No.	KGS 2011 - 118

Quality Control System Requirements

for manufacture registration of foreign products

KOREA GAS SAFETY CORPORATION

0. Introduction

0.1 Object

This quality control system requirements are applied to the quality control organization of the applicants who want to 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 quality control system requirements are limited to the manufacture registration scope and items defined by the Article 5-2 of the Enforcement Decree of the High-Pressure Gas Safety Control Act and Article 6 of the Enforcement Decree of the Safety Control and Business of Liquefied PetroleumGas Act. These are to use to assess whether the applicant organization's ability meets customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements. Information marked "Note" is for guidance in understanding or clarifying the associated requirement, statutory and regulatory requirements and the organization's own 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 domestic 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 domestic laws and regulations.

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

0.5 Obligations

0.5.1 The manufacturer shall establish the documented regulation to control the certificate and keep up to date with the records on receipt, use, storage and disposition of the certificate. The regulation shall include the followings.

a) certificate shall be handled only by authorized staffs

b) certificate shall be used after approval of CEO/administration deputy by planned procedure.

c) records on use of certificate

d) the internal plan for preventing misuse of certificate shall be established.

e) certificate shall be stored to be prevented from damage or misplace.

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 KGS in case significant change occurs in quality system management.

0.5.4 The manufacturer shall fulfill the obligations of manufacture registration of foreign cylinders etc. specified by 'High-Pressure Gas Safety Control Act'. and foreign gas appliance specified by 'Safety Control and Business of Liquified Petroleum Gas Act'

1. Quality Control System

The manufacturer subject to the factory registration shall establish, document, implement, and maintain a quality control system and continuously improve its effectiveness. Where The manufacturer chooses to outsource any process that affects the qualities, the manufacturer shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality control system.

Note1. The registration manufacturer include the manufacturer subject to the factory registration initially and the manufacturer subject to renewal or alteration application.

Note2. The type and extent of control to be applied to the outsourced process shall be defined within the quality control system. The manufacturer is also responsible for the conformity of the outsourced process.

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 Where the term "documented procedure" appears within this quality control system requirements, this means that the procedure is established, documented, implemented and maintained.

1.1.2 The documented procedure shall include the followings. However, they may be omitted when excluded from manufacturing process.

a) Responsibility and Authority
b) Organization structure
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 of measuring and test device,
m) Marking etc.(High-Pressure Gas Safety Control Act & Safety Control and Business of Liquefied Petroleum Gas Act)
n) Control of documents andrecords

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 organization as necessary for the planning and operation of the quality control system s be properly identified and managed.
1.1.6 appropriate identification shall be applied for preventing unintended use of invalidated documents.

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 procedure shall be identified for how to collect and manage the records.

2. Management Responsibility

2.1 Top management shall provide evidence of its commitment to the development and implementation, and continually improving its effectiveness of the quality control system

2.2 Top management shall assure of meeting customer requirements,

2.3 Top management shall ensure that the quality policy including management commitment are determined to comply with its purpose and the referred requirements in the manual and communicated within the organization.

2.4 Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

3. Resource Management

3.1 Human Resources

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

3.1.2 The personnel shall be appropriate for the based on their education, training, skills and experience.

Note. The organization shall provide on-site training for personnel performing new job or changed duty affecting product quality including contractors and proxies.

3.1.3 The organization ensure that personnel responsible for designing and developing products are skilled at understanding and applying code requirement and design program.

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 Work Environment

The organization shall determine and manage the work environment neededto achieve the conformity of products.

3.4 Control of monitoring and measuring equipment

3.4.1 The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

3.4.2 The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

3.4.3 Where necessary to ensure valid results, measuring equipment shall,

a) be 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) have identification in order to determine its calibration status.

c) be safeguarded from adjustments that would invalidate the measurement result.

d) be protected from damage and deterioration during handling, maintenance and storage.

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

3.4.5 In addition the organization 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.

3.4.6 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 Realization

4.1 Planning

The organization must plan and develop the process necessary for product attainment. 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 organization shall establish control property which put the requirements into product realization process and also define its method.

4.2 Customer-related process

The organization shall determine statutory and regulatory requirements, requirements not stated by the customer but necessary and requirements considered necessary by the organization, and maintain records by reviewing prior to the commitment. The organization shall determine effective process for communicating with in and out customers to determine and implement such requirements.

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

4.2.1 If the customer does not provide the requirements in a documented state, the customer requirements must be verified by the organization before acceptance.

4.2.2 When a requirement for a product is changed, the organization shall ensure that the relevant documented information is modified and that the related personnel are aware of the changed requirements.

4.3 Design and Development

4.3.1 The organization shall define and manage to plan and control the design and development of product including the responsibilities and authorities for design and development, the review, verification and validation that are appropriate to each design and development stage.

4.3.2 The organization shall appropriately implement and record planning, inputs, outputs, review, verification, validation and control of its changes generally.

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 organization shall ensure that purchased product conforms to specified purchasing requirements. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

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

a) inspection on final products of suppliers

b) following-up control for conforming purchase requirements

c) verification for conforming international accreditation codes or technical book

d) verification for continuity or effectiveness on M&A or affiliation

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 organization 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 monitoring and measuring equipment,

d) the implementation of 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.

4.5.2 The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and as a consequence deficiencies become apparent only after the product is in use or the service has been delivered.

4.5.2.1 Validation of process includes criteria for review and approval, approval of equipment, qualification of personnel, use of specific methods and procedures, requirements for records and revalidation.

4.5.3 The organization shall identify the product by suitable means throughout product realization. Where traceability is a requirement, the organization shall control and record the unique identification of the product.

4.5.4 The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification. handling, packaging, storage and protection.

5. Measurement Analysis and Improvement

The organization 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 Internal audit

5.1.1 The organization shall conduct internal audits at planned intervals in order to determine the conformities and effectiveness of the system, and shall establish documented procedures and maintain the records.

5.1.2 The procedure shall define the responsibilities and requirements for the planning and execution of the audit, the recording and reporting of the results.

5.1.3 Managers responsible for the audit should ensure that all necessary corrective and corrective actions are taken in a timely manner to eliminate any found nonconformities and causes. The follow-up should include verification of the action taken and reporting of the results of the verification.

5.2 Monitoring and Measurement of Product

5.2.1 The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements.

5.2.2 Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product.

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.

5.3.1 The documented procedures to control on-site nonconforming product detected after delivery or use shall include nonconforming product, accidents identification, reporting method, cause perception and handling process.

5.3.2 If nonconforming product is detected after delivery or after use has started, appropriate controlling shall be taken to the effects of nonconformities or their potential impact.

5.4 Corrective and Preventive action

5.4.1 The organization shall appropriately take action to eliminate the causes or potential causes of nonconformities in order to prevent recurrence. and shall define documented procedures to implement and maintain related records.

5.4.2 Documented procedures shall include review, determining causes, evaluation of corrective actions, implementation, recording and review of effectiveness.

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