

How are functional safety requirements ensured throughout the production phase, and how must changes during production be handled to maintain compliance?

Functional safety requirements are ensured throughout the production phase by a combination of thorough planning, stringent process controls, capability evaluations, and adherence to approved configurations.

The primary objective during the production phase is to achieve functional safety by the relevant manufacturer or organization responsible for the production of items and elements (ISO26262-7:2018 Clause 6.1). This necessitates compliance with all safety-related special characteristics of items or elements during their production (ISO26262-7:2018 Clause 5.2, ISO26262-10:2018 Clause 14.1).

To achieve this, the following steps and requirements are mandated:

- **Planning:** The production process for the item and its elements must be planned (ISO26262-7:2018 Clause 5.4.1.1). This planning must consider production requirements, safety-related special characteristics, handling and management conditions for elements, configurations defined during product development, lessons learned, suitability of equipment and tools, and personnel competence (ISO26262-7:2018 Clause 5.4.1.1). The safety-related content of this production plan is a prerequisite for the production phase (ISO26262-7:2018 Clause 6.3.1).
- **Implementation and Control:** The planned production process and its control measures must be implemented and maintained (ISO26262-7:2018 Clause 6.4.1.1). The production process, including deviations of safety-related special characteristics, must be analyzed to identify process failures, potential effects on functional safety, and to implement and verify the effectiveness of appropriate avoidance or mitigation measures (ISO26262-7:2018 Clause 6.4.1.2). Controls, as defined in the production control plan, must be performed and documented in a control measures report (ISO26262-7:2018 Clause 6.4.1.5, ISO26262-7:2018 Clause 6.5.1). Only approved configurations, as defined in the release for production report, are permitted to be produced unless explicitly authorized (ISO26262-7:2018 Clause 6.4.1.6).
- **Capability Evaluation:** The capability of the production process, equipment, tools, and test equipment must be evaluated and maintained with regard to functional safety (ISO26262-7:2018 Clause 6.4.1.3). Test equipment specifically must be controlled in accordance with the applied quality management system (ISO26262-7:2018 Clause 6.4.1.4). A production process capability report is a work product of this activity (ISO26262-7:2018 Clause 6.5.2).
- **Organizational Responsibilities:** Organizations must appoint persons with responsibility and authority to achieve and maintain functional safety during production (ISO26262-2:2018 Clause 7.4.2.1). Activities for ensuring functional safety during production must be planned according to ISO 26262-7:2018, Clause 5, initiated during product development at the system level (ISO 26262-4), and executed according to ISO 26262-7:2018, Clauses 6 and 7 (ISO26262-2:2018 Clause 7.4.2.2). Requirements for production, including measures to achieve, maintain, or restore safety-related functions and properties, safety-related special characteristics, identification requirements, and verification measures, must be specified during system architectural design (ISO26262-4:2018 Clause 6.4.8.1).

To maintain compliance, changes initiated during the production phase must be handled as follows:

- **Change Management Process:** Changes to the production process must be managed in accordance with the requirements in ISO 26262-8:2018, Clause 8 (ISO26262-7:2018 Clause 6.4.1.7).

- **Release for Production Update:** If the item changes during production, the release for production (ISO26262-2:2018 Clause 6.4.13) must be updated accordingly. These changes are subject to change management (ISO26262-2:2018 Clause 7.4.2.4).

**Additional list of ISO 26262 clauses used:**

- ISO26262-2:2018 Clause 6.4.13
- ISO26262-2:2018 Clause 7.4.2.1
- ISO26262-2:2018 Clause 7.4.2.2
- ISO26262-2:2018 Clause 7.4.2.4
- ISO26262-4:2018 Clause 6.4.8.1
- ISO26262-7:2018 Clause 5.2
- ISO26262-7:2018 Clause 5.4.1.1
- ISO26262-7:2018 Clause 6.1
- ISO26262-7:2018 Clause 6.3.1
- ISO26262-7:2018 Clause 6.4.1.1
- ISO26262-7:2018 Clause 6.4.1.2
- ISO26262-7:2018 Clause 6.4.1.3
- ISO26262-7:2018 Clause 6.4.1.4
- ISO26262-7:2018 Clause 6.4.1.5
- ISO26262-7:2018 Clause 6.4.1.6
- ISO26262-7:2018 Clause 6.4.1.7
- ISO26262-7:2018 Clause 6.5.1
- ISO26262-7:2018 Clause 6.5.2
- ISO26262-10:2018 Clause 14.1

Correctness = 5P

Completeness = 3.5P,

-0.5P More in depth mention of Clause 5 would be beneficial, about how individual functional safety requirements are maintained through the production process.

-1P Only high-level mention of change management; insufficient depth.