Quality Assurance Manual for Low Level Radioactive Waste Disposal Facility

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ABSTRACT

This Quality Assurance Manual which includes the Quality Assurance management plan, QAMP provides the quality assurance requirements for meeting the objectives jointly established by the International Atomic Energy Agency, IAEA and Egyptian Atomic Energy Authority, EAEA for assessing the management of radioactive waste. It is the policy of the Hot Laboratories and Waste Management Center, HWMC and EAEA that all works will be performed to the highest levels of quality commensurate with project requirements. Project-specific quality controls are established to ensure that all activities meet the highest standards of excellence that can be attained within the scope, schedule, and budget established for the project. Quality is defined as satisfying the EAEA in the most resource-efficient manner possible. The quality program must be flexible and adaptable to the needs of the program. Quality assurance provisions are considered a resource to project participants and an asset to the program and are intended to provide verification of good engineering and management practices. Attainment of quality is an integral part of day-to-day activities and is the responsibility of all project participants. It is the responsibility of all participants to understand and adhere to the provisions set forth in this plan.

It will be the EAEA policy to encourage staff to assume project responsibilities at levels where decisions can be most efficiently made and implemented.

1.0 INTRODUCTION

1.1 Purpose and Objectives.

This Quality Assurance Management Plan (QAMP) documents the requirements and approach for implementation of appropriate quality assurance (QA) provisions for the radioactive waste management project. The specific objectives of this document are to (1) define the QA requirements for the technical activities to be performed, (2) provide guidance for the development and implementation of subordinate QA plans and procedures, and (3) provide the means to measure and report the degree of success attained in meeting quality objectives.

It is expected that revisions of the work scope may occur during the course of project activities. It is intended that this QAMP be a living document that is closely integrated with project planning. As a work scope is adjusted to reflect schedule adjustments, resource limitations, or other scope changes due to programmatic considerations, changes or revisions of project QA requirements that result will be accomplished by revisions of this QAMP and its subordinate quality plans.

1.2 Scopes and Applicability.

This QAMP meets the general intent and spirit of radioactive waste management policies of EAEA, standards and policies of IAEA, and other referenced guidance. This QAMP applies to all EAEA Project participants, including management, staff, EAEA other organizations and EAEA subcontractor employees. Any questions regarding specific implementation requirements shall be referred to the HWMC QA Coordinator for resolution.

1.3 Definitions.

The following are definitions of terms used in this QAMP applicable to the Project.

Activity. Continuing efforts that do not have a start or end date and which may occur in a number of tasks, and over the life of the Project such as, Calibration of survey instruments and control of measuring and test equipment.

Deliverable. An item (quarterly monitoring report, annual inventory report, etc.) that has been formally scheduled for creation and release by the EAEA such as, the Annual Report on the status of the radioactive waste management project.

Document. Any written information that defines, describes, or reports activities, procedures, and results related to the radioactive waste management Project.

Documents do not become Project records until finalized and entered into the Records Center.

Controlled Document. Critical project documents require controlled and accurate distribution of the latest revision. They are typically "living documents" which are maintained and periodically revised to reflect the latest scope of all activities addressed by the document. Example for controlling documents might include procedure for calibrating instruments or inventory reports.

RadWaste Project Management. A collective term used to refer to the EAEA, radioactive waste management Project Manager, HWMC Manager, and the RadWD Leader.

Plan. A document that describes what will be accomplished or controlled and corresponding requirements. Planning documents can include QA plans, project plans, task plans, test plans, analytical plans, etc..

Procedure. An implementation document that provides detailed instructions regarding how requirements specified in a plan are to be implemented. Examples include QA procedures and instrument calibration procedures. Procedures closely tied to technical plans.

Quality. Satisfying EAEA requirements and expectations in the most resource-efficient manner.

Quality Assurance. All those planned and systematic actions necessary to provide adequate confidence those requirements are being met throughout the life of the Project.

Record. Document, entered into the Record Center (not necessarily a controlled document) that includes appropriate review and approvals and describes activities related to Project tasks.

Records Center. A centralized records storage system that provides for the housing of records in one location. Centralization provides a uniform approach to the records system. All records are stored by the same rules and retrieved by the same procedures.

Task. An identified set of activities that have a definite start and end date, and that prescribe efforts needed to provide information and input to follow-on tasks. Tasks will typically be defined for each fiscal year and will be included in the project Work Breakdown Structure.

2.0 RadWaste Project Organization

The EAEA shall be responsible for the establishment and execution of the quality assurance program. The EAEA may delegate to others such as Ministry of Health, Ministry of Environment or consultants like IAEA and SNL, the work of establishing and executing the quality assurance program or any part of quality assurance program, but shall retain responsibility for the program. The EAEA shall clearly establish and define, in writing the authority and duties of persons and organizations performing activities affecting the safety related functions of structures, systems and components. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

The quality assurance functions are:

1. Assuring that an appropriate quality assurance program is established and effectively executed
2. Verifying, by procedures such as checking, audits, and inspection that activities affecting the safety functions have been performed.

The persons and organizations performed quality assurance functions must have sufficient authority and organizational freedom to

1. Identify quality problems
2. Initiate, recommend or provide solutions
3. Verify implementation of solutions

A current listing of the specific tasks and responsible staff along with detailed discussions of specific responsibilities and authorities are provided in the radioactive waste management Project Plan. The following subsections provide a summary discussion of the roles, responsibilities and authorities of project participants specific to QA requirements outlined in this QAMP.

2.1 All EAEA Project Participants. Responsibility for quality resides with each and every program participants.

2.2 Hot Laboratories. and Waste Management Center Director. Unless he delegates such authority to a staff member in center, the HWMC Director is officially the project manager for all projects in the center. He is responsible for ensuring that adequate resources and personnel are available to perform the work required and to ensure timely completion of Project activities. The HWMC Director ensures that all Project participants comply with the technical requirements of the

Project and the QA requirements of this QAMP and its subordinate plans and procedures. The HWMC Director consults with the RadWMD Leader, Task Leaders, Subtask Leaders, and QA Coordinator to resolve problems, conflicts, or disagreements.

2.3 Radioactive Waste Management Division Leader. The RadWMD Leader is appointed by the HWMC Director and is delegated the responsibility and authority for the overall management, planning, and conduct of the activities for the Project. He is responsible for developing and maintaining the Project Plan (this task is delegated to the Project Management Task Leader). The RadWMD Leader interfaces closely with Task Leaders, Subtask Leaders and the QA Coordinator to ensure the quality of technical efforts and to resolve any conflicts or disagreements concerning interpretation or implementation of Project requirements. The RadWMD Leader is the primary interface with the EAEA Project Manager and interfaces closely with other EAEA contractors involved with the Project to ensure coordination of efforts common to the radioactive waste management project.

2.4 Task Leaders. Task Leaders are selected by the HWMC Director and the RadWMD Leader and have overall responsibility for the technical adequacy and quality of the activities involved for their respective tasks. Task and Subtask Leaders must define the technical details of their respective portions of the Project and may consult with the QA Coordinator to develop and implement the applicable set of QA requirements associated with their tasks. Task and Subtask Leaders closely coordinate efforts with other EAEA contractors, interfacing with their technical staff, the HWMC Project Leader, and/or contractor management as appropriate to accomplish joint efforts.

2.5 Technical Staff. Technical Staff interface closely with Task Leaders and, as appropriate, the QA Coordinator to understand Project requirements and to effectively resolve problems and questions regarding implementation of the QA provisions for radioactive waste management project. Technical staffs that conduct specific subtask activities related to the Project are responsible for identifying and adhering to subtask quality requirements.

2.6 QA Coordinator. The QA Coordinator is appointed by the HWMC Director and reports to the RadWMD Leader. The QA Coordinator is responsible for the development and maintenance of the QAMP and assists in the development of appropriate QA controls throughout the project, verifies adherence to those controls,

and keeps Project Management abreast of progress and of any problems or difficulties encountered. The QA Coordinator is delegated the responsibility, authority, and access to work areas and project documentation to ensure that appropriate QA provisions are established and effectively executed.

2.7 Other Organizations. Other Egyptian organizations that work with EAEA or provide technical support to the EAEA. The individuals in those organizations report administratively to their line management but technically to the RadWMD Leader. When performing work for the Project, other organizations such as (The Egyptian Ministry of Health or Egyptian Ministry of Environment etc.) shall comply with the requirements of the radioactive waste management QA program.

2.8 EAEA Contractor Employees. Outside organizations may be contracted to provide services for specific Project activities. These contractor employees report administratively to their line management but technically to the RadWMD Leader. EAEA contractor employees shall perform Project activities in accordance with terms spelled out in EAEA contract documents. The requirements of this QAMP shall be specified, as appropriate, in the Statement of Work for EAEA contracts and shall be adhered to by all contractor personnel.

3.0. Organizational Interface

It is vital that all people and organizations concerned in the radioactive waste management project have a clear understanding of their own interfacing responsibilities and limits of operation and control and also those of others. Such an understanding can be achieved by definition of responsibilities. Where internal interface occurs, the organization should clearly identify them within its QA program, possibly in the documentation/procedures for a particular activity. Where external interfaces occur, they should be identified and agreed upon and care should be taken to ensure that responsibilities have been clearly defined in appropriate documents such as purchase orders, specifications and contracts. Correct interface recognition and definition of responsibility enable one organization or part of an organization to pass on a package or design knowing not only that its responsibilities and actions have been fully completed but also that the recipient of that package or design understands clearly what has or has not been done. Within a large organization like EAEA, correct definition and understanding of interfaces can prevent for example, a package being dispatched before all the necessary checks such as package closure, leak testing or labeling have been completed. Similarly failure in design can result from

inadequate communication between the designer and user, with a package not meeting specific or regulatory requirements during test or use. This may occur because both parties have assumed, but not confirmed, that all necessary requirements have been taken into account by the other party in their interfacing activities. Interfaces between groupings such as design, testing and manufacture or user, carrier, storage operator, disposal operator and conditioning unit will frequently occur however, other more infrequent interfaces should not be overlooked as these often create or add to problems and misunderstandings in radioactive waste management processes.

4.0 QA Program Overview

The radioactive waste management QA program has been kept as simple, brief, concise, and clear as possible. Use of existing procedures and standards have been referenced, when appropriate. The QA Program emphasizes the following concepts and activities:

1. A preventive approach that stresses plans and reviews early in the program rather than corrective actions later.
2. A flexible program is based on a modular structure for ease of adaptation to changes in direction and scope that the Project may take.
3. Project planning, documentation, control of testing and data quality, software, technical/peer and management reviews, and change control are the primary emphasis of project technical activities.
4. Training, document control and records management, reporting (deliverable) requirements, identification of nonconformance and corrective action, and surveillance and quality reviews.
5. Calibration and control of measuring and test equipments, measures should be established for ensuring that measurement and test equipment are calibrated, adjusted and maintained at prescribed interval or prior to use.
6. Record management, the QA program should include written procedures for identifying, collecting, indexing, filing, storing, retrieving and disposing of pertinent records.
7. The RadWMD Leader and Task Leaders identification of QA requirements and development, with the assistance of the QA Coordinator, of task planning and QA documents tailored to the needs of their respective portions of the technical program.

5.0 Technical Control Provisions

This section describes the "core" of the quality assurance control provisions as they apply to the majority of Project activities. This section emphasizes elements, which, together, comprise good engineering and management practices. Project planning is one of the most important requirements for effective problem definition and for providing the desired approach to achieve Project objectives. Other major activities in this process important to the Project include instrument calibration, records management database.

5.1 EAEA Project Planning. The EAEA Project Manager is expected to provide an overall project plan that defines the technical requirements and objectives; project participants and their roles, responsibilities, and interfacing methods; budget and schedule considerations; and expected milestones and deliverables.

5.2 HWMC Planning Documents. All Project activities shall be appropriately planned as provided below. All project-planning documents are "living documents" and shall be revised and updated in the event of significant shifts in Project status.

5.2.1 Radioactive waste Management Project Plan. The Project Plan encompasses the technical and quality requirements for the entire Project. It establishes the basis for all subordinate planning, implementation, and assessment activities for the program. The Project Plan discusses the project management plan details, project organization, communications, the project work breakdown structure, schedule and cost control provisions, milestones and deliverables, and other general and pertinent information. It is a "living document" that is periodically updated as work progresses.

5.2.2 Quality Assurance Management Plan (QAMP). Like the Project Plan, the QAMP is a living document that provides overall QA requirements for all tasks, activities and procedures related to the Project. The QAMP applies to all HWMC project management and staff, EAEA other organizations, and EAEA contractors working on the radioactive waste management Project..

5.2.3 Technical plans and procedures. RadWMD Leader is responsible for preparing Task Plans that are responsive to the requirements of higher-level planning/requirements documents. The Task Plan is meant as a vehicle for communication and to focus and review the task activities. This plan shall specify requirements (both technical and quality), outline the approach and strategy for

accomplishing the work, specify the requirements for periodic project reviews and define the requirement for, and scope of, any detailed technical plans and procedures. Applicable QA plans and procedures may be incorporated into Task Plans by reference. Task Plans are "living documents" and may be revised periodically to reflect changes in project direction or scope. Example of task plan might include: instrument maintenance and calibration, recovery, treatment, conditioning, and storage of radioactive waste and Record Management.

5.2.4 QA Procedures. QA Procedures are implementation documents that provide detailed requirements regarding how the QA requirements specified in QA plans or Task Plans will be met. QA procedures (QPs) are generated where detailed implementation guidance is required; examples include procedures for calibration of a particular type of survey instrument or conducting specific type of leak testing. QA procedures are implementation documents that provide detailed requirements and steps to follow, including prerequisites, to ensure that the conduct of specific technical activities is controlled, repeatable, and documented

5.2.5 Preparation, Review and Approval. *HWMC Planning Documents*. Task Leaders are responsible for the preparation of Task plans and QA procedures. Preparation may be delegated to members of technical staff who are familiar with the technical requirements and who may actually perform the work. Task Leaders should consult with the QA Coordinator to develop and implement the QA requirements for their respective tasks. All plans and procedures shall be reviewed and approved by appropriate Project Management and staff and signature blocks shall be provided on the title page. Revisions to plans and procedures are subjected to the same review and approval process as the original documents. HWMC Task Leaders are responsible for identifying HWMC -prepared plans and procedures that may affect the activities of other EAEA contractors and for ensuring that appropriate informal reviews are obtained from the affected organizations.

Quality Assurance Program

1. Organization

1.1 This section identifies the function organization and assigns the responsibility to assure effective execution of the Hot Labs. Waste Facility HLWF Quality Assurance program (See Appendix D)

1.2 The director of HLWF has full authority over Center functions and delegate authority and responsibility for selected functions to other personnel or organizations.

1.3 The Quality Assurance Manger is vested with the authority and responsibility to ensure that activities affecting quality are performed and documented correctly to the established requirements.

1.3.1 The quality Assurance Manager is vested with the organizational freedom and responsibility to:

- ❖ Identify quality problems
- ❖ Initiate, recommend or provide solutions to quality problems through designated channels.
- ❖ Verify implementation of solutions.
- ❖ Stop unsatisfactory work or further processing, delivery, installation or use of material until proper disposition of a nonconformance, deficiency condition has accrued.

1.4 The Quality Assurance Manger shall have sufficient expertise in the quality discipline to direct the quality functions as appropriate to the established requirements. The quality Assurance Manager's responsibilities include the development, implementation and administration of the quality program and supporting procedures.

1.5 Activities involving radioactive material are controlled as a joint effort by health physics, health & safety and quality control personnel.

1.6 Qualified personnel perform monitoring activities and verification of regulatory, contractual and/or technical requirements in accordance with health physics, health & safety and/or quality procedures.

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2. Quality Assurance Program.

2.1 The HLWF Quality Assurance program complies with the intent of the IAEA recommendations, NRC regulations, 10CFR50, Appendix B, 10CFR71, Subpart H and NCNSRC regulations as appropriate to the activities performed by HLWF personnel. Corporate policies are defined herein and in those procedures written to further delineate the methods of implementation and compliance.

2.2 The program provides for the graded application of quality requirements to quality related activities in the operation and maintenance of equipment and services supplied to the nuclear industries. This is accomplished by insuring that written procedures and/or instructions are in place before engaging in these activities.

2.3 Individuals responsible for quality function are trained and /or evaluated in accordance with written procedures, regulations, appropriate standards and requirements of the radioactive materials license. These individuals are approved and certified by the Quality Assurance Manager or designee as required. The HLWF Quality Assurance program assures compliance with the quality requirements of engineering specifications, regulatory guidance and specific provisions of contractual agreements. Personnel performing special process shall be trained/certified in accordance with applicable procedures and/or instructions.

2.4 Activities affecting quality shall be accomplished under suitably controlled conditions and according to documented procedures/instructions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions such as cleanliness, and assurance that prerequisites have been established.

2.5 Any Controversies involving quality that arise from a difference of opinion shall be elevated to the division managers for resolution or to the center director if all other efforts are unproductive.

3. Design Control

HLWF does not currently engage in design activities affecting quality. HLWF will implement the following quality requirements (as applicable) should design activities become necessary.

3.1 Design activities shall be properly planned, documented and controlled in accordance with approved procedures.

3.2. Procedures/instructions are developed, approved and implemented to assure that the applicable technical requirements such as design bases, regulatory requirements and customer specifications for systems, structure and components are correctly translated into specifications, drawing or checklists.

3.3 Design review shall be controlled in such a manner to assure that the following occur:

- Regulatory and design requirements are correctly translated into specifications, drawings, procedures or checklists.
- Design document or quality/safety requirements as applicable
- Deviations from design or quality/safety requirements are controlled.
- Design verification is performed by personnel independent of the design activity. These verifications may include tolerance studies, alternate calculations or test.
- Interface control is established and adequate
- Design error and deficiencies are documented and corrective action is taken to prevent their recurrence.

3.4 Revision and/or changes to design documents or specifications shall be reviewed and approved by the same level or higher that performed the original review.

4. Procurement Document Control

Purchased material, components, assemblies and services become part of the EAEA's products. The quality of services such as calibration and special processes should be considered. The procurement of supplies should be planned and controlled. The purchasing procedures should include measures specification, drawing elements applicable.

4.1 Procurement activities are performed in accordance with approved procedures that implement the applicable requirements define in this QA program.

4.2. Procurement documents shall identify the scope of work, technical requirements, quality/safety program requirements, right of access inspection and test requirements, special process requirements, documentation requirements and reporting and disposition of nonconformance as applicable to the item or service being procured.

4.3 Quality related purchase orders and request for quotes shall include requirements as applicable such as:

- Identification of the quality requirements for inspection and control, acceptance and rejection criteria, program and/or customer requirements and invoking standards and codes (i.e. 10 CFR 21).
- Material information such as size , type and grade.
- Basic technical requirements such as specifications, drawings, codes, industrial standards, hold points, inspections or tests.
- Documentation requirements such as inspection records, test records or certification documents
- A statement that allows QA personnel or designee to have the right of access to supplier facilities for sources inspection and/or audit activities as appropriate.

4.4 Quality related purchase orders and requests for quotes shall be reviewed prior to release by qualified management, health & safety, QA personnel or designee to assure compliance with the applicable section of the QA manual and procedures.

4.5 Changes to procurement documents shall be subject to the same review and approval as the original documents

4.6 Procurement documents may require an adequate Quality assurance program be in place.

5. Procedures, Instructions and Drawings

5.1 Activities affecting quality shall be accomplished in accordance with QA approved written procedures, instructions and/or drawings as appropriate to the activity being performed.

5.2 Procedures, Instructions and drawings shall contain appropriate quantitative and/or qualitative acceptance criteria (including record keeping requirements) for determining that important activities have been satisfactorily accomplished.

5.3 The documents when applicable will reference related codes, standards, specifications, customer requirements and/or procedures.

5.4 The approved documents shall be made available to personnel responsible for the specified activity.

6. Document Control

Documents such as procedures and instructions should be prepared to implement the requirements of QA program. All documents used to implement the QA program, as well as the program itself need to be formally controlled and arrangements made for their preparation, approval, issue and review.

6.1 The requirements for quality document review, approval, release and change control are delineated in written procedures and provide for review, approval and issuance of documents. Document control responsibilities and requirements are also addresses.

6.2 A document is controlled if it is on the EAEA Document control list and is marked as controlled.

6.3 Controlled documents shall be reviewed within three years of isse or revision whichever is later.

6.4 Changes to documents shall be reviewed and approved by the same level or higher, that performed the initial review and approval. Changes may be made to documents by a department or individual specifically selected by original reviewers.

6.5 A list of control documents is maintained delineating the title, number and current revision for drawings, procedures and specifications, which require Quality Assurance approval.

6.6 Controlled distribution of documents affecting quality activities shall be accomplished by the use of distribution logs and transmittal forms or by other means of positive receipt acknowledgement.

6.7 A document release and distribution system shall be established utilizing up-to-date distribution lists. Measures shall be provided for ensuring that those participating in an activity are aware of and use appropriate and correct documents for performing the activity.

6.8 The control measures shall include the identification of all individuals or organizations responsible for preparing, reviewing, approving and issuing documents related to activities affecting quality.

7. Control of Purchased Items and Services

7.1 Control of purchased items and services shall be performed in accordance with approved procedures.

7.2 Suppliers of Quality related items or services are evaluated by qualified personnel to assure supplier acceptability. These evaluations are based on one or all of the following criteria:

- The supplier's capability to comply with the applicable requirements of this program and/or the material or service specifications
- A review of previous records and performances of supplier
- An evaluation of the supplier's facilities and QA program to determine his capability to supply a product or service, which meets the design, manufacturing and quality requirements.

Results of all supplier evaluations are recorded and retained in the QA files.

7.3 technical and quality assurance evaluations are not required for any of the following conditions.

- The supplier is currently on the approved supplier list for similar items or services.
- The supplier is a nationally recognized manufacturer of test equipment and related calibration services and calibration services are verified by HLWF prior to use of the equipment.
- The supplier is a regulatory agency or a nationally recognized standards laboratory such as the Egyptian National Institute of standards and Calibration or EORP office.

7.4 Items and services shall be controlled, monitored (surveilled) and verified upon receipt by qualified personnel to assure conformance with procurement documents in accordance with Section 10.

7.5 Surveillance of the supplier's activities shall be performed when determined necessary by the quality Assurance Manager or designee. The extent or need of surveillance activities by HLWF at the suppliers location, is dependent on the following conditions:

- The complexity or uniqueness of the items and its importance to safety.

- The need for special controls and surveillance is performed on those items where verification of procurement requirements cannot be determined upon receipt.
- The degree to which functional compliance can be demonstrated by receipt inspection and test
- The availability of quality history or the degree of standardization of identical items.

7.6 For commercial off-the-shelf items, where specific quality assurance controls for nuclear applications cannot be imposed in a practical manner, additional quality verification requirements shall be performed to the extent necessary to verify acceptability of the item to procurement document requirements.

7.7 An approval Suppliers List (ASL) shall be maintained by Quality Assurance. Purchasing shall be provided a current copy of the ASL.

7.8 Documentary evidence that purchased material and equipment conform to the procurement documents shall be available at the HLWF before installation or use. This evidence shall be sufficient to identify all requirements met by the purchased items.

8. Identification and Control of Material, Parts and Components

Measures shall be established for the identification and control of items including partially fabricated assemblies as required throughout fabrication, erection, installation and use. These identification and control measures shall be designed to prevent the use of incorrect or defective materials, parts and components.

8.1 The identification and control of material, parts and components shall be in accordance with approved procedures, instructions and/or checklists to assure that identification is maintained, either on the item or records traceable to the item to preclude use of incorrect or defective items.

8.2 when required by applicable specifications the identification of materials, parts and components shall be traceable to the appropriate documentation, such as drawings, purchase orders, inspection documents, nonconformance reports and physical and chemical test reports.

8.3 The procedures shall identify the appropriate criteria and responsibilities in order to assure the correct identification of items is verified and documented in accordance with section 10 of this QA program.

8.4 Identification requirements shall be established when applicable during the generation of drawings and specifications to assure that the location and method of the identification is not detrimental to the material and does not affect the form, fit function or quality of the item.

8.5 These measures ensure that identification of the item is maintained by batch number, part number, serial number etc on the item or records traceable to the item as required.

9. Control of Special Processes

Processes affecting quality such as used in design construction, fabrication, testing, commissioning and operation of a Waste Facility shall be controlled in accordance with specific requirements.

9.1 Special process such as nondestructive examination, chemical cleaning, welding, heat-treating, waste processing and others as required by applicable codes, standards, specifications and contract requirements shall be delineated in approved procedures that assure control of the processes.

9.2 Special process procedures, equipment and personnel shall be qualified for conformance to applicable codes, standards and specifications.

9.3 Qualification records of special process procedures, equipment and personnel shall be established and maintained.

9.4 When special processes are subcontracted, HLWF procurement documents shall require the supplier to submit special process procedure qualification data to HLWF for review. Selection and control of subcontractors shall be in accordance with Section 7 of this QA program.

9.5 These measures shall be established and documented to ensure that these processes are accomplished by qualified personnel, using qualified procedures and equipment.

10. Inspection

To verify conformance to the documented instructions, procedures and drawings a program for inspection of items and services and the activities shall be established and executed by Egyptian Atomic Energy Authority.

10.1 Inspection and surveillance personnel shall have been appropriately trained, qualified and certified as required by the discipline manager responsible for the activity being performed. Inspection personnel qualifications are

reviewed and approved by Quality Assurance Manager or Designee, prior to the inspection activity.

10.2 Inspection and surveillance activities for receipt source and in process shall be performed in accordance with approved procedures. The inspection process shall be documented on approved checklists or procedures containing sign off steps, which delineate the acceptance criteria for the items being inspected.

10.3 Personnel assigned to perform quality assurance are persons other than those who perform the activity being inspected and report directly to the Quality Assurance Manager, corporate EHS&QA or the Director.

10.4 Inspection personnel qualifications are based on their capability to perform the required inspection function in accordance with applicable codes, standards, experience and EAEA training programs. Qualification reviews are performed periodically to maintain personnel proficiency and to ensure current qualification.

10.5 Inspection and test records shall as a minimum identify the inspector or data recorder, the type of observation, the results, the acceptability and the action taken in connection with any deficiencies noted.

10.6 Such inspection shall be performed by individuals other than those performing the activities being inspected.

11. Test Control

A test program shall be established to ensure the identification, performance and documentation of all testing required to demonstrate that the structures, system and components will perform satisfactorily in service. The test programs shall cover all required tests and include as appropriate, procedure and equipment qualification tests prototype qualification test, proof tests before installation, pre-operational, and start-up tests and operational tests.

11.1 The control of tests shall be in accordance with approved procedures or instructions that provide for the following:

- The requirements and acceptance limits contained in applicable test specifications, designs, procurement documents and customer contracts as applicable.
- Instructions for performing the test.

- Test prerequisites such as calibrated instrumentation, required test equipment and instrumentation (including their accuracy requirements) suitable and controlled environmental conditions and provisions for data collection and storage.
- Acceptance and rejection criteria
- Methods of documenting or recording test data and results
- Provisions for assuring test prerequisites have been met.
- The test results shall be documented and evaluated to assure the test requirements and acceptance criteria have been satisfied.
- Test personnel shall have appropriate training and qualifications for the level of testing being performed.
- Testing records and records of training shall be maintained as quality records.

11.2 Subcontractors performing tests for HLWF shall be evaluated for acceptance by Quality Assurance for capabilities to perform the test. The subcontractors test procedures shall be evaluated to insure hey are adequate for both performance and control.

12. Control of Measuring and Test Equipment

Testing and measuring devices used in activities affecting quality shall be controlled, calibrated and adjusted at specified intervals or before use to maintain accuracy within necessary limits.

12.1 Administration of the calibration of measuring and test equipment and instrumentation is delineated in procedures and approval by Quality Assurance. The calibration system assures that all measuring and test instrumentation, used in the acceptance of material, equipment and components is calibrated properly at specified intervals and are traceable to national standards (when required) to maintain accuracy within predetermined limits. Calibrated equipment must be identified and traceable to the calibration test data.

12.2 approved procedure provide detailed requirements for the control of calibration inspection and required documentation for measuring and test equipment.

12.3 When measuring and test equipment are found to be out of calibration, an evaluation shall be made and documented of the validity of precious

inspection or test results and the acceptability of items previously inspected or tested.

12.4 Records of calibration of measuring and test equipment shall be maintained as quality records in accordance with Section 17.0 of this QA program.

13. Handling, Storage and Shipping

13.1 Approved procedures and/or instructions shall be established to describe the controls necessary for handling, packing, storage, cleaning and shipping of materials, components and systems as required by design and procurement specification requirements to preclude damage, loss or deterioration.

13.2 Special handling, preservation, storage, cleaning, packaging and shipping requirements shall be established by qualified individuals in accordance with predetermined work and inspection instructions and/or industry practice.

13.3 Special handling tools and equipment shall be inspected and tested in accordance with written, approved procedures, and at specified time intervals, to verify that the tools and equipment are adequately maintain.

13.4 Measures shall be established and documented to control handling, storage and shipping including cleaning packing and preservation.

14. Inspection, Test and Operation Status

Test and inspection status of individual items of the HLWF shall be identified by the use of marking, stamps, tags, labels, routing cards, inspection records, physical location or other suitable means that can indicate the acceptability or nonconformance of items with regard to tests and inspections performed.

14.1 HLWF personnel shall be provided with training in procedural requirement to assure their awareness and understanding of status tag usages. Status tags placed on items by quality Assurance may only be removed by Quality Personnel.

14.2 The status of nonconformance, inoperative or malfunctioning structures, systems and components shall be documented and identified to prevent inadvertent.

14.3 Procedures shall be established to assure that items accepted released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for further work, operation or installation.

15. Control of Nonconforming items

Non-conformance may occur when an item, operation or service does not comply with specification or applicable working procedures. Such procedures should clearly identify responsibilities for reviewing non-conformance and the use of non-conformance forms and may provide examples of markings to be non-conformance items. The non-conforming items should be segregated, wherever possible, from conforming items and adequately identified to prevent further use until the appropriate action is taken. Similarly, non-conforming operation or services should be suspended until appropriate decisions are made.

15.1 Procedures shall be established to describe the identification, documentation, segregation, review, disposition and notification to affect affected organizations of nonconforming items, materials, systems, parts and components. Procedures shall be developed to insure the requirements of 10 CFR 21 are followed when they are applicable.

15.2 Nonconforming items shall be dispositioned as “use-as-is”, “reject”, “repair”, “rework”, or “return to vendor”.

15.3 Nonconforming items shall be dispositioned as “use-as-is”, or “repair” shall include technical justification to indicate and assure continued compliance with design, regulatory and contractual requirements.

15.4 Items dispoistioned as ‘rework’, “repair”, or replacement items shall be inspected and tested in accordance with the original inspection and test requirements or acceptable alternatives which are in compliance with the specified acceptance criteria.

15.5 Nonconforming items shall be dispositioned as “use-as-is”, or repair’ shall be reported to the purchaser when contractually required by procurement documents or other documents such as specifications.

15.6 To ensure control, these nonconforming items shall be marking by tagging and/or by physical segregation where practical.

15.7 All employees are responsible for notifying their supervisor and/or QA personnel of any nonconforming conditions.

16. Corrective Action

The implementation of corrective action begins with the detection of a quality related problem and requires measures to eliminate a problem or to minimize its

recurrence. The responsibility and authority for instituting corrective action should be defined as part of the QA program.

16.1 Procedures shall be established to identify and correct conditions adverse to quality and provide measures to prevent recurrence.

16.2 A condition adverse to quality such as a nonconformance, failure, malfunction, deficiency, deviation, defective material or equipment shall be documented and corrected as soon as practical after the condition has been determined.

16.3 Significant conditions adverse to quality, including the cause of the condition and the corrective action shall be documented to preclude repetition and reported to the responsible manager. For the purpose of this section, a significant condition adverse to quality may be defined as but not limited to unsatisfactory quality trend, bypassing of required inspections, test or other critical operations, a significant deficiency as defined by 10 CFR 50.55 (e) or a defect or failure a defined by 10 CFR 21.

16.4 Timely follow-up action shall be taken to verify proper implementation and closeout of the required corrective action.

16.5 A summary report of the status of corrective action reports shall be periodically prepared by the Quality Assurance Manager and submitted to the HLWF Manager for review.

17. Quality Records

The QA program should include written procedure for identifying collecting, indexing, filing, storing, maintaining, retrieving and disposing of pertinent quality documentation and records. The records should adequately demonstrate the achievement of the required quality of the product or service. Quality assurance standards require that certain activities be documented, such as management reviews, audits and non-conformances.

17.1 Procedures shall be developed identifying documents, which are considered quality records. The quality records system assures that documented evidence pertaining to quality related activities is maintained and available for use by HLWF and regulatory agency as applicable.

17.2 Quality records are completed documents providing evidence of activity completion as required by procedural requirements.

17.3 Records are divided into two categories, lifetime and permanent. Lifetime records are those records, which provide evidence that critical operations, or activities are performed and documented in accordance with prescribed procedures. Non-permanent records are retained as appropriate by procedures and/or regulations. The Quality Assurance Manager or Designee shall have the responsibility for maintenance of the lifetime and non-permanent records.

17.4 Records shall be indexed, filled and maintained in facility that provide a suitable environment to minimize deterioration or damage and to prevent loss subsequent to completion of work, during the specified retention time or until transferred to General Record Center as required by applicable codes, standards and procurement documents.

17.5 Protection for QA records is provided by using one of the following storage methods:

- Two sets of identical records are maintained at separate storage locations or
- The official copy of all Qa records is maintained in approved fireproof files or vault at a single location.

17.6 Customer procurement documentation and/or other documents may require a specified retention time for records of a specified work scope or contract.

17.6 The following are examples of the types of quality records which may require control:

- Inspection reports
- Test data
- Qualification reports
- Validation reports
- Audit reports
- Material review reports
- Calibration data
- Fabrication records
- Servicing records
- Maintenance records
- Consignment documents

- Training records
- Radiation monitoring reports
- Package approval certification
- Management review reports
- Contract review records.

18. Audits

Establishing the requirements for QA to conduct audits and surveillances of transportation, conditioning, storage and packaging of HLWF. Defines the requirements and provides the procedures of the programming and scheduling of the internal and external QA audits.

18.1 Procedures shall be established to provide for a comprehensive system of planned and documented audits including audits of suppliers and internal audits and site activities to verify compliance with the applicable aspects of HLWF Quality assurance Program and to determine the effectiveness of the program.

18.2 Audits shall be scheduled in a manner to provide coverage and coordination with ongoing Quality assurance program activities commensurate with the status and importance of the activity. All elements of the HLWF Quality Assurance program shall be audited at least annually.

18.3 Area found deficient during audits are reaudited on a first priority basis to verify corrective action implementation and effectiveness.

18.4 Audits shall be performed in accordance with pre-established written procedures using checklists and conducted by training and certified personnel having no direct responsibilities in the areas being audited. Objective evidence shall be examined for compliance with quality assurance requirements.

18.5 Audit results shall be documented by auditors and shall be distributed to and reviewed by management having responsibility in the area being audited.

18.6 Follow-up action shall be taken to verify that deficiencies noted in the audit have been corrected.

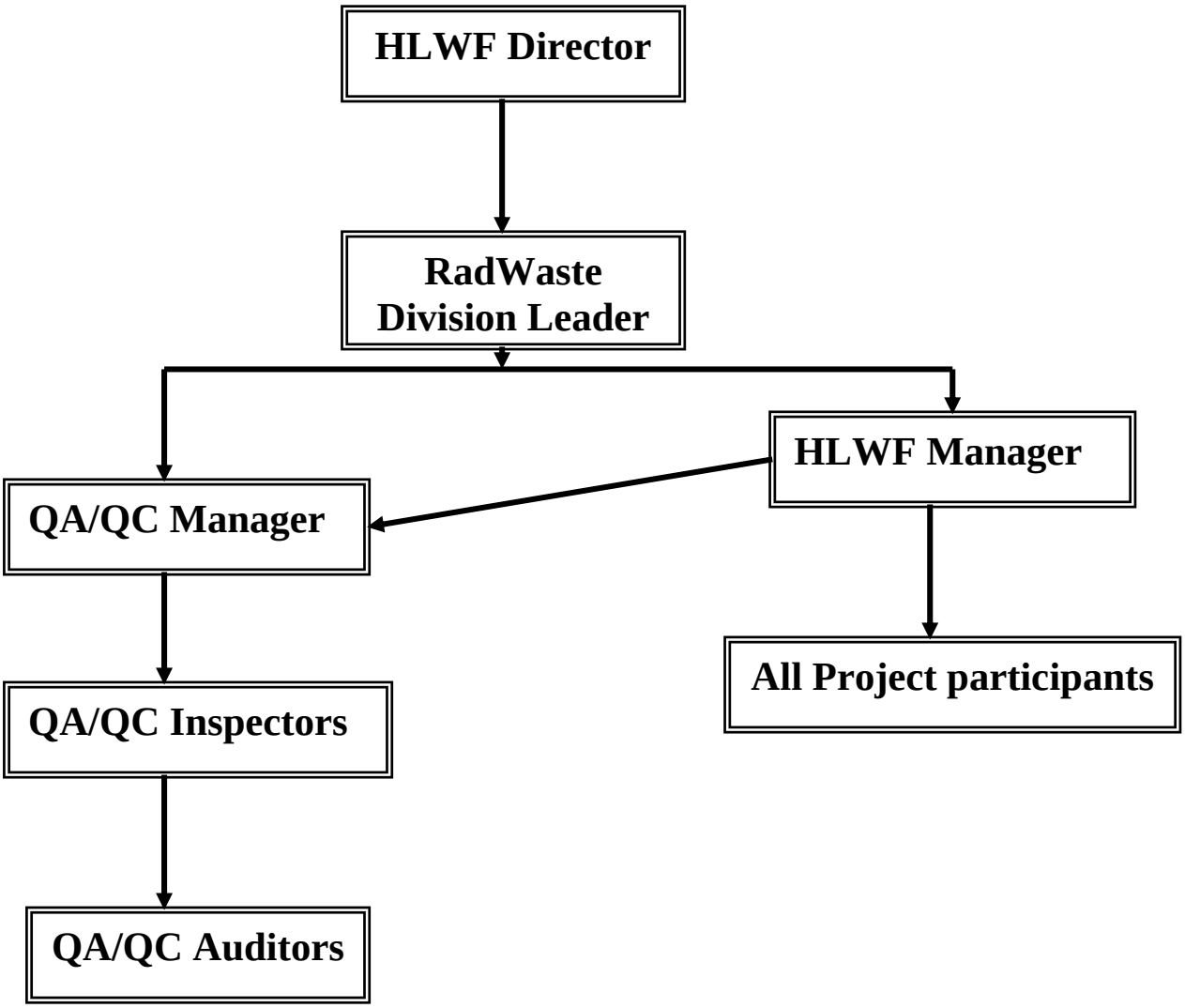
18.7 Quality Assurance Management Audits shall be performed to determine the effectiveness of functions for which quality assurance personnel are responsible.

Glossary of Terms.

- **Approval** – The act of endorsing or authorizing an action, document or related activity. As used in this manual, approval requires a signature and date.
- **Audit**- A planned and documented activity performed to determine by investigation, examination or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings and other applicable documents and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.
- **Certification** – The act of determining, verifying and attesting in writing to the qualifications of personnel, processes, procedures or items in accordance with specified requirements.
- **Controlled Documents** – A document is controlled if it is on the HLWF Document control list and is marked as controlled.
- **Criteria** – Technical requirements describing performance objectives, operating conditions and requirements, limitations regarding materials, compliance with codes or standards and any technical requirements for design fabrication, installation, testing operation, and maintenance or quality assurance.
- **Examination** – An elements of inspection consisting of investigation of materials, components, supplies or services to determine conformance to specified requirements that can be determined by such investigation. Examination is usually nondestructive and includes physical manipulation, gauging and measuring.
- **Inspection** – Examination or measurement to verify whether an item or activity conforms to specified requirements.
- **Item** – A broadly used item describing an assembly, component, equipment, material module, part, structure, subassembly, subsystem, system or unit.
- **Nonconformance** – A deficiency in the characteristics, documentation or procedure, which renders the quality of an item or activity unacceptable or indeterminate.

- **Procurement Documents -** Purchase requisitions, purchase orders, drawings, contacts, specification or instructions used to define requirements for purchase.
- **Quality Assurance –** The planned and systematic actions necessary to provide adequate confidence that a material, components, system or service meets the established requirements. Quality Assurance includes quality administration and quality control.
- **Quality Control –** Those quality assurance actions performed to measure and control the characteristics and/or process to established requirements.
- **Receiving –** Taking delivery of an item at a designated location.
- Records – Documentary evidence of the quality of items and activities affecting quality. For purposes of this manual, a document is considered to be a record only after the document is final.
- **Repair** – The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safety is unimpaired, even though that item still does not conform to the original requirements.
- **Review** – A technical assessment that a document/activity complies with the appropriate requirements. As used in this manual, review requires a signature and date.
- **Rework** – The process by which an item is made to conform to original requirements by completion or correction.
- **Surveillance** – the act of monitoring or observing to verify whether an item or activity conforms to specified requirements.
- **Specification** - A concise statement of the requirements that a product, material or process must satisfy in order to acceptable.

HLWF Quality Assurance Organization Chart



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