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REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 4.15

QUALITY ASSURANCE FOR RADIOLOGICAL MONITORING PROGRAMS (NORMAL OPERATIONS) — EFFLUENT STREAMS AND THE ENVIRONMENT

A. INTRODUCTION

This guide describes a method acceptable to the NRC staff for designing a program to assure the quality of the results of measurements of radioactive materials in the effluents and the environment outside of nuclear facilities during normal operations.

The NRC regulations that require the control of releases of radioactive materials from nuclear facilities, that require the measurements of radioactive materials in the effluents and environment outside of these facilities, that require quality assurance programs and establish quality assurance requirements for certain facilities, or that authorize license conditions not otherwise authorized in the regulations are as follows:

Section 20.106, "Radioactivity in Effluents to Unrestricted Areas," of 10 CFR Part 20, "Standards for Protection Against Radiation," provides that a licensee shall not release to an unrestricted area radioactive materials in concentrations that exceed limits specified in 10 CFR Part 20 or as otherwise authorized in a license issued by the Commission. Section 20.201, "Surveys," of 10 CFR Part 20 further requires that a licensee conduct surveys, including measurements of levels of radiation or concentrations of radioactive materials, as necessary to demonstrate compliance with the regulations in 10 CFR Part 20.

Paragraph (c) of Section 20.1, "Purpose," of 10 CFR Part 20 states that every reasonable effort should be made by NRC licensees to maintain radiation exposure, and releases of radioactive materials in effluents to unrestricted areas, as far below the limits specified in Part 20 as is reasonably achievable, taking into account the state of technology and the economics of improvements in relation to public health and safety and to the utilization of atomic energy in the public interest.

Section 30.34, "Terms and Conditions of Licenses," of 10 CFR Part 30, "Rules of General Applicability to Licensing of Byproduct Material," provides that the Commission may incorporate in any byproduct material license such terms and conditions as it deems appropriate or necessary in order to protect health.

Section 40.41, "Terms and Conditions of Licenses," of 10 CFR Part 40, "Licensing of Source Material," provides that the Commission may incorporate in any source material license such terms and conditions as it deems appropriate or necessary to protect health.

Section 50.50, "Issuance of Licenses and Construction Permits," of 10 CFR Part 50, "Licensing of Production and Utilization Facilities," provides that each operating license for a nuclear power plant issued by the Nuclear Regulatory Commission will contain such conditions and limitations as the Commission deems appropriate and necessary.

Section 70.32, "Conditions of Licenses," of 10 CFR Part 70, "Special Nuclear Material," provides that the Commission may incorporate such terms and conditions as it deems appropriate or necessary to protect health.

Section IV.B of Appendix I, "Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion 'As Low As Is Reasonably Achievable' for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents," to 10 CFR Part 50, "Licensing of Production and Utilization Facilities," requires that licensees establish an ap-

*Lines indicate substantive changes from previous issue.

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Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. This guide was revised as a result of substantive comments received from the public and additional staff review.

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propriate surveillance and monitoring program to provide data on quantities of radioactive material released in liquid and gaseous effluents and to provide data on measurable levels of radiation and radioactive materials in the environment. Section III.B of Appendix I to 10 CFR Part 50 provides certain effluent and environmental monitoring requirements with respect to radioactive iodine if estimates of exposure are made on the basis of existing conditions and if potential changes in land and water usage and food pathways could result in exposures in excess of the guidelines of Appendix I to 10 CFR Part 50.

General Design Criterion 60, "Control of releases of radioactive materials to the environment," of Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50 requires that nuclear power plant designs provide means to control suitably the release of radioactive materials in gaseous and liquid effluents. General Design Criterion 64, "Monitoring radioactivity releases," of Appendix A to 10 CFR Part 50 requires that nuclear power plant designs provide means for monitoring effluent discharge paths and the plant environs for radioactivity that may be released from normal operations, including anticipated operational occurrences, and from postulated accidents.

General Design Criterion 1, "Quality standards and records," of Appendix A to 10 CFR Part 50 requires that a quality assurance program be established for those structures, systems, and components of a nuclear power plant that are important to safety in order to provide adequate assurance that they will satisfactorily perform their safety functions.

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 establishes quality assurance requirements for the design, construction, and operation of those structures, systems, and components of these facilities that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

The need of quality assurance is implicit in all requirements for effluent and environmental monitoring, and this need has been widely recognized. Regulatory Guide 1.21, "Measuring, Evaluating, and Reporting Radioactivity in Solid Wastes and Releases of Radioactive Materials in Liquid and Gaseous Effluents from Light-Water-Cooled Nuclear Power Plants;" Regulatory Guide 4.1, "Programs for Monitoring Radioactivity in the Environs of Nuclear Power Plants;" Regulatory Guide 4.8, "Environmental Technical Specifications for Nuclear Power Plants;" and Regulatory Guide 4.14, "Measuring, Evaluating, and Reporting Radioactivity in Releases of Radioactive Material in Liquid and Airborne Effluents From Uranium Mills," all give some guidance on means for assuring the quality of the measurements of radioactive materials in effluents and the environment outside of nuclear facilities. More complete and extensive guidance on this subject is provided in this document for nuclear power reactor facilities and for other facilities for which radiological monitoring is required by the NRC. This guidance does not identify separately the activities that are within the scope of Appendix B to 10 CFR Part 50. However, this guidance is intended to be consistent with the requirements of Appendixes A and B to 10 CFR Part 50 in that quality assurance requirements should be consistent with the importance of the activity. For the monitoring of production and utilization facilities that is within the scope of Appendix B to 10 CFR Part 50, other regulatory guides that provide guidance on meeting the quality assurance requirements of Appendix B to 10 CFR Part 50 should also be consulted.

B. DISCUSSION [1]

As used in the context of this guide, quality assurance comprises all those planned and systematic actions that are necessary to provide adequate confidence in the results of a monitoring program, and quality control comprises those quality assurance actions that provide a means to control and measure the characteristics of measurement equipment and processes to established requirements; therefore, quality assurance includes quality control.

To assure that radiological monitoring measurements are reasonably valid, organizations performing these measurements have found it necessary to establish quality assurance programs. These programs are needed for the following reasons: (1) to identify deficiencies in the sampling and measurement processes to those responsible for these operations so that corrective action can be taken, and (2) to obtain some measure of confidence in the results of the monitoring programs in order to assure the regulatory agencies and the public that the results are valid.

Existing published guidance on specific quality assurance actions that are applicable to radiological monitoring is limited and, in general, is restricted to quality control practices for radioanalytical laboratories (Refs. 1-5). However, quality assurance should be applied to all steps of the monitoring process, which may include sampling, shipment of samples, receipt of samples in the laboratory, preparation of samples, measurement of radioactivity, data reduction, date evaluation, and reporting of the monitoring results.

[1] Definitions of special terms used in this guide are given in the glossary on page 4.15-10.

The scope of this guide is limited to the elements of a quality assurance program, which is a planned, systematic, and documented program that includes quality control. Guidance on principles and good practice in the monitoring process itself and guidance on activities that can affect the quality of the monitoring results (e.g., design of facilities and equipment) are outside the scope of this guide. However, some references are provided to documents that do provide some guidance in these areas. The citation of these references does not constitute an endorsement of all of the guidance in these documents by the NRC staff. Rather, these references are provided as sources of information to aid the licensee and the licensee's contractors in developing and maintaining a monitoring program.

Every organization actually performing effluent and environmental monitoring, whether an NRC licensee or the licensee's contractor, should include the quality assurance program elements presented in this guide.

C. REGULATORY POSITION

The quality assurance program of each organization performing effluent or environmental monitoring of nuclear facilities for normal operations should be documented by written policies and procedures and records. These documents should include the elements given in this section.

In addition to its own program, a licensee should require any contractor or subcontractor performing monitoring activities for the licensee to provide a quality assurance program and to routinely provide program data summaries (sufficiently detailed to permit ongoing quality assurance program evaluation by the licensee) consistent with the provisions of this guide, as follows:

1. Organizational Structure and Responsibilities of Managerial and Operational Personnel

The structure of the organization as it relates to the management and operation of the monitoring program(s), including quality assurance policy and functions, should be presented. The authorities, duties, and responsibilities of the positions within this organization down to the first-line supervisory level should be described. This should include responsibilities for review and approval of written procedures and for the preparation, review, and evaluation of monitoring data and reports.

Persons and organizations performing quality assurance functions should have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions.

2. Specification of Qualifications of Personnel

The qualifications of individuals performing radiological monitoring to carry out their assigned functions should be specified and documented (e.g., as in a job description).

An indoctrination and orientation program, appropriate to the size and complexity of the organization and to the activities performed, should provide that (a) personnel performing quality-related activities are trained and qualified in the principles and techniques of the activities performed, (b) personnel are made aware of the nature and goals of the quality assurance program, and (c) proficiency of personnel who perform activities affecting quality is maintained by retraining, reexamining, and recertifying or by periodic performance reviews, as appropriate.

3. Operating Procedures and Instructions

Written procedures should be prepared, reviewed, and approved for activities involved in carrying out the monitoring program, including sample collection; packaging, shipment, and receipt of samples for offsite analysis; preparation and analysis of samples; maintenance, storage, and use of radioactivity reference standards; calibration and checks of radiation and radioactivity measurement systems; and reduction, evaluation, and reporting of data. Individuals who review and approve these procedures should be knowledgeable in the subjects of the procedures.

Guidance on principles and good practice in many of these activities is presented in NRC regulatory guides (Refs. 6-9) and other publications (Refs. 2-5, 10-35). In addition to these publications, Scientific Committee 18A of the NCRP has prepared NCRP Report 58, "A Handbook of Radioactivity Measurements Procedures," (Ref. 36) that is a revision of NCRP Report 28, NBS Handbook 80, "A Manual of Radioactivity Procedures."

4. Records

The records necessary to document the activities performed in the monitoring program should be specified in the quality assurance program.

One key aspect of quality control is maintaining the ability to track and control a sample in its progress through the sequence of monitoring processes. Records to accomplish this should cover the following processes: field and inplant collection of samples for subsequent analysis, including sample description; sample receipt and laboratory identification coding; sample preparation and radiochemical processing (e.g., laboratory notebooks); radioactivity measurements of samples, instrument backgrounds, and analytical blanks; and data reduction and verification.

Quality control records for laboratory counting systems should include the results of measurements of radioactive check sources, calibration sources, backgrounds, and blanks.

Records relating to overall laboratory performance should include the results of analysis of quality control samples such as analytical blanks, duplicates, interlaboratory cross-check samples and other quality control analyses; use of standards (radioactivity) to prepare working standards; preparation and standardization of carrier solutions; and calibration of analytical balances.

Additional records that are needed should include the calibration of inline radiation detection equipment, air samplers, and thermoluminescence dosimetry systems; verification and documentation of computer programs; qualifications of personnel; and results of audits.

The minimum period of retention of the records should be specified. For nuclear power plants, requirements for record retention are given in the plant technical specifications. In general, for other types of facilities, only the final results of the monitoring programs need be retained for the life of the facility.

5. Quality Control in Sampling (Including Packaging, Shipping, and Storage of Samples)

Continuous sampling of liquids and gases involves the measurement of sample flow rates and/or sample volumes. The accuracy of the devices used for this purpose should be determined on a regularly scheduled basis, and adjustments should be made as needed to bring the performance of the devices within specified limits. The results of these calibrations should be recorded. The frequency of these calibrations should be specified and should be based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement. Procedures for continuous sampling should use methods that are designed to ensure that the sample is representative of the material volumes sampled. The collection efficiencies of the samplers used should be documented; usually such documentation is available from manufacturers of the sampling equipment.

Procedures for grab samples should include steps designed to ensure that the sample is representative of the material sampled. Replicate grab samples should be taken periodically to determine the reproducibility of sampling.

Procedures for sampling, packaging, shipping, and storage of samples should be designed to maintain the integrity of the sample from time of collection to time of analysis. Aqueous samples may present a particular problem in this regard, and one of the most severe problems has been encountered with aqueous samples of radioactive wastes from operating nuclear reactors (Ref. 23).

Guidance on the principles and practice of sampling in environmental monitoring is provided in several publications (Refs. 2, 4, 5, 21, 23-31, 33, 35, 37). In addition, workers at the National Bureau of Standards (NBS) have published the results of a survey of information on sampling, sample handling, and long-term storage for environmental materials (Ref. 15). Some guidance on the principles and practice of air sampling is provided in References 17, 19, 24, 28-31, 33. Guidance on the principles and practice of water sampling is provided in numerous publications (Refs. 13, 14, 25-27, 35, 37).

6. Quality Control in the Radioanalytical Laboratory

6.1 Radionuclide Reference Standards—Use for Calibration of Radiation Measurements Systems

Reference standards are used to determine counting efficiencies for specific radionuclides or, in the case of gamma-ray-spectrometry systems, to determine counting efficiency as a function of gamma-ray energy. A counting efficiency value is used to convert a sample counting rate to the decay rate of a radionuclide or to a radionuclide concentration. Guidance on the calibration and usage of germanium detectors for measurement of gamma-ray emission rates of radionuclides has been prepared as an ANSI standard (Ref. 38). For converting gamma-ray emission rates to nuclear decay rates, two reports from the Oak Ridge National Laboratory (Refs. 39 and 40) provide useful compilations of gamma-ray intensities and other nuclear decay data for radionuclides in routine releases from nuclear fuel cycle facilities. The data from Reference 40 are included in NCRP Report 58 (Ref. 36).

Radionuclide standards that have been certified by NBS or standards that have been obtained from suppliers who participate in measurement assurance activities with NBS[2]

[2]Satisfactory measurement assurance interactions between source suppliers and NBS involve two basic mechanisms: (1) The supplier submits a calibrated radioactivity source (preferably selected from a batch or prepared series of sources) to NBS for confirmation that the supplier's calibration value agrees with NBS results within certain specified limits or (2) NBS provides calibrated radioactivity sources of undisclosed activity (test samples) to a supplier who is able to make activity or emission-rate measurements on the source that agree within certain specified limits with the measurements of NBS. For the routine production of commercial radioactivity standards, the first mechanism is preferable to the second but is not always feasible. These two mechanisms are used both in Measurements Assurance Programs (MAPs) with key laboratories and in other measurement assurance activities.

Two key laboratory source suppliers participate in MAPs with NBS and use both of the two basic mechanisms: (1) The NRC reference laboratory for the Confirmatory Measurements Program (for effluent monitoring) of the NRC Office of Inspection and Enforcement and (2) The EPA Environmental Monitoring and Support Laboratory in Las Vegas, which prepares and

should be used when such standards are available. In these measurement assurance activities, the supplier's calibration value should agree with the NBS value within the overall uncertainty stated by the supplier in its certification of the same batch of sources (when these are sampled for measurement by NBS) or in its certification of similar sources.

An "International Directory of Certified Radioactive Materials" has been published by the International Atomic Energy Agency (Ref. 41).

Acceptable standards for certain natural radionuclides may be prepared from commercially available high-purity chemicals. For example, potassium-40 standards for gross beta-particle measurements or gamma-ray spectrometry may be prepared gravimetrically from dried reagent-grade potassium chloride.

The details of the preparation of working standards from certified standard solutions should be recorded. The working standard should be prepared in the same form as the unknown samples, or close approximation thereto.

Efficiency calibrations should be checked periodically (typically monthly to yearly) with standard sources. In addition, these checks should be made whenever the need is indicated, such as when a significant change in the measurement system is detected by routine measurements with a check source.

6.2 Performance Checks of Radiation Measurement Systems

Determination of the background counting rate and the response of each radiation detection system to appropriate check sources should be performed on a scheduled basis for systems in routine use. The results of these measurements should be recorded in a log and plotted on a control chart. Appropriate investigative and corrective action should be taken when the measurement value falls outside the predetermined control value.

A check source for determining changes in counting rate or counting efficiency should be of sufficient radiochemical purity to allow correction for decay but need not have an accurately known disintegration rate, i.e., need not be a standard source.

For systems in which samples are changed manually, check sources are usually measured daily. For systems with automatic sample changers, it may be more convenient to include the check source within each batch of samples and thus obtain a measurement of this source within each counting cycle. For proportional counter systems, the plateau(s) or response(s) to the check source(s) should be checked after each gas change. Background measurements should be made frequently, usually daily or before each use, to ensure that levels are within the expected range. For systems with automatic sample changers, background measurements should be included within each measurement cycle.

For alpha- and gamma-ray-spectrometry systems, energy-calibration sources (i.e., a source containing a radionuclide, or mixture of radionuclides, emitting two or more alpha or gamma rays of known energies) are counted to determine the relationship between channel number and alpha- or gamma-ray energy. The frequency of these energy calibration checks depends on the stability of the system but usually is in the range of daily to weekly. The results of these measurements should be recorded and compared to predetermined limits in order to determine whether or not system gain and zero level need adjustment. Adjustments should be made as necessary.

Additional checks needed for spectrometry systems are the energy resolution of the system and the count rate (or counting efficiency) of a check source. These should be determined periodically (usually weekly to monthly for energy resolution and daily to weekly for count rate) and after system changes, such as power failures or repairs, to determine if there has been any significant change in the system. The results of these measurements should be recorded.

6.3 Analysis of Quality Control Samples

The analysis of quality control samples provides a means to determine the precision and accuracy of the monitoring processes and includes both intralaboratory and interlaboratory measurements.

The analysis of replicate samples (containing significant detectable activity) provides a means to determine precision; the analysis of

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distributes calibrated radioactivity standards primarily to laboratories involved in radiological environmental monitoring. Additionally, seven major radiopharmaceutical manufacturers (some of which supply radioactivity standards commercially) participate in a MAP organized by the Atomic Industrial Forum and NBS. In this MAP, NBS distributes standards as test samples to the manufacturer (second mechanism) and receives certified samples from the manufacturer for verification by NBS (first mechanism).

Measurement assurance interactions that use the first mechanism are available via special NBS calibration services. NBS will, on request and for a fee, perform calibrations of representative samples of standards provided by the supplier for NBS confirmation of the supplier's reported values. Calibration services are available for a large variety of radionuclides provided certain requirements (as to sample stability and suitable activity range) are met. Measurement assurance interactions that use the second mechanism are available via the issuance of test standards by NBS. For a nominal charge (beyond the price of the standard), NBS radioactivity Standard Reference Materials (SRMs) can be purchased as test sources of undisclosed activity that can be used to demonstrate agreement, within certain specified limits, between the source supplier's measurements and those of NBS. A Report of Test (for the first mechanism) or a Report of Measurement (second mechanism), containing both the source supplier's and NBS values, is issued by NBS to document the source supplier's participation in the measurement assurance activity.

samples containing known concentrations of radionuclides provides a means to determine accuracy. The analysis of laboratory blanks provides a means to detect and measure radioactive contamination of analytical samples, a common source of error in radiochemical analysis of low-level samples. The analysis of analytical blanks also provides information on the adequacy of background subtraction, particularly for environmental samples.

The fraction of the analytical effort needed for the analysis of quality control samples depends to a large extent on (1) the mixture of sample types in a particular laboratory in a particular time period and (2) the history of performance of that laboratory in the analysis of quality control samples. However, for environmental laboratories, it is found that at least 5%, and typically 10%, of the analytical load should consist of quality control samples.

6.3.1 Intralaboratory Analyses

Replicate samples, usually duplicates, should be analyzed routinely. These replicates should be prepared from samples that are as homogeneous as possible, such as well-stirred or mixed liquids (water or milk) and solids (dried, ground, or screened soil, sediment, or vegetation; or the ash of these materials). These samples may be replicates of monitoring program samples, replicates of reference test materials, or both. The size and other physical and chemical characteristics of the replicate samples should be similar to those of single samples analyzed routinely.

The analysis of the replicate samples as blind replicates is desirable but is not practicable for all laboratories or for all types of samples. For example, in small laboratories it may not be practicable to prevent the analysts from being aware that particular samples are replicates of one another.

Obtaining true replicates of all types of samples also is not practicable. For example, obtaining replicate samples of airborne materials usually is not practicable on a routine basis because it requires either a separate sampling system or splitting a single sample (e.g., cutting a filter in half). Use of replicate samplers usually is not economically feasible and splitting of samples results in replicates that do not represent the usual sample size or measurement configuration (counting geometry) for direct measurement. However, simulated samples of airborne materials may be prepared in replicate and submitted for analysis as unknowns.

Analysis of intralaboratory blank and spiked samples is an important part of each environmental laboratory's quality control program. To check for contamination from reagents and other sources, known analytical blank samples should be included frequently in groups of unknown environmental samples that are analyzed radiochemically. Spiked and blank samples should be submitted for analysis as unknowns to provide an intralaboratory basis for estimating the accuracy of the analytical results. These blanks and spikes may include blind replicates.

6.3.2 Interlaboratory Analyses

Analysis of effluent and environmental samples split with one or more independent laboratories is an important part of the quality assurance program because it provides a means to detect errors that might not be detected by intralaboratory measurements alone. When possible, these independent laboratories should be those whose measurements are traceable to NBS.[3]

Analysis of split field samples, such as samples of milk, water, soil or sediment, and vegetation, is particularly important in environmental monitoring programs to provide an independent test of the ability to measure radionuclides at the very low concentrations present in most environmental samples.

The NRC Office of Inspection and Enforcement conducts a Confirmatory Measurements Program for laboratories of licensees that measure nuclear reactor effluents. The analyses of liquid waste holdup tank samples, gas samples, charcoal cartridges, and stack particulate filters are included in this program. The results of the licensee's measurements of samples split with the NRC are compared to those of an NRC reference laboratory whose measurements are traceable to the National Bureau of Standards. Thus the results of this comparison provide to the NRC an objective measure of the accuracy of the licensee's analyses.

Laboratories of licensees or their contractors that perform environmental measurements should participate in the EPA's Environmental Radioactivity Laboratory Intercomparison Studies (Cross-check) Program, or an equivalent program. This participation should include all of the determinations (sample medium/radionuclide combinations) that are both offered by EPA and included in the licensee's environmental monitoring program. Participation in the EPA program provides an objective measure of the accuracy of the analyses because the EPA measurements are traceable to the National Bureau of Standards. If the mean result of a cross-check analysis exceeds the control limit as defined by EPA (Ref. 42), an investigation should be made to determine the reason for this deviation and corrective action should be taken

[3]NBS and NRC staffs recognize the need for a clearer definition of the term "traceability" as it applies to radiation and radioactivity measurements. These staffs are working together to develop such a statement, which will be published separately.

as necessary. Similarly, an investigation and any necessary corrective action should take place if the "normalized range," as calculated by EPA, exceeds the control limit, as defined by EPA. A series of results that is within the control limits but that exhibits a trend toward these limits may indicate a need for an investigation to determine the reason for the trend.

6.4 Computational Checks

Procedures for the computation of the concentration of radioactive materials should include the 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 should be verified by a knowledgeable individual. All computer programs should be documented and verified before initial routine use and after each modification of the program. The verification process should include verification, by a knowledgeable individual, of the algorithm used and test runs in which the output of the computer computation for given input can be compared to "true" values that are known or determined independently of the computer calculation. Documentation of the program should include a description of the algorithm and, if possible, a current listing of the program. Guidelines for the documentation of digital computer programs are given in ANSI N413-1974 (Ref. 43).

7. Quality Control for Continuous Effluent Monitoring Systems

Guidance on specification and performance of onsite instrumentation for continuously monitoring radioactivity in effluents is given in ANSI N13.10-1974 (Ref. 18).

The specified frequency of calibration for a particular system should be based on considerations of the nature and stability of that system. For nuclear power plants, specific requirements for calibrations and checks of particular effluent monitoring systems usually are included in the technical specifications for the plant.

Initial calibration of each measuring system should be performed using one or more of the reference standards that are certified by the National Bureau of Standards or standards that have been obtained from suppliers that participate in measurement assurance activities with NBS (see footnote 2). These radionuclide standards should permit calibrating the system over its intended range of energy and rate capabilities. For nuclear power plants, sources that have been related to this initial calibration should be used to check this initial calibration at least once per 18 months (normally during refueling outages).

Periodic correlations should be made during operation to relate monitor readings to the concentrations and/or release rates of radioactive material in the monitored release path. These correlations should be based on the results of analyses for specific radionuclides in grab samples from the release path.

Any flow-rate measuring devices associated with the system should be calibrated to determine actual flow rates at the conditions of temperature and pressure under which the system will be operated. These flow rate devices should be recalibrated periodically.

Whenever practicable, a check source that is actuated remotely should be installed for integrity checks of the detector and the associated electrical system.

8. Review and Analysis of Data

Procedures for review and analysis of data should be developed. These procedures should cover examination of data from actual samples and from quality-control activities for reasonableness and consistency. These reviews should be performed on a timely basis. General criteria for recognizing deficiencies in data should be established.

Provisions should be made for investigation and correction of recognized deficiencies and for documentation of these actions.

9. Audits

Planned and periodic audits should be made to verify implementation of the quality assurance program. The audits should be performed by individuals qualified in radiochemistry and monitoring techniques who do not have direct responsibilities in the areas being audited.

Audit results should be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, should be taken where indicated.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide.

Except in those cases in which the applicant or licensee proposes an acceptable alternative method, the staff will use the methods described herein in evaluating an applicant's or licensee's capability for and performance in complying with specified portions of the Commission's regulations after March 30, 1979.

If an applicant or licensee wishes to use the method described in this regulatory guide on or before March 30, 1979, the pertinent portions of the application or the licensee's performance will be evaluated on the basis of this guide.

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GLOSSARY

Accuracy–a qualitative concept in the statistical treatment of measurement data used to describe the agreement between the central tendency of a set of numbers and their correct value (or the accepted reference value). It is also used to describe the agreement between an individual value and the correct value (or the accepted reference value).

Analytical Blank (Sample)–ideally, a sample having all of the constituents of the unknown sample except those to be determined. In radioanalytical practice, the term often refers to the radiochemical processing of carrier(s) or tracers without the sample matrix material.

"Blind" Replicate (Sample)–replicate samples that are not identified as replicates to the persons performing the analysis.

Calibration–the process of determining the numerical relationship between the observed output of a measurement system and the value, based on reference standards, of the characteristics being measured.

Calibration Source–any radioactive source that is used for calibration of a measurement system.

Check Source (or instrument check source or performance check source)–a radioactive source used to determine if the detector and all electronic components of the system are operating correctly.

Instrument Background–the response of the instrument in the absence of a radioactive sample or other radioactive source.

Precision–a qualitative concept in the statistical treatment of measurement data used to describe the dispersion of a set of numbers with respect to its central tendency.

Quality Assurance (QA)–the planned and systematic actions that are necessary to provide adequate confidence in the results of a monitoring program.

Quality Control (QC)–those quality assurance actions that provide a means to control and measure the characteristics of measurement equipment and processes to established requirements. Thus, quality assurance includes quality control.

Reference Test Material–a large batch of homogeneous material from which aliquots may be taken for interlaboratory comparisons or for internal use by the laboratory. The material must be uniform but need not be standardized.

Spiked Sample–a sample to which a known amount of radioactive material has been added. Generally, spiked samples are submitted as unknowns to the analysts.

Split Sample–a homogeneous sample that is divided into parts, each of which is analyzed independently by separate laboratory organizations.

Standard (radioactive) Source–a radioactive source having an accurately known radionuclide content and radioactive decay rate or rate of particle or photon emission.

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