high-activity  $^{137}\text{Cs}$  will contain an automated dual calibrator producing a directional radiation beam and containing sources with activities of 3000 curies and 200 curies. This calibrator will be used for calibration of instrumentation designed for high-exposure rates and special calibrations of instrumentation used in classified projects. The low-activity gamma chamber will contain a similar automated calibrator, this one with four sources: 10 curie, 2 curie, and 10 millicurie  $^{137}\text{Cs}$  and 5 curie  $^{60}\text{Co}$ . This calibrator will be used to support instrumentation used for day-to-day Health and Safety, as well as by the AIRDC for TLD evaluation and TLD reader calibration. The high-energy x-ray range will contain a fully automated, constant potential 320 kilovolt (kV) x-ray system, to be used to support instrumentation used primarily by medical units, hospitals, etc.; and by the AIRDC for TLD evaluation. The low-energy x-ray calibration chamber will house a 50-kV x-ray machine to be used primarily for support of medical instrumentation. The alpha calibration chamber will contain calibration equipment for large area and small area alpha sources (plutonium-238, plutonium-239, americium-241) in turn used to calibrate a new generation of Army survey instruments, as well as specialized instrumentation used to monitor spills and contamination. The beta calibration chamber will house beta irradiators (strontium-

yttrium-90, promethium-147, thallium-204) to be used to irradiate TLDs for the AIRDC and to calibrate beta sensing instrumentation. Also available will be several small alpha, beta, and gamma sources used as standards to calibrate medical instrumentation which senses isotopes other than those previously mentioned. Resulting measurement capabilities of the Nucleonics section will be greatly enhanced through the use of these sources and systems, in terms of both range and accuracy. Projected measurement capabilities are listed in Table 1.

Current gamma and x-ray detector measurement capabilities are severely limited due to the lack of activity range in currently available sources and space limitations in the present Nucleonics facility. Projected accuracy figures in all areas are substantially better than those currently quoted and reflect the great improvement in calibration facilities in the PRSC.

## **NVLAP INFLUENCE ON FACILITY DESIGN AND SOURCE SELECTION**

The NVLAP is one of the main driving forces behind the design of the calibration facilities in the PRSC and in the selection of calibration sources to be used in these facilities. The AIRDC is already accredited under the NVLAP for Personnel Radiation Dosimetry, as mandated by the U.S. Nuclear Regulatory Commission. The Nucleonics section is not currently accredited under the new NVLAP for Secondary Calibration Laboratories for Ionizing Radiation due to the inadequacy of the present facility and available sources. However, with NVLAP accreditation criteria providing a basis for PRSC facility design and source selection, the potential for NVLAP accreditation of the Nucleonics section is significantly increased, should the Army decide to pursue accreditation voluntarily or if accreditation for such laboratories becomes mandatory.

The primary NVLAP guideline/requirement taken into account in PRSC facility design comes from the NVLAP Program Handbook for Secondary Calibration Laboratories for Ionizing Radiation (NIST, December 1990): "A laboratory must have adequate facilities .... This includes adequate space, proper shielding of areas from unwanted radiation, environmental controls, adequate measurement equipment and radiation sources, adequate safety systems ...." Each of the calibration ranges is 60-foot long by 15.5-foot wide and each of the calibration chambers is approximately 14 feet by 14 feet, with a sizeable preparation/repair area available. The shielding and radiation safety issues have been addressed previously. The environmental specifications for the PRSC will meet or exceed the guidelines and requirements of the Criteria for the Operation of Federally-Owned Secondary Calibration Laboratories (Ionizing Radiation) (October 1990). PRSC services (appropriate electrical power, adequate grounding, and appropriate compressed air sources) are provided in accordance with the Criteria.

Section 4 of the Criteria specifies that "the radiation room (or rooms) shall be of sufficient size and design that room-scattered radiation ... does not introduce an error inconsistent with overall accuracy goals." Each range is designed such that the floor is flat for the first 15 feet, has a 5° slope for the next 38 feet, then is flat again for the final 7 feet. This design has the effect of reducing floor scatter of the radiation beam. The effect of side and rear wall scatter in each range can be calculated, if necessary, as suggested by the Criteria. Selection of measurement equipment, especially radiation sources, is based on Criteria recommendations and requirements. The sources in the high-activity <sup>137</sup>Cs and low-activity gamma ranges will exceed the Criteria requirements for exposure rate range, shielding, beam collimation, source exposure, and exposure control. The Criteria requirement for a proper instrument/ionization chamber support and positioning system will be satisfied. The selected source and the source-instrument distance alone determine exposure rate, eliminating the need for

source attenuation and therefore, the Criteria requirement for determination of effect of the attenuator(s) on energy spectrum. The 320 kV x-ray system meets or exceeds Criteria requirements for voltage and current range, voltage ripple, beam collimation, and exposure control. Filters required for 11 different NIST beam qualities are on hand. The requirements for determination of the effect of room-scattered radiation and radiation quality will be met or exceeded. The beta irradiator to be located in the beta calibration chamber will contain Criteria-required radionuclides, as well as requirements for beam production and beam size. The large area alpha sources will meet or exceed Criteria requirements for isotope; source size, construction, and thickness; emission rate; and uniformity. Required source and detector support and positioning systems for several different detectors will be available. Two independent emission rate measurement systems will be on hand, each having the capability of measuring emission rate to within  $\pm 10\%$  with NIST traceability. The selected sources will be more than adequate for compliance with Criteria requirements for calibration of survey instruments and personnel dosimeter irradiation.

## CONCLUSION

The PRSC will greatly enhance the capabilities of the RSDL Nucleonics section, the Low Level Counting Laboratory, and the AIRDC. The improved facilities, and in the case of Nucleonics, improved radiation sources, will substantially enhance the quality of services offered by the three organizations. These refinements, as well as other state-of-the-art equipment and computers to be located in the PRSC will enable the organizations to maintain high standards for Army calibration, leak testing, and dosimetry well into the future.

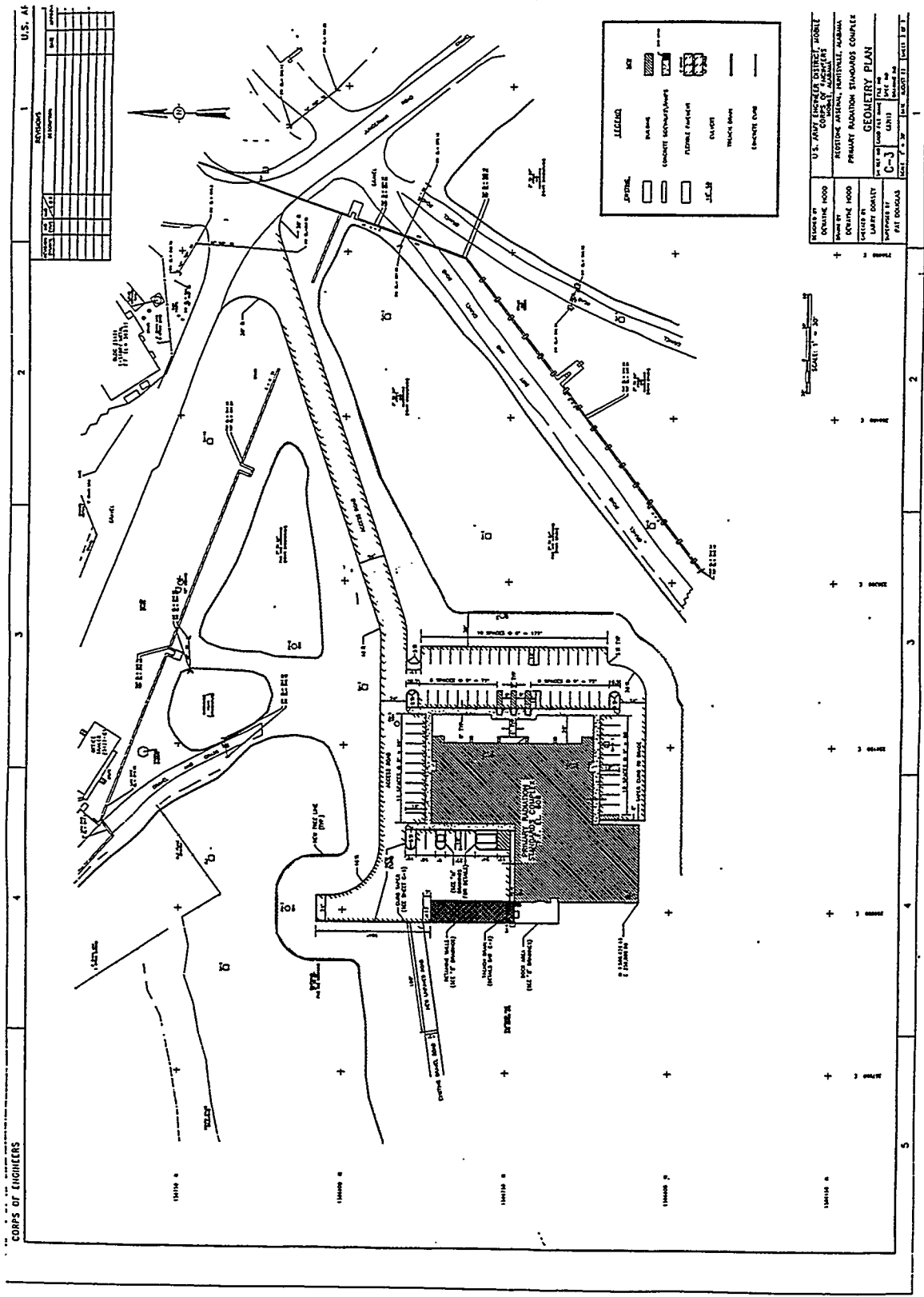


Figure 1 - Geometry Plan







*Table 1 - Projected Nucleonics Measurement Capabilities in the PRSC*

Parameter	Projected Range	Projected Accuracy
Alpha Sources (small area) ( <sup>239</sup> Pu, <sup>241</sup> Am)	0 - 10 <sup>7</sup> CMP (3 x 10 <sup>5</sup> Bq)	±2.5%
Alpha Sources (large area) ( <sup>238</sup> Pu, <sup>239</sup> Pu)	0 - 10 <sup>7</sup> CPM (3 x 10 <sup>5</sup> Bq)	±5.0%
Beta Sources	to 50 millicuries	±5.0%
Gamma Sources	0.05 mR/h - 06 R/h	±2.0%
X-ray Sources	0.05 mR/h - 106 R/h	±2.0%
Gamma Detectors	0.05 mR/h - 25,000 R/h	±5.0%
X-ray Detectors	0.1 mR/h - 250 R/h	±5.0%
Alpha Detectors	0 - 10 <sup>7</sup> CPM (3 x 10 <sup>5</sup> Bq)	±5.0%



# **TEST AND EVALUATION CAPABILITIES AT NAVELEXCEN CHARLESTON**

T. W. Stalvey<sup>(1)</sup>  
G. B. Anderson<sup>(1)</sup>  
T. L. Hinson<sup>(1)</sup>

## **WHO WE ARE**

The Environmental Systems and Instrumentation Engineering Department is located within the Special Programs Directorate of the Naval Electronic Systems Engineering Center (NAVELEXCEN Charleston). This Center is an echelon 4 Command under the Naval Command Control and Ocean Surveillance Center, San Diego (NCCOSC). NCCOSC is an echelon 3 Command under the Space and Warfare Systems Command (SPAWAR) which is located in Washington, D.C.

## **MISSION OF RADIAC PROGRAM**

Radiation Detection, Indication and Computation (RADIAC) equipment life-cycle management for the entire Navy falls under the auspices of the Naval Sea Systems Command (SEA 04R). The RADIAC Program provides centralized management for the execution of research, development, test, evaluation, maintenance, procurement, allowance, and equipment support for all Navy RADIAC instrumentation and assigned special monitoring equipments.

## **PURPOSE OF RADIAC EQUIPMENT**

RADIAC equipment is used throughout the Navy to support various functions associated with radioactivity, potential contamination, and personnel exposure to sources of ionizing radiation. Common sources in today's Navy include nuclear reactors, nuclear weapons, industrial radiography, and nuclear medicine. Types of radiation includes gamma, x-ray, alpha, and beta.

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<sup>(1)</sup> Naval Electronic Systems Engineering Center, Charleston, South Carolina 29418

## **CUSTOMERS**

In the broadest sense, organizations involved in the RADIAC Program include all elements of the Navy's operating forces and shore establishment. However, our primary customers within the Navy, Marine Corps, and Coast Guard include:

- 1) Nuclear Propulsion Program
- 2) Nuclear Weapons Program
- 3) Industrial Radiography Program
- 4) Medical Radiography Program
- 5) Disaster Preparedness.

## **CENTER OF EXCELLENCE**

As the assigned Center of Excellence for RADIAC equipment, NAVELEXCEN Charleston is tasked by Naval Sea Systems Command to perform the following functional responsibilities related to the RADIAC Program:

- 1) Acquisition
- 2) Test & Evaluation
- 3) Standardization
- 4) Calibration & Repair
- 5) Field Support Management
- 6) In-Service Engineering Agent.

## **TEST & EVALUATION (T&E) FUNCTION**

Provide facilities, equipment and personnel to perform tests and evaluations necessary to ensure acquisition and delivery of accurate and reliable radiation measuring equipment to the fleet. Specific testing includes:

- 1) Advanced development model testing
- 2) First article testing
- 3) Acceptance testing
- 4) Product verification.

## **MULTI-PURPOSE FACILITY**

NAVELEXCEN Charleston's T&E Facility is a uniquely constructed 4000 square foot building with 30-inch concrete walls to shield the various radioactive sources. It is equipped to apply mechanical shock tests, vibration tests, temperature, humidity and altitude cycling, salt spray and fog tests, and irradiation by cobalt 60, cesium 137, and x-ray radiation sources.

## **TEST CAPABILITIES**

The various chambers, machines, ionizing radiation sources, and electronic test equipment, which are operated by highly trained and experienced personnel, are used to perform all necessary testing to

comply with both military and commercial specifications. Extensive use is made of time-lapse, split-screen video recording techniques to provide a visual, sequential record of the tests performed.

*Environmental Chambers*

Type	Size (Cu. ft.)	Temperature °C	Humidity %	Altitude (Ft.)
Tenny Model 9990	384	-57 to +93	20 to 95	--
Tenny Model 8STR	8	-73 to +93	20 to 95	0 to 80,000
Thermotron Model SM-8C	8	-68 to +177	20 to 98	--
Envirotronics Model EH96-2-15	96	-73 to +177	20 to 95	--

*Vibration Machines*

Type	Table Size (ft.)	Max. Test Load (Lbs)	Freq. Range (HZ)
All American Tool & Mfr. Model 100HA	2 X 2	100	8 to 50
All American Tool & Mfr. Model 10VA	2 X 2	100	8 to 50

*Radiation Sources*

MFR	Type	Material	Amount	Remarks
AN/UDM-1B	Gamma	Cesium-137	122 Curies	Computer Controlled
J.L. Shepherd Model 81-22A	Gamma	Cobalt-60	300 Curies	Used for energy dependence tests
Ridge Instruments Model OCX-300	X-ray	--	300 KEV	Low energy response tests
MX-9335	Neutron	PuBe	5 Curies	Fast neutron range
AN/UDM-7B	Alpha	Pu-239	51 Curies	--

*Shock Machine & Salt Fog Chamber*

Type	Size (ft.)	Max. Load	Salt %	Mil Spec
Harshaw Model 23	4 X 4 X 6	--	5 to 20	Salt Fog
Cook Electric, light weight, high impact	1.25 X 2 ft. table	200 Lbs.	--	MIL-S-901D

**LOCATION**

The T&E Facility is located at the Naval Weapons Station, South Annex in North Charleston, South Carolina. It is approximately five miles from NAVELEXCEN Charleston's main offices at Marriott Drive and Mall Dive.

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## IMMEDIATE NEEDS FOR MQA TESTING AT STATE SECONDARY CALIBRATION LABORATORIES

Ray Cline<sup>(1)</sup>

*Abstract* - The Calibration Laboratory attempts to provide services that satisfy the needs and requests for a variety of customers. New needs and requests have resulted in calibration of instrumentation outside the original laboratory designs. These tasks require several changes at the laboratory and a need for new support services, especially measurement quality assurance (MQA). The MQA tests are gamma (Cs-137) below 0.5 mrem ( $5\mu\text{Sv}$ ) per hour and x-ray kVp. Modification to the current gamma (Cs-137) MQA test is recommended because lower intensity fields are commonly measured.

### INTRODUCTION

The Illinois Radiation Instrument Calibration Laboratory operates a State Secondary Calibration Facility, accredited by the Conference of Radiation Control Program Directors, Inc., (CRCPD). The CRCPD requires the laboratory be evaluated against prescribed laboratory operating criteria and successfully participate in periodic (MQA) testing provided by the National Institute of Standards and Technology (NIST). Laboratory calibration services are available for instruments used by state or local radiation monitoring programs. Calibrations are offered for x-ray monitors in the medical diagnostic energy range and portable radiation survey equipment.

The Laboratory has routinely participated in MQA testing since 1984. The testing is used to verify accuracy in producing and measuring, radiation reference fields using Cs-137 and various x-ray techniques. Test results have confirmed traceability to national standards and claimed accuracies for instrument calibrations. Until recently, MQA testing has satisfied the needs of laboratory credibility concerning the types of calibration services offered.

Demands on the laboratory for instrument calibrations have increased in number, variety, and accuracy in the past few years. These demands result from evolving regulations which expand the scope and detail of radiological surveillance, inspection, and remediation. These regulations require

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<sup>(1)</sup> Illinois Department of Nuclear Safety, Radiation Instrument Calibration Laboratory, Springfield, Illinois 62703.

determination of radiation exposures well below 0.5 mrem ( $5\mu\text{Sv}$ ) per hour; hence, they dictate the use of micro "R"-type survey meter and/or thermoluminescent dosimeters (TLDs). Of the laboratory instrument workload, 13% is micro "R" meters. About 2,000 environmental TLD measurements are made by the laboratory each year.

In general, the survey work performed with the remaining survey instruments involves detection and measurement of low-level radiation. Hundreds of survey meters are calibrated by the laboratory annually. Most ranges on these instruments are less than 500 mrem ( $5\text{mSv}$ ) per hour. To date, the laboratory has not been tested below approximately 400 mrem ( $4\text{mSv}$ ) per hour on gamma calibrations. This dose rate is greater than that in which most calibration work is performed and that encountered in the majority of surveys performed by the Department. Because of these factors, it seems reasonable that gamma radiation MQA testing be designed to evaluate laboratory calibration abilities at lower intensities.

State regulations concerning mammography equipment present another need for MQA testing beyond what is currently provided for x-ray calibration. In addition to testing laboratory accuracy of x-ray exposure measurements, it is now important to determine kVp in the energy range appropriate for mammography. MQA testing for x-ray kVp in the mammography energy range would provide the laboratory with a basis to assess estimated kVp uncertainties. This might also allow the laboratory to develop methods for testing non-invasive kVp meters currently used in x-ray inspection programs.

However, prior to implementing testing of this nature and in order to provide a basis for kVp regulatory measurement, it seems appropriate that a national standard for x-ray kVp be established.

Following are some of the regulatory changes affecting the Illinois Laboratory's workload:

The new 10 CFR Part 20 specifies a maximum allowable exposure to the public of 100 mrem ( $1\text{mSv}$ ) per year. Many facilities are currently designed to a 500 mrem ( $5\text{mSv}$ ) per year level--500 mrem ( $5\text{mSv}$ ) per year or approximately  $57\ \mu\text{rem}$  ( $0.57\mu\text{Sv}$ ) per hour is easily measured with existing dosimetry and survey meters; 100 mrem ( $1\text{mSv}$ ) per year is not as easy to directly measure. This dose rate is approximately  $10\ \mu\text{rem}$  ( $0.1\mu\text{Sv}$ ) per hour or about twice natural background radiation.

New suggested state regulations concerning Naturally Occurring Radioactive Material (NORM) are dealing with issues such as recycling of scrap metals. Recycling facilities need to make immediate go, no-go decisions as to the disposition of materials received at radiation levels of  $50\ \mu\text{rem}$  ( $0.5\mu\text{Sv}$ ) per hour. Piping from the oil industry and deep water wells contaminated with Ra-226 are a common example of a NORM matter.

A U.S. Nuclear Regulatory Commission (NRC) proposed decontamination and decommissioning standard addresses cleanup or actual removal of contaminated facilities. Several projects of this nature are being addressed in Illinois simultaneously, e.g., removal of mill tailings, decontamination of a steel fabricating facility. Many decisions made during this work are based on surveys of very low dose rates.

FEMA REP-14 presents another area of issues that require calibration work at the laboratory using very low levels of radiation. This work deals with instrumentation calibrated for use in the event of a nuclear power station accident. Personnel contamination screening for large population areas require use of portal monitors set to alarm at 0.1 mrem ( $1\mu\text{Sv}$ ) per hour above background. Surveys



performed with micro "R"-type instruments are used in evaluating re-entry decisions for evacuated areas.

A final issue recently affecting the laboratory workload results from state regulations concerning mammography. Inspections of mammography and other x-ray facilities require accurate determination of kVp, half-value layer, and exposure output regardless of machine target/filter material or power supply type. The interest in mammography has directed the laboratory to investigate an x-ray technique to calibrate equipment used to inspect mammography machines. If adopted, the laboratory's x-ray workload would triple.

## **SUMMARY**

In summary, the calibration laboratory, working within constraints of staffing, funding, and physical capabilities, attempts to provide calibrations according to the needs of its users. This has concentrated the laboratory workload in areas not currently tested. In order to provide verification that the majority of laboratory calibration work is as accurate as claimed, MQA testing is sought to model the actual tasks performed. Specifically, test laboratory abilities calibrating to at least 0.5 mrem ( $5\mu\text{Sv}$ ) per hour and non-invasive testing of x-ray kVp.

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# U.S. DEPARTMENT OF ENERGY LABORATORY ACCREDITATION PROGRAM (DOELAP) FOR PERSONNEL DOSIMETRY SYSTEMS

F. M. Cummings<sup>(1)</sup>  
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R. M. Loesch<sup>(2)</sup>

## INTRODUCTION

Accreditation of personnel dosimetry systems is required for laboratories that conduct personnel dosimetry for the U.S. Department of Energy (DOE). Accreditation is a two-step process which requires the participant to pass a proficiency test and an onsite assessment. The DOE Laboratory Accreditation Program (DOELAP) is a measurement quality assurance program for DOE laboratories. Currently, the DOELAP addresses only dosimetry systems used to assess the whole body dose to personnel. A pilot extremity DOELAP has been completed and routine testing is expected to begin in January 1994. It is expected that participation in the extremity program will be a regulatory requirement by January 1996.

## THE ACCREDITATION PROCESS

The Performance Evaluation (PE) Program Administrator coordinates the accreditation process for personnel dosimetry systems. To obtain accreditation, the DOE contractor first submits an application through the DOE field office to the PE program administrator. The application identifies key personnel in the dosimetry program, identifies the categories in which accreditation is sought, and describes the dosimetry system and the calibration methodology. The performance of the dosimetry system is evaluated by irradiating dosimeters in each category during three rounds of testing conducted over a three- to six-month period and comparing the reported results to delivered dose equivalents. If the performance of the dosimetry system is within the criteria, an on-site assessment is conducted by two DOE/DOE-contractor personnel from other sites. The areas that are scrutinized during the assessment include the quality assurance program, documentation of procedures and

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(1) U.S. Department of Energy, Radiological and Environmental Sciences Laboratory.

(2) U.S. Department of Energy, Office of Health Physics and Industrial Hygiene Programs (EH-411).

practices, personnel training, personnel competency, facilities and equipment, equipment maintenance and calibration, and record keeping. If the contractor uses a commercial processor, the processor facility is assessed as well. Deficiencies noted during the assessment must be addressed in a corrective action plan submitted to the DOE field office. When the contractor has met all the criteria in the standard, the PE program administrator recommends accreditation to the DOELAP Oversight Board for approval. The Oversight Board, consisting of DOE/DOE contractor personnel recommends accreditation to the DOE Headquarters (DOE/HQ) DOELAP administrator or tables the accreditation pending the receipt of further information. The DOELAP administrator will issue a certificate of accreditation to the DOE contractor if the recommendations of the Oversight Board are accepted or rejects accreditation pending the receipt of further information or testing. If accreditation is rejected, an appeal board has been established to allow the contractor to appeal this decision.

## **WHOLE BODY DOSIMETRY PERFORMANCE TEST**

The performance test includes irradiating dosimeters in the categories for which accreditation is sought and conducting a one-time study of the angular response and lower limit of detectability characteristics of the dosimeter. The categories include two accident level categories and five protection level categories.

The accident level categories extend from 10 to 500 rad at a depth of 1000 mg/cm<sup>2</sup> (Deep) and utilize either the M-150 x-ray beam (specified by the National Institute of Standards and Technology [NIST]) or a <sup>137</sup>Cs photon source.

The protection level categories extend from 0.03 to 10 rem at Deep and/or Shallow (7 mg/cm<sup>2</sup>) as specified. The test depths for the photon categories in the protection levels include both the Deep and Shallow depths. The general low-energy, x-ray category utilizes NIST-specified beams, M-30 (20 keV-effective), S-60 (36 keV-effective), M-150 (70 keV-effective), and H-150 (120 keV-effective). The plutonium series x-ray category includes K-fluorescence beams at 17.5 keV and 59 keV, as well as the <sup>241</sup>Am source (59 keV). The high-energy photon category utilizes a <sup>137</sup>Cs source.

The beta categories test only at the Shallow depth and include <sup>204</sup>Tl, <sup>90</sup>Sr/<sup>90</sup>Y and uranium. The radioisotopic sources are used in the point irradiation geometry and the level of doses extends from 0.15 to 10 rem. The uranium source is a slab source and the dose levels extend from 0.15 to 5 rem.

The neutron category includes bare and D<sub>2</sub>O-moderated <sup>252</sup>Cf. The dose level extends from 0.2 to 5 rem and the test depth is Deep.

The final category is a mixture category. It includes various mixtures of the above irradiations. A mixture irradiation is one that utilizes one source from one category and one source from another category (e.g., M-150 and <sup>137</sup>Cs). The standard specifies that the ratio of dose equivalents from the two sources may not exceed 3.

The test depths for photon mixtures and beta/high-energy photon mixtures are specified to be both Shallow and Deep. The dose levels extend from 0.05 to 5 rem for photon mixtures and 0.2 to 5 rem for photon/beta mixtures. The neutron/photon mixtures are evaluated at the Deep depth only, and the dose levels extend from 0.3 to 5 rem.

Fifteen dosimeters are tested in each category, in three groups of five, over a four- to five-month period. The only categories which are identified at the time dosimeters are returned to the contractor for processing are the accident categories and neutron categories. Performance of the dosimetry system is satisfactory if

$$|\bar{B}| + S - |E| \leq L$$

where B is the bias, or mean of the performance indexes, S is the standard deviation of the performance indexes, and E is a category-specific uncertainty term associated with the test irradiations. The S term is not employed for low-energy beta sources. The value of L is 0.3 for all categories except mixture categories and low-energy beta sources where the value of L is 0.4.

Contractors pursuing accreditation are also required to conduct a one-time angular dependence study and a lower limit of detectability study as specified in the standard. There are no criteria for passing or failing these tests, only the stipulation that they be conducted using the sources specified in the standard.

### **EXTREMITY DOSIMETRY PERFORMANCE TEST**

The performance test includes irradiating dosimeters in the categories for which accreditation is sought and conducting a one-time study of the angular response and lower limit of detectability for the dosimeter. The categories include one accident level category with two sources and three protection level categories. All doses are delivered at the shallow ( $7\text{mg}/\text{cm}^2$ ) depth.

The accident level category extends from 10 to 500 rad and utilizes either the M-150 x-ray beam (specified by NIST) or a  $^{137}\text{Cs}$  photon source.

The protection level categories extend from 0.25 to 10 rem. The general low-energy x-ray category utilizes NIST-specified beams M-30 (20 keV-effective) and M-150 (70 keV-effective). There is no plutonium series x-ray category as in the whole body standard. The high-energy photon category utilizes a  $^{137}\text{Cs}$  source.

The beta categories include  $^{204}\text{Tl}$ ,  $^{90}\text{Sr}/^{90}\text{Y}$  and uranium. The radioisotopic sources are used in the point irradiation geometry and the natural and depleted uranium sources are used in the slab geometry.

The neutron category includes bare and  $\text{D}_2\text{O}$ -moderated  $^{252}\text{Cf}$ . The fluence-to-dose conversion used in the extremity DOELAP standard is the same as the one used in the whole body DOELAP standard. The factor is currently under investigation and will be changed as appropriate even though the concept of neutron dose equivalent to extremities is technically inappropriate.

There are no mixture categories in the extremity DOELAP standard. Extremity dosimeters are usually employed in well-characterized fields where the response of the dosimeter has been measured or estimated. Therefore, the participants are notified regarding which source was used to irradiate each dosimeter. One further difference in the extremity DOELAP and whole body DOELAP is that all dosimeters, including those irradiated on the uranium slab, are irradiated on phantom.

Fifteen dosimeters are tested in each category, in three groups of five, over a four- to five-month period. Performance of the dosimetry system is satisfactory if

$$|\bar{B}| + S \leq L$$

where B is the bias, or mean of the performance indexes and S is the standard deviation of the performance indexes. The value of L is 0.30 for category 1 and 0.5 for other categories.

Contractors pursuing accreditation also are required to conduct a one-time angular dependence study and a lower limit of detectability study as specified in the standard. There are no criteria for passing or failing these tests, only the stipulation that they be conducted using the sources specified in the Standard.

### **QUALITY ASSURANCE PRACTICES**

Several practices are conducted to control and assure that the quality of performance test irradiations is maintained at a high level. Dosimeters from different participants are irradiated together. A quality control dosimeter which is calibrated and analyzed at the Performance Testing Laboratory (PTL) is included in every irradiation.

When dosimeters arrive at the PTL, a bar-coded label is attached to each dosimeter. The label is read at the irradiation station, and software checks are performed to assure that the dosimeter belongs in the group being irradiated and that the group of dosimeters (packet) is being irradiated in the right category. In addition, the dosimeter packet is assigned a bar-coded label that identifies the irradiation source and dose equivalent level to which it will be exposed.

Ionization chambers have been positioned in the dosimeter phantoms to provide direct assurance of the delivered doses. A message is displayed on the computer monitor if the discrepancy between the delivered dose and the dose recorded by the in-phantom monitor is greater than 2%. A summary of the pertinent irradiation data is printed at the irradiation station for each irradiation. The 2% flag is included on the printout if appropriate.

The entire testing process is automated and controlled by computer to the extent possible to reduce the amount of human interaction. The DOELAP computer is used to maintain the dosimeter database, read the bar-code labels at each station, control the dosimeter irradiations, collect irradiation data (temperature, pressure, in-phantom monitor currents), and generate reports.

Strict procedures are employed to store and handle dosimeters not being irradiated. Environmental dosimeters are placed at storage positions to monitor environmental doses and assure that transit doses are not delivered while dosimeters reside at the PTL. Only the dosimeters to be irradiated during a given shift, or on a given day are allowed to be removed from storage and taken to the irradiation facility.

The output of DOELAP radiological sources is verified by PTL personnel using the in-phantom monitors at the beginning of each round to assure that the irradiation systems are stable. In addition, the source output is verified quarterly using secondary transfer standards that are directly traceable to standards at the NIST. Annually, the PTL participates in the DOE Radiological Calibration

Intercomparison program administered by the Pacific Northwest Laboratory. Every two or two and one-half years, the PTL participates in the NIST Measurement Quality Assurance program. Finally, the DOE contracts with the NIST and DOE contractor personnel to conduct periodic oversight audits of the PTL facilities and procedures and the DOELAP program in general.

## **CURRENT STATUS OF THE DOELAP**

The DOELAP is responsible for accrediting 31 dosimetry systems for 38 DOE facilities under 10 field offices. The facilities are diverse, including small university research groups, environmental restoration programs, defense programs and complex multi-program facilities. The number of routinely processed dosimeters ranges from several dozen per month for small facilities to thousands per month for the large, complex facilities.

Currently, 15 dosimetry systems are fully accredited, 6 have passed performance testing and are awaiting onsite assessments, and 10 are in remediation or are participating in performance testing.

Of the 31 dosimetry systems, 19 are conducted using dosimeters processed within DOE facilities by DOE contractor personnel, 10 use commercial processors, and two are determining which way to go. All facilities use thermoluminescent dosimeters. Three facilities routinely use CR-39 for neutron dosimetry, and two facilities use commercially available film dosimetry.

The DOELAP oversight board consists of five individuals representing five different DOE field offices and the program administrator from DOE/EH.

The 23 DOELAP assessors used to conduct the onsite assessments represent 14 DOE/DOE contractor organizations at 9 of the 10 DOE field offices. Their expertise ranges from operating and managing personnel dosimetry programs to conducting research in personnel dosimetry.

The whole body DOELAP is currently conducting its fifteenth performance testing session. The extremity DOELAP is available for implementation, and voluntary testing will probably begin concurrent to the sixteenth whole body test session. The two LAPs will eventually be combined into a single accreditation program.

## **POTENTIAL CHANGES IN THE DOELAP**

### **Whole Body Personnel Dosimetry**

It is expected that during 1993, the whole body DOELAP standard and handbook will be revised. The revision may include some revision of the categories and radiological sources, a revision of the  $C_x$  conversion factors for photons, and a revision of fluence to dose equivalent conversion factors for neutrons. New sources that will be considered include International Organization for Standardization (ISO) narrow and broad beam x-rays, planar beta radiation sources, and high-energy neutron and photon sources. In addition, changes in existing conversion factors to become compatible with ISO standards or internationally accepted values will be considered.

The DOELAP standard refers to a later change in performance criteria for the mixture and low-energy beta categories. This change has not yet been implemented. The criteria change will be re-

evaluated during the revision of the standard. Additionally, new criteria may be included to routinely test the angular response of personnel dosimeters.

### **Extremity Personnel Dosimetry**

It is expected that testing of extremity personnel dosimetry systems will be incorporated into routine DOELAP testing in January 1994. As with the DOELAP for whole body dosimetry systems, participation will be voluntary for some period of time. Accreditation will then be required for both types of dosimetry and the two programs will be combined under external dosimetry in DOE Order 5480.15. The testing standards for the two dosimetry systems may be combined in the future into a single standard.



# FACTORS AFFECTING QUALITY FOR BETA DOSE RATE MEASUREMENTS USING ISO 6980 SERIES I REFERENCE SOURCES

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*Abstract* - Atlan-Tech, Inc. has performed several calibrations of ISO 6980 Series 1 reference beta sources over the past two to three years. There were many problems encountered in attempting to compare the results of these calibrations with those from other laboratories, indicating the need for more standardization in the methodology employed for the measurement of the absorbed dose rate from ISO 6980 Series 1 reference beta sources. This document describes some of the problems encountered in attempting to intercompare results of beta dose-rate measurements. It proposes some solutions in an attempt to open a dialogue among facilities using reference beta standards for the purpose of promoting better measurement quality assurance through data intercomparison.

## INTRODUCTION

The intention of this work is to establish a dialogue among individuals conducting beta dose-rate measurements for Series 1 reference beta standards as defined in International Organization for Standardization (ISO) Standard 6980-1984 (ISO 1984). Problems encountered in the course of calibrating reference beta sources at Atlan-Tech will be discussed, along with proposed actions to remedy these problems in the future and to promote standardized methods of performing reference beta measurements in order to ensure comparability of results among calibration laboratories.

Due to the increased number of facilities performing dosimetry irradiations with ISO 6980 Series 1 reference beta sources and the availability of the reference instrumentation used to calibrate these sources, there has been an increase in the number of these facilities that are performing their own calibrations of these sources or are having the calibrations performed by a third party. Over the past two to three years, Atlan-Tech has performed calibrations of several ISO 6980 Series 1 reference beta source sets on behalf of its clients and for the purpose of intercomparison among irradiation

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laboratories. The majority of these sources were the Amersham-Buchler calibration sets, containing  $^{147}\text{Pm}$ ,  $^{204}\text{Tl}$ , and  $^{90}\text{Sr/Y}$ . In performing these measurements, we encountered many problems in attempting to compare the results of these measurements with those of other laboratories performing calibrations on the same sources. We also experienced difficulty when we tried to compare data measured for our own sources with that measured by the National Institute of Standards and Technology (NIST).

The problems encountered in calibrating these source sets can be broken down into two main categories: those having to do with limitations of the equipment used in the calibration process, and those having to do with the lack of a standardized method for calculating and reporting beta absorbed dose-rate data. Since the reference class extrapolation chambers used for calibrating beta standards are considered to be an "absolute" instrument, i.e., no calibration factors or intercomparisons with a reference standard are employed, there exists the opportunity for a metrologist to employ several different measurement modalities. This fact can result in problems when it comes to intercomparing results of a beta dose-rate measurement from one laboratory to those from another laboratory for the same source or source type. This document will describe the calibration process employed at Atlan-Tech for determining the absorbed dose rate from reference beta sources, and then discuss some of the problems encountered in trying to ensure the integrity of measured values and propose solutions to these problems.

## METHODS AND MATERIALS

The majority of the beta dose-rate measurements performed by Atlan-Tech were done for Amersham-Buchler beta particle calibration sources installed in the beta secondary standard system. All measurements were performed using the appropriate beam-flattening filters and at the calibration distances recommended by the ISO 6980 standard for each nuclide. The measurement methodology employed follows as closely as possible the methods described in the National Bureau of Standards (NBS) Special Publication 250-21, Calibration of Beta-Particle Radiation Instrumentation and Sources (Pruitt, Soares, and Ehrlich 1988). The methodology employed at Atlan-Tech for beta dose-rate determination will be discussed here only briefly; the NBS Special Publication 250-21 should be consulted for more detailed information.

The reference instrumentation used at Atlan-Tech for beta dose-rate measurement consists of a reference class extrapolation chamber, manufactured by the Pychlau Technical Works (PTW) in Germany, and a Keithley Model 617 electrometer. The original entrance window supplied with the PTW chamber, constructed of graphite-coated polyethylene terephthalate (Mylar) having a nominal density thickness of  $2.61 \text{ mg cm}^{-2}$ , was replaced with an aluminized Mylar window having a density thickness of  $1.29 \text{ mg cm}^{-2}$ . The density thickness of the aluminized Mylar window used on the Atlan-Tech chamber was measured by weighing a  $100 \text{ cm}^2$  sample of the material on a precision analytical balance. The same sample was then cut to size and installed on the chamber. Therefore, the actual density thickness of the chamber entrance window was known without having to rely upon the accuracy of a nominal value. The bias voltage supplied to the chamber plates is provided by the electrometer's internal voltage supply.

The first step in the calibration process is to establish the desired source/detector geometry. The chamber is placed at a height such that the geometric center of the entrance window coincides with the beam centerline of the source to be calibrated. A laser alignment system that installs directly into the beta secondary standard is employed for this purpose. Once the proper height has been

established, the next step is to confirm that the plane of the source disk and the plane of the chamber entrance window are exactly parallel. Once these two conditions have been established, then the chamber is placed at the reference distance from the source and the appropriate beam-flattening filter is installed.

A word should be said here about the fact that the density thickness of the chamber entrance window ( $1.29 \text{ mg cm}^{-2}$  for the Atlan-Tech chamber) is not the same as the dose depth of interest,  $7 \text{ mg cm}^{-2}$ . As the intent of beta dose-rate measurement is to determine the absorbed dose rate to adipose tissue at the  $7 \text{ mg cm}^{-2}$  depth, one has two options when it comes to performing beta dose-rate measurements with an extrapolation chamber. The metrologist can either place additional filtration over the chamber entrance window to bring the total value to that desired, or the measurements can be performed with the chamber window unmodified and the measurements corrected mathematically for the dose depth of interest. Measurements performed at Atlan-Tech are performed with no additional filtration over the chamber entrance window. Data are collected in this manner so that the measurement threshold (lowest absorbed dose rate the system can measure) of the system is not compromised. The correction of data measured at a dose depth other than that desired to  $7 \text{ mg cm}^{-2}$  will be discussed later.

After the desired geometry has been established, the next step in the calibration process is to perform the charge collections that will be used to compute the ionization current as a function of chamber plate spacing. Charge collections are performed with the chamber plates at typically six different spacings while maintaining a constant voltage gradient. We have found that a constant voltage gradient of 10V per mm of plate spacing provides a good balance between collection efficiency and low chamber dark currents. Once the chamber plate spacing is set and the bias voltage is applied, the chamber is "pre-irradiated" before any charge collection data is recorded. Pre-irradiation consists of exposing the chamber with the source to be calibrated for an extended period of time while intermittently collecting charge with the electrometer. The purpose of pre-irradiation is to see that any stray charge in the chamber or on the electrometer capacitor are collected so that no erroneous results are produced. Once pre-irradiation has been performed, the source is shielded and the chamber dark current is monitored for several minutes. If the dark current is relatively constant with no spurious behavior, then the system is considered to be stable and charge collections can then be performed. Two sets of charge collection data are taken for each chamber plate spacing employed: one set with the chamber bias voltage at positive polarity and one with negative polarity. The polarity of the bias voltage is not switched until measurements for all plate spacings with either polarity have been completed. This minimizes the pre-irradiation time necessary when changing plate spacing and voltage. The final value for the ionization current measured for each plate spacing represents the average of the absolute values of the currents measured at positive and negative polarity. The data collection feature of the electrometer is employed in order to minimize errors associated with the charge collection process. The temperature, relative humidity, and barometric pressure are recorded with each set of charge collection data.

Once charge collection for all plate spacings has been completed, the individual values for each plate spacing and bias polarity are converted to electric current and averaged. This results in two separate sets of data consisting of positive and negative ionization current versus plate spacing. The absolute values of the positive and negative values are subsequently averaged to yield the raw collected current versus plate spacing for the source being calibrated. After the raw collected current data for each plate spacing has been determined, the next step is to apply corrections to this data so that it may be extrapolated properly.

Several correction factors are applied to the measured ionization current data in order to correct for various factors related to the instrument itself, the calibration geometry, and effects of the environment. These correction factors are specific for the PTW extrapolation chamber and are functions of several different parameters. They are also specific for each nuclide for which dose-rate measurement is being performed. The factors are discussed in detail in NBS SP 250-21 and will only be described briefly here.

The expression for correcting the raw ionization current values measured for each plate spacing is

$$I_c = I \cdot \prod_i c_i \cdot \prod_j k_j \quad (1)$$

where  $I_c$  is the corrected ionization current,  $I$  is the raw current, the quantities  $c_i$  are correction factors relating to the chamber and source, and the quantities  $k_j$  are correction factors relating to environmental conditions (Pruitt, Soares, and Ehrlich 1988). The quantities  $c_i$  consist of eight factors, while the quantities  $k_j$  number three. The eight factors that make up the quantities  $c_i$  represent corrections for entrance window thickness ( $c_{\text{foil}}$ ), beam divergence ( $c_{\text{div}}$ ), attenuation in the chamber air gap ( $c_{\text{atten}}$ ), air density ( $c_{t,p}$ ), chamber backscatter ( $c_{\text{back}}$ ), chamber sidescatter ( $c_{\text{side}}$ ), ion recombination and diffusion ( $c_{\text{recom}}$ ), and photon contribution to the ionization current ( $c_{\text{phot}}$ ). The three factors that make up the quantities  $k_j$  represent corrections for source decay ( $k_{\text{dec}}$ ), variations in the air mass between the source and the chamber ( $k_{\text{mass}}$ ), and the contribution of relative humidity to the air mass correction ( $k_{\text{hum}}$ ). Each of these correction factors is applied for each value of raw current for each plate spacing employed. Equation (1) is then used to compute values of corrected ionization current versus plate spacing. All of the correction factors are computed by following the methodologies outlined in NBS SP 250-21, with one exception. A method is not given in NBS SP 250-21 for computing values of  $c_{\text{foil}}$ , the correction factor for the thickness of the chamber entrance window. This is an area where we had to go beyond the NBS SP 250-21 document in our efforts to perform consistent dose-rate calculations that were directly comparable to others. The exact method we employ for computing values for  $c_{\text{foil}}$  will be discussed later. Our practice has been to compute a value for  $c_{\text{foil}}$  that will convert the current measured for air at a dose depth equivalent to the density thickness of the entrance window to current for air with no window present, i.e., 0 mg cm<sup>-2</sup> dose depth. This is done for two reasons: 1) because we feel that this is the standard convention for reporting absorbed dose rate for reference beta standards, and 2), it makes it more convenient to convert this value to values for other media and dose depths using stopping power values and application of the  $c_{\text{foil}}$  factor. Once all of the raw values for ionization current have been corrected, they are then used to compute the extrapolation curve for the source being calibrated.

The absorbed dose rate in air from a beta-particle fluence measured with an extrapolation chamber is computed as

$$\dot{D}_{\text{air}} = \frac{W}{e\rho A} \frac{dI}{dx} \quad (2)$$

where  $W$  is the mean energy expended in air per ion pair (electron) formed expressed in J per electron,  $e$  is the elementary unit of charge of 1.60218E-19 C per electron,  $\rho$  is the density of air expressed in kg m<sup>-3</sup>,  $A$  is the effective area of the chamber collecting electrode expressed in m<sup>2</sup>, and

$dI dx^{-1}$  is the slope of the corrected current versus plate spacing curve expressed in amps per meter. The slope of the corrected current versus plate spacing curve is found by performing a linear regression on the corrected current versus plate spacing data discussed previously. The result from Equation (2) is the absorbed dose rate to air expressed in gray (Gy) per second at a dose depth of  $0 \text{ mg cm}^{-2}$  ( $c_{\text{foil}}$  was used to correct for the entrance window thickness).

The final step in the calibration process is to convert this value to a value for the absorbed dose rate to adipose tissue at a dose depth of  $7 \text{ mg cm}^{-2}$ . A value for  $c_{\text{foil}}$  is computed for the  $7 \text{ mg cm}^{-2}$  depth for the beta particle spectrum of interest. This value is multiplied by the value for the absorbed dose rate to air from Equation (2). The result is then multiplied by the ratio of the collisional mass stopping power for tissue to air computed for the mean beta energy of the spectrum of interest. The values for the collisional mass stopping power are taken from NBSIR 82-2550, Stopping Powers and Ranges of Electrons and Positrons (Berger, Seltzer 1983).

## DISCUSSION

As eluded to previously, we have observed several problems with the method used for computing absorbed dose rate from reference beta standards using extrapolation chamber data, as well as problems with making the measurements themselves. The problems we have encountered can be broken down into three subject areas:

- 1) difficulties with comparing measured values with those from other laboratories
- 2) lack of published expressions for computing the  $c_{\text{foil}}$  correction factor
- 3) problems with low signal-to-noise ratio when attempting to make charge collection measurements with the extrapolation chamber.

The biggest problem we have encountered is that the beta dosimetry data is very difficult to compare due to differences in the methods of calculation. Since the extrapolation chamber is an absolute instrument, there are many factors that are applied to obtain the corrected current. For instance, the  $W$  value (energy required in eV to create an ion pair) used can affect the dose-rate calculation significantly. The  $W$  values quoted in literature range from 33.7 to 33.97. Currently, 33.97 is considered to be the most acceptable for dry air and 33.85 for moist air. However, it is easy to see how, depending on the judgement of the metrologist, the  $W$  may be quite different. This may not seem to be a problem, but, when one tries to intercompare two numbers, it is not immediately obvious whether the  $W$  of the original measurement should be changed to reflect current data. For instance, if a metrologist were comparing older NIST data using a  $W$  of 33.7 to current data (33.97), there may be a discrepancy in the dose rate of as much as 1% simply because of the difference in this one constant. This kind of situation leads to the broader question of whether the certified dose rate at a given time should be fixed, or whether enough information must be supplied such that the factors applied may be modified as appropriate, given the knowledge of the time.

We propose that all factors applied in the calculation of dose rate must be shown as applied so that during comparison measurements the most recent factors based on current scientific knowledge, may be applied. This would implicitly mean that the dose rate quoted for a source (even a NIST-calibrated one) may be modified as time goes on, based on current scientific data. It also suggests

that NIST must promulgate to the scientific community the accepted current values for these factors or other physical quantities.

Physical quantities that this might apply to are eV/ion pair (W), mass stopping power ratios (S), c(div), c(foil), or any other of the twelve factors that apply to dose rate measurement. There needs to be consensus opinion as to the values for these parameters to be used for computing absorbed dose rate from beta sources. We would also like to see a convention adopted for the media and dose depth for which beta dose-rate data are reported. At present, NIST reports absorbed dose to water at a depth of 7 mg cm<sup>-2</sup>, while the Physikalisch-Technische Bundesanstalt (PTB) reports absorbed dose to air at a depth of 0 mg cm<sup>-2</sup>. Our personal preference is the PTB convention of reporting dose rate to air at the 0 mg cm<sup>-2</sup> depth. This value could then be corrected by application of a standard  $c_{\text{foil}}$  factor and standard stopping power ratios.

Another problem area we encountered was coming up with a standardized means of computing the  $c_{\text{foil}}$  correction factor used for converting measured ionization current data for a particular dose depth to values for another depth. There is a set of curves published in SP 250-21 that show the  $c_{\text{foil}}$  factor for Mylar versus the dose depth, but there are no expressions given for computing these values. We therefore contacted NIST and obtained the following three equations for computing the  $c_{\text{foil}}$  factor as a function of entrance window thickness (Pruitt 1990). The expression for <sup>90</sup>Sr/Y is

$$c_{\text{foil}} = [1 + (0.0155t) + (2.02E-05t^2) + (1.27E-07t^3)]e^{-0.01t} \quad (3)$$

where  $t$  is the Mylar thickness of interest. This equation is valid for depths up to 130 mg cm<sup>-2</sup>. The expression for the <sup>204</sup>Tl source is

$$c_{\text{foil}} = 1.699e^{-0.026t} - 1.736e^{0.0844t} + 1.037e^{0.1t} \quad (4)$$

This expression is valid for dose depths up to 100 mg cm<sup>-2</sup>. The  $c_{\text{foil}}$  factor for the <sup>147</sup>Pm source is given by

$$c_{\text{foil}} = 0.994e^{-0.219t} + 0.006 \quad (5)$$

This expression is applicable up to a dose depth of 66 mg cm<sup>-2</sup>. Note that the expressions were derived using the Amersham-Buchler beta sources at the ISO 6980 reference distances. We would recommend that these expressions be adopted as the standard means of computing the correction factors used for converting ionization currents measured at a dose depth corresponding to the thickness of the chamber entrance window back to the 0 mg cm<sup>-2</sup> depth. These expressions should also be employed for converting the absorbed dose-rate value for air at 0 mg cm<sup>-2</sup> to the value for tissue at 7 mg cm<sup>-2</sup>, along with the appropriate stopping power ratio.

On a related note, we would also like to emphasize the importance of confirming the actual thickness represented by the entrance window of an extrapolation chamber. If an incorrect assumption is made regarding entrance window thickness, then tremendous errors in absorbed dose-rate determination could result. It is our opinion that the entrance window supplied with an extrapolation chamber should either have the thickness certified by a standards laboratory or be replaced with a certified window. It is also a good practice to check the accuracy of the chamber micrometer when a new unit is initially received.

A third problem area we have encountered has been recent attempts at calibrating several Series 1  $^{204}\text{Tl}$  sources. Recent batches of sources have been supplied that have activities far below the nominal values specified. This results in a tremendous problem in attempting to calibrate these sources in that the signal (current) being measured is so close to the dark current for the extrapolation chamber, that quality measurements are not possible. It is either impossible to measure the absorbed dose rate from these sources or values are determined that have unacceptably high uncertainty.

The current method of production for these sources is to create the foils and then send them to a different location for incorporation into the source. Upon investigating possible reasons for these "low-output"  $^{204}\text{Tl}$  sources, we found that sometimes the foils may go unused for long periods of time relative to the half-life of  $^{204}\text{Tl}$  (3.78 years) before they are incorporated into sources and sold. Therefore, these sources have activities that are far less than the nominal value stated by the vendor and are extremely difficult, if not impossible, to calibrate.

We suggest that some work be done to characterize the sources for absorbed dose rate as a function of source activity. In addition, the end user should require the vendors to supply assay data so there is some idea what the activity of a source is when it is received. Therefore, the end user would have some idea of what the dose rate from a source should be when it is received. If this value is too close to the measurement threshold for the laboratory responsible for performing the calibration of that source, then the metrologist would know that the source was unmeasurable and could not be calibrated. At present, there is no assay data being supplied by the primary vendor for reference beta sources.

In order to have some idea of what the capability of a beta measurement system is, we recommend that anyone performing beta dose-rate measurements determine what we call the measurement threshold for their system. The measurement threshold may be thought of as the lowest absorbed dose rate from a particular source nuclide that may be measured with good statistical confidence. We are in the process of developing the means by which to rigorously determine the measurement threshold for a system based on dark current measurements as a function of plate spacing while maintaining constant voltage gradient. We would welcome any input for other ways of determining this quantity.

One additional problem we have encountered did not have to do with comparing values measured for the absorbed dose rate from a particular beta source, but with comparing response of personnel dosimetry to two different sources of the same isotope. We found that dosimeters irradiated with the Atlan-Tech  $^{204}\text{Tl}$  source, an Amersham-Buchler source calibrated by NIST, to a known total absorbed dose would give a response approximately 30% higher than the same dosimeters irradiated with another model of  $^{204}\text{Tl}$  source, also calibrated by NIST. Both sources met the ISO 6980 criteria for  $R_{\text{res}}/E_{\text{res}}$ . The difference was that the dosimetry irradiations performed with the Atlan-Tech source were being performed at 30 cm while the irradiations with the other source were being performed at 57 cm. This was the distance used when the source was calibrated by NIST. This 27-cm difference in distance scattered down the electron energy spectrum from the other source to such an extent that the response of TLDs irradiated with this source was some 30% less than those irradiated at the recommended distance of 30 cm. Thus, it would appear that meeting the  $R_{\text{res}}/E_{\text{res}}$  requirements of the ISO 6980 standard does not guarantee equality among different sources. In order to keep the beta spectra as equal as possible, irradiation distances and source construction criteria should also be standardized. It may be necessary in the future to publish standard spectra and transmission data for Series 1 reference beta standards so that spectral purity can be confirmed by a laboratory by acquiring

spectra for its Series 1 sources and comparing these to the standards. Criteria may also be set requiring secondary laboratories to meet the transmission fit data of the reference laboratory to within some agreed upon value, or acceptance criteria for spectral composition (energy fluence) would have to be established.

## SUMMARY

In order to promote intercomparison between laboratories performing beta dose-rate measurement for ISO 6980 Series 1 reference sources, a standardized method of measurement and reporting needs to be adopted. Standardized values of physical constants and ionization current correction factors need to be decided upon and adhered to, and the measurement methodology employed should be that of NBS SP 250-21. Physical parameters of the reference instrument, such as entrance window thickness and micrometer accuracy, should also be confirmed.

In addition, there is the need for a standard reporting convention with respect to the media and dose depth for which beta absorbed dose rates are reported for intercomparison.

Further, there is the need for publication of nominal absorbed dose rate as a function of source activity for Series 1 reference beta sources and for the vendors of these sources to provide assay data with each one. Also, each facility should determine a measurement threshold for their beta measurement system so that decisions can be made as to what kind of calibration uncertainty can be expected as a function of source activity.

Finally, the requirements of ISO 6980 for Series 1 reference sources may need to be expanded in order to further guarantee comparability among laboratories employing these sources in their work.

We would like to propose an open discussion of problems encountered in beta dosimetry. To facilitate this, we are presenting the data in Table 1. Table 1 is a comparison of data from NIST calibrations of Atlan-Tech sources and the sources quoted in SP 250-21, an Atlan-Tech calibration of U.S. Air Force sources, and the PTB calibration of Oak Ridge National Laboratory sources. The important thing to note is that these numbers are significantly different, especially for  $^{204}\text{Tl}$  and  $^{147}\text{Pm}$ . While some of the differences may be linked to foil age due to long shelf times, it cannot be completely dismissed in this fashion. We encourage others to come forth with their ideas and to advocate our comparisons to eliminate some of these problems. Note that if a activity to dose-rate conversion were available and if the vendor had supplied proper assay dates, then it would make the mystery of these differences much easier to find.



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Table 1 - Comparison of Beta Dose Rates

Comparison data for several beta source sets								
				mg/cm2	Sr-90	Tl-204	Pm-147	
Conversion factors for 8 mg/cm2 to 7 mg/cm2				7.0	1.0345	0.9697	0.2206	
Conversion factors for 7 mg/cm2 to 0 mg/cm2				0.0	0.9666	1.0312	4.5333	
S-water/S-air				N/A	1.124	1.132	1.136	
S-air/S-water				N/A	0.890	0.883	0.880	
S-tissue/S-air				N/A	1.139	1.160	1.170	
S-air/S-tissue				N/A	0.878	0.862	0.855	
NIST data for AT sources in water @ 7 mg/cm2				<<<< Reference data				
	Date	Dist. (cm)	mCi	MBq	Gy/s	uGy/s	Rad/h	mrem/h
Sr-90	3-Aug-87	30	50.0	185	8.71E-05	87.100	31.356	31356.00
Sr-90	17-Aug-87	30	2.0	74	2.11E-06	2.110	0.760	759.60
Tl-204	3-Aug-87	30	0.5	18.5	1.82E-07	0.182	0.066	65.52
Pm-147	18-Aug-87	20	14.0	518	2.53E-08	0.025	0.009	9.11
NIST data for AT sources in water @ 0 mg/cm2				<<<< Reference data				
	Date	Dist. (cm)	mCi	MBq	Gy/s	uGy/s	Rad/h	mrem/h
Sr-90	3-Aug-87	30	50.0	185	8.42E-05	84.193	30.310	30309.65
Sr-90	17-Aug-87	30	2.0	74	2.04E-06	2.040	0.734	734.25
Tl-204	3-Aug-87	30	0.5	18.5	1.88E-07	0.188	0.068	67.57
Pm-147	18-Aug-87	20	14.0	518	1.15E-07	0.115	0.041	41.29
NIST data for AT sources in air @ 0 mg/cm2				<<<< Reference data				
	Date	Dist. (cm)	mCi	MBq	Gy/s	uGy/s	Rad/h	mrem/h
Sr-90	3-Aug-87	30	50.0	185	7.49E-05	74.905	28.968	28965.88
Sr-90	17-Aug-87	30	2.0	74	1.81E-06	1.815	0.653	653.25
Tl-204	3-Aug-87	30	0.5	18.5	1.88E-07	0.188	0.068	59.69
Pm-147	18-Aug-87	20	14.0	518	1.01E-07	0.101	0.038	38.35
NIST SP-250-24 data in water @ 7 mg/cm2				<<<< Reference data				
	Date	Dist. (cm)	mCi	MBq	Gy/s	uGy/s	Rad/h	mrem/h
Sr-90	1-Jan-83	30	50.0	185	-	-	-	-
Sr-90	1-Jan-83	30	2.0	74	2.01E-06	2.010	0.724	723.60
Tl-204	1-Jan-83	30	0.5	18.5	3.30E-07	0.330	0.119	118.80
Pm-147	1-Jan-83	20	14.0	518	6.00E-08	0.060	0.022	21.60
NIST SP-250-24 data in water @ 0 mg/cm2				<<<< Reference data				
	Date	Dist. (cm)	mCi	MBq	Gy/s	uGy/s	Rad/h	mrem/h
Sr-90	1-Jan-83	30	50.0	185	7.06E-05	70.600	25.416	25416.00
Sr-90	1-Jan-83	30	2.0	74	1.93E-06	1.930	0.695	694.80
Tl-204	1-Jan-83	30	0.5	18.5	3.41E-07	0.341	0.123	122.76
Pm-147	1-Jan-83	20	14.0	518	2.67E-07	0.267	0.096	96.12
NIST SP-250-24 data in air @ 0 mg/cm2				<<<< Reference data				
	Date	Dist. (cm)	mCi	MBq	Gy/s	uGy/s	Rad/h	mrem/h
Sr-90	1-Jan-83	30	50.0	185	6.28E-05	62.811	22.812	22812.10
Sr-90	1-Jan-83	30	2.0	74	1.72E-06	1.717	0.618	618.15
Tl-204	1-Jan-83	30	0.5	18.5	3.01E-07	0.301	0.108	108.45
Pm-147	1-Jan-83	20	14.0	518	2.35E-07	0.235	0.085	84.61
PIB data for ORNL in air @ 0 mg/cm2				<<<< Reference data				
	Date	Dist. (cm)	mCi	MBq	Gy/s	uGy/s	Rad/h	mrem/h
Sr-90	14-Nov-85	30	50.0	185	6.17E-05	61.670	22.201	22201.20
Sr-90	30-Sep-85	30	2.0	74	1.80E-06	1.795	0.648	648.20
Tl-204	1-Oct-85	30	0.5	18.5	2.42E-07	0.242	0.087	87.12
Pm-147	30-Sep-85	20	14.0	518	3.89E-07	0.389	0.140	140.04
USAF data in air @ 0 mg/cm2				<<<< Reference data				
	Date	Dist. (cm)	mCi	MBq	Gy/s	uGy/s	Rad/h	mrem/h
Sr-90	8-Aug-90	30	50.0	185	7.06E-05	70.640	25.430	25430.40
Sr-90	8-Aug-90	30	2.0	74	1.87E-06	1.865	0.671	671.40
Tl-204	8-Aug-90	30	0.5	18.5	4.39E-07	0.439	0.158	158.04
Pm-147	8-Aug-90	20	14.0	518	6.11E-07	0.611	0.220	219.98

# A METHOD FOR AUTOMATING CALIBRATION AND RECORDS MANAGEMENT FOR INSTRUMENTATION AND DOSIMETRY

J. M. O'Brien, Jr.<sup>(1)</sup>

R. O. Rushton<sup>(1)</sup>

R. E. Burns, Jr.<sup>(1)</sup>

*Abstract* - Current industry requirements are becoming more stringent on quality assurance records and documentation for calibration of instruments and dosimetry. A novel method is presented here that will allow a progressive automation scheme to be used in pursuit of that goal. This concept is based on computer-controlled irradiators that can act as stand-alone devices or be interfaced to other components via a computer local area network. In this way, complete systems can be built with modules to create a records management system to meet the needs of small laboratories or large multi-building calibration groups. Different database engines or formats can be used simply by replacing a module. Modules for temperature and pressure monitoring or shipping and receiving can be added, as well as equipment modules for direct IEEE-488 interface to electrometers and other instrumentation.

## INTRODUCTION

In the past, irradiators and calibrators were simple machines that had manual controls for operating the system. This design worked well but required extensive operator interaction for all operations. All data had to be recorded by hand. Repetitive calibrations had to be enacted step by step by the operator (little if any time could be saved by performing multiple calibrations). These systems were not linked to other calibrators or equipment, and a tremendous amount of technician time was required for recordkeeping. Additionally, these were mundane tasks and, often, transcription errors occurred. Now in the information explosion, laboratories are being required to keep more quality assurance records with less staff and smaller budgets. Other automated systems were implemented at some large laboratories; however, these systems were expensive, used custom software, and were partially implemented on mini-computers. What makes this new approach innovative is the use of a local area network and distributed computing in all phases of the calibration process. Those with a

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very tight budget can buy a computer-controlled irradiator that at least does the exposure calculations, based on saved information, and has multiple irradiator configurations which may be used as shorthand methods of calibration for specific instances. Large calibration laboratories may elect to network several irradiators in combination with pressure, temperature, interlock, and database modules.

## **THE INTELLIGENT IRRADIATOR**

The growth of the microcomputer industry and the advent of the inexpensive computer equipment has spawned a new era where the irradiator can be fully automated to streamline operations, reduce errors, and increase efficiency while still leaving full control with the operator. The new design paradigm joins the computer control and mechanical components to create a system that vastly improves overall performance as compared with older equipment. Just two or three years ago, programmable logic devices were used due to the high cost of microcomputers and software. By making routine operations more automated with preset configurations, the operator can focus on areas where his expertise is required and let the computer perform the redundant, mundane tasks. With a computer as an integral part of the calibrator, new functions can be integrated seamlessly into the system, such as source decay correction and network capability. The approach that Atlan-Tech has taken is to fully embrace new technology to help solve customers' needs in the best way possible. The basic component of these new systems is the "intelligent controller." Powered by a 80486 microprocessor, the intelligent irradiator includes 4 mb of RAM, 2 serial and 1 parallel ports, a 3.5" floppy disk, a large hard drive, high resolution color monitor, keyboard, and pointing device. A parallel port board for direct communication to solid-state relays controls all functions of the irradiator and displays system status on the monitor screen, acting as a control panel. The virtual interface is presented in Figure 1. It shows preset time, source selection, attenuator selection, and platform position.

Exposure time can range up to 10,000 minutes with an accuracy of  $\pm 0.01$  minutes and is entered via the keyboard or stored as a preset configuration. Source selection is made via the keyboard or using the mouse. Attenuators, which are also selected via the keyboard or using the mouse, can be selected in any combination. The selected attenuators are shown on the monitor. Distance, temperature, and barometric pressure are entered manually with the keyboard or modules can be installed to automate those functions. If any errors occur, an error message will be displayed on the monitor showing what error occurred. Two momentary switches are provided on the front panel of the controller and work as alternates to the computer virtual irradiator: an "Expose" pushbutton for sending the selected source to the exposed position, and a "Return" pushbutton for sending the source back to the storage position. During a preset timed irradiation, the irradiation can be temporarily stopped by pushing the "Return" switch. The irradiation can be restarted by pushing the "Expose" switch. The timer will stop when the "Return" switch is pushed and continue when the source reaches the exposed position after the "Expose" switch is activated. Indicator lights show source position at all times. Power to the system is controlled via a keyed power switch. When turned on, the controller will perform a complete system functional check, turn on all panel lamps for five seconds, and set default settings. Default settings are factory set for selecting the smallest source, all attenuators closed, and a pre-set time selected. These settings can be changed by the system manager if so desired. When a source is in the exposed position, it will return to storage whenever: 1) the "Emergency Off" pushbutton is pushed, 2) the "Return" pushbutton is pushed, 3) the timer times out, 4) power is lost, 5) the system is turned off, 6) the interlock circuit is opened, 7) an error occurs (including loss of air pressure and/or electronic error).

## THE MODULAR CONCEPT

The modular approach to modern calibration laboratory automation is the key to effective solutions for individual quality assurance records requirements. For a small facility not looking to be secondary accredited, they may choose to only buy an irradiator. This will still provide better quality assurance records since records of the system calibration and the irradiator use are kept in the irradiator. Additionally, the decay correction can be applied automatically and subsequent documentation is automated. Larger, more complex, calibration laboratories may elect to buy one or several of the irradiators which are all network aware and can transfer data on a peer-to-peer or ethernet network. In this way, they can add other modules for specific tasks. Traditionally, computers are being used extensively at most facilities; however, they are generally used for one isolated job. Networking seldom is used, and where it is present, the network is not used to tie the parts into a fully integrated system. The modular approach lets laboratories customize a system to meet their needs without the high cost of custom software. This broad, systems approach results in better, more consistent calibrations with iron-clad recordkeeping to assure the quality of the calibration. Aspects of this system include:

1. Network - A system-wide network that could link all computers, instruments, and calibration devices.
2. Database - A database system capable of storing instrument calibration records, thermoluminescent dosimeter (TLD) records, device calibration records, and other salient information.
3. Automation - The system automates as many functions as possible including: operator input, data entry, calibration work, report generation, and recordkeeping.
4. Flexibility - The system allows individual calibration laboratories to customize the system to match their unique set of requirements.
5. Consistent graphical user interface - Each workstation utilizes Microsoft Windows for a consistent interface to make the system easy to learn and operate.
6. Security - Password protection and security are integral to the system to protect data and prevent unauthorized access. The security system allows the system manager to set up security levels as required to meet the facility requirements.
7. Safety - The system integrates radiation monitoring equipment and provides a network-wide alarm for evacuation.
8. Integration - The software allows for new equipment and existing equipment (after modification) to be integrated into the system.

The basic component required for a beginning system is the intelligent irradiator. Available add-on modules consist of:

Instrument Database Module - A database for all radiation instruments to be calibrated can be added to the system. Information recorded in the database includes as a minimum: ID number, make and

model number, scale ranges, historical calibration data, repair history, error bands, and a comment section. The database is designed to accept a wide range of instruments. When special data requirements are needed, they can be added to the database. Remember that the irradiator use database is an integral part of the intelligent irradiator.

TLD & Dosimeter Database Module - The TLD and dosimeter database, while similar to the instrument database in function, records a different set of data. Both actual exposure and verification of deliver dose would be included in the database for all classes of exposure.

Calibration Source Database Module - This database is designed to record National Institute of Standards and Technology (NIST) traceable data for all calibration devices and radioactive calibration sources in the facility. Calibration data can be recorded over a wide range of distances and attenuators as required for each device. Exposure rate curves will be generated automatically for each source and attenuator combination. Historical data will be kept to assure a complete quality assurance (QA) audit trail. Decay correction is built into the database. In addition, records on the source status, location, and ultimate disposition are included in the database.

Scheduling & Tracking Module - This module provides several standard forms of scheduling. In addition, custom schedules can be defined by the system administrator. Additionally the software monitors where in the repair and calibration process an instrument resides. It can provide monthly reports for field locations (or as scheduled by the system administrator) to all field offices providing notification of which instruments need to be sent for calibration. Based on incoming instruments, estimated times for calibrations, and personnel work loads, schedules can be generated for internal work at the calibration facility. Schedules can be prepared for individual staff members as well as by calibration device or calibration task. For equipment that needs periodic calibration, schedules could be prepared that would integrate these calibrations into the work schedule in the least disruptive manner.

Report Generation Module - Results can be reported with a calibration serial number that relates the calibration data in the software database to the calibration report for excellent QA records.

Various Input Device Modules - Modules for these devices would include thermometers, barometers, radiation monitors, electrometers (or other IEEE-488 interface components), door interlocks, or bar-code scanners.

Linear Positioner Control Module - This module can interface to existing positioner systems row an Atlan-Tech created system. It provides control to let the software automate position, based on current calibration data or empirically derived exposure versus distance curves.

Shipping & Receiving Module - Logs in instruments via manual or, if present, a bar-code scanner. Prepares paperwork for shipping out completed jobs including 49 RX requirements for check sources.

Calibration Procedure Module - This module would be custom for each client and would codify the existing facility procedures to generate a computer-based procedure for each instrument or calibration process. These computer procedures can be generated by Atlan-Tech; or a flowchart-type method is used by the system administrator to input the procedures. The intelligent irradiator can then access those procedures to step a technician through a process using the available equipment to effect a proper and well-documented calibration.

Statistical Analysis Module - With the large amount of data accumulated in the different databases, analyses can be performed on a routine basis that would otherwise be very difficult to do on data collected manually. The software has incorporated several features that enhance the ability to monitor and track trends on a statistical basis. As part of the monitoring program, set points can be set to notify the operator of unusual data points and instrument readings. Automatic routines can be set up to periodically review data to analyze different characteristics and provide reports on trend analysis, drift versus time, etc.

## **THEORY OF OPERATION**

A typical calibration might execute in the following way: The instrument enters the facility for calibration and is logged in using the Shipping & Receiving and Scheduling & Tracking modules. If bar-code scanners are present, then that module would supply information to the other modules for direct input to the form. The screen forms are exact replicas of the printed forms. Based on the information present in the Calibration Procedures module, then the calibration process for that instrument is set. Also, note that if this instrument has been calibrated by this laboratory before they can be notified and look at historical information in the Instrument Database module. The "as found" check can be accomplished at some later date as well as the calibration. The software tracks what steps of the calibration procedure have been executed and what is left to do.

During the calibration the intelligent irradiator uses the calibration procedure to dictate the method for calibration. The irradiator uses the calibration protocol to set distance with the linear positioner module, get the temperature and barometric pressure from an input device module, and set the exposure time and attenuation. The technician then executes the irradiation and inputs the instrument reading, or the reading can be obtained from an input device module. If required, a verification chamber can then be polled via an input device module so that the actual field used can be documented. When the calibration is complete, the set of data is presented for review by the operator. If everything is acceptable, then he would enter a password which applies his initials to the calibration. The report can then be generated with the report generation module, and the statistical analysis module can print out the calibration history for that instrument with a trend analysis. The Shipping & Receiving module is then used to generate a shipping manifest and packing list and the instrument is sent back to the client. On a periodic basis the lab supervisor can then generate a series of statistical reports as part of the quality assurance program. These reports can demonstrate the historical performance for a certain percentage of calibrations performed and provide documentation of quality.

## **CONCLUSION**

This type of software system is expandable and affordable, yet can provide documentation of some aspects of the calibration process not readily available before. The quality of calibrations can be assured to a greater degree for a client or auditor because of the linking of records in the database system. Everything from the source calibration data and chamber calibration factors to the parameters used and the verification exposure are documented. Individual instrument history and calibration factors are documented. What would have taken an army of administrative clerks to file and maintain are all automated and documented in a consistent, high-integrity fashion. Atlan-Tech has taken the advice of many people throughout the calibration community and combined it with our own experience to produce software that we believe will greatly enhance the productivity, efficiency,

and accuracy of radiation calibration laboratories, while meeting the demanding quality assurance requirements in this enlightened era of total quality management.



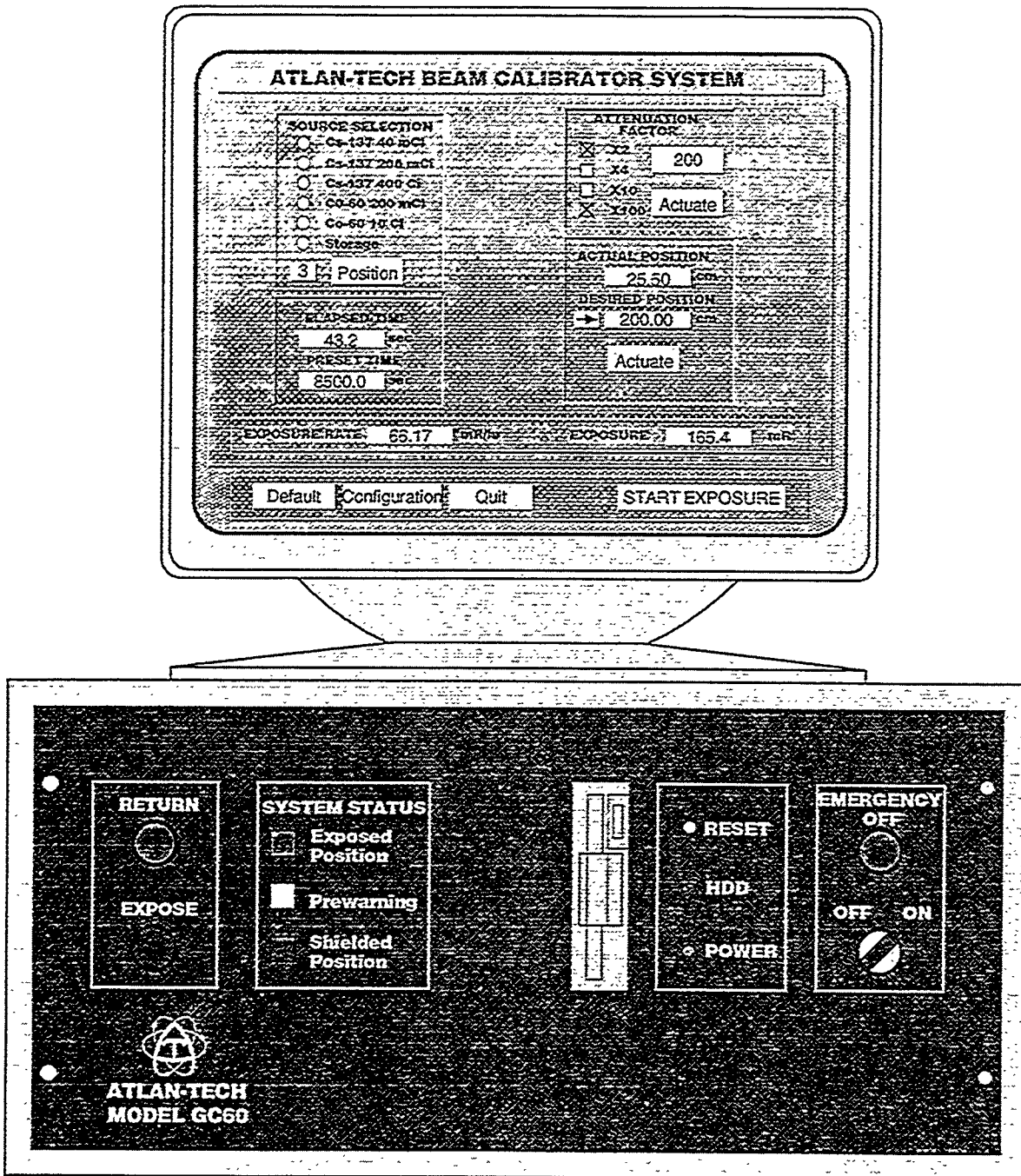


Figure 1 - Main control Screen for a Typical GC60 Beam Calibrator

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## Workshop on Measurement Quality Assurance Ionizing Radiation

### Agenda

#### Tuesday, March 16

- 8:00 a.m. Bus from hotel to NIST
- 8:15 a.m. Registration and Refreshments
- 9:00 a.m. **Welcome**  
Katharine B. Gebbie, Director, Physics Laboratory, NIST
- Opening Address  
Kenneth Inn, NIST
- 9:10 a.m. \* **Quality Assurance - The Competitive Edge** (Title varies)  
Curt Reimann, NIST

#### Fundamentals of MQA Session Chair: Kenneth Inn, NIST

- 9:30 a.m. **History and Overview**  
Elmer Eisenhower, HPS
- 9:50 a.m. **Need for Defensibility**  
Jerre Forbes, ANI
- 10:10 a.m. **Improvement in the Competitiveness of U.S. Industry through Standards and Laboratory Accreditation**  
Gary Davidson, TRW, Inc.
- 10:30 a.m. \* **CIRMS Role in Coordinating MQA Programs**  
Marshall Cleland, CIRMS
- 10:50 a.m. Break  
Poster Paper Setup
- 11:30 a.m. \* **Nist Commitment to National MQA Programs**  
Randall S. Caswell, NIST

\* Denotes papers published in this document.

**Standards for MQA Programs**  
**Session Chair: James Little, Eberline**

11:50 a.m.            **Domestic Criteria and Programs**  
Elmer Eisenhower, CIRMS

12:00 P.M.        \* **Foreign Criteria and Programs**  
Kenneth Swinth, PNL

**Perspectives and Policies**  
**Session Chair: Tom Heaton, FDA**

12:30 p.m.        **Developing MQA in Support of Rules and Regulations at DOE**  
Tom Bell, DOE-EH

12:50 p.m.        Lunch

2:05 p.m.        \* **Quality Assurance Programs Developed and Implemented by the U.S. Department of Energy's Analytical Services Program for Environmental Restoration and Waste Management Activities**  
Daniel Lillian, David Bottrell, Bob Newberry, DOE-EM

2:25 p.m.        \* **NVLAP Activities at Department of Defense Calibration Laboratories**  
Mike Shaeffer, DNA

2:45 p.m.        **Quality Assurance: FDA's Regulatory Perspective**  
Harvey Rudolph, FDA

3:05 p.m.        \* **Quality Assurance Measurement for Emergency Management**  
Mike Pawlowski, FEMA

3:25 p.m.        Break  
Poster Paper Setup

4:05 p.m.        \* **Current NRC Activities Related to MQA**  
Cheryl A. Trottier, NRC

4:25 p.m.        \* **Overview of EPA Quality Assurance Programs (Title varies)**  
Gary Johnson, EPA

4:45 p.m.        \* **Measurement Quality Assurance - CRCPD's Perspective**  
Pamela Dukes, SC/CRCPD

5:05 p.m.        **Open Discussion**  
Tom Heaton, CDRH

- 5:45 p.m. Bus to Hotel
- 6:15 p.m. Bus to Informal Dinner at Smokey Glen Farm
- 9:30 p.m. Bus to Hotel

**Wednesday, March 17**

- 8:00 a.m. Bus from hotel to NIST
- 8:15 a.m. Registration and Refreshments

**Complete MQA Programs  
Session Chair: Elmer Eisenhower, HPS**

- 9:00 a.m. \* **History, Organization, and Oversight of the Accredited Dosimetry Calibration Laboratories by the AAPM**  
Martin Rozenfeld, St. James Hospital and Health Care Centers
- 9:20 a.m. \* **CRCPD's Laboratory Accreditation Program**  
Pamela Dukes, Bureau of Radiological Health SC/CRCPD
- 9:40 a.m. \* **HPS Instrument Calibration Laboratory Accreditation Program**  
Frank Massé, MIT Bates Linear Accelerator
- 10:00 a.m. \* **NVLAP Accreditation of Secondary Calibration Laboratories for Ionizing Radiation (Title varies)**  
Paul Martin, NIST
- 10:20 a.m. \* **NVLAP Calibration Laboratory Program**  
James L. Cigler, NIST
- 10:40 a.m. Break  
View Poster Papers
- 11:20 a.m. **NVLAP Program for Personnel Radiation Dosimetry**  
Jeff Horlick, NIST

**Future MQA Programs  
Session Chair: Pamela Dukes, Bureau of Radiological Health SC/CRCPD**

- 11:40 a.m. **A New Department of Energy Laboratory Accreditation Program (DOELAP) for Bioassay Measurements - A Status Report**  
Doug Carlson, DOE/RESL

- 12:00 p.m. \* **MQA Programs for Radioassay Laboratories**  
David McCurdy, YAEL
- 12:20 p.m. \* **Accreditation Program for High Dose Secondary Calibration Laboratories**  
(Title varies)  
Jimmy Humphreys, NIST
- 12:40 p.m. \* **Intercomparison of High Energy Neutron Personnel Dosimeters**  
Joe McDonald, PNL
- 1:00 p.m. Lunch
- QA/QC Programs - Radioactivity**  
**Session Chair: Don Nellis, NRC**
- 2:15 p.m. \* **Traceability of EPA Radon Calibration** (Title varies)  
Mark Semler, EPA, Montgomery, AL
- 2:35 p.m. \* **Environmental Radioactivity Intercomparison Program and Radioactive Standards Program**  
George Dilbeck, EPA EMSL-LV
- 2:55 p.m. **Superfund and its Traceability to NIST**  
Jon Broadway, EPA Montgomery AL
- 3:15 p.m. Break  
**View Poster Papers and talk to Presenters**
- 3:55 p.m. **DOE Radiological Assessment Program**  
Don Bogan, EML, NY
- 4:15 p.m. \* **Nuclear Reactor Effluent Monitoring**  
John Minns, NRC-HQ, Washington, D.C.
- 4:35 p.m. \* **Radiopharmaceutical and Nuclear Power Measurements** (Title varies)  
Dan Golas, USCEA at NIST
- 4:55 p.m. **Open Discussion**  
Elmer Eisenhower, HPS
- 5:45 p.m. Bus to Hotel

**Thursday, March 18**

8:00 a.m. Bus to NIST

8:15 a.m. Registration and Refreshments

**QA/QC Programs - Dosimetry**

**Session Chair: Marty Rozenfeld, St. James Hospital and Health Center**

- 9:00 a.m. \* **Quality Audit Network for External Beam Radiotherapy** (Title varies)  
William Hanson, M.D. Anderson
- 9:20 a.m. \* **ACR Mammography Accreditation Program** (Title varies)  
Pamela Wilcox, ACR
- 9:40 a.m. \* **Instrument Performance Evaluation**  
Kenneth Swinth, PNL
- 10:00 a.m. \* **Calibration Services for Medical Applications of Radiation**  
Larry DeWerd, University of Wisconsin

**Laboratory Procedures for QA/QC**

**Session Chair: Tom Bell, DOE**

- 10:20 a.m. \* **Development of a Quality Assurance Program for Accredited Ionizing Radiation Calibration Laboratories** (Title varies)  
Tom Heaton, CDRH
- 10:40 a.m. Break  
**View Poster Papers and talk to Presenters**
- 11:20 a.m. **Measurement Uncertainty Assessments**  
Ron Collé, NIST
- 11:40 a.m. \* **Quality Assurance Programs at PNL Calibrations Laboratory**  
Joe McDonald, PNL
- 12:00 p.m. \* **Data Quality Objectives**  
Fred Haberer, EPA/QAMS

**In-house Controls of Reference Dosimetry Laboratories**

**Session Chair: Mike Schaeffer, DNA**

- 12:20 p.m. **Effects of Environmental Conditions on Laboratory Measurements**  
Dale Fleming, Tom Froelich, Michelle Johnson, PNL

- 12:40 p.m.            **A Neutron Field Characterization and Instrument Calibrations in a Dosimetry Laboratory**  
Leon West, University of Arkansas
- 1:00 p.m.            Lunch
- 2:15 p.m.            \* **Characterization of X-ray Fields at Center for Devices and Radiological Health**  
Frank Cerra, CDRH
- 2:35 p.m.            \* **Measurement Quality Assurance for Beta Particle Calibrations at NIST**  
Chris Soares, NIST
- In-house Controls of Radioactivity Laboratories**  
**Session Chair: Don Brogan, EML**
- 2:55 p.m.            \* **Quality Assurance Procedures and Requirements for the Operation of an Environmental Radiological Measurements Performance Evaluation Program** (Title varies)  
Isabel Fisenne, EML
- 3:15 p.m.            Break  
**Remove Poster Papers**
- 3:55 p.m.            \* **Evaluation of Controls for the Assurance of Quality Data in a Secondary Radiochemistry Laboratory** (Title varies)  
Stan Morton, RESL
- 4:15 p.m.            \* **The Role of the EPA Radiation Quality Assurance Program in the Measurement Quality Assurance Accreditation Program for Radioassay Laboratories**  
Terry Grady, EPA
- 4:35 p.m.            \* **Streamlining and Automation of Radioanalytical Methods at a Commercial Laboratory**  
James T. Harvey, IT Corp.
- 4:55 p.m.            **Open Discussion**  
Kenneth Inn, NIST
- 5:40 p.m.            Bus to hotel



**Invited Poster Papers**

1. \* **The Quality Assurance Program at K&S**  
Thomas W. Slowey, Kim R. Working and Larry G. Bryson  
K&S Associates, Inc.  
1926 Elm Tree Drive  
Nashville, TN 37210  
(615) 883-9760
  
2. **Instrument and Calibration Facility**  
James H. Lohaus, Jr., 2Lt. USAF, BSC  
Department of the Air Force  
Armstrong Laboratory (AFMC)  
AL/OEB8D - ICF  
Brooks Air Force Base, TX 78235-5000  
(512) 536-2613
  
3. \* **New Instrument Calibration Facility for the DOE Savannah River Site**  
W. H. Wilkie and E. J. Polz  
Westinghouse Savannah River Company  
P.O. Box 616  
735-A Savannah River Site  
Aiken, SC 29808  
(803) 725-3720  
FAX (803) 725-3272
  
4. \* **QA Experience at the University of Wisconsin Accredited Dosimetry Calibration Laboratory**  
L. A. DeWerd and J. A. Micka  
Department of Medical Physics  
1530 Medical Sciences Center  
1300 University Avenue  
Madison, WI 53706  
(608) 262-6320  
FAX (608) 262-5012
  
5. \* **Services of the CDRH X-ray Calibration Laboratory and Their Traceability to National Standards**  
H. T. Heaton and F. Cerra  
U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
5600 Fishers Lane  
Rockville, MD 20857  
(301) 443-2536 ext. 21  
FAX (301)443-9101

6. \* **U.S. Army Primary Radiation Standards Complex**  
Steve Rogers, William Harris and Paul Pittman  
U.S. Army TMOE Support Group  
ATTN: AMXTM-SR Nucleonics Section  
Radiation Standards and Dosimetry Laboratory  
Redstone Arsenal, AL 36898-5400  
(205) 842-8597  
FAX (205) 876-7611
  
7. \* **Test and Evaluation Capabilities at NAVELEXCEN-Charleston**  
George Anderson and Lee Hinson  
NAVELEXCEN-Charleston  
4600 Marriott Drive  
North Charleston, SC 29418-6504  
(803) 745-4822  
FAX (803) 745-4624
  
8. \* **Immediate Needs for MQA Testing at State Secondary Calibration Laboratories**  
Ray Cline  
Illinois Department of Nuclear Safety  
Calibration Laboratory  
1301 Knotts Street  
Springfield, IL 62703  
(217) 786-7221
  
9. \* **U.S. Department of Energy Laboratory Accreditation Program (DOELAP) for Personnel Dosimetry Systems**  
Doug Carlson  
U.S. Department of Energy  
Radiological and Environmental Sciences Laboratory  
785 DOE Place  
Idaho Falls, ID 83402-1562
  
10. **HPS Accredited Secondary Standards Laboratory**  
Jim Little  
HPS/Eberline
  
11. **FEMA Test Facility**  
Jose Cortes  
FEMA RITF  
Building 217 Special Facility  
P.O. Box 129, Rt. 601  
Berryville, VA 22611

- \* **Factors affecting Quality for Beta Dose Rate Measurements Using ISO 6980 Series 1 Reference Sources**  
R. E. Burns, Jr. and J. M O'Brien, Jr.  
Atlan-Tech, Inc.  
1345 Hembree Road  
Roswell, GA 30076
  
- \* **A Method for Automating Calibration and Records Management for Instrumentation and Dosimetry**  
J. M. O'Brien, Jr., R. O. Rushton, and R. E. Burns, Jr.  
Atlan-Tech, Inc.  
1345 Hembree Road  
Roswell, GA 30076

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# PARTICIPANTS LIST/DISTRIBUTION

APPENDIX B

## WORKSHOP ON MEASUREMENT QUALITY ASSURANCE FOR IONIZING RADIATION

March 16-18, 1993

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