Water Quality India Association

Certification Scheme for Drinking Water Treatment Systems that Make Microbiological Reduction Claims

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This scheme follows Certification System Type 5 according to ISO/IEC 17067:2013(E)

Forward

This scheme is owned by the Water Quality India Association. Water Quality India Association, an independent, not-for-profit organization, is dedicated to provide guidelines for the evaluation of Drinking water treatment devices for conformity to safety standards for use in drinking water treatment while representing the interest of manufacturers of these devices.

This Scheme is subjected to revision.
Contact WQA India to confirm this revision is current.

Users of this Scheme may request interpretations, clarifications and/or propose revisions by contacting:

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1. Introduction

1.1 Point-of-use (POU) systems for drinking water treatment are used at household to alleviate health risks is gaining widespread application throughout the world. Devices to reduce different forms of contaminants are being developed in accordance with water quality guidelines and health risks. Treatment devices that remove microbiological contaminants are playing a significant role in reducing disease burden, especially in developing countries.

1.2 Given the variety of technologies available for point-of-use (POU) drinking water treatment, it is important to develop performance standards that guide the consumers to choose an appropriate treatment system.

1.3 The USEPA in 1987 has come up with a comprehensive drinking water treatment guide standard for devices that perform microbiological treatment of water. This standard chose bacteria, viruses and disinfectant resistant parasites (cysts) as the key targets and the standard is relevant to water of unknown origin (unexplored ponds, water bodies on hills etc.).

1.4 In developing countries like India, urban consumers in general have access to improved water sources through pipes. However the complexity of the water supply system which includes lack of 24 X 7 water supply, leaky pipes, illegal tapping, contaminated intermediate storage tank etc., lead to a situation of frequent microbial contamination of water supplies. In terms of physical-chemical composition, such urban water supplies are better when compared to water of unknown origin. Except that at times high microbial load may be encountered in such waters. In view of the large infectious disease burden the need for prioritizing development of standards for microbiological treatment devices was evident. In terms of risk assessment the need for recognizing non-bacterial pathogen such as viruses and protozoa was emphasized. Qualitative risk assessment and data and prevalence of viruses as well as scientific recommendation further strengthen the need to recognize viruses and protozoa as important targets for drinking water treatment.

1.5 In view of the above, Water Quality India Association has come up with developing consumer relevant standards for drinking water treatment devices in India to protect its billion people from water related diseases. WQA India has taken a lead for the developing of a separate microbial reduction standard and certification scheme that is relevant for the Indian residential water treatment market.

2. Scope

2.1 This scheme establishes product certification criteria for any drinking water treatment system which is sold in India and makes microbiological reduction claims. It is intended for use by WQA India, and where indicated by subcontractors approved by WQA India. The requirements that the products will be assessed against are contained in The Water Quality India Association's Guide Standard and Protocol for Microbiological Evaluation of Drinking Water Treatment Devices (hereby referred to as the WQA India standard).

3. Glossary of Terms

3.1 Bill of Materials – A list of the raw materials, sub-assemblies, intermediate assemblies, sub-components, parts and the quantities of each needed to manufacture the end product.

3.2 Candidate Product – A product for which a manufacturer is seeking certification according to this scheme.

3.3 Certification Body - Responsible for verifying that a product sold or labeled as a certified product is produced, processed, prepared, handled, and traded according to applicable certification standards.

3.4 Certification Scheme - Certification system related to specified products, to which the same specified requirements, specific rules and procedures apply.

3.5 Certified Product – A product which is certified according to this scheme.

3.6 Facility Assessment – Inspection of the manufacturing facility by a WQA India approved certification body. Facility assessments fall into two types, Full Assessments and Surveillance Assessments.

3.7 Full Assessment - A Facility Assessment to review specific products, processes, and operations through the analysis of objective evidence. A full inspection includes: review of the quality system(s) to verify compliance to specific standard and scheme requirements; review of the production process; review of product information including the bill of materials and the wetted parts list.

3.8 Major Finding - Non-conformances found during audits that may directly affect Certification. Examples of Major Findings include: improper use of the WQA India Seal of Purity; unauthorized changes to a Certified Product.

3.9 Manufacturer – For the purposes of this scheme, the term manufacturer means the company applying for certification of a product according to this scheme. In practice this company may be manufacturing, designing, selling, assembling, distributing or marketing the product.

3.10 Manufacturing Facility – Location producing, assembling, distributing, and/or applying the WQA India Seal of Purity to a Certified Product.

3.11 Material Safety – Requirements designed to ensure that materials used in the product will not leach harmful chemicals into the drinking water supply.

3.12 Minor Finding – Non-conformances found during audits that do not directly affect Certification. Examples of Minor Findings include: records not being retained for required timeframe; complaint system not being followed or implemented.

3.13 Non-Conformity - One or more of WQA India's requirement(s) have not been met or approved.

3.14 Signature - For the WQA India Certification Contract Agreement" form, a signature is defined as a physical handwritten name, an electronically printed name accompanied by a statement of signature, or an electronic signature. For all other documentation a signature is additionally defined as any documented representation indicating that the document(s) submitted can be considered official and signed or an email stating that attached documentation is the formal submittal of the requested document(s).

3.15 Surveillance - Systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity

3.16 Surveillance Assessment – A Facility Assessment used to monitor standard requirements, scheme requirements, the production process, and the quality system. All elements of the Full Assessment may not be covered during a Surveillance Assessment.

3.17 Wetted Parts List – A list of components that come in contact with water intended for human consumption.

3.18 WQA India Certification – Compliance with all WQA India defined requirements.

3.19 WQA India Seal of Purity Mark – A registered Certification Mark that is authorized by WQA India for use on certified products that meet the content of this scheme.

3.20 WQA India Standard – Shorthand for the Water Quality India Association's Guide Standard and Protocol for Microbiological Evaluation of Drinking Water Treatment Devices.

4. WQA India Approved Laboratories

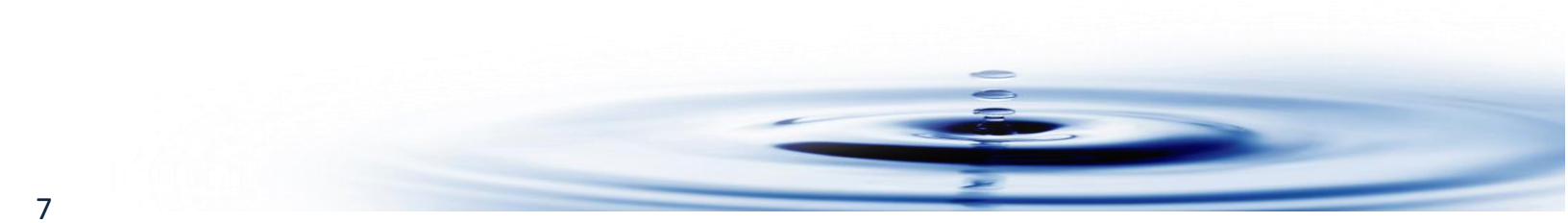
4.1 Only WQA India approved laboratories are authorized to perform testing for the purpose of demonstrating conformance to this scheme.

4.2 Application to become a WQA India Approved Laboratory

5. WQA India Approved Certification Bodies

5.1 The activities within this scheme that fall under the categories of Determination, Review, Decision, Attestation and Surveillance are handled by a WQA India approved certification body.

5.2 WQA India has approved IAPMO – India as the Certification Body to administer the scheme.



6. Scheme Overview

6.1 This scheme conforms to the guidelines in ISO/IEC 17067 “Conformity assessment - Fundamentals of product certification and guidelines for product certification schemes”, Certification System Type 5. The process of certification is broken down into six functional steps. The following definitions of each step have been adapted from ISO/IEC 17067:

- Selection (sometimes referred to as Application) - Planning and preparation activities necessary to collect or produce all the information and input needed for the subsequent determination function;
- Determination (of characteristics) - Conformity assessment activities such as testing, measuring, inspection, design appraisal, assessment of services and processes and auditing to provide information regarding the product requirements as input to the review and attestation functions;
- Review - Verification of the suitability, adequacy and effectiveness of selection and determination activities, and the results of these activities, with regard to fulfillment of specified requirements;
- Decision – The judgment on certification;
- Attestation (licensing) - Issue of a statement of conformity, based on a decision following review, that fulfillment of specified requirements has been demonstrated; and
- Surveillance - Systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity.

6.2 During Selection the manufacturer will submit information about the candidate product to WQA India, and WQA India will provide approximate cost estimate for product certification. It is important that the information submitted by the manufacturer be correct because incorrect information may lead to rework later on, resulting in additional fees and delays. The certification project will proceed past Selection when WQA India and the manufacturer have a legal contract in place defining the scope of the project and associated fees.

6.3 Determination includes inspection of the product literature and testing to verify the microbiological reduction claim. These activities are subcontracted by WQA India to a WQA India approved laboratory, and IAPMO – India the WQA India approved certification body, as outlined in the Determination section of this scheme.

6.4 The Review step involves examination of the inspection and test results from Determination against the requirements in the standard. This step is subcontracted to IAPMO India the WQA India approved certification body.

6.5 At the Decision step, a decision on certification is made and formal documentation on the outcome is provided to the manufacturer. This step is subcontracted to IAPMO India the WQA India approved certification body.

6.6 Projects will proceed to attestation if the decision on certification was that the product meets all requirements. During Attestation a statement of conformity is issued indicating fulfillment of specified requirements has been demonstrated. This step is subcontracted to IAPMO India the WQA India approved certification body.

6.7 Certified products will be subject to Surveillance requirements. Surveillance will include factory audits to assess the manufacturer's production and quality management system, and to verify correct use of the WQA India Seal of Purity logo. Surveillance will also include periodic retesting to verify performance. Surveillance activities are subcontracted to IAPMO India the WQA India approved certification body.

7. Scheme Requirement

7.1 Material Safety

7.1.1 All materials used in the candidate product, and which come in contact with the drinking water, shall:

7.1.1.1Comply with the material safety requirements in NSF/ANSI 42 or NSF/ANSI 61; or

7.1.1.2 Comply with U.S. Food and Drug Administration Title 21 Code of Federal Regulations for Food Additives; or

7.1.1.3 Comply with an applicable voluntary material safety standard that will provide reasonable assurance that any substances leached into drinking water are not of toxicological significance.

7.1.2 Voluntary material safety standards can include national or international consensus standards covering material safety, or the manufacturer's own internal quality control procedures for review and approval of acceptable materials. The mechanism used to comply with this requirement should be indicated in the approval section of the wetted parts list submitted by the manufacturer. If the manufacturer indicates that they rely on their own internal quality control procedures for review and approval of acceptable materials: the specific procedure shall be referenced and a copy of the procedure shall be provided to IAPMO India. IAPMO India approved certification body will review, and verify on an initial/annual basis during the surveillance assessment audit.

7.2 Performance

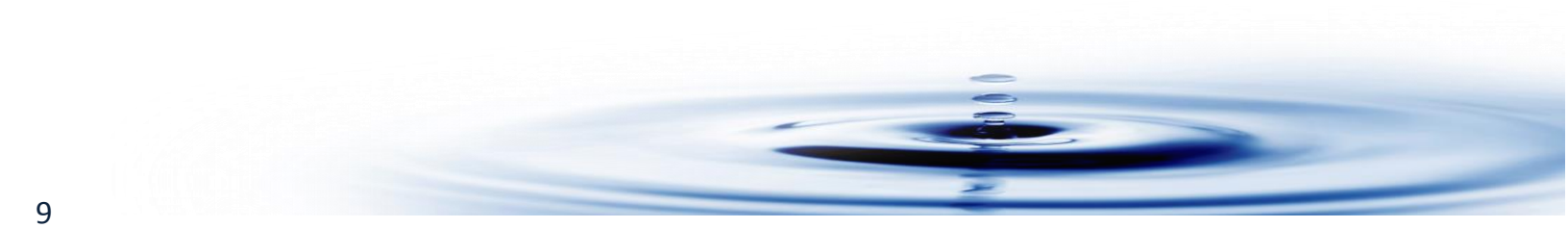
7.2.1 The candidate product shall meet the performance requirements in the WQA India Microbiological standard.

7.3 Product Literature

7.3.1 A permanent plate or label shall be affixed to the product in a readily accessible location and shall include the following information.

7.3.1.1 A model number and/or trade designation.

7.3.1.2 The name and address of the manufacturer, or the telephone number of the manufacturer.



7.3.1.3 A statement that the system conforms to the WQA India standard.

7.3.2 The product literature shall include any conditioning, installation and operating instructions necessary to meet the performance requirements in the WQA India standard.

7.3.3 The product literature shall also comply with any applicable literature requirements in the WQA India standard, and with the WQA India Product Certification Logo Policy.

7.4 Facility Assessment

7.4.1 Before certification is granted the manufacturing facility shall pass a full assessment performed by IAPMO India the WQA India approved certification body, including resolution of major findings. Facilities for which a full assessment has already been performed by IAPMO India do not normally require a new facility assessment prior to the decision on certification, but WQA India and IAPMO India reserves the right to require a facility assessment at any time.

7.5 Surveillance

7.5.1 Certified products will be subject to the surveillance requirements in this section.

7.5.2 IAPMO India shall perform surveillance assessments of all manufacturing facilities at least once per calendar year beginning the year after the initial full assessment. The IAPMO India shall inform the manufacturer on the outcome of the assessment, which will include any findings as well as a timeframe for resolution. IAPMO India shall inform WQA India within 30 days if any major finding is not resolved by the manufacturer within the established timeframe for resolution.

7.5.3 IAPMO India shall review the mechanism used by the manufacturer to ensure material safety and establish an appropriate surveillance plan. Where the mechanism relies on control of materials, IAPMO India shall monitor control of materials during annual facility assessments. Where the mechanism of compliance involves testing, IAPMO India shall require retesting at least once every 5 calendar years. IAPMO India can direct retesting within 5 years' time-frame if there is changes in certified products.

7.5.4 IAPMO India shall conduct periodic retesting for performance through an approved WQA India laboratory.

7.5.5 IAPMO India shall review literature to verify continued compliance with this scheme.

7.5.6 IAPMO India shall report to WQA India the final disposition of any complaint received about a certified product.

7.6 Changes to a Certified Product

7.6.1 IAPMO India shall have a mechanism for review and approval of proposed changes to a certified product to ensure continued compliance with the requirements in the WQA India standard and this scheme. At a minimum this shall include:

7.6.1.1 Prior to initiating a certification project the manufacturer shall be required to sign an agreement ensuring that certified products in production and/or distribution or sale will be maintained the same as the representative sample that was certified or otherwise approved. The agreement shall include changes related to production or production locations, materials, suppliers, or literature required by the WQA India standard or this scheme.

7.6.1.2 IAPMO India shall report unauthorized changes to a certified product as a major finding during surveillance assessments.

8. Selection (Application)

8.1 The purpose of Selection is to ensure WQA India has all relevant information about the candidate product in order to establish a legal contract with the manufacturer which will cover the activities required by this scheme, and the fees associated with those activities. It is important that the manufacturer submit complete and accurate information. Incorrect information may lead to rework, resulting in additional fees and delays.

8.2 The selection process requires the following:

8.2.1 Agreement - The manufacturer must have a valid “WQA India Certification Contract Agreement” on file with WQA India. This agreement establishes basic legal parameters within which the certification activities will be performed. The agreement is valid for the duration that a company successfully maintains a certified product with WQA India, commencing from the date an officer from WQA India signs the agreement.

8.2.2 Datasheet - The manufacturer must submit a “Purifier Datasheet” to WQA India covering the product for which they are seeking certification. The datasheet documents key product features and design elements which can impact testing and conformity assessment activities. Product families can be grouped on one datasheet as long as the performance and treatment technology characteristics are the same.

8.2.3 Product Material List (PML) – The manufacturer must submit a “Product Material List” to WQA India covering all the parts within the product which come in contact with the raw feed water or the treated product water.

8.2.3.1 Parts which only contact water sent to drain do not need to be included on the PML.

8.2.3.2 If multiple products have identical wetted parts, one PML with all model numbers listed on it may be submitted.

8.2.3.3 The top portion of the PML should indicate the manufacturing facility that corresponds with the PML. Where a product is made out of multiple facilities, the manufacturer must submit a separate PML for each facility.

8.2.4 Product literature – The manufacturer must provide all product literature associated with the candidate product including the data plates, performance data sheets, operation/installation guides.

8.2.5 The following additional information may also be submitted for review to reduce duplicate performance testing.

8.2.5.1 Performance Test data from an approved WQA India laboratory or certification body on any product being considered for certification. Test reports will be accepted for a minimum of five years from the completion date unless the product maintains a current listing with another approved accredited certification body and the recertification testing has not yet been completed.

8.2.5.2 Performance test data demonstrating conformance to the WQA India standard is required for all products. If the manufacturer is submitting existing test data which they believe fulfills this requirement, the proposal will be structured to assume no additional performance testing is required, and if the performance test data fails when evaluation done by IAPMO India, the manufacturer may submit a new project to WQA India or IAPMO India to retest.

8.2.6 The following additional information may be submitted for review to reduce duplication of facility assessment:

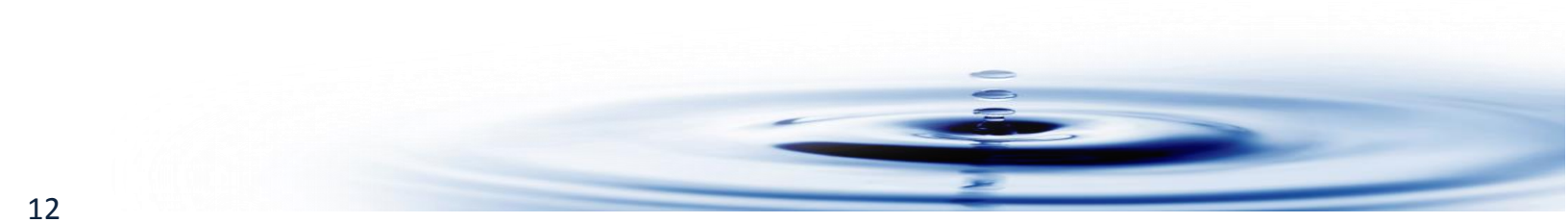
8.2.8.1 A copy of the most recent full assessment of the manufacturing facility(ies) performed by IAPMO India the WQA India approved certification body, including resolution of any major findings.

8.2.7 Proposal - Using the documents above, WQA India will establish fees that cover the approximate cost of the project and provide a written proposal to the manufacturer.

8.3 After the requirements in this section have been met, the project can proceed to Determination.

9. Determination

9.1 Assignment of project to IAPMO India the Certification Body



9.1.1 Once Selection requirements have been met, WQA India will initiate a project with IAPMO India. The scope of work performed by IAPMO India include Determination, Review, Decision, Attestation and Surveillance activities. To facilitate completion of this work, WQA India will provide IAPMO India copies of all forms and information that was submitted during the Selection phase.

9.2 The certification body shall coordinate with a WQA India approved laboratory for any product testing required to meet the requirements in the WQA India standard and this scheme.

9.3 IAPMO India shall perform any other necessary inspections required by the WQA India standard or this scheme including literature review and facility assessment requirements.

10. Review

10.1 IAPMO India shall review the evidence gathered during Selection and Determination, against the requirements of the WQA India standard and this scheme, to establish whether the specifications have been met. Any non-conformances shall be reported to WQA India and to the manufacturer.

11. Decision

11.1 IAPMO India shall make a decision on certification based on objective review of all evidence gathered. Formal documentation on the outcome shall be provided to WQA India and the manufacturer.

12. Attestation and Licensing

12.1 Products for which a positive Decision on certification has been made shall proceed to Attestation.

12.2 During Attestation IAPMO India shall:

12.2.1 Issue a statement of conformity indicating that all the requirements in this scheme have been met. At a minimum this shall include a formal certificate of conformance.

12.2.2 Authorize use of the WQA India Seal of Purity by the manufacturer.