***Good practices***

**ISO 19443 readiness version 2018**

**4 Context of the organization**

**4.1 The organization and its context**

* *diagnosis of the context includes the main external and internal issues*
* *the core values as part of the corporate culture are taken into account in the context of the company*
* *the results of the context analysis are widely diffused*
* *the SWOT analysis includes many relevant examples*
* *the SWOT analysis is a powerful tool for identifying the main threats and opportunities*

**4.2 Needs and expectations of stakeholders**

* *the list of stakeholders is updated*
* *the needs and expectations of stakeholders are established through meetings on-site, surveys, roundtables and meetings (monthly or frequent)*
* *the application of statutory and regulatory requirements is a prevention approach and not a constraint*

**4.3 Scope of the quality management system**

* *the scope is relevant and available upon request*
* *non applicable requirements are justified in writing*

**4.4 Quality management system and its processes**

* *the process map has enough arrows to show who is the customer (internal or external)*
* *for a process, it is better to use a lot of arrows (several customers) rather than to forget one*
* *reveal the added value of the process during the process review*
* *the analysis of processes performance is an example of continual improvement evidence of the effectiveness of the QSMS*
* *top management regularly monitors the objectives and action plans*
* *the purpose of each process is clearly defined*
* *process owners are members of the management team*

**5 Leadership**

**5.1 Leadership and commitment**

* *top management assumes its responsibility in communicating the importance of having an effective quality management system to sustain the company*
* *the director’s declaration of commitment is shown in a few key locations*
* *the commitments of top management on continual improvement are widely diffused*
* *nuclear safety is taken into account in every decision making*
* *every event, even minor, is deeply scrutinized*
* *criticism is accepted by top management*

**5.2 Policy**

* *the quality policy matches the available resources and associated objectives*
* *methods of internal and external communication are presented in the quality and safety manual*
* *the quality policy is shown at a few key locations*
* *nuclear safety considerations are included in the quality policy*
* *the quality policy is communicated to external providers*
* *the quality policy includes the commitment to continual improvement*
* *the policy takes into account all the specifics related to the corporate culture*

**5.3 Roles, responsibilities and authorities**

* *job descriptions for all positions (including management) are available on the intranet*
* *QSMS animation, coordination and training missions are explicitly defined*
* *a culture of self-questioning is present at all levels*

**6 Planning**

**6.1 Actions to address risks and opportunities**

* *planned changes are evaluated before they are applied*
* *the list of risks taken into account is exhaustive*
* *actions to reduce certain risks are integrated into key processes*
* *the action plan includes a column used for monitoring the effectiveness of actions*
* *the action plan takes into account the results of internal audits*
* *the list of external and internal issues is exhaustive*
* *when planning actions to address risks, the scope of the QSMS is taken into account*
* *ITNS determination is realized and documented for all products and services*
* *the graded approach is properly used for external providers*

**6.2 Quality objectives**

* *the available resources and associated objectives are in line with the quality policy*
* *quality objectives are realistic and ambitious*
* *indicators are monitored daily*
* *the dashboard is updated weekly*
* *the dashboard with all the indicators allows the daily display of key process performance*

**6.3 Planning of changes**

* *changes are planned and validated before any application*
* *changes do not compromise nuclear safety*
* *changes are communicated to all persons concerned*

**7 Support**

**7.1 Resources**

* *the needed resources are planned and available on time*
* *the resources are in line with the quality policy*
* *the list of equipment, machines and infrastructure is updated regularly*
* *the presentation of the organization on the website is very clear and up-to-date*
* *standards and calibration instructions are codified and archived*
* *provisions of resources do not compromise nuclear safety*

**7.2 Competence**

* *the competence for each activity is determined in a file*
* *the annual training program is updated at least twice a year*
* *during the staff appraisal, an employee may request an addition to the annual training program*
* *the training file of each employee is protected (restricted access)*
* *each course is evaluated at the end of the session and two to three months later*
* *an analysis of the effectiveness of the training is done at year-end*
* *the competence matrix is updated regularly*
* *the list of those requiring regulatory or usage authorizations is up-to-date*

**7.3 Awareness**

* *everyone contributes to continual improvement without any constraint*
* *all staff are made aware of the policy and quality objectives*
* *all staff are made aware of the importance of the potential consequences for nuclear safety of errors in their activities*

**7.4 Communication**

* *methods and means of internal and external communication are thoroughly described in the process sheet*
* *communication is transparent and systematic*
* *important issues for staff and stakeholders are consulted on and involved upstream*

**7.5 Documentation**

* *documentation management clearly shows the author and approver of the initial document and subsequent versions*
* *properly managing changes to documentation (a line in the middle of the old text, red) can quickly show the history*
* *the hierarchy of documentation is logical and clear (processes, procedures, records)*
* *the master list of documentation also includes the retention period*
* *records fulfill their role of controlling situations where their absence could lead to deviations from the legal requirements*
* *external documents (standards, regulations, documents of customers, external providers and machines) are coded as internal documents and the location is noted in a specific list*
* *a review of all documentation of the QSMS is conducted twice a year, it is very well organized and the actions are completed on schedule*
* *records show compliance with statutory and regulatory requirements, the requirements of ISO 19443 and the company's quality policy*
* *a list of dates of implementation of changes into production is available at the workshop*

**8 Operation**

**8.1 Operational planning and control**

* *the acceptance criteria of the products are established, posted and respected*
* *risks identified in production are analyzed, evaluated and treated on a case-by-case basis*
* *the results of the daily check of forklift trucks are recorded in the maintenance file*
* *work instructions, including critical tasks, are updated*
* *the instructions displayed are followed by all staff*
* *the phases of definition and realization of the product or service are included in the project management*
* *a catalog with photos of original components and materials helps staff make visual comparisons in case of doubt*

**8.2 Requirements for products and services**

* *methods and responsibilities for responding are known to all*
* *any order acceptance is preceded by an analysis of the changes requested by the customer*

**8.3 Design and development**

* *the customer is present at the launch meetings*
* *the new project coordination meetings end with a report signed by the customer including the list of actions to be undertaken*
* *the inputs of the design and development are systematically stripped of any ambiguous, incomplete or contradictory data*
* *a risk approach (identification, analysis, evaluation and treatment) is performed at the beginning of each project*
* *the responsibilities of team members are clearly defined and recorded*
* *any change is communicated to the customer for consultation*
* *verification of the software qualification scope is done in relation to its actual use*

**8.4 External providers**

* *the list of external providers also includes the history of evaluations*
* *each delivery is evaluated*
* *quarterly update of supplier performance (quality, cost, deadlines)*
* *regular audits at the premises of external providers*
* *partnerships with key external providers (pooling of assets and resources)*
* *critical characteristics of commercial grade items and activities are always verified*
* *controls applied by the external provider include control of its supply chain*
* *requirements are reviewed for adequacy prior to communication to external provider*

**8.5 Production and service provision**

* *the customer has live access to production data and inspections of their product on the network*
* *traceability of the product contains information on raw materials, machines, personnel and inspections*
* *controlled conditions takes into account the graded approach outputs*
* *monitoring and measurement of ITNS items and activities are performed by competent persons*
* *preservation of ITNS products includes access limitation*

**8.6 Release of products and services**

* *inspections are planned on time*
* *the deadline of the inspection arrangements is always met*
* *the traceability of each delivery is easily accessible*

**8.7 Control of nonconforming outputs**

* *any problem (internal or external) is retained (nonconformity treatment card, 8 D record)*
* *permission to use concession is always signed by the customer*
* *5 M, Pareto and other tools are used when identifying and analyzing root causes*
* *justification for repair is always approved by the customer*

**9 Performance evaluation**

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

* *in order to measure the performance of the QSMS, use everything you can get out of the toolbox of the quality and safety manager without restraint*
* *the results of data evaluation lead to many decisions for improvement*
* *customer complaints are answered in writing, if possible, on the same day*
* *each customer has a protected space on the network to follow the progress of their new projects live*
* *inspection results of the key characteristics of activities that could have an impact on quality are used as relevant data to evaluate the conformity of the QSMS*
* *all acceptance criteria for inspections are set*
* *the list of equipment requiring calibration is updated*
* *user manuals of the equipment are easily accessible and in English*
* *the location of each device is established in the master list of equipment*
* *standards and calibration instructions are coded and stored*

**9.2 Internal audit**

* *the crossover audit (of exchange between two companies) is very appropriate and delivers key findings*
* *the audit program covers all key processes of the quality management system*
* *the objectives of the audit program are consistent with the quality policy and the company's specificities*
* *the audit program is communicated to the persons concerned well before the first audit*
* *each audit report contains identified good practices*
* *any opportunity for improvement found during an audit is applied to other departments, processes or products*
* *an audit that is unscheduled but required by a department at a delicate stage often provides added value*

**9.3 Management review**

* *process review occurs prior to management review*
* *analysis of process performance is presented by each owner*
* *management review is coupled with the budget*
* *the importance of customer complaints is staked by all*
* *any proposed change is preceded by an impact evaluation*
* *when the opportunity presents itself, do not forget to praise the people who deserve it*
* *decisions are communicated to all*
* *the risks of the processes are analyzed and the effectiveness of the actions evaluated*
* *nuclear safety receives the attention it deserves*

**10 Improvement**

**10.1 General**

* *any opportunity for improvement found in a corrective action is applied to other departments, processes or products*
* *each nonconformity is used to improve the process*

**10.2 Nonconformity and corrective action**

* *nonconforming products are systematically identified and separated from other products awaiting analysis and treatment*
* *root cause analysis is performed by default*
* *repaired products are inspected 100% before being returned to the normal flow*
* *monitoring the effectiveness of corrective action is carried out systematically*

**10.3 Continual improvement**

* *the staff suggestion scheme is well oiled and bears fruit*
* *change management implementation is flawless*