ISO22163:2023

铁路行业应用--铁路质量管理体系：ISO9001:2015 及应用于铁路行业的特殊要求

Railway applications — Railway quality management system — ISO9001:2015 and specific require mentsfor application in the railway sector

1 范围

本标准为下列组织规定了质量管理体系要求：

a）需要证实其具有稳定提供满足顾客要求及适用法律法规要求的产品和服务的能力；

b）通过体系的有效应用，包括体系改进的过程，以及保证符合顾客要求和适用的法律法规要求，旨在增强顾客满意。

本标准的所有要求是通用的，旨在适用于各种类型、不同规模和提供不同产品和服务的组织。

注 1：在本标准中，术语“产品”或“服务”仅适用于预期提供给顾客或顾客所要求的产品和服务；

注 2：法律法规要求可称作法定要求。

1.1 范围 - 补充

本文件定义了轨道部门（RQMS）的质量管理体系要求

- 适用于铁路工业相关产品的整个供应链，用于设计开发，制造和维护活动（不包括铁路运营和运输服务）
- 提供持续改进，强调供应链中的缺陷预防和缺陷减少
- 增强和维持产品质量，包括其安全性。

1.1 Scope — Supplemental

This document specifies the requirements for a railway quality management system (RQMS)

— applicable throughout the whole supply chain of the railway sector related to industrial products and services,

— providing continual improvement, emphasizing defect prevention and defect reduction in the supplychain, and

— enhancing and sustaining product quality, including its safety aspects.

2 规范性引用文件

下列文件对于本文件的应用是必不可少的。凡是注日期的引用文件，仅注日期的版本适用于本文件。凡是不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

ISO9000:2015 质量管理体系基础和术语

3 术语和定义

ISO9000:2015 界定的术语和定义适用于本标准。

在本文件中，适用以下术语和定义。

3.1 术语和定义

3.1 术语和定义

3.1.1 系统

3.1.1.1

业务连续性

在中断期间，组织在可接受的时间范围内以预定义的能力继续交付产品和服务的能力

[来源:iso 22301：2019,3.3]

3.1 Terms and definitions
3.1.1 System
3.1.1.1
business continuity
capability of an organization to continue the delivery of products and services within acceptable time frames at predefined capacity during a disruption
[SOURCE: ISO 22301:2019, 3.3]

3.1.1.2
业务连续性计划
指导组织应对中断并重新开始、恢复和还原符合其业务连续性目标的产品和服务交付的文件化信息
[来源:iso 22301：2019,3.4]
3.1.1.2
business continuity plan
documented information that guides an organization to respond to a disruption and resume, recover and restore the delivery of products and services consistent with its business continuity objectives
[SOURCE: ISO 22301:2019, 3.4]

3.1.1.3
配置审计
根据文件化信息进行审核，以确定产品和服务是否符合其要求和配置信息(3.1.1.5)
[来源:iso 10007：2017,5.6]
3.1.1.3
configuration audit
audit performed in accordance with documented information to determine whether a product or service conforms to its requirements and configuration information (3.1.1.5)
[SOURCE: ISO 10007:2017, 5.6]

3.1.1.4
配置基线
已批准的配置信息(3.1.1.5)，确定产品或服务在某一时间点的特征，作为产品或服务整个生命周期活动的参考。
[来源:iso 10007：2017,3.2]
3.1.1.4
configuration baseline
approved configuration information (3.1.1.5) that establishes the characteristics of a product or a service at a point in time that serves as reference for activities throughout the life cycle of the product or service
[SOURCE: ISO 10007:2017, 3.2]

3.1.1.5
配置信息
产品或服务的设计、实现、验证(3.1.3.12)、运行和支持要求
[来源:iso 10007：2017,3.5]
3.1.1.5
configuration information

requirements for product or service design, realization, verification (3.1.3.12), operation and support
[SOURCE: ISO 10007:2017, 3.5]

3.1.1.6
配置状态记录
正式记录和报告配置信息(3.1.1.5)，建议的状态变更和已批准变更的实施情况
[来源:iso 10007：2017,3.4]
3.1.1.6
configuration status accounting
formalized recording and reporting of configuration information (3.1.1.5), the status of proposed changes and the status of the implementation of approved changes
[SOURCE: ISO 10007:2017, 3.4]

3.1.1.7
关键
临界
基于风险评估，具有引入可能威胁质量、安全或业务绩效的高风险的潜力的特性
3.1.1.7
critical
criticality
characteristic having the potential of introducing high risks that can threaten quality, safety or business performance, based on a risk assessment

3.1.1.8
信息安全
保持信息的保密性、完整性和可用性
注 1:此外，其他属性，如真实性、可问责性、不可否认性和可靠性也可能涉及。
注 2:信息安全包括网络安全。
[来源:ISO/IEC 27000:2018，3.28，修改-已添加注 2。]
3.1.1.8
information security
preservation of confidentiality, integrity and availability of information
Note 1 to entry: In addition, other properties, such as authenticity, accountability, non- repudiation, and reliability can also be involved.
Note 2 to entry: Information security includes cybersecurity.
[SOURCE: ISO/IEC 27000:2018, 3.28, modified — Note 2 to entry has been added.]

3.1.1.9
多方论证方法
在一个团队中涉及不同职能和专业知识的特定主题的工作方式
例：工程、安全和采购。
3.1.1.9
multidisciplinary approach
way of working involving different functions and expertise in one team on a specific subject

EXAMPLE Engineering, safety and procurement.

3.1.1.10
过程拥有者
负责过程的定义、应用、绩效和改进，以实现由绩效指标衡量的目标，并有权和有能力进行必要更改的人员
3.1.1.10
process owner
person who has the responsibility for the definition, application, performance and improvement of a process in realizing its objectives measured by performance indicators, and has the authority and ability to make necessary changes

3.1.1.11
安全
免受不可接受的伤害风险
[来源:iec 62278：2002,3.35]

3.1.1.11
safety
freedom from unacceptable risk of harm
[SOURCE: IEC 62278:2002, 3.35]

3.1.1.12
安全完整性等级
SIL
若干已定义的安全完整性独立等级，用于指定分配给安全(3.1.1.11)相关系统的安全功能的安全完整性要求。
[来源:iec 62278：2002,3.38]
3.1.1.12
safety integrity level
SIL
one of a number of defined discrete levels for specifying the safety integrity requirements of the safety functions to be allocated to the safety (3.1.1.11) related systems
[SOURCE: IEC 62278:2002, 3.38]

3.1.1.13
安全相关
承担安全责任(3.1.1.11)
[来源:iec 62425:2007，3.1.54]
3.1.1.13
safety-related
carries responsibility for safety (3.1.1.11)
[SOURCE: IEC 62425:2007, 3.1.54]

3.1.1.14

场所
从事与工业产品和服务有关的活动的组织所在地。
3.1.1.14
site
location of an organization, having activities related to industrial products and services.

3.1.1.15
供应链
为顾客转化产品或服务中的材料和知识所涉及的组织、人员、活动、信息和资源的系统。
3.1.1.15
supply chain
system of organizations, people, activities, information and resources involved in transforming materials and knowledge in a product or a service for the customer.

3.1.2 过程
3.1.2 Process
3.1.2.1
调试
在向顾客移交(3.1.2.8)之前的阶段，在运行条件下对产品进行测试，以验证其功能符合产品规格
注 1:产品准备开始运行。
3.1.2.1
commissioning
phase before handover (3.1.2.8) to a customer, in which a product is tested under operational conditions to verify that it functions according to its specifications
Note 1 to entry: The product is then prepared to start operation.

3.1.2.2
关键路径
确定项目(3.1.2.18)或阶段最早可能完成日期的一系列活动。
[来源:iso 21502:2020, 3.8]
3.1.2.2
critical path
sequence of activities that determine the earliest possible completion date for the project (3.1.2.18) or phase
[SOURCE: ISO 21502:2020, 3.8]

3.1.2.3
延期的工作
在一个被推迟或推迟的过程中，作为预定顺序的一部分的活动。
3.1.2.3
deferred work
activity which is part of a predetermined sequence in a process that is delayed or postponed.

3.1.2.4
首件检验
FAI

为验证生产(3.1.2.16)过程而进行的一组检验和验证(3.1.3.12)活动
3.1.2.4
first article inspection
FAI
set of inspection and verification (3.1.3.12) activities in order to validate a production (3.1.2.16) process.

3.1.2.5
门的标准
可交付成果的验收标准(3.1.4.3)，以支持将要做出的决定，例如接受、有条件地接受或拒绝。
3.1.2.5
gate criteria
acceptance criteria for deliverables (3.1.4.3) at gates in order to support the decisions to be taken, e.g. accepted, conditionally accepted or rejected.

3.1.2.6
门方法
项目管理实践，在每个重要阶段结束时，利用适当的风险评估和缓解计划，评估可交付成果(3.1.4.3)的成熟度，以便进入下一阶段
注 1:两个阶段之间的过渡由控制里程碑形式化。
3.1.2.6
gate methodology
project management practice to evaluate, at the end of each significant phase, the maturity of deliverables (3.1.4.3) for moving to the next phase, with the proper risk assessment and mitigation plan.
Note 1 to entry: The transition between two phases is formalized by control milestones.

3.1.2.7
良好的实践
已被证明行之有效、成功实现其目标的过程或方法得到认可，因此可以作为一种方法加以推荐
3.1.2.7
good practice
process or method that has been shown to work well, succeeds in achieving its objective(s), is acknowledged and therefore can be recommended as an approach

3.1.2.8
交接
将产品的控制权从一个组织转移到另一个组织，包括将责任转移到接收组织
3.1.2.8
handover
passing control authority of the subject item from one organization to another, including transfer of responsibilities to the receiving organization

3.1.2.9
安装
在客户现场交付后和调试前的阶段(3.1.2.1)。
注 1:安装是基础设施活动的一个典型阶段。

3.1.2.9
installation
phase after delivery at customer premises and prior to commissioning (3.1.2.1)
Note 1 to entry: Installation is a typical phase of infrastructure activities.

3.1.2.10
生命周期成本
LCC
在产品的生命周期内产生的成本的总和
注 1:对于物品的使用者或所有者，总生命周期成本只能包括与获取、运行、维护(3.1.2.12)和处置有关的成本。
[来源:en 13306：2017,11.1]
3.1.2.10
life cycle cost
LCC
sum of the costs generated during the life cycle of the item
Note 1 to entry: For a user or an owner of an item, the total life cycle cost may include only those costs pertaining to acquisition, operation, maintenance (3.1.2.12) and disposal.
[SOURCE: EN 13306:2017, 11.1]

3.1.2.11
生命周期成本计算
评价两个或多个备选方案的生命周期成本(3.1.2.10)之差的过程
注 1:生命周期成本核算可涉及定量和/或定性评价。
[来源:iso 15663:2021，3.1.27]
3.1.2.11
life cycle costing
process of evaluating the difference between the life cycle cost (3.1.2.10) of two or more alternative options
Note 1 to entry: Life cycle costing can involve quantitative and/or qualitative assessment.
[SOURCE: ISO 15663:2021, 3.1.27]

3.1.2.12
维护
所有技术和管理行动的组合，目的是使某项保持或恢复到能按要求执行的状态
注 1:假定管理包括监督活动。
3.1.2.12
maintenance
combination of all technical and management actions intended to retain an item in, or restore it to a state in which it can perform as required
Note 1 to entry: Management is assumed to include supervision activities.
[SOURCE: IEC 60050-192:2015, 192-06-01]

3.1.2.13
新技术
为开发和生产(3.1.2.16)从来不属于组织控制活动的产品和服务提供比现有技术有重大改进的一套技

术，这些技术可以超越现有技术水平 注
1:输入通常来源于研究或创新活动。
注 2:一项新技术可以连接到一个完整的系统，如刹车、暖通空调、电子设备。
3.1.2.13
new technology
set of techniques which offer a significant improvement over the established techniques for the development and production (3.1.2.16) of products and services which have never been part of the controlled activities of the organization, and which can be beyond the state of art
Note 1 to entry: The inputs are generally originated from research or innovation activities.
Note 2 to entry: A new technology can be linked to a complete system, e.g. brakes, HVAC, electronics.

3.1.2.14
检修
为维持某一项目所要求的性能水平而实施的一套全面的预防性维护(3.1.2.15)措施
注 1:修可按规定的时间间隔或操作次数进行。
注 2:修可能需要全部或部分拆卸物品。
[来源:en 13306：2017,8.6]
3.1.2.14
overhaul
comprehensive set of preventive maintenance (3.1.2.15) actions carried out, in order to maintain the required level of performance of an item.
Note 1 to entry: Overhaul may be performed at prescribed intervals of time or number of operations.
Note 2 to entry: Overhaul may require a complete or partial dismantling of the item.
[SOURCE: EN 13306:2017, 8.6]

3.1.2.15
预防性维护
进行维护(3.1.2.12)以减轻退化和降低故障概率
[来源:IEC 60050-192:2015，192-06-05，修改-条目注 1 已删除。]
3.1.2.15
preventive maintenance
maintenance (3.1.2.12) carried out to mitigate degradation and reduce the probability of failure
[SOURCE: IEC 60050-192:2015, 192-06-05, modified — Note 1 to entry has been deleted.]

3.1.2.16
生产
实现产品的活动包括安装(3.1.2.9)、调试(3.1.2.1)、检修(3.1.2.14)和维修
注 1:生产是组织价值链的一部分。
3.1.2.16
production
activities to realize products including installation (3.1.2.9), commissioning (3.1.2.1), overhaul (3.1.2.14) and repair.
Note 1 to entry: Production is part of an organization's value chain.

3.1.2.17

产品生命周期
产品从开始到设计制造、服务、维护(3.1.2.12)和处置的整个生命周期的时间
3.1.2.17
product life cycle
time of the entire life cycle of a product from inception to design and manufacture, service, maintenance (3.1.2.12) and disposal

3.1.2.18
项目
为达到某一目标而进行的独特过程
注 1:项目通常由一组有开始和结束日期的协调和控制的活动组成，进行这些活动是为了实现符合特定要求的目标，包括时间、成本和资源的限制。
注 2:单个项目可以构成较大项目结构的一部分，并且通常具有确定的开始和结束日期。
注 3:在一些项目中，随着项目的进行，目标和范围会逐步更新，产品或服务特性会逐步确定。
注 4:项目的输出可以是一个或几个产品或服务单位。
注 5:项目的组织通常是临时的，并在项目的整个生命周期内建立。
注 6:项目活动之间相互作用的复杂性与项目规模没有必然的关系。
[来源:iso 10006：2017,3.3]
3.1.2.18
project
unique process undertaken to achieve an objective
Note 1 to entry: A project generally consists of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements, including the constraints of time, cost and resources.
Note 2 to entry: An individual project can form part of a larger project structure and generally has a defined start and finish date.
Note 3 to entry: In some projects, the objectives and scope are updated and the product or service characteristics defined progressively as the project proceeds.
Note 4 to entry: The output of a project can be one or several units of product or service.
Note 5 to entry: The project's organization is normally temporary and established for the lifetime of the project.
Note 6 to entry:The complexity of the interactions among project activities is not necessarily related to the project size.
[SOURCE: ISO 10006:2017, 3.3]

3.1.2.19
项目核心团队
从不同职能部门任命人员，以支持项目经理领导和控制项目(3.1.2.18)
3.1.2.19
project core team
people from different functions appointed to support the project manager in leading and controlling the project (3.1.2.18).

3.1.2.20
项目管理
计划、组织、监视、控制和报告项目(3.1.2.18)的所有方面，以及所有参与其中的人实现项目目标的动

机。
[来源:iso 10006：2017,3.4]
3.1.2.20
project management
planning, organizing, monitoring, controlling and reporting of all aspects of a project (3.1.2.18), and the motivation of all those involved in it to achieve the project objectives.
[SOURCE: ISO 10006:2017, 3.4]

3.1.2.21
项目管理计划
指明为达到工程计划的目标所需要的文件(3.1.2.18)。
注 1:项目管理计划应包括或参照项目质量计划。
注 2:项目管理计划还酌情包括或引用其他计划，如与组织结构、资源、进度、预算、风险管理、环境管理、健康与安全(3.1.1.11)管理和安全管理有关的计划。
[来源:iso 10006：2017,3.5]
3.1.2.21
project management plan
document specifying what is necessary to meet the objective(s) of the project (3.1.2.18)
Note 1 to entry: A project management plan should include or refer to the project quality plan.
Note 2 to entry: The project management plan also includes or references other plans such as those relating to organizational structures, resources, schedule, budget, risk management, environmental management, health and safety (3.1.1.11) management and security management, as appropriate.
[SOURCE: ISO 10006:2017, 3.5]

3.1.2.22
项目组织
临时组织结构，包括需要定义并传达给项目所有相关方的项目角色、职责、权限级别和边界(3.1.2.18)
[来源:iso 10006：2017,3.6]
3.1.2.22
project organization
temporary structure that includes project roles, responsibilities and levels of authority and boundaries that need to be defined and communicated to all interested parties of the project (3.1.2.18).
[SOURCE: ISO 10006:2017, 3.6]

3.1.2.23
质量保证方法
用于确认、验证或确认需求实现的方法，以便将重点放在错误预防而不是错误检测上
失效模式和影响分析(FMEA)，失效模式、影响和关键性分析(FMECA)，质量功能部署，设计评审，有限元分析。
注 1:质量保证方法可用于，例如设计和开发。
3.1.2.23
quality assurance method
method applied to qualify, verify or validate the implementation of requirements in order to focus on error prevention rather than on error detection
EXAMPLE Failure mode and effects analysis (FMEA), failure mode, effects and criticality analysis

(FMECA),quality function deployment, design reviews, finite element analysis.
Note 1 to entry: Quality assurance method can be used, for example, in design and development.

3.1.2.24
质量缺陷成本
不合格产品、服务、工艺或设备造成的额外费用
注 1:质量缺陷成本可按原因(如投标、设计和开发、生产、采购项目管理过程中的失败)和按发生阶段(如投标、设计、生产(3.1.2.16)、交付后)区分。
注 2:质量缺陷成本可包括:
-由于不正确设计导致的故障或变更以及由此采取的措施(如返工、重新设计、维修、回购、特殊运输)所产生的额外人工、材料或其他直接成本;
-停机造成的成本;
-废料成本;
-产品无法使用或储存过剩的成本;
-因接受第三方索赔而产生的费用和因组织未对第三方提出索赔而产生的费用;
-因违约或延误而造成的罚款。
例:质量缺陷成本的一些例子包括不合格成本、不合格成本、不良质量成本、损失成本、补偿成本。
3.1.2.24
quality deficiency cost
additional costs resulting from nonconforming products, services, processes or equipment
Note 1 to entry: Quality deficiency cost can be distinguished by causes (e.g. failures in tender-, design and development-, production-, purchasing-project management processes) and by phase of occurrence (e.g. tender, design, production (3.1.2.16), post-delivery).
Note 2 to entry: Quality deficiency cost can include:
— additional labour, material or other direct costs in the context of failures or changes due to incorrect design and the resulting actions taken (e.g. rework, redesign, repair, repurchase, special shipments);
— costs due to downtimes;
— costs of scrap;
— costs of products rendered unusable or oversupply of storage;
— costs due to accepted third-party claims and costs due to claims not asserted by the organization against third parties;
— costs due to penalties for default or delays.
EXAMPLE Some examples of quality deficiency cost include nonconformity cost, cost of non-quality, cost of poor quality, lost cost, compensation cost.

3.1.2.25
项目质量计划
详细说明将应用于特定项目的行动、责任和相关资源(3.1.2.18)。
[来源:ISO 10005:2018, 3.2, 修改-术语已从“质量计划”更改为“项目质量计划”,定义中的“对象”已更改为“项目”。]
3.1.2.25
project quality plan
specification of the actions, responsibilities and associated resources to be applied to a specific project (3.1.2.18)
[SOURCE: ISO 10005:2018, 3.2, modified — the term has been changed from “quality plan” to “project

quality plan" and "object" has been changed to "project" in the definition.]

3.1.2.26
转移
将过程全部或部分(3.1.2.8)移交给内部站点(多站点组织)或外部组织。
3.1.2.26
transfer
complete or partial handover (3.1.2.8) of processes to an internal site (multi-site organizations) or an external organization.

3.1.3 要求
3.1.3 Requirement
3.1.3.1 可用性
在给定的条件下，在给定的时间或给定的时间间隔内，产品处于执行所需功能的状态的能力，假设提供了所需的外部资源
[来源:iec 60050-821:2017，821-05-82]
3.1.3.1 availability
ability of a product to be in a state to perform a required function under given conditions at a given instant of time or over a given time interval assuming that the required external resources are provided
[SOURCE: IEC 60050-821:2017, 821-05-82]

3.1.3.2 功能需求
指定产品或服务执行的功能的需求
例：铁路载重轨距，在地铁车辆中增加一节车厢的可能性。
注 1:见附件 B。
3.1.3.2 functional requirement
requirement that specifies a function that a product or a service performs
EXAMPLE Railway loading gauge, possibility to add a car in a metro vehicle.
Note 1 to entry: See Annex B.

3.1.3.3 集成要求
描述产品或服务的组成系统/子系统/组件如何与其他系统/子系统/组件接口，以执行集成功能的需求。
例：重量，外部尺寸，运动包络，电源要求，网络(通信)。
注 1:见附件 B。
3.1.3.3 integration requirement
requirement of a product or service to describe how a constitutive system/subsystem/component interfaces with others, to perform an integrated function.
EXAMPLE Weight, external dimension, kinematic envelope, power supply requirements, network. (communication).
Note 1 to entry: See Annex B.

3.1.3.4
可维护性
在规定的使用条件下，使用规定的程序和资源进行维修(3.1.2.12)，使物品在规定的使用条件下保持或恢复到能执行所需功能的状态的能力

注 1:给定的条件包括影响可维护性的方面，如:维修地点
(3.1.2.12)、可及性、维护程序和维护资源。
[来源:EN 13306：2017.4.5，修改-增加了 IEC 60050-192：2015,192-01-27 的条目注 1。]
3.1.3.4
maintainability
ability of an item under given conditions of use, to be retained in, or restored to, a state in which it can perform a required function, when maintenance (3.1.2.12) is performed under given conditions and using stated procedures and resources.
Note 1 to entry: Given conditions include aspects that affect maintainability, such as: location for maintenance (3.1.2.12), accessibility, maintenance procedures and maintenance resources.
[SOURCE: EN 13306:2017, 4.5, modified — Note 1 to entry from IEC 60050-192:2015, 192-01-27 has been added.]

3.1.3.5
非功能性需求
定义作为约束或限制的属性的技术需求，确保可用性和有效性，但不影响产品和服务的功能。
注 1:如附件 B 所示，非功能性需求包括:
-性能要求(3.1.3.8)；
-集成要求(3.1.3.3)；
-其他非功能需求。
注 2:其他非功能需求的一些例子如下:
-颜色；
-腐蚀控制；
-电磁干扰/电磁兼容(EMI/EMC)；
-噪声；
-可靠性、可用性、可维护性、安全性(RAMS)；
-铝制车身；
-标签；
-过时；
-可用性。
3.1.3.5
non-functional requirement
technical requirement that defines attributes serving as constraints or restrictions and ensuring the usability and effectiveness but not affecting the functionality of products and services
Note 1 to entry: As shown in Annex B, non-functional requirements include:
— performance requirements (3.1.3.8);
— integration requirements (3.1.3.3);
— other non-functional requirements.
Note 2 to entry: Some examples of other non-functional requirements are:
— colour;
— corrosion control;
— electro-magnetic interference/electro-magnetic compatibility (EMI/EMC);
— noise;
— reliability, availability, maintainability, safety (RAMS);
— aluminium car body;

— labels;
— obsolescence;
— usability.

3.1.3.6
非技术需求
影响产品或服务交付的需求
注 1:见附件 B。
例：保修，付款，质量保证，培训，沟通，时间，商务。
3.1.3.6
non-technical requirement
requirement affecting the delivery of the product or service
Note 1 to entry: See Annex B.
EXAMPLE Warranty, payments, quality assurance, training, communication, time, commercial.

3.1.3.7
运营成熟度
产品或服务的技术要求(3.1.3.10)的实现程度。例
1：不存在，正在开发，准备使用，正在使用。例
2：不满足，部分满足，完全满足。
3.1.3.7
operational maturity
degree of fulfilment of the technical requirements (3.1.3.10) of a product or service
EXAMPLE 1 Not existing, under development, ready to use, in use.
EXAMPLE 2 Not fulfilling, partially fulfilling, fully fulfilling.

3.1.3.8
性能需求
指定产品或服务达结果的需求。
注 1:见附件 B。
例：最大速度，最大加速度。
3.1.3.8
performance requirement
requirement that specifies the result that a product or a service reaches
Note 1 to entry: See Annex B.
EXAMPLE Maximum speed, maximum acceleration.

3.1.3.9
可靠性
在给定的时间间隔、给定的条件下，按要求无故障地工作的能力
注 1:一个项目的可靠性可以通过观察到的该项目或/和一系列的失效来计算在给定时间间隔内的可比项目。
注 2:项目的预测置信度表示对该项目的信心水平，该水平是根据观察到的可比项目的置信度和对其实际状态的了解估计出来的。
注 3:在某些情况下，可以考虑给定的使用单位数量，而不是给定的时间间隔(循环次数、运行小时数、

公里数等)。
注 4:给定的条件可包括预防性维护(3.1.2.15)措施和操作模式和条件。
[来源:IEC 60050-192:2015, 192-01-24, 修改-已添加 EN 13306:2017,4.1 条目的注释 1,2,3 和 4。]
3.1.3.9
reliability
ability to perform as required, without failure, for a given time interval, under given conditions
Note 1 to entry: The reliability of an item can be calculated from the observed failures of it or/and a set of comparable items during a given time interval.
Note 2 to entry: The forecasted reliability of an item expresses the level of confidence on it, estimated from the observed reliability of comparable items and the knowledge about its actual state.
Note 3 to entry: In some cases, a given number of unit of use can be considered instead of a given time interval (number of cycles, number of running hours, number of km, etc.).
Note 4 to entry: The given conditions may include preventive maintenance (3.1.2.15) actions and operational modes and conditions.
[SOURCE: IEC 60050-192:2015, 192-01-24, modified — Notes 1, 2, 3 and 4 to entry from EN 13306:2017,4.1 have been added.]

3.1.3.10
技术要求
定义产品或服务特性的需求
注 1:技术需求可以是功能性的，也可以是非功能性的。
注 2:见附件 B。
3.1.3.10
technical requirement
requirement that defines the features of the product or service
Note 1 to entry: A technical requirement can be functional or non-functional.
Note 2 to entry: See Annex B.

3.1.3.11
验证
通过提供客观证据，确认特定预期用途或应用的要求已得到满足。
[来源:iso9000:2015, 3.8.13, 修改-条目的注释 1、2 和 3 已被删除。]
3.1.3.11
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.
[SOURCE: ISO 9000:2015, 3.8.13, modified — Notes 1, 2 and 3 to entry have been deleted.]

3.1.3.12
验证
通过提供客观证据确认规定的要求已得到满足
[来源:iso9000:2015, 3.8.12, 修改-条目的注释 1、2 和 3 已被删除。]
3.1.3.12
verification
confirmation, through the provision of objective evidence, that specified requirements have been

fulfilled [SOURCE: ISO 9000:2015, 3.8.12, modified — Notes 1, 2 and 3 to entry have been deleted.]]

3.1.4 产品和工具

3.1.4.1

组件

为特定的计划或控制目的而被认为不可分割和/或在不被销毁的情况下无法拆卸的唯一可识别的产品

注 1:一个组织组的组件可能是另一个组的最终装配，例如电动马达。

[来源:en 15380-2:20 6,3.11]

3.1.4 Product and tools

3.1.4.1

component

uniquely identifiable product that is considered indivisible for particular planning or control purpose and/or which cannot be disassembled without it being destroyed.

Note 1 to entry: A component for one organizational group may be the final assembly of another group, e.g. an electric motor.

[SOURCE: EN 15380-2:2006, 3.11]

3.1.4.2

寄售库存

由外部供方拥有但由组织持有以确保可得性的库存(3.1.3.1) 的零件。

3.1.4.2

consignment stock

inventory owned by an external provider but held by the organization to ensure the availability (3.1.3.1)of parts.

3.1.4.3

可交付成果

供应范围内的输出满足规定的要求。

例：产品、服务、用户手册、培训手册、维护手册、测试报告、测试设备、培训、备件和支持部件。

3.1.4.3

deliverable

output for the scope of supply to fulfil defined requirements

EXAMPLE Product, services, user manual, training manual, maintenance manual, test reports, test equipment, training, spare and support parts.

3.1.4.4

(解决问题的)八大原则

8D

以团队为导向的系统方法，定义一系列步骤来解决产品、服务和流程中的问题

注 1:其目的是识别、纠正和消除反复出现的问题。

注 2:8D 问题解决模型建立了基于问题分析的纠正措施，通过确定问题的根本原因，关注问题的根源。注 3:8D 模型可简化为四个步骤(4D)。

3.1.4.4

eight disciplines (of problem solving)

8D

team-oriented and systematic approach defining a sequence of steps to resolve problems in products, services and processes

Note 1 to entry: Its purpose is to identify, correct and eliminate recurring problems.

Note 2 to entry: The 8D problem solving model establishes a corrective action based on the analysis of the problem and focuses on the origin of the problem by determining its root causes.

Note 3 to entry: The 8D model can be reduced to four steps (4D).

3.1.4.5

故障报告分析和纠正措施系统

FRACAS

通过反馈测试、修改和使用经验来提高当前和未来设计的可靠性的闭环过程

[来源:iec 60050-192: 2015,192-12-04]

3.1.4.5

failure reporting analysis and corrective action system

FRACAS

closed loop process used to improve dependability of current and future designs by feedback of testing, modification and use experience

[SOURCE: IEC 60050-192:2015, 192-12-04]

3.1.4.6

关键绩效指标

KPI

由最高管理者选择的绩效指标，用于评价 RQMS 的绩效及其对组织的持续成功至关重要的业务目标(3.1.1.7)

注 1:KPI 可以是几个性能指标的组合。

注 2:参见图 3。

3.1.4.6

key performance indicator

KPI

performance indicator, selected by the top management, to evaluate the performance of the RQMS and its business objectives that is critical (3.1.1.7) to the sustained success of an organization

Note 1 to entry: A KPI can be a combination of several performance indicator (PIs).

Note 2 to entry: See Figure 3.

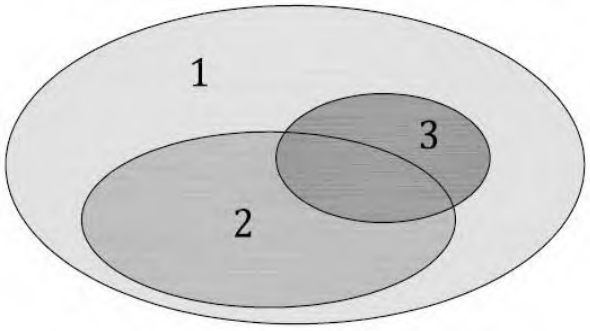

图 3 -指标与关键绩效指标的关系

关键

1 个 PI 符合 ISO 9001(见 4.4.1)

2 PI 符合 ISO 22163 补充标准(见 9.1.1.1)

3 KPI 符合 ISO 22163 补充标准(见 5.3.1)

Key

1 PI according to ISO 9001 (see 4.4.1)
2 PI according to supplemental ISO 22163 (see 9.1.1.1)
3 KPI according to supplemental ISO 22163 (see 5.3.1)
Figure 3 — Relation of PIs and KPIs

3.1.4.7

绩效指标 PI

量过程有效和/或高效运行和控制的指标，但不限于过程

注 1:绩效指标可以与单个过程相关，也可以与多个过程或任何活动相关。

3.1.4.7

performance indicator

PI

indicator measuring the effective and/or efficient operation and control of a process but that is not limited to processes

Note 1 to entry: A performance indicator can be related to a single process or to multiple processes or any activity.

3.1.4.8

防错

预防方法是一种简单的技术，用于防止任何人对系统进行计划外或不需要的更改，或防止任何错误对系统产生负面影响。

[来源:iso 13053-2:2011，2.19]

3.1.4.8

poka yoke

prevention method designed as a simple technique to prevent either anyone from making unplanned or unwanted changes to a system, or any errors from negatively impacting on a system

[SOURCE: ISO 13053-2:2011, 2.19]

3.1.4.9

生产设备

制造产品和提供服务的工具或设备

机械，工具，夹具，夹具，模板，纹理，测试台，软件生产工具。

注 1:手工设备(如锤子、螺丝刀)不被视为生产设备。

3.1.4.9

production equipment

tool or device to make products and provide services

EXAMPLE Machineries, tools, jigs, fixtures, templates, textures, test benches, software production tools.

Note 1 to entry: Handcraft equipment (e.g. hammer, screwdrivers) is not considered as production equipment.

3.1.4.10
保质期控制
旨在确保库存不会超期或被认为不能用于最初生产的目的的技术
先进先出(FIFO)，监测货架寿命。
3.1.4.10
Shelf life control
technique aimed at ensuring that the inventory is not overaged or regarded as unserviceable for the purposes for which it was originally manufactured.
EXAMPLE First-in-first-out (FIFO), monitoring of shelf life.

3.1.4.11
软件工具
执行一组功能以支持进程执行的计算机程序
从市场购买或由组织开发的软件程序、数据库、计算机电子表格、电子文件或网络工具。
3.1.4.11
software tool
computer programme that performs a set of functions to support the execution of a process
EXAMPLE Software programme, database, computerized spreadsheet, electronic file or web tool, bought from the market or developed by the organization.

3.2 缩略语

缩写	缩写说明
ATE	自动化测试设备
EPPPS	外部提供的流程、产品和服务
FAI	首件鉴定
FMEA	失效模式和影响分析
FMECA	失效模式，影响和关键性分析
FRACAS	故障报告分析与纠正措施系统
KPI	关键绩效指标
LCC	生命周期成本
LLRU	最低更换单元
OTD	准时交货
PI	绩效指标
RAM	可靠性，可用性，可维护性
RAMS	可靠性，可用性，可维护性，安全性。
RFT	首次正确
RQMS	铁路质量管理体系
SIL	安全完整性等级
SMART	具体的、可衡量的、可实现的、相关的、有时间框架的
SWOT	优势劣势机会威胁
8D	解决问题的方法

3.2 Abbreviated terms

ATE	automated test equipment
EPPPS	externally provided processes, products and services

FAI first article inspection
FMEA failure mode and effects analysis
FMECA failure mode, effects and criticality analysis
FRACAS failure reporting analysis and corrective action system
KPI key performance indicator
LCC life cycle cost
LLRU lowest line replaceable unit
OTD on time delivery index
PI performance indicator
RAM reliability, availability, maintainability
RAMS reliability, availability, maintainability, safety
RFT right first time
RQMS railway quality management system
SIL safety integrity level
SMART specific, measurable, achievable, relevant, time framed
SWOT strengths weaknesses opportunities threats
8D eight disciplines (of problem solving)

4 组织环境

4.1 理解组织及其环境

组织应确定与其宗旨和战略方向相关并影响其实现质量管理体系预期结果的能力的各种外部和内部因素。

组织应对这些外部和内部因素的相关信息进行监视和评审。 注1：这些因素可能包括需要考虑的正面和负面要素或条件。

注 2：考虑来自于国际、国内、地区和当地的各种法律法规、技术、竞争、市场、文化、社会和经济环境的因素，有助于理解外部环境。

注 3：考虑与组织的价值观、文化、知识和绩效等有关因素，有助于理解内部环境。

4.1.1 了解组织及其环境—补充

4.1.1.1 在规划组织的战略方向时，应考虑确保可持续的产品和服务质量进行业务规划。

组织应至少形成一份简要的业务计划，并每年对其进行评审。

注 1:组织可以决定将机密信息从简要的业务计划中排除。

业务计划应考虑:

a)经营目标;

b)市场战略;

c)产品和服务战略，包括新产品和服务的开发计划，和/或过程、创新和逐步淘汰战略;

注 2:研究与开发活动可视为创新活动的一部分。

d)管理评审的输出(见 9.3.3);

e)资源规划(见 7.1.1.1);

f) 组织的风险和机遇(见 6.1);

注 3 SWOT 分析可用于企业规划中的风险管理。

g) 业务连续性(见 6.1.4);

h)顾客的需求和期望;

i)相关方(如外部供方)的输入;

j)技术和法律法规要求变化的影响;

k) 考虑预测的组织能力；

l)合并、收购、外包和转让(如适用)。

4.1.1 Understanding the organization and its context — Supplemental

4.1.1.1 When planning the strategic direction of an organization, business planning shall be considered to ensure sustainable product and service quality.

The organization shall document at least a summarized business plan and review it on a yearly basis.

NOTE 1 The organization can decide to exclude confidential information from the summarized business plan.

The business planning shall consider:

a) business objectives;

b) market strategy;

c) product and service strategy, including development plans of new products and services, and/or processes, innovations and phase-out strategies;

NOTE 2 Research and development activities can be considered as part of innovation activities.

d) outputs of management reviews (see 9.3.3);

e) resource planning (see 7.1.1.1);

f) risks and opportunities of the organization (see 6.1);

NOTE 3 SWOT analysis can be applied for managing risks in business planning.

g) business continuity (see 6.1.4);

h) needs and expectations of customers;

i) inputs from interested parties (e.g. external providers);

j) impact of changes in technologies and in statutory and regulatory requirements;

k) organization capacity considering the forecast;

l) merger, acquisition, outsourcing and transfer, if applicable.

4.1.1.2 此业务计划应当考虑:

a) 外部趋势和相关方需求的变化(如经济政策、环境保护、社会或文化问题、产品和服务的信息安全需求);

b) 组织的财务年度日历;

c) 业务计划输出的适当沟通;

d) 作为业务计划评审输出的行动。

4.1.1.2 This business planning should consider:

a) change of external trends and interested parties' needs (e.g. economic policies, environmental protection, social or cultural issues, information security needs for products and services);

b) the fiscal year calendar of the organization;

c) an appropriate communication of business planning outputs;

d) actions as output of business planning review.

4.1.2 社会责任

组织应考虑社会责任原则。

注:ISO26000 定义的核心主题是组织治理、人权、劳工实践、环境、公平经营实践、消费者问题、社区参与和发展。

4.1.2 Social responsibility

The organization should consider social responsibility principles.

NOTE Core subjects defined in ISO 26000 are organizational governance, human rights, labour practices,the environment, fair operating practices, consumer issues, community involvement and development.

4.2 理解相关方的需求和期望

由于相关方对组织稳定提供符合顾客要求及适用法律法规要求的产品和服务的能力具有影响或潜在影响，因此，组织应确定：
a) 与质量管理体系有关的相关方；
b) 与质量管理体系有关的相关方的要求。 组织应监视和评审这些相关方的信息及其相关要求。

4.3 确定质量管理体系的范围
组织应确定质量管理体系的边界和适用性，以确定其范围。在确定范围时，组织应考虑：
a） 4.1 中提及的各种外部和内部因素；
b） 4.2 中提及的相关方的要求；
c） 组织的产品和服务。
如果本标准的全部要求适用于组织确定的质量管理体系范围，组织应实施本标准的全部要求。
组织的质量管理体系范围应作为成文信息，可获得并得到保持，该范围应描述所覆盖的产品和服务类型， 如果组织确定本标准的某些要求不适用于其质量管理体系范围，应说明理由。只有当所确定的不适用的要求不影响组织确保其产品和服务合格的能力或责任，对增强顾客满意也不产生影响时，方可声称符合本标准的要求。
4.3.1 确定质量管理体系的范围——补充
组织还应确定RQMS 具体要求的边界和适用性。
注：此附加要求不影响组织的灵活性。与有时限的组织设置(如多场所、过程转移)相关的活动、产品、服务和要求可列为不适用。
4.3.1 Determining the scope of the quality management system — Supplemental
The organization shall also determine the boundaries and applicability of the specific requirements of the RQMS.
NOTE This additional requirement does not affect the flexibility of organizations. Activities, products, services and requirements that are linked to timely bounded organizational setups (e.g. multi-site, transfer of processes) can be put as not applicable.

4.4 质量管理体系及其过程
4.4.1 组织应按照本标准的要求，建立、实施、保持和持续改进质量管理体系，包括所需过程及其相互作用。
组织应确定质量管理体系所需的过程及其在整个组织中的应用，且应：
a） 确定这些过程所需的输入和期望的输出；
b) 确定这些过程的顺序和相互作用；
c) 确定和应用所需的准则和方法（包括监视、测量和相关绩效指标），以确保这些过程有效运行和控制； d) 确定这些过程所需的资源并确保其可获得；
e) 分配这些过程的职责和权限；
f) 按照 6.1 的要求应对风险和机遇；
g) 评价这些过程，实施所需的变更，以确保实现这些过程的预期结果； h) 改进过程和质量管理体系。
4.4.2 在必要的范围和程度上，组织应： a) 保持成文信息以支持过程运行；
b） 保留成文信息以确信其过程按策划进行。
4.4.3 质量管理体系及其过程——补充
4.4.2 a)中强制性过程和推荐过程描述的文件化信息(见附件 a)应至少涵盖 4.4.1 a)至 4.4.1 e)中所述的要求。

注 1:过程可以在软件工具和模板的支持下，以程序、说明、方法说明、流程图或工作流程等形式形成

文件。
注 2:组织可根据其 RQMS 涵盖过程。只要满足本标准的所有要求，它们可以由组织单独、组合或分割。注 3:过程绩效评价的详细要求见 9.1.1，并在附件 C 中作进一步解释。
组织应:
a) 记录其过程的层次结构;
b) 沟通过程和过程变更(见 7.4)，确保人员了解过程;
4.4.3 Quality management system and its processes — Supplemental
The documented information in 4.4.2 a) for the process description of mandatory and recommended processes (see Annex A) shall cover as a minimum the requirements described in 4.4.1 a) to 4.4.1 e).
NOTE 1 Processes can be documented in procedures, instructions, method descriptions, flowcharts or workflows etc. supported by software tool and templates.
NOTE 2 Processes can be covered by the organization according to their RQMS. They can be single, combined or split by the organizations, provided that all requirements of this document are fulfilled.
NOTE 3 Detailed requirements for performance evaluation of the processes are described in 9.1.1 and further explained in Annex C.
The organization shall:
a) document a hierarchical structure of its processes;
b) communicate processes and process changes (see 7.4) and ensure that people are aware of the processes;

5 领导作用

5.1 领导作用和承诺
5.1.1 总则 最高管理者应通过以下方面，证实其对质量管理体系的领导作用和承诺： a)
对质量管理体系的有效性负责;
b) 确保制定质量管理体系的质量方针和质量目标，并与组织环境相适应，与战略方向相一致;
c) 确保质量管理体系要求融入组织的业务过程;
d) 促进使用过程方法和基于风险的思维;
e) 确保质量管理体系所需的资源是可获得的;
f) 沟通有效的质量管理和符合质量管理体系要求的重要性； g)
确保质量管理体系实现其预期结果;
h) 促使人员积极参与，指导和支持他们为质量管理体系的有效性作出贡献;
i) 推动改进;
j) 支持其他相关管理者在其职责范围内发挥领导作用。
注：本标准使用的“业务”一词可广义地理解为涉及组织存在目的的核心活动，无论是公有、私有、营利或非营利组织。
5.1.2 以顾客为关注焦点
最高管理者应通过确保以下方面，证实其以顾客为关注焦点的领导作用和承诺：
a) 确定、理解并持续地满足顾客要求以及适用的法律法规要求;
b) 确定和应对风险和机遇，这些风险和机遇可能影响产品和服务的合格以及增强顾客满意的能力； c)
始终致力于增强顾客满意。
针对这条加入也是加到总经理的职责或者手册中提及就可以

5.2 方针
5.2.1 制定质量方针
最高管理者应制定、实施和保持质量方针，质量方针应：

a）适应组织的宗旨和环境并支持其战略方向；

b) 为建立质量目标提供框架；
c) 包括满足适用要求的承诺；
d) 包括持续改进质量管理体系的承诺。
5.2.2 沟通质量方针 质量方针应：
a) 可获取并保持成文信息；
b) 在组织内得到沟通、理解和应用； c)
适宜时，可为有关相关方所获取。
5.2.3 质量方针——补充
质量方针应解决：
a) 故障预防；
b) 顾客期望；
c) 安全方面。
注 1：本文件中的安全是指产品和服务的安全。
注 2：质量和安全方针可以分开处理。
注 3：质量方针是公司总体方针的一部分。欲了解更多信息，请参见 ISO 9004:2018，7.2。
5.2.3 Quality policy — Supplemental
The quality policy shall address:
a) failure prevention;
b) customer expectations;
c) safety aspects.
NOTE 1 Safety in this document means safety of products and services.
NOTE 2 Quality and safety policies can be addressed separately.
NOTE 3 The quality policy forms a part of the overall corporate policy. For more information, see ISO 9004:2018, 7.2.

5.3 组织的岗位、职责和权限
最高管理者应确保组织相关岗位的职责、权限得到分配、沟通和理解。 最高管理者应分配职责和权限，以：
a) 确保质量管理体系符合本标准的要求；
b) 确保各过程获得其预期输出；
c) 报告质量管理体系的绩效及改进机会（见 10.1），特别是向最高管理者报告；
d) 确保在整个组织中推动以顾客为关注焦点；
e) 确保在策划和实施质量管理体系变更时保持其完整性。
需要针对各岗位建立职位说明书，描述岗位职责和权限 一般企业权限会漏掉，但也没什么大问题
5.3.1 组织角色、职责和权限——补充
最高管理者应：
a) 定义关键绩效指标，以便指导和控制 RQMS(见附件 C)；
b) 任命过程所有者[见 4.4.1 e)]；
c) 记录和沟通相关角色(如过程拥有者)的职责和权限的更新；
d) 任命独立于过程执行的代表，并授权他们在质量(包括安全)不符合要求时停止过程或生产或服务的提供。
注：所要求的代表的独立程度与组织的规模成正比，如小型组织。
组织应保留相关的形成文件的信息。
在任务委托的情况下，应该定义和传达这种委托。
5.3.1 Organizational roles, responsibilities and authorities — Supplemental

The top management shall:
a) define KPIs to enable steering and control of the RQMS (see Annex C);
b) appoint process owners [see 4.4.1 e)];
c) document and communicate updates of responsibilities and authorities for relevant roles (e.g.process ownership);
d) appoint representatives independent from the process execution and empower them to stop the process or production or service provision if quality, including safety requirements, are not met.
NOTE The required degree of independence of the representatives is proportionate to the size of the organization, e.g. small organizations.
The organization shall retain related documented information.
In case of delegation of tasks, this delegation should be defined and communicated.

5.3.2 过程所有者的职责和权限
除资源可获得性外，过程所有者应对过程符合 4.4 所列要求负责[见 4.4.1 d)]。
这职责应由最高管理者确定并确保。
5.3.2 Responsibilities and authorities of process owners
Process owners shall be responsible for the process conformity to requirements listed in 4.4 except availability of resources [see 4.4.1 d)].
This responsibility shall be defined and ensured by top management.

6 策划

6.1 应对风险和机遇的措施
6.1.1 在策划质量管理体系时，组织应考虑到 4.1 所提及的因素和 4.2 所提及的要求，并确定所需应对的风险和机遇，以：
a) 确保质量管理体系能够实现其预期结果；
b) 增强有利影响；
c) 预防或减少不利影响；
d) 实现改进。
6.1.2 组织应策划：
a) 应对这些风险和机遇的措施； b)
如何：
1) 在质量管理体系过程中整合并实施这些措施（见 4.4）；
2) 评价这些措施的有效性。应对措施应与风险和机遇对产品和服务的潜在影响相适应。
注 1：应对风险可选择规避风险，为寻求机遇承担风险，消除风险源，改变风险的可能性或后果，分担风险，或通过信息充分的决策而保留风险。
注 2：机遇可能导致采用新实践，推出新产品，开辟新市场，赢得新顾客，建立合作伙伴关系，利用新技术和其他可行之处，以应对组织或其顾客的需求。
6.1.3 应对风险和机遇的措施——补充
6.1.3.1 组织应建立、实施并保持风险和机会管理过程。
这过程应包括：
a) 6.1.1 和 6.1.2 所述的要求；
b) 对风险、机会和措施的定期评审和更新；
c) 保留来自风险和机会评估、评审和行动形成文件的信息；
d) 确定需要采取行动的标准；

e)对其有效性的评价(如基于质量缺陷成本)。

注 1:方法(如 FMEA、SWOT)可用于管理风险，例如过程、设计与开发、项目或生产中的风险。
注 2:类似 FMECA 的方法可用于管理关键功能或项目(如安全相关)的风险。
6.1.3.2 此外，该过程应:
a)让顾客和外部供方参与风险和机会评估审查和行动的联合工作;
b)要求采用多方论证的方法进行风险和机会评审。
6.1.3 Actions to address risks and opportunities — Supplemental
6.1.3.1 The organization shall establish, implement and maintain a risk and opportunity management process. This process shall include:
a) the requirements described in 6.1.1 and 6.1.2;
b) a regular review and update of risks, opportunities and actions;
c) the retention of documented information from risk and opportunity assessments, reviews and actions;
d) the definition of criteria to determine the need for action;
e) the evaluation of its effectiveness (e.g. based on quality deficiency costs).
NOTE 1 A methodology (e.g. FMEA, SWOT) can be applied for managing risks, e.g. in processes, design and development, projects or production.
NOTE 2 A methodology like FMECA can be applied for managing risks of critical functions or items (e.g. safetyrelated).
6.1.3.2 In addition, this process should:
a) involve customers and external providers in joint work on risk and opportunity assessments,reviews and actions;
b) require a multidisciplinary approach for risk and opportunity reviews.

6.1.4 业务连续性
组织应:
a) 根据对其业务风险的评价，在适用的情况下(例如，通过定期测试的方式)建立、核实、确认其业务连续性计划，并定期审查其业务连续性计划;
b) 管理其业务连续性;
定义业务连续性行动的责任。
注 1:经营风险可能涉及:
-中断;
-供应链中断;
-劳动力短缺;
-关键技术;
-关键生产设备故障;
-现场退货;
-继任计划，特别是对质量至关重要的关键角色;
-信息技术;
-沟通;
-损失;
-紧急情况或危机。
注 2:有关业务连续性的详细内容，请参见 ISO 22301。
6.1.4 Business continuity
The organization shall:
a) establish, verify, validate, if applicable (e.g. by means of periodical tests), and regularly review its business continuity plan based on an evaluation of its business risks;

b) manage its business continuity;
c) define responsibilities for business continuity actions.
NOTE 1 Business risks can concern:
— interruptions;
— interruptions in the supply chain;
— labour shortages;
— critical technologies;
— key production equipment failures;
— field returns;
— succession plan, in particular for key roles critical to quality;
— information technology;
— communication;
— losses;
— emergencies or crisis.
NOTE 2 For details on business continuity, see ISO 22301.

6.2 质量目标及其实现的策划
6.2.1 组织应针对相关职能、层次和质量管理体系所需的过程建立质量目标。
质量目标应：
a） 与质量方针保持一致；
b） 可测量；
c) 考虑适用的要求；
d) 与产品和服务合格以及增强顾客满意相关； e）
予以监视；
f） 予以沟通；
g） 适时更新。
组织应保持有关质量目标的成文信息。
6.2.2 策划如何实现质量目标时，组织应确定： a）
要做什么；
b） 需要什么资源；
c） 由谁负责；
d) 何时完成；
e) 如何评价结果。

6.3 变更的策划
当组织确定需要对质量管理体系进行变更时，变更应按所策划的方式实施（见 4.4）。 组织应考虑：
a） 变更目的及其潜在后果；
b） 质量管理体系的完整性；
c） 资源的可获得性；
d） 职责和权限的分配或再分配。

7 支持
7.1 资源
7.1.1 总则 组织应确定并提供所需的资源，以建立、实施、保持和持续改进质量管理体系。 组织应考虑：

a）现有内部资源的能力和局限；
b）需要从外部供方获得的资源。

7.1.1.1 总则—补充
组织应建立、实施并保持资源策划、批准和控制的过程。
这过程应包括：
a)执行过程所需的人员和基础设施资源[见 4.4.1 d)]；
b)对当前订单的影响及预测；
c)与风险准备相关的影响(例如，在潜在资源短缺的情况下)。
组织应保留相关的形成文件的信息。
7.1.1.1 General — Supplemental
The organization shall establish, implement and maintain a process for resource planning, approval and control.
This process shall include:
a) the resources needed for people and infrastructure as a minimum for the execution of processes [see 4.4.1 d)];
b) the impact of the current order book and forecast;
c) the impact linked to risk provisions (e.g. in case of potential scarcity of resources).
The organization shall retain related documented information.

7.1.2 人员
组织应确定并配备所需的人员，以有效实施质量管理体系，并运行和控制其过程。
7.1.3 基础设施组织应确定、提供并维护所需的基础设施，以运行过程，并获得合格产品和服务。
注：基础设施可包括：
a）建筑物和相关设施；
b）设备，包括硬件和软件；
c）运输资源；
d）信息和通信技术。

7.1.4 过程运行环境
组织应确定、提供并维护所需的环境，以运行过程，并获得合格产品和服务。 注：
适宜的过程运行环境可能是人为因素与物理因素的结合，例如：
a 社会因素（如非歧视、安定、非对抗）；
b 心理因素（如减压、预防过度疲劳、稳定情绪）；
物理因素（如温度、热量、湿度、照明、空气流通、卫生、噪声）。 由于所提供的产品和服务不同， 这些因素可能存在显著差异。

7.1.5 监视和测量资源
7.1.5.1 总则
当利用监视或测量来验证产品和服务符合要求时，组织应确定并提供所需的资源，以确保结果有效和可靠。
组织应确保所提供的资源：
a）适合所开展的监视和测量活动的特定类型；
b）得到维护，以确保持续适合其用途。
组织应保留适当的成文信息，作为监视和测量资源适合其用途的证据。

7.1.5.2 测量溯源

当要求测量溯源时，或组织认为测量溯源是信任测量结果有效的基础时，测量设备应：

a) 对照能溯源到国际或国家标准的测量标准，按照规定的时间间隔或在使用前进行校准和（或）检定，当不存在上述标准时，应保留作为校准或检定依据的成文信息；

b) 予以识别，以确定其状态；

c) 予以保护，防止由于调整、损坏或衰减所导致的校准状态和随后的测量结果的失效。

当发现测量设备不符合预期用途时，组织应确定以往测量结果的有效性是否受到不利影响，必要时应采取适当的措施。

7.1.5.3 资源监控与测量—补充

组织应建立、实施并保持对特殊过程中使用的监视和测量资源以及工具进行校准或验证的过程。

这过程应包括：

a) 7.1.5.1 和 7.1.5.2 规定的要求；

b) 当发现监视或测量资源或工具不适合其预期用途时，如何作出反应(见 7.1.5.2)。

组织应保持这些资源的登记簿，记录其类型、唯一标识、位置或负责人、校准或验证间隔(如在软件工具中)。

注 1:监视和测量资源可以是:检测硬件、检测软件、ATE 或用于产生检验数据的绘图机。这也包括个人拥有的、内部开发的或由客户或外部供应商提供的设备。

注 2:参见 ISO 10012。

在进行内部校准或验证时，组织应：

c) 建立相关方法和验收准则；

d) 确保环境条件适合进行校准或验证。

校准或验证结果的记录应提供：

e) 被校准或验证的测量资源的唯一标识；

f)进行校准或验证的日期；

g)用于校准的参考标准(如量块)；

h)用于校准或验证的程序。

7.1.5.3 Monitoring and measuring resources — Supplemental

The organization shall establish, implement and maintain a process for calibration or verification, or both, of monitoring and measuring resources as well as of tools used in special processes.

This process shall include:

a) the requirements defined in 7.1.5.1 and 7.1.5.2;

b) how to react when monitoring or measuring resources or tools are found to be unfit for their intended purpose (see 7.1.5.2).

The organization shall retain related documented information.

The organization shall maintain a register of these resources recording their type, unique identification,location or person in charge, intervals for calibration or verification (e.g. in a software tool).

NOTE 1 Monitoring and measuring resources can be: test hardware, test software, ATE or plotters used to produce inspection data. This also includes equipment that is personally owned, developed in house or supplied by the customer or an external provider.

NOTE 2 See also ISO 10012.

In case of internal calibration or verification, the organization shall:

c) establish related methods and acceptance criteria;

d) ensure that ambient conditions are suitable to carry out calibration or verification.

The records of calibration or verification results shall provide:

e) the unique identification of the measuring resource calibrated or verified;

f) the date(s) of when the calibrations or verifications were carried out;
g) the reference standard (e.g. gauge blocks) used to calibrate;
h) the procedure used for calibration or verification.

7.1.6 组织的知识
组织应确定必要的知识，以运行过程，并获得合格产品和服务。这些知识应予以保持，并能在所需的范围内得到。
为应对不断变化的需求和发展趋势，组织应审视现有的知识，确定如何获取或接触更多必要的知识和知识更新。
注 1：组织的知识是组织特有的知识，通常从其经验中获得，是为实现组织目标所使用和共享的信息。
注 2：组织的知识可基于：
a) 内部来源（如知识产权；从经验获得的知识；从失败和成功项目汲取的经验和教训；获取和分享未成文的知识和经验；过程、产品和服务的改进成果）；
b) 外部来源（如标准；学术交流；专业会议；从顾客或外部供方收集的知识）。
7.1.6.1 组织知识—补充
7.1.6.1.1 关于组织知识，组织应：
a) 管理经验回报，包括：
1) 识别、记录、实施和更新良好实践和经验教训学习；
2) 与相关过程和正在进行的项目沟通良好实践和经验教训；
注：经验反馈可以来自但不限于：不符合项、RAMS/LCC 数据、顾客投诉、内部审核、外部供方审核和基准。
b) 分配产品、过程和项目的知识管理职责(例如：在职位描述中)；
c) 在需要时转移知识，例如人员加入或离开组织。
7.1.6.1.2 组织应建立、实施并保持组织知识管理过程，以充分实现产品和服务的符合性。
关于组织知识，组织应：
a) 利用软件工具分享知识；
b) 通过网络鼓励知识共享；
c) 保护知识不被意外泄露到组织外部(例如，从经验中获得的知识；从失败和成功项目中吸取的教训；获取和分享未成文的知识和经验；过程、产品和服务改进的结果)。
7.1.6.1 Organizational knowledge — Supplemental
7.1.6.1.1 Regarding organizational knowledge, the organization shall:
a) manage return of experience including:
1) identification, documentation, implementation and update of good practices and lessons learned;
2) communication of good practices and lessons learned to relevant processes and active projects;
NOTE Return of experience can be derived from, but not limited to, nonconformities, RAMS/LCC data,customer complaints, internal audits, external provider audits and benchmarks.
b) allocate responsibilities for knowledge management regarding products, processes and projects(e.g. in the job descriptions);
c) transfer knowledge when required, e.g. people joining or leaving the organization.
7.1.6.1.2 The organization should establish, implement and maintain an organizational knowledge management process for adequacy to achieve conformity of products and services.
Regarding organizational knowledge, the organization should:
a) use a software tool to share its knowledge;
b) encourage knowledge sharing by networking;

c) protect knowledge from unintended disclosure outside the organization (e.g. knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services).

7.2 能力
组织应:
a) 确定在其控制下工作的人员所需具备的能力，这些人员从事的工作影响质量管理体系绩效和有效性；b) 基于适当的教育、培训或经验，确保这些人员是胜任的；
c) 适用时，采取措施以获得所需的能力，并评价措施的有效性；
d) 保留适当的成文信息，作为人员能力的证据。 注：适当措施可包括对在职人员进行培训、辅导或重新分配工作，或者聘用、外包胜任的人员。
7.2.1 能力——补充
7.2.1.1 组织应建立、实施并保持能力管理过程。
能力可包括技术技能，如产品、过程或项目知识、软件工具、技术(如质量保证方法)、社会(如团队合作、沟通)以及个人(如分析思维、商业头脑)技能。
这过程应包括:
a) 7.2 规定的要求;
b) 识别实际能力与必要能力之间的差距;
c) 策划、组织、执行和监视所采取的措施[见 7.2 C)];
d) 培训要求:
1) 包括来自组织知识的输入，如良好实践、经验管理(见 7.1.6);例如，来自产品、服务或过程不符合项的输入;
2) 为组织规定的培训提供受训者理解培训内容的证据(例如，通过笔试或口试的结果，通过保留实际练习的样本)。
该流程适用于所有员工，包括临时工和新员工的入职，至少包括产品质量和安全。
组织应保留与能力管理活动有关的形成文件的信息。
7.2.1 Competence — Supplemental
7.2.1.1 The organization shall establish, implement and maintain a competence management process.
NOTE Competence can include technical skills such as product, process or project knowledge, software tools,techniques (e.g. quality assurance methods) and social (e.g. teamwork, communication) as well as individual (e.g.analytical thinking, business acumen) skills.
This process shall include:
a) the requirements defined in 7.2;
b) identification of gaps between actual and necessary competencies;
c) planning, organizing, executing and monitoring of actions taken [see 7.2 c)];
d) the requirements for training:
1) including inputs from organizational knowledge such as good practice, management of experience (see 7.1.6); e.g. inputs from nonconformities of products, services or processes;
2) providing evidence that trainees understood the training content (e.g. by results of written or oral examinations, by keeping samples of practical exercises) for training defined by the organization.
The process shall apply to all employees including the induction for temporary workers and newcomers, covering as a minimum product quality and safety.
The organization shall retain documented information related to competence management activities.

7.2.1.2 该过程应当:

a) 包括对从事影响产品质量和安全工作的人员的必要能力与实际状态进行比较的方法；
注 1:作为一种方法，技能矩阵可用于将必要能力与实际状态进行比较，考虑到渐进水平(如:学习者、基本、高级、教练)。
注 2:从事影响产品质量和安全工作的人员不仅限于质量、工程和生产部门。采购、现场服务或组织其他也会影响产品质量和安全职能部门的人员。
b) 确保定期审核和更新内部培训材料。
7.2.1.2 This process should:
a) include a method to compare the necessary competencies versus the actual state, for persons performing work that affects product quality and safety;
NOTE 1 As a method, a skill matrix can be used to compare the necessary competencies versus the actual state, considering progressive levels (e.g. learner, basic, advanced, coach).
NOTE 2 Persons performing work that affects product quality and safety are not limited to quality,engineering and production. People from procurement, field services or other functions of the organization can also impact product quality and safety.
b) ensure regular reviews and updating of internal training materials.

7.3 意识
组织应确保在其控制下工作人员知晓：
a) 质量方针；
b) 相关的质量目标；
c) 他们对质量管理体系有效性的贡献，包括改进绩效的益处； d) 不符合质量管理体系要求的后果。

7.4 沟通
组织应确定与质量管理体系相关的内部和外部沟通，包括：
a) 沟通什么；
b) 何时沟通；
c) 与谁沟通；
d) 如何沟通；
e) 谁来沟通。

7.4.1 沟通—补充
组织应建立、实施和保持与 RQMS 相关的内部和外部沟通管理过程。
7.4.1 Communication — Supplemental
The organization should establish, implement and maintain a communication management process for internal and external communication relevant to the RQMS.

7.5 文件化信息
7.5.1 总则
组织的质量管理体系应包括：
a) 本标准要求的成文信息；
b) 组织确定的、为确保质量管理体系有效性所需的成文信息；
注：对于不同组织，质量管理体系成文信息的多少与详略程度可以不同，取决于：
- 组织的规模，以及活动、过程、产品和服务的类型；

– 过程及其相互作用的复杂程度；

- 人员的能力。这
条 可 以 不 管
7.5.2 创建和更新
在创建和更新成文信息时，组织应确保适当的：
a) 标识和说明（如标题、日期、作者、索引编号）；
b) 形式（如语言、软件版本、图表）和载体（如纸质的、电子的）； c)
评审和批准，以保持适宜性和充分性。
7.5.3 成文信息的控制
7.5.3.1 应控制质量管理体系和本标准所要求的成文信息，以确保： a)
在需要的场合和时机，均可获得并适用；
b) 予以妥善保护（如防止泄密、不当使用或缺失）。7.5.3.2
为控制成文信息，适用时，组织应进行下列活动： a) 分发、
访问、检索和使用；
b) 存储和防护，包括保持可读性；
c) 更改控制（如版本控制）；
d) 保留和处置。
对于组织确定的策划和运行质量管理体系所必需的来自外部的成文信息，组织应进行适当识别，并予以控制。
对所保留的，作为证据的成文信息应予以保护，防止非预期的更改。
注：对成文信息的“访问”可能意味着仅允许查阅，或者意味着允许查阅并授权修改。
7.5.3.3 文件化信息的控制——补充
组织应建立、实施并保持对文件化信息的控制过程。
该过程应包括:
a) 7.5.1、7.5.2、7.5.3.1、7.5.3.2 规定的要求;
b)确定 RQMS 文件化信息的层次结构(如:政策、程序、说明、模板);
c)识别创建、验证、批准和更新文件化信息人员的权限;
d)确定符合法律法规、合同和 RQMS 要求的记录类型(如报告、测量表、图纸)及其保存期限。组织应保留与 b)、c)和 d)有关的文件化信息。
此过程应包括确定机密级别(例如，公共、内部、机密)、存储介质和销毁方法。
组织应利用信息系统控制形成文件的信息，并定义其备份程序。
7.5.3.3 Control of documented information — Supplemental
The organization shall establish, implement and maintain a process for the control of documented information.
The process shall include:
a) the requirements defined in 7.5.1, 7.5.2, 7.5.3.1, 7.5.3.2;
b) the determination of the hierarchy of documented information of the RQMS (e.g. policies,procedures, instructions, templates);
c) authorities for and identification of persons creating, verifying, approving and updating documented information;
d) the determination of the types of records (e.g. reports, measurement sheets, drawings) and their retention periods that comply with statutory and regulatory, contractual and RQMS requirements.
The organization shall retain documented information in relation to b), c) and d).
The process should include the determination of level of confidentiality (e.g. public, internal,confidential), storage media and method of destruction.
The organization should use information systems to control documented information and define their back up routines.

8 运行

8.1 运行的策划和控制

为满足产品和服务提供的要求，并实施第 6 章所确定的措施，组织应通过以下措施对所需的过程（见 4.4）进行策划、实施和控制：

a) 确定产品和服务要求；

b) 建立下列内容的准则：

1）过程；

2）产品和服务的接收。

c) 确定所需的资源以使产品和服务符合要求；

d) 按照准则实施过程控制；

e) 在必要的范围和程度上，确定并保持、保留成文信息，以：

1）确信过程已经按策划进行；

2）证实产品和服务符合要求。

策划的输出应适于组织的运行。

组织应控制策划的变更，评审非预期变更的后果，必要时，采取措施减轻不利影响。组织应确保外包过程受控（见 8.4）。

8.1.1 运行计划和控制—补充

8.1.1.1 创新管理

组织应建立、实施并保持新产品、新服务和新技术的创新管理过程。

这过程应包括：

a) 识别组织经营环境的变化；

b) 创新规划；

c) 基于创新的紧迫性、资源的可得性和组织战略之间的平衡来确定创新的优先次序；

d) 相关方(如外部供方)的参与。

注：研究与开发活动可视为创新活动的一部分。

8.1.1 Operational planning and control — Supplemental

8.1.1.1 Innovation management

The organization should establish, implement and maintain an innovation management process for new products, services and technologies.

This process should include:

a) the identification of changes in the organization's business environment;

b) planning of innovations;

c) prioritization of innovations based on the balance between their urgency, the availability of resources and the organization's strategy;

d) involvement of interested parties (e.g. external providers).

NOTE Research and development activities can be considered as part of innovation activities.

8.1.1.2 过程转移的策划

组织应建立、实施并保持过程，对影响组织产品和服务质量的过程的转移进行策划。

该过程的实施应与业务策划(4.1.1)、业务连续性(6.1.4)、生产和服务提供(8.5)、产品和服务的设计和开发(8.3)相关决策联系起来：

-由多场所组织将过程从一个场所转移到另一个场所；

-由单场所或多场所组织将过程传递给外部组织时。

这过程应包括：

a) 可行性研究；
b) 风险评估（见 6.1）；c)
策划转移所需的措施；d)
必要时与顾客沟通；
e)FAI（见 8.9）；
f)保留转移活动形成的文件化信息。
每当组织确定需要转移过程时，在发生变化时，应应用和控制本款所述过程转移策划的要求（见 8.1.4.2）。
注 1:过程转移的策划可作为实施 8.4 要求之前做出或购买决策的输入，例如，基于资源的稀缺性或战略决策。
注 2:8.1.1.2 未涵盖的过程在 8.4 中涵盖。
8.1.1.2 Planning of the transfer of processes
The organization shall establish, implement and maintain a process for the planning of the transfer of processes that can affect the organization's products and services quality.
The implementation of this process shall be linked to business planning (4.1.1), business continuity (6.1.4), production and service provision (8.5), design and development of products and services (8.3)related decisions:
— by multi-sites organization when transferring a process from one site to another;
— by single site or multi-sites organizations when transferring processes to external organizations.
This process shall include:
a) a feasibility study;
b) a risk assessment (see 6.1);
c) planning of required actions for transfer;
d) communication to customers when required;
e) FAI (see 8.9);
f) retention of documented information from transfer activities.
Whenever the organization identifies the need to transfer a process, the requirements regarding the planning of the transfer of processes described in this subclause shall be applied and controlled in case of changes (see 8.1.4.2).
NOTE 1 Planning for the transfer of processes can be an input for a make or buy decision prior to implementing the requirements of 8.4, e.g. based on scarcity of resources or a strategic decision.
NOTE 2 Processes not covered by 8.1.1.2 are covered under 8.4.

8.1.2 投标管理
组织应建立、实施并保持投标管理过程。
这过程应包括：
a) 需求管理（见 8.2）；
b) 控制的类型和程度[见 4.4.3 f)]；
c) 风险和机会管理（见 6.1），包括财务评价；
d) 来自组织知识的输入（如经验反馈）（见 7.1.6）；
e)策划可交付成果，包括成本；
注 1:投标时可采用工程标准成本核算结构进行计算。
f)合同执行资源的规划；
g)提供批准。
组织应保留与其投标管理活动有关的文件化信息。

注 2:在本标准中，投标管理包括几种通常称为招标、报价、公开招标、招投标等的活动。

8.1.2 Tender management

The organization shall establish, implement and maintain a tender management process.

This process shall include:

a) requirements management (see 8.2);

b) the type and extent of controls [see 4.4.3 f)];

c) risks and opportunities management (see 6.1), including monetary evaluation;

d) inputs from organizational knowledge (e.g. return of experience) (see 7.1.6);

e) planning of deliverables including costs;

NOTE 1 The standard cost account structure of projects can be used for the calculation in the tender.

f) planning of resources for contract execution;

g) offer approval.

The organization shall retain documented information related to their tender management activities.

NOTE 2 In this document, tender management includes several activities commonly called tendering, offering,open bidding, bidding, etc.

8.1.3 项目管理

8.1.3.1 总则

8.1.3.1.1 组织应建立、实施并保持项目管理过程。

注 1:项目管理过程的范围取决于组织的业务模式。在大多数铁路部门组织中，它是从招标阶段到保修期结束。然而，在其他情况下，它可以限于：

-仅用于设计和开发(例如，用于开发新产品系列或平台)；

-生产工艺的开发；

-重复已批准的产品和服务(如:从生产到库存)；

-订单和合同管理(如按订单生产)。

这过程应包括：

a) 需求管理(见 8.2)；

b) 控制的类型和程度[见 4.4.3 f)]；

注 2:组织可根据风险对项目进行分类，从而确定控制的类型和程度。

c)项目阶段和活动；

注 3:项目活动包括但不限于策划、执行、监视、控制和收尾。

d)每个阶段的里程碑和可交付成果，由门方法管理；

注 4:每个阶段的可交付成果可在门检查清单中定义。

e)在阶段评审中决定接受、有条件接受或拒绝的门准则，以授权进入下一阶段；

注 5:有条件的接受可与行动计划一起接受。

f) 8.1.3.2 至 8.1.3.11 规定的要求；

g)记录和控制未解决问题，并投入适当的资源解决问题。

8.1.3 Project management

8.1.3.1 General

8.1.3.1.1 The organization shall establish, implement and maintain a project management process.

NOTE 1 The scope of the project management process depends on the business model of an organization. In most railway sector organizations, it is from tender phase until the end of warranty period. However, in other cases it can be limited to:

— design and development only (e.g. for the development of a new product family or platform);

— development of the production process;

— repetition of approved products and services (e.g. make to stock);
— order and contract management (e.g. make to order).
This process shall include:
a) requirement management (see 8.2);
b) the type and extent of controls [see 4.4.3 f)];
NOTE 2 The organization can classify projects depending on the risk and consequently define the type and extent of controls.
c) the project phases and activities;
NOTE 3 Project activities can be, but are not limited to planning, executing, monitoring, controlling and closing.
d) milestones and deliverables per phase, managed by gate methodology;
NOTE 4 Deliverables per phase can be defined in gate checklists.
e) gate criteria to decide, in phase reviews, on acceptance, conditional acceptance or rejection, to authorize progression to the next phase;
NOTE 5 Conditional acceptance can be acceptance with an action plan.
f) the requirements defined in 8.1.3.2 to 8.1.3.11;
g) records and control of open issues, putting appropriate resources in place to close them.

8.1.3.1.2 该过程应当包括：
a) 拒绝决定时的升级过程，作为阶段评审的输出，以促进问题的解决；
b) 与客户和主要外部供应商就 SWOT 进行审查；
c) 至少识别项目结束期间的良好做法和经验教训（见 7.1.6）。
8.1.3.1.2 This process should include:
a) an escalation process in case of rejection decision as an output of phase reviews to facilitate problem solving;
b) a review with the customer and key external providers regarding SWOT;
c) the identification of good practices and lessons learned during project closure as a minimum (see 7.1.6).

8.1.3.1.3 组织应按 7.5 的要求管理其项目的文件化信息
包括：
a) 项目信息的评审、存储（如标准化文件夹结构）、控制和维护；
b) 保留形成文件的信息（如计划、进度表、评审输出、报告）。
阶段评审应：
c) 被执行：
1) 从工作分解结构的定义层次开始；
2) 在项目层面，考虑可交付成果的评审；
d) 除非前一阶段评审的未决问题被关闭，否则不会通过。否则，由最高管理者或其授权的高级代表批准。组织应确定阶段评审的强制性参与者和可选性参与者。
8.1.3.1.3 The organization shall manage its project's documented information as required in 7.5 including:
a) review, storage (e.g. standardized folder structure), control and maintenance of project information;
b) retaining documented information (e.g. plans, schedules, output of reviews, reports).
Phase reviews shall:
c) be performed:

1) starting at defined level of work breakdown structure;
2) at project level considering the reviews of the deliverables;
d) not be passed unless open issues of prior phase reviews are closed. Otherwise, approval shall be given by top management or its authorized high-level representative.
The organization shall define mandatory and identify optional participants of phase reviews.

8.1.3.2 项目管理计划
组织应建立、实施和保持项目管理计划，并保留相关的文件化信息。该计划应包括或提及：
a) 项目组织结构图；
b) 项目目标、框架条件、分配资源、排除事项；
c) 项目组织的具体职责和权限；
d) 项目执行过程中应遵循的具体规则；
e) 从相关的职能、地点和财团合作伙伴中协调计划，以提出一个协调的项目管理计划；
注 1：典型职能包括销售、设计、生产、质量、采购、现场支持和其他适当人员，适当时包括外部供方和顾客。
f) 每阶段的可交付成果(如：对顾客的合同可交付成果或拟用于产品批准的设计输出的文件化信息)，包括：
1) 识别待顾客批准的可交付成果(如顾客产品验收点)或法律法规部门(如需要)；
2) 外部供方的可交付成果(如文件、资料、服务)；
3) 顾客可交付成果，如顾客财产，如适用； g)
对项目变更的控制(如范围、时间、成本)。
注 2：项目管理计划可包括 8.1.3(沟通、人力资源、质量)中要求的任何其他附属计划。
当项目涉及多个场所或联合体伙伴时，项目管理计划还应包括或参考：
h) 工作拆分和操作接口；
i) 具体职责和权限；
j) 沟通渠道(项目内部及与客户或相关方)；
k) 适用过程和与过程有关的其他形成文件的信息。
8.1.3.2 Project management plan
The organization shall establish, implement and maintain a project management plan and retain related documented information. This plan shall include or refer to:
a) project organization chart;
b) project targets, frame conditions, assigned resources, exclusions;
c) specific responsibilities and authorities of the project organization;
d) specific rules to follow during project execution;
e) aligned plans from involved functions, sites and consortium partners, in order to come up with a harmonized project management plan;
NOTE 1 Typical functions are sales, design, production, quality, purchasing, field support and other appropriate personnel including external providers and customer when appropriate.
f) deliverables per phase (e.g. contractual deliverables for customers or documented information of the design outputs intended for product approval) including:
1) identification of deliverables to be approved by the customer (e.g. customer product acceptance points) or statutory and regulatory authorities, where required;
2) external providers' deliverables (e.g. documents, material, services);
3) customer deliverables, such as customer properties, as applicable;
g) the control of project changes (e.g. scope, time, costs).

NOTE 2 The project management plan can include any other subsidiary plans required in 8.1.3 (communication, human resource, quality).
In cases where a project involves multiple sites or consortium partners, the project management plan shall additionally include or refer to:
h) work split and operational interfaces;
i) specific responsibilities and authorities;
j) communication channels (project internal and with the customer or interested parties);
k) applicable processes and other documented information related to the processes.

8.1.3.3 项目范围管理
关于项目范围管理，项目管理过程应包括：
a) 项目需求(如时间、商业、技术)的识别(见 8.2)；
b) 工作范围的界定；
c) 将工作细分为工作包(如工作分解结构)；
d) 将工作包分配给工作包所有者；
e) 工作包的验证。
未经批准，项目组织不得变更由组织定义项目范围(见 8.1.4.2)。
关于范围管理，项目管理过程应包括标准化工作分解结构。
设计和开发中的范围管理详见 8.3.2。
8.1.3.3 Project scope management
Regarding project scope management, the project management process shall include:
a) identification of project requirements (e.g. time, commercial, technical) (see 8.2);
b) definition of the scope of work;
c) subdivision of work into work packages (e.g. work breakdown structure);
d) assignment of work packages to work package owners;
e) verification of work packages.
The project organization shall not change the project scope unless a change has been approved (see 8.1.4.2) as defined by the organization.
Regarding scope management, the project management process should include a standardized work breakdown structure.
NOTE Scope management in design and development is detailed in 8.3.2.

8.1.3.4 项目时间管理
关于项目时间管理，项目管理过程应包括：
a) 活动的定义和顺序；
b) 活动资源和持续时间的估计；
c) 调度，考虑：
1) 过往经验；
2) 长交货期项目，与外部供应商共同管理。
项目进度计划应：
d) 包括工作包(包括外部供方的工作包)的持续时间、开始、完成和相互依赖关系；
e) 包括关键路径；
f) 向主生产计划提供输入(见 8.5.1.2)。
除非已及时向客户提出变更请求，否则项目组织不得更改有关客户交付日期的进度(见 8.1.4.2)。
项目组织应该使用软件工具来进行日程安排和活动跟踪。

8.1.3.4 Project time management

Regarding project time management, the project management process shall include:

a) definition and sequences of activities;

b) estimation of resources and duration of activities;

c) scheduling, considering:

1) past experience;

2) long lead time items, managed jointly with external providers.

The project schedule shall:

d) include duration, start, finish and interdependencies of the work packages including those of external providers;

e) include the critical path;

f) provide input to the master production schedule (see 8.5.1.2).

The project organization shall not change the schedule regarding the customer delivery dates unless a change request has been timely addressed to the customer (see 8.1.4.2).

The project organization should use a software tool for scheduling and activity tracking.

8.1.3.5 项目成本管理

对于项目成本管理，项目管理过程应包括：

a) 根据投标计算分配项目预算；

b) 在考虑所有需求的情况下，在成本核算结构中分配项目预算(例如，包括工作包中的组织、法律和法规要求)；

c) 对成本的定期控制，包括结束时的实际成本和估算成本。

项目组织不得增加项目预算，除非获得组织规定的授权(见 8.1.4.2)。

项目组织应该使用软件工具进行成本跟踪。

8.1.3.5 Project cost management

Regarding project cost management, the project management process shall include:

a) allocation of the project budget based on calculation from tender;

b) the assignment of project budget in a cost account structure, considering all requirements (e.g.including organizational, statutory and regulatory requirements in work packages);

c) a regular control of costs including actual and estimated cost at completion.

The project organization shall not increase the project budget unless authorized as defined by the organization (see 8.1.4.2).

The project organization should use a software tool for cost tracking.

8.1.3.6 项目质量管理

关于项目质量管理，组织应建立、实施和保持至少包括质量保证和控制活动的项目质量计划，并保留相关的文件化信息。

注 1:参考 ISO10005 和 ISO10006。

注 2:项目质量计划建立了项目质量管理体系，即组织的 RQMS 在项目中的应用，并增加了合同要求(如有)。

注 3:项目质量计划可包括或参考具体的项目程序(如项目不符合管理程序)、项目质量控制计划、模板或表格。

8.1.3.6 Project quality management

Regarding project quality management, the organization shall establish, implement and maintain a project quality plan, that includes at least quality assurance and control activities, and retain related documented

information.
NOTE 1 See ISO 10005 and ISO 10006 for guidance.
NOTE 2 The project quality plan establishes the project quality management system, i.e. the application of the organization's RQMS to the project, with the addition of contractual requirements (if available).
NOTE 3 The project quality plan can include or refer to specific project procedures (e.g. project nonconformity management procedure), project quality control plan, templates or forms.

8.1.3.7 项目人力资源管理
关于项目人力资源管理，项目管理过程应包括：
a) 项目角色(如项目经理、项目采购员、项目质量经理)和职责的定义和描述，与部门职能、报告关系和授权(如财务审批权限、损益责任)的定义和描述；
b) 获取项目组织；
c) 按照 7.1.2、7.2 和7.3 规定的要求，从人员、能力和意识方面对项目组织进行管理；
项目组织应建立、实施和保持项目人力资源计划，并保留相关的文件化信息。该计划应在有关各级包括：d)项目核心团队和人员的分配(如提名信)；
e) 除 7.2 中定义的能力外，定义所需的特定能力(例如，项目管理软件工具、团队合作和沟通、交付的产品和服务、建立信息模型、工作分解结构)；
f) 必要时，识别相关培训。
8.1.3.7 Project human resource management
Regarding project human resource management, the project management process shall include:
a) the definition and description of project roles (e.g. project manager, project buyer, project quality manager) and responsibilities versus those of line functions, reporting relationships and empowerment (e.g. financial approval authorities, profit and loss responsibilities);
b) acquiring the project organization;
c) managing the project organization in terms of people, competence and awareness, in accordance with requirements defined in 7.1.2, 7.2 and 7.3;
The project organization shall establish, implement and maintain a project human resource plan and retain related documented information. This plan shall include, at related levels:
d) the assignment of project core team and staff (e.g. nomination letters);
e) the definition of required specific competencies (e.g. project management software tool, team work and communication, products and services to be delivered, building information modelling, work breakdown structure) in addition to competencies defined in 7.2;
f) the identification of related training, if necessary.

8.1.3.8 项目沟通管理
对于项目沟通管理，项目组织应：
a) 应用 7.4 和8.2.1 规定的要求；
b) 建立、实施和保持项目沟通计划，并保留相关文件信息。在项目沟通管理方面，当即将发生偏差时，项目组织应向顾客和相关方传达相关影响和应对措施(见 8.1.3.11)。
8.1.3.8 Project communication management
Regarding project communication management, the project organization shall:
a) apply requirements defined in 7.4 and 8.2.1;
b) establish, implement and maintain a project communication plan and retain related documented information. Regarding project communication management, in case of imminent deviation, the project organization should communicate relevant impacts and countermeasures to customers and interested parties

(see8.1.3.11).

8.1.3.9 项目风险和机会管理

8.1.3.9.1 关于项目风险和机会管理，项目组织应：

a) 实施 6.1 规定的要求；

b) 建立、实施并保持包括风险和机会的成本效益分析的登记册；

c) 保留形成文件的风险和机会管理信息。

8.1.3.9 Project risk and opportunities management

8.1.3.9.1 Regarding project risk and opportunities management, the project organization shall:

a) apply the requirements defined in 6.1;

b) establish, implement and maintain a register including a cost and benefit analysis of risks and opportunities;

c) retain documented information of risk and opportunities management.

8.1.3.9.2 关于风险和机会管理，项目组织应：

a) 让职能部门经理参与风险评审；

b) 考虑与顾客商定的产品的运行成熟度等级作为风险管理的输入；

注：风险分析可以考虑与技术需求相关的操作成熟度。

c) 管理节约成本(平衡损失)或提高成本(增加利润)的机会，特别是为了恢复项目预算的恶化。

8.1.3.9.2 Regarding risk and opportunities management, the project organization should:

a) involve the functional line managers in risk reviews;

b) consider operational maturity levels of the products agreed with the customer as inputs for risks management;

NOTE Risk analysis can consider operational maturity relevant to technical requirements.

c) manage opportunities for cost savings (to balance losses) or cost enhancements (to increase margin), especially in order to recover the project budget deteriorations.

8.1.3.10 项目采购管理

对于项目采购管理，项目组织应适用 8.4 中规定的要求。

8.1.3.10 Project procurement management

Regarding project procurement management, the project organization shall apply requirements defined in 8.4.

8.1.3.11 项目评审管理

组织应定期进行项目评审，由项目核心团队(或授权代表)参加(见 8.1.3.7)，以监控项目进度。

在即将发生偏离项目目标的情况下，项目组织应确定并实施适当的对策，以减轻对顾客、组织和/或其他相关方的影响。

项目评审应包括：

a) 基于 9.1.1.1 规定的绩效指标 PI(如需求、时间、成本)的项目绩效(实际情况与计划情况)；

b) 预测(如时间、完工时的估计成本)；

c) 风险和机遇，包括相关措施的状况；

d) 跟踪以前评审中未解决的问题和采取的措施。

项目评审的输出应报告给比项目经理更高的管理层，包括供决策或升级的问题。

项目评审的目的是监视整个项目的进度。项目阶段评审(见 8.1.3.1)的目的是检查一个项目阶段是否可以结束，下一个项目阶段是否可以开始。

8.1.3.11 Project review management

The organization shall perform regular project reviews to monitor project progress, with the attendance of the project core team (or empowered deputies) (see 8.1.3.7).
In case of an imminent deviation to the project objectives, the project organization shall identify and implement appropriate countermeasures to mitigate the impact on customer, the organization and/or other interested parties.
Project reviews shall include:
a) the project performance (actual situation versus planned situation) based on PIs as specified in 9.1.1.1 (e.g. requirements, time, costs);
b) the forecast (e.g. time, estimated cost at completion);
c) the risks and opportunities, including status of related actions;
d) tracking of open issues and actions from previous reviews.
The output of project reviews should be reported to management level higher than the project manager including issues for decision or escalation.
NOTE Project reviews are intended to monitor the progress of the complete project. Project phase reviews (see 8.1.3.1) are intended to check whether a project phase can be closed and whether the next project phase can begin.

8.1.4 配置管理和变更控制
8.1.4.1 配置管理
8.1.4.1.1 组织应建立、实施并保持与产品相适应的工艺的配置管理
说明配置管理流程适用于硬件和软件。
这过程应包括：
a) 配置管理计划；
b) 在 LLRU 之前产品分解结构的定义；
c) 配置项的识别，至少是与安全有关的配置项；
d) 配置基线的定义(例如“按设计”、“按建造”和“按维护”配置)及时建立；e)
根据 8.1.4.2 对配置的变更控制；
f) 配置状态记录；
g) 可追溯性标识标准的定义(如序列化、批号)。
组织应为配置管理过程保留形成文件的信息。
8.1.4.1.2 该过程应：
a) 包括定期的内部配置审核；
b) 整合外部供应商的配置管理系统(如数据传输接口)；
c) 包括用于设计、开发、生产和维护的工具和软件配置项；
d) 被软件工具支持。
注：参考 ISO 10007。

8.1.4 Configuration management and change control
8.1.4.1 Configuration management
8.1.4.1.1 The organization shall establish, implement and maintain a configuration management process appropriate to the product.
NOTE The configuration management process is applicable for hardware and software.
This process shall include:
a) the configuration management plan;
b) the definition of a product breakdown structure until the LLRU;

c) the identification of configuration items, at least the safety-related ones;
d) the definition of configuration baseline(s) (e.g. “as-designed”, “as-built” and “as-maintained”configurations) to be established in a timely manner;
e) the change control of the configuration in accordance with 8.1.4.2;
f) configuration status accounting;
g) the definition of criteria for identification of traceability (e.g. serialization, batch number).
The organization shall retain documented information for the configuration management process.
8.1.4.1.2 This process should:
a) include regular internal configuration audits;
b) integrate external providers' configuration management system (e.g. interfaces for data transfer);
c) include tools and software used in design, development, production and maintenance as configuration items;
d) be supported by a software tool.
NOTE See ISO10007 for guidance.

8.1.4.2 变更控制
组织应建立、实施并保持变更控制过程。
这过程应包括:
a) 第 8 条规定的与变更有关的要求;
b) 变更请求;
c) 对由失败引起的变化进行原因分析;
d) 考虑风险和机遇的变化影响分析;
e) 对提出的变更进行验证，以避免不良影响;
f) 至少在发生影响顾客、外部供方和主管部门要求(如适合性、形式和功能)的变更时，通知顾客、外部供方和主管部门并与之达成一致;
注 1:影响顾客要求的变更可触发偏差许可。
注 2:由偏差许可触发的变更请求，在变更得到顾客批准后可以关闭。
g) 变更批准的职责和权限分配(如变更控制委员会);
h) 变更实施前的批准;
i) 变更的实施;
j) 变更实施的验证和有效性的跟踪;
k) 变更的可追溯性(例如由软件工具支持)。
这过程应包括行动计划，以尽量减少变化的影响。
对于产品和服务的技术变更，该过程还应包括:
l) 分析变化对以下方面的影响:
1) 组成部件及已交付的产品;
2) 客户规范与配置;
3) 相关文件化信息(如质量计划、FMEA 结果);
4) 技术要求;
m) 根据影响分析的结果对技术要求进行重新评价;
8.1.4.2 Change control
The organization shall establish, implement and maintain a change control process.
This process shall include:
a) the requirements defined in Clause 8 related to changes;
b) change requests;

c) a cause analysis in case of changes deriving from failures;
d) an impact analysis of the change considering risks and opportunities;
e) the verification of proposed changes to avoid adverse effects;
f) notification to and agreement with customers, external providers and authorities in the event of, as a minimum, changes affecting their requirements (e.g. fit, form and function);
NOTE 1 A change affecting customer requirements can trigger a deviation permit.
NOTE 2 A change request triggered by a deviation permit can be closed when the change is approved by the customer.
g) the assignment of responsibilities and authorities for the approval of changes (e.g. change control board);
h) the approval of change before implementation;
i) the implementation of changes;
j) the verification of implementation and follow-up of the effectiveness of the change;
k) the traceability of changes (e.g. supported by a software tool).
This process should include planning of actions in order to minimize the impact of change.
For technical changes on products and services, this process shall include in addition:
l) an analysis of the change impact on:
1) constituent parts and products already delivered;
2) customer specification and configuration;
3) related documented information (e.g. quality plan, FMEA results);
4) technical requirements;
m) the re-evaluation of technical requirements depending on the results of the impact analysis;

8.2 产品和服务的要求
8.2.1 顾客沟通
与顾客沟通的内容应包括：
a) 提供有关产品和服务的信息； b)处理问询、合同或订单，包括更改； c)获取有关产品和服务的顾客反馈，包括顾客投诉； d)处置或控制顾客财产； e)关系重大时，制定应急措施的特定要求。
8.2.1.1 顾客沟通－补充
当预计延误且不能避免（如延误来自外部提供方），组织必须向顾客沟通。
注：项目沟通管理请参见 8.1.3.8。
8.2.1.1 Customer communication — Supplemental
The organization shall communicate with customers when delays are foreseen but cannot be avoided (e.g. delays from external providers).
NOTE For project communication management, see also 8.1.3.8.

8.2.2 产品和服务要求的确定 在确定向顾客提供的产品和服务的要求时，组织应确保： a)
产品和服务的要求得到规定，包括：
1）适用的法律法规要求；
2）组织认为的必要要求。
b) 提供的产品和服务能够满足所声明的要求。
8.2.2.1 确定与产品和服务有关的要求——补充
8.2.2.1.1 在确定要求时(见附件 B)，组织应考虑：
A)功能性和非功能性需求；
b) RAMS/LCC 要求；
C)适用的过时要求(如来自市场、外部供方、法规的信息)；

D) 由组织和/或顾客定义的关键产品特性。

8.2.2.1.2 组织在确定要求时应考虑：

A) 类似产品/招标/项目的经验；

B) 由市场分析得出的要求；

C) 关于产品生命周期结束的要求(如处置、再循环)。

8.2.2.1.3 组织应保留与 8.2.2 a)至 b)、8.2.2.1.1 a)至 b)以及 8.2.2.1.2 a)至 c)相关的文件化信息。

要求的从属概念见附件B。

8.2.2.1 Determining the requirements related to products and services — Supplemental

8.2.2.1.1 When determining the requirements (see Annex B), the organization shall consider:

a) functional and non-functional requirements;

b) RAMS/LCC requirements;

c) obsolescence requirements, as applicable (e.g. information coming from market, external providers, regulations);

d) critical product characteristics as defined by the organization and/or the customer.

8.2.2.1.2 When determining the requirements, the organization should consider:

a) experience from similar products/tenders/projects;

b) requirements resulting from market analysis;

c) requirements regarding end of product life (e.g. disposal, recycling).

8.2.2.1.3 The organization shall retain documented information in relation to 8.2.2 a) to b) and 8.2.2.1.1 a) to b) and, if considered, 8.2.2.1.2 a) to c).

NOTE The subordinate concept of requirements is shown in Annex B.

8.2.3 产品和服务要求的评审

8.2.3.1组织应确保有能力向顾客提供满足要求的产品和服务。在承诺向顾客提供产品和服务之前，组织应对如下各项要求进行评审：

a) 顾客规定的要求，包括对交付及交付后活动的要求；

b) 顾客虽然没有明示，但规定的用途或已知的预期用途所必需的要求； c）

组织规定的要求；

d） 适用于产品和服务的法律法规要求； e）

与以前表述不一致的合同或订单要求。

组织应确保与以前规定不一致的合同或订单的要求已得到解决。若顾客没有提供成文的要求，组织在接受顾客要求前应对顾客要求进行确认。

注：在某些情况下，如网上销售，对每一个订单进行正式的评审可能是不实际的，作为替代方法，可评审有关的产品信息，如产品目录。

8.2.3.2适用时，组织应保留与下列有关的成文信息： a）

评审结果；

b） 产品和服务的新要求。

8.2.4 产品和服务要求的更改

若产品和服务要求发生更改，组织应确保相关的成文信息得到修改，并确保相关人员知道已更改的要求。

8.2.5 产品和服务要求—补充

组织应建立、实施和保持以下方面的产品和服务需求管理过程

这过程应：

a)包括 8.2 规定的要求；

b) 适用于：

1） 在投标(如平台、产品系列)前设计和开发符合市场预期的新产品和服务;
2)招标管理(如提交标书、接受合同或订单);
3)项目执行(如接受合同或订单的变更);
4)变更控制(见 8.1.1.2 8.1.4.2,8.2.4,求值,8.4.3.1 和 8.5.6);
注 1:该过程可包括在项目管理过程中。
c)采用多方论证方法实施，包括内外部相关方(如适用);
d)至少包括以下步骤:
1)测定(见 8.2.2.1);
2)评审(见 8.2.3);
3)验证;
4)验证;
注 2:“验证”和“确认”的定义见 3.1.3.12 和3.1.3.11。
e)确保要求是:
1)逐条单独检查符合性;
2)评价和考虑;
3)与风险和机遇相关的评估(见 6.1);
4）在参与人员内被恰当地转移、理解、承认、向下传递和承诺
5)完整、明确、可核查和可行;
6)形成技术规范，包括功能和非功能要求;
注 3:技术规范可由客户提供，也可由组织定。
7)如有变更，及时更新。
8.2.5 Requirements for products and services — Supplemental
The organization shall establish, implement and maintain a requirement management process for products and services.
This process shall:
a) include the requirements defined in 8.2;
b) be applicable for:
1) design and development of new products and services meeting market expectations prior to tender (e.g. platform, product family);
2) tender management (e.g. submission of tenders, acceptance of contracts or orders);
3) project execution (e.g. acceptance of changes to contracts or orders); 4) change control (see 8.1.1.2, 8.1.4.2, 8.2.4, 8.3.6, 8.4.3.1 and 8.5.6);
NOTE 1 This process can be included in the project management process.
c) be performed by a multidisciplinary approach including internal and external interested parties as applicable;
d) include as a minimum these steps:
1) determination (see 8.2.2.1);
2) review (see 8.2.3);
3) verification;
4) validation;
NOTE 2 For definitions of “verification” and “validation”, see 3.1.3.12 and 3.1.3.11.
e) ensure that requirements are:
1) individually checked for conformity clause by clause;
2) evaluated and taken into account;
3) assessed in relation to risks and opportunities (see 6.1);

4) properly transferred, understood, acknowledged, cascaded down and committed to, by the involved persons;
5) complete, unequivocal, verifiable and feasible;
6) documented in a technical specification including functional and non-functional requirements;
NOTE 3 The technical specification can be provided by the customer or established by the organization.
7) updated in case of change.

8.3 产品和服务的设计和开发
8.3.1 总则
组织应建立、实施和保持适当的设计和开发过程，以确保后续的产品和服务的提供。
8.3.1.1 总则-补充
8.3 中规定的要求应适用于产品和服务的设计和开发，以及新技术的引入(如适用)。组织应识别新技术并评估其风险(如通过过程 FMEA)。设计开发过程应：
a)包括 8.3.2、8.3.3、8.3.4、8.3.5 和8.3.6 中所述的关于策划、输入、控制、输出和变更的要求；
b)包括与产品架构相关的需求，包括接口，如软件产品；
c)包括关于“可靠性”、“可用性”、“可维护性”、“安全性”以及(如果适用)8.8 中所述的“生命周期成本”的要求；
d) 要求与安全相关的产品符合 IEC 62278 或等效标准(如适用)。
8.3.1.1 General — Supplemental
The requirements defined in 8.3 shall apply to the design and development of products and services, as well as to the introduction of new technologies, if appropriate.
The organization shall identify new technologies and assess their risks (e.g. through process FMEA).The design and development process shall:
a) include the requirements regarding planning, inputs, controls, outputs and changes described in 8.3.2, 8.3.3, 8.3.4, 8.3.5 and 8.3.6;
b) include the requirements related to the product architecture, including interfaces, e.g. software products;
c) include the requirements regarding 'reliability', 'availability', 'maintainability', 'safety' and, if applicable, 'life cycle costing' described in 8.8;
d) require conformity for safety-related products with IEC 62278 or an equivalent, as applicable.

8.3.2 设计和开发策划
在确定设计和开发的各个阶段和控制时，组织应考虑：
a） 设计和开发活动的性质、持续时间和复杂程度；
b） 所需的过程阶段，包括适用的设计和开发评审；
c） 所需的设计和开发验证、确认活动；
d) 设计和开发过程涉及的职责和权限；
e) 产品和服务的设计和开发所需的内部、外部资源； f）
设计和开发过程参与人员之间接口的控制需求； g） 顾
客及使用者参与设计和开发过程的需求；
h) 对后续产品和服务提供的要求；
i) 顾客和其他有关相关方期望的对设计和开发过程的控制水平； j）
证实已经满足设计和开发要求所需的成文信息。
8.3.2.1 设计和开发规划—补充
8.3.2.1.1 在确定设计和开发的阶段和控制时，组织应考虑：
A)每个过程阶段的目标；

B) 产品架构(如产品分解结构);

C)配置管理(见 8.1.4.1);
D)在产品架构的定义层次上进行设计评审、验证和确认(例如，从组件设计评审开始，然后是子系统设计评审，直至系统设计评审);
E)特殊工艺的设计评审、验证和确认。
设计和开发的阶段和控制应形成文件(如在质量计划中)。
设计阶段分为概念设计、初步设计和最终设计。
8.3.2.1 Design and development planning — Supplemental
8.3.2.1.1 In determining the stages and controls for design and development, the organization shall consider:
a) the objectives for each process stage;
b) the product architecture (e.g. product breakdown structure);
c) the configuration management (see 8.1.4.1);
d) design reviews, verification and validation at defined levels of the product architecture (e.g.starting from component design review, then sub-system design review and up to system design review);
e) design reviews, verification and validation for special processes.
The stages and controls for design and development shall be documented (e.g. in a quality plan).
NOTE Design stages can be conceptual design, preliminary design and final design.

8.3.2.1.2 在确定设计和开发的阶段和控制时，组织应考虑:
A)每个设计和开发阶段的质量保证方法，以满足目标(如在质量计划中定义的);
B)控制技术要求的方法;
C)控制运营成熟度的方法。
注 1:控制可考虑运行成熟度，包括非功能需求的成熟度，如性能、集成和其他非功能需求。
注 2:如果特殊过程的要求是设计的输入，则对这些特殊过程的风险评估可作为设计和开发过程的一部分。
注 3:与外部工程的协作可视为外部提供的服务(见 8.4)。
8.3.2.1.2 In determining the stages and controls for design and development, the organization should consider:
a) the quality assurance methods for each design and development stage in order to meet the objectives (e.g. defined in a quality plan);
b) the method to control technical requirements;
c) the method to control the operational maturity.
NOTE 1 Controls can consider operational maturity including maturity of non-functional requirements, such as performance, integration and other non-functional requirements.
NOTE 2 If requirements of special processes are inputs to the design, the risk assessment of these specialprocesses can be part of the design and development process.
NOTE 3 Collaboration with external engineering can be considered as externally provided services (see 8.4).

8.3.3 设计和开发输入
组织应针对所设计和开发的具体类型的产品和服务，确定必需的要求。组织应考虑：
a） 功能和性能要求；
b） 来源于以前类似设计和开发活动的信息；
c） 法律法规要求；
d) 组织承诺实施的标准或行业规范；
e) 由产品和服务性质所导致的潜在失效后果。
针对设计和开发的目的，输入应是充分和适宜的，且应完整、清楚。 相互矛盾的设计和开发输入应得到解决。组织应保留有关设计和开发输入的成文信息。

8.3.3.1 设计和开发输入—补充

8.3.3.1.1 关于设计和开发输入，组织应考虑：

a) 8.2.2 规定的要求；

b) 标识和可追溯性。

8.3.3.1 Design and development inputs — Supplemental

8.3.3.1.1 Regarding design and development inputs, the organization shall consider:

a) the requirements defined in 8.2.2;

b) identification and traceability.

8.3.3.1.2 此外，组织应当考虑：

a) 生产和常规检验要求，包括特殊工艺，直至生产在这个阶段，设施是已知的；

b) 防护要求。

8.3.3.1.2 In addition, the organization should consider:

a) production and routine testing requirements, including special processes, so far as the production facilities are known at this stage;

b) preservation requirements.

8.3.4 设计和开发控制

组织应对设计和开发过程进行控制，以确保：

a) 规定拟获得的结果；

b) 实施评审活动，以评价设计和开发的结果满足要求的能力；

c) 实施验证活动，以确保设计和开发输出满足输入的要求；

d) 实施确认活动，以确保形成的产品和服务能够满足规定的使用要求或预期用途；

e) 针对评审、验证和确认过程中确定的问题采取必要措施；

f) 保留这些活动的成文信息。

注：设计和开发的评审、验证和确认具有不同目的。根据组织的产品和服务的具体情况，可单独或以任意组合的方式进行。

8.3.4.1 设计和开发控制——补充

组织应考虑以下因素对设计和开发过程实施控制：

A) 功能分解；B)

业务成熟度；

C) 质量保证方法的实施。

8.3.4.1 Design and development controls — Supplemental

The organization should apply controls to the design and development process considering:

a) the functional breakdown;

b) the operational maturity;

c) the implementation of quality assurance methods.

8.3.4.2 设计评审

关于设计评审，组织应规定：

A) 批准进入下一阶段的标准(如检查清单、验收规则)；

B) 强制性和非强制性参与者。

参加设计评审的职能代表应有决策权。

组织应采用多学科方法执行设计评审。

注 1:参与者可以是职能部门负责人(如服务部门)、内部和外部顾客、生产专家。

注 2:设计评审可作为项目阶段评审的一部分或作为项目阶段评审的输入(见 8.1.3.1)。

8.3.4.2 Design reviews
Regarding design reviews, the organization shall define:
a) criteria for authorization of progression to the next stage (e.g. checklist, rules for acceptance);
b) mandatory and optional participants.
Representatives of functions joining design reviews shall have the authority to make decisions.
The organization should perform design reviews with a multidisciplinary approach.
NOTE 1 Participants can be head of functions (e.g. RAMS, services), internal and external customers, experts in production.
NOTE 2 Design reviews can be part of or an input for project phase reviews (see 8.1.3.1).

8.3.4.3 设计验证
组织应确保技术要求得到验证。
注:设计验证活动可以是有限元分析、计算、模型和设计附带试验。
8.3.4.3 Design verification
The organization shall ensure that technical requirements are verified.
NOTE Design verification activities can be finite element analysis, calculations, mock-up and design accompanying tests.

8.3.4.4 设计验证
对于设计验证，组织应:
A) 确保技术要求得到验证;
B) 在交付或调试结束前完成验证，或与顾客商定控制计划，并监督其完成。
注:设计验证活动可以是，例如，确认试验、型式试验和产品批准试验。
8.3.4.4 Design validation
Regarding design validation, the organization shall:
a) ensure that technical requirements are validated;
b) complete validation prior to the delivery or end of commissioning or agree on control plans with customers and monitor them until completion.
NOTE Design validation activities can be, for example, qualification tests, type tests and product approval tests.

8.3.4.3 设计验证
组织应确保技术要求得到验证。
注:设计验证活动可以是有限元分析、计算、模型和设计附带试验。
8.3.4.3 Design verification
The organization shall ensure that technical requirements are verified.
NOTE Design verification activities can be finite element analysis, calculations, mock-up and design accompanying tests.

8.3.4.4 设计验证
对于设计验证，组织应:
A) 确保技术要求得到验证;
B) 在交付或调试结束前完成验证，或与顾客商定控制计划，并监督其完成。
注:设计验证活动可以是，例如，确认试验、型式试验和产品批准试验。
8.3.4.4 Design validation

Regarding design validation, the organization shall:
a) ensure that technical requirements are validated;
b) complete validation prior to the delivery or end of commissioning or agree on control plans with customers and monitor them until completion.
NOTE Design validation activities can be, for example, qualification tests, type tests and product approval tests.

8.3.4.5 设计验证和验证试验要求
当需要进行验证和确认时，组织应策划、控制和评审
这些测试。组织应确保：
a) 测试计划、测试规范或测试程序提供可重复性并定义：
1) 测试目标；
2) 试验条件和环境；
3) 待测产品；
4) 所需资源；
5) 试验验收标准；
6) 需要记录的参数；
7) 试验操作方法；
8) 试验性能；
b) 产品的正确配置提交测试并记录为配置基线；
c) 满足测试验收标准。
8.3.4.5 Design verification and validation test requirements
When tests are necessary for verification and validation, the organization shall plan, control and review these tests. The organization shall ensure that:
a) test plans, test specifications or test procedures provide reproducibility and define:
1) test objectives;
2) test conditions and environment;
3) the product to be tested;
4) resources needed;
5) test acceptance criteria;
6) parameters to be recorded;
7) the test method of operation;
8) the performance of the test;
b) the correct configuration of the product is submitted for the tests and recorded as a configuration baseline;
c) the test acceptance criteria are met.

8.3.5 设计和开发输出
组织应确保设计和开发输出：
a） 满足输入要求；
b) 满足后续产品和服务提供过程的需要；
c) 包括或引用监视和测量要求，适当时，包括接收准则；
d) 规定产品和服务特性，这些特性对于预期目的、安全和正常提供是必需的；组织应保留有关设计和开发输出的成文信息。
8.3.5.1 设计和开发输出—补充
8.3.5.1.1 组织应确保设计和开发输出：

a) 放行前的验证和批准；
b) 针对生产过程输入进行验证(见 8.5.1.1.3)；
c) 包括与应用有关的文件化信息(如操作、维护手册)和培训。
8.3.5.1 Design and development outputs — Supplemental
8.3.5.1.1 The organization shall ensure that design and development outputs:
a) are verified and approved prior to release;
b) are verified against production process inputs (see 8.5.1.1.3);
c) include the documented information (e.g. operations, maintenance manuals) and training related to the application.

8.3.5.1.2 组织应：
a) 确保输出对输入要求的可追溯性；
b) 确定设计审批的权限和验收标准；
c) 在不符合批准接受标准的情况下，确定上报规则；
d) 确保生产和服务提供的信息包括产品防护。
注:设计和开发输出可包括，例如，规格书和图纸(也可来自外部供方)、材料信息、生产过程流程图和/ 或布局图、检验和试验计划、生产作业指导书、过程和产品批准接受准则、识别要求、错误预防活动的结果(如 FMEA)、产品和/或生产过程不符合的快速检测和反馈方法。
8.3.5.1.2 The organization should:
a) ensure the traceability of outputs to the input requirements;
b) define authorities and acceptance criteria for design approval;
c) define escalation rules in case acceptance criteria for approval are not met;
d) ensure that information for production and service provision includes requirements for the preservation of product.
NOTE The design and development outputs can include, for example, specifications and drawings (also from external providers), information on materials, production process flow charts and/or layouts, inspection and test plans, work instructions for production, process and product approval acceptance criteria, identification requirements, results of error prevention activities (e.g. FMEA), methods of rapid detection and feedback of product and/or production process nonconformities.

8.3.6 设计和开发更改
组织应对产品和服务在设计和开发期间以及后续所做的更改进行适当的识别、评审和控制，以确保这些更改对满足要求不会产生不利影响。
组织应保留下列方面的成文信息：
a） 设计和开发更改；
b） 评审的结果；
c） 更改的授权；
d） 为防止不利影响而采取的措施。

8.4 外部提供的过程、产品和服务的控制
8.4.1 总则
组织应确保外部提供的过程、产品和服务符合要求。 在下列情况下，组织应确定对外部提供的过程、产品和服务实施的控制：
a） 外部供方的产品和服务将构成组织自身的产品和服务的一部分；
b） 外部供方代表组织直接将产品和服务提供给顾客；

c) 组织决定由外部供方提供过程或部分过程。
组织应基于外部供方按照要求提供过程、产品或服务的能力，确定并实施对外部供方的评价、选择、绩效监视以及再评价的准则。对于这些活动和由评价引发的任何必要的措施，组织应保留成文信息。
8.4.1.1 总则-补充
8.4.1.1.1 外部供应商
组织应确定 8.4 中适用于外部供方的要求的类型和程度，并根据已定义的标准进行风险评估。组织应建立、实施和保持 EPPPS 的过程
确保符合 ISO 9001:2015 8.4.1 的要求。
该过程应包括以下方面的要求：
a) 外部供方和 EPPPS 的分类(见 8.4.1.1.2)；
B) 外部供方评价(见 8.4.1.1.3)；
C) 外部供方的批准(见 8.4.1.1.4)；
D) 外部供方的报价选择(见 8.4.1.1.5)；
E) 外部供方信息(见 8.4.3)；
f) 放行 EPPPS 的批准(见 8.4.2.1)；
g) 发布后的 EPPPS 验证(见 8.4.2.2)；
H) 对外部供方的绩效、再评价和排名的监控(见 8.4.2.3)。
此外，组织应：
i) 管理整个供应链的 EPPPS 风险；
J) 识别要与外部供方沟通的风险，并要求外部供方提供他们的风险反馈；
k) 除 ISO 9001:2015 8.4.1 外，还应根据 a) 至 g) 保留外部供方的文件化信息。

8.4.1.1 General — Supplemental
8.4.1.1.1 External providers
The organization shall determine the type and extent of requirements from 8.4 that apply to external providers, with risk assessments based on defined criteria.
The organization shall establish, implement and maintain a process for EPPPS described in ISO 9001:2015, 8.4.1 to ensure conformity to requirements.
This process shall include requirements defined for:
a) classification of external providers and EPPPS (see 8.4.1.1.2);
b) external providers' evaluation (see 8.4.1.1.3);
c) external providers' approval (see 8.4.1.1.4);
d) external providers' offer selection (see 8.4.1.1.5);
e) information for external providers (see 8.4.3);
f) EPPPS approval of release (see 8.4.2.1);
g) EPPPS verification after release (see 8.4.2.2);
h) monitoring of external providers' performance, re-evaluation and ranking (see 8.4.2.3).
In addition, the organization shall:
i) manage the EPPPS risks throughout the supply chain;
j) identify risks to be communicated to external providers and ask external providers for their feedback;
k) in addition to ISO 9001:2015, 8.4.1, also retain documented information on external providers in accordance with a) to g).

8.4.1.1.2 外部供方和外部提供的产品、过程及分类
外部供方和EPPPS 的服务分类应按照确定的标准进行，以确定对外部供方和EPPPS 的控制类型和程度[见

4.4.3 f)]。作为输出，应识别关键的外部供方。
分类标准应包括外部供方按照要求提供 EPPPS 的能力。
此外，组织应定期评审外部供方的分类。
分类标准应包括：
A)战略需要；B)
过去的经历；
C)可获得的市场信息；
D)外部基准；
E)外部提供的产品的运行成熟度(如：可供使用)。
8.4.1.1.2 Classification of external providers and external provided products, processes and
Services Classification of external providers and EPPPS shall be performed on defined criteria to determine the type and extent of control applied to external providers and the EPPPS [see 4.4.3 f)]. As an output, key external providers shall be identified.
Classification criteria shall include the ability of external providers to provide EPPPS in accordance with requirements.
In addition, the organization shall regularly review the classification of external providers.
Classification criteria should include:
a) strategic needs;
b) past experiences;
c) available market information;
d) external benchmarks;
e) the operational maturity of externally provided products (e.g. ready to use).

8.4.1.1.3 对外部供方的评价
外部供方的评价应包括：
a) 外部供方的人员、基础设施和流程；
b) 外部供方资格的可获得性(如根据本标准、ISO9001 的认证)，并在适当时通过其他方式补充(如审核)。组织应确定并监视一项战略，以实现以下目标：
c) 符合本标准要求的外部供方；
d) 外部供方符合 ISO9001 或同等质量管理要。应根据目标外部供应商的产品范围、战略相关性、年度支出、产品关键性、设计活动、铁路部门的营业额以及交付和质量绩效来确定目标外部供应商。
8.4.1.1.3 Evaluation of external providers
External providers' evaluation shall include:
a) people, infrastructure and processes of external providers;
b) availability of external providers' qualifications (e.g. certifications according to this document,ISO9001), supplemented, when appropriate, by other means (e.g. audit).
The organization shall determine and monitor a strategy to enable the targeting of:
c) external providers that meet the requirements of this document;
d) external providers that meet the requirements of ISO 9001 or an equivalent quality management system.Targeted external providers shall be identified considering their product scopes, strategic relevance,annual spend volume, product criticality, design activities, turnover in the railway sector and delivery and quality performance.

8.4.1.1.4 外部供方的批准
组织应：

a 建立批准外部供方的标准；
b) 确保有权批准的职能部门也有权拒绝已批准的外部供方； c）
保持已批准的外部供方的登记册，包括其批准范围的定义。
EPPPS 应仅由经批准的外部供应商提供。
8.4.1.1.4 Approval of external providers
The organization shall:
a) establish criteria to approve external providers;
b) ensure that functions having the authority to approve have also the authority to reject already approved external providers;
c) maintain a register of approved external providers, including the definition of their scope of approval.
EPPPS shall be provided exclusively by approved external providers.

8.4.1.1.5 外部供方报价选择
8.4.1.1.5.1 组织应确保在分析的基础上选择外部供方的报价，该分析应考虑：
a) 符合要求，例如逐个条款；
b) 总拥有成本，包括最低成本(如适用)；
c) 以往 EPPPS 的外部供方的质量、成本和交付绩效，包括由外部供方造成的质量缺陷成本；
d) 要约所涉及的外部供方的分类。
8.4.1.1.5 External provider offer selection
8.4.1.1.5.1 The organization shall ensure that the external provider's offer is selected on the basis of an analysis which takes into account:
a) conformity with the requirements, e.g. by clause by clause;
b) the total cost of ownership including, as applicable, LCC;
c) the quality, cost and delivery performance of the external provider for previous EPPPS, including quality deficiency costs caused by the external provider;
d) the classification of the external providers concerned by the offer.

8.4.1.1.5.2 分析应考虑：
a) 风险分析的输出；
b) 外部提供产品的运行成熟度。
在发出采购订单之前，组织应确保外部供方已充分理解所有技术要求，例如通过联合合同评审。
8.4.1.1.5.2 The analysis should take into account:
a) the output of a risk analysis;
b) the operational maturity of externally provided products.
Prior to the issuance of a purchase order, the organization should ensure that the external provider has fully understood all technical requirements, e.g. by a joint contract review.

8.4.2 控制类型和程度
组织应确保外部提供的过程、产品和服务不会对组织稳定地向顾客交付合格产品和服务的能力产生不利影响。
组织应：
a） 确保外部提供的过程保持在其质量管理体系的控制之中；
b） 规定对外部供方的控制及其输出结果的控制；
c) 考虑：
1） 外部提供的过程、产品和服务对组织稳定地满足顾客要求和适用法律法规要求的能力的潜在影响；

2） 由外部供方实施控制的有效性；
d) 确定必要的验证或其他活动，以确保外部提供的过程、产品和服务满足要求。
8.4.2.1 外部提供的产品、过程和服务的放行批准
8.4.2.1.1 批准新的或修改的 EPPPS 的放行应包括：
a) 审批方式的确定；
b) 策划验证、确认和批准活动；
c) 适用时，对外部供方场所进行 FAI(见 8.9)，或适当的进/出检验；
d) 在顾客合同中对外部提供的产品或技术(如新的设计软件)首次使用前进行验证，除非与顾客另有约定；
e) 放行批准(如开始批量生产)；
f) 考虑变更控制的配置基线的定义或更新(见 8.1.4)。
8.4.2.1 Externally provided products, processes and services approval of release
8.4.2.1.1 Approval of release for new or modified EPPPS shall include:
a) determination of approval methods;
b) planning of verification, validation and approval activities;
c) as applicable, conducting FAI at external providers' premises (see 8.9), or appropriate incoming/outgoing inspection;
d) validation of externally provided products or technologies (e.g. new design software) before first use in a customer contract unless otherwise agreed with the customer;
e) approval of release (e.g. to start serial production);
f) definition or update of configuration baseline considering change control (see 8.1.4).

8.4.2.1.2 批准发布新的或修改的 EPPPS 时应考虑：
a) 生产前评审；
注：生产前评审可为开始第一批产品生产提供受控条件和准备情况的证据。
b) 第一次系统集成。
组织应向外部供方报告实现设计和开发目标的进展情况以及质量保证活动的状态。
8.4.2.1.2 Approval of release for new or modified EPPPS should consider:
a) pre-production reviews;
NOTE Pre-production reviews can provide evidence of controlled conditions and readiness for the start of the first article production.
b) first system integration.
The organization should report progress in achieving design and development objectives and status of quality assurance activities to its external providers.

8.4.2.2 外部提供的产品、过程和服务放行后的验证
EPPPS 在经验证符合规定之前，不得使用或加工
除非是在授权特许下放行(见 8.7.3)。
发布后的 EPPPS 验证活动应包括：
a) 活动策划[例如，在检验和测试计划中，包括控制范围、频率、样本量和方法的确定，见 4.4.3 f)]；
b) 为验证活动提供指示、清单或模板；
c) 获取 EPPPS 符合要求的证据(例如，通过检查随附的文件化信息，如符合性证书、测试报告、统计记录、过程控制单)；
d) 确认 EPPPS 的发布；

e) 不符合 EPPPS 的管理。

当组织使用检测报告来验证 EPPPS 时，报告中的数据应与报告中所述的可接受准则相比较，这些准则来源于采购信息，如规范、标准。
组织应在风险评估的基础上确定原材料的定期验证计划。
注 1:原材料成分或合格性的验证可以通过检查，例如证书、化学分析、自己的实验室测试来完成。
8.6 中规定的检验和测试要求应适用于 EPPPS 验证。
在将验证活动委托给外部供方的情况下，组织应确定委托的要求并确定控制措施，例如，对外部供方场所进行定期审核。
当组织将验证活动委托给外部供方时，应提供证据证明外部供方已接受该协议。
应建立并保持外部提供者代表登记册。
任何授权都应在随后的变更后进行审查。
注 2:放行后的 EPPPS 验证可以是来料检验或外部供方场所质量门的一部分。
8.4.2.2 Externally provided products, processes and services verification after release
The EPPPS shall not be used or processed until it has been verified as conforming to specified requirements or unless it is released under authorized concession (see 8.7.3).
Activities for EPPPS verification after release shall include:
a) planning of activities [e.g. in an inspection and test plan, including the determination of the extent,frequency, sample size and methods of control, see 4.4.3 f)];
b) provision of instructions, checklists or templates for verification activities;
c) obtaining evidence that the EPPPS is conforming to requirements (e.g. by check of accompanying documented information such as certificate of conformity, test reports, statistical records, process control sheets);
d) confirmation of release of the EPPPS;
e) management of nonconforming EPPPS.
Where the organization utilizes test reports to verify EPPPS, the data in those reports shall be comparable with acceptance criteria stated on the report, that are derived from purchasing information, e.g. specifications, standards.
The organization shall determine a plan for periodical verifications of raw material based on risks assessment.
NOTE 1 Verification of raw material composition or conformity can be done by checking, for example,certificates, chemical analyses, own laboratory tests.
Inspection and testing requirements as defined in 8.6 shall apply for EPPPS verification.
In case of delegation of verification activities to the external provider, the organization shall define the requirements for delegation and shall define controls, e.g. regular audits at external provider premises.
Where the organization delegates verification activities to the external provider, there shall be evidence that the external provider has accepted such agreement.
A register of external provider delegations shall be established and maintained.
Any delegation should be reviewed after subsequent changes.
NOTE 2 EPPPS verification after release can be the incoming inspection or part of a quality gate at external provider premises.

8.4.2.3 外部供方绩效监控、再评价和排名
关键外部供方的绩效监控、再评价和排名应考虑:
a)对外部供方绩效的定期评审(相关 KPI 见 9.1.1.1);
b)确定审核外部供方的准则;
c)评审的结果，作为确定实施控制的类型和程度的基础;
d)当外部供方不满足技术要求和/或绩效目标时计划采取的措施;

e) 将其绩效反馈给外部供方;
f) 定期联合绩效评估。
此外，组织应:
g) 识别待开发的外部供方;
h) 根据商定的目标实施行动计划，以提高他们的能力。
8.4.2.3 Monitoring of external providers' performance, re-evaluation and ranking
Monitoring performance, re-evaluation and ranking of key external providers shall consider:
a) periodical reviews of external providers' performance (see 9.1.1.1 for related PIs);
b) definition of criteria to audit external providers;
c) results of these reviews as a basis for establishing the type and extent of controls to be implemented;
d) actions planned to be taken when the external provider does not meet technical requirements and/or performance targets;
e) feedback of their performance to be given to the external providers;
f) regular joint performance reviews.
In addition, the organization shall:
g) identify external providers to be developed;
h) implement action plans based on agreed objectives to improve their capabilities.

8.4.3 提供给外部供方的信息
组织应确保在与外部供方沟通之前所确定的要求是充分和适宜的。
组织应与外部供方沟通以下要求：
a) 需提供的过程、产品和服务；
b) 对下列内容的批准：
1) 产品和服务；
2) 方法、过程和设备；
3) 产品和服务的放行；
c) 能力，包括所要求的人员资格；
d) 外部供方与组织的互动；
e) 组织使用的对外部供方绩效的控制和监视；
f) 组织或其顾客拟在外部供方现场实施的验证或确认活动。
8.4.3.1 提供给外部供方的信息-补充
提供给外部供方的信息应考虑:
a) 顾客要求通过供应链向下级传递;
b) 发生变更时，需求的可追溯性(见 8.2)； c)
需要时，由组织或其顾客批准特殊过程。组
织还应向外部供方传达以下要求:
d) 规范、图纸、过程要求(包括特殊过程要求)、检验指导书、组织项目质量计划的适当细节和其他相关技术资料的识别和适用的修订;
e) 与 EPPPS 相关的可交付成果(如 EPPPS 文件化信息)和相关进度;
f) 变更和不合格品输出的管理;
g) EPPPS 的交付时间表;
h) 产品临界信息(如安全临界);
i) 组织、其顾客或其他相关方（如法定机构）接触接触订单的设施、适用成文信息的权力;
注:与外部供方沟通的进一步要求可能与下列相关:

–设计评审；

-用于调查或设计批准的测试样品(如生产方法、数量、储存条件);
-生产:日常测试、检验和验收,包括相关说明;
-老化管理;
-审计;
-供应链物流,包括包装和标签;
-将需求级联到外部提供者。

8.4.3.1 Information for external providers — Supplemental

Information for external providers shall consider:

a) that customer requirements are cascaded down through the supply chain;

b) in case of changes, the traceability of requirements (see 8.2);

c) approval of special processes by the organization or its customer, where required.

The organization shall also communicate to external providers its requirements for:

d) identification and applicable revisions of specifications, drawings, process requirements including the ones for special processes, inspection instructions, appropriate details from the organization's project quality plan and other relevant technical data;

e) deliverables associated to the EPPPS (e.g. EPPPS documented information) and the related schedule;

f) management of changes and nonconforming outputs;

g) delivery schedule of EPPPS;

h) information about the product criticality (e.g. safety critical);

i) right of access by the organization, its customers or other relevant parties (e.g. regulatory authorities) to facilities involved in the order and to applicable documented information.

NOTE Further requirements communicated to external providers can be related to:

— design reviews;
— test samples (e.g. production method, number, storage conditions) for investigation or design approval;
— production: routine testing, inspection and acceptance, including related instructions;
— obsolescence management;
— auditing;
— supply chain logistics including packaging and labelling;
— cascading requirements to its external providers.

8.4.4 供应链管理

组织应:

a)要求外部供方对采购订单进行确认,直到收到为止,并保留确认的文件化信息;

b)记录发送给外部供方的变更请求(见 8.4.3.1)。

组织应将更新的交付进度和预测通知外部供方,为其资源规划提供输入。这应包括组织向外部供方交付过程、产品和服务的延迟。

与顾客、外部供方和组织(如设计、生产)交换的供应链信息(如交货日期、数量)应得到管理并保持最新(如通过软件工具)。

组织应与其外部供方就其可预见的延迟供应达成早期预警政策,否则组织应定期检查交付进度。

这种早期预警政策还应包括过时问题。

8.4.4 Supply chain management

The organization shall:

a) request acknowledgement of its purchase orders from the external providers until receipt, and retain documented information of this acknowledgement;

b) document requests of changes sent to the external providers (see 8.4.3.1).

The organization shall communicate updated delivery schedules and forecasts to its external providers in order to give inputs for their resources planning. This shall include delays to the deliveries of processes, products and services from the organization to the external providers.

Supply chain information (e.g. delivery dates, quantities), exchanged with customers, external providers and the organization (e.g. design, production), shall be managed and be maintained up-to-date (e.g. by a software tool).

The organization should agree on an early warning policy with its external providers regarding their delayed provisions foreseen, otherwise the organization should regularly check the delivery schedule.

This early warning policy should also include obsolescence issues.

8.5 生产和服务提供

8.5.1 生产和服务提供的控制 组织应在受控条件下进行生产和服务提供。 适用时，受控条件应包括： a) 可获得成文信息，以规定以下内容：

1） 拟生产的产品、提供的服务或进行的活动的特征；

2） 拟获得的结果。

b) 可获得和使用适宜的监视和测量资源；

c) 在适当阶段实施监视和测量活动，以验证是否符合过程或输出的控制准则以及产品和服务的接收准则；

d) 为过程的运行使用适宜的基础设施，并保持适宜的环境； e) 配备胜任的人员，包括所要求的资格；

f) 若输出结果不能由后续的监视或测量加以验证，应对生产和服务提供过程实现策划结果的能力进行确认，并定期再确认；

g) 采取措施防止人为错误；

h) 实施放行、交付和交付后活动。

8.5.1.1 生产和服务提供的控制——补充

8.5.1.1.1 总则

注：本条所指的生产也适用于客户现场(如调试期间)或安装，直到移交)。

组织应建立、实施并保持生产和服务过程规定。

这过程应：

a) 包括以下要求：

1) 确保受控条件的活动(见 8.5.1.1.2)；

2) 生产和服务提供过程的验证(见 8.5.1.1.3)；

3) 生产和服务提供过程的验证(见 8.5.1.1.4)；

4) 生产调度(见 8.5.1.2)；

5) 控制生产设备的活动(见 8.5.1.4)；

6) 确保识别和可追溯性的活动(见 8.5.2)；

7) 顾客或外部供方财产的管理(见 8.5.3)；

8) 防护(见 8.5.4)；

b) 参考：

1) 配置管理(见 8.1.4.1)；

2) 变更控制(见 8.1.4.2)；

3) 特殊过程(见 8.5.1.3)；

4) 产品和服务的发布(见 8.6)；

5) 不合格品输出控制(见 8.7)；

6) FAI(见 8.9)。

8.5.1.1 Control of production and service provision — Supplemental

8.5.1.1.1 General

NOTE Production in the context of this clause can also apply at customer premises (e.g. during commissioning or installation until handover).

The organization shall establish, implement and maintain a process for production and service provision.

This process shall:

a) include requirements for:

1) activities to ensure controlled conditions (see 8.5.1.1.2);

2) verification of the process for production and service provision (see 8.5.1.1.3);

3) validation of the process for production and service provision (see 8.5.1.1.4);

4) production scheduling (see 8.5.1.2);

5) activities to control production equipment (see 8.5.1.4);

6) activities to ensure identification and traceability (see 8.5.2);

7) management of property belonging to customers or external providers (see 8.5.3);

8) preservation (see 8.5.4);

b) refer to:

1) configuration management (see 8.1.4.1);

2) change control (see 8.1.4.2);

3) special processes (see 8.5.1.3);

4) release of products and services (see 8.6);

5) control of nonconforming outputs (see 8.7);

6) FAIs (see 8.9).

8.5.1.1.2 受控条件

受控条件应包括：

a) 生产和服务提供活动的批准数据。这些数据应包括：

1) 图纸、物料清单、生产工艺流程图、检验试验计划;生产文件(如作业指导书、生产进度表、工单、工艺流程卡)；

2) 所需的工具和数控机床程序清单以及任何具体的使用说明:与其使用有关的说明；

b) 监控所有班次的生产和服务提供(如零件数量、拆分订单、不合格输出)；

c) 所有生产和服务的提供，包括检查，已被授权并按计划完成的证据；

d) 防止过去问题再次发生的措施；

e) 用适用的方法进行涵盖所有生产和服务提供活动的风险评估；

f) 对延期工作的风险影响进行评估，以确保对未实施的工作进行控制影响质量安全；

g) 返工和修复不合格输出(见 8.7.3)；

h) 如适用，采用统计过程控制。

8.5.1.1.2 Controlled conditions

Controlled conditions shall include:

a) approved data for production and service provision activities. These data shall contain:

1) drawings, bill of material, production process flow charts, inspection and test planning, production documents (e.g. work instructions, production schedules, work order, process cards);

2) a list of tools and numerical control machine programmes required and any specific instructions associated with their use;

b) monitoring of production and service provision in all shifts (e.g. parts quantities, split orders,nonconforming outputs);

c) evidence that all production and service provision, including inspections, have been authorized and completed as planned;
d) actions to prevent recurrence of past problems;
e) risk assessment covering all the production and service provision activities with the applicable method(s);
f) assessment of risk impact of deferred work to ensure control of work to be carried out without affecting quality and safety;
g) rework and repair of nonconforming outputs (see 8.7.3);
h) use of statistical process control, if applicable.

8.5.1.1.3 生产和服务提供过程的验证
生产和服务提供过程的验证应包括：
a) 针设计和开发输出对生产过程输入的验证完整性(见 8.3.5.1)；
b) 生产设备符合设计和开发要求的能力验证(例如，关于生产设备公差或精度等级)；
c)在过程的早期阶段用适用的方法(如生产过程 FMEA)进行风险评估。
8.5.1.1.3 Verification of the process for production and service provision
Verification of the process for production and service provision shall include:
a) verification of production process inputs against design and development outputs regarding completeness (see 8.3.5.1);
b) verification of production equipment ability to comply with design and development requirements (e.g. regarding production equipment tolerances or precision classes);
c) risk assessment at an early stage of the process with applicable methods (e.g. production process FMEA).

8.5.1.1.4 生产和服务提供过程的验证
8.5.1.1.4.1 生产和服务提供过程的验证应确保：
a)满足设计和开发要求；
b)达到受控条件；
c) FAI 已完成(见 8.9)；
d)在向顾客移交产品和服务之前完成验证；
e)作为变更实施的一部分完成再验证；
f)对设计和开发提供反馈，以支持对生产及相关文件信息的持续改进。
8.5.1.1.4 Validation of the process for production and service provision
8.5.1.1.4.1 Validation of the process for production and service provision shall ensure that:
a) design and development requirements are fulfilled;
b) controlled conditions are achieved;
c) FAI is completed (see 8.9);
d) validation is completed prior to handover of the products and services to the customer;
e) re-validation is completed as part of changes implementation;
f) feedback to design and development is given in order to support continual improvement of production and the related documented information.

8.5.1.1.4.2 生产和服务提供过程的验证应包括：
a)测量能力研究；
b)过程能力研究；
c)公差分析以减轻生产过程。
8.5.1.1.4.2 Validation of the process for production and service provision should include:

a) measurement capability studies;
b) process capability studies;
c) analysis of tolerances to ease the production process.

8.5.1.2 生产调度
8.5.1.2.1 关于生产调度，组织应：
a) 对生产(包括生产设备)进行短期、中期(主生产计划)和长期(销售和运营计划)计划，以满足客户的交货要求；
b) 由软件工具支持，该软件工具：
1) 涵盖生产阶段；
2) 获取更新的生产状态信息；
3) 每次客户合同事件/变更(变更单)更新内容；
c) 根据客户和外部供方的预测和订单，根据工作量定期规划和调整资源，并考虑风险(如临时增加订单、外部供方失效)；
d) 确定生产中的瓶颈。
8.5.1.2 Production scheduling
8.5.1.2.1 Regarding production scheduling, the organization shall:
a) schedule production (including production equipment) in short-, mid- (master production schedule)and long-term (sales and operation plan) in order to meet the customer delivery requirements;
b) be supported by a software tool which:
1) covers the production phases;
2) captures updated production status information;
3) content is updated on each event/change of customer contract (variation order);
c) use customers' and external providers' forecasts and orders to plan and adjust regularly its resources in accordance with its workload, taking into account risks (e.g. extra order at the last minute, external providers' failure);
d) identify bottlenecks in production.

8.5.1.2.2 关于生产调度，组织应：
a) 考虑：
1) 风险分析结果；
2) 过往经验；
3) 效率测量；
b) 制定相应的改进行动计划。
8.5.1.2.2 Regarding production scheduling, the organization should:
a) consider:
1) results of risk analysis;
2) past experience;
3) efficiency measurements;
b) establish an improvement action plan accordingly.

8.5.1.3 特殊进程
组织应建立、实施并保持对特殊过程的管理。
这一过程应包括：
a) 组织计划使用的特殊过程的识别；

b) 对于每一特殊工艺，定义：

1) 职责和权限；

2) 适用标准；

3) 采用适用的方法(如过程 FMEA)进行风险评估；

4) 在没有适用标准的情况下，至少要有作业指导书，包括：

-管理；

-人力资源；

-机器；

-方法；

-材料；

-自然力量(环境条件)；

5)人员资格；

6) 质量保证和控制方法及相关文件化信息；

7) 特殊工艺的认定；

8) 每种具体应用的验证；

9) 变更后再验证；

c) 与上述要求有关的文件化信息的保留。

注:在 iso9000:2015，3.4.1，注 5 中定义的特殊工艺，可以是，例如，粘接和密封，铸造，压接，热处理，铆接，表面处理，包括油漆和涂层，扭矩拧紧和焊接。

8.5.1.3 Special processes

The organization shall establish, implement and maintain a process for the management of special processes. This process shall include:

a) the identification of special processes that the organization is planning to use;

b) for each special process, the definition of:

1) responsibilities and authorities;

2) applicable standards;

3) risk assessment with the applicable method(s) (e.g. process FMEA);

4) work instructions, as a minimum when there is no applicable standard, including:

— management;

— manpower;

— machine;

— methods;

— material;

— mother nature (environmental conditions);

5) personnel qualification;

6) quality assurance and control methods and related documented information;

7) qualification of the special process;

8) validation for each specific application;

9) re-validation after changes;

c) retention of documented information in relation to the above requirements.

NOTE Special processes as defined in ISO 9000:2015, 3.4.1, Note 5 to entry, can be, for example, bonding and sealing, casting, crimping, heat treatment, riveting, surface treatment, including painting and coating, torque tightening, and welding.

8.5.1.4 生产设备

8.5.1.4.1 对于生产设备，组织应：
a) 如适用，开发其生产设备；
b) 计划和实施预防性维护活动，确保生产设备：
1) 按照规定的方法和验收准则进行验证；
2) 首次使用前验证(见 8.9)；
3) 有个人身份注册的；
4) 防止变质，包括在设备不使用时适当的储存和保存；
5) 按计划的时间间隔检查其状况(例如，关于退化，目测检查)；
6) 根据风险和故障率，按计划的时间间隔重新验证；
c) 根据故障的发生调整计划的时间间隔和活动；
d) 着眼未来，定期评审生产设备(输入 7.1.1)；
e) 确保较长的交货周期备品备件和耗材的供；
f) 考虑防止生产中出现错误的方法(如 poka yoke)；
g) 保留有关维护活动的文件化信息。

8.5.1.4 Production equipment

8.5.1.4.1 Regarding production equipment, the organization shall:
a) develop its production equipment if applicable;
b) plan and implement preventive maintenance activities to ensure that production equipment is:
1) verified in accordance with defined methods and acceptance criteria;
2) validated prior to first use (see 8.9);
3) registered with individual identification;
4) protected against deterioration, including storage and preservation as appropriate, when the equipment is not in use;
5) inspected for its condition at planned intervals (e.g. regarding degradation, by visual inspection);
6) re-verified at planned intervals, depending on risk and failure rate;
c) adjust the planned intervals and activities in accordance with occurrence of failures;
d) periodically review the production equipment with the future in mind (inputs for 7.1.1);
e) ensure the availability of spare parts and consumables with long lead time;
f) consider methods which prevent errors in production (e.g. poka yoke);
g) retain documented information on the maintenance activities.

8.5.1.4.2 组织应：
a) 适用生产设备的设计和开发过程(见 8.3)；
b) 如果适用，实施预测性维护活动。

8.5.1.4.2 The organization should:
a) apply the design and development process (see 8.3) for production equipment as appropriate;
b) implement predictive maintenance activities, if applicable.

8.5.2 标识和可追溯性

需要时，组织应采取适当的方法识别输出，以确保产品和服务合格。组织应在生产和服务提供的整个过程中按照监视和测量要求识别输出状态。

当有可追溯要求时，组织应控制输出的唯一性标识，并应保留所需的成文信息以实现可追溯。

8.5.2.1 标识和可追溯性——补充

产品应按合同或配置管理要求(见 8.1.4.1)进行追溯，应从其来源至少到可追溯的保修结束

组织应确定识别项目的方法(例如，通过机读代码、盖章、标签)。

注 1:识别项目的方法可与顾客商定。
注 2:法律或法规规范可能要求可追溯性。
如果产品的状态或其标识是未知的，组织应按不合格产品要求对产品进行管理
组织应该使设备可读的标识。
8.5.2.1 Identification and traceability — Supplemental
Items shall be traceable from their origin up to at least the end of warranty where traceability is required by contract or configuration management (see 8.1.4.1).
The organization shall define the method to identify items (e.g. by machine readable codes, stamping,labelling).
NOTE 1 The method to identify items can be agreed with the customer.
NOTE 2 Statutory or regulatory norms can require traceability.
If the status of a product or its identification is not known, the organization shall manage the product as a nonconforming product.
The organization should use machine readable identification.

8.5.3 顾客或外部供方的财产
组织应爱护在组织控制下或组织使用的顾客或外部供方的财产。
对组织使用的或构成产品和服务一部分的顾客和外部供方财产，组织应予以识别、验证、保护和防护。若顾客或外部供方的财产发生丢失、损坏或发现不适用情况，组织应向顾客或外部供方报 告，并保留所发生情况的成文信息。
注：顾客或外部供方的财产可能包括材料、零部件、工具和设备以及场所，知识产权和个人资料。
8.5.3.1 顾客或外部供方的财产 - 补充
组织顾客或外部供方财产进行追溯管理直至交付或返回。
注:可追溯性要求可由双方定义。
如财产发生丢失、损坏或发现不适用时，组织应执行原因分析和采取必要措施。
8.5.3.1 Property belonging to customers or external providers — Supplemental
The organization shall manage traceability of property belonging to customers or external providers up to delivery or return.
NOTE The traceability requirements can be defined by the parties.
In the event that property is lost, damaged or otherwise found to be unsuitable for use, the organization should perform a cause analysis and take required actions.

8.5.4 防护
组织应在生产和服务提供期间对输出进行必要的防护，以确保符合要求。
注：防护可包括标识、处置、污染控制、包装、储存、传输或运输以及保护。
8.5.4.1 防护 - 补充
组织应根据产品规范和适用法规建立文件化的防护规范，并在交付前处理以下事项:
A)标识和标签;
B)敏感产品的特殊处理;
C)有关污染控制和储存的清洁;
D)保质期控制和库存周转(如先进先出);
E)环境条件(如温度、湿度)。
对产品符合性有影响的保存条件应作为文件化规范的输入加以识别、分析和考虑。
这些形成文件的规范应适用于组织场所内管理的实物产品(如:从外部供方收到的材料、属于顾客的财产、正在进行的工作和组织生产的产品)。

注:这些文件化的规范适用于仓库、内部加工、到最终目的地的交货过程。

8.5.4.1 Preservation — Supplemental

The organization shall have documented specifications for preservation in accordance with product specifications and applicable regulations, addressing the following until handover:

a) marking and labelling regarding identification;

b) special handling for sensitive products;

c) cleaning regarding contamination control and storage;

d) shelf life control and stock rotation (e.g. first in, first out);

e) environmental condition (e.g. temperature, humidity).

Conditions regarding preservation having impact on product conformity shall be identified, analysed and taken into account as inputs for these documented specifications.

These documented specifications shall be applied to physical items managed in the organization's premises (e.g. material received from external providers, property belonging to customers, work in progress and products manufactured by the organization).

NOTE These documented specifications can apply to warehouses, internal processing, delivery processes to the final destination.

8.5.5 交付后的活动

组织应满足与产品和服务相关的交付后活动的要求。

在确定所要求的交付后活动的覆盖范围和程度时，组织应考虑：

a) 法律法规要求；

b) 与产品和服务相关的潜在不良的后果；

c) 产品和服务的性质、使用和预期寿命；

d) 顾客要求；

e) 顾客反馈。

注：交付后活动可包括保证条款所规定的措施、合同义务（如维护服务等）、附加服务（如回收或最终处置等）。

8.5.5.1 交付后活动-补充

注 1:交付后活动在交付给顾客后进行，直至合同义务结束(如现场技术培训、解决质量问题)。

组织应建立、实施并保持交付后活动的过程。

这一过程应包括:

a) ISO 9001:2015 8.5.5 规定的要求;

b)技术文件信息(如操作指导书)的控制和更新;维修手册、备件清单);

c)问题解决方法(例如 8D, FRACAS)(见 8.8 和 10.2.3);

d)维修指导书的批准、控制和使用;

e)备件的提供和/或当经顾客与组织之间同意时寄售库存的管理,

f)顾客投诉知识，作为改进组织 RQMS 的输入(如设计和开发改进、生产、维护活动)。

注 2:在首次交付活动中，可以收集足够的数据来支持 RAM 数据收集[例如，故障症状、里程、运行时间；见 8.8.2 c)]和 LCC 数据收集[见 8.8.4 c)]。

8.5.5.1 Post-delivery activities — Supplemental

NOTE 1 Post-delivery activities are performed after handover to the customer, until contract obligations end (e.g. on-site technical training, solving quality problems).

The organization shall establish, implement and maintain a process for post-delivery activities.

This process shall include:

a) requirements defined in ISO 9001:2015, 8.5.5;

b) the control and updating of technical documented information (e.g. operational instructions,maintenance

manuals, spare parts list);
c) problem solving methodology (e.g. 8D, FRACAS) (see 8.8 and 10.2.3);
d) the approval, control and use of repair instructions;
e) the provision of spare parts and/or the management of consignment stock, where agreed upon between the customer and the organization;
f) knowledge of customer complaints as inputs for improving the organization's RQMS (e.g. for design and development improvements, production, maintenance activities).
NOTE 2 During first delivery activities, adequate data can be collected to support RAM data collection [e.g.failure symptoms, mileage, operating hours; see 8.8.2 c)] and for LCC data collection [see 8.8.4 c)].

8.5.6 更改控制
组织应对生产和服务提供的更改进行必要的评审和控制，以确保持续地符合要求。
组织应保留成文信息，包括有关更改评审的结果、授权进行更改的人员以及根据评审所采取的必要措施。

8.6 产品和服务的放行
组织应在适当阶段实施策划的安排，以验证产品和服务的要求已得到满足。除非得到有关授权人员的批准，适用时得到顾客的批准，否则在策划的安排已圆满完成之前，不应向顾客放行产品和交付服务。组织应保留有关产品和服务放行的成文信息。成文信息应包括：
a) 符合接收准则的证据；
b) 可追溯到授权放行人员的信息。
8.6.1 产品和服务的放行—补充
组织应规定：
a) 检验和检测计划中沿生产流程进行的检验和检测活动的顺序，包括控制范围、频率、样本量和方法的确定[见 4.4.3 f)]；频率应与风险等级相适应，以防止不合格输出；
b) 检验和试验规程中对产品和服务验收的要求；
c) 授权放行。
这些说明和计划应成为生产投入的一部分(见 8.5.1)。
如果策划的安排不能圆满地完成，组织应在产品和服务放行前要求顾客做出让步(见 8.7.3)。
检验和试验指导书应包括：
d) 验收标准；
e) 检验和试验结果的文件化信息；
f) 所需监视和测量资源的类型及其使用的具体指示。
检验和试验记录应包括符合检验和试验指示的实际结果数据。
组织应建立、实施和保持放行产品和服务的过程。
8.6.1 Release of products and services — Supplemental
The organization shall define:
a) the sequence of inspection and testing activities along the production flow in an inspection and test plan, including the determination of the extent, frequency, sample size and methods of control[see 4.4.3 f)]; frequency shall be adopted in accordance with the risk level in order to prevent nonconforming outputs;
b) requirements for product and service acceptance in inspection and test instructions;
c) authorities for release.
These instructions and plans shall be part of the production inputs (see 8.5.1).
In case planned arrangements are not satisfactorily completed, the organization shall request a concession to the customer (see 8.7.3) prior to the release of products and services.
Inspection and test instructions shall include:

d) the criteria for acceptance;
e) documented information for inspection and test results;
f) the type of monitoring and measuring resources required and any specific instructions associated with their use.
Inspection and test records shall include actual results data in accordance with the inspection and test instructions.
The organization should establish, implement and maintain a process to release products and services.

8.7 不合格输出的控制
8.7.1 组织应确保对不符合要求的输出进行识别和控制，以防止非预期的使用或交付。
组织应根据不合格的性质及其对产品和服务的影响采取适当措施。这也适用于在产品交付之后，以及在服务提供期间或之后发现的不合格产品和服务。
组织应通过下列一种或几种途径处置不合格输出：
a） 纠正；
b） 隔离、遏制、退货或暂停对产品和服务的提供；
c） 告知顾客；
d） 获得让步接收的授权。对不合格输出进行纠正之后应验证其是否符合要求。
8.7.2 组织应保留下列成文信息：
a) 描述不合格；
b) 描述所采取的措施； c）
描述获得的让步；
d） 识别处置不合格的授权。

8.7.3 不合格输出的控制——补充
组织应建立、实施并保持控制不合格品输出的过程。
注 1:所有过程都可能产生不合格输出(如设计和开发输出)。
注 2:控制不合格品输出的过程可与管理过程合并
10.2.3 中规定的不符合和纠正措施或 8.1.4.2 中规定的变更控制过程。
该过程应包括:
a） 8.7.1、8.7.2 和10.2 规定的要求;
b) 不合格输出的记录。
对于 8.5 产生的不合格输出，过程应包括:
c) 确定以下方面的准则和权限:
1) 返工、返修、报废;
2) 内部及客户优惠;
d) 组织和外部供方特许登记簿，记录有效期和授权数量;
e) 对让步(如有效性)和不符合纠正的定期监测输出。对于不合格品输出的控制，组织应确保:
f) 特许权授权到期，则该产品不能再使用;
g) 需要客户批准的让步:
1) 交货前应获得顾客认可;
2) 外部供方的减让在提交给客户;
3) 特许产品的标识与顾客一致同意;
4) 记录产品符合性声明上的让步。
8.7.3 Control of nonconforming outputs — Supplemental

The organization shall establish, implement and maintain a process for the control of nonconforming outputs.

NOTE 1 All processes can cause nonconforming outputs (e.g. design and development outputs).
NOTE 2 The process for the control of nonconforming outputs can be combined with the process for managing nonconformity and corrective action defined in 10.2.3 or the change control process in 8.1.4.2.
The process shall include:
a) requirements defined in 8.7.1, 8.7.2 and 10.2;
b) a register of nonconforming outputs.
For nonconforming outputs resulting from 8.5, the process shall include:
c) identification of criteria and authorities for:
1) rework, repair and scrap;
2) internal and customer concessions;
d) a register of concessions from the organization and external providers, recording expiration date and authorized quantities;
e) regular monitoring of the concessions (e.g. validity) and of the correction of nonconforming outputs. Regarding control of nonconforming outputs, the organization shall ensure:
f) when the authorization of the concessions expires, then the product cannot be used anymore;
g) in case of concessions requiring customer approval:
1) customer approvals shall be obtained prior to delivery;
2) concessions from external providers shall be internally approved before submission to the customer;
3) identification of product under concession is agreed with the customer;
4) recording of concessions on the product declaration of conformity.

8.8 可靠性、可用性、可维护性、安全性和生命周期成本
8.8.1 总则
组织应处理下列过程:
a) RAM(见 8.8.2);
B)安全(见 8.8.3)。
组织应处理 LCC 过程(见 8.8.4)。
组织应保留与这些过程有关的文件化信息。
8.8 Reliability, availability, maintainability, safety and life cycle costing
8.8.1 General
The organization shall address the following processes:
a) RAM (see 8.8.2);
b) safety (see 8.8.3).
The organization should address the LCC process (see 8.8.4).
The organization shall retain related documented information in relation with these processes.

8.8.2 可靠性、可用性和可维护性
组织应建立、实施并保持产品的 RAM 管理过程和服务。因此,组织应确定适用于 RAM 过程的法规、标准(如 IEC 62278 或同等标准)或指南。
这一过程应包括:
a)在投标或设计阶段计算 RAM 数据,在整个产品生命周期中予以考虑;
b)在供应链的设计和开发中实施 RAM 要求;
C)交付后活动、维护、更换或维修合同期间的数据收集(如现场数据或维修数据);
d)与以前类似产品(如 8D, FRACAS)的现场数据进行分析和比较;

e)将 RAM 数据反馈给相关运营团队，以改进设计；
f)向相关外部供应商反馈 RAM 数据；
g)监测 RAM 目标;当目标未达到时，组织应分析现场数据，按 10.2 的要求采取纠正措施，并跟踪现场数据，直至目标达到。
应根据故障类别、部件分配和影响(补救措施和严重程度)进行原因分析。
如果组织不执行维护、更换或修理合同，在保修期后也应向客户索要现场数据。
8.8.2 Reliability, availability and maintainability
The organization shall establish, implement and maintain a RAM management process for products and services. Therefore, the organization shall identify regulations, standards (e.g. IEC 62278 or an equivalent) or guidelines, which are applicable for RAM process.
This process shall include:
a) calculation of RAM data during tender or design stages, to be considered through the entire product life cycle;
b) implementation of RAM requirements into the design and development along the supply chain;
c) data collection (e.g. field data or repair data) during post-delivery activities, maintenance,replacement or repair contracts;
d) analysis and comparison with field data from previous similar products (e.g. 8D, FRACAS);
e) feedback on RAM data to relevant operational teams to improve design;
f) feedback on RAM data to relevant external providers regarding their supplies;
g) monitoring RAM objectives; in case objectives are not met, the organization shall analyse field data,perform corrective actions as required in 10.2 and follow up field data until objectives are met.
Cause analysis should be executed based on failure category, component allocation and impact (remedy and severity).
In case the organization does not execute maintenance, replacement or repair contracts, it should request field data from customers also after warranty.

8.8.3 安全
当组织提供与安全相关的机械和/或电气/电子/可编程产品和服务时，组织应建立、实施和保持产品和服务的安全管理过程。因此，组织应确定适用于安全活动的法规、标准(如 IEC 62278、IEC 62425、IEC 62279 或同等标准)或指南。
注 1:本过程可适用于自行设计的用于验证安全相关产品和服务的测量资源。
注 2:安全活动旨在涵盖 SILs 以及与安全相关的电子系统，也可以是门系统、制动系统和电源系统。
8.8.3 Safety
In case the organization delivers safety-related mechanical and/or electrical/electronic/programmable products and services, it shall establish, implement and maintain a safety management process for products and services. Therefore, the organization shall identify regulations, standards (e.g. IEC 62278,IEC 62425, IEC 62279 or an equivalent) or guidelines, which are applicable for safety activities.
NOTE 1 This process can apply to self-designed measuring resources used to verify safety related products and services.
NOTE 2 Safety activities are meant to cover SILs as well as safety-related electronic systems which can also be door systems, braking systems and power supply systems.

8.8.4 生命周期成本计算
组织应建立、实施和保持产品和服务的生命周期成本管理过程，考虑市场的需要以及他们的利益(作为运营商、系统集成商、设备制造商)。

这一过程应包括：
a) LCC 数据计算；
B) 在整个供应链的设计开发、生产和维护中实施措施；
C) 交付后活动、维护期间的数据收集(如现场数据、维修数据)；更换或修理合同；
d) 与以前类似产品(如 8D, FRACAS)的现场数据和 LCC 进行分析和比较；
e) 监测 LCC 目标。
8.8.4 Life cycle costing
The organization should establish, implement and maintain a life cycle costing management process for products and services by taking into account the need of the market as well as their interest (as operator, system integrator, equipment manufacturer).
This process should include:
a) calculation of LCC data;
b) implementation of actions into the design and development, production and maintenance along the supply chain;
c)data collection (e.g. field data, repair data) during post-delivery activities, maintenance,
replacement or repair contracts;
d) analysis and comparison with field data and LCC from previous similar products (e.g. 8D, FRACAS);
e) monitoring LCC objectives.

8.9 首件检验
8.9.1 组织应建立、实施并保持 FAI 管理过程。
这一过程应包括：
a)根据确定的准则进行策划，以识别受 FAI 影响的产品；
b)FAI 的编制；
c)检查和验证活动，包括对生产过程的评审，重点是关键过程和特殊过程；
d)标准：
1) 用于批量生产的放行；
2) 有条件释放；
3) 拒绝。
e)纠正措施的跟踪。
组织应保留相关的形成文件的信息。
8.9 First article inspection
8.9.1 The organization shall establish, implement and maintain a FAI management process.
This process shall include:
a) planning in accordance with defined criteria in order to identify products subjected to the FAI;
b) preparation of the FAI;
c) inspection and verification activities, including review of production processes with focus on critical and special processes;
d) criteria:
1) for release of the serial production;
2) for conditional release;
3) for rejection.
e) follow-up of corrective actions.
The organization shall retain related documented information.

8.9.2 此外，该过程应规定：
a) 执行 FAI 前需要评估的先决条件；
b) 基于项目确定 FAI 的参与者。
8.9.2 In addition, this process should define:
a) pre-conditions to be evaluated before performing the FAI;
b) participants of the FAI depending on the item.

8.9.3 FAI 过程应适用于：
a) 内部产品和EPPPS（见8.4），以发布系列生产并验证生产设备（见8.5.1.4）和生产过程（见8.5.1.1.4）；
B) 新产品的第一次系列生产或现有产品的重大变更中的代表性项目，如下：
1) 生产过程的验证；或
2) 使先前的 FAI 结果无效的更改。
注：现有产品的重大变化包括：
-主要的设计变更（例如有关性能、可靠性、可用性、可维护性、安全性或其他重要特性）；
-生产过程的重大变更（如工艺方法、测试方法、生产或测量设备或其他变更）；
-从一个工厂转移到另一个工厂；
-如果工艺条件发生变化，重新开始生产；
-其他可能影响产品符合性的变更。
8.9.3 The FAI process shall be applied:
a) to internal products and EPPPS (see 8.4) in order to release serial production and to validate production equipment (see 8.5.1.4) and production processes (see 8.5.1.1.4);
b) on a representative item from the first series production run of a new product or significant change of an existing product, following:
1) the verification of the production process; or
2) a change that invalidates a previous FAI result.
NOTE Significant changes of existing products can include:
— major design changes (such as relating to performance, reliability, availability, maintainability, safety or other important features);
— major production process changes (such as process methods, test methods, production or measuring equipment, or other changes);
— transfer from one factory to another;
— restart of production if process conditions have changed;
— other changes that can affect the conformity of the product.

8.10 老化管理
组织应建立、实施并保持老化管理过程，以确保按合同要求或组织规定供应的产品和备件至少在保修期结束前是可用的。
这一过程应包括：
A) 对供应产品进行老化风险评估；
B) 为供应产品制定老化管理计划并定期评审，以主动预防或减轻报废风险；
C) 与顾客的沟通。
此外，这个过程应该定义对产品组合的监控，以防止未来的老化问题。
注 1：过时问题可能是技术、功能或相关知识。
注 2：IEC 62402 提供了报废管理的要求和指南。
注 3：老化可通过以下方式进行管理：

-第二来源策略的手段;
-储存方法;
-采用标准化接口的模块化设计;
-升级到更现代化的技术。

译者注：老化是指产品退化，寿命期到后的更换。

8.10 Obsolescence management

The organization shall establish, implement and maintain an obsolescence management process toen sure the availability of the supplied products and spare parts, as contractually required or defined by the organization, as a minimum until the end of the warranty.

This process shall include:

a) undertaking obsolescence risk assessment of the products to be supplied;

b) the definition and regular review of an obsolescence management plan for the supplied products to proactively prevent or mitigate obsolescence risks;

c) communication with customers.

In addition, this process should define the monitoring of the product portfolio to prevent future obsolescence problems.

NOTE 1 Obsolescence issues can be technical, functional or concern knowledge.

NOTE 2 IEC 62402 provides requirements and guidance for obsolescence management.

NOTE 3 Obsolescence can be managed, for example, by:

— means of a second source strategy;
— storage approach;
— modular design with standardized interfaces;
— upgrade to more modern technology.

9 绩效评价

9.1 监视、测量、分析和评价

9.1.1 总则

组织应确定：

a) 需要监视和测量什么；

b) 需要用什么方法进行监视、测量、分析和评价，以确保结果有效； c）

何时实施监视和测量；

d） 何时对监视和测量的结果进行分析和评价。

组织应评价质量管理体系的绩效和有效性。

组织应保留适当的成文信息，以作为结果的证据。

9.1.1.1 监视与测量—补充

9.1.1.1.1 组织应识别、建立、实施和保持形成文件的质量指标(pi)，以监视和改进其过程[见4.4.1 c)]、产品、服务和项目的绩效。

进一步说明见附件C。

组织应按照规定的准则收集与内部和外部故障报告有关的数据。

注:部分 pi 可视为 kpi[见 5.3.1 a)]。

每个 PI 的定义应明确:

a) 其所属的相关过程、过程或活动;

b） PI 是如何计算的(例如公式)； c)

在规定时间内可实现的相关目标;

d） PI 测量值由谁提供;

e)何时报告产品质量指数，向谁报告(包括从产品质量指数向下级联到组织内的相关层次)；
f)谁负责确定相关行动；
g)数据来源。
PI 应测量：
h)顾客满意(见 9.1.2)；
i)客户按时交货；
j) 顾客提出的不符合项(见 8.7)；
k) 内部不符合(见 8.7)；
l) 外部供方的不符合(见 8.7)；
m)外部供方按时交货；
n)质量缺陷成本；
o)项目费用(见 8.1.3.5)。
9.1.1.1 Monitoring and measurement — Supplemental
9.1.1.1.1 The organization shall identify, establish, implement and maintain documented PIs to monitor and improve the performance of its processes [see 4.4.1 c)], products, services and projects.
For further explanation, see Annex C.
The organization shall collect data relating to reports of internal and external failures, in accordance with defined criteria.
NOTE Some PIs can be deemed as KPIs [see 5.3.1 a)].
The definition of each PI shall specify:
a) the related process, processes or activities it belongs to;
b) how the PI is calculated (e.g. formula);
c) the related target achievable in a defined period;
d) who provides the PI measurements;
e) when the PI is reported and to whom (including cascading down the PI to relevant levels within the organization);
f) who is in charge of defining related actions;
g) data sources.
PIs shall measure:
h) customer satisfaction (see 9.1.2);
i) customer on time delivery;
j) nonconformities raised by the customer (see 8.7);
k) internal nonconformities (see 8.7);
l) external providers' nonconformities (see 8.7);
m) external providers on time delivery;
n) quality deficiency costs;
o) project costs (see 8.1.3.5).
9.1.1.1.2 绩效指标应当测量：
a) 对顾客提出的不合格和投诉的响应时间；
b) 生产能力包括预测(包括生产和基础设施安装)；
c) 问题的解决时间，如未解决问题、不符合项、纠正措施；
d) 生产设备停机。
9.1.1.1.2 PIs should measure:
a) response time on nonconformities and complaints raised by customer;
b) production capacity including forecast (including for production and infrastructure installation);

c) resolution time of problems, e.g. open issues, nonconformities, corrective actions;
d) downtime of production equipment.

9.1.2 顾客满意
组织应监视顾客对其需求和期望已得到的满足的程度的感受。组织应确定获取、监视和评审该信息的方法。
注：监视顾客感受的例子可包括顾客调查、顾客对交付产品或服务的反馈、顾客座谈、市场占有率分析、顾客赞扬、担保索赔和经销商报告。
9.1.2.1 顾客满意—补充
组织应通过以下方式管理顾客投诉：
a)记录他们和他们的反应，以便可以很容易地共享共同的解决方案和经验教训(例如，在软件工具中)；
b)按照 10.2 与顾客就确认及相关纠正措施进行沟通。
组织应建立、实施并保持顾客满意管理的过程。
顾客投诉处理见 ISO 10002，顾客满意度监控见 ISO 10004。
9.1.2.1 Customer satisfaction — Supplemental
The organization shall manage customer complaints by:
a) recording them and their responses in such a way that common solutions and lessons learned can be readily shared (e.g. in a software tool);
b) communication with the customer in terms of acknowledgement and related corrective actions in accordance with 10.2.
The organization should establish, implement and maintain a customer satisfaction management process.
NOTE For customer complaints handling, see ISO 10002 and for monitoring customer satisfaction, see ISO 10004.

9.1.3 分析和评价 组织应分析和评价通过监视和测量获得的适当的数据和信息。应利用分析结果评价：a)产品和服务的符合性；
b) 顾客满意程度；
c) 质量管理体系的绩效和有效性； d)
策划是否得到有效实施；
e) 针对风险和机遇所采取措施的有效性；
f) 外部供方的绩效；
g) 质量管理体系改进的需求。
注：数据分析方法可包括统计技术。
9.1.3.1 分析与评价—补充
组织应分析和评价用于监视和测量的所有数据(见 9.1.1)。
当组织定义的必要的关键绩效指标相关目标未能实现时，纠正措施应按照 10.2 进行管理。
当组织定义的必要的与产品质量点相关的目标没有实现时，纠正措施应按照 10.2 进行管理。
当超额完成目标时，组织应分析是什么使超额完成目标成为可能，以保持绩效。
分析和评价的输出应在相关的规定时间内(如项目生命周期、过程评审)显示出趋势。
注 1:关于可用于趋势分析的统计技术的描述，见 ISO 10017。
数据分析的结果应按照 7.4 的规定提供给相关方，特别是那些直接受到失败影响或需要采取纠正措施的相关方。
注 2:在这种情况下，相关方可以是内部或外部供方或顾客、最终用户、最高管理者或法规机构。
9.1.3.1 Analysis and evaluation — Supplemental
The organization shall analyse and evaluate all data defined for monitoring and measurement (see 9.1.1).

When targets related to KPIs defined as necessary by the organization are not achieved, corrective actions shall be managed in accordance with 10.2.
When targets related to PIs defined as necessary by the organization are not achieved, corrective actions should be managed according to 10.2.
When targets have been exceeded, the organization should analyse what made it possible in order to maintain the performance.
The output from analysis and evaluation shall show a trend over a defined period of time, when relevant (e.g. project lifetime, process review).
NOTE 1 For descriptions of statistical techniques that can be used for trend analysis, see ISO 10017.
Results of analysis of data shall be made available for defined interested parties in accordance with 7.4,especially for those being directly affected by the failure or need to take corrective actions.
NOTE 2 Interested parties in this case can be internal or external providers or customers, end users, top management or authorities.

9.2 内部审核
9.2.1 组织应按照策划的时间间隔进行内部审核，以提供有关质量管理体系的下列信息： a）是否符合：
1) 组织自身的质量管理体系要求；
2) 本标准的要求；
b） 是否得到有效的实施和保持。
9.2.2 组织应：
a) 依据有关过程的重要性、对组织产生影响的变化和以往的审核结果，策划、制定、实施和保持审核方案，审核方案包括频次、方法、职责、策划要求和报告；
b) 规定每次审核的审核准则和范围；
c) 选择审核员并实施审核，以确保审核过程客观和公正； d）确保将审核结果报告给相关管理者；
e) 及时采取适当的纠正和纠正措施；
f) 保留成文信息，作为实施审核方案以及审核结果的证据。
注：相关指南参见 ISO19011。
9.2.3 内部审核 – 补充
组织必须建立、实施和保持内部审核过程，以证实过程与内外部要求的符合性。
该过程必须包括：
a） 9.2.1 和 9.2.2 所规定的要求；
b） 审核方案的管理（见 9.2.3.2）；
c） 内审员的管理（见 9.2.3.3）；
内部审核必须为经验总结提供机会（见 7.1.6）。
9.2.3 Internal audit — Supplemental
9.2.3.1 General
The organization shall establish, implement and maintain an internal audit management process to verify the conformity of processes with internal and external requirements.
This process shall include:
a) requirements defined in 9.2.1 and 9.2.2;
b) management of the audit programme (see 9.2.3.2);
c) management of the internal auditors (see 9.2.3.3).
Internal audits shall provide opportunities for return of experience (see 7.1.6).

9.2.3.2 审核方案

除 9.2.2 外，年度审计方案的要求应考虑以下方面：

a) 在 RQMS 的过程层次结构上识别的过程[见 4.4.3 a)]；

b) 关键项目、产品和服务；

c) 审核的频率应考虑审核范围的状态和重要性，但对过程和本标准文件的要求应至少每三年一次；

d) 审核员不审核自己的工作；

9.2.3.2 Audit programme

In addition to 9.2.2, requirements for the annual audit programme shall consider the following:

a) processes identified on the process hierarchical structure of the RQMS [see 4.4.3 a)];

b) critical projects, products and services;

c) the frequency of audits takes into consideration the status and importance of the audit scope but shall be as a minimum of once every three years for processes and the requirements of this document;

d) auditors do not audit their own work;

9.2.3.3 审核员管理

9.2.3.3.1 组织应确保审核组对本标准文档的要求进行审核

A) 知识和技能，保持和改进(例如，至少通过定期的内部审核更新培训)，关于：

1) 审核原则(如个人行为)、流程和方法；

2) 审核范围(如产品和服务、组织职能)；

3) 符合审核范围的本标准文件相关条款；

4) 审核准则(如内部程序、本文件)；

B) 审核经验(如审核见证人、审核的定期实施或审核组领导、规定的最少审核次数)。

组织应保留相关的形成文件的信息。

9.2.3.3 Auditors management

9.2.3.3.1 The organization shall ensure that the audit team auditing the requirements of this document has:

a) knowledge and skills, maintained and improved (e.g. as a minimum, through regular internal refresh trainings), about:

1) audit principles (e.g. personal behaviour), process and methods;

2) the audit scope (e.g. products and services, organizational function);

3) relevant clauses of this document in accordance with the audit scope;

4) the audit criteria (e.g. internal procedures, this document);

b) audit experience (e.g. audit witness, regular conduct of audits or audit team leading, defined minimum number of performed audits).

The organization shall retain related documented information.

9.2.3.3.2 对于审核员的管理，组织应：

a) 从相关职能部门(如采购、工程、项目管理)任命审核员；

b) 被审核员根据准则评价内部审核员的工作绩效，并将其作为内部审核员胜任力管理的输入；

c) 建立并保持一份内部审核员名单，其中包含他们在审核范围(如职能领域、产品、标准)方面的资格和能力。

9.2.3.3.2 Regarding auditors' management, the organization should:

a) appoint auditors from relevant functions (e.g. purchasing, engineering, project management);

b) evaluate the performance of internal auditors by the auditees based on criteria and used as inputs for the management of auditors' competencies;

c) establish and maintain a list of internal auditors containing their qualification and competencies in terms of

audit scope (e.g. functional area, products, standards).

9.3 管理评审

9.3.1 总则

最高管理者应按照策划的时间间隔对组织的质量管理体系进行评审，以确保其持续的适宜性、充分性和有效性，并与组织的战略方向保持一致。

9.3.1 总则 - 补充

组织应确保每年根据组织的经营日历进行管理评审。

组织应保留与管理评审有关的文件化信息，包括输入和输出。

当发生对 RQMS 有潜在影响的重大质量事件或 RQMS 发生重大变更时，组织应进行额外的管理评审。

9.3.1.1 General — Supplemental

The organization shall ensure that management reviews are carried out on a yearly basis aligned with the business calendar of the organization.

The organization shall retain documented information related to management reviews, including inputs and outputs.

In the event of a major quality incident with potential impact on the RQMS or significant changes to the RQMS, the organization shall conduct an additional management review.

9.3.2 管理评审输入 策划和实施管理评审时应

考虑下列内容：

a) 以往管理评审所采取措施的情况；

b) 与质量管理体系相关的内外部因素的变化；

c) 下列有关质量管理体系绩效和有效性的信息，包括其趋势： 1）

顾客满意和有关相关方的反馈；

2) 质量目标的实现程度；

3) 过程绩效以及产品和服务的合格情况；

4) 不合格及纠正措施；

5) 监视和测量结果；

6) 审核结果；

7) 外部供方的绩效； d）

资源的充分性；

e） 应对风险和机遇所采取措施的有效性（见 6.1）；

f） 改进机会。

9.3.2.1 管理评审输入 - 补充

管理评审必须考虑：

a） 来自项目评审的主要问题；

b） 选定的过程审核结果；

注：过程审核可以用来提供对表现绩效指标的分析；

c） 对 5.3.1 a)中定义的所有关键绩效指标和 9.1.1.1 中定义的至少其他关键绩效指标的分析结果进行评审；

d） 实际和潜在内外部技术故障及其安全影响的分析。

d)业务计划的输出。

管理评审应考虑到组织知识。

9.3.2.1 Management review inputs — Supplemental

Management reviews shall take into consideration:

a) key issues from project reviews;

b) selected results of process reviews;
NOTE Process reviews can be used to provide analysis of PIs.
c) reviews of the results from the analysis of all KPIs defined in 5.3.1 a) and the other PIs defined in 9.1.1.1 as a minimum;
d) analysis of actual and potential internal and external failures and their impact on safety;
e) outputs of business planning.
Management reviews should take into consideration organizational knowledge.
9.3.3 管理评审输出 管理评审的输出应包括与下列事项相关的决定和措施：
a) 改进的机会；
b) 质量管理体系所需的变更；
c) 资源需求。 组织应保留成文信息，作为管理评审结果的证据。
9.3.3.1 管理评审输出 - 补充
管理评审的输出必须包括与下列事项相关的决定和措施：
a) 目标达成，至少包括质量和安全目标；
b) 顾客满意。
当目标未达成时，必须依据 10.2 来管理纠正措施。
9.3.3.1 Management review outputs — Supplemental
The outputs of the management review shall include decisions and actions related to:
a) objectives achievement, including quality and safety objectives as a minimum;
b) customer satisfaction.
Corrective actions shall be managed in accordance with 10.2 when objectives are not achieved.

9.4 过程评审
关于过程评审，组织应结合管理评审，每年评审表a .1 所列过程。
此外，组织应评审表 a .2 中列出的推荐过程，以及组织根据风险确定的时间框架所确定的必要的附加过程。
过程评审的输出应包括：
A) 在过程评审中处理过程与 4.4.1 A)、b)、c)和 f)要求的符合性；
B) 对先前过程评审的措施进行监控；
C) 对过程的不合格输出进行监视；
D) 实施过程所需的可用和有效的资源；
e) 分析与过程相关的质量指标的测量(见 9.1.1.1)，包括对质量指标目标实现情况的评审；
9.1.3 中分析和评价的要求可适用于过程评审的表现绩效指标。
f) 评审过程产品参数的相关性，必要时调整措施；
G) 对审核产生的纠正措施进行管理。
每当进行过程评审时，组织应确保：
H) 过程所有者进行过程评审时涉及内部利害关系方管理代表参与。
I) 考虑 4.2 中所述的内外部相关方的输入和要求；
J) 在需要时作出决定和采取行动；
K) 向最高管理者报告过程评审的输出；
L) 过程评审的输入和输出形成文件并予以保留。
此外，过程所有者应确保过程评审能够识别与过程能力相关的任何必要的知识获取和变更。
9.4 Process reviews
Regarding process reviews, the organization shall review the processes listed in Table A.1 on a yearly basis aligned with the management review.

Moreover, the organization should review the recommended processes listed in Table A.2 and additional processes defined as necessary by the organization upon a risk based defined time frame.
The outputs of the process reviews shall include:
a) process conformity with requirements of 4.4.1 a), b), c) and f) is addressed during process reviews;
b) actions from previous process reviews are monitored;
c) nonconforming outputs of the process are monitored;
d) resources are available and effective to perform the process;
e) measurement of PIs related to the process (see 9.1.1.1) are analysed, including review of PI target achievement;
NOTE Requirements for analysis and evaluation in 9.1.3 can apply to PIs for process reviews.
f) the process PIs relevance is reviewed and actions are adjusted as necessary;
g) corrective actions resulting from audits are managed.
Whenever a process review is performed, the organization shall ensure that:
h) process owners perform process reviews involving management representatives of the process internal interested parties;
i) take into account the inputs and requirements of relevant internal and external interested parties referred to in 4.2;
j) decisions and actions are taken when required;
k) outputs of process reviews are reported to the top management;
l) inputs and outputs of process reviews are documented and retained.
In addition, process owners should ensure that process reviews address the identification of any necessary acquisition of knowledge and changes with regard to competencies for the process.

10 改进

10.1 总则 组织应确定和选择改进机会，并采取必要措施，以满足顾客要求和增强顾客满意。 这应包括：
a) 改进产品和服务，以满足要求并应对未来的需求和期望；
b) 纠正、预防或减少不利影响；
c) 改进质量管理体系的绩效和有效性。
注：改进的例子包括纠正、纠正措施、持续改进、突破性变革、创新和重组。
10.2 不合格和纠正措施
10.2.1 当出现不合格时，包括来自于投诉的不合格，组织应：
a) 对不合格作出应对，并在适用时：
1) 采取措施以控制和纠正不合格；
2) 处置后果；
b) 通过下列活动，评价是否需要采取措施，以消除产生不合格的原因，避免其再次发生或者在其他场合发生：
1) 评审和分析不合格；
2) 确定不合格的原因；
3) 确定是否存在或可能发生类似的不合格； c)
实施所需的措施；
d) 评审所采取的纠正措施的有效性；
e) 需要时，更新在策划期间确定的风险和机遇；
f) 需要时，变更质量管理体系。纠正措施应与不合格所产生的影响相适应。
10.2.2 组织应保留成文信息，作为下列事项的证据：

a) 不合格的性质以及随后所采取的措施； b）
纠正措施的结果。
10.2.3 不合格和纠正措施 – 补充
组织必须建立、实施和保持一个文件化过程，为管理不合格和纠正措施，包括：
a） 10.2.1 和 10.2.2 所规定的要求；
b） 明确准则以评估纠正措施的需求；
c） 应用问题解决方法（如 4D、8D）；
d） 监视纠正措施。
组织必须保留有关形成文件的信息。
注 1：这些要求可以应用到产品、服务、过程、项目执行的不合格。
10.2.3 Nonconformity and corrective action — Supplemental
The organization shall establish, implement and maintain a process for managing nonconformities and corrective actions.
This process shall include:
a) requirements defined in 10.2.1 and 10.2.2;
b) definition of criteria to evaluate the need for corrective actions;
c) application of problem-solving methods (e.g. 4D, 8D);
d) monitoring of corrective actions;
e) criteria for escalation towards relevant management (e.g. decision matrix).
NOTE These requirements can apply to nonconformity of products, services, processes and project execution

10.3 持续改进
组织应持续改进质量管理体系的适宜性、充分性和有效性。
组织应考虑分析和评价的结果以及管理评审输出，以确定是否存在需求或机遇，这些需求或机遇应作为持续改进的一部分加以应对。

Annex A
(informative)

List of processes

A.1 Mandatory processes

Table A.1 lists the mandatory processes of this document.

Table A.1 — Mandatory processes

Clause	Requirement
6.1.3.1	The organization shall establish, implement and maintain a risk and opportunity management process.
7.1.1.1	The organization shall establish, implement and maintain a process for resource planning, approval and control.
7.1.5.3	The organization shall establish, implement and maintain a process for calibration or verification, or both, of monitoring and measuring resources as well as of tools used in special processes.
7.2.1.1	The organization shall establish, implement and maintain a competence management process.
7.5.3.3	The organization shall establish, implement and maintain a process for the control of documented information.
8.1.1.2	The organization shall establish, implement and maintain a process for the planning of the transfer of processes that can affect the organization's products and services quality.
8.1.2	The organization shall establish, implement and maintain a tender management process.
8.1.3.1.1	The organization shall establish, implement and maintain a project management process.
8.1.4.1.1	The organization shall establish, implement and maintain a configuration management process appropriate to the product.
8.1.4.2	The organization shall establish, implement and maintain a change control process.
8.2.5	The organization shall establish, implement and maintain a requirement management process for products and services.
8.3.1 [a]	The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services. [a]
8.4.1.1.1	The organization shall establish, implement and maintain a process for externally provided processes, products and services (EPPPS) described in ISO 9001:2015, 8.4.1 to ensure conformity to requirements.
8.5.1.1.1	The organization shall establish, implement and maintain a process for production and service provision.
8.5.1.3	The organization shall establish, implement and maintain a process for the management of special processes.
8.5.5.1	The organization shall establish, implement and maintain a process for post-delivery activities.
8.7.3	The organization shall establish, implement and maintain a process for the control of nonconforming outputs.
8.8.2	The organization shall establish, implement and maintain a RAM management process for products and services.
[a] This process is a mandatory process of ISO 9001.	

Table A.1 *(continued)*

Clause	Requirement
8.8.3	In case the organization delivers safety-related mechanical and/or electrical/electronic/ programmable electronic products and services, it shall establish, implement and maintain a safety management process for products and services.
8.9.1	The organization shall establish, implement and maintain a FAI management process.
8.10	The organization shall establish, implement and maintain an obsolescence management process to ensure the availability of the supplied products and spare parts, as contractually required or defined by the organization, as a minimum until end of warranty.
9.2.3.1	The organization shall establish, implement and maintain an internal audit management process to verify the conformity of processes with internal and external requirements.
10.2.3	The organization shall establish, implement and maintain a process for managing nonconformities and corrective actions.
a This process is a mandatory process of ISO 9001.	

A.2 Recommended processes

Table A.2 lists the recommended processes of this document.

Table A.2 — Recommended processes

Clause	Recommendation
7.1.6.1.2	The organization should establish, implement and maintain an organizational knowledge management process for adequacy to achieve conformity of products and services.
7.4.1	The organization should establish, implement and maintain a communication management process for internal and external communication relevant to the RQMS.
8.1.1.1	The organization should establish, implement and maintain an innovation management process for new products, services and technologies.
8.6.1	The organization should establish, implement and maintain a process to release products and services.
8.8.4	The organization should establish, implement and maintain a life cycle costing management process for products and services by taking into account the need of the market as well as their interest (as operator, system integrator, equipment manufacturer).
9.1.2.1	The organization should establish, implement and maintain a customer satisfaction management process.

Annex B
(informative)

Subordinate concept of requirements for products and services

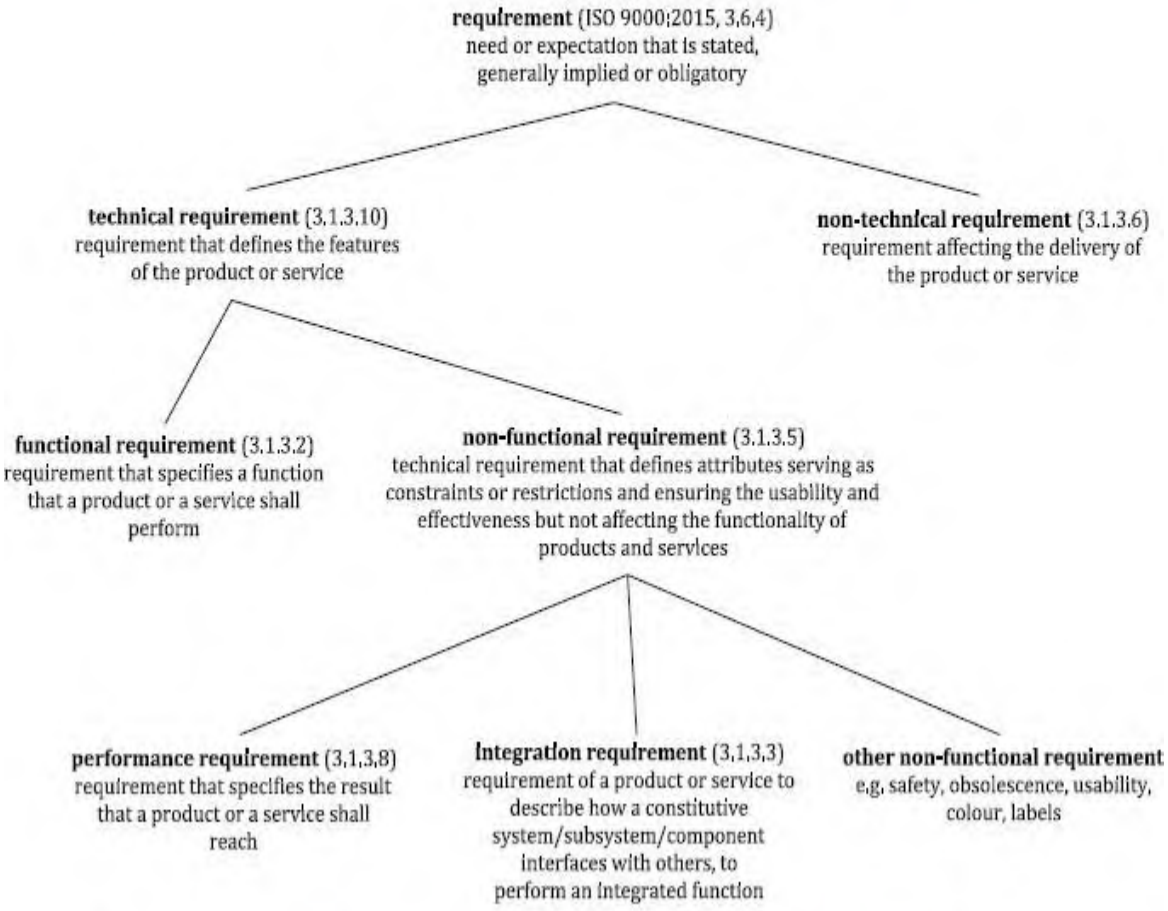

Figure B.1 — Subordinate concept of requirements for products and services