Designation: C 1188 – 04

Standard Guide for Establishing a Quality Assurance Program for Uranium Conversion Facilities[1]

This standard is issued under the fixed designation C 1188; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide provides guidance and recommended practices for establishing a comprehensive quality assurance program for uranium conversion facilities.

1.2 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate health and safety practices and determine the applicability of regulatory limitations prior to use.*

1.3 The basic elements of a quality assurance program appear in the following order:

FUNCTION	SECTION
Organization	5
Quality Assurance Program	6
Design Control	7
Instructions, Procedures & Drawings	8
Document Control	9
Procurement	10
Identification and Traceability	11
Processes	12
Inspection	13
Control of Measuring and Test Equipment	14
Handling, Storage and Shipping	15
Inspection, Test and Operating Status	16
Control of Nonconforming Items	17
Corrective Actions	18
Quality Assurance Records	19
Audits	20

2. Referenced Documents

2.1 *ANSI Standard:*[2]

ANSI/ASME NQA-1 Quality Assurance Program Requirements for Nuclear Facility Applications

3. Terminology

3.1 *Definitions:*

3.1.1 *operation*—the terms *operation*, *operations*, and *operation activities* are used interchangeably to describe collectively all activities and functions executed by the conversion facility.

3.1.2 *special process*—a process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

3.1.3 *uranium conversion facility*—a chemical processing plant whose primary function is to convert uranium ore concentrates or uranium oxide to purified uranium hexafluoride.

4. Significance and Use

4.1 Quality assurance provides a planned and systematic approach for establishing practices to meet requirements of safe facility operation and product quality.

4.2 In the operation of a uranium conversion facility there are many requirements established by regulatory bodies, codes, customers, and the facility itself. These requirements are identified by facility management and acted upon by various facility groups. Implementation of the practices described in this guide are intended to assist with compliance with these requirements.

4.3 In the operation of a uranium conversion facility there is a potential for both chemical and radiological exposure to employees, the public, and the environment. This potential is reduced by implementation of the practices described in this guide. The development of this guide, as part of sound management practice, provides a means for ensuring consistency between facilities, and documentation and formalization of existing practices.

4.4 To establish a quality assurance program for a uranium conversion facility, the practices in use should be evaluated against the recommended practices of this guide. Existing practices may then be modified or new practices implemented to correct any identified deficiencies. This approach highlights the fact that the basic foundation of a quality assurance program is already present.

---

[1] This guide is under the jurisdiction of ASTM Committee C26 on Nuclear Fuel Cycle and is the direct responsibility of Subcommittee C26.08 on Quality Assurance Applications.

Current edition approved June 1, 2004. Published June 2004. Originally approved in 1991. Last previous edition approved in 1997 as C 1188–91(1997)ε1

[2] Available from American National Standards Institute, 25 W. 43rd St., New York, NY 10036.

TABLE 1 NQA-1 Basic Requirements Related to Principles of Conversion Facility Quality Assurance

Elements of Conversion Facility Quality Assurance	NQA-1 BASIC REQUIREMENTS																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Organization	X																	
Quality Assurance Program		X																
Design Control			X															
Document Control				X		X												
Instructions, Procedures & Drawings					X													
Procurement							X											
Identification and Traceability								X										
Processes									X									
Inspection										X	X							
Control of Measuring and Test Equipment												X						
Handling, Storage, and Shipping													X					
Inspection, Test and Operating Status														X				
Control of Non-conforming Items															X			
Corrective Actions																X		
Quality Assurance Records																	X	
Audits																		X

4.5 ANSI/ASME NQA-1 is a quality assurance standard that is being applied broadly across the nuclear industry. NQA-1 was used as guidance in the development of the program elements of this guide.

4.6 The program functions detailed in this guide should be selected based on the particular needs and applications at the facility. Those activities or programs to be included in a uranium conversion facility should be defined in that program.

5. Organization

5.1 *Summary*—The organizational structure of a facility is the basis from which authority, functional responsibility, lines of communication and interfaces are derived. Since, in every case, facilities are composed of smaller organizations of various functions, it is necessary to define the organizational structure and the controls and responsibilities delegated to each component.

5.2 *Recommendations*:

5.2.1 *Organizational Structure*—All facilities have an internal organizational structure. The organizational structure should be defined and documented. This is necessary to define relationships between groups and to assign responsibilities for the accomplishment of required activities. Without a defined organizational structure, the efficiency and quality of output of the organization will be adversely affected. The most common method of documenting the organizational structure is via the organization chart.

5.2.2 *Functional Responsibilities*—Each position detailed on the organization chart should be defined. This can be done via a position description or other method. The job description should include the functional responsibilities and relationship to the organization.

5.2.3 *Levels of Authority*—Included with functional responsibilities should be the authority level of the position. This authority should include decision making and approval of actions necessary to carry out the assigned functional responsibility. The delegation of authority should also be addressed. This may be necessary in order to most efficiently or effectively accomplish the assigned responsibilities.

5.2.4 *Communication*— Lines of communication for formal interaction between groups should be defined. This is especially important when more than one group is responsible for the completion or performance of an activity. Interfaces, both internal and external to the facility, may be defined through position descriptions. Specific interfaces may be detailed in the quality assurance program in order to clarify or emphasize the proper protocol. It should be stressed that the quality assurance personnel be formally given, via appropriate lines of communication, the organizational freedom and access to management to effectively perform quality assurance functions.

6. Quality Assurance Program

6.1 *Summary*—A quality assurance program should be established, documented and implemented. The program should consist of suitable policies, programs, and written procedures that provide for the planning and accomplishment of activities affecting quality under controlled conditions. The program should provide for training, as necessary, of personnel to ensure that adequate proficiency is achieved and maintained. The quality assurance program should provide for routine assessment of policies, programs, and procedures to ensure their continued effectiveness, to ensure compliance, and to identify opportunities for improvements.

6.2 *Recommendations*:

6.2.1 The uranium conversion facility should document the quality assurance program in sufficient detail to demonstrate that the recommendations of this guide have been met. This is usually provided by means of a quality assurance manual, which is approved and signed by senior facility management.

6.2.2 The quality assurance function should be staffed by personnel who are independent of the organizations responsible for performing quality related functions.

6.2.3 Personnel involved in quality assurance activities should have training or experience commensurate with the scope of the activities. This training and experience should be documented.

6.2.4 Quality assurance activities may utilize other personnel in order to obtain the necessary knowledge or expertise to properly perform the function in question. The quality assurance organization should maintain ultimate responsibility for the results of the actions of the other persons.

6.2.5 Quality assurance program documentation should be submitted, if so required, to the appropriate regulatory body, customer or other jurisdiction for approval prior to implementation. Any substantive changes made after receipt of approval should be approved in the same manner.

6.2.6 The quality assurance program documentation should contain the following as a minimum:

6.2.6.1 Policy statement by senior executive, directing compliance to the quality assurance program,

6.2.6.2 Organizational description meeting the requirements of Section 5, Organization, of this guide,

6.2.6.3 A description or reference of the program procedures that implement the requirements of this guide,

6.2.6.4 Identification of the interrelationship and hierarchy of documents used in the program,

6.2.6.5 Identification of programs items, procedures, and services to which the program applies, and

6.2.6.6 Provision for the periodic review of the program to determine its adequacy, effectiveness, and opportunities for improvement. The method of review, frequency, and documentation should be stated.

7. Design Control

7.1 *Summary*—This section describes design control measures required to ensure that design bases, design calculations, and specifications are correct. It also provides the means for ensuring that new or modified designs are in compliance with applicable codes, standards, and regulations.

7.1.1 Uranium conversion facilities, based on proven design and technology, have been in operation for many years. As such, the application of design control should focus on changes made to these original designs based on facility operating experiences, changes in process technology, emissions requirements, etc.

7.2 *Recommendations*:

7.2.1 *Change Control*— Changes to approved designs that may alter the performance of the design should be subject to review and verification similar to that used for the original design. Changes should be requested and documented in a formal change request letter or form.

7.2.2 *Design Analysis*— Design input should be solicited from each affected organization in order to provide for adequate initial design. Information for design should be obtained from appropriate production, maintenance, technical, or other personnel to ensure that all requirements are anticipated and satisfied.

7.2.3 *Design Verification*:

7.2.3.1 Designs, including pertinent drawings, specifications, and calculations should be reviewed according to any or all of the following, as appropriate:

(*a*) Upon completion of the design and prior to construction or implementation,

(*b*) By a competent individual or group not directly involved in the preparation or selection of the design methods, and

(*c*) For accuracy, compliance with regulatory stipulations, compliance with plant or company standards.

7.2.3.2 Extent of design verification should be commensurate with the scope and complexity of the design.

7.2.3.3 Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculation and verification testing.

7.2.4 *Documentation*— Sufficient records should be generated to provide evidence that design processes are performed in accordance with the requirements of this guide. Documentation should include such items as drawings, specifications, design bases and design input that support the final design. Documentation should also include any revisions to the design including the appropriate review and verification documentation.

8. Instructions, Procedures and Drawings

8.1 *Summary*—Typically, in industry, there are many activities that, when performed incorrectly, could adversely affect the quality of the products, the health and safety of workers and the public, the environment, or a combination thereof. It is widely accepted that the best way to ensure that these activities are consistently performed in the proper manner is to define the requirements and the actions to be taken. This is done in appropriate documents such as instructions, procedures, and drawings. For simplicity, when the term *procedure* is used in this guide, it will refer to any of these types of documents.

8.2 *Recommendations*:

8.2.1 In the operation of a uranium conversion facility, procedures should be used to help ensure the proper performance tasks by employees. The following activities are some candidate areas for the development of procedures. Note that when procedures are designated “appropriate to” these activities, the activity often defines a category or type of procedure (for example, operating procedures.)

8.2.1.1 Process operations,

8.2.1.2 Maintenance and calibration,

8.2.1.3 Laboratory analyses,

8.2.1.4 Emergency actions, and

8.2.1.5 Quality assurance (including inspections, tests, audits, etc.).

8.2.2 Procedures should be written to ensure consistency in the operation of a facility. For operating procedures (and as appropriate for other types of procedures) the following should be considered as the minimum to be included:

8.2.2.1 Start-up and shutdown sequences,

8.2.2.2 Normal conditions and monitoring activities,

8.2.2.3 Emergency conditions and expected responses,

8.2.2.4 Identification of chemical and radiological hazards, and

8.2.2.5 Identification of significant environmental aspects of the operation.

8.2.3 Procedures should be designed to match the way they will be used. Consideration should be given to the use of special documents such as operating checklists, log books, shift reports, etc.

8.2.4 Whenever possible, quantitative or qualitative criteria that help determine the proper course of action or define the result of step or process should be included in procedures.

8.2.5 The requirement to follow procedures should be documented and employees should be made aware of this requirement.

8.2.6 The system for development of procedures should be documented. This should include the requirements for review and approval.

8.2.7 A documented system for making changes to procedures, including temporary changes, should be established. It is recommended that the review of changes to procedures be equivalent to what was required when the procedure was issued.

9. Documents and Document Control

9.1 *Summary*—Quality activities are normally defined in instructions, procedures, specifications, drawings, and other documents that are issued and distributed to appropriate individuals or organizations. In order to ensure that only approved and current issues are available and in use, a document control system should be developed and documented.

9.2 *Recommendation*:

9.2.1 Types of documentation that are addressed by this section include but are not limited to:

9.2.1.1 Standard operating procedures,

9.2.1.2 Emergency contingency plans,

9.2.1.3 Maintenance procedures (for critical equipment and processes),

9.2.1.4 Quality assurance program,

9.2.1.5 Engineering and design drawings,

9.2.1.6 Health, safety and environment requirements,

9.2.1.7 Procurement documents, and

9.2.1.8 Product specification.

NOTE 1—All essential documentation affecting quality should be identified, reviewed for adequacy and approved by authorized personnel prior to issue. Some of the functions identified throughout this guide provide a generic description of the types of documents to be considered.

9.2.2 The system of document control should identify the individual or organization responsible for specific documents and ensure that the applicable and current issues are available in the required area(s).

9.2.3 Where documentation is found to be ambiguous, incomplete, or conflicting, the responsible individual or organization should be responsible for corrective actions.

9.2.4 All changes to documents should be implemented in writing and processed promptly. Revisions should be reviewed and approved in the same manner as the original document, except where changes are of an editorial nature.

9.2.5 Regulatory or customer documentation should be controlled in the same manner and requirements for making document changes should be clearly defined.

9.2.6 Parties responsible for document control should maintain a controlled distribution list for each document, which should be controlled by document and revision number.

10. Procurement

10.1 *Summary*:

10.1.1 In the course of operating a uranium conversion facility, equipment, material and services will need to be purchased. The purchase of critical items and services identified in 6.2.6.5 should be controlled to ensure that they conform to defined requirements.

10.1.2 Control should be established through a documented, planned, and systematic procurement process. The procurement process should identify the methods and organizational responsibilities for implementation of the process.

10.2 *Recommendations*:

10.2.1 Quality requirements should be established and identified in the procurement documentation. Such documentation may include drawings, specifications, design codes, supplier identification, etc., as appropriate.

10.2.2 Selection of supplier(s) should be based on the supplier's ability to meet the quality requirements. Such an evaluation may be based on historical evidence, supplier documentation (for example, quality assurance manual), and surveillance of the supplier's facility. The degree of evaluation will be determined by the quality requirements.

10.2.3 Inspection requirements should be clearly identified in the procurement documents, including identification of hold points. Requirements for continuing a process beyond hold points should be stated. Some guidelines concerning inspections are provided in Section 13, Inspection, of this guide.

10.2.4 The supplier should be required to identify all non-conformances to the buyer. Disposition of nonconformances and corrective actions should be performed in accordance with Section 17, Control of Nonconforming Items, and Section 18, Corrective Action, of this guide.

10.2.5 Required supplier documentation to ensure compliance with quality requirements should be verified. Examples of this type of documentation are material test certificates, equipment operation and maintenance instructions, welder and welding procedure qualifications, etc.

10.2.6 Procurement documents and records should be reviewed and approved in accordance with guidelines described in Section 9, Documents and Document Control, and Section 19, Quality Assurance Records, of this guide.

10.2.7 Amendments to procurement documentation should be reviewed, approved, and controlled in the same manner as the original.

11. Identification and Traceability

11.1 *Summary*:

11.1.1 The use of the correct and acceptable items in the process plant is essential in the operation of a conversion facility. It is therefore necessary to establish a control system for items identified in 6.2.6.5 to ensure proper use and control.

11.1.2 Control is obtained by identifying these items either directly or in documents traceable to the items.

11.2 *Recommendations*:

11.2.1 *Identification Methods*:

11.2.1.1 Items should be identified from receipt through to final installation and use, relating the items to applicable design or other pertinent specifications.

11.2.1.2 Physical means—engraving, labels, paint, etc.—should be used as much as possible to identify items. Where this is not practical other suitable methods, such as segregation or procedural control, should be used.

11.2.1.3 When identification markings are used, the materials and methods of application should provide a clear, legible identification and not adversely effect the function of the part.

11.2.1.4 When items are subdivided (for example, metal plates used for pressure vessel fabrication), each part should be identified in a similar manner as the original.

11.2.1.5 If identification is to be obliterated by surface treatment or coating, suitable means of identification should be substituted.

11.2.2 *Requirements*:

11.2.2.1 Identification and traceability requirements may be specified by codes, standards, or specifications. The control system should provide for a means of identifying these and the degree of markings required.

11.2.2.2 Items with a limited shelf or operating life should be identified and controlled to preclude their use after the limited life has expired.

11.2.2.3 Provisions should be made to maintain identification of items in storage, considering shelf-life, environment, and handling.

12. Processes

12.1 *Summary*—Certain processes which cannot be directly measured may affect the quality of items or services produced. These may include construction, maintenance, and plant operations. Quality assurance is provided by ensuring that they are performed properly by qualified personnel in accordance with written and approved procedures.

12.2 *Recommendations*:

12.2.1 *General*:

12.2.1.1 Processes should be controlled by instructions, procedures, drawings, checklists, monitoring, or other appropriate means. This is to ensure that process parameters are controlled, and are reproducible, and that specified environmental conditions are maintained.

12.2.1.2 Uranium conversion facilities are chemical process plants that normally employ standard processes and commercially available equipment. In the event that testing of a non-standard nature is required, test procedures and objectives should be performed in accordance with approved procedures.

12.2.2 *Special Processes*:

12.2.2.1 Special processes should be identified in the quality assurance program.

12.2.2.2 Special processes should be performed in accordance with written and approved procedures that identify or reference personnel and equipment qualification requirements. Procedures should include or reference control parameters, calibration requirements, and applicable codes and standards, including acceptance criteria. Records should be maintained of personnel qualification, processes and equipment.

12.2.3 *Chemical Processes*:

12.2.3.1 Process operations are controlled through the use of qualified operating procedures and personnel. Operating procedures should be considered quality documents and handled as described in Section 8, Instructions, Procedures, and Drawings, and Section 9, Documents and Document Control.

12.2.3.2 Operating procedures should be written to ensure consistency in the operation of the facility. Whenever possible, these procedures should include quantitative (preferred) and qualitative criteria that describe the desired operating state or result of an action.

12.2.4 *Maintenance*:

12.2.4.1 All process equipment should be maintained. A preventive maintenance program is recommended. The system of identifying areas of responsibility and how the work is performed should be documented.

12.2.4.2 The maintenance system description should consider the following as a minimum:

(*a*) Identification of equipment,

(*b*) Evaluation of preventive maintenance and spare parts requirements,

(*c*) Records,

(*d*) Work methods, such as welding or repair procedures,

(*e*) Inspections, such as pressure tests,

(*f*) Interfacing with regulatory bodies,

(*g*) Identification of special protective equipment,

(*h*) Isolation of process equipment to ensure safe continued operation and the work to be performed, and

(*i*) Performance of tests prior to returning a system to service conditions.

13. Inspection

13.1 *Summary*—Inspections are required to verify conformance of an item or activity to specified requirements. To ensure that inspections are effective they should be planned, implemented, and documented as an integral part of the facility's functions.

13.2 *Recommendations*:

13.2.1 *Inspection Personnel*:

13.2.1.1 Personnel performing an inspection should be independent of personnel producing the item or conducting the activity.

13.2.1.2 Qualifications of inspection personnel should be established and documented.

13.2.2 *Inspections*:

13.2.2.1 Inspections should be performed by qualified personnel in accordance with written procedures or instructions. When inspections are performed by personnel in the process of being qualified, the inspection should be performed under the direct observation and supervision of qualified personnel.

13.2.2.2 Procedures or instructions used to perform an inspection should identify the characteristics, methods, acceptance criteria, and reporting requirements of the inspection. When acceptance of a group of items is based on a representative sampling, the sampling procedure should be documented and based on recognized standard practices.

13.2.2.3 Inspection reports indicating conformance status should be issued by qualified personnel.

13.2.2.4 The inspection should be planned and implemented as part of a facility function-procurement, maintenance, or operating practice. As such, inspections may be comprised of any one or more of the following:

(*a*) In-process inspection,

(*b*) Final inspection, and

(*c*) In-service inspection.

13.2.2.5 In-process inspections are performed during the course of producing an item or performing an activity. They are used to verify that quality requirements are met before an item or activity is completed. These inspections may be direct or indirect, the latter may be used when it is not possible or

practical to perform an inspection. The latter is referred to as process monitoring, and may include chemical testing.

13.2.2.6 Final inspections are performed on completed items or activities and are intended to conclusively establish conformance to requirements. This should include a review of records, status of nonconformances, markings, certification, etc. necessary to verify quality. Final acceptance should be documented and approved by authorized personnel. Modifications, repairs or replacement of parts after final inspection should require the item to be reinspected or retested.

13.2.2.7 In-service inspections are performed in the course of operating the facility. They are intended to show that characteristics of a structure, system, or component are still within acceptable limits. This may include integrity of equipment or instrumentation, calibration and verification of proper maintenance, or an intermediate stage of the chemical process.

13.2.2.8 When mandatory hold points are identified in the inspection process, they should be indicated on the appropriate documents. Requirements for continuing a process beyond hold points should be stated. Consent to waive or release such hold points should be recorded prior to proceeding past the hold point.

13.2.3 *Records*:

13.2.3.1 Inspection personnel qualification requirements and records should be documented, including retention requirements.

13.2.3.2 Results of inspections should be traceable to the item inspected. As a minimum it should include: item inspected, date of inspection, inspector, type of observation, results/acceptability, and reference to nonconformance status and actions.

13.2.3.3 Records should be maintained as described in Section 19, Quality Assurance Records, of this guide.

14. Control of Measuring and Test Equipment

14.1 *Summary*:

14.1.1 In the performance of facility functions—quality control, health physics, environmental monitoring, laboratory analyses, plant operation, etc.,—measurement and test equipment is used to monitor the process for the purpose of controlling and verifying quality. As these measurements are then used to alter processes or accept items, it is essential that they meet bias and precision requirements. This requires that the measuring and test equipment is operated properly, and that adequate calibration and measurement control procedures are used.

14.1.2 This section is not applicable to rulers, tape measures, levels and other devices when normal commercial equipment provides adequate accuracy.

14.2 *Recommendations*:

14.2.1 A documented system describing the selection and registration of measuring and test equipment should be established.

14.2.2 All measuring and test equipment should be uniquely identified and a listing of such equipment maintained, indicating calibration frequency and calibration procedure.

14.2.3 Measuring and test equipment should be assessed as to calibration requirements based on intended use, operating environment, type of equipment, required accuracy and other conditions affecting measurement control.

14.2.4 Calibration and measurement should be performed in accordance with written procedures against standards that are traceable to recognized standards. Where recognized standards do not exist, the source of the standards and their preparation and characterization should be documented. Frequency of calibration and required intervals for using control standards should be included in the procedures as appropriate.

14.2.5 The calibration status of the measuring and test equipment should be available, either by means of calibration dates on the items or traceable to a record.

14.2.6 Records should be maintained for each item of measuring and test equipment showing its location, type, frequency of calibration, method of calibration, date of calibration, and acceptance criteria. These should be maintained as described in Section 19, Quality Assurance Records, of this guide.

14.2.7 When measuring and test equipment is found to be out of calibration, the validity of previous inspections should be assessed and documented. Such equipment should be identified to prevent its continued use until it is recalibrated.

15. Handling, Storage, and Shipping

15.1 *Summary*—The operation of a uranium conversion facility requires the use of uranium-bearing and other hazardous materials. The handling, storage and shipping of these materials should be done in accordance with regulatory codes and licensing requirements. This is done to minimize the hazards to workers and to the general public and to ensure the quality of the material. Applicable items should be documented as in 6.2.6.5. Activities should be performed in accordance with written and approved procedures.

15.2 *Recommendations*:

15.2.1 Items or uranium materials requiring special handling, storage, and shipping instructions should be identified in accordance with 6.2.6.5. These instructions should be considered quality documents and handled as described in Section 9, Documents and Document Control.

15.2.2 Special equipment should be tested on a regular basis, commensurate with the importance of the equipment to the safe operation of the plant and regulatory and code requirements.

15.2.3 Testing and reporting should be performed in accordance with written and approved procedures.

15.2.4 Records of tests should be handled as described in Section 19, Quality Assurance Records.

16. Inspection, Test, and Operating Status

16.1 *Summary*

16.1.1 Those activities requiring inspection, test, and operating status control should be designated by the facility.

16.1.2 The status of inspection and test activities should be identified either on the items or in documentation traceable to the items. Nonconforming items should be controlled in accordance with Section 17, Control of Nonconforming Items.

16.2 *Recommendations*:

16.2.1 Procedures for the determination of the status of inspection and test activities should specify which items are to be included and the method by which the status should be determined.

16.2.2 The status should be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means, as specified in the procedures.

16.2.3 The procedures should specify who has the authority for application and removal of tags, markings, labels, and stamps.

16.2.4 Where applicable, status indicators should also be provided for the indication of the operating status of designated systems and components of the conversion facility to prevent inadvertent operation.

17. Control of Nonconforming Items

17.1 *Summary*—Items that do not conform to specified requirements should be controlled to prevent inadvertent installation or use. Controls should provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.

17.2 *Recommendations*:

17.2.1 Procedures should be established to provide the means for identification of nonconforming items.

17.2.2 Procedures should be established to designate what type of action is required for each nonconforming item.

17.2.3 Procedures should be established for the disposition of nonconforming items, and should include:

17.2.3.1 Control of the nonconforming items for preventing inadvertent use prior to evaluation and disposition,

17.2.3.2 Designation of who has the responsibility and authority for the disposition of nonconforming items, and

17.2.3.3 Specification of the qualification requirements for personnel determining the disposition of nonconforming items, for ensuring that those performing evaluations for determining disposition should have demonstrated competence in the specific area they are evaluating.

17.2.4 The disposition, such as use-as-is, reject, repair, or rework, of nonconforming items should be identified and documented. Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use-as-is should be documented.

17.2.5 Repaired or reworked items should be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

18. Corrective Action

18.1 *Summary*:

18.1.1 Conditions adverse to quality should be identified promptly and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition should be determined and corrective action taken to preclude recurrence.

18.1.2 The identification, cause, and corrective action for significant conditions adverse to quality should be documented and reported to appropriate levels of management. Follow-up action should be taken to verify implementation of the corrective action.

18.1.3 Consideration should also be given to initiating corrective actions when a nonconformance has not occurred, but the potential for a nonconformance has been identified. In such instances the actions are considered preventative in nature.

18.2 *Recommendations*:

18.2.1 Appropriate corrective action should be determined according to the nature of the nonconformance, or potential nonconformance. The magnitude of the corrective action should be commensurate with the scope of the nonconformance, or potential nonconformance, and its impact upon the safe operation of the facility.

18.2.2 Procedures should specify the type of conditions requiring corrective action, and the person responsible for taking the necessary corrective action.

18.2.3 Those responsible for verifying that the corrective action has been taken should be designated.

19. Quality Assurance Records

19.1 *Summary*:

19.1.1 Records that furnish documentary evidence of quality should be specified, prepared, and maintained.

19.1.2 Records should be protected against damage, deterioration, or loss.

19.1.3 Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition should be established and documented.

19.2 *Recommendations*:

19.2.1 *Records Administration*:

19.2.1.1 A quality assurance records system should be established. The system should address specification, preparation, approval, validation, indexing, classification for retention time purposes, provisions for reviews, distribution, storage, and maintenance of records. The records system should be defined and implemented in accordance with written procedures that are consistent with applicable regulatory or license requirements.

19.2.1.2 The records system should designate those records to be included in the system. Records to be entered in the system should be legible, accurate, complete, and appropriate to the work accomplished.

19.2.2 *Storage, Preservation, and Safekeeping*:

19.2.2.1 The records should be stored in predetermined location(s) that meet the requirements of applicable standards, codes, and regulatory agencies.

19.2.2.2 A written storage procedure should be used, and should include:

(*a*) A description of the storage facility,

(*b*) The filing system to be used,

(*c*) A method for verifying that the records are legible,

(*d*) A method for verifying that the records are those to be included,

(*e*) The rules governing access and control of the files,

(*f*) A method for maintaining control of and accountability for records removed from the storage facility,

(*g*) A method for filing supplemental information and disposing of superseded records, and

(*h*) Retention period requirements.

20. Audits

20.1 *Summary*—The facility compliance with the quality assurance program and the effectiveness of the program is established through an audit program. Audits should be performed in accordance with a documented system outlining such areas as auditor qualifications, audit schedules and methods, reporting, and follow-up activities.

20.2 *Recommendations*:

20.2.1 The facility should identify the organization responsible for the audit function. The organization may be either internal or external to the facility. If an external organization is used then the facility should identify an internal organization responsible for ensuring that the requirements of this guide are met.

20.2.2 All audits should be scheduled and performed on a minimum specified frequency. The frequency should be based on the relative importance of the area to be audited. The need for additional auditing may be identified by program reviews, assessment of trends in nonconformances, major changes to the program, or other knowledge of the situation.

20.2.3 Audits should be performed in accordance with written procedures. The use of checklists is highly recommended, as it assists in the planning of such audits.

20.2.4 Audit personnel should not be directly responsible for the area to be audited.

20.2.5 Qualification requirements of audit personnel and the qualification records requirements should be documented.

20.2.6 To ensure that audits verify facility compliance with the quality assurance program and to check the effectiveness of the program, they should be performed on:

20.2.6.1 All of the areas or functions identified in this guide,

20.2.6.2 Procedures and instructions, and

20.2.6.3 Items, processes and records.

20.2.7 Method of audit reporting, responses, and follow-ups to ensure that any identified actions are implemented should be documented. Consideration should be given to identified deficiencies requiring immediate responses, facility management responsible for resolving quality matters, and distribution of the findings to senior management.

20.2.8 Audit protocol may need to be defined, especially when an external organization is used to perform the audit function or if a regulatory organization is involved.

21. Keywords

21.1 facilities; quality assurance; uranium