Quality Management System Review Procedures
IAPMO Evaluation Service (IAPMO UES)

No.: ES-010
Title: Review Procedures for Certified Manufacturer's Quality Management System (QMS) Documentation
By: B. Berneche Ck: SD Approved By: OD

This Procedure (ES-010) is one of several developed by IAPMOUES 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, to assess the Quality Management System (QMS) documentation that defines the methods used by the producer to achieve this conformity, to verify that the QMS is effectively implemented at the production facility, and to control the use of the IAPMOUES Mark of Conformity that provides assurance to users of the certified product and the certification documents [ISO Guide 53]. ES-010 provides guidance on the required elements of the QMS of each applicant for certification, 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. Appendix A to ES-010 can be used by manufacturers to make sure their quality documentation is complete, and by UES reviewers as a guide in verifying the adequacy of the manufacturer's quality management system. The QR-1 and IR-1 Forms (Appendices B and C, respectively) are used by UES inspectors to document the initial and surveillance inspections. Appendix A to ES-010, which is included below, gives required Points of Verification (POV) for the inspector during inspections, which are correlated to the inspection forms. All criteria used for evaluations 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 IAPMOUES 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 inspections of the quality management systems under which the products are manufactured. These certifications are recognition of code conformance and provide assurance to users that the certified products meet the applicable provisions of the building code. This recognition is valid only as long as the products continue to be manufactured as described in the approved QMS documents, meet the given specifications, and are used as described in the evaluation report. This assurance is possible through regular surveillance inspections by qualified and accredited inspection bodies, on behalf of IAPMO UES, which report on the continued adherence to given specifications and documented QMS procedures. 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 consistent quality of its products. Descriptions of elements of this quality management system, along with descriptions and specifications of the

product, must be submitted to IAPMOUES 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 manufactured product will remain consistent with the specific product represented by the submitted documentation, and subsequently by the evaluation report. The documentation is kept by IAPMOUES in its archives for reference when questions arise and for use in future reviews. IAPMOUES 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 responsible 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 superfluous, 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, and engineering time will be wasted reviewing irrelevant documentation. It is highly recommended that the documentation required by ES-010 and other criteria be submitted in a meticulously organized fashion, with descriptions and explanations to avoid confusion and the wasting of resources. Each document should be sent only once; except revisions, which should be identified as such and all changes highlighted for easy review and understanding.

Required Elements of a Quality Management System

The following information (categories taken from ISO Guide 53) concerning the applicant's quality management system shall be provided to IAPMOUES for review. The submitted documents shall be clear and correct since the information will be relied upon in the assessors' certification decisions: (A copy of these requirements in a worksheet format is provided in Appendix A.)

1. Legal information about the Report Holder 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 relationship to the report holder.
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.

    In process verification procedures used to monitor product compliance, including steps in the process where each occurs and where samples are taken, frequency of verification, testing devices used, and target specifications.
8. 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.
9. 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.
10. Procedures for control of non-conforming materials and products throughout production, including identification and segregation from conforming product.
11. Procedures for recording significant quality management data throughout production, record keeping, and record retention.
12. Procedures for recording and handling complaints concerning the certified products.
13. Procedures for making changes to the products and QMS processes, and reporting these changes to the inspection agency and IAPMOUES for verification of continued recognition.

Once the presence of the minimum elements of quality control are verified to be in place and functioning, IAPMOUES requires ongoing reports of continued compliance in support of its surveillance obligation under ISO 17065. This includes reports of inspections by qualified inspection 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.

Appendix A-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)			

	Point of QC Verification (POV)	QCM Section:	☑☒⊘
1.	Legal information about the report holder that is the subject of the certification, including name, location, and contact information.		☐
2.	Legal information about the manufacturing facility, including its name, location, and relationship to the report holder.		☐
3.	Explanation of the chain of responsibility for the product, its manufacturing, and compliance.		☐
3a.	Contact information of the person or persons responsible for matters pertaining to the certification, including authority to make any required changes.		☐
3b.	Contact information of the person or persons responsible for implementing the quality management system at the manufacturing location(s).		☐
3c.	Any special required competency of key manufacturing and testing personnel.		☐
4.	Is the Quality Management System compatible with the product and production process?		☐
4a.	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.		☐
6a.	Description of raw material, goods, and assembly constituents of the product under certification.		☐
6b.	Minimum acceptance criteria and standards that these constituents must meet.		☐
6c.	Details of purchasing and receiving procedures to verify acceptability.		☐
6d.	Storage and staging procedures of constituents in preparation for production.		☐

	Point of QC Verification (POV)	QCM Section:	☑☒⊘
7.	Description of manufacturing process, highlighting stages of significant effect on product quality.		☐
7a.	Traceability procedures used throughout production to isolate non-conformances when they occur.		☐
8.	In process verification procedures used to monitor product compliance, including steps in the process where each occurs and where samples are taken, frequency of verification, 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.		☐
9a.	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.		☐
10a.	Labeling procedures, including a copy of the label and description of its contents, how the product is numbered, and specific model or assembly information.		☐
11.	Procedures for control of non-conforming materials and products throughout production, including marking and segregation from conforming product.		☐
12.	Procedures for recording significant quality management data throughout production, record keeping, and record retention.		☐
13.	Procedures for recording and handling significant complaints concerning the certified products.		☐
14.	Procedures for making changes to the products and QMS processes, and reporting these changes to the inspection agency and IAPMOUES for verification of continued recognition.		☐

Findings		
Issue #:	**Identify the Point of QC Verification by POV Number and describe the issue to be resolved** (add rows as needed)**:**	**Resolved:**
1		☐

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