No.	KGS 2011 - 118

Quality Control System Requirements

for manufacture registration of foreign products

KOREA GAS SAFETY CORPORATION

0. Introduction

0.1 Object

This regulation is applied to the quality control organization of the manufacturer who will register to MOTIE according to the Article 5-2(manufacture registration of foreign cylinders etc.) of the High-Pressure Gas Safety Control Act and Article 10 (manufacture registration of foreign gas appliance) of the Safety Control and Business of Liquified Petroleum Gas Act.

0.2 Scope

This regulation is limited to the items specified in the criteria and the scope of manufacturing registration and re-registration(Renewal) of Foreign Cylinders etc. under Article 5-2 of the Enforcement Decree of the High Pressure Gas Safety Management Act and Foreign Gas Appliances under Article 6 of the Enforcement Decree of the Safety Control and Business Act of Liquefied Petroleum Gas. And this quality control system requirement is used to evaluate whether a manufacturer's product can satisfy the laws and regulations and the manufacturer's own requirements. Information marked with "Note" is used to assess whether it can meet the relevant requirements.

0.3 Terms and Definitions

For the purposes of these quality control system requirements, the terms and definitions given in followings apply.

a) The Article 3 of the High-Pressure Gas Safety Control Act and The Article 2 of the Enforcement Regulation of the High-Pressure Gas Safety Control Act
b) The Article 2 of the Safety Control and Business of Liquified Petroleum Gas Act and Article 2 of the Enforcement Rule of the same act
c) ISO9000 Quality management system- Fundamentals and Vocabulary
d) ISO17000 Conformity assessment - Terms and General principle

0.4 Relation with Korea laws

The followings shall be fulfilled in order to assure the safety of products and users.

a) Rules provided especially for user's safety in Korea laws and regulations.

b) Cases applicable to Korea law by priority due to the divergence between the domestic law and the foreign law.

0.5 Obligations

0.5.1 The manufacturer shall faithfully implement the obligations of the manufacturing registrant in the "High Pressure Gas Safety Control Act" and "Safety Control and Business Act of Liquefied Petroleum Gas".

0.5.2 The manufacturer shall take a proper measure if product quality is deteriorated or user's safety is harmed significantly.

0.5.3 The manufacturer shall notify the Korea Gas Safety Corporation if there is a change in the company name, representative, location, manufacturing standard, or process etc.

0.5.4 The manufacturer shall comply with the following in managing the manufacturing registration certificate.

a) The registration certificate must be received by an authorized manufacturer.

b) The registration certificate must be approved and used according to the planned procedure.

c) The registration certificate must be kept to prevent damage or theft

1. Quality Control System

The manufacturer should establish, documentate, implement and maintain a quality management system and continuously improve its effectiveness.

When outsourcing processes that have a significant impact on quality, they should be described in the manual and ensure that these processes are managed.

Note1. The manufacturer includes a company subject to first factory registration, renewal audit or alteration audit.

Note2. The management method to be applied to the processes, products and services provided from outside of the manufacturer should be determined and the suitability should be guaranteed.

1.1 Control of documents

A documented procedure shall be established in order to control documents and records and it shall be identified, executed and controlled to prevent the unintended use of obsolete documents.

1.1.1 The term "documented information" used in this regulation means that the documented information is established and the latest version of it is implemented and maintained.

1.1.2 The documented information shall include the followings. However, they could be added or omitted in accordance with quality control system or manufacturing process.

a) Responsibility and Authority
b) Document and Record control
c) Design and Drawing control
d) Material control
e) Purchasing control(including the supplier control)
f) Procedure of test and examination,
g) Control of nonconformity product and Corrective action
h) Welding
i) NDE
j) Heat treatment,
k) Hydrostatic test,
l) Calibration and Control of manufacturing, measuring and test equipment,
m) Marking etc. (High-Pressure Gas Safety Control Act & Safety Control and Business Act of Liquefied Petroleum Gas)

1.1.3 Relevant versions of applicable documents shall be available at points of use.

1.1.4 The current revision status of documents shall be controlled to be identified.

1.1.5 Documented information from external sources determined by the manufacturer as necessary for the planning and operation of this quality control system shall be properly identified and managed.

1.1.6 Prevent unintended use of ineffective documented information, and when retained for any purpose, appropriate identification should be applied.

1.2 Control of records

The manufacturer shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records established to provide evidence of the effective operation of the quality control system shall be controlled. Records shall remain legible, readily identifiable and retrievable.

1.2.1 Records required providing evidence of conformity to requirementsand of effective operation of quality control system shall be preserved more than 5 years.

1.2.2 The documented information shall be identified for how to collect and maintain the records.

2. Manufacturer Responsibility

2.1 The manufacturer shall ensure that the quality control system in operation meets legal and standard requirements.

2.2 The manufacturer shall continuously improve and maintain the construction, implementation and effectiveness of the quality control system and record and manage the details.

2.3 The manufacturer shall comply with the requirements for registration of factory audit and ensure that they are communicated and understood within the organization.

3. Resource Management

3.1 Human Resources

3.1.1 The manufacturer shall determine the necessary competence for personnel affecting product quality, provide necessary training, evaluate effectiveness appropriately and maintain records of education.

3.1.2 These personnel must ensure that they have the necessary competencies based on training, skill and experience, and specification requirements.

3.1.3 Personnel affecting product quality must have the ability to perform inspections, including product inspection methods, inspection equipment use, and familiarity with relevant standards.

3.2 Infrastructure

The organization shall determine and manage the infrastructure needed to achieve the conformity of products.

3.2.1 Infrastructure includes buildings, workspace, utilities, process equipment (both hardware and software) and supporting services.

3.3 Manufacturing and measuring·testing equipment

3.3.1 When manufacturing and measurement and test equipment are used to verify that a product conforms to requirements, the manufacturer shall determine and provide the necessary manufacturing and measurement and test equipment to ensure valid and reliable results.

3.3.2 Manufacturing and measuring and testing equipment must be able to meet requirements and establish and maintain documented information that includes:

a) Management procedures for manufacturing and measurement/testing facilities (inspection, maintenance, etc.)

b) Possesses manufacturing and measurement and test facilities suitable for the relevant standard requirements

c) Records of manufacturing and measurement and test facility inspection results, calibration and verification results

3.3.3 To ensure valid results, manufacturing and measuring·testing equipment should be:

a) calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded.

b) identified to verify their calibration status.

c) protected from adjustment, damage or deterioration which may invalidate the measurement results.

d) Manufacturing and measurement/test equipment list, calibration target, calibration cycle, etc. should be specified in the procedure.-For self-calibration, calibration method, calibration equipment, etc. should be included.

e) Have equipment that meets relevant standards requirements

f) Periodic inspection and maintenance should be maintained.

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

3.3.5 The manufacturer shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. If the manufacturer and the measurement and test equipment are found to be inadequate to the requirements, the manufacturer shall determine whether the effectiveness of the previous measurement results has been affected and take appropriate action.

3.3.6 When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

4. Product Requirements

4.1 Planning

The manufacturer shall plan, develop and control the process necessary for product requirements. Such a plan shall be consistent with the requirements of the other processes of the quality control system.

4.1.1 As product requirements including inputs or outputs of design and development are provided by outside, the manufacturer shall establish and maintain the documented information to control the matter.

4.2 Customer-related process

The manufacturer shall determine requirements related to the product, including law and standard requirements, requirements etc. prescribed by the organization, and review and maintain records before acceptance. Effective internal and external communication procedures shall be established to determine and implement these requirements.

Note : laws or regulation requirements are referred to as legal requirements

4.2.1 When product requirements are changed, the manufacturer shall reflect the changes in the relevant documents and ensure that the relevant personnel are aware of the changed requirements.

4.3 Design and Development

4.3.1 The manufacturer shall define and manage the planning and management methods for the design and development of products, including responsibility and authority for design and development, appropriate review, verification and feasibility confirmation at each design stage.

4.3.2 The manufacturer shall perform appropriately for the planning, input, output, review, verification, feasibility confirmation, and change management for design and development of the product and maintain relevant records.

4.3.3. Change of design and development, including change of its documents, shall be controlled as the same as initial design and development. The documented procedure for change of design and development shall be established.

Note1 : Design output of products may include potential failure effects analysis result, reliability result, feature of products, specifications, mistake proofing action of products, definition of product etc.

Note2 : Process design outputs may include drawings, specifications, potential failure effects analysis result, management plan, work guidelines, process approval criteria, process non-conformities detection and feedback methods etc. of products or process.

4.4 Purchasing

4.4.1 The manufacturer shall ensure that purchased product conforms to specified purchasing requirements. The manufacturer shall evaluate and select suppliers based on their ability to supply product in accordance with the manufacturer's requirements. The manufacturer shall establish criteria about selection, evaluation and re-evaluation for suppliers and maintain relevant record.

4.4.1.1 Criteria of selection, evaluation and re-evaluation for suppliers shall include one of followings.

a) inspection on products of suppliers
b) following-up control for conforming purchase requirements
c) verification for conforming international accreditation codes or technical book

4.4.2 Purchase information including the requirement of organization shall be communicated with the supplier. The organization shall ensure the adequacy of specified purchasing requirements and verify the purchased product.

4.5 Production

4.5.1 The manufacturer shall plan and carry out production under controlled conditions. Controlled conditions shall include, as applicable.

a) the availability of work instructions, as necessary,

b) the use of suitable equipment,

c) the availability and use of manufacturing and measuring·testing equipment,

d) product release, delivery and post-delivery activities.

4.5.1.1 Process control

Path, transfer, check-list, process sheet or various types of control property shall be documented for process control. It shall include verification requirements for conforming to quality plans, control property and related regulations or codes. Process control documents may include or refer guidelines, skills, process, test, acceptable inspection standards and inspection designation point witness point.

4.5.1.2 Documented procedures shall be established for all personnel affecting product quality. The relevant procedures shall be easily accessible on-site.

4.5.1.3 Incoming Inspection

Manufacturers shall document and manage important items (materials, parts, etc.) that affect safety and quality of product, including the following:

a) Selection of appropriate items (materials, parts) for incoming inspection

b) Incoming inspection standards and methods according to the target items (sample selection criteria, acceptance criteria, re-inspection criteria, processing criteria for non-conforming products)

c) Record of incoming inspection results

4.5.2 Manufacturers should establish and implement procedures that include:

a) Criteria for review and approval to verify the validity of the process,

b) equipment approval,

c) qualification,

d) use of specific methods and procedures,

e) record requirements,

f) reconfirmation of feasibility, etc.

4.5.3 Manufacturers should identify products by appropriate means at all stages of production and, if traceability is required, The manufacturer shall manage and record the identification of the product.

5. Self Inspection

The manufacturer shall plan and implement the monitoring, measurement, analysis, and continuous improvement process in order to continuously demonstrate, assure, and improve the conformities and the effectiveness of the product.

5.1 Inspection requirement

The manufacturer shall determine the following and evaluate the performance and effectiveness of the quality requirements.

a) Object of measurement and test equipment

b) Methods of analysis and evaluation, measurement, test equipment, in order to ensure valid results.

c) When to perform measurements and tests

d) Analysis and evaluation timing of measurement and test results

5.2 Product Inspection

5.2.1 Manufacturers shall perform self-inspection at planned intervals to verify that product requirements have been met. In addition, documented information must be maintained for this.

5.2.2 Records shall indicate personnel approving the release of the product. In addition, the items of product verification inspection and methods shall be implemented by reflecting relevant manufacturing standards for the product. However, if the test is performed by an external institution, the suitability should be checked through a test report.

5.2.3 Procedures shall define the responsibilities and requirements for planning and performing inspections, writing records and reporting results.

5.2.4 Self-inspection shall be managed to ensure that passing values, criteria, and results are maintained as documented information.

5.2.5 The manufacturer shall ensure that all necessary corrective actions to eliminate any nonconformities and causes found are taken in a timely manner.

5.3 Control of nonconforming Products

A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product. The organization shall ensure that nonconforming product is identified and controlled to prevent its unintended use or delivery. When the nonconforming product is corrected it must be re-verified to demonstrate conformity.

5.4 Corrective action

5.4.1 To prevent recurrence of nonconformity, the need for action to eliminate the cause or potential cause of nonconformity shall be evaluated by the following.

a) Review and analysis of nonconformities

b) Determination of the cause of nonconformity

c) Determining the presence or potential occurrence of similar nonconformities

5.4.2 The manufacturer shall retain documented information as evidence of:

a) The nature of the nonconformity and any follow-up taken

b) Results of all corrective actions

5.5 Continuous Improvement

Manufacturer shall continually improve the adequacy, fulfillment and effectiveness of these requirements. In addition, the manufacturer shall consider changes in the system in order to continuous improvement.

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