Safety Standards

of the
Nuclear Safety Standards Commission (KTA)

KTA 1401 (2017-11)

General Requirements for the Quality Assurance

(Allgemeine Anforderungen an die Qualitätssicherung)

The previous versions of this safety standard were issued in 1980-02, 1987-12, 1996-06 and 2013-11

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

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PLEASE NOTE: Only the original German version of this safety standard represents the joint resolution of the 35-member Nuclear Safety Standards Commission (Kerntechnischer Ausschuss, KTA). The German version was made public in the Federal Gazette (Bundesanzeiger) on May 17, 2018. Copies of the German versions of the KTA safety standards may be mail-ordered through the Wolters Kluwer Deutschland GmbH (info@wolterskluwer.de). Downloads of the English translations are available at the KTA website (http://www.kta-gs.de).

All questions regarding this English translation should please be directed to the KTA office:

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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, 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.

Basic Principles

(1) The safety standards of the Nuclear Safety Standards Commission (KTA) have the objective to specify safety-related requirements, compliance of which provides the necessary precautions in accordance with the state of the art in science and technology against damage arising from the construction and operation of the facility (Sec. 7 para. 2 subpara. 3 Atomic Energy Act - AtG) in order to achieve the fundamental safety functions specified in the Atomic Energy Act and the Radiological Protection Ordinance (StrlSchV) and further detailed in the Safety Requirements for Nuclear Power Plants as well as in the Interpretations of the Safety Requirements for Nuclear Power Plants.

(2) The Safety Requirements for Nuclear Power Plants contain in Sec. 1, No. 3 the general requirement, that the Integrated Management System shall – besides other aspects – include all goals and requirements of quality assurance. The requirements for quality assurance are further detailed in Sec. 3.1. According to Sec. 3.1, para. 2 it is mandatory to respect safety-building design, production and operating principles for all measures and installations designed for safety levels 1 to 4a in all operating phases, and for all measures and installations, that are required for internal and external events as well as man-made hazards. According to Sec. 3.1, para. 2, subclause f) this includes specification and adherence to the respective quality features during production, construction and operation. Furthermore, according to Sec. 3.1, para. 4, the quality and reliability of all installations of the nuclear power plant shall reflect their safety relevance.

(3) The purpose of quality assurance is to ensure in a verifiable way that the required quality characteristics are achieved and, taking the respective loadings into account, are maintained to the extent individually required during operation and maintenance until decommissioning of the nuclear power plant.

(4) The quality characteristics can only be planned, achieved and the achievement verified if the required tasks are carried out with technical expertise and under consideration of the specified requirements, and if the conduct of the parties involved is based on reaching the quality goals.

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

(6) The individual quality assurance measures complement each other to produce a comprehensive quality assurance by which the achievement of quality characteristics is verified and the gained experience can be fed back into the planning. The cooperation between license applicant or licensee and their contractors is such that it is ensured that the quality characteristics are specified by the license applicant or licensee and are fulfilled by the contractors and their subcontractors.

(7) Quality tests and inspections are performed to verify that the quality characteristics have been achieved and that they are maintained to the extent individually required during operation and maintenance until decommissioning of the nuclear power plant.

(8) The present safety standard establishes the basic requirements for quality assurance. It specifies superordinate requirements regarding planning, organization, technical and organizational procedures, documentation, tests and inspections. These are intended to help prevent a later occurrence of nonconformances. Detailed requirements for quality assurance with regard to structural and other materials, to components, systems and the overall power plant are specified in other standards, guidelines and specifications, in particular, in building codes and in KTA safety standards (e.g. the series KTA 3200, KTA 3400, KTA 3500 and KTA 3700).

1 Scope

The present safety standard applies to the quality assurance during

- safety-related conceptual design,
- planning and design,
- procurement,
- fabrication and assembly of product forms, parts, components and systems,
- manufacture or the providing of products,
- erection and subsequent work on building structures,

as well as

- commissioning

including the tests and inspections performed with special regard to those quality characteristics important to the precautionary measures against damage of the safety-related parts and services for stationary power plants during construction, operation and until decommissioning.

(2) The requirements regarding the quality management system of the license applicant or licensee are specified in safety standard KTA 1402.

(3) The license applicant or licensee shall ensure that the contractors and their subcontractors during the phase specified under para. (1) perform the quality assurance as specified in the present safety standard.

2 Definitions

(1) Deviation

Deviation is the difference between the required condition and the actual condition.

(2) Procurement

Procurement comprises all activities from the creation of the procurement documents to the testing and acceptance of the delivered products.

(3) Procurement documents

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

(4) Certified satisfactory service life

Proven satisfactory service life is the characteristic of a product showing that no impermissible failures have occurred within a sufficiently large observation period and under functional and environmental conditions comparable to those of the intended deployment.

Notes:

(1) An observation period is considered to be sufficient if it allows for the detection of possible design errors and for the assessment of the planned maintenance concept.

(2) Impermissible failures are those, in particular, that would be identified as common mode failures (e.g., overloading of components, wrong choice of materials) or that occur impermissible often as random failures.

(5) Documentation

Documentation is a systematic compilation of documents.

Note:

The plant documentation is comprised of, e.g., the design, procurement, fabrication, commissioning, test and inspection documents and certificates.

(6) Qualification test

Qualification test is a plant-independent verification that a series-produced item can be deployed under defined boundary conditions.

(7) Product forms

Products forms are products used for the fabrication of parts and components.

N o t e :

Product forms are, e.g., sheet metal, forgings, pipes, castings, concrete, cables.

(8) Nonconformance

Nonconformance is the non-fulfillment of a requirement.

(9) Commissioning

Commissioning comprises all measures necessary for the first functional operation of components and systems at their final place of installation.

(10) Component

Component is a specific part of a system that is well-defined according to structural or functional aspects.

(11) Product

A product is the result of a process and can consist of hardware, software or a service.

N o t e :

Examples for products are:

a) Results of work tasks or processes:
   aa) material products, e.g., a system, a fabrication series, a device, a functional unit, a module or part.
   ab) immaterial products, e.g., a service, a software, a draft design, an operating instruction.
b) The individual work task or process, e.g., provision of a service, a mechanical process, a procedure.

(12) Test identification number

Test identification number is a numeric code of a type-tested series-produced item that enables an unambiguous correlation to the corresponding type test.

(13) Quality

Quality is the level with which a set of distinctive characteristics of a product is achieved.

(14) Quality characteristic

Quality characteristic is a distinctive feature of a product with regard to a specific requirement.

N o t e :

A quality characteristic is, generally, also a test or inspection characteristic.

(15) Quality planning

Quality planning is the process of choosing and specifying the overall required quality characteristics and the measures meant to ensure that the quality characteristics will be achieved.

(16) Quality inspection

Quality inspection is the determination of the extent to which the quality characteristics of a product have been achieved.

N o t e :

Part of the quality inspection is also the verification that the building materials and structural components are in conformance with the building codes.

(17) Quality assurance

Quality assurance is that part of quality management that is directed at creating the confidence that the quality characteristics are being achieved. Quality assurance comprises, in particular, product-related measures intended to verify that the quality characteristics of a product have been achieved.

(18) Quality management

Quality management comprises the coordinated activities for the guidance and control of an organization with regard to quality.

N o t e s :

(1) Guidance and control with regard to quality usually comprises the specification of quality politics and quality goals, the quality planning, quality control, quality assurance and quality improvement as well as the systematic feedback of information in the course of the individual processing phases.

(2) Processing phases are, e.g., safety-related concept processing, planning and design, procurement, fabrication and assembly of product forms, parts, components and systems, manufacture and provision of products, erection of building structures as well as commissioning including the associated tests and inspections.

(19) Authorized expert

Authorized expert is a competent person or organization consulted in accordance with Sec. 20 AtG by the nuclear licensing or supervisory authority.

(20) Series-produced items

Series-produced items are factory-made products that are fabricated in larger quantities with the same design and same quality.

N o t e :

Series-produced items are usually fabricated without prior knowledge of their later deployment.

(21) Software

Software comprises the programs (i.e., sets of well-ordered instructions), the data, the standards and the associated documentation concerning the operation of a computer-based system.

(22) System

System is the combination of components forming a technical equipment that, as integral part of the plant, will function independently.

(23) Type testing

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

N o t e s :

(1) The characteristics are specified in, e.g., specifications, technical data sheets and building-code related test certificates.

(2) The scope of the type test does not include the inspection of the product with respect to its proper deployment.

(24) Design review

Design review is the assessment of the documents prepared for manufacturing (e.g., blue prints, written instructions, drawings, calculations) with regard to meeting the licensing provisions.

3 General Requirements

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

(2) Quality assurance shall be performed in all phases of work in which the quality characteristics can still be influenced and in which they can be determined. These are phases specified under Section 1, para. (1), including the associated tests and inspections.

In this context, the quality characteristics themselves and how they will be achieved shall be understandably planned and shall be verified taking the corresponding legal directives and the organizational procedures into account, and the quality characteristics shall be maintained.

(3) The license applicant or licensee shall prepare a description of the integrated management system in accordance with safety standard KTA 1402. In this context, the license applicant or licensee shall specify the measures for assuring the quality. The description shall be comprehensive with regard to how and by whom the requirements of the present safety standard will be fulfilled and how their fulfillment will be certified.

(4) The quality assurance of the contractors and subcontractors shall be based on the application of an effective quality management system (e.g., one that is certified in accordance with DIN ISO 9001).

(5) Independent of the requirements specified under para. (4), the client shall check that the contractors and subcontractors fulfill the requirements of the present safety standard.

(6) In those cases where a contractor or subcontractor does not fulfill individual requirements of the present safety standard, the client shall specify suitable substitute measures and shall document these substitute measures.

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

(8) The specified quality assurance measures shall ensure that a detected non-fulfillment of specified requirements or procedures is documented and that the associated experience gained is utilized. Generally known and assured experience should also be taken into account.

(9) In the case of series-produced items, the achievement of the quality characteristics shall be verified by type tests, or by qualification tests performed in accordance with specified procedures, or by proving a satisfactory service life. In addition, the achievement of the quality characteristics shall be verified by tests in the course of fabrication or by factory tests. Furthermore, it shall be verified that the series-produced items will not be impermissibly stressed in the planned circumstances of deployment.

Note:

(1) A result of this verification may be that, in addition to the type test and qualification test, further tests and verifications should be performed.

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

When re-ordering series-produced items the client shall ensure by suitable measures that the series-produced item has not been changed with regard to the original order. In the case of changes, a renewed qualification may be required if necessary.

(10) The erection and subsequent work on building structures is primarily subject to the quality assurance measures which are specified by the building code (building surveillance according to state building regulations) and, furthermore – insofar as required for the achievement of protective goals – subject to additional safety-related requirements regarding quality assurance. These additionally required quality assurance measures shall be specified by the client in accordance with the safety-related significance of the building measures and shall be observed by the contractor or subcontractor.

(11) In the case of software, specifications are required regarding development and acceptance as well as an acceptance test and a verification. It shall be verified that module tests (tests of the smallest unit, e.g., a function), component test (e.g., software libraries) and integration tests (interaction of software components among themselves as well as the interaction of software and hardware) have been performed.

The program tests shall comprise numeric verifications and physical validations.

Whenever changes are incorporated in the software, the corresponding tests shall be performed and the documentation shall be continued.

4 Organization

4.1 General Requirements

(1) The license applicant or licensee is responsible for the planning and execution of the quality assurance and for surveilling 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, nevertheless, ensure that the quality assurance is performed by the contractor or his subcontractor in accordance with the present safety standard. The license applicant or licensee shall convince himself of the qualification and reliability of his contractors.

4.2 Structural and Procedural Organization

Within the framework of establishing the structural and procedural organization the following basic requirements shall be fulfilled:

a) The individual persons charged with executing tasks in the phases specified under Section 1, para. (1) shall see to it that the specified quality assurance measures are fulfilled;

b) Only those persons shall be charged with the document review as required by the present safety standard who did not themselves create these documents;

c) As far as the testing and inspecting of products or the surveillance of activities are required to be carried out independently, only those persons shall be charged with these activities who did not themselves manufacture the products or who were neither charged with, nor responsible for performing these activities;

Note:

Which tests and inspections are required to be carried out independently is specified in guidelines and safety standards or in the course of design review.

d) Persons charged with the task of implementing and auditing the quality management system shall be authorized to collect information, to suggest solutions and to surveil that the specified quality assurance measures are fulfilled; these persons shall not belong to the group of persons specified under item a).

4.3 Cooperation Between the Involved Companies and their Departmental Units

(1) The license applicant or licensee shall ensure that, in respect to the cooperation between all companies and their departmental units involved in providing quality assurance, the respective tasks of each party and the interfaces between these parties are clearly specified and described, and that this is communicated.

(2) With respect to the preparation and control of the flow of information, a schematic shall be prepared showing which companies and departmental units specified under para. (1) shall prepare, review and release the documents and which of these companies and departmental units will receive the documents.

(3) An agreement shall be reached between the companies and departmental units specified under para. (1) with regard to the number of copies of the documents to be prepared and with regard to their distribution.

(4) It shall be specified timely enough which of the companies and departmental units specified under para. (1) will, in the course of providing quality assurance, be responsible for coordinating the measures by the proper authorities or their authorized expert.

4.4 Personnel Qualification

(1) The requirements regarding personnel qualification shall be specified for all work tasks that have an effect on the fulfillment of the product and service requirements.

(2) Upon request, the personnel qualification and the maintenance of qualification shall be verified for each individual person.

5 Planning and Design

5.1 General Principles

(1) It shall be ensured that the design principles and the requirements specified in legal standards, safety standards, license decrees and legal directives are transferred to the proper documents (e.g., specifications, design review documents, drawings, blue prints, plans, and the instructions for functional tests, for acceptance tests and for commissioning). Before applying these documents, the validity of the documents shall be checked.

(2) The requirements essential to the achievement of quality characteristics and to the procedural flows shall be specified in writing and timely enough before the start of fabrication and assembly of product forms, parts, components and systems, and before the manufacture or creation of products as well as before the start of construction of civil structures; these specifications shall, preferably, cite to the corresponding standards, guidelines and other specifications. In this context, the following shall be specified:

a) The safety-related classification of the respective parts, products, components, systems and building structures;

b) The quality characteristics of the plant components specified under item a) that must be considered with regard to precautions against damages that would impair safety;

c) The quality assurance measures that are needed to achieve and verify the quality characteristics specified under item b).

(3) In the case of quality requirements and procedural flows that are not specified in technical standards or in case it is necessary to deviate from the requirements of accepted engineering standards, special criteria for selecting structural and other materials, product forms, component parts and components as well as their manufacturing procedures shall be specified. In this context, the information specified under para. (2) items a), b) and c) shall also be provided.

(4) The procedural flow of quality assurance shall basically be planned and specified timely enough (exceptions, cf. paras. (5) and (6)) such that the quality characteristics can still be achieved by a correction of the procedures regarding procurement, fabrication, assembly or construction, or by taking additional measures.

(5) With regard to their quality, structural materials and parts of building structures are considered to be in accord with the present safety standard, provided, they are qualified in accordance with the building code and no overriding or other requirements arise from the protective goals of the Atomic Energy Act.

(6) With regard to their quality, the series-produced items are considered to be in accord with the present safety standard, provided, the requirements specified under Section (3), para. (9), are met. In the case of type-tested series-produced items, the declaration of the test identification number or of the type test certificate and, if required, the type test report (in the building trade: test report under building law) suffices as verification that the quality characteristics have been achieved. In the case of series-produced items with a certified satisfactory service life, it is sufficient to provide information regarding design, quality and former deployment. The individual requirements for verifying satisfactory service life shall be specified with regard to the individual component.

5.2 Test and Inspection Documents

(1) Unless already specified in technical standards or in testing or surveillance instructions, detailed test and inspection documents shall be prepared for all tests and inspections of plant components and building structures specified under Section 5.1, para. (2), item a); these documents shall normally contain the following information:

a) Test object;

b) Quality characteristics;

c) Required values of the quality characteristics;

d) Type of tests or inspections (e.g., material test, final test, construction test, functional test, in-service inspection);

e) Test and inspection procedure and, if necessary, the type of measuring and testing equipment to be used;

f) Extent of the tests or inspections;

g) Performance of tests or inspections with regard to the fabrication, commissioning or operating procedure;

h) Party to perform the test or inspection (e.g., contractor, subcontractors, license applicant or licensee, proper authority or their authorized expert);

i) Requirements regarding the certificates of tests and inspections; and

j) Requirements regarding the storage of material specimens if such material specimens are required.

(2) Depending on the test objects, the certificates may consist of the following:

a) A mutually agreed upon marking of the tested parts or reviewed documents;

b) Certificates (e.g., statement of compliance with the order, production test certificate, acceptance test certificate);

c) Test reports.

N o t e :

Series-produced items with a certified satisfactory service life are, usually, documented by manufacturer certificates.

5.3 Document Review

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). If necessary, these documents shall also be presented for a design review to the proper authority or their authorized expert.

Note:
In the case of building structures, the design review is the civil engineering review of the documents which is performed in accordance with the Building Document Submittal Ordinance of the German federal states.

5.4 Document Revision

(1) The revisions of documents shall be reviewed in the same manner as the original documents, namely, as specified under Section 5.3. All revised parts of the documents shall be marked or shall be collated in a list. The reasons for the revisions shall be presented to all parties involved in the document review, insofar as these reasons are important for carrying out the review.

(2) In the case of a revision of the documents specified under Sections 5.1 and 5.2, all involved companies and their departmental units shall be informed without delay.

(3) The involved companies and their departmental units shall ensure within their own organization that the use of incorrect or invalid documents is prevented and that the tasks are performed strictly on the basis of valid documents.

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 state of revision of the individual document.

(2) With regard to general correspondence and documents an organizing filing system shall be established which will enable the unambiguous allocation of the documents.

(3) With regard to procurement, fabrication, assembly and erection an identification code shall be established which will enable an unambiguous allocation between documents and products, insofar as this allocation is necessary or if it must be ensured that the entire process is traceable to its origin.

6 Procurement

6.1 Assessment of the Contractor by the Client

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

(2) Each client may base their assessment of a contractor on assessments of this contractor previously performed in accordance with KTA safety standards by third parties.

(3) The assessment of a contractor shall be directed at verifying that the contractor can ensure that the product will be manufactured with the required quality characteristics. Major topics of this assessment are:

a) Technical equipment;

b) Personnel and personnel qualification;

c) Quality management system, in particular, quality assurance;

d) Self and third-party surveillance;

e) Experience (e.g., credentials, certified satisfactory service life).

(4) To enable the assessment by the client, the contractors shall provide a description of their quality management system as well as of the quality assurance with particular emphasis on the product-related requirements.

(5) Every client shall ensure that their contractors meet the requirements on which the assessment had been based.

(6) The contractor assessment may be waived if other measures (e.g., product-related measures) are employed to verify that the quality characteristics are achieved.

(7) In those cases where a contractor does not meet individual requirements of the present 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 ensure that the requirements applying to the respective work tasks to be performed are fulfilled.

6.2 Procurement Documents

(1) The procurement documents regarding structural and other materials, product forms, products, parts and components for the plant components specified according to Section 5.1 para. (2), item a), shall basically contain the requirements established during the design phase (exception: cf. para. (2) below). The necessary data pertaining to these requirements are:

a) Intended application and the operating conditions;

b) Quality characteristics;

c) Structural and other materials;

d) Requirements concerning the execution and surveillance of the intermediate, final and functional tests and inspections; these shall be collated in a contract-related test sequence plan that shall specify all work task and test steps, the respective requirements and verification logs as well as the individually responsible persons;

e) Feasibility of the initial and the in-service inspections;

f) Right-of-access of the parties involved to fabrication and to the tests and inspections;

g) Extent and archiving of the documents regarding the design, fabrication and assembly of parts, components and systems, the manufacture and provision of products as well as the erection of civil structures including the associated tests and inspections;

h) Handling, storage, transportation and packaging;

i) Identification coding of the documents to be prepared and of the items to be procured; and

j) Safety-related relevance of the product to be procured.

(2) In the case of series-produced items, it is sufficient to specify the coding (e.g., type number, order number), provided, this coding unambiguously identifies the individual item and its manufacturer (e.g., technical data sheets or parts list, associated technical lists or test certificates of the qualification test). Within the framework of procurement, the clients shall require from their contractors that they will be be informed whether changes have been made to the series-produced items with regard to former procurements.

(3) The procurement documents shall be reviewed, revised and coded for identification as specified under Sections 5.3, 5.4 and 5.5, respectively.

6.3 Receiving Tests and Inspections

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

(2) The individual receiving tests and inspections to be performed as well as the review of the associated documents shall be specified, shall be performed accordingly and shall be documented.

(3) Measures according to Section 10 for dealing with nonconforming products shall be specified.

7 Fabrication, Assembly and Erection Including Quality Tests and Inspections

7.1 Assessment of the Manufacturer by the Proper Authority or their Authorized Expert

(1) Insofar as required on account of legal ordinances and provisions, or of technical codes (e.g., regarding pressure retaining parts), the proper authority or their authorized expert shall assess the manufacturer before the start of fabrication and assembly of product forms, parts, components and systems and prior to the erection of building structures; this assessment is aimed at verifying that the manufacturer has appropriate technical means and qualified personnel at his disposal and that the tests and inspections are performed independently as specified under Section 4.2, item c).

(2) A written, product-related certificate by the proper authority or their authorized expert shall be issued confirming the successful assessment of the manufacturer; this certificate shall contain an exact designation of the manufacturing plant, and shall state its scope of application and its period of validity. Within this period of validity, the manufacturer may use this certificate within its scope of application for the verification of the quality of follow-up products, provided, no supplementary or renewed assessments are required.

(3) A supplementary or renewed assessment of the manufacturer with respect to fulfillment of the assessment criteria specified under para. (1) shall be performed whenever significant changes with respect to the essential prerequisites of the prior assessment have been introduced.

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

(1) Fabrication, assembly and erection shall be executed based on documents (e.g., fabrication instructions, fabrication schedules, construction documents). In this context, quality assurance measures shall be applied to ensure that

a) the individual quality characteristics are being achieved,

b) only well-mastered procedures and appropriate technical means are employed,

c) the technical means are sufficiently maintained,

d) the required ambient conditions are maintained, and

e) the achievement of the quality characteristics is recorded to the required extent in documents.

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

(3) It shall be verified that the tests and inspections required as specified in the documents according to Section 5.2 are performed. The test certificates shall meet all requirements specified in the test and inspection documents.

(4) In the case of specific procedures (e.g., welding, forming, heat treatment) the achievement of the quality characteristics shall be verified by procedure qualification tests.

(5) In case the achievement of a quality characteristic cannot be verified by quality tests or inspections then the production processes essential to this quality characteristic shall be monitored and documented.

(6) The tests and inspections specified under para. (2) and the monitoring specified under para. (5) shall be documented in accordance with the sequence of the work progress. The results of these tests and inspections shall be evaluated timely enough such that possibly needed corrective actions on the product can still be applied. The certificates and inspection records to be specified according to Section 5.2, item i), shall be filed and stored if so required.

(7) In the case of series-produced items, none of the records specified under paras. (3) and (6) are required, provided, a satisfactory service life (cf. Section 5.1, para. (6)) has been certified. The quality assurance tests and inspections during production shall be documented at the manufacturing plant.

7.3 Marking, Handling, Storage, Transportation and Packaging

(1) The units shall be marked according to the identification code specified under Section 5.5, para. (3).

(2) Protective measures shall be implemented to ensure that the quality of structural and other materials, of product forms, products, parts, components and test specimens is not impaired of during handling, storage, transportation and packaging and, in particular, that damages and mix ups are avoided and the required cleanness is maintained.

(3) Tests and inspections shall be performed to ensure that the requirements regarding identification marking, handling, storage, transportation and packaging are fulfilled (e.g., chloride free ambience; shelf life limitation; traceability; avoiding of damaging ambient conditions).

8 Commissioning

(1) The commissioning leading up to the initial functional operation of components and systems shall be carried out on the basis of written commissioning documents.

Note:
The commissioning procedure is dealt with in safety standard KTA 1402.

(2) The cooperation between the involved companies and their departmental units shall be specified in accordance with Section 4.3.

(3) The documents required for the initial functional operation of components, systems, instrumentation and control equipment (e.g., design and operating documents, circuit diagrams) shall be prepared and reviewed based on the specifications, on the plant-internal regulations under observance of the designed boundary conditions, and on the relevant rules and standards, and they shall, if necessary, be presented to the proper authority and their authorized expert.

(4) The documents specified under para. (3) shall contain all information necessary with regard to the safety-related requirements that pertain to commissioning. These documents shall form the basis for the special commissioning program in accordance with safety standard KTA 1402.

(5) It shall be ensured that the experience gained during commissioning is recorded and evaluated to the required extent. The procedure for dealing with a nonconformance, a deviation or damage shall be as specified under Section 10.

9 Measuring and Testing Equipment

(1) The measuring and testing equipment needed for verifying that the quality characteristics are achieved and for monitoring the parameters essential to quality shall be tested initially and thereafter in periodic intervals, shall be protected against damages and deterioration during handling, maintenance and storage, and shall, as necessary, be subjected to maintenance, be replaced or renewed.

(2) The measuring and testing equipment shall be unambiguously marked with regard to their state of calibration.

(3) Special documents of the owner of the measuring and testing equipment shall contain the information regarding when, how and by whom the necessary tests and adjustments are to be performed and repeated in specified intervals, and who, before their deployment, will carry out the calibration or verify the adjustments. These activities shall be carried out with measurement standards that must be based on international or national measurement standards. If no such measurement standard exists, the basis for the calibration or verification shall be documented.

(4) Whenever it is detected that the measuring and testing equipment does not meet the requirements, the validity of previous measuring results shall be assessed and documented. In this case, suitable measures shall be taken regarding the associated measuring and testing equipment and all products concerned.

10 Dealing with Nonconforming Products

(1) If a nonconformance, a deviation or damage is detected on a product or the associated documentation, this product shall be unambiguously marked and shall be blocked or removed in order to prevent it being used any further.

(2) It shall be specified in writing who shall be notified in case of a nonconformance or deviation, in what way the notification shall occur and who is authorized to decide about the further actions to be taken. The procedure specified under Section 5.4 shall be applied when dealing with a nonconformance of documents. All requirements regarding the handling of deviations, including the creation of deviation reports, shall be fulfilled.

(3) It shall be ensured that no tasks are performed on the non-conforming section of a part or product or in other areas that would prevent or hinder identifying the cause of the nonconformance or prevent or hinder performing the possibly necessary reworking or repair tasks.

(4) Any nonconformance or damage shall be assessed and documented together with the corrective measures taken. The corrective measures shall be performed and their effectiveness checked with the goal of avoiding any recurrence.

(5) All work tasks directed at rectifying a nonconformance shall be performed on the basis of documents that are equivalent to those on which the fabrication of the respective parts was based. These documents shall be reviewed, filed and stored in the same way as the original documents.

11 Documentation and Document Storage

(1) Type and extent of the documentation shall be specified.

(2) The extent of documentation shall be orientated on the information necessary for a later assessment. Its specification shall take the requirements in accordance with safety standard KTA 1404 into account and, as necessary, of other component-related KTA safety standards (e.g., safety standard series KTA 3201).

(3) The documentation shall be reviewed with regard to its completeness.

(4) All documents specified under para. (2) that are in any way affected by a modification shall be updated accordingly.

(5) The retention period and storage location of documents as well as of necessary residual materials and test specimens shall be specified in accordance with KTA 1404. In this context, the corresponding specifications in component-related KTA safety standards shall be taken into account. The retention period and storage location of any documents specified under the present safety standard (KTA 1401) for which, however, no specifications are contained in KTA 1404, shall be specified in writing.

12 Auditing of the Quality Management Systems

(1) Basically, every contractor shall audit their own quality management system according to a time plan to be specified with special regard to its implementation and its effectiveness. Excepted from this audit are those contractors for which the effectiveness of their quality assurance can be sufficiently verified by product-related measures.

(2) The quality management system shall be audited by persons in accordance with Section 4.2, item d).

(3) Clients shall basically convince themselves of the effectiveness of the quality management system of their contractors following a time plan to be specified; they shall orient their auditing on the product-related requirements. These audits may be waived by performing tests on the products concerned.

(4) The results of these audits shall be documented.

(5) Detected deficiencies or weak points of the quality management system shall be corrected without delay. The audit shall, then, be repeated to the necessary extent.

Appendix A

Regulations Referred to in this Safety Standard

(Regulations referred to in the present safety standard are valid only in the versions cited below. Regulations which are referred to within these regulations are valid only in the version that was valid when the latter regulations were established or issued.)

AtG		Act on the peaceful utilization of atomic energy and the protection against its hazards (Atomic Energy Act – AtG) of December 23, 1959, revised version of July 15, 1985 (BGBl. I, p. 1565), most recently changed by Article 2 of the Act of July 20, 2017 (BGBl. I, p. 2808)
StrlSchV		Ordinance on the protection from damage by ionizing radiation (Radiological Protection Ordinance – StrlSchV) of July 20, 2001 (BGBl. I, p. 1714; 2002 I, p. 1459), most recently changed according to Article 10 by Article 6 of the Act of January 27, 2017 (BGBl. I, p. 114, 1222)
SiAnf	(2015-03)	Safety Requirements for Nuclear Power Plants (SiAnf) of 22 November 2012 (BAnz AT 24.01.2013 B3), revised version of 3 March 2015 (BAnz AT 30.03.2015 B2).
Interpretations to SiAnf	(2015-03)	Interpretations of the "Safety Requirements for Nuclear Power Plants of 22 November 2012" (BAnz AT 24.01.2013 B3), revised version of 3 March 2015 (BAnz AT 30.03.2015 B2)
KTA 1402	(2017-11)	Integrated management systems for the safe operation of nuclear power plants
KTA 1404	(2013-11)	Documentation during construction and operation of nuclear power plants
KTA 3507	(2014-11)	Factory tests, post-repair tests and certification of satisfactory performance in service of modules and devices for the instrumentation and controls of the safety system
DIN EN ISO 9001	(2015-11)	Quality management systems - Requirements (ISO 9001:2015); German and English version EN ISO 9001:2015