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Recommended Procedures for Performance Testing of Radiobioassay Laboratories

Volume 1: Quality Assurance

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November 1988

Prepared for
the U.S. Department of Energy
Assistant Secretary for
Environmental, Safety and Health
and the U.S. Nuclear Regulatory Commission
under Contract DE-AC06-76RLO 1830
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RECOMMENDED PROCEDURES FOR PERFORMANCE TESTING OF RADIOBIOASSAY LABORATORIES

VOLUME I: QUALITY ASSURANCE

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FOREWORD

In recent years, extensive research has been contracted to improve occupational radiation protection. Of particular concern to the U.S. Department of Energy (DOE) and U.S. Nuclear Regulatory Commission (NRC) have been the accuracy, quality control, and performance of personnel radiation dosimeters, radiation survey instruments, and bioassay laboratories.

The U.S. Oepartment of Energy Order 5480.1, Chapter XI (DOE 1983) and Title 10, Part 20 of the U.S. Code of Federal Regulations (NRC 1982), require assessment of occupational radiation exposures. Accurate bioassay measurements are necessary to correctly assess internal exposure to radioactive materials. However, a concern of both DOE and NRC is that bioassay laboratories may not be providing accurate and consistent results. To address this concern a Health Physics Society working group was formed to prepare a draft American National Standards Institute (ANSI) standard on bioassay laboratory performance. The resultant document was designated draft ANSI N13.30, Performance Criteria for Radiobioassay.[a]

Draft ANSI N13.30 provides performance criteria in the form of the minimum numerical values necessary to meet an acceptable minimum detectable amount, relative bias, and relative precision. The acceptance values for these criteria have been reviewed and revised throughout the process of developing the draft standard.

Companion documents to this report include the Recommended Procedures for Performance-Testing of Radiobioassay Laboratories, Volume 2: In Vitro Samples, and Volume 3: In Vivo Counting, which are being published in parallel with this report.

The quality assurance procedures described in this document were developed as a part of a project to evaluate the performance criteria of draft ANSI N13.30 by testing the current measurement capabilities of various

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(a) Copies of published draft ANSI N13.30 are available from the Executive Secretary, Health Physics Society, 8000 Westpark Drive, Suite 400, McLean, VA 22102.

bioassay laboratories. Included in the project was a nationwide, two-round bioassay intercomparison study to test the analytical performance of both in vitro (excreta analysis) and in vivo (external measurements) bioassay laboratories and to determine their capability to meet the minimum performance criteria specified in the draft standard.

The purpose of this report is to provide recommended quality assurance procedures for 1) preparing standard radionuclide solutions, 2) preparing and distributing test samples, and 3) evaluating the performance of bioassay service laboratories.

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SUMMARY

Draft American National Standards Institute (ANSI) Standard N13.30 (Performance Criteria for Radiobioassay) was developed in response to a concern expressed by the U.S. Department of Energy and the U.S. Nuclear Regulatory Commission to help ensure that bioassay laboratories provide accurate and consistent results. The draft standard specifies the criteria for defining the procedures necessary to establish a bioassay performance-testing laboratory and program. The testing laboratory will conduct tests to evaluate the performance of service laboratories.

Pacific Northwest Laboratory[(a)] helped define responsibilities and develop procedures as part of an effort to evaluate the draft ANSI N13.30 performance criteria for quality assurance at bioassay laboratories. This report recommends elements of quality assurance and quality control responsibilities for the bioassay performance-testing laboratory program, including the qualification and performance of personnel and the calibration, certification, and performance of equipment. The data base and recommended records system for documenting radiobioassay performance at the service laboratories are also presented.

(a) Pacific Northwest Laboratory is operated for the U.S. Department of Energy under Contract DE-ACD6-76RLO 1830 by Battelle Memorial Institute.

CONTENTS

ACRONYMS

AMDA	acceptable minimum detectable amount
ANSI	American National Standards Institute
CFR	U.S. Code of Federal Regulations
DOE	U.S. Department of Energy
DOELAP	Department of Energy Laboratory Accreditation Program
HPSSC	Health Physics Society Standards Committee
LLD	lower limit of detection
MDA	minimum detectable amount
MQA	Measurement and Quality Assurance
M&TE	Measurement and Test Equipment
NBS	U.S. National Bureau of Standards
NCRP	U.S. National Council on Radiation Protection and Measurements
NRC	U.S. Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
QA	quality assurance
QC	quality control
SA	coefficient of variation
SRM	Standard Reference Material
TRS	Transfer Reference Standard

1.0 INTRODUCTION

1.1 PURPOSE

This report provides recommended quality assurance (QA) procedures for handling standard radionuclide solutions and for preparing and distributing test samples and phantoms. The overall goal is to specify the content of the QA procedures that are necessary to establish a bioassay performance-testing laboratory. The intended purpose of the testing laboratory is to conduct performance tests and identify service laboratories meeting accepted standards.

1.2 SCOPE

The procedures recommended in this report are based on technical specifications given in the draft American National Standards Institute (ANSI) Standard N13.30, Performance Criteria for Radiobioassay.[a] This performance standard was prepared by Working Group 2.5 of the Health Physics Society Standards Committee (HPSSC). The U.S. Department of Energy (DOE) and the U.S. Nuclear Regulatory Commission (NRC) requested the HPSSC to provide guidance on acceptable criteria for bioassay laboratory measurements.

1.3 PROCEDURE REVISION

The testing laboratory implementing the recommended procedures is expected to adapt them to the laboratory's working environment. These initial modifications should not compromise the QA requirements of this report.

The procedures given in this report may also require revision depending on the final version of ANSI N13.30. Each change to procedures should be documented by noting the revision date on the bottom of the revised page and the individual who approved the revision. A record of each procedure change should be maintained and should include: date, description of change, section changed, and name of person who approves the change.

(a) Copies of published draft ANSI N13.30 are available from the Executive Secretary, Health Physics Society, 8000 Westpark Drive, Suite 400, McLean, VA 22101.

1.4 DEFINITION OF TERMS

The definitions of the terms used in this report are in accordance with Section 2 of draft ANSI N13.30. Specific terms used in draft ANSI N13.30 are defined here.

- Acceptable Minimum Detectable Amount (AMDA): The amount of radioactive material that measurement procedures should be able to measure, assuming they are free of interference from other radionuclides unless specifically addressed. The values listed should not be construed as being the minimum detectable amount, but rather an acceptable minimum detectable amount based on good practice and need.
- Activity: Disintegration rate of a specified quantity of radioactive material stated in nuclear transformation rate, becquerels, curies, or other acceptable units.
- Aliquant: A part of the whole that divides it and leaves a remainder. This is not to be confused with "aliquot."
- Aliquot: A part of the whole that divides it and leaves no remainder, i.e., is contained an exact number of times in that which is being divided.
- Analyte: The particular radionuclide to be determined in a sample of interest.
- Appropriate Blank: A sample, person, or phantom that is, ideally, identical in physiochemically and radiologically significant ways with the sample, person, or phantom to be analyzed. The appropriate blank may contain ambient quantities of the analytes. For direct bioassay the appropriate blank may also be the subject of analysis, if one analyzes a portion of the count versus energy spectrum that is unaffected by the radionuclide of interest, and if one applies a correction factor appropriate for obtaining a blank count for the spectral region(s) of interest. An appropriate blank provides the necessary signal response in the final measurement process so that signals resulting from ambient amounts of the analyte, interfering nuclides, and extraneous background radiation can be subtracted from

signals from routine samples to permit detection and measurement of an additional amount of analyte above the ambient amount of the analyte normally contained in the medium of interest.

- Background: Ambient signal response recorded by measurement instruments that is independent of radioactivity contributed by the radionuclides being measured in the person or sample.
- Bias: (a) The deviation of the expected value of a random variable from a corresponding correct value. (b) A fixed deviation from the true value that remains constant over replicated measurements within the statistical precision of the measurement. (Synonyms: deterministic error, fixed error, systematic error.)
- Bias Statistic: An estimation of bias calculated from a finite sample of data using a specified formula.
- Bioassay: Another word for radiobioassay.
- Coefficient of Variation (S_A): The quotient of the estimated standard deviation of a series of determinations, x_1, x_2,...x_i,...x_N, of a quantity divided by the mean value of x_i; i.e.,

$$S_A = \left[\sum_{i=1}^{N} (x_i - \bar{x})^2/(N - 1)\right]^{\frac{1}{2}} / \bar{x} = \left[\sum_{i=1}^{N} (x_i/\bar{x} - 1)^2/(N - 1)\right]^{\frac{1}{2}}$$

$$\text{where } \bar{x} = \sum_{i=1}^{N} x_i/N$$

or for a single measurement the quotient of the estimate of the standard deviation (i.e., Poisson) divided by the value of the single measurement (synonymous with the standard deviation multiplied by 100 when expressed as percent).

- Concentration: The quantity of radioactive material stated in terms of activity (or mass) per unit of volume or mass of a medium.
- Confidence Interval: The interval for an estimate of a stated quantity within which the correct value of the quantity is expected to be (with a specified probability).

- Decision Level (L_c): The amount of a count or final instrument measurement of a quantity of analyte at or above which a decision is made that a positive quantity of the analyte is present.
- Diagnostic Examinations: Measurements performed to estimate the amount of radionuclide deposited in a person when an intake is known or is suspected to have occurred.
- Direct Bioassay: The measurements of radioactive material in the human body using instrumentation that detects radiation emitted from the radioactive material in the body. (Synonymous with in vivo measurement.)
- Emergency Measurements: Measurements for persons known or suspected to have been exposed to intakes of radioactive material greater than normally encountered in routine operations. For these situations, rapid analytical procedures giving a timely measurement result may be preferred.
- Indirect Bioassay: Measurements to determine the presence of or to estimate the amount of radioactive material in the excreta or in other biological materials removed from the body. (Synonymous with in vitro measurement.)
- In Vitro Measurement: Synonymous with indirect bioassay.
- In Vivo Measurement: Synonymous with direct bioassay.
- Lower Limit of Detection (LLD): The amount of analyte material that has a 95% chance of being detected when a signal occurs at or above the decision level. It has the same meaning as minimum detectable amount (MDA), which is preferred terminology for the standard.
- Minimum Detectable Amount (MDA): The smallest amount of a radionuclide in a sample that will be detected with a β probability of non-detection (Type II error), while accepting an α probability of erroneously detecting that radionuclide in an appropriate blank sample (Type I error). For this standard, the α and β probabilities are both set at 0.05. (See definition for acceptable minimum detectable amount.)

- Non-Blind Testing: Testing of capabilities when the service laboratory personnel are aware that they are being tested for conformance.
- Phantom: A simulated person or part of a person used for calibration of in vivo measurement systems. A phantom is sometimes constructed to allow placement of radionuclides in a geometry representing internal depositions.
- Precision: Dispersion of measurements with respect to a measure of location or central tendency (ANSI 1982).
- Precision Statistic: An estimator of precision calculated from a finite sample using a specified formula.
- Quality Assurance: Planned and systematic actions necessary to provide adequate confidence that analyses, measurements, or surveillance programs are satisfactory.
- Quality Control: Actions that control the attributes of the analytical process, standards, reagents, measurement equipment, components, system, or facility according to predetermined quality requirements.
- Radiobioassay: Measurement of radioactive material in the body or in a sample excreted or removed from the body.
- Relative Bias: The quotient of the bias and the "true" value.
- Relative Standard Deviation: Same as coefficient of variation.
- Relative Precision: The quotient of the dispersion of the measurement and either the true value or the mean of the measurement.
- Routine Measurements: Radiobioassays conducted on a planned schedule to determine if any intake may have occurred.
- Screening Measurements: Periodic measurements to determine the presence of, but not necessarily the quantity of radioactive material under routine conditions.
- Service Laboratory: Laboratory performing direct and/or indirect radiobioassay measurements for and in behalf of a user of radioactive material.

- Standard Deviation: The estimated dispersion of a set of measurements as given in the equation for the coefficient of variation.
- Standard Error: The standard deviation of the mean of a set of measurements. It includes the propagated random and systematic uncertainties. The standard error may be reduced to the standard deviation of the measurement when there is only one determination.
- Standard Reference Material (SRM): Material characterized by the National Bureau of Standards (NBS) for content of radionuclides. It is issued with a certificate specifying the contents.
- Testing Laboratory: A laboratory authorized to prepare bioassay specimens (excreta samples and phantoms) by adding known amounts of radioactive material for distribution to service laboratories. The testing laboratory is responsible for evaluating the performance of the service laboratories in meeting the performance specifications of this standard.
- Traceability: The ability to show that the assigned value of radioactivity of a sample does not differ from that obtained from the NBS for the same sample by more than 5%. Traceability may either be implicit, insofar as the laboratory's ability to assay any given radionuclide at any given time has been established, or explicit, when two or more samples are randomly selected from a batch for verification by NBS.
- Transfer Reference Standard (TRS): A material, containing radionuclides of interest in chemical and physical forms similar to bioassay specimens used to certify the amount of activity present in a person or sample measured. The radionuclides used for the preparation of the TRS are, when possible, related to Standard Reference Materials. The procedures for preparation of TRS are verified and documented.
- Unbiased: Measurement of a random variable is unbiased if it has zero bias; i.e., if the expected value of the measurement is equal to the correct value of the measured quantity.

- Verification: An act of confirming, substantiating, or assuring that an action, condition, or goal has been implemented, completed, or accomplished according to the specific requirements.

2.0 GUIDELINES FOR QUALITY ASSURANCE

Quality assurance is a planned program to verify that each part of the bioassay testing program is being accomplished adequately and that the intended purpose, to provide uniform acceptable bioassay measurements, is met. A QA program is in place for the DOE Laboratory Accreditation Program (DOELAP) and the National Voluntary Laboratory Accreditation Program (NVLAP) (DOE 1986a; DOE 1986b; RESL 1987; Roberson and Holbrook 1984; ANSI 1983). The bioassay QA program is intended to interface smoothly with the other programs and, where possible, use existing QA mechanisms (such as the Measurement and Quality Assurance (MQA) Program for the bioassay performance-testing program). Other references for QA programs include Quality Assurance Practices for Health Laboratories (APHA 1978), Requirements for an Effective National Radiation Measurements Program (NBS 1981), and DOE 5700.6B, Quality Assurance (DOE 1986c).

The following sections describe the recommended QA elements to be used by the bioassay performance-testing laboratory.

2.1 QUALITY ASSURANCE RESPONSIBILITY AND AUTHORITY

The overall responsibility for the QA program should rest with a QA coordinator. This person should act independently from the administrator of the bioassay performance-testing laboratory. This individual should have authority and organizational freedom to identify QA problems, to initiate, recommend or provide solutions, and where necessary, to control or stop further work until these problems are corrected. Such authority should be documented in writing and bear the signature of the performance laboratory administrator.

All personnel involved with bioassay testing should be cognizant of and comply with QA and quality control (QC) practices and procedures.

2.2 PERSONNEL QUALIFICATION AND TRAINING

Established training and retraining programs and procedures ensure that an adequate level of proficiency is achieved and maintained. Elements of such a training program include the following:

- description of the overall bioassay testing program
- goals of the program
- methods and practices used to achieve program goals
- review of safe operating and radiation work procedures
- procedural review and hands-on operation of equipment
- review of the draft ANSI N13.30
- review of QA and QC procedures
- bioassay handling and processing techniques
- documentation/record keeping procedures
- auditing methods and practices.

The QA coordinator should maintain an updated list of personnel who are qualified to work in the bioassay performance-testing laboratory, including the instruments that they are qualified to use. Training should be conducted by senior laboratory staff, who are required to review the content of the training sessions on a yearly basis to ensure that they meet the requirements of this manual.

2.3 CERTIFICATION OF NATIONAL BUREAU OF STANDARDS TRACEABILITY

Draft ANSI N13.30 specifies that radionuclide standards used to test the accuracy of analytical procedures and/or measurement equipment are either those designated as SRM by the National Bureau of Standards (NBS) or those directly compared with appropriate SRMs. The standard also states,

> "The ability of the testing laboratory to measure quantitatively shall be affirmed by establishing traceability to the NBS as described in NCRP Report No. 58 (NCRP 1985)"

Test radionuclides may gain traceability to the NBS in two ways: 1) by direct determination of the test radionuclide concentration at the NBS, 2) by the intercomparison pathway. The latter is a pathway whereby radionuclide concentration is determined using a measuring system that NBS has agreed independently assigns values of activity to an amount of radionuclide in a sample within a specified range of the value obtained by NBS for the same sample before the NBS value is revealed. Samples may also be calibrated directly by the NBS.

A "certificate of measurement and purity of absolutely standardized radioactive solution," from an NBS-certified laboratory shall be kept on file for each radionuclide used in the preparation of test samples and phantoms. Any dilutions of the standard radionuclide solutions should be documented. The goal of the traceability program is to ensure that the testing laboratory can provide test samples of accurately known radionuclide concentrations. Activities of samples should be determined with a standard deviation of 5% or less using methods given in the appendix.

2.4 QUALITY CONTROL CHECKS

An effective QA program requires continuing evaluation of procedures and equipment.

2.4.1 Equipment Checks

Daily QC checks of all level equipment should be performed and documented. These checks are considered Level 3 tests as described in Section 3.0 and are performed on the days that test samples and phantoms are prepared, including:

- the performance of balances used in gravimetric dilutions
- the response of counting equipment used to check the radionuclide concentration in test samples.

If checks reveal the need for adjustment to equipment the adjustment are followed by an appropriate Level 1 or Level 2 test.

2.4.2 In-House Audits

Extensive internal audits of all systems and record keeping should be conducted at least once per year, or more frequently if discrepancies are noted. At least one laboratory technician should assist the QA coordinator and the bioassay testing laboratory administrator in this auditing effort. Spot checks of record keeping for selected radionuclide test samples should be made and documented monthly. Visual checks of equipment and laboratory spaces should be made daily or before each use, and findings documented. The QA coordinator should provide monthly reports to the testing laboratory administrator on the status of the QA program.

2.4.3 Inspections by the National Bureau of Standards and Other Authorizing Organizations

Site review teams from NBS and organizations authorizing the performance testing program may perform periodic inspections of testing laboratory facilities. Consultation may be offered by the inspectors while onsite. Items of discrepancy should be brought to the immediate attention of the testing laboratory administrator, the laboratory supervisor, and the QA coordinator. The inspectors should follow up with a written list of the findings to the testing laboratory administrator and the laboratory supervisor. The laboratory supervisor should report the planned corrective actions to the testing laboratory administrator and QA coordinator immediately following the inspection. The laboratory supervisor should report monthly to the QA coordinator the current status of corrective actions. The laboratory supervisor should supply a corrective action letter to the inspection team leader.

2.4.4 Third-Party Cross-Checks of Samples

At the discretion of the QA coordinator, an aliquant from the diluted calibration solutions may be submitted to a third-party analytical laboratory for cross-check analysis as a further QC check. The third-party laboratory must be implicitly traceable to NBS. Special handling and nonroutine analyses are also requested of the third-party laboratory. In the event of greater than a 5% disagreement between the radionuclide concentration specified by the testing laboratory and the concentration found by the third-party laboratory, the test samples or phantoms from that batch are not used until the cause of the disagreement is resolved. After completion of in vivo counting performance tests, the test phantom may also be submitted to a third-party analytical laboratory for cross-check analysis using either destructive or nondestructive means.

2.5 DOCUMENTATION AND RECORD KEEPING

A laboratory notebook should be maintained to document QA-related information. All entries should be dated, signed, and nonerasable. When errors are made, the entry should be crossed through and initialed. Pages in the notebook should be used consecutively with no pages skipped. It is desirable to index entries of major significance to aid in rapid data retrieval.

The QA notebook should include or reference the file where the following documents are kept:

- certificates for standard solutions
- dilution factors and/or worksheets for calculating concentrations of diluted standards
- standard laboratory and QA/QC procedures
- entries that indicate any changes, deviations, or modifications to any device or system that may impact the quality of any measurement.

When worksheets are not stored in a QA notebook, a reference to the storage location should be entered in the notebook.

Records of bioassay test sample preparations are stored in the process-control data base. The minimum information that is included is:

- sample identification
- batch identification
- batch preparation date
- identification of the individual who prepared the batch
- dilution factors of standard radionuclides
- confirmation of test sample radionuclide content or concentration.

Test sample shipment dates should also be documented. The system should be designed for rapid retrieval of information at present and future dates.

3.0 GUIDELINES FOR THE CALIBRATION AND USE OF MEASUREMENT AND TEST EQUIPMENT

The equipment and devices used to maintain QA are referred to as Measurement and Test Equipment (M&TE). The M&TE includes devices or systems that are used to calibrate, measure, gauge, test, inspect, or control the acquisition of research, development, or operational data. The M&TE may also be used to determine compliance with specifications or other technical requirements. M&TE may include devices used for indication only. For that reason, M&TE is divided into three categories or levels as defined in the following sections. Calibration stickers should be attached to each device to identify its appropriate level. A list of all M&TE equipment with its current status and classification level should be maintained on file by the QA coordinator. The most common M&TE used by a testing laboratory will be balances and radiation measurement instruments. The following sections describe the recommended procedures for calibration and use of M&TE.

3.1 LEVEL 1 M&TE - STANDARDS

Level 1 M&TE is defined as equipment that is either classified as a primary standard or has been calibrated by a qualified standards or metrology laboratory. These are the devices by which traceability to the NBS is attained. Examples of Level 1 M&TE include radionuclide sources that have been calibrated at NBS, intercomparison standards for radiation measurements, and local standards for mass, temperature, pressure, voltage, current, time, and distance.

A primary calibration of Level 1 equipment should be conducted at least once every 2 years. A successful demonstration of calibration proficiency through a measurement performance test with NBS is considered equivalent to a primary calibration of Level 1 equipment. At the time of calibration of the Level 1 equipment, the calibrating standards laboratory should either 1) adjusts the equipment to respond accurately when compared to a known standard, or 2) provides calibration factors. A calibration certificate that shows pertinent calibration information, such as tolerances and standards to which the device was intercompared, should also be provided. A calibration

sticker that shows serial number, calibration date, expiration date, limitations, and by whom the device was calibrated should be applied to the equipment. If such a sticker is not attached or if limitations are found to be outside of the area of accepted tolerances, the device should not be used as Level 1 equipment. Level 1 M&TE is usually calibrated over the entire range of the device.

The QA coordinator should file the calibration certificates. References to these certificates and other pertinent information should be in the QA notebook.

3.2 LEVEL 2 M&TE - EQUIPMENT

Level 2 M&TE includes devices that are calibrated by the user. This equipment may be calibrated for a particular use and not necessarily over the entire useful operating range. Examples of Level 2 equipment include monitoring and counting equipment, and temperature, pressure, time, and distance measurement devices that are intercompared to a Level 1 standard.

Level 2 equipment should be identified by a "User to Calibrate" sticker that contains the serial number of the device. The calibration frequency may be determined by the user. However, it is suggested that frequently used devices receive a performance check at least once every 3 months; devices that are less frequently used must be calibrated before each use.

Calibration and QA data should be documented and kept on file by the QA coordinator as part of the QA program. The QA notebook should reference the storage locations for Level 1 and Level 2 maintenance and calibration data.

3.3 LEVEL 3 M&TE - EQUIPMENT

Level 3 equipment includes devices that may be used as "shop aids" or for "indication only" and for which calibration is not required. A sticker that identifies the device as "Not Calibrated, for Indication Only" should be attached.

Record keeping for Level 3 M&TE is at the discretion of the QA coordinator or laboratory personnel and need not be a requirement of the QA program.

4.0 DATA BASE FOR RADIOBIOASSAY PERFORMANCE TESTING

The data base for the bioassay performance-testing laboratory provides a means for tracking test samples, entering reported concentrations from service laboratories, and generating reports. The data base is the primary means of documenting service laboratory performance. It is recommended that the data base be maintained on a computer system. The following sections describe the recommended records system for the testing laboratory.

4.1 SAMPLE CODING INFORMATION

The sample designation (i.e. AAUSR0898610022), provides a unique identifier for each test sample and phantom. The first two letters identify the laboratory to which a test sample was sent. The third letter identifies the test matrix - U, if artificial urine; F, if artificial feces, W, if whole body phantom; L, if lung phantom, and T, if thyroid phantom. The fourth and fifth letters and first three numbers are the symbol and three-digit mass number of the test radionuclide (e.g., SR089, OI131). For single letter symbols, the blank space is filled with a zero. The ninth- and tenth-place digits are the last two numbers of the year; the next two digits are the batch number; and the last three digits are the sample number.

4.2 RECORD FORMAT

Each record (all data for a single sample), should consist of the following:

- sample code i.e., AAUSR0898610022
- true nuclide concentration or phantom activity including units (i.e., 10 pCi/L or 200 nCi)
- reference date of calibration
- background and/or appropriate blank value used by the service laboratory and a reference for the procedure used to obtain the value
- reference for brief description of apparatus and equipment used in the analysis

- reference for analytical procedures used in the analysis
- service laboratory estimate of standard error
- reported nuclide concentration, including units corrected for decay
- counting time for analysis
- volume of samples analyzed with units
- reference time and date of reported analysis.

4.3 DATA BASE ORGANIZATION

The data base should be organized in such a way that all data specified in Sections 4.1 and 4.2 may be easily obtained for the following subsets of the data base:

- any specified service laboratory
- any particular test nuclide
- a given test matrix and a particular year
- a given test matrix and a particular batch.

4.4 DATA ENTRY

Prior to shipping the samples to the service laboratory, the sample code, true nuclide concentration, and reference date of calibration should be entered into the data base. When results are received from the service laboratory, the reported nuclide concentration, reference date of the reported analysis, background count, counting time, standard error, equipment used, sample volume (where appropriate), units, and a procedures reference for each sample should then be entered.

4.5 PERFORMANCE REPORTS

Following the receipt of analysis data for all samples sent to a service laboratory, the test statistics for the performance report should be calculated. The test statistics include the relative bias (B_r), relative precision (S_A and S_B), and the MDA for each nuclide and performance category in which

the service laboratory has requested accreditation. Test statistics are calculated in accordance with draft ANSI N13.30 and Volumes 2 and 3 of this report.

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APPENDIX

PROPAGATION OF ERROR IN SPIKED IN VITRO SAMPLES

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PROPAGATION OF ERROR IN SPIKED IN VITRO SAMPLES

The methods used to estimate the total error in the analysis of in vitro test samples and in vivo phantoms shall be the same as those discussed by Kanipe (1977). Assume that the individual components of the total error are independent normally distributed variables and that propagation for the manipulation of various functions is expressed as below.

Function	Error Formula
$Q = X \pm Y$	$\sigma_Q = (\sigma_x^2 + \sigma_y^2)^{\frac{1}{2}}$
$Q = aX \pm bY$	$\sigma_Q = (a^2 \sigma_x^2 + b^2 \sigma_y^2)^{\frac{1}{2}}$
$Q = XY$	$\sigma_Q = XY (\sigma_x^2/X^2 + \sigma_y^2/Y^2)^{\frac{1}{2}}$
$Q = X/Y$	$\sigma_Q = X/Y (\sigma_x^2/X^2 + \sigma_y^2/Y^2)^{\frac{1}{2}}$

Using the error formulas above, the equations detailed in the procedure, and the error estimates quoted in the solution certificates supplied for each nuclide, the total error in the prepared samples may be estimated.

REFERENCE

Kanipe, L. G. 1977. Handbook for Analytical Quality Control in Radioanalytical Laboratories. PB-277-254, U.S. Department of Commerce National Technical Information, Springfield, Virginia.

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