



**ENVIRONMENT  
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# **MCERTS for Laboratories Undertaking Direct Toxicity Assessment of Effluents**

## **Laboratory Assessment**

**Environment Agency  
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## Laboratory Assessment

### 1. Background.

Direct Toxicity Assessment (DTA) is the use of whole effluent ecotoxicity testing to assist in the assessment and control of complex industrial effluents discharged directly to controlled waters. Whole effluent ecotoxicity integrates the additive, synergistic and antagonistic effects of substances and their breakdown products within complex mixtures. The approach allows an assessment of the combined biological effects of all constituents, including unknown substances and those for which Environmental Quality Standards (EQSs), Environmental Assessment Level (EALs) or chemical analysis methods do not currently exist.

The extension of MCERTS to include DTA is built on laboratories operating a suitable Quality Management System (QMS) based on recognised international standards and operating a level of Analytical Quality Control (AQC) that is sufficient to ensure that the quality of test data is high. The MCERTS performance standard for laboratories undertaking DTA of effluents details the requirements for a laboratory undertaking DTA where results are ultimately to be submitted to the Environment Agency for regulatory purposes.

This document outlines the processes to be undertaken by the Environment Agency in assessing laboratories for compliance with the standard.

### 2. Audit Requirements.

The MCERTS performance standard for DTA provides detail on all of the requirements that laboratories must satisfy to gain MCERTS approval. These summarise to four specific areas, namely QMS, DTA methods, and internal and external quality control.

Three broad categories are used to assess a laboratory's compliance with the QMS and DTA methods requirements:

- Category 1 - Laboratories that are currently UKAS accredited for the DTA tests they wish to undertake.
- Category 2 - Laboratories which are GLP compliant *or* hold UKAS accreditation for tests other than those used for DTA testing (for those not accredited for the test in question they would have to demonstrate that the management requirements of ISO 17025 are applied to the relevant tests).
- Category 3 - Laboratories which are neither UKAS accredited nor GLP compliant.

The category assigned will determine the level of audit required:

**Category 1** The laboratory is required to submit their internally documented methods or standard operating procedures for the DTA methods for which they seek MCERTS approval and an example of a typical DTA test report as provided to clients. In addition laboratories will be required to submit evidence of UKAS accreditation.

**Category 2** In addition to the internally documented methods or standard operating procedures for the DTA methods and an example of a typical DTA test report required in Category 1, the laboratory is required to submit the following QMS documentation:

- Training and Competence Manual (or equivalent QMS documentation).
- AQC Procedures.
- Sample (test item) Management Manual (or equivalent QMS documentation).
- Policy and procedures for control of non-conforming work and preventive/corrective action.
- Evidence of compliance with GLP if appropriate.
- Evidence of UKAS accreditation and scope if appropriate.

A Category 2 laboratory *may* be required to undergo an MCERTS inspection of their technical activities (with respect to their DTA testing) depending on the outcome of the documentation review.

**Category 3** In addition to the requirements of Category 2, the laboratory is required to submit the following QMS documentation:

- Quality Manual (or equivalent 'top level' QMS document);
- Policy and procedures for document and record control;
- Internal audit procedures and schedules;
- Policy and procedures for addressing complaints, customer feedback and contract review;
- Policy and procedures for procurement of supplies and services.

A Category 3 laboratory is required to undergo an MCERTS inspection of both their quality management and technical activities with respect to DTA testing.

The assessment of internal and external quality control aspects shall be identical for all applicant laboratories.

### **3. The Assessment Process.**

All ecotoxicological testing laboratories are invited to apply for MCERTS approval of their DTA activities. Contact details are posted on the Environment Agency MCERTS website at [www.mcerts.net](http://www.mcerts.net).

#### **3.1 Application for MCERTS approval**

An applicant laboratory shall decide which of the three assessment categories is appropriate for their own situation and inform the Environment Agency of their wish to apply and the category under which they wish to be considered. The Environment Agency will then request an applicant laboratory to provide information supporting their application as appropriate for their assessment category (See Section 2).

### 3.2 Initial assessment.

The Environment Agency shall then undertake an assessment of the applicant laboratory. This will be based on the supporting information provided by the laboratory under the appropriate categorisation.

The outcome of this assessment shall be fed back to the laboratory and further supporting information may be requested at this time. Laboratories shall also be informed of the need for an MCERTS inspection and what form this will take (technical or full QMS).

### 3.3 MCERTS inspections.

On completion of the initial assessment stage, the Environment Agency shall, if appropriate, schedule the required MCERTS inspection and laboratories shall be formally contacted to arrange a date. The Environment Agency shall undertake inspections on the agreed date.

Technical inspections shall involve a single Environment Agency auditor attending the laboratory for one day. Such assessments will be focused on the technical aspects of the testing process (although some QMS documentation may be requested for inspection, e.g. training records) and shall require a method witness of the tests for which the laboratory wishes to gain MCERTS approval.

Full QMS inspections shall involve two Environment Agency auditors attending the laboratory for one day. These assessments shall involve auditing the entire QMS including the technical aspects. The audit shall also require a method witness of the tests the laboratory wishes to gain MCERTS approval for.

There will be a cost incurred by laboratories requiring an MCERTS inspection (See Section 4).

### 3.4 Final assessment and reporting.

The findings of all parts of the assessment against the MCERTS for DTA standard shall be collated, summarised (See Appendix, Compliance Summary Matrix), including internal and external (proficiency testing) quality control aspects. The Environment Agency will then report back to the applicant laboratory stating whether the laboratory has succeeded in obtaining MCERTS approval for its DTA testing activities.

### 3.5 Correspondence and feedback.

At all stages of the assessment process, contact will be maintained between the applicant laboratories and the Environment Agency. Where the Environment Agency is not satisfied with a particular aspect of the assessment for a laboratory (for example as a result of documentation submitted or an inspection) the laboratory shall be given an opportunity to remedy the aspect within a defined timescale. This may involve further submission of documented evidence to demonstrate corrective action in this respect.

### 3.6 MCERTS register.

The MCERTS for DTA register shall contain the names of all those laboratories succeeding in gaining MCERTS approval for its DTA testing activities. Every effort will be made by the Environment Agency to ensure transparency and consistency in the MCERTS assessment process, and laboratories will be given time to address issues that may affect their eventual MCERTS status. The Environment Agency's decision on which laboratories will be listed on the MCERTS register shall be final.

All MCERTS approved laboratories shall be responsible for keeping the Environment Agency informed of any changes in their status with regard to their QMS, technical portfolio or other aspect which may impact upon their MCERTS approval. A reassessment of certain areas of the laboratories systems may be necessary as a result of such changes.

### 3.7 Re-assessment and maintenance of the DTA register.

Once MCERTS approval for DTA testing is granted to a laboratory they laboratory shall remain on the register unless:

- The laboratory suspends its DTA testing activities.
- The laboratory withdraws from, or suspends its activities in, one of the overall requirements of the MCERTS for DTA standard (e.g. QMS or Proficiency Testing Scheme).
- The laboratory has its accreditation suspended by the relevant accrediting body (UKAS or GLP monitoring authority). An affected laboratory shall inform the Environment Agency immediately.
- The laboratory fails to maintain its standard of data quality at the level originally determined in the assessment (e.g. internal QC testing, performance in Proficiency Testing Scheme, use of appropriate test methods). Where such a failure becomes apparent to the Environment Agency without prior notification from the laboratory, the laboratory shall be given an opportunity to remedy the situation, and may be required to undergo a re-assessment. The laboratory shall not be removed from the MCERTS register until the results of this re-assessment are finalised.
- The laboratory fails to meet its original standard of data quality as determined following a re-assessment.

Re-assessments shall normally take place for MCERTS approved laboratories every three years.

## 4 Costs.

There will be no charge for laboratories in applying or for assessment against the performance standard unless a site inspection is required.

Inspections will be charged at the rates shown below. The costs are correct at the time of publication of this document but are subject to change.

Inspection Type	No. of Methods	No. of Auditors	Cost (+ Travel and Expenses)
Full	1-3	2	£900
	4-6	2	£1400
Technical	1-3	1	£450
	4-6	1	£700

The quoted costs cover the site visit and both pre and post assessment. Expenses and travelling time will be added to the unit cost and so the total amount payable will vary.

## **5 Confidentiality.**

With the exception of the register of MCERTS approved laboratories, full confidentiality shall be maintained with respect to the identities of applicant laboratories throughout the entire assessment process. Only the Environment Agency and collaborators on the proficiency-testing scheme will know the full list of applicants.

## Appendix A

### Example of Compliance Summary Matrix.



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<b>Monitoring Certification Scheme (MCERTS)</b>
<b>Direct Toxicity Assessment (DTA)</b>
<b>Compliance Summary Matrix</b>

<b>Laboratory</b>	
<b>Laboratory Identification Code</b>	
<b>Assessment Category</b>	

<b>Section 1: QMS</b>		
<b>Area</b>	<b>Assessment Method</b>	<b>Compliance/ Notes/ Observations</b> (See Performance Standard for specific requirements)
<i>Quality Policy</i>	Documents / Audit	
<i>Management System and Responsibilities</i>	Documents / Audit	
<i>Document and Record Control</i>	Documents / Audit	
<i>Test Reports</i>	Documents / Audit	
<i>Internal Audit</i>	Documents / Audit	
<i>Control of Non-conforming Work</i>	Documents / Audit	
<i>Preventive and Corrective Action</i>	Documents / Audit	
<i>Complaints, Feedback and Contract Review</i>	Documents / Audit	
<i>Procurement of Services and Supplies</i>	Documents / Audit	

<b>Section 2: Technical</b>		
<b>Area</b>	<b>Assessment Method</b>	<b>Compliance/Notes/ Observations</b>
<i>Staff Qualifications, Training and Competence</i>	Documents / Audit	Records available? Staff appropriately qualified and trained? Ongoing competence monitored?
<i>Accommodation and Environmental Conditions</i>	Documents / Audit	Environmental conditions monitored and recorded?
<i>Equipment and Measurement Traceability</i>	Documents / Audit	Equipment inventory details available? Equipment operation instructions available? AQC systems defined and documented? External maintenance / calibration traceable and recorded? Internal AQC / calibration traceable and recorded?
<i>Test Methods</i>	Documents/ Audit	SOPs/ prescriptive laboratory test methods and/ or specific test protocols available? SOPs/ methods (or related documents) address lab- specific validation and ongoing AQC of test process? DTA test methods comply with latest SCA guideline methods? Methods defined in scope of activities?
<i>Sample Management</i>	Documents/ Audit	Sample Management System/ procedures in place? Sample identification traceable throughout process? Sample storage documented? Sample disposal procedure available?

<b>Section 3: Internal Quality Control</b>					
<i>Method</i>	<i>Daphnia</i>	<i>Tisbe</i>	<i>OEL</i>	<i>FW Algae</i>	<i>Marine Algae</i>
<i>Lab Validation available?</i>					
<i>Concurrent Reference Testing undertaken with samples?</i>					
<i>Process Control?</i>					
<i>Preventive/Corrective Action when AQC fails?</i>					
<i>Data Submitted (PS)</i>					
<i>Target Criteria Met? (PS)</i>					

<b>Section 4: External Quality Control</b>					
<i>Method</i>	<i>Daphnia</i>	<i>Tisbe</i>	<i>OEL</i>	<i>FW Algae</i>	<i>Marine Algae</i>
<i>Participation in PS?</i>					
<i>Precision Criteria met?</i>					
<i>Accuracy Criteria met?</i>					