

Checklist for Manufacturers Examination For EU Mutual Recognition

Name of Manufacturer : _____

Address : _____

Product Coverage : _____

Kind of Assessment : _____

Date of Assessment : _____

ISO9001 certification (certification body, valid date)
: _____

Signature of the Surveyor : _____

Nippon Kaiji Kyokai

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- List of requirements for improvement
- Overall appraisal

1. This is Checklist applies to all manufacturers
2. Entries in the column “Check Results” in the Checklist are to be made as follows :
 - When the requirements are satisfied : ○
 - When there are minor requirements : △
 - When there are major requirements, or the requirements are bit satisfies : ×
 - When not applicable : —

Note that in case △ or × is marked, the contents of items requiring improvement are to be entered in the “ List of requirements for improvement.”

3. An overall appraisal is to be made after the contents of items requiring improvement have been examined.
4. The contents of the check results covered in the Checklist are to be treated strictly as secret information, and must not be divulged to anybody except those in charge.

Checklist for Approval of Manufacturers (for Common Assessment of Quality of Manufacturers)

No.	Requirements	Check Results	Remarks
1	<p>Manufacturing facilities</p> <p>(1) Are there appropriate manufacturing facilities (Hardware and Software) necessary ensure quality?</p> <p>(2) Is there any appropriate environmental equipment in the works?</p> <p>(3) Are there appropriate means of assistance (transportation, communication, information system etc.) in the works?</p>		
2	<p>Establishment of quality system</p> <p>(1) Has quality control system been certified in accordance with ISO9001 or equivalent standard by certification body?</p> <p>(2) Has top management responsible for the quality assurance system been assigned with the policy and objectives of quality and disseminated to all members?</p> <p>(3) Are quality target set by proper departments and hierarchy? Is the quality target determinable and conformity with the quality policy?</p> <p>(4) Has a control procedure for quality manuals been documented as well as the other quality control document? And are the procedure included establish, revise, approval procedure?</p> <p>(5) Are adequate revision quality manuals readily and available in each department and section?</p>		
3	<p>Responsibility and authority</p> <p>(1) Are control systems on production and quality specifically shown in the organization chart?</p> <p>(2) Are the responsibilities and the authority of the major organizations specifically shown in the organization chart?</p> <p>(3) Are the responsibilities and the authority in the departments and sections responsible for class surveys specified?</p> <p>(4) Is any person who is exclusively responsible for quality management assigned? Is the person independent from the manufacturing and sales departments, and has he been given authority to execute his responsibilities?</p> <p>(5) Is the person responsible for quality management authorized to stop manufacturing and product if a serious quality problem arises in the product?</p>		

4	<p>Verification resources and personnel</p> <p>(1) Are the responsibilities and the authority of the quality assurance department clearly specified?</p> <p>(2) Are the following carried out by persons of the quality assurance department in charge?</p> <p>(a) To identify nonconforming products and control nonconforming product record.</p> <p>(b) To take initiatives for nonconformity disposition and direct implementation of disposition.</p> <p>(c) To verify corrective actions (repair, renewal, etc.) for nonconforming product.</p> <p>(d) To suspend advancement of nonconforming product to subsequent processed until completion of corrective action has been verified.</p> <p>(3) Is an internal audit carried out periodically according to scheduled audit plan with corrective actions taken for items pointed out in the audit report?</p> <p>(4) Is the auditor authorized to carry out audit activities?</p> <p>(5) Does the auditor not carry out audit him / her self-activities?</p>		
5	<p>Contract review</p> <p>When contract, are the following items assured and these result and adapted measures (if necessary) recorded?</p> <p>(1) Are the contents of an order sufficiently checked upon receiving the order, and is a procedure for drawing up manufacturing specifications established and implemented?</p> <p>(2) Are the contents of an order investigated to verify compliance with the Rule of the Society?</p> <p>(3) Are the manufacturing of specifications approved as necessary by the orderer.</p> <p>(4) Is there a system capable of responding to the contents of the order when changes are made?</p> <p>(5) When order content changed, are the related documents revised? And does ensure that related persons understand the retirement of after the changing?</p>		
6	<p>Design control</p> <p>(1) Are technical items to be considered in the design process defined clearly?</p> <p>(2) Are design appraisal and verification supported by sufficient records (experiment) Date, calculations and analytical assessments?</p> <p>(3) When compliance with the Guideline of the Society is required, has the designed been approved by the Society?</p> <p>(4) Are changing and alternation of design appropriately carried out and promptly the contents disseminated to the section of department concerned?</p>		
7	<p>Document control</p> <p>(1) Are the procedure (for drafting, deliberation and approval) to establish, amend and abolish rules, standards, specifications and notices, and the person in charge specified for</p>		

	<p>each set of documents?</p> <p>(2) Are document classified into control documents and non-control document?</p> <p>(3) Are the methods of transmission, distribution and recovery of control documents prescribed, and are they carried out as required?</p> <p>(4) Are the forms of control document and the numbering system prescribed, and carried out as required?</p> <p>(5) Are dates of establishment and revision of control documents provided to verify their latest status? And are voided documents handled as no further use? In case where keep voided documents for any means, are properly identification provided?</p> <p>(6) Are important documents affecting quality readily available at all work place and test and inspection sites to which only their latest edition applies? Are they controlled in such a way that they can be readily shown to the Surveyor upon his request relating to inspections of the society?</p> <p>(7) Are procedures of the submission, revision and control procedures of plans for ship classification established?</p> <p>(8) Do plans for ship classification have relevance to working plans?</p>		
8	<p>Purchased and sub-contracted products control</p> <p>(1) Are work flows from the purchasing stage and ordering sub-contracted product until receipt and their appraisal and approval procedures clearly defined?</p> <p>(2) Are the procedures to investigate and evaluate the manufacturing and quality assurance abilities of maker and subcontractor to which purchase order are placed clearly defined with their implementation and recording followed?</p> <p>(3) Has it been established the system appropriate to dispose of nonconforming products it such occurs?</p> <p>(4) Are the following items included as appropriate in an order sheet to maker and subcontractor?</p> <p>(a) Specifications of items to be ordered(including technical date)</p> <p>(b) Names and document No. of plans and documents applying to items to be ordered</p> <p>(c) Manufacturing method, procedure, equipment and qualification of personnel</p> <p>(d) Manufacturing process, test and inspection methods for products</p> <p>(e) Whether or not compliance with the Rules of the Society is required</p> <p>(f) Presentation of non-conforming product</p> <p>(g) Requirements for product identification</p>		

	<p>(h) Requirements for product storage, packing and shipment</p> <p>(i) Requirements for preservation and submission of quality records</p> <p>(5) Are Proper instructions given for cases in which the Rules of the Society apply to Purchased or subcontracted products?</p> <p>(6) After receiving purchased or sub-contracted products, are they properly stored and maintained?</p> <p>(7) Are purchaser supplied items for assembling into products properly verified, stored and maintained?</p>		
9	<p>Identification of products</p> <p>(1) Are product, its important components, or parts provided with identification marks so that they can be correlated with documents such as drawings or specifications in all phases of the process?</p> <p>(2) Are suitable measures taken for preventing erroneous use of materials and parts in all phases of process?</p> <p>(3) Is traceability available for marking clear the damage causality even after shipment of products?</p>		

10	<p>Manufacturing process control</p> <ol style="list-style-type: none">(1) Do quality plans and work procedure manuals have contents to secure quality required of products?(2) Can the control procedure, quality characteristics, test method, person in charge, record and quality related documentation for each process be identified by the quality plan of the product?(3) In each process, is a work standard manual specifying work procedures, process control points, and permissible range prepared with work carried out in accordance therewith?(4) Are work standard manuals ready for use by workers?(5) Has it been established to modify work standards, etc., when they are found to be inappropriate?(6) Are the methods of reporting, disposing and recording of nonconformities during processes appropriate, and connected to corrective actions to be made later?(7) Are welding and heat treatment methods subject to approval in accordance with the Guideline of the Society as necessary?(8) Are welders qualified in accordance with the requirements of the Society, etc. for qualifying welding operates as necessary?(9) When approval is required for a manufacturing process or operation, is approval obtained from the Society?(10) Are periodic inspections carried out for equipment(including jigs and tools) with the control items, method and the inspections intervals established?(11) Is work safety secured?(12) Is producing procedure of NC machining data established and ensured implementation?(13) Is dimension check of NC machined products established and ensured implementation?		
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11	<p>Inspection and test control</p> <p>(1) Inspection and test in general</p> <ul style="list-style-type: none">(a) In each process, are the times for check by worker, inspection by company inspector, inspection by class surveyor and hold points clearly defined?(b) Are the test and inspection methods and acceptance criteria clearly defined?(c) Are those test and inspection methods and acceptance criteria approved by personnel who are responsible for quality?(d) Are recording, reporting and preserving of the results of test and inspection done properly?(e) Are trained personnel assigned for tests and inspections? <p>(2) Receiving inspection</p> <ul style="list-style-type: none">(a) Is it verified that purchase order specifications are satisfied?(b) Is it established that receiving is retained until the requirements of order specifications for purchase or sub-contracted products are satisfied?(c) Is it established that when nonconformity is found, it is identified, segregated, stored and disposed?(d) Are lists of contractor for nonconformities and their control appropriate?(e) Are storage of purchased / sub-contracted products and shipping control appropriate?(f) Are records, certificates, etc. required by the specification checked and controlled properly? <p>(3) Inspection during manufacturing process</p> <ul style="list-style-type: none">(a) Are all the contents that cannot be verified in the subsequent process included in inspections during manufacturing process?(b) Is transfer of products to subsequent processes held until required tests / inspections are completed and reports are received?(c) When a nonconforming is found in the final inspection, is identification provided and disposal carried out properly?(d) Are items reducing witness number in spite of required in the presence of NK surveyor carried out inspection by company inspector properly according to test procedure? (in case where parts of approval tests were carried out in national accredited laboratories) <p>(4) Final inspection</p> <ul style="list-style-type: none">(a) Is the final inspection of a product carried out in accordance with the test and		
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	<p>inspection plan with the specified identification mark provided?</p> <ul style="list-style-type: none">(b) Are all tests and inspections during the whole processed done so far checked in the final inspection with their test and inspection records collated?(c) When nonconformity is found in the final inspection, is identification provided and disposal carried out properly?(d) Is the person who officially permitted release the products recorded <p>(5) Inspection required by the Guideline of the Society</p> <ul style="list-style-type: none">(a) Are all tests and inspections required by the Guideline included in inspections during manufacturing and final inspections?(b) Are those test and inspection methods and acceptance criteria approved by the Society as necessary?(c) Are the results of tests and inspections required by the Society verified by the Surveyor of the Society?(d) Is the procedure for preparing for inspections required to be witnessed by the Surveyor established?(e) Are operators of non-destructive examinations qualified as deemed appropriate by the Society?		
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12	<p>Control of inspecting, testing and measuring equipment</p> <ol style="list-style-type: none">(1) Are Sections / Departments responsible for controlling testing inspecting and measuring equipment for vilification of product clearly defined and are the following controls carried out?<ol style="list-style-type: none">(a) Designation of instruments and equipment to be controlled(b) Calibration of instruments and equipment to be controlled(c) Identification and marking of instruments and equipment to be controlled(d) Disposition of nonconforming products(e) Maintenance and nonconforming products(f) Countermeasure against damage / keeping qualities(2) Are procedures to assess the appropriateness of measurement record during a certain period and record it established when measuring equipment does not meet the requirements?(3) Are material tensile testing, impact testing machined and hardness testers adequate?(4) Are control sections / departments of standard material testing machined to be used for calibration assigned and properly managed?(5) Are standard testing machined and calibration standards traceable to notional standards or recognized standards?		
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13	<p>Control of nonconforming product</p> <p>(1) Are the following control items adhered to for products judged to be nonconforming in an acceptance inspection, an in process inspection and a final inspection? These controlled by sections / departments having no direct connection with the manufacture of the product? And are the procedure documented including clarification of responsibility and authority?</p> <p>(a) Confirmation of nonconformity (including complain from customers).</p> <p>(b) Identification of cause of nonconforming product.</p> <p>(c) Evaluation of the need of measures to ensure prevention of recurrence nonconformity.</p> <p>(d) Decision and implementation of necessary action.</p> <p>(e) Record of the result of the action taken.</p> <p>(f) Review of the effectiveness of the corrective action.</p> <p>(2) When the following dispositions are carried out, is approval obtained from the Society?</p> <p>(a) In case being used after subjecting to prefabrication or repair.</p> <p>(b) In case specially used without reconditioning.</p> <p>(c) In case being reclassified due to change of application.</p> <p>(d) In case being rejected or discarded.</p>		
14	<p>Quality records</p> <p>(1) Are quality records of tests and examinations, nonconforming product corrective action etc., easy to read, readily, identifiable, and searchable? Are necessary documented procedure established about the identification of the record, safekeeping, protection, searching, safekeeping period and disposal?</p>		
15	<p>Product handling, storing, packing and shipping control</p> <p>In all processed from receipt of materials and parts to shipment of products, are handling, storage, packing and shipping control done properly to prevent damage, fouling, deterioration, missing or misuse?</p>		
16	<p>Education and training</p> <p>(1) Does it clear that necessary ability for the personnel required engaging in work to influence the conformity to product requirements?</p> <p>(2) Does it plan and implement that education, training program to acquire a necessary ability and evaluate their effectiveness?</p> <p>(3) Are education and training carried out to qualify personnel engaged in welding, non-destructive examinations and special inspections?</p>		

17	<p>After delivery service</p> <p>(1) Is necessary guidance given for assemblies, installations and trial running to be carried out before shipment products?</p> <p>(2) Are information and instructions provided as necessary for product handling and maintenance?</p> <p>(3) Is information covering problems using product collected, analyzed and disposed of properly?</p> <p>(4) For nonconformities concerning product quality detected after shipment relative to (3) above, are examinations on their causes, corrective actions and their prevention carried out by the sections / departments concerned? (13. Control of uncomforting products)</p>		
18	<p>Data analysis</p> <p>The adequacy and effectiveness of quality control shall be verified. In order to evaluate a possibility of continuous improvement, the data shall be collected and analyzed.</p> <p>a) Customer satisfaction</p> <p>b) Compatibility to product requirements</p> <p>c) The characteristic and predisposition of the process and products including taking the opportunity of preventive measures.</p> <p>d) Ability evaluation of that a supplier (subcontractors) can supply a product according to requirements</p>		
19	<p>Quality improvement</p> <p>Does the company perform the continuous improvement of the quality system through the quality policy, quality target, audit result, data analysis, corrective action, preventive measures and the top management review?</p>		

