



## 1. Audit details

<b>Primary Manufacturing Unit (PMU) Name:</b>			
<b>PMU Idx</b> <small>(see PRIMIS)</small>		<b>Project no:</b>	
<b>PMU Address</b>			
<b>Lead Auditor:</b>		<b>Other auditors:</b>	
<b>Organisation representatives:</b>			
<b>Additional notes:</b>			



## 2. Other audit results

### 2.1. ISO 9001 (Quality Management System – QMS – optional)

☐ Not Applicable

<b>Name of external auditing organisation:</b>		<b>Date of last audit:</b>	
<b>Non-conformance detected:</b>			
<b>Has all the non-conformances been satisfactorily addressed and closed out by the auditing organisation?</b> <input type="checkbox"/> Yes <input type="checkbox"/> Not yet <input type="checkbox"/> Not Applicable			
<b>Does the scope of accreditation include the technical function?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>Is the scope of accreditation appropriate for ActivFire requirements?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>Comments related to this aspect:</b>			



## 2.2. ISO 14001 (Environmental Management System – EMS – optional)

☐ Not Applicable

<b>Name of external auditing organisation:</b>		<b>Date of last audit:</b>	
<b>Non-conformance detected:</b>			
<b>Has all the non-conformances been satisfactorily addressed and closed out by the auditing organisation?</b> <input type="checkbox"/> Yes <input type="checkbox"/> Not yet <input type="checkbox"/> Not Applicable			
<b>Comments related to this aspect:</b>			



## 2.3. ISO 45001 (OH&S Management System – optional)

☐ Not Applicable

<b>Name of external auditing organisation:</b>		<b>Date of last audit:</b>	
<b>Non-conformance detected:</b>			
<b>Has all the non-conformance been satisfactorily addressed and closed out by the auditing organisation?</b> <input type="checkbox"/> Yes <input type="checkbox"/> Not yet <input type="checkbox"/> Not Applicable			
<b>Comments related to this aspect:</b>			



## 2.4. Other FPC audits – optional

☐ Not Applicable

<b>Name of external auditing organisation:</b>		<b>Date of last audit:</b>	
<b>Non-conformance detected:</b>			
<b>Has all the non-conformances been satisfactorily addressed and closed out by the auditing organisation?</b> <input type="checkbox"/> Yes <input type="checkbox"/> Not yet <input type="checkbox"/> Not Applicable			
<b>Comments related to this aspect:</b>			



## 2.5. Last ActivFire® Audit

☐ Not Applicable

<b>Date of last audit:</b>	
<b>Non-conformance detected:</b>	
<b>Has all the non-conformances been satisfactorily addressed and closed out by the auditing organisation?</b> <input type="checkbox"/> Yes <input type="checkbox"/> Not yet <input type="checkbox"/> Not Applicable	
<b>Comments related to this aspect:</b>	



### 3. Details about the PMU

<b>Details of key personnel in the PMU who have a direct impact on technical, quality or manufacturing outputs:</b>	
<b>Any changes to key personnel since last audit:</b>	<input type="checkbox"/> Not Applicable
<b>Is the PMU also the Producer of the products?</b> <input type="checkbox"/> Yes <input type="checkbox"/> Not yet <input type="checkbox"/> Not Applicable	



## 4. Audit

### 4.1. Leadership

Requirements	Evidence sighted	Conforms
<p>Personnel with the responsibility and authority that includes the following is appointed by management and is a member of management:</p> <ul style="list-style-type: none"> <li>Ensuring that processes needed for the Quality Management System (QMS) are established, implemented, and maintained.</li> <li>Reporting to top management on the performance of the QMS and any need for improvement.</li> <li>Ensuring the promotion of awareness of customer requirements throughout the organisation.</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

### 4.2. Management commitments and resources

Requirements	Evidence sighted	Conforms
<p>Management is committed to developing and implementing the QMS, providing adequate resources to support continuous improvement and effectiveness of the system.</p> <p>The organisation and management shall determine and provide the resources needed to:</p> <ul style="list-style-type: none"> <li>Implement and maintain the QMS and continually improve its effectiveness.</li> <li>Enhanced customer satisfaction by meeting customer requirements.</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

## 4.3. Personnel

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>The staff structure at the PMU is appropriate and current key personnel are suitably qualified and competent to undertake the roles and responsibilities assigned to their respective positions.</li> <li>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.</li> <li>Key decision makers in Quality Control (QC) are free from pressure and conflicts of interest that may negatively impact on product quality decisions.</li> <li>The PMU personnel are aware of the relevance and importance of their objectives and how they contribute to the achievement of the quality objectives.</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

## 4.4. Training and competence

Requirements	Evidence sighted	Conforms
<p>The PMU shall:</p> <ul style="list-style-type: none"> <li>Provide training and / or take actions to ensure that personnel have the necessary competence to perform their required work.</li> <li>Evaluate the effectiveness of the training and / or actions taken.</li> <li>Ensure that appropriate records of education, training, skills, and experience are maintained.</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

## 4.5. Quality Management System

Requirements	Evidence sighted	Conforms
<p>The PMU has established and maintained a Quality Manual that includes:</p> <ul style="list-style-type: none"> <li>Reference to the documented procedures established for the QMS.</li> <li>A description of the interaction between the processes of the QMS.</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

Note: Evidence of accreditation to ISO 9001 quality management system (QMS) by an appropriately accredited agency<sup>1</sup> will be accepted.

## 4.6. Review of previous non-conformities

Requirements	Evidence sighted	Conforms
<p>The PMU shall have taken appropriate corrective and preventive actions for any previous non-conformities. These should be satisfactorily completed and implemented.</p>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

Note: For the first audit by ActivFire®, a review of the PMU's complaints or non-conformance register or similar shall be undertaken.

## 4.7. Document control

Requirements	Evidence sighted	Conforms
<p>The PMU shall have a document procedure which defines the control needed to ensure:</p> <ul style="list-style-type: none"> <li>Changes to the documentation are sanctioned only by an approved person e.g. Quality Manager.</li> <li>Changes and current revision status of the documentation are identified.</li> <li>Documents are available and readily identified with the relevant versions</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

<sup>1</sup> In Australia and New Zealand, such accreditation is provided by JASANZ accredited agencies.

Requirements	Evidence sighted	Conforms
<p>of the applicable documents at the points of use.</p> <ul style="list-style-type: none"> <li>Documents of external origin are identified and their distribution controlled.</li> <li>Most recent documentation versions are used therefore preventing the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purposes.</li> <li>Instructions in the documentation are comprehensive, clear, and unambiguous, especially to a new operator.</li> </ul>		

## 4.8. Purchasing

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>The PMU shall identify the purchasing requirements for the controls used in the purchase of each components/parts for use in a specific product.</li> <li>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.</li> <li>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.</li> <li>The PMU shall maintain records of the results of assessment i.e., 2<sup>nd</sup> party audit of the supplier, review of the supplier list, etc, and any necessary action arising from the assessment.</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>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: <ul style="list-style-type: none"> <li>Component name.</li> <li>Part Number.</li> <li>Manufacturer.</li> </ul> </li> <li>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.</li> <li>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.</li> </ul>		

Note: 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.

## 4.9. Product specification

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>A product specification assessment shall be carried through comparison to the ActivFire® document register against the current build status.</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>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: <ul style="list-style-type: none"> <li>Notify CSIRO via the Registrant of the product through ActivFire® Form AF-F003.</li> <li>Carry out validation and verification to ensure that the product continues to comply with the requirements of the relevant standard.</li> </ul> </li> </ul>		

## 4.10. Storage, preservation and protection of raw materials and components

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>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.</li> <li>The PMU shall ensure that incoming raw materials and components meet their compliance requirements and/or shall be able to perform consistently.</li> <li>The PMU warehouses and areas of storage shall be well organised and have good housekeeping.</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

## 4.11. Manufacturing process

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>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.</li> <li>The PMU shall have a fully documented manufacturing process for each product which references in a systemic manner to the following: <ul style="list-style-type: none"> <li>Applicable Procedures.</li> <li>Work Instructions.</li> <li>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.</li> </ul> </li> <li>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.</li> <li>The PMU shall ensure that individual products are identifiable and traceable with regards to their production origin.</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

## 4.12. Non-conforming products

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>The PMU shall establish procedures on how non-conforming products are dealt with and includes the following: <ul style="list-style-type: none"> <li>Assurance that if the product does not conform to the requirements, it is identified and controlled to prevent its unintended use or delivery.</li> <li>Instigate action to eliminate the cause of non-conformities to prevent recurrence.</li> <li>Controls and related responsibilities and authorities for dealing with non-conforming products.</li> <li>Assurance that when a non-conforming product is corrected, the product is subject to re-verification to demonstrate conformity to the relevant requirements.</li> </ul> </li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

## 4.13. Inspection and in process testing

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>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.</li> <li>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.</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>The PMU shall keep the evidence of product conformance which identifies the acceptance criteria and the authority of releasing the verified product.</li> <li>The PMU shall have controls in place to prevent product release and service delivery until planned arrangements have been satisfactorily completed.</li> </ul>		

## 4.14. Equipment

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>The PMU shall ensure that the equipment used for monitoring and measurement is: <ul style="list-style-type: none"> <li>Regularly inspected and maintained, and that all equipment is calibrated as per documented requirements.</li> <li>Adjusted or re-adjusted when necessary and documented accordingly.</li> <li>Identified with their calibration status.</li> <li>Protected from damage or deterioration during use or storage.</li> </ul> </li> <li>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.</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

## 4.15. Storage, handling, packaging, and transportation

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>The PMU shall ensure that its warehousing facilities are adequate to prevent damage or deterioration of the product during storage.</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>The PMU shall have procedures for handling that prevents damage to the products.</li> <li>The PMU shall have good housekeeping procedures.</li> <li>The PMU shall label packaging and/or pallets with a batch number and ensure that the product designations are clear and unambiguous.</li> </ul>		

## 4.16. Occupational, health and safety (OH&S)

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>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.</li> <li>The PMU shall have a system for identifying hazardous raw materials, where relevant.</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

## 4.17. Records

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>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.</li> <li>The records shall remain legible, readily identifiable, traceable and retrievable.</li> <li>The PMU shall have an established documented procedure to define the controls needed for the identification, storage, protection,</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

Requirements	Evidence sighted	Conforms
retrieval, retention time and disposition of records.		

## 4.18. Complaints

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>The PMU shall have an effective arrangement for communicating with customers, including seeking customer feedback and handling complaints.</li> <li>The PMU shall keep a register of any complaints received and that the associated corrective and preventive actions carried out are satisfactory. The complaints shall be dealt with in a timely and effective manner.</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other

## 4.19. Internal product audits

Requirements	Evidence sighted	Conforms
<ul style="list-style-type: none"> <li>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: <ul style="list-style-type: none"> <li>Build and design standard.</li> <li>Labelling.</li> <li>Installation instructions</li> <li>Technical manuals.</li> <li>Manufacturing records.</li> <li>Manufacturing process.</li> </ul> </li> <li>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.</li> <li>The extent and frequency of internal audits shall be determined by the PMU.</li> <li>The test procedures / requirements shall be reviewed as part of the audit to review the inspection criteria.</li> </ul>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Other



## 4.20. Other observations



## 5. Conclusion

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## Appendix A Document review

Version: 1

Issued date: 23-May-2025

Authorised by: Kai Loh

Document version no:	Issued date:	Change description:
1	23-May-2025	<ul style="list-style-type: none"><li>Initial issue</li></ul>