Contents

1. Allocation of Responsibilities

1.1 Legislative requirements for the control of Legionella put the responsibility for compliance clearly with the owner/ operator of water systems, therefore it is the client's responsibility to ensure they comply with all relevant law in the respect of Legionella control. Clients are requested to make themselves aware of their obligations by referring to www.hse.gov.uk/pubns/imdg458.pdf which is listed on Legionella quotations. Quotations are issued in accordance with internal procedure QA002 Contract review.

1.2 Bluezone Scientific only offer laboratory based Legionella analytical services. Bluezone Scientific do not offer any form of interpretation of the data that it provides. This is stated on quotations issued in accordance with internal procedure QA002 Contract review. Bluezone Scientific are UKAS accredited to ISO 17025:2017 for the detection, enumeration and identification of Legionella species, and Legionella pneumophila serogroup 1 and serogroups 2-14. Bluezone Scientific do not conduct sampling activities, other than collection of samples from a site specified by the client. Bluezone Scientific provide sterile sample bottles containing a suitable neutralising agent.

2. Training and Competence of Personnel

2.1 The Laboratory Manager is responsible for assessing the strategic training requirements of all new and existing staff as described in internal procedure QA011 Training. Irrespective of their previous experience new staff must be trained to the extent necessary to ensure that they will conduct all procedures in accord with the laboratory documentation. This training should be documented on the Staff Training Checklist (Form 035).

2.2 Training is conducted in accordance with internal quality procedure QA011 Training. The Laboratory Manager makes the relevant documentation (SOP/ H&S Information) available for study by the trainee and must ensure that the trainee understands the documentation before proceeding to the next stage. Training may only be performed by those members of staff who are authorised trainers and have been deemed competent to do so. (TR09) The authorised trainer will now demonstrate the procedure to the trainee. The trainee should

next be allowed to conduct the procedure under supervision. For Legionella, the trainee must complete 6 training spikes of the daily AQC achieving satisfactory results over a minimum of 2 days. This result will be calculated using the mean certified value from the certificate of analysis for the specific batch of CRM used within the Laboratory at the time of training, taking into consideration the volume of spike used. The trainee must also pass a round of external proficiency testing. The ongoing assessment of the competence of laboratory staff is carried out using the Test Witness Audit program (see QA010: Internal Audits) and participation in external proficiency testing. Each member of staff authorised on a method should analyse at least one PT sample every 6 months in accordance with QA007 External proficiency testing. Results of external proficiency testing are recorded, analysed and trended. They are used to form part of an annual competency assessment.

2.3 Each staff member has a training record file as described in QA011 Training, held by the Management Team. The file contains at least the following:

- Job Description (Job Brief & Person Specification)
- Staff Training Record (Form 034)
- Staff Training Checklist (Form 035)
- Internal/External training courses, details and certificates
- Training Records (TR01 etc)

The Laboratory Manager ensures that training records for their staff are updated to reflect any changes in status or qualifications of their staff members. Results are recorded in the appropriate Training Record eg TR01 (kept in the trainee's training file). Once satisfactory training results have been produced and the authorised trainer is confident that the trainee is competent to conduct the procedure as documented, they enter the date of qualification onto the relevant Training Record and Form 034.

2.4 Laboratory Management keep abreast of new developments within the industry and review all relevant documentation on a monthly basis as per QA009 – Document Control. When changes are identified, gap analysis is conducted and communicated to all personnel. The Management of the Laboratory are chartered and maintain a CPD portfolio. CPD records for laboratory analysts are maintained where applicable.

3. Control Measures

3.1 Bluezone Scientific maintain LCA membership and are registered with the LCA for Legionella Monitoring Services – Laboratory analysis in house. This is communicated to clients via the website www.bluezonescientific.com and listed on all Legionella quotations generated.

3.2 Bluezone Scientific only provide Legionella testing which is performed in accordance with in house method QA005 – Method quality control, to ensure the validity of test results.

3.3 Instances of non conforming work are identified and managed in accordance with QA008 Non conforming work procedure. This procedure incorporates the management and handling of queries, complaints and internal anomalies by Bluezone Scientific. Each process is clearly defined and its requirements described. The responsibilities of staff involved in

these processes are also detailed to ensure prompt investigation, resolution and response to the client and in doing so maintain continued customer satisfaction. Nonconforming work may be identified from a number of sources including QC Failures, customer queries and complaints, anomalies, internal or external audits and PT failures. QC Failures, Internal Audits, PT Failures and Internal Quality Assessments are described in procedures QA005, QA010, QA007 and QA013 respectively.

3.4 Bluezone Scientific do not offer field testing therefore there is no requirement to calibrate/validate equipment of this nature. All internal equipment is calibrated and maintained in accordance with procedure QA012.

4. Communication

4.1 Bluezone Scientific request clients complete Form 31 – New client application form, prior to commencement of work in accordance with internal procedure QA002 Contract review. Bluezone Scientific only send results to the email addresses listed on this form. It is the client's responsibility to ensure that the duty holder and responsible person are known to them and notified if necessary.

4.2 Bluezone Scientific will communicate any instance of non conforming work to the email addresses listed on Form 31. Non conforming work will be managed in compliance with QA008 – Non conforming work.

4.3 Section 4.3 of the LCA code of conduct is not applicable to Bluezone Scientific as we do not interact with the service user or perform site visits. Samples are received and tested on an "as received" basis.

4.4 Bluezone Scientific notify the designated client contacts via email at the earliest opportunity if a positive Legionella result is obtained. Bluezone Scientific are registered with LCA for Legionella Monitoring Services – Laboratory analysis in house, therefore subsequent remedial actions are the responsibility of the client.

5. Record Keeping

5.1 Records to be maintained include chain of custody forms (where applicable), analytical records, certificates of analysis and invoices. Control of records is described in detail in QA009. Certificates of analysis are available on the client portal. Where samples are submitted electronically via the LIMS app, the client is responsible for ensuring that the data entered is correct and all information required for sample integrity is supplied. Certificates of analysis generated by Bluezone Scientific will not be shared with a third party unless specifically requested by the client, in writing.

5.2 Bluezone Scientific will maintain all internal data generated throughout the analytical process and retain for 6 years. Bluezone Scientific are not responsible for defining what records the client retains in relation to Legionella control. Certificates of analysis may be emailed to the client or downloaded from the client portal as agreed in accordance with internal procedure QA002 Contract review. The method of receipt of reports will be agreed

in writing at the contract implementation stage. Once in receipt of the certificate of analysis, it is the responsibility of the client to retain. Bluezone Scientific data retention period is 6 years after which the data may be deleted. This information is provided with the quotation.

5.3 Bluezone Scientific will retain all data and certificates of analysis for 6 years as documented in Document Control procedure QA009.

6. Reviews

6.1 Bluezone Scientific perform a contract review with each client in accordance with QA002 Contract review. Details of any client communications are recorded on Form 032 Client Communication record, and retained in the appliable client file. Senior members of staff may attend ad hoc meetings with the client at any point throughout the contract term. The Laboratory Manager also sends an annual customer satisfaction survey to every client to gain feedback on the services provided and seek opportunities for improvement.

6.2 Bluezone Scientific do not conduct an assessment of their client's training needs. Bluezone Scientific welcome clients to visit the laboratory and provide an overview of the Legionella analytical method to allow the client to gain a better understanding tests conducted in the laboratory.

7. Internal Auditing

7.1 Bluezone Scientific are UKAS accredited to ISO IEC 17025:2017 and operate an internal audit schedule to incorporate all testing activities on an annual basis which is described in detail in internal procedure QA010 Internal audits. Each audit conducted is a systematic examination of the quality management system carried out by a member of the internal audit team to verify conformance to standards through review of objective evidence. The audit schedule incorporates an internal audit of the LCA Code of Conduct.

7.2 Internal audits are performed in accordance with QA010 Internal audits and incorporate systems audits, technical audits and vertical audits to encompass the whole of the quality management system and its compliance with ISO IEC 17025:2017. Review of the Legionella test method is conducted annually including outputs.

7.3 Internal audits are conducted in accordance with internal procedure QA010 Internal audits. The audit report (Form 038) describes and summarises the outcome of the audit which must be balanced, include details of both the compliant and non-compliant aspects of the audit and offer suggestions for improvement. Any instances of non conforming work are described in detail and the non-compliance/recommendation stated without ambiguity. Supporting document references and clauses are detailed where applicable. The impact of any finding is recorded. Should any audit findings cast doubt upon the validity of any test data reported, those clients whose analytical results may have been affected, shall be notified in writing by the Management Team. The root cause for any non-compliance is considered, identified and pertinent and appropriate corrective actions proposed by the auditor, and agreed by the

Laboratory Manager. The effectiveness of any corrective actions are reviewed to ensure the corrective action has been satisfactorily addressed.

7.4 Bluezone Scientific ensure only current, controlled versions of documents are in use, in accordance with internal procedure QA009 Document Control.

8. Sub-contractors

8.1-8.4 Bluezone Scientific do not currently subcontract any Legionella analysis. Should the need to subcontract arise for non-routine work, workload, need for further expertise, temporary incapacity etc, Bluezone Scientific would select a laboratory who hold UKAS Accreditation for Legionella analysis for the appropriate matrix, and who were on the approved subcontractor register. The process is described in QA001 Externally provided goods and services.

9. Promoting Awareness of the LCA

9.1 A reference to the LCA Code of Conduct and LCA Membership is listed on all quotations generated. A link to the LCA Code of Conduct and certificate of registration is on the Bluezone Scientific website.