NYE COUNTY NUCLEAR WASTE REPOSITORY PROJECT OFFICE

QUALITY ASSURANCE PROGRAM PLAN

APPLICABILITY:	SUPERSEDES:	REVISION: 05
All quality-affecting activities of NWRPO technical programs.	Revision 04, 6-15-03	Date: 7-9-08 Page: 1 of 38

Approved by:

Director — Date: 7/10/08

Concurrence:

Assistant Director — Date: 7/10/08

Geoscience Manager — Date: 7/10/08

Quality Assurance Officer — Date: 7/10/08

REVISION HISTORY

Revision Number	Effective Date	Affected Pages	Revision Description
05	July 9, 2008	All pages	Update QAPP to show current organization, responsibilities, and requirements.
04	June 15, 2003	All pages	Update QAPP to show current organization, responsibilities, and requirements.

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LIST OF ACRONYMS

AD	Assistant Director
ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
CFR	Code of Federal Regulations
DOE	U.S. Department of Energy
EPA	U.S. Environmental Protection Agency
GSM	Geoscience Manager
LA	License Application
NQA-1	Nuclear Quality Assurance, Level 1
NRC	U.S. Nuclear Regulatory Commission
NUREG	US Nuclear Regulatory Commission Regulation
NWPA	Nuclear Waste Policy Act
NWRPO	Nuclear Waste Repository Project Office
PI	Principal Investigator
QA	Quality Assurance
QAO	Quality Assurance Officer
QAP	Quality Administrative Procedure
QAPP	Quality Assurance Program Plan
QARC	Quality Assurance Records Center
QARS	Quality Assurance Records Specialist
SM	Staff Member
TP	Technical Procedure
TPN	Test Plan
WP	Work Plan

INTRODUCTION

This Quality Assurance Program Plan (QAPP) was prepared by the Nye County, Nevada, Nuclear Waste Repository Project Office (NWRPO) according to policies established by the Nye County Board of Commissioners, upon the advice of the County Manager and the NWRPO Director, and with the counsel of the District Attorney. The QAPP is designed to establish plans and procedures for ensuring the quality of NWRPO technical products and is based on requirements set forth by the U.S. Nuclear Regulatory Commission (NRC), the American National Standards Institute (ANSI), and the American Society of Mechanical Engineers (ASME) for nuclear power plants as adapted for a nuclear waste repository.

NUCLEAR WASTE REPOSITORY BACKGROUND

Nuclear Waste Policy Act

In 1982, the Nuclear Waste Policy Act (NWPA) defined a process to site, construct, operate, and decommission a geologic repository for spent fuel from commercial nuclear power plants and high-level radioactive waste from federal weapons plants. In 1987, amendments to the NWPA designated Yucca Mountain, in Nye County, as the sole candidate site for a repository.

The NWPA assigned roles to three separate agencies of the executive branch. The U.S. Environmental Protection Agency (EPA) was directed to establish generally applicable standards for protection of the general environment from off-site releases of radioactive material in repositories; the U.S. Department of Energy (DOE) was directed to characterize Yucca Mountain for its suitability for a repository, as well as construct, operate, and decommission the facility, if licensed; and the NRC was charged with establishing technical requirements and criteria for licensing, including construction, operation, closure, and decommissioning a repository. The NRC was also charged with evaluating and awarding, if appropriate, the DOE license application (LA) to construct, receive waste, operate, close, and decommission the repository.

Nye County Nuclear Waste Repository Project Office

Upon designation of Yucca Mountain as a site for suitability determination for the nation's first potential high-level nuclear waste repository, Nye County established the NWRPO to investigate the potential impact such a repository might have on human health, safety, and the environment of Nye County.

To achieve this purpose, the NWRPO administers programs of oversight, scientific investigations, impact assessment, and impact mitigation. In particular, the NWRPO and its contractors perform the following:

1. Monitor DOE activities pertaining to the Yucca Mountain high-level waste repository.
2. Review and/or analyze applicable plans, reports, and data from DOE and other sources.

3. Conduct such independent investigations as may be needed to:
    a. Evaluate and validate DOE data, assumptions, conclusions, and designs.
    b. Assess potential future impacts to groundwater and other environmental media that ultimately affect human health and the environment of Nye County.
    c. Develop and implement a mitigation plan.
    d. Support potential licensing and impact mitigation proceedings.
4. Support and sponsor, as appropriate, other independent technical activities related to oversight of long-term DOE environmental stewardship responsibilities.

QUALITY ASSURANCE PROGRAM

The QA program is designed to provide documented assurance that data derived from NWRPO technical programs are of the highest quality. Furthermore, it is intended to ensure that scientific activities are conducted in a systematic manner, using documented instructions and procedures that ensure the validity, integrity, preservation, and retrievability of the data generated.

QUALITY ASSURANCE PROGRAM PLAN

This QAPP focuses on NWRPO activities during the period of DOE preparation of the LA and subsequent NRC review, approval, and authorization; if appropriate, construction of the repository, operation, closure, and decommissioning of the repository. The plan outlines QA requirements for the operation of NWRPO technical programs; delineates responsibilities for implementing program elements; describes the manner in which work is defined, implemented, documented, and reviewed to ensure quality; and provides methods to verify that QA requirements have been met.

It is recognized that the NWRPO was created primarily to collect scientific data and is not involved in repository construction. Therefore, although this QAPP is based upon interpretation of federal requirements for nuclear power plants (ANSI/ASME, 1986; 10 Code of Federal Regulations [CFR] 50, Appendix B), not all of the federal requirements are applicable. In particular, Basic Requirement #9, *Control of Processes*, is not applicable. The ANSI/ASME Nuclear Quality Assurance, Level 1 (NQA-1) Basic Requirements listed in Table 1 correlate directly with the sections of this QAPP.

Table 1
NQA-1 Basic Requirements and Equivalent Code of Federal Regulations Criterion

ANSI/ASME NQA-1 Basic Requirement	Equivalent Code of Federal Regulations Criterion 10 CFR 50, Appendix B
1. Organization	I
2. Quality Assurance Program	II
3. Design Control	III
4. Procurement Document Control	IV
5. Instructions, Procedures, and Drawings	V
6. Document Control	VI
7. Control of Purchased Items and Services	VII
8. Identification and Control of Items	VIII
9. Control of Processes	IX
10. Inspection	X
11. Test Control	XI
12. Control of Measuring and Test Equipment	XII
13. Handling, Storage, and Shipping	XIII
14. Inspection, Test, and Operating Status	XIV
15. Control of Nonconforming Items	XV
16. Corrective Action	XVI
17. Quality Assurance Records	XVII
18. Audits	XVIII

1.0 ORGANIZATION

1.1 PURPOSE

This section defines the organizational structure, functional responsibilities, and lines of communication for the direction and execution of the NWRPO QA program.

1.2 SCOPE

This section applies to all NWRPO personnel participating in quality-affecting activities for the NWRPO technical program. NWRPO personnel include Nye County employees, contractors, and subcontractors.

1.3 RESPONSIBILITIES

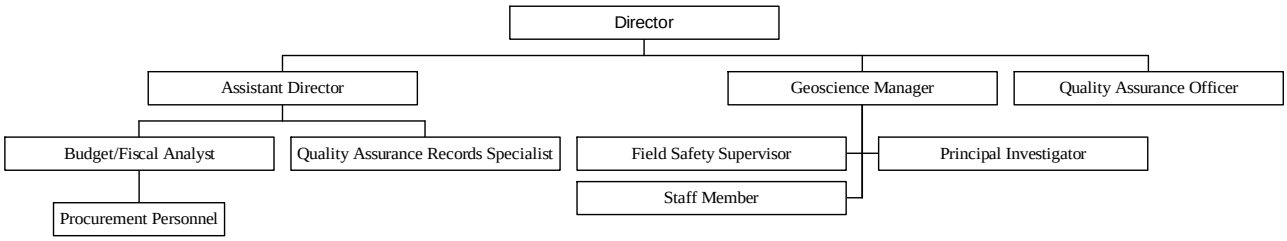
The NWRPO QA structure is organized so that quality can be achieved and maintained by personnel doing quality-affecting work and that quality achievement will be verified by an individual not directly responsible for performing that work.

All NWRPO personnel who perform quality-affecting activities are responsible for the quality of their work. Personnel responsible for implementing the technical program will have the appropriate authority, access to work areas, and organizational freedom to meet their QA responsibilities.

The technical responsibility and authority of the Nye County employees will be clearly established in Nye County position descriptions. The responsibilities and authority for each contractor will be clearly established in contract documents, and assigned activities will be monitored by the Quality Assurance Officer (QAO) for QA compliance. The contractor is responsible for similarly establishing and documenting the responsibilities of its subcontractors and ensuring that the subcontractors comply with the requirements of the NWRPO QA program. Contractors and subcontractors may perform work according to their own QA programs upon review and acceptance of such programs by the QAO and approval by the Director or designee.

The NWRPO QA organizational structure is illustrated in Figure 1. Specific NWRPO QA responsibilities are defined in Sections 1.3.1 through 1.3.10. All activities described in these sections are defined as quality-affecting activities.

Figure 1
NWRPO QA Organization Chart



1.3.1 Director

The Director is responsible for the overall direction, performance, and management of the NWRPO QA program. The Director has designated the Assistant Director (AD) to assist the QAO and QARS with the day-to-day management of the QA program.

1.3.2 Assistant Director

The AD is responsible for ensuring that NWRPO technical programs are supported by and carried out under a program of QA. The responsibilities of the AD include, but are not limited to, the following:

- Ensuring implementation of the QA program.
- Reviewing and making decisions based on QAO recommendations regarding the acceptance of contractor and subcontractor QA programs.
- Resolving disputes that may arise between the QAO and technical personnel.
- Ensuring that the QAO periodically audits project activities to verify that they are conducted in accordance with established project procedures.

1.3.3 Quality Assurance Officer

. The responsibilities of the QAO include, but are not limited to, the following:

- Establishing controls to ensure that activities are performed in full compliance with QA program requirements.
- Performing routine checks and inspections of data and activities, both in the field and the NWRPO.
- Developing, maintaining, and ensuring the safety of the QA records. The QAO may delegate these duties to the Quality Assurance Records Specialist (QARS), as appropriate.

- Conducting periodic surveillances and audits to verify that project activities are performed in accordance with the QA program.

- Issuing nonconformances, verifying implementation of corrective actions, and recommending work stoppage, if necessary, to address nonconformance issues.

- Reviewing and approving work plans (WPs), technical procedures (TPs), test plans (TPNs), and other documents that contain QA directives issued to NWRPO project personnel.

- Verifying that technical and peer reviews are conducted as required, job descriptions and qualifications of project personnel are on file, and controlled documents are appropriately distributed.

- Assessing the effectiveness of the QA program and initiating and/or reviewing appropriate revisions to the QAPP or related QA documents.

- Reviewing contractor and subcontractor QA programs as necessary, and recommending their acceptance, if appropriate, to the AD.

1.3.4 Quality Assurance Records Specialist

The QARS is responsible for maintaining electronic and hard copy records submitted to the QA Records Center (QARC). The QARS is responsible for cataloging and storing the records for easy identification and use, accurately entering information into the QARC database, and maintaining record control and security.

1.3.5 Geoscience Manager

The Geoscience Manager (GSM) is responsible for designing, planning, and managing the NWRPO technical programs. The responsibilities of the GSM include, but are not limited to, the following:

- Staffing technical programs with NWRPO personnel and/or contractor personnel.

- Monitoring the performance of technical personnel.

- Writing job descriptions for technical personnel.

- Writing scopes of work for technical contractors that clearly define lines of authority, work tasks, deliverables, and schedules for the deliverables.

- Organizing and implementing technical and peer reviews, as appropriate.

- Ensuring that nonconformances are adequately addressed.

1.3.6 Principal Investigator

The Principal Investigator (PI) reports to the GSM and is responsible for planning, coordinating, performing, and documenting NWRPO work requirements. The responsibilities of the PI include, but are not limited to, the following:

- Applying the NWRPO QA program to assigned activities, including developing, revising, if necessary, and implementing WPs, TPs, and TPNs.
- Developing and maintaining a file of relevant QA program documents.
- Ensuring that personnel are trained in NWRPO QA program requirements and the use of the procedures applicable to the performance of their work.

1.3.7 Budget/Fiscal Analyst

The Budget/Fiscal Analyst reports to the AD in QA matters and works directly with the QAO to ensure that procurement processes are conducted and documented in accordance with QA program requirements. The Budget/Fiscal Analyst is responsible for procuring and managing contracts for professional and support services and procuring materials and tools for NWRPO activities.

1.3.8 Procurement Personnel

Procurement personnel are responsible for processing purchase order and contract procurement requests, by generating procurement documents, coordinating procurement, tracking receipt, and arranging for payment.

1.3.9 Staff Member

The Staff Member (SM) reports to the PI and/or the GSM, as appropriate, and is responsible for completing assigned activities in accordance with applicable aspects of the QA program.

1.3.10 Field Safety Supervisor

The Field Safety Supervisor (FSS) reports to the GSM and is responsible for developing and implementing the NWRPO Health and Safety Plan.

1.4 MANAGEMENT CONTROLS

In order to satisfactorily achieve NWRPO QA program objectives, the controls described in the following sections will be implemented.

1.4.1 Lines of Communication

Clear and effective lines of communication for NWRPO technical activities will be established between the GSM and PI.

1.4.2 Responsibility Assignments

The Nye County Board of Commissioners has authorized the Nye County Manager to staff the Director, AD, and GSM positions to manage the NWRPO programs. The Nye County Manager has authorized the Director to implement the NWRPO QA program. The Director has assigned the responsibility for managing the day-to-day operation of the QA program to the QAO and AD and the responsibility for operation of the technical program to the GSM. The GSM in turn has assigned PIs and SMs (i.e., the technical personnel) the responsibility for conducting technical work in accordance with the QA program. The Director has assigned the QAO the responsibility for ensuring that an appropriate QA program is established and verifying that activities affecting quality have been correctly performed. It should also be noted that QA is the responsibility of all NWRPO personnel performing quality-affecting activities.

1.4.3 Verification of Conformance

The QAO, in consultation with the GSM, will verify that work performed by the PIs and SMs conforms to QA program requirements.

1.4.4 Performance Accountability

The AD is responsible for ensuring that NWRPO personnel comply with QA program requirements.

Since compliance with the QA program is essential to the success of the NWRPO mission to protect human health, safety, and the environment in Nye County, supervisors will include QA effectiveness in performance evaluations of all NWRPO personnel. The GSM will use QA effectiveness as a major criterion for determining whether to renew yearly contracts of NWRPO contractors and subcontractors performing quality-affecting activities for the technical program.

1.5 PERSONNEL QUALIFICATIONS AND TRAINING

All personnel performing quality-affecting activities will have experience or training commensurate with the scope, complexity, or special nature of the activities they perform for the NWRPO technical program. Personnel will be provided with a general written description of their roles and responsibilities. Experience and/or training to perform assigned responsibilities will be independently verifiable. Personnel will be trained in and capable of performing their QA responsibilities.

The effectiveness of personnel qualifications and training requirements in implementing the QA program will be monitored, verified, and documented by the QAO.

2.0 QUALITY ASSURANCE PROGRAM

2.1 PURPOSE

This section describes the purpose and scope of the NWRPO QA program and responsibilities for implementing the program. The program complies with the basic portions of the requirements of ANSI/ASME NQA-1 and criteria delineated in 10 CFR 50, Appendix B that are applicable to the NWRPO scope of work. The NWRPO QA program is designed to ensure that all data, analyses, and conclusions developed and documented by NWRPO technical programs are credible, defensible, retrievable, and traceable within any future licensing or impact mitigation proceedings. In addition, data not collected under the NWRPO QA program may be subject to qualification procedures as well. NWRPO accepts, on a limited basis, the controls of Nuclear Regulatory Commission Regulation (NUREG)-1298, *Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories* (NRC, 1988).

The NWRPO QA program will provide controls to ensure that computer software categorized by the QAO as quality-affecting will be appropriately documented, used, and controlled. Software QA is implemented at a level commensurate with the impact of such software on NWRPO technical programs. NWRPO accepts, as applicable to its scope of work**,** NUREG-0856, *Final Technical Position on Documentation of Computer Codes for High-Level Waste Isolation* (NRC, 1983).

Quality-affecting documents and electronic media used to record NWRPO data, analyses, and conclusions will be appropriately protected for future reference.

2.2 SCOPE

The NWRPO QA program applies to all aspects of the technical program judged by the Director and GSM to potentially affect the credibility, defensibility, and traceability of future claims concerning licensing of Yucca Mountain as a high-level radioactive waste repository and the potential impacts of repository-related DOE activities on Nye County.

The QA program applies to all data collection and analyses for the NWRPO technical program. Application of QA program control and verification procedures to specific activities will be commensurate to their importance to any future licensing proceedings and potential impacts of DOE repository-related activities on Nye County.

This QA program does not conform to regulatory requirements that are intended to control the license applicant (i.e., the DOE) in the design, construction, and operation of the repository. Therefore, portions of 10 CFR 50, Appendix B, and ANSI/ASME NQA-1 are not applicable to the NWRPO QA program. Additionally, various key NRC QA guidance documents are not applicable. For example, NUREG-1318, *Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements* (Duncan et al., 1988), categorizes activities subject to QA based upon their importance to safety or waste isolation; since these activities relate to repository construction, they are not applicable to the NWRPO technical program.

2.3 RESPONSIBILITIES

NWRPO activities and performance requirements will be assigned to qualified NWRPO personnel by providing a written description of the work to be completed and QA program compliance requirements. The PI, assigned by the GSM, will be responsible for 1) writing a WP and appropriate TPs and TPNs for completing the work and protecting data sets, 2) securing resources needed to perform the work, 3) identifying any training required for performing the work, 4) documenting work performance, and 5) submitting the documents to the QARC.

PIs, with the aid of the QAO and GSM, as appropriate, will regularly assess and document the adequacy of that part of the QA program for which they are responsible to ensure its effective implementation.

The AD, with the support of the QAO, will verify that l) work has been performed as planned and that variances from plans and the impacts, if any, have been documented; 2) QA requirements have been met; and 3) documented nonconformances have been corrected.

The QAO will be responsible for preparation and revision, if necessary, of the QAPP and QAPs. Revisions to the documents will be prepared, approved, and distributed in accordance with QAP-6.1, *Issuance and Control of Quality Assurance Documents*

The Director will be responsible for the approval of the QAPP as well as the annual review of the QA program.

2.4 IMPLEMENTATION

The AD, supported by the NWRPO personnel mentioned in the preceding section, will be responsible for implementing the QA program.

3.0 DESIGN CONTROL

3.1 PURPOSE

This section describes how design control applies to NWRPO technical program activities.

The standard regulatory definition of design control has been modified for the NWRPO QA program. The difference lies in the scope of the oversight activities performed by NWRPO versus the scope of DOE repository design activities. NWRPO work consists of monitoring DOE activities, overseeing (i.e., reviewing, analyzing, and evaluating) DOE technical products, conducting a program of independent scientific investigations, assessing and mitigating impacts to groundwater, and other independent technical activities deemed necessary to protect long-term human health and the environment of Nye County. Therefore, the applicability of design control to the NWRPO is limited to independent technical review and analysis of the products of its technical and QA programs and the review and approval of these products by the QAO to ensure that QA requirements have been adequately addressed. These products include, but are not limited to, the QAPP, QAPs, WPs, TPs, TPNs, scientific notebooks, technical reports, and progress reports. For the purpose of the NWRPO QA program, electronic records (e.g., compact disks) of scientific information are considered to be scientific notebooks.

The NWRPO application of design control requires that changes to any of these products are subject to the same controls and reviews applied in the original independent review and approval process. Any deviations from this process will be justified and documented.

This section describes how the NWRPO will review plans for data acquisition as well as reports of the results of data collection, analysis, and interpretation. Independent technical reviews will be conducted to ensure that planned and completed technical work is founded upon sound and defensible technical concepts, methods, assumptions, calculations, and projections and to verify the accuracy and completeness of data acquisition, analysis, and overall study methodologies. Independent technical reviews will facilitate the documentation and correction of errors and deficiencies. These controls comply with Basic Requirement 3 of ANSI/ASME NQA-1, as applicable to the NWRPO scope of work, and Criterion III of 10 CFR 50, Appendix B.

3.2 SCOPE

This section applies to independent technical reviews and QA reviews of all NWRPO products generated by its technical programs. Because of the potential uncertainty in most geoscience data and subsequent analysis, expert judgment may be needed to assess the adequacy of the work. External peer review may be used as one of the mechanisms by which such judgments are made.

3.3 RESPONSIBILITIES

Design control through independent review will be accomplished by internal technical review or, if appropriate, by external peer review. Internal technical reviews shall be conducted by

qualified NWRPO personnel and the external peer reviews shall be conducted by qualified individuals not associated with the NWRPO. The PI, in consultation with the GSM, will be responsible for ensuring that technical products undergo independent technical review. If necessary, the PI will convene an external peer review for technical issues that cannot be resolved by an internal technical review. Design control by QA review and approval will be accomplished by the QAO.

3.4 IMPLEMENTATION

QA review and approval will include verification that appropriate QA requirements have been adequately addressed. Independent internal technical review will be undertaken as a check on the thoroughness and accuracy of the WPs, TPNs, TPs, and subsequent analysis and documentation of results. All review comments and resolutions will be formally documented. Additionally, the independent technical review process will ensure that reviewers are qualified, their qualifications are documented, and they have not been directly responsible for the work under review.

External peer reviews will be conducted in situations where uncertainties inherent in geoscience data, methodologies, interpretations, or conclusions cannot be resolved by internal technical review. NWRPO peer review procedures will be generally based upon the guidance of NUREG-1297, *Peer Review for High-Level Nuclear Waste Repositories* (NRC, 1988), with the understanding that the NWRPO scope of activities is more limited than that of the DOE. In addition, all peer reviewers will be approved by the QAO.

QAP-3.1, *Independent Technical Review*, will establish systems for internal technical review and external peer review. Documentation and review of technical plans, procedures, results, analyses, and reports will be specified in QAP-3.2, *Documentation of Technical Investigations*.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 PURPOSE

This section describes how applicable QA requirements are included or referenced in procurement documents for the NWRPO technical program. This section complies with Basic Requirement 4 of ANSI/ASME NQA-1, as well as Criterion IV of 10 CFR 50, Appendix B.

4.2 SCOPE

This section applies to all contract and purchase order procurement documents for quality-affecting tests, items and services for the NWRPO technical program. Examples of QA requirements in procurement documents include 1) specifications for test equipment and acceptance-inspection records, 2) contracts or purchase orders for chemical analyses of groundwater, 3) geotechnical analyses of core and cutting samples, and 4) contract specifications for drilling boreholes.

4.3 RESPONSIBILITIES

The PI or designee will incorporate QA requirements into procurement documents. Procurement documents containing contracts for analytical tests, items, or services for the NWRPO technical program will be reviewed by the QAO for conformance to procurement document requirements. In addition, NWRPO personnel will participate in procurement reviews, if requested by the QAO. The results of all procurement reviews will be appropriately documented.

4.4 IMPLEMENTATION

All quality-affecting procurement documents will be reviewed by the QAO prior to approval by the Director and GSM to ensure that applicable QA program requirements have been met. If applicable, procurement documents will specify that the contractor or vendor will grant access to their facilities, including field locations, and records for inspections and audits. Adequate acceptance or rejection criteria will be included in all procurement documents. The supplier will be required to furnish the NWRPO with documentation identifying the procurement, the specific procurement requirements met (e.g., codes, standards, and specifications), and any requirements not met, as well as a description of any nonconformances resulting from not meeting the procurement requirements.

Procurement activities will be specified in QAP-7.1, *Procurement of Items and Services*.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 PURPOSE

This section describes how quality-affecting activities are prescribed by and accomplished in accordance with documented QA plans and procedures. QA plans and procedures are developed to provide a consistent basis for accomplishing a task, making decisions, verifying measures, and evaluating and documenting changes. This section complies with Basic Requirement 5 of ANSI/ASME NQA-1, as well as Criterion V of 10 CFR 50, Appendix B.

5.2 SCOPE

This section applies to the development of instructions and procedures for the performance of quality-affecting activities, including the documentation of those activities. The NWRPO prescribes activities through QAPs, WPs, TPs, and TPNs. In addition to step-by-step instructions for accomplishing an activity, these documents include appropriate qualitative and/or quantitative acceptance criteria, technical requirements, and responsibilities for conducting the activity.

5.3 RESPONSIBILITIES

The GSM is responsible for assigning a PI or designee to develop necessary WPs, TPs and TPNs for a specific activity. All NWRPO personnel are responsible for performing quality-affecting activities in accordance with the requirements of applicable QAPs, TPs, WPs, and TPNs. When an activity cannot be accomplished as described in the appropriate procedure and would result in an unsafe or undesirable condition, the activity will be stopped and the procedure corrected.

As specified in Section 3.0, the QAO is responsible for reviewing and approving completed WPs, TPs, and TPNs. Additionally, QAO review will establish controls to ensure that plans and procedures for data collection and analysis are completed before such activities take place.

5.4 IMPLEMENTATION

Plans and procedures controlling quality-affecting activities of the NWRPO technical program will be developed and approved on a timely basis, with an adequate level of detail to enable the activities to be carried out in a timely manner. The documents will be as brief as possible, with well-defined steps to facilitate implementation. Appropriate flow diagrams and checklists may be included to make procedures easier to follow.

Review, approval, issuance, change, revision, and cancellation of plans and procedures will be controlled and documented. Controls on the review and issuance of the documents will ensure that technical and QA requirements are included prior to issuance.

The preparation of QAPs, WPs, TPs, and TPNs will be specified in QAP-5.1, *Preparation of Quality Administrative Procedures,* and QAP-5.2, *Preparation of Work Plans, Test Plans and Technical Procedures.*

6.0 DOCUMENT CONTROL

6.1 PURPOSE

This section describes the control of NWRPO QA program documents. This section complies with Basic Requirement 6 of ANSI/ASME NQA-1, as well as Criterion VI of 10 CFR 50, Appendix B.

6.2 SCOPE

This section applies to the issuance, distribution, and/or revision of NWRPO QA program documents, including, but not limited to, the QAPP, QAPs, WPs, TPs, TPNs, nonconformance reports, and corrective action reports.

6.3 RESPONSIBILITIES

The QAO is responsible for control of the issuance, distribution, and/or revision of documents that regulate the manner in which the quality-affecting NWRPO activities are to be performed. The QAO may assign such document control to the QARS, as appropriate.

6.4 IMPLEMENTATION

Applicable and current documents will be made available at the location where the work takes place before the work is commenced. Superseded, revised or cancelled documents will be replaced by applicable revisions in a timely manner.

Changes to controlled documents will be reviewed and approved by the individuals who performed the original review and approval, unless the Director or designee assigns the task to other qualified reviewers.

The QARS will maintain a master list of all controlled documents issued by the NWRPO, as well as a controlled document distribution list that includes the document number and the individual to whom the document was issued. Unless otherwise specified by the QAO, no controlled documents will be released prior to review and signature approval.

The manner in which controlled documents are issued, revised, and archived to ensure retrievability and traceability will be specified in QAP-6.1, *Issue and Control of Quality Assurance Documents*.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 PURPOSE

This section describes the controls on procurement of items and services for the NWRPO technical program. This section complies with Basic Requirement 7 of ANSI/ASME NQA-1, as well as Criterion VII of 10 CFR 50, Appendix B.

7.2 SCOPE

This section applies to the control of all procured items and services that affect the quality of work performed for the NWRPO technical program. An example of such controls includes the qualification of vendors performing analytical work, providing professional services, or drilling boreholes.

7.3 RESPONSIBILITIES

The QAO, with the assistance of the QARS, is responsible for maintaining a current file of all procurement documentation for quality-affecting NWRPO activities. The QAO is also responsible for determining the need for and performing, as necessary, vendor qualifications (i.e., on-site inspection and evaluation of QA furnished by the supplier), audits, and/or examination of items or services upon delivery or completion. NWRPO technical personnel may assist the QAO with these activities, as necessary. Acceptance for supplier QA programs will be recommended by the QAO and accepted by the AD, if appropriate, prior to commencing work.

7.4 IMPLEMENTATION

Methods used for selecting procurement sources and suppliers will include one or both of the following:

- Evaluation of the supplier's technical and QA capability based on supplier facilities, personnel, QA records, and QA program implementation.
- Evaluation of the supplier's history of providing an identical or similar product that has performed satisfactorily.

Methods for accepting supplier-furnished items or services will include one or more of the following:

- Surveillance or audit of the production of item or service. Surveillances and audits are discussed more fully in Section 18.0.
- Inspection of the delivered item. Inspections are discussed more fully in Section 10.0.
- Evaluation of the Certificate of Conformance, which is a supplier-signed statement that certifies that the product provided conforms with the product specified in the contract or procurement document.

- Review of objective evidence of conformance to procurement requirements, such as technical information furnished with the product.

The control of purchased items and services will be specified in QAP-7.1, *Procurement of Items and Services*.

8.0 IDENTIFICATION AND CONTROL OF ITEMS

8.1 PURPOSE

This section describes the identification and control of items, defined herein as geologic and hydrologic samples, for the NWRPO technical program. This section complies with Basic Requirement 8 of ANSI/ASME NQA-1, as well as Criterion VIII of 10 CFR 50, Appendix B.

8.2 SCOPE

This section applies specifically to geologic and hydrologic samples, including gas samples, collected and handled for quality-affecting NWRPO activities. Independent Nye County scientific investigations are designed to produce hydrogeologic data that can be used to model and monitor potential groundwater flow pathways and characteristics downgradient from Yucca Mountain. Data produced from samples taken during drilling may be used at the NRC proceedings to evaluate the DOE LA. These data may also be used in any future proceedings for mitigation of impact on Nye County due to DOE activities or for any future investigations involving the evaluation of the impacts of the repository on Nye County. Identification and control of samples is essential for ensuring that 1) sample integrity is protected for the long term and 2) data obtained using the samples are directly traceable to the source material.

8.3 RESPONSIBILITIES

The PI is responsible for defining sample management methodology in the appropriate WP, supplemented by TPNs and TPs. SMs are responsible for implementing these plans and procedures in the field. The QAO is responsible for verifying that appropriate QA requirements have been incorporated into the plans and procedures intended for the purpose of sampling, documentation, sample transport, and storage. In addition, the QAO will verify the use of appropriate identification and control procedures through audits and surveillances of activities of the NWRPO personnel involved with controlling or handling samples.

8.4 IMPLEMENTATION

Physical identification will be used to ensure traceability of a sample to its origination. Chain-of-custody procedures will be followed to maintain control of samples. If physical identification markings are impractical, other means, such as physical separation, labels, or tags attached to containers, will be used. Sample identification will be verified and documented before release of the samples for use or analysis. Direction for sample handling and control will be specified in QAP-8.1, *Sample Management.*

9.0 CONTROL OF SPECIAL PROCESSES

Basic Requirement 9 of ANSI/ASME NQA-1, section II, subsection 9, which states *"Processes affecting the quality of items or services shall be controlled. Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements."* is not applicable to current NWRPO activities.

10.0 INSPECTION

10.1 PURPOSE

This section describes how inspections are incorporated into the NWRPO technical program. Inspections are used to verify whether an item conforms to specified requirements. This section complies with Basic Requirement 10 of ANSI/ASME NQA-1, as well as Criterion X of 10 CFR 50, Appendix B.

10.2 SCOPE

This section applies to all applicable inspections of procured items that support quality-affecting NWRPO activities. Examples of such items include test materials (e.g., pH buffer solution and tracer chemicals) and test equipment (e.g., borehole pressure transducers and submersible centrifugal pumps). Examples of inspections include 1) verifying that equipment, such as probes used for hydrologic investigations, conform to specifications described on the procurement documentation; 2) examining supplier-provided gravel material to verify that it conforms to the requested specification; and 3) verifying that a borehole meets the specifications in the drilling contract.

10.3 RESPONSIBILITIES

The QAO is responsible for verifying that inspection activities are included in QA program documents, as appropriate. The PI or SM is responsible for performing the inspection or designating the inspection task to other qualified NWRPO personnel.

10.4 IMPLEMENTATION

Appropriate inspection methods are included in NWRPO technical program contracts and purchase orders, as applicable. Characteristics to be inspected and inspection methods will be specified in these documents. Inspections will be planned, conducted, and documented by qualified personnel.

11.0 TEST CONTROL

11.1 PURPOSE

This section describes how test control is incorporated into the NWRPO technical program. Tests are used to verify conformance of an item to specified requirements and to demonstrate satisfactory performance for service. This section complies with Basic Requirement 11 of ANSI/ASME NQA-1, as well as Criterion XI of 10 CFR 50, Appendix B.

11.2 SCOPE

This section applies to all applicable test control activities. Examples of applicable test controls include 1) making a manual water-level measurement to verify the water level indicated by a pressure transducer and 2) including a blind sample within the scope of an analytical purchase order.

11.3 RESPONSIBILITIES

The PI is responsible for ensuring that test control activities are included in WPs and other QA documents, as appropriate, and are conducted and documented by trained and appropriately qualified NWRPO personnel. The QAO is responsible for verifying that appropriate test control activities are planned, executed, evaluated, and documented by qualified personnel. The qualifications of test personnel will be documented and maintained as QA records.

11.4 IMPLEMENTATION

Test control activities are generally included in WPs, TPs, TPNs, and vendor contracts or purchase orders. However, appropriate sections of related documents, such as American Society for Testing and Materials (ASTM) methods, supplier manuals, equipment maintenance instructions, or approved drawings with acceptance criteria, may be used when appropriate.

Test procedures will include or reference test objectives and provisions for ensuring that prerequisites for the test have been achieved. Test procedures provide for the following as appropriate: 1) requirements and acceptance limits, including required levels of precision and accuracy; 2) instructions for performing the test; 3) test prerequisites, such as calibrated instrumentation, adequate test equipment, and instrumentation; 4) suitable and controlled environmental conditions; 5) provision for data collection and storage; 6) mandatory inspection hold points; 7) methods for documenting or recording test data and results; and 8) provisions for ensuring that test objectives have been met.

Test results will be documented and evaluated by the PI or designee to ensure that test requirements have been met. Applicable test control activities are specified in QAP-5.2, *Preparation of Work Plans, Test Plans, and Technical Procedures.*

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 PURPOSE

This section describes how the NWRPO ensures that measuring and test equipment is properly controlled, calibrated at specified intervals, and adjusted when necessary. This section complies with Basic Requirement 12 of ANSI/ASME NQA-1, as well as Criterion XII of 10 CFR 50, Appendix B.

12.2 SCOPE

This section applies to NWRPO personnel responsible for field and laboratory testing and measurement. Examples of test equipment include borehole pressure and temperature sensors; pH, temperature, and conductivity meters; and on-site geophysical measuring tools. Some standard commercial equipment, such as rulers, tape measures, levels, and other such devices, provide adequate accuracy and do not require calibration and control.

12.3 RESPONSIBILITIES

The PI or designee will determine the schedule for calibration. NWRPO personnel using measuring and/or test equipment are responsible for ensuring that the equipment is properly controlled, calibrated, and adjusted as required. In addition, they will maintain a list of all equipment requiring calibration and the status of the calibration. The QAO is responsible for monitoring and verifying the effectiveness of the control system.

12.4 IMPLEMENTATION

All measuring and test equipment will be assigned a unique NWRPO identification number. To provide traceability to calibration data, all equipment will be labeled with one of the following statements:

1) No calibration is required.
2) Equipment requires calibration before and after every use.
3) Calibration is required at specified intervals. Dates of the last and next scheduled calibration will be included on the label.

All labels will display the instrument identification and the name of the individual who performed the calibration. Label information will be maintained in the list described in Section 12.3.

Measuring and test equipment will be calibrated, adjusted, and maintained against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standard exists, the basis for calibration will be documented.

The PI will specify the calibration schedule in the plans or procedures as appropriate. In addition, unscheduled calibration may be performed when accuracy of the data produced by the equipment is suspect.

If equipment is found to be out of calibration, an evaluation will be made and documented of the validity of the previous data and the acceptability of items previously tested or inspected. Out-of-calibration equipment will be tagged or segregated and not used until it has been recalibrated. If any measuring or test equipment is consistently found to be out of calibration, it will be repaired or replaced. A calibration will be performed when the accuracy of the equipment is suspect.

Calibration standards will have greater accuracy than the measuring and test equipment being calibrated, unless standards with the same accuracy are shown to be adequate for requirements. The basis for acceptance will be documented by the PI and authorized by the QAO.

Detailed information about the implementation of the measuring and test equipment system will be specified in QAP-12.1, *Control of Measuring and Test Equipment*.

13.0 HANDLING, STORAGE, AND SHIPPING

13.1 PURPOSE

This section describes how the NWRPO ensures that the handling, storage, and shipping of samples (such as those described in Section 8.0) is accomplished by procedures that prevent damage, deterioration, or loss. This section complies with Basic Requirement 13 of ANSI/ASME NQA-1, as well as Criterion XIII of 10 CFR 50, Appendix B.

13.2 SCOPE

This section applies to cores, cuttings, fluids, and other physical samples collected for testing and evaluation.

13.3 RESPONSIBILITIES

The PI, in consultation with the GSM, as appropriate, is responsible for specifying handling, shipping, and storage requirements, including packaging and preservation, of samples in applicable WPs, TPs, and TPNs. NWRPO personnel are responsible for implementing these procedures. The QAO is responsible for verifying through surveillance and audit that appropriate sample handling, storage and shipping procedures are followed.

13.4 IMPLEMENTATION

Samples associated with drilling activities for the NWRPO technical program will be maintained and preserved in a manner that ensures sample integrity prior to use or for the life of the NWRPO project, unless a sample is limited by a shelf-life expiration.

Handling, storage, packaging, preservation, and shipment of samples will be specified in QAP-8.1, *Sample Management*.

14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 PURPOSE

This section describes how the status of inspection and test activities is identified on quality-affecting items in the NWRPO technical program. This section complies with Basic Requirement 14 of ANSI/ASME NQA-1, as well as Criterion XIV of 10 CFR 50, Appendix B.

14.2 SCOPE

This section applies to all NWRPO quality-affecting activities where status indicators for inspections, tests, and other operations are applicable. Examples of status indicator activities include 1) posting a calibration status tag on a probe that requires periodic calibration, 2) inspecting a tag for its expiration date, and 3) determining the completion status of a collection of specified samples and any required shipment of the samples to the laboratory for analysis.

14.3 RESPONSIBILITIES

The PI or designee is responsible for applying and removing appropriate status indicators, where applicable, to indicate operational status. The QAO is responsible for verifying that the use of status indicators is properly documented in QA procedures and that only authorized personnel will apply or remove the indicators.

14.4 IMPLEMENTATION

The status of inspection and test activities will be indicated either on the item or in documents traceable to the item where it is necessary to ensure the following: that required inspections and tests are performed, and that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status will be maintained through the use of legible and easily recognizable status indicators, such as physical location, tags, labels, markings, stamps, or inspection records.

NWRPO inspection, test, and operating status activities will be specified in QAP-12.1, *Control of Measuring and Test Equipment*.

15.0 CONTROL OF NONCONFORMING ITEMS

15.1 PURPOSE

This section describes how items, activities, and services that are found not to conform to program specifications and/or procedures are prevented from being used inadvertently in the NWRPO technical program. This section complies with Basic Requirement 15 of ANSI/ASME NQA-1, as well as Criterion XV of 10 CFR 50, Appendix B.

15.2 SCOPE

This section applies to samples, data, software, and other items and activities that do not conform to specified requirements. Examples of nonconformances include 1) not collecting, preserving, or storing a water sample according to the prescribed procedure for certain chemical analyses, 2) collecting pressure data with a pressure transducer that is out of calibration, 3) receiving an instrument-detection limit instead of the method-detection limit as requested on the purchase order for laboratory chemical analyses, and 4) receiving a borehole from a drilling contractor that exceeds borehole deviation limits specified in contract documents.

15.3 RESPONSIBILITIES

All NWRPO personnel are responsible for bringing nonconformances to the attention of the QAO. The QAO is responsible for verifying that the documentation of nonconformances is carried out according to the requirements of this section.

15.4 IMPLEMENTATION

Nonconforming conditions will be reported to the QAO and GSM as soon as reasonably possible. A memo or email to the QAO and GSM regarding the suspected nonconformance will be sent by the discoverer. The nonconformance will be addressed by the QAO and GSM and the appropriate actions will be taken to correct the nonconformance. A log of nonconformances and associated corrective actions will be maintained in the QARC by the QARS, under supervision of the QAO. At a minimum, the log will include the date, a description of the problem, the action(s) taken or proposed, and the name of the individual responsible for correcting the nonconformance.

All nonconforming conditions will be tracked and reported to the AD and GSM for indications of a possible trend. Nonconforming items will be marked "use as is," "reject," or "repair," and segregated, if appropriate, immediately upon discovery to prevent inadvertent use.

All nonconformances will be acted upon in a timely matter. Methods for reporting, labeling, and correcting nonconformances will be specified in QAP-15.1, *Control of Nonconforming Items or activities*.

16.0 CORRECTIVE ACTION

16.1 PURPOSE

This section describes how conditions adverse to quality in the NWRPO technical program, identified as nonconformances in Section 15.0, are corrected. This section complies with Basic Requirement 16 of ANSI/ASME NQA-1, as well as Criterion XVI of 10 CFR 50, Appendix B.

16.2 SCOPE

This section applies to all actions taken to correct the nonconformances described in Section 15.0. Examples of corrective actions include rejecting, repairing or modifying deficient items or activities and taking actions to prevent recurrence of the situations.

16.3 RESPONSIBILITIES

The PI, SM or designee in the area of the nonconformance is responsible for carrying out and documenting the completion of corrective actions proposed by the GSM and QAO. The QAO is also responsible for verifying that these corrective actions have been implemented and documented.

16.4 IMPLEMENTATION

Reports of nonconformance will be reviewed promptly by the QAO for evaluation of problem trends resulting from failures or deviations from requirements. The QAO, through consultation with appropriate NWRPO personnel, will determine whether corrective action is necessary. If corrective action is deemed necessary, the QAO will suggest a corrective action to personnel in the area in which the nonconformance occurred. The underlying cause of the adverse condition will be determined in order to rectify the condition and prevent recurrence, and corrective action will be taken. An evaluation will be made of the effects of the reported deficiency on past work, data, analyses, and/or experiments. If necessary, the QAO will conduct a follow-up audit or surveillance, as discussed in Section 18.0, to ensure the adequacy of the corrective action. A log of nonconformances and associated corrective actions will be maintained in the QARC by the QARS.

Corrective action activities will be specified in QAP-16.1, *Corrective Action.*

17.0 QUALITY ASSURANCE RECORDS

17.1 PURPOSE

This section describes how records are prepared to provide QA documentation of activities and items for the NWRPO technical program. This section complies with Basic Requirement 17 of ANSI/ASME NQA-1, as well as Criterion XVII of 10 CFR 50, Appendix B.

17.2 SCOPE

This section addresses the collection, storage, and disposition of QA records and the types of records to be maintained for the NWRPO technical program. Records for all quality-affecting activities will be collected, stored, and protected in a manner to ensure ease of identification and retrievability. Records will be maintained on paper, microfilm, photographic, or electronic media.

Hydrologic and geotechnical samples are not considered records for the purposes of this section. These samples are addressed in Section 8.0.

17.3 RESPONSIBILITIES

The AD is responsible for the development of a documentation system to control the identification, generation, validation, classification, filing, and storage of QA records. The QAO is responsible for reviewing, monitoring, and auditing project QA records to ensure that they meet the requirements specified in this section. The QAO is responsible for identifying administrative QA records in QAPs; the GSM and PI are responsible for identifying QA records in WPs, TPs, and TPNs. PIs are responsible for 1) the control of data in their individual areas of investigation, 2) proper definition, retention, authentication and security of QA records in their activity files, and 3) submitting the QA records to the QARC. The QARS is responsible for managing and maintaining QA records and implementing a system to ensure that access to QA files is controlled.

17.4 IMPLEMENTATION

Criteria and an implementing procedure will be established for determining when a document becomes a QA record, and the retention periods for such records. Documents that are designated QA records will be legible, accurate, and appropriately completed. QA records will be maintained in accordance with the requirements specified in QAP 17.1, *Records Management*.

18.0 AUDITS

18.1 PURPOSE

This section describes how surveillances and audits, both planned and spontaneous, are carried out to verify compliance with the NWRPO QA program and to determine its effectiveness. This section complies with Basic Requirement 18 of ANSI/ASME NQA-1, as well as Criterion XVIII of 10 CFR 50, Appendix B.

18.2 SCOPE

This section applies to the surveillances and audits of internal and external activities, as appropriate, that are conducted for the NWRPO technical program. A surveillance is performed to verify that scientific activities are conducted according to applicable procedures; an audit is performed to verify that scientific activities are conducted according to all aspects of the QA program and effectiveness of the program.

18.3 RESPONSIBILITIES

The QAO is responsible for scheduling, managing, performing, and following up on internal surveillances and audits. The QAO may be assisted by technical personnel. Audits will be performed in accordance with pre-established written, approved procedures and conducted by trained, qualified, and competent QA and technical personnel with no direct responsibilities in the areas being audited.

The appropriate lead, such as the PI, is responsible for ensuring that necessary actions are taken to facilitate the audit and promptly correcting deficiencies found during the audit.

The QAO is responsible for documenting and analyzing the audit and reporting the results to management for review, assessment, and appropriate action.

18.4 IMPLEMENTATION

Surveillances and audits will be scheduled in a manner to provide coverage of and coordination with ongoing quality-affecting activities. Surveillances will be conducted as deemed necessary by the QAO. Audits will be scheduled at a frequency commensurate with the status and importance of the activity. The audit schedule will be reviewed periodically and revised as necessary to ensure that current coverage is maintained. A tracking system for audit findings will be established to help ensure that all findings are appropriately addressed and prioritized, and that trends are identified. The cause of each audit finding will be identified, the corrective action will be described, and follow-up action will be taken to ensure proper closeout of deficiencies.

Detailed instructions for the performance and reporting of audits and surveillances will be specified in QAP-18.1, *Audits and Surveillances.*

19.0 REFERENCES

10 CFR (Code of Federal Regulations) Part 50. *Energy: Domestic Licensing of Production and Utilization Facilities.* Appendix B–Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants. Washington, DC: U.S. Government Printing Office. 5 pp.

ANSI/ASME (American National Standards Institute/American Society of Mechanical Engineers). 1986. *Quality Assurance Program Requirements for Nuclear Facilities.* ANSI/ASME NQA-1-1986 (and current amendments), New York., New York. 44 pp.

Duncan, A.B.; Bilhorn, S.G.; and Kennedy, J.E. 1988. *Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements*. NUREG-1318. Washington, D.C.: U.S. Nuclear Regulatory Commission. TIC: 200650.

NRC (Nuclear Regulatory Commission). 1983. *Final Technical Position on Documentation of Computer Codes for High-Level Waste Isolation*, NUREG-0856, Washington, DC.

NRC (Nuclear Regulatory Commission). 1988. *Peer Review for High-Level Nuclear Waste Repositories*, NUREG-1297, Washington, DC, February 1988.

NRC (Nuclear Regulatory Commission), 1988 *Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories*, NUREG-1298, Washington, DC, February 1988.

NWPA (Nuclear Waste Policy Act) of 1982, 42 U.S.C. 101719(c) *et seq*., Section 151 and 1987 amendments to the Act.

Applicable NWRPO Quality Assurance Procedures

QAP-3.1, *Independent Technical Review*. Nuclear Waste Repository Project Office (NWRPO), Pahrump, Nevada.

_QAP-3.2, *Documentation of Technical Investigations.*

_QAP-5.1, *Preparation of Quality Administrative Procedures.*

_QAP-5.2, *Preparation of Work Plans, Test Plans and Technical Procedures.*

_QAP-6.1, *Issue and Control of Quality Assurance Documents.*

_QAP-7.1, *Procurement of Items and Services*.

_QAP-8.1, *Sample Management*.

_QAP-12.1, *Control of Measuring and Test Equipment*.

_QAP-15.1, *Control of Nonconforming Items or Activities*.

_QAP-16.1, *Corrective Action.*

_QAP 17.1, *Records Management.*

_QAP-18.1, *Audits and Surveillances.*