

Safety Standards

of the
Nuclear Safety Standards Commission (KTA)

KTA 1401 (06/96)

General Requirements Regarding Quality Assurance

(Allgemeine Forderungen an die Qualitätssicherung)

The previous version of this safety
standard was issued 12/87

If there is any doubt regarding the information contained in this translation, the German wording shall apply.

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KTA SAFETY STANDARD

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General Requirements Regarding Quality Assurance

KTA 1401

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PLEASE NOTE: Only the original German version of this safety standard represents the joint resolution of the 50-member Nuclear Safety Standards Commission (Kerntechnischer Ausschuss, KTA). The German version was made public in Bundesanzeiger No. 216a on November 19, 1996. Copies may be ordered through the Carl Heymanns Verlag KG, Luxemburger Str. 449, D- 50939 Koeln (Telefax 0221-4601092).

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Comments by the editor:

Taking into account the meaning and usage of auxiliary verbs in the German language, in this translation the following agreements are effective:

- shall** indicates a mandatory requirement,
- shall basically** is used in the case of mandatory requirements to which specific exceptions (and only those!) are permitted. It is a requirement of the KTA that these exceptions - other than those in the case of **shall normally** - are specified in the text of the safety standard,
- shall normally** indicates a requirement to which exceptions are allowed. However, the exceptions used shall be substantiated during the licensing procedure,
- should** indicates a recommendation or an example of good practice,
- may** indicates an acceptable or permissible method within the scope of this safety standard.

Fundamentals

(1) The safety standards of the Nuclear Safety Standards Commission (KTA) have the task of specifying safety related requirements which shall be met with regard to precautions to be taken in accordance with the state of science and technology against the damage arising from the construction and operation of the facility (Sec. 7 para. 2 subpara. 3 Atomic Energy Act), in order to attain the protection goals specified in the Atomic Energy Act and the Radiological Protection Ordinance (StrlSchV) and which are further detailed in "Safety Criteria for Nuclear Power Plants" and in "Guidelines for the Assessment of the Design of PWR Nuclear Power Plants against Incidents pursuant to Sec. 28 para. 3 of the Radiological Protection Ordinance - Incident Guidelines".

(2) Criterion 1.1 of the Safety Criteria states as the first and foremost principle that high requirements are put to the design and quality of the nuclear power plant as well as to the qualification of the personnel in order to already ensure by these measures that the nuclear power plant can be operated as free from incidents and as well suited to the environment as possible even without required actions of the equipment of the safety system. This requirement is detailed with special regard to quality assurance in Criterion 2.1.

(3) The purpose of quality assurance is to ensure in a verifiable way that the quality requirements with respect to the product forms, parts, components and systems are established and, taking the respective load conditions into account, that these requirements are met to the required extent during fabrication and assembly as well as during the construction of civil structures and are, furthermore, met during operation and maintenance until decommissioning of the nuclear power plant.

(4) The quality requirements can only be planned, fulfilled and the fulfillment verified if, during planning and design, during procurement, fabrication and assembly of product forms, parts, components and systems as well as during construction of civil structures, during commissioning and operation until decommissioning of the nuclear power plant including maintenance with the required tests and inspections, the tasks are carried out with, especially, technical know-how and under consideration of the specified requirements and if the activities of the people involved is oriented toward achieving the quality goals.

(5) The goal of quality planning should be to ensure that the protection goals stipulated in laws (e.g. Atomic Energy Act) and ordinances (e.g. Radiological Protection Ordinance) are reached.

(6) The individual quality assurance measures supplement each other to make up the complete quality assurance program by which the fulfillment of quality assurance measures can be verified and the gained experience fed back into the planning. With regard to the cooperation between applicant or licensee and their contractors, it is ensured that the quality requirements are specified by the applicant or licensee and are fulfilled by their contractors.

(7) With the help of quality tests and inspections it is verified that the quality requirements were fulfilled and continue to be so to the extent individually required during operation until decommissioning of the nuclear power plant.

(8) This safety standard establishes the basic requirements for quality assurance. Its scope is to specify superordinate requirements regarding planning, organization, technical and organizational procedures, documentation, tests and inspections. These should be met with the goal of preventing the later occurrence of mistakes and failures. Specific requirements for the quality assurance of structural and other materials and components, of the systems and the overall plant are specified in other standards, guidelines and specifications and here, foremost, in civil engineering regulations and the KTA safety standards (e.g. the KTA series 3200, 3400, 3500 and 3700).

(9) KTA 1404, Documentation During the Construction and Operation of Nuclear Power Plants, establishes further basic requirements detailing Section 12 of this safety standard. Requirements regarding the verification of (correct) operation of the nuclear power plant are specified in its operating manual, those regarding the in-service tests and inspections in its testing manual.

1 Scope

This safety standard applies to the quality assurance during planning and design, during procurement, fabrication and assembly of product forms, parts, components and systems as well as during construction of civil structures, during commissioning and operation including the related tests and inspections, with special regard to the quality characteristics important to the precautionary measures against damage of the safety relevant parts in stationary power plants.

2 Terminology

(1) Appraisal

Appraisal is the assessment and evaluation of the license application documents.

Note: The appraisals are carried out by the competent authority, if needed, in consultation with authorized experts. The appraisal concerns itself, among other things, with the question of whether or not the requirements contained and substantiated in the application documents for civil structures, systems and components regarding precautionary measures against damages are state-of-the-art and whether or not these requirements can be met during procurement, fabrication and assembly of product forms, components and systems as well as during construction of civil structures, during commissioning, during specified normal operation and during incidents including the necessary tests and inspections. The appraisal also extends to the evaluation of results of the analyses of events and plant behavior under normal operation and incident conditions.

(2) State and condition

State and condition of a unit is the entirety of its characteristics and characteristic values.

(3) Procurement

Procurement is the activity from setting up the procurement documents up to and including the receiving inspections and acceptance of the delivered units.

(4) Procurement documents

Procurement documents are documents in which technical data, requirements and measures are specified for the items to be procured.

(5) Specified normal operation

- a) Operating conditions for which the plant, assuming the able function of all systems (fault free condition), is intended and suited (normal operation);
- b) Operating processes which occur in the event of plant component or system malfunction (fault condition), insofar as safety related reasons do not oppose continues operation (abnormal operation);
- c) Maintenance procedures (inspection, servicing, repair).

(Source: Safety Criteria)

(6) Proven operational experience

Proven operational experience is a characteristic of a unit for which it has been shown within a sufficient observation period under functional and environmental conditions that are comparable to the intended application that no impermissible failures have occurred.

Note: An observation period is considered to be sufficient if design errors of the unit can be detected and the intended concept regarding servicing can be assessed.

Inadmissible failures are such which can be categorized as common-mode failures (e.g. excess loading of parts and incorrect choice of materials) or excessive occurrence of random failures.

(7) Documentation

Documentation is the systematic compilation of documents.

Note: The plant documentation, for instance, comprises the documents from the design, procurement, fabrication, commissioning and specified normal operation together with the license decrees, test and inspection records.

(8) Unit

Unit is a material or immaterial object under consideration.

Note: Units are, for instance:

a) the results of activities or processes:

- *material products such as a system, a fabrication series, a device, a functional unit or structural element,*
- *immaterial products such as a service, a computer program, a construction draft, an operating instruction.*

b) the activities or processes themselves such as the activity of carrying out a service, or a machining sequence, or a procedure.

(9) Product forms

Products forms are products from which structural components and parts are fabricated.

Note: Product forms are, for instance, sheet metal, forgings, pipes, castings, concrete, cables.

(10) Nonconformity

Nonconformity is the non-fulfillment of a requirement.

(11) Commissioning

Commissioning is the entirety of measures that are necessary for the initial functional operation of components and systems at their final assembly location.

(12) Maintenance

Maintenance is the entirety of measures for sustaining and restoring the required condition as well as for determining and evaluating the actual condition.

Note: Maintenance comprises inspection, servicing and repair.

(13) Repair

Repair is the entirety of measures for restoring the required condition.

(14) Component

Component is a confined part of a system according to structural

or functional aspects.

Note: A component may still perform partial functions.

(15) Inspection identification number

Inspection identification number is a numeric code of a type-tested series-produced item or component by which its type test is unambiguously identified.

(16) Inspection mark

Inspection mark is a marking of the series-produced item or component by which it is verified that the product is in conformance with a generally accepted engineering standard.

(17) Quality

Quality is the characteristic of a unit with respect to its qualification for fulfilling the quality requirements.

(18) Quality characteristic

Quality characteristic is the distinctive feature characterizing the quality.

Note: A quality characteristic is, generally, also an inspection characteristic.

(19) Quality planning

Quality planning is the process of choosing and specifying the overall required quality characteristics and the measures that shall normally ensure the fulfillment of the quality requirements.

(20) Quality inspection

Quality inspection is the determination in how far a unit fulfills the quality requirements.

Note: Part of the quality inspection is the verification that the structural building materials and structural components are in conformance with the laws of the building trade.

(21) Quality assurance

Quality assurance is the entirety of all organizational and technical measures to assure the quality.

Note: Quality assurance, thus, comprises quality planning, quality inspections, measures for ensuring that the quality requirements are fulfilled and the documentation is carried out, and includes the feedback of experience during the individual processing phases.

Processing phases are, e.g., establishing the safety concept, planning and design, procurement, fabrication and assembly of product forms, parts, components and systems, construction of civil structures, commissioning and specified normal operation including the corresponding tests and inspections.

(22) Quality assurance system

Quality assurance system is the established structural and procedural organization for executing quality assurance.

(23) Authorized expert

Authorized expert is a competent person or organization to be consulted in accordance with guidelines, license provisions or provisional conditions or acting as consultant to the proper authority.

(24) Series-produced items or components

Series-produced items or components are products which are fabricated in larger quantities, each with the same design and quality.

Note: Series-produced items or components are usually fabricated without prior knowledge of their later application.

(25) Type testing

Type testing is the testing of one or more units of a product to demonstrate the specified characteristics.

Note: The characteristics are specified in, e.g., in specifications, technical data sheets and building code related test certificates.

The scope of the type test does not include the inspection of the product with respect to proper usage.

(26) In-service inspections

In-service inspections are such tests and inspections which, in accordance with legal requirements, provisions by the proper authorities or on the basis of other requirements, are performed in specified time intervals or after specific occurrences.

3 Basic Requirements

(1) The license applicant or licensee shall ensure that the companies participating in carrying out quality assurance measures - these are he himself, his contractors and subcontractors - will plan and perform the quality assurance in accordance with the requirements of this safety standard.

(2) The quality assurance shall be performed during all phases of work in which the quality characteristics are influenced and can be determined (these are: establishment of the safety concept, planning and design, procurement, fabrication and assembly of product forms, parts, components and systems, construction of civil structures, commissioning and specified normal operation including the corresponding tests and inspections) with the goal of planning and achieving and of maintaining in a documented way the individual quality requirement taking the corresponding legal requirements and the organizational procedures into account.

(3) The license applicant or licensee shall prepare a description of the quality assurance program. The essential part of this program is the established structural and procedural organization for assuring the quality. The description shall comprehensively describe how and by whom the requirements of this safety standard are fulfilled and how their fulfillment is certified. The description shall normally refer to the existing internal instructions concerning the activities within the quality assurance program. The description of the quality assurance program and these internal instructions shall be adapted to conform to changes and shall be documented.

(4) During planning and performance of quality assurance, organizational measures related to the quality assurance system and technical measures related to the product shall be applied and shall complement each other.

(5) The quality assurance characteristics including their specified values as well as the quality assurance measures shall be chosen early in the planning phase with special regard to the individual type of nuclear power plant and its parts. Type and extent of the quality assurance measures in planning, creating, maintaining and in demonstrating the quality characteristics shall be in accordance with their importance regarding the protection against damages including impermissible radioactivity release and radiation exposure.

(6) The implementation of quality assurance measures within each organization shall ensure that a detected nonconformance of specified requirements or procedures is registered and that the experience gained is utilized. Generally known and assured experience shall normally also be taken into account.

(7) In the case of series-produced items, the planning and fabrication does not have to meet the requirements of paragraphs 1 through 5 if the fulfillment of the quality requirements is assured and verified in accordance with paragraph 8.

(8) In the case of series-produced items the verification that the quality requirements are fulfilled shall either follow generally accepted engineering standards or shall be carried out by demonstrating proven operational experience or by type testing in accordance with specified procedures. In addition, the fulfillment of the quality requirements shall be verified by tests in the course of fabrication or by factory tests and inspections. Furthermore, it shall be verified that the series-produced items are not impermissibly stressed in the planned application.

Note: It may follow from this verification that further tests and verifications are required in addition to the type test.

The requirements regarding factory tests and inspections of the instrumentation and control equipment of the safety system are specified in safety standard KTA 3507.

4 Organization

4.1 Basic Organizational Requirements

(1) The license applicant or licensee is responsible for the planning and performing quality assurance and for supervising its effectiveness.

(2) In the case that the license applicant or licensee delegates the fulfillment of requirements regarding quality assurance measures to contractors, he shall ensure that the quality assurance performed by the contractor or his subcontractor is in accordance with this safety standard. The license applicant or licensee shall convince himself of the qualification and reliability of his contractors.

4.2 Internal Organization

(1) In establishing the internal organization the departmental units involved shall meet the following basic requirements:

- a) The individual persons charged with executing tasks in planning and design, procurement, fabrication and assembly of product forms, parts, components and systems, construction of civil structures, commissioning and specified normal operation including the corresponding tests and inspections shall provide that the individual quality requirement is met.
- b) Only those persons shall be charged with the review of documents required by this safety standard who did not themselves prepare these documents.
- c) As far as tests and inspections of products or the supervision of activities are to be carried out independently, only those persons shall be charged with these duties who did not themselves produce the products or were not charged with, or were not responsible for performing the activities.

Note: Which tests and inspections are to be carried out independently is specified in guidelines and safety standards or in the course of the design review (i.e. the review of manufacturing documents).

- d) Persons charged with the task of implementing and auditing the quality assurance system shall be authorized to collect information, suggest solutions and to supervise the adherence

to the specified quality assurance measures; these persons shall not belong to the personnel described under item a.

4.3 Cooperation Between the Involved Companies and Departmental Units Installed Therein

(1) It shall be ensured that, in case of a cooperation between companies and their departmental units which are involved in the performance of quality assurance, each party has its defined task and that the interface between the units is clearly specified and described.

(2) In preparation and for the control of the flow of information, it shall be schematically shown which companies and departmental units in accordance with paragraph 1 shall prepare, review and release the documents and which of these companies and units will receive the documents.

(3) An agreement shall be reached between the companies and departmental units in accordance with paragraph 1 as to the number of copies and to the distribution of the documents to be prepared.

(4) From an early point on it shall be specified which of the companies and departments in accordance with paragraph 1 will be responsible for coordinating the corresponding measures of the proper authorities and their consulting authorized experts in the overall procedure.

4.4 Personnel Qualification

(1) In so far as it is required for the individual tasks, the requirements regarding personnel qualification shall be specified.

Note: This applies, in particular, to the requirements in legal standards. The qualification can be specified by referencing the corresponding legal standard or safety standard.

(2) The personnel qualification and its maintenance shall be verified upon request.

5 Planning and Design

5.1 Basic Principles

(1) It shall be ensured that the design principles and the requirements in accordance with legal standards, safety standards, license decrees and legal directives are transferred to documents, e.g., specifications, drawings, plans and commissioning instructions.

(2) The requirements that are essential to quality and to procedural processes shall be specified early before the start of fabrication and assembly of product forms, parts, components and systems as well as before the construction of civil structures; the specification shall be in writing and, preferentially by reference to the corresponding standards, guidelines and other specifications. The following shall be stated:

- a) which are the parts, components, systems and civil structures of the nuclear power plant that are relevant to safety,
- b) which are the quality characteristics of the plant components in accordance with item a that have to be considered in conjunction with precautions against damages that could impair safety,
- c) which are the quality assurance measures that shall normally be performed in order to achieve the quality characteristics in accordance with item b.

Note: The statements required in accordance with items a, b and c are also reviewed by the proper authorities or their consulting authorized experts in the course of appraisal, design review and quality tests and inspections (in the building trade: in the course of testing and surveillance in accordance with the building code).

(3) In the case that quality requirements and procedural processes are not specified in technical standards or in case it is intended to deviate from the specifications in engineering standards, the criteria for selecting structural and other materials, product forms, components parts and components as well as the procedures for their manufacture shall normally be specified if this is important with regard to the safety relevance of the systems. Hereby, the statements required in accordance with paragraph 2 items a, b and c shall also be provided.

(4) The procedural process of quality assurance basically shall be planned and specified (exceptions are stated in paragraphs 5 and 6) such that, early on in the procedures of procurement, fabrication, assembly or construction can be corrected or by taking additional measures, the quality requirements can be fulfilled and a specified normal operation of the nuclear power plant be made possible.

(5) Structural materials and components satisfy the requirements of this safety standard with regard to their quality, provided, they are qualified in accordance with the building code and no overriding requirements arise from the protection goals of the Atomic Energy Act.

(6) The quality of series-produced items is also assured in accordance with this safety standard, if the requirements in accordance with Section 3 paragraph 8 are met. In the case of type-tested series-produced items the statement of the inspection identification number or of the certification of the type test, possibly together with the type test report (in the building trade: the legal structural test certificate) suffices as verification of meeting the quality requirements. In the case of series-produced items with a proven operational experience, information regarding design, quality and past deployment is sufficient. The individual requirements for demonstrating operational experience shall be specified depending on the individual component.

5.2 Inspection Documents

If it is not already specified in technical standards or in testing or inspection instructions, inspection documents shall be prepared for all tests and inspections of plant components in accordance with Section 5.1 paragraph 2 item a; these documents shall normally contain the following information:

- a) item to be tested or inspected,
- b) quality characteristics,
- c) requirements regarding the values of the quality characteristics,
- d) type of test or inspections (e.g., material test, in-process inspection, construction test, functional test, in-service inspections),
- e) inspection procedure and, if necessary, the type of measuring and testing equipment to be used,
- f) extent of inspection,
- g) performance of inspection with respect to the fabrication, commissioning or operating procedure,
- h) inspecting party (e.g., manufacturer, supplier of the nuclear power plant, licensee/operator, proper authority or authorized expert),
- i) requirements regarding the recording of tests and inspections,

Note: Depending on the items to be inspected, the following types of records are possible:

- a generally accepted marking of the tested parts or of the reviewed documents,
- test certificates (e.g., statement of compliance with the order, manufacturer test certificate, acceptance test certificate),
- test reports.

In the case of series-produced items with a proven operational experience, inspection or surveillance instructions are usually available.

- k) requirements regarding the storage of material specimens if such material specimens are required.

5.3 Document Review

(1) The documents prepared in accordance with Sections 5.1 and 5.2 shall be reviewed and formally released prior to their application. This review shall be performed by persons in accordance with Section 4.2 item b. As required, these documents shall also be presented to the proper authority or their consulting authorized expert for a design review.

Note: In the case of civil structures, the design review is carried out in form of the civil engineering review of the documents to be submitted in accordance with the Building Document Submittal Ordinance of the German federal states.

5.4 Document Revision

(1) In the case that documents in accordance with Sections 5.1 and 5.2 need to be revised, all companies and parties involved shall be informed without delay. The involved companies and parties shall ensure within their own organization that the use of incorrect or invalid documents is prevented and that the tasks are performed only in accordance with valid documents.

(2) The revisions of these documents shall be similarly reviewed in accordance with Section 5.3 as the original documents. All revised parts of the documents shall be marked or collated in a list. The reasons for the revisions shall be presented to the parties involved in the document review, provided, the reasons are important for carrying out the review.

5.5 Filing System and Identification Code

(1) All documents shall be unambiguously marked for identification. The identification code shall also contain reference to the revisional state of the document.

(2) With regard to correspondence and filing of documents a filing and identification system shall be established to enable their unambiguous identification.

(3) With regard to procurement, fabrication, assembly and erection an identification code allowing an unambiguous coordination between parts and documents shall be established if this coordination is required or if it must be ensured that the entire process be traceable to its origin.

6 Procurement

6.1 Evaluation of the Contractor by the Client

(1) Each client shall normally evaluate the qualification of their intended contractors with regard to the tasks to be performed.

(2) Each client may base his evaluation of a contractor on prior evaluations of this contractor by other parties that were carried out in accordance with KTA safety standards.

(3) The criteria for evaluating the contractor shall be based on product oriented requirements. The following shall be evaluated:

- a) technical equipment,
- b) personnel,
- c) quality assurance system,
- d) internal and external surveillance,
- e) experience.

(4) The contractor shall prepare a description of his quality assurance system that is specially oriented toward the product requirements for the evaluation by the client.

(5) Each client shall ensure that his contractors meet the requirements on which the client based his evaluation.

(6) The contractor evaluation is not required if other measures (e.g., product oriented measures) are employed to show that the quality requirements are met.

(7) In those cases where a contractor does not meet individual requirements of this safety standard, the respective client shall specify alternative measures. In this context, it is permissible that tests or inspections are performed either by the client or, on his behalf, by the contractor which provide evidence that the performed work meets the respective requirements.

6.2 Procurement Documents

(1) The procurement documents for structural and other materials, product forms, parts and components of the plant in accordance with Section 5.1 paragraph 2 item a shall basically contain the requirements established during the design phase (refer to paragraph 2 for the exception). These are, as required, information on

- a) the intended application and the operating conditions,
- b) the quality characteristics,
- c) the structural and other materials,
- d) the requirements concerning the performance and surveillance of the in-process, final and functional tests and inspections,
- e) the feasibility of the initial and recurrent in-service inspections,
- f) the right of access of the parties concerned to fabrication and inspection,
- g) the extent and archiving of the documents to be established regarding design, fabrication and assembly of parts, components and systems as well as regarding the erection of civil structures including the associated tests and inspections,
- h) the handling, storage, transportation and packaging,
- i) the identification coding of the documents to be prepared and of the procured items.

(2) In the case of series-produced items it is sufficient to specify the coding (e.g., type number, order number) if, thereby, the individual item or component, its manufacturer as well as the corresponding technical data sheets or lists can be identified.

(3) The procurement documents shall be reviewed, revised and coded for identification in accordance with Sections 5.3, 5.4 and 5.5.

6.3 Receiving Inspection

Upon receipt of the delivered structural and other materials, product forms, parts, components and systems as well as the parts of civil structures these shall be inspected with regard to transport damages and whether or not the delivered products correspond to the procurement documents.

7 Fabrication, Assembly and Erection Including Quality Tests and Inspections

7.1 Evaluation of the Manufacturing Plant by the Proper Authority or their Consulting Authorized Expert

(1) If it is so required in legal ordinances or provisions, or in engineering standards (e.g., for pressure retaining parts), the proper authority or their consulting authorized expert shall evaluate the manufacturing plant prior to the begin of fabrication and assembly of product forms, parts, component and systems and the erection of civil structures; in this evaluation it shall be ascertained whether or not the manufacturing plant has appropriate technical facilities and equipment and qualified personnel at its disposal and whether or not the tests and inspections are performed independently in accordance with Section 4.2 item c.

(2) A written, product oriented certificate of the authorized expert confirming the successful evaluation of the manufacturing plant shall be issued; it shall contain an exact statement of its scope of application and of its period of validity. If no supplementary or renewed evaluations are required, the manufacturer may use this certificate within the period of validity for his verification of the quality of follow-up products produced within the scope of the certification.

(3) A supplementary or renewed evaluation of the manufacturing plant with respect to its fulfilling the evaluating criteria in accordance with paragraph 1 shall then be required if essential changes have occurred with respect to the decisive prerequisites of the prior evaluation.

7.2 Performance and Surveillance of Fabrication, Assembly, Erection, Tests and Inspections

(1) The fabrication, assembly and erection shall be performed on the basis of documents (e.g., fabrication instructions, fabrication schedules). Quality assurance measures shall be applied to ensure that

- a) the individual quality requirements are met,
- b) only well mastered processes and appropriate equipment and facilities are employed,
- c) the equipment and facilities are sufficiently maintained,
- d) the required ambient conditions are maintained,
- e) the fulfillment of the quality requirements is recorded to the required extent in documents.

(2) Quality tests and inspections shall be performed at specified hold points during and at completion of fabrication, assembly and erection. The fabrication and inspection steps shall be coordinated (e.g., by an inspection sequence plan) such that the tests and inspections are performed at a stage when the required quality characteristics can still be determined without restriction.

(3) The performance of the tests and inspections specified in the documents in accordance with Section 5.2 shall be recorded. The

inspection records shall meet all requirements specified in the inspection documents.

(4) If the fulfillment of a required quality characteristic cannot be verified by quality tests or inspections then the fabricating processes essential for this quality characteristic shall be surveyed and, as required, shall be documented.

(5) The tests and inspections in accordance with paragraph 2 and the surveillance in accordance with paragraph 4 shall be documented sequentially as the work proceeds. The results of the tests and inspections shall be evaluated early enough that corrective actions can be applied. The certificates and inspection records specified in accordance with Section 5.2 item d shall, as required, be filed in the document storage.

(6) The records in accordance with paragraphs 3 and 5 are not required for series-produced items for which a proven operational experience (cf. Section 5.1 paragraph 6) has been demonstrated.

7.3 Marking, Handling, Storage, Transportation and Packaging

(1) The units shall be marked with the system in accordance with Section 5.5 paragraph 3 to which it belongs.

(2) Protective measures shall be implemented to ensure that during handling, storage, transportation and packaging of structural and other materials, product forms, parts, components and test specimens, their quality is not impaired and, mainly, that no damages and mix ups will occur; it shall also be ensured that the required cleanness is maintained.

(3) Surveillance measures shall be applied to ensure that the requirements regarding marking, handling, storage, transportation and packaging are met.

8 Commissioning

(1) The commissioning of the systems and of the nuclear power plant shall be carried out on the basis of written commissioning procedures.

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

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

(3) The commissioning procedures shall be reviewed by the departmental units to be specified in accordance with Section 4.3 paragraph 3 and, if required, by the proper authority or their consulting authorized expert.

(4) Repairs, modifications and in-service inspections during commissioning shall be performed in accordance with Section 9 paragraphs 5 through 7.

(5) It shall be ensured that the experience gained during commissioning is transferred in the required extent to the operating manual.

9 Specified Normal Operation and Incidents

- (1) The licensee shall ensure that safety relevant measures are only performed and decisions only made by those persons who are appropriately qualified and in positions to be authorized accordingly.
- (2) The procedures for fulfilling the quality requirements shall be specified in operating instructions in accordance with KTA 1201 and KTA 1202.
- (3) The specified normal operation shall be performed in compliance with the specified operating instructions.
- (4) The properly authorized personnel of the nuclear power plant shall be responsible for, and shall be free to decide upon:
 - a) surveillance of the parameters necessary for evaluating the operating condition during specified normal operation and during incidents,
 - b) ordering and performing of tasks (e.g., protective actions) and taking precautionary measures in all operating conditions and incidents.
- (5) Repairs and modifications shall be performed in accordance with this safety standard and in observance of the maintenance regulation to be specified for the plant (cf. Sec. 4.3 KTA 1201).
- (6) Damages shall be analyzed and shall be documented together with the corrective actions taken. Precautionary measures shall be taken to prevent a recurrence of these damages.
- (7) The in-service tests and inspections shall be planned on the basis of, e.g., operating experience, safety analyses, manufacturing results and inspection documents in accordance with Section 5.2, and shall be performed within fixed time intervals. The test and inspection results shall be documented.

10 Inspection, Measuring and Testing Equipment

- (1) The inspection, measuring and testing equipment needed for providing evidence of fulfillment of the quality requirements and for the surveillance of parameters decisive for the quality shall, initially and thereafter in periodic intervals, be controlled and maintained.

Note: The plant instrumentation does not, in this sense count as measuring and inspection equipment. Plant instrumentation is subjected to in-service inspections in accordance with Section 9 paragraph 7.

- (2) In special documents of the owner of the inspection, measuring and testing equipment it shall be specified when, how and by whom the necessary controls and calibrations shall be performed, repeated and documented.

11 Nonconformance Control

- (1) If a nonconformance is detected on an item, this item shall be segregated or shall be correspondingly marked.

- (2) It shall be specified in writing who shall be notified, in what way the notification shall occur and who is authorized to decide about the further actions to be taken. In the case of nonconforming documents the corrective actions shall follow a procedure in accordance with Section 5.4.

- (3) It shall be ensured that no tasks are performed on the nonconforming section of a component or in other areas that would prevent or hinder identifying the cause of the nonconformity or the possibly necessary rework or repair.

- (4) Rework and repair shall be based on documents that are equivalent to those on which the fabrication of the respective parts was based. These documents shall be reviewed and filed in the document storage in the same way as the original documents.

12 Documentation and Document Storage

- (1) Type and extent of the documentation shall be described.
- (2) The extent of documentation shall be oriented on the information required for a later evaluation.
- (3) The documentation shall be reviewed with regard to its completeness.
- (4) All records in accordance with paragraph 2 that are in any way concerned with a modification shall be updated accordingly.
- (5) The retention period and storage location of documents as well as of the possibly required residual materials and test specimens shall basically be specified in accordance with KTA 1404. Hereby, the corresponding specifications in the component related KTA safety standards shall be taken into account. In case of those documents required in accordance with KTA 1401 for which, however, no specifications are contained in KTA 1404, the retention period and storage location shall be specified in writing.

13 Auditing of the Quality Assurance System

- (1) Basically, every party involved shall periodically audit its quality assurance system with regard to its implementation and effectiveness. Excepted are those companies where the effectiveness of the quality assurance system can be sufficiently verified by product related measures.
- (2) An audit of the quality assurance system shall be performed by persons in accordance with Section 4.2 item d.
- (3) Clients shall convince themselves of the effectiveness of the quality assurance system of their contractors in regular time intervals; they shall orient their audit on product related requirements. This may be done by tests of the products concerned.
- (4) The results of the audits shall be documented.
- (5) Detected deficiencies or weak points of the quality assurance system shall be corrected without delay. The audit shall be repeated to the necessary extent.

Annex

Regulations Referred to in this Safety Standard

(The references exclusively refer to the version given in this annex. Quotations of regulations referred to therein refer to the version available when the individual reference below was established or issued.)

KTA 1201	(12/85)	Requirements Regarding the Operating Manual
KTA 1202	(06/84)	Requirements Regarding the Testing Manual
KTA 1404	(06/89)	Documentation During the Construction and Operation of Nuclear Power Plants