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Supplier PIA Guide

The purpose of this document is to provide guidelines to F4E Suppliers of PIC for the activities which will be assessed as Protection Important Activities under the INB Order within their scopes of work

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Areas and functions

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Purpose

The purpose of this document is to provide guidelines to F4E contractors and suppliers on how to identify and classify activities in their scope of work that will be assessed as Protection Important Activities (PIA) under the INB Order.

Scope

The scope of this guide is to reinforce the safety-grading approach to identify activities that genuinely present a risk to Nuclear Safety including activities related to Protection Important Components. This document is based on ASNR guide [3], and on the ASNR presentation delivered at the GIFEN Safety Days in March 2025.

This guide is to be applied in the context of a nuclear safety working environment where all activities are considered to carry potential risk and governed by an Integrated Management System (IMS) adapted to nuclear activities for the design and construction of the ITER Basic Nuclear Installation (INB).

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Reference Documents

[1] INB Order - French Order of 7 February 2012 - République Française - Arrêté du 7 février 2012

[2] ITER_D_PSTTZL List of ITER-INB Protections Important Activities

[3] ASNR Guide to design and manufacturing requirements intended for equipment suppliers and their subcontractors

[4] ITER_D_SBSTBM MQP L3 Provisions for Implementation of the Generic Safety Requirements by the External Actors/Interveners

[5] ITER_D_SBYJXD IO Guideline for Identification of the Protection Important Activities (PIA

[6] ITER_D_347SF3 Protection Important Functions and Components Classification Criteria and Methodology

[7] F4E_D_3FZDYV QA-100 - Supply Chain Quality and Nuclear Safety Requirements

Terms and Definitions

Refer to the F4E Roles and Terms and Definitions in the Manual.

Term/Acronym	Definition
CFD	**C**omputational **F**luid **D**ynamic
FEA	**F**inite **E**lement **A**nalysis
FMEA	**F**ailure **M**odes and **E**ffect **A**nalysis
HAZID	**Haz**ard **Id**entification
HAZOP	**Haz**ard and **Op**erability Report
HVAC	**H**eating, **V**entilation and **A**ir **C**onditioning
INB	Nuclear Facility – ***I****nstallation* ***N****ucléaire de* ***B****ase*
IO	**I**ter **O**rganization
ITER	**I**nternational **T**hermonuclear **E**xperimental **R**eactor
NCR	**N**on-**C**onformity **R**eport
PFD	**P**rocess **F**low **D**iagram
P&ID	**P**rocess **&** **I**nstrumentation **D**iagram
PIA	**P**rotection **I**mportant **A**ctivity
PIC	**P**rotection **I**mportant **C**omponent
QD	**Q**ualité **D**efinie (old definition of Nuclear Safety Defined Requirement)
RAMI	**R**eliability, **A**vailability, **M**aintainability and **I**nspectability
PpRS	Preliminary Safety Report – ***R****apport* ***Pr****éliminaire de* ***S****ûreté*
SQEP	**S**uitably **Q**ualified & **E**xperienced **P**erson
SMART	**S**pecific, **M**easurable, **A**chievable, **R**elevant & **T**imebound
SSC	**S**ystem, **S**tructure or **C**omponent
TC	**T**echnical **C**ontrol

1 Definitions from the Regulations

Protection Important Component (INB order)	Element important for the protection of the interests referred to in Article L. 593-1 of the Environmental Code (public security, public health and sanitation, protection of nature and environment), i.e. structure, equipment, system (programmed or not), hardware, component or software present in a basic nuclear installation or placed under the responsibility of the licensee, that fulfils a function necessary for the demonstration referred to in the second paragraph of Article L. 593-7 of the Environmental Code, or checking that verifies that this function is ensured.	PIC
Protection Important Activities (INB order)	(as defined in the French Order – 07 February 2012) Activity important for protection of the interests referred to in Article L. 593-1 of the Environmental Code (public security, public health and sanitation, protection of nature and environment), i.e. activities contributing to the technical or organisational provisions referred to in the second paragraph of Article L. 593-7 of the Environmental Code, or that could affect them.	PIA
Defined Requirement (Safety) Nuclear Safety Defined Requirement Specified requirement (INB order)	Requirement assigned to a protection-important component so that it can perform its function, with the expected characteristics, as defined in the demonstration referred to in the second paragraph of Article L.593-7 of the Environmental Code (PIC DR), or assigned to a protection- important activity so that it can fulfil its objectives with regard to this demonstration (PIA DR). A defined requirement may be attached to either a PIC or a PIA.	DR (PICDR) (PIA DR)
Technical Control (INB Order)	Each activity that is important for protection is subject to technical control to ensure that: — the activity is carried out in accordance with the requirements specified for that activity and, where applicable, for the Protection Important Components concerned. — appropriate corrective and preventive actions are defined and implemented. The technical control of a Protection Important Activity is carried out by persons other than those who performed the activity.	TC

2 Principles

2.1 Protection Important Components

2.1.1 In Practice

Protection Important Component (PIC) carry out or monitor a nuclear safety function

- PICs are components that ensure the nuclear safety functions of nuclear installations. They support a safety function credited in the safety demonstration submitted to the Nuclear Regulator (ASNR). The IO classifies PIC components according to their importance with respect to their safety function. This classification is specified in [6] (not developed here as it is under clarification by IO for the Safety Report update).
- There is also a PIC classification for non-radiological hazard called Environment Important Components (EIC). They are the PIC associated with the control of nuisances arising from the normal operation of the INB (construction, operation, dismantling). Examples include systems related to water intake and releases to the environment.
- Based on safety objectives and justifications presented by the IO to the nuclear regulator, the IO identifies the PICs and their associated Defined Requirements.
- The IO then propagates the list of PICs to F4E through the Procurement Arrangements, and F4E subsequently propagates it to the supply chain.
- The IO bears ultimate responsibility for the PICs as the safety demonstration relies on them. However, in the case of functional PAs, it is expected that, based on the understanding of the system's safety functions, the Designer identifies potential PICs and proposes them to the IO.

2.1.2 Examples

- PICs may be structures, equipment, systems (with or without software), hardware, components or software that contribute to the protection of people or the environment such as confinement barriers or nuclear shielding.

2.2 Protection Important Activity (PIA)

2.2.1 In Practice

Protection Important Activities are activities for which a risk of failure is identified that could affect the required characteristics of a Protection Important Component, thereby impair the safety demonstration or the associated safety function.

- The risk should be understood as the probability that the activity may fail combined with the severity of the consequences that such a failure would have on the safety function.
- PIAs are generally associated with PICs. However, activities not associated with a PIC that have a direct impact on nuclear safety or environmental protection are also classified as PIAs (e.g.: waste management, in vessel dust measurement).
- PIAs are activities whose proper execution ensures that the PIC performs its safety function.
- An activity is not classified as a Protection Important Activity if an error affecting that activity can be detected and corrected by a subsequent activity that is itself classified as a Protection-Important Activity. Note that the so-called "subsequent activity" PIA cannot be the technical control of the PIA (Technical controls are not PIAs).

- Each PIA shall be subjected to a SMART technical control (see Section 2.4).
- Not all the activities related to PICs are classified as PIA: the classification as a PIA is proportionate to the issues and risks associated to the incorrect execution of the activity.
- Assessment of activity failure's probability and its consequences constitute a good practice for identifying PIAs and their associated Technical Controls. However, it should not constitute a mandatory deliverable.
- Investment protection or machine availability are not criteria for classifying an activity as a PIA.
- General PIAs are defined by the IO [2]. Suppliers, who possess the relevant knowledge and expertise in their respective domains, then identify the specific PIAs within their scope of work and their associated Defined Requirements. The Nuclear Operator endorses the proposed PIAs.

2.2.2 Examples

- Examples of PIAs include definition of maintenance operation, reception of raw material, shaping, heat treatment, assembly, mounting, machining, welding, qualification. Design activities shall be limited to activities with a potential impact on the safety function, such as analysis for PIC sizing, definition of PIC characteristic to ensure its safety function.
- Non-conformity management: the contractor raising the NCR and proposing a remedial and corrective action on IO database is a PIA (as requested by the INB order), the review process is surveillance / supervision but not a PIA.
- Considering manufacturing activities in relation to a component thickness requirement, it may be demonstrated that any machining error could be detected during the subsequent grinding operation. In such a case, only the grinding activity may be classified as a PIA, not the machining activity.
- Manufacturing of a PIC is a PIA.
  PIC manufacturing cannot be declassified as non-PIA because a subsequent activity such as Factory Acceptance Test (FAT) classified PIA could detect any manufacturing error:
  - The FAT is generally part of a Technical Control associated to the PIA manufacturing.
  - The FAT cannot detect all errors. As example, even successful, a pressure test during the FAT of a PIC valve can miss an error on the sealing material that will fail under radiation or a bad weld which will break after 2 years of services.

Examples of Non-PIA associated to a PIC: For Component off the shelf (COTS), manufacturing is non-PIA (however, an analysis of essential characteristics and risk of failure shall be performed to put in place a verification program to ensure the PIC COTS functionality, these verifications will be classified PIA).

2.3 Defined Requirements

2.3.1 In Practice

A Defined Requirement is a specific rule or condition that a PIC or a PIA must meet to properly fulfil its intended role with respect to Nuclear Safety

- Within ITER, Defined Requirements in ITER may also be referred to Nuclear Safety Defined Requirement (NSDR) or QD (In French Qualité Définie), these requirements are directly linked to Nuclear Safety.
- Defined Requirements are initially defined by the IO. As the scope of work is progressively refined and propagated, these Defined Requirements are also cascaded and refined through detailed specifications.
- Each PIC has at least one Defined Requirement; however, PIAs have also their own associated Defined Requirements. They are generally specified in detailed defined requirements when the PIA is defined.

  As example, for a PIC with a safety function that must be ensured under seismic loading,

  - the Defined Requirement is the seismic resistance (e.g. Structural stability maintained in the event of an earthquake of level SL2),

- for the PIA design, the requirement could be to perform the seismic analysis according to standard XX,
- for the PIA qualification, the requirement could be the consideration of seismic spectrum, and compliance with testing procedure,
- for PIA manufacturing, the requirement could be compliance with the procedures and criteria defined in the design phase (material grade, weld dimension, etc.).

2.3.2 Examples

- Defined Requirement for a PIC: pipe thickness, valve closure time, pump flowrate, weld thickness, seismic class, a vacuum class, etc.
- Defined Requirement for a PIA: a specified dimension during machining, a tightening torque during assembly, a parameter during welding, involvement of an inspector holding COFREND certification, or the use of a specific tool.

2.4 Technical Controls

2.4.1 In Practice

Technical Controls are activities that ensure that the Protection Important Activities are carried out correctly, and that their Defined Requirements are met. They also verify that corrective actions are implemented in the event of a non-conformity during the execution of a PIA.

- Technical Controls are specific activities that ensure the correct execution of a PIA.
- Technical Control shall be performed by a competent person other than the person who performed the activity.
- Technical Control is mandatory for every PIA. All PIAs shall be controlled.
  Exceptionally, in some cases where full control is not possible, control by sampling may be performed with justification of its representativity (e.g. control of concrete texture).
- Technical Controls are documented and tracked such that compliance with the specified requirements can be demonstrated in principle and verified retrospectively. On this basis, a Technical Control cannot be only a single visa on a document, it must be supported by records of the item controlled (it shall be possible to justify, at a later stage, which controls were performed).
- For design activities classified as PIAs, the content of the Technical Control (see Section 5.3 below), like any other, shall be predefined, approved, completed and recorded. It may include
  - parameters to check in the document output of the PIA design such as methodology used, used of up-to-date data, qualified tool…
  - control of the performer qualification,
  - control of the analysis (independent calculation), etc.
- Technical controls shall be measurable with clear criteria.
- Technical control can be performed during the activity (monitoring parameters by a second person during the performance of the PIA) or can be a distinct activity (control of a weld after the performance of the PIA welding).

- Suppliers, who have a more detailed knowledge of the risks associated to the activities within their scope, define the technical controls to be performed for the PIAs. The proposed Technical Controls for the PIAs are endorsed by F4E, prior to the start of the PIA.

2.4.2 Examples

- Examples include non-destructive testing (NDT), inspection of welding parameters, functional testing, control of qualification parameters, end-of-production testing, presence of a second operator during the activity, etc.
- For design activities: verification of relevant assumptions, validation of input data, control of uncertainties, etc.

3 PIAs - Practical Application

This section provides practical guidance on the identification of PIAs and TCs. See Section 6 for some practical examples.

In a nuclear environment, the baseline assumption is that all activities, whether classified as PIAs or not, are carried out correctly, to the highest standards of quality and by qualified personnel. It is standard practice that all work produced is reviewed by at least one qualified person other than the author.

This constitutes the baseline. The classification of activities as PIAs goes above – it is to secure the activities identified with a high risk for nuclear safety while TCs provide verification of their correct execution.

3.1 STEP 1 – Activity Definition

Define the activity by addressing the following questions:

- **WHAT** is the activity?
  This is the description of the activity, what is to be carried out. The activity should be defined in a *SMART* manner – Specific, Measurable, Achievable, Relevant and Time-Bound.

- **HOW** will the activity be carried out?
  This is the process by which the activity will be executed. It is defined through applicable plans and procedures. Executing the activities as per these plans and procedures should ensure the correct performance of the activity and compliance with the Defined Requirements.

- **WHY** is the activity carried out?
  This explains the rationale for the activity, its fundamental objective. Consider whether the execution of the activity fulfils Defined Requirements.

  - At this stage, we have activities but not yet a PIA classification.

3.2 STEP 2 – Identification of potential failure and its consequences

Identify potential failures associated with the incorrect execution of the activity. Consider the following questions:

- What could go wrong?
- What is the worst thing that could happen?
- Could the incorrect execution of the activity introduce a latent error?
- What can be the consequences on the defined requirement and/or safety function?

PIAs are identified on the safety-impact potential associated with the probability of incorrect execution of the activity. While all activities are expected to carry some degree of safety-impact, this does not automatically justify their classification as PIAs.

The classification shall be proportionate to the issues at stake and the potential consequences on nuclear safety – systematically classifying all activities related to PICs as PIAs is neither a good practice nor a conservative approach.

As a rule of thumb, if the potential failure or consequence of the incorrect execution of an activity could lead to a non-compliance with the Defined Requirements of the PIA or with the safety function of a component, and such non-compliance cannot be recovered by a downstream activity (that is itself classified as PIA), the activity should be classified as a PIA.

- At this stage, we have classification of activities as PIAs or non-PIAs.

3.3 STEP 3 – Error Detection Provisions: The Technical Control

Identify the actions that can be taken to detect any errors in the execution of the PIAs or, the actions required confidently demonstrate that the activity has been carried out correctly and the Defined Requirements have been met. **These actions constitute the Technical Controls.**

Such actions may already be defined in accordance with the requirements associated with the component quality classification (generally QC1). Where these actions meet the conditions specified in Section 4.4, they may be considered as the technical controls of the PIAs.

Technical Controls are independent activities, technical in nature, that are also SMART and whose objective is to provide additional assurance that a PIA has been carried out correctly. **A Technical Control is not limited to a simple documentary check.**

When a non-conformity is identified during the execution of the activity, the technical control also aims to verify that correction actions have been properly implemented.

A graded approach shall be applied to the definition and number of technical controls, proportionate to the issues at stake, and the associated potential activity failure and consequences.

If a SMART Technical Control cannot be defined for an activity, the activity definition should be reconsidered (whether it is sufficiently SMART) or whether the PIA classification is adequate. **Vague TCs or those limited to a documentary check are indicative of an inadequately defined PIA.**

- At this stage, we have classification of activities as PIAs and their associated TCs.

4 Consequences of a PIA classified activity

If an activity is classified as PIA, it is because it is recognised as being critical to ensuring a safety function; as such, it is subject to Technical Control and additional quality requirements apply:

4.1 PIA Performer & Technical Controller

- The performer of the PIA shall be a Suitably Qualified and Experienced Person in the technical field of the PIA, ie, they should be competent in the relevant technical field.
- The performer of the TC shall also be a Suitably Qualified and Experienced Person in the technical field of the TC, ie, they should be competent in the technical field.
- The TC performer shall be different from the performer of the PIA. The owner of the PIA may decide to outsource Technical Control to a different party, provided the technical controller is SQEP.
- Auditable records demonstrating the competence / training / skills of the PIA and TC performers shall be maintained.

4.2 Traceability

The execution of PIAs and of their associated TCs shall be traceable. This includes:

- When and by whom the PIAs and TCs were executed
- What procedure was followed for the execution of the PIA, and the resulting outcome
- What procedure was followed for the execution of the TC, and the resulting outcome
- The records related to the execution of PIAs and TCs shall be auditable. This implies that they shall be easily accessible, complete and sufficiently clear to allow an independent party to understand what was performed and what the outcome was.

4.3 Surveillance

As required by the INB Order [1], PIAs are subject to mandatory and systematic TCs, as well as to overall surveillance performed by the nuclear operator IO. The IO has the right to perform surveillance of PIAs as deemed necessary, and any member of the supply chain involved in the execution of PIAs shall grant IO and ASNR access for them to carry out any surveillance they consider appropriate.

Surveillance is performed on a sampling basis, in proportion to the importance of the activities carried out.

4.4 Supervision

As required by the Nuclear Operator [4], PIAs are also subject to Supervisions, equivalent to Surveillance by the Nuclear Operator IO, but performed by an External Intervener on its own supplier.

Supervision is performed on a sampling basis, in proportion to the importance of the activities carried out.

5 PIA Dos, Don'ts & Practical principles

DISCLAIMER: The existence of this guide does not exempt you from understanding the risk and consequence associated with or all activities within your scope. If the underlying reason you give for a PIA classification is solely based on the practical principles provided by this guide and not through your own technical reasoning, then you should read this guide again.

5.1 Dos & Don'ts

Don't	**Do instead**
Classify all activities as PIA	Identify PIAs based on potential failure and consequence to nuclear safety associated with the incorrect execution of the activity
Classify an activity as PIA solely to ensure that it is performed correctly	All activities are expected to be performed correctly and to the highest quality standards. PIAs are activities that present a specific nuclear safety risk and therefore require specific identification, tracking and control
Assume that the list of PIAs is fully defined by your client or by the IO	Identify PIAs based on your scope of work and the associated potential failure and consequence to nuclear safety. Propose them to your client for endorsement by the IO
Assume that the identification of PIAs is solely the responsibility of the Nuclear Safety Officer	Identify PIAs through experienced personnel in the relevant field of work. The NSO provides oversight and endorsement
Assume that the execution of a PIA or of its TC is the responsibility of the Nuclear Safety Officer	Ensure that PIAs and their associated TCs are executed by SQEP people in the relevant technical field. The NSO provides oversight and supervision.
Identify PIAs based on contractual deliverables.	Identify PIAs as activities, based on the scope and associated potential failure and consequence to nuclear safety. Deliverables may be used to document or report on PIAs but they are not PIAs themselves.
Identify PIAs solely on the basis of contractually defined requirements	Identify PIAs based on the potential failure and consequence to nuclear safety associated with the incorrect execution of the activity. The contractual defined requirements might need refinement before the

Don't	Do instead
	relevant PIAs can be properly identified

5.2 Practical principles

Typically:

- Activities that do not define the safety characteristics of a PIC but specify the scope of work or explain how work is to be carried out are not in themselves, PIAs (production of plans, purchase orders without PIC characteristics, contracts, etc.). The PIA is rather the execution of the work that affects the safety function, not the preparation of the associated documentation.
- Activities that summarize/justify work that has already been performed are not PIA (production of summary reports, summary design documents, manufacturing dossiers, VCDs, nuclear safety file). The PIA is the activity itself, not the summary.
- Activities related to quality management are not PIA (e.g. preparation and production of PQMP, MCP, MIP, SCAR, etc.).
- Reports or deliverables are not PIA. For instance, writing a structural integrity analysis report might be a PIA, the report itself is the PIA output.
- Qualification of a PIC and issuing its report is typically a PIA. TCs aim to control the test during the qualification and the strict test result's transcription in the qualification report. For accredited laboratories (ISO 17025), visa on the test report can be accepted as TC record (the accreditation supposes already defined controls).
- Preliminary, intermediate or scoping activities are NOT PIA. It is the final activity that carries the risk and is therefore classified as PIA.
- As a rule of thumb, if the only TC you can think for a PIA is a document review evidenced by a single visa <u>without records of the control performed</u>, either the activity is likely not a PIA or not sufficiently well defined.

5.3 PIAs by project phase

These are typical PIAs you can expect in the lifecycle of a project:

<u>Design</u>

- During the design stage, PIAs are likely to be activities that result in safety related specifications for the manufacturing phase or activities that directly contribute to the safety demonstration. Examples may include:
  - producing a technical specification that defines the safety characteristics of a PIC,
  - performing structural integrity analyses alongside any critical supporting analyses (e.g.: electromagnetic, neutronic, hydraulic), to be determined on a case-by-case basis which justify or define the characteristics of a PIC necessary to ensure its safety function.
- During the Preliminary Design phase, the identification of PIAs is generally limited, as the design remains at a conceptual level, safety requirements and verification criteria are not yet fully defined. PIAs typically become relevant from the Final Design stage onward, when the sizing and definition of Protection-Important Components are established through validated analyses and calculations, and where errors in execution could have non-recoverable consequences for the safety demonstration.
- PIA typically arises at Final Design stage where the sizing of PIC is determined and "locked" on the basis of analyses and calculations. However, if compliance with the Defined Requirements is justified solely on the basis of calculation or qualification results that are not updated/repeated after the FDR, the corresponding activity is typically considered a PIA.
- During the design stage, qualification activities are also likely to be classified as PIA.
- The Technical Check for design analysis and calculation requested by the F4E-QA-114 can be considered as the Technical Control if the calculation/analysis is classified as PIA if the analysis is in the scope of QA-114.

Manufacturing

- Procurement of material for final components is likely to be classified as PIA as it directly affects the characteristics of PICs in the safety demonstration.
- Prototyping is generally not classified as a PIA provided the prototype remains exploratory, intended for learning, feasibility assessment, or early design maturation, and is not the final model. In such cases, its outcomes can be fully confirmed or corrected through later configuration controls (in the reference defining final manufacturing parameters).
- On the other hand, prototyping activities may be classified as PIAs where they contribute to the qualification, validation or justification of safety characteristics of a PIC, or where an error could affect the nuclear safety demonstration and cannot be fully recovered downstream.
- Manufacturing PICs is often classified as a PIA since the as-built condition is essential to ultimately ensure the safety function, particularly for manufacturing steps that:
    - create, fix or significantly influence the characteristics of the component that ensure its safety function such as geometry, material properties, integrity, leak-tightness, strength, functionality.
    - cannot be fully verified or corrected downstream: inspection is partially feasible, destructive testing is limited or rework is impractical.
    - directly affects the safety function credited in the safety demonstration.

  This includes activities such as welding or brazing of pressure or confinement barriers, heat treatment affecting mechanical properties, critical machining (that relates to safety critical dimensions), or other processes where incorrect execution could introduce latent defects that cannot be fully detected or recovered through subsequent controls.

  Not all manufacturing activities related to PICs are PIAs; classification shall be proportionate to the safety significance and recoverability of the activity.
- Assembly of components or systems may be classified as a PIA where the assembly operation defines or "locks in" safety characteristics and where errors in assembly cannot be readily detected or fully remedied by subsequent activities. For example, assembly steps that irreversibly set sealing, or functional behavior contributing to a safety function are likely to be classified as PIA classification.

Transport & Storage

- Although the classification depends on the nature and type of the PIC, transport to the ITER site is generally not considered a PIA. However, an analysis, as described in Section 3, shall be carried out to assess the risks associated with transport and determine whether any potential damage can be fully recovered by downstream PIA activities.
- It is the same for storage of PIC, except if preservation provisions must be put in place to preserve the PIC qualification: preservation is then likely PIA.

6 EXAMPLES

For each example, the potential failure and consequences shall be assessed as regards the PIC function and the material role in the safety function

WHAT is the activity?	**HOW** will the activity be carried out?	**WHY** is the activity carried out?	**What are the potential consequences of a failure?**	**What is the PIA classification?**	**Technical control**	**Who are the performers?**
Design: Seismic calculation of a PIC structure that shall withstand seismic events to guarantee confinement	Using RFS-I.c, ITER Seismic Nuclear Safety Approach.	To define the design specifications of the system to answer to its seismic classification	Incorrect calculation (due to inputs, assumptions, methodology, etc.) leads to incorrect characteristics defined for the system, which are not compatible with the seismic classification of the structure.	**PIA** -> high potential to impair the safety function of the structure. **Defined Requirements of the PIA** *(Also called Detailed Defined Requirement):* - Calculation performed according to appropriate standard - Calculation using validated software - Use of appropriate and verified input data - Use of a Model representative of the structure and its boundary conditions	Technical Check from F4E-QA-114 (F4E-QA-114-ORG-PRO-05) when the analysis is in the scope of QA-114 (which is the scope for seismic analysis) or the technical controls defined for analysis in QA-100 for other scopes	PIA – a SQEP in structural analysis TC – a SQEP in structural analysis
Qualification test of PIC Sensor to high temperature	Qualification sequence as per qualification plan Tests as per test procedures According to RCC-E standard	To ensure that the component will deliver its safety function under the postulated harsh environmental conditions and possibly to define the maintenance plan	Non-representative test Instrumentation or set-up error Testing to an incorrect value which could lead to the installation of a PIC that cannot sustain the ITER environmental conditions	The definition of environmental and accidental values that shall sustain the PIC component is at risk and should be **PIA**. The realisation of the test itself is identified as an activity with high potential of errors with important impacts: **PIA** **Defined Requirements of the PIA**: - Test carried out at the right temperature - Temperature profile representative of the real conditions (ramp rate, duration of max temperature) - Sensor representative of chosen design	**TC for qualification definition:** Independent verification of qualification envelope & acceptance criteria vs Defined requirements **TC for the Test:** . Independent witness/review of test execution & results - Verification of test setup calibration & configuration	PIA – A SQEP in test, a SQEP in RCC-E TC – A SQEP in qualification.
Writing a **technical specification** of a PIC to subcontract its manufacturing/procurement	According to the outputs of the design/qualification phase	To define the general specification of a contract including Nuclear Safety requirements	Ambiguous, unclear or incorrect requirement→ mis-manufacture	This activity is likely **a PIA** because it has a direct and significant influence on the component's ability to fulfil its safety function, considering the importance of the PIC. However, if a PIA is defined downstream to recover any error (such as reception of PIC) it could be non-PIA.	Documental review by competent persons based on a checklist that specify all design outputs that characterise the component to ensure its safety function. The record should be linked to the technical specification.	PIA – SQEP on the concerned technical domain TC – SQEP on the concerned technical domain
Deviation Management Assessment, justification, and disposition of deviations or non-conformities affecting PIC items,	According to IO Deviation Management process	To deviate from a Safety requirement and verify that it does not compromise the safety demonstration	Underestimation of safety impact: inadequate technical or safety analysis may lead to acceptance of a deviation that degrades the PIC's safety function.	The risk to impact the safety demonstration is high: **PIA** (as requested by the INB order) The PIA concerns only the activities that	TC should be a control of the proposition (or remedial/corrective action for NCR): - inputs data	PIA – SQEP from the entity that propose the deviation TC –SQEP external or from the entity that proposes the

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including the definition of corrective or compensatory measures and the formal decision on acceptability with respect to nuclear safety requirements. It also includes lessons learned from this process.			Inadequate compensatory measures: poorly defined or incorrectly implemented compensatory actions may fail to restore the required safety margin, introducing latent risk.	have an impact on the requirements (propose/justify the deviation) in the database. **Management of the deviations without impact on the requirement such as its review/approval are surveillance/supervision but not PIA**	- control of calculation (see previous example), - impact on safety requirement/demonstration, etc.	deviation
Manufacturing: Procurement/reception of raw material for PIC	Procurement and reception of raw material intended for the manufacturing of a PIC, including verification that the received material complies with the specified requirements (material grade, properties, traceability).	To procure raw material used to manufacture the PIC with intrinsic properties required to achieve the safety function credited in the safety demonstration (e.g. mechanical strength, fracture toughness, corrosion resistance).	Use of non-conforming or incorrect material: wrong grade, incorrect heat treatment, or falsified certificates leading to inadequate mechanical or physical properties.	Procurement and reception of raw material for a PIC is likely to be a **PIA** because it establishes intrinsic, non-modifiable characteristics of the component that may be fundamental to its safety function. Errors at this stage are often latent and not fully recoverable downstream, even with subsequent manufacturing and inspection activities. Nevertheless, risk shall be assessed as regards the PIC function and the material role in the safety function. **Defined Requirements of the PIA**: - Material grade and standard - Mechanical and chemical properties (grain size, impurities) - Certified documentation (e.g. certificate type 3.1 EN10204/ISO10474) - Identification and traceability	Technical Control can include: - Mechanical properties test by an independent lab - Impurities test by an independent lab	PIA – materials SQEP TC – materials SQEP
Manufacturing: Welding of a support structure associated with a Protection-Important Component (PIC), intended to provide mechanical support, positioning, or load transfer necessary for the PIC to perform its safety function.	In line with the welding book in compliance with the applicable welding code/standard and project specifications. In line with the qualified welding process (WPQS)	To ensure that the PIC support provides the required mechanical strength, stiffness, and integrity to correctly position and sustain the PIC under all applicable loads (including normal, incidental, and accident conditions), as assumed in the safety demonstration.	Structural weakness or failure: welding defects (lack of fusion, cracks, porosity) could reduce load-bearing capacity, leading to support failure under design loads. Residual stresses or distortion: poor control of welding parameters could induce distortion or residual stresses, affect alignment or load paths and potentially stress the PIC.	**PIA:** Welding of a PIC support is likely to be classified as a Protection-Important Activity when the support contributes to the correct positioning, integrity, or load transfer of the PIC credited in the safety demonstration. Welding defects may introduce latent, non-recoverable weaknesses that cannot be fully detected or corrected downstream. **Defined Requirements of the PIA**: - Control of welding parameters (current, filler material, etc.) - Applicable welding procedure - Cooling rate - Defect size < x	Technical Control can include: - Control of the welding parameters during the welding activity - NDT - Visual inspection	PIA – SQEP welder TC – SQEP in welding or NDT

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Manufacturing: Cleaning prior to assembly of PIC seals in order to remove contaminants (particles, residues, oils, moisture) that could affect sealing performance.	Cleaning performed in accordance with a dedicated cleaning procedure specifying: - approved cleaning methods (e.g. solvent cleaning, ultrasonic cleaning, wiping), - authorized cleaning agents and materials, - cleanliness acceptance criteria, - environmental conditions (clean area, humidity control where required). Execution under controlled conditions, with traceability of the cleaning operation and materials used.	Assembly in "dirty" conditions will compromise the sealing capability of the seals, causing the leak rate to be higher than the specified limit	Residual contamination: insufficient or inappropriate cleaning could leave particles or films that impair seal integrity, leading to leakage that may not be detectable until operation. Seal degradation due to improper cleaning: use of incompatible solvents or methods could chemically or mechanically damage the seal material, reducing its long-term performance.	If there is a means of detecting a faulty seal during or after assembly (for example, a leak test), then **NOT PIA**. If there is no means of detecting a faulty seal, then **PIA**. **Defined Requirements of the PIA**: - Cleaning equipment material (type of cloth) - Cleaning material composition (presence or prohibition of certain chemicals) - Handling and protection after cleaning: after cleaning, seals and cleaned surfaces shall be protected from re-contamination - Approved cleaning method: Cleaning shall be performed using approved methods and materials that are compatible with the seal material and mating surfaces.	Cleanliness inspection prior to assembly: Inspection of seals and mating surfaces against predefined cleanliness acceptance criteria (visual inspection under controlled lighting, particle limits, surface condition). Leak test	PIA – a SQEP in the cleaning procedure TC – a SQEP in the cleaning procedure, a SQEP in the defined requirements of the PIA.
Transport: Transport of standard size PIC support	Transport performed in accordance with standard handling and transport procedures applicable to structural steel or mechanical supports. Use of conventional packaging and securing methods appropriate to the size, mass, and geometry of the support (e.g. frames, slings, restraints).	To deliver the PIC support to its destination without deformation, damage, or loss of dimensional conformity that could affect its ability to correctly support or position the PIC and thereby contribute to the overall safety function credited in the safety demonstration.	Mechanical damage or deformation: improper securing or handling could bend or distort the support, affecting fit-up or load paths.	Transport of a standard-size PIC support is generally not classified as a PIA, provided that: - The support is robust, - transport-induced damage is readily detectable by visual and dimensional inspection, and - any non-conformity can be corrected or recovered before installation. - The activity may warrant PIA classification only in specific cases, for example if the support has tight tolerances, complex geometry, or if deformation would be difficult to detect or correct downstream.	N/A Note that the fact that there is no PIA or TC does not mean that no quality control provisions are put in place.	N/A Note that the fact that there is no PIA or TC does not mean that the activity should not be performed by a SQEP.
Transport: Transport of a PIC diamond window including loading/unloading phases	Transport performed in accordance with a dedicated transport and handling procedure Use of qualified packaging and transport means appropriate to the fragility and safety function of the diamond window.	To ensure that the diamond window arrives at its destination without degradation	Window damaged during transport: - Shocks/vibrations - Scratches - indents - minor dents Environmental degradation or contamination: exposure to humidity, oxidation, or particulate contamination could impair leak-tightness, optical performance, or long-term reliability.	**PIA** -> the type of damage possible can affect the safety function (microcracks introduced in the diamond, indents in the diamond) and **cannot be fully detected or recovered downstream**. **Defined Requirements of the PIA:** - component secured inside case with compatible foam - no weight placed on top of case - maximum acceleration experienced < x ms^{-2}	Technical Control can include: Check of accelerometers on reception, use of shock, vibration, and/or environmental indicators or data loggers where specified. Visual inspection of window and brazing (reception inspection after transport)	PIA – a SQEP in the packaging of the window (someone familiar with the procedure). An experienced courier for fragile equipment TC – Someone familiar with the window, trained on the detection of defects.

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Preservation / Storage	According to the preservation/storage procedure, by the entity in charge of PIC	To put in place the PIC preservation measure to ensure conservation of the PIC capacity to fulfil its defined requirement.	Risk to miss an essential preservation measure that could affect the component to fulfil its safety function during its lifecycle	**PIA** -> ensure that all preservation measures are considered. Storage: Reception of a PIC by means of physical reception/inspection and verification of manufacturing documents or transportation can be considered as a control of previous activity. **Defined Requirements of the PIA:** - Preservation measure in place and managed	The technical control will be - the verification that the measures in place are in line with the requirements defined by the manufacturer, - control of the parameters of these measures (storage conditions, etc.)	PIA TC – SQEP in maintenance / preservation