MANUAL CHAPTER 1230

QUALITY ASSURANCE PROGRAM FOR RADIOLOGICAL CONFIRMATORY MEASUREMENTS

1230-01 PURPOSE

This chapter establishes criteria for a quality assurance (QA) program for radiological measurements performed by Regional Offices as a part of the inspection and investigation process.

1230-02 OBJECTIVE

The objective of the QA program is to ensure that all measurements being performed by Regional Offices or their contractors are of acceptable precision and accuracy so that the measurements are a proper reflection of actual conditions and of licensee performance.

1230-03 DEFINITIONS

03.01 Quality Assurance (QA): Planned and systematic actions necessary to provide adequate confidence in the results of a measurement or measurement program. Quality assurance includes "quality control."

03.02 Quality Control (QC): QA actions that provide a means to control and measure the characteristics of measurement equipment and processes to established requirements.

03.03 Radiation Protection Instruments: For the purpose of this manual chapter, radiation protection instruments are defined as portable health physics survey meters used for detection and measurement of levels of ionizing radiation fields or levels of radioactive surface contamination.

03.04 Radiological Confirmatory Measurements: Radiological confirmatory measurements are those measurements of radiation or radioactivity that are performed by NRC inspectors or IE contractors as checks on the ability of licensees to make accurate measurements.

03.05 Cooperative Agreement: A written agreement between NRC and an entity (State, etc.) under which the entity performs a service and is reimbursed from NRC funds. The Office of Administra-

tion is responsible for officially consummating the cooperative agreement.

1230-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Director, Division of Quality Assurance, Safeguards, and Inspection Programs

a. Establishes criteria and guidance for the QA program for radiological confirmatory measurements.

b. Evaluates regional radiological measurements activities and the implementation of the QA program.

c. Monitors those activities of the Department of Energy's Radiological Environmental Sciences Laboratory and the National Bureau of Standards that are related to contracted analytical laboratory support to the NRC.

04.02 Regional Administrators, NRC Regional Offices

a. Develop and implement instructions and procedures necessary to implement the provisions of this chapter.

b. Audit the performance of their regional confirmatory measurements activities to ensure adherence to requirements of the QA program.

c. Appraise the performance of States under cooperative agreement to the NRC according to the provisions of IE MC 1415.

1230-05 BASIC REQUIREMENTS

05.01 Applicability. This chapter and appendix apply to the Office of Inspection and Enforcement, NRC Regional Offices, and contractors. All radiological confirmatory measurements performed by these organizations in fulfillment of the NRC mission are subject to the quality assurance program established in this chapter.

05.02 Appendix 1230. The appendix sets forth the main elements, criteria and guidelines to implement the QA program.

05.03 Audits. Periodic audits shall be planned and conducted to verify implementation of the quality assurance program. Regional Offices shall plan and conduct audits of their own operation. An overall assessment of the quality assurance program and its implementation shall be completed periodically by the Division of Quality Assurance, Safeguards, and Inspection Programs.

05.04 Implementation. Regional Offices shall develop and implement a system of procedures and records which are consistent with their operations and necessary to implement the requirements of the quality assurance program described in the appendix.

05.05 References

a. ANSI N323-1978, Radiation Protection Instrumentation Test and Calibration.

b. Regulatory Guide 4.15, Quality Assurance for Radiological Monitoring Programs (Feb. 1979), contains guidance and a list of references on the subject of quality assurance for radiological measurements.

END

Appendix

APPENDIX 1230

A. PURPOSE AND SCOPE

This appendix establishes requirements for a program to assure the quality of the results of independent radiological measurements made by Regional Offices and contractors during the conduct of inspection and investigation activities.

The scope of the requirements established here is limited to the basic elements of the quality assurance program. Regional Offices and contractors shall develop and implement a system of procedures and records which are consistent with operations and necessary to implement the requirements of the quality assurance program.

B. BASIC ELEMENTS AND REQUIREMENTS

1. Organizational Responsibilities

There shall be a written designation of assignment of the person(s) responsible for performing quality assurance functions in the Regional Office. The assignment(s) shall include a written expression of authorities, duties, and responsibilities for quality assurance, including the responsibilities for review and approval of written procedures, and for the preparation, review, and evaluation of measurements data and reports. The assignment(s) shall also grant authority and assign responsibility to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions.

2. Personnel Qualifications

Persons performing independent radiological measurements activities, including the functions of quality assurance, must have training and experience in health physics or radioisotope technology fields, including experience in handling and using radiation measurement instrumentation. Persons performing quality-related activities must have experience in principles, practices, and techniques of the activities performed.

3. Procedures and Instructions

Each Regional Office and contractor shall prepare written procedures and instructions which are consistent with the Region's radiological measurements activities and necessary for implementation of the requirements of the

quality assurance program. These procedures shall cover all quality-related activities such as: the collection, packaging, shipment, and receipt of samples; preparation and analysis of samples, health physics surveys; operation of instrumentation; maintenance, storage, and use of radioactive reference standards; calibration and performance checks of radiation and radioactivity measurements systems; and reduction, evaluation, recording, and reporting of data. The procedures shall establish a system for coding individual samples for the purpose of identification and tracking through the analytical process.

4. Records

Records shall be maintained of the performance of significant quality assurance activities. Records shall be kept:

a. to track and control a sample in its progress through the process sequence of collection, analysis, data reduction and verification, final recording of results, and reporting;

b. of calibrations and performance tests that check the reliability and stability of radiation protection instruments and all counting and major laboratory analytical equipment;

c. of results of analytical measurements of spiked or blind samples sent from the Radiological and Environmental Sciences Laboratory (RESL), and of results of the cross-check program of the Environmental Protection Agency (EPA); and

d. to identify and maintain pertinent information on radioactive standards and sources and audits.

These records shall be maintained for a minimum period of two years.

5. Quality Control in Sampling

Procedures for sampling shall specify methods (type and periodicity) designed to ensure that the sample is representative of the material sampled. Replicate grab samples may be used to determine the reproducibility of sampling. The validity of the sampling process for samples split with the licensee may be confirmed by immediate analysis and comparison with the licensee's analysis, or by collection of replicate samples if they are to be shipped elsewhere for analysis or held for analysis at a later time.

The collection efficiency of samplers shall be documented and used throughout applicable procedure; such information is usually available from manufacturers of the

sampling equipment or sampling media. Air samplers should be calibrated periodically.

Procedures for sampling, packaging, shipping, and storage of samples shall be designed to maintain the integrity of the sample from time of collection to time of analysis.

Guidance on the principles and practices of sampling is provided in several of the publications referenced in Regulatory Guide 4.15.

6. Quality Control for Radiation Protection Instruments

Procedures developed and implemented by the Regional Offices should incorporate the following requirements, wherever possible, which reflect adoption of ANSI Standard N323-1978, Radiation Protection Instrumentation Test and Calibration. The requirements may be incorporated by reference.

a. Inspection, calibration and performance test requirements should be those specified in Section 4 of ANSI N323-1978.

b. Calibration services that are used should conform to the criteria specified in Section 5, Calibration Equipment Required, and Section 6, Maintenance of Quality Calibration, of ANSI N323-1978.

7. Quality Control in the Radioanalytical Laboratory

a. Radionuclide Reference Standards

Radionuclide standards used to determine counting efficiencies of radiation measurements systems shall have been certified by the National Bureau of Standards (NBS) or obtained from suppliers who participate in measurement assurance activities with the NBS.

Counting efficiencies of radiation measurement systems shall be determined at least once each year.

Guidance on this subject is given in Section 6.1 of Regulatory Guide 4.15.

b. Performance Checks of Radiation Measurement Systems

Procedures shall specify the type and periodicity of performance checks of each radiation measurement system. The guidance in Section 6.2 of Regulatory Guide 4.15 is adopted as minimum requirements for the quality assurance program.

The results of the performance checks of measurement systems shall be recorded. Appropriate statistical methods, e.g., chi-square tests and quality control

chart techniques, should be used to evaluate system performance over time.

Procedures should establish criteria to effect corrective action (adjustment, repair, calibration, etc.) when indicated by the results of the performance checks.

These samples are to be supplied by RESL or by EPA under its cross-check program.

1. One spike sample shall be analyzed each calendar quarter for all types of analyses performed on a regular basis.

2. Interlaboratory samples should be analyzed when they are made available by the EPA.

3. RESL will operate a regional interlaboratory test program. Under this program, RESL will run four tests per year. Each test will include one of the following sample types: charcoal cartridge, particulate filter, liquid, or gas. All sample types will be tested annually.

The regions are required to participate fully in these tests. The regions are to meet or exceed the acceptance criterion which states that the ratio between the region's value and RESL's value shall fall within the specified values expressed in percent. These values for the various samples are listed below:

liquid	10%
charcoal cartridge	15%
particulate filter	15%
gas	15%

All samples analyzed for quality control purposes shall be analyzed using the same procedures normally used for the particular sample matrix. Records shall be kept of each analysis.

8. Computational Checks

Procedures for the computation of the concentration of radioactive materials shall require independent verification of a substantial fraction of the results of the computation by a person other than the one performing the original computation.

For computer calculations, the input data shall be verified before initial routine use and after each modification of the program.

9. Review and Analysis of Data

Procedures for review and analysis of data shall cover examination of data from actual samples and from quality control activities. General criteria for recognizing deficiencies in data shall be established. Procedures shall require investigation and correction of recognized deficiencies and for documentation of these actions.

10. Audits

Regional Offices shall plan and conduct periodic audits of their own operation to verify implementation of the quality assurance program. The audits shall be performed by qualified individuals (see Section B.2) who do not have direct responsibilities in the areas audited. The results of audits shall be documented and reviewed by management or supervision having responsibility in the area audited. Corrective action shall be taken where indicated by the results.

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