Standard Operating Procedures For IAPMO Evaluation Service (IAPMO ES)

No.: ES-010
Title: Review Procedures for Certified Manufacturer's Quality Management System (QMS)
By: B. Berneche Ck: B.Gerber & S. Dewi Approved By: OD Rev Date: 05/15/2016

This Procedure (ES-010), is one of several developed by IAPMO-UES in accordance with ISO 17065 to provide guidance in its certification activities, which, broadly speaking, are to verify a product's conformity to an identified standard or set of criteria, assess the Quality Management System (QMS) documentation that defines the methods used by the producer to achieve this conformity, verify that the QMS is effectively implemented at the production facility, and to control the use of the IAPMO-UES Mark of Conformity that provides assurance to users of the certified product and the certification documents [ISO Guide 53 Section 1]. ES-010 provides guidance on the required elements of the QMS of each applicant for certification [ISO Guide 65 Section 7.1], and is structured to assess the manufacturer's capability to consistently produce to the product specifications in the certification document, the evaluation report (ER), and its associated documentation. Other documents such as evaluation criteria are intended to be used in conjunction with ES-010 to give a complete set of requirements that, if met, provide a basis for certification. These criteria shall be based-on appropriate and commonly accepted standards, whenever possible, and on sound engineering principles and practices where elements must be developed from scratch. Where existing criteria is inadequate or lacking entirely, appropriate criteria shall be developed by relevant and impartial persons, possessing the necessary technical competency. Every effort is made by IAPMO-UES to develop each to be compatible with associated criteria, and to apply the criteria consistently, equitably, and fairly.

IAPMO-UES product certifications are based on product descriptions and specifications, reports of product sampling, testing and analysis, and reports of audits of the quality management systems under which the products are manufactured. Product certifications have certain practical limitations. One prevailing limitation is that total item-by-item compliance with the codes, standards, and specifications is not attainable. However, a properly devised certification system can provide the optimum assurance that products have been produced under the best practicable conditions of manufacture, in compliance with the commercial and legal requirements prevailing at the time, and it thus can minimize the chance or risk of the users obtaining substandard products. These certifications are recognition of codes and standards conformance and provide assurance to users that the certified products meet the building code. "Product certification" is defined as "a procedure by which a third party (IAPMO Uniform ES) gives written assurance (evaluation report, listing, certificate) that a product, process or service conforms to specified requirements (Codes, standards, evaluation criteria)". This recognition is valid only as long as the products meet the given specifications, are used as described in the evaluation report, and continue to be manufactured as described in the QMS documents. IAPMO Uniform ES then permits use of its mark and assigned report number on the product to demonstrate that the product meets a defined set of requirements, such as safety, fitness for use, or specific interchangeability characteristics that are usually specified in a standard. A product bearing an IAPMO Uniform ES mark carries assurances that:

1. The product has been produced according to an applicable standard;
2. The production process has been supervised and controlled;
3. The product has been tested in an independent laboratory;

4. If the customer finds that a marked product does not meet the declared code or standard, he or she can approach IAPMO Uniform ES for redress of the complaint.

This assurance is possible through regular surveillance audits by IAPMO Uniform ES or pre-qualified and accredited inspection bodies who report on the continued adherence to given specifications and documented QMS procedures. IAPMO Uniform ES is obligated to verify the following:

- The manufacturer must continue to follow the scheme of testing and inspection and to maintain records of testing and inspection, which are checked through periodic inspections by IAPMO Uniform ES or accredited inspection bodies;
- During the inspections product samples are tested in the laboratory of the manufacturer and test results are compared with the testing data of the manufacturer;
- If the inspection reports and the test reports are satisfactory, then renewal of the report or listing is granted and the above checks continue every year.

The manufacturer and the inspection agency are expected to inform the certification body promptly in writing of any changes in organization, personnel, product specification and any other aspect that might affect the certification.

To this end, every manufacturer shall have in place a system to manage the quality (consistency) of its products. Descriptions of elements of this quality management system, along with descriptions and specifications of the product, must be submitted to IAPMO-UES for review. The review is to make sure that certain general elements are present in the QMS, and that sufficient checks are in place to make sure that the product manufactured will remain consistent with the specific product represented by the submitted documentation, and subsequently by the evaluation report. The documentation is kept by IAPMO-UES in its archives for reference when questions arise and for use in future reviews. IAPMO-UES may, at its sole discretion, require the submittal of fewer documents if appropriate for the specific product under review, or additional documents that the reviewer/assessor feels are important and relevant to the certification.

All of the documents including procedures, charts, drawings, test records, inspection reports, etc., should be submitted by the same person in responsible charge for the certification on behalf of the applicant so that the applicant is completely aware of, and takes responsibility for, each. All submitted documentation is reviewed, therefore the documentation submitted should include only that which is necessary for certification and which is directly relevant to the product and process being certified. Submitting discrepant, non-readable (by the assessor), and unclear documentation should be avoided; corrections will be required for each discrepancy and clarification for each non-legible document. It is highly recommended that the documentation required by this criteria be submitted in a meticulously organized fashion, with descriptions and explanations of contents to avoid confusion and the wasting of resources. Each document should be sent only once; with the exception of revisions, which shall be identified as such and all changes highlighted for easy review and understanding.

The following information (categories taken from ISO Guide 53) concerning the applicant's quality management system (QMS) shall be provided to IAPMO-UES for review. The submitted documents shall be clear and correct since the information will be relied upon in the assessors certification decisions:

1. Legal information about the company that is the subject of the certification, including its name, location, and contact information.
2. Legal information about the manufacturing facility including its name, location, and ownership.
3. Explanation of the chain of responsibility for the product, its manufacturing and compliance.
    a. Contact information of the person or persons responsible for matters pertaining to the certification, including authority to make any required changes.
    b. Contact information of the person or persons responsible for implementing the quality management system at the manufacturing location(s).
    c. Any special required competency of key manufacturing and testing personnel.
4. Description of the procedures in place to control each document of significance to the quality of the product to make sure the applicable editions and revisions are available and used where required.
5. Design verification procedures for products, where design is required to define specific product characteristics.
6. Incoming materials.
    a. Description of raw material, goods, and assembly constituents of the product under certification.
    b. Minimum specifications and standards that these constituents must meet. Inspections and tests are conducted to verify conformance. Suppliers should be rated based on the inspection results and steps must be taken to improve or discontinue unsatisfactory suppliers.
    c. Details of purchasing and receiving procedures to verify acceptability. Suppliers should be evaluated for their ability and willingness to meet quality specifications.
    d. Storage and staging procedures of constituents in preparation for production.
7. Description of manufacturing process, highlighting stages of significant effect on product quality.
    a. Traceability procedures used throughout production to isolate non-conformances when they occur.
8. In process verification procedures used to monitor product compliance during a run. In-process inspection can take the form of:
    - First-piece inspection: ensure the process starts correctly.
    - Patrol inspection: ensure the whole run is done correctly.
    - Operator inspection: patrol inspection done by operator instead of inspector.
    - Last-piece inspection: discovers deficiencies before next lot is run
    - Stage inspection: inspections scheduled after certain operations or groups of operations are completed.

    Descriptions needed include steps in the process where each occurs and where samples are taken, testing devices used, and target specifications.

9. Identification and description, including measurement quantities and accuracies, for all measuring and testing devices used to verify conformity of the product under the QMS.
    a. Calibration procedures (calibration frequency and status, record keeping, etc.) for the measuring and testing devices.
10. Final product verification procedures, including measurement and tolerance criteria. Final inspection and/or testing is done after manufacture has been completed, making sure that the goods concerned are satisfactory for dispatch to the customer or another department for the next operation. Inspection instructions must be prepared that address:
    a. The details of the tests to be carried out,
    b. The measuring instruments or test equipment to be used, and
    c. The specifications for deciding acceptance of the product with respect to each characteristic.
    d. Details of the sampling plan such as size of sample and the criteria of acceptance to be followed.
    e. Measuring instruments or test equipment used for inspection must be calibrated periodically to verify their accuracy.
    f. Labeling procedures including a copy of the label and description of its contents, how the product is numbered, and specific model or assembly information.
    g. Procedures for reporting significant indicators of product compliance to IAPMO-UES.
11. Procedures for control of non-conforming materials and products throughout production, including marking and segregation from conforming product.
    a. Procedures for reporting significant or chronic non-conformances to IAPMO-UES.
12. Procedures for recording significant quality management data throughout production, record keeping and record retention.
13. Procedures for handling complaints concerning the certified products and for reporting these to IAPMO-UES.
14. Procedures for making changes to the products and QMS processes, and reporting these changes to the inspection agency and IAPMO-UES for verification of continued recognition.

Once the presence of the minimum elements of quality control are verified to be in place and functioning, IAPMO-UES requires ongoing reports of continued compliance in support of its surveillance obligation under ISO 17065. This includes reports of inspections by qualified auditing bodies, which shall include records of complaints and non-conformances or lack thereof, product and process changes or lack thereof, significant indicators of compliance for both manufacturing and management system processes, continuity of the manufacturing location(s) and company legal status, and verification of the continued adequacy of the quality management system (QMS) to produce the product as certified and the intent of the manufacturer to do so.

Review and Resolution Worksheet (optional)			
Report Holder: (company name)		**Review Date:**	
Product: (Trade name or descript.)		**Report:** (ER#)	
Manufacturer: (if different)			
Plant Location: (address, city, state)			
Plant Contact: (name, phone, email)			

	QMS Aspect:	QCM Section:	☑☒⊘
1.	Legal information about the company that is the subject of the certification, including its name, location, and contact information.		☐
2.	Legal information about the manufacturing facility including its name, location, and ownership.		☐
3.	Explanation of the chain of responsibility for the product, its manufacturing and compliance.		☐
a.	Contact information of the person or persons responsible for matters pertaining to the certification, including authority to make any required changes.		☐
b.	Contact information of the person or persons responsible for implementing the quality management system at the manufacturing location(s).		☐
c.	Any special required competency of key manufacturing and testing personnel.		☐
4.	Description of the procedures in place to control each document of significance to the quality of the product to make sure the applicable editions and revisions are available and used where required.		☐
5.	Design verification procedures for products, where design is required to define specific product characteristics.		☐
6.	Incoming materials.		☐
a.	Description of raw material, goods, and assembly constituents of the product under certification.		☐
b.	Minimum acceptance criteria and standards that these constituents must meet.		☐
c.	Details of purchasing and receiving procedures to verify acceptability.		☐
d.	Storage and staging procedures of constituents in preparation for production.		☐
7.	Description of manufacturing process, highlighting stages of significant effect on product quality.		☐
a.	Traceability procedures used throughout production to isolate non-conformances when they occur.		☐

QMS Aspect:		QCM Section:	☑ ☒ ⊘
8.	In process verification procedures used to monitor product compliance including steps in the process where each occurs and where samples are taken, testing devices used, and target specifications.		☐
9.	Identification and description, including measurement quantities and accuracies, for all measuring and testing devices used to verify conformity of the product under the QMS.		☐
a.	Calibration procedures (calibration frequency and status, record keeping, etc.) for the measuring and testing devices.		☐
10.	Final product verification procedures, including measurement and tolerance criteria.		☐
a.	Labeling procedures including a copy of the label and description of its contents, how the product is numbered, and specific model or assembly information.		☐
b.	Procedures for reporting significant indicators of product compliance to IAPMO-UES.		☐
11.	Procedures for control of non-conforming materials and products throughout production, including marking and segregation from conforming product.		☐
a.	Procedures for reporting significant or chronic non-conformances to IAPMO-UES.		☐
12.	Procedures for recording significant quality management data throughout production, record keeping and record retention.		☐
13.	Procedures for handling complaints concerning the certified products and for reporting these to IAPMO-UES.		☐
14.	Procedures for making changes to the products and QMS processes, and reporting these changes to the inspection agency and IAPMO-UES for verification of continued recognition.		☐

Findings		
Issue #:	(add rows as needed)	**Resolved:**
		☐

Reviewer							
Name:		**Review Date:**		**All Issues Resolved:**	☐	**Date Resolved:**	