

## LCA Statement of Compliance

EMS is an independent contract testing laboratory. The company is registered with Company's House and its registration number is 245466. The company's Directors are Dr Jennifer Newton and Mr William Bates. Dr Newton has more than 15 years' experience in the Food and Beverage Industries. She has a Bachelors in Food Science and a Masters in Science and a Doctorate in Philosophy. She is assisted in running the business by a team of highly qualified scientists.

The company has established a testing regime which meets the requirements of ISO 17025. This regime is set out in the Express Micro Science Quality and Management system EMSOS which comprises of 27 platforms which are used to document activities to ensure consistent application of our service to our customers.

EMS operates its accredited testing out of its premises at 22/4 and 22-25 Mill Road Industrial Estate, Linlithgow, EH49 7SF. It offers a collection service to its customers for transporting samples under chilled or ambient conditions to the laboratory.

Express Micro Science maintains UKAS accreditation for the testing of potable, piped and industrial water samples for total viable counts, Pseudomonas, Enterococcus and Legionella. The company is also registered with the Legionella Control Association (LCA) for the provision of Legionella Analytical Services – Laboratory Analysis.

### 1. Allocation of responsibilities

Express Micro Science draws up comprehensive service agreements with our clients for whom we are contracted to provide services associated with the control of Legionellosis. This Statement of Compliance is part of that annual service review (ASR).

- i. The ASR formally advises our clients of their responsibility as defined in the Approved Code of Practice (which gives practical advice on the requirements of the Health and Safety at Work Act 1974 and COSHH regulations 2002 concerning the risk from exposure to Legionella bacteria)
- ii. The ASR makes reference to:
  - a. The L8 Guideline which requires that a UKAS accredited laboratory will carry out Legionella testing for monitoring. In compliance with this requirement EMS will maintain UKAS accreditation for this test and inform all Legionella testing customer's immediately if a change in scope is made to this testing
  - b. BSEN ISO 19458:2006 and BS 7592:2008 which requires that samples for Legionella testing shall be transported at ambient temperatures and be tested within preferably 24 hours and no longer than 48 hours. We will inform our customers of these requirements and make a statement to the collection date, temperature of sample at arrival and testing date on all test reports.
  - c. COSHH regulations 2002 provides a framework of duties designed to assess, prevent or control the risks from hazardous substances, including biological agents such as Legionella, and take suitable precautions.
  - d. Employers must be aware of other legislation they may need to comply with, which includes the Notification of Cooling Towers and Evaporative Condensers Regulations 1992;4 Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR);5 the Safety Representatives and Safety Committees Regulations 1977 and the Health and Safety (Consultation with Employees) Regulations 1996.
  - e. It is also recommended all treated waters be collected in a sampling bottle containing minimally 0.1 mL/100mL of bottle capacity of sodium thiosulphate. We will supply suitable one-time use water bottles to our customers meeting the requirements of BS EN 19458:2006.
  - f. We will provide a sampling procedure as described in BS EN ISO 19458 and 5667-5 and 13 and L8 guidelines to our clients.

- g. Samples submitted to the laboratory must be clearly identifiable with unique descriptions. It is also recommended ancillary testing information is recorded, e.g. the name of the person taking the sample and other details may be necessary for the correct interpretation of the results (e.g. temperature, biocides, exact sampling point, any observations or phenomena which could affect microbiological quality).
  - h. The aerobic colony count also called the total viable count (as represented on our test reports) is a general test that indicates whether the disinfectant regime (if present) is effective in controlling contamination. This colony count test is carried out in accordance with BS EN ISO 6222.
  - i. Further guidance on water sampling and testing is covered by The Microbiology of Recreational and Environmental Waters (2000) Report 175.
  - j. BS EN ISO 11731 – Horizontal Method for the detection and enumeration of Legionella in Water is the method employed by EMS for testing for Legionella.
- iii. The ASR (P7.2.3) clearly defines the scope of works EMS is contracted to carry out including a reference to the procedure for the collection and transportation of samples, methods for the testing of microorganisms, sample types, specifications for unsatisfactory results, and reporting structure both written and verbal.
  - iv. The ASR contains the current LCA Certificate of Registration for EMS (see appendix E). This Certificate of Registration details the service we offer under LCA approval (Legionella Analytical Services – Laboratory Analysis) and can also be found on the EMS website by clicking on the Legionella Control Association icon - <http://www.expressmicroscience.co.uk/about-us/>
  - v. Wherever possible the client is encouraged to sign and return form 7.2.1 Acknowledgement Form for Service Review as his acceptance of the Annual Service Review.
  - vi. The procedure for issuing customer annual service reviews (ASR) is detailed in document 7.1.1 Review of Test Requests Policy and Procedure.

## **2. Training and competence of personnel**

- i. EMS maintains a comprehensive training programme for all staff involved in the testing of samples for Legionella.
- ii. EMS maintains a training matrix directly related to Legionella control as required by the code of practice.
- iii. Skills and knowledge will be assessed on an ongoing basis using questionnaires, audits, proficiency testing, spiked samples and duplicate testing. Evidence of ongoing competency verification will be kept in the employees training folder.
- iv. EMS ensures competency of all staff involved in the control of Legionella by including all microbiologists in ring testing run by PHE, test method and procedure witnessing and audit and reviews of practice. Records of both written and verbal assessment of personnel's understanding and knowledge are kept. Procedure P2.1.1 is used to assess competency for all staff in each area.
- v. All staff "in training" will be suitably supervised by a competent and fully trained member of staff.
- vi. Staff are informed of changes to Legionella procedures, regulations, and guidance as per procedure P1.1.2 company communications.

## **3. Control Measures**

- i. EMS has a management system which assesses the requirements and ensure an appropriate programme of control measures is designed monitored and maintained.
- ii. All test methods and ancillary procedures (e.g. Sample handling, choice of suppliers and subcontractors, method validation, etc) are written documents controlled from misuse and uncontrolled changes. See document 18.1.1 Document Control Procedure for more information.

- iii. All activities are audited against these written procedures to ensure satisfactory application.
- iv. All procedures are reviewed minimally once every three years or more frequently due to a change in guidance notes or legislation. Document review is carried out by senior personnel and is recorded.
- v. A problem with the management system or with the technical operations of the laboratory will require corrective actions to be implemented. Corrective actions taken should be detailed on the non-conformance, non-compliance and/or management review document where the problem was identified.
  - a. All non-conformance investigations will contain the following points: all areas, samples, results, methods etc affected will be named, the root cause of the non-conformance will be identified and all investigations into the root cause will be recorded, the effects on customer service will be identified, corrective actions will be detailed and implemented, monitoring activities ensuring corrective actions are satisfactory will be recorded and where possible improvements to the system will be implemented.
  - b. Detailed procedures and records on corrective actions are stored in P21 Corrective Actions Policy and Procedures.
  - c. Corrective actions will be included in the annual audit programme. Should a non-compliance be of such a serious nature as to cast doubt on results or on the lab's compliance with the ISO 17025, the corrective action will need to be audited as soon as possible after the corrective action's implementation, usually within 1 month.

#### **4. Communication and Management**

- i. The lines of communication and reporting between us and our clients will be clearly defined as well as the management plan in the event of remedial or corrective action being required, including matters of evident concern outside contract obligations.
- ii. Customer annual service reviews detail sample types, specifications and communication lines. Additionally, lines of communication to the most senior level of management in both organisations is clearly set out. Document 7.1.1 Review of Test Requests Policy and Procedure details how communication details are recorded and updated.
- iii. EMS will agree with the client how it will communicate with the client's nominated personnel in the event of any necessary actions. When positive Legionella is suspected or confirmed, an email will be sent from flaggedresults@expressmicroscience.co.uk to the client's nominated email addresses providing details of the sample and expected level of contamination. Upon request, the client may also be telephoned to alert them of the finding.
- iv. Test reports will have unsatisfactory results reported in red unless otherwise stated by the customer, with a comment stating "results reported in red are unsatisfactory". Test reports also contain method reference and denotation for UKAS accredited methods.
- v. EMS will bring to the client's attention any significant matters affecting the control of Legionella of which we have become aware, beyond the responsibilities of the contract. In the case of findings outside the contractual agreements a Director, Quality Manager or Customer Service Manager will contact the nominated contact provided by the client in document 7.2.2 Communications Tree, to fully explain findings and circumstances. A record of the telephone conversation will be made and kept in the client's folder. Should it be deemed appropriate, EMS reserves the right to report findings which indicate potential harm to the public to regulatory authorities.

#### **5. Record Keeping**

- i. EMS will retain records pertaining to the testing of all samples for up to six years. Every effort will be made to secure the control of the records, i.e. off-site back up of electronic records.
  - a. EMS maintains procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records.
  - b. All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide suitable environment to prevent damage or deterioration and to

prevent loss. Retention times of records shall be established. See document 18.1.1 Document Control Policy and Procedure.

- c. All records shall be held secure and in confidence.
- d. Procedures for the protection and backing up of records stored electronically and to prevent unauthorized access to or amendment of these records can be found in P16.
- ii. Agreement with the client will be made with regards to who will be responsible for the maintenance of sample submission records.
- iii. EMS does not take responsibility for the maintenance of records held at client's sites. It will thus be the responsibility of the client to maintain all logbooks, investigation reports of corrective and preventative actions, etc. It is recommended that these records are retained for 5 years.

## **6. Reviews**

- i. Customer reviews will be held as frequently as necessary, at least annually, to deliver the contract satisfactorily and meet the criteria of LCA.
- ii. See procedure 7.1.1 Review of Test Requests Policy and Procedure

## **7. Internal Auditing**

- i. The auditing of all activities associated with the LCA accreditation will be incorporated into the EMS auditing programme which is run annually (see P22.2.1 Audit Schedule).
- ii. Document P22.1.1 Internal Auditing Policy and Procedure describes the steps required to audit activities involved in the control of Legionella.
- iii. When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of our test results, timely corrective action shall be taken. All auditors have the authority to initiate these corrective actions including notifying the clients in writing when investigations show that results or other control measures may have been affected.

## **8. Sub-contractors**

- i. A procedure is in place for selecting subcontractors
- ii. All sub-contractors associated with the control of Legionella will be listed on the approved subcontractors list and they will hold their own registration number with the association.
- iii. All subcontractors associated with the control of Legionella who are not independently registered with the association must be audited, with records kept of the audit and all findings cleared before use
- iv. Regular reviews, at least once annually, will be held to ensure continued compliance with the LCA code. Records of these reviews will be held.

## **9. Distribution of the code**

- i. A list of all clients carrying out Legionella testing will be maintained by the Customer Service team who will ensure all customers listed receive a copy of the certificate of registration.
- ii. A copy of the code will be sent to customers annually within the Annual Service Review. A copy will also be made available upon request.