Requirements for the Acceptance and Recognition of Test Laboratories for WRAS Approvals

Abstract: As the test results of the performance of a water fittings product / material provided by Testing Laboratories supply a significant contribution to the WRAS Approval Schemes it is imperative that Water Regulations Approval Scheme Ltd has total confidence in the results provided by the Testing Laboratory. This policy identifies the mechanisms employed to verify and identify “Recognised Laboratories” under the WRAS Approvals Certification Scheme.

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Table of Contents

Introduction

1 Under the requirements of ISO17065 (6.2.2.2) Water Regulations Approval Scheme Limited (WRAS) is responsible for ensuring the quality of all activities outsourced to another body. As the mechanical testing results of a product make up a significant part of the Certification Assessment process, the mechanical testing laboratories who provide these results are considered to be an external resource. As such it is imperative that WRAS has full confidence in the processes and output of any laboratory that it approves as a provider of this outsourced activity.

2 All laboratories submitting test reports to support Applications for WRAS Approvals must be Recognised by WRAS prior to any reports being accepted.

3 Depending on the product type, different routes to WRAS approval are available to Applicants.

4 Any fitting may be tested by an independent Third-Party Test Laboratory to demonstrate compliance with an appropriate British Standard or a specification approved by the regulator.

5 Products falling under the Construction Product Regulations 2013 (list 1 below) may also be considered for approval on presentation of the Manufacturers CE declaration of Performance and supporting documentation. In these cases, the mechanical testing undertaken to support the self-declaration may have been performed by the manufacturers' in-house laboratories and WRAS will require additional assurance regarding test acceptance (First Party Test Laboratory).

6 Applicants may choose a third party to facilitate the application process. For example, a recognised test laboratory may manage the application for all product types however the applicant remains responsible for the completion of the application forms including the signature of the declaration. A test laboratory may choose whether to offer services to their clients to facilitate an application for WRAS approval.

List 1 (CE marking)	**List 2** (all other fittings including, but not limited to:)
WC suite	Backflow prevention devices
WC flushing cisterns	Boilers
Urinal systems	Cisterns
Inlet valves (Only as part of WC suite or cistern application)	Cylinders
	Fittings & Pipes
	Shower outlets
	Switches
	Taps
	Valves
	Washing machine
	Water storage

7 Regardless of the approach taken for application, it is critical that the Recognised Test Laboratory provides WRAS with assurance that the testing used to demonstrate compliance to the Regulations has been performed competently and under the appropriate level of quality control.

8 The following requirements apply to all Recognised Test Laboratories recognised by WRAS to provide test reports in support of a Product or Material Approval application.

Process for Testing Laboratories to obtain WRAS Recognition.

Stage 1 – Contract Review of Laboratory Suitability

Prospective Recognised Laboratories must:

9 Be accredited to ISO 17025 for all the tests required for the product or material as specified on the WRAS website, by a signatory of the ILAC mutual recognition arrangement of Accreditation Bodies, or

10 Be the First-Party Test Laboratory of a manufacturer operating under the scope of the Construction Product Regulations 2013.

11 Provide WRAS with copies (written in English) of the organisation's:

- ISO/EN 17025 Accreditation certificate and schedule of accredited tests,
- Quality Manual (including details of laboratory facilities & resources)
- Evidence of the Legal Status of Organisation (e.g. Certificate of Incorporation)
- A signed copy of the WRAS Recognised Test Laboratory Agreement (WRAS.Cust-404)
- A signed copy of the WRAS Requirements & Code of Practice (WRAS.Cust-402)

12 A desktop review of these documents will be performed within 2 months of receipt.

Stage 2 – Initial Audit

13 On completion of a satisfactory desktop Contract Review WRAS will schedule an audit of the relevant laboratory. The audit will be undertaken by a team consisting of a minimum of a Quality Management System Auditor and a technical expert. This will be performed as described in WRAS.Cust-406; Conduct of Laboratory Inspections and External Audits.

14 The laboratory shall provide additional information as detailed on the provided visit plan prior to the initial audit to allow the assessment team preparation. This will include copies of (written in English), but not limited to, the organisation's:

- Specified procedures and records including:
  - Test operating procedures
  - Training & competency records of personnel performing the tests & details of the number of authorised Report Signatories
- Procedure for producing CE Declaration of Performance (DoP) and supporting Technical Folder if applying under the CE marking route.

15 The cost of the audit, including a daily rate, travel costs, interpreter fees (if required) and assessor expenses, shall be met by the prospective Recognised Test Laboratory in accordance with the agreement it has entered into with WRAS.

16 The audit will consist of a review of the Quality System and a review of the technical performance of tests appropriate to WRAS approval. Test samples will be provided which must be tested during the visit and witnessed by the Technical Assessor.

17 The report detailing the findings of the inspection will be issued to the Laboratory within two weeks of the audit.

18 Any non-compliances observed must be addressed by the prospective Recognised Test Laboratory within 3 months of the audit report date. Evidence of the corrective action taken by the laboratory, along with details of the appropriate mechanisms to prevent reoccurrence, shall be provided by the prospective Recognised Test Laboratory to WRAS.

19 Serious non-compliances which could (in the opinion of WRAS, acting reasonably) have a critical effect on the confidence of results being reported by the prospective Recognised test laboratory may be notified by WRAS to appropriate authorities, including (without limitation) the Accreditation Body. Serious non-compliances would include, but not be limited to:

- situations where the non-compliance would require the withdrawal, or a significant modification (e.g. reduction of the level of backflow protection) of, approvals based on the effected test
- a systematic failure
- fraudulent reporting or
- falsification of records.

Stage 3 - Recognition

20 When any mandatory findings have been satisfactorily cleared, the WRAS Quality and Compliance Manager will submit a recommendation to the WRAS Product Approvals Manager or Director for an independent decision. Once that decision has been made WRAS shall notify the prospective Recognised Test Laboratory of the result in writing.

21 If WRAS decides to grant Recognition, the laboratory will be added to the “Recognised Laboratories” section of the Website.

22 Recognised Test Laboratories will be categorised into three levels of WRAS recognition:

- Certificate
- Affiliate
- Secondary

23 Certificated recognition is granted to newly recognised laboratories and non-accredited First-Party Laboratories will be given this designation. This indicates that they have been assessed against WRAS requirements and have demonstrated an acceptable level of competence.

During the initial five years of recognition, WRAS will submit additional samples (at least one per year) for the “Certificate” laboratories to test and report. The Laboratories will meet the costs of this testing. If any of these generate unexpected results, and a subsequent review identifies that the laboratory has submitted an incorrect report, the laboratory WRAS reserve the right to suspend the Laboratory from the “recognised Laboratories” section of the WRAS website and consider the impact on previous and current approvals and applications. WRAS will identify any conditions that must be fulfilled in order for reinstatement to be considered.

24 Affiliate Laboratories have been recognised by WRAS for over 5 years and will have demonstrated a consistent level of submissions and positive surveillance outcomes.

25 Secondary Recognition is a linked recognition of an externally provided service used by a WRAS recognised laboratory and may be granted to laboratories routinely used by a Certificated or Affiliated Recognised test laboratory for externally provided testing that is included as part of an application for WRAS Approval. A reduced technical audit would be undertaken to establish competence of the sub-contracted lab for the specified tests. The primary laboratory remains responsible for assuring the quality of the externally provided content of the test report submitted to WRAS.

Stage 4 – Continued Evaluation & Surveillance

26 All laboratories will be subject to ongoing surveillance. The level and type of surveillance will vary in line with experience / perceived risk to WRAS approvals, e.g. newly recognised laboratories and non-accredited First-Party laboratories operating under the Construction Products Regulations would be subjected to more frequent auditing until confidence is established.

27 For Independent test laboratories, accreditation to ISO 17025 must be maintained throughout the time the laboratory wishes to be Recognised; WRAS must be informed by the laboratory if accreditation is withdrawn for any reason and must be notified of any major non-conformances identified by their Accreditation Body which are related to their scope of WRAS recognition. The laboratory shall disclose to WRAS, significant quality-related issues relating to tests that may be performed to support WRAS Approvals and will share accreditation inspection reports relevant to WRAS Approvals with WRAS on request.

28 Non-accredited First-Party Laboratories providing test results in support of CE Marking, will be subject to annual WRAS inspection, reviewing both technical and management aspects of the testing and manufacturing processes.

29 Every two years an interlaboratory / proficiency test will be issued by WRAS, in which each recognised laboratory will be provided with a test sample for analysis.

Note: Where possible several items from the same manufacturing batch would be purchased by WRAS and submitted to all labs at the same time. Both approved products/materials and items that would fail testing may be submitted throughout the period of the approval.

30 Laboratories shall expect to be audited by WRAS on site periodically (at least once during each ISO 17025 accreditation cycle (4 years), or annually for in-house non-accredited laboratories) where the analysis of a blind test sample will be witnessed by a Technical expert.

31 A Laboratory may request WRAS to forego a surveillance audit so long as the Laboratory has maintained accreditation to the latest revision of ISO 17025 being assessed by an International Laboratory Accreditation Corporation (ILAC) signatory. With such requests the Laboratory shall provide WRAS with the ISO 17025 audit reports provided by the ILAC signatory accreditation body that cover the period since the last WRAS review. The ultimate decision to forego an audit shall be for WRAS, in its sole discretion and will be made based on a risk assessment which will take into account a range of factors including any non-conformances / non-compliances raised.

32 WRAS will notify the Laboratory of the assessment team in advance and the Laboratory may raise objections to any member of that team on reasonable grounds notified in writing within 10 business days of such notification. WRAS will consider any such objections and will use its reasonable endeavours to accommodate them but will retain ultimate discretion as to the choice of an appropriate team to carry out any assessment.

33 As part of the audit of first-party, in-house test facilities being used for providing CE Mark assurance, an additional review of the manufacturing Factory Process Control processes will be undertaken. Critical non-conformances will be highlighted to the Test Laboratory representative who made the application, at the time of inspection.

34 The report detailing the findings of the inspection will be issued to the laboratory within two weeks of the audit.

35 Any non-conformances observed must be addressed within 3 months of the audit report date. Evidence of the corrective action taken by the laboratory, along with details of the appropriate mechanisms to prevent reoccurrence, shall be provided to WRAS.

36 Serious non-compliances which could have a critical effect on the confidence of reported results may have the effect of the laboratory recognition being suspended, removed or have their scope of recognition amended. When any mandatory findings have been satisfactorily cleared, the WRAS Quality and Compliance Manager will recommend to the WRAS Product and Materials Manager that WRAS recognition is maintained.

Structure of Surveillance Audits Undertaken by WRAS

37 WRAS will take UKAS accreditation to ISO 17025 (or other national Accreditation Body evaluation) into account as part of the monitoring of Recognised Test Laboratories as long as the scope of such accreditation is applicable to the work being undertaken as part of WRAS approvals. The validity and appropriateness of this accreditation will be verified periodically as part of the on-going surveillance audits as required by BS ISO 17065 section 6.2.2.4 Note 1.

38 The Surveillance Audits will confirm that an appropriate quality assurance system is operated effectively by the Testing Laboratories (e.g. ISO 17025, ISO 9001) in addition, factory production control (fpc) will also be evaluated during First-Party laboratory audits.

39 The audit undertaken by WRAS will review:

- Laboratory Management structure and control of confidentiality and impartiality
- Management of Resources – including:
  - Personnel training and authorisation, competency, and allocation of responsibilities.
  - Maintenance, traceability, and calibration of testing equipment
  - Control of facilities & environment
  - Subcontracting of external services
- The Laboratory Quality System including:
  - Policies and document control
  - Control of records, data and information management
  - Risk management & disaster recovery
  - Non-conforming work and corrective actions

  - Quality assurance & internal audits
  - Management review
  - Complaints & feedback
- Process Requirements including:
  - Review of requests and contract review
  - Method selection
  - Proficiency testing
- Test item handling and technical records
- Quality control and result validity assurance
- Test Reports – conformity statements & amendment control.

40 The Process for performing these Audits is defined in WRAS.Cust-407: Conduct of Laboratory Inspections and External Audits.