SUPPLIER MANAGEMENT SYSTEM SPECIFICATION

By way of supplement to ISO 9001: 2015

Supplier edition of October 2023

1. PURPOSE OF THE DOCUMENT

This specification formalizes the requirements specific to nuclear activities which supplement those of the ISO 9001: 2015 [10.].

The supplier or service provider must comply with these requirements when executing a contract awarded by an Orano entity operating a nuclear facility or otherwise involved in nuclear activities.

They also apply to suppliers carrying out radioactive cleanup and dismantling services under Orano CAEAR acceptance. Appendix 2 details the requirements for this type of service, in addition to those in this specification.

In practice, the generic requirements of this specification are supplemented by specific requirements noted in the expression of needs and/or in the contract.

2. DEFINITIONS AND ABBREVIATIONS

2.1 ABBREVIATIONS

ACQ	Activity Concerned by Quality
AP / AE	Authorization to Practice / Autorisation d'Exercer
IAEA	International Atomic Energy Agency
AIP	Activity Important for Protection
ASN	Autorité de Sûreté Nucléaire [French Nuclear Safety Authority]
CAEAR	Commission d'Acceptation des Entreprises d'Assainissement Radioactif [commission on acceptance of radioactive cleanup companies]
CEP	Periodic inspections and tests [Contrôles et Essais Périodiques]
CFS	Counterfeit, Fraudulent, Suspect
CSFN	Comité Stratégique de la Filière Nucléaire [strategic committee for the French nuclear sector]
CT	Technical Inspection [Contrôle Technique]
DR	Defined Requirement
EIP	Element Important for Protection
EIS	Element Important for Safety
GE	grouping of companies / consortium [Groupement d'Entreprises]
HSE	Health, safety and environment
ICPE	Installation Classé pour la Protection de l'Environnement [facility classified on environmental protection grounds]
INB / BNI	Installation Nucléaire de Base [regulated nuclear facility / Basic Nuclear Installation - BNI per ASN]
INBS / SBNI	Installation Nucléaire de Base Secrète [defense nuclear facility - SBNI per ASN]
ITNS	Important To Nuclear Safety [10]
IS	Information System
ISO	International Organization for Standardization
MMR	Measure of Management of Risks
RFQ	Request For Quotation

2.2 REMINDER OF DEFINITIONS PER BNI ORDER[1.]

Activity Important for Protection: activity that contributes to the technical or organizational measures to prevent or sufficiently limit the risks and drawbacks presented by the facility in terms of protected interests.

The AIPs detailed in the internal reference systems of the operational entities concern the following areas:

- Studies and changes;
- Works and changes;
- Scheduled maintenance, periodic inspections and tests (CEP), conformity assessments;
- Facility operation, management and monitoring;
- Purchasing;
- Training;
- Handling of deviations.

Element important for protection (EIP): a structure, equipment, system, component and/or software present in the facility or falling under the operator's responsibility that performs a function necessary to the demonstration of the protection of interests or that verifies that that function is ensured.

Defined requirement (DR): Requirement assigned to an element important for protection, so that it fulfills with the expected characteristics of the function provided for in the demonstration mentioned in the second paragraph of article L. 593-7 of the French environmental Code, or to an activity important for protection so that it meets its objectives with respect to this demonstration (as per BNI order).

Operator: natural or legal person operating a basic nuclear installation (INB/BNI), whether its situation is in order or not, or having made a creation authorization application provided for by article L. 593-7 of the environment code with a view to operating such an installation.

Subcontractor: natural or legal person other than the operator, performing operations or supplying goods or services which participate in an AIP or relate to an EIP.

2.3 OTHER DEFINITIONS RELATED TO THE SPECIFICATION

Activity concerned by quality (ACQ): an activity whose failure may impact the quality of Elements Important for Safety (EIS).

Defined requirements (for each ACQ): requirements necessary to obtain and maintain the quality of structures, equipment and materials, the assemblies associating them and the operating conditions of the installation (EIS).
They must be defined for each activity concerned by quality, taking into account its importance for safety.

CAEAR: Commission Orano d'Acceptation des Entreprises d'Assainissement Radioactif [Orano commission on acceptance of radioactive cleanup companies].

CFS item (or CFSI): counterfeit, fraudulent or suspect item [per IAEA NP-T-3.21]

- **Counterfeit**: item intentionally manufactured, reconditioned or modified in such away as to imitate the original product without authorization in order to be passed off as genuine;
- **Fraudulent**: item intentionally tampered with with intent to deceive (including an item supplied with incorrect identification, falsified or inaccurate certification. This also includes an item sold by an entity that has acquired the legal right to manufacture a specified quantity of an item, but produces a larger quantity than authorized and sells the excess as legitimate stock);

- **Suspect**: item for which there is an indication or suspicion that it may not be genuine, because it may be fraudulent, counterfeit or non-compliant.

Customer: an Orano entity responsible for the construction or operation of a nuclear facility (under INB/BNI, INBS/SBNI or ICPE status), which receives a product or a service based on a formalized expression of requirements and on a contract.

Technical Inspection: is a means of ensuring that products and services are compliant.

Supplier: internal or external to Orano, it signs a contract with an Orano entity (the customer) and provides the product or service requested. Depending on the contract, it may intervene on an Orano site or carry out its activities on premises of its choosing.
In this document, the term "supplier" includes service providers.
The "supplier" may be an "outside contractor" in the sense of the BNI Order.

Grouping of companies / consortium [GE - Groupement d'Entreprises]: a number of suppliers working together in association on a temporary footing to carry out a contract order. A joint venture (JV) agreement is then drawn up and a legal representative is appointed for the grouping.

Protected interests:

- For INB/BNIs, the interests protected by law are listed in Article L593-1 of the French Environmental Code. It concerns public safety, nuclear safety, public health, public hygiene, and the protection of nature and the environment.
- The nuclear safety functions adopted by Orano [14.] take into account the protection of people and the environment against ionizing radiation.
- For ICPE/BNIs, the interests protected by law are listed in Article L511-1 of the French Environmental Code. It concerns local residents, public health and safety, agriculture, the protection of nature, the environment and the countryside, the rational use of energy, the conservation of sites and monuments, as well as elements of archaeological heritage.
- For INBS/SBNI, interests are defined in Article 1 of the Order of September 26, 2007. It concerns local residents, public health and safety, agriculture, the protection of nature, the environment and the countryside, the conservation of sites and monuments.

Intermediate documented information: these are document records which are not final documents but serve as a basis, containing the initial/original information, with which to draw up final documents.

Risk management measures or **M**easures of **M**anagement for **R**isks (Mesures de Maîtrise des Risques – **MMR**): set of technical and/or organizational measures that are necessary and sufficient to reduce the probability of occurrence and/or the effects and consequences of a major accident (as per circular of May 10, 2010).

Hold point: point beyond which the design, development, production and preparation of the product should not continue without the customer's approval.

Witness point: point at which the customer decides whether or not to witness the operation or its inspection. This notice does not stop continuation of the operations.

Product, Service: as defined in ISO 9001:2015 [9.]

Nuclear safety: all technical and organizational measures relating to the design, construction, operation, shutdown and decommissioning of basic nuclear installations and the transport of radioactive substances, taken with a view to preventing accidents or limiting their consequences [Article L-591-1 of the French Environment Code].

Subcontractor: organization which signs a contract for supplies or services with a supplier. There is no direct contractual link with the customer.

Monitoring: the end goal of monitoring is to provide the Operator with the assurance that external contractors are applying the policies communicated for the protection of interests, that the requirements defined in this specification are being met, and that the requirements notified in the order documents are being complied with.

Management system as defined in ISO 9000:2015 [9.]. It notably takes account of nuclear safety-related challenges.

3. CONTEXT OF THE ORGANIZATION (§4 OF ISO 9001:2015)

The supplier complies with all of the legal and regulatory requirements applicable to its field of activity.

The supplier defines what it commits to doing to comply with these requirements in a "**quality document**".

This documented information is mandatory in the four specific cases below:

- When the contract includes an ISO 9001 certification requirement and the supplier:
  - is either not ISO 9001 certified,
  - or is ISO 9001 certified but not for the scope concerned by the contract order;
- If the supplier's management system does not meet the requirements of this specification;
- When the contract order requires a specific organization for a given period of time;
- in the case of a grouping of companies, even if each of the companies is ISO 9001 certified and meets this specification.

The supplier must take the protection of interests into account in its management system (for instance in the "quality document" mentioned above), and the associated objectives are to be passed onto the right level of the organization and its processes. It shall take into account the interested parties relevant to its activity.

This documented information is submitted to the customer for review and approval.

Any grouping of companies thus gives rise to:

- A **joint venture (JV) agreement**,
- a "**quality document**" based on the grouping's architecture/organization which describes the organization implemented, the responsibilities, interfaces and control and monitoring requirements of the other members of the grouping by the legal representative.

  The document defines the procedures established by the grouping as concerns project follow-up (including contract/order review), compliance with specified requirements, risk analysis, identification and handling of deviations, and internal audits.

  The legal representative coordinates and validates this document.

The supplier notifies the customer without delay of any change in its management system or its organization.

For contract orders requiring approvals, certifications or accreditations, the supplier commits to sending to the customer evidence that they are maintained over time throughout the contract order period.

4. LEADERSHIP (§5 OF ISO 9001:2015)

In carrying out Orano projects, the supplier's Management agrees to comply with:

- The Code of Ethics and Business Conduct [5.];
- The Nuclear Safety Charter [6.];
- The specific HSE Charter or Policy in the case of jobsites;
- The Safety-Environment Policy[7.] [8.];
- The Social Specification, within the limit of its field of application [2.]
- Any "local" policies.

The supplier's Management is responsible for:

- The exactness of the data transmitted for its listing and responses to calls for bids (RFQs);
- Countering reprehensible or risky acts, behaviors and situations;
- The level of nuclear safety, occupational safety and quality culture of its employees, teams and organization, including of its subcontractors;
- The technical skills of its employees and their knowledge of what is at stake in their activity in terms of protected interests and the risks of the nuclear installation or of the site;
- Paying the necessary attention to ensure nuclear safety and environmental protection are not compromised by decisions taken;
- Its contribution to providing feedback on operating experience for events concerning it, followed if necessary by the definition and deployment of a performance improvement plan.

The supplier's Management promotes and supports a culture of quality, nuclear safety, conventional safety, environmental and radiation protection:

- By appointing one of the managers of the organization, having independence and authority, to manage aspects related to quality and nuclear safety; he/she will have direct access to the supplier's Management;
- By fostering a shared understanding of the fundamental aspects of quality, safety, security, environmental protection and radiation protection within the organization;
- By providing the means enabling individuals and teams to complete their work successfully in the context in which they work;
- By strengthening a learning and questioning approach at each level of the organization to contribute to tangible continual improvement in the protection of interests;
- By instilling a policy of responsibility, transparency and constant employee commitment to meeting customer requirements and striving for customer satisfaction.

In that sense, the supplier develops management practices and a working environment that promote on a long-term basis the appropriate attitudes, behaviors and actions.

Components of awareness are given in Appendix 1 of this specification.

5. SUPPORT (§7 OF ISO 9001 :2015)

5.1 COMPETENCE AND AWARENESS (§7.2 AND §7.3 OF ISO9001:2015)

Awareness

People assigned to an AIP/ACQ or working on an EIP/EIS/MMR-type important element must also be aware:

- Of the importance of their tasks;
- Of the potential impacts that any failing in exercising their activity could have on the protection of interests;
- Of how to identify CFS items and falsified documents.

This awareness training must be adapted to the supplier's activity, e.g. adaptation to cases likely to be encountered in its activities.

The supplier takes the appropriate steps to ensure that these people have been made aware of at least the aspects mentioned above, and that this awareness is maintained over time. These topics form part of the safety culture awareness that needs to be deployed more widely within the organization.

Points to raise awareness are given in the flyer in appendix 3 "Ethics & Compliance - Combating quality fraud, irregularities and document falsification".

Competence / Skills

The skills of the persons assigned to perform, or to carry out the technical inspection, verification and, where necessary, monitoring of an AIP/ACQ or persons working on an important EIP/EIS/MMR-type element must be defined.

Persons shall be assigned by comparing skills acquired with the skills required.

The supplier puts processes in place to confirm that the persons it assigns to AIPs/ACQs, or working on an EIP/EIS/MMR-type important element, to modifications to design and development, to technical inspections, verification activities or assessment of those activities, possess the necessary mandatory qualifications and skills.

The skills of the persons assigned to carry out technical inspection, verification and, where necessary, monitoring activities must be at least identical to those of the person performing the intervention.

The supplier takes appropriate measures in terms of regulatory training to ensure that the persons assigned to an AIP/ACQ and working on an EIP/EIS/MMR-type important element have the necessary skills and that their skills are maintained over time.

Qualifications/authorizations/permits

The supplier takes appropriate measures in terms of training or special authorization to practice (AP/AE) to ensure that persons assigned to activities for which the challenges in terms of the protection of interests requires individual authorization by the customer meet the required conditions for authorization.

The supplier takes the appropriate training measures to be able to issue and maintain the regulatory qualifications or certifications, as well as the authorizations or permits of the persons assigned to an AIP/ACQ and working on an EIP/EIS/MMR-type important element.

Auditors must be qualified, must not audit their own activity and shall not exercise any direct responsibilities in the area to be audited.

5.2 DOCUMENTED INFORMATION (§7.5 IN ISO9001:2015)

The supplier's management system must specify the language used and include control of the language translation of the documented information under the contract.

The supplier guarantees that its personnel and that of its sub-contractors have the necessary skills to carry out the activities related to the contract.

Particular attention is paid to verifying compliance with the original text in terms of form and content, and to communicating the requirements applicable to its personnel and to its subcontractors.

Documented information related to the contract:

- Is verified. The verification is done by persons other than those who collected the data and drew up the documented information.
- Must be up to date, known, understood and used appropriately by the personnel concerned.
- The verification/validation procedures implemented must enable formal, unambiguous identification of the person who carried out the task. For example, the use of images for signatures is prohibited; electronic signatures or manual signatures with specimen presented in the "quality document" mentioned in §3 are authorized.
- If "intermediate" documented information is produced, it is kept, filed, archived and made available to the customer. Any information copied into an information system must be verified by a person other than the person who made the copy.

Reports, meeting reports and other documented information to be drawn up for purposes of the contract, along with their methods of validation, keeping and filing, are described in the "quality document" mentioned in §3.

The supplier sends the documented information specified under the terms of or in the contract to the customer.

In particular, technical inspections (§6.5.1) and verification and assessment activities (§6.4.2), as well as monitoring activities where applicable (§6.4.2), carried out for an AIP/ACQ or for work on a EIP/EIS/MMR-type important element are subject to documented information and traceability requirements for purposes of before-the-fact and after-the-fact verification of compliance with defined requirements (DR).

6. OPERATIONAL ACTIVITIES (§8 IN ISO 9001:2015)

When the purpose of the order is identified as an AIP/ACQ or as work on a EIP/EIS/MMR-type important element, the supplier must take appropriate technical and organizational measures, including with regard to its subcontractors, in order to meet the requirements relating to the AIP/ACQ or EIP/EIS/MMR.

The supplier must also take all necessary steps to safeguard against CFS items at all levels of operational activities (including, in particular, through the selection of its suppliers and the specific information passed on to suppliers and requirements relating to the control of their own

subcontractors; the control of outsourced processes, products and services; and monitoring and measurement activities).

6.1 OPERATIONAL PLANNING AND CONTROL (§8.1 IN ISO9001:2015)

When carrying out a project, contract or order, and in addition to activity planning actions, the supplier defines and implements an organization and measures enabling it to ensure project management, project risk management and configuration management meeting the customer's requirements and addressing the challenges in terms of protected interests and product quality.

These measures must be proportionate to the stakes involved in the project, while respecting customer requirements, resource constraints, deadlines and product quality.

The supplier implements a project risk management initiative as necessary in connection with compliance with listed requirements.

6.2 REQUIREMENTS RELATED TO PRODUCTS AND SERVICES (§8.2 IN ISO9001:2015)

6.2.1 Review of the requirements for products and services (§8.2.3 in ISO9001:2015)

The supplier analyzes the customer's requirements and verifies that all the provisions of its management system take into account all risks that may compromise its proper operation and the achievement of the performance objectives (risk analysis), including those associated with CFS items/services.

This risk analysis is done for purposes of the contract review. The conclusions are formulated and integrated into the "quality document" for the cases concerned.

For any service or supply presenting issues in terms of protected interests and product quality, the requirement levels for the management system, for control, for monitoring and for documentation are proportionate to the importance of the risks and challenges in terms of protected interests and product quality.

6.2.2 Changes of the requirements for products and services (§8.2.4 in ISO9001:2015)

Design and development changes must be controlled: they must be identified, justified (their impacts must be documented), validated by the customer when required in the expression of needs and filed.

6.3 DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES (§8.3 IN ISO9001:2015)

The supplier defines its organization and, when required under the terms of the contract, requests customer's acceptance about:

- The interfaces;
- The input data and output data;
- The necessary reviews;
- The approaches to verification, validation and control of changes.

Plus:

- The supplier produces the documented information, procedures and qualifications required by the contract order. It specifies the conditions for all qualifications and demonstrates that the design tools are suitable for the intended use and qualified for the intended use. This concerns, for example, computer codes and tools, digital models, etc.

- The persons in charge of design and development verification are different from the persons who participated in those activities.
- In the case of design, the review, verification and validation activities can be performed by technical inspection (§6.5.1) and verification (§6.4.2),

6.4 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES (§8.4 IN ISO9001:2015)

6.4.1 General (§8.4.1 in ISO9001:2015)

The requirements of this specification must be taken into account in the methods of assessment and selection of subcontractors.

The results of the assessment of subcontractors shall be valid for a limited period and for an identified field of activity. The documented information relating to the control of subcontractors is up to date and kept.

6.4.2 Type and extent of control (§8.4.2 in ISO9001:2015)

Verification:

The supplier performs verifications, regularly and in a way that is proportionate to the challenges, based on spot checks on the performance of operations and/or inspections concerning product realization.

These verifications are performed by persons different to those who carried out the AIP/ACQ or who worked on an EIP/EIS/MMR-type important element and must have the appropriate skills and qualifications.

Monitoring:

The objective of the supplier's monitoring of subcontractors is set out in §2.3.

The supplier monitors its subcontractors in a way which is proportionate to the importance of the challenges involved in the contracts entrusted to it by the customer.

For operations entrusted to subcontractors, the supplier performs independent assessments, regularly and in a way that is proportionate to the challenges, relying as necessary on:

- Scheduled (and possibly unannounced) monitoring of the performance of operations and/or technical inspections carried out by trained personnel;
- An overall analysis of the performance of a given subcontractor, based on data including a summary of monitoring actions;
- The documented information relating to the results of monitoring and carried out by the supplier are transmitted to the designated Orano contacts.

It should be noted that the customer monitors its suppliers in a way which is proportionate to the importance of the challenges involved in the contracts it has entrusted to them.

Hold points and witness points are indicated in the documented information sent by the customer or, in their absence, in the supplier's own documents and validated by the customer.

6.4.3 Information for external providers (§8.4.3 in ISO9001:2015)

The external service provider must be clearly informed that the services and/or products delivered are destined for the nuclear industry.

Whenever an AIP/ACQ or the supply of / work on an EIP/EIS/MMR-type element is subcontracted, the applicable requirements are passed onto the supplier's subcontractors concerned by the contract, regardless of their tier.

The order must unambiguously specify the AIP/ACQ nature of its service or intervention on / supply of an EIP/EIS/MMR-type element.

The supplier facilitates the work of verifying the application of this specification carried out by the customer or its representative during audits or when executing the monitoring plan or spot checks. It will transmit any documented information or data necessary to the preparation of these verifications.

The supplier provides access to the places where the activities are being performed and to the necessary documented information. It will ensure that the same is true among its sub-contractors, regardless of their tier within the limit authorized by the customer.

The supplier favors any action by the customer to assess the ability of subcontractors to apply its protection of interests, occupational safety and quality policies, to accomplish all or part of an AIP/ACQ-type activity or to provide an IIP/IIS/MMR-type element, and to contribute to the improvement of the protection of interests.

The customer must be informed without delay of any event that may affect the protection of interests, the qualification of the product or related to a CFS item/service.

6.5 PRODUCTION AND SERVICE PROVISION (§8.5 IN ISO9001:2015)

6.5.1 Control of production and service provision (§8.5.1 in ISO9001:2015)

Whenever an activity involved in product realization is identified as an AIP/ACQ, or as work on an EIP/EIS/MMR-type element, it must be subject to a systematic technical inspection, to ensure that:

- The activity is accomplished according to the defined requirements;
- The results correspond to the defined quality;
- The appropriate corrective and improvement actions are defined and implemented;
- The persons in charge of technical inspection tasks are:
    - different from the persons who accomplished the activity;
    - competent and informed of the issues related to the quality of execution of the activity;
    - present during key phases of the execution of the activity.

An organization is defined by the supplier and approved by the customer for the conduct of technical inspections on AIPs/ACQs or work on an EIP/EIS/MMR-type elements.

Technical inspections are recorded by the supplier or its subcontractors and transmitted to the customer in the tools specified by the customer or, in their absence, in the supplier’s own recording materials, but in these cases they must have been validated by the customer.

6.5.2 Identification and traceability (§8.5.2 in ISO9001:2015)

Traceability: When a supplier executes all or part of an AIP/ACQ or works on an EIP/EIS/MMR-type important element, traceability is required whenever it is a matter of elements demonstrating:

- Compliance of the product with the defined requirements,
- The competence of the personnel assigned to perform the related tasks.

If "intermediate" documented information is produced, it is kept, filed, archived and made available to the customer. Any information copied into an information system must be verified by a person other than the person who made the copy.

Specific measures may be required under the terms of the contract.

The persons having performed the activities are identified.

6.5.3 Control of changes (§8.5.6 in ISO9001:2015)

The supplier plans, implements and controls, when necessary, a process for change control and management of product configuration, data, and documented information that it transmits to the customer.

6.6 CONTROL OF NONCONFORMING OUTPUTS (§8.7 IN ISO9001:2015)

The supplier takes the necessary steps to detect and deal with any deviations in its products or activities.

Items/services detected as CFS must be treated as deviations.

The supplier informs the customer without delay of:

- Any observed failing or incident that could alter the protection of interests;
- Any change or anomaly that could compromise the product qualification;
- Any event, anomaly or observation related to a CFS item.

Any proposal for use of the product that does not comply with the specified requirements is presented to the customer or to its representative for a waiver before operations continue.

Any proposal for repairs using a process that was not previously approved by the customer is presented to the customer or its representative for a waiver.

In the specific case of deviations from defined requirements or events liable to be declared as significant events, the supplier and customer take the necessary steps to exchange the information required for analysis and processing, in accordance with ASN guide no. 21 [11.]).

Documented information relating to the nonconforming product control are kept, filed and made available to the customer.

6.7 DUTY TO ALERT IN THE EVENT OF FRAUD OR INAPPROPRIATE BEHAVIOR

If an Orano supplier or subcontractor detects a case of quality fraud or inappropriate behavior in relation to quality, it must immediately inform its Orano customer (see § 6.6).

7. CONTINUOUS IMPROVEMENT (§10.3 IN ISO9001:2015)

The supplier adopts a continuous improvement approach in terms of protection of interests which promotes the detection and handling of deviations and the collection and analysis of operating experience.

The supplier is committed to optimizing the products or services it produces for Orano, and to innovation. It makes proposals to the customer in terms of the offer or during execution for validation.

The supplier incorporates information and analytical results concerning operating experience transmitted by the customer into its continual improvement initiative as concerns the protection of interests. It disseminates them internally to persons who may benefit from them.

It also incorporates a verification of the pertinence of measures intended to prevent against CFS items.

8. CHARACTERISTICS OF THE DOCUMENT

8.1 REFERENCE DOCUMENTED INFORMATION

[1.] French Order of February 7, 2012, setting the general rules concerning basic nuclear installations

[2.] French Order of February 15, 2022 setting the general rules concerning defense-related nuclear facilities and activities

[3.] The French Order of May 26, 2014 relating to the prevention of major accidents in classified facilities mentioned in Section 9, Chapter V, Title I of Book V of the French Environmental Code

[4.] CSFN – Social specification applicable to services or construction/repairs carried out on a basic nuclear installation – July 2012

[5.] Code of Ethics and Business Conduct - Reference Orano CM ORN DIR CPL 1

[6.] The Nuclear Safety Charter - Reference Orano CM ORN HSE SUR 1

[7.] The Safety-Environment Policy - Reference Orano CM ORN HSE SUR 2

[8.] The Health - Safety - Radiation Protection policy - Reference Orano CM ORN HSE SAN 1

8.2 ASSOCIATED DOCUMENTED INFORMATION

[9.] ISO 9000: 2015 - Quality management systems – Essential principles and vocabulary

[10.] ISO 9001: 2015 - Quality management systems - Requirements

[11.] ASN Guide No. 21: Processing conformity deviations with respect to a defined requirement for an element important for protection (EIP)

[12.] ASN Guide No. 30: Policy for the management of risks and drawbacks of INB/BNIs and the integrated management system for operators

[13.] ASN brochure - Control of the design and manufacture of equipment for basic nuclear installations.

[14.] Approach for demonstration of nuclear safety – GU ORN HSE SUR 16

8.3 PURPOSE OF THE REVISION

R0	• Supersedes SP FR 3SE GEN 1
	• Application of Orano graphic guidelines
	• Rebuilding of requirements to align with ISO paragraph breakdown
	• Throughout document:
	  ○ "product" becomes "product and service"
	  ○ AIP replaced by AIP/ACQ or activity important for product quality
	  ○ EIP replaced by EIP/EIS/MMR
	  ○ Focus on product quality
	• §1 and §2: clarification of the document's purpose and scope of application
	• §3 : clarification of acronyms and definitions
	• §4 : clarification of the need for and content of the "quality document"
	• §5 : §6.2 : "order" becomes "contact"
	• §7 : introduction of suitable technical and organizational measures
	• §7.1 : adjustment of planning requirements.
	• Addition/clarification on:
	  ○ transparency (§5),
	  ○ CFS items (§7.6, §8),
	  ○ quality independence (§5),
	  ○ competence management (§6.1, §6.2),
	  ○ safety challenges (§5),
	  ○ HSE aspects (§5),
	  ○ documented information to be kept and traceability (§7.5.2),
	  ○ control of execution (§7.2.2, §7.3, §7.4.2) and nonconforming products (§7.6),
	  ○ clarification of the configuration management process (§7.1, §7.5.3),
	  ○ control of sub-contracting supply chain (§4.5, §5, §7, §7.4.1, §7.4.3).
	• Update of Orano reference documentation (§5 and §9).
	• Appendix:
	  ○ Safety culture appendix updated,
	  ○ Deletion of reference to NSQ-100,
	  ○ Addition of Appendix 2 as a cross reference matrix between PO ORN QP MS 5, PO ORN QP MS 8 and SP FR 3SE GEN 1.

R1	• §3.3 : clarification of supplier definition. • §5 : corrected link to references in §9.1. • §6.2 : correction for missing word "data". • §7.3 : clarification on design tools. • "Record" changed to "documented information", AIP changed to AIP/ACQ.
R2	• ASN requests taken into account (particularly regarding unannounced actions and the duty to alert - §6.4.2, §6.4.3 and §6.7). • Notion of activity important to product quality covered by AIP/ACQ (§5 (5.1 and 5.2) and §6 (6.4.2, 6.4.3, 6.5.1 and 6.5.2)) • Orano's suggestions for raising awareness about fraud in quality and irregularities (§5.1) • More information on the scope of application: Orano entity operating or involved in nuclear activities (§1) • Deletion of unused references (§8). • Removal of the subcontracting rank: requirement included in the CGA/GTCP (§6.4.1 of the Appendix). • Deletion of Appendix 2 - cross-reference matrix between PO ORN QP MS 5 and SP FR 3SE GEN 1 • Clarification of the concepts of awareness and skills (§5.1)

	• Integration of requirements for radioactive cleanup and dismantling services in Appendix 2
R3	• §1 : deletion of reference to PO ORN QP MS 8 • §2 : addition of the ITNS concept (iso 19443 standard) • §2.3 ; definition of protected interests that explicitly include nuclear safety • §5.2 : addition of the need to be able to unambiguously identify the persons validating the documented information • §6.4.3 : information relating to an order for the nuclear industry and concerning an EIP/AIP to be sent to the supplier • §8.2 : addition of reference [2], [3] (regulations to also cover activities and facilities under INBS/SBNI, ICPEs), [12], [13]; and deletion of the reference to the ASN letter of May 15, 2018 relating to consideration of the risk of fraud, replaced by the ASN brochure on control of the supply chain

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APPENDICES

Appendix 1 WORKING TOGETHER FOR NUCLEAR SAFETY

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Safety Culture
The Cornerstone of Nuclear Safety

Safety Culture is not something that you just declare to exist. It is something that you have to build and maintain on a daily basis. The awareness and acceptance of individual responsibilities are essential to developing this Safety Culture which is key to ensuring Nuclear Safety. This applies to everyone who plays a part in the lifetime of a facility from its design, the manufacturing of equipment, its construction and operation through to its definitive shutdown.

In what way do I play a part in nuclear safety?

- I am involved in the design and engineering, manufacturing, control, operation or maintenance of equipment that is important to the protection of interests.
- Through the activities I conduct, I ensure that nuclear safety requirements are met.
- I scrupulously comply with the documentation and applicable rules and I am aware that my actions can have consequences for Nuclear Safety.

Safety Culture

In order to adopt and develop its Safety Culture, every participant in the supply chain must:

- **Understand the risks** associated with the activity,
- **Adopt a questioning attitude** whatever its function may be,
- **Take a strict and careful approach,**
- **Raise the alert** as soon as weak signals or inappropriate behaviors occur.

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WORKING TOGETHER FOR NUCLEAR SAFETY

Practical guide for suppliers and their sub-contractors

«Safety culture is that assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance.»

SAFETY SERIES No.75-INSAG-4 (AIEA)

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Safety Culture
The Cornerstone of Nuclear Safety

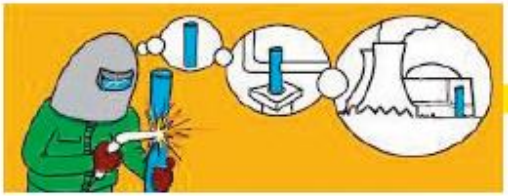
On a daily basis
I adopt a questioning attitude

I look for the right answers

The Protection of Interests includes occupational safety, nuclear safety, public health and hygiene, and the protection of nature and the environment.

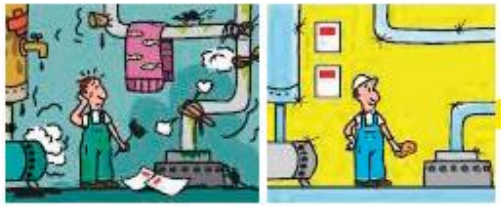
Nuclear Safety includes all measures taken at all stages in the lifetime of a facility from design, manufacturing of equipment, construction, and operation through to its definitive shutdown to ensure its safe operation and to prevent incidents and limit their effects [French Nuclear Safety Transparency Act (Loi TSN), 2006].

Does my activity (design and engineering, manufacturing, intervention, etc.) have an impact on nuclear safety?



How do I prepare for and carry out my activity?

How do I handle any difficulties related to my activity?



- I am aware of the importance and impact of my activity for the nuclear facility
- I know what the critical steps in my activity are and what the associated risks of error are
- I have received information about the applicable requirements from my management and it is clear to me what they are
- I make sure that I have passed on all the requirements that are applicable to my sub-contractors

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- I prepare for my activity by ensuring that I have the qualifications and skills, and the necessary procedures, instructions, tools at my disposal
- I ensure that the environment in which I work does not have an impact on my ability to carry out my activity
- I work according to an applicable and approved procedure, and I comply with it strictly
- The performance of my activities which are important for protection is checked by a competent and independent third party
- I know and comply with the hold points and control points
- When I provide important information to a colleague or sub-contractor, I check that it has been received correctly and that my message has been understood. Conversely, when someone provides me with important information, I make sure that I have understood it properly
- When I propose improvements, I wait for them to be validated before applying them

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- I provide information about any difficulties encountered and I obtain the instructions necessary to correct and continue my activity
- If I am interrupted when performing my activity, I pause for a moment before resuming operations to assess the impact of the interruption
- I take the time to identify and report on deviations and problems encountered when performing my activity

Appendix 2 ADDITIONAL AND SPECIFIC REQUIREMENTS FOR RADIOACTIVE CLEANUP AND DISMANTLING SERVICES

This appendix sets out specific requirements for radioactive cleanup and dismantling activities, supplementing those set out in paragraphs 3 to 7 above.
All these requirements must be met by the supplier or service provider who has been granted CAEAR acceptance.

1. CONTEXT OF THE ORGANIZATION

Requirement No. 1
The requirements of this specification are all applicable. They are specified in greater detail for activities in domains D2, D3 and D4 subject to CAEAR acceptance.

Requirement No. 2
Companies working on Domains 2 and 3 must be CEFRI / QUALIANOR or equivalent. In particular, the company:

- takes into account the rules laid down in a document such as radiation protection instructions or rules for the site(s) concerned, which is given to the company,
- presents the process(es) for defining dosimetry targets in relation to risk, and for effective dosimetry monitoring. It also specifies the organization it implements to comply with the radiation protection rules laid down,
- specifies the methodology for taking into account the criteria leading to the implementation of the ALARA approach on worksites.

Requirement No. 3
The company describes in its "quality document" the entities concerned by the CAEAR acceptance procedure.

2. SUPPORT

Requirement No. 4
The company defines and lists the skills required for its activities, and how these skills will evolve over the duration of the CAEAR acceptance (according to the attached table 1).

Requirement No. 5
The company describes the conditions and level of qualification of its staff (operating and supervisory personnel) (as per table 2 attached).

Requirement No. 6
The company describes the procedures for managing training and accreditation of its personnel in connection with process implementation.

Requirement No. 7
The company describes the steps taken to ensure the suitability of the processes used and the qualifications of its employees.

3. Operational activities

Requirement No. 8
The company lists the processes and resources it has mastered, and the associated operating procedures (as per table 2 attached).

Requirement No. 9
For each process, the company defines the operating conditions and qualifies the processes and resources used.

Requirement no. 10
The company defines its validation procedure for the processes used (pilot worksite, blank tests, endurance tests, etc.).

Requirement No. 11
The company defines the conditions for using its equipment, and the limits and constraints for its use.

Requirement No. 12
The company defines internal rules to ensure regulatory compliance of equipment used on worksites.

Requirement No. 13
The company defines the measures that will enable it to control radiological measurement and control techniques at its own level, as well as the procedures for their implementation.

Table 1 – Changes in staff numbers at sites and/or local branches involved in cleanup/dismantling operations

	Pour l'ensemble de la société (effectifs)				
	N-2	N-1	N	N+1	N+2
Effectifs	0	0	0	0	0
Embauches	0	0	0	0	0
Départs en retraite	0	0	0	0	0
Autres départs anticipés (turn-over estimé,...)	0	0	0	0	0

	Nom (+ ville et dept) de l'établissement et/ou agence				
	N-2	N-1	N	N+1	N+2
Effectifs	0	0	0	0	0
Embauches					
Départs en retraite					
Autres départs anticipés (turn-over estimé,...)					

	Pour l'ensemble de la société (effectifs)						
Effectifs	Ingénieurs Cadres	Techniciens assimilés	Employés Ouvriers qualifiés	Agents non qualifiés	Autres	Total	Activité parfois sous-traitée (Oui / Non)
Administration / Finances							
Recherche & Développement							
Bureau d'études							
Achats / Planning / Ordonnancement							
Commercial / Marketing							
Chantier							
Qualité - Sureté - Radioprotection							
Autres à préciser (Service après vente, Informatique,...)							
Total (Dernière année)							

	Nom (+ ville et dept) de l'établissement et/ou agence locale N°1						
Effectifs	Ingénieurs Cadres	Techniciens assimilés	Employés Ouvriers qualifiés	Agents non qualifiés	Autres	Total	Activité parfois sous-traitée (Oui / Non)
Administration / Finances							
Recherche & Développement							
Bureau d'études							
Achats / Planning / Ordonnancement							
Commercial / Marketing							
Chantier							
Qualité - Sureté - Radioprotection							
Autres à préciser (Service après vente, Informatique,...)							
Total (Dernière année)							

Nom (+ ville et dept) de l'établissement et/ou agence locale N°2						
Ingénieurs Cadres	Techniciens assimilés	Employés Ouvriers qualifiés	Agents non qualifiés	Autres	Total	Activité parfois sous-traitée (Oui / Non)

Table 2 – Justification of skills, technical means and resources

Compétences techniques relatives à l'assainissement radioactif et au démantèlement par domaine		D2	D3	D4	Eléments concourant à la maîtrise sous les aspects organisationnels, de compétences, de la documentation et du REX,	Pour l'ensemble de la société			Pour l'établissement et/ou agence locale N°1		
						Moyens techniques (1)	Moyens humains (nb pers.)	Niveau de compétence (2)	Moyens techniques (1)	Moyens humains (nb pers.)	Niveau de compétence (2)
Organisation de chantier	Organiser un chantier de démantèlement		X	X		xx	yy	zz			
	Concevoir/assurer/respecter la Sécurité des chantiers de démantèlement		X	X							
	Savoir analyser les risques liés aux opérations de démantèlement		X	X							
Gestion de projet	Gérer des projets qui ne remettent pas en cause la conception		X	X							
	Gérer des projets qui remettent en cause la conception			X							
Radioprotection	Détecter les rayonnements : balises, appareillages, dosimètre etc.	X	X								
	Détecter les rayonnements : réaliser des cartographies	X	X								
	Gérer les sources radioactives	X	X								
	Contrôler les sources radioactives	X	X								
	Connaissance et mise en œuvre du principe ALARA	X	X	X							
	Protection contre les expositions externes et internes :	X	X	X							
	- écrans, criticité	X	X	X							
	- enceintes de confinement cellules etc.	X	X	X							
Déchets	Aptitude à travailler sur des déchets :	X	X								
	Déchets α	X	X								
	Déchets β g	X	X								
	Concevoir le zonage déchets		X	X							
	Concevoir l'entreposage temporaire et stockage	X	X	X							
	Caractériser et classifier les déchets	X	X	X							
	Optimiser la production de déchets : concevoir la stratégie, les scenarii, la filière de recyclage des déchets radioactifs, le recyclage des matières existantes, l'évaluation et planification du démantèlement			X							
	Gérer les déchets (niveau exécution)	X	X								
	Mettre en oeuvre le traitement et le conditionnement des déchets solides	X	X								
	Mettre en oeuvre le traitement et le conditionnement des effluents radioactifs	X	X								
	Connaître les emballages, les colis	X	X	X							
	Connaître la caractérisation des déchets	X	X	X							
	Connaître les filières d'évacuation	X	X	X							
	Connaître les transports déchets solides et des effluents			X							
	Techniques maîtrisées de décontamination	X	X								
Transverse	Analyser de la sûreté (y compris la dimension FOH)		X	X							
Travaux d'assainissement et démantèlement	Assainissement par chiffonette, ou autres	X	X								
	Autres techniques (Gels, Cryo, …)		X								
	Travail par télémanipulateurs	X	X								
	Outils à distance spécifiques		X								
	Robotique : engins de chantier télécommandés, porteurs		X								
	Engins de levages de zone 4 UL - ponts de maintenance - pont perche	X	X								
	Equipements individuels d'intervention en milieu hostile		X								
	Assistance habillage deshabillage & air respirable	X	X								
	Assainissement radioactif / Réduction de volumes : intervention sous eau		X								
	Assainissement radioactif / Réduction de volumes'intervention sur béton		X								
	Assainissement radioactif / Réduction de volumes matériaux métalliques	X	X								
	Dimensionnement er et mise en place de ventilation d'intervention		X								
	Dimensionnement er et misee en place le confinement, sas rigide, souple, ignifugés démontage, repli de chantier, contrôle		X								
	Concevoir une stratégie de démantèlement intégrant l'objectif de travailau contact ou de rdv à distance - impact planning, déchets, effluents, dosimétrie…. Formalisation argumentaire de choix			X							
	Evaluation de l'impact sûreté du scenario proposé - capacité à proposer des options selon les risques probables		X	X							
Exploitation d'installation et intervention	Maintenance 1er niveau	X									
	Contrôle périodique installation dédiée,	X									
	Maitrise du référentiel sûreté	X	X	X							
	Connaissance CMN / Protection physique	X	X	X							
	Gestion des produits chimiques	X	X								
	Gestion des consommables	X	X								
	Surveillance des fonctions de sûreté (ventilation, CRP, confinement, ..)	X	X								

(1) : Préciser les moyens disponibles déjà utilsés en situation, les moyens projetés, les codes de calcul,…

(2) : Niveaux de compétence: 0: Aucune S: Sous-traité D: Débutants E: Expérience M: Maîtrisé R: Etudes & Recherches

Appendix 3 Ethics & Compliance flyer

6 FIGHTING QUALITY FRAUD, IRREGULARITIES, AND DOCUMENT FALSIFICATION

Our rules

Quality-related fraud involves manipulating a situation to make out that a product or service complies with quality requirements when it actually does not.

Orano constantly endeavours to **deliver quality products and services**.

To this end, the Group ensures compliance with all current legal, regulatory and contractual requirements, as well as international best practices, and to meet its customer expectations regarding **the quality of its products and services**.

Furthermore, Orano requires that the behaviour of individuals, as well as activities carried out on its sites, are **compliant with the Group's rules of conduct and policies regarding quality. This vigilance applies to all levels of its production and supply chains**.

Compliance with these requirements is an essential criterion in the selection of our suppliers and partners.

As such, every person involved must **demonstrate vigilance and report** any misconduct, deviation, fraud or situation that is contrary to these requirements **to their manager**.

The alert must be raised at the first sign of any hint of fraud, defective products, actual or potential deviation to Group rules and policies, standards difficult to apply, or unattainable objectives, or objectives that may be reached to the detriment of quality.

Key message

The quality of our products and services is a key success factor for the Group, which will not tolerate any compromise when it comes to quality.

The Group strongly fights irregularity and quality fraud, whether these are committed internally or by suppliers and subcontractors.

Failure to report an observed case of fraud equates to aiding and abetting!

High-risk situations

There are several conditions that may motivate an individual or organisation to commit fraud.

Pressure is clearly identified as one condition that may cause an irregularity to occur (tight schedules, technical or industrial difficulties, financial constraints, etc.).

The second risk factor is the extent to which a given management system or organisation allows opportunities for irregularity (lack of controls, instructions that can be interpreted in various ways, etc.).

Below are some examples of situations that are conducive to irregularity, quality fraud or document falsification:

- **wanting to finish a task at any cost** despite an unrealistic deadline,
- **having technical difficulties** to obtain expected results,
- **thinking a simple conversation with an expert can validate a deviation from the rules,**
- **not being aware of the impact of one's activity** on nuclear safety and product quality,
- **not removing equipment that is non-calibrated or unsuitable for its intended use,**
- **carrying out a task without being sure of one's qualification** or authorisation to do so,
- **not planning for the absence of qualified and competent staff** in a particular position.

Ask questions!

As part of your work or responsibilities, situations of irregularity, quality fraud or document falsification may appear. Do not hesitate to ask yourself a few simple questions:

Do I have the skills and qualifications required to do this?

Do I have the means to complete my task (materials, instructions, time, tools, etc.)?

Am I aware of the impact of the quality of my work on nuclear safety and product quality?

Has the work or product been adequately verified in-house?

For further training on preventing quality-related fraud: **quality-related fraud e-learning module** (Catalogue of Orano training modules).

What to do if...

The concrete examples provided below may help you to better identify high-risk situations and the right behaviour to adopt. However, as this list cannot cover every eventuality, situations involving irregularities, document falsification or quality-related fraud will need to be solved on a case-by-case basis.

Q: What should I do if my superior insists that I do something I feel is not compliant with requirements?

A: You must report it to your superior's manager or use one of the reporting channels available (quality network, Group Quality Department, Group whistleblowing platform).

Q: I am going to ask my on-site colleagues, who are carrying out the operation, to validate my inspection and sign the document. Is that acceptable?

A: No. You must physically check the proper completion of an activity on-site before you can validate and sign my inspection. By signing this document, you are attesting to its content and becoming liable for it.

Q: Can someone sign off my name on a record if I did not carry out or witness the operation or verify its completion?

A: No. This is not an option. Records must reflect operational reality and incur the liability of the persons mentioned.

Q: I need to make a "minor change" in a deliverable that has already been sent. Whom should I inform? Must I tell everyone?

A: Yes. When they cannot be avoided, any corrections (even handwritten) must be legible and understandable; they must bear the date of the correction, the name of the author and their signature. All amendments must follow the same validation process as the original information. All users must be informed of all amendments.

Q: Can I round off measurements to remain within tolerance limits?

A: No. This is not an option. Information that is written down must be representative of actual measurements. Accepting a value outside the tolerance range must be covered in a documented waiver.

Q: I would need to make compromises or skip steps in the process in order to meet deadlines. What should I do?

A: You must comply with requirements and carry out all steps of the process. Should you have a problem meeting planned or required deadlines, you must speak to your superior to warn them and to find appropriate solutions that comply with the Group's rules of conduct and applicable processes.

Find out more

Timely reporting of any undesirable or suspect event may help prevent irreversible damage and consequences.

In the event of an irregularity, of fraud, or if you suspect quality-related fraud, you must immediately notify your line manager. If the situation requires you to report it to a neutral, independent third party, please notify your organisation's Quality representative or the Group Quality Department.