# AF-D008

## Factory Production Control

Commercial-in-confidence

# Copyright



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CSIRO, as managers of this product certification program (CSIRO's ActivFire® Scheme), try to provide a high level of verification of the conformance of chosen products for end users (asset and infrastructure owners/managers, either public or private).

CSIRO seeks to achieve this by insisting that applicants, customers, and Registrants comply with the minimum requirements of this document and other processes and documents through which the program is administered.

This verification and certification processes do not provide any guarantee or warranty as to the performance of the product. It is merely meant to provide increased confidence that a chosen product conforms with the Registrant's evidence of conformity. Other factors such as installation and maintenance will significantly and affect the performance of a product. CSIRO cannot therefore, with any certainty, predict absolute outcomes and disclaims all liability and loss that a person or organisation may suffer as a result of them using any information produced and provided by CSIRO, CSIRO Verification Services or the ActivFire® Scheme.

# Document Review

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# Contents

# 1. Scope

This document outlines the requirements and procedures for auditing a manufacturing unit (MU) that produces products certified by CSIRO's ActivFire® Scheme ("the Scheme"). It also covers post-certification requirements as described in the relevant technical documents.

Audits of manufacturing units are conducted by the Scheme to verify that Factory Production Control (FPC) systems have been established, documented, and maintained to ensure that a certified product placed on the market complies with the declared performance of essential characteristics and conform to the samples subjected to type testing.

# 2. Referenced Documents

Details of the documents referenced by this document are detailed in Table 1.

**Table 1 List of documents referenced by or relevant to this document.**

| | |
|---|---|
| **AS/NZS ISO 9001:2016** | Quality management systems - Requirements |
| **AS/NZS ISO/IEC 17065:2013** | Conformity assessment – Requirement for bodies certifying products, processes, and services |
| **AS/NZS ISO/IEC 17021.1** | Conformity assessment – Requirements for bodies providing audit and certification of management systems Part 1: Requirements |
| **AF-D001** | Rules Governing ActivFire® Scheme |

# 3. Definitions

ActivFire® definitions and acronyms can be found in on ActivFire® document AF-D001 or ActivFire®'s website.

- **Primary Manufacturing Unit (PMU):** The Producer, or a business entity contracted with the Producer, providing the total, substantive, or final production/assembly process of the product.
- **Registrant[1]:** The business entity validated and registered under the conformity assessment scheme as the Producer, or Producer Management Representative of Certified Products. The Registrant is subject to the Rules Governing the ActivFire® Scheme as applicable to the Certified Products registered under its name.
- **The Scheme:** The third-party product certification program operating under the conformity assessment system of CVS and covering active fire detection and suppression equipment as used by the building and construction industries. ActivFire® is the applicable Scheme.

[1] The Registrant is responsible for the payment of fees and charges associated with the maintenance of their product certifications, on-going conformity of the Certified Products with specified requirements and providing evidence of conformity by the process and in a form as specified and / or deemed necessary by the ActivFire® Scheme.

# 4. Pre-audit

## 4.1. General

The Scheme shall notify the Registrant's main contact(s) of the audit requirements as described in their respective technical specifications, and proposed audit dates for the manufacturing unit(s) for ongoing verification of conformity. This shall occur at least five months prior to the revalidation date of the Certified Product's Certificate of Conformity (CoC).

The manufacturing unit audit shall take place at the Primary Manufacturing Unit (PMU) of the certified product. It is the Registrant's responsibility to notify the Scheme of any changes to the PMU as part of the post-certification requirements of a certified product. If the PMU has part of the product manufactured, assembled, packed, processed and/or labelled by another manufacturing unit (MU), an FPC audit may be carried out in the other MU.

The Scheme shall provide the Registrant with an audit plan containing the criteria listed in Section 5 of this document and any additional requirements as listed in the respective product's technical specifications.

## 4.2. PMUs with Multiple Certified Products

PMUs that manufacture multiple certified products may be audited in a single visit. This shall be discussed with the Scheme prior to the first audit deadline for the Registrant's certified product.

# 5. Manufacturing Unit Audit Criteria

Table 2 lists the requirements for conformance to be established by the audit of the manufacturing unit, and what the Scheme considers as a non-conformance to the stated requirements.

**Table 2 Criteria and evidence of conformance required for the audit of a manufacturing unit.**

| No | Activity | Requirements | Notes |
|---|---|---|---|
| **1.** | Leadership | Personnel with the responsibility and authority that includes the following is appointed by management and is a member of management:<br>• Ensuring that processes needed for the Quality Management System (QMS) are established, implemented and maintained.<br>• Reporting to top management on the performance of the QMS and any need for improvement.<br>• Ensuring the promotion of awareness of customer requirements throughout the organisation. | - |
| **2.** | Management commitments and resources | Management is committed to developing and implementing the QMS, providing adequate resources to support continuous improvement and effectiveness of the system.<br>The organisation and management shall determine and provide the resources needed to:<br>• Implement and maintain the QMS and continually improve its effectiveness.<br>• Enhanced customer satisfaction by meeting customer requirements. | - |
| **3.** | Personnel | • The staff structure at the PMU is appropriate and that the current key personnel are suitably qualified and competent to undertake the roles and responsibilities assigned to their respective positions.<br>• Key positions in the technical, manufacturing and quality functions of the PMU have Position Descriptions (PD) that define the role(s), responsibilities, and limits to authority relevant to the position.<br>• Key decision makers in Quality Control (QC) are free from pressure and conflicts of interest that may negatively impact on product quality decisions. | - |

| No | Activity | Requirements | Notes |
|---|---|---|---|
| | | • The PMU personnel are aware of the relevance and importance of their objectives and how they contribute to the achievement of the quality objectives. | |
| **4.** | Training and competence | • The PMU shall:<br>○ Provide training and / or take actions to ensure that personnel have the necessary competence to perform their required work.<br>○ Evaluate the effectiveness of the training and / or actions taken.<br>○ Ensure that appropriate records of education, training, skills and experience are maintained. | - |
| **5.** | Quality Management System (QMS) | The PMU has established and maintained a Quality Manual that includes:<br>• Reference to the documented procedures established for the QMS.<br>• A description of the interaction between the processes of the QMS. | Evidence to ISO 9001 quality management system (QMS) by appropriately accredited agency[2] will be accepted. |
| **6.** | Review of previous non-conformities | The PMU shall have taken appropriate corrective and preventive actions for any previous non-conformities. These should be satisfactorily completed and implemented. | For the first audit by ActivFire®, a review of the PMU's complaints or non-conformance register or similar shall be undertaken. |
| **7.** | Document control | The PMU shall have a document procedure which defines the control needed to:<br>• Ensure changes to the documentation are sanctioned only by an approved person e.g. Quality Manager.<br>• Ensure changes and current revision status of the documentation are identified.<br>• Ensure that documents are available and readily identified with the relevant versions of the applicable documents at the points of use.<br>• Ensure that documents of external origin are identified and their distribution controlled.<br>• Ensure that most recent documentations are used therefore preventing the unintended use | |

[2] In Australia and New Zealand, such accreditation is provided by JAS-ANZ accredited agencies.

| No | Activity | Requirements | Notes |
|---|---|---|---|
| | | of obsolete documents, and to apply suitable identification to them if they are retained for any purposes.<br>• Ensure that instructions in the documentation are comprehensive, clear, and unambiguous, especially to a new operator. | |
| **8.** | Purchasing | • The PMU shall identify the purchasing requirements for the controls used in the purchase of each components/parts for use in a specific product.<br>• The PMU shall establish a list of suppliers identifying their name, address, and the components/parts, products, materials and/or services they have been authorised to supply.<br>• The PMU shall identify the type and extent of the controls applied to the supplier and the purchased item and shall continue to assess it.<br>• The PMU shall maintain records of the results of assessment i.e., 2nd party audit of the supplier, review of the supplier list, etc, and any necessary action arising from the assessment.<br>• The PMU shall produce a list of components critical to the operation of the product. The list shall include all components used within the manufacture of the product that if changed could alter or prevent compliance to the requirements of the relevant product standard. The critical components shall have the following information recorded:<br>o Component name.<br>o Part Number.<br>o Manufacturer.<br>• The PMU shall have a documented procedure to ensure that 'critical' components are not changed without informing the scheme via the Registrant of the product.<br>• If the PMU subcontracts any aspects of the production, the PMU shall retain overall control of the product or service, and shall ensure that all received information that is necessary to fulfil the manufacturer's responsibilities is in accordance with the relevant certification criteria. | If the PMU has part of the product manufactured, assembled, packed, processed and/or labelled by another MU, an FPC audit may be carried out in the other MU. |

| No | Activity | Requirements | Notes |
|---|---|---|---|
| **9.** | Product specification | • A product specification assessment shall be carried through comparison to the ActivFire® document register against the current build status.<br>• The PMU shall have a procedure to manage modifications to the product. When modifications to the product are required, the production process or factory production control system of the PMU that could affect the compliance of the product against the specific requirements of the certification criteria shall:<br>○ Notify CSIRO via the Registrant of the product through ActivFire® Form AF-F003.<br>○ Carry out validation and verification to ensure that the product continues to comply with the requirements of the relevant standard. | - |
| **10.** | Storage, preservation and protection of raw materials and components | • The PMU shall store raw materials and components in such a way that they are adequately identifiable to avoid mistaken identity, well segregated to avoid cross-contamination, and well-protected from deterioration from the effects of the weather.<br>• The PMU shall ensure that incoming raw materials and components meet their compliance requirements and/or shall be able to perform consistently.<br>• The PMU warehouses and areas of storage shall be well organised and have good housekeeping. | - |

| No | Activity | Requirements | Notes |
|---|---|---|---|
| **11.** | Manufacturing process | • The PMU shall have a plan and process for product realisation and shall provide the resources to ensure that the product meets the specified requirements.<br>• The PMU shall have a fully documented manufacturing process for each product which references in a systemic manner to the following:<br>○ Applicable Procedures.<br>○ Work Instructions.<br>○ Verification, validation, monitoring, inspection and test(s) specific to the product through various process including goods-in, in process, final testing and authorisation to release the product.<br>• The PMU shall have records that the products have been sampled and tested. These records shall clearly indicate that the production has been successful and meet the defined acceptance criteria. The records shall be available for a minimum for 10 years and have indication that they have been passed / authorised by the person responsible for the control / test.<br>• The PMU shall ensure that individual products are identifiable and traceable with regards to their production origin. | - |
| **12.** | Non-conforming products | • The PMU shall establish procedures on how non-complying products are dealt with and includes the following:<br>○ Assurance that if the product does not conform to the requirements, it is identified and controlled to prevent its unintended use or delivery.<br>○ Instigate action to eliminate the cause of non-conformities to prevent recurrence.<br>○ Controls and related responsibilities and authorities for dealing with non-conforming products.<br>○ Assurance that when a non-conforming product is corrected, the product is subject to re-verification to demonstrate conformity to the relevant requirements. | - |

| No | Activity | Requirements | Notes |
|---|---|---|---|
| **13.** | Inspection and in process testing | • The PMU shall monitor and measure all process, where applicable, to ensure that production maintains its planned results. If planned results are not achieved, correction and corrective actions shall be taken, as appropriate, to ensure the conformity for the product.<br>• The PMU shall monitor and measure the characteristics of the manufactured product at appropriate and predefined stages of the product realisation to ensure the product is and continues to conform to the appropriate specified requirements.<br>• The PMU shall keep the evidence of product conformance which identifies the acceptance criteria and the authority of releasing the verified product.<br>• The PMU shall have controls in place to prevent product release and service delivery until planned arrangements have been satisfactorily completed. | - |
| **14.** | Equipment | • The PMU shall ensure that the equipment used for monitoring and measurement is:<br>○ Regularly inspected and maintained, and that all equipment is calibrated as per documented requirements.<br>○ Adjusted or re-adjusted when necessary and documented accordingly.<br>○ Identified with their calibration status.<br>○ Protected from damage or deterioration during use or storage.<br>• The PMU shall ensure that calibration records are being assessed, that previously measured results are valid, and appropriate action is taken when the equipment is found out of calibration. | - |
| **15.** | Storage, handling, packaging and transportation. | • The PMU shall ensure that its warehousing facilities are adequate to prevent damage or deterioration of the product during storage.<br>• The PMU shall have procedures for handling that prevents damage to the products.<br>• The PMU shall have good housekeeping procedures. | - |

| No | Activity | Requirements | Notes |
|---|---|---|---|
| | | • The PMU shall label packaging and/or pallets with a batch number and ensure that the product designations are clear and unambiguous. | |
| **16.** | Occupational, health and safety (OH&S) | • The PMU shall have an effective system of ensuring that operators are aware of hazards associated with handling materials and that there are effective ways of minimising the risks associated with all stages of the production cycle – receipt, use, disposal etc. This shall include ready identification of hazards and PPE (Personal Protective Equipment) requirements.<br>• The PMU shall have a system for identifying hazardous raw materials, where relevant. | - |
| **17.** | Records | • The PMU shall have records that are established and maintained to provide evidence of conformity to the requirements and of the effective operation of the QMS.<br>• The records shall remain legible, readily identifiable and retrievable.<br>• The PMU shall have an established documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. | - |
| **18.** | Complaints | • The PMU shall have an effective arrangement for communicating with customers, including seeking customer feedback and handling complaints.<br>• The PMU shall keep a register of any complaints received and that the corrective and preventive actions carried out are satisfactory. The complaints shall be dealt with in a timely and effective manner. | - |

| No | Activity | Requirements | Notes |
|---|---|---|---|
| **19.** | Internal product audits | • The PMU shall conduct internal product audits on finished samples taken from the production line which are tested and verified independently from the production line testing. Verification of the following, where applicable, shall be conducted:<br>○ Build and design standard.<br>○ Labelling.<br>○ Installation instructions<br>○ Technical manuals.<br>○ Manufacturing records.<br>○ Manufacturing process.<br>• Independent testing records shall be reviewed to determine that the production samples correspond with samples submitted for type testing. Where the product fails to satisfy the acceptance measures, corrective actions shall be taken immediately and the products or batches not conforming shall be isolated and identified accordingly.<br>• The extent and frequency of internal audits shall be determined by the PMU.<br>• The test procedures / requirements shall be reviewed as part of the audit to review the inspection criteria. | - |

# 6. Post-audit

## 6.1. Closing meeting

Upon completion of the audit of the manufacturing unit, a closing meeting shall be held between the audit team and representatives of the Registrant and the PMU (if applicable). The closing meeting shall include the following:

1. The audit results.
2. Non-conformities found during the audit, if applicable.
3. Consequences on the revalidation of the CoC for the product due to non-conformities, if applicable.
4. Set a time for corrective action and follow-up audit, if required.
5. Identification of the timeframe for delivery of the audit report.

## 6.2. Audit report

An audit report will be provided to the Registrant by the Scheme within the agreed timeframe.

## 6.3. Revalidation of the Product's CoC

Once the audit report is issued, corrective actions (if applicable) are in place and the results are satisfactory, the CoC's of the Certified Products shall be revalidated for the period specified in the respective product's technical specification.

## 6.4. Modifications

The Registrant shall notify the Scheme of any changes to the Certified Product. The Scheme shall be notified of any significant changes to the FPC system or to the production process which could affect the performance of the Certified Product. The Scheme shall determine if revaluation of the product and/or audit of the PMU is required for the product to maintain certification by the Scheme.

# 7. Appeals and Complaints

Registrants may:

1. Appeal a determination or decision made by the Scheme and/or its officers.
2. Lodge a complaint against the Scheme or its officers.

Appeals and complaints shall be processed in accordance with the requirements of ActivFire® Document AF-D004.