



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, 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 appropriate 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

USNRC REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations, to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the Commission.

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. However, comments on this guide, if received within about two months after its issuance, will be particularly useful in evaluating the need for an early revision.

Comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

The guides are issued in the following ten broad divisions:

- | | |
|-----------------------------------|------------------------|
| 1. Power Reactors | 6. Products |
| 2. Research and Test Reactors | 7. Transportation |
| 3. Fuels and Materials Facilities | 8. Occupational Health |
| 4. Environmental and Siting | 9. Antitrust Review |
| 5. Materials and Plant Protection | 10. General |

Requests for single copies of issued guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Document Control.

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 pertinent requirements of this Appendix apply to all safety-related functions of these structures, systems, and components. This guide describes a method acceptable to the NRC staff for the design and operation of a program to meet the requirements of Appendix B to 10 CFR Part 50, for the safety functions of radiological monitoring of effluents and the environment.

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*.

The need for quality assurance is implicit in all requirements for effluent and environmental monitor-

ing, 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 applies both to monitoring that is safety-related and monitoring that is not. For safety-related monitoring of nuclear power plants and fuel reprocessing plants, other regulatory guides on quality assurance (in the Division 1 and the Division 3 series of regulatory guides) should be consulted to determine their applicability, if any, to the radiological monitoring activities.

B. DISCUSSION*

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, (2) to provide a means of relating the results of a particular monitoring program to the National Bureau of Standards and thereby to provide a common basis for comparing the results of various programs, and (3) 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 which are applicable to radiological monitoring is limited and, in general, is restricted to quality control practices for radioanalytical laboratories (Refs. 1-3). However, quality assurance should be applied to all steps of the monitoring process that may include sampling, shipment of samples, receipt of samples in the laboratory, preparation of samples, measurement of radioactivity (counting), data reduction, data evaluation, and reporting of the monitoring results.

*Definitions of special terms used in this guide are given in a glossary in Appendix A.

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 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 persons holding specified positions within this organization should be stated, including responsibilities for review and approval of written procedures and for 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 qualification of individuals performing radiological monitoring to perform their assigned functions should be specified and documented. Specification of these qualifications in terms of previous training and performance on the job or satisfactory completion of proficiency testing is preferred to specification of education and experience levels.

An introduction and orientation program, appropriate to the size and complexity of the organization, should provide that (a) personnel performing quality-related activities are trained and qualified in the principles and techniques of the activities performed, and (b) proficiency of personnel who perform activities affecting quality is maintained by retraining, reexamining, and recertifying, as appropriate to the activity performed.

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 radioactive 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.4-7) and other publications (Refs. 2,3, 8-25). In addition to these publications, the American Public Health Association is preparing a book on quality assurance practices in health laboratories that will include a chapter on radiochemistry, and Scientific Committee 18A of the NCRP is preparing a manual of radioactivity measurement procedures that will be 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 sample collection and sample description; sample receipt and laboratory identification coding; sample preparation and radiochemical processing (e.g., laboratory notebooks); radioactivity measurements (counting) 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 standard (radioactive) reference materials 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. 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. Continuous sampling should be demonstrably representative of the material volumes sampled. The collection efficiencies of the samplers used should be documented.

Grab samples should be demonstrably representative of the material sampled, and replicate samples should be taken periodically to demonstrate 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. 21).

Guidance on the principles and practice of sampling in environmental monitoring is provided in several publications (Refs. 2,9,19). 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. 13). Some guidance on the principles and practice of air sampling is provided in References 15, 17, and 22. Guidance on the principles and practice of water sampling is provided in numerous publications (Refs. 11, 12, 23-25).

6. Quality Control in the Radioanalytical Laboratory

6.1 Radionuclide Reference Standards—Use for Calibration of Radiation Measurement 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 disintegration rate of a radionuclide or to a radionuclide concentration. (Guidance on calibration and usage of germanium detectors for measurement of gamma-ray emission rates of radionuclides is being prepared by a writing group of the Health Physics Society Standards Committee for publication as an ANSI Standard.)

Radionuclide standards that have been certified by the NBS, or standards that have been standardized using a measurement system that is traceable to that of the NBS,* should be used when such standards are

*For a discussion by NBS staff members of the concept of *traceability* of radioactivity measurements to NBS, see Reference 27. A brief summary of this discussion is as follows: There are both direct and indirect traceability. Direct traceability to NBS exists when any outside laboratory prepares a batch of calibrated radioactivity standards and submits several randomly selected samples to NBS for confirmation or verification. Indirect traceability to NBS exists when NBS provides "unknown" calibrate radioactivity samples to one or more laboratories which in turn make measurements of activity that agree within certain specified limits with those of NBS. Thus there can be 1%, etc., traceability. Regular use of NBS radioactivity standards by an *outside* laboratory to calibrate its measuring equipment does not, in the view of the NBS staff, constitute traceability. Only when the *outside* laboratory can measure the activity of an unknown sample and send back values to NBS that agree with NBS values within a certain specified range of error does NBS consider that traceability has been established. NBS notes that this condition can be achieved without using a single NBS standard.

available. Otherwise, standards should be obtained from other reputable suppliers. An "International Directory of Certified Radioactive Materials" has been published by the International Atomic Energy Agency (Ref. 26).

Acceptable standards for certain natural radionuclides may be prepared from commercially available high-purity chemicals. For example, potassium-40 standards for gross beta measurements or gamma-ray spectrometry may be prepared 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/or 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) should be checked after each gas change. Background measurements should be made frequently to ensure that levels are within the expected range. For systems

with automatic sample changers, background measurements should be included within each counting 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 provides a means to determine precision; the analysis of 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 samples measured by gamma-ray spectrometry.

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, in general 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). 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 laboratory's quality control program. A known analytical blank sample should be analyzed with each group of unknown samples that is processed radiochemically to determine a specific radionuclide or radionuclides. 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 (Ref. 27).

Analysis of split field samples, such as samples of milk, water, soil or sediment, and vegetation, is particularly important in environmental monitoring pro-

grams 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 (Ref. 27). 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. 28), an investigation should be made to determine the reason for this deviation and corrective action should be taken 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 a current listing of the program. Guidelines for the documentation of digital computer programs are given in ANSI N413-1974 (Ref. 29).

7. Quality Control for Continuous Effluent Monitoring Systems

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 that are calibrated by a measurement system that is traceable to that of the National Bureau of Standards (Ref. 27). For nuclear power plants, these calibrations are usually repeated at least annually. The radionuclide standards should permit calibrating the system over its intended range of energy and rate capabilities. Periodic inplant calibration should be performed using a secondary source or method that has been related to the initial calibration. For nuclear power plants, these calibrations are usually performed at least monthly.

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.

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, Analysis, and Reporting Data

Procedures for review, analysis, and reporting of data should include examinations for reasonableness and consistency of the data and investigative and corrective actions to be taken under specified circumstances.

9. Audits

Planned and periodic audits should be made to verify implementation of the quality assurance program. The audits should be performed by qualified individuals 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.

This guide reflects current NRC staff practice. Therefore, except in those cases in which the applicant or licensee proposes an acceptable alternative method, the staff will use the method described herein in evaluating an applicant's or licensee's capability for and performance in complying with specified portions of the Commission's regulations until this guide is revised as a result of suggestions from the public or additional staff review.

REFERENCES

1. Section 6.2, "Validation of Analyses," Chapter 6, "Validity of Results," *Methods of Radiochemical Analysis*, World Health Organization, Geneva, 1966.
2. "Analytical Quality Control Methods," *Environmental Radioactivity Surveillance Guide*, U.S. Environmental Protection Agency Report, ORP/SID 72-2, June 1972.
3. *Environmental Radiation Measurements*, Report of NCRP SC-35, NCRP Report No. 50, 1976.
4. 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."
5. Regulatory Guide 4.5, "Measurements of Radionuclides in the Environment—Sampling and Analyses of Plutonium in Soil."
6. Regulatory Guide 4.6, "Measurements of Radionuclides in the Environment—Strontium-89 and Strontium-90 Analyses."
7. Regulatory Guide 4.13, "Performance, Testing, and Procedural Specifications for Thermoluminescence Dosimetry: Environmental Applications."
8. *HASL Procedures Manual*, U.S. Energy Research and Development Administration Report, HASL-300, 1972 (updated annually).
9. *A Guide for Environmental Radiological Surveillance at ERDA Installations*, Energy Research and Development Administration Report, ERDA 77-24, March 1977.
10. *Handbook of Radiochemical Analytical Methods*, U.S. Environmental Protection Agency Report, EPA-680/4-75-001, February 1975.
11. *Standard Methods for the Examination of Water and Wastewater*, Thirteenth Edition, American Public Health Association, 1975.
12. *Handbook for Sampling and Sample Preservation of Water and Wastewater*, U.S. Environmental Protection Agency Report, Office of Research and Development, Environmental Monitoring Support Laboratory, EPA-200/4-76-049, September 1976.
13. E. J. Maienthal and D. A. Becker, "A Survey on Current Literature on Sampling, Sample Handling, and Long-Term Storage for Environmental Materials," *Interface* 5 (#4), 49-62 (1976). Also available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, as NBS Technical Note #929, October 1976, C 13.46:929, S/N 003-003-01694-2.
14. *Tritium Measurement Techniques*, Report of NCRP SC-36, NCRP Report No. 47, 1976.
15. "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities," ANSI N13.1-1969.
16. "Specification and Performance of On-Site Instrumentation for Continuously Monitoring Radioactivity in Effluents," ANSI N13.10-1974.
17. *Air Sampling Instruments for Evaluation of Atmospheric Contaminants*, Fourth Edition, American Conference of Industrial Hygienists, 1972.
18. *Users' Guide for Radioactivity Standards*, Subcommittee on Radiochemistry and Subcommittee on the Use of Radioactivity Standards, Committee on Nuclear Science, National Academy of Sciences—National Research Council Report, NAS-NS-3115, February 1974.
19. *Environmental Impact Monitoring for Nuclear Power Plants, Source Book of Monitoring Methods*, Vol. 1, Atomic Industrial Forum Report, AIF/NESP-004, February 1975.
20. *Instrumentation for Environmental Monitoring: Radiation*, Lawrence Berkeley Laboratory Report, LBL-1, Vol. 3, First Ed., May 1972; First update, February 1973; Second update, October 1973.
21. C. W. Sill, "Problems in Sample Treatment in Trace Analysis," National Bureau of Standards Special Publication 4-22, *Accuracy in Trace Analysis: Sampling, Sample Handling, and Analysis*, pp. 463-490, August 1976.
22. "General Principles for Sampling Airborne Radioactive Materials," International Standard, ISO-2889, 1975.
23. *Manual of Methods for Chemical Analysis of Water and Wastes*, EPA-625/6-74-003, U.S. Environmental Protection Agency, Office of Technology Transfer, Washington, D.C. 20460, 1974.
24. *Annual Book of ASTM Standards (Part 31), Water*, American Society for Testing and Materials, Method D, 3370, pp. 71-82, Philadelphia, PA, July 1975.

25. *Biological Field and Laboratory Methods for Measuring the Quality of Surface Waters and Effluents*, EPA-670/4-73-001, Office of Research and Development, U.S. Environmental Protection Agency, Cincinnati, Ohio, July 1973.

26. *International Directory of Certified Radioactive Materials*, International Atomic Energy Agency Report, STI/PUB/398, 1975.

27. L. M. Cavallo et al., "Needs for Radioactivity

Standards and Measurements in Different Fields," *Nuclear Instruments and Methods*, Vol. 112, pp. 5-18, 1973.

28. *Environmental Radioactivity Laboratory Inter-comparison Studies Program*, FY 1977, EPA-600/4-77-001, January 1977.

29. "Guidelines for the Documentation of Digital Computer Programs," ANSI N413-1974.

APPENDIX A GLOSSARY

Accuracy—normally refers to the difference (error or bias) between the mean, \bar{X} , of the set of results and the value \hat{X} , which is accepted as the true or correct value for the quantity measured. It is also used as the difference between an individual value X_i and \bar{X} .

Absolute accuracy of the mean is given by $\bar{X} - \hat{X}$ and of an individual value by $X_i - \bar{X}$.

Relative accuracy of the mean is given by $(\bar{X} - \hat{X})/\hat{X}$.

Percentage accuracy is given by $100(\bar{X} - \hat{X})/\hat{X}$.

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, performance check source, or reference 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—relates to the reproducibility of measurements within a set, that is, to the scatter or dispersion of a set about its central value.

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.

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 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 disintegration rate or particle or photon emission rate.