CNBOP-PIB

CERTIFICATION DEPARTMENT

REQUIREMENTS FOR TECHNICAL AND ORGANIZATIONAL CONDITIONS OF THE MANUFACTURER OF PRODUCTS BEING SUBJECTED TO THE PROCESS OF ADMITTANCE FOR USE IN FIRE PROTECTION

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1. Scope

This document is used for the assessment of technical and organizational conditions (hereinafter referred to as TOC) of the manufacturer of products being subjected to the process of admittance for use, referred to in Article 7 of the Act on fire protection.

This document was prepared based on:

- ISO/IEC TR 17026:2015 *Conformity assessment – Example of a certification scheme for tangible products*;
- CNBOP-PIB requirements for ensuring measurement traceability, (as of the date of the WTO assessment and published on the Institute's website www.cnbop.pl),

taking into account the applicable requirements of:

- ISO 9001:2015-10 *Quality management systems – Requirements*.

2. General provisions

The requirements are intended for manufacturers of products designed to ensure public safety or protection of health and life and property, which can be used only after obtaining a certificate of admittance for use.

The aim of establishing and maintaining appropriate technical and organizational conditions of production it is essential to ensure a stable and reproducible production of products that meet the requirements of applicable technical reference documents (i.e. Polish Standards and / or technical and operational requirements)[1], which are the basis for the admittance process.

These guidelines are used as criteria for assessing TOC in the admittance process conducted by CNBOP-PIB.

3. Organization of production

The manufacturer shall establish, document, implement and maintain technical and organizational conditions of production which are appropriate for ensuring that the products introduced for fire protection units and used by these units to alert about a fire or other hazards and to conduct rescue operations, as well as portable fire fighting equipment are compliant with the requirements of technical reference documents which are the basis for the admittance process.

Technical and organizational conditions of production should be described in the documentation adapted to the level of usability requirements for the product, the specific nature of the production process and the degree of automation, staff competence and size of the organization and the scope of its activities.

Documentation of technical and organizational conditions of production should contain information regarding:

a) the organizational structure, responsibilities and powers;
b) control plans, tests;
c) used documented procedures; guidelines or instructions,
d) required external documents (Polish Standards, technical and operational requirements);
e) specific documents established by the organization (e.g. specifications, drawings, work instructions and forms necessary for the effective implementation of the conditions of quality management and supervision of production or supply and conformity assessment of the product);
f) records;
g) actions taken in case products are not compliant with the requirements of technical reference documents.

4. Production

Documentation of technical and organizational conditions regarding of production's should contain:

a) description of production process;
b) sub-contracted operations (description of operation, name and address of sub-contractor, details of contract relevant for fulfilling by the product the requirements of technical reference documents);
c) description of principal items of the production resources and equipment (proprietary and specially made or adapted);
d) control of inventory;
e) description of the supervision of production process;

[1] defined in the annex to Regulation of the Minister of the Interior and Administration of 20 June 2007 on a listing of products used to assure public safety or protection of health and life and property, as well as rules for the issuance of certificates of admittance for use of these products

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f) description of the control and supervision of finished products;
g) description of the procedure regarding nonconformities for: materials, components, sub-assemblies and finished products.

5. Organizational structure, responsibilities and authority

The manufacturer shall specify the organization of activities related to the production (e.g. organizational chart). He should also specify what range of activities, linked to the production of the product, is carried out outside of the organization (i.e. by subcontractors, external staff – if applicable). In case of external commissioning of any of processes which affect the performance of the product, the manufacturer shall determine the rules for supervision of these processes.

TOC documentation should specify the responsibilities and authority of all personnel responsible for product design, calibration of measuring instruments, verification of supplied products, inspection and testing of products in relation to the requirements of technical reference documents and for keeping records of carried out controls and testing.

The organization should appoint a person to be responsible for supervising system / TOC documentation.

6. Design documentation of the product

The manufacturer shall specify the requirements for the product based on the technical reference document and specify the form of reference technical specifications of the manufactured products (e.g. drawings, list of product parts, reference samples, other available records).

These requirements should be documented in the form of records and supervised.

Technical reference documents owned by the manufacturer (Polish standards, European and / or international standards) which are the basis for determining the requirements for the manufactured product, should be original.

The manufacturer shall specify the procedure during the change of technical specifications of the manufactured products, including the method of informing the admittance body of the planned amendments in the materials, design or technology related to the product which subjected to the admittance process.

7. Purchasing and supply control

If the manufacturer implemented quality management system according to ISO 9001, technical and organizational conditions of the production should meet the requirements of the chapter regarding purchasing of this standard including the requirements of the applicable technical reference documents.

The manufacturer should determine and document the requirements for materials and components and the criteria for confirmation of their compliance. The manufacturer shall verify, based on the established criteria, supply compliance with the order (documents, possibly controls and tests).

Records of all verified materials and components should be maintained. They should include the following information:
a) description of the component;
b) name of the supplier;
c) catalogue marking or model which are sufficient to ensure specific identification;
d) technical characteristics, parameters;
e) records of requirements used to determine compliance;
f) results of the tests/controls.

Method, form and time for keeping records regarding purchasing and supply control should be specified.

Records should be kept at least for the period of validity of the issued certificate of admittance.

8. Control and testing during production and / or of final product

If the manufacturer implemented quality management system according to ISO 9001, technical and organizational conditions of the production should meet the requirements of the chapters regarding the monitoring and measurement of the product and the control of nonconforming product of this standard including the requirements of the applicable technical reference documents.

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The manufacturer should develop a documented control plan for monitoring and measurement that describes the process of monitoring and measurement during production which are necessary for ensuring that each product meets the requirements covered by the admittance before delivery. This plan should include the following details of its implementation:

a) details of verification control of the delivered materials and components, monitoring and measurement during production and in the final product;
b) system for recording the results of monitoring and measurement;
c) details about methods used to supervise products which do not meet the requirements of technical reference documents (i.e. Polish Standards and / or technical and operational requirements).

In each location where controls and/or tests/ controls are carried out, there should be a list of properties that are controlled and/or tested/controlled as well as a list of appropriate acceptance criteria.

Records of monitoring and measurement demonstrating compliance with the requirements of the final product should contain at least:

- identification of the product;
- carried out monitoring and measurement;
- results of monitoring and measurements;
- acceptance criteria;
- information on not fulfilling the requirements (non-conformities);
- date of monitoring and / or measurement;
- person(s) authorizing above activities.

These records should be maintained and kept at least for the period of validity of the issued certificate of admittance.

The organization shall establish a procedure for dealing with half-products and final products which do not meet the requirements. The components and final products which have been altered or repaired in order to ensure compliance with the requirements should be verified once again.

The manufacturer should ensure the removal of the mark of the admittance body from products bearing that mark which do not meet the requirements of appropriate technical reference documents or are not covered by the scope of the granted certificate of admittance prior to sending the product from a given location.

9. Control of monitoring and measuring equipment

If the manufacturer implemented quality management system according to ISO 9001, technical and organizational conditions of the production should meet the requirements of the chapter regarding the control of monitoring and measuring equipment of this standard including CNBOP-PIB requirements for ensuring measurement traceability (see point 1).

NOTE! "Calibration" is carried out by an external body having appropriate competence, specified in CNBOP-PIB document defining the requirements for ensuring traceability. In turn, "checks" of the measurement equipment (also called "verification"), meaning confirmation by presenting objective evidence that specified requirements for traceability have been fulfilled, is carried out by the personnel of the manufacturer within the company – the manufacturer is responsible for ensuring adequate competence of the personnel assigned to carry out the tasks in question.

The manufacturer should identify the equipment used for monitoring and measuring. Time periods and calibration procedures (usually performed outside the manufacturing plant) or checks (usually carried out within the manufacturing plant) of each measuring equipment should be defined.

The following should be specified and available for each measuring equipment:

- status of calibration / verification;
- records of calibration / verification;
- the method of marking the instrument, indicating at least the date of the next calibration / verification and containing the identification symbol from the list of control and measurement equipment.

The terms for calibration of control and measurement equipment should take into account CNBOP-PIB requirements for ensuring measurement traceability (see point 1).

The manufacturer shall specify (if applicable) the manner of supervision of the required environmental conditions that have been specified for monitoring and measurement.

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10. Handling, storage, packaging and labelling of products

The manufacturer shall specify a method of handling the final product, method of packaging and protection against damage or change of properties. If justified, the manufacturer shall periodically check the condition of the stored product in order to detect any damage or change of properties.

Acceptance conditions of the final product to the warehouse should be defined. Proper records should be prepared regarding the acceptance and release process of the product. If it is necessary and if it can have an effect on the quality of the product, the manufacturer shall ensure proper environmental conditions of storage of the product and, if necessary, to monitor them.

If the products require special transport conditions, the manufacturer shall provide them.

Final products meeting the requirements of technical reference documents and covered by the scope of the granted CNBOP-PIB admittance, shall be marked in accordance with the requirements of technical reference documents and the law.

11. Traceability of the products

Individual products and their parts or batches of products should be identifiable.

If possible, the manufacturer shall ensure traceability of the product, i.e. the possibility to reconstruct the history of the product's production process.

The manufacturer or his representative shall keep records for individual products or batches of products, including information on production and tests. Based on the records it should be possible to recreate all the relevant information about the product and the production process. These records should be kept for the period of validity of the certificate of admittance.

12. Complaints

The manufacturer shall define and document the method of handling complaints both reported by product users as well as reported by the manufacturer to the suppliers of materials and components used in the production.

The manufacturer is obliged to:

a) store and archive records related to complaints;
b) take action in connection with any reported complaints.

The manufacturer shall analyse the causes for the lack of conformity of the product with the requirements of technical reference document (Polish standards and / or technical and operational requirements), and take appropriate action in order to eliminate it in the future.

The manufacturer should keep all records regarding product complaints and corrective actions concerning these complaints at least for the period of validity of the issued certificate of admittance.

13. Competence and training

The manufacturer shall specify:

- required competence of personnel involved in work affecting the fulfilment by the manufactured products of the requirements of technical reference documents (Polish Standards and / or technical and operational requirements);
- requirements for records concerning competence of personnel (education and / or training and / or experience and / or skills);
- methods for ensuring of staff complete development.

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