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Application of quality assurance to radioactive waste disposal facilities

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August 1996

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FOREWORD

Nuclear power generation and the use of radioactive materials in medicine, research and industry produce radioactive wastes. The safe management of these wastes is an essential activity if the benefits of the uses of nuclear fuels and radioactive materials are to continue to be available to society.

In order to assure that wastes are managed safely, the implementation of appropriate management controls is necessary. This system of management controls is known as a quality assurance programme. The IAEA has developed a Standard on the Safety of Nuclear Power Plants dealing with quality assurance (Safety Series No. 50-C-QA (Rev. 2)), and the general principles laid out in that report can be applied to nuclear facilities other than nuclear power plants. However, no IAEA Safety Series document dealing explicitly with quality assurance for radioactive waste management currently exists. However, the IAEA is preparing interim reports to provide guidance on this important matter. IAEA-TECDOC-680, "Quality Assurance Requirements and Methods for High Level Waste Package Acceptability", was published in December 1992. The present publication deals with quality assurance principles for safe disposal. The report should be of interest to managers responsible for the safe disposal of radioactive waste, to assist them in developing management control and assessment systems; to implementors of waste disposal systems, to help them in achieving quality in their work; and to regulatory bodies, to provide guidance for their oversight of licensee waste disposal programmes.

The preparation of this report took place between May 1991 and January 1996, during which time three consultants meetings and an Advisory Group meeting were held. Seventeen experts with experience in the application of quality assurance programmes to radioactive waste management, including radioactive waste disposal, participated in its preparation.

The IAEA officer responsible for the final compilation of this report was J.U. Heinonen.

EDITORIAL NOTE

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1. INTRODUCTION

1.1. BACKGROUND

The most viable options for protecting man and the environment from the effects of radioactive wastes are disposal into either a near surface or a geological disposal facility. Near surface disposal of low and intermediate level radioactive wastes in engineered trenches has been practiced for several decades in many countries around the world and appropriate technologies for safely designing and operating such facilities are available. Geological disposal facilities for high level and long lived radioactive wastes are under development in certain countries.

All activities associated with waste disposal facilities must be managed, performed and assessed to provide adequate confidence that the waste disposal facility will meet safety requirements. The effective application of a quality assurance programme at each phase of the project (siting process, design, construction, operation, closure and post-closure period), contributes to meeting safety requirements.

Quality assurance requirements for radioactive waste disposal facilities have their origins in those developed for other nuclear facilities. In most countries, quality assurance requirements for nuclear facilities now appear in various national and international standards and regulations, including those of the IAEA.

The IAEA Safety Standard 50-C-QA [1][1] can be applied to waste disposal facilities, but guidance is needed to address the specialized aspects of waste disposal. For example, for geological repositories for long lived and high level wastes, containment times of the order of 10 000 years may be required. More than a decade may be necessary to develop such disposal facilities, starting from the initial research and development up to the application for a licence. Measures need to be developed to assure that the important site investigation data are controlled throughout this period.

It is the responsibility of the facility owner to perform the relevant stages of the siting process to design, construct, operate and close the disposal facilities in accordance with applicable national regulations. These regulations will contain performance objectives and other technical criteria designed to ensure the protection of public health and safety. Safety principles and criteria for underground disposal of high level waste are contained in IAEA Safety Series No. 99 [2]. The facility owner must implement a quality assurance programme which complies with national regulations. Effective implementation of a quality assurance programme will ensure that all work meets expectations of regulators, authorizing agencies and other interested groups. Many examples of national and international standards and regulations applicable to quality assurance of nuclear facilities exist to assist in developing criteria and guidance [3–13].

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[1]Note on the use of terminology: Since this report is part of the TECDOC series and not a Safety Standard, use of the word "shall" is not appropriate. Therefore, whenever a quality assurance principle is stated here, where the corresponding principle of Safety Series No. 50-C-QA (Rev. 2) is a "shall" statement, this report uses "must", as it is an action that would be necessary to satisfy the Code of Practice. The word " should" indicates a recommendation which should be given careful consideration but is not considered a necessity.

1.2. OBJECTIVE

The objective of this report is to present information to Member States on the applicability and content of quality assurance programmes for the disposal of radioactive waste.

1.3. SCOPE

This report addresses quality assurance for the siting process (characterization and confirmation), design, construction, operation, closure and post-closure period of radioactive waste disposal facilities. It is applicable to near surface and geological disposal facilities, but does not apply to sanitary landfills, uranium mining and mill tailings stabilization and subseabed disposal. Quality assurance programmes for conditioning of the waste form will be the subject of another document. The quality assurance requirements may also be applied by the owner to evaluate the safety of existing radioactive waste disposal facilities.

1.4. STRUCTURE

The background to the application of quality assurance in the development of radioactive waste repositories is described in this report, including the origin of the quality assurance criteria used in it. The report discusses regulatory interfaces, the identification of items important to safety and quality assurance issues for the most important phases of a disposal project (Section 2). The key quality assurance criteria are described for the requirements related to management (Section 3), performance (Section 4) and assessment (Section 5). An example of how grading might be applied is given in the Appendix.

2. DISPOSAL SAFETY CONSIDERATIONS

2.1. SAFETY AUTHORITIES AND OTHER REGULATORY INTERFACES AND SUBMISSIONS

Those government agencies (regulatory bodies) which have an interest in the project must first be identified and consulted. As several agencies may be involved, it is essential to identify the lead agency for effective communication.

Within the framework established in individual countries for ensuring health and safety of the public, or the standards established for the oversight and licensing of nuclear facilities, there must be provision for the effective implementation of a quality assurance programme. This quality assurance programme may be based on, or otherwise equivalent to the IAEA 50-C-QA series.

A document submission programme must be agreed with the lead regulator at the earliest opportunity to confirm the timescale and scope of document submission. The quality assurance programme adopted to satisfy the regulatory bases must be reviewed at appropriate intervals to ensure its continuing suitability and effectiveness. The agency responsible for the licensing of the disposal facility should review the development, implementation and maintenance of the quality assurance programme at appropriate intervals.

Regulatory approval may be needed at set stages during the life of the facility (e.g. siting process, design, construction, operation, closure and post-closure period). Early information may be required by the regulatory body on items which are important to safety to assure timely review and approval.

2.2. IDENTIFICATION OF ITEMS IMPORTANT TO SAFETY

Structures, systems and components which are essential to the prevention of radiological harm to individuals are termed "items important to safety". Such items are identified early and continue to be defined throughout each phase of the project.

In identifying items important to safety, a systematic analysis must be used. This analysis identifies external and internal initiating events and scenarios, analyses the response of safety systems, and calculates the offsite dose consequences. Structures, systems or components whose failure could initiate an incident should not be overlooked due to the addition of mitigating features.

The probability with which incidents could occur and their consequences will be analysed to determine items important to safety. In identifying these items all incidents must be considered where occurrence is deemed sufficiently likely. In addition, it is necessary to assess potential incidents which have a very low probability but where dose consequences are sufficient to warrant consideration. Probabilistic safety assessments provide a framework for grading of quality assurance measures based on the risk or consequences associated with the failure of individual components.

The graded application of quality assurance is the degree of management controls applied to a structure, system or component. An example of a grading process is described in the Appendix.

2.3. SITING PROCESS

In the siting process for a radioactive waste disposal facility, four stages may be recognized:

(a) conceptual and planning stage
(b) area survey stage
(c) site characterization stage
(d) site confirmation stage.

The transition from one stage to the next may be somewhat arbitrary due to the overlap. In each of these stages a set of procedures is implemented with the aim of selecting suitable areas or sites. The amount and precision of the data generally increases as the overall siting process progresses towards its goal of confirming a preferred site.

2.4. AREA SURVEY STAGE

The site may be designated by the national authorities or may be selected through a criteria based screening process. In all cases, the aim of the area survey is to propose a manageable number of potentially suitable sites and not necessarily to select the "best" site, as the weight of the various criteria can only be determined once safety studies have been performed.

2.5. SITE CHARACTERIZATION AND CONFIRMATION STAGES

The site characterization stage involves the study and investigation of one or several potential sites to demonstrate that they are acceptable in various respects, and in particular from the safety point of view. The information needed to develop a preliminary site related design should be obtained at this stage.

The activities undertaken and the data collected during the characterization stage and the following site confirmation stage will provide an input to waste disposal performance and safety assessment. A quality assurance programme must be established and implemented prior to the beginning of the characterization stage.

Constant interaction between site characterization, confirmation and the design of the proposed facility is essential. The relations between site studies and design studies must be identified, organized and described in the quality assurance programme.

2.6. POST-CLOSURE SAFETY

Engineered and natural barriers relied on to meet containment performance objectives are termed "items important to post-closure safety".

The items important to post-closure safety may include but are not limited to:

- components of the engineered barrier system relied on to meet the performance objectives,
- elements of the natural barrier system (e.g., groundwater flow, host rock and geochemical retardation characteristics) relied on to meet the performance objectives,
- activities necessary to demonstrate that the performance objectives will be met, including collection of data to characterize the site or performance of engineered barriers,
- activities in the preclosure phase that could affect post-closure performance.

The performance objectives provide the owner with flexibility in design criteria for barrier system components. Performance assessments of these barriers must be completed to ensure that they will meet the waste isolation and containment performance objectives. A quality assurance programme must be used to control site characterization activities which provide data to be relied on for performance assessments of the containment capabilities of barriers, as well as the performance assessments themselves.

3. MANAGEMENT

3.1. MANAGEMENT RESPONSIBILITY

Management must define and document its policy for quality including objectives for quality and its commitment to quality. Management must ensure that this policy is understood, implemented and maintained at all levels. Management must have total

responsibility for establishing, executing and assessing the effectiveness of the quality assurance programme. The organizational and procedural structure must be delineated in writing, including functional responsibilities, levels of authority and interfaces for those managing, performing and assessing the adequacy of quality affecting activities. Should management delegate to other organizations the work of establishing and implementing all or a part of the overall programme, it must retain responsibility for its effectiveness.

Management at all levels must periodically assess the effectiveness of their management function and the quality assurance programme, including that which has been delegated to another organization. The broad management functions include: providing resources, motivation, training, communications, and integration. Sufficient resources (personnel, materials, budget and schedule) must be provided by management. Management barriers and weaknesses that hinder the achievement of the organization's safety and quality objectives must be corrected.

Management must define and document the organizational element who has the responsibility and authority to independently assess and review the adequacy and effectiveness of the quality assurance programme.

3.2. QUALITY ASSURANCE PROGRAMME

Management must establish a documented quality assurance programme applicable to the siting process, design, construction, operation, closure and post-closure of a radioactive waste disposal facility. The quality assurance programme must be documented by written policies, plans, procedures, and instructions and be implemented and maintained throughout the life of the project. These documents must identify the scope of activities covered and provide for performing work under controlled conditions, by qualified personnel. The language used for documentation must be stated and measures taken to ensure it is understood by all concerned.

Activities must be prescribed and performed in accordance with documented instructions, procedures or drawings, which may include criteria for determining that activities have been satisfactorily accomplished.

Procedures for implementing the quality assurance programme at different phases of the project must be developed and documented by the organization performing the constituent activities. The procedures must be periodically reviewed and updated to assure control of those activities.

The conduct of field and laboratory geotechnical tests requires documented procedures to be followed, but as testing progresses, the procedures may need to be revised to reflect new information. At the conclusion, the procedure followed and the information gathered will be fully documented.

Adequate confidence in the quality of the items and activities within the scope of the quality assurance programme, may be obtained with graded QA measures consistent with their importance to safety and operational considerations. The owner must define the criteria and method for grading and describe the approach in a procedure. IAEA guidance for grading of quality assurance measures for nuclear facilities is given in Technical Reports Series No. 328 [14]. An example for grading is given in the Appendix.

3.3. QUALIFICATION AND TRAINING

Management must establish qualification (education and experience) and training requirements for personnel performing functions subject to the quality assurance programme during the different phases of radioactive waste disposal facility development.

Minimum education and experience requirements commensurate with the scope, complexity, and nature of the work must be identified. A documented training programme must be established to assure personnel are indoctrinated and trained to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities. Appropriate records of qualification and training of personnel must be maintained.

3.4. NON-CONFORMANCE CONTROL AND CORRECTIVE ACTION

Measures must be established to control items, services and processes that do not conform to specified requirements in order to prevent their inadvertent use or installation. These measures include the establishment and maintenance of documented procedures providing for identification and documentation, segregation (when practical), evaluation and disposition, notification of concerned organizations at the appropriate level of management, and for implementation and verification of effectiveness of corrective actions. Suspected non-conformances must be immediately identified and the occurrence(s) recorded.

The responsibility for review and authority for disposition of non-conformances must be defined. In order to define the disposition, a safety impact assessment must be performed, and depending on the results of such assessment, the items, services and processes may be either accepted, reworked to meet the specified requirements, repaired or rejected.

Repaired and/or reworked items, services and processes must be reinspected in accordance with the applicable documents (procedures, quality plan, etc.). To ensure improvement, the causes of the non-conformances must be determined and corrective actions taken to prevent or minimize the recurrence of a problem. The corrective actions must be to a degree appropriate to the magnitude of the problem and commensurate with the risk encountered.

Item characteristics, processes implementation, experience, audit results, and other quality related information must be reviewed and the data analysed to identify, implement and verify improvements, ensuring that relevant information on actions taken is submitted for management review (see Section 3.1).

3.5. PROCEDURE FOR CHANGES OF THE LICENSED STATUS

A change of the licensed status refers to the revision or modification of a licensing document or the licensed operating mode of the disposal facility to be in line with the new condition.

Quality improvements may result in the introduction of changes of the licensed status of the disposal facility. These changes may affect different components and items as well as operational procedures of the disposal repository system and all the phases of its development including operation and post-operational period. Reasons for changes may be derived from advancement of technology, new scientific knowledge and experience gained

during the repository development and operation, as well as new requirements set by the authorities. The changes vary in terms of magnitude, extent and importance to the safety.

There must be a specified procedure for management and control of the introduction of changes of the licensed status. This procedure must assure the appropriate review and analysis of changes. An appropriate procedure regulates the necessary reviews. Analysis, and administrative measures according to the established categories of changes in terms of the importance to the safety of the facility. An example a procedure for changes is given in Ref. [15].

Changes introduced according to procedure leads to revision of documentation which reflect the licensed status of the disposal facility and its operation.

The following sections also deal with the changes with reference to the different components of the facility, i.e. Section 3.6 to documentation and Section 4 to performance issues.

3.6. DOCUMENT AND DATA CONTROL AND RECORDS

3.6.1. Document and data control

Preparation, review, approval, issue and revision of documents (e.g. procedures, instructions, specifications, drawings or other media which describe processes, specify requirements or establish design) and data for the management, performance and assessment of the work must be controlled. This must include the identification of authorized individuals or organizations responsible for preparing, reviewing, approving, issuing and revising documents and data related to activities.

All personnel preparing, reviewing, approving, issuing or revising documents and data must have access to appropriate information upon which to base their input.

Documents and data can be in the form of any type of media, such as hard copy, electronic media and specimens.

A document and data release and distribution system must be established. Measures must be provided for ensuring that:

- the pertinent issues of appropriate documents and data are available at all locations where the concerned operations are performed;
- those performing an activity are aware of, and use, the appropriate and correct documents and data;
- invalid and/or obsolete documents and data are promptly removed from all points of issue or use, or otherwise to preclude their unintended use; and
- obsolete documents and data retained for legal and knowledge preservation purposes are suitably identified.

The system must provide for co-ordination and control of interface documents and data.

Revision of documents and changes to data must be reviewed and approved either:

- by the same organizations that performed the original review and approval, or
- by other qualified organizations having access to the pertinent original information.

Where practicable, the nature of the change must be identified in the document or its attachments. When more than one item or activity is potentially affected by a change, the items or activities to which the change applies must be identified.

3.6.2. Records

Records that provide evidence that activities affecting quality and safety have been performed according to specified requirements and that the quality assurance programme is effective, must be specified, prepared, reviewed, approved and maintained.

A record system must be established and maintained to provide for the identification, collection, indexing, filing, storing, maintenance, retrieval and disposal of records, including provision for long term storage.

All records must be legible, complete and identifiable with the item or activity involved, and must be stored and maintained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

Retention periods for records and associated test materials and specimens must be specified and consistent with the nature or scope of activity, type of record, material and specimens involved.

4. PERFORMANCE

This TECDOC has separated the phases, i.e. siting process, design, construction. In practice, the interfaces remain throughout the process of establishing the facility. The uncertainty that may be associated with geology and mining is such that design reviews are more frequent than for other nuclear facilities, to take full account of changes to data or predictions.

4.1. SITE CHARACTERIZATION AND CONFIRMATION

Scientific investigations carried out for the description of the site and to develop design inputs must be defined, controlled, verified and validated. The intended use of data must be documented as part of the planning. Other uses of the data must be evaluated and justified. Planning must assure the compatibility of scientific investigations with any conceptual or mathematical models used at each applicable stage. Planning must establish provisions for the evaluation of data quality to assure that data generated is valid, comparable, complete, representative, precise and accurate. Characterization data must be controlled in order to assure the current status and latest revision.

The range, accuracy and precision of equipment used for scientific investigations must be compatible with the end use of the data. Scientific investigations must be performed by suitably trained and qualified persons implementing methods in accordance with nationally

recognized standards where available. Such standards if used without modification require documentation by reference only. Modifications or new methods must be documented in sufficient detail to be repeatable and evaluated, validated and approved.

Peer reviews of documentation may be employed to provide additional confidence in the work under review, which may be a design, plan, test procedure, scientific/research report, materials choice, or a site exploration. Uncertainties exist in geological data and their analyses, in which projections must be made for long time spans. Peer reviews are used to make judgments on these types of analyses and provide direction for further work.

Computer software used to calculate, model or develop data in support of the design must be verified, validated and documented. Computer software must be placed under configuration control as each baseline element is approved and released. Changes to computer software must be systematically evaluated, co-ordinated and approved to assure that the impact of a change is carefully assessed before updating the baseline.

4.2. DESIGN CONTROL

The design of a radioactive waste disposal facility includes:

- predicting the long term safety performance;
- predicting the environmental interactions between the site and its surroundings;
- planning and specifying processes for handling radioactive waste; and
- specifying requirements for constructing and operating the facilities for handling such waste taking full account of site characterization information;
- specifying requirements for the closure of the facility and post-closure, if required.

The design process includes developing computer programmes used in modelling the characteristics of the site geology, in predicting environmental impacts, such as groundwater flow and seismic activity and in probabilistic safety modelling. The ability to demonstrate the adequacy of the design in terms of meeting safety or performance objectives is a key consideration in establishing management controls.

As previously stated, the derivation of the final "long term" or "post-closure" safety assessment is a long and iterative process. Accordingly, there are many data sets which are progressively revised and used for each assessment. The control of these data sets must be established in order to ensure traceability during the evaluation of each assessment.

A design control programme must be documented and established before design work starts. Measures must be established to assure that applicable regulatory requirements are correctly taken into account in the design documents. These measures must include provisions to assure that appropriate technical, operational and quality standards are specified and included in the design documents, and that deviations from such standards are controlled. Measures must also be established for selection, and for review for suitability of application, of materials, parts, equipment and processes that are essential to the functions of the structures, systems and components. The quality assurance programme should:

(a) describe the measures used to assure verification or checking of design adequacy, such as design review, use of alternative calculational methods, or performance of a qualification testing programme under the most adverse design assumptions;

(b) identify the positions or organizations responsible for design verification or checking;

(c) describe the measures taken to assure that the verification or checking process is performed; and

(d) describe the measures for validation of the design, i.e. the item or service conforms to defined user needs and/or requirements.

Verification and checking must be done by individuals or groups possessing an appropriate level of skill other than those responsible for the original design, but who may be from the same organization.

Validation of the final item or service must follow successful design verification and be defined.

The owner must describe the measures of identifying and controlling design interrelationships, both internal and external, and for providing co-ordination between participating design organizations. The control of information between these interfaces must be formalized.

Information collected outside the quality assurance programme termed "existing data", may be used in support of the design in process. Typical examples include research results published in the literature on rock types; solubility, speciation and sorption on different rocks and repository materials of various radionuclides; and on the radiotoxicity of various radionuclides. Existing data must be reviewed and evaluated before use.

Design changes must be subject to design control measures commensurate with those applied to the original design and should be reviewed and approved by the organization that performed the original design, or by another qualified organization that has access to the original design information.

Deficiencies in the design that could adversely affect the performance of any item covered by the quality assurance programme must be identified, documented, and corrective action taken.

4.3. CONSTRUCTION

Upon receipt of the delivered structures, systems and components, they must be inspected to determine whether or not the delivered items correspond to the procurement documents (see Section 4.9).

Construction has to be carried out according to the licence. Any changes have to be approved in compliance with a change procedure. The fulfillment of the requirements must be documented. Control methods for manufacturing, construction and installation work have to be followed. Effective communication has to be maintained to ensure that the specified requirements are fulfilled. To achieve quality and safety of work, maximum efforts must especially be paid to the education and training of the personnel.

If it is required in the licence, the regulatory body or their consulting authorized expert, must evaluate the work prior to or after construction. The evaluation has to certify that the construction is in accordance with the licence. A supplementary or renewed evaluation of the construction work has to be performed if essential changes have occurred.

Quality assurance measures [16] must be applied to ensure that:

(a) the individual quality requirements are met,
(b) the equipment and facilities are sufficiently maintained,
(c) the required ambient conditions are maintained,
(d) the fulfillment of the quality requirements is recorded to the required extent in documents.

Quality tests and inspections must be performed and documented at specified hold points during and at completion of construction. The construction and inspection steps must be co-ordinated.

4.4. COMMISSIONING [16]

The commissioning of the structures, systems and components have to be carried in accordance with written commissioning procedures.

The commissioning procedures, in accordance with the safety related requirements must contain all essential information for commissioning. These include:

(a) the objective of the commissioning procedure,
(b) the conditions of the necessary structures, systems and components,
(c) the actions required for achieving the conditions,
(d) the individual limit values to be observed,
(e) information about the necessary records and about the test records and inspection documents (commissioning documents) to be filed in document storage.

It has to be ensured that the experience gained during commissioning is transferred in the required extent to the operating manual. Commissioning arrangements must provide for the demonstration of the functioning of the structures, components and systems.

4.5. OPERATION

The procedures for handling the waste have to be performed in compliance with the licence, and are specified in the operating instructions. The handling must be performed by qualified personnel in accordance with the procedures.

The qualified personnel of the disposal facility are responsible for [16]:

(a) surveillance of the parameters necessary for evaluating the operating condition during specified normal operation and during incidents,

(b) requesting and performing tasks (e.g. protective actions) and taking precautionary measures in all operating conditions and incidents.

Repairs and changes must be performed in accordance with the relevant procedures and specifications. Incidents must be analysed and documented together with corrective actions taken. Tests and inspections must be planned in accordance with the licence.

The operational quality assurance programme must describe the monitoring arrangements for the demonstration of compliance with the licence requirements. This

monitoring programme serves to confirm the operating parameters, which were used with a certain range of values in the safety analyses basic to construction.

As an example, the thermo-mechanical reaction of the host medium to the introduction of high level radioactive wastes has to be followed, as well as the mechanics of the medium. If significant deviations from the original data are found, their effects on the safety of the disposal facility analysed and if necessary modifications of the further operation of the disposal facility are to be considered [15].

4.6. CLOSURE/POST-CLOSURE

A quality assurance programme for closure/post-closure of the disposal facility must be developed, implemented and maintained to ensure that all licence requirements are complied with and demonstrable.

4.7. PROCUREMENT

Measures must be established and documented to ensure that purchased item or services conform to specified requirements which include (but are not limited to):

(a) a complete statement of the scope of the work to be performed by the supplier,
(b) identification of quality requirements applicable to the items or services procured,
(c) acceptance criteria and applicable technical and administrative requirements (e.g. specifications, codes, standards, tests and inspection requirements),
(d) arrangements for "in-process" inspections,
(e) arrangements for handling, storage, transport and packaging,
(f) the provision for the owner's (or his representative's) right of access to the supplier's facilities and records for source inspection and audit,
(g) record requirements to be retained by the supplier and those to be delivered to the owner before the product is used or installed,
(h) the provisions for the notification and resolution of non-conformances which require the owner's approval or awareness,
(i) the provisions related to the application of commensurate requirements to subcontractors.

Procurement documents and their revisions must be reviewed and approved before release. Measures must be taken to assure that purchased items or services conform to procurement document requirements. These measures may include source evaluation and selection, supplier certification, source inspection and receipt inspection. Documentary evidence that items or services conform to procurement requirements must be available at the facility before installation and use. At intervals consistent with the importance of the items or services, management must periodically assess the effectiveness of contractors' quality assurance programme.

4.8. INSPECTION AND TEST CONTROL

Management must define the types of work which require independent inspections and tests, and specify the nature, timing and responsibility for undertaking these. Inspections or tests may be performed by the organization responsible for the work, or another independent department. Personnel responsible for performing inspections or tests must be technically

competent. Inspection types include source, in-process, final, receipt, maintenance and in-service.

Inspections and tests must be planned and conducted according to documented procedures. Test procedures should include requirements for:

(a) assuring that all prerequisites have been met,
(b) test instrumentation of the proper range, type, accuracy and precision is used,
(c) the test to be performed under suitable conditions,
(d) acceptance and/or performance criteria,
(e) restoration to pretest conditions, and
(f) results to be reviewed and documented.

The inspection, test and operating status of samples, structures, systems and components must be identified. Management systems must provide for documented controls, e.g. hold points and status indicators which prevent further processing and bypassing of the required inspection and/or test.

All measurements that affect siting process, the quality of the design, construction, operation, closure or post-closure must be taken only with instruments, tools, gauges or other measuring devices that are accurate, controlled, calibrated and adjusted at predetermined intervals to maintain accuracy within necessary limits.

Measuring and test equipment must be calibrated in accordance with documented procedures which include manufacturer' s requirements, technical standards or facility specific requirements, and identified to indicate calibration status. When a piece of measuring and test equipment is found to be out of calibration, evaluations must be made to determine the validity and acceptability of measurements performed since the last calibration.

Hardware or software used for inspection or test must be checked to prove that they are capable of verifying the acceptability of item prior to use. Records must be maintained specifying the extent and frequency of such checks.

4.9. IDENTIFICATION AND CONTROL OF ITEMS

4.9.1. General

Measures must be established for identifying and controlling materials, parts, components, geological cores and field and laboratory samples. These measures must ensure that identification is maintained on the item or in records traceable to the item. These measures must identify the time and location of collection of geological and environmental data and ensure that identification is maintained during collection, shipment, sample splitting (subsamples) and subsequent analysis.

Items may be identified by batch number, part number, serial number, or other suitable means, throughout fabrication, storage, delivery, construction, installation and use. These measures must be designed to prevent the use of incorrect or defective items.

4.9.2. Handling, storage and shipping

Procedures must provide for handling, packaging, preservation, cleaning, storage and shipping of items in accordance with design and specification requirements to prevent

damage, loss or deterioration by environmental conditions. Handling, preservation, storage, cleaning, packaging and shipping must be performed by qualified individuals in accordance with documented instructions.

4.9.3. Maintenance

Maintenance of items important to safety must be performed in accordance with documented procedures to ensure the original specification is complied with.

5. ASSESSMENTS

5.1. GENERAL

All activities which affect quality must be assessed, documented and reported to management on a regular planned basis. Assessments must be performed in order to verify implementation adequacy and effectiveness of the documented quality assurance programme and to confirm compliance with requirements. The results of assessments must be reviewed by management who, where necessary, must take actions to implement improvements. Assessments must be performed by qualified individuals and scheduled on the basis of the status and importance of the activity.

5.2. SELF-ASSESSMENT

Persons at all levels must regularly assess their performance against compliance with the procedures, specifications and test schedules which control their area of work.

Management, at all levels, must determine their effectiveness in establishing, promoting and achieving quality assurance objectives. Where procedural or system weaknesses are identified, actions are taken to improve quality performance.

5.3. INDEPENDENT ASSESSMENT

The management will appoint the persons and organizations responsible for undertaking and documenting reports of independent assessments. The persons and organizations performing these assessments must have sufficient authority and organizational freedom to identify problems with quality, to initiate, recommend solutions, and to verify implementation of solutions. Such persons and organizations must report to management at such a level that this required authority and organizational freedom, including sufficient independence from cost and schedule, are provided.

In practice, independent assessment may include various types of monitoring, or a blend of these. Types of monitoring may include, but are not limited to, audits, surveillance inspection, documentation reviews and meetings.

Appendix

GRADED APPLICATION OF QUALITY ASSURANCE

The quality assurance programme should provide the necessary controls over activities which affect the quality of structures, systems and components in order to ensure the performance objectives and the technical requirements are met and the results can be demonstrated. The management controls, applied to an item or activity to ensure the integrity of the results, will vary as a function of the degree of confidence needed regarding the quality of the item or activity.

Criteria for grading quality assurance, which could be used in the disposal facility programme are described below.

1. Grading in terms of complexity

Structures, systems or components may also be graded in a way that reflects the complexity of the organization, functions and activities involved in the various areas, the complexity of design or fabrication of an item, or design and implementation of a test, or uniqueness of the items or test.

Complex structures, systems or components may require extensive design efforts, extensive inspection or peer review during their development to assure satisfactory performance.

2. Grading in terms of uncertainty

This grading refers to the control and surveillance needed over special processes, tests, and equipment which affect the quality of structures, systems or components whose effects on the data or analyses cannot be easily measured or evaluated.

3. Grading in terms of operational importance

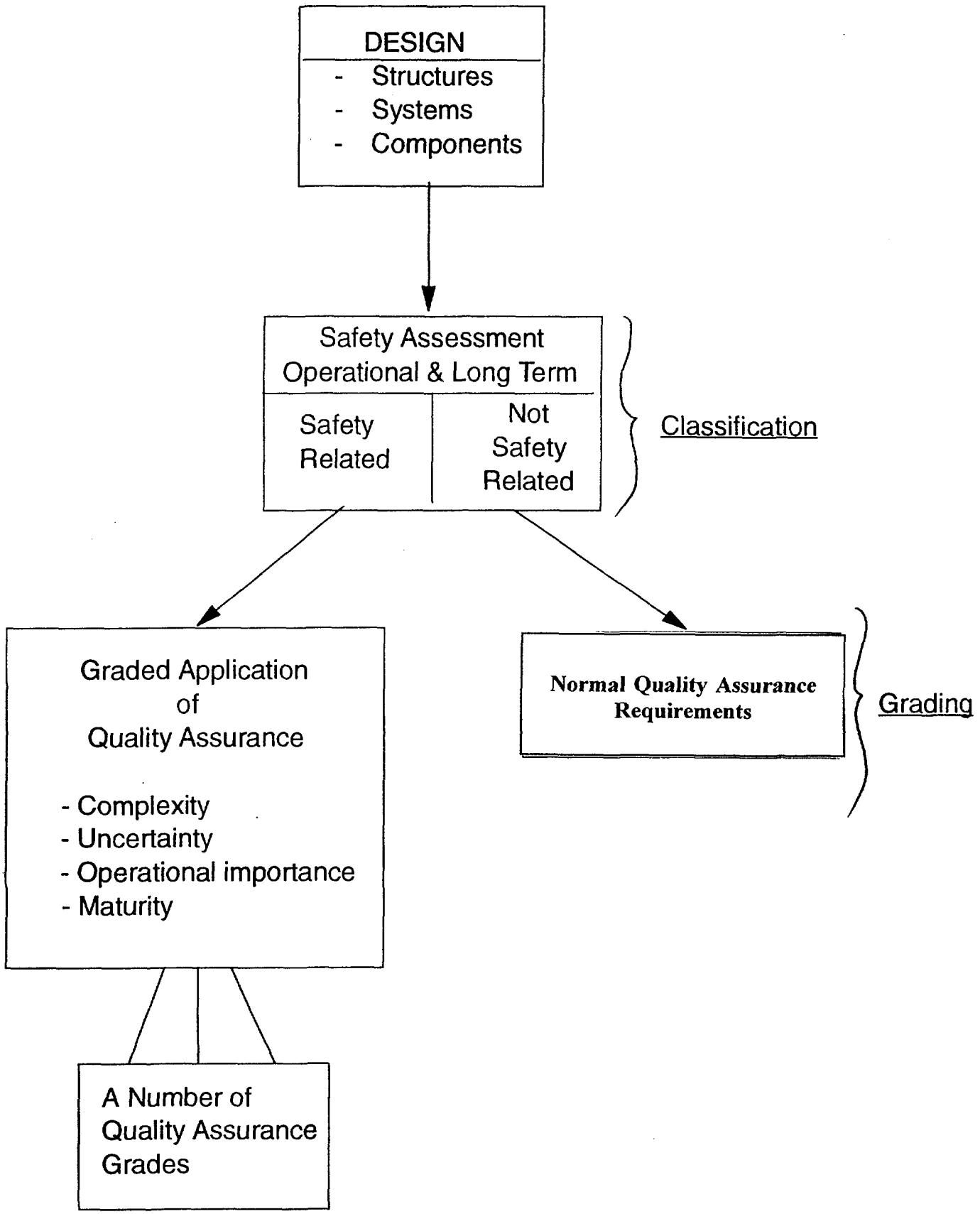
Structures, systems or components may be graded with respect to the importance of the function they perform to assure overall operational safety and reliability.

4. Grading in terms of maturity

Maturity is a measure of the availability of reliable scientific knowledge in a subject, organizational experience and proven design processes or any other activity.

Structures, systems or components may be graded in a way that reflects the maturity and experience available and the quality performance history and degree of standardization.

For example, if a manufacturer or organization has been producing a particular standard item or conducting a standard test for a long period and if the quality performance history of the item or test indicates acceptable performance, quality assurance measures may be tailored to that item or test to reflect the demonstrated performance. Conversely, if certain characteristics are determined to be unsatisfactory based on operational data, additional quality assurance measures may be required to assure that experienced deficiencies are identified and corrected.



Classification and grading process

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GLOSSARY

These definitions are in addition to those identified in the Radioactive Waste Management Glossary [17] and Safety Series No. 50-C-QA (Rev. 2) [1].

acceptance criteria
Specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other requirement documents for acceptance.

activities
Deeds, actions, work, or performance of a specific function or task.

baseline element
An individual component of a software baseline.

certification
The act of determining, verifying and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

characteristics
Any property or attribute of an item, process, or service that is distinct, describable, and measurable.

corrective action
Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

data
Factual information used as a basis for reasoning, discussion, calculation or from which conclusions can be inferred.

data quality
The measure of the legibility, reliability, accuracy, precision, completeness, representativeness, and comparability of data.

design change
Any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

design documents
Specifications, drawings design criteria and component performance requirements for the natural and engineered components of the disposal facility.

design input
Those criteria, parameters, bases, or other design requirements upon which detailed final design is based.

design output
Drawings, specifications, and other documents used to define technical requirements of structures, systems, components, and computer programs.

design process

Technical and management processes that commence with identification of design input and that leads to and includes the issuance of design output documents.

design review

A formal, documented, comprehensive and systematic examination of a design to evaluate the design requirements and the capability of the design to meet these requirements and to identify problems and propose solutions.

deviation

A departure from specified requirements.

final design

Approved design output documents and approved changes thereto.

measuring and test equipment

Devices or systems used to calibrate, measure, gauge, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

owner

The person, group, company, agency, or corporation who has or will have title to the repository and will be legally responsible for every aspect of it.

peer review

A documented critical review of work that goes beyond the state of the art or where potential uncertainty exists. Peer reviews are performed by one or more individuals who collectively have technical expertise at least equivalent to those who performed the original work. A peer review is an in depth critique of assumptions, documents, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, conclusions, and material or data that require interpretation or judgement to verify or validate them.

performance criteria

procedure

A document that specifies or describes how an activity is to be performed.

procurement document

Purchase requisitions, purchase orders, drawing, contracts, specifications, or instructions used to define requirements for purchase.

qualification testing

Demonstration that an item meets design requirements.

record

A completed document that furnishes evidence of the quality of items, services or activities affecting quality.

right of access

The right of a purchaser or designated representative to enter the premises of a supplier for the purpose of inspection, surveillance, or quality assurance audit.

scientific investigation

Any research, experiment, test, study, or activity that is performed for the purpose of investigating a natural or man-made system.

service

The performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation.

site characterization

The programme of exploration and research, both in the laboratory and in the field, that is undertaken to establish the conditions and the ranges of parameters of a particular site.

site confirmation

The final stage of the site selection process for a nuclear facility (e.g. a repository). Site confirmation is based on detailed investigations on the preferred site which provide site specific information needed for safety assessment. This stage includes the finalization of the repository design and the preparation and submission of a licence application to the regulatory body.

surveillance

The act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

test

An operation employed to resolve an uncertainty; a process to ascertain effectiveness, value, proper function, quality or other characteristics; a process to understand a system, component or structure; or a process of submitting a statement to such conditions as will lead to its proof or refutation or to its acceptance or rejection.

traceability

The ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.

verification

The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

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