

MEASUREMENT QUALITY ASSURANCE FOR RADIOASSAY LABORATORIES

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INTRODUCTION

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

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

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

COMMITTEE MEMBERSHIP

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

PURPOSE

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

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

SCOPE

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

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

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

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

NATIONAL PERFORMANCE TESTING PROGRAM

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

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

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

QUALITY ASSURANCE

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

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

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

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

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

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

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

SUPPORTING INFORMATION AND GUIDANCE

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

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

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

- record retention by the service laboratory
- test selection.

STATUS OF ANSI N42.2 STANDARD

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

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

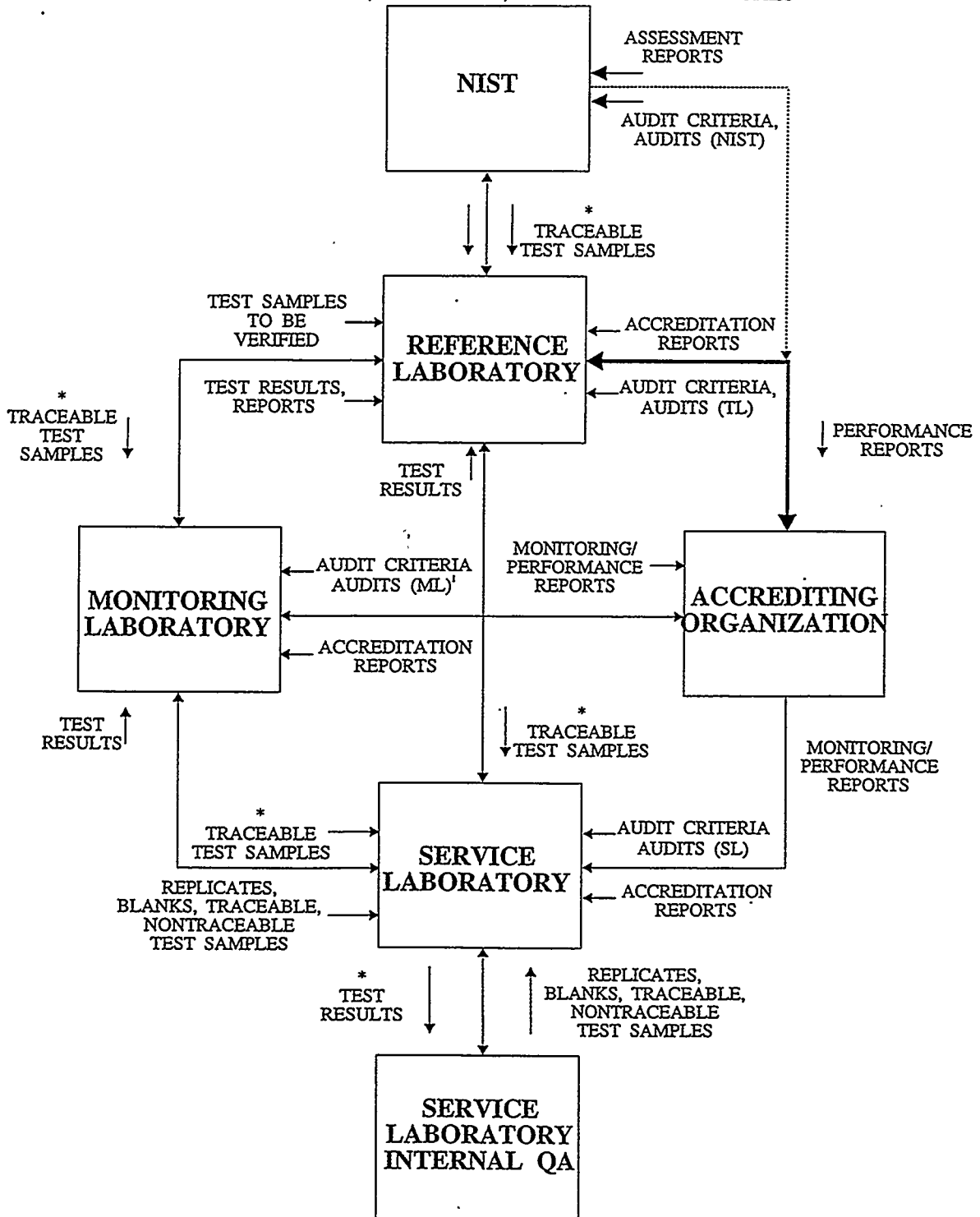


Figure 1 - National Performance Testing Program