***Bad practices***

**ISO 19443 readiness version 2018**

**4 Context of the organization**

**4.1 The organization and its context**

* *the issues of the context of the company, such as the competitive environment, are not taken into account*
* *in some cases, the corporate culture is not taken into account*
* *risk analysis does not take into account strategic issues*
* *no clear link between the SWOT analysis and the actions undertaken*

**4.2 Needs and expectations of stakeholders**

* *statutory and regulatory requirements are not taken into account*
* *the delivery time is not validated by the customer*
* *the expectations of stakeholders are not determined*
* *the list of stakeholders does not contain their area of activity*

**4.3 Scope of the quality management system**

* *some products are outside the scope of the QSMS without justification*
* *the paint shop is not included in the scope of the QSMS*
* *the requirements of a customer are not accepted and no justification is present*
* *the scope is obsolete (a new subsidiary is not included)*

**4.4 Quality management system and its processes**

* *some process outputs are not set correctly (customers not considered)*
* *process efficiency criteria are not established*
* *the process owner is not formalized*
* *outsourced processes are not determined*
* *control of outsourced services are not described*
* *sequences and interactions of certain processes are not determined*
* *criteria and methods for ensuring effective processes are not determined*
* *monitoring the effectiveness of certain processes are not established*
* *the QSMS resources do not allow achievement of quality objectives*
* *the QSMS is not updated (new processes are not determined)*
* *the threats and weaknesses identified in the SWOT analysis remain without actions*

**5 Leadership**

**5.1 Leadership and commitment**

* *top management commitment does not include objectives*
* *communication of customer requirements is not ensured in the workshop*
* *some indicators are difficult to interpret*
* *some indicators are not consistent with the objectives*
* *overconfident based on past performance*
* *refusal to react to minor events*
* *criticism is hardly accepted*
* *lessons learned are not part of the nuclear safety culture*

**5.2 Policy**

* *the quality policy is not up-to-date*
* *the quality policy is undated*
* *the quality policy is not signed by the director*
* *the quality policy lacks ways to increase customer satisfaction*
* *the quality policy is not posted outside the office of the director*
* *communication of the quality policy to stakeholders is not defined*

**5.3 Roles, responsibilities and authorities**

* *managers’ roles and missions are not well known or understood in the workshop*
* *the quality and safety manager job description is not updated*
* *responsibilities and authorities of the quality and safety manager is not saved*
* *the authority to stop production is not included in the quality and safety manager job description*
* *self-questioning is not used at all*

**6 Planning**

**6.1 Actions to address risks and opportunities**

* *the list of risks is not updated*
* *risks are not ranked by priority*
* *the risk assessment is not up-to-date*
* *threats and opportunities are not identified for certain processes*
* *some requirements of stakeholders are not taken into account when planning actions to address risks*
* *there is no planning of actions to reduce negative impacts*
* *there is no opportunity to increase the desirable effects*
* *some products are not identified as being ITNS items and activities*
* *excessive requirements due to improper grading*

**6.2 Quality objectives**

* *a dashboard is non-existent*
* *no action is planned to achieve quality objectives*
* *no action is planned to address risks*
* *no risk reduction objectives*
* *resources to achieve certain objectives are not provided*
* *some indicators are difficult to interpret*
* *some indicators are not consistent with the objectives*
* *some objectives are not measurable*
* *some objectives are not monitored regularly*
* *the effectiveness of actions to address risks is not evaluated*
* *the objectives are not broken down into indicators*
* *the responsibility for actions to achieve the objectives is not defined*
* *there are no objectives to improve products*

**6.3 Planning of changes**

* *some changes are applied without planning and risk analysis of potential harm*
* *the person in charge of a change is not known to the persons concerned*
* *change is applied without a clearly established goal*

**7 Support**

**7.1 Resources**

* *financial resources are not unblocked on time*
* *unscheduled investment for equipment maintenance and infrastructure renewal*
* *no evidence of compliance with statutory and regulatory requirements of the working environment*
* *cleanliness of the production premises is not adapted to the process requirements*
* *the expectations of staff are not identified*
* *the quality and safety manager does not have a deputy or a substitute*

**7.2 Competence**

* *the necessary skills are not defined for each function*
* *missing skills are not listed*
* *some departments do not determine their training needs*
* *evaluating the effectiveness of training is not practiced*
* *some training has not been evaluated, either at the end of the session or later*
* *the annual training program is not updated (training is planned but not provided)*
* *training activities at the workplace are not systematically recorded*
* *persons working on specific missions are not qualified*

**7.3 Awareness**

* *there is no formal document to raise awareness of new recruits or outside providers’ staff*
* *new hires do not receive formal information on preparing for emergencies*
* *some persons are not made aware of the importance of the potential consequences for nuclear safety of errors in their activities*

**7.4 Communication**

* *complaints are not taken into account*
* *requests made by stakeholders are not recorded*
* *monitoring of actions in response to complaints is not transmitted to the stakeholder*

**7.5 Documentation**

* *the scope of the QSMS is not mentioned in any document*
* *some process sheets are incomplete*
* *many real activities are not identified in any document*
* *some documents are not codified*
* *documents are not approved prior to release*
* *documents are incomprehensible to staff*
* *documents are not located where needed*
* *instructions are outdated (version before the last one)*
* *during the project launch meeting, the list of participants is not recorded*
* *protection of documents on the network is not set*
* *documents of external origin are not under control (codified)*
* *retention period and methods of disposal of documents are not determined*
* *no documentation prohibits the use of dangerous equipment (non-compliance with legal requirements)*
* *documents are not stored until the date of disposal*
* *quality meeting without retained report*

**8 Operation**

**8.1 Operational planning and control**

* *the traffic plan is not displayed*
* *some people do not wear personal protective equipment*
* *there are no signs prohibiting unqualified personnel from using certain machines*
* *temporary and permanent changes to processes are not mastered*
* *change consequences are not analyzed*
* *acceptance criteria for products are not clearly defined*
* *records on processes are not retained*
* *the set for the use of personal protective equipment is not displayed*
* *no internal threat awareness program for counterfeit, fraudulent or suspect items*

**8.2 Requirements for products and services**

* *responsibilities for communication with customers are not known to some people*
* *claims remain unanswered or without action*

**8.3 Design and development**

* *the stages of the design and development are not planned*
* *the planning of stages is not updated*
* *records on some reviews do not exist (or was not kept)*
* *statutory and regulatory requirements are not determined*
* *recycling is not taken into account*
* *verifications and validations are not retained*
* *some changes are not retained*
* *incomplete test instruction (the method is missing)*
* *outputs are not in the form requested by the customer*
* *acceptance criteria are not specified in the outputs*
* *no process is in place for demonstrating the qualification of software for the design of IPSN product or service*
* *the stages requiring authorization before progressing to the next stage are not identified*

**8.4 External providers**

* *records on evaluation and selection of external providers are not retained*
* *lack of technical specifications in some data sheets*
* *lack of acceptance criteria for certain products*
* *untrained personnel to verify compliance with requirements at product receipt*
* *the results of verification of purchased product are not recorded*
* *delays in delivery are not taken into account*
* *corrective actions are not required from failing suppliers*
* *the performance indicator of some external providers is not monitored*
* *the requirements for adequacy communicated to external provider are not always reviewed before being sent*

**8.5 Production and service provision**

* *batch tracking sheet partially filled*
* *inadequate training of the operator on the use of a new machine*
* *unplanned control of spare parts of machines*
* *inventory of products is not done at the planned deadline*
* *the activities of handling, packaging and storage are not described*
* *the documentation for export is not translated*
* *non-compliance with certain traceability requirements*
* *equipment owned by the customer is not identified as such*
* *incidents of equipment owned by the customer are neither retained nor communicated to the customer*
* *pallets are stored outside without protection against rain*

**8.6 Release of products and services**

* *a nonconforming product is delivered without approved concession*
* *lack of certain information on the traceability of products*
* *not all required documents are present at delivery*

**8.7 Control of nonconforming outputs**

* *send a bill for the recovery or repair to the customer*
* *when awaiting the analysis of a nonconforming product, failure to place it immediately in an isolation area (red, prison)*
* *lack of records on repaired products*
* *concession applied without any signature*

**9 Performance evaluation**

**9.1 Monitoring, measurement, analysis and evaluation**

* *communication with the customer is slow (response to a request after one week)*
* *monitoring of actions following complaints are not promptly transmitted to the customer*
* *the decisions of the data analysis are not retained*
* *trends that can be discovered in the data are neither sought nor used*
* *QSMS performance measurements are not available*
* *monthly monitoring of activities with impact on quality are not retained*
* *equipment with outdated calibration date*
* *inspection activities are neither defined nor planned*
* *the equipment calibration and verification list is not updated or is incomplete*
* *calibration instruction of an equipment is non-existent*
* *labels to identify the state of calibration are not present on some equipment*
* *verification of an equipment is not retained*
* *appropriate methods of process inspecting do not exist*

**9.2 Internal audit**

* *the audit program is neither followed nor updated*
* *the audit program does not cover all the requirements of the ISO 9001 standard*
* *the list of internal auditors is not updated*
* *the scope of the audit falls within the responsibilities of the auditor*
* *the audit report is not retained*
* *the audit report does not contain any track for improvement or any action*
* *the action requested in the audit report is not implemented in the proposed deadline*
* *the audit was conducted by a student without enough skill and experience (and not part of the list of auditors)*
* *results of audits are not routinely proposed as part of inputs of management review*
* *monitoring at certain stages of the product is not retained*

**9.3 Management review**

* *the monitoring of the actions of the previous review is not presented*
* *performance trends are not in the inputs*
* *audit results are only partially presented*
* *significant changes are not taken into account*
* *the effectiveness of the QSMS is not evaluated*
* *the chosen periodicity is not followed*
* *the management review is incomplete (some key processes are not evaluated and some departments are not represented)*
* *complaints are not properly addressed*
* *the level of achievement of objectives is not analyzed*
* *the status of on-going actions is not commented upon*
* *some inputs of the review are absent (results of the surveys of customer satisfaction)*
* *there is no decision to update indicators*
* *decisions on improving the effectiveness of the QSMS and processes do not exist*
* *no proposal to improve the products is taken*
* *the need for people and material resources is not expressed in numbers or is insufficient to achieve the objectives*
* *lack of resources is not examined*

**10 Improvement**

**10.1 General**

* *some opportunities for improvement are determined without any action being undertaken*
* *lessons learned from experience are not applied in all departments*

**10.2 Nonconformity and corrective action**

* *responsibility and authority for the control of nonconformities are not defined*
* *after analyzing the causes no corrective action follows*
* *a customer complaint without any follow-up*
* *lack of analysis of causes of nonconformities*
* *lack of evidence of elimination of causes of nonconformities*

**10.3 Continual improvement**

* *improvements are applied without being communicated at management review*
* *the nuclear safety culture is not present by default in the continual improvement process*