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 20 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 UKAS 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.

EMS 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

1.1 EMS 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). 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 the Management of Health and Safety Regulations 1999 and COSHH regulations 2002 concerning the risk from exposure to Legionella bacteria). 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. Detailed guidance on the control of Legionella can be found on the Health and Safety Executive websites including ACOP L8 guidelines and HSG274

1.2 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. EMS is UKAS accredited for the testing of water samples

The ASR contains a link to the EMS website which details our current accreditations, including the current LCA Certificate of Registration. This Certificate of Registration details the service we offer under LCA approval (Legionella Analytical Services – Laboratory Analysis). The certificate can be found by clicking on the Legionella Control Association icon - http://www.expressmicroscience.co.uk/about-us/

EMS is UKAS accredited to perform the testing of water samples for legionella based on BS EN ISO 11731 – Horizontal Method for the detection and enumeration of Legionella in Water

The procedure for issuing customer annual service reviews (ASR) is detailed in document 7.1.1 Review of Test Requests Policy and Procedure. 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.

Acceptance of a formal quote, EMS terms and condition and signed ASR acknowledgement form 7.3.1 is considered a formal agreement between the customer and EMS.

2. Training and competence of personnel

2.1 EMS maintains a comprehensive training programme for all staff involved in the testing of samples for Legionella, training is depended on duties and is detailed in P2.1.1 Assessment of competency and recorded in EMS Training and Witnessing Matrix. The training covers sample handling, sample preparation, colony identification, colony enumeration and confirmation.

2.2 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. All staff “in training” will be suitably supervised by a competent and fully trained member of staff

2.3 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

2.4 Staff are informed of changes to Legionella procedures, regulations, and guidance as per procedure P1.1.2 company communications

3.Control Measures

3.1 EMS is registered with LCA for the provision of Legionella Analytical Services – Laboratory Analysis.

3.2 EMS has a quality management system (EMSOS) which assesses the requirements and ensures an appropriate programme of control measures is designed, monitored and maintained.

a) 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 P18.1.1 Document Control Procedure for more information. All activities are audited against these written procedures to ensure satisfactory application.

b) 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

c) Certified reference materials are used for interlaboratory testing, the results from these are reviewed and trended to determine any bias, systematic errors or other errors present within our quality system.

d) All analysts participate in external proficiency testing minimally once per year each stage of the method, if this is not possible to assess all analyst using EQA, they will, participate in internal proficiency testing.

e) Concentrates of all Legionella samples are retained for 3 months from the test date, retests can be carried out within this period at the clients requests.

f) A vertical audit is carried out annually on Legionella testing

3.3 Any non-conforming work is documented as per EMSOS P15.1.1 Non-Conforming work procedure. All-corrective actions, preventative and improvements are documented through EMSOS system. Corrective actions taken should be detailed on the non-conformance, non-compliance 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 P21.1.1 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 that it has an effect in the validity or correctness of the result or on the lab's compliance with the ISO 17025, the corrective action will be audited as soon as possible after the corrective action's implementation, usually within 1 month.

3.4 All equipment must be fit for purpose and maintained in good condition this is detailed in P4.1.1 Equipment procedure. Equipment must undergo regular checks and calibrations to ensure it is working accurately, this is detailed in procedure P4.1.3

4. Communication and Management

4.1 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. The client is responsible for ensuring that emergency contact information is up to date.

The 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.

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 early indication will be sent by email 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.

Customers are sent an early alert of any out of specification Legionella results. A PDF is emailed to the client. It is the responsibility of the client to take the relevant action.

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.

4.2 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 recorded in the telephone reporting document.

4.3 Any matters that may have an effect on the control of Legionella will be raised through the non-conforming work procedure or deviating sample procedure as per Non-Conforming work procedure P15.1.1

4.4 EMS does not provide or take responsibility for any risk assessments. 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

5.1 EMS maintains procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records. EMS will retain records pertaining to the testing of all samples for up to six years.

All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.. See document 18.1.1 Document Control Policy and Procedure.

All records shall be held secure and in confidence. 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..

5.2 Written agreement with the client will be made with regards to who will be responsible for the maintenance of sample Submission records.

5.3 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

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

The review covers the following areas:

a) What test are required

b) Test method that will be used

c) What specifications the sample are tested against

d) Accreditation status

e) Matrix

f) Number of samples

This information is collated by means of the customer onboarding form P7.3.7 or acceptance of the quotation. If the customer wants to change their testing requirements, then the contract review process should begin again.

There are times when deviations occur. These deviations may make the sample unsuitable for testing other times it is better to test the item but make the deviation known to the customer.

6.2 EMS provides an analytical service to the client only. We encourage as much interaction with our customer as possible - either via the telephone or face to face meetings. Customers can visit our laboratories and carry out audits. We will visit our customers at their sites for review meetings and training sessions.

7. Internal Auditing

7.1 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). Audit checklist P22.3.29 LCA is used to ensure compliance to the LCA is met. Document P22.1.1 Internal Auditing Policy and Procedure describes the steps required to audit activities involved in the control of Legionella.

7.2 EMS internal audit schedule covers all areas of the EMS Quality system, including management, training, traceability, proficiency, technical records, UoM, facilities, suppliers, equipment and calibrations

7.3 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. Audit Findings are discussed regularly at Quality Meetings to determine if the issues are caused by systemic or symptomatic issues.

8. Sub-contractors

8.1 EMS carries out all analysis on all samples that are covered by UKAS accreditation. Subcontracting is only done on UKAS accredited tests under exceptional circumstances as per P6.1.3 Subcontracting of Tests and P1.1.3 Disaster Recovery Plan.

In exceptional circumstances where EMS cannot perform Legionella testing this will be subcontracted to an UKAS accredited and LCA approved laboratory

8.2 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.

8.3 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

8.4 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

9.1 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.

A copy of the Statement of Compliance can be found on the company website and will also be made available upon request.