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International Standard ISO 6215

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Nuclear power plants — Quality assurance

Centrales nucléaires — Assurance de la qualité

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards institutes (ISO member bodies). The work of developing International Standards is carried out through ISO technical committees. Every member body interested in a subject for which a technical committee has been set up has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council.

International Standard ISO 6215 was developed by Technical Committee ISO/TC 85, *Nuclear energy*, and was circulated to the member bodies in June 1978.

It has been approved by the member bodies of the following countries :

Austria	India	South Africa, Rep. of
Belgium	Italy	Sweden
Brazil	Japan	Switzerland
Bulgaria	Mexico	United Kingdom
Czechoslovakia	Netherlands	USA
Finland	Poland	Yugoslavia
Hungary	Romania	

The member bodies of the following countries expressed disapproval of the document on technical grounds :

Canada
France
USSR

This International Standard has been prepared to provide an internationally recognized industrial standard for implementing national legislative requirements. The requirements of this International Standard are fully compatible with the IAEA Code of Practice on Quality Assurance for Safety in Nuclear Power Plants (IAEA Safety Series No. 50-C-QA, Vienna 1978).

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Nuclear power plants — Quality assurance

0 Introduction

This International Standard and the IAEA Code of Practice on quality assurance were developed in parallel, the former addressing specifically the needs arising from contractual arrangements between manufacturing and operating organizations. If in the use of this International Standard any doubt arises of compatibility with safety requirements for quality assurance, the user may find it helpful to consult the IAEA Code of Practice and Safety Guides.

This International Standard sets out principles for quality assurance for a complete nuclear power plant, and for each of the constituent areas of activity relevant to a safe and successfully operating plant. It covers activities such as design, procurement, fabrication, construction, commissioning, operation, maintenance and decommissioning of structures, systems and components of nuclear power plants.

The proper establishment and implementation of a quality assurance programme from the design through to decommissioning of a nuclear power plant is necessary to provide adequate assurance of quality and to meet statutory requirements imposed by regulatory authorities. In order to achieve this objective it is important to recognize that the basic responsibility for quality achievement in the performance of a particular task (for example, in design, in manufacturing, in commissioning, in operation) belongs with the individual or individuals assigned the task, and not only with those seeking to ensure by means of verification that it has been achieved. It is emphasized that plant will not be designed, manufactured, constructed and operated successfully solely as a consequence of the preparation of a quality assurance programme : it is its application that is important.

Quality assurance is an essential aspect of good management. Good management contributes to the achievement of quality through thorough analysis of the task to be performed, the identification of the skills required, the selection and training of appropriate personnel, the use of appropriate equipment, the creation of a satisfactory environment in which activity can be performed and recognition of the responsibility of the individual who is to perform the task. Briefly stated, then, a quality assurance programme provides for a disciplined approach to all activities affecting quality, including verification, where appropriate, that each task has been satisfactorily performed, and production of documentary evidence to demonstrate that the required quality has been achieved.

This International Standard should be applied to all safety-related items, and it may be desirable to apply these quality activities to items which could affect successful plant operation.

Many practical methods are in existence to implement the principles set out in this International Standard. These methods should take into account the industrial, commercial and regulatory arrangements of the country in which this International Standard is to be applied.

1 Scope and field of application

1.1 This International Standard defines principles for the establishment and implementation of quality assurance programmes during all phases of design, procurement, fabrication, construction, commissioning, operation, maintenance and decommissioning of structures, systems and components of nuclear power plants. These principles apply to activities affecting the quality of items, such as designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, testing, commissioning, operating, inspecting, maintaining, repairing, refuelling and modifying and eventually decommissioning.

1.2 The manner in which the principles described in this document will be implemented in different organizations involved in a specific nuclear power project will depend on regulatory and contractual requirements, the form of management applied to a nuclear power project, and the nature and scope of the work to be performed by different organizations.

2 Language

Measures shall be taken to ensure that persons having direct control over the performance of activities affecting quality have adequate knowledge of the language in which documentation is written. Translations of the documentation shall be reviewed by competent persons, to verify conformance to the original documentation.

3 Responsibility

It is the responsibility of the owner of the nuclear power plant to ensure that a quality assurance programme for the plant is established and executed in a manner consistent with the provisions of this International Standard. The owner may delegate to other organizations, or to specialists, the work of establishing and executing the quality assurance programme, or any part thereof, but shall retain responsibility for overall programme effectiveness. In no way shall the programme operate to diminish the responsibility of any participant for the quality of items or services furnished, or for the execution of the participant's designated portion of the quality assurance programme.

4 Definitions

The following definitions are provided to ensure a uniform understanding of selected terms as they are used in this document. The definitions apply only to quality-related terms used generally in this International Standard. It has not been intended to define terms that are adequately defined in common dictionaries. When the words "shall", "should" and "may" occur, they have the following meanings :

— "shall" denotes a mandatory requirement;

— "should" denotes a recommendation;

— "may" denotes an acceptable method for satisfying a requirement.

4.1 audit : A documented activity performed in accordance with written procedures or check lists to verify, by examination and evaluation of objective evidence, that applicable elements of the quality assurance programme have been developed, documented, and effectively implemented in accordance with specified requirements. An audit does not include surveillance or inspection for the purpose of process control or product acceptance.

4.2 code : A standard which is recommended or imposed by a regulatory body.

4.3 commissioning : The initial testing and start-up process by which a nuclear power plant is put into operation.

4.4 decomissioning : The permanent retirement from service of a nuclear plant and the work which follows in bringing it to a definitive condition.

4.5 documentation : Any recorded or pictural information describing, defining, specifying, reporting or certifying activities, requirements, procedures or results.

4.6 inspection : Examination or measurement to verify whether an item or activity conforms to specified requirements.

4.7 item : An all inclusive term covering structures, systems, components, parts or materials.

4.8 non-conformance : A deficiency in characteristics, documentation or process implementation which renders the quality of an item indeterminate or outside that required by the specification.

4.9 objective evidence : Any fact or documentation containing information, either quantitative or qualitative, pertaining to the quality of an item or service which can be verified.

4.10 owner : The organization (industrial or governmental) which has overall responsibility for the nuclear power plant.

4.11 plan : A document describing or identifying specific practices and procedures relavant to particular items, processes or services.

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

4.13 purchaser : Any individual or organization who places an order for items or services.

4.14 quality : The totality of features and characteristics of a product or service that bear on its ability to satisfy a defined requirement.

4.15 quality assurance : All those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in service.

4.16 quality assurance programme : A description of the overall management and procedures covering the quality assurance actions for the execution of a specific contract or project.

4.17 repair : The process of restoring a non-conforming characteristic to an acceptable condition even though the item may still not conform to the original requirement.

4.18 review : An independent appraisal undertaken by an individual or group competent in the area being considered.

4.19 rework : The process by which an item is made to conform to the original requirement by completion or correction.

4.20 safety-related : Pertaining to those structures, systems and components of nuclear power plants the satisfactory performance of which is important to the prevention of accidents that could cause undue risk to the health and safety of the public, or to mitigation of the consequences of such accidents.

4.21 specification : A document describing requirements to be satisfied by items or processes, indicating, whenever appropriate, the methods by means of which it may be determined whether the requirements given are satisfied.

4.22 standard : A document approved by a generally recognized body which results from the process of formulating and applying rules for an orderly approach to a specific activity.

4.23 supplier evaluation : An appraisal to determine whether or not a supplier is capable of producing a component, product or service in accordance with a specified requirement, and providing objective evidence thereof.

4.24 surveillance : Monitoring or observation to verify whether an item or activity conforms to specified requirements.

4.25 testing : The determination of verification of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental or operating conditions.

4.26 verification : The act of reviewing, inspection, testing, checking, auditing, or otherwise verifying and documenting whether items, processes, services, or documents conform to specified requirements.

5 Criteria for quality assurance

5.1 Quality assurance programme

5.1.1 General

5.1.1.1 A quality assurance programme which complies with the applicable clauses and elements of this International Standard shall be established at the earliest practicable time consistent with the schedule for implementing the activities associated with a specific project or constituent activity. The programme shall identify the procedures necessary to ensure implementation of the various activities, and shall include the methods of assuring that the plant items and services are supplied in accordance with the specified requirements.

5.1.1.2 The programme shall define the structure, responsibility, levels of authority and the internal and/or external interface arrangements of the personnel and organizations involved.

5.1.1.3 Programme documents shall be made available in a language agreed to by the purchaser and supplier.

5.1.1.4 The programme shall identify the items and services to which this International Standard applies. Since items and services will differ in regard to relative safety, reliability, and performance importance, various methods or levels of control and verification may be used to assure adequate quality. Regardless of the methods or levels used, the programme shall provide for the assurance of quality consistent with applicable codes, standards, and other requirements. As a guideline, some factors to be considered in assigning methods or levels of quality assurance are as follows :

a) the consequence of malfunction or failure of the item;

b) the design and fabrication complexity or novel features of the item;

c) the need for special controls and surveillance over processes and equipment;

d) the degree to which functional compliance can be demonstrated by inspection or test;

e) the quality history and degree of standardization of the item;

f) the difficulty of repair or replacement, or accessibility for in-service inspection.

5.1.2 Documentation and management aspects of a quality assurance programme

5.1.2.1 The programme shall provide for documents such as plans, procedures and instructions, and, where necessary, shall contain provisions to ensure compliance with other relevant documents such as standards, engineering codes and practices.

5.1.2.2 The programme shall provide for training and qualification of personnel performing activities affecting quality as necessary to ensure that suitable proficiency is achieved and maintained.

5.1.2.3 The programme shall provide for the accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The programme shall take into account the need for special controls, processes, test equipment, tools and skills to attain the required quality, and the need for verification of quality by inspection, examination, or test.

5.1.2.4 The programme shall provide for the regular review by management of organizations participating in the programme of the status, adequacy and effectiveness of that part of the quality assurance programme for which they have designated responsibility.

5.2 Organization

5.2.1 Responsibility, authority and communications

5.2.1.1 A documented organizational structure shall be established with clearly defined functional responsibilities, levels of authority and lines of internal and external communication for management, direction and execution of the quality assurance programme.

5.2.1.2 In structuring the organization and assigning responsibility, quality assurance should be recognized as an interdisciplinary function involving many organizational components; it should not, therefore, be regarded as the sole domain of a single quality assurance group.

5.2.1.3 The organizational structure and the functional responsibility assignments shall be such that :

a) attainment of quality objectives is accomplished by those who have been assigned responsibility for performing work (for example, the designer, the welder, or the nuclear facility operator); this may include interim examinations, checks and inspections of the work by the individual performing the work;

b) verification of conformance to established quality requirements is accomplished by those who do not have direct responsibility for performing the work (for example, the design reviewer, the checker, the inspector, or the tester).

5.2.1.4 The authority and duties of persons and organizations responsible for activities affecting quality shall be delineated in writing.

The persons and organizations performing the quality assurance functions of

a) ensuring that an appropriate quality assurance programme is established and effectively executed, and

b) verifying that activities have been correctly performed

shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions and to verify implementation of solutions; and, where necessary, to control further processing, delivery, or installation of a non-conforming item, deficiency, or unsatisfactory condition until proper dispositioning has occured.

Such persons and organizations performing quality assurance functions shall report to a management level such that this required authority and organizational freedom, including sufficient independance from cost and schedule considerations, are provided. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance programme may take various forms provided that the persons and organizations assigned the quality assurance fuctions have this required authority and organizational freedom. Irrespective of the organizational structure, the individual or individuals assigned the responsibility for ensuring effective execution of any portion of the quality assurance programme at any location where activities affecting quality are being performed shall have direct access to such levels of management as may be necessary to perform this function.

5.2.2 Organizational interfaces

5.2.2.1 Where multiple organization arrangements are involved, the responsibility of each organization shall be clearly established and documented, and interfaces and co-ordination among organizations ensured by appropriate measures.

5.2.2.2 Provision shall be made for communication among organizations and organizational groups participating in activities affecting quality. The communication shall be by means of appropriate documents to ensure the dissemination of required information.

5.2.3 Staffing and training

5.2.3.1 Personnel performing activities affecting quality shall be qualified on the basis of appropriate education and/or training and/or experience as required for performing the specific assigned tasks.

5.2.3.2 Where training is applied it shall ensure that suitable proficiency is achieved and maintained.

5.3 Design control

5.3.1 General

5.3.1.1 Control measures shall be established and documented to ensure that applicable specified design requirements, such as regulatory requirements, design bases, codes and standards, are correctly translated into specifications, drawings, procedures, acceptance criteria, or written instructions. They shall include provisions to ensure that applicable quality requirements are specified and included or referenced in design documents. Changes to, or deviations from, specified design and quality requirements shall be identified, documented and controlled.

5.3.1.2 Design control measures shall provide for design analyses; evaluation of accessibility for in-service inspection, maintenance and repair; and delineation of acceptance criteria for inspections and tests. Measures shall also be established for the selection and review for suitability of application and compatibility of items and processes that are essential to the function of the plant or part thereof.

5.3.1.3 Design activities shall be documented to permit adequate assessment by technical personnel other than those executing the original design.

5.3.2 Design interface control

Design control measures shall be applied as necessary to identify and control design interfaces and for coordination among participating design organizations. These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution and revision of documents involving design interfaces.

5.3.3 Design verification

5.3.3.1 Design control measures shall provide for verifying the adequacy of design, such as by the performance of design reviews, by the use of alternative calculating methods, or by a suitable testing programme. Design verification shall be carried out and documented by persons other than those who executed the original design but who may be from the same organization.

5.3.3.2 Where a test programme is used to verify the adequacy of a specific design feature, it shall include suitable testing under the most adverse design conditions for the specific design features being verified. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions. If testing indicates that modifications to the item are necessary to obtain acceptable performance, the item shall be modified and retested as necessary to assure satisfactory performance. Where testing cannot be carried out under the most adverse design conditions, testing is permissible if the results can be extrapolated to the most adverse design conditions.

5.3.4 Design changes

5.3.4.1 Procedures shall be provided for effecting design changes, including on-site changes. The technical impact of changes shall be carefully considered, and required actions documented. The changes shall be subjected to design control measures commensurate with those applied to the original design.

5.3.4.2 Design changes shall be reviewed and approved by the same groups or organizations responsible for review and approval of the original design documents, unless other organizations are specifically designated. Information concerning the changes shall be transmitted to all affected persons and organizations.

5.3.4.3 In the event that it is not practical for the original organizations to perform the required review or approval, other responsible design organizations may be designated, provided that the designated organizations have access to pertinent background information, have demonstrated competence in the specific design area, and have adequate understanding of the original design.

5.4 Procurement document control

5.4.1 Measures shall be established and documented to ensure that applicable regulatory requirements, design bases, standards, specifications and other requirements necessary to assure adequate quality are clearly specified or referenced in the documents for procurement of items and services.

5.4.2 Procurement requirements for assuring quality shall include, but need not be limited to, the following, as applicable :

a) a complete statement of the scope of the work to be performed by the supplier;

b) technical requirements specified by reference to technical documents such as codes, regulations, standards, specifications and drawings, including issue identification and any revisions thereto;

c) test, inspection, and acceptance requirements, and any special instructions and requirements for such activities;

d) provisions for access to plant facilities and records for the purpose of source inspection, surveillance and audit when the need for such activities has been determined;

e) identification of quality assurance requirements and the elements of the programme applicable to the items or services procured;

f) identification of documentation required, such as specifications, manufacturing and/or inspection plans, instructions, procedures, inspection and test records, and other records to be prepared and submitted or made available for review or approval by the purchaser;

g) provisions for specifying the timing of the submittal of documentation;

h) provisions for controlled distribution, retention, maintenance and disposition of quality assurance records;

j) requirements for reporting non-conformances that require purchaser's approval or knowledge;

k) provisions for extending applicable requirements of procurement documents to lower-tier suppliers, including purchaser's access to facilities and records.

5.5 Instructions, procedures and drawings

Activities affecting quality shall be prescribed in instructions, procedures, drawings, or any other type of document appropriate to the circumstances, and shall be accomplished in accordance with these documents. Where applicable, instructions, procedures or drawings shall include appropriate quantitative criteria such as dimensions, tolerances, and operating limits, or qualitative criteria such as comparative workmanship samples, for determining satisfactory work performance and quality compliance.

5.6 Document control

5.6.1 Document preparation, review and approval

5.6.1.1 Preparation, review, approval and issue of documents essential to the performing and verifying of the work (such as instructions, procedures and drawings) shall be controlled. This includes the identification of individuals or organizations responsible for preparing, reviewing, approving and issuing documents related to activities affecting quality.

5.6.1.2 The reviewing and approving organization or individuals shall have access to pertinent background information upon which to base their review or approval.

5.6.2 Document release and distribution

A document release and distribution system shall be established. Measures shall be provided for ascertaining that those participating in an activity are aware of, and use, appropriate and correct documents for performing the activity.

The system shall provide for coordination and control of interface documents.

5.6.3 Document change control

5.6.3.1 Changes to documents shall be subject to review and approval in accordance with documented procedures.

5.6.3.2 Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. Reviewing and approving organizations shall have access to pertinent background information upon which to base their review and approval.