

**SUPPLEMENTARY REGULATIONS
SPECIFIC TO CERTIFICATION OF
PRODUCTS UNDER THE
ENVIRONMENT AGENCY'S
MCERTS SCHEME**



Introduction

One of the conditions placed on all holders of Sira Certificates is that they shall accept and comply with the current version of 'Regulations Applicable to the Holders of Sira Certificates' (SCS/SF/053) and any applicable supplementary regulations.

These supplementary Regulations are specific to the Certification of Products under the Environment Agency's Monitoring Certification Scheme, MCERTS.

Definition of Terms

'Manufacturer' An organisation, situated at a stated location or stated locations, that carries out or controls such stages in the manufacture, assessment, handling and storage of a product that enables it to accept responsibility for continued compliance of the product with the relevant requirements and undertakes all obligations in that connection.

'Certificate Holder' The party responsible for ensuring that certified products meet and continue to meet the requirements on which the certification is based.

'Product' Any measuring device, instrument, analyser, continuous emission monitoring system or automated measuring system.

This means that a **'certificate holder'** (and therefore the **'manufacturer'**) of a certified **'product'** is responsible for ensuring that the **'product'** meets and continues to meet the requirements on which the certification is based.

These supplementary regulations summarise the various conditions, requirements and guidance contained in the following publications:

- Regulations applicable to the holders of Sira certificates
- The National Accreditation Logo and Symbols – Conditions for Use by UKAS and UKAS Accredited Organisations – July 2009 (URN 09/1090)
- Rules on use of the MCERTS Logo by Companies with MCERTS Certification or Accreditation- Environment Agency, January 2003

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 Sira.

In addition, Sira shall require reasonable evidence that the performance of current production of the certified product continues to comply with the MCERTS standard and the performance data stated on the certificate. This shall normally be demonstrated by repeating certain tests in an accredited laboratory. Sira shall take account of any appropriate test data from an accredited laboratory that is already available, and possibly any routine monitoring data already available from the manufacturer.

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 Sira 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 worse than stated on the certificate, then the change shall not be implemented without first consulting Sira. It is the manufacturers' responsibility to conduct an assessment and provide the results to Sira. 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). Sira shall then evaluate

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

Audit of the manufacturing process

MCERTS performance standards require that an audit of the manufacturing process is undertaken by the certification body to confirm that the manufacturer has provisions to ensure manufacturing reproducibility and to control any design changes that may degrade product performance.

Therefore, Sira is required to undertake an audit prior to initial certification. Subsequent surveillance audits are normally conducted annually until sufficient evidence of a well-proven, robust system has been collected. Once this has been established, Sira may progressively extend the interval between audits or waive an audit visit and instead require submission of specific audit data for review off-site. If necessary, Sira may also undertake random audits.

In accepting and using a certificate the holder agrees to pay promptly all fees due and to co-operate with Sira regarding surveillance audits. Certificate holders who do not co-operate may have their certificates suspended or withdrawn. Certificate holders who do not clear outstanding audit non-compliances within the agreed timescale may have their certificates suspended or withdrawn.

Certification marks

Holders of Sira MCERTS certificates are licensed to use the Sira certification mark, which incorporates the UKAS product certification mark and the MCERTS logo, on certified products and on literature or documentation directly associated with the certified product(s).

When using these certification marks, they must be legible, durable, indelible and generally no less than 20mm in height. The Sira accreditation number (011) shall appear centrally under the UKAS product certification mark. The certification mark shall be considered as a single entity for purposes of enlargement or reduction. All marks shall be enclosed in a box and the corresponding Sira certificate serial number(s) shall appear centrally under the box. An example is given below.

The Environment Agency's MCERTS logo may also be used in isolation by certificate holders on literature or documentation directly associated with certified product(s). When using the MCERTS logo the documentation shall also include the corresponding Sira certificate serial number(s). An example is given below.



MCERTS certification is for a complete system and when applying certification marks to a product it must not be implied that individual components are certified.

Use of these certification marks will be verified for compliance with these regulations during audit and surveillance of the manufacturing process.

Certificate holders shall immediately cease to use all certification marks referred to in these regulations in the event that Sira suspends or cancels the relevant certificate(s).

Certification marks shall not be displayed on vehicles, buildings or flags and shall only be used in the format prescribed in these regulations.