Quality Assurance Manual

Manual Number:
QAM0101R12

Effective Date:
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Analysis and Measurement Services Corporation

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QUALITY ASSURANCE MANUAL

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AMS QUALITY ASSURANCE MANUAL

Revision 12

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Submitted By: Allyson Pearce Date: 01/08/2021

Reviewed By: Dan Beverly Date: 01/08/2021

Approved By: H.M. Hashemian Date: 01/18/2021

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(Date)

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REVISION HISTORY

Revision	Date	Pages Involved	Description
AMS QA/QC 7701R0	12/77	All Pages	First QA Manual
AMS QA/QC 8201R0	12/81	Multiple Pages	Major changes in format. New manual includes overall program of eight (8) general requirements and explanations of each.
AMS QA/QC 8201R1	5/82	Multiple Pages	Major changes in format. States responsibilities of QA Supervisor. Departmental QC added. Department managers added. The manager will develop and maintain all procedures and records for his department and will be directly responsible to QA Supervisor.
AMS QA/QC 8201R2	9/82	Multiple Pages	Submitted by QA Supervisor and approved by President. Format change. References to 10 CFR Part 50 Appendix B, ANSI/ASME NQA-1-1979. Added AMS organization chart. Added section on "QA/QC Procedures," "Control of Purchased Items and Services," "Receiving and Shipping," "Definition of Terms" and a reference page.
AMS QA/QC 8201R3	1/83	Front Cover 3-4	Added controlled/uncontrolled copy statement on cover. Operations manager's responsibilities added to manager list. Organization Chart restructured.
AMS QA/QC 8201R4	7/83	Multiple Pages	Sections for document control, nonconforming items, corrective action, and quality assurance records were added. Nuclear engineering manager added. Responsibilities added. Nuclear engineering added to organization chart. Explanation of "out-of-tolerance" calibration on M&TE added. Section 3.9 Policy Review-Internal Auditor and Manager of Research and Development taken out. Definition of terms section expanded.
AMS QA/QC 8201R5	3/97	Cover, i, ii, iii, iv, 5	These pages were completely changed to update the AMS address, revise signature pages to include current President and QA Manager, and to update the organization chart. Revision History was also modified and updated.

REVISION HISTORY (continued)

Revision	Date	Pages Involved	Description
QAM0101R6	07/01	All Pages	The purpose of this revision was to (1) bring the AMS Quality Assurance Manual in tune with today's practices, (2) perform a major rearrangement and expansion of the entire manual according to the "18 Criteria" of 10 CFR Part 50, Appendix B, (3) update the organization chart, (4) add appendices to the manual that include sample forms, procedures and information of general interest about AMS and its other activities in addition to the Quality Assurance Program, and (5) rename the manual to conform to the AMS document naming convention.
QAM0101R7	12/09	All Pages	The manual has been updated to clearly describe AMS' commitment to 10 CFR Part 50, Appendix B and ANSI N45.2 and our use of other standards including NQA-1 and the ANSI daughter standards for guidance in the execution of our QA program. AMS has previously committed, by procedure, to maintaining records for the life of the company. This commitment was added to the manual section on Control of Documents and Records. During the re-write, the manual was thoroughly reviewed and the format and structure of the document were made consistent.
QAM0101R8	05/12	All Pages	The manual was modified to incorporate editorial changes to clarify the definition of an audit team, and address the AMS process of evaluating A2LA and NVLAP suppliers for the Approved Suppliers List (ASL). This list contains approved suppliers for commercial items and services, suppliers who are audited to 10 CFR Part 50, Appendix B, suppliers of calibration services that are dedicated according to approved procedures or dedicated via commercial grade survey.
QAM0101R9	09/13	All Pages	In addition to minor readability changes, modifications have been made to demonstrate enhanced review and communication of customer purchase order requirements, tracking the performance of the AMS QA program, training of internal personnel, qualifying approved suppliers, and further identifying QA roles in the company (e.g., AQM, QAA, TSM).

REVISION HISTORY (continued)

Revision	Date	Pages Involved	Description
QAM0101R10	07/15	All Pages	The QA Manual was modified to address issues raised during the first AMS A2LA assessment and also to incorporate changes to bring the program closer to compliance with NQA-1-2008 and NQA-1a-2009. Additional changes are anticipated as we examine all the criteria to ensure compliance with NQA-1-2008 and NQA-1a-2009. A new revision of this QA Manual is planned to be issued by early 2016.
QAM0101R11	07/16	All Pages	The QA Manual was updated to address issues raised during the last A2LA assessment as well as suggestions for improvement from internal and external audits. The organizational chart was changed to closely represent the current organization and the management positions with respect to their role in quality assurance were described. Changes were also made to move the program closer to compliance with NQA-1-2008, NQA-1a-2009 as well as the requirements of NEI 14-05, Revision 0 for CGD. Additional changes are anticipated for future revisions to ensure compliance. Additional wording changes for clarity and updated Policy Statement were also made.
QAM0101R12	01/21	All Pages	All sections of the QA Manual were updated to address and comply with ASME NQA-1: 2017. The organizational chart was also updated to represent the current organization and the management positions with respect to their role in quality assurance.

LIST OF ABBREVIATIONS

A2LA	American Association for Laboratory Accreditation
AB	Accrediting Body
ACLASS	Assured Calibration and Laboratory Accreditation Select Services
AMS	Analysis and Measurement Services Corporation
ANSI	American National Standards Institute
AQM	Assistant Quality Assurance Manager
ASL	Accredited Suppliers List
ASME	American Society of Mechanical Engineers
CFR	Code of Federal Regulations
COC	Certificate of Conformance
CR	Condition Report
CRDM	Control Rod Drive Mechanism
DOD	U.S. Department of Defense
DOE	U.S. Department of Energy
EMC	Electromagnetic Compatibility
EMI	Electromagnetic Interference
FME	Foreign Material Exclusion
I&C	Instrumentation and Control
ILAC	International Laboratory Accreditation Corporation
ISO	International Organization for Standardization
M&TE	Measurement and Test Equipment
MRA	Mutual Recognition Agreement
NASA	National Aeronautics and Space Administration
NCR	Non-Conformance Report
NVLAP	National Voluntary Laboratory Accreditation Program
NIS	Nuclear Instrumentation System
NIST	National Institute of Standards and Technology
NQA	Nuclear Quality Assurance
NRC	Nuclear Regulatory Commission
NUPIC	Nuclear Procurement Issues Corporation
OOT	Out of Tolerance
QA	Quality Assurance
QAM	Quality Assurance Manager
QAA	Quality Assurance Assistant
QC	Quality Control
QSL	Qualified Suppliers List
RFI	Radio Frequency Interference
SQA	Software Quality Assurance
V&V	Verification and Validation

POLICY STATEMENT

AMS' goal is to provide its products and services with the highest standard of quality, integrity, and dedication to its customers. The AMS President, management, and employees work and train together to achieve this goal consistent with local, national, and international regulations, standards, and laws.

This Quality Assurance Manual describes the steps that AMS will follow to yield the highest quality in its products and services and document the process by which the highest quality is achieved.

Our mission is to ensure the safe operation of the worldwide nuclear fleet through innovative testing services, engineering solutions, and data analysis.

H.M. Hashemian, Ph.D.
AMS President

EXECUTIVE SUMMARY

This manual describes the Quality Assurance (QA) Program for Analysis and Measurement Services Corporation (AMS). It was prepared by the AMS QA Manager (QAM) and Assistant QA Manager (AQM) under the direction of the AMS President, and generally outlines the basic elements that make up the AMS QA Management System. It is important to note here that the terms QA Program and QA Management System are considered to be interchangeable as used in this manual. The AMS QA Management System is intended to comply with applicable requirements of 10 CFR Part 50, Appendix B, "*Quality Assurance Criteria for Nuclear Power Plants*," ANSI N45.2, 1977, "*Quality Assurance Program Requirements for Nuclear Facilities,*" and ANSI/ASME NQA-1-2017, "*Quality Assurance Requirements for Nuclear Facility Applications."* In addition, the activities associated with AMS' Electromagnetic Compatibility (EMC) testing services meet the requirements of ISO/IEC 17025, 2017 "*General Requirements for the Competence of Testing and Calibration Laboratories*." Relevant industry standards have been used for guidance in the preparation of this manual and the implementing procedures that make up the AMS QA Management System.

As shown in Figure 1, this manual is the foremost document describing the AMS QA Management System that applies to all products and services provided by AMS. It is supported and further defined by a second tier of documents including: AMS QA Procedures, work instructions, or test and work plans that describe and outline the steps for performing specific activities. These documents are not included in this manual, but they are maintained at AMS for use and review. The most recent AMS Procedures List is available from the AMS website at: www.ams-corp.com/quality-assurance-program and informational copies of specific procedures can be obtained by contacting the QA Department by e-mail at: QA@ams-corp.com, or phone at: (865)-691-1756. The foundation for the AMS QA Management System is made up of the QA Records which are produced through the implementation of the program described in this manual. These records are also maintained at AMS and are available for review and audit.

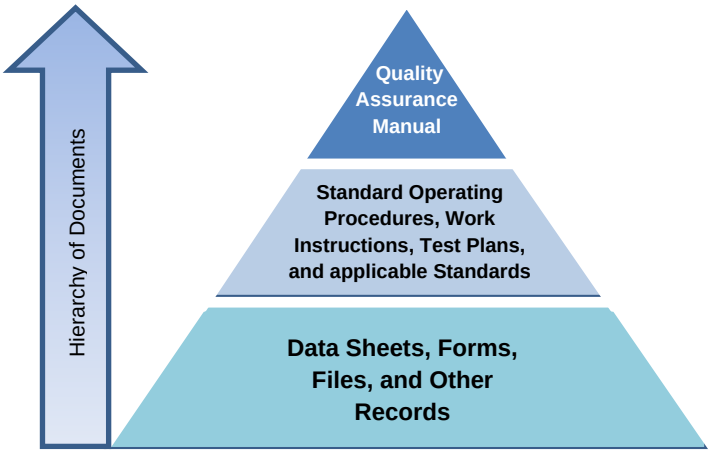

Figure 1. Hierarchy of AMS QA Documents

AMS was founded in July 1977 and has since grown to become the leading industry supplier of equipment, training, and services for a variety of testing such as:

- Response time measurement and calibration of process instrumentation systems
- Predictive maintenance of reactor components
- Process diagnostics and on-line monitoring
- Cross calibration of temperature sensors
- Rod drop time measurements
- Rod position indication system testing and diagnostics
- Rod control system testing and diagnostics
- EMC testing to Mil and international standards
- EMI/RFI troubleshooting
- Cable testing, troubleshooting and diagnostics
- Cable aging management and useful life evaluations
- Nuclear instrumentation system (NIS) testing
- EMI/RFI and Wireless site mapping and diagnostics
- Development of specialized, automated test equipment and technologies
- Materials Testing
- And other activities (See Attachment A: About AMS for more details)

The company has grown consistently since its inception by developing new expertise, new testing capabilities, and expanding laboratory facilities for other testing. The company's home offices are located in Knoxville, Tennessee (Figure 2) in a campus setting consisting of laboratory, engineering, administrative, and operations areas.

Figure 2. AMS Laboratory Buildings

The policies described in this manual are the basis for the normal execution of all activities related to the production of products and services at AMS. These policies are applicable for work associated with AMS products or services provided to nuclear power plants, vendors who serve nuclear facilities for both safety-related services or non-safety-related items, and other AMS customers. They are followed as normal operating procedures such that any departure(s) from normal operating procedures must be documented, reviewed, and approved by senior management and/or the QA department. AMS' services are provided by trained and qualified engineering staff that use approved procedures, properly verified and validated (V&V) software for data acquisition and analysis, and measurement and test equipment (M&TE) with calibrations traceable to the National Institute of Standards and Technology (NIST). AMS also relies upon calibration laboratories accredited by A2LA, NAVLAP, ACLASS or other accrediting bodies (AB) that are members of the Mutual Recognition Agreement (MRA) of the International Laboratory Accreditation Cooperation (ILAC) for the calibration of specialized EMC test equipment. The calibrations of equipment using accredited calibration laboratories are accepted following a commercial grade dedication process which is intended to comply with NEI 14-05A, Revision 0 and Revision 1, "*Guidelines for the use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services.*"

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ATTACHMENTS

PREFACE

AMS is a technical consulting firm with offices and laboratories located at the AMS Technology Center, 9119 Cross Park Drive, Knoxville, Tennessee, 37923, USA (Figure 3). The company has been in business since 1977 and has an extensive background and considerable expertise in testing the process instrumentation and control (I&C) systems of nuclear facilities; cable testing and fault finding; component condition monitoring; aging management of plant systems; specialized methods for improved plant maintenance and system diagnostics; research and development of new products; and laboratory/field evaluations for EMC (Figure 4). In support of these activities, AMS also constructs its own specialized test equipment. The equipment, which is not safety-related, may be purchased by clients for their own use, but typically it is utilized by AMS' expert staff who perform the testing services at the plant sites.

Any work that AMS performs for the nuclear industry (nuclear power plants, nuclear fuel reprocessing plants, and other nuclear suppliers or vendors) or other customers is described by AMS as **"quality related"** work whether it is safety-related or not. The QA Management System is applied to all activities affecting the quality of products, services, and software produced by AMS for quality related work.

All AMS employees working on quality related work are given proper QA indoctrination and training to ensure that they are qualified for the work they perform and fully understand the requirements of working under the AMS QA Management System. AMS will issue a Certificate of Conformance (COC) to affirm that quality related work was performed according to the system described in this manual and any specific customer requirements.

Figure 3. AMS Headquarter Building in Knoxville, TN

The following standards and regulations have been consulted for guidance in the preparation of this manual, AMS' supporting procedures, and other elements of the AMS QA Management System:

- Title 10 U.S. Code of Federal Regulations, Part 50, Appendix B[1]
- Title 10 U.S. Code of Federal Regulations, Part 21[2]
- ANSI/ASME N45.2-1977[3]
- ANSI/ASME NQA-1-1994[4]
- ANSI/ANS 3.1-2014, R2014[5]
- Regulatory Guide 1.8 - Revision 4, 2019[6]
- ISO/IEC 17025:2017[7]
- ANSI/ASME NQA-1-2017[8]

The manual is organized according to the 18 criteria of 10 CFR Part 50, Appendix B, as shown in the Table of Contents, and also includes Section 19 which describes AMS' compliance with 10 CFR Part 21, Section 20 which describes performance of work, and Section 21 which provides references. It should be noted that this manual addresses all 18 criteria of 10 CFR Part 50, Appendix B, although the scope of AMS activities under the AMS QA Management System does not require compliance with all the 18 criteria.

Please refer to Attachment A at the end of this manual for additional information about AMS and its capabilities.

Figure 4. 3-meter Semi-Anechoic EMC Chamber at AMS

1. ORGANIZATION

The AMS QA Organization Chart is presented in Figure 5. The positions shown are intended to be filled by various AMS personnel; however, due to the size of the company and the dynamics of AMS' business, the same individual may fill more than one position from time to time, and some positions, other than the President and QAM, may not be filled depending on the needs of the company. AMS also employs qualified consultants and other part time employees who are often involved in support work.

The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality are documented in the QA organizational chart. These responsibilities for establishing and implementing the Quality Management System are defined as follows:

1.1 AMS President

Ultimate responsibility and final authority for the execution of the QA Management System and the quality of products and services provided by AMS is vested in the President of AMS. The President is also responsible for compliance of the QA program to 10 CFR Part 50, Appendix B, ASME NQA-1-2017, and ISO/IEC 17025:2017. Furthermore, the President shall direct the QAM to execute at least one annual internal QA audit of the ISO/IEC 17025 program, to be conducted in the second quarter of each year, and one annual internal QA audit of the 10 CFR Part 50, Appendix B program using an independent auditor. These internal audits shall be used to confirm the effective implementation of the QA Management System described by this manual. The President also shall ensure, through management reviews and/or internal audits, that the integrity of the Quality Management System is maintained whenever changes affecting the program are planned or implemented. It is understood that the U.S. Nuclear Regulatory Commission (NRC) has endorsed ASME NQA-1-2015. Furthermore, AMS understands that the NRC may continue to review and approve the latest version of the ASME NQA-1 standard; AMS will continue to update the QA Manual and QA operations in a timely manner as necessary to comply with the latest NRC approved version of ASME NQA-1.

The President may delegate oversight of the responsibilities and authorities above to designated individuals who are trained and therefore qualified to carry out specific QA activities. If delegated to others, the President remains ultimately responsible for the QA Management System. The President is also responsible for assigning a QAM (and AQM, as needed) to direct all functions related to implementation of the QA Management System.

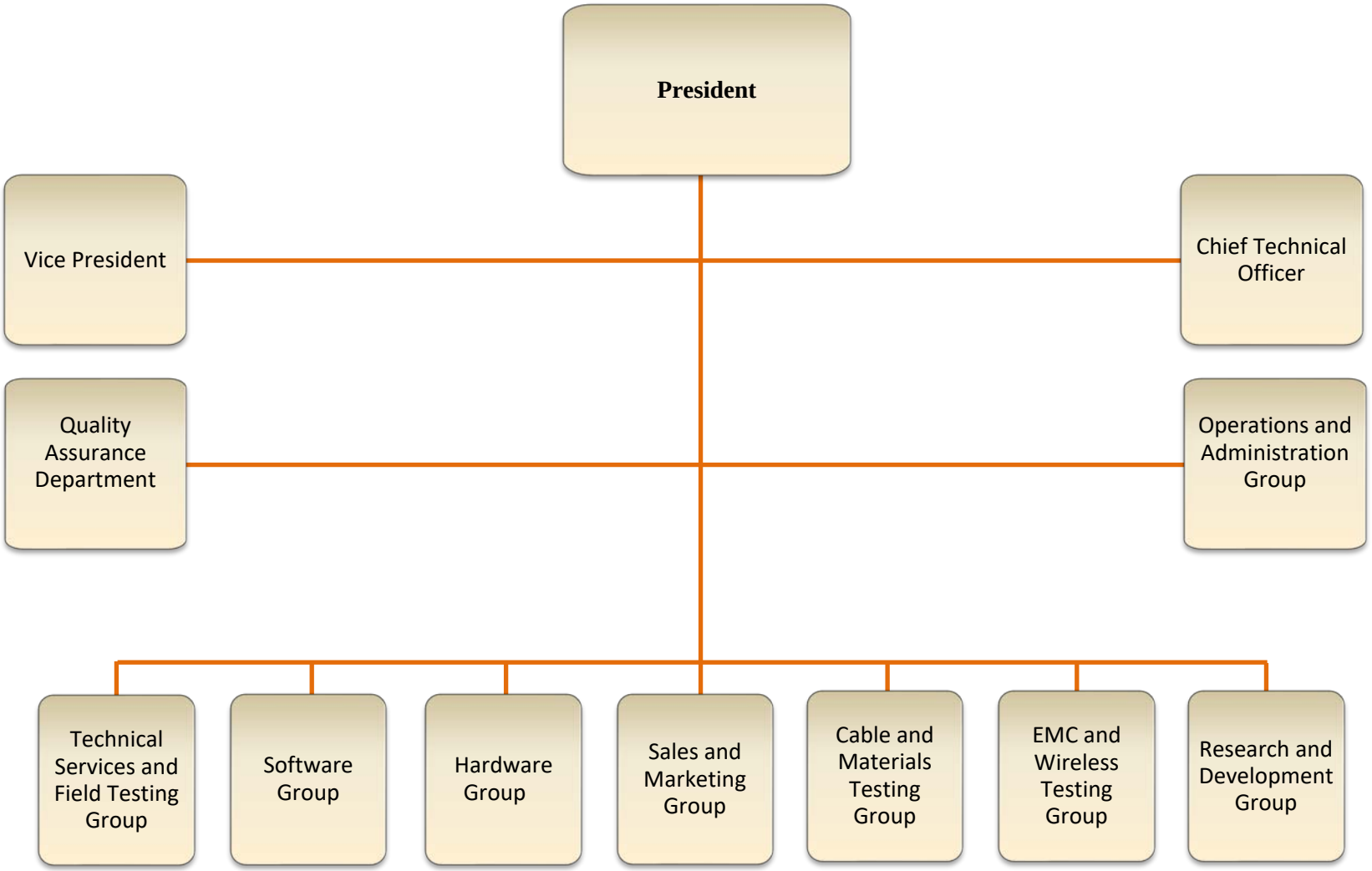

Figure 5. Simplified AMS Organization Chart

1.2 QA Manager (QAM)

The responsibility for establishing, monitoring, and implementing the AMS QA Management System to ensure that it meets the objectives of the AMS QA Policy and complies with the applicable requirements of relevant industry standards, as outlined below, is delegated to the AMS QAM. The QAM reports directly to the AMS President and management team and is responsible for informing them of the status and adequacy of the QA Program, verifying that all QA activities are effectively performed, resolving findings, completing corrective action, ensuring records integrity, training or qualifying employees, revising the program as necessary, and any other activities necessary to maintain the adequacy, and/or acceptability of the program. The QAM shall oversee the QA organization with authority second only to the AMS President. The QAM is also responsible (along with the President) for compliance of the QA program with the standards listed in the Introduction above.

The QAM shall also perform or oversee additional specific QA activities including the following, at a minimum:

- Interpretation of this manual
- Quality planning and execution to ensure compliance with referenced laws, regulations, and standards
- Preparation, revision, and/or approval of changes in written QA procedures
- Revision and/or approval of changes in the QA Manual
- Performance of periodic internal reviews
- Control of QA documents and records
- Procurement
- Personnel qualification and training
- Review and oversight of all quality related work
- Traceability of the calibrations of measurement and test equipment
- Hosting outside audits of the AMS QA Program
- QA review of client purchase documents
- Effective implementation of the QA Management System

In addition, the AMS QAM shall have the organizational freedom to initiate action to prevent the occurrence of quality deficiencies and verify solutions to quality problems. Whenever a deficiency is recognized, the QAM shall be responsible for establishing conformance to approved policies as soon as practical. As seen in the QA organizational chart, the QAM has direct access to the AMS President to resolve any quality concerns and is empowered to halt any work at any time to ensure compliance with the QA Program. Once stopped, work may only resume with the approval and/or authorization of the QAM.

1.3 Assistant Quality Assurance Manager

The ***Assistant Quality Assurance Manager (AQM)*** shall be trained as needed and assigned to assist the QAM in performing QA functions including records maintenance, employee training, internal reviews, pre-job briefings, control of in-house safety related work, etc. He/she shall also oversee document control, including duplication, filing, maintenance of qualification and calibration databases, records retention, electronic duplication of documents to the electronic QA filing system, and maintenance of the AMS Qualified Suppliers List (QSL) and the AMS Accredited Suppliers List (ASL). The AQM shall also assist the QAM directly in the performance of internal reviews and audits and the resolution of Non-conformance Reports (NCR) and Condition Reports (CR). The AQM shall also serve as the QAM's designee for QA activities in his/her absence.

1.4 Quality Assurance Assistants

The ***Quality Assurance Assistants (QAAs)***, **who also** include the ***Laboratory Supervisors*** and others who may be appointed by the QAM or President, are responsible for the technical and QA oversight of activities associated with: (1) shipping and receiving of AMS equipment sent for calibration, (2) tagging and removal of nonconforming items from use as directed by the QAM, (3) receiving, storage, and shipping of customer equipment, (4) performance of all "quality related" laboratory activities, and (5) other responsibilities as delegated by the QAM or AQM. QAAs may only perform work for areas in which they are trained and qualified. They shall report to the QAM and AQM on all QA activities to ensure compliance with the laws, regulations, and standards referenced above.

The QAAs and other QA department employees who are responsible for monitoring and verifying activities affecting quality shall have direct access to the QAM and the AMS President for all QA issues. They shall have freedom to identify quality problems and write CRs (as do all AMS employees). They should provide suggested solutions and recommendations for quality problems to the appropriate levels of management and monitor implementation of approved solutions until any conditions are properly disposed. They shall also have access to work areas

and necessary records to perform monitoring and verification tasks, and sufficient independence from cost and schedule factors when they are contrary to quality and/or safety considerations. QA department employees shall not monitor or audit activities for which they are directly responsible.

1.5 AMS Quality Assurance Engineer

The ***Quality Assurance Engineer*** is responsible for QA and Quality Control (QC) in the laboratories at AMS. In addition to his/her other engineering duties, He/she is responsible for reviewing and approving calibration documents, work order authorizations for customer equipment, receipt inspection of customer equipment, coordination of external calibrations, purchasing accredited calibration services, commercial grade dedication assessments, receipt inspections in conjunction with other engineering staff, and vendor qualifications. He/she will report to the AQM and QAM and will assist in all internal and external audits.

1.6 AMS Technical/Management Functions

The ***Operations Group*** serves as the liaison between the second level managers, upper management group, and the President. These individuals are responsible for all the administrative and business functions of company operation and report to the President. The Operations Group can participate in annual internal management reviews, help resolve personnel issues, represent the company at national and international industry meetings and host visitors to AMS.

The ***Sales and Marketing Group*** directs all commercial functions associated with AMS' work by quoting AMS' services, quoting equipment sales, reviewing customer contracts, serving as point of contact with the customer from contract initiation to completion, reviewing personnel assignments for service projects, and evaluation of customer feedback and comments. They also perform all marketing and business development activities, coordinating training, equipment sales, and presentations and demonstrations to prospective clients. Management of this group may also serve, along with the Assistant Operations Manager, Senior Engineering Manager, Chief Technical Officer, Cable Services Manager, and the EMC Engineering Manager as representatives for yearly internal QA management reviews.

The ***Chief Technical Officer*** has overall responsibility for working with the Software Development Manager to direct design control functions relating to the AMS Software Quality Assurance (SQA) Program including participating in initial software request meetings, approving software procedures, approval of V&V of AMS produced software, coordination and evaluation of the Software Development Manager's training, and management of the software development team. This individual shall randomly evaluate the quality of software development documentation and assist the QAM in performing evaluations of software nonconformances and CRs. He/she is also responsible for the organization, scheduling, staffing, and deadlines of all technical developments and research projects. The Chief Technical Officer, or his/her designee, will assist the QAM in hosting outside audits of the QA Program, as needed.

The ***EMC and Wireless Testing Group*** is responsible for the activities associated with all services provided under ISO/IEC 17025:2017 and all testing that is performed in the AMS EMC laboratory or at customer sites. They are also responsible for determining and certifying the compliance of customer equipment to the appropriate specifications and for all commercial grade dedication activities associated with the calibration of specialized EMC test equipment.

The ***Software Group*** is responsible for the development of all software produced at AMS and is responsible for the effective execution of the SQA Program. This group is comprised of a team of trained and qualified software developers who are responsible for the quality of the software they produce, and a team of test engineers who perform the verification and validation of all AMS software. This group includes the ***Software Configuration Manager*** who is responsible for maintaining control of software identification, version management, issue of latest revisions, and training of staff in software use.

1.7 Other Company Employees

The QAM is responsible for establishing and effectively executing the Quality Management System and for verifying that quality is achieved by the workforce. The QAM may delegate any or all the work to others who are trained and qualified but shall retain responsibility for the work. All AMS employees (Figure 6) are indoctrinated at the time of, or shortly after, being hired as to AMS' commitment to the QA program outlined in this manual. Those in management positions, including technical managers and supervisors, who are not directly responsible for performing some work activities are, however, specifically qualified to verify quality is achieved through the work of their subordinates. They are to ensure that the highest standards of quality are implemented and maintained at AMS in compliance with the standards listed in Section 1.2 and the AMS Quality Policy.

Figure 6. Cable and Materials Testing Laboratory

2. QUALITY MANAGEMENT SYSTEM

2.1 General

The AMS QA Management System was established shortly after the company was founded in 1977. Since inception, the program has been maintained, revised, and updated as needed to ensure adequacy, effectiveness, and industry acceptance. The QA program empowers the QAM to exercise control over all work activities, including reviewing test/work plans or processes, monitoring progress, ensuring controls or special controls are effective, reviewing or auditing work performance, verifying proper tools are available, or stopping work, if needed, to provide assurance that the activities affecting quality are performed as specified by the QA program or other customer requirements

The QA program is applied to all work activities AMS performs for nuclear power plants as well as work performed for clients who are doing work for nuclear power plants. These “quality related” activities are planned, monitored, and conducted according to written procedures and test plans containing sufficient acceptance criteria to ensure the work is performed satisfactorily. These procedures and work plans describe the necessary equipment, and as appropriate, the environmental conditions, process conditions, personnel qualifications, and necessary prerequisites to ensure conditions for performing the activities are appropriately controlled. Any specific QA requirements contained in client purchase order documents are evaluated and either met or an exception is noted and communicated to the client. QA requirements are communicated to the engineers who perform the work during pre-job or pre-trip meetings.

The established procedures and work plans: (1) direct the development, verification, and monitoring of company products, software, and services; (2) provide the framework for indoctrination and training of AMS personnel performing these quality activities; (3) ensure traceability of M&TE calibrations to NIST; and (4) describe the administration and operation of the QA Program. These instructions, procedures, work plans, and the QA manual fully describe the AMS QA Program. These documents are reviewed, updated, and maintained as needed to ensure adequacy and effective implementation per the 18 criteria of 10 CFR Part 50, Appendix B, and the standards and guidelines listed in Section 1.2, as applicable. Performance under the program is further supported by the records, data sheets, and other documents produced through implementation of the program procedures. These records are maintained and are available for review.

2.2 Personnel Qualification and Training

All personnel involved in quality activities, as defined in this manual, shall have adequate knowledge, training, and experience to perform work of the highest quality. This shall be achieved through a combination of formal education outside of AMS and indoctrination and training at AMS using specific procedures and qualified instructions to assure that suitable proficiency is achieved and maintained.

AMS has a formal training program for personnel performing or managing activities affecting quality. Personnel performing quality functions shall receive indoctrination and training in their job responsibilities and authority. The training shall include understanding and applying general QA criteria, understanding the QA nature of technical objectives, QA requirements of applicable codes and standards, regulatory QA requirements, company QA procedures, and other AMS QA program requirements.

Training for administrative and technical personnel is provided to achieve initial understanding of the role of QA in their position. Technical personnel are further trained to achieve proficiency, maintain proficiency, and adapt to changes in technology or methods to achieve the QA and technical requirements of their position. On-the-job training and hands-on laboratory training are also used wherever possible, as experience is helpful for familiarization with both field and laboratory testing.

AMS personnel are further certified as Technical Staff, QA Staff, or Administrative Staff. Technical Staff are given a designation of Staff Engineer Level 1, Staff Engineer Level 2, Staff Engineer Level 3, or Staff Engineer Level 3 - Expert based on their education and experience according to guidelines in the AMS “Personnel Qualification Procedure,” PQP8501. This procedure is intended to comply with ANSI/ANS 3.1, 2014, (R2020) and NRC Regulatory Guide 1.8, Rev. 4, June 2019. All technical employees must serve AMS as “Technical Staff” for their first year of employment at AMS. These classifications are not indicative of actual educational level but are based on a combination of education and experience for QA purposes only.

The QAM or his/her designee shall be responsible for ensuring that workers are qualified to perform quality activities according to AMS procedures. AMS personnel files shall include: resumes, certificates, diplomas, courses completed, records of experience, and any other records that support the training and qualifications of each worker. These records shall be maintained and are available for review or audit.

3. DESIGN CONTROL

AMS designs and produces specialized M&TE and the software used to operate it for its own use and use in the nuclear power industry. All equipment produced by AMS is provided commercially and is not offered as safety-related equipment. Nevertheless, hardware and software design/development procedures are established and controlled to provide a format for assembling development documentation for verification of quality design and construction. AMS designed software is provided only for use with AMS equipment and is used by AMS and nuclear plant test engineers for laboratory and field data acquisition and data analysis. The software is designed, developed, and V&V according to written procedures included in the AMS SQA Program. All testing and V&V of software products are performed by a qualified team of engineers independent of the software developers (Figure 7).

3.1 Software QA (SQA) Program

The development of AMS software products is performed according the Software Development and Modification procedure. This procedure is intended to meet the requirements for software according to NQA-1-2017. The software is not produced for plant operation and is not intended to be used on plant computer systems. Rather it is produced in support of AMS' commercial test equipment which is used by trained and qualified AMS or plant engineering personnel for data acquisition and analysis.

3.1.1 Software Design/Development Process

Initiation of software design and development activities at AMS can originate at any level of the organization. Requests for new software developments or changes/modifications to existing software are submitted to the AMS Systems Group Manager to be organized and prioritized for inclusion in the Systems Group workload. Development begins with an initial request meeting that includes software (and if needed, hardware) engineers and/or appropriate engineering management to clearly identify what must be developed, by whom, and identify a consensus for proceeding with the development. Reviewed and approved procedures ensure that design requirements, design descriptions, test plans, and final V&V testing for software developments are properly reviewed, approved, and documented. Proper implementation of these design and development procedures within the SQA Program is very effective in helping to produce robust and reliable software products.

3.1.2 Software Design Documentation

The development of software is documented such that (1) design activities are described in written procedures, (2) trained and qualified personnel are assigned to the activities, and (3) the design activities are reviewed and approved according to written procedures. Procedures for design and modification of software include data sheets that provide a format for assembling the documentation, including design and development notes, records of test results, design drawings, user's guides, flowcharts, etc. Finally, a V&V plan and V&V report are completed, reviewed, approved, and included with the other documentation, which is controlled according to AMS procedures.

3.1.3 Software Verification and Validation (V&V)

New or modified software products produced at AMS are subjected to final testing in order to ensure that they meet the design requirements and any applicable standards, regulations, or special contract requirements (if they are developed specifically for a customer). Documentation from a development is reviewed and approved by qualified personnel other than those who performed the design/development. V&V tests are performed on both new software designs and modifications to existing designs. The final tests are compared to alternative, accepted methods, proven designs already in existence, laboratory data, and real or synthetic data, as applicable and practical.

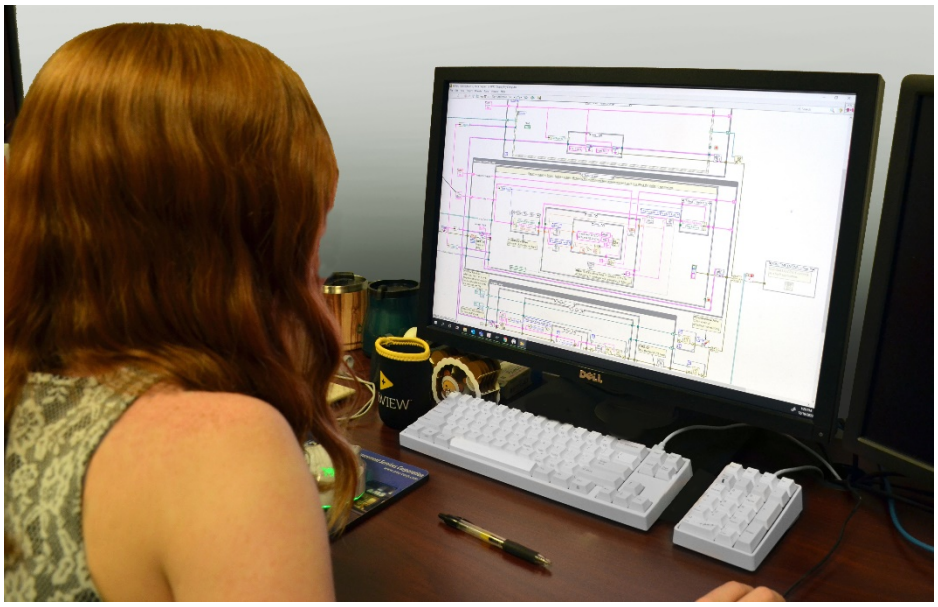

Figure 7. AMS Software in Development

4. PROCUREMENT

Reviewed and approved procedures describe the documentation required and steps necessary to purchase materials and services from suppliers or subcontractors to ensure the quality of the materials or services purchased. Procedures are also in place that define the assessment and qualification of suppliers and subcontractors and the receipt inspection/verification of purchased items as outlined in Section 7 of this manual.

All purchases of materials, parts, and components to be used in AMS-built test equipment are procured commercially from suppliers who are nevertheless maintained on the AMS' QSL. Purchase orders for calibration services used in supplying AMS services to a client may be issued only to suppliers who are maintained on the ASL. These lists include a register of commercial suppliers along with completed data sheets and/or supporting documentation of their qualifications, certifications, or accreditations (such as compliance with the latest revision of ISO/IEC 17025). Both lists are updated, maintained, and reviewed on a periodic basis under the direction of the QAM.

AMS typically procures calibration services from NIST for in-house standards that are used to calibrate laboratory transfer standards. Most AMS equipment is then calibrated in-house using the transfer standards with traceability directly to NIST. However, AMS also procures calibrations of specialized test equipment from calibration laboratories accredited to ISO/IEC 17025, 2017. Calibration services procured from accredited calibration laboratories on the ASL are dedicated (in lieu of source surveys) according to written inspection procedures in compliance with NEI 14-05A, Revision 0 and Revision 1 for use in fulfilling safety-related client purchase orders.

Purchasing documentation consists of a purchase order completed according to AMS procedures, including any necessary drawings, specifications, and logistical requirements. Special technical requirements for purchased material or services are also documented on or attached to the purchase order and may reference other drawings, standards, codes, and/or requirements as needed to fully describe the item(s) or service(s) being purchased

Where applicable, QA requirements specified by the AMS QA Program or Client purchase orders shall be incorporated into purchase order documents to subcontractors and sub-tier suppliers. All purchase orders for "quality related" items or services must be reviewed and approved by at least two of the following: the QAM, AQM, Senior Engineering Manager, President of AMS, or their designated representatives.

5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

The criteria for assuring the quality of AMS products and services are outlined and generally described in the AMS QA Manual. The descriptions of these criteria are further amplified by written AMS procedures. These procedures include instructions and/or step-by-step directions, as necessary, for carrying out specific tasks related to the quality of AMS products and services. Procedures typically include the purpose for the procedure, instructions, data sheets, and quantitative or qualitative acceptance criteria for determining satisfactory completion of the activities, as applicable.

The AMS "List of Procedures" documents the current AMS procedures in the following categories: Administrative, Calibration, Test, EMC, and Miscellaneous. It also documents applicable industry standards used in the performance of AMS' work, as well as the documents and instructions necessary to maintain accreditation of the EMC Laboratory to ISO/IEC 17025, 2017. A current copy of this list is prepared and maintained by the QA Department and approved by the AMS QAM or his/her designee. The most recent AMS Procedures List is available in the QA Program section of the AMS website at: www.ams-corp.com. Informational copies of specific procedures can be obtained by AMS customers by contacting the QA Department through email at: QA@ams-corp.com, or phone at: (865)-691-1756.

These procedures are reviewed for adequacy and applicability while in use, during quarterly reviews, as needed for internal annual audits, and discussed with management during the internal annual review. They are revised as necessary according to other written procedures which direct the author to include the detail necessary to fully describe the process and allow trained and qualified personnel to complete even the most complex tasks.

6. DOCUMENT CONTROL

The preparation, issue, and change of documents that specify quality requirements or describe activities affecting quality are controlled to assure that the correct documents and latest revisions are used. Records of performance under the QA Program, including reports, completed data sheets, training and qualification records, personnel files, calibration records, procurement records, and other documents are controlled and securely maintained to ensure the traceability and effective operation of the program.

All current hard-copy quality documents are maintained in filing cabinets in a secured QA Filing Office where access is limited to QA Department Personnel only, who may duplicate and distribute copies as needed. These documents are also scanned and duplicated electronically where possible and practical, and maintained in a QA document database which is backed up daily to a locked backup file. The backup server is in a location separate from the primary server (Figure 8). The original electronic files are secured in protected, restricted-access files to prevent unauthorized modification.

The latest revisions of controlled documents and procedures can be obtained from the QAM or the AQM. Informational copies of procedures, data sheets, or other QA documents may also be obtained electronically in PDF from the AMS Network in the:

FILESERVER2\QA\PROCEDURES

folder where the latest revisions are filed. Electronic documents from this location may be used as working copies as they are locked for editing and maintained to be the latest revision by the QA Department. It is the responsibility of the QAM and AQM to periodically review QA documents and ensure that only current, appropriate revisions of controlled documents are available for use.

“Quality-related” records maintained at AMS are those documents and records associated with any work AMS performs for a nuclear utility, nuclear power plant, fuel reprocessing plant, or any other vendor doing work for nuclear facilities. These records may be for safety-related or non-safety-related work activities. They also include records directing the programmatic operation and maintenance of the QA program not directly related to specific “quality-related” work.

Figure 8. AMS Computer Server Room

QA documents and “quality related” records include (for example):

- Calibration Records
- QSL
- ASL
- Procedures and completed data sheets
- Procurement Documents
- QA Manual
- Personnel Records (only available from the QAM or AQM)
- Software V&V Documentation
- A2LA Accreditation and Normative Documents and Records
- Audit Records

Changes and/or modifications to documents are performed according to approved procedures, reviewed for adequacy, and approved by qualified personnel who may obtain any information upon which to review and approve changes from the QA Department. Minor changes may be accumulated by the QA Department and made collectively during the next major change to the document. They are reviewed and approved as outlined above.

7. CONTROL OF PURCHASED ITEMS AND SERVICES

Items and services purchased from suppliers and subcontractors shall be controlled, as necessary, according to written procedures to ensure conformance with the AMS QA Program and any specific requirements of the client as outlined in their purchase documents. AMS suppliers shall be selected based on the quality of the products/services offered, historical performance, availability, and suitability of the products or services for AMS' purposes. All products and parts are purchased commercially from suppliers that have been evaluated and placed on the QSL according to written procedures. However, some calibration services are secured from accredited metrology laboratories as described above. Such calibrations are dedicated according to written procedures. Suppliers of these services are placed on the ASL according to written procedures and their continued acceptability for remaining on the ASL is evaluated with each receipt inspection and during annual management reviews.

7.1 Supplier Assessment

Selection of suppliers for the AMS QSL is based on an evaluation performed by trained personnel according to written procedures. Suppliers of commercial items are evaluated by one, or a combination of the following: commercial grade surveys, past performance history, product documentation review, and/or product appraisal. When surveys or audits are necessary to verify that a supplier or subcontractor is acceptable, annual evaluations and triannual audits will be conducted by trained and qualified personnel according to written procedures. (AMS does not currently audit or survey any of its suppliers.) Past performance is reviewed with management annually to assess supplier's historical performance for supplying similar products and services on time and of high quality. Evaluations are reviewed and maintained according to approved procedures as directed by the QAM. Suppliers must continue to meet the requirements of quality, availability, and suitability to remain on the QSL.

7.2 Procurement Plan

Commercial purchase orders for parts, pieces, and components are prepared or specified by engineering or trained technical staff involved in producing AMS products or services. Once components are specified, they are selected from suppliers already on the QSL. If no supplier is found on the QSL that can supply a particular item, other suppliers are evaluated until an acceptable supplier is found, evaluated, and placed on the QSL. Items to be procured are listed on the purchase order using the manufacturer's or supplier's part number and description. The purchase orders are then routed for review and approval according to established, approved procedures. Changes required after an order is placed are also documented on the purchase order, reviewed, and approved.

Purchase orders for calibration services are issued to NIST or to suppliers that have been placed on the ASL because they are currently accredited by ACLASS, A2LA, NAVLAP, or other ILAC affiliated organizations for the required calibration service(s). Specifications for providing these services and the required documentation are included as a separate page to our purchase orders which are verified during receipt inspection. Services from accredited suppliers are then dedicated according to written procedures for M&TE equipment that will be used to make measurements or tests under safety-related purchase orders. AMS does not place calibration services out for competitive bids and does not use the bidding process for procurement.

7.3 Receipt Inspection

Trained and qualified AMS personnel perform receipt inspections of commercial items by documenting that the items received are correct as specified on the approved purchase order. Attention is also paid to any indications that received items are suspected of being fraudulent or counterfeit. Following receipt inspection, acceptable items are segregated and stored in the QA parts cabinets or placed in equipment construction kits. Large items, those too big for the cabinets or a construction kit, are tagged for identification and may be stored at appropriate locations in the laboratories. Completed purchase order documents are properly duplicated and filed in the QA files according to written procedures. Any items that are found to be unacceptable or suspect are segregated in a clearly marked, nonconforming items section of the laboratory. These items are then either repaired at AMS, returned for replacement or repair, or disposed of according to AMS procedures.

Receipt inspections of items purchased from suppliers of calibration services, who are on the ASL, are conducted using approved procedures to fully document that all the requirements of the purchase order have been met including a supplier statement that all of the purchase order requirements were incorporated. CRs are initiated in any situation where specifications on the purchase order are not met and corrective action requires tracking. Inspections of commercial calibration services may include tests or measurements and review of documentation as part of the dedication of the services.

7.4 Identification of Defective Parts

Defective parts, if any, are identified not only through the steps outlined above, but also through inspection, testing, and examination of the final product into which an item is manufactured. This approach was adopted to ensure that AMS products meet expected quality and performance requirements. Identified defects are handled according to written non-conformance procedures and nonconforming equipment is either repaired, returned to the manufacturer for repair, or scrapped.

8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

Materials, parts, and components used in the manufacture of AMS products are purchased, received, and segregated as described in Section 7 of this manual. These components are identified by physical description, manufacturer's, or supplier's part number, AMS' part number or serial number, as applicable. Identification is either marked on the item itself or on the container or package in which it is stored. Only components from the QA cabinets, shelving (Figure 9), or construction kits are used in the manufacture of AMS products.

Material or equipment supplied by clients of AMS intended to be incorporated into other products, to be tested, repaired, or calibrated, are controlled in the same manner as purchased items, unless special handling is required by the client. They are receipt-inspected using approved procedures and are maintained in a clean climate-controlled work area of the AMS laboratory. They are identified by a work order authorization form, receipt inspection data sheets, purchase order number, and/or other documentation that is kept with them until they are shipped from AMS.

Figure 9. Typical Equipment Shelves

9. CONTROL OF SPECIAL PROCESSES

Development of AMS commercially supplied products and services is performed using commercial off-the-shelf components and, therefore, do not require any special processes. In the event that special processes become required, procedures will be developed, and personnel will be trained and qualified to perform the task accordingly. Records of personnel qualifications and documentation of conditions, equipment, requirements, and results will be maintained in the QA files.

10. INSPECTION

Material, components, and equipment used in the production of AMS commercial products will be inspected and tested, as applicable, according to documented procedures to ensure quality, and compliance with AMS and/or customer requirements. AMS personnel involved in inspection and testing activities will be trained and qualified to perform the work according to written procedures.

10.1 Receipt Inspection

All material, components, services, and equipment purchased for use in AMS products shall be inspected upon receipt to verify conformance to the requirements, specifications, and drawings found in the AMS purchase order documentation, as applicable. Reviewed and approved procedures describe the steps necessary for procuring, receiving, and documenting receipt of these materials, components, and equipment.

All items, including calibration services that are purchased from suppliers on the AMS ASL and intended to support AMS products and services will also be receipt inspected and commercially dedicated by trained/qualified personnel using approved procedures. The inspections will include a verification that the critical characteristics for commercial grade dedication and that the purchase order requirements were met.

10.2 In-Process Inspection and Hold Points

In-process inspections, when required by procedure or client requirements, shall be performed by trained and qualified personnel including members of the QA department or laboratory management, as needed. Any mandatory hold points that may also be required by procedure or client requirements shall be identified and performed as directed using written instructions. Project managers must approve continuing work beyond mandatory hold points or the waiver of any hold points. Trained and qualified personnel who have not performed or directly supervised the work will perform these in-process inspections.

10.3 Final Inspection and Testing

All products manufactured by AMS are subjected to final inspection and testing according to documented test plans and/or instructions developed per written procedures. These inspections (or re-inspections if needed) are performed after any modifications or repairs. This process is to ensure that the items (1) comply with applicable specification or contractual requirements, (2) have passed all inspections and testing required, (3) function as expected, (4) are operationally ready to be released to the client, (5) have adequate and complete QA records, (6) are adjusted to be within the “as left” calibration tolerance, as applicable, and (7) any nonconformances identified by prior inspections are resolved. The final inspection checklists are completed to document this process.

11. TEST CONTROL

Customer purchase orders and contract documents entered with AMS to procure products and/or services are reviewed for both specific commercial and specific QA requirements, and the reviews are documented according to approved procedures. Any QA requirements specific to the scope of supply for services or products that are specifically indicated on the purchase order from the client, will be indicated on the data sheet documenting the review of the purchase documents. Any specific commercial requirements will also be indicated on the data sheet. Specific requirements will be passed on to the personnel performing the work during a documented pre-job brief or pre-trip checkout meeting with the QAM, AQM, or other trained and qualified members of management prior to the start of work.

Testing services performed by AMS shall be performed using reviewed and approved procedures. These test procedures will outline the test equipment required for the test, the conditions under which the test is to be performed, instructions for performing the test, and acceptance criteria for the test, as applicable. In lieu of test procedures a test plan or work instructions can be written according to applicable standards and any customer requirements.

In performing field work at nuclear power plants and other facilities, a package of QA documents, including personnel qualification certificates, and calibration certificates are produced for each job and made available for the client at the plant site. These documents are also included with the final report supplied to the client after the testing is completed. The results from field testing or laboratory testing services are reviewed and approved by trained and qualified personnel and then communicated to the client and/or documented in a final report. AMS will work with its clients to clarify any unusual requests in the purchase order documents as well as any request to monitor AMS' performance in the field or laboratory. AMS shall seek feedback from its customers according to written AMS procedures and review the feedback to identify opportunities to improve the Quality Management System and its products and services. AMS will provide its customers reasonable access to relevant areas of the laboratory for witnessing tests performed for the customer and access to its measurement and test equipment for any verifications needed.

12. CONTROL OF MEASUREMENT AND TEST EQUIPMENT

AMS has established a system for the control, calibration, and maintenance of M&TE that is used in the production of AMS products or services. This system ensures that M&TE is checked for proper operation and calibration using established, reviewed, and approved procedures. All M&TE that is controlled, calibrated, and approved for use according to this system are identified by unique serial numbers or asset numbers and, when calibration is required, labeled with a calibration sticker that specifies the calibration date, the calibration due date, and/or the calibration status. M&TE equipment that does not require calibration, is no longer or rarely used, or is used only for research and development is labeled as such and may not be subject to periodic calibration. This equipment is appropriately marked and if it is needed for quality activities it must be calibrated before use if calibration is required.

Each test procedure identifies the M&TE required for the test and whether calibration is required. Calibration procedures are maintained for all M&TE which describe the steps for calibration and the acceptance criteria. Reference standards shall have a minimum accuracy four times greater than the M&TE being calibrated and, if a 4 to 1 ratio is not possible, the basis for accepting the calibration must be technically justified.

12.1 Calibration

Unless otherwise specified in the procedure for calibration of an instrument, calibration checks shall be performed on an annual basis, or on an interval that meets the manufacturer's specifications and assures the required accuracy for the measurements that are made with the instrument. Calibrations must be performed following repair or anytime the accuracy or performance of the instrument is suspect. Some M&TE may be calibrated on a longer interval if statistical analysis of previous calibrations according to accepted practices supports a longer interval or if a longer interval is specified by standards that direct the use of the M&TE. Rarely used equipment may just be calibrated prior to use. M&TE will have a sticker attached that identifies its status, whether it is in-calibration, out-of-calibration, limited calibration, or other status.

12.2 Traceability

AMS maintains primary laboratory standards that are calibrated at NIST. These standards are used to calibrate laboratory transfer standards that are, in turn, used to calibrate other AMS M&TE. Traceability is thus maintained directly to NIST for this AMS equipment.

AMS also has M&TE that is traceable to national and/or international standards through their accreditation to ISO/IEC 17025, 2017. The commercial grade dedication process is used to accept these calibrations. Traceability of measurements used to produce test results is

documented on pre-trip documents, maintained in customer files, on calibration certificates, and/or included in reports of the work.

12.3 Calibration Procedures

AMS maintains reviewed and approved calibration procedures for the internal calibration verification and/or adjustment of AMS M&TE. These procedures include the instructions for performing the calibration check or adjustment, the test equipment to be used in performing the calibration, the acceptance criteria, and data sheets for documenting the results of the calibration check or adjustment. A calibration certificate is completed and attached to the calibration data sheets. AMS also has approved procedures for accepting, testing (if needed), reviewing, and receiving equipment and documentation from NIST or commercially dedicating equipment received from accredited metrology laboratories that have been placed on the AMS ASL.

12.4 Calibration Records

All current calibration documents for M&TE as well as historical calibration records are maintained and controlled QA records. A master recall list of all M&TE under calibration control is also maintained, denoting the model, serial number, calibration date, and calibration due date. This list is updated as necessary to show the current status of AMS test equipment that is in regular use.

12.5 Out-of-Tolerance

If any M&TE is found to be out-of-calibration, lost, or damaged, the instrument is tagged and segregated, and an NCR is issued. An evaluation is made and documented regarding the validity of previous measurements if they were made with OOT instrument and of the acceptability of items previously tested or measured with the instrument. This evaluation shall extend backwards to the last acceptable calibration of the M&TE.

If repeated instances of equipment being OOT are identified, or if previous results have been compromised by an OOT condition, a CR will be initiated to evaluate the full extent of the problem. This evaluation might determine that this M&TE should be repaired or replaced.

For accredited calibrations, AMS shall be notified by the calibration laboratory if the as-received condition of the instrument is out of the manufacturer's or AMS' specified tolerance. The specific out-of-tolerance (OOT) condition shall be identified and communicated to AMS along with any supporting OOT data. No adjustment shall be made without AMS' consent, which may be given after notification and evaluation of the equipment condition.

13. HANDLING, STORAGE, AND SHIPPING

Approved handling and storage procedures are established to provide instructions to ensure that all materials, components, M&TE, customer equipment, and products received at or shipped from AMS are properly handled, labeled, stored, protected, and maintained to prevent damage or deterioration. Personnel performing the tasks described in these procedures or any special handling required by customer purchase documents, shall be trained in receipt inspection, shipping, storage, and foreign material exclusion (FME) and that training shall be documented.

AMS laboratories are climate-controlled and maintained to provide a clean, safe environment for the storage of materials, parts, components, M&TE, and customer equipment and to meet any environmental requirements for the calibration and maintenance of M&TE. When necessary, and if requested by a customer, special containers or environmental conditions may be used for storage of customer equipment while onsite at AMS (Figure 10).

Designated storage areas are set aside for segregation of parts and components used in AMS products and for nonconforming items. Customer-supplied equipment pending calibration, testing, and/or repair and maintenance is properly tagged upon receipt by trained and qualified personnel and stored in the AMS laboratories. This equipment is handled and shipped according to approved procedures or special customer requirements that outline specifications for packaging, handling, identification, storage, and/or shipping. Any tags added to customer equipment are removed prior to shipment by trained and qualified personnel.

Figure 10. Building C Laboratory

14. INSPECTION, TEST, AND OPERATING STATUS

All finished products, including all M&TE (Figure 11), are identified by unique serial or asset numbers. Final test data sheets, calibration data sheets, and certificates, as applicable, are produced with traceability to the serial or asset numbers to indicate that the products are released for use. M&TE will have a sticker attached that identifies its status, whether it is in-calibration, out-of-calibration, limited calibration, or other status. Customer equipment is tagged upon receipt by the receipt inspector and identified by its purchase order number and/or serial number, which is included on the work order authorization documents that accompany it while at AMS. The work order authorization also identifies the status of work to be performed and is used to discuss aspects of the work during a pre-job brief. Other indicators such as physical location, tags, markings, shop travelers, or other suitable means may be used for identification where necessary.

Figure 11. Laboratory Testing in Progress

15. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

Procedures are established and maintained for the control of materials, parts, components, and equipment that does not conform to requirements. These procedures include instructions for identification, properly tagging of items, documentation, evaluation, segregation, notification to affected organizations, and disposition of nonconforming items (Figure 12). The QA Department and/or other trained and qualified engineering staff (if needed) shall perform an evaluation of any nonconformance to determine the proper disposition and corrective action that must be taken. If corrective action is lengthy, or requires evaluation and/or notification, a CR is completed and logged for tracking purposes. The evaluation of NCRs and CRs shall include the effect, if any, on previous activities and identify any affected organizations. Documented notification to the affected organizations shall be made, when necessary, to prevent inadvertent use or installation of nonconforming items.

Nonconforming items shall be legibly tagged and segregated immediately and evaluated according to the established nonconformance procedure. The item(s) shall be stored in an area in the laboratories designated for nonconforming items unless they cannot be kept in the designated area or are being evaluated or repaired. In such cases, the items may be situated at any convenient location in the laboratories as long as the shop non-conforming traveler remains with them. NCRs shall be logged, tracked, and reviewed for status according to reviewed and approved procedures.

AMS shall inform the customer as soon as practical of any delays, deviations, or nonconformances in the performance of field and laboratory tests and/or the analysis of plant specific data.

Figure 12. Segregated Non-Conforming Equipment

16. CORRECTIVE ACTION

Procedures are established to document and ensure that conditions adverse to quality, such as malfunctions, deficiencies, deviations, defective material and equipment, procedural errors, and other nonconformances, are identified and corrected as soon as practical. CRs should be initiated for any condition adverse to quality and should be evaluated for their significance and any 10 CFR Part 21 applicability according to approved procedures. For a condition deemed to be significant, the evaluation shall be extended to determine the root cause of the condition. All CRs document the corrective action that will be taken to preclude recurrence. Any Part 21 conditions are handled according to written procedures.

Suggestions or procedures for preventive action may be developed in the conduct of normal business just as those for corrective actions. However, preventive action is intended to eliminate possible future adverse conditions, while CRs are to report conditions that have already occurred. Both corrective and preventive action, from a CR, are performed with the intention of preventing recurrence. Preventive actions may be initiated independently of corrective action, but they should still be documented on a CR form for tracking and evaluation. Similarly, all CRs are tracked until completion and made available for review during any internal or external reviews or audits.

The QAM, the AQM, or their qualified designee have the responsibility and authority to determine the significance of a condition adverse to quality and the extent of any corrective action, notifications, or further actions required. The QAM or AQM shall also document follow-up activities, as necessary, to ensure effective implementation of the corrective action. The identification, cause, and corrective action for significant conditions adverse to quality shall be reported to appropriate levels of management.

Prompt action shall be taken on customers' comments, recommendations, deviations, and findings that result from inspections and audits. AMS shall also record customer complaints requiring corrective action on CRs. Any complaint shall be evaluated for significance and corrective action proposed for the resolution of the complaint. Corrective action records shall be maintained according to written procedures.

AMS shall, through actions developed during annual internal and management reviews of audits, CRs, and NCRs, continually strive to improve the effectiveness of its Quality Management System.

17. QA RECORDS

QA Records are generated and maintained to document the effective operation of the AMS Quality Management System, the quality and manufacture of AMS products, the development, testing, and V&V of AMS software and hardware, the qualification of personnel, the calibration of M&TE, and the conformance of AMS laboratory and field services to specified quality and commercial requirements. The responsibility for controlling and maintaining quality-related documents and records lies with the QAM, the AQM, and QAAs. According to written procedures, these records are identified, collected, indexed, filed, stored, maintained, issued, and controlled, as necessary.

Where possible, QA records are maintained electronically and a backed up daily in separate locations. Backups are also copied every 6 months to an external hard drive and maintained off site. Paper records are duplicated and stored in filing cabinets in separate locations in such a manner as to prevent damage, loss, or deterioration from harmful conditions such as excessive light, stacking, temperature, and humidity. The QA records must be legible, identifiable, and easily retrievable. All QA records are intended to be kept for the life of the company; however, if it should become necessary to discard (destroy or dispose of) any QA documents, the affected customer(s) shall be formally notified by letter and given ample opportunity to assume possession and control of their records.

AMS QA records are stored in password protected electronic files, in the filing room in the QA department, or by QAAs in work areas where they are used and are easily retrievable for review and evaluation by AMS' clients, representatives of clients, or auditors. Copies of selected records, necessary for work activities, are available electronically as secure PDF documents and/or forms or are available from the QAM, AQM, or QAAs located in the work areas. The records system is reviewed periodically as part of the internal evaluations/audits/reviews of the AMS Quality Management System. Documents are only considered valid QA records if they are stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Electronic documents are authenticated through a similar process as paper records.

18. AUDITS

Planned and periodic reviews of the AMS QA Management System shall be performed to verify that performance criteria are met and to determine the effectiveness of the program. Qualified personnel shall be assigned to perform the audits using reviewed and approved procedures.

18.1 Internal Audits

An internal audit performed by a lead auditor appointed by the AMS President or AMS QAM shall be conducted annually or more often as directed by the AMS President. This audit shall be performed and documented using reviewed and approved procedures. AMS may also secure the services of a qualified external quality assurance auditing organization to perform this internal audit at the discretion of the AMS President. The audit team that performs the internal audit must include a lead auditor and may include other auditors as needed. The lead auditor, whether contracted by AMS or secured from an outside organization must be qualified before the audit according to AMS approved procedures to be a lead auditor. Auditors must also be qualified before the audit according to AMS approved procedures.

Personnel performing quality audits must be qualified as either an auditor or lead auditor under the AMS QA Program and will be able to audit areas in which they do not have direct responsibility for the activities performed or the products/services produced. Training and qualification of audit personnel will be performed according to AMS procedures and records of the auditor's training and/or qualifications will be maintained and available for review.

18.2 Internal Reviews

The QAM shall arrange for at least one annual internal management review of the AMS QA Program. This review shall be conducted according to approved written procedures, and the results shall be documented and reviewed by AMS management. Internal reviews of the AMS QA Program shall be performed by the QAM or personnel assigned by the QAM who have sufficient training or qualifications and do not review areas in which they perform work. In addition to the annual internal management review, the QAM, AQM, or other QA department personnel shall arrange for quarterly reviews of the QA program. These quarterly reviews are conducted according to written procedures and may supplement scheduled reviews and audits to determine status and insure timely completion of evaluations, corrective action, nonconformances, audit findings, procedures under revision or development, personnel training, and other QA activities.

18.3 External Audits

Any audits or source inspections of AMS suppliers or subcontractors, if required, will be planned and scheduled in consultation with the supplier or subcontractor and be performed by qualified personnel using approved written procedures, audit plans, and checklists. The audit team must include a qualified lead auditor and may include other qualified auditors working under the lead auditor, as necessary. The auditors will be qualified according to AMS approved procedures. The results of these audits shall be documented and maintained in the AMS QA files.

For both external and internal audits and annual evaluations of supplier performance a grace period of 90 days may be applied. When a grace period is utilized, the next scheduled date for the auditing activity should be based on the original date the auditing activity was scheduled to take place, not the actual date the audit or activity was performed. If an auditing activity takes place before the scheduled date, the next occurrence of this activity should be based on the date the audit or activity took place.

18.4 Audit Results

At the conclusion of an audit, an audit report should be issued that is signed or endorsed by the lead auditor. The audit report should include the audit scope, the auditors and other personnel involved, a summary of the audit results including the effectiveness of the items audited and describe any and all audit findings. External audit results are documented and filed according to written procedures and reviewed by responsible management. Internal audit results are documented in a similar manner but may also require a review by management or the AMS President.

Conditions requiring immediate corrective action should be reported to management as soon as practical so that they can be resolved. For internal audits, the QA department and management must work together to resolve any audit findings and to initiate corrective and preventive action where necessary. Once a solution to an audit finding has been identified, the auditing organization should be notified, in writing, of the changes that will be implemented.

19. 10 CFR PART 21 REPORTING

AMS accepts the requirements for reporting defects, nonconformances, and failures to comply that might impact the health and safety of the public as directed by 10 CFR Part 21. Handling of any reporting shall be the responsibility of the AMS QAM and ultimately, the AMS President. AMS maintains reviewed and approved procedures for administering and documenting nonconformances, conditions adverse to quality, corrective action, and 10 CFR Part 21 reports.

20. PERFORMANCE OF WORK

AMS engineering and technical personnel are responsible for performing their work (Figure 13) under the AMS QA Program using approved procedures and/or QA Plans. Work is expected to be of the highest quality and meet the intention and purpose of the Quality Policy. As such, they are not subjected to time pressures or other undue pressures which might impact the quality of their work. Where needed, additional employees will be assigned to tasks to reduce the pressure to meet deadlines.

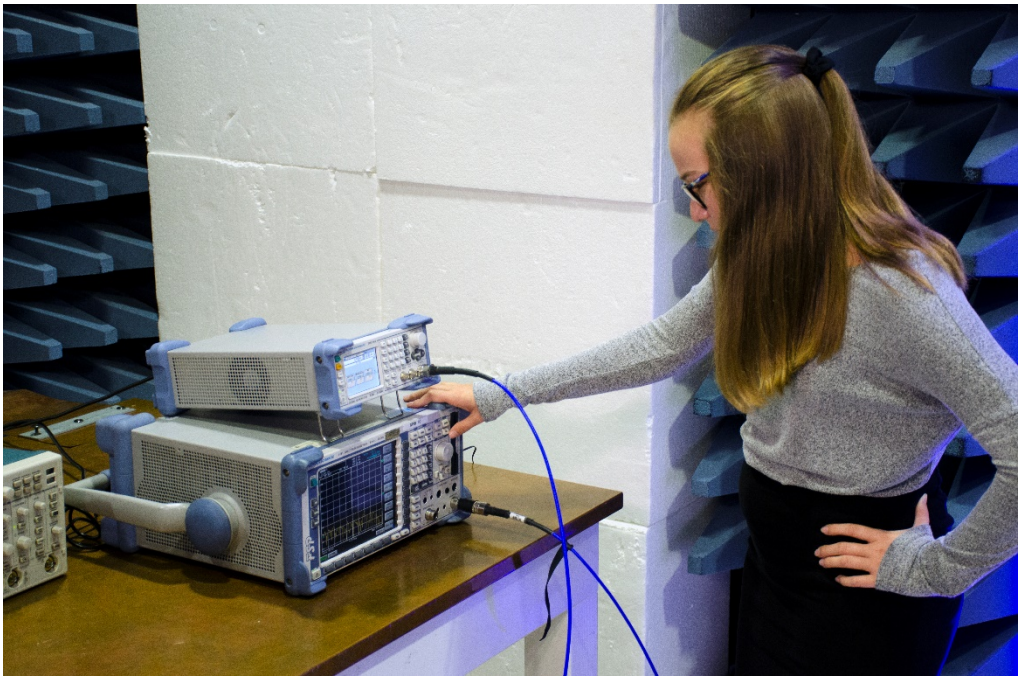

Figure 13. EMC Laboratory Testing

21. REFERENCES

1. NRC, Title 10 U.S. Code of Federal Regulations, Part 50, Appendix B, “QA Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” Domestic Licensing of Production and Utilization Facilities, December 19, 2019.

2. Title 10 U.S. Code of Federal Regulations, Part 21 (10 CFR Part 21)

3. ANSI/ASME N45.2-1977, “Quality Assurance Program Requirements for Nuclear Power Plants.”

4. ASME NQA-1-1994, “QA Requirements for Nuclear Facility Applications,” American Society of Mechanical Engineers, "Revision and consolidation of ASME NQA-1-1989 and ASME NQA-2-1989", July 29, 1994.

5. ANSI/ANS 3.1-2014, R2014, “Selection, Qualification, and Training of Personnel for Nuclear Power Plants.”

6. NRC Regulatory Guide 1.8 - Revision 4, 2019, “Qualification and Training of Personnel for Nuclear Power Plants.”

7. ISO/IEC 17025, 2017, “General requirements for the competence of testing and calibration laboratories.”

8. ANSI/ASME NQA-1-2017, “QA Requirements for Nuclear Facility Applications,” The American Society of Mechanical Engineers, January 18, 2018.

ATTACHMENT A

About AMS

Attachment A

This attachment contains information about AMS. Additional information may be obtained from the AMS web site at

www.ams-corp.com

or by contacting AMS via e-mail at

info@ams-corp.com

ABOUT AMS

Analysis and Measurement Services Corporation (AMS) is a technical consulting firm serving the nuclear power industry since July 1977. The company was founded on supplying equipment and services for in-situ response time testing of temperature and pressure sensors in nuclear power plants and remains the leader in that field today. It has also grown to be the foremost provider of on-line calibration testing equipment and services for temperature and pressure sensors, automated rod drop time measurements, testing the timing and sequencing of control rod drive mechanisms (CRDM), and performing predictive maintenance, equipment and process diagnostics and prognostics. Furthermore, AMS has become the leading provider of cable testing, cable diagnostics and cable aging management services and equipment in the industry. AMS also provides engineering and testing services for EMI/RFI troubleshooting, site mapping, and EMC evaluation of new equipment installations, including full laboratory and field-testing capabilities to meet MIL STD 461, EPRI Guidelines, and NRC regulations.

Since its inception, AMS has performed testing services and/or sold equipment and training to over one hundred nuclear power plants in the U.S. and around the world including plants in: Canada, Great Britain, Spain, Switzerland, Russia, Slovakia, South Korea, Taiwan, China and other countries (Figure 14). All work in the United States originates from AMS' location in Knoxville, Tennessee. The company has also provided testing services and conducted research for other vendors and nuclear sensor manufacturers. In addition, the company has been heavily involved in research and development projects for the U.S. Department of Energy (DOE), U.S. Nuclear Regulatory Commission (NRC), U.S. Department of Defense (DOD), and the National Aeronautics and Space Administration (NASA).

AMS is staffed by highly qualified electrical, nuclear, chemical, mechanical, instrumentation and maintenance engineers and technicians who have extensive hands-on experience from actual work in nuclear power plants worldwide. The staff also has considerable research and development experience and scientific background evident in the publication of over four hundred technical papers and reports on nuclear power plant instrumentation and related subjects. The publications include nine major research reports in the area of nuclear power plant instrumentation and maintenance written by AMS for the U.S. NRC. A full listing of AMS publications can be obtained from the AMS website at www.ams-corp.com.

Figure 14. Worldwide AMS Work Locations

Based on the extensive experience that AMS has with hands-on work in nuclear power plants, the company is a recognized expert in many technological areas and provides testing services, analysis, troubleshooting, training, and publications for:

- Evaluating aging characteristics of critical plant equipment
- Equipment aging management technologies
- Increasing plant output, improving safety, and reducing maintenance costs
- Extending the calibration intervals for pressure transmitters and other instrumentation through on-line monitoring
- Testing and trending the response time and health of RTDs, thermocouples, pressure transmitters, and neutron detectors
- Diagnosing pressure sensing line blockages, voids and leaks using on-line testing technologies such as noise analysis
- Characterizing the flow through the core and detection of flow anomalies in the primary system

- Determining venturi fouling in the secondary system
- Predictive maintenance testing
- Evaluating the health and operating condition of small and large plant equipment including the reactor vessel, and reactor internals
- Automated measurement of drop times of multiple control and shutdown rods
- Testing the timing and sequencing of CRDM
- Making precision calorimetric measurements in nuclear power plants
- Equipment condition monitoring using wireless sensor technologies
- Making wireless measurements inside containment during plant operation
- I&C cable/connector diagnostics and problem resolution
- Cable aging management programs and services
- Equipment for cable testing and diagnostics and aging evaluations
- Diagnosing nuclear instrumentation cable/detector problems
- Evaluations of the EMC emissions and susceptibility of new or upgraded plant equipment in the new state-of-the art AMS laboratory
- Electrical Condition Monitoring
- Testing EMC emissions and susceptibility of new or upgraded equipment on-site after it is installed in the plant
- Designing for EMC
- Root cause evaluations
- Solving noise problems caused by EMI/RFI problems in the plant
- On-site Electromagnetic Environment mapping and evaluations
- Training personnel

In the performance of this work, AMS has maintained its 10 CFR Part 50, Appendix B QA Program. The program has been audited by most of the nuclear utilities in the U.S. and some in Europe, as well as being audited regularly by the Nuclear Procurement Issues Corporation (NUPIC) since November 1992.

This is the final page of the Quality Assurance Manual.