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Performance Testing of Radiobioassay Laboratories: In-Vivo Measurements, Pilot Study Report

Health Physics Department

October 1986

Prepared for the U.S. Department of Energy
and the U.S. Nuclear Regulatory Commission
under Contract DE-AC06-76RLO 1830
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Pacific Northwest Laboratory
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PERFORMANCE TESTING OF RADIOBIOASSAY LABORATORIES: IN-VIVO MEASUREMENTS, PILOT STUDY REPORT

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October 1986

Prepared for
the U.S. Department of Energy
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FOREWORD

In recent years, the U.S. Department of Energy (DOE) and the U.S. Nuclear Regulatory Commission (NRC) have sponsored research to improve occupational radiation protection. Of particular concern to these agencies have been the accuracy, quality control, and performance of personnel radiation dosimeters, radiation survey instruments, and bioassay laboratories. Bioassay measurements include in-vitro excreta analysis and in-vivo external counting.

The U.S. Department of Energy Order 5480.1, Chapter XI (DOE 1983), and the Code of Federal Regulations, Title 10, Part 20 (10 CFR 20), require assessment of occupational radiation exposures. Accurate bioassay measurements are necessary to correctly assess internal exposure to radioactive materials. However, a concern of DOE facilities and contractors, and licensees of the NRC is that bioassay laboratories may not be providing accurate and consistent results. To address this concern, DOE and NRC requested that a Health Physics Society working group be formed to prepare a draft American National Standards Institute (ANSI) standard on bioassay laboratory performance. The resultant document was designated draft ANSI Standard N13.30, Performance Criteria for Radiobioassay.

Draft ANSI Standard N13.30 provides performance criteria in the form of the minimum numerical values that are necessary to meet an acceptable minimum detectable amount (MDA), provides limits for measurement bias (B_r); and specifies the precision (S_A and S_B) required for meeting the Standard. The acceptance values for these criteria have been reviewed and revised throughout the Standard's development process. The DOE is now reviewing the feasibility of an accreditation program for bioassay laboratories serving its facilities and contractors. While the draft Standard was being prepared, NRC issued notice of intent to require licensees to obtain services from "accredited" in-house or commercial laboratories (Federal Register 1981). Presently, however, this notice is not included in the NRC regulatory agenda.

The project described by this document was jointly sponsored by DOE and NRC to evaluate the draft Standard performance criteria by testing the current measurement capabilities of various bioassay laboratories. Thus, the final

performance criteria in the Standard will be based on data from bioassay laboratories. Included in the project was a nationwide, two-round bioassay intercomparison study to test the analytical performance of both in-vitro and in-vivo bioassay laboratories and determine their capability to meet the miniumum performance criteria specified in the draft Standard. Round One is the pilot study involving a small number of voluntary participating laboratories. Round Two will involve a larger number of laboratories and will continue the efforts started in Round One. This report presents the background information pertinent to this program, details the phantom preparation, and reviews the results of the Round One in-vivo measurements.

This document is the second of four reports on the results of the research project. The first report is Performance Testing of Radiobioassay Laboratories: In-Vitro Measurements, Pilot Study Report, NUREG/CR-3809 DOE/NBM 1071, Vol. 1.

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ABSTRACT

This document describes a project to evaluate the in-vivo counting performance criteria of draft ANSI Standard N13.30, Performance Criteria for Radiobioassay. The draft ANSI Standard provides guidance to in-vivo counting facilities regarding the precision and accuracy of measurements for certain categories of commonly assayed radionuclides and critical regions of the body.

The draft ANSI Standard was evaluated by conducting an intercomparison test involving a number of whole-body counting facilities. The testing involved three types of measurements: chest counting for detection of radioactive materials in the lung, whole-body counting for detection of uniformly distributed activity, and neck counting for detection of radioactive material concentrated in the thyroid.

Results of the first-round intercomparison test are presented in this report. The appropriateness of the draft Standard performance criteria was judged by the measurement results reported by participating in-vivo counting facilities. The intercomparison testing showed that some laboratories had difficulty meeting the performance criteria specified in the draft ANSI Standard N13.30.

EXECUTIVE SUMMARY

To evaluate the appropriateness of draft American National Standards Institute (ANSI) Standard N13.30, Performance Criteria for Radiobioassay, the U.S. Department of Energy (DOE) and the U.S. Nuclear Regulatory Commission (NRC) jointly sponsored a research program at the Pacific Northwest Laboratory (PNL). This report documents the first round of a two-round nationwide bioassay intercomparison tudy to test the analytical performance of in-vivo bioassay laboratories and determine their capability to meet the minimum performance criteria specified in the draft Standard. Background information pertinent to this program, details of phantom preparation, and the results of the Round One in-vivo measurements are presented.

Of the 15 facilities that participated in the whole-body and lung counting portions of the in-vivo study, most failed to meet the performance criteria specified in the draft ANSI Standard, particularly for measurement of ^{60}Co and ^{137}Cs in the whole body and ^{60}Co in the lung. Only one in fifteen laboratories passed all three criteria for whole-body counting of ^{144}Ce at the levels tested. A majority of the 22 facilities participating in the ^{131}I determination did not fail, but 4 facilities failed the bias criterion by a wide margin, and 4 facilities failed the MDA criterion; some failed both. Facilities that participated in the ^{241}Am and ^{235}U lung counting categories were generally able to meet all of the performance criteria.

In each category tested, the large diversity in performance, indicated that the techniques necessary to successfully count radioactivity in phantoms at the test levels are available but are not always used. The exception is ^{144}Ce, where it appears that the test levels are below current detection capabilities when comparable amounts of higher-energy interfering nuclides (^{60}Co, ^{137}Cs, etc.) are present.

Recommendations provided to the working group preparing draft ANSI Standard N13.30 included comments regarding the following:

- standardization of count times and background determinations used for MDA calculations

- effects of interference nuclides in the test phantom on MDA
- the need for explanations of the selection criteria (state-of-the-art, health physics needs, etc.) for acceptable MDAs
- the desirability of using point sources rather than uniformly distributed activity for short half-life, mixed fission, and activation products in the lung phantom
- calculation of relative bias and relative precision.

ACKNOWLEDGMENTS

The Health Physics Department wishes to acknowledge the assistance of Mr. H. Earl Palmer and Mr. Gunars A. Rieksts of PNL for preparing low-level radioactive lung phantoms and for providing a crosscheck of activities in the whole-body, neck and torso phantoms. We appreciate the donation of a neck and thyroid phantom by Mr. Sam Alderson of Humanoid Systems (Carson, California). The radionuclide standard solutions used in this project were prepared by the staff of the Radioactivity Group of the National Bureau of Standards under the direction of Dr. J. M. R. (Robbin) Hutchinson and Dr. Ken G. W. Inn; we also appreciate their many valuable suggestions regarding radionuclide handling and dilution. Finally, we wish to thank our word processor, M. Cross; our editor, A. Marshall.

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INTRODUCTION

The measurement and quantification of radiation is the foundation of radiation protection. However, radioactivity measurements are subject to a wide variety of potential errors and uncertainties. The quality of measurement results depends on the quality of calibration techniques, quality control procedures, human factors, and quality of the detector systems employed.

The U.S. Department of Energy (DOE) and the U.S. Nuclear Regulatory Commission (NRC) are concerned with the quality of radiation measurements that are used to determine worker exposures to sources of radioactivity, and have in recent years sponsored research to improve standards for radiation measurements. Of particular concern to these agencies is the accuracy and precision of personnel radiation dosimeters, radiation survey instruments, and bioassay laboratories, including facilities that perform in-vivo measurements (whole- or partial-body external counting).

Research projects have involved the performance testing of personnel dosimetry services in support of ANSI Standard N13.11 (Yoder et al. 1979; Plato and Hudson 1980; Plato and Miklos 1983; Roberson and Holbrook 1984), the technical evaluation of the capability of radiation protection survey instrumentation to meet the performance specifications of draft ANSI Standard N42.17 (Selby et al. 1983; Swinth et al. 1983; Kenoyer et al. 1983), and the study of in-vitro radiobioassay laboratory performance in the technical evaluation of draft ANSI Standard N13.30 (Robinson, Fisher and Hadley 1984). The research documented in this report assesses the performance of in-vivo counting facilities so that the appropriateness of the sections of draft ANSI Standard N13.30 Performance Criteria for Radiobioassay dealing with in-vivo counting may be evaluated.

BACKGROUND FOR THIS RESEARCH PROGRAM

Radiobioassay may be defined as the quantitative assessment of radionuclides in humans exposed to radioactive materials. In-vitro sample analysis, or "indirect bioassay," involves the measurement of radioactivity in urine, feces, or other biological materials taken from the body. In-vivo counting,

or "direct bioassay," involves measurements of radiations emitted from the body using external detector systems. Usually a combination of indirect and direct bioassay are used to estimate a worker's burden of internally deposited radioactivity. Accurate bioassay measurements are necessary to determine the radionuclide deposition in the body and thus the internal radiation exposure received by workers with internal deposition of radionuclides.

External counting of the whole body or of specific regions of the body is a method for estimating depositions of photon-emitting radionuclides and some beta-emitting radionuclides. Highly specialized detectors and spectrum analyzers are required. Shielding is also important for reducing external background radiation. Whole-body counting facilities for direct bioassay measurements are located at national laboratories, commercial nuclear power generating stations, universities, medical institutions, and some private companies. In addition, whole- and partial-body counting facilities are available from private service laboratories and mobile counting laboratories.

Haskins, Earls and Hudson (1982) conducted a survey of whole-body counting facilities at nuclear sites in North America to determine the status of instrumentation and equipment, data processing capabilities, operator training and qualifications, investigation and action levels, and future trends in whole-body counting. The survey reported that in-vivo counting was the primary method for determining internal contamination by radioactive materials. Their report also showed that there were wide variations in in-vivo counting practices from one facility to another.

Proper interpretation of in-vivo measurement results requires that the counting equipment be calibrated for the radionuclide energies and intensities involved. Energy calibration provides the correct identification of radionuclides. Intensity calibration provides knowledge of the counting efficiency and the correct quantification of the radionuclide activity. In-vivo counters are usually calibrated with known amounts of radionuclide sources in phantoms that simulate the human body. The radiation absorption characteristics of the phantoms and the geometrical distribution of the sources must be known by the technician operating the counting system.

The quality and reliability of in-vivo counting services is highly variable due to the variety of available facilities, detectors and electronic equipment, to the natural background differences, to the quality and accuracy of computer software packages used for spectral analyses, and to the training of operating personnel. Analytical methods for in-vivo counting are not currently standardized, and there are a number of different methodologies at whole-body counting service laboratories. There are, however, many aspects common to bioassay program management, including quality control, calibration, recordkeeping, and intercomparison tests.

To establish standards of bioassay performance upon which a uniform national program of performance testing of in-vivo and in-vitro bioassay laboratories could be based, DOE and NRC asked the Health Physics Society to form a working group to develop radioactivity measurement performance criteria for an American National Standard Institute (ANSI) standard. In 1979, at the request of Robert E. Alexander, NRC, the Health Physics Society Standards Committee, chaired by Edward J. Vallario of DOE, formed Working Group 2.5 to prepare ANSI Standard N13.30, Performance Criteria for Radiobioassay. The group was chaired by Kenneth R. Heid of the Pacific Northwest Laboratory (PNL). The initial draft of the bioassay Standard was completed in 1981. Subsequent drafts have been produced from time to time since then.

The primary reason for the proposed Standard is the concern that bioassay service laboratories, both commercial and institutional, may not be providing accurate results for analyses performed. A number of factors may contribute to analytical inaccuracy:

- Current analytical procedures may be deficient.
- Neither uniform standards of performance nor standard methods of analysis have been adopted.
- Lack of motivation or financial constraints may inhibit the upgrade of analytical capabilities. State-of-the-art instrumentation is expensive.
- Quality assurance may be deficient. This may involve a lack of adequate calibration procedures or a lack of written procedures.

Although a formal system for certifying the bias, precision, and quality control of bioassay laboratory procedures has not been established, NRC issued advance notice of proposed rulemaking that would require NRC licensees to use accredited laboratories after NRC establishes an accreditation program (Federal Register 1981). However, this is not presently on the NRC regulatory agenda. In addition, DOE is reviewing the feasibility of a similar accreditation program for its laboratories and contractor laboratories. Most bioassay laboratories welcome the concept of accreditation.[a] An accreditation program would be based on recommendations contained in the final version of ANSI Standard N13.30.

Draft ANSI Standard N13.30 provides quantitative performance criteria for bias and precision in radiobioassay measurements for a selected list of in-vitro and in-vivo measurement categories and commonly assayed radionuclides. Standard quality control guidelines are also provided for the internal quality assurance programs of radiobioassay laboratories. Draft versions of the Standard have included criteria to be used by a testing laboratory for assessing whether bioassay service laboratories conform to quantitative performance criteria (such as might be employed in an accreditation program) for bias and precision.

PROJECT PURPOSE

The purpose of this research project is to evaluate the appropriateness of draft ANSI Standard N13.30 performance criteria. A two-round bioassay performance intercomparison study is being conducted by the Pacific Northwest Laboratory (PNL). This study, which was begun at about the time the first draft of the Standard was completed, has several objectives:

(a) From an informal survey by Dr. Allen Brodsky, NRC, of participants at the 28th Annual Conference on Bioassay, Analytical and Environmental Chemistry, October 13-14, 1982, at Natick, Massachusetts. Discussions by the authors with bioassay laboratory participants in this intercomparison further support this statement.

- Conduct two rounds of in-vitro and in-vivo intercomparison testing.
- Compile results and compare the performance of laboratories to the draft Standard performance criteria.
- Recommend any necessary revisions to the draft Standard.
- Prepare a procedures manual for conducting an ongoing performance testing program for bioassay laboratory accreditation or certification.

The work involves three major phases: 1) develop testing procedures and prepare test samples and in-vivo test phantoms, 2) conduct a pilot intercomparison study with a small number of voluntarily participating laboratories, and 3) conduct a second-round intercomparison study (yet to be completed) involving a larger number of participating laboratories. A procedures manual and a project final report are planned as part of the third phase.

This document contains the results of the jointly sponsored pilot study intercomparison testing (round one) involving a limited number of in-vivo counting facilities.

STATISTICAL INDICATORS OF MEASUREMENT PERFORMANCE

A laboratory may be judged on its ability to accurately measure radionuclide inventories, to reproduce results consistently, and to detect radionuclides at reasonably low levels. Opinions among experts vary, though, about what is meant by "accurately measure," "consistently reproducible results," and "reasonably low levels."

For example, the National Council on Radiation Protection and Measurements (NCRP) recommended that "for the purposes of radiation protection, the desirable accuracy of activity or dose estimates should be within ±30 percent, particularly at levels on the order of the maximum permissible dose" (NCRP 1978 §4.3.1.4).

ANSI Standard N44.3-1973, Thyroid Radioiodine Uptake Measurements Using a Neck Phantom, provides guidance on the reference activity (source) and the neck phantom to be used for the thyroid radioiodine uptake measurement, the measuring equipment to be used, and some procedural aspects that should be considered to obtain valid test results. It does not, however, specify measurement performance criteria for in-vivo thyroid counting (ANSI 1973).

ANSI Standard N343-1978, American National Standards for Internal Dosimetry for Mixed Fission and Activation Products, provides performance criteria for direct analysis of internally deposited fission and activation products by in-vivo counting, but no minimum values for absolute accuracy or precision are specified:

> The in-vivo system detector shall be sufficiently shielded and located to allow measurements of 5% of the MPOB [maximum permissible organ burden] of the radionuclides listed ... for at least 95% of the in-vivo measurements performed. The radiation background of the system should not be significantly influenced by variations in ambient fields caused by piping or ventilation systems or by the movement of radioactive materials. The facility should be located or constructed (or both) such that personnel-decontamination facilities are not directly associated with areas containing radioactive material....[15.1] Because of the importance of accuracy in in-vivo determinations, an effort should be made to participate in an intercalibration program where several facilities can compare results using the same standard phantom (or geometry) with sources having calibrations traceable to the National Bureau of Standards....The

precision for each phantom-activity combination shall be recorded as the upper and lower bounds defined by the distribution mean, plus or minus the three-standard-deviation value associated with the distribution (ANSI 1978).

Draft ANSI N13.30 Standard currently provides performance criteria for judging the quality of measurements performed by an in-vivo counting system. Performance is judged by three specific criteria: the relative bias, the relative precision, and the minimum detectable amount (MDA) of a particular radionuclide. The following sections detail how these criteria are calculated and what are acceptable levels for each criterion.

RELATIVE BIAS

The relative bias is a statistical indicator of how close the measurement results are to the true activity in a particular organ or in the whole body. Since the actual activity must be known to calculate this number and since this is rarely known in human subjects, the relative bias can be calculated only for measurements on phantoms or on other suitable mockups.

The draft Standard defines the relative bias, B_R, for a single measurement as the difference between the measured activity (or amount), A, and the actual activity (or amount), A_a, divided by the actual activity:

$$B_R = \frac{A - A_a}{A_a} \qquad (1)$$

For N measurements of the activity, the relative bias is calculated as the average value of the relative bias:

$$\overline{B}_R = \frac{1}{N} \sum_{i=1}^{N} B_R \qquad (2)$$

PRECISION AND RELATIVE PRECISION

The precision of a group of replicates is a statistical measure of how closely the replicate answers are grouped together. The draft Standard defines the precision, S_a, as:

$$S_a = \sqrt{\frac{1}{N-1} \sum_{i=1}^{N} (A_i - \bar{A})^2} \qquad (3)$$

where the number of measurements, N, is at least five, and A_i is the measured activity in the ith measurement. $\bar{A}$ is the average value of A_i, where:

$$\bar{A} = \frac{1}{N} \sum_{i=1}^{N} A_i \qquad (4)$$

For clarity and to cast the precision in the same fraction form as the bias, we are defining a term called the relative precision, $S_{\bar{A}}$, as:

$$S_{\bar{A}} = \frac{1}{\bar{A}} \sqrt{\frac{1}{N-1} \sum_{i=1}^{N} (A_i - \bar{A})^2} \qquad (5)$$

MINIMUM DETECTABLE AMOUNT

Because radioactive decay is a random process, all measurements of activity are limited to a lesser or greater degree by counting statistics. For a given counting system, as the level of detection is pushed lower and lower, there will be a point at which the counts from the radioisotopes being measured will be lost in the background noise of the system. Two types of error can occur when activities near the detection limits are being measured. Type I statistical errors occur when activity is determined to be present when, in fact, there is no activity. Type II statistical errors occur when a certain level of activity is present but is undetected hy the counting system because of random errors.

The draft Standard recommends the calculation of a quantity called the "minimum detectable amount" (MDA) for a given isotope and counting system. The value of the MDA indicates the ability of a counting facility to discern between the count rate from the desired radionuclide and that from an appropriate blank. The value of the MDA is calculated from:

$$MDA(1) = k_\alpha / C \sqrt{B/T + S_B^2} \qquad (6)$$

where

k_α = multiple of the standard deviation to obtain the α risk level for a type I statistical error; at the 95 percent confidence level, $\alpha = 0.05$, and $k_\alpha = 1.645$

C = the count rate per unit activity; when C is a function of variables such as body stature, gamma energy, size, or chest thickness, the value for the average person shall be used for describing the measurement capability of the counting facility

B = count rate in the region of interest from an appropriate blank

T = counting time of subject

S_B = uncertainty (standard deviation) in the value B.

Working Group 2.5 is considering another formula for calculating the MDA from a series of measurements:

$$MDA(2) = \frac{1}{C} \left[4.65\ S_B + \frac{3}{T}\right] \qquad (7)$$

where C, S_B, and T are as defined above.

The MDA formula is "MDA(1)" and the formula presently under consideration is "MDA(2)." The principal difference between these two formulas is that the MDA(1) formula protects against type I errors (95 percent of the time) the MDA(2) formula protects against both type I and type II errors (95 percent of the time). For comparison, both MDA calculations were done using the data from the intercomparison study.

MINIMUM PERFORMANCE CRITERIA

Table 1 shows one possible system considered by Working Group 2.5 for limiting values of acceptable bias, precision, and MDA. These were the performance criteria chosen at the time our phantoms were being fabricated for this pilot study. Several of the limits have changed in the later drafts and are still subject to revision by the working group.

TABLE 1. Categories and Performance Criteria for Round One In-Vivo Testing

Category	Organ	MDA (nCi)	Bias	Relative Precision
Measurement of ^{241}Am representing photons with energy ≦60 keV	Lung	0.3	0.20	0.15
Measurement of ^{235}U	Lung	0.2	0.20	0.15
Measurement of ^{60}Co representing photons with energy >200 keV	Lung	60.0	0.20	0.15
Measurement of nuclides uniformly distributed in the total body:				
^{60}Co	Whole Body	50.0	0.20	0.15
^{137}Cs		60.0	0.20	0.15
^{144}Ce		450.0	0.20	0.15
Measurement of ^{131}I representing nuclides in the thyroid	Thyroid	10.0	0.20	0.15

The draft Standard describes acceptable MDAs[(a)] for each of seven categories of in-vivo measurements in units of activity per nuclear transformation (radioactive decay) corrected for the photon efficiency of the transformation. For example, the draft Standard specifies an acceptable MDA[(a)] of 0.1 nCi/(photon of interest per nuclear transformation) for the measurement of ^{241}Am in the lung. Since the 60 keV photon of ^{241}Am has an abundance of 36 percent, the acceptable MDA[(a)] is 0.1 nCi/0.36 = 0.3 nCi. A similar calculation for ^{235}U shows the acceptable MDA[(a)] to be 0.2 nCi.

(a) Early versions of the draft standards referred to the calculated lower detection limits as the "minimum specific photon activity (MSPA)." The committee has called this limit the MDA in later drafts to unify the language in the in-vivo and in-vitro standards.

PILOT STUDY PROTOCOL

Participants for Round One of the in-vivo intercomparison test were selected from among whole-body counting facilities and medical institutions. The intercomparison involved measurements on three types of phantoms:

- a whole-body bottle phantom for measurement of radionuclides uniformly distributed throughout the body
- a Realistic torso phantom with interchangeable lung sets for measurement of radioactivity in the lungs
- neck and thyroid phantoms for measurement of radioactivity in the thyroid gland.

The whole-body phantom and the torso phantom were prepared and shipped to one participating in-vivo counting laboratory at a time. Small ^{131}I capsules[(a)] were shipped simultaneously to laboratories participating in the thyroid counting intercomparison. Each facility loaded the capsules in their own phantoms, and then the phantoms were counted. The measurement results were returned to PNL.

LABORATORY PARTICIPATION

Invitations to participate in the intercomparison study were extended during the 27th Conference on Bioassay, Analytical and Environmental Chemistry in 1981. Announcements regarding the opportunity to participate in the study were also published at various times in the Newsletter of the Health Physics Society. Invitations to participate and details of the testing were mailed to about 40 bioassay laboratories that had responded to the announcement and to other potential participants. With each invitation was a response form and this information:

- participation would be entirely voluntary.
- all costs pertaining to the measurement of samples or phantoms would be borne by the participating laboratory.

(a) Prepared and shipped by Dr. K. G. W. Inn and Dr. J. M. S. Hutchinson of the Radioactivity Group at the National Bureau of Standards.

- all laboratory names, categories of participation, and the identification of individual results would be strictly confidential to allow uninhibited participation.

In-vivo counting facilities responding favorably to the invitation to participate were then contacted by telephone. Further information and instructions regarding the study were sent to each interested participant.

Seven in-vivo measurement categories were offered during the first round of testing:

- lung measurements for ^{241}Am
- lung measurements for ^{235}U
- lung measurements for ^{60}Co
- whole-body measurements for ^{60}Co, ^{137}Cs, ^{144}Ce
- thyroid measurements for ^{131}I.

Table 2 shows the test radionuclides and activity ranges for in-vivo performance testing that were chosen for the first-round intercomparison study. The radionuclides were selected from a list in an early version of draft ANSI Standard N13.30. Strontium-90 and/or ^{40}K were added to the phantom to

TABLE 2. Test Radionuclides, Organs, and Activity Ranges for Direct (In-Vivo) Performance Testing (from 1982 draft of ANSI Standard N13.30)

Category	Organ	Radionuclide(s)	Acceptable Activity Test Ranges (nCi)
Photons with energy ≤60 keV	Lung	^{241}Am(a)	1.0-10.0
Photons with energy 100-200 keV	Lung	^{235}U(a)	0.75-7.5
Photons with energy >200 keV	Lung	^{60}Co(a)	40.0-400
Uniformly distributed fission and activation products	Whole Body	^{60}Co ^{137}Cs ^{144}Ce(b)	200-2000 250-2500 300-3000
Radionuclides in the thyroid	Thyroid	^{131}I	40.0-400

(a) With ^{40}K present.
(b) With ^{40}K and ^{90}Sr present.

provide an intentional background "interference" so as to more closely represent the actual counting of human subjects. The acceptable test ranges given in Table 2 have been changed in later versions of the draft Standard.

Fifteen facilities participated in the lung and whole-body counting. These included five national laboratories, one university, one fuel fabrication facility, and eight reactor sites with whole-body counting capabilities. Laboratories were given the option of performing measurements in any or all of the above categories, depending on individual need and interest. In general, DOE-contractor laboratories were interested in performing all the above measurements, whereas NRC-regulated facilities were primarily interested only in measurements involving fission and activation products or uranium.

PREPARATION OF IN-VIVO PHANTOMS

An initial task of this study was to prepare phantoms with precisely known levels of radionuclides. Under an interagency agreement between the National Bureau of Standards (NBS) and NRC, NBS provided calibrated, standardized radioactive stock solutions for this project. The radionuclides were shipped to PNL in flame-sealed glass ampules. Standard solutions of radioactive materials were then carefully prepared from the stock solutions by gravimetric dilution.

Torso Phantom with Lungs

A Realistic Torso Phantom (Humanoid Systems, Carson, California)[(a)] was obtained for the chest counting intercomparison study (Figures 1 and 2). The phantom is based on a design by Lawrence Livermore National Laboratory (LLNL). The molds and specifications for the phantom were developed during a DOE-sponsored research program at LLNL (Griffith et al. 1979). The phantom, constructed of tissue-equivalent materials and simulated bone, simulates a

(a) Reference to a company or product name does not imply approval, recommendation, or endorsement by Pacific Northwest Laboratory, the U.S. Nuclear Regulatory Commission, or the U.S. Department of Energy to the exclusion of other companies or products that may be suitable.

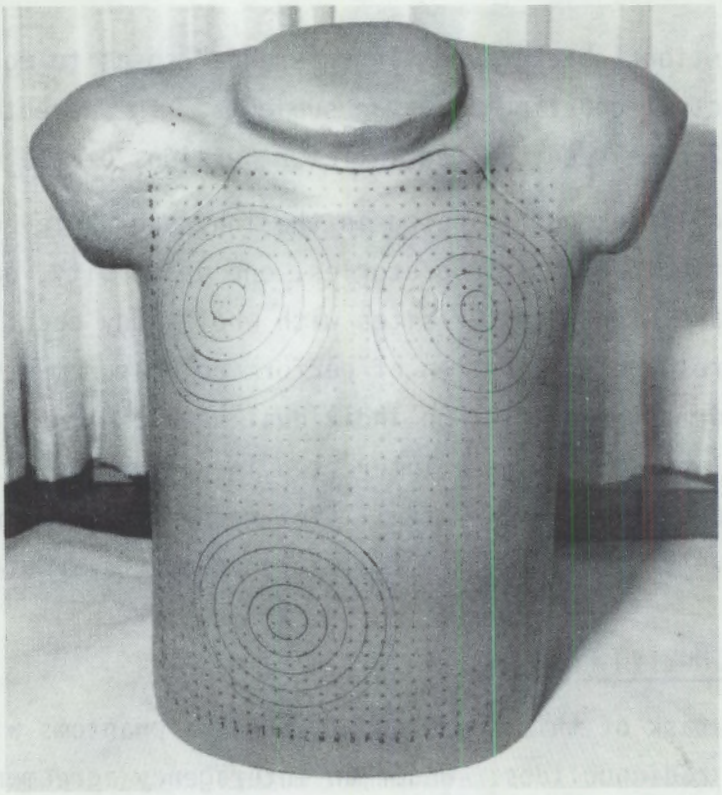

FIGURE 1. Lawrence Livermore Realistic Torso Phantom (Humanoid Systems, Carson, California). The chest is marked for positioning of detectors over the right and left lungs and the liver.

human male torso, without head or arms, terminated at the pelvis. The skeleton of the phantom resembles the human skeleton and rib cage in shape, constitution, and position in the phantom. The simulated tissues, consisting of polyurethane with different concentrations of calcium carbonate, have transmission and scatter characteristics for low-energy photons that approximate those of normal human tissues.

The torso phantom contains an interchangeable pair of simulated lungs of density similar to human lungs. The lungs are exchanged by removing the chest plate. The effective chest wall thickness of the plate for two 5-in. diameter areas over the lungs was certified by the manufacturer to be 1.52 cm for the right lung and 1.60 cm for the left lung. The phantom also contains interchangeable abdominal, heart, and lymph node components.

FIGURE 2. Lawrence Livermore Realistic Torso Phantom (Humanoid Systems, Carson, California) with Chest Cover Removed, Exposing the Interchangeable Internal Organs

The heart block of the torso phantom was drilled to receive a sealed capsule containing approximately 80 nCi of enriched ^{40}K. The ^{40}K source provided a source of natural potassium background interference for the lung counting measurements.

One lung pair containing ^{241}Am and one pair containing ^{235}U were obtained from the same supplier (Humanoid Systems, Carson, California). These lungs consisted of foam polyurethane with calcium carbonate added to approximate the density and photon attenuation of human lungs. The radionuclides were sent to the supplier by NBS (under contract with NRC) and were incorporated into the lungs (Figure 3). The manufacturer originally certified the activity of the lung sets to be 3.73 nCi for the ^{241}Am lungs and 2.75 nCi for the ^{235}U lungs. However, following the first round of in-vivo testing, an average negative

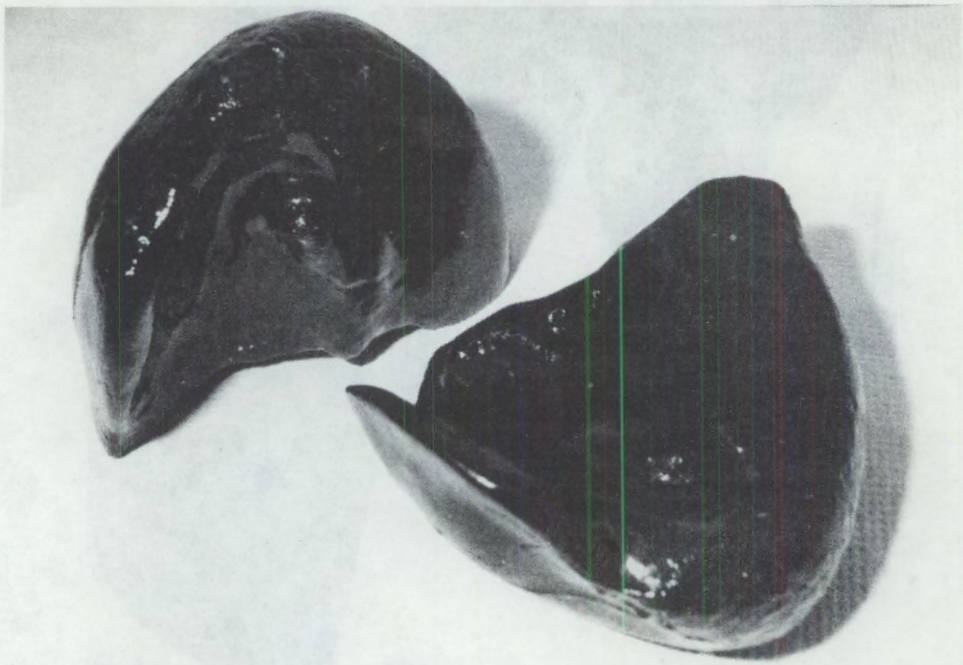

FIGURE 3. Livermore Phantom Lungs (Humanoid Systems, Carson, California)

bias of 32.5 percent was observed for ^{241}Am and 11.0 percent for ^{235}U. The two lung sets were then subjected to a series of crosscheck analyses to recalculate their absolute activities.

Several standard americium and uranium lung sets were obtained from Lawrence Livermore National Laboratory, Livermore, California. These lung sets, containing known amounts of radionuclide, were all counted at the PNL whole-body counting facility. Six intrinsic germanium planar detectors were used, and each lung set was counted in the same phantom and position. The phantom was lowered only to exchange lung sets, and then it was raised to the fixed position once again. The results of this procedure are given in Table 3.

TABLE 3. Intercomparison Assessment of ^{241}Am Inventory in Phantom Lungs

Lung Set	Counting Time (sec)	Net cpm	cpm per nCi	^{241}Am Content (nCi)
1	80	36,405	15.1	2,430
2	300	9,521	15.4	620
3	300	7,953	16.2	492
4	300	8,731	14.9	587
Torso Phantom	20,000	47.3	15.4(a)	3.07(b)

(a) Average counting efficiency of lung sets 1-4.
(b) Lung content calculated by applying the average counting efficiency to the net cpm obtained.

Using the average calibration factor for the four standard lung sets (15.4 cpm per nCi), the ^{241}Am content of the phantom lungs was calculated to be 3.07 nCi. When this value was used as the correct content rather than the 3.73 nCi reported by Humanoid Systems, the average bias in the intercomparison study changed from -32.5 percent to -5.6 percent ±6.0 percent.

The phantom lung set containing ^{235}U was measured to establish the radioactivity content. Based on these measurements, the ^{235}U inventory was corrected from the reported value of 2.75 to 2.35 nCi and the average bias in the intercomparison study was changed from 11.0 percent to 5.6 percent (±14.3 percent).

A third pair of polyurethane lungs containing ^{60}Co was prepared at PNL for the intercomparison study. The desired amount of ^{60}Co (in hydrochloric acid, as supplied by NBS) was obtained by gravimetric dilution and added to one part of a two-component polyurethane polymer (CPR-1940D-black, Upjohn Company, Torrance, California). To part B were added 8 g acetone, 0.4 g water, lanthanum nitrate carrier, and 10 drops of catalyst. Part A of the polymer was added to part B, and the mixture was shaken for about five seconds then poured into a two-piece silicone rubber mold where uniform foaming and polymerization occurred. The mold was then placed in an oven and baked at 50°C for one hour.

An identical set of cobalt lungs was prepared at the same time so that the uniformity of the mixture and the accuracy of the radionuclide inventory could be confirmed. The extra set of ^{60}Co-labeled lungs was cut up into 35 samples. Each of these individual pieces was counted using a shielded sodium-iodide [NaI(Tl)] well detector. The specific activities of the 35 samples were approximately normally distributed with a mean value of 104 dpm/g and a sample standard deviation of 4.5 dpm/g. The sum of the inventories of the individual samples agreed (±3 percent) with the calculated activity that was incorporated into the lung set.

Whole-Body Bottle Phantom

A "BOMAB" polyethylene whole-body bottle phantom, consisting of ten sturdy polyethylene circular or elliptical right cylinders, was purchased (EMI Gencom, Inc., Plainview, New York). Each cylinder was fitted with a sturdy screw-cap for filling (Figure 4). The bottles of the phantom were of various sizes and volumes approximating the whole-body proportions of an adult male of average stature (Table 4).

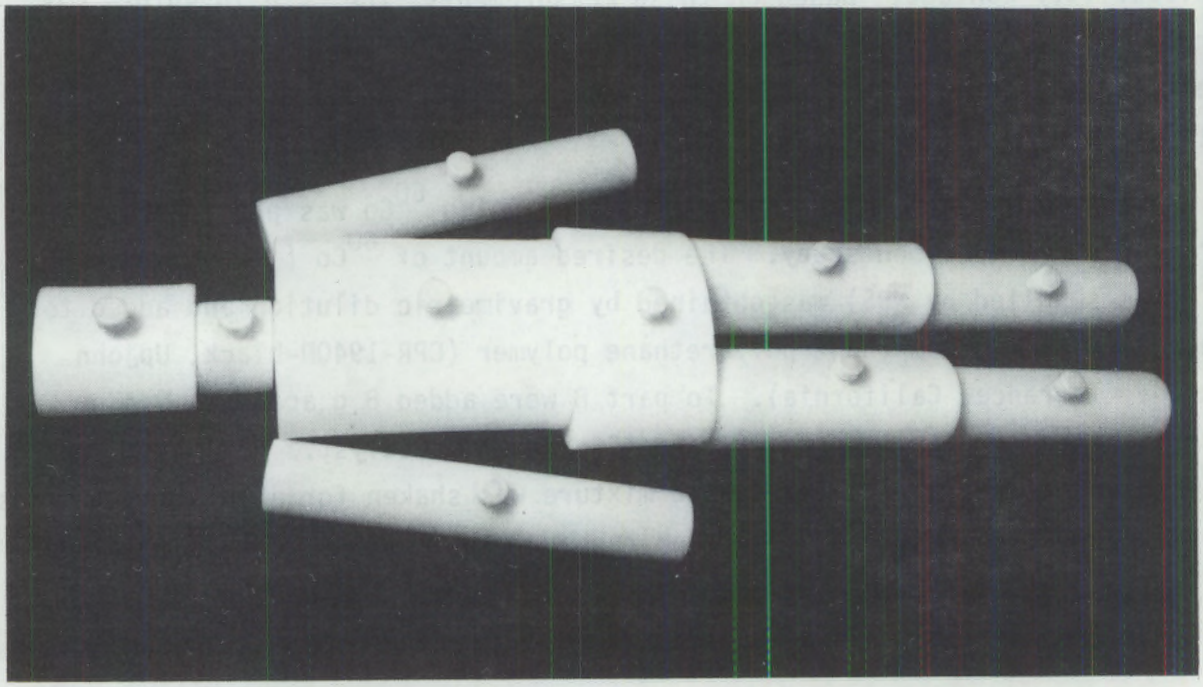

FIGURE 4. Ten-Piece "BOMAB" Polyethylene Bottle Phantom (EMI Gencom, Inc., Plainview, New York)

TABLE 4. Dimensions of Phantom Bottles Representing Human Body Parts

Part	Shape	Cross Section (cm)	Length (cm)
Head	Ellipse	19 x 14	20
Neck	Circle	13	10
Thorax	Ellipse	30 x 20	40
Arms (2)	Circle	10	60
Abdomen	Ellipse	36 x 20	20
Thighs (2)	Circle	15	40
Legs (2)	Circle	12	40

Each of the bottles of the phantom were filled with a concentrated gelatin mixture containing precisely known amounts of certain radionuclides and potassium chloride. The potassium provided a whole-body distribution of the naturally existing radionuclide ^{40}K in an amount corresponding to approximately 1.6 nCi/kg of body weight (130 nCi in the whole body).

The gelatin mixture was prepared by adding approximately 300 g (40 packets) of Knox® Gelatin to 2.5 L of distilled water in a large beaker and stirring with a magnetic bar. After the stirring bar was removed, the beaker was placed on a balance and additional distilled water was added until the weight reached 3 kg. A few drops of red food coloring were added, and the beaker was placed in an autoclave for final dissolution of the gelatin. Several similar batches of gelatin mixture were prepared.

The hot gelatin mixture was poured into the phantom segments until the bottles were about one-half full. A radioactive standard solution was prepared containing the following radionuclides suppled by NBS: ^{144}Ce (7.90 nCi/g), ^{137}Cs (0.996 nCi/g), ^{60}Co (0.746 nCi/g), and ^{90}Sr (0.685 nCi/g). Natural ^{40}K was added as KCl. An appropriate amount of standard (2.870 g per kg filled segment weight) was added, and each bottle was filled to the base of the filling spout, shaken, and placed in a refrigerator to jell. The neck of

® Registered trademark of Knox Gelatin, Inc., Englewood Cliffs, New Jersey.

TABLE 5. Activity of ^{60}Co, ^{137}Cs, ^{144}Ce, ^{90}Sr, ^{40}K in the Whole-Body Bottle Phantom

Phantom Part	pCi/g in Each Phantom Segment[a]		
	^{60}Co	^{137}Cs	^{144}Ce
Head	2.066	2.760	21.88
Neck	2.081	2.781	22.04
Thorax	2.076	2.766	21.94
Arm	2.081	2.776	22.00
Arm	2.071	2.766	21.92
Abdomen	2.076	2.771	21.98
Thigh	2.081	2.776	22.00
Thigh	2.112	2.817	22.34
Leg	2.086	2.781	22.05
Leg	2.143	2.863	22.69
Average	2.086 ± 0.026	2.786 ± 0.031	22.08 ± 0.25
Total Activity nCi	145.0 ± 2.7	193.6 ± 3.9	1535 ± 90

(a) Activity as of 2/17/83; ^{90}Sr and ^{40}K present as interference only;
^{90}Sr = 133.1 ± 3.0 nCi in the entire phantom
^{40}K = 113.3 ± 1.1 nCi in the entire phantom.

each bottle was then sealed with silicone rubber, and the bottles were tightly capped. The calculated activity per gram for each segment and the calculated activity in the whole phantom are given in Table 5. The standard deviations of the average listed in Table 5 are calculated assuming linear propagation of the error in the NBS standard and using the weighting errors associated with the phantom preparation.

Thyroid Counting

For the Round One thyroid counting intercomparison, the 22 participating laboratories used their own calibration phantoms.[a] Only source capsules (vials) containing the short-lived radionuclide ^{131}I were provided.

(a) Most of the participating facilities used a neck phantom prescribed by the American National Standards Institute (see ANSI 1973).

The ^{131}I sources (half-life = 8.021 d) were prepared at NBS by the Radioactivity Group. Approximately 15 mg of solution containing a known concentration of the short-lived radionuclide ^{131}I was dried on a 6.4-mm diameter disc of amberlite anion-exchange resin-impregnated paper. The disc was enclosed in adhesive tape and centered in a polyurethane vial with polyurethane spacers. The plastic vial was then capped and sealed with polyurethane cement. Dimensions of the plastic vials are given in Figure 5.

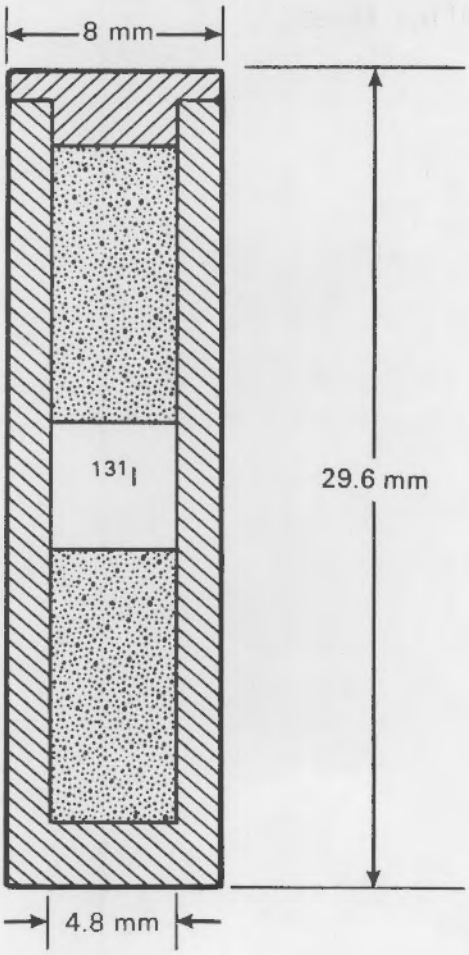

FIGURE 5. Dimensions of Plastic Vials Containing ^{131}I

Each plastic vial was then calibrated by NBS to determine the amount of ^{131}I contained in it using a 4 π pressurized ionization chamber. The total random plus systematic uncertainty of the calibration procedure was 2.3 percent for each vial.

Vials were identified by number. Two ^{131}I vials were shipped by air express to each of the 25 participating in-vivo counting laboratories. The participants were instructed to place the vials in the thyroid position of their normal thyroid counting calibration phantom and perform five separate counts using normal counting times.

RESULTS OF THE INTERCOMPARISON PILOT STUDY

The results of the first-round in-vivo intercomparison are presented in Tables 6 through 12 (beginning on page 28). A separate table of results is presented for each radionuclide assayed. The facilities are identified by code number to maint in confidentiality. Some participating laboratories failed to report their measurement results. These tables show the activity present (corrected for decay at time of measurement), the mean assay obtained from five separate measurements, and the calculated values for the three performance criteria: relative bias, precision (and relative precision), and minimum detectable amount (MDA). The MDAs are calculated using two different formulas [MDA(1) and MDA(2)]. Failure to meet any one of the criteria resulted in failure for the category. The two subheadings under the pass/fail column relate to the different methods used to calculate the MDAs. The MDA(2) criterion is stricter than the MDA(2) criterion, so passing MDA(2) ensures passing MDA(1).

Many of the respondents apparently did not realize that replicate background counts were necessary to calculate an MDA and only reported a single background count.

Figure 6 (page 28) is a scatter diagram of the mean assay reported by each respondent for measurement of ^{241}Am in the lung. The double-dashed line in the center of the diagram represents complete agreement of the measured activity and the true activity. The dashed-and-dotted lines at -20 and +20 percent relative bias indicate the limits recommended in the draft Standard for this criterion. Measurement results lying to the left of the center line were biased negatively; those to the right were biased positively. Data points lying between the two 20-percent relative bias lines have acceptable bias, and those outside the two lines have unacceptable bias.

Similar scatter diagrams for ^{235}U in the lung, for ^{60}Co in the lung, for ^{60}Co, ^{137}Cs, and ^{144}Ce in the whole body, and for ^{131}I in the thyroid are presented in Figures 7 through 12, respectively. The precision for each measurement set is given in Tables 6 through 12. (Error bars giving an indication of the precision of each set of measurements would make the diagrams incomprehensible.)

In the intercomparison test for ^{241}Am in the lung, four facilities reported and two other facilities failed to report. All four respondents passed the relative bias criterion and the relative precision criterion. One laboratory failed to provide replicate background counts so that the MDA criterion could not be calculated for that laboratory. Of the remaining three respondents, all three passed the MDA(1) criterion, and one passed the MDA(2) criterion.

For the intercomparison of measurement of ^{235}U in the lung, five facilities reported and two others failed to report. Of the five respondents, all passed the relative precision criterion, and four passed the relative bias criterion. Two failed to provide replicate background counts, one of which was the respondent that had failed bias. Of the four respondents passing bias and precision criteria and providing replicate background counts, two passed MDA(1), and one passed MDA(2).

Thirteen facilities reported results for the measurement of ^{60}Co in the lung -- two others did not report. Of the 13 respondents, all passed the relative precision criterion, but only five passed the relative bias criterion. One of the five that passed the bias criterion failed to provide replicate background counts. Among the four remaining facilities, all passed the MDA(1) and MDA(2) criteria.

For the intercomparison of measurements of ^{60}Co in the whole body, 13 facilities reported and two others failed to report. Of the 13 respondents, one failed the relative precision criteria (but passed the relative bias criterion), and five failed the relative bias criterion. From among the seven facilities passing both the bias and the precision criteria, two failed to provide replicate background counts. From this last group of five, four passed MDA(1) and MDA(2).

Thirteen facilities reported results for the measurement of ^{137}Cs measurements on whole-body phantoms -- two other facilities did not report. All 13 of the respondents passed the relative precision test, and 11 had acceptable relative biases. From this group of 11, two did not submit replicate background counts. From the remaining nine, the same four respondents passed both MDA(1) and MDA(2).

Twelve facilities reported results for the measurement of ^{144}Ce -- two other facilities did not report. Of the 12 respondents, five failed the relative precision criterion, seven failed the relative bias criterion, and three failed both of the criteria. Of the three remaining facilities, one failed to include replicate background counts, one failed both MDA criteria, and one passed both MDA criteria.

The intercomparison study of ^{131}I in the thyroid had the largest group to report measurement results -- 22. Three laboratories each provided two measurement results, one for each capsule. Three other facilities received iodine standards but did not report. All 22 respondents passed the relative precision criterion, and 16 passed the relative bias criterion. From these 16, 11 facilities did not include replicate background counts. Of the remaining seven facilities, two failed both MDA criteria and the other five passed both.

A summary of the Round One in-vivo results for all test categories is presented in Table 13. There were 41 participants in the study (some participated in more than one category). Data were received from 85% of the participants. Each of the results received consisted of a tabular report of five separate in-vivo measurements.

TABLE 6. ^{241}Am Lung In-Vivo Intercomparison Results[a] (acceptable MDA = 0.3 nCi)

Laboratory Code	Sample Activity (nCi)	Mean Assay (nCi)	Relative Bias	Precision	Relative Precision	MDA(1)	MDA(2)	Overall Pass/Fail Using MDA(1)	Overall Pass/Fail Using MDA(2)
401	3.07	3.10	+0.010	0.069	0.022	0.209	0.568	P	F
402	3.07	2.88	-0.062	0.042	0.015	0.297	0.817	P	F
403	3.07	2.96	-0.036	0.060	0.020	- (b)	- (b)	-(b)	-(b)
404	3.07	2.65	-0.136	0.048	0.018	0.061	0.127	P	P
Group Average ± S.D.			-0.056 ±0.060		0.018 ±0.003	0.189 ±0.119	0.504 ±0.349		

(a) Two other laboratories failed to report.
(b) No replicate background counts were given; MDA could not be calculated.
MDA(1) Calculated using formula (6), page 10.
MDA(2) Calculated using formula (7), page 10.

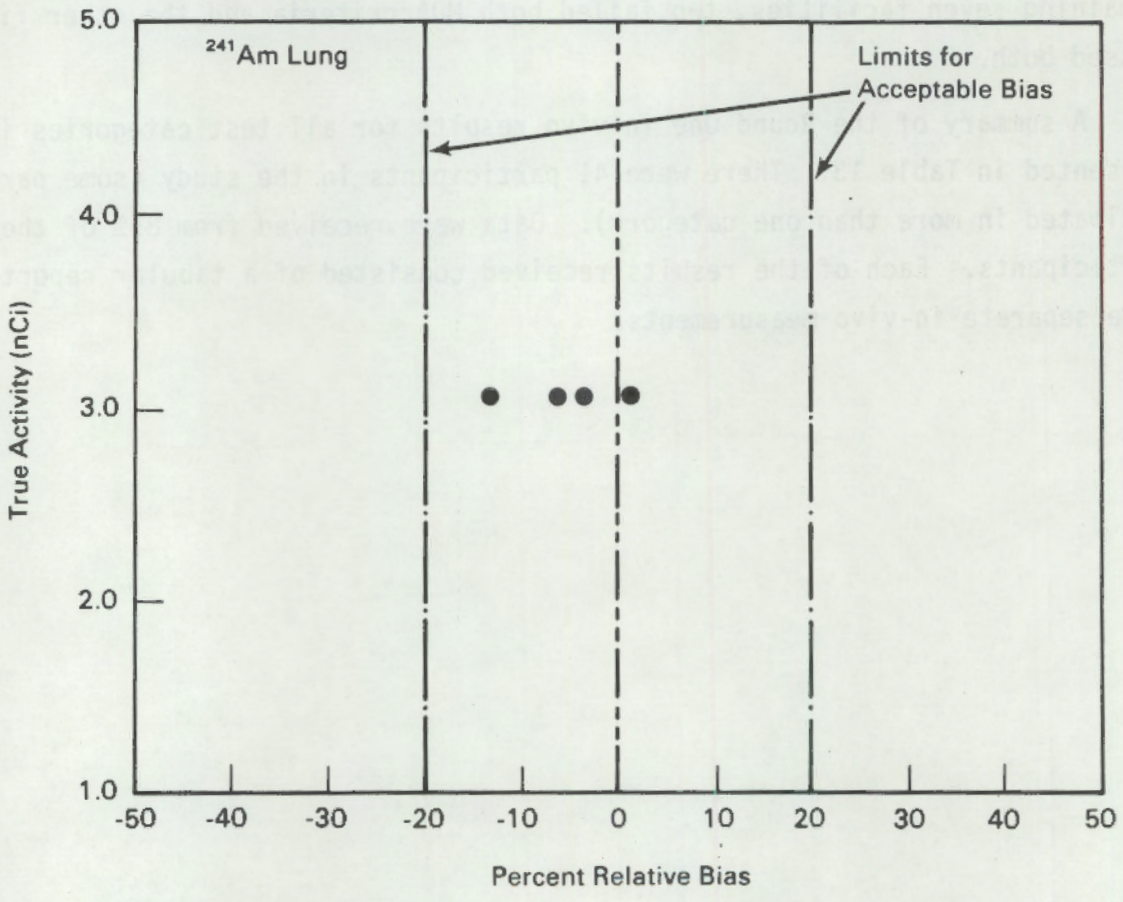

FIGURE 6. Scatter Diagram Comparing Measurements of ^{241}Am in the Lung with the True Activity. Percent Relative Bias calculated using equation (2).

TABLE 7. ^{235}U Lung In-Vivo Intercomparison Results[a] (acceptable MDA = 0.2 nCi)

Laboratory Code	Sample Activity (nCi)	Mean Assay (nCi)	Relative Bias	Precision	Relative Precision	MDA(1)	MDA(2)	Overall Pass/Fail Using MDA(1)	Overall Pass/Fail Using MDA(2)
301	2.35	3.07	+0.309	0.040	0.013	- (b)	- (b)	F	F
302	2.35	2.29	-0.026	0.120	0.052	0.297	0.804	F	F
303	2.35	2.40	+0.021	0.053	0.022	- (b)	- (b)	-(b)	-(b)
304	2.35	2.28	-0.030	0.059	0.026	0.124	0.224	P	F
305	2.35	2.35	0.000	0.029	0.012	0.038	0.069	P	P
Group Average ± S.D.			-0.056 ±0.143		0.025 ±0.015	0.153 ±0.132	0.366 ±0.387		

(a) Two other laboratories failed to report.
(b) No replicate background counts were given; MDA could not be calculated.
MDA(1) Calculated using formula (6), page 10.
MDA(2) Calculated using formula (7), page 10.

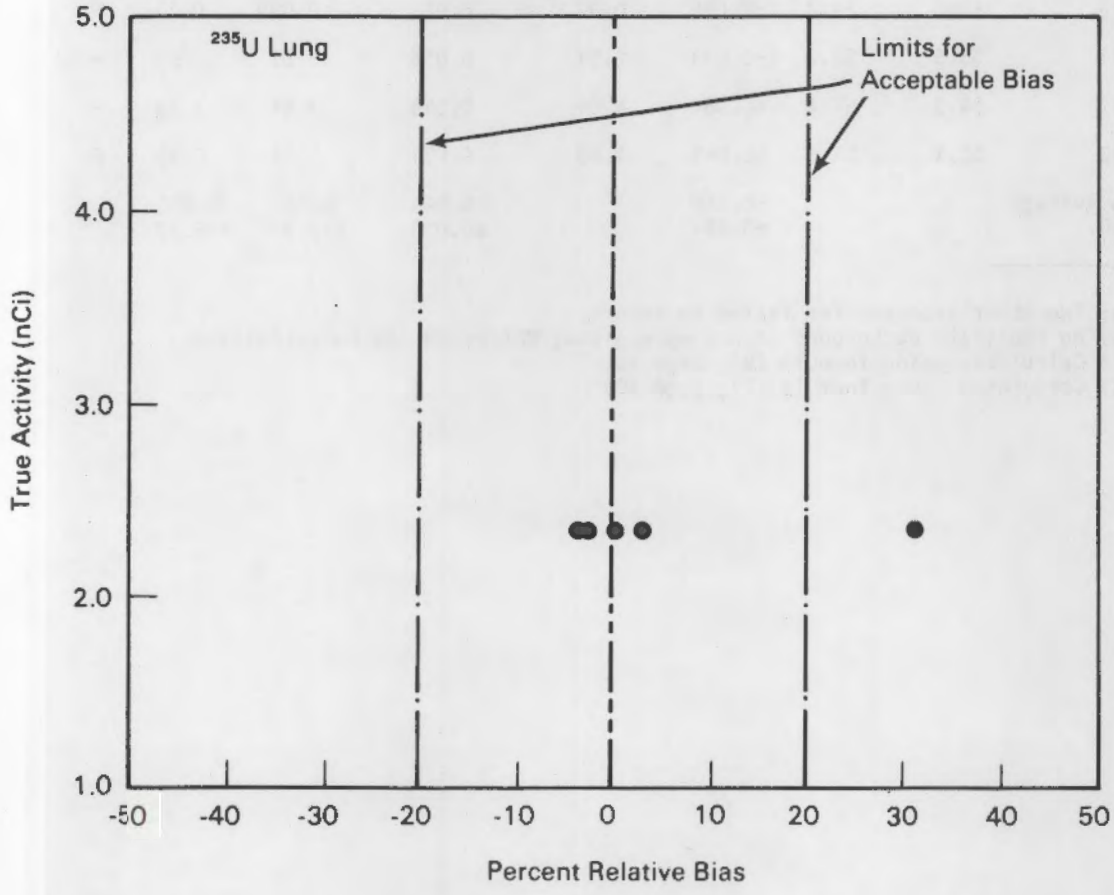

FIGURE 7. Scatter Diagram Comparing Measurements of ^{235}U in the Lung with the True Activity. Percent Relative Bias calculated using equation (2).

TABLE 8. ^{60}Co Lung In-Vivo Intercomparison Results[a]
(acceptable MDA = 60 nCi)

Laboratory Code	Sample Activity (nCi)	Mean Assay (nCi)	Relative Bias	Precision	Relative Precision	MDA(1)	MDA(2)	Overall Pass/Fail Using MDA(1)	Overall Pass/Fail Using MDA(2)
501	55.0	69.8	+0.269	1.79	0.026	-(b)	-(b)	-(b)	-(b)
502	55.0	67.4	+0.225	3.13	0.046	3.48	9.06	F	F
503	55.0	67.0	+0.218	6.56	0.098	9.34	26.11	F	F
504	55.0	72.6	+0.320	5.50	0.076	9.03	25.20	F	F
505	59.7	90.0	+0.508	12.4	0.138	39.38	110.80	F	F
506	59.7	88.6	+0.484	9.76	0.110	23.14	64.60	F	F
507	59.7	48.4	-0.189	0.89	0.018	1.14	2.55	P	P
508	57.7	57.2	-0.008	4.78	0.083	1.78	5.20	P	P
509	57.7	38.5	-0.333	3.30	0.086	-(b)	-(b)	F	F
510	60.5	54.7	-0.096	0.92	0.017	0.089	0.22	P	P
511	53.5	52.0	-0.028	2.91	0.056	-(b)	-(b)	-(b)	-(b)
512	54.5	91.6	+0.681	4.04	0.044	1.44	3.83	F	F
513	52.3	54.5	+0.043	1.88	0.034	0.31	0.45	P	P
Group Average ± S.D.			-0.160 ±0.294		0.064 ±0.038	8.90 ±12.8	24.80 ±36.13		

(a) Two other laboratories failed to report.
(b) No replicate background counts were given; MDA could not be calculated.
MDA(1) Calculated using formula (6), page 10.
MDA(2) Calculated using formula (7), page 10.

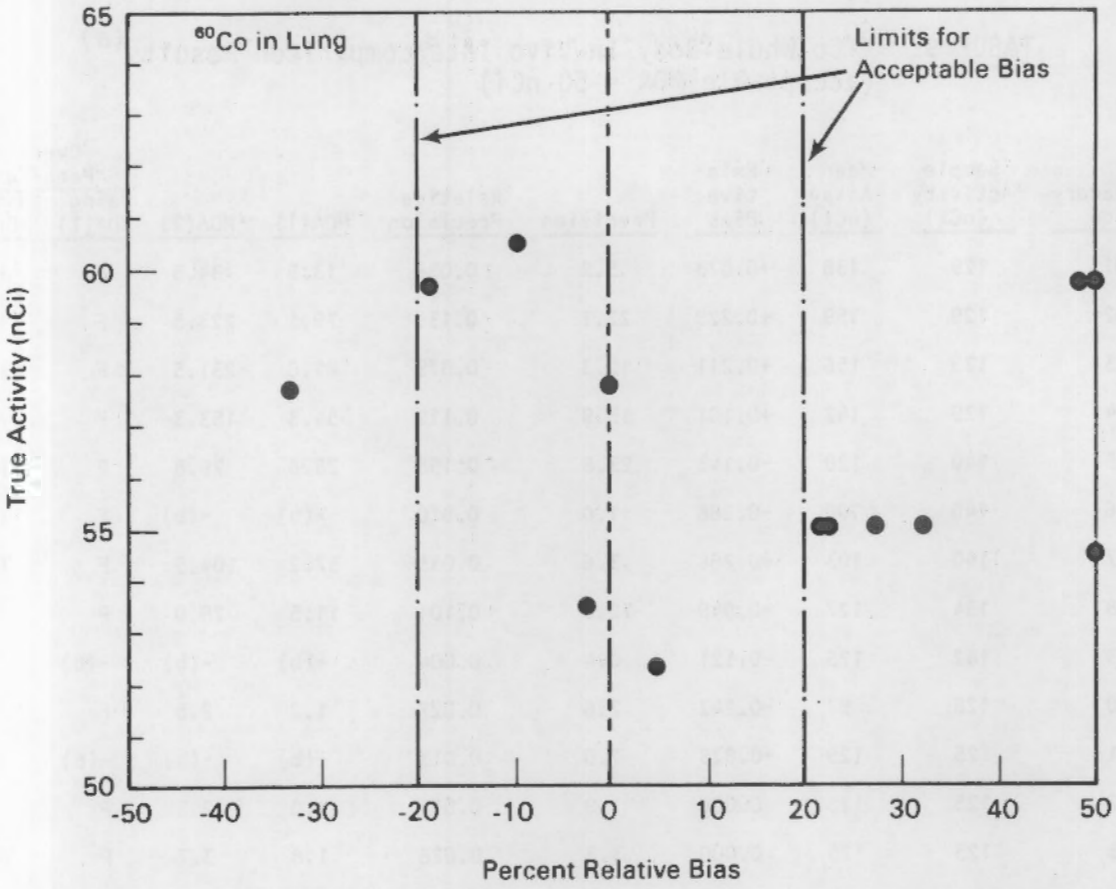

FIGURE 8. Scatter Diagram Comparing Measurements of ^{60}Co in the Lung with the True Activity. Percent Relative Bias calculated using equation (2).

TABLE 9. ^{60}Co Whole-Body In-Vivo Intercomparison Results[a] (acceptable MDA = 50 nCi)

Laboratory Code	Sample Activity (nCi)	Mean Assay (nCi)	Relative Bias	Precision	Relative Precision	MDA(1)	MDA(2)	Overall Pass/Fail Using MDA(1)	Overall Pass/Fail Using MDA(2)
601	129	138	+0.073	5.2	0.038	13.5	34.5	P	P
602	129	159	+0.229	22.1	0.139	79.1	223.5	F	F
603	129	156	+0.211	12.3	0.079	82.0	231.5	F	F
604	129	142	+0.101	15.9	0.112	54.3	153.3	F	F
605	140	120	-0.143	23.8	0.198	28.6	79.8	F	F
606	140	100	-0.286	1.0	0.010	-(b)	-(b)	F	F
607	140	103	-0.264	3.6	0.035	37.2	104.5	F	F
608	134	127	-0.049	12.8	0.101	11.5	25.0	P	P
609	142	125	-0.121	0.4	0.004	-(b)	-(b)	-(b)	-(b)
610	128	97	-0.242	2.6	0.027	1.2	2.5	F	F
611	125	129	+0.028	1.6	0.013	-(b)	-(b)	-(b)	-(b)
612	125	125	0.000	1.9	0.015	1.0	2.3	P	P
613	125	125	0.000	3.3	0.026	1.8	3.7	P	P
Group Average ± S.D.			-0.036 ±0.169		0.061 ±0.060	31.0 ±31.3	86.1 ±89.5		

(a) Two other laboratories failed to report.
(b) No replicate background counts were given; MDA could not be calculated.
MDA(1) Calculated using formula (6), page 10.
MDA(2) Calculated using formula (7), page 10.

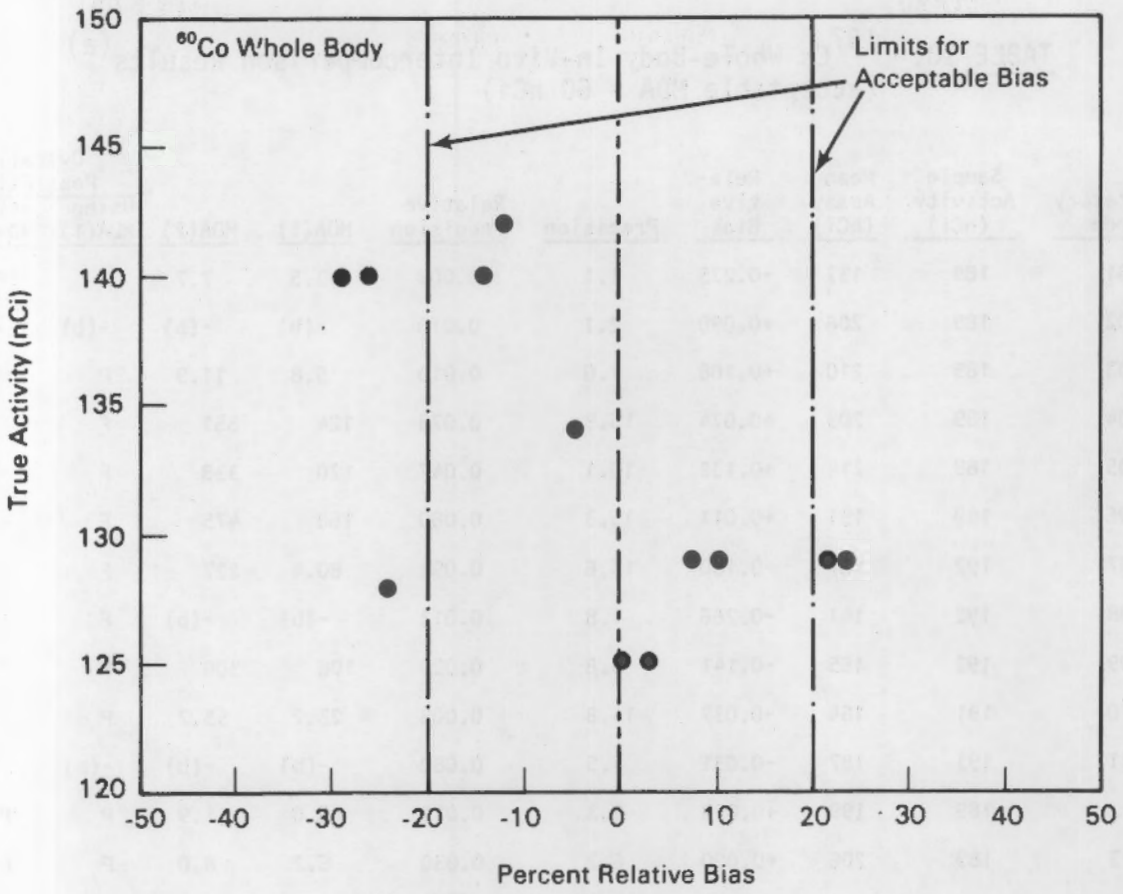

FIGURE 9. Scatter Diagram Comparing Measurements of ^{60}Co in the Whole Body with the True Activity. Percent Relative Bias calculated using equation (2).

TABLE 10. ^{137}Cs Whole-Body In-Vivo Intercomparison Results[a] (acceptable MDA = 60 nCi)

Laboratory Code	Sample Activity (nCi)	Mean Assay (nCi)	Relative Bias	Precision	Relative Precision	MDA(1)	MDA(2)	Overall Pass/Fail Using MDA(1)	Overall Pass/Fail Using MDA(2)
701	189	137	-0.275	1.1	0.008	3.5	7.7	F	F
702	189	206	+0.090	2.1	0.010	-(b)	-(b)	-(b)	-(b)
703	189	210	+0.108	2.0	0.010	5.8	11.9	P	P
704	189	203	+0.074	15.9	0.078	124	351	F	F
705	189	214	+0.132	10.1	0.047	120	338	F	F
706	189	191	+0.011	15.3	0.080	168	475	F	F
707	192	167	-0.130	15.6	0.093	80.4	227	F	F
708	192	141	-0.266	1.8	0.013	-(b)	-(b)	F	F
709	192	165	-0.141	4.8	0.029	106	300	F	F
710	191	184	-0.037	14.8	0.008	23.2	55.7	P	P
711	193	187	-0.031	1.5	0.080	-(b)	-(b)	-(b)	-(b)
712	189	199	+0.053	2.3	0.012	5.0	11.9	P	P
713	189	206	+0.090	6.2	0.030	6.2	8.0	P	P
Group Average ± S.D.			-0.025 ±0.139		0.038 ±0.032	64.2 ±64.4	178 ±179		

(a) Two other laboratories failed to report.
(d) No replicate background counts were given; MDA could not be calculated.
MDA(1) Calculated using formula (6), page 10.
MDA(2) Calculated using formula (7), page 10.

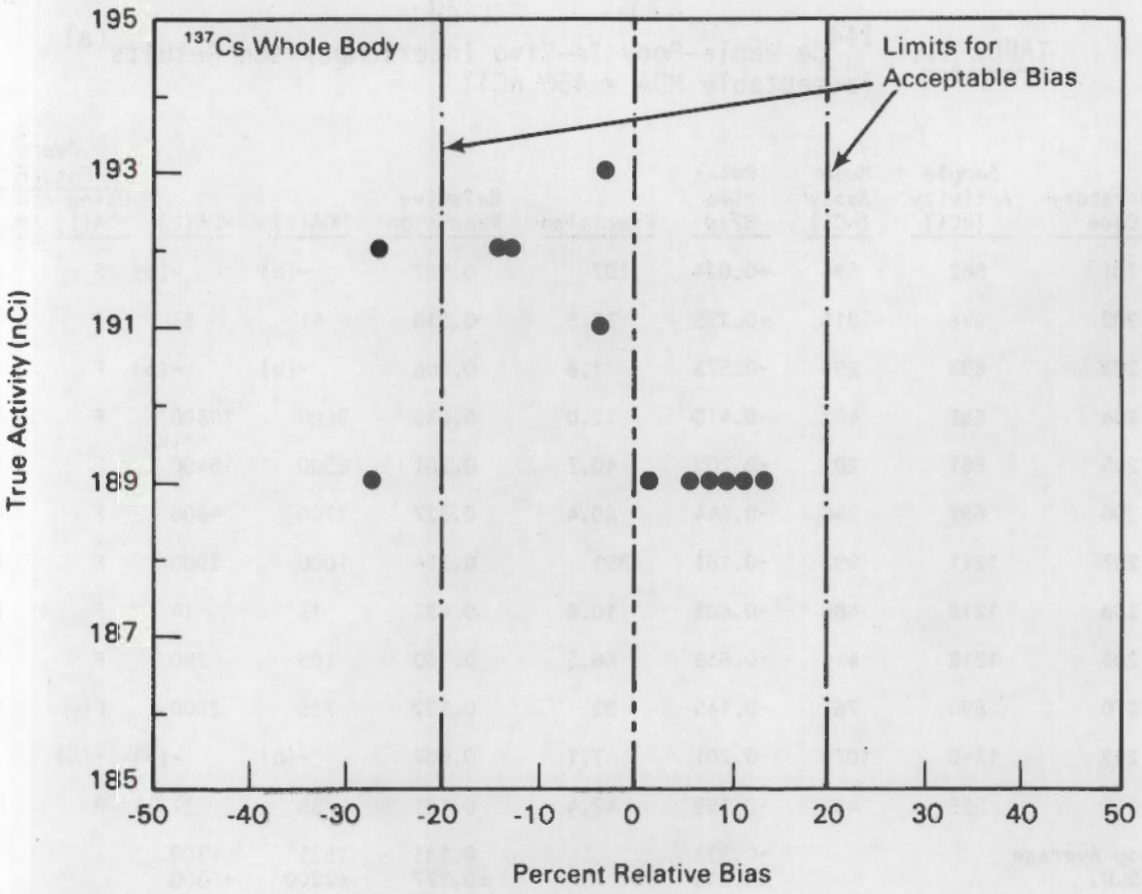

FIGURE 10. Scatter Diagram Comparing Measurements of ^{137}Cs in the Whole Body with the True Activity. Percent Relative Bias calculated using equation (2).

TABLE 11. ^{144}Ce Whole-Body In-Vivo Intercomparison Results[a] (acceptable MDA = 450 nCi)

Laboratory Code	Sample Activity (nCi)	Mean Assay (nCi)	Relative Bias	Precision	Relative Precision	MDA(1)	MDA(2)	Overall Pass/Fail Using MDA(1)	Overall Pass/Fail Using MDA(2)
201	582	594	+0.024	107	0.181	-(b)	-(b)	F	F
202	646	811	+0.255	31.5	0.039	41	53	F	F
203	693	296	-0.573	1.8	0.006	-(b)	-(b)	F	F
204	681	402	-0.410	12.0	0.030	3600	10300	F	F
205	681	202	-0.703	40.7	0.201	6500	18400	F	F
206	691	246	-0.644	80.4	0.327	1700	4800	F	F
207	1211	992	-0.181	391	0.394	1000	2900	F	F
208	1218	484	-0.603	10.6	0.022	13	14	F	F
209	1218	416	-0.658	66.5	0.160	105	290	F	F
210	890	761	-0.145	93	0.122	735	2000	F	F
211	1340	1070	-0.201	7.1	0.007	-(b)	-(b)	-(b)	-(b)
212	555	467	-0.159	47.4	0.101	35	27	P	P
Group Average ± S.D.			-0.333 ±0.310		0.133 ±0.127	1525 ±2200	4300 ±6300		

(a) Two other laboratories failed to report.
(b) No replicate background counts were given; MDA could not be calculated.
MDA(1) Calculated using formula (6), page 10.
MDA(2) Calculated using formula (7), page 10.

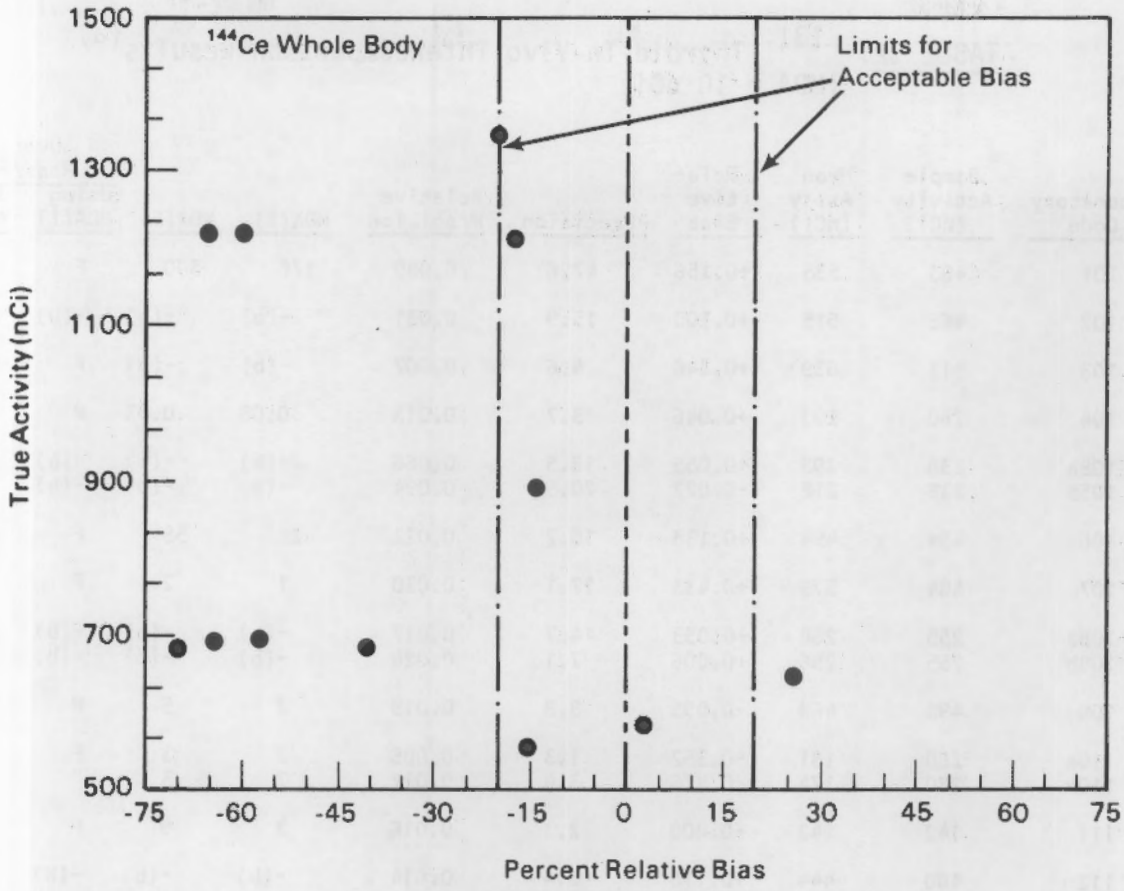

FIGURE 11. Scatter Diagram Comparing Measurements of ^{144}Ce in the Whole Body with the True Activity. Percent Relative Bias calculated using equation (2).

TABLE 12. ^{131}I Thyroid In-Vivo Intercomparison Results[a]
(MDA = 10 nCi)

Laboratory Code	Sample Activity (nCi)	Mean Assay (nCi)	Relative Bias	Precision	Relative Precision	MDA(1)	MDA(2)	Overall Pass/Fail Using MDA(1)	Overall Pass/Fail Using MDA(2)
101	463	535	+0.156	47.6	0.089	176	500	F	F
102	468	515	+0.100	15.9	0.031	-(b)	-(b)	-(b)	-(b)
103	513	639	+0.246	4.6	0.007	-(b)	-(b)	F	F
104	280	293	+0.046	3.7	0.013	0.08	0.03	P	P
105a	238	295	+0.055	18.5	0.066	-(b)	-(b)	-(b)	-(b)
105b	238	218	-0.022	20.5	0.094	-(b)	-(b)	-(b)	-(b)
106	434	494	+0.138	10.7	0.022	20	55	F	F
107	404	579	+0.433	17.1	0.030	1	2	F	F
108a	255	268	+0.053	4.7	0.017	-(b)	-(b)	-(b)	-(b)
108b	255	256	+0.006	7.1	0.028	-(b)	-(b)	-(b)	-(b)
109	495	468	-0.055	8.8	0.019	2	5	P	P
110a	280	181	-0.352	1.3	0.005	2	3	F	F
110b	280	174	-0.376	3.4	0.012	2	3	F	F
111	142	142	+0.000	2.3	0.016	3	9	P	P
112	400	444	+0.110	6.4	0.014	-(b)	-(b)	-(b)	-(b)
113	259	276	+0.066	1.1	0.004	-(b)	-(b)	-(b)	-(b)
114	439	849	+0.934	4.6	0.005	19	54	F	F
115	71	65	-0.085	1.0	0.015	-(b)	-(b)	-(b)	-(b)
116	450	511	+0.136	1.4	0.003	-(b)	-(b)	-(b)	-(b)
117	70	82	+0.171	4.4	0.054	2	4	P	P
118	136	136	+0.000	0.8	0.006	-(b)	-(b)	-(b)	-(b)
119	492	638	+0.297	46.9	0.074	25	72	F	F
120	472	420	-0.110	9.4	0.022	-(b)	-(b)	-(b)	-(b)
121	338	296	-0.124	4.1	0.014	-(b)	-(b)	-(b)	-(b)
122	411	435	+0.058	3.4	0.008	5	7	P	P
Group Average ± S.D.			+0.102 ±0.247		0.024 ±0.023				

(a) Three laboratories counted the two sources separately and three other laboratories failed to report.
(b) No replicate background counts were given; MDA could not be calculated.
MDA(1) Calculated using formula (6), page 10.
MDA(2) Calculated using formula (7), page 10.

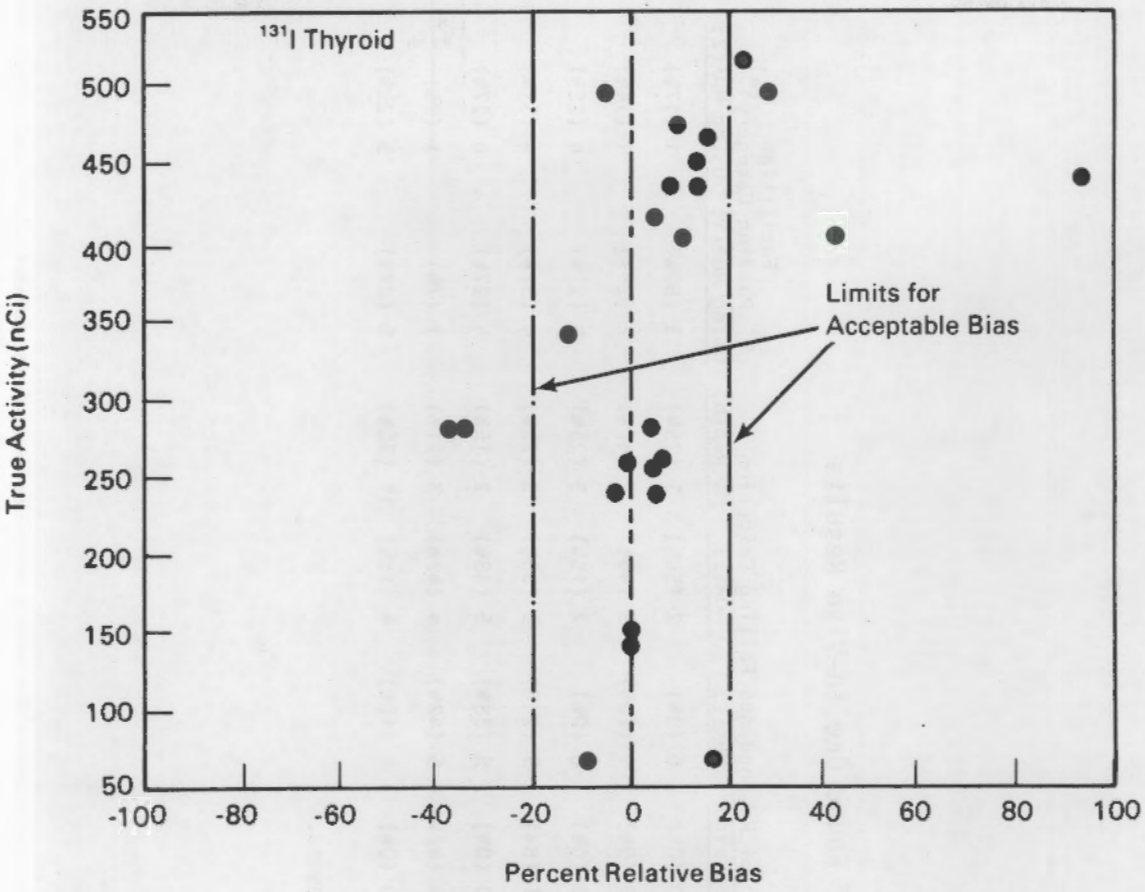

FIGURE 12. Scatter Diagram Comparing Measurements of ^{131}I in the Thryoid with the True Activity. Percent Relative Bias calculated using equation (2).

TABLE 13. Summary of Round One In-Vivo Results

Category	Nuclide	Number Sent Phantoms	Number of Respondents	Number of Respondents Failing Criterion					Facilities Passing Category[a]	
				Bias	Precision	MDA(1)	MDA(2)	No Rep[b]	Using MDA(1)	Using MDA(2)
Lung	^{241}Am	6	4	0 (0%)	0 (0%)	0 (0%)	2 (50%)	1 (25%)	3 (50%)	1 (17%)
Lung	^{235}U	7	5	1 (20%)	0 (0%)	1 (20%)	2 (40%)	2 (40%)	2 (29%)	1 (14%)
Lung	^{60}Co	15	13	8 (62%)	0 (0%)	0 (0%)	2 (15%)	3 (23%)	4 (27%)	4 (25%)
Whole Body	^{60}Co	15	13	5 (38%)	1 (8%)	3 (23%)	5 (38%)	3 (23%)	4 (31%)	4 (31%)
Whole Body	^{137}Cs	15	13	2 (15%)	0 (0%)	5 (38%)	5 (38%)	2 (15%)	4 (27%)	4 (27%)
Whole Body	^{144}Ce	14	12	7 (50%)	5 (42%)	5 (42%)	4 (42%)	3 (21%)	1 (7%)	1 (7%)
Thyroid	^{131}I	25	22	5 (20%)	0 (0%)	4 (18%)	4 (18%)	11 (50%)	5 (23%)	5 (23%)

(a) Percentages of facilities sent phantoms.
(b) Facilities failing to provide replicate background counts.
MDA(1) Calculated using formula (6), page 10.
MDA(2) Calculated using formula (7), page 10.
Failures determined using criteria in Table 1, page 11.

SUMMARY OF PERFORMANCE FOR EACH CRITERIA

The minimum detectable amount criterion is not independent from relative precision. If the relative precision is poor (large variations), MDA will be high, and vice versa. The MDA is therefore only a general indicator of what the "lowest detectable level" is for a given procedure, instrument, and nuclide. In several cases, respondents passed the relative bias and relative precision criteria by measuring activities substantially lower than their calculated MDA. This should not happen if the true detection limit was being calculated. Either the data supplied by participants was misinterpreted in some way, or the MDA formulas are overly conservative.

Although the use of the MDA(2) formula essentially raises MDA by a factor of 3 when compared to the MDA(1) formula, only three facilities would have failed a category using MDA(2) and passed using MDA(1) (two for ^{241}Am in the lung and one for ^{235}U in the lung). The data imply that there are two main groups within the respondents - those that pass the MDA criterion by a wide margin and those that fail by an equally wide margin.

Only six facilities failed the proposed relative precision criterion, and five of those failures resulted from the measurement of ^{144}Ce in the whole-body phantom. These failures were understandable, because the sample activities were often less than the facilities' calculated MDAs.

While low MDAs are helpful in establishing the worker protection plan and good precision is a prerequisite for low MDAs, if the measurements do not assign activity values close to the actual values, useful data will not be obtained. The relative bias criterion, as proposed by the working group, is the criterion failed by the most respondents. A substantial fraction of the respondents performing measurements that should be routine for most of the facilities (such as ^{60}Co in the lung), failed the bias criterion. More than half the responding facilities failed the bias criterion for measurements of ^{60}Co in the lung and for whole-body measurements of ^{141}Ce. Measurement of ^{60}Co in the whole body was failed by 38 percent of the respondents, and 24 percent failed the ^{131}I measurements.

In general, the MDA criterion was less difficult to meet than the relative bias criterion, except for ^{137}Cs in the whole body, where approximately equal numbers of respondents failed the relative bias and the MDA criteria.

The means of the relative bias and relative precision for each of the radionuclides and categories are shown in Table 14, along with the sample standard deviation of the means. Generally, the mean bias of the group is small; the exception is the measurement of ^{144}Ce (where the activity in the phantom was below the MDAs of some respondents).

Also included in Table 14 are the mean relative bias and the mean relative precision for the respondents who passed the proposed precision and bias criteria and the MDA(1) criterion. As would be expected, after removing the facilities with replies outside the limits of the proposed criteria, the means clustered closer to the actual activities and the sample standard deviation was smaller. The only exception to this was the test for ^{241}Am in the lung. Because three out of the four respondents passed the proposed criteria for this category, the two groups were nearly the same.

COUNTING EQUIPMENT USED BY STUDY PARTICIPANTS

Participants in the in-vivo intercomparison described their detector types, shielding, and counting geometry used for each test. Among the respondents in the test for measurement of ^{241}Am or ^{235}U in the lung, three used dual-phoswich detector systems, one used a four-phoswich detector system (two anterior and two posterior), and one used a planar arrangement of six intrinsic germanium detectors. Among the respondents analyzing for fission and activation products in the lung or whole body, two used lithium-drifted germanium (GeLi) detectors, two used high-purity germanium detectors, and the remainder used NaI(Tl) detector systems. Two facilities used a high-purity germanium detector to measure ^{131}I in the thyroid, and the remainder of the facilities used small-diameter shielded NaI(Tl) detectors. A combination of two or three NaI(Tl) detector probes was sometimes used.

TABLE 14. Averages of Bias and Precision for Round One

Category	Nuclide	Number of Responding Facilities	For All Responding Facilities		Number of Passing Facilities	For Facilities That Passed All Three Criteria(a)	
			Mean Relative Bias (b)	Mean Relative Precision		Mean Relative Bias	Mean Relative Precision
Lung	^{241}Am	4	-0.056 ± 0.060	0.018 ± 0.003	3	-0.062 ± 0.072	0.018 ± 0.004
Lung	^{235}U	5	+0.056 ± 0.143	0.025 ± 0.016	2	-0.013 ± 0.023	0.019 ± 0.010
Lung	^{60}Co	13	+0.160 ± 0.294	0.064 ± 0.038	4	-0.063 ± 0.102	0.038 ± 0.031
Whole Body	^{60}Co	13	-0.036 ± 0.169	0.061 ± 0.060	4	+0.006 ± 0.050	0.045 ± 0.038
Whole Body	^{137}Cs	13	-0.025 ± 0.139	0.038 ± 0.032	4	+0.054 ± 0.065	0.033 ± 0.033
Whole Body	^{144}Ce	12	-0.333 ± 0.310	0.133 ± 0.127	1	-0.159	0.101
Thyroid	^{131}I	22	+0.102 ± 0.247	0.024 ± 0.023	5	+0.044 ± 0.084	0.022 ± 0.018

(a) MDA calculated using formula (6), page 10.
(b) Error range is ± one standard deviation.

In-vivo counting facilities at nuclear power plants generally employed sodium iodide [NaI(Tl)] detectors in shadow-shielded scanning-bed or stand-up configurations. These instruments are usually purchased or leased from commercial vendors with computer software for spectral analysis. The national laboratories and other non-power-plant in-vivo counting facilities that need to detect transuranic radionuclides and uranium utilize custom-built detector systems housed in plate steel rooms with graded shielding on the interior walls. The graded shielding usually consists of sheets of lead, cadmium, and copper to reduce the background count rate and improve detection capabilities for low-level, low-energy sources. These heavily shielded rooms offer a substantial advantage, and generally, these facilities performed better in the intercomparison tests.

However, the more sophisticated and more expensive detection systems did not always guarantee more accurate measurement results. A number of performance failures were from facilities with state-of-the-art instrumentation, shielding, and computer-based spectrum analyzers. In contrast, some very simple detector systems performed well during the intercomparison test. For example, excellent results for ^{131}I measurement were reported by one facility using a simple analyzer, homemade scaler, and hand-held scintillation probe. Quality system calibration and quality control procedures can make the difference between accurate and inaccurate measurement results, regardless of the sophistication of the instrumentation.

APPROPRIATENESS OF PERFORMANCE CRITERIA

In evaluating the appropriateness of the performance criteria for in-vivo counting as proposed in the draft ANSI Standard, one must consider whether the specified values are reasonable (whether laboratories can meet these proposed values without expending unnecessary amounts of time and money) and whether the proposed values are adequate (will workers be adequately protected if these values are used). Unfortunately, these two goals of reasonableness and adequacy are sometimes in conflict. It is conceivable that a laboratory using state-of-the-art equipment and procedures could be unable to detect an activity level that delivers a significant dose to a worker.

RELATIVE BIAS

The draft ANSI standard states that the relative bias is to be calculated as the average of the relative biases for multiple measurements on a test phantom. An average relative bias of 20 percent or less is acceptable under the draft standard. The bias may be positive or negative. The calculated bias is only a meaningful number at concentration levels three to five or more times the MDA. Between one and three to five times the MDA, the activity may be considered detectable, but not measurable.

The bias is the most crucial aspect of a measurement; a series of measurements may have excellent precision and low MDAs, but if the answer is not close to the actual value, it is of limited value. Fortunately, if the measurements are reproducible and the activities are sufficiently above the MDA, unacceptable bias can usually be corrected fairly easily by appropriate calibration using phantoms and standards and can be checked by participation in intercomparison tests.

While 20 percent seems a reasonable criterion for the relative bias for all nuclides tested (except ^{144}Ce), a substantial fraction of the participants in most of the test categories regularly failed this criterion. If participation in intercomparison tests helps the facilities correct any systematic bias in their procedures, then improvement should be observed in the Round Two testing.

RELATIVE PRECISION

The relative precision is an indicator of the reproducibility of a series of measurements. A precision of ±15 percent is allowed in the draft ANSI Standard. Excluding the measurement of ^{144}Ce, only one laboratory failed the precision criterion.

The failure of the precision criterion by a large percentage of the participants in the ^{144}Ce whole-body test was due to interference counts from ^{137}Cs, ^{60}Co and background. For activity levels close to and below the MDA, the counts from sources other than the nuclide of interest play an ever increasing role in determining the measurement assay. At these activity levels, the precision is governed too much by statistical variations to be maintained within the performance criteria limits.

MINIMUM DETECTABLE AMOUNTS

The draft ANSI Standard gives acceptable MDAs for each of the seven categories of in-vivo measurements in terms of activity per photon of interest released during the radioactive decay.

The MDA's importance in determining activity levels at which a given laboratory can be expected to pass relative bias and relative precision criteria has already been discussed. However, the MDA is not independent from relative precision. If the background at a counting facility is high and variable, both the the relative precision and the MDA levels will be affected. Stated another way, a facility can have an acceptable MDA only if it has an acceptable precision.

The calculated MDA is an indicator of what the actual lower limit of detection might be. For example, during the Round One testing, several facilities passed the relative precision and relative bias performance criteria at levels well below their calculated MDA(1). Even more facilities displayed this phenomenon when formula(2) was used to calculate the MDA, because the MDA calculated by formula(2) is approximately three times higher than the MDA calculated by formula(1). Also, a facility's MDA is not fixed. If the background level varies in a systematic fashion, the MDA could change

from day to day or even more frequently. An example of this would be the MDA at a facility located near an operating power reactor, where the background count rate might follow the power level of the reactor. Furthermore, the MDA is sensitive to the presence or absence of other interfering radionuclides in the test phantom or human subject and therefore varies from measurement to measurement.

The calculated detection limits required to adequately protect workers vary widely depending on the frequency of counting, type of instrumentation, chemical form of the nuclide, etc. In Round One testing, the major source of failure was related to the MDA, and, thus, the choice of acceptable MDA for the performance criteria in ANSI N13.30 is crucial, in terms of both the pass/fail criteria and the degree of worker protection implied by the term "acceptable."

The test results indicate a need for laboratory accreditation to ensure quality bioassay results. This project provided an opportunity for laboratories and counting facilities to assess their capabilities and evaluate their performance in light of the industry standards and the performance of other facilities. Respondents were often surprised to learn that they failed certain aspects of the test. The pilot testing helped facilities identify areas of weakness so that corrective action could be taken and demonstrated the need for continual quality assurance. The testing program also helped the ANSI working group to identify established acceptance criteria that may need revision.

RECOMMENDATIONS

The Pilot Study, or first-round intercomparison, was designed as a limited study to assist Working Group 2.5 in preparing draft ANSI Standard N13.30. Experience and information gained from the Pilot Study were also valuable for designing the second round of testing.

SUGGESTED REVISIONS TO DRAFT ANSI STANDARD N13.30

During the performance of this project, there has been frequent dialogue between the Pacific Northwest Laboratory research staff and members of the Health Physics Society Working Group 2.5 preparing the draft Standard. Project representatives have attended each of the meetings of the committee to ensure that the intercomparison testing corresponds to the recommendations of the draft Standard. Project staff members provided numerous suggestions for improving the draft during these meetings. Many of these recommendations were incorporated or are currently under consideration by the working group. For example, recommendations have involved the following:

- definition of terms
- procedures for in-vivo and in-vitro testing
- revision of statistical performance formulas
- selection of categories and radionuclides for in-vitro and in-vivo testing
- descriptions of phantoms for in-vivo testing
- descriptions of quality control procedures.

Listed below for consideration by the working group are suggestions for future revision of the draft Standard.

1) The precision criterion should be expressed as a relative value similar to the relative bias. Otherwise, values of the precision for a set of test measurements cannot be easily compared. For comparison, Tables 6 through 12 contain both the absolute precision and the relative precision. The relative precision allows more direct comparison of performance

among categories to determine if a facility passed or not. The mean precision plus or minus the sample standard deviation for a test category is somewhat meaningless standing alone. However, the mean and standard deviation of the relative precisions are statistically valid indicators of overall performance. Thus, we recommend that the value of the precision be normalized to the mean assay.

Using the mean of the assays rather than the known activity as the normalization factor serves to separate the bias criterion from the precision criterion as much as possible. Using the mean of the assays removes the influence of multiplicative systematic bias from calculation of the precision.

2) The MDA criterion should be clarified by the working group in several areas. First, the group needs to decide whether the MDA should include protection against type II errors. The working group must evaluate the concern for protection ag inst missing activity that is really present.

   Second, the working group should consider the effect of multiple radionuclides and limit the test phantoms to a single radionuclide, give some sliding scale for adjusting performance criteria or testing ranges, or make clear that the facilities must meet the criteria no matter what the interferences.

   Third, and most important, the working group should clarify to what degree the MDA criterion should be based on the current capabilities of the testing facilities and to what degree it should be based on worker protection.

3) The proposed relative bias performance criterion should remain unchanged at ±20 percent.

4) The draft Standard should provide guidance to ensure that standard counting times for blanks and samples are used to calculate the MDA. MDA estimates should be calculated with the average count times used for routine samples. A facility should not exaggerate their capabilities by

counting test samples for unrealistically long times or by using very long background counts to calculate the MDA.

5) Procedures for obtaining background count rates should be explicitly defined. During the Round One testing, facilities used inappropriate blanks, used computer programs to interpolate across the bottoms of the photon peaks, counted for five times as long as for phantom measurements and divided by five, submitted only one background count, etc. For valid comparisons among laboratories, a uniform method must be adopted. Taking background counts near the photopeak (with the same energy width as was used to measure the photopeak) may be the most appropriate.

6) The working group should consider whether or not to specify a uniform distribution of mixed fission and activation products in the lung. The short half-life of ^{58}Co in particular will necessitate increased costs in the administration of an ongoing testing/accreditation program if uniform distribution is specified.

If the phantom lungs could be reloaded with fresh ^{58}Co capsules, much effort could be saved. Experiments are underway to compare counting results between multiple-point-source loaded lungs and uniformly loaded lungs under various counting configurations.

PROPOSED ROUND TWO TESTING

A second round of in-vivo testing similar to the first round is planned. The purposes of Round Two are 1) to determine whether laboratories have improved their capabilities, 2) to obtain a larger sample measurement data base, and 3) to test revisions in the draft Standard that were incorporated by the working group during Round One testing. For the Round Two testing, the ^{125}I will be incorporated into an ANSI thyroid phantom and shipped to participating facilities. Table 15 shows the test categories and radionuclides proposed for Round Two.

TABLE 15. Test Radionuclides, Organs, and Activity Ranges for Round Two Performance Testing

Category	Organ	Radionuclide(s)	Activity Ranges (nCi)
Photons with energy <60 keV	Lung	^{238}Pu(a)	3.0-30
Measurement of Uranium	Lung	U nat(a)	60-600
Fission and Activation Products	Lung	^{60}Co + ^{54}Mn(b)	100-1000
	Whole Body	^{137}Cs + ^{134}Cs(c)	100-1000
Measurement of Iodine	Thyroid	^{125}I	100-1000

(a) With ^{40}K present in the heart cavity.

(b) With ^{134}Cs, ^{137}Cs, and ^{40}K present.

(c) With ^{60}Co, ^{54}Mn, and ^{40}K present.

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APPENDIX

IN-VIVO COUNTING DATA REPORT FORM

IN-VIVO COUNTING DATA REPORT FORM

Radionuclide_____

Name of Facility:_____

Location:_____

Contact Person_____ Phone ( )_____

Procedure: Chest Count (torso phantom) Whole-Body Count (bottle phantom)

Date Received_____ Date(s) Counted_____

Brief description of counting equipment (shielding, detection, geometry):

Count No.	Total Counts[a]	Counting Time	Background Count Rate[a]	Counting Efficiency[b]	Assay (μCi)	Est. Error
1						
2						
3						
4						
5						

(a) Region of interest, cpm.
(b) Count rate per unit activity in the phantom (cpm/μCi).

Please return this form by_____ to: Darrell Fisher
Pacific Northwest Laboratory
Richland, WA 99352
(509) 375-6852

Thank you for participating in this intercomparison study.

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