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EV AV STANDARDS
WHAT TO AUDIT?

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Martin is the Managing Director for Omnex Europe. He is also the Director of Integrated Management Systems, a senior consultant and certified corporate trainer for Omnex Inc. As an Operations and Program (APQP) Manager, he has launched nine (9) new manufacturing and assembly plants, and is a leading SME for new production facility launches. Previously employed by Toyota in their new product development group, Martin focused on gated Program Management for new vehicle and assembly plant launches.

He is a PMI certified Project Management Professional (PMP) and maintains more than ten (10) professional certifications including certified Manager of Quality Organizational Excellence (ASQ CMQOE).

Martin is certified by the VDA and Exemplar Global as a Lead Auditor who specializes in the implementation of integrated business management systems, and continuous improvement projects for clients.

Contact Martin if wish to discuss or simply learn more about ASPICE assessments, Agile APQP and Scrum at Scale. Effective team problem solving methods and Automotive core tools with PPAP and APQP for Aerospace and Automotive product launches.

Please join Martin and Omnex Europe on LinkedIn. Share your experiences and industry knowledge with industry SMEs.

One of the key purposes of an integrated management system is to act as a preventive tool. Prevention, coupled with risk-based thinking, enables the organization to determine the factors that could cause its business management system and its processes to deviate from the planned results. Once those factors are determined, the firm can place preventive controls to minimize negative effects and make maximum use of opportunities as they arise. Auditing integrated business management systems must remain a priority for every organization.

Audits are a management tool intended to add value and isolate ineffective processes that do not achieve their intended outcomes. The organization's audit program should be carefully planned and managed to ensure that it also meets its objectives and intended outcomes. Underperforming and inefficient organizational processes must be identified by their process owners and audits are then prioritized; to ensure that improvements are planned and implemented.

An organizations' integrated business management system is often divided into three categories:

01 Customer Oriented Processes (COPs)

02 Management Oriented Processes (MOPs)

03 Support Oriented Processes (SOPs)

Because of their direct impact on overall customer satisfaction, this paper will focus on the auditing of COPs that include specific requirements and expectations of automotive OEMs and their Tier 1 suppliers.

01 **Customer Focus** *(Cl. 5.1.2 ISO 9001:2015)***: Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:**

ⓐ Customer and applicable statutory and regulatory requirements are determined, understood and consistently met;

ⓑ The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction is determined and addressed;

ⓒ The focus on enhancing customer satisfaction is maintained.

Using the organizations' own process map and its Key Performance Indicators (KPIs); process owners, top management and the audit Program owners shall prioritize the auditing of business processes that have an impact on overall customer satisfaction. These are referred to as the COPs, or customer oriented processes.

02 Design and development of products and services *(Cl. 8.3.1.1 IATF 16949:2016)*

The organization shall document its design and development process and shall focus on error prevention rather than detection. The IATF 16949 standard requirements apply to both the product and manufacturing process design and development. Is the organization's design and development process for its products and manufacturing processes truly effective? How is prevention used to mitigate high-risk concerns and to reduce the occurrence of potential failures?

03 Design and development planning *(Cl. 8.3.2 ISO 9001 / 8.3.2.1 IATF 16949)*

The organization shall ensure the design and development planning includes all affected stakeholders (interest parties) within the organization and, as appropriate, it's supply chain.

Using a multi-disciplinary approach to assess product design and manufacturing process design risks and potential alternatives. The use of DFMEA's for design responsible parties and DFA, DFM and PFMEA's for manufacturing process risk analysis is expected by automotive OEMs.

04 Review requirements for products and services *(Cl. 8.2.3.1 ISO 9001)*

The most common source of failures and complaints are a lack of understanding of functional requirements, special process characteristics and customer expectations (stated, assumed, and implied). Cl. 8.2.2 and 8.2.3.1 ISO 9001 / 8.2.2.1 and 8.2.3.1.1 IATF 16949 are key to understanding and agreeing to each of the requirements for products and services to be delivered to the customer.

Further, the ISO/IATF (QMS) standard makes it clear that without formal review and subsequent agreement of the requirements for product or services, that no party should accept nor enter into a purchase agreement. All requirements must be fully understood and accepted before the formal agreement to supply is approved and signed.

The organization's own process for the review and acceptance of customer requirements shall be audited to ensure that it is effective and can reduce business risk to an acceptable level.

This review of requirements process is driven down through the entire supply chain to ensure no party (no supplier) is forced to deliver a product or service for which the requirements and expectations have not been fully defined and accepted in writing.

There is likely no greater business risk than not knowing what the actual requirements and expectations are for products and services to be delivered.

That said, to accept a purchase order without knowing all requirements remains a business decision. A decision where the supplier then assumes the risk for failure, rejections and complaints.

Consequently, before a purchase order is given to a sub-supplier, have all relevant customer requirements and expectations been made clear and accepted by the potential supplier?

Design and development planning and the review of product requirements are both **Customer Oriented Processes (COPs).**

05 Development of products with embedded software *(Cl. 8.3.2.3 IATF 16949:2016)*

Within the scope of its audit program the organization shall use a process for ensuring quality assurance for the products with internally developed embedded software.

> **"A software development capability self-assessment, such as ASPICE** (PAM3.1), should be used to determine the risk and potential impact to the customer requirements. "

The organization shall require the same of their suppliers of automotive product-related software or automotive products with embedded software *(Cl. 8.4.2.3.1 IATF 16949:2016).*

The customer and its suppliers of embedded software must agree on the capability level of the software development process. Assessments of the software development process will confirm the project quality level and the current capability of their processes.

06 Internal audit programme *(Cl. 9.2.2.1 IATF 16949:2016)*

The organization shall document its own internal audit process including its internal audit programme objectives and methods for meeting those objectives and their intended outcomes. The internal audit programme shall prioritize audits based upon risks, internal and external issues, trends, nonconformities, customer complaints, and the criticality of processes. Management system auditing, manufacturing process audits (VDA 6.3) and product audits (VDA 6.5) shall be incorporated into the audit programme.

The effectiveness of the audit programme shall be reviewed as a part of management review. As previously mentioned, audits are a management tool intended to add value for the organization.

It cannot be stressed enough that prevention is a key driver of an effective integrated business management system. Prioritize audits for poorly performing processes and then conduct those audits with a greater focus on prevention (error-proofing cl. 10.2.4), potential risks and opportunities.

07 Problem solving *(Cl. 10.2.3 IATF 16949:2016)*

The organization shall have a documented process(es) for problem solving, that includes root cause analysis and the verification of the effectiveness of implemented corrective actions.

When nonconformities recur and complaints repeat themselves, it is clear to the auditor, and everyone else, that the process for problem-solving is ineffective. The implemented corrective actions simply need to work and prevent similar nonconformities.

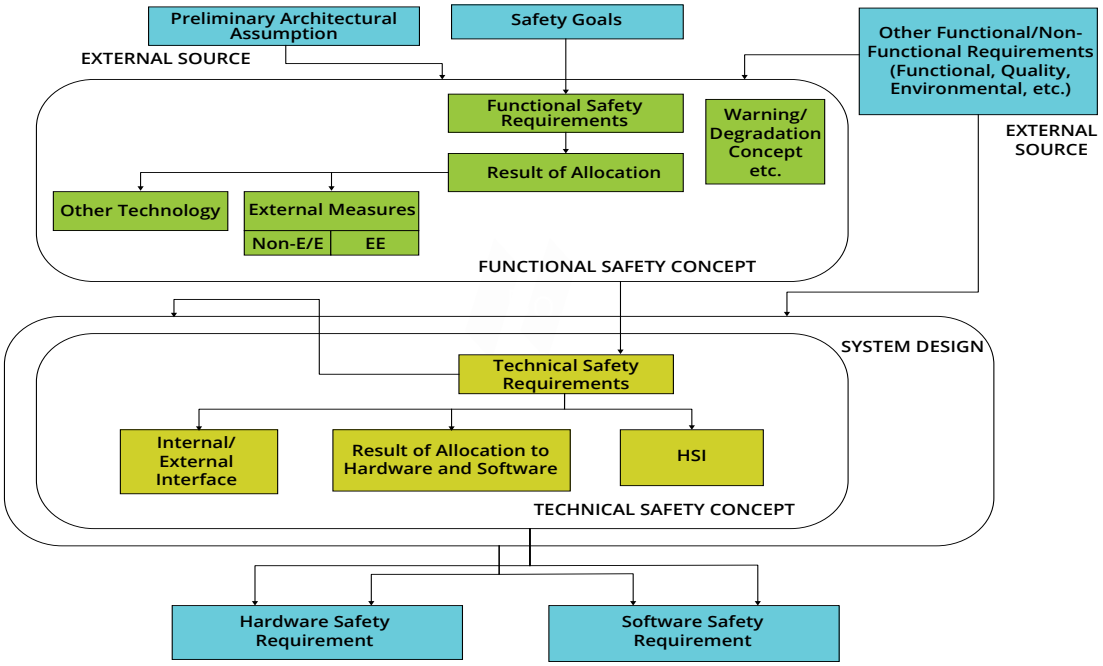
08 Auditing Functional Safety Management System (FSMS) *(ISO 26262)*

The organization shall institute, execute, and maintain organization-specific rules and processes to comply with the requirements of ISO 26262. Therefore, the audit programme for its FSMS shall include a provision to audit the new product development process to ensure it explicitly identifies and treats all safety requirements. Without an effective functional safety management system, it is likely that work products do not exist or could be noncompliant.

Safety Culture: The organization shall create, foster, and sustain a safety culture that supports and encourages the effective achievement of functional safety and there shall be evidence of an implemented ISO 9001:2015 Quality Management System.

Following the organization's **functional safety assessment** procedure, ensure the organization has competent assessors or has used external assessors to conduct a product release evaluation in concert with a safety case evaluation. Reviews can coincide with a gate review and be incorporated into the Safety Plan.

System Design and Technical Safety Concept



The Technical Safety Concept and FSC requirements are to be evaluated.
ISO 26262-4, Clause 6.

Within the system design phase, the technical safety concept (TSC) is derived. The TSC specifies how functional safety requirements (FSR) will be implemented. These technical safety requirements will indicate the partitioning of the elements between hardware and the software.

09 Information Security Management System *(ISO/IEC 27001)*

There is a direct link between contingency planning (Cl. 6.1.2.3 IATF 16949) and the implementation of an effective Information Security Management System (ISMS).
According to ISO/IEC 27001 the organization shall define and apply an information security risk treatment process to:

ⓐ Select appropriate information security risk treatment options, taking into account the risk assessment results;

ⓑ Determine all controls that are necessary to implement the information security risk treatment option(s) chosen.

The organization shall design its own controls as required or identify them from any source.

Controls established as part of the Information Security Risk Assessment (Cl. 8.2, 6.3.1) shall be regularly tested as part of the organizations' contingency plan for its IT infrastructure, information management system and its cybersecurity controls. Contingency plans for the ISMS shall be part of the internal audit programme (Cl 9.2). The organization is obligated to keep customer information and its own data secure from intrusion and potential loss. An ISMS to ISO/IEC 27001 is an expectation for many customers, especially automotive OEMs.

10 Conformance of products, processes, product safety, statutory & regulatory requirements.

The organization shall ensure the conformance of all products and processes, including service parts and those that are supplied by external sources (Cl. 4.4.1.1 IATF 16949). Including all customer, statutory, and regulatory requirements in the country of receipt, the country of shipment, and the customer identified country of destination (Cl. 8.4.2.2). The organization shall have a process for the management of product-safety related products, identified safety characteristics, and their manufacturing processes (Cl. 4.4.1.2).

Further, the organizations top management shall ensure that responsibilities and authority for product requirements and corrective actions is assigned to competent individuals (Cl. 5.3.2). Some automotive OEMs have a mandate to assign the role of Product Safety and Conformity Representative(s) to competent individuals within the organization. The internal audit programme must include a provision to interview persons responsible for product-safety, statutory and regulatory requirements, product conformance to ensure that they understand their role, their responsibilities, and authorities. This includes top management because of their accountability for product safety, product conformance, statutory and regulatory requirements.

Summary

This is not an exhaustive list of IMS processes to audit, rather it points to customer processes and specific sections of ISO/IATF standards, that impact the development and delivery of EV/AV products.

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