Performance of Laboratory Inspections and External Audits

Abstract: As the mechanical testing performance of a Water Fittings Product / Material provides a significant contribution to the Approval Scheme operated by Water Regulations Approval Scheme Limited it is imperative that the Organisation has total confidence in the results provided by the Testing Laboratory. This document details the process WRAS will follow to inspect Laboratories wishing to be Recognised under the WRAS Approvals Certification Scheme.

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Introduction

1 This publication gives general guidance on the conduct of laboratory assessments however due the nature of assessments a certain level of flexibility of approach may be expected from the assessment team and the laboratory.

Water Regulations Approval Scheme limited (WRAS) assesses and recognises the competence of laboratories to carry out the testing required for the WRAS Product Approvals and subsequently ensures, by monitoring, that the required standards are maintained.

2 Application for laboratory recognition initially involves a paper review of the laboratory's quality system and documented procedures for performing the testing. The laboratory will be required to send WRAS a copy of its quality manual (however named) and basic information on its activities, equipment and staff in an Application Form (downloadable from the WRAS website, www.wrasapprovals.co.uk).

3 Subsequently, the competence of the laboratory is checked by an assessment at the laboratory and, where appropriate, at other sites.

The purpose of the assessment is to determine whether the laboratory has the appropriate technical competence and complies with the requirements of ISO/IEC 17025.

All information obtained before, during or after assessment, including the fact that a particular laboratory has applied for recognition, or that an application for accreditation has been deferred or rejected, is treated as strictly confidential by WRAS and its assessors.

4 WRAS technical experts are used to assess the competence of the laboratory to perform the testing (including sampling) for which recognition is sought. Their assessment will be confined to investigating and reporting the findings that result from observation and discussion in the laboratory and through examination of documentation.

In addition to its own staff, WRAS may use assessors contracted from external sources to assess laboratories on its behalf. All WRAS assessors, including WRAS staff acting as assessors, must meet defined criteria in terms of their technical expertise and experience, must be trained in WRAS assessment procedures and are bound by confidentiality agreements.

WRAS laboratory assessment procedures are applicable to all sizes of laboratory and the assessment will take account of the size and complexity of the organisation when assessing the management system of a laboratory.

The laboratory management system must provide WRAS with assurance that the laboratory, whatever its size or complexity, or the location(s) where work is carried out, meets the requirements of the Standard.

5 The procedures described in this publication apply to all assessment visits, whether initial assessment or surveillance visits after recognition. Although it's primary focus is on the assessment of Test Laboratories, the same process and principles apply for all external inspection undertaken by WRAS.

Processing of Application for Recognition

Stage 1 – Contract Review

6 All applications for laboratory recognition are initially reviewed by WRAS to identify an appropriate assessment team with all the necessary expertise and competence and to make realistic estimates of the timescales and costs involved.

7 The WRAS Quality Manager will manage the application and will be able to discuss any matters that may arise during the processing of the application with the Laboratory's representative.

The WRAS Quality Manager will normally act as the Lead Assessor and is responsible, for selecting and appointing the assessment team.

The assessment team will comprise of a Lead Assessor and as many Technical Assessors as necessary to provide the technical expertise to adequately assess the laboratory's competence.

8 Laboratories have the right to object to the appointment of the nominated assessor(s) and, in such cases, WRAS will endeavour to offer an alternative. In the event that a suitable alternative cannot be identified, or the grounds for objection are considered to be unreasonable, WRAS reserves the right to appoint the assessor(s) originally selected.

The Lead Assessor will review the documentation supplied by the Laboratory and will assess the laboratory's apparent competence:

a. The Laboratory's ISO 17025 Accreditation Certificate and Schedule of Accreditation (if appropriate) will be reviewed to assess whether all the tests required for clients to demonstrate compliance with the Water Supply (Water Fittings) Regulations 1999 are accredited.
b. The Quality Manual (however named) describing the quality management system operated by the laboratory and including details of facilities and resources available to undertake tests appropriate for WRAS Approvals,
c. If the applicant is a First-Party Test Laboratory, impartiality processes will be reviewed to assess the processes and the independence and separation between testing facilities and manufacturer.
d. A list of the staff approved and trained to perform testing applicable to WRAS approval,
e. any supporting documentation supplied by the laboratory,

9 At this point, the Lead Assessor will recommend:

a. The composition of assessment team, potential timescale and estimation of the cost for an Assessment Visit or
b. That the organisation is not in a position to proceed to an Assessment Visit.

10 The laboratory will be informed of the outcome of the initial review within two months of the receipt of application

Creation of Visit Plan

11 If a recommendation to proceed to Stage 2 – Assessment Inspection is recommended, a draft visit plan will be created.

12 For Mechanical laboratories the template WRAS.Cust-405A should be used. The Approvals Manager / assigned Technical Assessor should be consulted to identify which

tests will need to be witnessed during the assessment and to confirm the amount of time that will be required for the inspection.

13 For Material Laboratories, the template WRAS.Cust-405B should be used to detail the arrangements for the inspection.

Creation of quotation

14 A quotation will be produced as part of the Application Review using WRAS.Cust405F2 using quotation template 405F4. This will include the one-off fee for the application review and the detailed breakdown of the costs of the initial inspection, including: assessment time for each assessor, travel time, assessor expenses and transport costs (if applicable).

15 The costings will be in line with the price list detailed in Appendix C of the Laboratory Agreement WRAS.Cust-404.

16 The quote will be given a reference number based on the laboratory code and expected date of the inspection.

17 Following the Inspection, this quotation will be converted to an invoice and transferred into the Sage Finance software by the WRAS Administrator to be issued to the Laboratory for payment. The information transferred to the invoice must include the date of the inspection and the quotation reference number.

Stage 2 –Assessment Inspection

18 The visit should be structured so that the Lead Assessor can ascertain that the essential components of a management system for quality, administrative and technical operation of the laboratory have been put in place or have been addressed.

19 The Assessment Team will usually take the opportunity to carry out a brief examination of the laboratory's facilities and discuss with the laboratory any documented in-house methods used for testing activities and any in-house calibrations used to support reports submitted as part of a WRAS Product Approval application. This will allow the Lead Assessor to be satisfied that such methods have been validated and review the laboratory's policy and procedures for estimating uncertainty of measurement.

Preparation for the Assessment

20 A detailed visit plan will be prepared by the Lead Assessor (see above) which will indicate which activities are to be assessed by each assessor. This will specify the aspects of the testing that each assessor must witness during the visit.

21 WRAS will distribute copies of the visit plan to the Laboratory and to all the assessment team at least two weeks before the agreed date of the inspection; all parties are given the opportunity to raise any queries with the visit plan.

Performance of the Assessment

Introductory Meeting

22 The visit shall begin with an Introductory Meeting between the Assessment Team and representatives of the laboratory.

23 This meeting is held on arrival to enable the assessment team and the laboratory's representatives to become acquainted, to confirm the purpose of the assessment and to

remind the laboratory of what is expected during the assessment. This sets the scene, and is chaired by the Lead Assessor and will cover, but not necessarily in this order:

a. an explanation of the purpose of the assessment, the functions of the assessors and confirmation that the laboratory staff understand the procedure,
b. confirmation of the range of testing and sampling covered by the laboratory's application for WRAS recognition,
c. confirmation of the visit plan and of the programme for witnessing tests,
d. outline the mechanism for recording observations and the reporting process,
e. confirmation that a representative of the laboratory has been assigned to accompany each assessor, and an explanation of the role of this representative in the assessment.

   Note: It is often appropriate for the accompanying laboratory representative (or relevant section manager, for example) to propose and agree possible corrective actions that could address observations recorded.
f. an explanation of what will happen at the Final Meeting and confirmation of the attendees, time and venue,
g. an assurance that the visit and any observations made will be treated in confidence;
h. arrangements for providing an office and any services needed by the assessors e.g. printing facilities, internet access,
i. a discussion about the normal work hours, breaks etc, within which the Assessment Team will endeavour to work,
j. an opportunity for the laboratory management and staff to ask relevant questions.

Assessment

24 The Assessment Team will then be shown to their respective areas to begin the assessment. The assessors will examine procedures and records and witness the relevant testing and sampling activities as required.

25 The Lead Assessor will normally assess the Management System documentation. The Lead Assessor will also manage the assessment team to ensure that the relevant activities are assessed and provide support and advice as necessary. A member of the laboratory staff nominated by the management should accompany each assessor.

26 Witnessing of the testing activities carried out by the laboratory form the most important part of the assessment. The Technical Assessor should observe, as far as possible, the on-going testing as well as witnessing the testing of a sample provided by the Assessment team. This will have been made evident from the visit plan. Assessors need to establish the laboratory's overall competence in all aspects required by the Water Supply (water fittings) Regulations 1999.

27 The Lead Assessor will examine the laboratory's management system and quality documentation with the Laboratory Quality Manager and any other appropriate staff, to verify that it meets the requirements of the ISO 17025 Standard for test Laboratories.

28 The Assessment shall proceed according to the agreed programme and will examine the management system in operation and the competence of the laboratory staff to perform specific activities. All components of the management system involved will be assessed.

29 Assessors will examine the testing procedures and their implementation in the laboratory. They will determine whether the treatment of measurement uncertainty is in accordance

with ISO 17025 and international criteria. It may not always be necessary to examine every procedure in operation because of the similarities between some activities, but assessors will verify the implementation of the procedures for the tests listed in the visit programme. The assessors will ask to see the equipment involved, the manufacturer's manuals, and establish the status of the calibration of the equipment.

30 Assessors will witness measurements and examine documentation concerning the testing & sampling in progress, and will review associated records and reports/certificates.

31 During the assessment assessors will examine the laboratory's processes for establishing traceability of measurements including any in-house calibrations and the results from participation in appropriate proficiency testing schemes and other QC/QA procedures. Assessors will also assess procedures used to establish the validity of methods used.

32 The object of assessment is to establish by observation whether the work of the laboratory meets the requirements of the WRAS Approvals Scheme. Observations made will be based on objective evidence and will be recorded and verified with the accompanying laboratory representative.

Interlaboratory Trial: Consistency and proficiency test

33 An interlaboratory test will normally be conducted during the inspections of both Mechanical and Material Laboratories.

34 For Material laboratories, at the initial inspection a set of 10 known flavour samples will be provided for the laboratory Odour and Flavour panel to assess. The composition of samples for this initial test will be the same for each laboratory and will establish a baseline of performance. The initial sample preparation of the test samples will be undertaken with the help of one of the WRAS inspectors, who will add the test powder to the test water.

35 For Mechanical laboratories, a set of samples will be provided for testing, depending on the laboratory's scope of recognition. The tests that the laboratory will be requested to perform on these samples will be a reduced list of tests compared to those required for an approval of the product type. These tests will be targeted to demonstrate specific aspects of the product and the laboratory's capability. Note, if multiple products require the same test, the individual test will only need to be demonstrated once.

36 The inclusion of proficiency test during a laboratory inspection will be identified in the detailed visit plan issued to laboratories when an inspection is planned.

Recording of Observations

37 Assessment findings, including possible nonconformities and opportunities for improvement will be recorded and possible action to address the observation will be discussed with the laboratory representative.

38 Assessors will also record which activities they have observed. These records provide the objective evidence on which the Lead Assessor's recommendations on Laboratory Recognition for the WRAS Approvals Scheme will be based.

39 After the assessors have completed their individual assessments, they will meet in a private meeting to produce a co-ordinated view of the laboratory's work. Each Assessor will produce a brief summary of their findings to be presented to the Laboratory representatives at a closing meeting.

Closing meeting

40 A closing meeting will be held where the assessors will assessors present their findings to the laboratory management/staff. The Lead Assessor presents a summary of the results of the assessment and informs the management of the recommendation that will be made to the WRAS Approvals Manager.

41 The following items will be addressed at the closing meeting:

a. A reminder of the purpose of the visit and reiteration of confidentiality;

b. A statement to indicate that the assessment is for the purpose of WRAS Approvals Recognition only and in no way negates the requirements of any National Accreditation body nor does it conflict with any other assessment requirements,

c. A reminder that it is possible that non-conformities may exist that were not found in areas witnessed and the importance of internal checks

d. Each assessor will provide an overview of their findings, and where necessary complete any outstanding Observation Report forms with proposed actions to address findings (ideally these will have been completed before the Final Meeting).

e. The laboratory will have an opportunity to discuss the assessment and to ask any questions, including questions about the findings,

f. the Executive Summary, conclusions and recommendation will be presented with a statement that the inspection report will be issued to the Laboratory within one month of the closing meeting,

42 On return to the WRAS office, the Lead Assessor will compile an Assessment Report based on the assessor's findings using the form WRAS.Cust-406F1: *Laboratory Inspection Report template*. This report will summarise the assessors' findings, indicate key areas needing improvement action, and give the Lead Assessor's recommendation regarding WRAS Recognition. This formal report will be issued to the Laboratory within a month of the inspection.

43 Where there are findings that require improvement action, the recommendation will usually be that Recognition is offered subject to satisfactory action being taken by the laboratory by the agreed close-out date.

44 Observations will be classified as the following levels of significance:

Level	Seriousness	Urgency
1	• Where a critical failure of a process is observed, or • It was not possible to witness the demonstration of a test or process in accordance with the required standard, or • An observation relates to testing of the safety aspect of a safety device	If the laboratory is already recognised the finding must be dealt with promptly. Affected testing should be halted and customers informed where applicable. A corrective action is required immediately that must be provided to WRAS. A change plan is required. Close-out of these observations will require a re-inspection to ensure the remedial action fully addresses the concerns.
2	• Major Failure to comply with documented requirement. Issue may have the potential to lead to a critical failure if not addressed, or • A significant number of minor non-compliances that potentially indicate a	Where the laboratory is already recognised, corrective evidence will need to be provided to WRAS within 1 month of the report date. Where the laboratory is a new applicant, it is probable that a re-inspection will be required for

	larger systematic failing of the management system	WRAS to ensure the observations are satisfactorily addressed.
3	Minor non-compliance of practice with the with process or WRAS requirements. Evidence of departure from requirements but the risk is neither major nor critical.	Recognised laboratories must resolve these observations and provide WRAS with evidence of the corrective action taken within 3 months of the report date. Close-out evidence may be provided to WRAS in the form of updated documents, photographs and/or videos. The inspection report will indicate whether the laboratory will need to provide evidence of corrective action, or whether the solutions employed will be reviewed at the next scheduled visit.

45 Any non-conformances observed for existing Recognised Laboratories must be addressed within 3 months of the inspection 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 by this date. If improvement actions are not implemented within three months, then it will normally be necessary to suspend the recognition.

46 The implications of any recommended sanctions will also be discussed and serious failings may be reported to the Laboratory's ISO 17025 Accreditation Body.

47 Where the number and seriousness of the findings are such that the laboratory's management system and organisation fails to demonstrate competence or conformity with the WRAS requirements, the Lead Assessor's recommendation will be that WRAS Recognition is refused and that the laboratory is advised to discuss future actions with the WRAS Approvals Manager.

Stage 3 - Laboratory Recognition

48 Following the laboratory audit and the successful clearance of any observations raised, the WRAS Quality Manager will submit the recommendation for recognition to the WRAS Approvals Manager for an independent review and decision. Once the ratification is made the Laboratory will be notified in writing.

49 The process defined in WRAS.Cust-405 "WRAS Requirements for Test Laboratories" shall be followed to grant Recognition.

50 If the laboratory disagrees with the recommendation / decision it may appeal. The appeal must be in writing and must be received by WRAS within one month of the decision letter.