

# 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**

Table of Contents	2		
ntroduction			
Process for Testing Laboratories to obtain WRAS Recognition	3		
Stage 1 – Contract Review of Laboratory Suitability	3		
Stage 2 – Initial Audit	2		
Stage 3 - Recognition	5		
Stage 4 – Continued Evaluation & Surveillance	<del>(</del>		
Structure of Surveillance Audits Undertaken by WRAS			
Appendix A: Example Certificate of recognition			

WRAS Recognition of Test Laboratories Version Control			
Version	Issue Date	Summary of Changes	
WRAS.Cust-404	20/10/2020	New document to describe the WRAS Laboratory Recognition	
Ver 1.0		process	
Ver 2.0	1/4/2021	Document re-issued in the name of the new legal entity:	
		Water Regulations Approval Scheme Limited	
Ver 3.0	29/06/23	Inclusion of Material Test laboratories	
		Removal of recognition of in-house test laboratories for CE	
		Marking of construction products	
		Update to commitment to provide proficiency trials.	
		Expansion of requirements for Secondary Recognition	
		Example recognition certificate added as Appendix A	
Ver 3.1	29/06/23	Correction of footer	
Ver 3.2	14/11/23	Removal of duplicate paragraph (#15&36) & Correction of	
		WRAS.Cust-407 to 406 in para #42	



### Introduction

- 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 and the testing of materials make up a significant part of the Certification Assessment process, the 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.
- Fittings may be tested by either recognised manufacturers in-house test laboratories, or by an independent Third-Party Test Laboratory to demonstrate compliance with an appropriate British Standard or a specification approved by the regulator.
- Non-metallic materials which will be in direct contact with wholesome water may be considered for WRAS approval if they have satisfied the requirements of BS 6920:2000/2014 Parts 1 and 2, together with Part 3 for hot water usage. No standard of any other EEA State includes the same suite of tests, although individual tests may be considered as providing evidence for an equivalent level of performance. Test Laboratories for materials testing must be able to report all elements of the British Standard to be recognised.
- 4 All laboratories submitting test reports to support Applications for WRAS Approvals must be Recognised by WRAS prior to any reports being accepted.
- 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.
- 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.
- 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 be accredited to ISO 17025 for all the tests required for the product or material as specified on the WRAS website. The Accreditation Body performing the accreditation must be a signatory of the ILAC mutual recognition arrangement of Accreditation Bodies.
- To apply for recognition the laboratory must complete an Application form for Laboratory Recognition (WRAS.Cust-405F1, which can be downloaded from the <u>WRAS website</u>) and 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)

WRAS.Cust-405 Version 3.2 Issued on: 14/11/2023 Page 3 of 9



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

### Stage 2 - Initial Audit

- 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.
- 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
- 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 (see appendix C of the Recognised Laboratory Agreement WRAS.Cust-404).
- 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.
- The report detailing the findings of the inspection will be issued to the Laboratory within one month of the audit being performed.
- Any observations raised 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.
- 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.

WRAS.Cust-405 Version 3.2 Issued on: 14/11/2023 Page 4 of 9



### Stage 3 - Recognition

- When any observations have been satisfactorily cleared, the WRAS Quality Assurance Manager will submit a recommendation to the WRAS Approvals Manager or Director to grant the Recognition. Once that decision has been made WRAS shall notify the prospective Recognised Test Laboratory of the result in writing.
- Successfully recognised laboratories will be presented with a Certificate of Recognition (see Appendix A.) which will detail the scope of recognised tests.
- If WRAS decides to grant Recognition, the laboratory will be added to the "Recognised Laboratories" section of the Website.
- 21 Recognised Test Laboratories will be categorised into three levels of WRAS recognition:
  - Certificate
  - Affiliate
  - Secondary
- Certificated recognition is granted to newly recognised laboratories. 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 monitor closely the reports submitted as supporting evidence for WRAS applications, and if appropriate will submit test samples for the "Certificate" laboratories to test and report. The Laboratories will meet the costs of this testing.
- Affiliate Laboratories have been recognised by WRAS for over 5 years and will have demonstrated a consistent level of submissions and positive surveillance outcomes.
- 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 "Primary" test laboratory for externally provided testing that is included as part of an application for WRAS Approval. It is the responsibility of each Recognised laboratory to ensure that any laboratory they use (or intend to use) for subcontracting tests which will be part of an application for a WRAS approval, are recognised by WRAS, either in their own right or as a Secondary Lab, for the appropriate tests.
- The application for a secondary recognised laboratory must be submitted (using application form WRAS.Cust-405F7) by the existing "Primary" Recognised Laboratory, who will be responsible for obtaining the agreement and cooperation of their nominated secondary laboratory(s) to proceed with the application. This includes the responsibility to fund any additional technical inspection of the secondary laboratory as may be required by WRAS.
- A reduced technical audit will be undertaken to establish competence of the subcontracted lab for the specified tests. Additionally, a desktop review of the applicant's procedure and records for reviewing and approving the externally provided test results to fulfil requirements of BS EN ISO 17025:2017 section 6.6 will be performed. This will also evaluate the contractual arrangements with the "Primary" recognised laboratory and compliance with the WRAS Requirements. The primary laboratory remains responsible for assuring the quality of the externally provided content of the test report submitted to WRAS which includes sub-contracted testing.
- Once a laboratory has been recognised as a Secondary laboratory, any WRAS Recognised laboratory can use them for subcontracting the tests on the scope of



recognition. However, a review of the contract review aspects between the laboratories will be required for each subsequent relationship, which will usually be performed by WRAS as a desktop / remote review with the laboratory engaging the secondary lab.

WRAS will only accept sub-contracted results for tests that have been included on the Secondary Laboratory's Scope of Recognition. If other tests are sub-contracted by a "Primary" lab these will need to be added to the scope. This applies even if these are tests additional to those required by the regulator specifications but are required to complete the testing required for Standards that have been recognised by WRAS as being equivalent.

### Stage 4 – Continued Evaluation & Surveillance

- 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.
- 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.
- Where practical, WRAS will issue test samples for the laboratories as a proficiency test to evaluate consistency of reporting between similar laboratories. 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.
- Note: Where possible several items from the same manufacturing batch be 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.
- Laboratories shall expect to be audited by WRAS on site periodically (at least once during each ISO 17025 accreditation cycle (4 years), where the analysis of a blind test sample will be witnessed by a Technical expert.
- 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.
- WRAS will notify the Laboratory of the assessment team in advance and the Laboratory

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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.

- Any non-conformances observed during surveillance inspections must be addressed within one month 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.
- 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

- 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.
- The Surveillance Audits will confirm that an appropriate quality assurance system is operated effectively by the Testing Laboratories.
- 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

WRAS.Cust-405 Version 3.2 Issued on: 14/11/2023 Page 7 of 9

### **WRAS** requirements for Test Laboratories



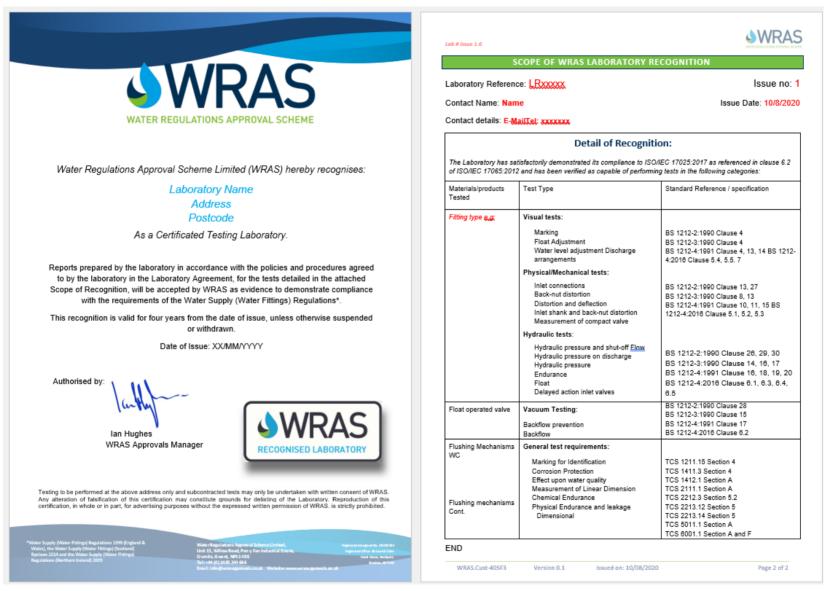
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- Test item handling and technical records
- Quality control and result validity assurance
- Test Reports conformity statements & amendment control.
- The Process for performing these Audits is defined in WRAS.Cust-406: Conduct of Laboratory Inspections and External Audits.



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## Appendix A: Example Certificate of recognition



WRAS.Cust-405 Version 3.2 Issued on: 14/11/2023 Page 9 of 9