

16 Bank Street • Peekskill, NY 10566
914-736-7100 • Fax: 914-736-7170
www.wmginc.com

July 20, 2012

ATTN: Document Control Desk
Director, Spent Fuel Project Office
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Application For Review - Quality Assurance Program Approval For
Radioactive Material Packages

Reference: Docket No. 71-0954

Enclosed please find the WMG, Inc. Quality Assurance Program Description Rev. 1 –
for your review.

Questions regarding this submittal may be directed to:

WMG, Inc.
Attn: Jeffrey Nelson (914) 736-7100
Email: jnelson@wmginc.com
16 Bank Street
Peekskill, New York, 10566

Sincerely,

Edward J. Posivak
Executive Vice-President

Enclosure: WMG, Inc. Quality Assurance Program Description

WMG, INC.

QUALITY ASSURANCE PROGRAM DESCRIPTION

FOR

NRC SUBMITTAL

Revision 1

July 2012



**16 Bank Street
Peekskill, NY 10566**



QUALITY ASSURANCE PROGRAM DESCRIPTION
Rev. 1

WMG, Inc. 16 Bank Street Peekskill, NY 10566			
APPROVALS			
Rev No.	Prepared By:	Reviewed By:	Approved By:
0	Signatures on File		
	J. Nelson 3/19/2012	E. Posivak 3/20/2012	K. Tuite 3/20/2012
1	<i>J. Nelson</i> 7/20/12	<i>E. Posivak</i> 7/20/2012	<i>K. Tuite</i> 7/20/2012



**QUALITY ASSURANCE PROGRAM DESCRIPTION
REVISION LOG**

Rev No.	Date	Page No.	Description	Change Made Signature – Date
0	3/9/2012	All	Original preparation of the QAPD for NRC Submission	J. Nelson 3/19/2012
1	7/20/2012	All	Incorporation of NRC comments and clarification of requirements.	<i>[Signature]</i> 7/20/12



Table of Contents

1.0	Introduction	1
1.1.	Organization	1
1.2.	Organization Activities	1
2.0	Quality Assurance Program	3
3.0	Design Control	5
4.0	Procurement Document Control	8
5.0	Instructions, Procedures, and Drawings	9
6.0	Document Control	9
7.0	Control of Purchased Items and Services	10
7.1.	Noncommercial Grade Items and Services	11
7.2.	Commercial Grade Items and Services	14
8.0	Identification and Control of Items	15
9.0	Control of Special Processes	16
10.0	Inspection	17
11.0	Test Control	18
12.0	Control of Measuring and Test Equipment	19
13.0	Handling, Storage, and Shipping	20
14.0	Inspection and Test	20
15.0	Control of Nonconforming Items	21
16.0	Corrective Actions	22
17.0	Quality Assurance Records	22
18.0	Audits	23
18.1.	Internal Audits	23
18.2.	External Audits	24



1.0 Introduction

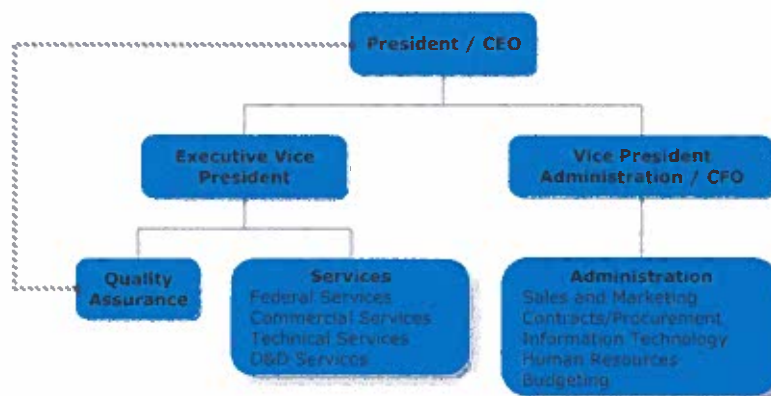
The Quality Assurance Program Description (QAPD) described herein applies to the technical services, package design and computer software supplied by WMG and meets the applicable sections of 10 CFR 50 Appendix B and 10 CFR 71 Subpart H.

WMG, Inc. is located in Peekskill, New York. The Quality Assurance Program (QAP) is applied using a graded approach as described in Section 2.0 of this QAPD.

1.1. Organization

The organizational structure of WMG, Inc. (WMG) has been established to provide assurance that activities associated with each project/product are defined and controlled by the responsible manager.

Figure 1: WMG Organization Structure



1.2. Organization Activities

The WMG Executive Vice President has overall responsibility for the day-to-day operational activities and reports to the President.

The Executive Vice President has designated the Nuclear Services General Manager the responsibility for day-to-day operations and associated support activities that include;

- Commercial Services



- Packaging and Transport Services
- Federal Services
- Technical Services
- D&D Services

The Nuclear Services General Manager is responsible for the overall implementation of the QAP as applicable to quality specific activities.

The QAP is binding on all WMG and contractor personnel involved in activities assigned specific quality requirements.

The Operations Manager reports to the Nuclear Services General Manager and is responsible for day-to-day coordination for off-site personnel and Training Services.

The Engineering Manager reports to the Nuclear Services General Manager. The Engineering Manager is responsible for characterization services, design services and the design control process; configuration management; engineering; and acceptance test coordination, including test control. The Engineering Manager is also responsible for nuclear criticality safety, safety analysis, and approving disposition of nonconforming items when dispositioned as "repair" or "use-as-is."

The Vice President Administration / CFO reports to the President and is responsible for the day-to-day administration operations including procurement; and providing procurement material control services (including supplier qualification coordination, purchasing, contracting, receiving and control of nonconforming items); and material control (including handling, storage and shipping).

The WMG Quality Assurance Manager (QAM) is responsible for the Quality Assurance Program (QAP) and for determining the status, adequacy, and overall effectiveness. The QAM reports to the Executive Vice President and has sufficient authority and autonomy to implement the QAP with direct access to the President.

The QAM is responsible for independent oversight of WMG activities covered by this QAPD. This includes maintenance of the QAP and assessing its effective implementation.

This includes the responsibility and authority for:

- Review and approval of QAP implementing procedures;
- Review and approval of supplier QA programs;
- Monitoring the implementation of the QAP and assessing the effectiveness through audit and surveillance;



- Investigating any aspect of the QAP to identify problems with execution and to verify that corrective action is taken in a timely manner;
- Stopping unsatisfactory work or controlling further processing when warranted for safety considerations;
- Remaining informed of day-to-day activities to ensure adequate oversight; and
- Providing quality control activities for purchased and in-house manufactured items.

The organizational philosophy is based on the following principles:

- Quality is achieved by those responsible for performing work. This includes identifying, correcting, or recommending solutions for quality problems.
- Quality verifications and controls are performed by persons who are independent of the work performance activities, but who may report to the management of the same organization. Persons responsible for assurance and verification of quality have sufficient organizational freedom to identify problems, initiate solutions, verify solutions and control further processing when necessary.
- Quality related activities may be delegated to others, but management retains responsibility for the overall effectiveness of the QAP.
- Suppliers and contractors are required to have approved quality assurance programs consistent with the QAP, as applicable to the scope of work as specified in Section 4.0 of this QAPD.

Specific organizational responsibilities are defined in the implementing procedures developed in accordance with Section 5.0 of this QAPD.

2.0 Quality Assurance Program

QA elements of this section are applied to the design, testing, operation, procurement, inspection, maintenance, and modification of items or services provided by WMG. The QAP is applied to those items and/or services in a graded approach to an extent commensurate with an assigned Quality Level. The Quality Levels are determined based on the scope of work to be performed in accordance with their importance to safety as follows:

<u>Level</u>	<u>Description</u>
Augmented Quality	QA Requirements imposed on items or services that do not require the full breadth of the QA Program
Safety Related	The full extent of the QA Program will be implemented for those activities classified as Safety-Related



Part 71 Applicable

The full extent of the QA Program will be implemented for those activities classified as Part 71 Applicable with details captured in a Part 71 Supplement to the QAP.

The application of the QAP is documented, planned, implemented, and maintained to provide reasonable assurance that, together with other management measures, WMG provided items/services will be available and can be relied on, when needed.

Implementing procedures provide for a graded approach taking into consideration:

- Quality Level (risk significance);
- Applicable regulations, industry codes, and standards;
- Complexity or uniqueness of an item or activity and the environment in which it has to function;
- Degree to which functional compliance can be demonstrated or assessed by test, inspection, or maintenance methods;
- Degree of standardization;

By appropriately balancing considerations of importance to safety and process capability, an appropriate level of quality is selected and achieved commensurate with the activity's importance to safety.

The results of the application of the graded approach to quality are incorporated into design requirement documents, specifications, procedures, instructions, drawings, inspection plans, test plans, procurement documents, and other documents that establish the specific requirements for each item or activity.

Compliance with QAP requirements and associated procedures is mandatory. Questions on QAP requirements are referred for resolution as necessary to the QAM, who is the final authority on QAP requirements.

The terms used in the QAP are as defined in 10 CFR 70.4 Definitions, 10 CFR 71.4 Definitions, and American Society of Mechanical Engineers (ASME) NQA-1-2008, Part I, Introduction, Section 400.

Indoctrination and training of personnel performing or managing activities affecting quality will meet the requirements of ASME NQA-1-2008, Part I, Requirement 2, Section 201.

Quality Control personnel performing inspection and testing will meet the requirements of ASME NQA-1-2008, Part III, 2A-1 Guidance on the Qualifications of Inspection Personnel.

QA audit personnel will meet the requirements of ASME NQA-1-2008, Part III, 2A-3, Guidance on the Education and Experience of Lead Auditors.



Management of those organizations implementing the QAP, or portions thereof, regularly assesses the adequacy of that part of the program for which they are responsible and will assure its effective implementation.

Management regularly assesses the adequacy and effective implementation of the QA elements through methods such as review meetings, audit reports, and corrective action reports.

3.0 Design Control

Approved procedures provide for performing the design process in a planned, controlled and documented manner. The design control process includes the assessment of designed components and transportation packaging to identify individual components as "important to safety" or "not important to safety". Those that are determined to be "important to safety" are then assigned classification category and document.

Classification Category	Importance to Safety	Description
A	Critical to safe operation	Category A items include structures, components, and systems whose failure could directly result in a condition adversely affecting public health and safety. The failure of a single item could cause loss of primary containment leading to release of radioactive material, loss of shielding, or unsafe geometry compromising criticality control.
B	Major impact on safety	Category B items include structures, components, and systems whose failure or malfunction could indirectly result in a condition adversely affecting public health and safety. The failure of a Category B item, in conjunction with the failure of an additional item, could result in an unsafe condition.
C	Minor impact on safety	Category C items include structures, components, and systems whose failure or malfunction would not significantly reduce the packaging effectiveness and would not be likely to create a situation adversely affecting public health and safety.

Each "important to safety" component is identified on Design Drawings with an indicator based on the Classification Category.

Design inputs, such as design bases, performance requirements, regulatory requirements, codes and standards, are identified and documented as design



requirements (e.g., primary requirements, functional requirements, and system requirements). Design requirement documents are reviewed and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out correctly and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. Changes are identified, approved, documented, controlled, and include the reason for the changes.

Design process activities are planned on a timely basis and to the level of detail necessary to permit the design process to be carried out correctly; to permit verification that the design inputs are correctly translated into design documents; and to support interfacing design, procurement, fabrication, and operation. Appropriate quality standards are identified and documented. Changes from specified quality standards, including the reasons for the changes, are identified, approved, documented, and controlled. Design methods, materials, parts, equipment, and processes that are essential to the function of a WMG provided item or service are selected and reviewed for suitability of application. Assemblies, subassemblies and parts are clearly identified.

Final design output documents, including changes thereto, are relatable to the design input by documentation in sufficient detail to permit design verification.

Design outputs that consist of computer programs are developed, validated, and managed in accordance with ASME NQA-1-2008, Basic Requirement 11 and NQA-1, Part II, Subpart 2.7, QA Requirements for Computer Software for Nuclear Facility Applications.

Design analyses documents (e.g., calculations) contain sufficient detail as to the purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can understand the analyses and verify the adequacy of the results without recourse to the originator. Design analysis, performed with computer systems, will list the software and version; hardware; inputs and outputs; and evidence of computer program verification/validation or alternate verification of the results. Design analysis documents are identifiable by subject, originator, reviewer, and date.

Design verification is performed and documented, in accordance with approved procedures, by competent individuals or groups other than those who performed the original design. The extent and method of the design verification is a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, past performance, and similarity with previous proven designs. Where changes to previously verified designs are made, design verification is performed for the changes, including an evaluation of the effects of the changes on the overall design and on any design analysis on which the design is based. Methods of design verification include any one or a combination of the following (as defined in ASME NQA-1-2008, Part I, Requirement 3, Section 501): design reviews, alternate calculations, or the performance of qualification tests.



Verification by testing is performed when deemed necessary and demonstrates adequacy of performance under conditions that simulate the corresponding design requirements. Verification of computer programs includes appropriate testing and validation. Design verification is performed in a timely manner and is completed prior to relying upon the WMG provided item, service, or computer program to perform its function.

Verifiers are knowledgeable in the areas to be verified. The verifier may be a supervisor, provided the supervisor was not directly responsible for the design (i.e., did not specify a singular design approach or rule out certain design consideration and did not establish the design inputs used in the design) or provided the supervisor is the only individual in the organization competent to perform the verification. However, verification is more than a cursory supervisory review. A supervisor with direct responsibility for the design may verify General Design items and services.

Changes to final designs, field changes, modifications, and nonconforming items dispositioned "use-as-is" or "repair" are justified, documented, and subject to the design control measures commensurate with the original design. Changes are reviewed and approved by the person or group with assigned design authority. The approved change(s) are further evaluated to determine if NRC Approval is required prior to implementation and documented.

Internal and external design interfaces are identified and controlled and design efforts are coordinated among participating organizations. Design information transmitted across interfaces is reviewed, approved, documented, and controlled.

Final design documentation and records that provide evidence that the design and design verification processes were performed in accordance with this section are collected, stored, and maintained.



4.0 Procurement Document Control

Procurement documents include those necessary to assure that the items and services to be provided will be of the desired quality. These include the following, as appropriate:

- Scope of Work.
- Basic Technical Requirements - These include drawings, specifications, codes and industrial standards with applicable revision data; test and inspection requirements; special processes; and special requirements such as for designing, fabricating, cleaning, identification marking, erecting, packaging, handling, shipping, and storage.
- QA Requirements - These include the requirements for the supplier to have an acceptable QA program consistent with the applicable portions described in this QAPD (the requirement for the supplier to have a documented QA program may be waived for commercial grade items); provisions for access to the supplier's facilities and records for source inspection and audit; and requirements for reporting. The extent of the program required will depend upon the defined quality level and use of the item or services being procured.
- Requirements for the control of nonconformances and changes - These include provisions to control and report nonconformance and changes to products being delivered.
- The subsequent flow down of all requirements to all Sub-tier Suppliers - These include the specification of procurement requirements on sub-tier suppliers.
- Documentation Requirements - These include requirements identifying documents to be submitted for information, review or approval; instructions on record retention, turnover and disposition; and the requirements for delineating the technical and quality data required for ordering recommended spare and replacement parts and assemblies.

Procurement documents and changes thereto are reviewed to ensure they include the appropriate requirements as listed above. The review and documented concurrence is performed by independent personnel having an understanding of the requirements and intent of the procurement document.

Changes to procurement documents, including changes made during contract negotiations or post award, are subject to the same review and control as the original document.

The use, management, storage, and protection of Procurement documents are conducted in accordance with the requirements of this Section of the QAPD and Section 6.0 of the QAP.



"Non important to safety" items and services are procured as commercially available in accordance with the criteria in this section and the criteria applicable to commercial grade items and services contained in Section 7.0 of the QAP. However, commercially available items and services, unlike commercial grade items and services, are not required to be dedicated.

5.0 Instructions, Procedures, and Drawings

Activities affecting the availability and/or reliability of WMG provided items or services are prescribed by and accomplished in accordance with documented procedures, instructions, specifications, and drawings of a type appropriate to the circumstances. These documents include or reference appropriate acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. Standard guidelines for the format, content, and review and approval processes are established.

The QAP establishes the policy requirements approved by the WMG President. Procedures are the second tier of documents that implement the QAP. Procedure and instruction preparation, review, and approval are the responsibility of the applicable manager. The QAM reviews QA implementing procedures for compliance and consistency with the QAP. QA review of procedures is performed to ensure that the provisions of the QAP are effectively incorporated into QA implementing procedures.

Adherence to policy, procedures, and instructions is mandatory. In the case of conflict or error involving a procedure, the activity in question shall be placed in a safe condition and the procedure shall be corrected or changed before proceeding to implement the corrected/verified procedure.

Activities that require skills normally possessed by qualified personnel do not require detailed step-by-step delineation in a procedure. They are performed in accordance with documents of a type appropriate to the circumstances such as planning sheets, job descriptions, external manuals, or other forms.

6.0 Document Control

Documents and changes to documents that prescribe or specify quality requirements or activities affecting the availability and/or reliability of WMG provided items or services are controlled in a manner that assures the use of correct documents. Such documents, including changes thereto, are reviewed for adequacy and approved for release by authorized personnel.

Procedures and instructions assure that documents are prepared; reviewed for adequacy, correctness, and completeness by a qualified individual; approved for release by authorized personnel; distributed to the location where the activity is performed prior to commencing work; and used in performing the activity.



Obsolete or superseded documents are removed or appropriately identified. Procedures identify documents to be controlled; responsibility for preparing, reviewing, approving, and issuing documents to be used; and require the establishment of current and updated distribution lists. Procedures also require the creation and maintenance of a controlled document index to track and control approved revision levels of those documents.

Changes to documents are reviewed and approved in the same manner as the original unless other organizations are specifically designated. Reviewing personnel have access to the pertinent background information upon which to base their approval. Procedures provide for simplified approval of editorial or minor changes.

7.0 Control of Purchased Items and Services

The procurement of items and services is controlled to assure conformance with specified requirements. These controls provide for the following, as appropriate: source evaluation and selection; evaluation of objective evidence of quality furnished by the supplier, source inspection; audit; and examination of items or services upon delivery or completion.

Procurement activities are planned and documented to assure a systematic approach to the procurement process. Procurement document control is described in Section 4.0 of this QAPD.

The following interfaces and responsibilities apply for purchasing actions discussed in Sections 4.0 and 7.0 of this QAPD.

- The QA Manager is responsible for providing the necessary QA function to support procurement. These QA functions include review of supplier quality documentation; evaluation of supplier's QA capability, supplier audits and evaluations; and for the development and maintenance of an approved suppliers list. The QA Manager provides support functions (i.e., source verification or surveillance; receipt inspections; installation inspections; and review of procurement documents during receipt inspections).
- The Engineering Manager is responsible for assisting the QA Manager by performing evaluations of supplier's technical capabilities. The Engineering Manager is also responsible for determining specific methods of acceptance to be applied to purchased items and reviewing the specific method of acceptance to be applied to services. The Engineering Manager is also responsible for the approval of dispositions and technical evaluation of supplier-generated nonconformances for items and services dispositioned as "repair" or "use-as-is."



- The Chief Financial Officer (CFO) is responsible for procurement planning, contract negotiations, and procurement of items and services on the Approved Suppliers List (ASL), when required.

7.1. Noncommercial Grade Items and Services

Supplier selection is based, in part, on a pre-award evaluation of capability to provide items or services in accordance with the requirements of procurement documents. The evaluation includes one or more of the following:

- An evaluation of the potential supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The supplier's history will reflect current capability. The potential supplier's current quality records are supported by documented qualitative and quantitative information that can be objectively evaluated.
- Depending on the part or service involved, a supplier QA program meeting the applicable requirements of accepted industry regulations or standards such as, NQA-1, ISO 9000 series, American National Standards Institute (ANSI) Z540-1, or 10 CFR Part 50, Appendix B may be acceptable. When actions that demonstrate the implementation of the QA program have commenced, the potential supplier's technical and quality capability is determined by a direct evaluation of the supplier's personnel, and implementation of the supplier's quality assurance program. Supplier audits are conducted in accordance with Section 18.2 of this QAPD).
- QA reviews and approves the results of recognized industry shared supplier audits. The review ensures that the requirements in Section 7.0, first bullet, have been met. When using this method, an initial implementation audit will be performed in accordance with Section 18.2 of this QAPD.
- The potential supplier implements and maintains an NRC approved QA program. When using this method, an initial implementation audit will be performed in accordance with Section 18.2 of this QAPD.
- The supplier maintains a valid ASM 71 Code certification for the item or service being provided. When using this method, an initial implementation audit will be performed in accordance with Section 18.2 of this QAPD.

Suppliers with acceptable technical, quality and commercial qualifications are placed on the ASL maintained by the QAM. Retention on the list is based on performance. Suppliers that are not pre-qualified may be used with appropriate compensatory controls as agreed upon by the QAM.

Depending on the type of procurement, suppliers are evaluated for technical considerations, quality assurance requirements, production capability, past



performance, alternates, and exceptions; as well as commercial, cost, and schedule considerations, as applicable.

Measures are established to interface with the supplier and to verify supplier's performance, as necessary. The purchaser's verification activities; however, do not relieve the supplier of their responsibilities for verification of quality achievement. The measures include:

- Establishing an adequate understanding between WMG and the supplier on the provisions and specifications of the procurement documents;
- Requirements for the supplier to identify the methods and processes to be used by the supplier in fulfilling the requirements of the procurement;
- Reviewing the supplier documents generated or processed during activities fulfilling procurement requirements;
- Identifying and processing necessary change information;
- Establishing methods for exchange of information with the supplier, and
- Establishing the extent of source surveillance and inspection activities for sub-tier suppliers.

Supplier-generated documents required for submittal are reviewed for acceptability. Measures ensure that submittal of these documents is accomplished as required by the procurement documents. Evaluation depends on the type of documents submitted. The three categories are: engineering documents requiring WMG technical approval (e.g., shop drawings and test procedures); verification documents (e.g., test reports and inspection reports); and information documents (e.g., external manuals and parts lists).

Acceptability verification activities are based on quality level, complexity, and quantity of items or services provided.

Acceptance of items, including spare and replacement parts, includes one or more of the following methods:

- Certificate of Conformance - When this method is utilized, the following minimum criteria are met:
 - The certificate identifies the purchased material or equipment or purchase order number.
 - The certificate identifies the specific procurement requirements met.
 - The certificate identifies any procurement requirements that were not met and approved waiver.
 - The certificate is authenticated by a person responsible for this QA function.



- The procedures, used for the preparation, review, and approval of the certificate, are described in the supplier's quality assurance program or the purchase order.
- The validity of the supplier's certificates and effectiveness of certification system is verified, and the interval of verification is based on the supplier's past quality performance.
- Source Verification - When this method is utilized, it is performed at intervals consistent with the quality level and complexity of the item or service. This method provides plans to perform inspections, examinations, or tests at predetermined points. Source inspection may be performed at lower tier suppliers when necessary. Results may be utilized at receiving inspection.
- Receiving Inspection - When this method is utilized, purchased items are inspected to verify conformance to procurement documents. This method verifies by objective evidence such features as proper configuration; identification; dimensional, physical, or other characteristics; freedom from damage from shipping; cleanliness, and review of supplier documentation when procurement documents require such documentation to be furnished.
- Post-Installation Testing - When this method is utilized, post-installation test requirements and acceptance criteria are established in conjunction with the supplier, if necessary.
- Supplier qualification and performance history. For Important to Safety items, at least: one of the other methods of acceptance is used.

Documented evidence of acceptability must be complete prior to placing an item in service. Controls are established for conditional release, such as for post-installation testing.

Acceptance of services is based on one or more of the following methods:

- Technical verification of data produced;
- Surveillance and/or audit of the activity, and
- Review of objective evidence for conformance to procurement document requirements.

Acceptance of services includes review of contractor deliverables (including documentation and records), determination of acceptability for WMG use, completion of acceptance testing, completion of start-up testing, turnover, etc.

Supplier nonconformance is processed in accordance with Section 15.0 of this QAPD. Supplier nonconformance consists of one or more of the following:

- Deviation from technical or material requirement;
- Deviation from requirement of purchaser-approved supplier document;



- Nonconformance that cannot be corrected by continuation of the manufacturing process or by rework; and
- Items that do not conform to the original requirements even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

Supplier nonconformance may be identified either by WMG or by the supplier. For supplier identified nonconformance, WMG requires a supplier recommended disposition and technical justification. Nonconforming items are not released for use until the nonconforming condition is reviewed and accepted by engineering and the implementation of the disposition is verified. Records of supplier nonconformance are maintained.

7.2. Commercial Grade Items and Services

Changes to commercial grade items specified in design documents are subject to design control measures in accordance with Section 3.0 of this QAPD. The criteria and methods for identifying the characteristics (controls) for acceptance are established. The characteristics (controls), which once selected to be verified, provide reasonable assurance that the item or service provided meets specified requirements. In selecting the controls, the impact of the activities associated with the item or service on the safety function is considered.

Supplier evaluation, when deemed necessary, is in accordance with Section 7.0 of this QAPD.

Procurement documents are issued and controlled in accordance with the requirements of Section 4.0 of this QAPD.

Commercial grade items are identified in procurement documents by manufacturers published product descriptions, in accordance with Section 4.0 of this QAPD. Commercial grade services are identified in the purchase order by the service provider's published service description (e.g., supplier's bulletin describing standard calibration services that are provided by the supplier) or other appropriate documents.

A commercial grade item or service satisfies the following:

- Not subject to design or specification requirements that are unique to nuclear facilities as applicable;
- Used in applications other than nuclear facilities; and
- Is to be ordered from the manufacturer/supplier on the basis of a specification set forth in the manufacturer's published product description (e.g., catalog).



As a minimum for acceptance of commercial grade items, receipt inspection, as described in the paragraph below, is performed to provide reasonable assurance that the item received is the item ordered and to ensure that the item will fulfill its intended safety function.

Acceptance reviews will be performed, for acceptance of commercial grade services, to provide reasonable assurance that the service performed is the service ordered. If designated by engineering, based on the complexity of the item or services or its importance to safety, one or more of the following may also be used:

- Special test or inspection
- Commercial grade survey of the supplier.
- Source verification
- Acceptable supplier/item performance record.

The selection of the method or combination of methods as described above is based on the following:

- Selected controls;
- Available supplied information;
- Quality history;
- Degree of standardization of the service; and
- Importance to safety and complexity of the service.

Receipt inspections of commercial grade items are performed to determine that damage was not sustained during shipment; that the item received is the item ordered; that inspection and testing was performed by the supplier, as required by engineering, to ensure conformance with manufacturer's published requirements and to ensure that required documentation is received and is acceptable. Acceptance reviews are performed to determine the commercial grade service performed is the service ordered and that required documentation is received and is acceptable.

Dedication of a commercial grade item or service occurs when that item is accepted in accordance with the above requirements.

The requirements of 7.0 of this QAPD are imposed through the procurement process on all Sub-Tier Contractors if commercial grade items or services are to be provided to WMG.

8.0 Identification and Control of Items

WMG is not a fabricator, If equipment is furnished as a WMG deliverable, the vendor or subcontractor furnishing such equipment is required to provide and



implement a Quality Assurance Program covering the criteria of 10 CFR part 50 Appendix B, 10 CFR Part 71 Sub-Part H or ASME NQA-1 as applicable.

Prior to vendor selection, WMG verifies that the vendor has and implements measures for the identification and control of materials, parts and components consistent with the level of Quality imposed on the specific purchase.

This verification ensures that the vendor applies controls to assure that only correct and accepted items are used or installed. Identification is maintained on the items or in documents traceable to the items, or in a manner that assures identification is established and maintained as described in this section.

Items are identified and controlled, as necessary, from initial receipt and fabrication of the items up to and including installation and use to assure that only correct and accepted items are used or installed. Physical identification is used to the maximum extent possible. When physical identification is either impractical or insufficient to control the item, physical separation, procedural controls, or other means are employed. When markings are used, measures are established to ensure that the markings are clear, legible, and do not have a detrimental effect on the function or service life of the item. Markings are transferred to each part of an identified item when subdividing and are not to be obliterated by surface treatments or coatings unless other means of identification are provided.

Traceability of items to specific records is provided when specified by codes, standards, or specifications. Where specified, items having a limited operating life or shelf life are identified and controlled to preclude use of items whose operating life or shelf life has expired.

Procedures provide for item identification consistent with the planned duration and conditions of storage, such as:

- Provisions for maintenance or replacement of markings and identification records due to damage during handling or aging;
- Protection of identifications on items subject to excessive deterioration due to environmental exposure; and
- Provision for updating existing records. Documentation is provided to show that items released for use are the items specified

9.0 Control of Special Processes

WMG is not a fabricator, If equipment is furnished as a WMG deliverable, the vendor or subcontractor furnishing such equipment is required to provide and implement a Quality Assurance Program covering the criteria of 10 CFR part 50 Appendix B, 10 CFR Part 71 Sub-Part H or ASME NQA-1 as applicable.

Special processes affecting quality of items and services performed by suppliers are documented and controlled by procedures, instructions, drawings, checklists,



travelers, work orders, or other appropriate means to control the processes. These means assure that special process parameters are controlled and that specified environmental conditions are maintained.

Special processes that control or verify quality (i.e., those used in welding, heat treating, and nondestructive examination) are performed by qualified personnel using qualified procedures in accordance with specified requirements, codes, or standards. When the outcome of the process is highly dependent on personal skills, such individuals are certified in accordance with specified requirements. When the outcome is highly dependent on control of process parameters, the process and equipment are pre-qualified in accordance with specified requirements. Special processes are identified and documented that prescribe the necessary equipment, process parameters, calibration, and acceptance criteria.

Completed special processes, when applicable, are reviewed and approved prior to use or continuation of work.

Records are maintained of currently qualified personnel, processes, and equipment for special processes.

10.0 Inspection

WMG currently has no Quality Control inspectors. The inspection function at WMG is accomplished if required through the use of established written procedures and written instructions. The inspection verifies that activities affecting safety and quality have been or are being performed in accordance with the applicable requirements.

Planned inspections are performed, as required, to verify conformance of items or activities to specified requirements. Inspection requirements are specified in written procedures, with provisions for documenting and evaluating the inspection results. Inspection personnel are qualified and documented in accordance with Section 2.0 of this QAPD. Personnel other than those who performed or directly supervised the work being inspected perform inspection for acceptance.

Inspection planning provides for witness hold points to ensure that work does not bypass required inspections. The hold points are established in work controlling documents. Work does not proceed beyond an inspection hold point without specific documented consent of the designated inspection representative.

The planning of inspection activities, methods, and attributes is based on the importance of the item or activity to be inspected; mandatory inspections required by codes, standards, regulatory requirements and commitments; the complexity of the item or activity, and the quality history of the process. Inspection planning includes characteristics to be inspected; responsibility; method; measuring and test equipment; acceptance criteria; and referenced instructions and design documents.



Calibration information in accordance with Section 12.0 of this QAPD for measuring and test equipment utilized during inspections is reviewed and documented prior to use to ensure accuracy of the results.

When a sample is used to verify acceptability of a group of items, the sampling procedure is documented and clearly identifies the sampling basis (typically based on recognized standard/practices).

If inspection of completed work is impossible or disadvantageous, indirect verification by process monitoring is provided. Both inspection and process monitoring are provided, when necessary, to ensure quality.

Final inspections include record review of the results and resolution of nonconformance identified by prior inspections. Acceptance by final inspection verifies conformance of the item to specified requirements.

Modifications, repairs, or replacements of items performed subsequent to final inspection require re-inspection or re-test, appropriate to the circumstances, to verify acceptability.

- Inspection records contain the following, as a minimum:
- Item inspected;
- Date of inspection;
- Inspector,
- Type of observation and inspection plan;
- Results or acceptability, and
- Action taken in connection with nonconformance.

11.0 Test Control

WMG is not a fabricator, If equipment is furnished as a WMG deliverable, the vendor or subcontractor furnishing such equipment is required to provide and implement a Quality Assurance Program covering the criteria of 10 CFR part 50 Appendix B, 10 CFR Part 71 Sub-Part H and ASME NQA-1 as applicable. WMG is a supplier of computer software and has implemented a program to test software and assure compliance with applicable regulations.

Planned tests are performed as required to verify conformance with specified requirements, to demonstrate satisfactory performance, or to collect data. Tests include design verification tests, acceptance tests, pre-operational tests, post-maintenance tests, and operational tests. Planning for tests may include mandatory hold points, as required.

Test procedures contain the following information as appropriate to the test:

- Test purpose or objectives, responsibilities, characteristics to be tested, hold points and test methods to be employed;



- References and related documents;
- Provisions for ensuring that prerequisites for a given test have been met. These include, as applicable: calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, and provisions for data acquisition;
- Adequate instrumentation is available and suitable environmental conditions are maintained;
- Provisions for documenting and evaluating the test results for conformance with acceptance criteria; and
- Qualifications for test personnel.

In lieu of written test procedures, appropriate sections of related documents (i.e., American Society for Testing and Materials methods, external manuals, maintenance instructions, or approved drawings or travelers with acceptance criteria) may be used. Such documents must include adequate instructions to ensure the required quality of work.

Test records contain the following information: item tested, test date, tester or data recorder, type of observation, test procedure, results and acceptability, actions taken in connection with any deviations noted, and person evaluating the results.

Computer Program Testing is carried out in accordance with ASME NQA-1-1994, Basic Requirement 11, Test Control, and Supplement 1IS-2, Supplementary Requirements for Computer Program Testing

12.0 Control of Measuring and Test Equipment

Measuring and Test Equipment (M&TE) used in activities affecting the availability and/or reliability of WMG provided items or services are controlled, calibrated, and adjusted at specified intervals to maintain equipment performance within required limits. Procedures ensure that devices and standards used for measurement, tests, and calibration activities are of the proper type, range and accuracy. Calibration control is not necessary for rulers, tape measures, levels, and other such devices.

A list of devices is established to identify those items within the calibration control system. This identification listing includes, as a minimum, the due date of the next calibration and any use limitations (when it is calibrated for limited use).

M&TE is calibrated at specified intervals or prior to use against equipment having a known valid relationship to nationally recognized standards. If no nationally recognized standard exists, the basis for calibration is documented. M&TE is properly handled and stored to maintain accuracy.

When M&TE is found to be out of calibration, as-found data are recorded and an evaluation is made and documented as to the validity of previous inspection and



test results and of the acceptability of items previously inspected or tested. Out-of-calibration devices are tagged or segregated and are not used until re-calibrated. When M&TE is consistently found to be out of calibration, it is repaired or replaced. Also, calibrations are performed when personnel performing measurements and tests deem the accuracy of the equipment suspect.

Records are maintained and equipment is suitably marked or otherwise identified to indicate its calibration status.

13.0 Handling, Storage, and Shipping

Material and equipment are handled, stored, and shipped in accordance with design, quality assurance, and procurement requirements to protect against damage, deterioration, or loss.

Special coverings, equipment, and protective environments are specified and provided where necessary for the protection of particular items from damage or deterioration. When such special protective features are required, their existence is verified and monitored as necessary to ensure they continue to serve the intended function.

Special handling tools and equipment are provided where necessary to ensure items can be handled safely and without damage. Special handling tools and equipment are controlled and maintained in a manner such that they will be ready and fit to serve the intended function when needed. Such control includes periodic inspection and testing to verify that special handling tools and equipment has been properly maintained. Operators of special equipment are experienced or trained as required.

Attention is given to marking and labeling items during packaging, shipment, and storage. Additional marking or labeling is provided as necessary to ensure that items can be properly maintained and preserved. This includes indication of the presence of special environments or the need for special control.

Special handling, preservation, storage, cleaning, packaging, or shipping instructions are established and used when essential to maintain acceptable quality.

14.0 Inspection and Test

Procedures are established to ensure that the status of inspection and test activities are either marked or labeled on the item or in documents traceable to the item. This activity is required when it is necessary to ensure that required inspections and tests are performed, and to ensure items that have not passed the required inspections and tests are not inadvertently installed, used, or operated.



Status indicators (i.e., physical location, and tags; markings; work controlling documents; stamps; inspection records; or other suitable means) are utilized when required. This includes indicating the operating status of systems and components (i.e., by tagging valves and switches) to prevent inadvertent operation. Authority for the application and removal of tags, markings, labels, and stamps is specified.

15.0 Control of Nonconforming Items

Items and related activities that do not conform to specified requirements are controlled to prevent inadvertent installation or use.

Nonconforming items are identified in a manner that does not adversely affect the end use of the item, by markings, tagging, and other appropriate methods.

Nonconforming items are segregated, when practical, by placing them in a clearly identified and designated area until properly dispositioned. When segregation is impractical or impossible due to physical conditions (e.g. size, weight, or access limitations), other measures are employed to preclude inadvertent use of the item.

Nonconforming items are reviewed and dispositioned as "reject," "rework," "repair," or "use-as-is." Further processing, delivery, installation, or use of the nonconforming item is controlled pending an evaluation and approved disposition by engineering personnel, and documented notification to affected organizations is provided.

The responsibility and authority for the evaluation and disposition of nonconforming items is defined. The personnel performing evaluations to determine the dispositions have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information. The disposition of nonconforming items is identified and documented as required to carry out the disposition.

For items that are "important to safety" the disposition review includes identifying the Part 21 reportability requirements or if NRC approval is applicable.

Technical justification for the acceptability of nonconforming items dispositioned "repair" or "use-as-is" is documented and subject to design control measures as described in Section 3.0 of this QAPD. The disposition process includes consideration of the need for design documents to be "as-built" to facilitate operations, maintenance, or modification. The as-built records, if the disposition determines such records to be required, reflect the accepted deviation.

Repaired or reworked items are re-examined in accordance with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.



Nonconformance documentation identifies the nonconforming item; describes the nonconformance; contains the disposition and any re-inspection requirements; and contains the signature(s) approving the disposition.

16.0 Corrective Actions

Conditions adverse to quality are identified and corrected promptly. In the case of a significant condition adverse to quality, the cause of the condition is determined, and corrective action is taken to preclude recurrence. Significant conditions, their causes, and corrective actions are documented, reported to appropriate levels of management, and follow-up action is taken to verify implementation of corrective actions.

17.0 Quality Assurance Records

The QA records system ensures that records are specified, prepared, and maintained in a manner to provide protection and retrievability. Design specifications, procurement documents, test procedures, operational procedures, or other documents specify the records to be generated, supplied, or maintained.

Records are considered valid when they are complete, identified, authenticated and legible. Documents are considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Lifetime records are entered into record storage after receipt or validation. Temporary storage in approved containers is provided until records are entered into lifetime storage.

Electronically stored QA records have established access controls and are redundant by way of backups to prevent inadvertent use/loss.

Lifetime records are defined in accordance with ASME NQA-1-2008, Part I, Requirement 17, Section 401. In the case of specified records produced by suppliers, an agreement for records turnover is established within procurement documents.

Lifetime records are labeled or marked and retained for the life of the item to which they apply or as required by regulation. An indexing system ensures the record can be retrieved. Storage is in a central location unless the applicable procedure specifies otherwise. Records may be originals, copies, or electronic format.

Nonpermanent records are those required to show evidence that an activity was performed in accordance with applicable requirements. Nonpermanent records are not required to be retained for the life of a particular item. Nonpermanent records are retained by the responsible organization until they are no longer useful. The retention periods for nonpermanent records will be established in writing by the responsible organization.



Corrections to records are approved by the originating organization. The corrections include the date and the identification of the individual authorized to issue the correction.

Custodianship responsibility is assigned for lifetime records storage. Custodianship includes receipt and status control; storage; preservation; and safekeeping using hard copy or electronic document management system.

Storage facilities protect against the risk of loss or deterioration of lifetime records. Hard copy storage facilities meet the requirements of ASME NQA-I -2008, Part I, Requirement 17, Section 601. For electronic storage, backups or duplicate files are generated. Lost or damaged records are replaced, unless deemed impractical with the concurrence of the QA organization.

Single copy records are checked out of storage only if they cannot be copied and then only for a limited period. Temporary protection in such cases is provided by prudent business practices (e.g., record of custody, office environment, and work place security).

18.0 Audits

Planned and scheduled audits are performed by the QAM to verify compliance with the aspects of the QA program and to determine its effectiveness.

18.1. Internal Audits

Internal audits of organizational units performing quality program activities are performed at a frequency commensurate with the status and importance of the activity. Regularly scheduled audits are supplemented by additional audits/assessments of specific subjects. The system of audits and assessments is designed to ensure comprehensive program oversight at least once every five years. The five-year cycle provides for flexibility to maximize effectiveness of QA resources by targeting areas of weakness using supplemental assessments verses using resources auditing areas that are known to be functioning adequately . This flexibility results in more effective quality oversight and use of resources. The proper mix of audit and assessment provides an effective and comprehensive oversight of the QA Program. Audits are conducted in accordance with a documented procedure. A plan is prepared for each audit area to identify the audit scope, requirements, audit personnel, activities to be audited, applicable documents, organizations to be audited, schedule and written procedures or checklists.

The audit area team contains one or more auditors, one being designated lead auditor who prepares, organizes, and directs the audit; coordinates the preparation and issuance of the audit report; and evaluates responses.



Auditors (including technical specialists) have experience commensurate with the scope, complexity, or special nature of the audit. The lead auditor is qualified in accordance with Section 2.0 of this QAPD.

Audits are performed in accordance with checklists or equivalent. Organizations being audited provide access and assistance to the audit team. Objective evidence is examined to determine if the QAP elements are being implemented effectively. Conditions requiring prompt corrective action are reported immediately to management of the audited organization. The results of the audit are discussed with management of the audited organization.

The audit report includes the following information, as appropriate:

- Description of the audit scope;
- Identification of the auditors;
- Identification of persons contacted during audit activities;
- Summary of audit results, including a statement on the effectiveness of the QA program elements audited; and
- Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

Management of the audited organization or activity investigates adverse audit findings, schedules corrective action, including measures to prevent recurrence, and notifies the QA organization in writing of the action taken. Adequacy of audit responses is evaluated by the QA organization and verification of corrective action is documented.

Follow-up action is taken by the QA organization to verify the implementation and effectiveness of the corrective action and to determine if repetitive problems require further corrective action in accordance with Section 16.0 of this QAPD. Audit records include audit plans, audit reports, written replies, and the record of completion of corrective action.

18.2. External Audits

External audits are performed to verify the acceptability of Safety Related/Part 71 applicable suppliers. After the placement of the supplier on the approved supplier list, follow-up audits are performed at a frequency commensurate with the status and importance of the activity, based on evaluations of the supplier's performance.

Third party audits may be used to satisfy the supplier audit requirement, after review and acceptance of the audit records by QA.



Augmented Quality suppliers need not be audited provided their performance continues to be acceptable.

The external audit team contains one or more auditors, one being designated lead auditor who prepares, organizes, and directs the audit; coordinates the preparation and issuance of the audit report; and evaluates responses. Auditors (including technical specialists) have experience commensurate with the scope, complexity, or special nature of the audit. The lead auditor is qualified in accordance with Section 2.0 of this QAPD.

External audits are performed in accordance with checklists or equivalent. Objective evidence is examined to determine if the QAP elements are being implemented effectively. Conditions requiring prompt corrective action are reported immediately to management of the audited organization. The results of the audit are discussed with management of the audited organization.

The external audit report includes the following information, as appropriate:

- Description of the audit scope;
- Identification of the auditors;
- Identification of persons contacted during audit activities;
- Summary of audit results, including a statement on the effectiveness of the QA program elements audited; and
- Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

Follow-up action is taken by the QA organization to verify the implementation and effectiveness of the corrective action and to determine if repetitive problems require further corrective action in accordance with Section 16.0 of this QAPD. Audit records include audit plans, audit reports, written replies, and the record of completion of corrective action.



Matrix of Quality Assurance Requirements

WMG Quality Assurance Plan (WMG-QA-011 Rev. 6)	10CFR50 Appendix B	10CFR71 Subpart H	ASME NQA-1	Applicability of Requirements to WMG Activities
1. Organization	I	71.103	1	✓
2. Quality Assurance Program	II	71.105	1,2,9	✓
3. Design Control	III	71.107	6	✓
4. Procurement Document Control	IV	71.109	7	✓
5. Instructions, Procedures & Drawings	V	71.111	5	✓
6. Document Control	VI	71.113	4	✓
7. Control of Purchased Material, Equipment & Services	VII	71.115	7	✓
8. Identification & Control of Materials, Parts & Components	VIII	71.117	5	✓
9. Control of Special Processes	IX	71.119	5	N/A*
10. Inspection	X	71.121	8	✓
11. Test Control	XI	71.123	8	✓
12. Control of Measuring & Test Equipment	XII	71.125	5,8	✓
13. Handling, Storage & Shipping	XIII	71.127	5	✓
14. Inspection, Test & Operating Status	XIV	71.129	8	✓
15. Non-Conforming Materials, Parts or Components	XV	71.131	3	✓
16. Corrective Actions	XVI	71.133	3,9	✓
17. Quality Assurance Records	XVII	71.135	4	✓
18. Audits	XVIII	71.12	3,10	✓

*WMG addresses this requirement in the QAP and will manage these activities but all special processes are performed by qualified sub-contractors.