

**SUPPLEMENTARY REGULATIONS  
SPECIFIC TO FUNCTIONAL  
SAFETY CERTIFICATION**

## 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 functional safety certificates, that is, those meeting the requirements of IEC 61508 or related standards.

Any revisions to the general regulations and supplementary regulations can be found on the Sira website [www.siracertification.com](http://www.siracertification.com).

## Definition of Terms

**'Manufacturer'** An organisation, situated at a stated location or stated locations, that carries out or controls such stages in the manufacture, integration, 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 a certified system or product meets and continues to meet the requirements on which the certification is based.

**'Product'** Any measuring device, instrument, analyser, logic solver, final element (actuator, valve etc) or combination of such devices, which carry out a safety function as described in IEC 61508 or related standards.

## The CASS Scheme

The CASS Scheme Ltd is an independent body that, in the interests of promoting transparent and consistent certification, publishes assessment methodologies for accredited certification to IEC 61508 and related standards. Certificates issued under the aegis of The CASS Scheme bear the CASS logo which may be used by certificate holders as specified in these Supplementary Regulations.

It should be noted that a copy of all CASS certificates issued will be supplied, in confidence, to The CASS Scheme Ltd as required by their rules for monitoring compliance with their scheme.

## **CERTIFICATES FOR MANAGEMENT OF FUNCTIONAL SAFETY-*an 'APPROVED COMPANY' certificate***

### **Certificate validity**

Certificates are valid for three years, subject to the certificate holder maintaining the system to the required standards which will be monitored by Sira. The frequency and duration of such surveillance shall be in accordance with the requirements of the relevant standards. Normally this means there will be an annual surveillance audit with reassessment every third year.

Failure to permit surveillance or reassessment, to clear non-compliances within specified timescales or to pay fees may result in the suspension or withdrawal of the certificate.

### **Modifications to a certificated management system**

Any change that affects, or may affect, any of the information contained in the certificate or the conduct of a future audit shall be notified in writing to Sira prior to implementation. Sira shall advise the certificate holder whether there are any audit implications and will reissue the certificate if appropriate.

## Use of the Sira Certification Mark and references to certification

Holders of certificates for the Management of Functional Safety may use the Sira Certification Mark. Where the certificate bears the CASS logo and holders of such certificates wish to use the CASS logo, it shall be shown alongside the UKAS and Sira Certification Mark as follows, with the certificate number printed below the Mark in a font design and size that is visually similar to that used for the words 'Approved Company' that appear inside the Mark:



**Certificate No. CASS 09999**

An electronic copy is available as a download via the Sira web-site ([www.siracertification.com](http://www.siracertification.com)) or on request from Sira.

When using the Sira Certification Mark the general conditions contained in the main Regulations shall be followed.

Certificate holders shall immediately cease to use the certification mark in the event that the certificate is suspended or withdrawn.

An organisation holding certification for the Management of Functional Safety shall not use the certification mark on a product or in a way that may be interpreted as denoting product conformity.

Any references to certification shall not be misleading.

## **CERTIFICATION OF PRODUCTS - an 'Approved Product' certificate**

### **Certificate validity**

Product functional safety certificates are valid for five years. After this time, the certification is reviewed and renewed if the certified conditions have remained valid.

### **Modifications to certified products**

Certificate holders are required to inform Sira of any modification affecting any of the documents, drawings or other information referred to in the certificate. Modifications to a certified product are not permitted until a new certificate has been issued by Sira, or it is agreed that the changes do not affect certification.

### **Audit of the manufacturing process**

The functional safety product certification scheme requires that an audit of the manufacturing process is undertaken by the certification body to confirm that the manufacturer has adequate provisions to ensure manufacturing reproducibility and to control any design changes that may degrade product performance. This audit does not duplicate any which may be performed in support of certification to other management system requirements, such as ISO 9001:2000, but assesses the organisation's functional safety capability in respect of the requirements of IEC 61508-1 Clause 6 or equivalent standard.

Where a product has been certified on the basis of 'Proven in Use' the manufacturer shall have provisions to continue to obtain evidence of failures in use and to analyse the effects of this on the on-going reliability of the product. The manufacturer shall inform Sira immediately if the certified safety integrity capability of the product is adversely affected.

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 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, to co-operate with Sira regarding surveillance audits and to clear non-compliances within specified timescales. Certificate holders who fail to observe these requirements may have their certificates suspended or withdrawn.

## Use of the Sira Certification Mark and references to certification

Holders of Sira functional safety product certificates bearing the CASS logo may use the following Sira Certification Mark on certified products, and on literature or documentation directly associated with the certified product(s). The certificate number shall be printed below the Mark in a font design and size that is visually similar to that used for the words 'Approved Product' that appear inside the Mark. An electronic copy is available from Sira as a download.



**Certificate No. FSP 09999/00**

When using the Sira Certification Mark the general conditions contained in the main Regulations shall be followed.

Certificate holders shall immediately cease to use certification marks in the event that the certificate is suspended or withdrawn.

Any references to certification shall not be misleading.