C. REGULATORY POSITION

The QA program of each organization performing radiological effluent or environmental monitoring of nuclear facilities using, processing, or storing radioactive materials during all phases of the facility's life cycle should be documented by written policies and procedures. Licensees should have sufficient RECORDS of program conduct and performance to demonstrate program adherence. In addition to its own program, a licensee should require any contractor or subcontractor performing support program activities (e.g., sampling, analysis, evaluations, and records) retain records sufficient for the licensee to develop and maintain a QA program covering the applicable program elements.

The following presents the QA program elements that should be developed and implemented to ensure the quality of data/results for radiological effluent and environmental monitoring programs.

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 programs, including QA policy and functions, should be defined and documented. 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 the preparation, review, and evaluation of monitoring data and reports.

Persons and organizations performing QA functions should have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. Reporting should be at a management level that is independent of activity performance, costs, and schedule.

Section 2.1.1 of ANSI/ASQC E4-1994 (Ref. 21) and Section 5.2.1 of ANSI N42.23-2003 (Ref. 22) provide additional guidance on management structure and organizational responsibilities for radiological effluent and environmental monitoring programs.

2. Specification of Qualifications of Personnel

The qualifications of individuals needed to carry out assigned radiological monitoring functions should be defined and documented (e.g., as in a job description). Individuals with responsibility for performing quality-related activities should be trained and qualified in the principles and techniques of the activities to be performed. These individuals should maintain proficiency by retraining, reexamining, and recertifying or by periodic performance reviews, as appropriate. Continual training should be conducted as needed to ensure that personnel maintain awareness of events and issues that could affect the quality of program performance.

Section 2.3.1 of ANSI/ASQC E4-1994 (Ref. 21) provides additional guidance and criteria for developing personnel training and qualification specifications for radiological effluent and environmental monitoring programs.

3. Operating Procedures and Instructions

Monitoring programs should have written procedures for all activities that generate data, such as dose calculations and measurements, sample collection, sample management and CHAIN OF CUSTODY, sample preparation and analysis, data reduction and recording, data assessment and reporting, and final sample disposal. Procedures are also needed for addressing support functions, such as operation of process monitors, training, preparation of QUALITY CONTROL SAMPLES, collection of meteorological data, corrective actions, AUDITS, and records. Individuals satisfying the qualifications described in Section C.2 of this regulatory guide should write, review, and revise these procedures.

Instructions, procedures, or schedules should be prepared for the functions associated with the QA program, such as the following:

- ancillary laboratory functions (including cleaning of glassware, contamination control, and storage of standards and chemicals)
- CALIBRATION and QC of instrumentation (including range of activity, range of energy, and frequency of calibration)
- internal QC and external PE programs (including frequency, types, acceptance criteria for the laboratory PERFORMANCE TESTING samples, and individual analyst qualifications)
- timetable for VERIFICATION and VALIDATION (V&V) of data

Chapters 9, 11, and 12 of MARLAP (Ref. 20) provide guidance on the radioanalytical laboratory activities for which procedures are used. MARLAP Chapters 12 – 16 provide technical information that can be used to write or revise procedures. Section 5.4 of ISO/IEC 17025-2005 (Ref. 17) provides additional guidance regarding the content and quality aspects of procedure and method technical content. Section 2.5.2 of ANSI/ASQC E4-1994 (Ref. 21) identifies procedures that should be documented and may need control.

4. Records

licensees should maintain a system that produces unequivocal, accurate records that document all monitoring activities. Licensees should maintain records of implementation or ongoing activities, such as the following:

- procedure revision
- personnel training and qualification records
- analytical results
- audits
- corrective actions
- intermediate activities or calculations (as may be needed to validate or substantiate final results)
- records of tracking and control (chain of custody) throughout all processes from sample collection through analysis and reporting of results, including unique identifiers, descriptions, sources, dates/times, packaging/preparation/shipping, and required analyses
- field logs with sufficient information describing environmental conditions and recording related information and data documenting the nature of the sample and where and how it was taken
- laboratory notebooks recording related information and data, observations of analysts, and laboratory or other conditions potentially affecting the measurement process
- electronic data collection and algorithms and QA documentation
- calculations (including data reduction, analysis, and verification)

- QC records for radiation monitoring equipment, including the results of RADIOACTIVE SOURCE checks, calibrations, INSTRUMENT BACKGROUND determinations, and maintenance activities affecting equipment performance
- notifications to qualified staff that procedural changes affecting data quality have been made
- QC records for laboratory counting systems and support instrumentation and equipment, including calibrations, maintenance or repair, QC sample results, and traceability of standards used for instrument calibration

Records should be legible and identifiable, retained in predetermined locations, and protected against damage, deterioration, or loss. Records should be maintained in a format that is easily retrievable. If the media for storage is electronic (as opposed to paper or microfilm/fiche), the licensee should maintain the equipment necessary to read and present the data in an uncorrupted form. The document retention system should allow reconstruction of all activities associated with the generation of analytical results. The licensee should establish a retention time for records consistent with licensing conditions and in accordance with the licensee's overall QA program.

Section 2.5 of ANSI/ASQC E4-1994 (Ref. 21) provides guidance on specific types of documents that should be maintained, while Basic Requirement 17 of ASME NQA-1-1994 (Ref. 11) details the administrative criteria that should be considered for inclusion in a program for records and their retention. Section 4.13 of ISO/IEC 17025-2005 (Ref. 17) also provides guidance on the control of records. Chapters 4 and 11 of MARLAP (Ref. 20) discuss documents that should be retained as records. Nuclear Information and Records Management Association (NIRMA) TG11-1998 (Ref. 23), TG15-1998 (Ref. 24), TG16-1998 (Ref. 25), and TG21-1998 (Ref. 26) provide additional information addressing issues in developing and maintaining electronic records programs.

5. Quality Control in Environmental Sampling

Sampling of solids, liquids, and gases involves the measurement of sample masses, flow rates, or volumes. The ACCURACY of the instruments or containers used for this purpose should be determined and checked regularly to ensure that sampling performance criteria remain within the limits specified by the MQOs. The results of mass, flow rate, or volume calibrations and associated UNCERTAINTIES should be recorded. The frequency of these calibrations should be specified and should be consistent with the DQOs of the measurement program. The collection efficiencies of the sampling equipment used should be documented; often such documentation is available from the manufacturer. HPS/ANSI N13.1-1999 (Ref. 27) provides guidance on QA and QC for air sampling instruments. Chapter 19 of MARLAP (Ref. 20) discusses measurement uncertainties in general and volume and mass measurements in particular.

Sampling or measurements should be performed using equipment and methods that yield a result that is representative of the population in the particular environmental media. FIELD DUPLICATES are co-located spatially or temporally and should be collected periodically to check REPRODUCIBILITY. Chapter 10 of MARLAP (Ref. 20) discusses the field and sampling issues that affect laboratory measurements, including packaging, shipping, and storage of samples.

Some individual environmental samples are collected simply to confirm that radioactivity levels are below a specified (small) fraction of an established concentration limit. In those cases, the MINIMUM DETECTABLE CONCENTRATION of the method used should be below that specified fraction of the limit. Chapter 20 of MARLAP (Ref. 20) discusses detection limits, while Appendix C to MARLAP covers the relationship between the desired fraction of the limit that is important to detect and the uncertainty of the measurement method. In some cases, a series of measurement results will be averaged for comparison with BACKGROUND LEVELS or a regulatory limit. For such measurements, an appropriate MQO would be the MINIMUM QUANTIFIABLE CONCENTRATION (see Chapter 20 of MARLAP).

For an isolated, well-mixed population, a single sample or measurement may be sufficient. It is more common, however, for spatial or temporal variations to exist. In that case, the frequency of sampling and number of samples and locations will depend on the level of variability and amount of radioactivity (compared with an established risk-informed limit). NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual" (Ref. 28, hereafter referred to as MARSSIM), discusses the effect that such variability has on the number of samples that may be appropriate for SURVEYS. In general, the DQO process may be used together with specific statistical designs (EPA QA/G-9S-2006, Ref. 29) to optimize the sampling. Continuous sampling or integrated measurements may be used to mitigate temporal variability.

Part 1, Sections II-11 and II-12, of ASME NQA-1-1994 (Ref. 11) discuss test control and control of measuring and test equipment. Part II, Subpart 2.20, of ASME NQA-1-1994 discusses QA standards for subsurface investigations for nuclear power plants.

6. Quality Control in the Radioanalytical Laboratory

The output of the directed planning process includes DQOs that encompass both sampling and analysis activities for a project or program. From the DQOs, a set of MQOs are developed for radioanalytical measurements (see Chapter 3 of MARLAP, Ref. 20). In a performance-based approach, MQOs are critical criteria used for the selection and validation of analytical methods and protocols (see Regulatory Position 8, below) and subsequently form the basis for the ongoing and final evaluation of the analytical data. The type, frequency of, and evaluation criteria for QC samples are developed during the directed planning process and are incorporated into ANALYTICAL PROTOCOL SPECIFICATIONS (APSs) for a project (see Chapter 3 of MARLAP, Ref. 20).

Chapter 18 of MARLAP provides guidance on monitoring key laboratory PERFORMANCE INDICATORS to determine whether a laboratory's measurement processes are in control. The chapter also provides information on likely causes of excursions for selected laboratory performance indicators, such as chemical yield, instrument background, and QC samples. Appendix C to MARLAP provides the rationale and guidance for developing MQOs for select method performance characteristics and gives guidance on developing criteria for QC samples.

Performance criteria for radioanalytical measurements should be selected to provide a management tool for tracking and trending performance and to identify precursors to nonconforming conditions. Laboratories should satisfy program-specific criteria for all measurement processes, including necessary levels of PRECISION, acceptable BIAS, and applicable detection levels.

6.1 Calibration and Quality Control of Instruments, Measuring Devices, and Test Equipment

Instruments, devices, and test equipment used for measuring radioactivity should be operated, calibrated, and maintained to ensure that analytical specifications are met. All equipment should be operated, calibrated, and maintained in adherence to any applicable standards and methods and as specified in the laboratory's quality manual and standard operating procedures. Instrument configurations during calibration should match those used for subsequent analytical measurements of samples.

Calibrations of instruments should be made using CERTIFIED REFERENCE MATERIALS of known and documented value and stated uncertainty and should be traceable to a national standards body, such as the National Institute of Standards and Technology (NIST) in the United States. CALIBRATION SOURCES should be prepared in a manner that provides comparability to TEST SOURCES with respect to source geometry, positioning relative to the detector, source composition, and distribution of the test-source material within a container or on a source mount (see Section 15.2 of MARLAP, Ref. 20).

The frequency of calibrations should be consistent with the stability and performance of the instrument. Complete system calibration should be performed before initial use or following system maintenance, repair, or any other changes in environment or operating conditions that could affect performance (ASTM D7282-2006, Ref. 30). In addition, Sections 15.2 and 15.3 of MARLAP (Ref. 20) present general guidance regarding calibrations of instruments. Chapter 15 of MARLAP also presents guidance specific to calibrations of different instrumentation types.

The continuing validity of calibrations should be checked periodically as specified in a laboratory's quality manual (see Chapter 18 of MARLAP, Ref. 20). Quality control checks of radioanalytical instrument calibration parameters, such as detector response or energy and resolution calibrations for spectrometers, should be performed by measuring the response of each radiation detection system to appropriate CHECK SOURCES. Instrument QC frequencies are generally performed daily for systems used continually or before use for those systems periodically employed, but frequencies may vary by instrument type. Instrument QC checks should meet predefined acceptance criteria for the respective calibration parameter and should ensure that conditions have not significantly changed since initial calibration (ASTM D7282-2006, Ref. 30).

Instrument-calibration QC check results should be tracked, trended, and compared with predetermined ranges of acceptable performance. For example, if a monitor's response to a daily check source showed a trend that may lead to a condition outside of established acceptance criteria, a calibration may be needed to reestablish acceptable operation. Section 18.5 of MARLAP (Ref. 20) and ASTM D7282-2006 (Ref. 30) discuss radioanalytical instrument-calibration QC parameters.

Additional method-specific quality controls (e.g., chemical yield, spectral quality, resolution) may apply to certain methods and should be tracked and trended using control or tolerance charts to identify conditions that could be adverse to quality.

The laboratory quality manual and standard operating procedures should address the use, calibration, maintenance, and QC of all nonradiological instruments, measuring devices, and test equipment used for measuring or quantifying other necessary data (e.g., sample masses or volumes, temperatures). All measurement and test equipment should be calibrated before use and adjusted to maintain accuracy within established limits. Quality control checks should be performed at specified frequencies and should verify that instruments are operating to specified performance levels.

Nonradiological instruments, measurement, and test equipment should be operated according to manufacturers' instructions, according to established standards, or as specified in the laboratory quality manual and procedures. Section 18.6.7 of MARLAP (Ref. 20) provides guidance on control, calibration, and maintenance of calibration of apparatus used for mass and volume measurements. ISO/IEC 17025-2005 (Ref. 17) provides general guidance on establishing quality controls for nonradiological instruments. Items that do not conform to specified criteria should be controlled to prevent inadvertent use. These items should be tracked through the corrective action program.

Careful control of contamination and routine monitoring of instrument background are integral parts of a measurement QC program. Determination of the background counting rate should be performed on a regular, predefined frequency for systems in routine use and should ensure that analytical specifications for applicable programs can be met. Instrument backgrounds used to determine a net count rate should replicate actual sample measurement conditions as closely as possible (i.e., using appropriate sample containers and geometries).

Section 18.5.1 of MARLAP (Ref. 20) provides guidance on measurement and control of instrument backgrounds. Section 18.3 and Attachment 18A of MARLAP contain guidance on the statistical evaluation of performance indicators and on using control and tolerance charts.

Sections 10-13 and 20-25 of ASTM D7282-2006 (Ref. 30) and Section A.5.2 of ANSI N42.23-2003 (Ref. 22) provide additional guidance on instrument response source checks, background checks, and the use of control charts. ASTM MNL 7A-2002 (Ref. 31) provides guidance on setting up and using control charts.

6.2 Internal Quality Control Samples and Analysis

The use of QC samples should be an integral element of a laboratory QA program. Chapter 18 of MARLAP (Ref. 20) defines the different types of laboratory QC samples and provides guidance on evaluation techniques for QC samples. The laboratory should have as part of the normal operational sample load the following QC samples:[3]

- BLANK
- MATRIX SPIKE
- LABORATORY CONTROL SAMPLE
- LABORATORY DUPLICATE

Analysis of QC samples should be performed as a part of the routine operation of a laboratory to verify that laboratory operations are consistent with applicable specifications. The QC program should specify the type of and minimum frequency for processing QC samples. For example, this frequency may be defined as a minimum percentage of the total number of samples analyzed, a certain number per operational time interval (e.g., once per shift) or per sample batch, or a licensee-specified frequency based on laboratory-specific parameters. As part of its QC program, the laboratory may prepare and analyze BLIND SAMPLES, provided the individuals responsible for preparing the samples are not directly responsible for conducting the laboratory analysis. For example, the laboratory's assigned QC specialist may have the responsibility for preparing and submitting blind samples (blank, duplicate, laboratory control sample, and matrix spike). Blind samples are used primarily as a tool for evaluating the performance of individuals rather than as part of the laboratory QC load.

Acceptability of QC sample results should be evaluated based on criteria from the QC program, which include specific equations based on METHOD UNCERTAINTY. Chapters 7 and 18 of MARLAP (Ref. 20) provide guidance on the evaluation of QC samples.

Quality control sample results should be tracked, trended, and compared with predetermined ranges of acceptable performance to identify conditions that are in, or may lead to, nonconformance with program specifications. Such conditions should be tracked through the corrective action program.

6.3 Performance Evaluation Program (Interlaboratory Comparison)

Participation in an external PE program is an important independent check on the accuracy, possible bias, and precision of some radioanalytical or measurement methods used in a radiological monitoring program. Internal and contract radioanalytical laboratories used in the monitoring program should participate in one or more applicable PE programs that are administered by organizations that have an active measurement assurance (traceability) program with NIST (ANSI N42.22-1995, Ref. 32). Chapter

[3] Note that this list does not include field duplicate samples that are part of the QC requirement for sampling.

5 of MARLAP (Ref. 20) recommends incorporating the criteria for a radioanalytical laboratory to participate in a PE program into the statement of work for services. Several external PE programs administered by government agencies or commercial radioactive-source suppliers are available for radionuclides and matrices germane to radiological monitoring programs. The PE program should provide fundamental sample types (e.g., solid, liquid, gas) and radionuclides (e.g., alpha-, beta-, and gamma-emitting nuclides) of interest at the facility. When available, laboratories should analyze samples as offered by a PE program on a frequency stipulated by the monitoring program's QA criteria, with all types of samples and analyses repeated at least biennially. Chapter 18 of MARLAP (Ref. 20) provides information on organizations that administer PE programs.

Acceptable performance criteria for results of performance-testing samples should be established that are consistent with the MQOs for the radiological monitoring project or program. For certain monitoring activities, the acceptance criteria of the PE program may be satisfactory. The performance in a PE program should be tracked and trended as one of the performance indicators for the laboratory and evaluated as part of the corrective action program.

7. Quality Control for Radioactive Effluent Monitoring Systems

7.1 Radioactive Effluent Process Monitors

An initial, primary radiation monitor calibration that meets the specifications of ANSI N42.18-2004 (Ref. 33), should be performed with radioactive sources traceable to a national standards body (such as NIST). Calibrations should be repeated periodically using (1) STANDARD REFERENCE MATERIALS or (2) certified reference materials that can be directly traced to the initial, primary calibration. Complete system calibration — including electronics, detector, and any support functions (such as alarm, display, and recording devices) — should be performed at a frequency that ensures system reliability and accuracy or after repair or maintenance that may affect instrument calibration. Unless otherwise specified in license requirements, the licensee should verify and validate the complete effluent monitoring system every 12 months. This frequency may be extended to longer time periods coinciding with facility maintenance schedules, such as refueling for nuclear power plants, if the licensee has verified proper system operation through established system reliability and more frequent source checks and functional checks.

Detectors should be response-checked periodically[4] for continuous effluent release points (e.g., ventilation systems and secondary water systems) and before release for batch discharges (e.g., primary boundary or containment purges and liquid waste tank releases). Licensees should ensure that check sources are of sufficient radiochemical purity so that the activity of the source may be corrected for decay to the date of measurement. These check sources need not be traceable to a national standards body (e.g., NIST). Whenever practicable, check sources should be an integral part of the monitoring system and should be remotely actuated. The functionality of isolation or alarm functions should be verified periodically, preferably by use of a radiation source.

Trends of process radiation monitor readings versus total radionuclide concentrations in the monitored release path should be performed routinely. These trends should be based on the results of analyses for specific radionuclides in samples taken from the release path that will yield a monitor response. Deviations in the trend may occur if concentrations or the mixture of radionuclides changed significantly (for example, during a fuel cycle in which significant fuel defects exist). The licensee should define the monitor-response parameter for all radiation monitors. The monitor-response constant should be adjusted to maintain this correlation between effluent radionuclide concentration and monitor response.

[4] Frequencies should be appropriate to the instrument under consideration and may be dictated by license conditions.

7.2 Flow Monitoring Instrumentation

Continuous sampling of liquids and gases involves the measurement of sample flow rates and/or sample volumes. The accuracy and associated uncertainty 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 necessary accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement.

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 operate. These flow rate devices should be recalibrated annually, but the frequency may be extended to that established for the radiation detector system, provided sufficient operating experience exists and an accelerated measurement check frequency gives sufficient data to ensure reliable performance.

Flow measuring devices should be checked periodically on an established frequency, considering the variability of the instrument, and recalibrated when established control limits are exceeded. HPS/ANSI N13.1-1999 (Ref. 27) provides additional guidance on QA and QC measures for the use, maintenance, and calibration of airborne sampling instrumentation. ANSI N42.18-2004 (Ref. 33) provides additional guidance on the calibration of liquid flow monitors.

7.3 Grab Sampling of Effluent Process Streams

Whenever practicable, effluent releases should be batch-controlled and released when the volume to be released has been mixed sufficiently to ensure uniform concentration. Sampling and analysis for each batch should be performed, and release conditions set, before release. A certain percentage of all batch releases should have field duplicates taken either before or during the release to assess the reproducibility of sampling and the effectiveness of the mixing process before release. Where possible, samples that are spatially or temporally separated should be collected periodically to verify representativeness.

For continuous-effluent discharges, composite samplers should be employed. However, periodic grab samples may be used when composite sampling of a continuous discharge point is not feasible. When grab samples are collected instead of composite samples, licensees should design the sampling program to sample at the time, location, and frequency that ensures each sample is representative of the radioactive materials released.

7.4 General Quality Control Considerations

The QC plan should address the following items:

- Sampling should be performed using calibrated instruments and equipment when taking a composite sample.
- Collection efficiencies based on the physical configuration of the sampling point and the type of collector should be documented. Vendor-supplied data may be used where adequate documentation exists to ensure the reliability and accuracy of data.
- Volumes of tanks and containers should be established during initial installation and should be verified again following any physical changes that could alter the system configuration.

- The frequency of duplicates and REPLICATES[5] should be established based on time (for continuous discharges) or number of batches (for batch discharges).
- Sample integrity should be maintained through chain of custody procedures.

Procedures for continuous sampling should use methods that are designed to ensure that the sample is representative of the volumes being discharged.

8. Verification and Validation

The V&V of certain aspects and support activities of the radiological measurement process or monitoring program are essential to the QA program. These aspects and activities include data and computer software V&V and project method validation.

Project method validation is the demonstration that a method (radioanalytical or radiation measurement) using performance-based method selection is capable of providing analytical results to meet a project's MQOs and any other criteria in the analytical protocol specification (APS). Acceptable method validation is necessary before the radiological analysis of samples or the taking of measurements in a monitoring program. Chapter 6 of MARLAP (Ref. 20) presents detailed guidance on project method validation for radioanalytical methods. In addition, Section 5.2.7 of ANSI N42.23-2003 (Ref. 22) and Section 5.4.5 of ISO/IEC 17025-2005 (Ref. 17) provide limited guidance for radioanalytical method validation.

Chapter 8 of MARLAP (Ref. 20) gives detailed guidance and applicable tools for the radioanalytical data V&V evaluation process as well as information for developing a data V&V plan, determining acceptable criteria and tests, and applying data qualifiers for radioanalytical data validation, as related to MQOs. EPA QA/G-8-2002 (Ref. 34) provides guidance for nonradioanalytical data V&V.

Computer programs used in the implementation of the radiological environmental monitoring program should be documented, verified, and validated before initial routine use and after each modification of the program. As described in Section 5.4.3.2 of MARLAP (Ref. 20), the laboratory's quality manual should include the criteria for computer software V&V and documentation. The software data reduction and reporting functions should be verified to perform as expected.[6]

9. Assessments and Audits

Assessments, audits, and surveillances are elements used to evaluate the initial and ongoing effectiveness of the QA program to monitor and control the quality of a radiological monitoring program. Management having responsibility in the area being reviewed should document and review the results of these activities. Assessments that are independent of the day-to-day operations should be performed routinely, including management surveillance, peer reviews, and READINESS REVIEWS for new or revised systems and methods. Key performance indicators should be tracked and trended, with periodic management reporting. The QA program or project plan should outline the scope, frequency, and schedule of assessments, audits, and surveillances. A plan should be developed for each assessment audit or

---

[5] Replicate samples may be prepared by removing separate ALIQUANTS from the same grab sample.

[6] The Institute of Electrical and Electronics Engineers (IEEE) Standard 1063, "IEEE Standard for Software User Documentation" (Ref. 35); EPA Directive 2185, "Good Automated Laboratory Practices" (Ref. 36); Subpart 2.7 of ASME NQA-1-1994 (Ref. 11); Regulatory Guide 1.168, "Verification, Validation, Reviews, and Audits for Digital Computer Software Used Safety Systems of Nuclear Power Plants" (Ref. 37); and Section 8 of ANSI N42.14-1999, "Calibration and Use of Germanium Spectrometers for the Measurement of Gamma-Ray Emission Rates of Radionuclides" (Ref. 38), also provide guidelines on software V&V.

surveillance for each area of the monitoring program being evaluated. A report of these activities should be generated according to the outline, format, and content established in the plan.

Only qualified QA staff (see Regulatory Position 2, above), supported as needed by experts in the technical areas under evaluation, should conduct assessments, audits, and surveillances. (See ASME NQA-1-1994, Supplement 2S, Ref. 11.) Deficiencies, areas for improvement, and observations noted should be incorporated into the corrective action program and tracked. Section 18 of ASME NQA-1-1994 (Ref. 11) and Section 4.10 of ISO/IEC 17025-2005 (Ref. 17) provide guidance on establishing and conducting an audit program.

When the monitoring program will depend upon the services of a radioanalytical laboratory, prior onsite audits of the laboratory may be conducted to ensure that the laboratory is capable of fulfilling the project criteria in accordance with the APS (including MQOs) outlined in a statement of work (MARLAP Chapter 5 and Appendix E). The ongoing evaluation of the laboratory's QUALITY SYSTEM and operations is accomplished through onsite audits and desk audits. These audits are focused more on whether the laboratory is meeting project or program specifications than whether the laboratory has the capability to meet monitoring program or project criteria. Chapter 7 of MARLAP provides guidance and statistical tests to determine whether a laboratory is meeting the MQOs, especially the REQUIRED METHOD UNCERTAINTY. Section 5.2.10 of ANSI N42.23-2003 provides additional guidance for radioanalytical laboratory assessments.

Audits of the QA programs of contractors providing materials, supplies, or services affecting the quality of the laboratory's operations should be performed periodically (Section 4.6 of ISO/IEC 17025-2005, Ref. 17).

10. Preventive and Corrective Actions

Integral components of a QA program include identifying areas for improvement, defining performance or programmatic deficiencies, and initiating appropriate corrective or preventive actions. The QA program for radiological effluent and environmental monitoring programs should contain both a continuous-improvement program and a program for implementing corrective actions when conditions adverse to quality have been identified. In addition, needed improvements and potential sources of nonconformance should be identified and reported as part of a preventive action initiative of the continuous-improvement program (ISO/IEC 17025-2005, Sections 4.10–4.12) — for example, a condition-reporting program. Investigations should be initiated for degrading conditions, and corrective actions should be taken when conditions fall outside quality or regulatory acceptance criteria. For conditions that are adverse to quality, the corrective action process includes the following basic elements:

- identification and documentation
- classification
- cause analysis
- corrections
- followup
- closure

Findings and corrective actions should be documented, tracked, and reported to management. Followup reviews should be performed to verify the effectiveness and adequacy of the corrective actions. Section 2.10 of ANSI/ASQC E4-1994 (Ref. 21) provides specifications and guidelines for developing the process, programs, and procedures necessary to detect and correct items of nonconformance and for implementing continuous quality improvement.

When conducting an audit or surveillance of laboratory services, a prime area of review should be the effectiveness of the laboratory's corrective action program (Section 7.4.2 of MARLAP, Ref. 20). Section 4.11 of ISO/IEC 17025-2005 (Ref. 17) provides general guidance on preventive and corrective action programs for laboratories. Annex C of ANSI N42.23-2003 (Ref. 22) provides additional guidance that should be considered in developing a corrective action program, including root cause analysis for radioanalytical services.

D. IMPLEMENTATION

The purpose of this section is to provide information to licensees regarding the NRC staff's plans for using this regulatory guide. No backfit is intended or approved in connection with its issuance.

Non-nuclear power reactor applicants and licensees may continue to use Revision 1 of Regulatory Guide 4.15, dated February 1979, or may adopt other procedures or practices that reflect generally accepted standards for ensuring quality in environmental data collected for effluent monitoring purposes. Except in those cases in which a nuclear power reactor applicant or licensee proposes or has previously established an acceptable alternative method for complying with specified portions of the NRC's regulations, the methods and practices described in this guide will be used in evaluating QA practices for environmental radiological monitoring programs.