TSG Z0004-2007

Fundamental Requirements of Quality Management System for Special Equipment Manufacture, Installation, Alteration, and Repair

Fundamental Requirements
of Quality Management System for Special Equipment
Manufacture, Installation, Alteration, and Repair

Article 1 In accordance with the *Regulations on Safety Supervision of Special Equipment* and the *Decision of the State Council on the Licensing of the Reserved Items Requiring Administrative Approval*, These Requirements are formulated to regulate the establishment and implementation of the quality management system for special equipment manufacture, installation, alteration, and repair (hereinafter referred to as quality management system) in order to effectively control the safety performance of special equipment.

Article 2 These Requirements are applicable to the establishment and implementation of the quality management system of special equipment (including raw material, parts, safety appurtenance and safety protection devices) manufacture, installation, alteration, and repair units.

Article 3 Units for special equipment manufacture, installation, alteration, and repair shall establish the quality management system and effectively implement the quality management system in accordance with the specialty of the licensed items and the actual condition of the companies as well as the following principles:

1) comply with the laws, regulations, safety technical codes and corresponding standards;
2) have effective control on the special equipment safety performance;
3) quality policy and quality objectives are in accordance with the actual condition of the company;
4) quality management system can independently exert special equipment safety performance management;
5) the duties and responsibilities of the responsible persons for quality management system (the quality control engineer and the responsible persons of quality control systems) as well as the coordinate measures among the quality control systems shall be clearly defined;
6) the fundamentals of the quality management system is rationally set, and the control scope, procedure, contents, and record for quality control systems, control links and control points are complete.;
7) the documents for quality management system is normative, systematic and complete;
8) meet the requirements of special equipment licensing.

Article 4 The requirements of the responsible person of the quality management system for special equipment manufacture, installation, alteration, and repair units is as following:

1) the legal representative (or his authorized agent) of the special equipment

manufacture, installation, alteration, and repair unit is the No.1 responsible person for safety quality. He shall appoint a quality management engineer from the management to assist the top management in the establishment, implementation and improvement of the quality management system for special equipment manufacture, installation, alteration, and repair; he shall appoint responsible persons of quality control systems to be responsible for the quality of special equipment during manufacture, installation, alteration, and repair.

2) the quality management engineer and the responsible persons of quality control systems shall be engineers or technicians employed by the special equipment manufacture, installation, alteration, and repair units. Their qualifications shall meet the requirements of the safety technical codes and having labor contract with the special equipment manufacture, installation, alteration, and repair units, but they shall not be employed by two or more companies at the same time.
3) The responsible persons of quality control systems can hold two concurrent posts for quality control systems at most.

Article 5 The special equipment manufacture, installation, alteration, and repair units shall establish the quality management system documents, which include quality manual, procedures, technological documents, and records etc. The quality manual shall be approved and proclaimed by the legal representative (or his authorized agent).

Article 6 The fundamental Requirements of Quality Management System is attached as the annex. The special equipment manufacture, installation, alteration, and repair units shall set the fundamental requirements for its quality management system according to the specialty of the licensed item and their quality control needs, but shall include at least management responsibilities, quality management system documents, document and data control, contract control, design control, material and parts control, technology control, inspection and testing control, equipment and inspection and testing equipment control, non-conformity control, quality improvement and service, training and examination control, the procedure for implementing China special equipment manufacture licensing system, and other processes control as required by special equipment safety technical codes.
Where subcontract is permitted by regulations and safety technical codes, the special equipment manufacture, installation, alteration, and repair units shall define the basic quality control requirements on subcontracted items and contents, including qualification verification, evaluation, supervision, record, and report verification.

Article 7 Special equipment manufacture, installation, alteration, and repair units shall conduct regular management review to the quality management system and keep the relevant review record.

Article 8 Where there is any change to the quality management system, the quality management system documents shall be revised in time, and when necessary to update the edition of the quality manual.

Article 9 The General Administration of Quality Supervision, Inspection, and Quarantine of the P. R. China is responsible for the interpretation of These Requirements.

Article 10 These Requirements shall become effective as of July 1, 2007. The requirements for the special equipment manufacture, installation, alteration, repair management system stipulated in the relevant regulations and documents before the proclamation of These Requirements shall be abolished at the mean time.

Appendix

Fundamental Requirements of Quality Management System for Special Equipment Manufacture, Installation, Alteration, and Repair

1. Management responsibilities

1.1 Quality policy and quality objectives

The quality policy and quality objectives shall be approved by the legal representative (or his/her authorized person) and documented, and shall meet the following requirements.

(1) In conformity with the actual conditions of the company, the licensed scope and specialty, and stress the special equipment safety performance requirements;

(2) The quality policy shall reflect its commitment on the continual improvement of the safety performance and quality of special equipment, and define the quality direction and quality objectives it pursues.

(3) The quality objectives shall be quantized and broken down to responsible persons of quality control systems and relevant departments, and shall be examined at regular intervals.

1.2 Quality management system

In accordance with the specialty of the licensed items and the actual condition of the company, the company shall establish a quality management system which can independently exert special equipment safety performance management.

1.3 Authority and responsibilities

The legal representative is responsible for the safety quality of special equipment. The management shall appoint a Quality Assurance Engineer and responsible persons for quality control systems. The Quality Assurance Engineer shall be a member of the management and has the knowledge related to the licensed items, and shall be responsible for the establishment, implementation, maintenance and improvement of the quality management system.

The management shall appoint the responsible persons for quality control systems (design, material, technology, welding, machining, heat treatment, NDT and other main processes), define the responsibilities and authority of the responsible persons of

quality control systems and those who are authorized to conduct work independently for special equipment safety performance. There shall be the control and coordinate measures for the interrelation among the quality control systems, among quality control engineer and responsible persons of quality control systems, and among the responsible persons of quality control systems.

1.4 Management review

At least once a year, the company shall conduct the management review to the quality management system for special equipment manufacture, installation, alteration and repair to determine its suitability, adequacy, effectiveness to ensure it meets the requirements of the quality policy and quality objectives. The management review records shall be documented.

2. Quality management system documents

The quality management system documents include quality manual, procedures, technological documents (working instructions, technological procedures, technology card and operation specification, same below), records (chart, card) etc.

2.1 Quality manual

The quality manual shall outline the structure and the interrelationship of the quality management system documents and contains the following contents at least.

(1) Terminology and abbreviations;
(2) Its applicable scope;
(3) Quality policy and quality objectives;
(4) Quality management system and management responsibilities;
(5) The fundamental requirements of quality management system, quality control systems, control links and control points.

2.2 Procedures

Procedures shall be consistent with the quality policy and meet the fundamental requirements of quality management system, and in accordance with the actual condition of the company, and practical.

2.3 Technological documents and quality record

Technological documents and quality record shall correspond with the specialty of the licensed items, and meet the implementation requirements of the quality management system. The format, entries and contents of the documents shall be standardized.

2.4 Quality plan (product processing card, construction design or construction plan)

Quality plan shall effectively control the safety of the product, and set the control links and control points (checkpoints, witness points and hold points) in accordance to the requirements of quality control systems and the specialty of the licensed items as well as the actual condition of the company. Quality plan shall contain the following.

(1) Control contents and requirements;
(2) The operational requirements during process;
(3) The requirements of signatures of the responsible persons for quality control systems and relevant persons.

3. Document and data control

3.1 Document control

The scope, procedure, and contents for document control are as following.

(1) Determination of controlled documents, which includes quality management documents, external documents(see the note below), and other documents needs to be controlled;

Note. external documents includes laws, regulations, safety technical codes, standards, design documents, design documents appraisal reports, type test report, supervisory inspection report, subcontractor's certificate of quality and qualification certificate. The safety technical codes and standards must be legal copies.

(2) Document draft, joint review, approval, marking, distribution, revision, and recovery. For external documents control, there shall be procedures for collection, purchase, and acceptance;

(3) The relevant departments, personnel and premises for the implementation of quality management system shall use valid edition of controlled documents;

(4) Rules for document maintenance measures, maintenance facilities, retention period and destruction.

3.2 Record control

The scope, procedure and contents for record control are as following.

(1) The filling, verification, collection, filing, retention of the record for special equipment manufacture, installation, alteration, and repair;

(2) Maintenance and the storage life of record;

(3) The relevant departments, personnel and premises for the implementation of quality management system shall use valid edition of records forms.

4. Contract control

The scope, procedure, and contents for contracts control are as following.

(1) There shall be provisions for recording and saving contract review. Contract review shall include scope, contents, the applicable laws, regulations, safety technical codes, standards, and technical requirements.

(2) Procedures for contract conclusion, modification, and joint review.

5. Design control

The scope, procedure, and contents for design control are as following.

(1) The contents for design input include the applicable regulations, safety technical codes, standards, and technical requirements. The design input shall be documented(for example, design specification);

(2) The design output shall be documented(including design explanations, design calculations, design drawings) and shall meet the requirements of regulations, safety technical codes, and technical condition;

(3) Where design verification is required according to regulations, the procedure for design verification shall be established;

(4) There shall be provisions for design modification;

(5) Where the design documents are provided by external companies, provisions for the control of external design documents shall be established;

(6) Where design license, design documents appraisal, and type test are required by regulations and safety technical codes, relevant provisions shall be established.

6. Material and parts control

The scope, procedure, and contents for material and parts control are as following.

(1) The purchase of material and parts (including purchase plan and purchase contract) control shall clearly define the measures and contents for the quality control of subcontractors including the subcontractor evaluation, selection, and re-evaluation. The company shall file the subcontractor evaluation report and establish the name list for qualified suppliers. If the licensing to the supplier is required by regulations and safety technical codes, the provision for the verification of the supplier's qualification shall be established;
(2) Material and parts acceptance inspection (re-inspection) control shall establish the provision that the material and part cannot be used for production unless they are re-inspected and pass the re-inspection;
(3) The formation of material identification (traceability marks), marking method, marking location and material identification transplantation.
(4) The storage and maintenance of material and parts including storage location and segregation method, according to designated area or according to batch No. (heat No.);
(5) Material release and use control, including certificate of quality, marks, specifications, heat No., verification of the inspection results, material requisition, cutting and blanking, forming, material identification transplantation and verification before machining, disposal of surplus materials and scrap materials.
(6) Material and parts substitution control, including the basic requirements for substitution and substitution scope, and the approval procedures for substitution, and the inspection for substitution.

7. Technology control

The scope, procedure, and contents for technology control are as following.

(1) The basic requirements of conditions and principles for making technological documents, including general type documents and specific technological documents;
(2) Operating discipline inspection, including inspection interval, personnel, inspected processes, inspected items and contents;
(3) Control of fixtures and moulds, including the design, manufacture, inspection of fixtures and moulds as well as their files, identifications, maintenance, periodical inspections, repair and scrap.

8. Welding control

The scope, procedure, and contents for welding control are as following.

(1) Welding personnel control, including training, examination, qualified items of qualified welders, identification of qualified welders, welding personnel files and their examination record;

(2) Welding consumable control, including the purchase, acceptance inspection, inspection, storage, drying, distribution, use and recovery of welding consumables;
(3) Welding procedure qualification report (PQR) and welding procedure specification (WPS) control, including the storage of PQR, related inspection and testing report, welding record and the test coupon for welding procedure qualification;
(4) The welding procedure qualification items shall cover the welding procedures needed for the welding of special equipment;
(5) Welding process control, including welding procedure, welding record, welding equipment, welding quality statistics and analysis;
(6) Welding repair(welding repair of flaws in base metal) control, including welding repair (welding repair of flaws in base metal) procedure, welding repair frequency and approval, and the re-examination of repaired welds (welding repair of flaws in base metal);
(7) Where product welding coupon is required by safety technical codes and standards, there shall be controls on welding coupon, including its quantity, fabrication, welding method, identification, heat treatment, inspection and testing items, testing specimen machining, inspection and testing method, disposal of unqualified testing coupons and testing specimen, and disposal of specimen.

9. Heat treatment control

In accordance with the specialty of the licensed items and the actual condition of the company, and in line with the requirements of safety technical codes and standards, the company shall formulate the scope, procedure, and contents of heat treatment control as following.

(1) The basic requirements for heat treatment;
(2) Heat treatment control, including the applied heat treatment facilities, thermometric device, automatic temperature recorder, heat treatment record(record the No. of the heat treatment furnace, job No./product serial No., heat treatment date, the signature of the heat treatment operator and the signature of the heat treatment responsible person) ,heat treatment report, the filing of heat treatment report, and report review;
(3) Where the heat treatment is subcontracted, there shall be requirements on the control of heat treatment subcontractors, including subcontractor evaluation, selection, re-evaluation. There shall be controls of subcontractor’s heat treatment procedures, verification of subcontractor’s report, records(record the No. of the heat treatment furnace, job No./product serial No., heat treatment date, the signature of the heat treatment operator and the signature of the heat treatment responsible person) , and f report review.

10. NDT control

In accordance with the specialty of the licensed items and the actual condition of the company, and in line with the requirements of safety technical codes and standards,

the company shall formulate the scope, procedure, and contents of heat treatment control as following.

(1) NDT personnel control, including training, examination, qualification certificate, qualified items, duties and responsibilities of NDT personnel;
(2) The basic requirements on the general type NDT procedure and specific NDT procedure, including NDT method, the applicable safety technical codes and standards;
(3) NDT process control, including NDT method, quantity, percentage, inspections of the defect location, additional NDT percentage and evaluation criteria;
(4) NDT record and report control, including the filling of the NDT records and report, review，re-evaluation, release, storage of the negative films of RT and the testing pieces of UT;
(5) NDT facilities and equipment control;
(6) Where NDT is subcontracted, there shall be controls on the subcontracted NDT, which includes the verification of the subcontractor's qualifications, scope and personnel qualifications. The evaluation, selection, re-evaluation to subcontractors shall be filed as a report, and there shall be verification to the NDT procedures, records and reports of the subcontractors.

11. Chemical and physical examination and testing control

The scope, procedure, and contents for chemical and physical examination and testing are as following.

(1) The chemical and physical examination and testing personnel cannot perform their duties before training;
(2) Chemical and physical examination and testing control, including the determination of method and the control during operational processes;
(3) The filing of the chemical and physical examination and testing record and report, review, results verification, release, re-examination and testing and the control of testing piece, reagent，and standard testing piece control;
(4) The machining and inspection of the testing piece for chemical and physical examination and testing;
(5) Where the chemical and physical examination and testing are subcontracted, there shall be quality control on the subcontracted chemical and physical examination and testing, which includes evaluation, selection, re-evaluation to subcontractors and these shall be filed as a report, and there shall be verification to the chemical and physical examination and testing procedures, records and reports of the subcontractors.

12. Inspection and testing control

The scope, procedure, and contents for inspection and testing are as following.

(1) The basic requirements for inspection and testing technological document shall cover the applied requirements resources, contents, and methods;
(2) Process inspection and testing control shall formulate the provisions that the product cannot go on for next process or be released before it finishes the

required inspection and testing by last process or before it receives the confirmation signature for the compulsory inspection and testing ;

(3) Final inspection and testing control (delivery inspection, final acceptance of construction, debugging acceptance inspection, acceptance inspection for test run), shall provide that before the final inspection and testing, all the process inspection and testing must complete and the inspection and testing results must meet the requirements of safety technical codes and standards;

(4) Inspection and testing condition control, including inspection and testing site, environment, temperature, medium, equipment(device), fixture, test load, safety protection, inspection and testing supervision and verification;

(5) Inspection and testing status control, for example identifications for pass, fail or pending for inspection and testing;

(6) Where type test or other specific testing is required by safety technical codes, there shall be provisions for the drafting of type test controls or other specific testing controls, which shall include type test items and the type test coverage, type test institute, type test report, type test results and other special testing conditions, methods, technologies, record, reports and testing conclusions;

(7) Inspection and testing record and report control, including the filing of inspection and testing record and report, review and verification. There shall be the special requirements on the collection, filing and storage of inspection and testing record, reports, prototype(testing samples and testing specimen).

13. Equipment and inspection and testing equipment control

The scope, procedure, and contents for equipment and inspection and testing equipment control are as following.

(1) Equipment and inspection and testing equipment control, including purchase, acceptance inspection, operation, maintenance, operating environment, calibration, inspection and repair, scrap;

(2) Equipment and inspection and testing equipment documents control, including the establishment of equipment and inspection and testing equipment directory and files which contain documents of certificate of quality, instruction manual, service record, maintenance and repair record, calibration plan, record and report;

(3) Equipment and inspection and testing equipment status control, which includes calibration marks and the mandatory periodical inspection report.

14. Non-conformity control

In accordance with the actual condition of the company, the company shall formulate the non-conformity control scope, procedure, and contents as following.

(1) Non-conformity record, identification, storage and segregation;

(2) Non-conformity cause analysis, disposition and inspection after disposition;

(3) The making, review, approval, execution and tracking of the corrective action to non-conformities.

15. Quality improvement and service

The scope, procedure, and contents for quality improvement and service are as following.

(1) Quality information control, including internal and external quality information, quality issues brought by quality & technical supervision organs and inspection institute, quality information collection, summarizing, analysis, feedback and disposition;
(2) At least once a year the company shall conduct one complete internal audit, and analyze the findings, take corrective action and track the effectiveness of the corrective action;
(3) The company shall keep regular statistics and analysis to pass rate and repair rate, and bring forth specific preventive measures;
(4) Customer service, including service plan, execution, verification, report and the concerned personnel responsibilities.

16. Training

The scope, procedure, and contents for training and examination control are as following.

(1) Training requirements, contents, plan, and execution;
(2) Training and examination documents as required by the special equipment licensing system;
(3) Employment, loaned personnel and personnel transfer control as required by the special equipment licensing system;

Note. This article is not applicable to welding personnel, NDT personnel, chemical and physical testing personnel. The training and examination to the above personnel is defined in the corresponding articles.

17. Other process control

In accordance with the specialty of licensed items, the company shall make other processes as an independent control element and formulate the control scope, procedure, and contents as following.

(1) Identify other processes which affect the safety quality of special equipment;
(2) Appoint the responsible persons for other processes and define their authorities and responsibilities;
(3) Special control requirements for other processes, process record, inspection and testing items, inspection and testing record and report.

（Note. Other processes refer to those processes during the special equipment manufacture, installation, alteration, and repair, which have great influence to safety and therefore needs special control. For example, notch groove of rupture discs, petal fabrication for spherical tank, forming of heads, manufacture of forged pieces, surface treatment of pressure vessels, the winding and coil winding of pressure vessels, the forming of gas cylinder drum, the closing of top and bottom and the treating of bottleneck of seamless gas cylinders; the filling, dispensing, autoclaving and drying of dissolved acetylene gas cylinders; wrapping, drying and solidifying of wrapped gas cylinders; the installation of medical oxygen cabins and its communication system,

electric system, illumination system, oxygen supplying and venting systems; the jointing of the boiler tubesheet and fire tube, boiler installation debugging, the extrusion molding of nonmetallic tube and piping, the steel making process, continuous casting, die casting, heating, heat treatment, press working and finishing of boiler and pressure vessel steels; the bending and forming of metal piping; the mounting and testing of valves, the undercrossing, the mounting of cathode protection, pigging operation, corrosion prevention and concealed work; electric control system, hydraulic system, pneumatic system, installation and debugging, machining of important parts, manufacture and inspection of safety appurtenance, manufacture of metallic structures, and control of mass produced products.

In compliance with the licensing requirements and safety technical codes, the company shall make the main processes of the defined other processes as independent control elements and formulate special control requirements. For other general processes, the control requirements can be documented in the technological documents. Where there are no requirements for welding, heat treatment, and NDT for some licensed item, the company need not formulate any control requirements.

18. The procedure for implementing China special equipment manufacture licensing system

In accordance with the specialty of licensed items, the company shall make the procedures for implementing China special equipment manufacture licensing system and formulate the scope, procedure, and contents as following.

(1) Implementation of the China special equipment manufacture licensing system;
(2) Accept the supervision of quality & technical supervision organs of all levels;
(3) Accept the supervisory inspection. Where supervisory inspection to special equipment manufacture, installation, alteration, maintenance and repair is required by regulations and safety technical codes, the company shall make provisions for accepting supervisory inspection, and appoint a contact person for liaison with supervisory inspection agencies, provide conditions for supervisory inspection, and formulate procedures for the disposal of the *Liaison Sheet of Supervisory Inspection* and the *Notice of Supervisory Inspection* provided by supervisory inspection agencies.
(4) Special equipment license control, including observation of the relevant laws, regulations and safety technical codes, change application and registration where there is any change to the license (for example, name, address, quality manual and etc.), special equipment license and license symbol control, license renewal procedure;
(5) Provide information as required by regulations, safety technical codes to quality & technical supervision organs, inspection institutes and society, which includes information on special equipment manufacture, installation, alteration, and repair.