

中华人民共和国  
锅炉压力容器制造许可实施指南

**IMPLEMENTATION GUIDELINE FOR  
BOILER & PRESSURE VESSEL  
MANUFACTURE LICENSING OF P.R.CHINA**

[WWW.CSE](http://www.cse.com.cn)

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## **1 Introduction**

The Implementation Guideline for Boiler and Pressure Vessel Manufacture Licensing of P.R. China (hereinafter referred to as the Guideline) is formulated in accordance with cardinal principles of the Regulations on Safety Supervision of Special Equipment issued by the State Council of the People's Republic of China, the Supervision Administration Regulation for Manufacture Licensing of Boiler and Pressure Vessel released by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ), and other related laws, regulations. This Guideline is a guidance document for implementation of boiler and pressure vessel manufacture licensing.

Overseas manufactures of boilers and pressure vessels may use this Guideline when they file the application of manufacture license for exporting their products to PR China. Meanwhile, the Guideline is also applicable for appraisal and assessment personnel who conduct boiler and pressure vessel manufacture licensing as well as other involved individuals.

This Guideline aims at assisting readers to acquire a better understanding of the nature, contents, requirements, procedures, and relevant stipulations of the boiler and pressure vessel manufacture licensing system of the People's Republic of China in order to correctly implement it. This Guideline does not have a legal value and if the statement of this Guideline contradicts with relevant laws and regulations, the relevant laws and regulations shall prevail.

This Guideline was reviewed by the Bureau of Special Equipment Safety Supervision Administration (SESA) of AQSIQ, and was published by the China Special Equipment Inspection and Research Institute (CSEI).

CSEI is responsible for the interpretation of this Guideline.

## **2 Glossary of Terms**

**2.1** Boiler & Pressure Vessel – A general designation of boilers, pressure vessels and safety appurtenances of boilers and pressure vessels.

**2.2** Guideline - Implementation Guideline for Boiler and Pressure Vessel Manufacture Licensing of P.R. China, unless otherwise indicated.

**2.3** AQSIQ – Abbreviation for the General Administration of Supervision, Inspection and Quarantine of the People's Republic of China.

**2.4** SESA - Abbreviation for the Bureau of Special Equipment Safety Supervision

Administration of the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China.

**2.5 SELO** - Abbreviation for the Special Equipment Licensing Office of the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China.

**2.6 CSEI** - Abbreviation for the China Special Equipment and Research Institute.

**2.7 Safety Supervision Organ** - Unless otherwise stipulated, it refers to the Bureau of Special Equipment Safety Supervision Administration, a division of the General Administration of Quality Supervision, Inspection and Quarantine for special equipment safety supervision, also known as administrative government body for overseeing the special equipment safety and the manufacture licensing.

**2.8 Safety Supervisor** – The governmental staff in the special equipment safety supervision organs, who have the relevant certificates and who are authorized to oversee special equipment safety.

**2.9 License-issue Organ** - The General Administration of Quality Supervision, Inspection and Quarantine, the governmental branch authorized to issue manufacture licenses, unless otherwise indicated.

**2.10 Manufacture License** - Manufacture License for Boiler and Pressure Vessel issued by an authorized officer of the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China.

**2.11 Applicant** - Boiler and pressure vessel manufacturers that apply for manufacture licenses for their products to the General Administration of Quality Supervision, Inspection and Quarantine.

**2.12 License Holder** - Boiler and pressure vessel manufacturers that hold valid manufacture licenses issued by the General Administration of Quality Supervision, Inspection and Quarantine.

**2.13 Agent** - The company or individual that delegates or assists the applicant to handle the procedures of applying for manufacture licensing, authorized by the applicant in writing.

**2.14 Manufacturer** - A general designation of corporations, factories and product manufacturers that produce boilers and pressure vessels for use in the People's Republic of China.

**2.15 Boiler & pressure vessel product accompanying documents** – Relevant documents and technical materials delivered with boiler and pressure vessel products to end-users, generally including as-built drawing, strength calculation sheets, calculation sheets for

safety appurtenances, a certificate of compliance, a related inspection and test record or report, and installation and use instructions.

**2.16 Certificate of Compliance** - A document that the manufacturer declares his products satisfy the stipulated requirements in design and manufacture standards after inspection and / or tests.

**2.17 Inspection & Testing Institution** –Special equipment inspection and testing institutions, approved by the Bureau of Special Equipment Safety Supervision Administration of the General Administration of Quality Supervision, Inspection and Quarantine.

**2.18 Appraisal & Assessment** - The process of appraisal, assessment and inspection of special equipment manufacturers in accordance with safety and technical regulations and other related laws and regulations.

**2.19 Appraisal & Assessment Institution** - The institutions engaged in appraisal and assessment business under the approval of the Bureau of Special Equipment Safety Supervision Administration of the General Administration of Quality Supervision, Inspection and Quarantine.

**2.20 Appraisal & Assessment Auditor** – Technicians who independently carry out appraisal & assessment after obtaining qualification from the Bureau of Special Equipment Safety Supervision Administration of the General Administration of Quality Supervision, Inspection and Quarantine.

**2.21 Trial-manufacture** - The sample product or its pressure component manufactured by the applicant when he files an application for manufacture licensing or license scope extension to demonstrate that the applicant is capable of manufacturing the applied-level product and is able to satisfy the safety quality requirements of China.

**2.22 Safety Technical Code** - A general designation of various regulations, rules, guidelines, provisions and technical codes released by the General Administration of Quality Supervision, Inspection and Quarantine, unless otherwise indicated.

**2.23 Type Test** - A test where the tested product goes through the stipulated items in safety technical regulations and standards and is assessed in accordance with appraisal rules in safety technical regulations and standards, with an aim to determine whether the product meets its particular intended use purpose or application requirements.

**2.24 Type Test Organ** –Technical institutions and laboratories that undertake tests of special equipment or its components, approved by the General Administration of Supervision, Inspection and Quarantine.

### **3 General Provisions**

#### **3.1 Legal basis for implementation of manufacture licensing of boilers and pressure vessels**

The boiler and pressure vessel manufacture licensing system of the People's Republic of China is based upon the following regulations and sector rules:

- 1) Regulations on Safety Supervision of Special Equipment (Adopted by the 68<sup>th</sup> standing committee of the State Council and promulgated by State Council Decree No. 373 of the People's Republic of China and coming into effect as of June 1, 2003);
- 2) Supervision Administration Regulation for Manufacture of Boiler and Pressure Vessel (released by Decree No. 22 of the General Administration of Quality Supervision, Inspection and Quarantine on July 18, 2002 and coming into effect as of January 1, 2003);
- 3) Requirements for Boiler and Pressure Vessel Manufacture Licensing (Released by Document No. 194 of the General Administration of Quality Supervision, Inspection and Quarantine on July 18, 2003 and coming into effect as of January 1, 2004);
- 4) Procedures for Manufacture Licensing of Boiler and Pressure Vessel (Released by Document No. 194 of the General Administration of Supervision, Inspection and Quarantine on July 18, 2003 and coming into effect as of January 1, 2004);
- 5) Supervisory Inspection Rule for Safety Performance of Boiler and Pressure Vessel Products (Released by Document No. 194 of the General Administration of Supervision, Inspection and Quarantine on July 18, 2003 and coming into effect as of January 1, 2004).

#### **3.2 Boilers and pressure vessels subject to the manufacture licensing**

The following categories of boiler and pressure vessel products manufactured for use in China are subject to the manufacture licensing system and the compulsory safety performance supervisory inspection system according to the laws and regulations released by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China.

##### **3.2.1 Boilers, including:**

- 1) Pressure-bearing steam boilers with volume no less than 30 liters;
- 2) Pressure-bearing hot water boilers with outlet water no less than 0.1 MPa (gauge pressure) and rated power no less than 0.1MW;
- 3) Organic fluid boilers.

##### **3.2.2 Pressure vessels:**

- 1) Various types of pressure vessels for containing gas, liquefied gas and liquid with maximum working temperature no less than its standard boiling point, and the maximum working pressure no less than 0.1MPa(gauge pressure) ,and the product of pressure and

volume no less than  $2.5 \text{ MPa} \cdot \text{L}$  ( $2.5 \times 10^{-3} \text{ MPa} \cdot \text{m}^3$ );

2) Various types of gas cylinder containing gas, liquefied gas and liquid with standard boiling point less than  $60^\circ\text{C}$ ; the maximum working pressure no less than  $0.2 \text{ MPa}$  (gauge pressure) and the product of pressure and volume is not less than  $1.0 \text{ MPa} \cdot \text{L}$  ( $1.0 \times 10^{-3} \text{ MPa} \cdot \text{m}^3$ );

3) Hyperbaric oxygen chambers;

4) Simple pressure vessels: refers to pressure vessels having simple structure and little danger and at the same time meet the below conditions:

① The pressure vessel is consisted of a drum, a flat head and a convex head (spherical head is not included), or two convex heads;

② The material of the drum, head, nozzle and main pressure bearing parts is carbon steel or austenitic stainless steel;

③ The design pressure is smaller than or equal to  $1.6 \text{ MPa}$ ;

④ The volume is smaller than or equal to  $1000\text{L}$ ;

⑤ The product of working pressure and volume is no less than  $2.5 \text{ MPa} \cdot \text{L}$  and no more than  $1000 \text{ MPa} \cdot \text{L}$ ;

⑥ The medium is air, nitrogen or vapor derived from medical distilled water;

⑦ The maximum design temperature is greater than or equal to  $-20^\circ\text{C}$ , the maximum working temperature is lower than or equal to  $150^\circ\text{C}$ ;

⑧ The pressure vessel is unfired fusion welded pressure vessel.

### 3.2.3 Safety appurtenances of boilers and pressure vessels

The safety appurtenances installed on or used for boilers and pressure vessels include safety valves, rupture discs and cylinder valves.

Safety valves include various valves used on boilers and pressure vessels as defined in Article 3.2 of the Guideline with maximum working pressure no less than  $0.02 \text{ Mpa}$ .

### 3.3 Level classification of the boiler and pressure vessel manufacture licensing

#### 3.3.1 Classification of the level for manufacture licensing of boilers

Level	Scope of Boiler Manufacture
A	Without limitation
B	Steam boilers with the rated steam pressure less than or equal to of $2.5 \text{ MPa}$ (gauge pressure, the same below)
C	Steam boilers with rated steam pressure less than or equal to of $0.8 \text{ MPa}$ and rated evaporation capacity

	less than or of 1 t/h. Hot water boilers with rated output water temperature less than 120°C
D	Steam boilers with rated steam pressure less than or equal to of 0.1 MPa; Hot water boilers with rated output water temperature less than 120°C and rated thermal power less than or of 2.8MW

Notes:

1. Hot water boilers with output water temperature higher than or equal to 120°C are Level C or even higher levels depending on the pressure of output water.

2. A higher-level license holder of boiler manufacturer has free access to produce boiler products of lower levels.

3. The manufacturers with manufacture license of Level C or higher than Level C may produce organic fluid boilers. For those manufacturers, which solely produce organic fluid boilers, may apply for the qualification of manufacture license for organic fluid boiler only and no Level classification of manufacture licensing is needed.

4. For those manufacturers only producing rather single products, some limitation may be given to their licensing scope, such as assemblies, materials or categories.

5. Manufacturer may produce the assemblies of boiler to be fitted up to the same Level boiler as in its licensing scope, such as steam distribution cylinders or water distribution cylinders.

### 3. 3. 2 Classification of the level for manufacture licensing of pressure vessels

Level	Manufacturing scope	Typical Products
A	Super-high pressure vessel, high pressure vessels (A1); Category III pressure vessels with lower or medium pressure (A2), Field assembling welding of and petal fabrication for spherical tank (A3), Non-metallic material pressure vessel (A4) and Oxygen cabin for medical treatment (A5)	For Level A1, structure type should be clearly indicated, such as, single layered, forged-and-welded, coil wounded, hot-shrink-fitted, spiral wrapped, seamless, forging, tube-made pressure vessel.
B	Seamless gas cylinders (B1), Welded gas cylinders (B2), Special gas cylinders (B3)	For Level B2, shall indicate including (or for containing) dissolved acetylene or liquefied petroleum gas cylinders (only); For Level B3 shall indicate for motor-driven vehicles or wrapped, non-rechargeable, vacuum and thermal insulation cryogenic gas cylinder, etc.
C	Railway tank (C1), Tank truck or tubular trailer (C2), Tubular container (C3)	
D	Pressure vessel of Category I	

	(D1), Low and medium pressure vessels of Category II(D2)	
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Notes:

1. Pressure vessel classification according to pressure:

Super-high pressure vessels: pressure vessels with design pressure higher or equal to 100 MPa;

High-pressure vessels: pressure vessels with design pressure higher or equal to 10 MPa and less than 100 MPa;

Medium pressure vessels: pressure vessels with design pressure higher or equal to 1.6 MPa and less than 10 MPa;

Low-pressure vessels: pressure vessels with design pressure higher or equal to 0.1 MPa and less than 1.6 MPa.

2. Category III pressure vessel: pressure vessels under anyone of the following conditions are defined as the category III pressure vessels.

- (1) High pressure vessels;
- (2) Medium pressure vessels (for containing extreme or highly toxic substance only);
- (3) Medium pressure storage vessels (for containing inflammable or moderate toxic substance with  $pV$  product greater than or equal to  $10\text{MPa} \cdot \text{m}^3$  only);
- (4) Medium pressure reaction vessels (for containing inflammable or moderate toxic substance with  $pV$  product greater than or equal to  $0.5\text{MPa} \cdot \text{m}^3$  only);
- (5) Low pressure vessels (for containing extreme or highly toxic substance with  $pV$  product greater than or equal to  $0.2\text{MPa} \cdot \text{m}^3$  only);
- (6) High pressure or medium pressure shell-tube waste-heat boilers;
- (7) Medium pressure glass-lined vessels;
- (8) Pressure vessels made of high strength materials (the corresponding standards stipulates the lower limit of tensile strength is greater than or equal to 540 MPa);
- (9) Transportable pressure vessels including railway tank (containing substance of liquefied gas or cryogenic liquid), tank truck (trailers containing substance of liquefied gas, cryogenic liquid or permanent gas) and tank container (containing substance of liquefied gas or cryogenic liquid) etc.;
- (10) Spherical tanks (volume greater than or equal to  $50 \text{m}^3$ );
- (11) Cryogenic liquid storage vessels (volume greater than  $5 \text{m}^3$ ).

3. Category II pressure vessels: pressure vessels under anyone of the following conditions are defined as the category II pressure vessels:

Medium pressure vessels;

Low-pressure vessels (containing extreme or highly toxic substance);

Low-pressure reaction/storage vessels (containing inflammable or moderate toxic substance);

Low-pressure shell-tube waste-heat boilers;

Low-pressure glass-lined vessels.

4. category I pressure vessels:

Low-pressure vessels

5. For fabricating pressure vessels designed by analysis, the manufacturer shall have manufacture license of Level A or Level C.

6. The title under petal fabrication for spherical tank shall include the fabrication of various kinds of heads with diameter lager or equal to 1800mm.

7. For the manufactures producing rather single products, their licensing scope shall be restricted, such as giving the limitation of their products or manufacturing process, material, types or use.

### 3.3.3 Classification of the level for manufacture licensing of safety appurtenances (safety valves) for boilers and pressure vessels

Level	Product Range
A1	Every kind of safety valve
A2	The nominal pressure less than 10.0MPa
B	(1) The nominal pressure less than 1.6MPa and the operation temperature higher than or equal to -20°C for nontoxic and non-combustible gas (including steam) (2) Highest operation temperature lower than or equal to the boiling point of liquid medium

Note:

1 Manufacture licensing grade A can cover grade B, grade A1 can cover grade A2.

2 According to the manufacture licensing and the test product supplied, some certain safety valve manufacture items can be restricted, for example, low temperature safety valve less than -20°C.

### 3.4 Chinese institutes involved in the manufacture licensing procedure

AQSIQ is the government body to issue the manufacture license. SESA is a division of

AQSIQ, responsible for acceptance of manufacture licensing applications, approval of appraisal and assessment results and management of issued manufacture licenses.

Address: No.9 Madian Donglu, Haidian District, Beijing, P. R. China

Postcode: 100088

Tel: +8610 8226 2248

Fax: +8610 8226 0190

E-mail: [lijun@aqsiq.gov.cn](mailto:lijun@aqsiq.gov.cn)

Website: <http://www.aqsiq.gov.cn>

SELO is an institution established by SESA to deal with daily routines such as handling reception of application documents and appraisal and assessment reports printing and dispatch of licenses, consultative service for manufacture licensing procedures, and reception of export notices from overseas license holders.

Address: No.9Madian Donglu, Haidian District, Beijing, P. R. China

Postcode: 100088

Tel:+86 10 8226 1762

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E-mail: [selo@csei.org.cn](mailto:selo@csei.org.cn)

Website: <http://www.cbpmi.org/selo/selo/index.asp>

CSEI is an implementation organization authorized by SESA, responsible for appraisal and assessment for manufacture licensing.

Address: Room B202,2 Building,Xiyuan,Hepingjie, Chaoyang District, Beijing,China

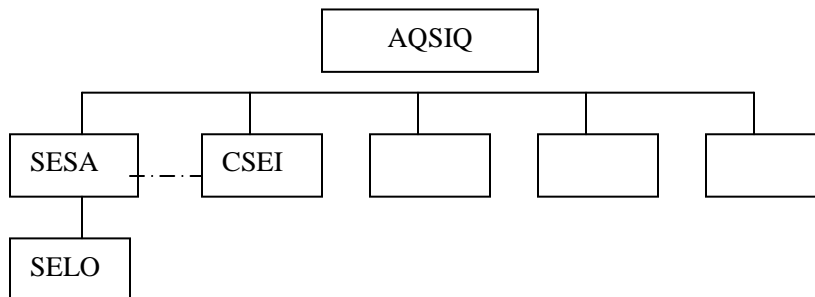
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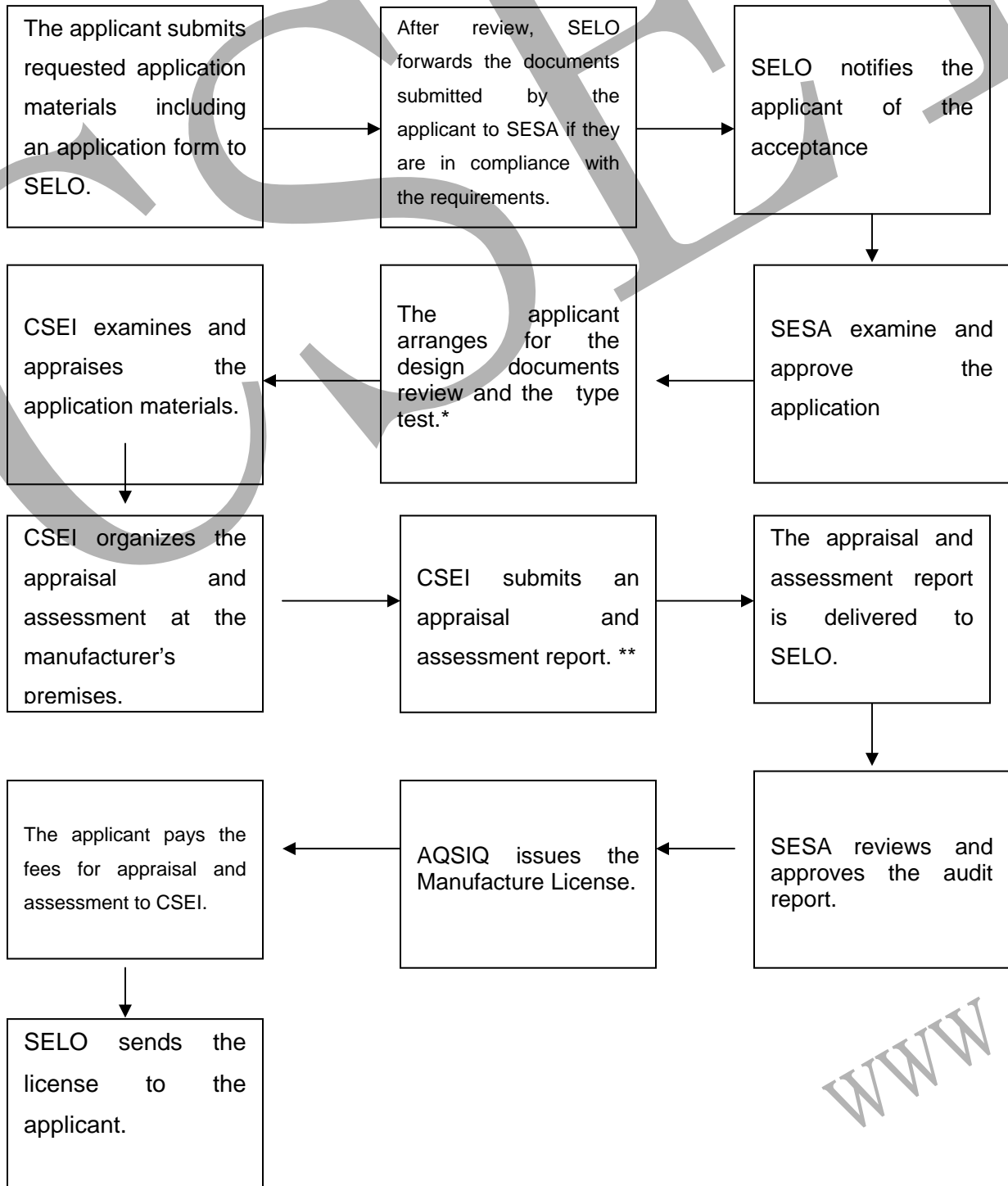
Website: <http://www.csei.org>



### 3.5 Procedures for applying for manufacture licensing

Procedure for applying for manufacture license is the same as that for renewal of manufacture license, as is illustrated as Figure 1.

Figure 1



Notes:

\*This is only applicable to products for which a type test is requested.

\*\* In the case of failure to pass the assessment, please refer to Article 5.6.3 of this Guideline.

### **3.6 Basic requirements for manufacturers**

The manufacturing enterprise or the company with manufacturing facilities shall possess the independent legal person status or be a manufacturer approved or registered in the local government in accordance with local law where the product manufacturer is located, in addition to the following conditions:

#### **3.6.1 Resource requirements**

The manufacturer shall possess the necessary resources and capability required for the manufacturing of its products and for the product level application, including production site, manufacturing and processing facilities, inspection and test equipment and conditions as well as the suitable and appropriate human resources, with details referred to in Appendix 10.3 and 10.4.

#### **3.6.2 Quality management system requirements**

A quality management system appropriate for production of boiler and pressure vessel products shall be established and operate effectively. Documentation of the system, including a quality handbook and supporting documents for quality procedures, shall be ensured and carried out for effective performance of product quality.

The quality management system documents shall conform to the requirements of the China manufacture licensing system, with details referred to in Appendix 10.5.

#### **3.6.3 Product safety quality requirements**

1) The Chinese boiler and pressure vessel manufacture licensing system requires the design and manufacture of boiler and pressure vessel products to be manufactured and used inside China shall be subject to Chinese codes and standards. Manufacturers outside China, who have difficulty to completely carry out Chinese boiler and pressure vessel safety technical codes, are allowed to adopt the technical codes and standards, which is conventional and complete in system and are used by most countries after having been approved by safety supervision administration under the General Administration of Quality Supervision, Inspection and Quarantine (with reference to Article 7.4). But, in this case, they must meet the relevant Chinese requirements on safety quality (with reference to Appendix 10.6, 10.7 and 10.8).

2) The product design, manufacture and inspection shall also meet the requirements of the manufacturer's quality management system and the stipulations of the sales contract.

3) The manufacturer is responsible for the quality and safety of its products.

## **4 Application**

### **4.1 Preparation for application**

The applicant is required to carefully read the Guideline and relevant information provided by SELO on the Internet (<http://www.cbpmi.org/selo/selo/index.asp>) to have a thorough understanding of the China manufacture licensing system. If necessary, the applicant may also make an inquiry to SELO for a better understanding.

### **4.2 Submitting the application**

Having decided to put in an application, the applicant shall fill out the Application Form in quadruple either in Chinese or English (with reference to Appendix 10.1), and forward it together with one set of other requested application documents to SELO.

Documents required for the manufacture licensing are listed as follows:

- General introduction of the manufacturer;
- Quality manual of the manufacturer;
- Copy of the registration certificate with local authorities;
- Copy of certifications obtained by the manufacturer;
- Catalogue of typical products;
- Product drawings and design documents (applicable to products which type test is required).

Unless agreed by SELO in advance, the language of the submitted application documents shall be Chinese or English. Registration certificates as well as other certificates of the applicant are not subject to this requirement.

To meet the delivery date of the contract, the applicant is recommended to submit the application 6 to 8 months ahead of the date he wishes to obtain the license.

### **4.3 Acceptance of the application**

#### **4.3.1 Review and acceptance of the application**

Upon confirming the completeness and correctness of the completed Application Form and related documents after reception of them, SELO will forward them to SESA to determine whether to accept the application.

#### **4.3.2 Handling of acceptance**

If SESA accepts the application and settles the application scope and product level, SELO will inform the applicant of SESA's acceptance decision in writing within two working

days. One copy of the Application Form that has been signed by SESA for the acceptance approval shall be returned to the applicant. The applicant shall also be informed for the preparation for taking the appraisal and assessment.

#### **4.3.3 Handling of rejection**

If SESA rejects the application, SELO will inform the applicant of the SESA's non-acceptance decision in writing within two working days and account for the rejection.

#### **4.4 Notes to the applicant**

##### **4.4.1 Commitment of the applicant**

The representative or the authorized person of the applicant shall express his or her commitment by signature under the following declaration in the Application Form:

"I hereby declare that my party is willing to apply for the manufacture licensing by following the provisions on the Supervision Administration Regulation for Manufacture of Boiler and Pressure Vessels. My party will accept the review, survey and assessment, product (sample) inspection & testing, and engage our full guarantee for product quality by following relevant regulations, and accept subsequent surveillance & product supervisory inspection, and provide the necessary working conditions, and pay the relevant fees and expenses as stipulated."

##### **4.4.2 Application made by a manufacturer who has more than one sub-manufacturer or production facility**

1) If the manufacturing enterprise has more than one production site and each of the production facilities is capable of providing complete boiler and pressure vessel products independently, the manufacturer shall submit one application for each site. The appraisal and assessment shall also be conducted for each site separately;

2) If the manufacturing enterprise has more than one production site, but none of them can provide complete boiler and pressure vessel products, the manufacturer shall submit one application only. The appraisal and assessment will be conducted on one audit tour. One manufacture license will be issued, on which all the pressure parts production locations will be listed.

##### **4.4.3 Application made by the manufacturer's agent**

The agent shall possess the official letter of authorization or power of attorney, where the scope and time limit of empowerment should be clearly stipulated. The original of the letter of authorization or power of attorney shall be entrusted with SELO for file. The agent may handle the application procedures on behalf of the manufacturing enterprise. The manufacture license is issued to the manufacturer rather than the agent.

#### **4.4.4 Application for license modification**

The license holder shall fill out the Application Form for Special Equipment License Modification (Sample at Appendix 10.13) and submit it to SELO in the case of the following conditions:

- 1) The license holder applies for an extension of the license scope (including product upgrading) due to increasing market demand;
- 2) The license holder applies for changing name or business address due to enterprise re-structuring, moving to a new place or other reasons.

#### **4.4.5 Re-application**

The manufacturing enterprise is not allowed to put in an application again until one year later in the case of the following conditions:

- 1) The applicant is rejected when applying for manufacture licensing;
- 2) The application is accepted but the applicant fails the appraisal and assessment on site.

#### **4.4.6 Non-acceptable conditions for application**

Under the following conditions, the application will be unacceptable in principle.

- 1) If the name and address of the manufacturer is not indicated in the application documents, the application is unacceptable;
- 2) If the manufacturer is not of the independent legal person status or is not approved or registered with the local government according to laws and regulations of the nation where the manufacturer is located, the application is unacceptable;
- 3) If the application products are not covered in the List, the application is unacceptable;
- 4) If the manufacturer has not established a documented quality management system or submitted the quality manual, the application will be suspended;
- 5) If the application documents are not adequate, the application will be suspended;
- 6) If type test is required, but the applicant does not indicate the product category, series, type, specification, and quality standards needed for type test, the application will be suspended;
- 7) If the previous application is rejected or fails the review and examination after acceptance, the subsequent application will not be accepted within one year since rejection or failure;
- 8) If the license holder fails to make a renewal application in due time or is rejected in the renewal application due to incompliance, the new application is unacceptable within one year since the expiry date of the previous license.

## **5 Appraisal and Assessment**

### **5.1 General description of appraisal and assessment for manufacture licensing**

#### **5.1.1 Primary principles and contents of appraisal and assessment for manufacture licensing**

The appraisal and assessment for manufacture licensing is principally to confirm the capability and degree for a manufacturer to assure the safety quality of his products, through the appraisal and assessment of the manufacturer's production resources, manufacturing and processing strength, inspection and testing capabilities, quality management system as well as inspection of its typical products. The appraisal and assessment consists of the following items:

- 1) To verify the production site, manufacturing and processing facilities, inspection and testing equipment and working personnel;
- 2) To review and assess the quality manual and relevant documents;
- 3) To appraise and assess the implementation of the quality management system;
- 4) To review and assess the relevant technical documents;
- 5) To inspect and test the trial-manufacture products (not applicable to license renewal application).

#### **5.1.2 Basic procedures of appraisal and assessment for manufacture licensing**

- 1) Appraisal and assessment of the documents submitted by the applicant;
- 2) If requested, type test of samples shall be conducted after confirming that the product design meets the requirements;
- 3) Appraisal and assessment of spot conditions at the manufacturer's premises;
- 4) After the type test and/or the appraisal and assessment of spot conditions is finished, if the applicant is found in line with the requirements, CSEI, the authorized appraisal and assessment institution, will give an overall assessment to the survey and inspection, and draft an appraisal and assessment report, which will be submitted to SESA via SELO for approval;
- 5) SELO will release the manufacture license issued by AQSIQ, upon approval that the applicant is in compliance with the requirements for manufacture license.

#### **5.1.3 Basic requirements of appraisal and assessment for manufacture licensing**

- 1) The appraisal and assessment for manufacture licensing shall strictly comply with the stipulations of Article 3.1 of the Guideline and relevant requirements to ensure the objectiveness, fairness, correctness and reliability.
- 2) Part of the document review such as review of the quality manual is conducted before

the appraisal and assessment; the other part of document review is conducted on the spot.

3) CSEI, the authorized appraisal and assessment institution, reviews the design documents before the type test; the type test organs authorized by SESA conduct the type test of sample product (please refer to Annex 10.14 for the contact information of the type test organs).

4) The organizations and personnel carrying out the appraisal and assessment and the type tests shall keep confidential the product design, manufacture, inspection techniques, and inspection results in accordance with the international custom and practice.

5) The applicant may cooperate with the appraisal and assessment and/ or the type test following the requirements of the Guideline.

## **5.2 Preparation for appraisal and assessment application**

### **5.2.1 Arrangement with appraisal and assessment institution**

Upon receipt of the acceptance notice, the applicant of new application shall prepare for product trial-manufacture in due time. After finishing the trial-manufacture, the applicant shall contact with appraisal and assessment institutions for arrangement of appraisal and assessment on the spot. Upon receipt of the acceptance notice, the applicant of renewal application can directly contact with appraisal and assessment institutions for arrangement of appraisal and assessment on the spot.

The applicant may mail to CSEI, the appraisal and assessment institution authorized by SESA, making an appointment for appraisal and assessment and proposing a time period for appraisal and assessment.

### **5.2.2 Product trial-manufacture (applicable for new application)**

1) The products for trial-manufacture shall be the typical products or major components produced by the applicant that represent the applied licensing level, the manufacture of which is requested to be finished before the appraisal and assessment on the spot. The application acceptance becomes invalid if the applicant fails to complete the trial-manufacture within two years after the acceptance.

2) The design, manufacture, inspection and tests of the trial-manufactured products shall in principle comply with Chinese codes and standards. The applicants who are unable to carry out Chinese codes and standards are allowed to reference Article 3.6.3 of the Guideline.

### **5.2.3 Review of the design documents**

1) Design document review is applicable to boilers, gas cylinders and medical oxygen cabins;

2) Before export the products listed in a) to China, the license holder shall submit the product design documents to review and appraisal institutions recognized by SESA. After obtaining the design documents review report the license holder can deliver his products.

#### **5.2.4 Type test**

- 1) Type test is applied to gas cylinders, accumulators, simple pressure vessels, vacuum insulated cryogenic tanks, safety valves, rupture discs and cylinder valves.
- 2) For type test details, please refer to Article 5.4 of the Guideline.

### **5.3 Document review**

#### **5.3.1 Content and method of document review**

The document review is in principle to determine whether the documents submitted by the applicant are complete, correct and effective, whether they conform to the laws and regulations as well as the requirements of the boiler and pressure vessel manufacture licensing system in China, whether they comply with product standards and quality management system adopted by the applicant. It mainly covers the following aspects:

- 1) Review of the documents related with the manufacturer's basic conditions, manufacturing experience and other application documents;
- 2) Review of the documents related with the manufacturer's production conditions, manufacturing and processing facilities, inspection and testing equipment and technical capabilities;
- 3) Review of the manufacturer's quality management system documents, including the quality manual and the supporting documents;
- 4) Review of design documents, quality plan, inspection and testing record, and reports of trail-manufactured products or in-process products, and finished products.

The review of the documents submitted by the applicant is generally carried out before the appraisal and assessment on the spot. The review of the other documents is conducted along with the appraisal and assessment on the spot. The review of the documents for type-test products is conducted along with design document review. The means of document review generally include checking of documents, questioning key points and manufacturer explanation.

#### **5.3.2 Validation of the document review result**

For the document review results, if any addition or change to the documents is deemed necessary, the manufacturer shall make up the additional documents and/or modify the documents after joint confirmation by the appraisal and assessment personnel and the representative of the applicant. The addition and / or change of the document will be

validated by the assessment team.

## **5.4 Type test**

### **5.4.1 Basic procedures and requirements for type test**

#### **5.4.1.1 Type-test application**

Upon receiving the acceptance notice, the manufacturer whose products require type test shall put in an application according to the category of the applied product to a type-test institution approved by SESA. The Directory of Type-test Institutions can be found in Appendix 10.14.

#### **5.4.1.2 Sample taking and delivery**

The samples for type test are chosen randomly from the normal production, which are acceptable after inspection by the applicant. The sampling amount and method shall comply with requirements of the type-test institution.

The applicant is responsible for the delivery of the samples to the designated place and provide the type-test institution with the relevant documentation, including material reports or material property test data, sample inspection and testing records, quality certification documents, product performance documents and the applied product standards. When necessary, the essential inspection and test method referenced in the product standards shall also be provided.

The type-test institution shall confirm the receipt of the product samples and the documents and inform the applicant in writing if they are acceptable.

If the applicant has difficulty in forwarding the samples and hopes to conduct the type test locally, it shall obtain the approval of SESA in advance.

#### **5.4.1.3 Type test of samples**

Type test aims to determine whether the safety quality of the samples sent by the applicant satisfies the product standards and the requirements of safety technical codes by means of inspection, test and experiment of the samples' material, structure, strength and safety quality. Type test shall follow the Chinese standards. In the case of contemporary lack of corresponding Chinese standards, the product standards and the safety quality appraisal (or type-test) standards applied shall be reported to SESA for review.

The type test shall be objective, fair and correct. The type test results of the samples offered by the applicant shall be kept confidential in accordance with the international customs and practice.

### **5.4.2 Notification of type-test results**

After completion of the type test, the type-test institution shall make a type-test report

and deliver it to the applicant in due time. Meanwhile, it shall also inform CSEI of the type-test result

#### **5.4.3 Disposal of samples after type test**

The type-test institution shall seal and preserve the product samples and any surplus product samples appropriately after the type test. The disposal of the samples after type test shall be handled in a way jointly settled by the type-test institution and the applicant.

### **5.5 Appraisal of on-site conditions**

#### **5.5.1 Main contents of appraisal of on-site conditions**

The appraisal of spot conditions is principally to assess the applicant's manufacture and inspection conditions, the manufacturing technology and the establishment and implementation of the quality management system by checking product manufacture, inspection and test. Its main contents include:

- 1) On-site checks and sampling of the product production conditions, manufacturing and processing facilities, inspection and testing equipment, technical strength and professional staff of the manufacturer;
- 2) Review and assessment of the manufacturer's quality management system documentation;
- 3) Audit and assessment of the implementation of the manufacturer's quality management system;
- 4) Spot checks of the product safety quality; In the case of application for obtaining a license, inspection and test of safety performance of trial-manufactured products shall be conducted;
- 5) Other checks and inspection if deemed necessary by the appraisal and assessment personnel.

#### **5.5.2 Time and method of appraisal of on-site conditions**

##### **5.5.2.1 Time of appraisal of on-site conditions**

The appraisal of on-site conditions is a comprehensive review, survey and assessment of the manufacturer, performed by a team organized by CSEI and with participants from SESA when necessary. The team members performing the appraisal of on-site conditions are generally three people. According to the different application levels, the valid working period for the appraisal of on-site conditions is usually from three to five days for license application, and from two to four days for license renewal application.

##### **5.5.2.2 Methods of appraisal of on-site conditions**

- 1) The survey and checks of the product manufacture conditions, manufacturing and

processing facilities, inspection and testing equipment, and technical personnel qualifications will be carried out mainly by means of inspection tour, verification, and spot-check, etc.

2) The review and assessment of the quality system documents will be carried out mainly by means of documentation review and questioning, etc.

3) Appraisal and assessment of the implementation of the quality management system will be carried out mainly by means of checking and witnessing, tracing and inquiring, verifying, and spot-checks etc. in combination with the design, manufacture, inspection and test of the typical products of the applied level.

4) The inspection of the product safety quality will be performed mainly by means of spot checks and test of the trial-manufactured products (only applicable for application for acquiring a license) or in-process products.

### **5.5.3 General procedures of appraisal of on-site conditions**

#### **5.5.3.1 Initial meeting**

The initial meeting is a meeting where both the personnel of the assessment team and the representatives from the manufacturer's management, quality control department, and other related departments attend. The meeting usually covers the following topics:

1) Introduction of personnel of the two parties

2) The manufacturer shall give an introduction covering the following contents:

A brief introduction of the manufacturer and its quality management system; the manufacturer's preparations for the appraisal and assessment; preparations of trial-manufacture products (only applicable in the case of application for acquiring a new license) and in-process products

3) The assessment team leader shall give an introduction mainly covering the following contents:

Describing the purpose, tasks and responsibility of the assessment team;

Introducing the China manufacture licensing system (if required by the manufacturer);

Describing the main contents, methods, procedures and requirements of the appraisal and assessment of on-site conditions;

Confirming the applied category, type and level of the manufacturer's products

Presenting the list for supplementary documents to be provided by the manufacturer;

Proposing a schedule for the appraisal and assessment of on-site conditions.

4) An address by the manufacturer's management officer

5) Settlement of the working schedule, supplementary documents, working conditions and

other relevant items by both parties

#### **5.5.3.2 Plant tour**

The plant tour will normally be arranged after the initial meeting. The assessment team will make a quick tour of the related departments, workshops and laboratories under the guidance of the relevant personnel of the manufacturer so as to have an initial understanding of the manufacture's situation, production conditions, product structures, manufacturing process, inspection conditions, etc.

#### **5.5.3.3 Assessment of the manufacturer resources**

After the initial understanding of the manufacturer's situation, the assessment team will review the lists of production facilities and human resources provided by the manufacturer and verify the manufacturer's resources on the site and make records accordingly. The two parties shall confirm the non-conformities.

#### **5.5.3.4 Document assessment of quality control system**

The review and assessment of the quality management system is usually carried out at a meeting, where the assessment personnel and the manufacturer's quality control staff attend to confirm whether or not the documents meet the manufacture licensing requirements. The main contents and requirements of the assessment shall be carried out in accordance with Appendix 10.5 "Quality System Requirements and Assessment Checklist". The assessment results shall be recorded item by item.

#### **5.5.3.5 Implementation assessment of quality control system**

In company of the manufacturer's representatives, the assessment team will sample the files of in-process products and finished products and appraise and assess the implementation of the quality management system documentation in a way described in Article 5.5.2.2 of the Guideline. The results shall be recorded. The problems found in the assessment shall be confirmed by both parties. The manufacturer shall take the corrective and preventive actions as stipulated in its quality system procedures.

#### **5.5.3.6 Inspection of product safety quality**

Accompanied by the manufacturer's representatives, the assessment team will conduct the inspection and test of in-process products and/or undelivered finished products on the production site to assess the conformity with the codes and standards adopted by the manufacturer and the relevant regulations on product safety quality of the China manufacture licensing system.

#### **5.5.3.7 Problem identification and solution settlement**

After the on-site inspection and assessment, the assessment team shall hold an

internal meeting to sum up the assessment results and identify the manufacturer's problems. The meeting is no more than an hour in principle. Then the assessment team shall confirm these problems found in the appraisal and assessment of spot conditions if any with the manufacturer's quality management officials. The two parties shall enter into a memo regarding corrective and preventive measures to be adopted by the manufacturer, the supplementary documents to be provided by the manufacturer, and the time limit for rectification. The memo shall be confirmed and signed jointly by the leader of the assessment team and the manufacturer's authorized representative. The assessment personnel shall keep confidential all the information, including the applicant or license holder's product design, manufacture, inspection technologies, test data and identified problems, which are revealed to them as they perform the appraisal and assessment for manufacture licensing.

#### **5.5.3.8 Exit meeting**

After the completion of the appraisal and assessment of on-site conditions, an exit meeting will be held where the appraisal team personnel and the manufacturer's management representative, quality control personnel and other staff from relevant departments attend. The meeting mainly covers the following:

- 1) The assessment team leader will make a comprehensive introduction of the checks, reviews, assessments and inspections and the results of each item, and give an oral conclusion of the appraisal and assessment of on-site conditions. The leader will further state requirements for corrective and preventive actions to be taken by the manufacturer and the items to be supplemented or improved by the manufacturer, and explain the work for next step.
- 2) The manufacturer's management representative delivers a speech and express opinions on the results of the appraisal and assessment of the spot conditions.

The exit meeting is an important step in the process of the appraisal and assessment of on-site conditions, shall be recorded by the appraisal and assessment team.

### **5.6 Conclusion for appraisal and assessment for manufacture licensing**

#### **5.6.1 Drawing the conclusion**

CSEI will summarize the results of the document review, the appraisal and assessment of spot conditions and the type test (only applicable to manufacturers that type test is required) to draft a conclusive appraisal and assessment report if the manufacturer has met the requirements of the manufacture licensing system.

#### **5.6.2 Approval of the conclusion**

SESA will determine whether to approve the conclusive report of appraisal and assessment for manufacture licensing, which is submitted by CSEI.

#### **5.6.3 Disposition of the non-conformities with manufacture licensing requirements**

If the appraisal and assessment results do not satisfy the manufacture licensing requirements, SESA will notify the conclusion and the disposal opinions to the applicant via SELO within 25 working days after receipt of the conclusive report sent by CSEI. The items and reasons of the non-conformities will be clearly described in detail.

#### **5.7 Handling of disputes for appraisal and assessment results**

If the applicant disagrees with the appraisal and assessment results, CSEI shall reconsider or give further explanation. If still dissatisfied with the reconsideration or further explanation by CSEI, the applicant may apply for final arbitration by SESA.

### **6 Manufacture License**

#### **6.1 Issuance and proclamation of the manufacture license**

##### **6.1.1 Issue of the manufacture license**

After approval of CSEI's appraisal and assessment report and the type test report filed by type test organ, SESA will submit it to the authorized official of AQSIQ for his/her formal signature.

##### **6.1.2 Delivery of the manufacture license**

After the applicant has submitted all the requested fees and expenses, SELO shall mail the manufacture license to the applicant or deliver it directly to the authorized representative of the applicant.

##### **6.1.3 Contents, format and validity period of the manufacture license**

The contents of the manufacture license include the license number, full name of the applicant, address of the manufacturing site, category (and classification) of the licensed product, licensed level, expiry date, signature, date of issuance, and the seal of the General Administration of Quality Supervision, Inspection and Quarantine. The format of the manufacture license is shown on Appendix 10.9. The manufacture license is valid for four years.

##### **6.1.4 Proclamation of the manufacture licensing**

SELO will publish the list of license holders on the Internet ([http://www.cnisn.com.cn/IRC/EIRC/special1\\_selo9.html](http://www.cnisn.com.cn/IRC/EIRC/special1_selo9.html)).

#### **6.2 Requirements for use and control of manufacture license**

A copy of the manufacture license shall be attached to the product quality certification

documents for examination when the applicant that has obtained the manufacture license (hereinafter referred as license holder) exports its licensed products to the People's Republic of China.

The license holder is obligated to preserve its license appropriately and is not allowed to transfer it to others. Use of the license for non-licensed products is forbidden. If the manufacture license is lost or damaged before its expiry date, the license holder shall give timely notice to SELO in writing to apply for reissue or change for a new one. For the new license, the contents and expiry date as per the original license will not be changed.

## **7 Administration and Supervision after Issuance of Manufacture Licenses**

### **7.1 Random inspection by safety supervision organs**

Within the validity period of the Manufacturer License, the license holder shall accept the on-site inspection of the use of the license; manufacture conditions, product quality and quality control by the safety supervision organs of AQSIQ in accordance with related laws and regulations.

### **7.2 Document review of product design**

The applicant or license holder for manufacturing boilers, cylinders and oxygen cabins for medical treatment shall not start production until they pass the design document review. The applicant for manufacturing boilers and oxygen cabins for medical treatment may arrange for the design document review as they apply for the manufacture license. The boiler and oxygen cabin license holders can start production only after they have passed the design document review. The procedures and the Application Form for the design document review and assessment are accessible on the Internet ([www.cbpmi.org/selo/survey/design.htm](http://www.cbpmi.org/selo/survey/design.htm)). The design documents for review shall be delivered to CSEI whose address is as follows:

Address: Building 2 Xiyuan Hepingjie Chaoyang District, Beijing China

Postcode: 100013

### **7.3 Supervisory inspection of safety performance of licensed products**

The qualified inspection institutions authorized by SESA undertake the supervisory inspection of product safety performance of overseas boiler and pressure vessel products. The list of the institutions is posted on the Internet. (<http://www.cbpmi.org/selo/selo/type.asp>)

The supervisory inspection of boiler and pressure vessels shall be carried out on the production site and during the manufacture process. After receiving the Notice, SELO shall

arrange inspection institutions for the supervisory inspection. In the case of failure to make such arrangements or when it is inappropriate to carry out supervisory inspection at the manufacturer's premises, the safety performance inspection of the boiler and pressure vessel products can be conducted after they reach the border of China.

#### **7.4 Application for use of non-Chinese standards and codes**

In principle, the boiler and pressure vessel products used in China shall comply with the standards and safety technical codes of China. The overseas manufacturers, who have difficulty to fully adopt Chinese standards or codes in the short run shall write to SELO, giving the reasons and apply for the intended non-Chinese standards or codes. SELO will apply for the approval of SESA on behalf of the applicant for the adoption of non-Chinese standards or codes. The applicant shall not begin the design and manufacture until it obtains the approval of SESA. The safety quality of boiler, pressure vessel and gas cylinder products shall satisfy the applicable requirements listed in Appendix 10.6, 10.7 and 10.8 depending on the category of products.

The non-Chinese standards or codes for the repeated manufacture of standard product are subject to one-time approval. The non-Chinese standards or codes for the manufacture of non-standard product are subject to approval case by case.

#### **7.5 Notice for exports to China**

The license holder shall deliver the Notice of Boilers and Pressure Vessels Exported to China by fax, e-mail or mail, etc. to SELO within ten working days since the establishment of the sales contract of exporting boiler and pressure vessels covered in the licensing scope to China. (The specimen of the Notice is shown in Appendix 10.10)

#### **7.6 Subcontract**

- 1) The license holder shall not subcontract the main part of boilers and pressure vessels or all the pressure-containing parts;
- 2) The subcontractor of complete pressure vessel or pressure-containing parts shall hold the appropriate manufacture license;
- 3) NDE, heat treatment, and physical and chemical performance test can be conducted either by the manufacturer itself or entrusted with qualified subcontractor. The subcontractor shall file report for the entrusted work. The manufacturer is responsible for the quality control of the entrusted work, which shall be incorporated into by manufacturer's boiler and pressure vessel quality control system;
- 4) Specific requirements for manufacturers shall not be subcontracted. (Details referred to Appendix 10.3 and 10.4)

## **7.7 Report and disposition in the event of major changes**

The license holder shall make a timely report to SELO in writing for the approval, or apply for a re-licensing when one of the following occurs:

- 1) Change of the manufacturer's name;
- 2) Change of ownership;
- 3) Change of production location or addition of production locations;
- 4) Change of materials, structure or quality standards to type-tested products.

According to the report submitted by the license holder, SELO will report to SESA to determine whether the approval will be given or whether the necessary appraisal and assessment shall be conducted before modification of the license. SELO will inform the license holder of SESA's decision.

## **8 Fees and Expenses for Manufacture Licensing**

### **8.1 Items of fees and expenses for applying for manufacture licensing**

#### **8.1.1 Items of fees and expenses for manufacturer assessment**

- 1) Application fees
- 2) Document review and assessment fees
- 3) Design review fees (applied to type-test products only)
- 4) Type-test fees (applied to type-test products only, which are paid by the applicant directly to the institution undertaking the type test)
- 5) Fees for the appraisal and assessment of on-site conditions (including traveling time)
- 6) Fees for the appraisal and assessment report
- 7) License fee
- 8) Fees for appraisal and assessment personnel's travel expenses, accommodation cost during the staying period and accident insurance.

#### **8.1.2 Items of fees and expenses for appraisal and assessment to product design**

- 1) Application fees
- 2) Fees for design document review
- 3) Fees for design document review report
- 4) Fees for express mail
- 5) Fees for appraisal and assessment personnel's travel expenses, accommodation cost during the staying period and accident insurance (only applicable to the appraisal and assessment conducted at the manufacturer's premise as required by the manufacturer)

### **8.2 Rates and payment of fees and expenses**

### **8.2.1 Rates of fees and expenses**

CSEI shall make an annual release of the rates for fees and expenses mentioned in Article 8.1. The applicant may ask for a copy.

### **8.2.2 Payment of fees and expenses**

The payment of the above-mentioned fees and expenses specified in Article 8.1.1 is paid in two installment. First, the applicant pays the advance payment after the application being accepted, and then clears the balance of the fees and expenses after the completion of appraisal and assessment. The amount and settlement method shall comply with the Rates for Fees and Expenses released annually by CSEI.

### **8.3 Fee disposition of rejected application**

If SESA concludes the application is unacceptable, the application fees shall be returned to the applicant.

### **8.4 Fee disposition of application withdrawal**

If the applicant withdraws its application after the application being accepted and before the start of appraisal and assessment of spot conditions, the application fees and document review and assessment fees shall not be returned to the applicant.

### **8.5 Fee items and payment for safety performance supervisory inspection**

The rates for fees and expenses for the supervisory inspection of product safety performance are released by inspection institutions respectively. The applicant may ask for a copy.

## **9 Supplementary Provisions**

**9.1** The applicant and license holder shall provide the necessary co-operation for the personnel performing the appraisal and assessment of spot conditions and the personnel performing the supervisory inspection. The applicant and license holder shall assist in handling entry and transit visa formalities as needed for the personnel to perform the work.

**9.2** This Guideline shall enter into effect as of the date of its publication by CSEI. CSEI reserves the right to revise the content of the Guideline without further notification. The updated version of the Guideline can be reached on the website of CSEI.

## **10 Appendix**

**10.1** A Specimen of Application Form

**10.2** A Specimen of Overseas Standard Adoption Application Form

**10.3** Resource Requirements for Boiler Manufacture Licensing

- 10.4** Resource Requirements for Pressure Vessel Manufacture Licensing
- 10.5** Quality System Requirements and Assessment Checklist
- 10.6** Quality Requirements for Boiler Safety
- 10.7** Quality Requirements for Pressure Vessel Safety
- 10.8** Quality Requirements for Gas Cylinder Safety
- 10.9** A Specimen of Manufacture License of Boilers and Pressure Vessels
- 10.10** A Specimen of Notice of Boiler and Pressure Vessel Products to be Exported to China
- 10.11** An Outline for Safety Performance Supervisory Inspection of Boiler and Pressure Vessel Products
- 10.12** A Specimen of Supervisory Inspection Certificate for Safety Performance of Boiler and Pressure Vessel Products
- 10.13** A Specimen of Application Form for the Change of Special Equipment License
- 10.14** List of Type Test Organs
- 10.15** Revised Regulation for Boiler and Pressure Vessel Manufacture Licensing