American National Standard—Traceability of Radioactive Sources to the National Institute of Standards and Technology (NIST) and Associated Instrument Quality Control

Sponsor
National Committee on Radiation Instrumentation, N42

Accredited by the

American National Standards Institute

Secretariat

The Institute of Electrical and Electronics Engineers, Inc.

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Abstract: A mechanism for manufacturers to estabilish traceability of radionuclide sources that are certified for radionuclide activity; concentration; or alpha, beta, x-, or gamma-ray emission rate to the National Institute of Standards and Technology (NIST) is described.
Keywords: instrument quality control, NIST, quality, quality assurance, quality control, radiation instrumentation, radioactivity, radionuclide sources, traceability

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Introduction

(This introduction is not a part of ANSI N42.22-1995, American National Standard—Traceability of Radioactive Sources to the National Institute of Standards and Technology (NIST) and Associated Instrument Quality Control.)

This standard is the responsibility of the Accredited Standards Committee on Radiation Instrumentation, N42. Committee N42 delegated development of this standard to Subcommittee N42.RM. Drafts were reviewed by Committee N42, Subcommittee N42.RM, and other interested parties, and the comments received were utilized in producing the standard as finally approved. The standard was approved by N42 letter ballot of 18 November 1994.

At the time it approved this standard, the Accredited Standards Committee on Radiation Instrumentation, N42, had the following members:

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American National Standard—Traceability of Radioactive Sources to the National Institute of Standards and Technology (NIST) and Associated Instrument Quality Control

1. Overview

1.1 Scope

The standard provides a description of the criteria necessary for manufacturers to maintain and assure measurement traceability of radionuclides to the National Institute of Standards and Technology (NIST). These criteria are provided in the following areas:

a) Quality assurance program
b) Facilities and equipment
c) Participation in a NIST Measurements Assurance Program (MAP)
d) Certificates

1.2 Purpose

The purpose of this standard is to describe a mechanism for manufacturers to establish traceability of radionuclide sources that are certified for radionuclide activity (Bq); concentration (Bq/g); or alpha, beta, x-, or gamma-ray-emission rate (s^{-1}) to NIST. Traceability requires the implementation of a quality assurance program and participation in a MAP as described in this standard.

2. References

This standard shall be used in conjunction with the following publications. If the following publications are superseded by an approved revision, the revision shall apply.

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ANSI N42.14-1991, American National Standard Calibration and Use of Germanium Spectrometers for the Measurement of Gamma-Ray Emission Rates of Radionuclides.[1]

ANSI N42.15-1990, American National Standard Performance Verification of Liquid-Scintillation Systems.

ANSI PN42.23/D2, Draft Measurement and Associated Instrumentation Quality Assurance for Radioassay Laboratories, Aug. 1994.[2]

ASME NQA-1-1994, Quality Assurance Program Requirements for Nuclear Facilities.[3]

ISO/IEC Guide 25: 1990, General requirements for the competence of calibration and testing laboratories.[4]

3. Definitions

3.1 Special word usage

The word “shall” denotes a requirement and the word “should” denotes a recommendation. To conform to this standard, sources shall be manufactured in accordance with the requirements of this standard, but not necessarily with its recommendations. However, justification should be documented for deviations from recommendations.

3.2 Glossary

3.1 certified sources. Sources that have been certified for radionuclide activity (Bq); concentration (Bq/g); or alpha, beta, x-, or gamma-ray emission rate (s^{-1}).

3.2 derived traceable sources. Sources prepared or derived from certified sources that have been calibrated in accordance with this standard. Examples are dilutions of a liquid standard and special geometries such as charcoal cartridges, marinelli (reentrant) beakers, and filters.

3.3 manufacturer. Any organization that produces and distributes sources that are certified with respect to radionuclide activity or a radiation emission rate.

3.4 Measurements Assurance Program (MAP). A program that allows manufacturers to verify the accuracy of their measurements through exchange and measurement of samples with NIST. This involves the analysis of blind test samples sent to the manufacturers by NIST, and NIST measurement of sources certified and provided by the manufacturers.

3.5 NIST. The National Institute of Standards and Technology, the US federal agency with legally mandated authority to maintain national physical standards for the activity of radionuclides.

3.6 NIST source verification. The process of verification of the capability of a manufacturer to calibrate a radionuclide source that is traceable to NIST. This is achieved through calibration by the manufacturer of a

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[2]This authorized standards project was not approved at the time this went to press. It is available from the IEEE.

[3]ASME publications are available from the American Society of Mechanical Engineers, 22 Law Drive, Fairfield, NJ 07007, USA.

[4]ISO publications are available from the ISO Central Secretariat, Case Postale 56, 1 rue de Varembé, CH-1211, Genève 20, Switzerland/Suisse. ISO publications are also available in the United States from the Sales Department, American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036, USA.

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source distributed by NIST without disclosure of the known value. The reported value is compared to the NIST value and, if appropriate, a report of traceability is issued.

3.7 product verification. The process of verification of the traceability of a calibration standard of a manufacturer by NIST. This is achieved by the submission of a source from a manufacturer to NIST for verification of the value certified by the manufacturer. The reported value is compared to the NIST value, and if appropriate, a report of traceability is issued.

3.8 NIST traceability. The process of relating the measurement accuracy of radionuclide sources to national physical standards. Traceability is achieved by demonstrating the capability to produce accurate standardized sources by participation in a MAP with linkage to NIST and production of certified materials in accordance with a quality assurance program that meets the guidance provided in this standard. Traceability of sources requires demonstrated measurement traceability as described in clause 6 and applies only to products produced in accordance with this standard.

3.9 reference material. A material or substance one or more properties that are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

3.10 total propagated uncertainty. An estimate or approximation of the accuracy of a measured value by propagation of individual uncertainties in accordance with NIST recommendations [B4].

3.11 verification. Confirmation by examination (testing) with evidence that specified requirements have been met.

4. Quality assurance program

To establish and maintain traceability, manufacturers shall implement a quality assurance program. Quality assurance consists of all planned and systematic actions that provide confidence in the manufacturing and calibration of sources. The quality assurance program shall be documented in a quality assurance manual, which is controlled to ensure that responsible individuals are utilizing the current version.

Guidance for establishing quality assurance programs can be found in a number of documents, including ASME NQA-1-1994,[5] ISO Guide 25, ANSI PN42.23, and [B6]. ASME NQA-1-1994 addresses Nuclear Regulatory Commission (NRC) quality assurance requirements contained in 10 CFR 50 Appendix B for nuclear facilities (nuclear power reactors and fuel facilities) [B5]. While there are no regulatory requirements for suppliers of certified radionuclide sources to meet this standard, appropriate sections of ASME NQA-1-1994 have been utilized in the preparation of this standard.

As a minimum, the quality assurance program shall address the following elements:

— Organizational structure
— Quality assurance manual
— Design control
— Control of purchased materials, equipment, and services
— Procedures and instructions
— Document control
— Records
— Personnel qualifications
— Quality control of instruments

[5]Information about references can be found in clause 2.

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— Product quality control
— Audits

4.1 Organizational structure

The operations of the manufacturer shall be organized in such a way as to meet the requirements of this standard.

The manufacturer shall

a) Provide managerial staff with the authority and resources to discharge their duties.
b) Be organized in such a way that confidence in its judgment and integrity is maintained at all times.
c) Define and document the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the quality of sources.
d) Provide adequate supervision by persons familiar with the calibration or test methods and procedures, the principles of the calibration technique, and assessment of results.
e) Have a technical manager or equivalent who has overall responsibility for technical operations.
f) Have a quality manager or equivalent with the responsibility for ensuring that the requirements of the quality system in the laboratory are met on a day-to-day basis. The quality manager shall have direct access to the highest level of management. The quality manager may also be the technical manager if resource limitations require it.
g) Provide alternates for the technical and quality managers when absent.
h) Where relevant, have documented policy and procedures to ensure the protection of the confidential information and proprietary rights of customers.
i) Where appropriate, participate in audits by clients, interlaboratory comparisons, and proficiency testing programs.

4.2 Quality assurance manual

A quality assurance program shall be established and maintained in accordance with commitments documented in a quality assurance manual. The quality assurance manual shall address, as a minimum, the elements specified in this standard and define and document policies and objectives for the commitment of management to the quality of sources. The quality assurance manual shall be available for use by all personnel associated with quality functions. Management shall ensure that policies and objectives in the quality assurance manual are communicated to, understood, and implemented by all personnel. The quality assurance manual shall be periodically reviewed and maintained under the responsibility of the quality assurance manager.

The quality assurance manual shall also state the policy of the organization for each applicable area in this standard. It shall contain

a) A policy statement by top management affirming its commitment to quality
b) The organization and management structure of the facility, its place in any parent organization, and a relevant organizational chart
c) The relation between management, technical operations, support services, and the quality assurance system
d) Procedures for control of documentation
e) Job descriptions of key staff and reference to the job descriptions of other staff with specifications of educational requirements and work experience
f) Identification of approved signatories for quality documents
g) The methods of the laboratory for achieving traceability of measurements
h) The scope of calibrations in the laboratory, including specification of radionuclide sources that are traceable

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i) Procedures to be followed for feedback and corrective actions whenever discrepancies or departure from documented policies and procedures are detected
j) Reference to applicable measurement assurance programs with NIST, the use of reference materials, and internal quality control procedures
k) Procedures for dealing with complaints and maintaining the confidentiality and proprietary rights of clients
l) Methodology for determination of uncertainties

4.3 Design control

Design control is the mechanism used to ensure that traceable sources meet design specifications with respect to physical, chemical, and radiochemical characteristics; geometry; quantity; and quality assurance requirements. If NIST traceability of sources requires special processing, then a determination of applicability shall be made. Specific areas that should be addressed include

a) Processing of purchase orders
b) Review and acceptance of orders, including technical review and evaluation
c) Process control during the manufacturing process
d) Verification of calibration techniques
e) Acceptance testing and approval of final product
f) Issuance of certificates
g) Records management

4.4 Control of purchased material, equipment, and services

Measures shall be established for documenting and controlling procurement of equipment, supplies, and services that have an impact on quality.

Provisions shall be made for receipt inspection to verify that items meet the description and requirements of the procurement document. Nonconforming items shall be labeled as such and shall not be used.

4.5 Procedures and instructions

Instructions and/or procedures for the operation of equipment and calibration of sources shall be implemented where the absence of such instructions could jeopardize the quality of sources. All instructions, manuals, and reference data relevant to production of certified radioactive sources shall be up-to-date and readily available to the staff. Staff shall be trained on all procedures relating to their job function. All training shall be documented and maintained as quality records.

Standard operating procedures should include, but not be limited to, the following:

a) Calibration and operation of laboratory instruments and equipment
b) Analytical methods
c) Data verification
d) Implementation of quality control programs, including the measurement assurance activities with NIST
e) Computer software quality assurance, including verification and validation of software
f) Nonconformance with quality assurance requirements and corrective actions
g) Procurement of quality-related items

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4.6 Document control

The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality shall be controlled to assure that correct documents are being employed. Such documents, including those with changes, shall be reviewed for adequacy and approved for release by designated personnel at an appropriate frequency.

The control system shall be documented and shall provide for

a) Identification of documents to be controlled and their distribution
b) Assignment of responsibility for preparing, reviewing, approving, and issuing documents
c) Review of documents for adequacy, completeness, and correctness prior to approval and distribution

4.7 Records

a) Records shall be maintained to document observations, calibration data, instrument calibrations, and other quality-related data necessary to reproduce calibration certificates.
b) Copies of all calibration certificates shall be maintained and available to customers for at least 10 years.
c) Records designated as quality records shall be stored and maintained in fire-resistant facilities, or duplicate sets shall be maintained in an alternate facility.
d) Quality records shall be maintained for a period of at least 10 years.

4.8 Personnel qualifications

a) Personnel shall have the necessary education, training, technical knowledge, and experience for their assigned functions.
b) There shall be a job description for each member of the technical staff.
c) Procedures shall be established and maintained for identifying training needs and ensuring that all staff are trained to perform their designated functions. Records of qualifications, training, skills, and experience relevant to their work shall be established and maintained for the technical staff. A qualification and re-qualification program shall be established for individuals performing calibrations or producing sources.

4.9 Quality control of instruments

Measures shall be implemented to ensure that systems used for measuring and testing of radioactive sources are operating properly and, where applicable, are accurately calibrated.

The instrument quality control program shall address the following:

a) Verification tests shall be performed on instrumentation used for NIST-traceable calibrations.
b) Periodic quality control checks shall be made to demonstrate the operability and accuracy of measuring equipment. These tests shall be performed according to a defined schedule appropriate for the type of test.
c) Procedures shall specify operating parameters for instruments and any specific operational limitations such as source geometry, counting rate, deadtime limits, etc.
d) Performance and qualification testing shall be documented and reviewed by management.

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4.10 Product quality control

a) The calibration of radionuclides and production of sources shall be documented so that each step of the process can be verified or checked.
b) Sources shall be clearly identified and labeled when first prepared and should retain this identity in all subsequent steps.
c) Calibration results shall be reviewed and approved by a qualified individual other than the person performing the calibration.
d) Sources derived from traceable material shall be tested prior to distribution to verify the certificate value. For certified sources made in batches, appropriate sampling of the batch is acceptable if the process has been demonstrated to produce reproducible sources or there are unlikely to be significant differences between sources.
e) Appropriate tests shall be performed to demonstrate the stability of sources when an expected lifetime or expiration date is specified by the manufacturer. Examples of tests include: evaluation of radiation damage for high-level sources, plateout of radionuclides from solution, and homogeneity of solid sources.

4.11 Audits

In addition to audits performed by clients, the facility shall arrange for audits of its activities at least annually to verify that its operations comply with the requirements of the quality assurance program. Such audits shall be carried out by trained and qualified staff who are, whenever possible, independent of the activity audited. Where audit findings cast doubt on the validity of a standard or calibration technique, the laboratory shall immediately initiate investigations and, when necessary, implement corrective actions. The laboratory shall immediately notify, in writing, all affected clients. All audit findings and corrective actions shall be documented. The quality assurance manager shall ensure that these actions are discharged in a timely manner.

5. Facilities and equipment

Adequate facilities and equipment are essential in producing accurate traceability certifications. Management shall provide necessary facilities and equipment to meet program quality objectives. The availability of necessary equipment and supplies is an integral part of assuring the quality of radioactive sources. For more detailed information regarding radiochemistry equipment and facilities, ANSI N42.14-1991, ANSI N42.15-1990, [B1], and [B3] may be useful.

5.1 Facilities

The laboratory facilities shall include space and utilities appropriate for the scope of work performed. This should include control of environmental factors, such as temperature, humidity, and other parameters that could affect the quality of radionuclide sources. If a facility is utilized for the production of both low-level sources (for example less than 3.7 MBq) and high-level sources (for example greater than 3.7 MBq), then the production areas for the low-level sources should be physically separated from those for the high-level sources to prevent cross-contamination of samples.

The laboratory areas shall include appropriate equipment, such as fume hoods, glove boxes, safety showers, etc. Adequate bench space for the number of employees working in the facility shall be provided. Laboratory areas shall be maintained to ensure the work areas are neat, clean, and orderly. Environmental conditions shall be maintained as appropriate for specific operations. For example, analytical balances shall be used in areas that are relatively free from dust, air currents, and vibration. A stable source of electrical power, prefer-

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ably regulated and uninterruptible, shall be available for radiation-detection instrumentation used to calibrate sources.

Contamination levels in laboratory areas shall be controlled to prevent contamination of sources and instruments. This will probably require control of contamination to a higher degree than required for personnel safety. Appropriate instrumentation and monitoring procedures shall be used to monitor the cleanliness of work areas utilizing radioactive material.

Radiation detection equipment should be physically separated from process areas for radioactive materials. If common facilities are used for both low-level and high-level radionuclide measurements, then strict contamination control procedures shall be employed before transfer of samples from production areas to the counting room(s).

The packing and shipping area should be separated from the production areas. All radioactive material should be monitored for removable contamination before transfer to the shipping area.

5.2 Equipment

Equipment for the calibration of radionuclide sources shall be maintained and controlled by the laboratory performing calibrations. The calibration facility shall maintain the equipment necessary to measure potential contaminants or interferences. For example, if gamma-ray-emitting radionuclides are calibrated by ionization chamber, then high-resolution gamma-ray spectrometry should be available for assaying gamma-ray-emitting impurities. Alpha-particle spectrometry may be necessary to assay impurities in alpha-emitting sources that are calibrated by liquid scintillation counting. More than one technique should be utilized for calibrations and verification.

6. Participation in NIST MAP

The production of NIST traceable radionuclide sources requires periodic verification of measurements through participation in a MAP with NIST. Manufacturers shall, when possible, utilize both product verification and NIST source verification to assure that preparation and quality control steps are adequate to ensure the traceability of radionuclide sources.

6.1 Verification tests

6.1.1 Frequency of tests

Verifications with NIST shall be performed at least annually for each calibration technique and instrument type involving relative or comparative calibrations. Absolute calibration techniques shall be verified with NIST every three years or prior to use if used less often than every three years.

6.1.2 Test requirements

For calibrations utilizing the same instrument and technique over a wide energy range, verifications shall include the following:

a) Separate tests for gamma-ray emitters with energies less than 250 keV and those with energies greater than 250 keV.
b) Separate tests for beta-ray emitters with average energies less than 100 keV and those with average beta energies greater than 100 keV.

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c) Separate tests for alpha-particle sources used for high-resolution spectrometry and alpha sources used for measuring total alpha activity.

6.1.3 Radionuclides

Each radionuclide for which traceable sources are issued should eventually be included in the testing program. However, until that time, traceability for an untested radionuclide is assumed if the calibration technique has been demonstrated for other radionuclides with like measured radiations for the energy ranges described in 6.1.2. The uncertainty attached to sources with indirectly tested traceability shall include uncertainties in radiation probabilities used, in assumed energy-efficiency relations, and in corrections for differences in geometry and scattering or absorption.

6.2 Acceptance criteria

a) Successful verification by NIST requires that the difference between the NIST value and the value (test value) of the manufacturer be less than the total propagated uncertainty of the difference with a coverage factor of three (99% confidence level).

b) If the verification test of a manufacturer does not meet these criteria, the manufacturer shall investigate the cause and resolve the difference with NIST. If the difference cannot be resolved within 90 days or within a time interval agreed to by NIST and the manufacturer, the standard in question and sources calibrated with the same instrument and technique shall not be considered traceable until a successful verification test has been performed.

c) If test results from a production lot do not meet the acceptance criteria, all customers receiving standards from that lot shall be notified of the disagreement with NIST and shall be provided with test results.

6.3 Traceability of derived sources

Traceability of derived sources can be established if the following conditions are met:

a) The derived traceable sources are prepared from material that is traceable.

b) Appropriate tests are conducted to demonstrate that the preparation process has not adversely affected the accuracy of the original calibration. Testing shall be designed to verify sample homogeneity to the level of intended use, quantitative dilutions or transfers, chemical stability, radionuclide purity, and accuracy of the derived standard.

c) If derived sources are produced in lots, testing shall include appropriate sampling of the lot to ensure product integrity. Standards that are stored for significant periods of time and that may be subject to deterioration (e.g., plateout or hydrolysis of liquid sources, leakage from gaseous sources) shall be periodically tested or shall be tested prior to distribution.

d) NIST verification of derived sources (e.g., charcoal cartridges, solids, water equivalent sources, filters, etc.) is recommended. However, due to the diversity of secondary sources, opportunities for verification with NIST may be limited due to the costs and extra resources necessary for special calibrations. In this case, the derived sources may be termed traceable provided the procedures subsequent to establishment of traceability are subjected to an internal MAP that has been examined and approved by qualified individuals. (Although the term traceable is applied to derived sources, NIST does not accept responsibility for the accuracy of the procedures used to prepare such sources.)

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7. Traceability by participation in a national standardizing laboratory (NSL) MAP

In special situations where NIST cannot provide measurement verification of the standards of a manufacturer, traceability may be established by demonstrating traceability with a NSL of another country. This would require the NSL to verify that the manufacturer adheres to International Committee for Radionuclide Metrology (ICRM) guidelines. The NSL would provide NIST with a report providing documentation that the manufacturer adheres to the ICRM guidelines and a summary of the testing by NSL of the sources of the manufacturer.

8. Certificates

The manufacturer shall provide a certificate for each standard and shall include at least the following information:

- Manufacturer
- Radionuclides calibrated
- Identification number
- Calibration method
- Activities or emission rates with associated uncertainties (random, systematic, and total) and the confidence limits
- Calibration or reference date and time (if appropriate for the half-life of the radionuclide)
- Physical and/or chemical description of the source
- Radionuclide impurities

The certificate shall include SI units for all values. Supplemental information, including preparation and intended use, may be presented in accompanying notes or attachments to the certificate or product specifications. In addition to the information required in the preceding list, supplemental information should be provided in the areas discussed in 8.1.

8.1 Physical description of the source

Liquid sources to be dispensed quantitatively by the user should be described in terms of chemical composition, acidity, carrier concentration, density, and total mass in grams. Special information needed for further dilution or deposition should be given in notes. For mixtures of solid particles (soil, dried biological materials, etc.), the details of homogeneity tests and the limiting sample size for which the standard may be used should be stated. Certificates for gases should include descriptions of dilution gases used when applicable.

Source dimensions, including active area for filters and radionuclide distribution for charcoal cartridges, should be specified as part of the certificate. Blank samples or construction material (e.g., Mylar® covering) should be available to a user for evaluating transmission or attenuation when necessary. Resolution tests for alpha-particle or low-energy photon sources should be described in sufficient detail to permit customers to determine their applicability for their use. Large area sources (greater than 10 cm^2) should be characterized with respect to surface uniformity.

8.2 Calibration method

A brief description of the calibration method shall be specified (i.e. ionization chamber, gas proportional counter, etc.). For comparative measurements, both the comparison instrument and the origin of its calibration should be specified. Literature references may be given if the method is not generally used or if special corrections or calculations are required.

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8.3 Impurities

All identified impurities shall be listed, together with their measured activities and uncertainties. An upper limit should be indicated for other possible impurities, as inferred from the known sensitivity of the stated measuring technique, with special reference to any impurities likely to have been produced with the primary radionuclide.

8.4 Uncertainty estimates

The certificate shall contain a clear and unambiguous statement of total uncertainty. Major individual random and nonrandom components of uncertainty should also be given, together with a statement of the method by which they have been combined to obtain the overall value. If the quoted uncertainty is less than the uncertainty specified in verification tests with NIST for the same radionuclide and calibration technique, then the certificate should state the justification for the lower estimate of uncertainty. Generally, the stated uncertainty should not be lower than the uncertainty specified by the manufacturer in the most recent NIST verification test.

8.5 Decay data and user notes

Each certificate should include decay data and references relevant to the calibration and intended use of the source. Notes accompanying the sources should provide warnings about any special precautions to be taken in the use of the source (such as those relating to fragility or sensitivity to moisture). Application notes dealing with common problems (cascade summing, interference from Compton edge, etc.) affecting complex applications such as gamma spectrometry should be included.

9. Bibliography

[B1] EPA-600/7-77-088, Handbook for Analytical Quality Control in Radioanalytical Laboratories, Aug. 1977.

[B2] Hoppes, D. D. and Hutchinson, J. M. R., “Guidelines for Acceptance of Radioactivity Calibration Sources,” *Applied Radiation Isotopes*, vol. 42, no. 9, 1991, pp. 893–897.

[B3] Inhorn, Stanley, *Quality Assurance Practices for Health Laboratories*. Washington, D.C.: American Public Health Association, 1978, Chapter 17 (Radiochemistry).

[B4] NIST Technical Note 1297, Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results, Jan. 1993.

[B5] US Code of Federal Regulations, Part 50, Domestic Licensing of Production and Utilization Facilities, Rule 10, Energy, Appendix B, Quality Assurance Criteria.

[B6] USNRC Regulatory Guide 4.15, Quality Assurance for Radiological Monitoring Programs, Feb. 1979.

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