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INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Nuclear power plants – Instrumentation and control important to safety – Hardware design requirements for computer-based systems

Centrales nucléaires de puissance – Instrumentation et contrôle-commande importants pour la sûreté – Exigences applicables à la conception du matériel des systèmes informatisés

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FOREWORD

This amendment has been prepared by subcommittee 45A: Instrumentation and control of nuclear facilities, of IEC technical committee 45: Nuclear instrumentation.

The text of this amendment is based on the following documents:

FDIS	Report on voting
45A/897/FDIS	45A/906/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

2 Normative references

Add the following standards:

IEC 62671, *Nuclear power plants – Instrumentation and control important to safety – Selection and use of industrial digital devices of limited functionality*

ISO 2768-1, *General tolerances – Part 1: Tolerances for linear and angular dimensions without individual tolerance indications*

ISO 2768-2, *General tolerances – Part 2: Geometrical tolerances for features without individual tolerance indications*

ISO 3951-1, *Sampling procedures for inspection by variables – Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL*

ISO 3951-2, *Sampling procedures for inspection by variables – Part 2: General specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection of independent quality characteristics*

9 Manufacturing

Replace the existing text with the following new text:

9.1 Quality assurance

9.1.1 Manufacturing may be one phase of the overall safety life cycle (see 4.1 and 4.2).

Where manufacturing is a phase of the overall safety lifecycle then manufacturing activities shall be included in the hardware quality assurance plan of the overall safety life cycle or, if not, shall be addressed by a separate manufacturing quality assurance plan (see 4.3).

Manufacturing-related activities during the design process (such as manufacturing assessments during product qualification) shall be included in the hardware quality assurance plan of the overall safety life cycle.

Hardware produced during the manufacturing phase, and addressed in this clause, includes individual modules, sub-assemblies or equipment as a whole.

9.1.2 The primary consideration when defining manufacturing processes to which the quality assurance plan applies shall be to ensure that the manufacturing does not compromise the delivery of the safety functions by the product.

9.1.3 Procedures and work instructions shall be established for the manufacturing activities. These activities include manufacturing processes and their control, inspection and testing, independent quality surveillance and inspection, identification, handling, packaging, storage and delivery.

9.1.4 The extent and details of procedures and work instructions necessary for manufacturing activities shall be defined according to the relative importance of the safety functions being performed by the hardware components (the intended system Class).

The objectives of the manufacturing activity are:

– to ensure the manufactured items are identical and meet the product description and specification generated during the design and development phases,

– to ensure the production items meet the requirements demonstrated by the initial model during the qualification programme.

9.1.5 When the hardware contains components provided by external suppliers, the suppliers shall be evaluated and selected based on their ability to manufacture and supply these items in accordance with the design requirements, including the requirements in Clause 9 and appropriate quality assurance program requirements.

In the case where a programmable electronic equipment component is part of the external scope of supply, an assessment of the supplier's ability and willingness to support a successful qualification of the equipment should be performed as part of supplier qualification.

NOTE Specific product selection and qualification criteria may be found, as appropriate, in standards such as IEC 60880, IEC 61513 or in related sub-tier standards such as IEC 62671 and IEC 62566.

9.1.6 When the designer of the I&C system chooses to outsource any process that affects product conformity to requirements, control over such processes shall be ensured. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management plan.

9.1.7 Criteria for the selection, evaluation and re-evaluation of either external suppliers or sub-contractors shall be established (e.g. general information such as business areas, scope of supply, technical capability and manufacturing capacity, quality organization, system and technical audits, financial health, market behaviour, etc.).

9.1.8 Criteria for selection, evaluation and re-evaluation of external products shall be established and these criteria shall be based on the requirements of relevant standards (e.g. IEC 60880, IEC 62671 and/or IEC 62566).

9.1.9 The use of manufacturing processes independently certified to recognised international standards by accredited bodies is recommended (e.g. the International Register for Certificated Assessors scheme for ISO 9001).

9.2 Training of personnel

9.2.1 The necessary competence for personnel performing any kind of work involved in the manufacturing and control activities shall be established, documented and maintained.

9.2.2 If personnel experience, education, and training records do not by themselves fulfil the requirements of 9.2.1, training or relevant other actions shall be provided to achieve the necessary competence. The effectiveness of the training and actions taken shall be evaluated and recorded.

9.2.3 The personnel shall be trained to be aware of the relevance and importance of their activities and how they contribute to the achievement of the quality and safety objectives. In addition, appropriate records of education, training, skills and experience shall be established and maintained.

9.3 Planning and organisation of the manufacturing activities.

9.3.1 As part of the overall project planning (see 4.3), a manufacturing plan shall be established at the start of the project and shall be kept up to date throughout the project.

9.3.2 Interfaces between different groups involved in the design and development shall be managed to ensure effective communication, clear definition of and assignment of responsibility for all aspects of the equipment relevant to the manufacturing process.

9.3.3 Effective arrangements for communicating with customers or inspectors shall be established to define and schedule manufacturing steps and the associated inspections, audits or controls.

9.4 Input data

9.4.1 Manufacturing inputs shall be established during the design and development phase in order to provide appropriate information for purchasing, production and quality controls including product acceptance criteria.

The input data shall include the following information:

– the need for independence between manufacturing activities and the associated processes documented formally;
– any requirements for the customer approval of changes during manufacture to the sourcing of components or manufacturing consumables (e.g. solder);
– any requirements for the customer approval of the substitution during manufacture of components or manufacturing consumables (e.g. solder);
– any special training as a consequence of the equipment having a nuclear application.

9.4.2 Any requirements specified during the design process which have an impact on the manufacturing process shall be taken into account. This includes any statutory or regulatory requirements applicable to the product as well as physical and technical characteristics.

NOTE Commonly used manufacturing standards may be considered based on the safety Class of the functions being performed by the hardware components. (e.g. ISO and ISA manufacturing standards, NEMA enclosures and protections standards, fire ratings standards, material processes standards, wiring techniques standards, etc.).

9.4.3 Input documents shall be reviewed prior to initiating purchasing activities and manufacturing activities. The review shall ensure that product requirements are defined and that the defined requirements can be met. The findings of the review shall be recorded.

9.5 Purchasing and procurement

9.5.1 Purchasing and procurement process

9.5.1.1 Specific purchase requirements shall be established based upon the effect of the purchased product on subsequent product realization or the final product. The requirement shall include a list of documents or access to documents necessary to achieve the qualification of the equipment.

9.5.2 Procurement process of commercially available components

9.5.2.1 Adequate demonstration or other suitable evidence shall be provided, that all the equipment components, including electronic components boards and housings meet the specified requirements (e.g. functionality, environmental withstand, reliability and lifetime).

9.5.2.2 Demonstration shall be provided that the selected components fulfil the expected characteristics.

The demonstration may be based on:

– data provided by the supplier of the components (nature and results of testing after manufacture, feedback, results of periodic tests, audits, approvals know-how, etc.),
– or self-established, formalized and documented feedback obtained through checks performed on successive batches, results of periodic tests conducted on samples, and operating results (such as operating time, failures of components),
– analysis (e.g. circuit level FMEA), component level operating history assessment, design quality assurance process and records, previous product/component certifications or qualifications,
– or results obtained during type test previously performed.

9.5.2.3 Adequate means shall be established to demonstrate the quality of the purchased component. This quality demonstration shall be commensurate with the safety Class of the intended function(s) of the component(s).

NOTE 1 Related means can consist of type tests of the component itself or of a sub-assembly including it.

NOTE 2 The expected quality includes the physical behaviour, static and dynamic electrical behaviour, under normal and extreme environmental conditions as well as the expected reliability.

For programmable electronic equipment, refer to specific product selection and qualification criteria in IEC 60880 and IEC 61513 and its related sub-tier standards such as IEC 62671, or IEC 62566 as appropriate.

9.5.3 Procurement process of parts used in the I&C equipment

9.5.3.1 The type and extent of control applied to the supplier and the purchased product shall be defined and contractually established with the supplier.

When the purchased products consist of programmable electronic components, specific additional requirements shall be in place to ensure strict configuration management and version control on hardware and software revisions as per approved qualification and manufacturing records. Any and all changes shall be reported by the manufacturer and a safety impact assessment provided.

9.5.3.2 Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

9.5.3.3 Purchasing information shall describe the product to be purchased, including, where appropriate:

– technical specification, (e.g. as schematics, drawings, control programs, test programs),
– requirements for approvals (e.g. processes, procedures, product and equipment),
– requirements for qualification of personnel,
– quality management system requirements.

9.5.4 Verification of purchased product

9.5.4.1 Inspection or other activities shall be established and performed to ensure that the purchased product, including the related expected documentation, meets the specified purchase requirements (see 4.2 and Clause 7).

9.5.4.2 Where verification at the supplier's premises is intended to be performed, verification arrangements and verification methods used shall be stated in the purchasing information. Requirements for preparation and acceptance of factory acceptance test plan(s), requirements for supervision and witnessing of acceptance testing, and requirements for final factory surveillance and inspection activities (i.e. to address any previously identified non-conformance issues and to confirm they have been resolved prior to shipment to site) shall be established.

9.5.4.3 The verification arrangements shall contain statements related to follow-up and control steps such as sampling tests, on-site observation or breakpoints.

9.5.4.4 Strict quality control shall be ensured of the incoming goods, including the use of bonded stores where appropriate. The controls on the incoming goods shall include non-intrusive controls (e.g. visual inspection) and, where appropriate, intrusive controls, such as electrical tests and functional behaviour.

9.5.4.5 Dimensional controls and sampling plans for inspection shall conform to those specified in ISO 2768-1, ISO 2768-2, ISO 3951-1 and ISO 3951-2.

9.6 Production

9.6.1 Control of production

9.6.1.1 The overall manufacturing activity shall be defined in a reference process description as part of the overall product life cycle.

9.6.1.2 Production shall be planned and carried out under controlled conditions.

Controlled conditions shall include, as applicable,

– availability of information that describes the characteristics of the product,
– availability of work instructions,
– availability of quality instruction,
– use and availability of suitable equipment and tools,
– full traceability of component parts,
– full recording of the dates and personnel involved for each production operation,
– implementation of product release, delivery and post-delivery activities.

9.6.2 Specification and control of production environmental conditions

9.6.2.1 Requirements for the environmental conditions for production and control areas shall be defined as necessary.

9.6.2.2 Area access conditions such as rights to enter, procedures to follow and clothing to be worn shall be defined as necessary.

9.6.2.3 Control plans for the environmental conditions of, and the access control to, the manufacturing facilities shall be established (e.g. dust in the atmosphere, creating an inert atmosphere, humidity or temperature regulation, control of chemical composition of water, control of electrostatic discharges).

9.6.3 Validation of processes for production

9.6.3.1 Specific processes for production provision shall be validated where the resulting output cannot be verified by subsequent monitoring or measurement and where, as a consequence, deficiencies become apparent only after the product has been in use or delivered.

9.6.3.2 Validation shall demonstrate the ability of these processes to be robust in order to achieve planned and repeatable results.

Arrangements shall be established for these processes including, as applicable:

– defined criteria for review and approval of the processes,
– approval of equipment and qualification of personnel,
– use of specific methods and procedures,
– requirements for records and validation,
– handling of defective parts including possible consequences for the production process.

9.6.4 Assessment of the manufactured I&C equipment acceptance and reproducibility

9.6.4.1 The equipment produced shall be assessed and stated to be accepted by the customer.

9.6.4.2 The acceptance shall be based on the quality assurance management, the overall hardware qualification process and successful qualification results of the component, modules or equipment which usually are the first of a kind.

9.6.4.3 The designer of the I&C system shall be deemed able to reproduce series equipment identical to the qualified hardware either by means of internal manufacture and assembly, or by means of sub-contract manufacture and assembly.

9.6.4.4 The evaluation of manufacturing should be based on surveys focusing on the I&C system manufacturer's organization and the technical means to manufacture the products.

9.6.4.5 When changes occur after the qualification of the initial item, an impact analysis shall be performed by the designer of the I&C equipment and conclusions shall be evaluated to decide if a new qualification has to be done or if the results of the previous qualification remain unchanged.

9.6.5 Control of production tools, monitoring and measuring devices

9.6.5.1 The tools necessary to manufacture the product shall be determined.

9.6.5.2 Monitoring and measurement processes to be undertaken on the product shall be determined to provide evidence that the product conforms to its requirements.

9.6.5.3 Processes shall be established to ensure that production, monitoring and measurement are carried out in a manner that is consistent with the production, monitoring and measurement requirements.

9.6.5.4 Where necessary to ensure valid results, tools and measuring devices shall:

– be calibrated or verified, at specified intervals or prior to use, against measurement standards or established basis used for calibration or verification which are recorded;
– be adjusted or re-adjusted when necessary;
– have identification in order to determine their calibration status;
– be safeguarded from adjustments that would invalidate the measurement result;
– be protected from damage and deterioration during handling, maintenance and storage.

9.6.5.5 Quality assurance processes shall ensure that if manufactured equipment is found not to conform to requirements due to faults in the manufacturing process that adequate corrective action is taken.

9.6.5.6 Records of the results of calibration and verification shall be maintained.

9.6.5.7 When software based devices are used in the monitoring and measurement activities, the ability of the device to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

9.6.6 Identification and traceability

9.6.6.1 The manufactured system shall be identified, as well as the parts and materials used to manufacture the system, by suitable means throughout product realization.

9.6.6.2 The manufactured system status shall be monitored throughout the overall production process.

9.6.6.3 A unique identification of the system, and of the included parts, shall be ensured and records of changes shall be maintained for traceability purposes.

9.6.6.4 An identification file shall be established for each equipment and/or subassembly in order to define the reference model including the description of the equipment, the internal assemblies, components and versions. These files may typically include a list of sub-assemblies, plans, drawings, diagrams, data sheets, references to sub-tier detailed files in order give an exhaustive description of a version of the system and/or sub-assemblies.

9.6.7 Preservation of product

9.6.7.1 The system, and the included parts, shall be preserved during internal processing in order to maintain conformity to requirements. Preservation shall include identification and as applicable, handling, packaging, storage and protection conditions given before the acceptance test of the equipment.

9.6.8 Sustainability of tools and skills

9.6.8.1 Requirements for the maintenance of tools and other means used during the manufacturing, testing, and validation activities shall be defined during the planning of the manufacturing activity and commensurate with the safety class of the functions being performed by the components.

9.6.8.2 Requirements shall be defined for maintaining the skills involved in manufacturing, validation and testing activities.

9.6.9 Resolution and control of non-conformities

9.6.9.1 Non-conformities detected during environmental qualification tests, verification activities or manufacturing shall be identified and recorded according to the quality assurance plan (see 4.3.3).

9.6.9.2 Corrections and solutions shall be identified and recorded in such a way that they can be easily auditable by external parties. The related records shall indicate the nature of the changes, include impact analysis and associated justifications and approval.

9.6.9.3 Controls shall be ensured on the production line to check that the modifications have correctly been taken into account and that controls and test procedures have been correctly adapted (manufacture, identification and acceptance tests).