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A Guide to the Certification of Products under the Environment Agency's MCERTS Scheme



MCERTS activities other than certification are delivered through CSA Group Testing UK Ltd;
Certified is undertaken by Sira Certification Service (SCS).

**Sira
Certification
Service**

Sira Certification Service (SCS or Sira) is a company limited by guarantee and operates internationally providing certification of management systems, personnel and products. SCS is accredited for these activities by the United Kingdom Accreditation Service (UKAS) and is appointed as a 'notified body' by the UK Government under European Directives.

**The MCERTS
scheme**

MCERTS is the Environment Agency's **M**onitoring **C**ertification **S**cheme. The scheme provides a framework within which environmental measurements can be made in accordance with the Agency's quality requirements. The product certification scheme covers a range of monitoring and sampling products including:

Air Monitoring(Emissions and Ambient Air)

- Continuous emissions monitoring systems (CEMS) and Transportable CEMS (T-CEMS)
- Automatic isokinetic samplers
- Continuous ambient air monitoring systems (CAMS)
- Indicative ambient particulate monitors
- Portable emissions monitoring systems

Water Monitoring

- Automatic water sampling equipment
- On-line water monitoring systems
- Portable water monitoring systems
- Water flowmeters

Software

- Data Acquisition and Handling Standard (DAHS)* see Annex C

*UKAS accreditation not applicable

SCS operates the MCERTS scheme on behalf of the Environment Agency. MCERTS Performance Standards and related documents can be downloaded from the Environment Agency website www.mcerts.net

This document provides guidance to organisations that wish to apply for MCERTS product certification and describes the evaluation and certification process.

**Application for
certification**

An application pack is available from SCS, which includes information on the certification process, including an application form and check sheet. The applicant will need to submit a completed application form to proceed.

Applications are accepted from product manufacturers. If the manufacturer is not based in the UK, a local representative or agent can apply where appropriate.

An information sheet on Own Brand Labellers (OBL) is available for manufacturers that re-badge monitoring systems and want to apply for certification, see 'Manufacturers, Own Brand Labellers and Distributors'.

The applicant specifies the measurement ranges for which the product is to be certified, in line with the performance standards published by the Environment Agency.

The applicant is required to provide evidence that an appropriate quality management system controls manufacture of the product. If the manufacturer has an ISO 9001 certificate from an accredited certification

body, details should be supplied with the application.

SCS is happy to assist the applicant in completing the Application Form, but the applicant must sign it.

THE ROUTE TO MCERTS CERTIFICATION



Quotation

Once an application form is received, SCS will supply a quotation for the cost of certification which excludes the cost of testing.

The estimated time taken to assess test reports and make the certification decision will be set out in the quotation.

A quotation will be provided within 10 days of receiving a completed application form.

Certification Committee Meeting

The Certification Committee consists of independent experts that offer technical support for certification projects.

If existing test data is available, it is advisable for a Certification Committee meeting to be held. The data should be sent through to SCS at least 2 weeks prior to the meeting to enable the Certification Committee time to review it.

At the meeting a test programme is generated by working through the performance standard, detailing gaps in evidence that need to be fulfilled. Minutes from the meeting are taken by SCS and will be circulated within 10 days of the meeting.

Testing

Existing test data may consist of third party test reports, or in-house test data. In order for SCS to accept in-house testing, it will be audited and witnessed by SCS for acceptance.

The applicant has the option of choosing which organisations perform the laboratory or field testing, providing they are qualified to do so

(generally this means they are accredited to ISO/IEC 17025). The applicant can also submit existing test reports, which will normally have to be from a suitably accredited laboratory.

For more information on testing please see information sheet 'MCERTS evidence and witnessed testing'.

To shorten certification time, field and laboratory tests may be conducted simultaneously, if the applicant can supply the correct number of instruments.

If the product should clearly fail any performance test, then the programme will be halted and the applicant asked to comment. The instrument may need to be removed and/or the test period may require to be extended to compensate.

The applicant can comment on the reports from both the laboratory and field tests before the Certification Committee considers them.

The duration of this stage of the certification process will depend on the acceptability of existing test data, and the availability of the laboratory to conduct testing.

Laboratory tests

The applicant will place an order for the test work direct with the test laboratory and will supply the product direct. The product will be operated according to its instruction manual. If the product should fail any performance test, then the programme will be halted and the applicant asked to comment.

Field tests

The applicant will place an order for the test work direct with the test laboratory. Alternatively an existing installation could be used, if acceptable to the Certification Committee.

The requirements for the field trial is at least 3 months on site, see the relevant MCERTS performance standard for more details.

Recognition agreement with UBA for CEMS certification

A type-approval scheme for CEMS, operated by the Umweltbundesamt (UBA) in Germany has many similarities with the MCERTS scheme. To minimise the burden on manufacturers seeking both UBA and MCERTS approval The Environment Agency and UBA have an agreement, which provides for the mutual recognition of laboratory and field test data. Therefore, manufacturers with UBA type-approval certificates may apply to SCS for MCERTS certification. Sira will review the UBA test data before recommending certification in accordance with its established procedures.

Further information on the Environment Agency/UBA recognition agreement is available from SCS.

Initial Audit of the manufacturing process

The MCERTS product certification scheme requires that an audit of the manufacturing process is undertaken by the certification body to confirm that the manufacturer has implemented procedures to ensure manufacturing reproducibility and control of any design changes so that they do not degrade performance below the MCERTS standard. The audit is conducted according to EN15267-2.

SCS conducts an initial audit of the manufacturing process prior to the certification of the product. Certification cannot be granted until the initial audit has been successfully completed.

Applicants with more than one manufacturing site may have sites audited on a sampling basis if there is a common quality system controlling all the sites.

For more information regarding audits, please see Annex B.

Manufacturer's with no accredited quality management system

SCS will perform an initial audit and will also perform an additional day of auditing to perform an assessment of the quality management system.

Assessment of test data

The laboratory and field test data is reviewed by the Certification Committee and assessed against the MCERTS performance standard. The estimated time taken to assess test reports and make the certification decision will be set out in the quotation and will vary depending on the complexity of the product certification.

Granting of a certificate

SCS, with technical support from the Certification Committee, will recommend whether a certificate should be granted, after assessment of the test data and successful completion of an initial audit. The Certification Committee will specify the wording on the certificate and any special conditions.

Certificate register

SCS maintains a register of all MCERTS certificates. The register can be viewed and copies of certificates downloaded at:
<https://www.csagroupuk.org/services/mcerts/mcerts-product-certification/mcerts-certified-products/>

Surveillance audits

SCS will conduct an annual surveillance audit, which will entail the manufacturer completing a questionnaire and supplying specific information or via an on-site audit in accordance with EN15267-2.

Modifications to certified products

Manufacturers shall establish and maintain a procedure to assess whether a design change, a change of component or a different manufacturing procedure may affect the certified performance of the product. All such assessments shall be documented and approved by an appropriate specified representative of the certificate holder.

If the assessment indicates that performance will be unchanged, or improved, then SCS need not be notified of the change until the annual audit of the manufacturing process.

If the assessment indicates that the certified performance may be affected, then the change shall not be implemented without first consulting SCS. It is the manufacturers' responsibility to conduct an assessment and provide the results to SCS. Results should be supported by any test data that is available and details of any changes required to the certificate or documentation referred to in the certificate (for example, drawings listed in the design schedule).

SCS shall then evaluate whether the manufacturer has adequately assessed the effect of the proposed modification. The modification shall not be implemented without authority from SCS who may require further independent testing to verify the assessment.

Certificate validity MCERTS certificates are valid for five years.

The MCERTS scheme requires that certificates shall only be renewed if the product complies with the version of the MCERTS standard that is then current. This may require additional assessment or testing. Any such testing may be performed either in an appropriately accredited laboratory or possibly through tests performed by the manufacturer and witnessed by SCS.

Recertification process

To recertify an instrument, the manufacturer must contact Sira to discuss the specific requirements for recertification. The recertification must be to the latest version of the standard and it is the responsibility of the manufacturer, in consultation with SCS, to determine and arrange any necessary testing to meet the current requirements. This would be a formality unless there have been significant changes to the performance standards or the certified system since the last certificate was issued.

Certificate validity during recertification

When a product is due for recertification, manufacturers must complete the recertification before the expiry of the certificate. If this is not completed, the validity of the certificate will lapse. Once lapsed, the certificate can be recertified with 12 months under the recertification process. After 12 months, the instrument must undergo a new certification process.

Certification Marks

Holders of SCS certificates are licensed to use the Sira Certification Mark on certified products and on literature or documentation directly associated with the certified product(s). The certificate number must be detailed under the logo. Full details and logos are available in Annex A of this document.

Withdrawal of certificates

SCS may suspend, withdraw or cancel certificates if the certificate is no longer valid. The certificate holder will be informed in the event of pending withdrawal, cancellation or suspension.

Appeals

Prospective and current certificate holders have the right to appeal against certification decisions taken by SCS. An appeal is initiated by submitting details in writing to the Managing Director of Sira Certification Service.

Further information:

For more information or to make an enquiry for MCERTS product certification, please contact any of the following address:

MCERTS Department

Tel: +44 (0)1244 670 900

e-mail: mcerts@csagroup.org

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Annex A

Rules on use of the MCERTS Logo by Companies with MCERTS Certification, Accreditation or Approval

The MCERTS logo is a registered trademark under the European Union Intellectual Property Office (trademark number 009500414).

Use of documentation and websites

1. The MCERTS logo may be used by companies on documentation and websites directly associated with instruments and monitoring, analytical, testing and inspection services that have been awarded:
 - Product certification under MCERTS;
 - Accreditation by UKAS to ISO 17025 for a MCERTS performance standard;
 - Note: This includes instrument-testing services in direct support of MCERTS product certification
 - Approval under the MCERTS flow or DTA schemes
2. When using the logo or referencing MCERTS the documentation shall include:
 - the certificate number or accreditation reference number, where applicable, for the specific instrument or monitoring, analytical or testing service.
 - The MCERTS standard the instrument has been certified to and version number (this can be abbreviated but the reference must be clear)
3. Any such documentation shall state clearly the scope of certification, accreditation or approval for the instrument or service.

Note: The MCERTS logo can only be used on test reports when you have MCERTS accreditation or approval for one or more of the determinands or tests in the report. It should state clearly on the report which ones are covered by MCERTS. Reports where no determinands or tests are covered by MCERTS must not carry the MCERTS logo.

Instrument labelling

4. The MCERTS logo may be used by instrument manufacturers on labels attached to instruments that have been awarded MCERTS certification. The labels shall also include the MCERTS certificate number applying to the specific instrument.



Use on vehicles

5. The MCERTS logo may be used by companies on vehicle directly associated with monitoring and analytical/testing services that have been accredited or approved under the MCERTS Scheme.

Logo colour options

6. The logo can only be reproduced in four colour options:

All black (on light backgrounds);

All white (i.e. negative, on dark backgrounds);
One colour option (Environment Agency green – Pantone 322C or Environment Agency Blue – Pantone 540C).
Two colour option (Environment Agency green - Pantone 322C and Environment Agency blue - Pantone 540C. Template available from the Agency.

No other colour options are permitted

General conditions

7. In the event of MCERTS certification, accreditation or approval being withdrawn, or suspended for any reason the company shall immediately cease labelling of any instrument and use of any document (including that on websites) associated with the instrument or service that includes reference to the MCERTS Scheme, the MCERTS logo or MCERTS certification or accreditation number. Any MCERTS logos on vehicles must be removed within a period of three months of accreditation or approval being withdrawn or suspended, unless it is subsequently reinstated within this period.
8. The MCERTS logo remains the property of the Environment Agency at all times.
9. Any abuse of these rules may result in withdrawal of certification, accreditation or approval and action by the Environment Agency to safeguard its property.

Rule on use of the word MCERTS

The word MCERTS is a registered trademark under the UK Intellectual Property Office (trademark number UK00003287256). The trademark covers the wording under class 9, class 42 and class 45 of the Intellectual Property Office.

The word MCERTS cannot be used as a name for a product or instrument part. It can only be used for the purpose of identifying the MCERTS trademark.

Annex B

Rules on the auditing process

An audit is required to maintain MCERTS certification in line with EN15267-2. The audit process covers the following:

Review of ISO 9001	Use of MCERTS and/or UKAS certification marks
Control of documents	Design & development
Management commitment	Purchasing
Responsibility, authority & communication	Identification and traceability
Management review	Customer satisfaction
Competence, training & awareness	Monitoring and measurement of product
Customer related processes	Control of non-conforming product

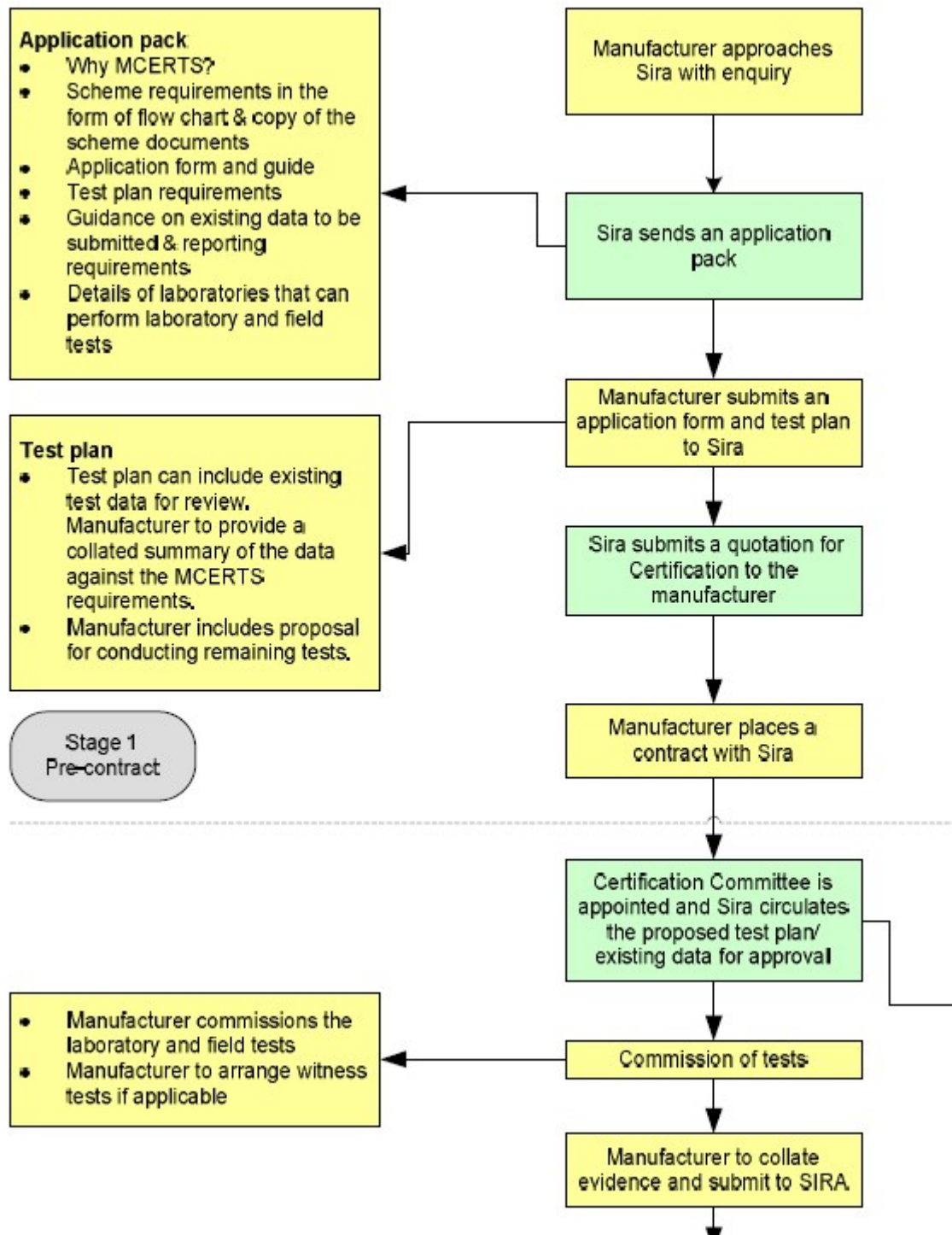
In order to maintain as 12 month timeframe between audits, an initial email will be sent to remind customers of the audit deadline at least one month before. A follow up email will then be sent a month later. From the date of the second email, the customer has two months to reply. If no email is received in this time, SCS reserves the right to withdraw or suspend any related certificates.

Before a certification or recertification can take place, an audit is required. If an audit has been conducted (which meets the requirements) in the 6 months prior to, then this audit can be used to support the certification/recertification.

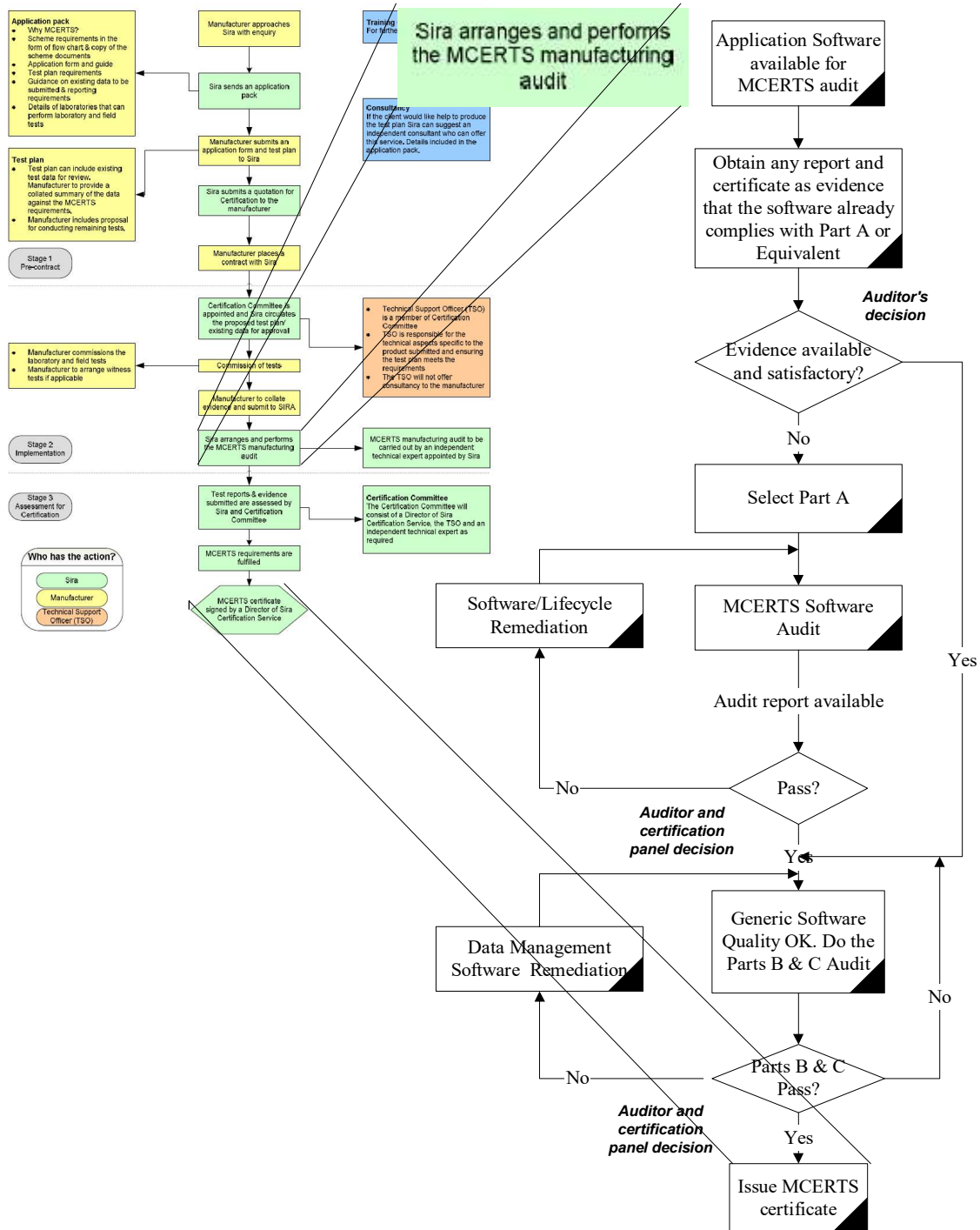
Annex C

MCERTS for DAHS

1 The Certification process



2 MCERTS certification process details for data management applications



The process for standards selection and the subsequent application audit is summarised in the above diagram.

Product certification comprises the following phases:

- part A audit, which can be replaced by an equivalent
- part B and C audit
- review of the audit report
- Issue of the MCERTS certificate.

The audit can cover all three parts of the standard in the same process.

Manufacturers seeking certification should contact the Certification Body who will advise on any specific requirements for the software under consideration.

The standard states that where an application can be configured into subsets of the functionality certification must cover the entire application and thereby include all options.

Instruments that include a data management application must still have their instrument functions certificated to the appropriate MCERTS standard.

3 Certification Committee

The role of the certification body is to assess and certify compliance with the MCERTS standard for defined applications and or conditions.

In performing this role the MCERTS scheme requires the certification body to consider the relevance of the procedures defined in the MCERTS standard to the specific product to be certified. The technology or defined application of a specific product may make certain of the documented tests inappropriate. The certification body is required by the MCERTS scheme to exercise its technical judgement when considering these matters.

Any certification decision based on technical judgement of the standard shall be taken by an appropriately independent, competent person or group of persons, who in this MCERTS standard are referred to as the “**Certification Committee**”.

When the certification body exercises its technical judgement the rationale supporting any such decision shall be appropriately documented.

Any certificate issued by the certification body shall identify any variations from the normative MCERTS standard.

On request the certification body shall provide the MCERTS scheme owner with the rationale for any decision based on technical judgement, within the relevant confidentiality constraints.

4 Certification Scope

This is established in the body of the standard. Basically, minor revisions are permitted for a certified application provided that the criteria laid down in the standard are followed for all revisions.

5 Testing

The application software shall be tested (at a number of levels) by its developers. This standard stipulates that evidence of that testing be archived by the developers and provided to the MCERTS assessor.

6 Auditing and surveillance

An audit of the software development process shall be conducted by the Certification Body to confirm that the application developer has followed this standard throughout the lifecycle of the application software.

Subsequent surveillance audits of the software development process are normally conducted

every five years to ensure that the application is being maintained appropriately.

7 Certificate validity

MCERTS certificates for the data management application software are valid for five years. After this time, the certification is reviewed and any necessary auditing will be identified to maintain the certification, known as recertification. Assessment for this five-yearly recertification shall be carried out against the MCERTS standards current at the time of recertification (see clause B8.5 and Annex E).

8 Modifications to certified application software

Modifications to certified application software are allowable so long as the developers can demonstrate to the Certification Body that these software changes have the characteristics:

- They are minor changes, as defined in the standard.
- The certified application software development process is adhered to.
- The cumulative effect of a sequence of minor software changes does not amount to a major change from the originally certified software.

Manufacturers must keep detailed records of all design changes to the application software as stated in the standard, and have provisions for design verification and review to ensure that the software still meets the required performance standards. These records shall be available for independent review and verification so that the Certification Body can decide whether the scope of any changes is either major or minor.

Details of the requirements for a recertification audit are outlined in Annex D of the MCERTS DAHS document.

Details of the requirements for a surveillance audit are outlined in Annex E of the MCERTS DAHS document.