PRACTICAL GUIDE

How to guarantee the quality of equipment intended for nuclear installations?

Guide to design and manufacturing requirements intended for equipment suppliers and their subcontractors.

asn
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At a time of considerable activity in the nuclear sector, controlling the supply chain is a particularly important challenge for the safety of the nuclear installations in service, as well as those being planned.

Licensees, suppliers and subcontractors: the quality of safety-important equipment in the nuclear installations concerns everyone and is everyone's responsibility.

Discussions with representatives from the nuclear sector show the need for better dissemination of the requirements concerning safety-important equipment and enhanced traceability of the manufacturing activities, notably to reduce the risk of fraud.

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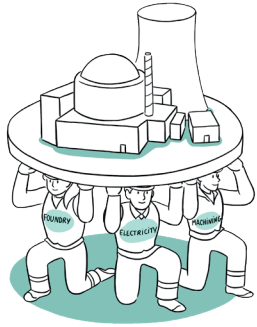


With this guide, ASN intends to improve the accessibility of the regulatory objectives and requirements concerning the design and manufacture of equipment intended for nuclear installations.

It explains the foundations of a robust supply chain and gives recommendations and good practices. They are illustrated by industrial examples, with a resolutely practical approach.

We would like to thank the hundred or so companies who contributed their responses to the on-line survey and their input during exploratory meetings about your needs and your concerns.

These valuable contributions were directly input into the "Your questions, our answers" part of each topic.

We would also like to thank the Gifen, the professional trades union of the French nuclear industry, for its support for this initiative.

Please don't hesitate to distribute the guide widely around you!

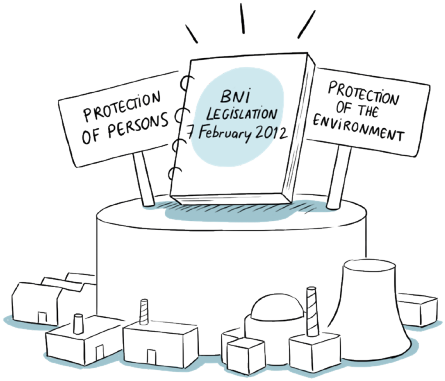
We hope you enjoy reading it.

REQUIREMENTS APPLICABLE TO NUCLEAR SUPPLIERS

Several requirements are **applicable to the nuclear licensees' supply chain**, that is all the suppliers of equipment and their subcontractors[1]. These requirements may come from legislation, in particular from the Environment Code, from regulations (Decrees and Orders), from rules of good practice (in particular as set out in standards or construction codes), or from contracts.

When an equipment item is identified as an "element important for the protection of interests" (EIP, see page 6), **the regulatory provisions of the Basic Nuclear Installations legislation of February 7th 2012 apply**. The licensee of the nuclear installation is responsible for applying this Order and must ensure that all of its suppliers also comply with it.

This practical guide details the main provisions stipulated in this legislation and gives examples of good practices for the supply of EIP.



What is the protection of interests?

The notion of the protection of interests is contained in the Environment Code. It is used to designate the objective of the legislation and the regulations: **protect people and the environment**.

Protected interests are specifically **public security (including nuclear safety), public health and safety, as well as the protection of nature and the environment.**

1. In this document, the terms suppliers and subcontractors are used in the broad sense to refer to legal or natural persons carrying out design and manufacturing operations.

Legislation of 7 February 2012

setting the general rules concerning Basic Nuclear Installations

The Basic Nuclear Installations legislation sets the general rules applicable to nuclear installations. It covers the design, construction, operation, final shutdown, decommissioning, maintenance and surveillance of nuclear installations.

The provisions applicable to the supply of EIP are contained in title II of this legislation, entitled "Organisation and responsibility".

This title in particular contains provisions concerning:

- **The monitoring of outside contractors and subcontracted activities** (*Chapter II: Articles 2.2.1 to 2.2.4*);
- **Policy in terms of protection of interests** (*chapter III: Articles 2.3.1 to 2.3.3*);
- **The integrated management system** (*Chapter IV: Articles 2.4.1 and 2.4.2*);
- **Items and activities important for the protection of interests** (*Chapter V: Articles 2.5.1 to 2.5.7*);
- **Management of deviations** (*Chapter VI: Articles 2.6.1 to 2.6.5*);
- **Continuous improvement** (*Chapter VII: Articles 2.7.1 to 2.7.3*).

Nuclear pressure equipment

The requirements of the Basic Nuclear Installations legislation apply to the design and manufacture of Nuclear Pressure Equipment (NPE).

Specific provisions also apply to the design and manufacture of NPE owing to the particular risks they represent for human safety and for the safety of the nuclear installations.
These provisions are binding on the licensee, but also on the equipment manufacturer. They are contained in the Nuclear Pressure Equipment legislation of 30 December 2015 concerning NPE and certain safety accessories designed to protect said equipment.

On-site transport of dangerous goods

On-site transport operations for dangerous good are those performed on the private roads of a nuclear installation.

The transport packagings used perform several safety functions, notably the confinement of the content and the prevention of criticality (nuclear chain reaction). **The Basic Nuclear Installations legislation therefore also applies to the supply of packagings for the on-site transport of dangerous goods.**

Off-site transports (outside the perimeter of the nuclear installation) are covered by specific regulations.

EIP

Element important for the protection of interests and specified requirements

The "Elements Important for the Protection of interests" (EIP) carry out or monitor a safety function in a nuclear installation. This can be a structure, an equipment item, a system (whether or not programmed), hardware, a component or software contributing to the protection of people or the environment.

The Basic Nuclear Installations legislation requires that the licensee identify the EIPs in its installation, based on its safety case, along with their associated requirements.

These requirements are referred to as "specified requirements". Compliance with them guarantees the EIP's ability to perform the function allocated to it.

The specified requirements for an EIP can be the thickness of a pipe, the closure time of a valve, the flowrate of a pump, etc.

The EIP are valves, sensors, motors, pressure equipment, etc.

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A pump important for the safety of a nuclear installation is classified as EIP. Its defined requirement can be the flowrate which guarantees its water make-up function.

AIP

Activities important for the protection of interests and specified requirements

The design and manufacturing activities for EIPs, which can affect their required characteristics, must be identified as “Activities Important of the Protection of interests” (AIP).

The AIP must also have their associated specified requirements.

The specified requirements of an AIP can for example be a dimension during machining, a tightening torque during assembly, a parameter during welding, or calling in an inspector holding COFREND certification.

The AIP are design, machining, welding, assembly, etc. activities

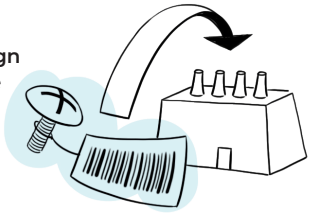
© KSB

The installation of this valve can have consequences for the NPP cooling function. The manufacturer must have full control over this AIP in order to comply with the defined closure time requirement.

The foundations of

You are the supplier of some or all of the equipment which plays an essential role in preventing, detecting or mitigating the consequences of an accident in a nuclear facility? As soon as the licensee informs you of its "important for the protection of interests" (EIP) classification, you are obliged to guarantee compliance with the particular requirements defined for this equipment.

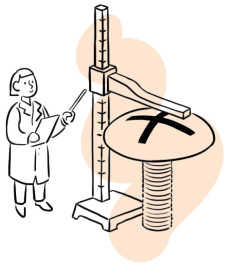
1. Activities Important for the Protection of interests (AIP) and technical inspections



The supplier specifies which AIPs are needed for the design and manufacture of this equipment. Technical controls are associated with these AIPs to ensure that these activities comply with the specified requirements associated with them. **The AIPs are subject to specific traceability**, notably allowing subsequent verification of compliance with the specified requirements.

• *See page 10*

2. Deviations during the design or manufacture of an equipment item

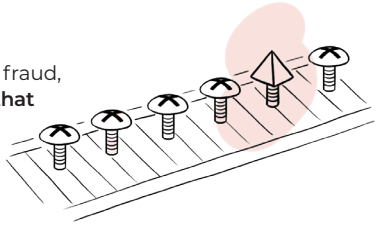


The supplier takes steps to detect deviations concerning the AIPs performance and the EIPs manufactured. These deviations must be recorded and the licensee must be notified accordingly as soon as possible. **The processing of deviations implies the performance of preventive, corrective and remedial actions.**
It is the subject of traceability measures.

• *See page 15*

3. Combatting the risk of fraud

The supplier plays a key role in preventing the risk of fraud, both internally and at its subcontractors. **It ensures that its personnel are aware of this risk,** guarantees the integrity of data and reports any cases detected.



• *See page 18*

a robust supply chain

4. Transfer of requirements to the subcontractors

When a supplier outsources activities, it ensures that its subcontractor has the required expertise and is familiar with and complies with the **requirement applicable to these activities. It in particular sends** its subcontractor **the specified requirements associated with the AIPs** covered by the sub-contract.

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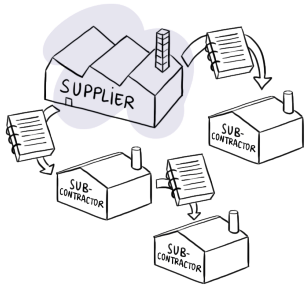

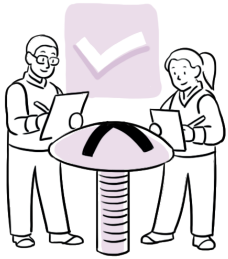

5. Qualification of Elements Important for the Protection (EIP)

The EIPs are qualified in order to guarantee their ability to perform the safety functions assigned to them. **Any modification to the design or a method of manufacturing of an EIP requires a demonstration that its qualification is not compromised.**

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6. Continuous improvement and internal audits

The supplier implements a quality management system which, by means of inspections, checks and internal audits, **ensures the correct working of the design and manufacturing processes and enables them to be improved.**

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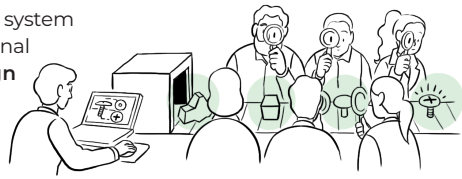

7. Training of personnel and raising awareness of the safety culture

Performance of an AIP and its technical control must be entrusted to trained personnel made aware of the **safety culture**. The supplier and its subcontractors therefore make provision for a theory and practical training plan in order to encourage a **questioning attitude giving priority to safety.**

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1. Activities Important for the Protection of interests (AIP) and technical controls

Some design or manufacturing activities are particularly sensitive, because they can affect the expected characteristics of an EIP.
It is your responsibility to identify these activities as AIPs, ensure their traceability and perform appropriate checks and controls.

Activities important for the protection of interests (AIP)

Design and manufacturing activities for which a failure can affect the characteristics of the EIP.

Technical control

The technical control is performed by someone other than the person who performed the activity and ensures that the activity was carried out in accordance with its specified requirements.
In principle it is more than just a simple second level documentary verification.

4 STEPS

TO GUARANTEE THE HIGH LEVEL OF QUALITY OF AN EIP

The licensee of a nuclear installation entrusts its supplier with the design and manufacture of a component classified as EIP, in other words essential for the safety of its facility or for protection of the environment. The licensee sends them the specified requirements for this EIP, for example the technical characteristics required when it is operating (Article 2.5.1 of the Basic Nuclear Installations legislation). The licensee ensures that it is possible to manufacture the EIP, which means that the supplier is technically capable of meeting the specified requirements with its production tool, within the required time.

1 Definition of requirements and manufacturing criteria

The specified requirements for the EIP are transcribed into manufacturing requirements and criteria (second paragraph of Article 2.5.2 of the Basic Nuclear Installations legislation).

2 Identification of AIPs (internal and subcontracted)

Knowledge of the manufacturing processes enables the supplier to specify and supplement the list of design and manufacturing activities identified by the licensee as AIPs. **The subcontracted activities must also comply with the specified requirements assigned to them.** They must be identified and the licensee must be informed accordingly. **The risk analysis is a good practice for identifying the AIPs and the associated technical controls.**

3 Technical control during manufacturing

When carrying out AIPs, a systematic **technical control** ensures that the activity has been correctly performed with respect to the risks identified (Article 2.5.3 of the Basic Nuclear Installations legislation).

The subcontracted activities are also subject to technical controls.

4 Surveillance of all AIPs

The licensee carries out **surveillance of all the AIPs** performed by the suppliers, irrespective of the level of subcontracting (Article 2.2.2 of the Basic Nuclear Installations legislation). The surveillance programme is defined according to the importance of the AIP and may take account of the oversight performed by the supplier. The surveillance performed by the licensee never prevents nor replaces the oversight provided by the supplier of its subcontractors, under the terms of the contracts placed with them (see Chapter 4).

INDUSTRIAL APPLICATION

The design, forming, heat treatment, assembly, installation, machining, welding, coating **activities** must, for example, be identified as AIPs **if they can affect the required characteristics of the EIP.**

The **technical controls** ensure that the **techniques have been correctly implemented and the specified requirements complied with** during performance of the AIPs.
This may, for example, be Non-Destructive Testing (NDT), an operating test, a cross-check, a manufacturing completion test, the presence of a second operator during the activity, and so on. **The technical control must not simply be a second level documentary check.**

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◀ Casting activity in a foundry is considered to be an AIP if it determines the strength of the parts of safety-important components in the nuclear installation (EIP).

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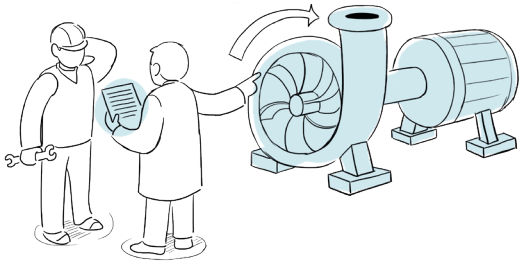
◀ If the properties of a part require pouring molten metal at 1,680°C, the technical control can consist in measuring the temperature of the crucible using a probe, as is being done here at Arcelor Mittal.

Example 1

A supplier assembles a rotor and installs it on the pump concerned.

The risk analyses identify a risk on the installation of the rotor vanes. If installed the wrong way round, the pump could fail to comply with the flowrate requirement assigned to it in order to perform its safety function in the nuclear installation.



This assembly activity must thus be classified as AIP, given its implications for the EIP. It undergoes technical controls to check the direction of installation (visual check on installation, pump tests, etc.).

Example 2

The risk analyses identify the risk of an error in tightening of the cable terminals when assembling the electrical cabinets. This could lead to malfunction of the systems protecting the nuclear installation.

This terminals cabling operation must thus be classified AIP. The technical controls, such as that on terminal tightening, ensure that the AIP is performed in accordance with the specified requirements assigned to it.

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YOUR QUESTIONS, OUR ANSWERS

When a supplier subcontracts the performance of an AIP, who is responsible for carrying out the technical controls?

All AIPs, whether or not subcontracted, must undergo technical control. If the AIP is performed by a subcontractor, the technical control can be performed by the subcontractor itself (but by a person other than the person who performed the activity) or by an outside entity.
In any case, the purpose of the technical controls must be the same: to ensure that the activity was performed in accordance with the specified requirements.

What is the link between AIP, EIP and ITNS (products or services important to nuclear safety)?

The notion of ITNS, as defined by standard ISO 19443, encompasses certain important activities (AIP) and certain important equipment (EIP).

However, the notions of EIP and AIP are not limited to nuclear safety. They also concern the impact on protection of the environment (for example, the measurement of discharges into the environment linked to the normal operation of the nuclear installation). In the factory, the notions of AIP and ITNS are similar, because they both concern manufacturing activities.

Has ASN drawn up a generic list of AIPs?

No. ASN does not produce a list of AIPs, because each manufacturing process is specific.

How to identify AIPs?

The equipment can be broken down into components in order to use **a risk analysis** to identify the AIPs associated with them.

Who identifies the AIPs?

In general, **the licensee confirms the AIPs identified or specified by the supplier**, which has a more detailed knowledge of the activities involving a risk and their impact on the corresponding equipment.

Are there any AIPs in the design of EIPs?

Yes. For example, the justification of the correct design and sizing of the EIP, the definition of the maintenance operations needed during its operation or the drafting of a technical specification are liable to be classified as AIPs.

2. Deviations during the design or manufacture of an equipment item

The deviations encountered during the equipment design or manufacturing process may influence its ability to perform its safety function.
You must be able to detect them, process them and trace them. All the personnel must be able to rapidly report any malfunction.

Deviation

A deviation refers to non-compliance with a specified requirement for the manufacture of an EIP or for an AIP. It is liable to affect the required characteristics of the future EIP component and must therefore systematically be analysed and dealt with.

INDUSTRIAL APPLICATION

The suppliers must take steps to **detect the deviations concerning the AIP** they are performing and the EIP components they are supplying. If a deviation is detected, they are required to notify the contract-holder, and the **licensee** (article 2.6.1 of the Basic Nuclear Installations legislation).

The processing of deviations relies on preventive, corrective and remedial measures:

- **preventive measures** act on the **cause of a potential deviation** (training action, etc.);
- **corrective measures** act on the **cause of a detected deviation** (modification of a procedure, organisational changes, etc.);
- **remedial measures** aim to **eliminate the deviation** (repair, scrapping of affected equipment, etc.).

All deviations must be recorded: this traceability makes it possible to demonstrate that the activities are performed in accordance with their requirements and that the equipment will be able to fulfil its function when so required.

Example 3

A supplier detects that several parts do not comply with their dimensional requirements. As their manufacturing is classified AIP, this deviation requires in-depth processing. The supplier examines the scope of the issue (list of parts concerned) and analyses the causes, following which it will modify the machining procedure (**corrective action**) and repair the parts already manufactured (**remedial action**).

If personnel training is implemented so that the deviation does not occur on a similar equipment item, this is then a **preventive action**.

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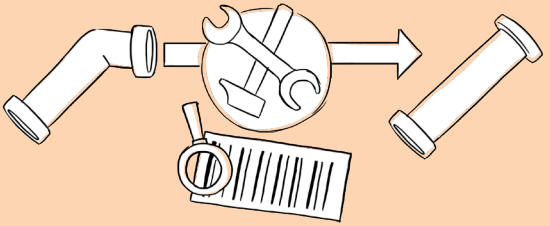
▲ Dimensional checks, here on a pipe, can detect any deviations and process them.

YOUR QUESTIONS, OUR ANSWERS



Is the traceability of component repairs required?

Yes. If the repair is the result of processing a deviation affecting an AIP or an EIP, the regulations require it to be traced. This allows retrospective verification that the conditions under which the repair was carried out do not compromise compliance with the specified requirements for this EIP.

Is traceability required for nonconformities detected on equipment not intended for nuclear installations?

In the usual standards, a nonconformity is non-compliance with the design or manufacturing requirements of an equipment item. Under the concept of continuous improvement, it is a **good practice** to identify and process any nonconformities detected during the course of activities similar to AIPs, even if they do not concern equipment intended for nuclear facilities, as a means of improving manufacturing quality.

Must the licensee of the nuclear facility be informed of deviations on the AIPs and the EIP components?

Yes. The licensee must receive this information, along with the corrective and remedial actions taken, in order to justify the equipment's ability to fulfil its functions once in service.

Does the licensee need to be informed of any scrapped parts?

Yes. Scrapping operations related to AIPs are traceable and the licensee must be so informed. A high scrapping rate may be indicative of an anomaly during a manufacturing AIP.

3. Combatting the risk of fraud

Fraudulent practices, such as counterfeit or falsification, are regularly detected in the nuclear industry: alteration of values or certificates, non-performance of activities, forged signatures, counterfeit components, etc.
You have a crucial role to play in preventing and detecting them.

Falsification

A falsification is the result of a modification, alteration or intentional omission of certain information or data, invalidating their authenticity.

Counterfeit

"Counterfeits are products that are intentionally manufactured, refurbished or altered to imitate original products, without authorization, in order to pass them off as genuine."

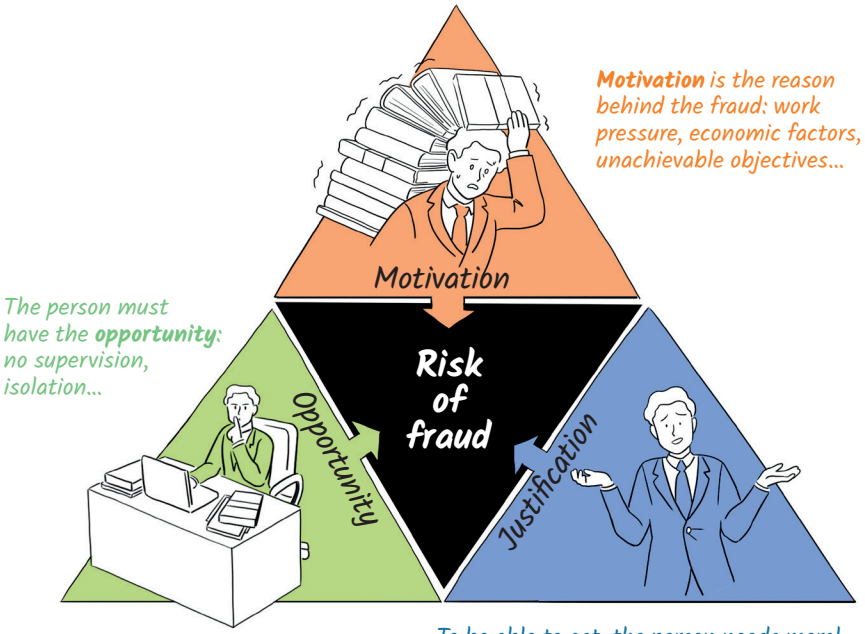
Definition by the International Atomic Energy Agency (IAEA)

Fraud

The fact that it is intentional is what makes fraud different from error.
It is punishable by law.

The fraud origins triangle

Fraud is the result of a combination of motivation, moral justification and opportunity. To prevent it, the company must be watchful of these **3 risk factors:**



***Motivation** is the reason behind the fraud: work pressure, economic factors, unachievable objectives...*

*The person must have the **opportunity**: no supervision, isolation...*

*To be able to act, the person needs moral **justification** to relieve them of personal responsibility: missed promotion, action considered to be of no consequence...*

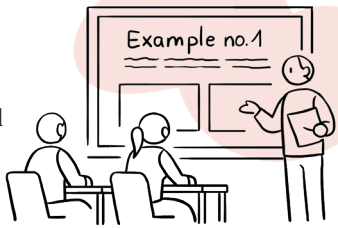
Neither the robustness of the surveillance and monitoring of the supply chain, nor the high level of quality demanded in the nuclear industry have been able to completely rule out the risk of fraud.

Weak signals can be the warning signs of a risk of fraud in a company, such as financial difficulties, severe scheduling pressure, original data not retained, deletion of source values, use of white-out, deletions without traceability, rounded off values in a certificate with no justification, or copied signatures.

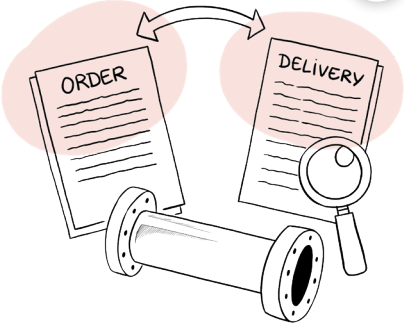
INDUSTRIAL APPLICATION

1 Raising personnel awareness

Training courses to deal with the risk of fraud are an effective means of preventing it. They should concern all AIPs and be tailored to each discipline. It is recommended that they be illustrated by means of examples observed in the industry.



2 Checking the procurement of components



The procurement of components must include specific provisions to prevent and detect fraud.

The implementation of independent checks at reception of components is a particularly effective means of preventing and detecting fraud that occurred during the manufacturing process. These may be joint inspections, destructive or non-destructive tests, or documentary cross-checks (recovery of the original of a document and comparing it with that supplied with the component procured).

3 Ensuring data traceability

Proof of compliance with the manufacturing requirements is generally based on written documents. This means that the **availability and traceability of the data must be guaranteed at all times**, for an appropriate duration. The licensee, supplier and its subcontractors must in particular **secure important source data** as soon as they are issued and **ensure the IT traceability** of any data deletion or modification.

The approach is graded: not all data have the same importance; a risk analysis on data integrity identifies those which have an influence on the specified requirements.

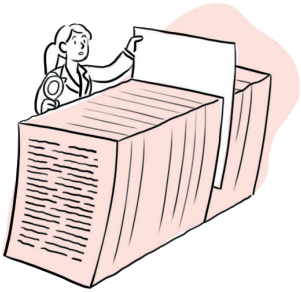
For the important data, ASN considers that the integrity of the data in the corresponding documents and recordings must be ensured in a manner appropriate to their characteristics, for example by using the "ALCOA+" method derived from international best practices

ALCOA+ characteristic	Requirement
Attribuable	The person/system originating the recording or the modifications made can be identified, along with the moment at which this was done.
Legible	The legibility of the recordings is guaranteed for the entire duration of the required conservation period.
Contemporaneous	The data are recorded at the moment of performance of the operations: these are the raw data.
Original	The information remains available in the state in which it was input the first time, whether recorded on paper (conservation, digitisation) or electronically.
Accurate	The accuracy of the data recording is guaranteed by a robust quality management system.
Complete	A recording must be complete, with no loss of information. The required level of detail depends on the criticality of this information.
Consistent	The information is created, processed and stored in a logical and consistent manner. This can comprise rules concerning chronological archival, measurement units, rounding up, number of significant decimal places, etc.
Durable	The recordings are conserved in a way ensuring that they remain intact for the duration of the required period.
Available	The recordings remain available at all times for the duration of the required conservation period.

4 Archival of documents and recordings

The traceability of manufacturing activities involves long-term access to the internal reports, recordings and documents. The quality management system defines the **archival procedures** and the conservation duration, in conformity with the regulatory obligations.

Throughout the duration of their conservation, the archives remain **legible, complete, identifiable, accessible and protected**, against the risks of both destruction (fire, flooding, ageing, etc.) and falsification. The conditions for the consultation of the archives guarantee that these principles are maintained.



5 Collect and process whistleblower reports

The obligation of vigilance with regard to the risks of corruption is enshrined in France's Act 2016-1691[2]. It requires that companies with at least 50 employees shall have a means of collecting reports outside the frameworks defined by the traditional working procedures, notably by anonymous means.

A report can be submitted by a whistleblower.

Submitting a whistleblower report on *french-nuclear-safety.fr*

You are aware of irregularities in the manufacture of equipment intended for nuclear installations?

ASN has competence to collect and process whistleblower reports regarding nuclear safety and radiation protection in nuclear activities.

Examples of irregularities that could be reported anonymously are the falsification of documents or measurement results, as well as practices not conforming to the rules of good practice.

2. Act 2016-1691 of 9 December 201 on transparency, the fight against corruption and the modernisation of economic life.

How to detect falsifications or counterfeiting?

Examples taken from real cases

Example 4

A steel supplier carries out chemical and mechanical tests as part of the technical controls of its heat of steel AIP. However, it admitted to entering false data in the material certificates when the values are below the required thresholds. These falsifications were **detected by a cross-check performed at acceptance** by an outside laboratory.

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Example 5

A technical inspection of the AIP for the assembly of a pump at the supplier's factory consists of a mechanical test of the pump with vibration tests.

When there was a test machine shutdown, it was impossible to carry out the vibration checks.

The party concerned admitted that it had simply copied the results of the previous readings taken. This falsification was **detected during internal verifications.**

Example 6

When components were ordered, a manufacturer decided to have a **cross-check inspection run by the laboratory** that issued the material certificates transmitted by its subcontractor.

It found differences in the two reports transmitted between its own inspection and the original certificate. The components were set aside and all the certificates were re-checked. More than a hundred to so certificates were finally found to be non-conforming.

Example 7

During a check on the qualifications of the welders hired by a subcontractor, a supplier verifies the certificates. **When they contacted the certification organisation**, they found that the organisation had not actually issued them and that those presented were falsifications.

YOUR QUESTIONS, OUR ANSWERS

Must the possibility of being able to submit a whistleblower report on *asn.fr* be made public?

Yes. ASN has set up a process for collecting whistleblower reports on its website. All the company personnel and the subcontractor's personnel must be informed of this possibility, in addition to the companies' own internal whistleblower reporting systems. This information can notably be displayed in the areas used by the personnel.

How to react if fraud is detected?

The management must not tolerate fraud. Particular attention must be paid to listening to the staff and any feedback mentioning a potential or actual case must be given appropriate treatment: it must be dealt with and the **member of staff who submitted the report must be protected.**

Is there a list of companies known to have been guilty of falsification or counterfeiting?

No. There is no public list of companies who have carried out falsification or counterfeiting.
It is up to each supplier to ensure that its subcontractors meet the requirements associated with AIPs.

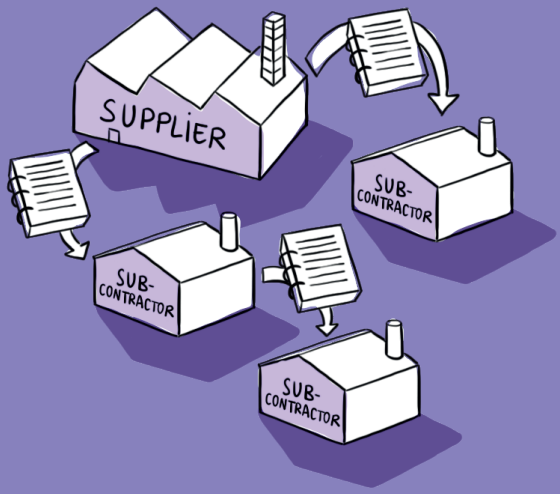
Are there weak signals indicative of a risk of fraud?

A significant variation in delivery times, a significant drop in the number of nonconformities recorded, or the rapid issue of certificates can be **weak signals indicative of fraud.**

What constitutes important data?

Not all data have the same importance in terms of safety. The analysis of the potential consequences of a loss of data integrity enables a graded approach to be adopted, proportionate to the issues, with adaptation of the measures taken to avoid it.
Important data can concern the results of an inspection, chemical measurements, manufacturing completion tests, etc.

4. Transfer of requirements to the subcontractors



If an AIP is outsourced, your subcontractor must be aware of the importance of the activity for the safety of the nuclear installation and protection of the environment.
It is up to you to determine and send it the associated requirements, ensuring that you limit them to what is relevant for performance of the activity.
You are responsible for checking these aspects.

Subcontracting

Operation whereby – under its own responsibility – the supplier entrusts performance of all or part of the contract concluded with the licensee to another party.

INDUSTRIAL APPLICATION

Check on ability to comply with requirements when performing AIPs

The supplier must ensure that its subcontractor complies with the contractual and regulatory requirements and that it is capable of manufacturing the components for which it is responsible. The controls concern all levels of the supply chain. They must be proportionate to the safety risks.

Depending on the activity and the possibility of performing controls either remotely or on the manufacturing site, the supplier chooses justified and appropriate methods, in particular:

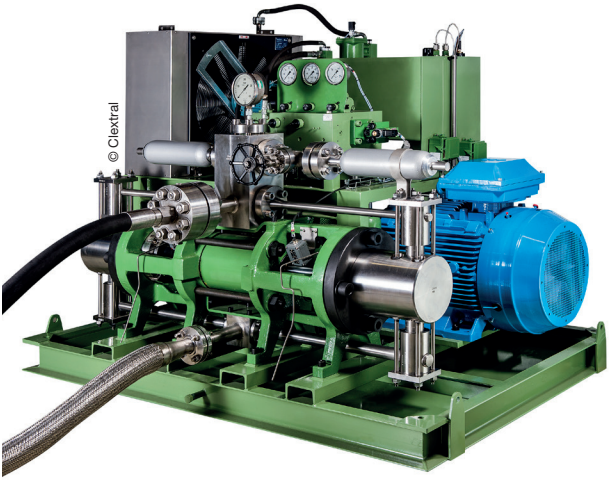
- **documentary audits** of the quality system;
- **factory controls**, whether scheduled or unannounced, to check the performance of the AIPs and the associated technical controls;
- **cross-checks** on acceptance of the manufactured components to ensure compliance with the requirements.

A combination of these methods can be used, and this is in fact recommended.

Monitoring of AIPs subcontracted by the licensee

The licensee of a nuclear installation is responsible for transmitting the specified requirements to all subcontracting levels. **It performs surveillance of all levels of AIP subcontracting**. It defines its surveillance programme according to the importance of the AIP and takes account of the checks already carried out by the suppliers and subcontractors. The surveillance provided by the licensee neither prevents nor replaces the supplier's oversight actions with regard to its subcontractors.

The licensee keeps an up-to-date list of the subcontractors. The suppliers are required to send it the list of their subcontractors performing AIPs.



◀ The tier 1 supplier for this SIS safety injection pump assembles parts supplied by more than 25 subcontractors. It must ensure that each one complies with the specified requirements for this EIP.

YOUR QUESTIONS, OUR ANSWERS

Must a high-tier subcontractor also comply with the requirements associated with an AIP?

Yes. When an AIP is identified at a subcontractor, it must comply with the associated requirements, whatever the subcontractor tier. The contract-holder makes sure to transmit the applicable requirements, but restricted only to what is pertinent, so that its subcontractor can be fully aware of the implications of this activity.

Is ore mining an AIP for the production of a metal component?

No. The production of the ingot in the foundry, associated with the chemical analyses, is generally considered to be the first AIP. The risk analysis of the heat of steel generally concludes that the conformity of the ingot is guaranteed by chemical analyses, independently of the quality of the ore used.

How to ensure that a subcontractor is competent to perform its AIPs?

The oversight actions can include site audits, hold points, joint checks, etc. **The method must be able to justify that both the AIP and the technical controls are correctly performed**.

Must all AIPs be checked in the same way?

No. Oversight is proportionate to the issues. The activities and operations with high stakes, or which are complex, must be the subject of oversight that is tailored to their performance.

How to choose the method to be used to check that an AIP complies with the specified requirements?

When the activity is liable to be subject to a dimensional check, it can undergo a joint check at acceptance of the components. On the other hand, **an activity requiring correct performance of a test or other control must be the subject of *in situ* surveillance.**

Must the feasibility of an activity within the contractual deadlines be checked when an AIP is subcontracted?

Yes. Quality will be as expected when a subcontracted activity is feasible, in terms of technical and human capabilities. **Stipulating deadlines that are manifestly too short**, or a level of requirement that it is not technically capable of achieving with its normal production level, is a significant factor in pressure on the subcontractor and **can lead to a situation conducive to fraud** (see Chapter 3).

5. Qualification of Elements Important for the Protection (EIP)

You are changing the manufacturing process or the subcontractor. These AIP modifications are not without their importance. They require that the initial qualification of the EIP is not compromised.

Qualification of an EIP

Studies, tests or calculations which establish the EIP's ability to perform its function in the conditions in which it is to be placed (temperature, pressure, humidity, radiological environment, vibrations, etc.).

INDUSTRIAL APPLICATION

Maintaining equipment qualification

The requirement for qualification of EIPs is crucial for the safety case of a nuclear facility. The design and manufacturing AIPs which could affect the characteristics of the EIP, and the changes made to these activities **must be analysed in order to check that they do not compromise the qualification and operation of the EIP**.

Spare parts and risk of obsolescence

Guaranteeing the correct operation of an EIP implies being able to maintain it over time. **The procurement of sufficient quantities of spare parts contributes to safety.** A spare part from a different manufacturer may call into question the qualification of the EIP, this situation must thus be analysed.

Example 8

Owing to bankruptcy, a supplier changes subcontractors to procure components used for an AIP activity. This change to the AIP manufacturing process must be analysed and traced, because it can change the required characteristics of the equipment manufactured.

Integration of experience feedback

Experience feedback is a means of **collecting information making it possible to prevent possible malfunctions and improve the processes**.
This is an essential approach for nuclear safety, which has tangible results: implementation of preventive, corrective or remedial actions, sharing of good practices.

YOUR QUESTIONS, OUR ANSWERS

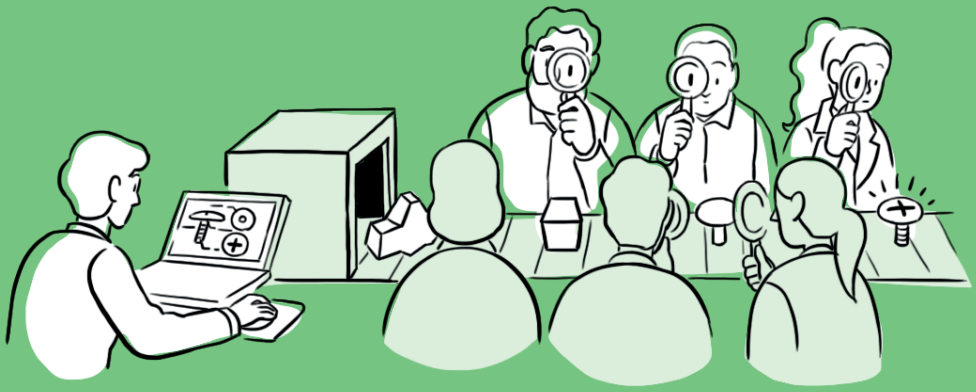
If an analysis concludes that the initial qualification is compromised, should the licensee be informed?

Yes. If an analysis calls into question the initial qualification of the manufactured equipment, the licensee must be informed in order to check that the equipment will be able to perform its function. It may be necessary to adapt the conditions of use of the equipment or run additional tests.

Is traceability required for the analysis of the modifications made to the design or to the manufacturing process?

Yes. The modifications made to the design or to the manufacturing process must be traced. A good practice is to use “modification data sheets” containing an assessment of impact in relation to the initial qualification.

6. Continuous improvement and internal audits



As a supplier, you take part in continuous improvement of the safety of nuclear installations through your process evaluation, internal audit or quality control actions.

Continuous improvement actions

The process evaluation, internal audit and quality control actions look at the correct working of the quality approach.
They should not be confused with technical controls (non-destructive and other tests, etc.), a crucial step in checking that the target AIP result is actually obtained.

INDUSTRIAL APPLICATION

The suppliers' provisions for quality management constitute second level controls. Technical controls and quality controls are complementary and must be performed by different people.

The personnel responsible for quality controls have the necessary skills and qualifications. They report directly to a person with authority over the personnel who performed the AIP or its technical control.

Evaluation and verification actions may be conducted on the occasion of the internal audits. They aim to ensure:

- **the conformity of the AIPs, by means of sampling**. They may be performed through documentary checks or on the premises where the AIPs are performed;
- **the correct working of the processes as a whole**, in order to improve AIP performance.

They are covered by appropriate documentation and a traceability system.

Example 9

To evaluate an activity classified AIP for equipment manufacturing, a company conducts interviews with its personnel, to identify any situations potentially able to lead to errors.

Example 10

To evaluate the pertinence of the steps taken to combat the risk of fraud, a supplier carries out documentation spot-checks.
It ensures that the information contained in the documents reflects the actions actually performed by comparing the values entered in the certificates with the raw data measured.

YOUR QUESTIONS, OUR ANSWERS

How to implement process evaluation and second level control actions?

Internal audits can be held. They are a means of ensuring that the procedures associated with the AIPs are actually implemented satisfactorily and that the documents accurately reflect the associated activity.

Are the actions performed for these second level controls traced?

Yes. The results of these audits are documented and archived.

Is it pertinent to include the risk of error or fraud among the points checked by these second level actions?

Yes. A good practice is to make spot comparisons between the values recorded in the certificates and the raw data recorded in the measuring instruments, in order to check that these values have been correctly transcribed. Evaluating processes during the internal audits, notably by means of interviews, can also help identify those situations where the risk of fraud is greatest.

7. Personnel training and raising awareness of the safety culture

All the personnel of the suppliers and subcontractors performing manufacturing activities for equipment intended for a nuclear installation must have the required technical skills and be made aware of the safety culture.

Safety culture

"The assembly of characteristics and attitudes which [...] establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance."

Definition by the International Atomic Energy Agency (IAEA)

INDUSTRIAL APPLICATION

Technical competence of personnel performing an AIP or its technical control.

A person's qualification is the formal recognition of their competence. It must be recorded and archived so that its validity can be demonstrated beforehand (before manufacturing) and afterwards (during a subsequent inspection).

An appropriate training programme must be implemented for the personnel performing AIPs. It is drawn up according to the activities the personnel are required to perform and covers both theory and practical aspects. **It is a means of ensuring the transmission of knowledge** and preventing the loss of the skills needed to perform AIPs and carry out their technical controls. This provision is set out in Article 2.5.5 of the Basic Nuclear Installations legislation.

YOUR QUESTIONS, OUR ANSWERS

Why train the personnel in the fundamentals of nuclear safety?

The activity of each person performing an AIP has a potential impact on the safety of the nuclear installation.
The personnel must be made aware that they are manufacturing components intended for a nuclear installation. They must also understand the importance of their actions or of the equipment on which they are working.

What are the foundations of safety culture?

Safety culture is built around the attitude of organisations and individuals:

- **priority given to safety:** the management is engaged and the personnel take these principles on board,
- **a questioning attitude** with checks by means of audits,
- **personnel responsibility:** the tasks to be performed are clearly assigned and associated with a formal description,
- **an approach proportionate to the safety issues of the activities performed.**

What examples of messages should be transmitted during nuclear safety awareness training?

- Warn of **the risks associated with nuclear installations**, notably in the event of an accident.
- Warn of **the importance of the EIP manufactured**, notably in the event of a nuclear accident.
- Provide information about **the links** with the required characteristics of the equipment.
- Raise awareness of the need for **AIP traceability**, so that if necessary, even several years later, the impact of the manufacturing conditions on the safety of the nuclear installation can be analysed.
- Raise awareness of the **risks of falsification and counterfeit** in the supply chain, the importance of reporting any case as soon as it is detected, the potential criminal risk, and the existence of a whistleblowing system *via* the ASN website.

ASN oversight at the suppliers

ASN recalls the requirement for industrial rigour that must be applied in the nuclear sector. It has been reinforcing its checks on the supply chain since 2017.

Faced with the two-fold challenge of a high level of quality required for the equipment intended for nuclear installations and the increase in the amount of falsification and counterfeiting detected, ASN carries out fifty or so inspections every year at the suppliers of the nuclear licensees.

The inspections target businesses of varying sizes and fields of activity, involved at different levels along the supply chain for the nuclear installations in service or under construction, both in France and abroad.

THE RESPONSABILITIES OF THE ASN INSPECTORS

The inspections are performed by nuclear safety inspectors. They have been trained and have professional experience, as well as considerable legal and technical competence, as recognised by a qualification decision.

The ASN inspectors may investigate and record criminal offenses.

THE SCOPE OF ASN OVERSIGHT AT THE SUPPLIERS

ASN inspections can cover the AIPs used both within and outside the nuclear installations, whether performed by the licensee, its suppliers or its subcontractors.

The ASN inspections may be scheduled or unannounced.

The letters sent out by ASN further to its inspections are made public: they are published on the ASN website.

THE INSPECTOR'S PROFESSIONAL CONFIDENTIALITY

The ASN inspectors are bound by professional confidentiality, pursuant to Article L. 596-2 of the Environment Code.

They are bound by an obligation of professional discretion and may not therefore divulge the information of which they become aware during the performance of their duties.

INDUSTRIAL CONFIDENTIALITY AND COMMUNICATION OF INFORMATION TO ASN

During its oversight activities, ASN may request and make copies of documents relating to the subject of the oversight.

APPLICABLE LEGISLATION

ASN checks compliance with Laws, Decrees, Orders and its own decisions. These texts are binding and compliance is mandatory.

Other texts, such as ASN Guides, standards, codes or technical baseline requirements give recommendations. They may however be made mandatory if so stipulated in a contract.

AUTORITÉ
DE SÛRETÉ
NUCLÉAIRE

Faire progresser la sûreté
nucléaire et la radioprotection

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