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Prepared by	Alan Bruce
Checked by	Shane Salmon
Approved by	Peter Smyth

CME DEPARTMENT

SAFETY MANAGEMENT STANDARD

CME-SMS-009

Approval for the supply of Safety Critical Components, Safety Related components, and contracted safety critical services.

This CME Departmental Standard sets out the obligations for the Control of Safety Critical Components, Safety Related components, and contracted safety critical services within the CME Department.

This CME Department Standard is mandatory.

The principles in this Standard are approved by the Head of Department and therefore constitute mandatory standard practices, which apply throughout the CME Department.

A handwritten signature in black ink, appearing to read "Peter Smyth".

Signed

Chief Mechanical Engineer

This standard, along with all CME Department Standards, is available on the CME Website. Electronic copies of the Standards are controlled and live. Holders of printed copies of the Standard are responsible themselves for ensuring that they have the most up to date version as appropriate.

This is a Controlled Document, as presented on-line. It

is Uncontrolled if printed, unless identified as a

"Controlled Copy".

(as per CME-QMS-002 Manual)

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Standard Revision History:

When amending a standard, the changes made should be summarised in the table below.

Issue Number	Date of Issue	Summary of Changes
1.0	01/07/2010	Initial Version
2.0	11/03/2011	Second Version – Complete re-write of section 4.0
3.0	08/10/2013	Section 2.0 – CME Definitions updated. Section 3.0 – Accountabilities & Responsibilities updated to reflect the split of Engineering with CME reporting to the Railway Undertaking (RU). Section 4.0: 4.1 & 4.2 added to clarify accountabilities & responsibilities, 4.3 updated to clarify control of safety critical equipment and requirements for certificates of conformance, 4.5.5 added, 4.3.4 extended through 4.3.4.1 – 4.3.4.4 (replacing previous section 4.4.4 & 4.4.5) to clarify ongoing control of safety critical equipment and associated supplier approvals, 4.3.5, 4.3.6 & 4.3.7 added, 4.3.8 replaces previous sections 4.4.6 Appendix 1: Updated Appendix 3: AFUR (material setup) form added. Appendix 4: AFUR (material amendment) form added.
4.0	24/02/2016	Integration of RU Procurement team with IM Procurement team, thereby removing RU procurement from RU SMS and replacing with references to the New Integrated Procurement department and the Chief Procurement officer as specifically described in CME-CRF-046.
5.0	12/07/2017	Complete review and rewrite of SMS 009 to resolve issues raised in Derogation Form Ref no: RU SMS 003 F1 and to Comply with ECM Regulation no: 445/2011
6.0	31/08/2018	Paragraph 1.1.1 amended, new reference made to CIE Group Procurement Policies and Procedures. Paragraph 1.3.2 amended New definition 2.2 –“Competent Authority”. Paragraph 4.1 amended, “Manager RU Stores, Materials and Fuel Distribution” changed to “Manager Stores & Materials, RU”. New paragraph 4.3.7 with responsibility of the Supplier Assurance Coordinator. Paragraph 4.4.2 amended; new reference made to CME-QMS-010-002. New section 4.4.4 –“Approval of Services”. Paragraphs 4.4.4, 4.4.4.1 and 4.4.4.2 changed to 4.4.3.4 – 4.4.3.6. Reference to CME-TMS-316 removed and replaced with Supplier Assurance Coordinator’s audit report in these paragraphs (as per CME-CRF-2017-013). Section 4 of Scoring Matrix for Vendor Surveillance Audit (section 4.8.4.1). Change from numerical value to percentage value of quality issues. New Scoring Matrix also added. Appendix 4 amended with a new flow chart. New Appendix 6.
7	29.08.2025	Complete rewrite due to a change in the definition of safety critical components as out lined in PD CEN/TR 17696:2021. Also including updates of regulation for E.C.M. - COMMISSION IMPLEMENTING REGULATION (EU) 2019-779 of 16 May 2019 COMMISSION DELEGATED REGULATION (EU) 2018-762 establishing common safety methods on safety management system.

1 Policy, Scope, and Principles

1.1 Policy

- 1.1.1 Iarnród Éireann, by way of the CIE Group Procurement Policies and Procedures Document, operates a policy of clear control and management for approval to supply Safety Critical Components, Safety Related components, and contracted safety critical services, including other contracted services, as required.

Note: Train cleaning services are not considered as part of the requirements of this standard.

- 1.1.2 Suppliers of Safety Critical Components, Safety Related components and contracted safety critical services to Iarnród Éireann must comply with all relevant Iarnród Éireann standards.
- 1.1.3 Suppliers of Safety Critical Components, Safety Related components and contracted safety critical services must ensure that compliance to this and other relevant Iarnród Éireann standards is maintained throughout the course of their supply of such components or services to Iarnród Éireann.

1.2 Scope

- 1.2.1 This standard covers the supply of Safety Critical Components, Safety Related components and contracted services which are deemed to be Safety Critical, or safety related for all Iarnród Éireann Rolling Stock.
- 1.2.2 This Standard describes the obligations that external suppliers must achieve and maintain to demonstrate an appropriate level of competency and control of the supply of these requirements to Iarnród Éireann.

1.3 Principles

- 1.3.1 This standard defines the process by which supplier approval must be demonstrated and achieved and maintained during any contractual period.
- 1.3.2 Original Equipment Manufacturer (OEM) Suppliers of Safety Critical **components** are considered to be an approved supplier under this standard for the replacement or repair of systems and equipment where the supplier is regarded as the OEM or system authority. For example, the OEM brake system supplier for a train would be approved to supply or repair all the brake system components.
- 1.3.3 Original Equipment Manufacturer (OEM) Suppliers of Safety Critical services are considered to be an approved supplier under this standard for the replacement or repair of systems and equipment where the supplier is regarded as the OEM or system authority. For example, the OEM brake system supplier for a train would be approved to install and test all the brake system components.
- 1.3.3.1 Where an OEM is using an external agent or third party to provide the services, they must demonstrate that this agent is validated under their training and competency management systems. This must be demonstrated during the tender process.
- 1.3.4 This standard details how we ensure the quality of Safety Critical components, safety related components and safety critical services using the following processes:

Qualification

- Suppliers must meet quality / safety requirements as specified in the procurement process.

Inspection

- Inspection and verification of relevant qualifications for supply of services, and Certificate of Conformance (where required) for components at point of entry.
- Inspection / testing at point of usage e.g. return to service exam.

Monitoring

- Suppliers are certified per this standard. Monitoring is conducted through running maintenance activities and reported through A3 reviews and Risk Register reviews.

2 Definitions

The Definitions for the CME Safety/Quality/Technical Management System are described in the CME Safety Management System Standard CME-SMS-001- "CME Safety Management System".

The following definitions listed below are specific to this CME Standard.

- 2.1 **Safety critical component:** These are components for which a single failure has a credible potential to lead directly to:
- any train collision or derailment of trains resulting in the death of at least one person or serious injuries to five or more persons or extensive damage to rolling stock, the infrastructure, or the environment; and
 - any other accident with the same consequences which has an obvious impact on railway safety regulation or the management of safety.
- 'Extensive damage'** means damage that can be immediately assessed by the investigating body to cost at least EUR 2 million in total. Those systems, components, or services which if they fail to function correctly, have the potential to cause an intolerable level of risk to the health and safety of people and operation of trains (CEN/TR 17696-2021).
- 2.2 **Safety Related (Relevant) Component** - These are defined as components performing safety relevant functions keeping the vehicle in a safe state and preventing a safety hazard occurring (see EN 17023:2018, Annex B).
- 2.3 **Safety Critical Worker** - means a person who performs a safety critical task in the course of the operation of a railway undertaking in a maintenance capacity, if his or her work in the operation involves installation, maintenance, repair, alteration or inspection of, railway infrastructure or trains. (RSA 2005)
- 2.4 **Safety Critical Task (for the purposes of this safety standard)** – Anyone working in a maintenance capacity, or as a supervisor of persons working in such capacity for the installation, maintenance, repair, alteration or inspection of trains, or persons involved in coupling or uncoupling trains, or performing pre-departure examination of trains.
- 2.5 **Safety Critical Services** - These are defined as services by partners, contractors or suppliers who perform any safety critical task on a rail vehicle or interact with any safety critical system.
- 2.6 **Certificate of Conformance**- is a document certified by a competent authority committing, or promising, that the supplied goods and/or services meets the agreed-upon or required specifications.
- 2.7 **Competent Authority** - The competent authority is an individual in the component or system supplier's organisation with the authority to issue a COC for the component or system they supply.

3 Accountabilities & Responsibilities

The full listing of CME Management Accountabilities & Responsibilities is shown in CME Safety Management Standard CME-SMS-001. The following Accountabilities & Responsibilities listed below are specific to this CME Standard.

3.1 The Chief Mechanical Engineer

The Chief Mechanical Engineer is the owner of this Standard and is accountable as shown in CME Safety Management Standard CME-SMS-001.

3.2 The Chief Procurement Officer

The Chief Procurement Officer is accountable for ensuring the procurement process for Safety Critical components, safety related components and safety critical services in the CME department is undertaken in accordance with the requirements of this standard to the extent that these are affected by the procurement process and procurement decisions.

This includes the related procurement activities specified by the relevant regulations for Entity in Charge of Maintenance.

- 3.2.1 The Chief Procurement Officer shall ensure that Suppliers of Safety Critical Components, Safety Related (Relevant) components and contracted safety critical services have a duty to supply the information required under this standard.

This information will be appropriately used within the procurement evaluation process. Any changes to this information during any contractual period must be notified to the C.M.E. department this is a contractual obligation for the contractor.

3.3 The Technical Manager

The Technical Manager approves the technical acceptability of Safety Critical Components, Safety Related components and contracted safety critical services such that they will perform their specified duties without introducing a Safety risk to the Iarnród Éireann railway.

3.4 The Supplier Assurance Coordinator

The Supplier Assurance Coordinator, reporting to the CME Technical Manager, is responsible for auditing suppliers of:

- safety critical components
- safety related components
- safety critical services

This is to ascertain if they achieve acceptability to supply safety critical components, safety related components or safety critical services.

- 3.4.1 The Supplier Assurance Coordinator is responsible for monitoring Quality and Performance of Suppliers of safety critical components, safety related components and safety critical services. This is achieved from feedback from through A3 reviews and Risk Register reviews. This feedback may initiate Vendor Surveillance Audits where necessary.

3.5 The Senior Fleet Technical Support (SFTS) Materials

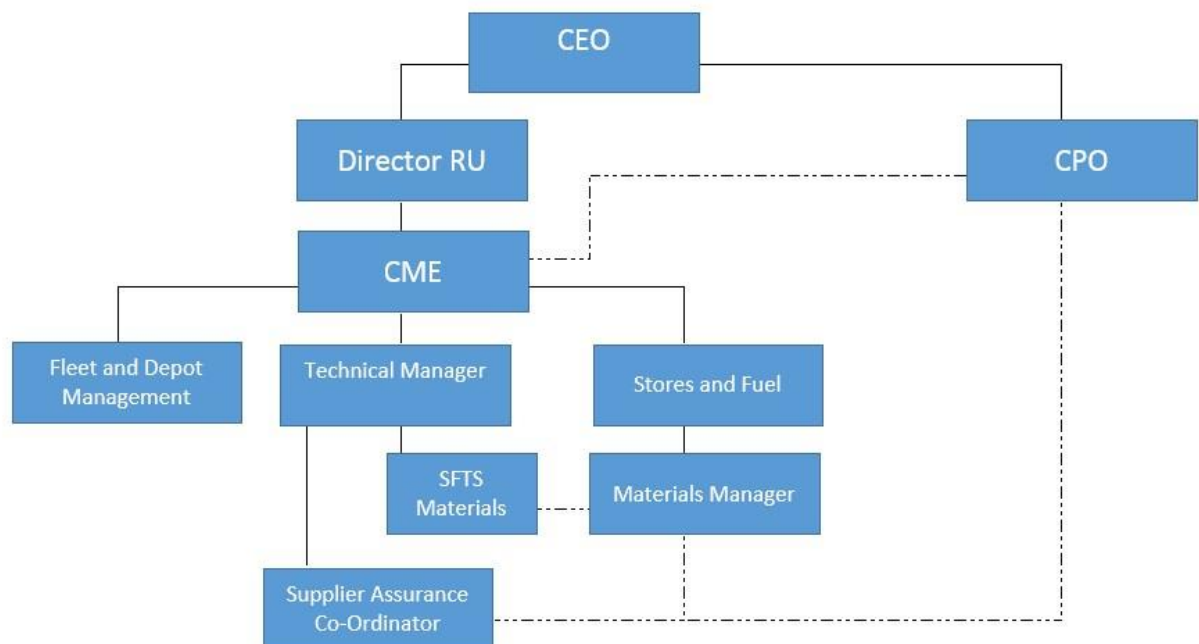
The Senior Fleet Technical Support (SFTS) Materials reporting to the CME Technical Manager, is the provider of technical support to the Materials Team when they are

purchasing safety critical components or safety related components. They are responsible for leading a cross functional team with the objectives of creating Technical Specifications, Bills of Materials and Kit Lists. The role also includes identifying new suppliers in support of the procurement process.

3.6 CME Organisation

3.6.1 For CME Organisation Chart and Roles and Responsibilities see CME-SMS-001

3.6.2 The Chart below shows the specific relationships between all parties involved in the implementation of CME-SMS-009 (Fig.1)



SMS 009 Organisation Chart

Figure 1: SMS 009 Organisation Chart

4 Implementation

4.1 Procurement Process for the supply of Safety Critical Components, Safety related Components or Safety Critical Service

- 4.1.1 Following the receipt of a request to procure a Safety Critical Component, Safety related component or Safety Critical Service, the procurement processes as set out in the standard operating procedure CPO-007 Purchase of Safety Critical requirements shall apply.
- 4.1.2 Appropriate controls to ensure the supply of the Safety Critical Components, Safety related components or Safety Critical Service's, from the appropriately selected vendor for the defined period of time shall be made available via a defined and controlled solution, such as SAP or other electronic means.

4.2 Safety Critical Components

- 4.2.1 Safety Critical Components are identified in the maintenance file for each fleet.
- 4.2.2 Safety Critical Components will be added to the SAP system from the maintenance file using the operating procedures in CME-QMS-010.

4.3 Safety Related Components

- 4.3.1 Safety Related Components will be identified by the relevant FTS team or Project team at SAP set-up.
- 4.3.2 Safety Related Components will be added to the SAP system using the operating procedures in CME-QMS-010.
- 4.3.3 Safety Related Components identified as needing CME-SMS-009 approval will be identified in the technical specifications by the Fleet Technical support teams, the project teams or the Bogies and Wheelsets FTS.

4.4 Control of Components

- 4.4.1 These components will be maintained by the Materials, Stores and Distribution Manager in the SAP MM System.
- 4.4.2 Safety Critical and related components must be stored as per OEM/Manufacturer's instructions where supplied.

4.5 The Supplier Assurance Coordinator

- 4.5.1 The Supplier Assurance Coordinator may audit, or arrange an audit of, suppliers of:
 - Safety critical components identified in the maintenance file,
 - Safety related components identified in technical specifications that meet the criteria of components that require CME-SMS-009 approval.
 - Contracted services who perform any safety critical task on a rail vehicle or interact with any safety critical system.

The purpose of the audit process is to ascertain if they are technically acceptable to supply these components or services for the contracted purpose.

- 4.5.2 The Supplier Assurance Coordinator will issue a formal approval certificate to the procurement department for suppliers following a satisfactory approval of the supplier's capabilities to supply safety critical components, safety related components or safety critical services.

The certificate will follow the format set out in Appendix 1. The Supplier Assurance Coordinator will maintain a register of supplier approval certificate issued and effective dates.

- 4.5.3 In exceptional circumstances where a full certificate cannot be issued to a supplier, a provisional certificate can be issued based on appropriate documentation being submitted and approved.

Note: The CME reserves the right to change suppliers at short notice where required in order to maintain the supply chain of safety critical and safety related parts and components.

- 4.5.4 Monitoring of Quality and Performance of Suppliers of safety critical components, Safety related components and safety critical services is conducted through running maintenance activities and reported through A3 reviews and Risk Register reviews.

- 4.5.5 Should continuous performance issues or a major quality issue be observed, an improvement plan will be sought. Continuous issues or a major quality issue may result in removal of the CME-SMS-009 certification.

4.6 Approval of suppliers of safety critical components and safety related components

- 4.6.1 The Technical Manager CME will approve the acceptability of safety critical components and safety related components such that they have been demonstrated to perform as intended without introducing a safety risk to the Iarnród Éireann railway.

The following is taken into consideration when approving the provision of safety critical components and safety related components:

- That the same safety critical components and/or safety related components has been approved for use in a similar application with similar operating conditions by a recognised approvals body for the appropriate industry standing.
- That the Safety Critical Components, Safety related components satisfy the requirements set out in the applicable international standards (e.g. TSI, EN, ISO, GMRT, UIC, EU Regs etc.).
- That the safety critical component and/or safety related components may satisfy either of the two conditions above or by any additional auditing, testing, assessment, verification, validation, and certification of the said components that may be required by the Technical Manager CME.
- The Technical Manager CME will ensure that the technical assessment of safety critical component and safety related components is transparent, documented and recorded with clear reasoning. Technical approval will be documented on SharePoint using the outcome of Supplier Assurance Coordinators audit report.

4.7 Approval of suppliers of safety critical services

- 4.7.1 When procuring services to conduct work on trains or train systems, it is essential that contracted staff are suitably qualified and competent to perform their duties safely and effectively.
- 4.7.2 External companies providing safety critical services are required to have a system for managing the competence of staff undertaking safety critical work on rail vehicles.

The following is taken into consideration when approving the provision of safety critical services:

- That companies have a proven and recognised safety, quality and competence management system in place.
- The Supplier Assurance Coordinator will audit the external companies' safety and quality management systems, and particularly the competence management system (CMS) which sets out the requirements for the competence of staff undertaking safety critical tasks on rail vehicles per the requirement of relevant directive (EU 2018-762 Establishing common safety methods on safety management system).
- The Technical Manager will ensure that the assessment of external companies that supply Safety Critical Service's is transparent, documented and recorded with clear reasoning. Approval will be documented on SharePoint using the outcome of Supplier Assurance Coordinators audit report.

4.7.3. Following the completion of a successful audit a Supplier Approval Certificate will be issued. The certificate will be passed to the procurement team confirming the approval of the contractor or service provider.

4.7.4 Prior to commencement of works, an assessment will be required to ensure contracted staff are suitably qualified and competent to perform the works required by the person procuring the service. This must also involve a training needs analyses to ensure staff are competent to work on specific trains or train systems.

4.7.5 Continuous competence management may be required to ensure that workers maintain the required skills and knowledge throughout the duration of the contracted works. This may involve regular assessments, training updates, and performance evaluations to verify competency levels. This must be provided for and demonstrated by the service provider.

Note: For some contracted services, IÉ Competence management may be required. This must first be discussed and agreed with the CME Competency Manager.

4.7.6 The person(s) responsible for procuring the required service is accountable for ensuring that the individuals provided to supply safety critical services on a rail vehicle meet the required competencies for the specific tasks. They are also responsible for ensuring the competency of those engaged in the contracted service is maintained during the term of the service for which they are engaged.

This can be achieved by:

- Review the C.V.'s for the specific individuals who will undertake the safety critical tasks to verify that they have the appropriate skills and competence to complete the specific tasks safely.
- Confirming the contractor has a current supplier assurance certificate.
- Checking the competency matrix of the contractor to verify the individual is competent for the task.

4.7.7 All contractors who have first been approved to conduct safety critical services on train or train systems as per CME-SMS-009 must then be managed in accordance with CME-SMS-005 Contractors and Permits to Work at the location where the works will take place.

4.8 Certificates of conformance (Traceability)

A Certificate of conformance (C.O.C) is a document certified by a competent authority committing, or promising, that the supplied goods and/or services meets the agreed-upon or required specifications.

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This document should accompany any delivery of any safety critical component or safety related component identified as needing a certificate.

- 4.8.1 Appendix 2 contains information and guidance on the requirement for certificates of conformance.
- 4.8.2 For Guidance on what may be included on a certificate of Conformity please refer to Appendix 3.
- 4.8.3 The Manager Materials, Stores and Distribution shall ensure:
- That stores staff are briefed on the appropriate documentation which should accompany Safety Critical components and safety related components. (Certificates of Conformance).
 - Stores staff will check for the presence of this documentation before releasing goods from Quality control. See Appendix 4 Process Flow Chart for Goods Inwards.
 - Certificates of Conformity are retained for records and verification purposes and are available when required by the technical manager
- 4.8.4 Suppliers who do not supply appropriate documentation will be advised in writing that they may have their approval withdrawn.
- 4.8.5 Non-conforming products delivered or found by Iarnród Éireann will be handled as per:
- CME-QMS-012 CME Stores Operations Manual

End of Standard.

Appendix 1 Supplier Approval Certificate



The certificate is enclosed in a decorative green border with a repeating pattern. At the top center is the logo for Iarnród Éireann (Irish Rail), consisting of a stylized 'I' made of two overlapping triangles (one green, one orange) followed by the text 'Iarnród Éireann' and 'Irish Rail' below it. Below the logo, the text 'C.M.E. Department' is centered. The main title 'Certificate Of Approved Supplier' is centered in a large, bold, green font. Below this, the word 'NAME' is centered in a blue font, followed by four lines for 'Address 1', 'Address 2', 'Address 3', and 'Address 4', all in blue. A paragraph of green text states: 'Has been assessed and approved in accordance with the requirements of CME-SMS-009 – "Supply, Overhaul, Storage and Contract Management of Safety Critical Requirements"'. Below this is the section 'Certificate Schedule' in green, followed by 'Scope of Supply' in green, and then 'SAFETY CRITICAL COMPONENT HERE' in red. Further down, the text 'This Certificate is valid until' is in green, followed by a date format 'XX / XX / XXXX' in black. Below this are two signature lines: 'Signature Here' in red, 'Supplier Assurance Coordinator' in blue on the left, and 'Signature Here' in red, 'Technical Manager' in blue on the right. Below the signatures is 'Issued On' in green, followed by another date format 'XX / XX / XXXX' in black. At the bottom, 'Certificate Number' is in green, followed by the alphanumeric string 'C M E - S A C - X X X X' where the letters are in blue and the numbers are in red.

 Iarnród Éireann
Irish Rail

C.M.E. Department

Certificate Of Approved Supplier

NAME
Address 1
Address 2
Address 3
Address 4

Has been assessed and approved in accordance with the requirements of CME-SMS-009 – "Supply, Overhaul, Storage and Contract Management of Safety Critical Requirements"

Certificate Schedule

Scope of Supply
SAFETY CRITICAL COMPONENT HERE

This Certificate is valid until
XX / XX / XXXX

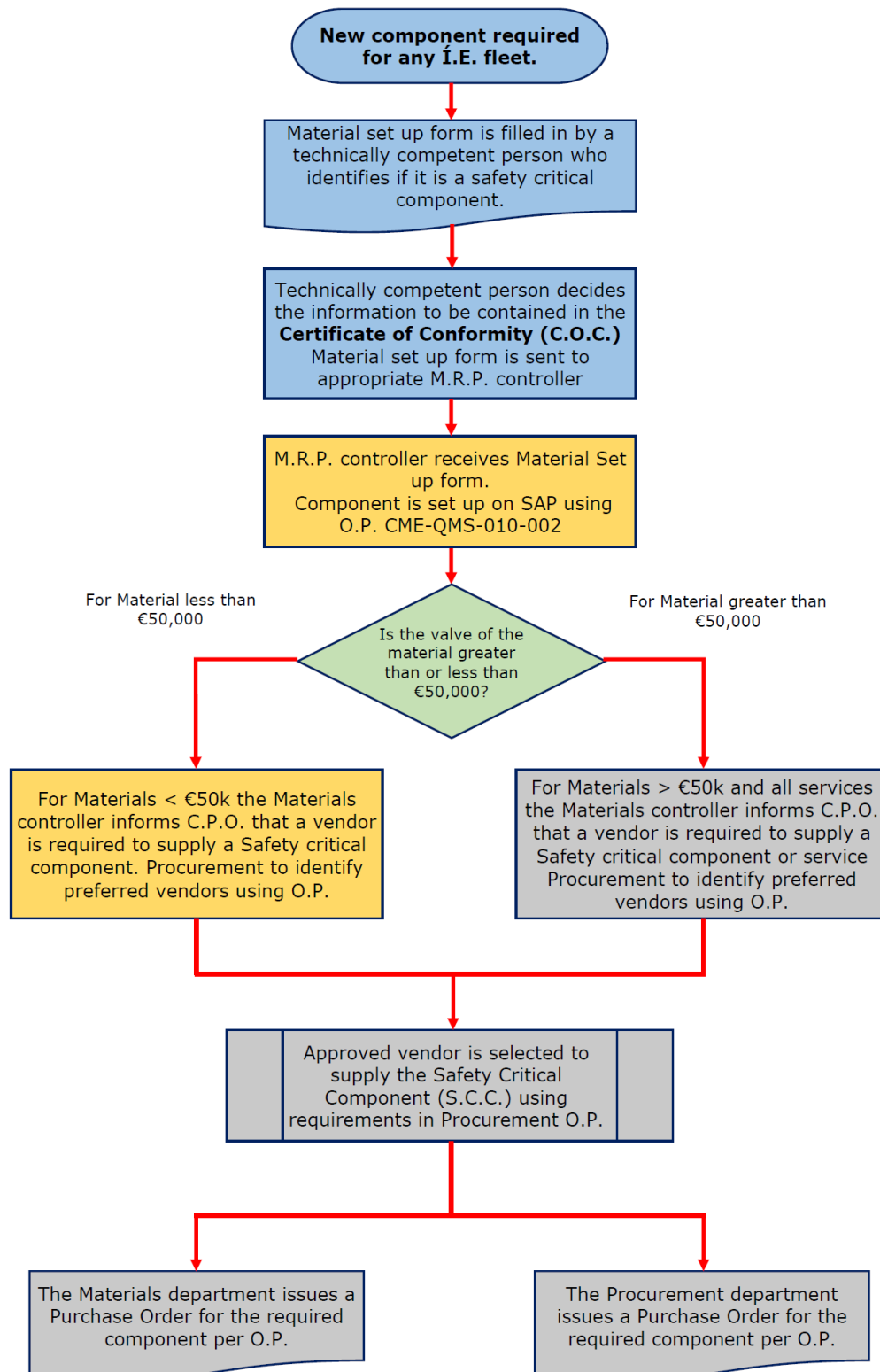
Signature Here
Supplier Assurance
Coordinator

Signature Here
Technical Manager

Issued On
XX / XX / XXXX

Certificate Number C M E - S A C - X X X X

Appendix 2: Process Flow Chart for the Procurement of Safety Critical Requirements



Appendix 3 Guidance Note on Certificate of Conformity

Guidance Note on Certificate of Conformance

The basic definition of a Certificate of Conformance is straightforward:

“It is a document certified by a competent authority committing or promising that the supplied good or service it covers meets the agreed-upon or required specifications.”

The Certificates of Conformance promise that the process itself was done in compliance with certain standards (ISO, EN, GMRT, UIC, and TSI).

Process

When a technically competent person sets up a new component they must decide if the item is to be deemed a safety critical component. Once the item is identified as a S.C.C. a Certificate of Conformance is required. The competent person will list the requirements for inclusion on the C.O.C. The Material set up form is forwarded to M.R.P. controller to be set up on S.A.P.

The following should be considered for inclusion:

- ☐ Certificate should be on Vendors Headed Paper
- ☐ Vendor Name
- ☐ Vendors Address
- ☐ Vendors Telephone Number
- ☐ Vendors E-mail address
- ☐ Vendors Order Number
- ☐ Vendors Part Number
- ☐ Vendors Quality control representative's signature
- ☐ Í.E. - P.O. Number
- ☐ Í.E – S.A.P. Number
- ☐ Component Description
- ☐ Component/material Serial Number
- ☐ Date of Manufacture
- ☐ Date of overhaul/repair
- ☐ The identification of the specification/drawing to which the material is supplied
- ☐ Batch number if applicable
- ☐ Any agreed variation from contract
- ☐ Where appropriate, the expiry dates of limited shelf-life material

Also, specific test results may be request that are representative of proof of test criteria being achieved.

Appendix 4 Process Flow Chart for Goods Inwards

