



Direct Toxicity Assessment Proficiency Scheme (DTAPS)

DTAPS Quality Manual

DTAPS Document 1

Issue 5

Issue	Date of Issue
1	19/9/05
2	<i>2/2/07</i>
3	20/7/07
4	14/2/08
5	18/8/08

Changes since last issue in *Italics*

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Authority

This Quality Manual is issued by the Environment Agency to ensure that the Direct Toxicity Assessment Proficiency Scheme (DTAPS) is operated in accordance with the ‘Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes; ILAC-G13:2007’ and the ‘Proficiency Testing by Interlaboratory Comparisons; ISO/IEC Guide 43-1 & 2: 1997’.

The DTAPS has been designed and implemented, and is operated, by the Environment Agency’s *Science Department*. The highest level of management at which decisions are taken on the operation of the DTAPS is that represented by the *DTAPS Technical Manager (Environment Agency Senior Scientist)*.

This Quality Manual is issued under the authority of the *DTAPS Technical Manager*.

.....Dean Leverett
DTAPS Technical Manager

The *DTAPS Technical Manager* is authorised to undertake and provide the DTAPS by the Environment Agency Science Department Resource Manager (Wallingford, Reading & Waterlooville). The Resource Manager represents the highest level of organisational management and responsibility within the Environment Agency for providing the resources for providing the DTAPS.

.....Stuart Homann
Science Resource Manager

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Direct Toxicity Assessment Proficiency Scheme (DTAPS)

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Background & Purpose

The Direct Toxicity Assessment Proficiency Scheme (DTAPS) will be used by the Environment Agency as part of the assessment process to evaluate the ability of laboratories to competently perform ecotoxicity tests used in the Direct Toxicity Assessment (DTA) of industrial effluents.

The DTAPS will form a component of the overall assessment process within the Environment Agency's Monitoring Certification Scheme (MCERTS) for DTA.

The DTAPS will be developed and operated by the Environment Agency but the assessment process may also utilise appropriate data generated by other inter-laboratory ecotoxicity test comparisons.

The primary aims of the DTAPS will be to establish and monitor accuracy and precision parameters for laboratories undertaking, or intending to undertake, the DTA testing for regulatory purposes using the test methods specified in the Integrated Pollution Prevention and Control (IPPC), Guidance on the use of Direct Toxicity Assessment in PPC Impact Assessments (2005).

This document has been produced by the provider of the DTAPS to act as;

- i) a Quality Management Manual for the operation of the scheme,
- ii) guidance and instruction to participating laboratories on the specific conduct of the scheme,
- iii) a guide to external assessors of the provider and scheme regarding its structure and operation.

Authorship

This document has been prepared by the Environment Agency's *Science Department*.

Quality Policy Statement

It is the policy of the Environment Agency's *Science Department* to maintain a consistently high standard throughout all areas of the DTAPS, and to hold suitable external accreditation for the proficiency scheme according to the latest guidelines published by the International Laboratory Accreditation Cooperation (ILAC). This is achieved through the operation of a Quality Management System which governs the quality of all aspects of the scheme. All participants in the scheme will be provided with a standard of service commensurate with the ILAC guidelines.

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Section 1: General

1.1 Scope

This document sets out the criteria that the provider of the DTAPS (and associated collaborators and contractors) shall meet in the development and operation of the scheme.

The document also provides guidance and instruction on laboratory participation in the scheme.

The provider will take full responsibility for ensuring that the operational requirements (both technical and management systems) of the scheme are met by the provider itself and any collaborators or contractors.

1.2 References

Environment Agency (2005) Integrated Pollution Prevention and Control (IPPC), Guidance on the use of Direct Toxicity Assessment in PPC Impact Assessments.

Environment Agency (2001) Assessment of the Options for a Regulatory Ecotoxicology Testing Quality Scheme (RETQS), Research & Development Technical Report P426.

Environment Agency (1996) Performance Standards for Ecotoxicity Tests, Research & Development Technical Report SR 4166/1.

Environment Agency (1999) Report on a ring test of the 48 h *Tisbe battagliai* lethality test, Research & Development Technical Report E90.

Environment Agency (1999) A Proposed Scheme to Ensure the Quality of Data Generated by Laboratories Undertaking Regulatory Ecotoxicological Testing, Research & Development Technical Report P166.

British Standards Institute (2005) General requirements for the competence of testing and calibration laboratories BS EN ISO/IEC 17025:2005.

Environment Agency Monitoring Certification Scheme (MCERTS) (2006) Performance Standard for Laboratories Undertaking Direct Toxicity Assessment of Effluents.

Environment Agency Monitoring Certification Scheme (MCERTS) (2006) Laboratory Assessment.

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Environment Agency Monitoring Certification Scheme (MCERTS) (2007)
MCERTS for DTA Steering Committee Terms of Reference.

ILAC (2007) Guidelines for the Requirements for the Competence of
Providers of Proficiency Testing Schemes, ILAC-G13:2007.

British Standards Institute (1997) Proficiency testing by interlaboratory
comparisons – Part 1: Development and operation of proficiency testing
schemes, ISO/IEC Guide 43-1:1997.

British Standards Institute (1997) Proficiency testing by interlaboratory
comparisons – Part 2: Selection and use of proficiency testing schemes by
laboratory accreditation bodies, ISO/IEC Guide 43-2:1997.

1.3 Definitions

Provider The body that undertakes the design, conduct and
operation of the proficiency scheme. The provider for
DTAPS will be the Environment Agency's *Science
Department*.

Collaborator An organisation operating a similar proficiency scheme
that supplies or allows the supply of proficiency testing
data on its participants to the provider for assessment
within the DTAPS.

Contractor An organisation undertaking contracted activities for the
provider of the DTAPS.

Coordinator The person with responsibility for coordinating all of the
activities involved in the operation of the proficiency
testing scheme. *The coordinator of the DTAPS shall be
the DTAPS Technical Manager.*

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An ecotoxicological interlaboratory testing scheme
designed and operated to ensure the performance of
laboratories undertaking DTA testing for regulatory
submission.

DTAPS Round A single operation of the DTAPS.

Section 2: Management System

2.1 Quality Management System

The DTAPS shall be conducted in conformance with the Management and Technical System requirements provided in Section 2 and 3 of the 'Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes; ILAC-G13:2007' and the 'Proficiency Testing by Interlaboratory Comparisons; ISO/IEC Guide 43-1 & 2: 1997'.

The Environment Agency's *Science Department* operates and maintains a quality management system (*in respect of the DTAPS*) which conforms to *ILAC-G13:2007 and ISO/IEC Guide 43* standards and is externally audited by the United Kingdom Accreditation Service (UKAS) on an annual basis. The quality *management* system *directly* supports the *DTAPS procedures* and covers all management areas appropriate to the *scheme's* Scope of Accreditation (UKAS *Proficiency Testing No. 4095*).

All technical aspects of the DTAPS supplied by the provider, including its policy, objectives and commitment to ensuring and maintaining the quality of all aspects of proficiency testing, characterisation, evaluation of participating laboratories' performance, distribution of test material, storage and transport procedures, statistical treatment of results, and reporting, are defined and documented in either Section 3 of this document or the DTAPS Operational Manual (DTAPS 3).

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2.2 Management

The DTAPS quality systems are managed and operated by the DTAPS Technical Manager.

In addition to the management of the quality systems, the DTAPS technical manager will:

- act as Coordinator for the DTAPS;
- take overall responsibility for the technical management and operation of the DTAPS, including ensuring the resources required to uphold the quality of the DTAPS;
- take responsibility and authority for ensuring that the guidelines provided in ILAC-G13 and ISO/ IEC Guide 43 are implemented and followed at all times;
- have direct access to the site specific Science Department Resource Manager, who represents the highest level of management at which decisions are taken on the DTAPS or resources for operating the DTAPS;
- perform and /or delegate (to other, suitably trained *Environment Agency* personnel) specific duties in operation of the DTAPS.

2.3 Document Control

The provider maintains a systematic and controlled record of all information pertinent to the operation of *the DTAPS quality management systems* as defined *in the DTAPS Document Control Manual (DTAPS 7)*. All quality system documentation and records are also itemised in the Document Control Manual (*DTAPS 7*).

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2.4 Contract Review

The Environment Agency does not *currently* charge a fee for participation in the DTAPS. Nevertheless, each agreement (contract) between the provider and participants or collaborators will be reviewed by the Technical Manager to ensure that:

- a) the requirements of participation/ collaboration are adequately defined, documented and understood by the participant/ collaborator;
- b) the provider has the capability and resources to accept the participant/ collaborator onto the scheme;
- c) any differences between the services agreed to be supplied by the provider in respect of the DTAPS, and the requirements of the participant/ collaborator are resolved.

Records of all agreements between the provider and individual participants and the review of such agreements will be maintained, as well as of pertinent discussions with participants, and/ or the results of work undertaken during the period of execution of agreements.

Such records will be held in DTAPS Register (DTAPS 2), which will also include details of all participants, correspondence between provider and participants/ collaborators and any external auditors, and minutes of meetings of the MCERTS for DTA Steering Committee which impinge (directly or indirectly) on the operation of the DTAPS.

2.5 Use of Collaborators and Contractors

The provider may use suitably evaluated and selected collaborators and contractors to undertake specific tasks for the DTAPS.

Collaborators are those individuals and/ or organisations providing reciprocal services to the DTAPS, such as the sharing of proficiency testing data with the providers of other similar schemes. Contractors are those individuals or organisations providing services to the DTAPS provider for a fee, such as the preparation and distribution of reference standards or chemical analysis of reference materials.

Both collaborators and contractors will be selected on the basis of their ability to meet the technical and quality assurance requirements of the DTAPS relevant to the tasks they are contracted to, or have agreed to, undertake.

A register of all collaborators and contractors used in provision of the DTAPS will be held in the DTAPS Register (DTAPS 2), and will include a record of any assessments made of their abilities to conduct the specified task and any correspondence between the provider and collaborator/ contractor. In particular, collaborators and contractors will be selected on the basis of their compliance with the relevant clauses of the ILAC-G13 and ISO/IEC guidelines.

2.6 Services, Supplies & Equipment

Services and supplies for use within the DTAPS, including the preparation, distribution and chemical analysis of reference materials will be procured, where possible, from UKAS accredited suppliers/ laboratories.

No laboratory equipment is held or maintained by the Environment Agency's Science Department.

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2.7 Client Feedback and Complaints

Client (participator) feedback will be sought through a series of different routes;

- i) workshops for participants which may be held after the completion of each DTAPS Round,
- ii) feedback requested from participants at the completion of each DTAPS Round,
- iii) MCERTS for DTA Steering Group meetings (See Appendix A),
- iv) feedback on specific issues raised by participants.

All client (participator) feedback (provided verbally or in writing) will be documented and held in the appropriate section of the DTAPS Register (DTAPS 2), including details of any resulting investigations and/ or actions.

Feedback obtained via the MCERTS for DTA Steering Group (sitting or corresponding members) will also be documented and held in the DTAPS Register (DTAPS 2).

Complaints from participants with regard to the operation of the DTAPS must be confirmed in writing and logged by the Technical Manager. Full details of all complaints will be held in a dedicated section of the DTAPS Register (DTAPS 2). Complaints will be dealt with promptly and full details of all complaints, including all correspondence between provider and complainant and resulting investigations and/ or actions will be recorded and held in a dedicated section of the DTAPS Register (DTAPS 2).

Complaints, including disputes regarding the evaluation of participator performance, will be dealt with in the following manner:

- i) Complaint logged in DTAPS Quality System.
- ii) Provider investigation, conclusion and actions.
- iii) Provider to report details of complaint to the MCERTS for DTA Steering Group, including proposals for resolution/ action.
- iv) MCERTS for DTA Steering Group to take final decisions regarding any further actions to be taken in relation to the complaint.
- v) Report findings and outcome back to complainant.

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2.8 Non-Compliance, Corrective/ Preventive Action and Review.

The provider's policy and procedures for the control of non-compliance in the DTAPS are defined in the DTAPS Internal Audit, Review & Investigation Manual (DTAPS 9).

Where a non-compliance or irregularity occurs in relation to the delivery of the DTAPS (e.g. reference material preparation, verification testing, etc) an investigation shall be carried out which addresses the following as a minimum:

- the corrective actions to be taken will be identified, promptly carried out and their effectiveness in correcting the non-compliance assessed;
- an evaluation of the significance of the non-complaint work to the operation of the DTAPS will be made;
- the operation of the DTAPS will be suspended if deemed necessary by the coordinator;
- the results of non-compliant reference materials or statistical evaluations already issued to participants will be recalled if deemed necessary by the coordinator.

All investigations will be documented and recorded (including corrective actions and timescales for completion). Records of investigations will be retained in the DTAPS Internal Audit, Review and Investigation Manual (DTAPS 9).

Corrective actions taken in discharge of non-compliances will ;

- be promptly implemented and assessed by the *DTAPS Technical Manager*;
- identify the root causes of the problem, eliminate those causes and prevent them from re-occurring;
- be appropriate to the problems encountered and commensurate with the risks to the operation of the DTAPS.

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The responsibility and authority for the management of non-compliant or irregular work, including suspension and resumption of the operation of the DTAPS will lie solely with the *DTAPS* Technical Manager.

All operational procedures, either directly involved with technical aspects of the DTAPS or within the overall quality management system shall be systematically reviewed at regular intervals (and at least annually) to identify any potential sources of non-compliance or opportunities for improvement. This will include a review of proficiency testing criteria to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements.

Technical aspects of the DTAPS will also be reviewed periodically by the MCERTS for DTA Steering Group. The Terms of Reference for the MCERTS for DTA Steering Group are provided in Appendix A.

Reviews will also account for any reports from the provider's senior management, the outcome of recent internal audits, assessments by external bodies (e.g. UKAS), feedback or complaints from participants and any other factors relevant to the operation of the DTAPS. The minutes of all MCERTS for DTA Steering Group meetings and records of DTAPS Reviews will be retained in the DTAPS Register (DTAPS 2).

Preventive actions deriving from such reviews will be developed to improve the operation of the DTAPS or quality management system, and where necessary, to reduce the likelihood of non-compliances occurring. Preventive actions will be implemented and assessed by the *DTAPS* Technical Manager.

2.9 Records

The provider maintains a systematic and documented record of all information pertinent to *the DTAPS* quality management system and *proficiency* testing activities. This documentation system is detailed in the *DTAPS* Document Control Manual (*DTAPS* 7).

Technical records specific to the operation of the DTAPS including:

- individual measurement observations;

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- appropriate calculations and derived data (e.g. statistical treatments);
- results from participants;
- scheme reports;
- overall results of each operational round of the DTAPS;
- reference material analysis results;
- other measurements and/ or supporting data specific to the DTAPS;

will be recorded accurately, legibly, indelibly, unambiguously and objectively, and in accordance with the provider's document control procedures. All such records will be retained in the DTAPS Operational Record (DTAPS 4) for a minimum of six years.

Reports on each operational round of the DTAPS will be retained for a minimum of ten years.

2.10 Internal Audits

The provider operates a formal, annual internal audit programme in accordance with its accreditation to the ILAC-G13:2007 standard and ISO/IEC Guide 43. Full details of the audit programme and of audits which have been undertaken are given in the DTAPS Internal Audit, Review and Investigation Manual (DTAPS 9).

Audit personnel will be appropriately trained staff in the employ of the Environment Agency's *Science Department*.

Section 3: Technical Systems

3.0 Expertise & Experience

The Environment Agency's Science Department (and its associated and predecessor sections and laboratories) has been a leader in the development of all five test methods used within the DTA regime, and has also developed a series of test method guidelines for use by laboratories performing such tests for use in the regulation of industrial effluents.

As well as developing the tests themselves, the Environment Agency's Science Department has also been very closely involved with previous research into the use of a proficiency testing scheme to quality assure the results of DTA tests performed by contract testing laboratories.

This includes the development of performance standards for ecotoxicology testing, and research into the structure and operation of a 'Regulatory Ecotoxicology Testing Quality Scheme (RETQS)'. Much of the structure and operational aspects of the DTAPS are based directly on the conclusions of this previous research, with respect to the proficiency testing of ecotoxicological tests.

3.1 Staff Training

The provider's formal training policy and procedures for the DTAPS are given in the DTAPS Training Manual (DTAPS 8).

Training Records for individual staff, including qualifications and previous work experience, are also retained in the DTAPS Training Manual (DTAPS 8).

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3.2 Organisation and Design Logistics

Detailed organisational, design, development and planning information is provided in the DTAPS Operational Manual, DTAPS 3.

A plan and schedule for each operational round of the DTAPS will be agreed by the MCERTS for DTA Steering Committee prior to commencement of each round. The MCERTS for DTA Steering Committee will also provide technical input to the scheme.

The provider will supply prospective participating laboratories with the following documentation on expression of interest:

- DTAPS 1 (current version);
- DTAPS 3 (current version);
- instructions on how to apply for registration onto the scheme.

The provider will give all registered participants a minimum of 4 weeks notice of the commencement of each round of the DTAPS. At (or before) this time, the provider will distribute documented instructions to all registered participants which will include as a minimum:

- the nature of test materials to be supplied by the provider;
- conditions of storage of reference materials;
- tests to be proficiency tested;
- timings of the specific operational round;
- reporting instructions.

All registered participants will also be automatically issued with new versions of DTAPS 1 and 3 following any changes and/ or amendments to the scheme or DTAPS documentation.

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The identity of each participant in the DTAPS will be known only to the provider but may be communicated to contractors if deemed necessary (and subject to a confidentiality agreement between contractor & Environment Agency) and will be confidential to all other participants and collaborators unless individual participants elect to waive such confidentiality. A written confidentiality waiver must have been received and registered by the provider prior to any communication with others regarding participant identity or proficiency testing data sharing. Participants may wish to waive confidentiality within the participant/ collaborator for a number of reasons including discussion and mutual assistance (e.g. through the MCERTS for DTA Steering Committee), or for regulatory or accreditation purposes.

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Appendix A: MCERTS for DTA Steering Committee Terms of Reference

Aims of Steering Committee

The aim of the steering committee is to oversee and guide implementation of the MCERTS performance standard for the direct toxicity assessment of effluents. Following implementation, the steering committee will provide input to, and generally support the future development of the scheme and ensure that the overall scheme continues to operate successfully.

Membership

To ensure the widest coverage while keeping the meetings to a manageable size, two categories of membership have been created:

- **Committee Members** - up to 10 in all, will be invited to attend all meetings.

Committee Members must fulfil one of the expertise criteria list below and be able to commit to attending regular steering group meetings and contributing to the development of the scheme.

Expertise Criteria for Steering Group Committee membership:

- Up to 2 members who are directly involved in the development of the MCERTS for DTA scheme.
- Up to 5 members from MCERTS for DTA approved laboratories.
- Up to 1 member from the trade body representing the approved laboratories (EIC).
- Up to 2 members who have experience of delivering proficiency testing schemes or ecotoxicological validation/ ring-testing.

The membership of the Steering Group Committee will be reviewed on an annual basis (by the group).

- **Corresponding members** - will receive copies of agendas, minutes, briefing notes and other correspondence relating to the committee. Corresponding members will be able to comment and raise concerns via the chair.

Membership of the Corresponding group is open to any interested party.

Terms of Reference

The Steering Committee will:

- Support and oversee the progress of implementation of the MCERTS performance standard for the direct toxicity assessment of effluents.
- Ensure effective input from all interested groups.
- Identify areas of the standard, methods or other documents or procedures relevant to the scheme that require further review and/ or development.
- Ensure all agreed developmental requirements are appropriately planned and implemented within the scheme, including incorporation into the standard where necessary.

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Appendix A: MCERTS for DTA Steering Committee Terms of Reference (cont)

- Disseminate information regarding the standard and scheme to the wider community.
- Review, provide feedback and provide guidance on any disputes between the approved laboratories and the MCERTS approvers (The Environment Agency).
- The steering committee will also be responsible for reviewing the proficiency testing element of the MCERTS scheme (the DTAPS) and providing feedback on design, fitness for purpose, etc as well as dealing with any disputes between the provider (the Environment Agency) and participants.

Meetings

Meetings will be held at least once annually and more often if required.