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RG 9

Edition 4 March 2022

Accreditation of Bodies Undertaking Legionella Risk Assessment Activities

Contents

Changes since last edition

Correction made to section 2.1 (a) – Spa pools moved to a separate bullet point.

References updated: BS 8580-1, BS 7592, ISO/IEC 17025:2017, Accreditation Logo and Symbols guidance.

Inclusion of appreciation of Health Technical Memorandum 04-01: Safe water in healthcare premises, BS 8580-2 Water Quality – Risk Assessment for Pseudomonas aeruginosa and Other Waterborne Pathogens, Code of Practice and BS 8680:2020 Water Quality – Water Safety Plans, Code of Practice.

ISO 9001 referenced.

Introduction of a requirement to specifically identify through schedules of accreditation where inspection bodies undertaken Legionella risk assessments in health and social care settings.

Clarification that UKAS extension to scope process will be applied to organisations wishing to expand their scope of activities into new sectors.

Relevant microbiological water sampling determinands reduced to Legionella and Total Viable Count only.

Simplified wording for insurance requirements.

Re-inspection expectations expanded and clarified.

Retention of inspection and quality records updated.

Various other minor updates throughout for clarity.

1. Introduction

1.1 The purpose of this publication RG 9 is to give guidance on the application of certain clauses of ISO/IEC 17020:2012 – Conformity assessment – Requirements for the operation of various types of bodies performing inspection[1]. Accredited inspection bodies are required to comply with all the requirements of ISO/IEC 17020:2012.

1.2 RG 9 should be read in conjunction with ISO/IEC 17020:2012. Inspection Bodies should also take note of ILAC-P15 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies[2].

1.3 RG 9 has been produced by UKAS and its technical advisors. It provides guidance for Legionella Risk Assessment Bodies for meeting the requirements of ISO/IEC 17020:2012. By following this guidance, it will be possible to demonstrate at assessment that these requirements are met. Alternative approaches may be used provided they are shown to give an equivalent outcome.

1.4 RG 9 should be used for accreditation of inspection bodies undertaking risk assessments for Legionella control as noted in the Approved Code of Practice and Guidance L8 (ACoP) published by the Health and Safety Executive (HSE)[3], the Water quality – Risk assessment for Legionella control - BS 8580-1[4], and HSG274 guidance[5]. It is intended to provide guidance to Inspection Bodies who will assist 'duty holders' in meeting their statutory obligations.

1.5 Unless stated otherwise, the terms used in this publication are consistent with terms used in ISO/IEC 17020 and ACoP L8 and its associated technical guidance[5]. Accreditation to ISO/IEC 17020 of an inspection body should not be confused with personnel certification, where a certification body issues a certificate of competence to an individual to undertake specified tasks. ISO/IEC 17020 and this RG 9 set out 'competence criteria' for the organisation, including those individuals who perform technical functions within it.

2. Inspection Services

2.1 Inspection bodies may be accredited for the following;

(a) Risk assessment for Legionella control;
- Cooling towers and Evaporative Condensers or dry/wet cooling systems
- Hot and cold water systems
- Spa pools
- Other systems containing water which is likely to exceed 20°C which may release a spray or aerosol during operation or when being maintained (the range of "other" systems should be specified on the application form and in the in-house procedure and would include for example humidifiers, air washes, vehicle washers, wet scrubbers, indoor fountains, water features and fire suppression systems)

(b) Water Sampling only for the purpose of Legionella risk assessment (range of sampling to be specified, restricted to sampling for Legionella and Total Viable Count only)

(c) Indicative Water testing for the purpose of Legionella risk assessment (range of testing to be specified, usually includes temperature, pH, conductivity, chlorine/bromine, additional testing requires justification at the application stage)

It is expected that all aspects of a Legionella risk assessment undertaken by an inspection body are accredited and not disclaimed.

2.2 Inspection bodies may be accredited for Legionella risk assessments as a support service, however, the ultimate responsibility for the management of Legionella in premises lies with the "duty holder".

2.3 Organisations may wish to undertake re-assessment of premises already risk assessed (Risk Review clause 10; BS 8580-1). This process may be included under accreditation provided the procedure is formalised in the quality system and comprehensive records are available to fully support the re-assessment and compliance with BS 8580-1. This will not have a specific entry on the schedule of accreditation.

2.4 Where the body intends to develop its inspection activities into unfamiliar sectors, it should define the approach to developing its capability and accreditation will be confirmed following satisfactory assessment through the UKAS extension to scope process.

2.5 Inspection bodies undertaking work in health and social care settings will be identified through an appropriate entry on the schedule of accreditation. This is a new requirement introduced for this edition and is designed to draw attention to expected additional awareness of implications for potentially vulnerable populations. Clause 2.4 applies where organisations do not currently offer work in this area but wish to do so. Those inspection bodies already accredited and historically offering risk assessments in health and social care settings will be subject to appropriate assessment in these areas as part of their ongoing assessment programme.

2.6 Where an inspection body is accredited for sampling and testing in relation to Legionella risk assessment, assessment against ISO/IEC 17020 will include these activities. UKAS will adopt the relevant requirements of ISO/IEC 17025, general requirements for the competence of testing and calibration laboratories[6], in relation to these activities. An inspection body that does not have its own facilities for the sampling and testing may be accredited to ISO/IEC 17020 for risk assessments and such an inspection body will be required to demonstrate that it has formal contractual arrangements with organisations meeting the requirements for competence as defined in ISO/IEC 17025 for the activities concerned (see 9.1).

2.7 Samples taken by an accredited organisation shall be analysed by a laboratory holding accreditation to ISO/IEC 17025 for the appropriate testing activities (e.g. detection and enumeration of Legionella).

3. Impartiality and Independence (ISO/IEC 17020 Clause 4.1)

Inspection bodies operating as Type A, B or C as defined in ISO/IEC 17020 may be accredited for Legionella risk assessment. Guidance on the definitions of Type A, B & C inspection bodies is given in Appendix A of ISO/IEC 17020.

3.1 It is important to ensure the independence, impartiality and integrity of all types of inspection bodies when carrying out risk assessments. Therefore, when providing inspection services, it is imperative that no inducement is offered or implied, in particular with regards to reducing the charge for the inspection in return for the opportunity to carry out any resulting work. Also, the inspection body should be able to demonstrate valid reasons for any proposed course of action. It should be clear, for example, why a certain number of samples were taken for a premises or why a particular type of recommendation was proposed.

3.2 Where an inspection body or its staff are involved in Legionella remedial works, consultancy and/or project management of or other similar activities, the inspection body is likely to be

considered as Type C. A Type C inspection body is required to have 'safeguards' (see Annex A.3) of ISO/IEC 17020 within the organisation to ensure adequate segregation of responsibilities and accountabilities through appropriate reporting structures).

4. Confidentiality (ISO/IEC 17020 Clause 4.2)

4.1 Confidentiality agreements shall be legally enforceable - i.e. encompassed within the employees signed Contract of Employment, formally issued Staff Handbook or other signed document.

4.2 Where the inspection body utilises the services of "contracted-in" risk assessors or outside support services (e.g. IT or HR services, etc.), who may be able to access the records of the inspection body, risks to confidentiality of client data should be considered and suitable agreements included in the contractual arrangements with the support service provider.

5. Administrative Requirements (ISO/IEC 17020 Clause 5.1)

5.1 The UKAS accreditation schedule will state the scope of Legionella risk assessment for which accreditation is granted, as defined in ACoP L8 and BS 8580-1 and, where appropriate section 2.5 above.

5.2 The precise scope of the risk assessment should be detailed in a plan or a confirmation letter to the inspection body's customer. If any of the services offered by the inspection body are not covered by UKAS accreditation, then this should be made clear to the customer. If the inspection body provides risk assessment review services *(see* section 2.3 *above)* the scope should be clearly defined within the contract review process to ensure the customer is fully aware of the services being provided.

5.3 Suitable insurance cover shall be obtained by the inspection body and shall provide suitable cover for liabilities (employer and public) and professional indemnity. Inspection bodies shall ensure that cover for 'bodily injury' and 'property damage' is included under the relevant cover. Larger organisations may choose to set aside specific reserves in lieu of insurance cover. These reserves must be commensurate with the level of cover generally provided through insurance within the asbestos inspection sector. If the inspection body chooses to rely upon reserves these shall be ring fenced.

5.4 The inspection body's terms and conditions of business shall form part of the controlled documents system and shall be conveyed to the customer prior to the commencement of any works.

6. Organisation and Management (ISO/IEC 17020 Clause 5.2)

6.1 The persons who perform supervisory activities of the risk assessments for Legionella control should have the expertise shown in Section 7.2 below.

6.2 Monitoring of the performance of risk assessors should include on-site witnessing of risk assessments (competency audits). This should be carried out by suitably trained staff that are technically competent and authorised to conduct on-site witnessing themselves. The inspection body's programme for witnessing assessors should be designed so that a representative sample of risk assessment activities is covered each year and that, as a minimum, each of the assessors engaged in risk assessing is witnessed at least once in this period for each type of inspection for

which they are authorised (e.g. domestic hot and cold water systems, cooling towers, etc., and health / social care settings).

7. Personnel (ISO/IEC 17020 Clause 6.1)

7.1 The inspection body should ensure that all persons undertaking risk assessments have, as a minimum, the qualifications, experience and knowledge, or be demonstrably equivalent, set out in Tables 1 and 2 unless they are working under the close supervision of appropriately qualified and authorised persons.

7.2 The persons responsible for the supervision of technical activities, in addition to the qualifications, experience and knowledge specified in Tables 1 and 2, should have demonstrable experience in:

(a) All aspects of the assessment of the risk of legionellosis presented by artificial water systems

(b) All areas of Legionella risk assessment, including inspection planning, resourcing, technical specifications, legal requirements, quality control and reporting

(c) If applicable to the scope of organisation's inspection activities, an in-depth appreciation of the susceptibility of water system users with particular respect to artificial water systems in health and social care settings

7.3 Records held by the inspection body should indicate the competence of Assessors to perform risk assessment work in different sectors (see 2.4 & 2.5) in which the inspection body's assessors are authorised to perform risk assessments together with relevant evidence to support their authorisation.

7.4 Changes to authorisation should be dated and a record kept of changes to ensure visibility of authorisation at any given date.

7.5 Portable instruments and test kits are used frequently in the field and it is important that assessors are competent in their use. Training in their use will need to be available and appropriate. At least one member of staff should be fully trained in the use of the instrument and/or test kit, have a good understanding of its basis of operation, fault finding and quality control, and be able to train others in its use.

8. Facilities and Equipment (ISO/IEC 17020 Clause 6.2)

8.1 An example of sampling and risk assessment equipment is included in BS 8580-1 Annex F and BS 7592[7]. The guidance given in these standards should be followed or deviations from the guidance justified and documented by the inspection body.

8.2 The requirements of ISO/IEC 17025 clause 6.4 and 6.5 will also apply to equipment used in Legionella risk assessments, as appropriate. It is expected that equipment will be appropriate to the sampling and testing required and that microbiological requirements be considered.

8.3 Measurements such as temperature, pH, and conductivity that are taken for the purpose of Legionella risk assessment should be traceable to National Standards and the requirements of ISO/IEC 17025 Clause 6.5 should be adopted as appropriate.

9. Subcontracting (ISO/IEC 17020 Clause 6.3)

9.1 Where an inspection body subcontracts sampling (e.g. for subsequent Legionella analysis), the subcontractor must demonstrate conformance with the relevant requirements of ISO/IEC 17025;

where an inspection body subcontracts Legionella risk assessment activities, the subcontractor must demonstrate conformance with the relevant requirements of ISO/IEC 17020 and of this guidance document (not withstanding clause 1.3); where an inspection body subcontracts analysis of samples, the subcontractor must demonstrate conformance with the requirements of ISO/IEC 17025 for the testing activities concerned. Accreditation by UKAS or another signatory of the EA multilateral agreement or of the ILAC mutual recognition agreement, as appropriate, is generally the only practical means of demonstrating conformance to these ISO/IEC standards.

10. Inspection Methods and Procedures (ISO/IEC 17020 Clause 7.1)

10.1 The general requirements for undertaking risk assessments for Legionella Control are outlined in ACoP L8, HSG 274 and BS 8580-1. Based on the requirements in these documents, the inspection body should develop its own procedures, instructions, checklists etc., as necessary, to enable the risk assessors to perform effectively and consistently.

10.2 BS 8580-1 refers to the examination of site maintenance records during the course of a Legionella risk assessment to enable the formulation of an opinion in relation to the effectiveness of the control measures. This often necessitates an evaluation of data provided by a third party (such as a water management company). There is a common failure to evaluate the quality of the records in relation to competence of persons carrying out tests and measurements and the calibration traceability and suitability of equipment used etc. Both the completeness and quality of the records in respect of the above should be evaluated during the Legionella risk assessment.

10.3 Quality assurance checks on risk assessments should be carried out on a regular basis by on site re-inspection of a minimum of 2% of the risk assessment work previously undertaken over a 12-month period (organisations must be able to justify re-inspection of less than this percentage). The re-inspection strategy should be documented and implemented, and as with competency audits (Section 6.2), shall be planned in proportion to the type of inspections carried out. Re-inspections can be part or all of a Legionella risk assessment and conducted following or in parallel in an impartial manner. These quality assurance checks should be conducted by assessors, or suitably experienced staff, without prior knowledge if undertaken at a later date, or collusion when conducted in parallel in order to provide an unbiased assessment. Subsequent comparison data of the original and re-inspection should be undertaken by an independent person with discrepancies in opinion and risk identification being subject to suitable investigation to determine impact and root cause as may be needed.

10.4 During the review of contracts/instructions from the client by the inspection body, consideration should be given to the sector/scope of the inspection work to be undertaken and the capability/competence of the inspection body to provide inspection work in that particular sector.

10.5 Building inspections are covered by health and safety legislation and any persons managing such work will need to ensure that they have assessed the health and safety risks and put in place suitable control measures to minimise exposure to themselves and others. As other hazards may be present on-site, site-specific hazards should be identified and risk assessed prior to and while carrying out the work. It should be remembered that risks that may be encountered during site surveys can change with time and sufficient enquiries should be made by Assessors to their clients on the day of the survey to ensure that all hazards that may be encountered are taken into account. Common hazards may include working at heights, electrical or ‘hot’ work, unidentified asbestos risk, potentially unsafe structures and confined spaces. If in any doubt, advice should be sought from a competent health and safety practitioner. Anyone carrying out Legionella risk assessment shall be equipped with appropriate PPE and have a duty to take responsible care of themselves and others who may be affected by their actions.

Table 1 Qualifications, Experience and Knowledge for Organisations / Individuals

Activity	Training / Qualification
A) Person carrying out a Legionella risk assessment	Undertaken and passed a course/qualification relevant to Legionella risk assessments. The following must be considered and recorded: • Quality/certification of the course provider • Technical content of the course/qualification and relevance to the Inspection Body's business and scope of work • Robustness of assessment for course attendees
B) Company carrying out Legionella risk assessment (refer to 7.2)	At least one member of the company having one of the following as a minimum, or evidence of an alternative demonstrating equivalent professional status: • Relevant Science or Engineering qualification • Relevant Chartered status • Membership of a relevant body/society

Table 2 Qualifications, Experience and Knowledge Guidance for Assessors Undertaking Legionella Risk Assessments

Training / Qualification	As per Table 1, activity A
Minimum experience	Significant experience in inspecting buildings, e.g. ≥6 months with inspection the predominant activity, followed by/in conjunction with: (i) New Assessor - At least 5 witnessed audits of Legionella risk assessments covering each category of system as defined in 2.1 during which competence is assessed by an authorised technical auditor. (ii) Experienced Assessor - At least 5 assessments of LRAs undertaken for each category of system as defined in 2.1 during which competence is assessed by an authorised technical auditor. A suitable level of assessment would include at least one witnessed audit for each type; other forms of non-witnessed assessment may also be used. To justify this approach, the experience of the Assessor must be demonstrable through curriculum vitae or similar.
Knowledge	• Familiarity with current ACoP L8, HSG274, BS 8580-1, BS 8680[8] HTM04-01[9] and BS 8580-2[10] (if applicable to the scope of inspection activities) and other relevant guidance • Knowledge of appropriate sampling strategies, guidelines & standards including an understanding of the H&S risks associated with carrying out a risk assessment • Familiarity with the range and ages of building types: construction, voids, health and safety considerations and risk

An Assistant Assessor or trainee may operate without formal qualifications or experience provided this is under the direct supervision of the Lead Assessor. However, training relevant to this role must be in place.

Inspection bodies may offer training courses for other companies. Use of this internal training resource may be acceptable for risk assessment staff, provided independence can be demonstrated.

11. Handling of Inspection Samples & Items (ISO/IEC 17020 Clause 7.2, ISO/IEC 17025 Clause 7.4)

11.1 The requirements in ISO/IEC 17025 clause 7.4 will also apply to sampled items.

11.2 The integrity of all samples shall be protected and any special requirements (e.g. for microbiological samples) shall be incorporated into procedures and implemented.

11.3 General guidance relating to sampling for Microbiological parameters can be found in The Microbiology of Drinking Water series[11] and BS 7592.

12. Inspection Records (ISO/IEC 17020 Clause 7.3)

12.1 Inspection records (e.g. notes, schematics, photos, test results all relevant supporting data) and risk assessment reports should be retained for a period consistent with its contractual and legal obligations.

12.2 Quality management system records such as training files, audits, re-inspection outcomes, nonconforming work etc should likewise be retained for a period with its contractual, regulatory and legal obligations.

13. Inspection Reports and Certificates (ISO/IEC 17020 Clause 7.4)

13.1 Certain specific information that should be included in the final inspection report is given in BS 8580-1. The report should be readily understandable by the people for whom it is intended, and most importantly to be clear and unambiguous in its findings and recommendations.

13.2 Issued inspection reports should be traceable to the lead Assessor who undertook the inspection and signed by a person within the organisation who is authorised to issue reports.

13.3 Test results and measurements taken as part of the risk assessment may only be reported in the inspection report, in support of the risk assessment conclusions; sampling activities that are not directly associated with a risk assessment (e.g. for the purposes of routine monitoring) shall not be reported in such a manner to suggest that the activity is covered under ISO/IEC 17020 accreditation.

13.4 An organisation which is accredited for risk assessments for Legionella control may only use the UKAS Inspection Symbol within a Risk Assessment Report. It is not appropriate to use the UKAS testing symbol for the support tests undertaken (refer to the Office for Product Safety & Standards guidance on *National accreditation logo and symbols: conditions for use*[12]) and likewise any certification held by the organisation should not be referenced on reports carrying the UKAS Inspection Symbol.

13.5 Reissued amended reports should carry a statement defining what has changed and why.

14. Complaints (ISO/IEC 17020 Clauses 7.5, 7.6)

14.1 A procedure for complaints and appeals against the findings of a survey is required.

15. Management System Requirements (ISO/IEC 17020, Clause 8)

15.1 The inspection body's quality manual should indicate where in the quality system the requirements of ISO/IEC 17020 are addressed. When implementing the quality system the inspection body should consider the guidance given in this RG 9, ACoP L8, HSG274 and BS 8580-1 (and HTM 04-01 and BS 85801-2 as applicable to scope of inspection activities).

15.2 Where the inspection body bases its management system on Option B as defined in ISO/IEC 17020 Clause 8.1.3, the management system should be certified to ISO 9001 Quality Management System - Requirements[13] and the scope of the certification should cover Legionella risk assessment activities.

15.3 Note that for assessment of inspection bodies adopting Option B for the management system requirements of ISO/IEC17020 for Legionella inspection, UKAS will assess consistent fulfilment and implementation of the requirements of ISO/IEC 17020 clauses 8.2 – 8.8 within the ISO 9001 system.

16. Testing and Sampling in Support of Legionella Risk Assessment

16.1 Test methods and method validation (ISO/IEC 17025, clauses 7.2, 7.3):

Test methods for sampling and testing should be based on published guidance where possible and manufacturer's instructions for equipment operation in relation to test kits as relevant.

Validation is not expected for indicative testing. The use of standard methods and equipment manufacturer's instructions (test kits) is expected where appropriate. Validation may be required when nonstandard methods and kits have been used.

16.2 Equipment and measurement traceability (ISO/IEC 17025, clauses 6.4, 6.5):

Indicative measurements such as temperature, pH, and conductivity that are taken for the purpose of Legionella risk assessment should be traceable to National Standards and the requirements of ISO/IEC 17025 Clause 6.5 should be adopted as appropriate.

Interim checks should be carried out to maintain confidence in the calibration status of equipment, the requirements of ISO/IEC 17025 clauses 6.4 should be adopted as appropriate.

16.3 Assuring the quality of test results (ISO/IEC 17025, clause 7.7):

Appropriate quality assurance measures are expected to be in place to provide confidence in the accuracy and precision of the on-site testing and sampling activities performed including steps to minimising cross contamination and equipment drift.

ILAC-P9:06/2014[14] states that participation in proficiency testing should be considered where testing activities directly affect and determine the inspection result, or when required by law or by regulators. Testing in support of Legionella risk assessment is considered indicative, and forms only part of the overall assessment of risk. Therefore participation in proficiency testing is not expected in the accreditation of Legionella risk assessment inspection.

REFERENCES

1 ISO/IEC 17020:2012 Conformity Assessment – Requirements for the operation of various types of Bodies performing inspection

2 ILAC-P15:05/2020 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies

3 L8 The Control of Legionella in Water Systems, Approved Code of Practice (ACoP) 2013

4 BS 8580-1:2019 Water Quality – Risk Assessment for Legionella Control, Code of Practice

5 Legionnaire's Disease: Technical Guidance Health and Safety Executive (HSG 274); part 1 (2013), part 2 (2014) & part 3 (2013)

6 ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories

7 BS 7592:2022 Sampling for Legionella in Water Systems, Code of Practice

8 BS 8680:2020 Water Quality – Water Safety Plans, Code of Practice

9 Health Technical Memorandum 04-01: Safe water in healthcare premises - Part B: Operational management (2016)

10 BS 8580-2:2022 Water Quality – Risk Assessment for Pseudomonas aeruginosa and Other Waterborne Pathogens, Code of Practice

11 Microbiology of Drinking Water Series – Environment Agency Series

12 Office for Product Safety & Standards – The National Accreditation Logo & Symbols: Conditions for use by UKAS and UKAS accredited organisations (2021)

13 ISO 9001:2015 Quality Management Systems – Requirements

14 ILAC-P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities