

## MQP Level 2

# Overall Surveillance Plan of the Chain of External Actors for Protection Important Components, Structures and Systems and Protection Important Activities

This document define the generic modalities of the global surveillance carried out by IO on the INB No. 174, ITER, to meet the requirements of the INB Order related to the surveillance of PIA (notably its articles 2..2.2, 2.2.3 and 2.5.4). It is applicable to all protection important activities within the ITER Project, whether performed by IO or by its external... (Please see complete abstract on document metadata.)

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Change Log			
Overall Surveillance Plan of the Chain of External Actors for Protection Important Components, Structures and Systems and Protection Important Activities (4EUQFL)			
Version	Latest Status	Issue Date	Description of Change
v0.0	In Work	05 Jul 2011	
v1.0	Signed	11 Jul 2011	This document defines the procedure which is to be implemented within the ITER Organisation (IO) for the conduct of supervision of the chain of suppliers in order to comply with the Order 10th August 1984. It is applicable to all safety-related activities within the ITER Project performed by the IO and its suppliers. The translation to French is available in
v1.1	Signed	08 Dec 2011	The document is a MQP-Plan. the name has them been changed from procedure to plan Typos have been corrected and references completed with the correct numbers.
v2.0	Signed	03 Apr 2012	This version integrated the request from ASN given in CW#2-from ASN - ASN Report on observations following ASN inspection #2 - EN (ITER_D_7GUF3B v1.0) concerning the categorization of NCR's and the supervision of this activity in the chain of suppliers (articles 4, 8 and d12 of the Order 10th August 1984)  if(typeof editorarray == 'object') {  editorarray.push('MasterPlaceHolder_DocumentView1_ctl01_ctl00_ctl00_ctl16_ver_description') } }
v2.1	Approved	04 Apr 2012	This version is as version 2.0, with typo corrections
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v5.0	Approved	24 Jan 2014	Comments from the reviewers have been taken into account
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v6.1	Approved	12 Apr 2016	- Addition of the reference to the provisions mentioned under Article 2.2.1. - SCS replaced by Safety Department - Minor typos.
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v7.1	Signed	22 May 2019	As per approved MQP doc Request with corrected file - XKPX7P:  *to introduce of a new chapter 12 regarding Counterfeit, Fraudulent and Suspect Items (CFSI).  *to Integrate of comments from preview Y4BUVN:  1/ introduce the requirements related to the role of The Systems Engineer (SE) and the Design Integration Responsible Officer (DIRO) (chapter 7 + ref 12 + ref 13) 2/ update the chapters 8.1 (title of surveillance plan) + 8.1.2 (annexes) + 8.1.3 (other reviewers) + Titles of approved version of the references 5+8+9 3/ replace MIP by Inspection plan
v7.2	Signed	03 Jul 2019	Definition of Inspection Plan added "Intervener" word changed to "actor"
v7.3	Signed	03 Jul 2019	Updated according to reviewers comments.
v7.4	Approved	03 Jul 2019	Correct file uploaded

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## 1 Purpose

The purpose of this document is to define the generic modalities of the global surveillance carried out by the ITER Organization (IO) on the INB No. 174, ITER, to meet the regulatory requirements of the INB Order [1] related to the surveillance of PIA (notably its articles 2.2.2, 2.2.3 and 2.5.4):

- The nuclear operator (IO) must survey the external actor to ensure that (art. 2.2.2):
  - they apply the IO policy [2];
  - the operations they carry out, or the goods or services that they provide, comply with the defined requirements;
  - they comply with the provisions mentioned under Article 2.2.1 [3].
- The surveillance must be ensured by the operator itself, who cannot entrust it to a service provider. The operator may meanwhile call upon assistance in the surveillance task on certain conditions (art. 2.2.3)
- Appropriate actions for spot-checking and assessment of the provision taken pursuant to article 2.5.2 and 2.5.3 shall be schedule and implemented by the nuclear operator (art. 2.5.4).

This document provides general rules which are developed in detail in specific surveillance plans focused on PIA for a specific System, Structure or Component (SSC) or group of SSC.

## 2 Scope

This document applies to all protection important activities (PIA) carried out for or in the INB No. 174 (ITER), that are performed by an external actor.

As specified in article 2.2.2 of the INB Order, it excludes the agreed notified bodies (ANB) when they carry out technical controls or compliance assessments pursuant to legislation.

The specific case of the Project Teams (PT) is also tackle in this document, in section 9.

## 3 References

- [1] Order of 7 February 2012 *setting the general rules relative to basic nuclear installations*, called “INB Order” ([7M2YKF](#))
- [2] ITER Policy on Safety, Security and Environment Protection Management ([43UJN7](#))
- [3] Provisions for Implementation of the Generic Safety Requirements by the External Actors ([SBSTBM](#))
- [4] ASN Letter CODEP-BDX-2013-031134 – *Entry into force of the Order of the 7 February 2012 called “INB Order”* ([HPZM67](#))
- [5] *Requirements for producing an Inspection Plan* ([22MDZD](#))
- [6] *Organization of nuclear safety inspections in ITER Organization and its supplier chain* ([CW8EL3](#))
- [7] *Accreditation of nuclear safety inspectors* ([DBFV2L](#))
- [8] *Procedure for the management of Deviation Request* ([2LZJHB](#))
- [9] *Procedure for management of Nonconformities* ([22F53X](#))
- [10] *Procedure for Processing Deviation Requests and Non-conformance Reports submitted by a DA, a Supplier or a Sub-contractor* ([3E65VE](#))

- [11] *Document Management Procedure* ([22K5JQ](#))  
 [12] *Sign-Off Authority (SOA) for Project Documents* ([2EXFXU](#))  
 [13] *Systems Engineering Management Plan* ([2F68EX](#))

## 4 Definitions and acronyms

The definitions and acronyms used in this document are those of [Nuclear safety common definitions \(RLZXMV\)](#). In addition the following definition is provided for clarity:

**Inspection Plan:** As defined in [5], any plan used for any inspection activities on products during the entire lifetime of the project (e.g. procurement, manufacture and testing, prototype, construction ... as defined by the contract) used as a tool to monitor quality control and to verify that applicable requirements and acceptance criteria have been met during execution.

The inspection plan may be named IP (Inspection Plan), for Manufacturing MIP (Manufacturing and Inspection Plan) or CP (Control Plan) ..., for Construction ITP (Inspection and Test Plan).

## 5 ASN precisions on surveillance

In the letter [4], the ASN provided some reminders and observations about the INB Order [1], and notably about the surveillance of the external actors:

Original French text	English translation for guidance
<i>Le terme « intervenants extérieurs » vise les personnes physiques ou morales autres que l'exploitant et ses salariés. Ainsi, toute activité importante pour la protection des intérêts mentionnés à l'article L. 593-1 du code de l'environnement est soumise à une telle surveillance, dès lors qu'elle est confiée à un tiers, quelle que soit la nature du contrat ou de la relation liant les parties concernées.</i>	The word “external actors” refers to natural or legal persons other than the licensee and its employees. So, any activity important for the protection of the interests mentioned in Article L. 593-1 of the Environmental Code, since it is entrusted to a third party, is subject to such surveillance, whatever the nature of contract or relationship binding the parties concerned.
<i>L'article 2.2.3 de l'arrêté, qui entrera en vigueur le 1<sup>er</sup> janvier 2014, interdit de déléguer cette surveillance à un prestataire.</i>	Article 2.2.3 of the decree, which comes into force on 1 January 2014, forbids delegating such surveillance to a provider.
<i>En cas de sous-traitance à plusieurs niveaux, il reviendra à l'exploitant d'assurer <u>de manière directe</u> la surveillance de l'ensemble des intervenants extérieurs dans la mesure de leur influence sur les intérêts protégés, notamment au regard des dispositions prévues dans la démonstration mentionnée au deuxième alinéa de l'article L. 593-7 du code de l'environnement.</i>	<b>In case of several levels of sub-contracting, the operator is in charge of ensuring <u>direct</u> surveillance on all external actors, to the extent of their influence on the interests protected, particularly with regard to provisions of the demonstration mentioned in the second paragraph of Article L. 593-7 of the Environmental Code.</b>

Original French text	English translation for guidance
<i>En particulier, un système consistant à charger l'intervenant extérieur de premier rang dans la chaîne de sous-traitance d'assurer entièrement la surveillance des sous-traitants auxquels il fait appel n'est pas conforme aux dispositions réglementaires précitées.</i>	In particular, a system in which the first level contractor is entrusted with the full surveillance of its supply chain does not comply with the above regulations.

## **6 Compliance with the requirements of the INB Order in terms of surveillance**

Articles of the INB Order	Article's text	Implementation for INB 174
<b>2.2.2</b>	<p>I. – The operator must survey the external actors to ensure:</p> <ul style="list-style-type: none"> <li>– that they apply its policy mentioned in Article 2.3.1, which was transmitted to them pursuant to Article 2.3.2;</li> <li>– that the operations they carry out, or the goods or services they provide, comply with the defined requirements;</li> <li>– that they comply with the provisions mentioned in Article 2.2.1.</li> </ul> <p>This surveillance must be proportional to the importance, for the demonstration mentioned in the second paragraph of Article L. 593-7 of the Environmental Code, of the activities carried out.</p> <p>It must be documented under the conditions set in Article 2.5.6.</p> <p>It must be undertaken by individuals with the appropriate skills and qualifications.</p>	<p>The external actors are surveyed by an IO staff through surveillance actions detailed in specific surveillance plans (cf. § 8.1).</p> <p>The surveillance actions are documented in a specific surveillance plan (cf. § 8.1) and are formalized in records (cf. § 8.1.2.7).</p> <p>The IO staff in charge of the surveillance are skilled (cf. § 8.2.1).</p>
	<p>II. – Notwithstanding, bodies and laboratories that are independent of the operator, that are accredited, approved, delegated, appointed, acknowledged or notified by the administration, are not subject to this surveillance when they carry out technical checks or compliance assessments pursuant to legislation.</p> <p>The operator must check the validity of the accreditation, the approval, delegation, acknowledgement or notification of the body that he calls upon to carry out the activities concerned, on their date of performance.</p> <p>For these activities, the operator and the body must be bound by specific contracts.</p>	<p>Agreed Notified Bodies in charge of technical checks or conformity assessments are not concerned by the ITER surveillance.</p> <p>This checking is done during the contract award</p> <p>The contracts for these activities are specific.</p>



Articles of the INB Order	Article's text	Implementation for INB 174
2.2.3	<p>I. – The surveillance of protection important activities that are carried out by an external actor of protection-important activities must be ensured by the operator itself, who cannot entrust it to a service provider.</p> <p>Notwithstanding, in specific cases, the operator may call upon assistance in the surveillance task on condition that it retains the necessary skills to master the surveillance.</p> <p>The operator must ensure that the organizations that assist it have the necessary skills, the independence and the impartiality required to provide the given services.</p>	<p>The surveillance is carried out directly by an ITER staff (cf. § 7.1.1).</p> <p>S/he may call upon assistance in the surveillance task.</p> <p>The nuclear operator retains the necessary skills to master the surveillance (cf. § 8.2.1).</p> <p>The contractors that assist the operator are selected to have appropriate skills. They must be independent from the persons carrying out the PIA they help to survey (cf. § 8.2.2).</p> <p>The modalities of this surveillance are detailed in specific surveillance plans.</p>
	<p>II. – The operator must transmit to the Nuclear Safety Authority, if so requested, the list of supporting bodies that he uses, if so requested, and specifies the reasons for this support as well as the way he implements the obligations defined under I.</p>	<p>On ASN's request.</p> <p>The list of the assistance to ITER for surveillance is kept updated in the appendices of the specific surveillance plans.</p>
2.5.4	<p>I. – The operator schedules and implements appropriate actions for spot checking the provisions taken pursuant to Articles 2.5.2 and 2.5.3, as well as actions for periodically assessing their appropriateness and effectiveness.</p> <p>The persons carrying out these checking and assessment actions are distinct from the persons who carried out the protection-important activity or its technical check.</p> <p>They report directly to a person having authority over these agents.</p>	<p>These actions are provided by the accredited nuclear safety inspectors conducting nuclear inspection within IO and its supplier chain, according to a annual inspection program (cf. § 10).</p> <p>The nuclear safety inspectors are from the Safety Department of IO, and do not carries out protection-important activity or its technical check.</p> <p>As detail in [6], the report is officially sent out by the IO-DG (or its delegate) to the inspected entity.</p>
	<p>II. – When the protection-important activities or their technical check are carried out by external actors, these checking and assessment actions are considered as a surveillance action on the external actors concerned, and the provisions under Article 2.2.3 apply.</p>	<p>The accredited nuclear safety inspectors are IO staff.</p> <p>Their inspection activities may not be outsourced.</p>

## 7 Roles and responsibilities

The heads of departments have the responsibilities to issue and implement the specific surveillance plans.

The different roles involved in the surveillance are the following:

- The Technical Responsible officer (TRO).
- The Safety Responsible Officer (SRO).
- The Quality Assurance Responsible Officer (QARO).
- The head of the Environmental Protection and Nuclear Safety Division (IO/SD/EPNS).
- The Systems Engineer (SE) and/or the Design Integration Responsible Officer (DIRO) and on need basis, e.g. for Equipment Qualification.

- The surveillance assistance.
- Any other IO staff or expert can be involved in the surveillance, on need basis.

The responsibilities of each role are described in the respective sections of this document. The present section provides a summary of the mains responsibilities.

## **7.1 Application of article 2.2.2: Surveillance**

The surveillance of the external actors is carried out by IO staff. The actors of this surveillance are:

- The TRO.
- The SRO.
- The QARO
- The SE and DIRO.

### **7.1.1 The Technical Responsible Officer (TRO)**

The TRO is responsible for the surveillance of PIA carried out by external actors, in the scope of their PBS. This implies s/he is responsible for the implementation of all the actions detailed in § 8.1:

- S/he shall issue a specific surveillance plan that details how the surveillance is carried out (§ 8.1.1 to 8.1.2.6).
- S/he shall perform the surveillance actions provided for in the specific surveillance plan, and formalize them in appropriate documents (cf. § 8.1.2.7).
- S/he shall archive the appropriate documents and records to demonstrate that the surveillance have been carried out appropriately (cf. § 13).

The TRO may be supported in part or all of these tasks to another skilled IO staff, for instance the SRO, QARO or SE/DIRO.

The TRO may be assisted for part or all of these tasks by an external contractor, called “Surveillance assistance”, provided that the TRO respect the principles of the § 7.2.

### **7.1.2 The Safety Responsible Officer (SRO)**

The SRO of the Safety Department (SD) supports the TRO for specific aspects related to the protection of the interests.

On request of the TRO, s/he may carry out part or all of the surveillance tasks.

### **7.1.3 The Quality Responsible Officer (QARO)**

The QARO of the Quality Management Division (IO/QMD) supports the TRO:

- By proposing him/her intervention points on inspection plan prepared by external actors.
- By giving him advices on specific aspects related to the quality integration issues.
- By participating in field inspection visits and in internal and external audits.

On request of the TRO, s/he may carry out part or all of the surveillance tasks, notably the release of the intervention point placed by IO on the inspection plan.

### **7.1.4 The Systems Engineer (SE) and the Design Integration Responsible Officer (DIRO)**

The SE/DIRO is responsible for supporting the TRO for integration topics, both functional and physical, and to guarantee the proper implementation of transverse functions related to internal events like Fire Protection, High Energy Line Break, etc. (see details in [13]).

The surveillance actions of SE/DIRO shall be integrated as necessary in the TRO surveillance plan, as per implementation of the ITER Sign-Off Authority [12].

## 7.2 Assistance by contractor(s) for surveillance tasks

When the nuclear operator (IO) wishes to strengthen surveillance for a fixed term, for instance to survey particular occasional projects whose duration is limited, it may be assisted in its surveillance by one or several contractors, in compliance with Article 2.2.3 of the INB Order.

These contractors are called “Surveillance assistants”.

Although the surveillance and the supervision of PIA is not a PIA, the surveillance assistants are subject to supervision by the TRO.

For example, it may be:

- The planning and participation in meetings (kick-off meeting, periodical meetings).
- The planning and participation in potential quality audits.
- The verification of deliverables before acceptance.
- The cross-check of surveillance actions done by the assistance and by the TRO.

This supervision and its formalization shall be specified in the specific surveillance plan (cf. § 8.1.2.3).

## 7.3 Application of article 2.5.4: Nuclear safety inspection

The Safety Department is in charge of the actions required by the article 2.5.4 (cf. § 10).

# 8 Application of article 2.2.2 - General case

## 8.1 Specific surveillance plan

For each PBS, the related TRO is responsible for the surveillance of the PIA carried out by external actor for the INB no. 174.

For each PBS, a document called “Surveillance plan for PBS <no. of the PBS> - <Name of the PBS>” shall detail the specific provisions implemented for the surveillance. The purpose of a specific surveillance plan is to detail *how*, *when* and *by who* the surveillance of the external actors is carried out.

For each surveillance action, the surveillance plan shall therefore clearly describe:

- The structure of the complete supply chain (in an annex 1, cf. § 0).
- The PIA and the related external actors surveyed (in an annex 2, cf. § 8.1.2.2).
- The nature of the surveillance.
- The frequency of the surveillance.
- The actor of the surveillance (e.g. TRO, other IO staff (SRO, QARO...), assistant).
- How the surveillance is formalized (e.g. meeting report, signature on document...).
- Any specific rules for the management of the records.
- Where the record is kept (e.g. dedicated IDM Folder, in dedicated physical folder).

### 8.1.1 General principles

As required by the article 2.2.2 of the INB Order, the definition and implementation of the surveillance actions are based on a proportionate approach to the issues of the protection of the interests, taking into account:

- The importance and complexity of the PIA and the products of this activity.
- The risks and the potential impact associated with PIA and the products resulting from this activity.
- The potential consequences of improper fulfilment of PIA or failure of a product resulting from this activity.

**The TRO (or his representative) shall therefore adapt the nature and the frequency of the surveillance actions to the surveyed PIA.**

### 8.1.2 Mandatory content of the specific surveillance plan

Annexes to the Surveillance Plan are mandatory; derogations could be accepted with proper justifications.

#### 8.1.2.1 **Structure of the supply chain (annex 1)**

In a separate annex 1 of the document, the TRO shall describe the whole supply chain, from IO to the last level of contractor.

This description shall be such as to identify, without ambiguity, who contracted with who and the level in the supply chain.

The annex 1 shall detail for each contractor:

- The reference of its quality plan.
- The references of the inspection plan (if applicable).
- The role of the external contractor through a short description of its work.

#### 8.1.2.2 **List of PIA and external actors surveyed (annex 2)**

In a separate annex 2 of the document, the TRO shall specify the list of PIA, the related defined requirements and the external actors in charge of it.

This may be for example “writing of technical specifications for PIC”; “design”, “manufacturing” or “transportation” of a PIC; “safety demonstration”; ...).

The name of the PIA and the external actors shall be such as to identify it without ambiguity.

*N.B.: The PIA carried out by IO staff are not subject to surveillance (art. 2.2.2). They are however subject to technical check (art 2.5.3).*

#### 8.1.2.3 **List of surveillance assistances (annex 3)**

In a separate annex 3 of the document, the TRO shall specify the complete list of the assistances obtained by the ITER organization for surveillance PIA.

As a reminder (cf. § 5), the article 2.2.3 of the INB Order forbids *delegating* the surveillance, but allows the nuclear operator to be *assisted* in this task, providing that the nuclear operator (IO) retains the necessary skills to master the surveillance.

This annex shall therefore:

- Demonstrate that IO retains the necessary skills to master the surveillance.

- Details how ITER controls the work of these surveillance assistances (cf. § 7.2).
- Provides evidences of the skill, independence and impartiality of such services.
- Provides the reasons for this support.

The TRO shall also specify which surveillance activity:

- *may* be performed by the surveillance assistance(s).
- *shall* be performed only by IO staff.

This allocation between IO staff and surveillance assistance(s) shall be made so as to demonstrate that IO retains the necessary skills to master the surveillance.

#### 8.1.2.4 Nature of the surveillance actions

For each PIA, the surveillance actions may be a combination of one or more of the followings activities (non-exhaustive list):

- Selection of the external actors (during the procurement process).
- Process of placing intervention points in the suppliers inspection plan (such as HP, NP, W, S1, S2, R, following the procedure [5]), and implementation of these intervention points.
- Audits.
- Observation of shop activities.
- Document reviews.
- Meeting.
- ...

**In every case**, the surveillance of the PIA must *a minima* be implemented by **checking that every external contractor**:

- **has a quality system** in agreement with the importance of products he has to deliver and in particular for the follow-up of the Protection Important Activities (PIA) corresponding to the Protection Important Components (PIC) to be provided under the contract.
- ensures that each of their sub-contractors has properly **applied their own individual quality system**.
- ensures that the requirements for the application of the INB Order [1], in particular the chapters 2, 5 and 6 are **conveyed throughout the whole supply chain**: they must be implemented through technical and management requirements in the specifications for the contracts.

The TRO shall specify for each PIA what are the surveillance actions (or combination of actions). S/he shall describe the principles of these actions in the specific surveillance plan.

#### 8.1.2.5 Frequency of the surveillance

For each surveillance action, the minimum frequency at which this action should be conducted shall be specified.

This may be for example “once”, “weekly”, “monthly”, “12 times during the contract”, “for each document/meeting”, “each time a PIC is received”, etc.

### 8.1.2.6 Actor of the surveillance

The TRO shall specify who (i.e. what position) is responsible for performing the surveillance action describe above.

This may be for example the TRO, another IO staff (SRO, QARO, expert, etc.), and/or the surveillance assistant.

*N.B. For each action, it is strongly recommended to clearly nominate a single person to avoid confusion about who shall do this surveillance action. This person is responsible for this surveillance action, and shall take all necessary provision to ensure the surveillance is performed (e.g. nominate a substitute).*

As mentioned in § 8.1.2.3, if the TRO have recourse to a surveillance assistant, s/he shall pay special attention to the allocation between IO staff's actions and surveillance assistant's action.

**As recalled in § 5, the surveillance action may not be fully *delegated* to a provider.**

### 8.1.2.7 Traceability of the surveillance actions

As request by the article 2.2.2 of the INB order, the surveillance actions must be documented under the conditions set in article 2.5.6, which means they must notably be formalized.

The level of formalization shall be adapted to the complexity of the PIA and the surveillance action, e.g.:

- For the action “document reviews”, the formalization of this review may be go from a simple signature with the date to a formalized comment form.
- For the action “meeting”, the formalization may be a meeting report.
- For the action “Observation of shop activities”, the formalization may be an inspection report.

In any case, these documents shall a minimum allow for identifying unambiguously the following information:

- A recall of the PIA and of the related defined requirements.
- The nature of the surveillance action(s) done.
- The date of the surveillance action(s).
- The name and the signature of the person(s) carrying out the surveillance.

### 8.1.2.8 Specifics rules for the management of the records.

If applicable, the specific surveillance plan shall detail the operational rules for the management of the records.

This may be for example “*the record on the surveillance being the paper-based inspection plan, the original is kept with the manufacturer. The DA QARO is responsible for scanning it each week and when finished and to upload it on IDM. S/he shall inform the TRO*”.

In any case, the standard IO rules for the management of document are applicable.

### 8.1.2.9 Archiving of the records.

The specific surveillance plan shall detail where the record is kept, allowing thus to retrieve them easily. This may be for instance the dedicated IDM Folder number, or the precise location of dedicated physical folder.

### 8.1.3 Development, review and approbation of the specific surveillance plan

- The TRO is responsible for issuing the specific surveillance plan.
- The SRO, SD and management line of the TRO are responsible for reviewing it. Other reviewers, such as the QARO, SE/DIRO should be involved in the review as necessary.
- The heads of EPNS have the responsibilities to approve the specific surveillance plans.

## 8.2 **Skills of the persons carrying out the surveillance**

### 8.2.1 IO Staff

The IO Staff who perform and are responsible for the surveillance of the PIA are competent on the basis of appropriate education, training, skills and experience. Records of staff education, training, skills and experience are kept by the Human Resources division.

Moreover, the actors of this surveillance carry out surveillance actions on a regular basis, what allow them to retain the necessary skills for mastering these actions.

### 8.2.2 Surveillance assistance

IO ensures that the service provider has the necessary qualifications through the selection process: the actors are selected on the basis of their curriculum vitae, which shall contain appropriate education, training, skills and experience.

The service provider that assists IO for surveillance actions on a PIA must be independent from the company in charge of the PIA (and its subsidiaries, or the companies it controls) or from its suppliers.

## 9 **Application of article 2.2.2 – Case of the Project Team (PT)**

Project Teams gathering IO-CT staff and IO-DA staff have been created with the objective of integrating the IO-DA and IO-CT teams within one single Project.

### 9.1 **Status of the IO-DA staff regarding the surveillance**

According to the definition of “external actor” provided in article 1.3 of the INB Order, **the DAs are considered as external actors**, having their own legal entity distinct of the IO.

In any case, the IO-DA staffs are then subject to surveillance directly by IO-CT staff.

### 9.2 **Surveillance of the project team**

In the Project Teams, there are both external actors (IO-DA staff) and staff of the nuclear operator (IO-CT staff) under the authority of a PT Leader.

- If the PT Leader is an IO-DA staff, the surveillance by IO-CT is necessary, since IO staff from the technical departments is under the authority of a non IO-CT staff.
- Even if the Leader of PT is an IO-CT, it seems difficult to justify that inside the PT, some IO-CT staff could perform some surveillance whereas their IO-DA colleagues could not.

So as a general principle, **in the case of the Project Team, the surveillance of the external actors is done by a member of the Safety Department of IO-CT.**

This person (usually the SRO) is therefore responsible for the tasks provided by the TRO in the general case, as listed in § 7.1.1. It means that this person is responsible for the implementation of all the actions detailed in § 8.1:

- S/he shall issue a specific surveillance plan that details how the surveillance is carried out (§ 8.1.1 to 8.1.2.6).
- S/he shall perform the surveillance actions provided for in the specific surveillance plan, and formalize them in appropriate documents (cf. § 8.1.2.7).
- S/he shall archive the appropriate documents and records to demonstrate that the surveillance have been carried out appropriately (cf. § 13).

### **9.3 Skills of the persons carrying out the surveillance of the project team**

The disposition of § 8.2 applies.

## **10 Application of article 2.5.4**

### **10.1 Nuclear safety inspections**

In application of the article 2.5.4 of the INB Order, IO programs and implements appropriate spot-checks of the PIA and technical check activities.

For the INB no. 174 (ITER), these actions are implemented through nuclear safety inspections, which shall be conducted following the reference [6].

### **10.2 Skills of the persons carrying out the nuclear safety inspections**

The nuclear safety inspections are performed by nuclear safety inspectors that are accredited following the reference [7].

## **11 Deviations and nonconformities management**

The deviations and nonconformities shall be managed in agreement with the IO procedures for DR and NCR [8], [9] and [10].

## **12 Counterfeit, Fraudulent and suspect Items (CSFI)**

In the course of the surveillance activities, the TRO (or the SRO in the case of Project Teams) shall ensure specific attention on the detection of potential CSFI.

For that purpose, the following means can be used (**the list is not exhaustive**):

- unscheduled inspections,
- independent analysis of samples,
- contact of certifying bodies to check the validity of certificates,
- interviews of External Actors selected randomly, ...

The nature and the frequency of the surveillance activity can be adjusted depending on the perception of vulnerability of the External Actor regarding CFSI. Some signals can raise the attention of the staff in charge of the surveillance: the previous occurrence of CFSI or of any known ethical issue in the company, a poor safety culture (including Health and Safety), QA audits with many findings, a lack of care (tools, maintenance, housekeeping...). More globally, a negligent work environment are



favorable elements to CFSI. A difficult financial situation is also an adverse parameter to be accounted when information is available.

If a CFSI is detected during the course of the surveillance, then a non-conformity has to be raised. The specific provisions for NCRs stemming from CFSI have to be followed (cf. [Procedure for management of Non-conformities \[9\]](#))

### **13 Documents and recordings**

The planning, implementation, results, and possible actions resulting from the surveillance are subject to the documentation and traceability defined in the applicable procedures.

The TRO (or SRO in the case of a PT) is in charge of archiving the appropriate documents and records to demonstrate that the surveillance and the technical check have been carried out appropriately.

S/he shall apply the procedure [11] to keep this documents and records to satisfy the requirement of the art.2.5.6 of the INB Order.

As specified in [6], the SD is in charge of the records issued from the inspection.

The specific surveillance plans are stored in the dedicated IDM folder [II.6.3.3. Surveillance Plan \(ITER\\_D\\_HPML7E\)](#).

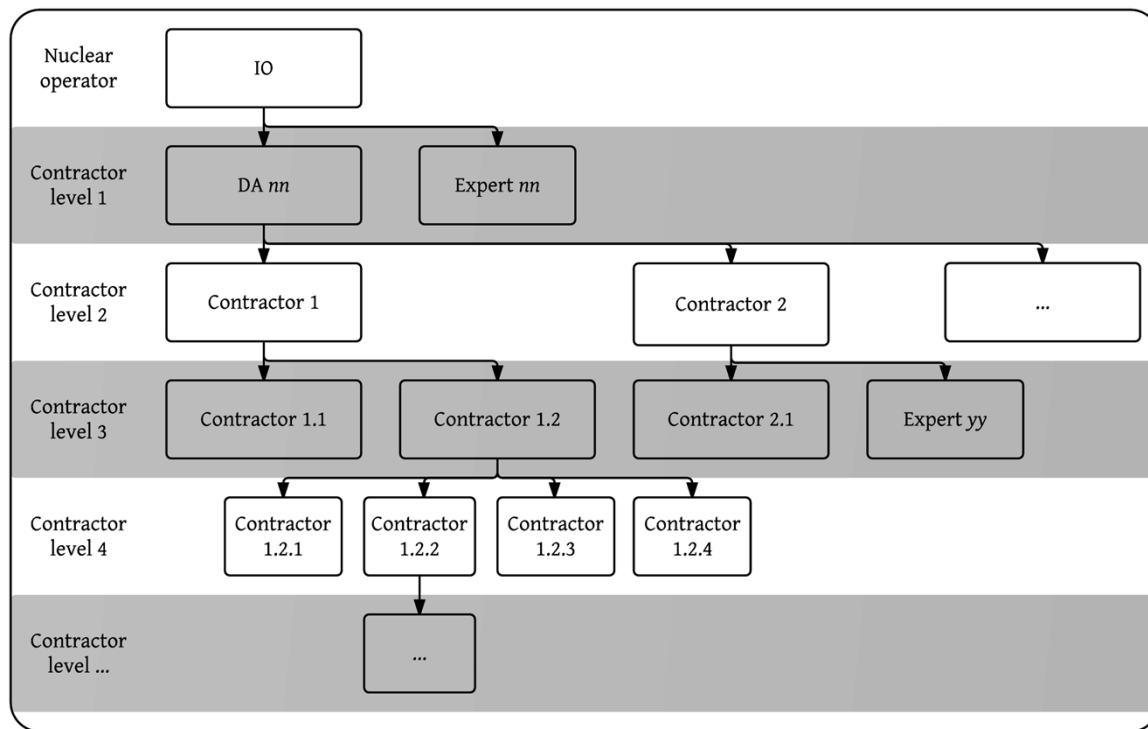
### **14 Revision of this plan**

On the experience feedback basis, the surveillance process may be update to change the frequency and / or the nature of the surveillance. These changes result in the update of the concerned specific surveillance plans.

Revision of this plan can take place in case of changes in the organization or in the references, for improvement of the surveillance processes or following an audit.

## Appendix 1: Examples of presentation for annex 1 of the specific surveillance plans

(for illustration purpose only)



External actor	Contractor level				Quality plan	Manufacturing and inspection plan	Work description/Role of the external contractor
	1	2	3	4			
DA nn	×				(IDM UID)	-	Procurement of system nn
Contractor 1		×			(IDM UID)	-	Design and supply of sub system n1
Contractor 1.1			×		(IDM UID)	(IDM UID)	Manufacturing of sub system n1.1
Contractor 1.2			×		(IDM UID)	(IDM UID)	Manufacturing of sub system n1.2
Contractor 1.2.1				×	(IDM UID)	(IDM UID)	Cutting and forming
Contractor 1.2.2				×	(IDM UID)	(IDM UID)	Steel plate foundry
Contractor 1.2.3				×	(IDM UID)	(IDM UID)	Steel plate polishing
Contractor 1.2.4				×	(IDM UID)	(IDM UID)	Welding
Contractor 2		×			(IDM UID)	-	Procurement of sub system n2
...							

## Appendix 2: Examples of formulations for the specific surveillance plans

(for illustration purpose only)

PIA	Defined requirement	External actors	Nature of the surveillance	Frequency of the surveillance	Actor of the surveillance	Formalization of the surveillance	Records management	Record location
Writing of technical specifications for system <i>nn</i>	<ul style="list-style-type: none"> <li>Control that the defined requirements are included in the contract</li> <li>Application of the procedure <a href="#">BG2GYB</a></li> </ul>	DA	Document review	For each document	SRO	Signature of the reviewers	Standard IO rule ( <a href="#">22K5JQ</a> )	IDM folder ABCD12
Design of PIC <i>nn</i>	<ul style="list-style-type: none"> <li>Compliance with System Requirements Document (<a href="#">29D6G7</a>)</li> </ul>	DA	Periodic meeting	Weekly	TRO PARO ...	Meeting report	Standard IO rule ( <a href="#">22K5JQ</a> )	IDM folder EFGH34
Design of PIC <i>nn</i>	<ul style="list-style-type: none"> <li>Compliance with System Requirements Document (<a href="#">29D6G7</a>)</li> </ul>	Manufacturer <i>nn</i>	Periodic meeting	Monthly	TRO PARO ...	Meeting report	Standard IO rule ( <a href="#">22K5JQ</a> )	IDM folder EFGH45
Design of PIC <i>nn</i>	<ul style="list-style-type: none"> <li>Compliance with System Requirements Document (<a href="#">29D6G7</a>)</li> </ul>	All involved in design	Final design review	At the completion of the detailed design phase	As detailed in <a href="#">2832CF</a>	Close-out report	Standard IO rule ( <a href="#">22K5JQ</a> )	IDM folder 1a2b3c

PIA	Defined requirement	External actors	Nature of the surveillance	Frequency of the surveillance	Actor of the surveillance	Formalization of the surveillance	Records management	Record location
Manufacturing	– Compliance with manufacturing requirement (AABBCC)	Manufacturer <i>nn</i>	Observation of shop activities.	Every two weeks	Surveillance assistant	Inspection plan Inspection report	Original hard copy of the Inspection plan is kept by the manufacturer.  It shall scan and send it to TRO every month to track progression.	In manufacturer's quality records.  IDM folder XXYYZZ
Manufacturing	– Compliance with manufacturing requirement (AABBCC)	Manufacturer <i>nn</i>	Observation of shop activities.	As required in the Inspection plan	QARO	Inspection plan Inspection report	Standard IO rule ( <a href="#">22K5JQ</a> )	
Implementation of ITER Policy		Sub-contractor <i>nn</i>	Audits	3 a year	QARO	Audit report	Standard IO rule ( <a href="#">22K5JQ</a> )	
...		...	...	...	...	...	...	...

Refer also to the ITER Sign-Off Authority [12] as necessary.

## **Appendix 3: Examples of formulations for annex 3 of the specific surveillance plans**

(for illustration purpose only)

### **Supervision by ITER of contractors undertaking surveillance activities**

*ITER controls the work of external resources carrying out surveillance activities as follows:*

- *Selection process for the company and the individuals (see above).*
- *Preparation and approval of surveillance activity processes is done by ITER staff.*
- *Contractors are directly supervised by and report directly to ITER staff.*
- *All documentation prepared by contractors is reviewed and approved by ITER staff.*
- *...*

### **List of surveillance assistances**

#### **Surveillance assistance 1**

*The selection of the company has been done on the basis of their large demonstrated expertise in testing, inspection and certification and their broad implantation in the world. In such a way, this contractor has the possibility of providing skilled staff in the countries of Domestic Agencies and other contractors.*

*Examples of outsourced activities include (but not limited to and depending on the specific systems):*

- *Verification of correctness of defined requirement for PIAs and PICs*
- *Ensure that the correct revision of drawings approved for manufacture is used by the manufacturer.*
- *Identification of Mill Certificates against material for all parts and ensuring that material complies with drawing requirements and IO material specifications.*
- *Examine all welds visually and where appropriate and witness the corresponding non-destructive examinations and review radiographs*
- *Witness and review tests of Production Proof Samples to the requirements specified.*
- *Witness pressure tests, vacuum tests, functional tests*
- *Detect immediately any non-conformities found during manufacture*
- *Review Data Package*
- *...*

#### **Surveillance assistance 2**

...

### **Retain of IO's skill - Justification for outsourcing**

*The contract is under the NN division's responsibility, which maintains its expertise on verification of the performances of the mechanical structures.*

*Moreover, involved IO staff (TRO, QARO, SRO notably) is performing direct surveillance activities on regular basis (i.e. release of intervention points in Inspection plans), what allows to retain the necessary skills to master the surveillance*

*For each specific system, **responsibility** of the manufactured products' compliance with the requirements belongs to the technical responsible officer, who maintains the competences of inspectors and reviews all documents issued by the external resources.*

*However, for the following reasons, the in-house team needs to be assisted by external resource:*

- Each responsible officer has a large number of contracts to supervise*
- The contracted activities in ITER are under procurement agreements or contracts distributed to the different domestic agencies all around the world. So **on-site resident inspectors** are needed in order to guarantee the efficiency of the control.*

*The reports provided by the external contractors are issued only after thorough review by the NN Division and the Technical Responsible officer of the corresponding PA.*