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Gas cylinders — International quality conformance system — Basic rules

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this Technical Report may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 14600 was prepared by Technical Committee ISO/TC 58, *Gas cylinders*.

Introduction

The purpose of this Technical Report is to provide and implement an international quality conformance system that ensures and documents compliance to relevant gas cylinder design and manufacturing standards, and to foster the international acceptance of gas cylinders. For the purposes of this Technical Report, the term 'gas cylinders' includes both gas cylinders and tubes.

This Technical Report is issued without prejudice to pertinent international and national regulations, which might be applicable. It is the responsibility of the user of the Technical Report to inquire about applicable regulations. This is a recommended text that could be adopted on an intergovernmental or similar level.

Gas cylinders — International quality conformance system — Basic rules

1 Scope

In order to ensure that gas cylinders are produced in compliance with gas cylinder design and manufacturing standards the conformance system described in this Technical Rerport specifies, where applicable, procedures and requirements for:

— regulatory authorities;

— accreditation bodies;

— inspection bodies and testing laboratories;

— manufacturers.

2 Terms and definitions

For the purposes of this Technical Report the terms and definitions given in ISO/IEC Guide 2:1996 and the following apply.

2.1
quality conformance system
system for overall approval by the regulatory authority, inclusive of gas cylinder design type approval, manufacturer's quality system, approval of manufacturers and approval of inspection bodies

2.2
regulatory authority
governmental body having legal authority over the manufacture and use of gas cylinders in a country

NOTE Also may be referred to as "competent authority".

2.3
accreditation body
government approved body having authority for the approval of inspection bodies

NOTE This may be the regulatory authority or a different entity.

2.4
inspection body
independent body approved by the regulatory authority or accreditation body having the organization, staffing, competence and integrity to perform one or more of the following:

— inspection services of gas cylinders;

— the surveillance of the manufacturer's quality system;

— testing.

2.5
quality system
organizational structure, procedures, processes and resources needed to implement quality management

2.6
verify
confirm by examination or provision of objective evidence that specified requirements have been fulfilled

2.7
design type
gas cylinder design as specified by a particular gas cylinder standard, e.g., ISO 7866, ISO 9809-1, ISO 9809-2, etc.

3 General requirements

3.1 Regulatory authority

3.1.1 The regulatory authority in the country of manufacture shall be responsible for ensuring the implementation of this quality conformance system in accordance with national law.

3.1.2 The regulatory authority of a country of gas cylinder manufacture shall supply, upon request, evidence demonstrating compliance to this quality conformance system to its counterpart in a country of use.

3.1.3 It is the objective of this Technical Report that the regulatory authority in the country of use shall accept for filling, transport, use and refilling, gas cylinders which have been certificated in accordance with the requirements of this quality conformance system, provided the relevant design standard has been ratified by that country.

3.1.4 Where the regulatory authority in a country of use believes, on reasonable grounds, that the applicable gas cylinder standard or the quality conformance system has not been complied with or that certain gas cylinders present a danger to public safety, it shall take appropriate steps to ensure an acceptable level of safety. The regulatory authority shall define what actions are required to enable the gas cylinders to be acceptable. The affected gas cylinders may be detained, condemned, re-exported, re-examined or subject to such other actions as the regulatory authority stipulates.

3.1.5 The regulatory authority shall retain its authority, but may delegate its functions in this quality conformance system in whole or in part to a qualified entity of its choice.

3.1.6 The regulatory authority, or its delegated entity, shall:

— be knowledgeable of relevant gas cylinder standards;

— have a staff sufficient in number, technical competence and skill to adequately carry out its supervisory and administrative responsibilities;

— when operating its own inspection and testing activities, ensure that these activities conform with the stipulations given in 3.2 and 3.4 for inspection bodies and testing laboratories;

— not require additional tests and results thereof in excess of those specified in the relevant standard unless there is evidence of undue risk to public;

— approve inspection bodies and make available a current list of approved inspection bodies and their identity mark;

NOTE In some countries this activity is undertaken by an accreditation body. ISO/IEC TR 17010 may be used for guidance.

— ensure confidentiality of the commercial and proprietary activities of the inspection bodies and manufacturers;

— provide a system for identification of the manufacturer for each gas cylinder;

— be free from any influence which could prevent it from operating in an impartial manner.

3.2 Inspection Body

3.2.1 The inspection body shall be approved by the regulatory authority or the accreditation body, if applicable, as an inspector of gas cylinders.

The inspection body may be an integral part of the regulatory authority or separate body, domestic or foreign.

An inspection body shall apply for approval to the regulatory authority or the accreditation body, if applicable, of the country of manufacture. Such application shall include detailed and complete information on the inspection body's organization, staffing, documented quality system, technical competence, inspection methods and procedures, records and reports, confidentiality and security, related to inspection of gas cylinders and/or a manufacturer's quality system.

The inspection body may use the manufacturer's testing laboratory or the manufacturer's selected testing laboratory.

The inspection body may delegate certain functions in accordance with 5.1.

3.2.2 The general requirements for an inspection body are as follows:

— to have a staff, with an organizational structure, capable, competent and skilled, to satisfactorily perform its technical functions;

— to have access to suitable and adequate facilities and equipment;

— to operate in an impartial manner and be free from any influence which could prevent it from doing so;

— to ensure confidentiality of the commercial and proprietary activities of the manufacturer and other bodies;

— to maintain clear demarcation between actual inspection body functions and unrelated functions;

— to operate a documented quality system;

— to ensure that the tests and inspections specified in the relevant gas cylinder standard are performed;

— to maintain an effective and appropriate report and record system in accordance with clause 6;

— to require a written and accepted order before providing its services to a client;

— to provide the regulatory authority with their registered identity mark.

NOTE ISO/IEC 17020:1998 or ISO Guide 65 :1996, may be used for guidance.

3.2.3 The services of an Inspection Body are required by manufacturers in design type approval, gas cylinder production testing and inspection, and certification to verify conformity with the relevant gas cylinder standard (see clauses 4 and 5).

3.3 Gas cylinder manufacturer

3.3.1 The manufacturer shall operate a documented quality system in accordance with 4.4.

3.3.2 The manufacturer shall apply for design type approvals in accordance with clause 4.

3.3.3 The manufacturer shall select an inspection body from the list of approved inspection bodies maintained by the regulatory authority.

3.3.4 The manufacturer may use his own testing laboratory or select a testing laboratory, subject to approval by the inspection body.

3.3.5 The manufacturer shall maintain records in accordance with clause 6.

3.4 Testing laboratory

3.4.1 The testing laboratory, or the function it performs, may be an integral part of the manufacturer, the regulatory authority, the inspection body, or a separate body, domestic or foreign. The services of a testing laboratory other than the one chosen by the manufacturer are required in cases where the testing capabilities are deemed by the inspection body to be insufficient.

3.4.2 The general requirements for a testing laboratory are as follows:

— to have a staff, with an organizational structure, sufficient in number, competence, and skill to perform the tests;

— to have suitable and adequate facilities and equipment to satisfactorily perform its technical functions;

— to generate an appropriate report and record and transmit copy to the inspection body and the manufacturer;

— to ensure that accurate measuring and testing equipment is used in the laboratory through initial and periodic calibration to the required level;

— to ensure that the environment in which the tests are undertaken does not invalidate the test results or adversely affect the required accuracy of measurement;

— to require a written and accepted order before providing its services to a client.

NOTE ISO/IEC 17025, may be used for guidance.

4 Approval process

4.1 Layout of the approval process

The approval process for the manufacture of gas cylinders shall consist of the following steps:

— application for initial design type approval (4.2);

— application for subsequent design type approval (4.3) if it follows an initial design type approval;

— quality system procedures (4.4);

— design type approval procedures (4.5).

4.2 Application for initial design type approval

4.2.1 The initial design type approval consists of approval of the manufacturer's quality system and approval of the gas cylinder design to be produced. An application for an initial design type approval encompasses the requirements of 4.2, 4.4 and 4.5.

4.2.2 A manufacturer desiring to produce gas cylinders in accordance with a gas cylinder standard shall apply for, obtain and retain a Design Type Approval Certificate issued by the regulatory authority in the country of

manufacture for at least one gas cylinder design type in accordance with the procedure given in 4.2.3. This written approval shall, on request, be submitted to the regulatory authority of the user nation.

4.2.3 The application shall be made by the manufacturer to the regulatory authority of the country of manufacture and shall include:

— the name and registered address of the manufacturer and in addition, if the application is submitted by an authorized representative, its name and address;

— the address of the manufacturing facility (if different from the above);

— the name and title of person(s) responsible for the quality system;

— the designation of the gas cylinder and the relevant gas cylinder standard;

NOTE The criteria for determining the design type are provided in the applicable gas cylinder standard.

— a written declaration that the same application has not been submitted and denied by any other regulatory authority;

— the technical documentation required for design type approval according to 4.2.4;

— the name of the inspection body for design type approval;

— documentation on the manufacturing facility as specified under quality system documentation 4.4.1.

4.2.4 The technical documentation for design type approval shall enable verification of the conformity of the gas cylinders with the requirements of the relevant gas cylinder design standard. It shall cover the design and method of manufacture and shall contain, as far as is relevant for assessment, at least the following:

— gas cylinder design standard, design and manufacturing drawings, showing components and subassemblies, if any;

— descriptions and explanations necessary for the understanding of the drawings and intended use of the gas cylinders;

— a list of the standards necessary to fully define the manufacturing process;

— design calculations and material specifications;

— design type approval test reports, describing the results of examinations and tests carried out in accordance with 4.5.1.

4.2.5 An initial audit in accordance with 4.4.2 shall be performed to the satisfaction of the regulatory authority.

4.2.6 If the manufacturer is denied approval, the regulatory authority shall provide written detailed reasons for such denial.

4.2.7 Following approval, changes to the information submitted under 4.2.2 relating to the initial approval shall be provided to the regulatory authority.

4.3 Application for subsequent design type approvals

4.3.1 An application for a subsequent design type approval encompasses the requirements of 4.3 and 4.5, provided a manufacturer is in the possession of an initial design type approval. In such a case, the manufacturer's quality system according to 4.4 shall have been approved during the initial design type approval and shall be applicable for the new design.

4.3.2 The application shall include:

— the name and address of the manufacturer and in addition, if the application is submitted by an authorized representative, its name and address;

— a written declaration that the same application has not been submitted to and denied by any other regulatory authority;

— evidence that initial design type approval has been granted;

— the technical documentation, as described in 4.2.4.

4.4 Manufacturer's quality system

4.4.1 Quality System documentation

The Quality System shall contain all the elements, requirements and provisions adopted by the manufacturer. It shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions.

The contents shall in particular include adequate descriptions of:

— the organizational structure, responsibilities and power of the management with regard to design and product quality;

— the design control and design verification techniques, processes and systematic actions that will be used when designing the gas cylinders;

— the relevant gas cylinder manufacturing, quality control, quality assurance and process operation instructions that will be used;

— quality records, such as inspection reports, test data and calibration data;

— management reviews to ensure the effective operation of the quality system arising from the audits in accordance with 4.4.2;

— the process describing how customer requirements are met;

— the process for control of documents and their revision;

— the means for control of non-conforming gas cylinders, purchased components, in-process and final materials;

— training programmes for relevant personnel.

4.4.2 Audit of the quality system

The quality system shall be assessed to determine whether it satisfies, to the satisfaction of the regulatory authority, the requirements referred to in 4.4.1.

The purpose of the audit is to make sure that the manufacturer duly fulfils the obligations resulting from the approved quality system.

For audit purposes the manufacturer shall provide unrestricted access to the locations of design, manufacture, service, inspection, testing and storage, and shall provide all necessary information and documentation.

The manufacturer shall be notified of the results of the audit. The notification shall contain the conclusions of the audit and any corrective actions required.

Periodic audits shall be carried out, to the satisfaction of the regulatory authority, to make sure that the manufacturer maintains and applies the quality system. Reports of the periodic audits shall be provided to the manufacturer.

4.4.3 Maintenance of the quality system

The manufacturer shall undertake to fulfil the obligations resulting from the quality system as approved and to maintain the quality system in order that it remain adequate and efficient.

The manufacturer shall notify the regulatory authority that approved the quality system, of any intended changes. The proposed changes shall be evaluated in order to decide whether the amended quality system will still satisfy the requirements referred to in 4.4.1, or whether a reassessment is required, to the satisfaction of the regulatory authority.

NOTE Certified quality systems, such as ISO 9000 series, may be accepted by the regulatory authority when assessing the quality system according to 4.4. ISO/IEC Guides 61 and 62 may be used for guidance.

4.5 Procedure for design type approval

4.5.1 Inspection body

The inspection body shall:

a) examine the technical documentation to verify that:

   — the design is in accordance with the relevant provisions of the standard,

   — the prototype lot has been manufactured in conformity with the technical documentation and is representative of the design;

b) verify that the production inspection has been carried out as required in accordance with clause 5;

c) randomly select the gas cylinders and supervise the tests of gas cylinders from a prototype production lot as required for Design Type Approval;

d) perform or have performed the examinations and tests specified in the gas cylinder standard to determine that:

   — the standard has been applied and fulfilled,

   — the procedures adopted by the manufacturer meet the requirements of the standard;

e) ensure that the various type approval examinations and tests are correctly and competently carried out.

4.5.2 Recommendations

After prototype testing has been carried out with satisfactory results, the inspection body shall recommend to the regulatory authority that the manufacturer be issued a Design Type Approval Certificate.

The recommendation shall contain the name and address of the manufacturer, results and conclusions of the examination and the necessary data for identification of the design type.

After these examinations and tests have been performed with acceptable results, the regulatory authority shall issue a written approval to the manufacturer with a Design Type Approval Certificate for each design type that is approved, including the authorization to affix the gas cylinder specification marking to each gas cylinder manufactured and approved. A list of the relevant parts of the technical documentation shall be annexed to the Design Type Approval Certificate.

If the manufacturer is denied a design type certification, the regulatory authority shall provide written detailed reasons for such denial.

NOTE In case the regulatory authority has delegated its authority to the inspection body, the design type approval certificate may be issued directly to the manufacturer, with a copy to the regulatory authority.

4.5.3 Modifications to approved design types

The manufacturer shall inform the issuing regulatory authority of modifications to the approved design type as specified in the gas cylinder standard. A subsequent design type approval shall be requested where such modifications constitute a new design according to the relevant gas cylinder standard. This additional approval shall be given in the form of an amendment to the original Design Type Approval Certificate.

Upon the request of the manufacturer, the regulatory authority shall communicate to any other regulatory authority, information concerning design type approval, modifications of approvals and withdrawn approvals.

5 Gas cylinder production inspection and certification

5.1 General requirements

An inspection body, or its delegate, shall carry out the inspection and certification of each gas cylinder. The inspection body selected by the manufacturer for inspection and testing during production may be different from the inspection body used for the design type approval testing.

Where it can be demonstrated to the satisfaction of the inspection body that the gas cylinder manufacturer has trained and competent inspectors at his disposal, independent of the manufacturing operations, inspection may be performed by those inspectors. In such a case, the gas cylinder manufacturer shall maintain training records of the inspectors.

The inspection body shall verify that inspection by the manufacturer, and tests performed on those gas cylinders, fully conform to the standard. Should non-conformance in conjunction with this inspection and testing be determined, the permission to have inspection performed by the manufacturer's inspectors may be withdrawn.

The manufacturer shall, after approval by the inspection body, make a declaration of conformity with the certified design type. The application of the gas cylinder specification marking shall be considered a declaration that the gas cylinder complies with the applicable gas cylinder standards and the requirements of this quality conformance system. The inspection body shall affix or delegate the manufacturer to affix the gas cylinder specification marking and the registered mark of the inspection body to each approved gas cylinder.

NOTE Misuse of the prescribed marks is subject to sanctions by the regulatory authority.

5.2 Production inspection — Details

The inspection body shall ensure that the requirements of the applicable gas cylinder standard and gas cylinder marking standard are complied with. A certificate of compliance, signed by the inspection body and the manufacturer, shall be issued before the gas cylinders are dispatched.

6 Records

Design type approval and certificate of compliance records shall be retained by the manufacturer and the inspection body for not less than 20 years.

Bibliography

[1] ISO 9000-1:1994, *Quality management and quality assurance standards — Part 1: Guidelines for selection and use.*

[2] ISO 9000-2:1997, *Quality management and quality assurance standards — Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003.*

[3] ISO 9000-3:1997, *Quality management and quality assurance standards — Part 3: Guidelines for the application of ISO 9001:1994 to the development, supply, installation and maintenance of computer software.*

[4] ISO 9000-4:1993, *Quality management and quality assurance standards — Part 4: Guide to dependability programme management.*

[5] ISO 9001:—[1)], *Quality systems — Model for quality assurance in design, development, production, installation and servicing.*

[6] ISO 9002:1994, *Quality systems — Model for quality assurance in production, installation and servicing.*

[7] ISO 9003:1994, *Quality systems — Model for quality assurance in final inspection and test.*

[8] ISO 9004-1:1994, *Quality management and quality system elements — Part 1: Guidelines.*

[9] ISO 9004-2:1991, *Quality management and quality system elements — Part 2: Guidelines for services.*

[10] ISO 9004-3:1993, *Quality management and quality system elements — Part 3: Guidelines for processed materials.*

[11] ISO 9004-4:1993, *Quality management and quality system elements —Part 4: Guidelines for quality improvement.*

[12] ISO/IEC TR 17010:1998[2)], *General requirements for bodies providing accreditation of inspection bodies.*

[13] ISO/IEC 17020:1998[3)], *General criteria for the operation of various types of bodies performing inspection.*

[14] ISO/IEC 17025:1999[4)], *General requirements for the competence of testing and calibration laboratories.*

[15] ISO/IEC Guide 2:1996, *Standardization and related activities — General vocabulary.*

[16] ISO/IEC Guide 22:1996, *General criteria for supplier's declaration of conformity.*

[17] ISO Guide 27:1983, *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity.*

[18] ISO Guide 28:1982, *General rules for a model third-party certification system for products.*

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1) To be published. (Revision of ISO 9001:1994)

2) Based on Guides 58 and 61.

3) Replaces Guides 39 and 57.

4) Replaces Guide 25.

[19] ISO Guide 61:1996, *General requirements for assessment and accreditation of certification/registration bodies.*

[20] ISO Guide 62:1996[5], *General requirements for bodies operating assessment and certification/registration of quality systems.*

[21] ISO Guide 65:1996[6], *General requirements for bodies operating product certification systems.*

[22] *UN Recommendations on the Transport of Dangerous Goods*, 11th Revised Edition.

5) Replaces Guide 48.

6) Replaces Guide 40.

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