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# Proceedings of the 14th Working Group on Inspection Practices (WGIP) Workshop

## Answers to the questionnaires

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# 14th WGIP Workshop Proceedings, Heidelberg, Germany

**9-12 April 2018**

Answers to the questionnaires

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# 14th International Nuclear Regulatory Inspection Workshop

## *Inspector's Role in the Regulatory Body's Assessment of the Licensee's Human and Organisational Aspects*

## *How to Inspect a Licensee's Corrective Action Programme*

## and

## *Inspection of the Current Design Basis*

**Heidelberg, Germany**

**8-12 April 2018**

# Questionnaires

Federal Ministry for the Environment, Nature Conservation and Nuclear Safety
Federal Office for the Safety of Nuclear Waste Management
Baden-Württemberg
MINISTRY OF THE ENVIRONMENT, CLIMATE PROTECTION AND THE ENERGY SECTOR

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**"INSPECTOR'S ROLE IN THE REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMAN AND ORGANISATIONAL ASPECTS"**

**COUNTRY: ……**

## NOTES

Only one response per country is required. If more than one person from your country is participating, please co-ordinate the responses accordingly.

Submittals should be sent by e-mail to luc.chanial@oecd.org by 11 February 2018.

## FOREWORD

Human and Organisational Factors (HOF) play a prominent role in nuclear safety in every stage of operation.

As they have a lot of interactions with the licensee, inspectors can have deep insight about licensee organisation through observations and inspections results. They can thus contribute to the regulatory body's (RB's) assessment of HOF (including safety culture).

This task will use the results of previous workshops:

- Budapest (2004): Risk informed inspection, inspection of performance of licensee organisation, and inspection aspects of plant near or at end-of-life.
- Toronto (2006): How International Nuclear Regulatory Inspections Can Promote, Or Not Promote, Good Safety Culture, Inspection of Interactions Between the Licensee and its Contractors and Future Challenges for Inspectors.
- Amsterdam (2010): Experience from Inspecting Safety Culture, Inspection of Licensee Safety Management System, and Effectiveness of Regulator Inspection Process.

## QUESTIONNAIRE

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for a dedicated area, such as electricity, radiological protection, etc.) but NOT to the RB's HOF specialists.

### 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.1 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations? **Y/N**

If yes, what are the areas covered by this framework (Competence management? Qualification of personnel? Management system? Safety culture? Organisational design?, Staffing?, Change management? etc….). Please list the covered areas:

### 2. INSPECTOR'S ROLE IN PERFORMING HOF INSPECTIONS

2.1 What are the main HOF areas covered by inspection?

Please list these areas:

2.2 Are HOF inspections planned on a regular (yearly, etc.) basis, reactive inspections [e.g. after an event, financial issues, results of periodic safety review (PSR), etc.], another trigger?

Please describe:

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?
Please describe:

2.4 Does your organisation have inspectors dedicated to HOF issues? **Y/N**
Please give details

2.5 What kind of support does the inspector receive from HOF specialists (e.g. for inspection preparation, during the inspection, etc.)?
Please describe:

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? **Y/N**
Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available):

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, a template for capturing observations, databases…)? Y/N
Please describe:

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?
Please describe (achievements, outputs, impacts…):

4.2 What is the specific role/added-value of inspectors regarding these "achievements, outputs, impacts".
Please describe:

Is there any specific topic you would like to see discussed at the workshop?

*QUESTIONNAIRE A*:

**"INSPECTOR'S ROLE IN THE REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMAN AND ORGANISATIONAL ASPECTS"**

**COUNTRY: BELGIUM**

## QUESTIONNAIRE

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for a dedicated area, such as electricity, radiological protection, etc.) but NOT to the RB's HOF specialists.

## 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.1 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations? **Y**

If yes, what are the areas covered by this framework (Competence management? Qualification of personnel? Management system? Safety culture? Organisational design?, Staffing?, Change management? etc.…). Please list the covered areas:

- Management system
- Staffing and Competence management (including training)
- Qualification of personnel
- OPEX

## 2. INSPECTOR'S ROLE IN PERFORMING HOF INSPECTIONS

2.1 What are the main HOF areas covered by inspection?
Please list these areas:

- « Leadership and management for Safety »;
- « Human Performance Programme »;
- « Competence and training management »;
- « Training on simulator and reactor operators certification »;
- « Safety Culture Assessment ».

2.2 Are HOF inspections planned on a regular (yearly, etc.) basis, reactive inspections [e.g. after an event, financial issues, results of periodic safety review (PSR), etc.], another trigger?
Please describe:

HOF inspections are mainly performed according to a pluriannual plan but also after an event (reactive inspection) or regarding a critical context having an impact on safety (*e.g.* bankruptcy).

According to the inspection pluriannual plan, all the inspections described in 2.1 have to be organised in a 6-year timeframe.

The specific HOF focus of these inspections is triggered by different inputs/tools at disposal:

- Safety culture assessment based on a RB process capturing safety culture observations.
- OPEX inputs and, more particularly, a trends analysis of HOF issues based on a tool for identifying HOF dimensions in incident reports.
- Results of Safety Factors 9 (OPEX), 10 (Management and organisation), 11 (procedures) and 12 (Human Factors).

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?
Please describe:

During HOF inspections, Bel V inspectors are supported by a HOF safety analyst. The HOF specialist is the pilot for this kind of inspection.
HOF assessments are conducted by a HOF safety analyst.
However, in the framework of safety culture inspections, inspectors are in charge of interviews with the licensee based on qualitative interview techniques.
Inspectors' safety culture observations are the main input for the safety culture oversight process implemented in Belgium (see 3.2.).

2.4 Does your organisation have inspectors dedicated to HOF issues? **N**
Please give details

2.5 What kind of support does the inspector receive from HOF specialists (e.g. for inspection preparation, during the inspection, etc.)?
Please describe:

The HOF safety analyst proposes an inspection program (see 2.2.) and co-pilots the inspection with the inspector in charge of the installation.

The HOF safety analyst is also in charge of the assessment of safety culture observations (see 3.2.) on a yearly basis but with a pluriannual perspective as well. These assessments are inputs for the inspection program.

The HOF safety analyst is also in charge of the organisation of safety culture inspections focused on specific safety culture topics (identified through safety culture assessments) and gathering several inspectors at the scale of a nuclear installation.

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? **Y**
Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available):

HOF training is not strictly included within the inspector's qualification.
However, Bel V developed an internal HOF training session for inspectors and safety analysts to be provided approximately every 3 years. This session is an overall view of HOF basic knowledge (latent error, human error, cognitive biases, performance shaping factors…).
In addition, a training session (theoretical and practical) dedicated to safety culture has been developed and provided to inspectors. Field coaching in safety culture observation are also provided each year to inspectors by a safety culture specialist (HOF Safety analyst). Also to be mentioned are the safety culture workshops (at a section level) aiming at improving the inspectors' capacity to identify safety culture issues. Since 2017, specific training sessions on qualitative interviews techniques are also organised in order to be applied, for instance, during safety culture inspections.

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, a template for capturing observations, databases…)? Yes.
Please describe:

The Belgian Regulatory Body has implemented a safety culture oversight process since 2013. In a nutshell, this process is based on field observations provided by inspectors or safety analysts during any

contact with a licensee (inspections, meetings, phone calls…). These observations are recorded within an observation (excel) sheet – aiming at describing factual and contextual elements – and are linked to IAEA Safety Culture attributes. The process is fully operational.

Operationally speaking, a "Safety Culture Coordinator" (SCC) is in charge of the observation analyses and reporting. Safety culture observations are assessed through four key safety dimensions: i.e. management system, leadership, human performance and learning. For each of these dimensions, observed safety culture strengths and weaknesses are yearly discussed with licensees.

In case of a significant safety (culture) problem, direct reporting to the licensee is considered.
On a regular basis, the SCC provides a series of reports. These reports aim at identifying early signs of safety problems and recording recurrent observations. As a result of this, it could be decided to analyse a licensee performance more in detail in order to understand the underlying causes of a problem or to focus inspections on specific aspects. On an annual basis, a detailed report is released and a synthesis is inserted within the yearly safety evaluation report transmitted to the concerned licensee. The content of this yearly safety evaluation report is discussed with the licensee in order to be sure that the regulatory concerns are understood. Pluriannual safety culture assessments are also performed in order to obtain a deeper cultural picture of a nuclear installation.

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?
Please describe (achievements, outputs, impacts…):

A better understanding of safety culture features and HOF room for improvement regarding a specific installation is an opportunity to request more accurate or deeper actions to a licensee.

As a RB, a deeper knowledge of the HOF characteristics of an installation is also an opportunity to verify the capacity of a licensee to address critical issues as the robustness of a management system, the learning capacity of an organisation, the level of human performance...

In addition, a stronger RB focus on these issues is an incentive for licensees to take into account non-technical safety issues.

4.2 What is the specific role/added-value of inspectors regarding these "achievements, outputs, impacts". Please describe:

The field presence and the knowledge of an inspector are pivotal elements in order to capture HOF safety culture observations feeding further safety assessments by HOF specialist.

Is there any specific topic you would like to see discussed at the workshop?

- What aspects of HOF areas are difficult for inspectors to consider?
- What are the difficulties of inspectors in explaining findings and initiatives from the RB's HOF specialists to the licensees?
- How can the RB's HOF specialists help the inspectors in the RB's assessment of HOF?
- Is there any training or information that could be provided to the inspectors or RB's HOF specialists, so that they are more effective in their work?
- Capacity of inspectors (especially resident) to keep a fresh/independent eye on HOF and cultural elements.

*QUESTIONNAIRE A:*

**"INSPECTOR'S ROLE IN THE REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMAN AND ORGANISATIONAL ASPECTS"**

**COUNTRY: CANADA**

## QUESTIONNAIRE

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for a dedicated area, such as electricity, radiological protection, etc.) but NOT to the RB's HOF specialists.

### 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.1 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations? Yes
If yes, what are the areas covered by this framework (Competence management? Qualification of personnel? Management system? Safety culture? Organisational design?, Staffing?, Change management? etc.…). Please list the covered areas:

Management System, Organisation, Change Management, Safety Culture, Business Continuity, Human Performance Programme, Personnel Training, Personnel Certification, Initial certification examinations and requalification tests, Work Organisation and Job Design, Fitness for Duty, Procedure Development and Use, Reporting and Trending, Accident management and recovery, Severe Accident Management and Recovery, Safety Analysis (credited human actions in Deterministic and Probabilistic analyses), Human Factors in Design.

### 2. INSPECTOR'S ROLE IN PERFORMING HOF INSPECTIONS

2.1 What are the main HOF areas covered by inspection?
Please list these areas:

As per the regulatory framework areas in question 1.1

2.2 Are HOF inspections planned on a regular (yearly, etc.) basis, reactive inspections [e.g. after an event, financial issues, results of periodic safety review (PSR), etc.], another trigger?
Please describe:

Planned on a cyclical basis, according to the areas in the CNSC's Safety and Control Area framework and the topics listed in question 1.1. There is not just one type of HOF inspection, because the domain covers many areas and topics, and is entirely cross-cutting across systems and the licensed activities.

Reactive inspections concerning HOF topics may be carried out, for cause, based on the licensee's performance.

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?
Please describe:

Site inspectors lead the area/topic inspections, which are carried out with support from specialist staff, including HOF specialists.
Inspections have standard verifications (performed where applicable) concerning procedure adequacy, procedural adherence, qualified workers and roles and responsibilities. The standard verifications relate

to inspections of all topics, and HOF specialists are not usually involved, unless they are supporting the specific inspection topic.

2.4 Does your organisation have inspectors dedicated to HOF issues? No.
Please give details:
Site inspectors are generalists and are not dedicated to HOF topics

2.5 What kind of support does the inspector receive from HOF specialists (e.g. for inspection preparation, during the inspection, etc.)?
Please describe:

For planned inspections, the specialists play an active role in preparing the generic inspection guide for a topic, tailoring the working guide for the specific inspection, conducting the inspection at site, analysing facts, preparing findings and writing the inspection report, including developing recommendations and enforcement actions on the licensee.

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? No
Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available):

Inspectors do not receive formal training in HOF.

On-going training does include some HOF familiarisation.

The CNSC intends to include training for inspectors on specific Regulatory Documents. Regulatory documents relate to the following HOF topics : Safety Culture; Fitness for Duty (Hours of Work; Managing Alcohol and Drug Use); Training; Personnel Certification; Nuclear Security Officer Medical, Physical and Psychological Fitness; Ensuring the Presence of Sufficient Qualified Staff. The Canadian Standards Association publishes standards that address HOF topics e.g., aspects of the Management System standard CSA N286-12, and CSA N290.12-14 Human Factors in Design for Nuclear Power Plants, which would be useful to include in training on HOF.

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, a template for capturing observations, databases…)? Yes
Please describe:

Generic inspection guides are prepared by specialists, and tailored for the specific inspections. During an inspection the guide is completed by the inspection team and retained as a permanent record. The CNSC is currently developing software to capture individual findings and provide trending codes.

Inspection Guides that relate to HOF topics include: Emergency Exercise, Fitness for Duty, Hours of Work Limits, Human Factors in Design, Human Performance Programme, Minimum Shift Complement, Operations, Testing and Maintenance Procedure, Verification and Validation, Contractor Management, Conduct of Simulator-based Initial Certification Examinations and Requalification Tests, Conduct of Certified Shift Personnel Simulator-based Requalification Test at Multi-unit Plants, Personnel Training, Problem Identification and Resolution (event investigation, effectiveness, problem resolution, trend analysis).

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?

Please describe (achievements, outputs, impacts…):

A HOF-related inspection is an opportunity to discuss HOF-related good practices with the licensee and to provide recommendations, with the aim of continual improvement. For example, the NPP's human factors in design programmes have matured significantly over the past 10 years, This improvement has been introduced by the NPP licensees over this period, catalysed by a consistent message from the regulator during inspections and by the development of a standard on human factors in design by the industry, with support from CNSC HOF specialists (Canadian Standards Association N290.12-14 Human Factors in Design for Nuclear Power Plants).

Through the inclusion of HOF considerations in inspections and the support of HOF specialists on a variety of inspections, the CNSC identifies and obtains resolution of non-compliances concerning aspects of HOF. Similarly, desktop reviews are undertaken by specialists to identify non-compliances and to obtain resolution.

The CNSC publishes a public annual report, which rolls up the findings for each specific area in the regulatory framework over the past year and provides a summary and rating. Topics included in this process have been listed in the response to question 1.1 above.

4.2 What is the specific role/added-value of inspectors regarding these "achievements, outputs, impacts". Please describe:

The site inspectors can often communicate the message coming from an inspection more clearly than specialists, because they are generalists and understand the licensee's organisation, culture and processes.

Is there any specific topic you would like to see discussed at the workshop?

- the breadth of the HOF domain and the range of areas and topics within it.
- HOF topics that can be verified through traditional inspections
- other compliance verification methods relating to HOF, such as surveys, interviews, observations of activities / meetings, and document review
- consideration of standard HOF topics across the range of inspections (where applicable)
- facts that can be gathered by inspectors and used by HOF specialists to assess or verify given topics
- areas of HOF that need specific clarification for inspectors
- areas of HOF that well-understood by inspectors
- ways that HOF specialists can support inspectors in understanding and inspecting HOF topics.

*QUESTIONNAIRE TOPIC A:*

**"INSPECTOR'S ROLE IN REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMAN AND ORGANISATIONAL ASPECTS"**

**COUNTRY: CZECH REPUBLIC**

## QUESTIONNAIRE

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for dedicated area, such as electricity, radiological protection,…) but NOT to the RB's HOF specialists.

## 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.1 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations? Yes

If Yes, what are the areas covered by this framework (Competence management? Qualification of personnel? Management system? Safety culture? Organisational design?, Staffing?, Change management? …etc.). Please list the covered areas:

Safety culture – site inspectors are obligated to assess safety culture characteristics based on German method KOMFORT in every inspection. Part of it is characteristic of Management system, Qualification of personnel and indirectly also Staffing issue.

Safety culture, management system (and its inherent part of qualification of personnel and staffing issue) and process of identifying and solving problems (operating experience) has to be inspected in every kind of inspection (include resident or site inspectors, system inspectors etc.). If there is no problem found, this area may not be evaluated and recorded in the inspection report.

## 2. INSPECTOR's ROLE in Performing HOF inspections

2.1 What are the main HOF areas covered by inspection?
Please list these areas:

Safety culture is covered mainly as a part of regular site inspections.

Operating experience is covered by special inspections on internal operating experience process (4 inspection for every site per year) and also on external operating experience system (1 inspection for whole licensee per year).

Qualification of personnel and staffing are inspected in every reactor unit refuelling outage. There is also another process of oversight: "licensing of qualification" for personnel and overall inside training programme (of licensee).

Other issues can be addressed in unplanned inspections on concerned topic.

2.2 Are HOF inspections planned on a regular (yearly,…) basis, reactive inspections (e.g. after an event, financial issues, results of PSR…), other trigger?
Please describe:

In the previous paragraph are described planned and regular activities in this area.

Unplanned inspection can by triggered by any concerned topic. In last few years it was always an event. As a part of multi-specialist team there was always RB HOF specialist and HOF issues was part of

investigation (corresponding to HOF contribution to event). Most of those events can be found in our national reports in IRS database.

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?
Please describe:

Inspectors should assess only safety culture characteristics for safety culture data collection. Any other serious issue in this area should be discuss with HOF specialist and should lead either to addition of this specialist to the inspection team, or trigger unplanned HOF inspection on issue.

2.4 Does your organisation have inspectors dedicated to HOF issues? Yes

RB has one inspector dedicated to qualification of personnel and staffing issues.

RB have approximately three inspectors (they also have other duties) dedicated to operating experience feedback system (if you count EOF as a HOF issue).

RB has 1 HOF specialist.

2.5 What kind of support does the inspector receive from HOF specialists (e.g., for inspection preparation, during inspection, etc.)?
Please describe:

Inspector can ask HOF specialist for any advice or help in HOF matter. HOF specialist may become a part of inspection team (can be added during on-going inspection).
Inspector can any HOF issue (e.g. as a result from finished technical inspection) propose as a topic for unplanned HOF inspection.

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? Yes
Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available):

Safety culture training (currently a break in these activities, a new kind of training is being prepared).

International training courses on event investigation are open for every inspector.

Other international training courses in HOF area open for every inspector, if the budget allows (most of the requests for international training courses are approved from historical point of view – RB has sufficient financial resources for this activities, language skills and time schedule of inspectors are the main limit).

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, template for capturing observations, databases…)? Yes
Please describe:

Inspector guide for assessing safety culture characteristics during inspection.

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?

Please describe (achievements, outputs, impacts…):

Licensee is clearly aware that this issue is important to RB. Safety culture issues and search for SC characteristics should be demonstrated in every inspection.

HOF part of even investigation in operating experience process is always an interest of RB and its importance is demonstrated regularly.

HOF issues were a great part of the new operating conditions in process of Czech NPP license renewal. On this basis Czech licensee CEZ started new improving programme on HOF and Safety culture. It is on-going dialogue - with better results in Safety culture area.

4.2 What is the specific role/added-value of inspectors regarding these “achievements, outputs, impacts”. Please describe:

Don’t understand the question.

Is there any specific topic you would like to see discussed at the workshop?

*QUESTIONNAIRE A:*

**"INSPECTOR'S ROLE IN THE REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMAN AND ORGANISATIONAL ASPECTS"**

**COUNTRY: FINLAND**

## QUESTIONNAIRE

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for dedicated area, such as electricity, radiological protection,…) but NOT to the RB's HOF specialists.

## 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.1 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations? Yes

If yes, what are the areas covered by this framework (Competence management? Qualification of personnel? Management system? Safety culture? Organisational design?, Staffing?, Change management? etc…). Please list the covered areas:

- Organisation (e.g. resource plan, medical examination of certain people, competence development)
- Personnel (Qualification)
- Management system(incl. good safety culture, project management, communication, managing organisational changes, self-assessment, non-conformances etc….)
- Safety culture

## 2. INSPECTOR'S ROLE IN PERFORMING HOF INSPECTIONS

2.1 What are the main HOF areas covered by inspection?
Please list these areas:

- Safety culture
- Management
- Atmosphere (of organisation)

2.2 Are HOF inspections planned on a regular (yearly,…) basis, reactive inspections (e.g. after an event, financial issues, results of PSR…), other trigger?
Please describe:

HOF inspections are part of STUK´s inspection programme. Normally planned on a yearly basis (following our internal schedule), but also reactive inspections has been done recently.

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?
Please describe:

It depends whether you are a resident inspector or HQ inspector. Head office plans the HOF inspections (like the other ones also) including time schedule, topics, people to be interviewed, inspected documents etc. Resident inspector gives information beforehand so that the HQ-team has the right information and they have correct situation awareness.

2.4 Does your organisation have inspectors dedicated to HOF issues? Yes.
Please give details:

In our office (operational safety) there is one inspector dedicated to HFE-issues. But then in the same department we have office (Organisation and management systems, "OJO") who are responsible only for this area of inspections.

2.5 What kind of support does the inspector receive from HOF specialists (e.g., for inspection preparation, during inspection, etc.)?
Please describe:

Support is received if asked. I, personally, had interview questions, which I wanted to justify from our HQ (whether questions are relevant or right targeted).

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? Y/N
Not that I knew.
Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available):

We don´t have specific training programme in our office that qualifies inspector.

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, template for capturing observations, databases…)? Yes
Please describe:

We have a database (HAKE) for our observations and findings. It´s meant to be used in every sector, not just in HOF issues.

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?

These processes contains:

- Daily monitoring at plant site by resident inspectors
- Carrying out inspections and interviews of licensees personnel
- Reviewing of plant documents

Please describe (achievements, outputs, impacts…):

4.2 What is the specific role/added-value of inspectors regarding these "achievements, outputs, impacts".
Please describe:

- Inspection memorandums
- Feedback to licensee to steer the licensees actions to improve its methods

Is there any specific topic you would like to see discussed at the workshop?

*QUESTIONNAIRE A:*

**"INSPECTOR'S ROLE IN THE REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMANAND ORGANISATIONAL ASPECTS"**

**COUNTRY: FRANCE**

## QUESTIONNAIRE

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for a dedicated area, such as electricity, radiological protection, etc.) but NOT to the RB's HOF specialists.

## 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.1 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations?

HOF aspects are parts of different thematic inspections. For instance, there are inspections focused on "staff competence" where training and qualifications are inspected. Likewise for "safety management and operation" inspections or "feedback experience" inspections.

## 2. INSPECTOR'S ROLE IN PERFORMING HOF INSPECTIONS

2.1 What are the main HOF areas covered by inspection?

Feedback experience, incident analysis, organisational mechanisms are inspected and assessed but more progress should be made on these issues.

2.2 Are HOF inspections planned on a regular (yearly, etc….) basis, reactive inspections [e.g. after an event, financial issues, results of periodic safety review (PSR), etc.], another trigger?
The inspections can be of different types.

Different circumstances may lead to HOF inspections. Following an event, a near-miss or incident, a reactive inspection may be organised with particular focus on HOF aspects. Programmed and announced inspections are also organised and allow deeper HOF investigations when appropriate. HOF is often looked at since most events derive from HOF as well as structure, system and component aspects.

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?

The inspector role is to performed interviews with any event or incident concerned staff. This staff is often psychologically weakened by the situation. The inspector has to be geared to such interviews to gain maximum information. The inspector may ask to see any staff without line managers beside for instance. Managers are also interviewed afterwards. All information is then processed to get a good review and assessment of the situation.

2.4 Does your organisation have inspectors dedicated to HOF issues?

The ASN does not have dedicated HOF specialists. However, there is a network of HOF correspondents in the regions lead by someone located in the ASN headquarters.

2.5 What kind of support does the inspector receive from HOF specialists (e.g. for inspection preparation, during the inspection, etc.)?

The HOF network mentioned above with the ASN headquarters established guidelines to help generalist inspectors to tackle HOF issues.

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? Non

Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available):
There is a specific HOF training for all ASN newcomers. The purpose of this training is to develop HOF awareness but not to turn inspectors into specialists.

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, a template for capturing observations, databases…)?

Guidelines were established to help inspectors. These guidelines are quite exhaustive and help shed light upon root causes comparing situations to what is expected.

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?

HOF may lead to enforcement actions. For instance, ASN imposed upon Licensees to better monitor maintenance operations especially with contractors. Such a decision was new and not based on structures, systems or components' issues but on practices. Nevertheless, it is difficult to assess the impact of a HOF based decision with clear parameters.

4.2 What is the specific role/added-value of inspectors regarding these "achievements, outputs, impacts".

The added-value is, somehow, a better view of Licensees' organisational mechanisms for the inspectors. HOF regulatory oversight allows HOF performance monitoring and help enforce prevention of any HOF degradations.

*QUESTIONNAIRE A:*

**"INSPECTOR'S ROLE IN THE REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMAN AND ORGANISATIONAL ASPECTS"**

**COUNTRY: GERMANY**

## QUESTIONNAIRE

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for a dedicated area, such as electricity, radiological protection, etc.) but NOT to the RB's HOF specialists.

## 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.1 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations? Yes.

If yes, what are the areas covered by this framework (Competence management? Qualification of personnel? Management system? Safety culture? Organisational design?, Staffing?, Change management? etc.…). Please list the covered areas:

The Atomic Energy Act establishes the national legal foundation containing the licensee's responsibility for nuclear safety as well as the licensee's obligations concerning the installation of a management system, appropriate resources, and training of the personnel. The "Safety Requirements for Nuclear Power Plants" further contain the fundamental regulatory requirements including HOF areas. Those are further specified in the safety standard KTA 1402 "Integrated Management System for the Safe Operation of Nuclear Power Plants". The regulatory framework covers the following areas of HOF requirements:

- Leadership and management for safety
- Management system
- Organisational structure and procedures
- Organisational changes and its management
- Operating experience
- Human resources management including anticipatory staff and competence planning
- Ergonomic working places
- Communication within the licensee and with external parties
- Qualification and training (This topic is further specified in guidelines concerning necessary technical qualification as well as scope and content of the continuous training for particular groups of the personnel.)

## 2. INSPECTOR'S ROLE IN PERFORMING HOF INSPECTIONS

2.1 What are the main HOF areas covered by inspection?
Please list these areas:

There are inspections dedicated especially to the following HOF areas:

- Management system
- Organisational changes
- Qualification and training
- Staffing and staff planning
- Event analysis

Moreover, inspectors pay attention to HOF during all (other) kinds of inspection activities. As an example, there are organisational units whose inspectors continuously collect information concerning the

licensee's safety culture with the help of a systematic HOF indicator system incorporating indicators like the compliance with rules or leadership behaviour.

2.2 Are HOF inspections planned on a regular (yearly, etc.) basis, reactive inspections [e.g. after an event, financial issues, results of periodic safety review (PSR), etc.], another trigger?
Please describe:

Most of the HOF inspections take place on a regular basis and are part of the yearly inspection programme that covers the HOF areas mentioned in 2.1. There are also reactive inspections, for instance, the supervision of the licensee's change management activities based on a previously approved organisational change. Furthermore, potential triggers for HOF inspections are recent recommendations and statements of the Reactor Safety Commission, e.g. on performing integrated event analyses or on monitoring of know-how and motivation loss, and current major developments, e.g. the decision of phase-out in Germany or the transition towards decommissioning.

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?
Please describe:

The inspector collects information about the inspection area. He/she evaluates the information by comparing it with the regulatory requirements or the licensee's operating regulations. He/she gives immediate feedback to the licensee about the inspection findings and hints for further improvements. He/she documents the inspection results in an inspection report.

The inspector triggers, when necessary, the enforcement measures, which are determined after the inspection by the organisational unit of the RB responsible for the specific plant. He/she assists this determination.
(RB's inspectors are authorised to impose enforcement measures immediately during the inspection. However, usually the responsible organisational unit decides on enforcement measures after the inspection.).

The RB's inspectors share their gained information and discuss the inspection results. On a yearly basis, all inspection reports and findings are reviewed and used to evaluate the overall insights from the inspections. Insights and findings concerning safety culture aspects (e.g. data from the systematic HOF indicator system mentioned in 2.1) are also incorporated in the evaluation. This evaluation is the basis for the inspection programme of the next year. The RB feeds back the results to the licensee during their regular/annual meetings dedicated to the licensee's safety management.

2.4 Does your organisation have inspectors dedicated to HOF issues? Yes.
Please give details

The RB has inspectors dedicated to HOF issues, but in a limited number. The majority of inspections in the HOF areas are performed by "generalist inspectors", i.e. professionals from varying fields with supplementary competences in the area of HOF. They perform inspections on a regular basis covering the different HOF topics listed in 2.1. In addition to these inspections dedicated to HOF, all inspections apply an "en-passant" approach that looks at HOF-related and safety culture related aspects during all kinds of inspections. The inspectors are expected to supervise the NPP as a holistic MTO (man, technology, organisation) system.
In addition, there are HOF specialists from technical support organisations (TSO) who perform inspections dedicated to check the licensee's management system on a yearly basis.

2.4 What kind of support does the inspector receive from HOF specialists (e.g. for inspection preparation, during the inspection, etc.)?
Please describe:

If necessary or conducive, the inspectors may ask HOF specialists from a TSO to accompany their HOF inspection. Furthermore, inspectors use recent expert reports by HOF specialists as a guidance on which specific aspects to survey when inspecting a HOF area. For instance, the inspector may check the fulfillment of requirements concerning staffing and staff training that were written down in the TSO report in the course of the preceding approval process of a licensee's organisational change. Finally, inspectors involved in HOF inspections exchange their views amongst themselves, e.g., experiences concerning important HOF topics in the course of decommissioning. This mutual support and exchange of information may result in written guidelines useful for other inspectors as well.

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? Yes.

Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available):

There are:

- training events for the RB's personnel provided by HOF specialists from TSOs, research institutes or consultancy firms, e.g. a seminar dedicated to safety culture organised by the GRS or a symposium dedicated to safety management organised by the TÜV
- collaborations in national committees and councils
- dissemination activities of research results covering, e.g. assessment methods and fostering techniques of safety culture considering the phase-out in Germany
- in-house-seminars or invited talks by national and international HOF experts from nuclear energy or other safety-critical domains covering fields like in-depth event analysis, HPO tools, leadership for safety etc.

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, a template for capturing observations, databases…)? Yes.

Please describe:

With respect to the HOF inspection areas in 2.1, each authority on the federal state ("Länder") level has its own written guidance or checklists. Furthermore, IT tools exist in order to support the documentation of inspection results/inspection reports.

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?
Please describe (achievements, outputs, impacts…):

By establishing the regulatory requirements, the RB provides a framework for the licensee's activities. The RB explicitly, concretely and clearly states its guidelines and reliably acts on them. This way the licensee has to check and improve its processes in order to comply with the RB's requirements.
E.g. the requirement of fixed minimum staff numbers for the safety relevant organisational units has led to a transparent and consistent staff planning.

In the context of a constructive safety-oriented dialogue, the RB informs itself of the licensee's activities and communicates its expectations regarding safety issues. It brings forward suggestions for safety improvements that may go beyond the requirements, e.g., as a reaction to negative trends even if safety limits are not reached yet.

E.g. in inspecting organisational changes and discussing regulatory expectations, the licensee improved the methods and instruments of its change management process.

In addition, the fact that the RB inspects specific HOF areas or issues has a positive impact on the licensee's actions in this area and strengthens the responsible personnel within the licensee's organisation.

4.2 What is the specific role/added-value of inspectors regarding these "achievements, outputs, impacts." Please describe:

In the direct interaction with the licensee's personnel, the inspectors show appreciation of its efforts and discuss concrete possibilities for safety improvements that go beyond the enforceable actions.

Furthermore, the inspectors persistently maintain their efforts to convince about important issues and keep up their requests, e.g. the applications of self-assessments to improve safety culture.

Finally, the inspectors improve the achievements of the RB by feeding back potential improvements concerning the RB's own processes.

Is there any specific topic you would like to see discussed at the workshop?

- methods and criteria for inspecting "leadership behaviour"
- actions and skills of inspectors that promote a constructive dialogue and stimulate safety improvements

*QUESTIONNAIRE TOPIC A:*

**"INSPECTOR'S ROLE IN REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMAN AND ORGANISATIONAL ASPECTS"**

**COUNTRY: HUNGARY**

## QUESTIONNAIRE

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for dedicated area, such as electricity, radiological protection,…) but NOT to the RB's HOF specialists.

## 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.1 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations? Yes.

If Yes, what are the areas covered by this framework (Competence management? Qualification of personnel? Management system? Safety culture? Organisational design?, Staffing?, Change management? etc.…). Please list the covered areas:

NSC (which is the Annex to Govt. Decree No. 118/2011 (VII. 11.)) contains the following areas:

Vol. 1

- 1.8.1 The Nuclear Safety Authority examination of employees
- 1.8.2 Safety important work positions shall only be filled holding a nuclear safety authority license (time validity of the licence)

Vol. 2

- 2.2.2 Safety Culture
- 2.4 Management systems of nuclear facilities

Vol. 3

- 3.3.9 Design requirements for operating nuclear power plants - Human factors

Vol. 4

- 4.4.1 The necessary number and knowledge of personnel that is required for safe operation
- 4.4.1.0700 The physical and psychological suitability of employees working in positions important to nuclear safety
- The licensee must have a comprehensive training policy with training and refresher training programme.
- 4.5.3 The personnel shall be prepared for carrying out accident management activities
- 4.8.3 Belonging to the technical modifications, relevant training programme shall be implemented.

Ministry of National Development Decree No. 55/2012 contains the required qualification of the personnel in the NPP or in all nuclear facilities.

## 2. INSPECTOR'S ROLE IN PERFORMING HOF INSPECTIONS

2.1 What are the main HOF areas covered by inspection?

Please list these areas:

During the inspection the RB supervises the practice of the licensee in the following topics:

- competence management,
- the Procedures suitablity to the NSC
- safety culture
- organisational design and modification
- the operation of the management system
- training policy and process
- self-control

2.2 Are HOF inspections planned on a regular (yearly,…) basis, reactive inspections (e.g. after an event, financial issues, results of PSR…), other trigger?

HOF inspection is a planned regulary supervision of the Authority, three times a year.
Event, authorisation request or organisational modification, can triggered unplanned inspections.

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?

In HAEA all of the HOF specialists are inspectors. Inspections contain interview, document control, Guides and procedures request for controlling, on site inspection.
During the Nuclear Safety Authority exams RB's as inspectors are only the part of the Examination Committee with veto right.

*2.4* Does your organisation have inspectors dedicated to HOF issues? Yes.

There are five member of the HOF specialised inspectors group in the Authority.

2.5 What kind of support does the inspector receive from HOF specialists (e.g. for inspection preparation, during inspection, etc.)?

All the HOF specialists are inspectors in HAEA.

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? Y/N
Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available):

The HOF specialists have college degree in this area, but several trainings are available such as inside-outside auditor training or System management trainings (based on ISO 9001).

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, template for capturing observations, databases…)? Y/N

No specific tools, but Guides (1.32 about Nucl. Safety Authority Examinations, 1.43 about Inspection of nuclear facilities, 1.54 about modification of the organisational and management system, 2.18 about Safety Culture). Database is available in the NPP's intranet.

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?

The planned inspections – which are aimed at different areas annually (safety culture, management system, education, etc.) - are part of the annual inspection programme. We use a Safety Performance Indicator System in the annual safety performance assessment in which the main areas related to HOF are Readiness of staff, Compliance of regulations, Human performance and Persuit for improvement. Regulatory Body examine the safety importance of the events based on the results of event investigation, taking into account international experience as well. The authority made an evaluation about the experiences of the inspections (deviation from the standards, good practices) and forward to the licensee who shall develop and execute an action plan. Regulatory Body shall be informed about the

implementation of the tasks in periodic reports. The actual state of the action plan may be part of subsequent annual inspections.

4.2 What is the specific role/added-value of inspectors regarding these “achievements, outputs, impacts”.

Inspectors have a major impact on the processes through the annual assessment, the investigation of the events, the inspections and the evaluation of the inspections as well.

*QUESTIONNAIRE A:*

**"INSPECTOR'S ROLE IN THE REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMAN AND ORGANISATIONAL ASPECTS"**

**COUNTRY: JAPAN**

## QUESTIONNAIRE

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for a dedicated area, such as electricity, radiological protection, etc.) but NOT to the RB's HOF specialists.

## 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.1 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations? Yes.

If yes, what are the areas covered by this framework (Competence management? Qualification of personnel? Management system? Safety culture? Organisational design?, Staffing?, Change management? …etc.). Please list the covered areas:

Article 43-3-24 (1) of Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors [1] stipulates that any licensee of power reactor operation shall specify operational safety programmes before commencing the operation of the power reactors and obtain the approval of the Nuclear Regulation Authority (hereinafter referred to as NRA).
Article 43-3-24 (4) stipulates that any licensee of power reactor operation and his/her employees must observe the operational safety programmes.
Article 43-3-24 (5) of the article stipulates that any licensee of power reactor operation shall undergo a periodic inspection conducted by the NRA regarding the compliance with operational safety programmes.

Article 92 (1) of NRA Ordinance concerning the Installation and Operation of Commercial Power Reactors stipulates that operational safety programmes are to be organised about items listed in the article 92 (1).
Item (ii) of the article 92 (1) of the NRA ordinance is organisation for fostering safety culture (including involvement of top manager).
Item (iii) of the article 92 (1) of the NRA ordinance is quality assurance of nuclear power facility. This quality assurance includes competence management, qualification of personnel, management system, organisational design, staffing, change management, etc.

## 2. INSPECTOR'S ROLE IN PERFORMING HOF INSPECTIONS

2.1 What are the main HOF areas covered by inspection?

Please list these areas:

List:

- QMS
  - Role assignment in the organisation, Change management of the organisation
  - Education and training of staffs, Competence management, Staff assignment
  - Commitment by company president
  - Human error and its improvement
  - Communication with inside and outside of the organisation
  - Root cause analysis (hereinafter referred to as RCA)

[1] Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (enacted on 1 March 2014) (Provisional Translation)
http://www.nsr.go.jp/data/000067232.pdf

- Safety culture
  - Activities to foster safety culture (including PDCA)
  - Symptom of decline in safety culture

Inspection (Evaluation) of safety culture is conducted from two viewpoints.
One is activity. NRA checks whether licensee is conducting activities to foster safety culture with plan, and PDCA activities to evaluate the activities to foster safety culture works effectively.
The other is symptom. NRA extracts safety culture matters from non-conformity events in licensee's activities and checks symptoms of decline in safety culture.
NRA defines fourteen safety factors, and inspectors conduct evaluation based on the factors.
Inspectors oversee licensee's activities through one year. They evaluate symptom of decline in safety culture, effect of licensee's activities to foster safety culture, etc. from the two viewpoints mentioned above. Then inspectors have discussion with licensee and they notify licensee by a letter of matters which need to be improved in the next year.

From the viewpoint of quality assurance, in operational safety inspection, inspectors focus on specific operational safety activity and conduct process-oriented inspection. Through the inspection, inspectors check validity of QMS, appropriateness of organisational change, appropriateness of competence management, appropriateness of staff assignment, improvement of human errors, etc. of licensee.

2.2 Are HOF inspections planned on a regular (yearly, etc.) basis, reactive inspections [e.g. after an event, financial issues, results of periodic safety review (PSR), etc.], another trigger?
Please describe:

HOF inspections (or similar practice) are planned on a regular basis (quarterly and annual) and reactive inspections.

As regular inspection (quarterly), through quarterly operational safety inspections which are planned as process-oriented inspection and focus on specific operational safety activities, inspectors check validity of QMS, appropriateness of organisational change, appropriateness of competence management, appropriateness of staff assignment, improvement of human errors, etc. of licensee.

As regular practice (annual), NRA evaluates licensee's activities to prevent decline in safety culture and organisational climate, through operational safety inspections, etc. This evaluation is largely divided into three phases by a guidance.

At 1st phase, at the time licensee plans activities to foster safety culture, NRA inspectors check whether the plan reflects matters which were considered to need to be improved in previous year's evaluation.

At 2nd phase, NRA inspectors oversee non-conformity events in licensee's activities, and extract safety culture matters from the events, then assess symptoms decline in licensee's safety culture.
At 3rd phase, by overseeing licensee's activities through 1 year, NRA inspectors conduct evaluation from two viewpoints, validity of licensee's activities to foster safety culture, and symptom of decline in licensee's safety culture. NRA inspectors have discussion with licensee, then NRA inspector notifies licensee by letter of matters to be improved by licensee in the next year.

As reactive inspection, NRA conducts additional inspection as necessary in operational safety inspection to check corrective actions, etc. by licensee, and sometimes NRA inspectors check HOF in the inspection. NRA checks whether licensee conducts RCA in case of events which have significant safety impact. In RCA, direct causes concerning human errors, QMS, etc., and root causes concerning QMS, organisation, safety culture, etc. are extracted. NRA evaluates licensees RCA. Then, NRA oversees continuously implementation and validity of licensee's corrective actions, etc.

In addition, there is a reactive operational safety inspection conducted when licensee carry out safety significant operation, etc. (start or shutdown operation of reactor, fuel changing operation, etc.). In this inspection NRA inspectors check training of operators, competence management, etc.

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?
Please describe:

NRA resident inspectors evaluates licensee's activities to prevent decline in safety culture and organisational climate, based on results of field observation and interviews concerning licensee's plan and its implementation in daily oversight. Inspectors and specialists in NRA headquarters supports the resident inspectors as necessary.

2.4 Does your organisation have inspectors dedicated to HOF issues? Y/N
Please give details

There are specialists of HOF, but there are not inspectors who are dedicated to HOF. NRA resident inspectors are required to take training courses of quality assurance, safety culture, RCA, etc…, and then they acquire basic knowledge about HOF.

2.5 What kind of support does the inspector receive from HOF specialists (e.g. for inspection preparation, during the inspection, etc….)?
Please describe:

As regular practice (annual), when NRA resident inspectors evaluate licensee's activities to prevent decline in safety culture and organisational climate through operational safety inspection, etc…., inspectors and specialists in NRA headquarters support and review the evaluation by the resident inspectors.
In addition, in case of inspections when licensee conducted RCA, inspectors and specialists in NRA headquarters support the inspection.

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? Y/N
Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available):

NRA conducts following three HOF-related trainings:

- Quality assurance (including matters concerning QMS, competence management, staff qualification, organisational design, staff assignment, change management, etc.)
- Human error analysis and RCA
- Safety culture

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, a template for capturing observations, databases…)? Y/N
Please describe:

There are guidance and a template for capturing observations.

About quality assurance (including RCA), there are following guidance:

- Guidelines for regulatory agency to evaluate licensee's autonomous activities to correct non-conformity, etc. concerning direct cause of human error
- Guidelines for regulatory agency to evaluate licensee's RCA

- Guidelines for regulatory agency to evaluate licensee's quality assurance activities

About safety culture, there is following guidance:

- Guidelines for regulatory agency to evaluate licensee's activities to prevent decline in safety culture and organisational climate

This guidance includes a template for capturing observations.
The template has columns to fill in licensee's activities to foster safety culture, inspector's findings, etc.
Based on the information written in the template, inspectors evaluate licensee's activities to prevent decline in safety culture and organisational climate at each NPP every year.

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?
Please describe (achievements, outputs, impacts…):

For example, inspectors evaluate licensee's activities to prevent decline in safety culture and organisational climate, and according to the result of the evaluation, inspectors request improvement activities to licensee ("further enhancement of good communication", etc.).
Such inspectors' activities prompt licensee to improve safety culture and organisational climate, and then leads to enhancement of safety of the NPP.
NRA makes to the public the result of the evaluation, so some municipalities utilise the information for their oversight of licensees.

4.2 What is the specific role/added-value of inspectors regarding these "achievements, outputs, impacts". Please describe:

Activities of resident inspectors, who are familiar with the NPP, include:

- Evaluation of licensee's activities to foster safety culture
- Activities to grasp licensee's HOF problems

These activities promote licensee's consideration of improving their HOF.

Is there any specific topic you would like to see discussed at the workshop?

What kind of trainings are effective to enhance competency of inspectors to evaluate/inspect HOF.

*QUESTIONNAIRE A:*

**"INSPECTOR'S ROLE IN THE REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMAN AND ORGANISATIONAL ASPECTS"**

**COUNTRY: MEXICO**

## QUESTIONNAIRE

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for a dedicated area, such as electricity, radiological protection, etc.) but NOT to the RB's HOF specialists.

## 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.2 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations? Yes.

If yes, what are the areas covered by this framework (Competence management? Qualification of personnel? Management system? Safety culture? Organisational design?, Staffing?, Change management? …etc.). Please list the covered areas:

We follow the recommendation of the NUREG 0711 Human Factors Engineering.
Programme Review Model, document which recommends us cover the following areas primarily:

- Operating Experience Review
- Safety Culture
- Human-Machine Interface Design
- Task Analysis
- Staffing and Qualifications
- Human Reliability Analysis
- Human-System Interface Design
- Procedure Development
- Training Programme Development

And another regulation issued by the IAEA related with the Safety Culture Topics implementation and measurement.

## 2. INSPECTOR'S ROLE IN PERFORMING HOF INSPECTIONS

2.1 What are the main HOF areas covered by inspection?
Please list these areas:

Those indicated in the point 1.1 of this questionnaire.

2.2 Are HOF inspections planned on a regular (yearly, etc.) basis, reactive inspections [e.g. after an event, financial issues, results of periodic safety review (PSR), etc.], another trigger?
Please describe:

HOF inspections are planned, and are part of the Basic Inspection Programme with a biannual periodicity.

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?
Please describe:

Verify compliance with the requirements recommendations of the national framework through the application of check list during the inspection.

2.4 Does your organisation have inspectors dedicated to HOF issues? Yes.
Please give details:

Yes, specifically assigned to the following Topics:

- Human-Machine Interface Design of the main Control Room
- Operational experience Safety Evaluation
- Safety Culture

2.5 What kind of support does the inspector receive from HOF specialists (e.g. for inspection preparation, during the inspection, etc.)?
Please describe:

The specialist support to the inspectors putting all their knowledge, experience and recommendations in the steps of planning, preparation and elaboration of Check list of the topics to be inspected.

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? Y/N

No; Only on the Job Training and Self-study

Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available):

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, a template for capturing observations, databases…)? Y/N
Please describe:

Yes, Guidance and checklist

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?

The RB's process uses Operational Experience (internal and external) to identify and assess events related to HOF. Then, these analyses results are used to modify the objective and scope of our inspections and finally feedback our inspection programme.

4.2 What is the specific role/added-value of inspectors regarding these "achievements, outputs, impacts."
Please describe:
The added-value is that our inspectors have a non-bias perspective to identify and analyse HOF issues within the nuclear installation; therefore, this helps to avoid event recurrence due to human error in all activities in the NPP.

Is there any specific topic you would like to see discussed at the workshop?

*QUESTIONNAIRE A:*

**"INSPECTOR'S ROLE IN THE REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMAN AND ORGANISATIONAL ASPECTS"**

**COUNTRY: POLAND**

## QUESTIONNAIRE

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for a dedicated area, such as electricity, radiological protection, etc.) but NOT to the RB's HOF specialists.

## 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.1 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations? Yes but limited.

- Requirement of qualification of the personnel and preparation of employees during decommissioning stage, staffing and available technologies for use in performing decommissioning activities
- Scope of the preliminary safety report for a nuclear facility includes in Postulated Initiating Event List events caused by human errors that could lead to damage caused by a common cause failure
- Requirement of a sufficient number of employees with qualifications and professional experience relevant to the tasks being performed at the stage of operation of a nuclear facility

If yes, what are the areas covered by this framework (Competence management? Qualification of personnel? Management system? Safety culture? Organisational design?, Staffing?, Change management? …etc.). Please list the covered areas:

## 2. INSPECTOR'S ROLE IN PERFORMING HOF INSPECTIONS

2.1 What are the main HOF areas covered by inspection?
Please list these areas:

- Interview: interview of Research Reactor Staff (operators, management, contractors);
- Monitoring and direct observation: observation of various staff activities like performance of testing and maintenance activities, shift-turnover, compliance of safety requirements in daily routine. Inspector focuses on whether management react for any staff deviations from safety standards and procedures;
- Records and documentation: checking how results of processes and activities are demonstrated for the HOF areas: checking training activities, work schedule (overtime, proper number of staff which has impact for safety).

2.2 Are HOF inspections planned on a regular (yearly, etc.) basis, reactive inspections [e.g. after an event, financial issues, results of periodic safety review (PSR), etc.], another trigger?
Please describe:

In Scheduled Periodic Inspection program there is no dedicated any special inspection for HOF so far. However, each inspector should take care of human factor standpoint while preparing final inspection report, especially during findings evaluation.

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?
Please describe:

See the 2.2 answer.

2.4 Does your organisation have inspectors dedicated to HOF issues? No.
Please give details

2.5 What kind of support does the inspector receive from HOF specialists (e.g. for inspection preparation, during the inspection, etc.)?
Please describe:

There are no HOF specialist dedicated for an inspection, however each inspector can get support in specific individual training activities and training plan from Training and Human resources Unit in the RB.

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? No.
Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available):

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, a template for capturing observations, databases…)? No.
Please describe:

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?
Please describe (achievements, outputs, impacts…):

RB processes dedicated to HOF would allow to inspect or identify issues such as organisation attitude and general behaviour, man/machine interfaces or safety culture. Knowledge of human and organisational factors can allow effective inspection of safety management processes. To achieve this RB must ensure improvement of inspectors skills from HF standpoint, inspectors should be able to describe technical issues and HOF contributor as well.

4.2 What is the specific role/added-value of inspectors regarding these "achievements, outputs, impacts".
Please describe:

The role of inspector is to be aware of existence of factors that affect human behaviour at work depending directly or indirectly from given task and work environment and being aware that dominate causes of accidents are related to inappropriate human behaviour and poor work organisation. Therefore inspector role is to attempt for specific training related to HOF or if possible try to self-train in this area.

Is there any specific topic you would like to see discussed at the workshop?
I would like to see discussion about correct ways of interviewing the operator and employees in the nuclear facility, types of questions which should be asked during the interview and the desired general atmosphere of the inspection.

*QUESTIONNAIRE A:*

**"INSPECTOR'S ROLE IN THE REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMAN AND ORGANISATIONAL ASPECTS"**

**COUNTRY: SLOVAK REPUBLIC**

## QUESTIONNAIRE

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for a dedicated area, such as electricity, radiological protection, etc.) but NOT to the RB's HOF specialists.

## 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.1 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations? Yes

If yes, what are the areas covered by this framework (Competence management? Qualification of personnel? Management system? Safety culture? Organisational design?, Staffing?, Change management? …etc.). Please list the covered areas:

Competence management – requirements on competences of personal with direct and indirect influence on nuclear safety, Qualification of personnel, Management system, Staffing.

## 2. INSPECTOR'S ROLE IN PERFORMING HOF INSPECTIONS

2.1 What are the main HOF areas covered by inspection?
Please list these areas:

Safety culture, licensee's system for training of personnel, staffing, qualification, management system.

2.2 Are HOF inspections planned on a regular (yearly, etc.) basis, reactive inspections [e.g. after an event, financial issues, results of periodic safety review (PSR), etc.], another trigger?
Please describe:

Safety culture inspections are periodical inspections as are the inspections of licensee's system for training of personnel. Changes in staffing and management system are inspected when a change is proposed to regulatory body (RB approves licensee's organisational structure as well as minimal shift composition)

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?
Please describe:

Inspector evaluates the compliance of licensee with the relevant legislation (regulations, atomic act, regulatory guides, etc.). This means that he might interview the licensee's personnel, check documentation, observe licensee's staff during test and regular work etc. If needed he might ask for external support in order to help with specific issues.

2.4 Does your organisation have inspectors dedicated to HOF issues? Yes
Please give details:
As said before NRA performs inspections of safety culture and of licensee's personnel training system periodically. However, if the licensee has performed and organisational change or if an HOR issue arises, the NRA might perform a special inspection on this topic (as has been done in 2017).

2.5 What kind of support does the inspector receive from HOF specialists (e.g. for inspection preparation, during the inspection, etc.)?
Please describe:

Inspectors that perform inspections of safety culture and licensee's systems for training of personnel are specialist in the given area. Regarding other inspection topics related to HOF inspectors rely on their training and previous experience. Also the RB has the possibility to use external consultants for given topic.

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? No.
Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available)

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, a template for capturing observations, databases…)?
Please describe:

All NRA inspections are performed according to inspection procedure. If a procedure does not exist, then the responsible inspector will elaborate one for the given inspection. If needed the regulatory body has the possibility of contracting external support for specific cases.

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?
Please describe (achievements, outputs, impacts…):

RB's processes dedicated to HOF include inspections as well as evaluation of licensee's application for approval of changes in organisational structure and minimal shift composition. These processes give feedback to the licensee on HOF and they might also stop a change related to HOF as well as initiate one.

4.2 What is the specific role/added-value of inspectors regarding these "achievements, outputs, impacts".
Please describe:
Inspector's role in the above mentioned processes is essential. He is the one performing the inspection or evaluation. This means that the result is mainly depended on him. This includes the inspector responsible for given issue as well as all other colleagues involved.

Is there any specific topic you would like to see discussed at the workshop?

*QUESTIONNAIRE A:*

**"INSPECTOR'S ROLE IN THE REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMAN AND ORGANISATIONAL ASPECTS"**

**COUNTRY: SLOVENIA**

## QUESTIONNAIRE

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for a dedicated area, such as electricity, radiological protection, etc.) but NOT to the RB's HOF specialists.

## 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.1 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations? Yes.
If yes, what are the areas covered by this framework (Competence management? Qualification of personnel? Management system? Safety culture? Organisational design?, Staffing?, Change management? …etc.). Please list the covered areas:

"Act on Ionising Radiation Protection and Nuclear Safety" and "Rules on Radiation and Nuclear Safety Factors" contain requirements on:

- Resource management
- Integrated Management system
- Organisational structure
- Safety culture
- Operational Experience Feedback
- Non-conformances and corrective and preventive actions
- Self-assessment, independent assessment
- Continuous improvements

## 2. INSPECTOR'S ROLE IN PERFORMING HOF INSPECTIONS

2.1 What are the main HOF areas covered by inspection?
Please list these areas:

- Management system
- Resource management, training and qualification of personal
- Operational Experience Feedback
- Non-conformances, analysis, corrective and preventive actions
- Safety culture
- Counterfeit, fraudulent and suspect items

2.2 Are HOF inspections planned on a regular (yearly, etc.) basis, reactive inspections [e.g. after an event, financial issues, results of periodic safety review (PSR), etc.], another trigger?
Please describe:

- YES - HOF is included into annual inspection plan. Frequency is once per year.
- SNSA also tries to include HOF aspects into other regular inspections i.e. "Performance of modifications", "Quality control of new installed equipment", "Performance of safety related activities", etc.
- Specific inspections on "Safety Culture" and "Management System" are performed in yearly basis.
- HOF aspects are also included into reactive inspections (following abnormal situations).

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?
Please describe:

- Inspector is responsible to prepare inspection report with facts on inspected topics including HOF aspects, when appropriate. When minor non-conformances are found inspector require corrective actions which are a part of inspection report.
- For more important findings evaluation is made by inspectors and dedicated SNSA experts. Corrective actions (or enforcement) are required by the inspection order.
- After finalisation of inspection review inspector prepares special "observations" regarding safety culture and submit them to SNSA safety culture administrator for further analysis.

2.4 Does your organisation have inspectors dedicated to HOF issues? No.
Please give details

2.5 What kind of support does the inspector receive from HOF specialists (e.g. for inspection preparation, during the inspection, etc.)?
Please describe:

- Several SNSA employees as part of their activities deal also with HOF. They are providing help to inspectors.
- Especially Safety Culture is covered by dedicated employee who has broader knowledge on the issue.

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? Y/N
Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available):

- SNSA employees, including some inspectors, have participated to the IAEA workshops/training courses connected to HOF.
- At the beginning of 2018 national IAEA workshop on Safety Culture was organised at the SNSA.

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, a template for capturing observations, databases…)? Y/N
Please describe:

- SNSA internal procedure is prepared for assessment and control of licensee's safety culture. Template for preparation of safety culture observations is a part of this procedure.
- Special SNSA tracking system (IT tool) is developed to follow implementation of required corrective actions. This is general inspection tool – for all inspection topics, not only HOF.

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?
Please describe (achievements, outputs, impacts…):

Within prepared and performed inspections the SNSA inspectors verifies that:

- operator has sufficient number of qualified and trained personnel;
- non-conformances are timely identified, reported, analysed and corrected;

- activities are performed in accordance with approved procedures/instructions;
- high level of safety culture is maintained in all organisational levels;
- appropriate management system is in place to ensure appropriate level of nuclear safety.

Above listed is maintaining and/or improving sufficient safety level within nuclear installations.

4.2 What is the specific role/added-value of inspectors regarding these "achievements, outputs, impacts." Please describe:

- Inspector is a key person in preparation and implementation of inspection reviews. Only inspector is authorised to require corrective actions or take enforcement actions.
- Of course, other SNSA experts are involved to ensure comprehensive end deep reviews of licensee processes.

Is there any specific topic you would like to see discussed at the workshop?

*QUESTIONNAIRE A:*

**"INSPECTOR'S ROLE IN THE REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMAN AND ORGANISATIONAL ASPECTS"**

**COUNTRY: SWEDEN**

## QUESTIONNAIRE

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for a dedicated area, such as electricity, radiological protection, etc.) but NOT to the RB's HOF specialists.

## 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.1 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations? Yes.

If yes, what are the areas covered by this framework (Competence management? Qualification of personnel? Management system? Safety culture? Organisational design?, Staffing?, Change management? …etc.). Please list the covered areas:

- Organisation and financial, administrative and human resources for the nuclear activity are contained in the Nuclear Activities Act (1984:3)
- Management system and internal audits
- Safety objectives and directives are
- responsibilities, authority and co-operation should be defined and documented
- Planning and decision-making
- Competence management
- Deviation management
- safety in the nuclear activity is routinely monitored and followed up, and deviations are identified and managed
- experience of importance for safety are utlised

## 2. INSPECTOR'S ROLE IN PERFORMING HOF INSPECTIONS

2.1 What are the main HOF areas covered by inspection?
Please list these areas:

- Management systems and processes
- Competence management and staffing
- Human factors engineering
- Safety culture
- Organisational design
- Processes for safety review

2.2 Are HOF inspections planned on a regular (yearly, etc.) basis, reactive inspections [e.g. after an event, financial issues, results of periodic safety review (PSR), etc.], another trigger?
Please describe:
Yes. HOF inspections are planned yearly in accordance to an inspection programme but reactive inspections are also carried out in case of events.

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?
Please describe:

The inspectors role is to provide knowledge of the licensee's organisation and provide the inspectors perspective on HOF issues in the inspection team during inspections or during assessments.

2.4 Does your organisation have inspectors dedicated to HOF issues? No.
Please give details:

Our organisation has HOF specialists dedicated to HOF issues, but inspections and assessments are carried out in close co-operation between inspectors and specialist.

2.5 What kind of support does the inspector receive from HOF specialists (e.g. for inspection preparation, during the inspection, etc.)?
Please describe:

All HOF inspections are planned and prepared by HOF specialists who also lead the inspection, in co-operation with the inspectors.

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? Yes.
Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available):

All inspectors are trained in organisational theory and safety culture.

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, a template for capturing observations, databases…)? No.

Please describe:

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?

Please describe (achievements, outputs, impacts…):

The HOF inspections contributes to the improvement of safety by providing increased understanding of HOF issues within the licensee's organisation and by highlighting the importance of HOF issues in regards of nuclear safety.

4.2 What is the specific role/added-value of inspectors regarding these "achievements, outputs, impacts".
Please describe:

The inspectors play an important role in the interaction between the RB and licensee regarding HOF issues as they can highlight important HOF questions and be an important link between licensee and the RB's HOF specialist.

Is there any specific topic you would like to see discussed at the workshop?

*QUESTIONNAIRE A:*

**"INSPECTOR'S ROLE IN THE REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMAN AND ORGANISATIONAL ASPECTS"**

**COUNTRY: SWITZERLAND**

## QUESTIONNAIRE

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for a dedicated area, such as electricity, radiological protection, etc.) but NOT to the RB's HOF specialists.

## 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.2 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations? Y/N
A: Yes
If yes, what are the areas covered by this framework (Competence management? Qualification of personnel? Management system? Safety culture? Organisational design?, Staffing?, Change management? etc.…). Please list the covered areas:
A: All areas of our Guidelines ENSI-G07 and ENSI-B10. This regulatory framework covers all listed topics and even more. In the frame of the Management System inspections performed on a yearly basis in all nuclear installations, we have focused on the following key topics:

| Year | Key issue | Regulatory requirement |
|---|---|---|
| 2013 | Quality assurance of documents (in depended assessment) | Chap. 7.5 der Guideline ENSI-G07 |
| 2014 | Procurement and customer competency | Chap. 7.9 der Guideline ENSI-G07 |
| 2015 | Competency management | Chap. 4.2, 5, 5.3 und 6.1 der Guideline ENSI-G07 und Chap. 4.1.1 Guideline ENSI-B10 |
| 2016 | Change management | Chap. 7.8 der Guideline ENSI-G07 |
| 2017 | OEF | Chap. 7.7 der Guideline ENSI-G07 |

The performance of the training programmes in different organisational units (engineering, rad. protection, electrical, etc.) were also inspected in all nuclear power plants on a yearly basis.

## 2. INSPECTOR'S ROLE IN PERFORMING HOF INSPECTIONS

2.1 What are the main HOF areas covered by inspection? Please list these areas:
A: See 1.1

2.2 Are HOF inspections planned on a regular (yearly, etc.) basis, reactive inspections [e.g. after an event, financial issues, results of periodic safety review (PSR), etc.], another trigger?
Please describe:
A: We perform planned inspections on a yearly basis with special focus according to actual HOF findings/issues/patterns and reactive inspections (e.g. after an event with root causes showing critical HOF issues).

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?
Please describe:
A: Compliance check (Regulatory requirements – Management system regulations – Work performed in practice)

2.4 Does your organisation have inspectors dedicated to HOF issues? Y/N
Please give details:
A: Yes, the HOF specialist team is doing inspections dedicated to HOF.

2.5 What kind of support does the inspector receive from HOF specialists (e.g. for inspection preparation, during the inspection, etc.)?
Please describe:
A: In ENSI, also specialists are trained to do inspections. Also holistic inspections are perform with the contribution of site inspectors & technical specialists and HOF specialists.

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? Y/N
Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available):
A: Yes, the HOF specialist team has prepared and carried out several times a HOF training mainly dedicated to new inspectors but also as a refreshment offer to the other inspectors.

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, a template for capturing observations, databases…)? Y/N
Please describe:
A: Yes, the ENSI has an approach of an integrated oversight (see also ENSI Report on Oversight Practice, November 2014 on the website). The subsequent matrix helps inspectors a group their findings.

| Subject of assessment / Objectives | | Requirements | | Operational experience | |
|---|---|---|---|---|---|
| | | Design requirements | Operational requirements | State and behaviour of the plant | State and behaviour of man and organisation |
| Levels of defence in depth | Level 1 | | | | |
| | Level 2 | | | | |
| | Level 3 | | | | |
| | Level 4 | | | | |
| | Level 5 | | | | |
| Barrier integrity | Fuel integrity | | | | |
| | Integrity of the primary cooling system boundary | | | | |
| | Containment integrity | | | | |
| Cross-level or cross-barrier importance | | | | | |

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?
Please describe (achievements, outputs, impacts…):
A:

- Increasing awareness/ consideration to HOF aspects.
- Positive influence on the increasing availability of HOF competencies at the regulators and licensees.
- (Continuous) improvement of regulatory framework for HOF.
- Revaluation of the Management System.
- Weak signals data collection on HOF issues for long-term assessment (trend/pattern analysis).
- More systemic/ holistic view – interdisciplinary work on both sides (Involvement of resident/site inspectors into HOF oversight.
- Effective regulator-licensee feedback loops on HOF can increase trust.

4.2 What is the specific role/added-value of inspectors regarding these “achievements, outputs, impacts”. Please describe:
A: Especially site inspectors are able to gather information on ”work-as-done” which adds a lot of value to the effective oversight.

Is there any specific topic you would like to see discussed at the workshop?

IAEA HOF TECDOC Draft on Regulatory Oversight of HOF for Safety of Nuclear Installations provide important input to this topic.

*QUESTIONNAIRE A:*

**"INSPECTOR'S ROLE IN THE REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMAN AND ORGANISATIONAL ASPECTS"**

**COUNTRY: UNITED KINGDOM (UK)**

**QUESTIONNAIRE**

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for a dedicated area, such as electricity, radiological protection, etc.) but NOT to the RB's HOF specialists.

## 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.1 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations? **Y**

If yes, what are the areas covered by this framework (Competence management? Qualification of personnel? Management system? Safety culture? Organisational design?, Staffing?, Change management? …etc.). Please list the covered areas:
Several of the Licence Conditions are HOF-related, notably:

- Licence Condition 10: Training LC 12 Duly Authorised and other Suitably Qualified and Experienced Persons; these two Licence Conditions combined, cover requirements for competency assurance.
- LC11 Emergency Arrangements; this require the Licensee to 'make and implement adequate arrangements for dealing with any accident or emergency arising on site and their effects'
- LC17: Management Systems; requires licensees to have adequate quality management arrangements.
- LC24: Operating Instructions, requires the Licensee to 'ensure that all operations which may affect safety are carried out in accordance with written instructions'
- LC 26 Control and Supervision; requires the Licensee to 'ensure that no operations are carried out which may affect safety except under the control and supervision of suitably qualified and experienced persons appointed for that purpose'.
- LC36: Organisational Capability which includes Management of organisational change and Nuclear baseline (organisational structure and human and financial resources.

In addition, ONR has technical inspection and assessment guides which are used by the inspectors to evaluate compliance with the Licence Conditions.
The Safety Assessment Principles (SAPs) present ONR's expectations when undertaking assessment of Licensee's safety submissions but are also used to inform what is considered to be relevant good practice in development and implementation of arrangements required under the Licence Conditions. There is a suite of HOF specific SAPs with associated Technical Assessment Guides, including:

- Intelligent customer
- Design authority
- Staffing levels and task organisation
- Human factors integration
- Procedure design and administrative control
- Supply chain management
- Internal oversight and challenge culture
- Control and supervision
- Management systems

## 2. INSPECTOR'S ROLE IN PERFORMING HOF INSPECTIONS

2.1 What are the main HOF areas covered by inspection?
Please list these areas:

- Leadership,
- Organisational capability;
- Decision-Making
- Organisational Learning
- Control and supervision
- Management systems
- Operating rules and instructions
- Event reporting and investigation
- Organisational capability and management of organisational change
- Training and competence

2.2 Are HOF inspections planned on a regular (yearly, etc.) basis, reactive inspections [e.g. after an event, financial issues, results of periodic safety review (PSR), etc.], another trigger?
Please describe:

Yes. HOF is a routine component of inspection activity on existing plants; it is integrated into all interactions with the Licensee. Reactive HOF inspections may also be prompted by emerging issues such as event investigation, Licensee improvement programmes, including those resulting from Periodic Safety Reviews.

Inspections are planned on an annual basis for each licensee / site and aligned to a 5-year cycle of topics and regulatory strategy and priorities. Planned inspections include:

- Licence condition compliance inspections
- Safety case informed, system based inspections
- Themed inspections focused upon particular topics, control of work, organisational learning.

ONR also undertakes unannounced inspections; these may be on HOF-related Licence Conditions.

Inspection plans are informed by ONR's corporate strategy and regulatory intelligence, from ONR's Regulatory Intelligence function and more local information obtained by the Nominated Site Inspector.

ONR has also appointed Corporate Inspectors (typically for large, multi-site Licensees), these inspectors plan and deliver a programme of corporate level inspections on HOF-related topics, e.g. organisational capability and leadership and management for safety.

The UK is also embarking on a programme of New Build ONR and this involves a particular focus on HOF matters in the pre-licensing, licensing and construction phase of new nuclear installations with organisational capability forming one of the cornerstones of ONR's intervention strategy.

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?
Please describe:

ONR's regulatory model has roles for Nominated Site Inspectors, who are a focal point for interaction with the Licensees and are also responsible for coordinating regulatory activities on multi-facility sites, Site Inspectors who focus on a single facility/site; these two roles are mainly focused on delivering a programme of licence condition and system based inspections. In addition, Project Inspectors co-ordinate and assessment and inspection of plant modification proposals and Periodic Safety Reviews and Specialist Inspectors undertake assessment/inspection leading or supporting all of these activities. ONR

does not utilise Technical Support Contractors in the planning or undertaking of these inspection activities.

2.4 Does your organisation have inspectors dedicated to HOF issues? Yes.
Please give details

ONR has a team 24 of professionally qualifies and fully warranted HOF inspectors comprising. These are deployed across ONR's divisions (New Reactors/Operating Facilities/Sellafield, Decommissioning, Fuel and Waste). HOF Inspectors lead or support inspections and assessments on HOF-related topics. The Corporate Inspectors (referred to above) are aligned to the HOF specialism.

2.5 What kind of support does the inspector receive from HOF specialists (e.g. for inspection preparation, during the inspection, etc.)?
Please describe:

HOF Inspectors are deployed using the governance of the Head of Human and Organisational Factors. This is in response to the annual inspection planning demand from ONR's divisions or to address particular themes emerging from the central Regulatory Intelligence function and from analysis within the HOF specialism.

HOF specialists may lead or support all aspects of inspection including planning, preparation, delivery, write-up and subsequent management of regulatory issues. Corporate Inspectors are part of the governance arrangements in each division / sub-division, e.g. division / sub-division board meetings, planning meetings etc.

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? ***Y***
Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available):

As described earlier, ONR has Inspectors who are HOF specialists
In addition, HOF is integrated into a number of general ONR internal training courses which are mandatory depending on the role undertaken:

- Site Inspection
- Safety Assessment Core Principles;

These course elements are delivered by HOF Inspectors.

There is also a 3-day dedicated ONR internal HOF course delivered twice per year, this is a 'Recommended' course aimed at providing familiarisation in HOF principles and application. As ONR has HOF inspectors, competence in HOF is not part of the mandatory requirements for inspectors to become warranted. ONR also utilises training in more specialist HOF topics for example Corporate Governance, from external sources (e.g. Civil Service Training and Institute of Directors).

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, a template for capturing observations, databases…)? Yes.
Please describe:

Yes. ONR has standard templates for Inspection, Assessment and Contact reports which are available on the ONR intranet; these are accompanied by guidance in format and content; ONR-INSP-GD-059 Revision five. In addition, an overall rating of the adequacy of the Licensee's arrangements and their implementation is made against the associated Technical Inspection and Assessment Guides and recorded

for each intervention. As described earlier there is a suite of HOF-related guidance documents available to inform this process. Support from HOF inspectors is often sought in addition to the guidance contained in these documents to assess the adequacy, develop appropriate regulatory issues and seek reasonably practicable improvements.

In the area of HOF, ONR has also carried out "deep slice" interventions (structured programme of interviews with a wide selection of staff) to evaluate aspects of licensee's Leadership and Management for Safety arrangements and practices and inform improvements required.

ONR is currently developing specific tools and techniques for evaluating LMfS performance.

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?
Please describe (achievements, outputs, impacts…):

HOF Inspectors are part of the normal regulatory processes; not considered to be ad hoc or 'bolt on'; as such they have regular and frequent contact with Licensees either leading or supporting inspections and assessment. The results of HOF inspections and assessments are subject to the same governance processes as any of ONR's activities and the means of securing improvements is through ONR's system of regulatory 'issues' which is the way ONR communicates its expected improvements, associated licensee actions and timescales.

HOF led inspections such as some themed and deep slice interventions and other forms of interaction have been used to set inspection priorities and drive improvements in licensees on HOF-related topics, e.g. leadership, organisational learning and internal regulator capability.

4.2 What is the specific role/added-value of inspectors regarding these "achievements, outputs, impacts," Please describe:

Site inspectors have significant interaction with the Licensees though a range of inspection activities and other interventions are a valuable conduit to the HOF inspectors bringing intelligence ("the eyes and ears on the ground") on HOF-related matters. Also they add knowledge of the operational context to ONR's generic expectations on HOF. ONR can then plan suitable interventions and improvement programmes on the basis of this. They also monitor and influence progress against regulatory issues and so are pivotal to driving necessary improvements in licensees.

Is there any specific topic you would like to see discussed at the workshop?
We would like to learn how other countries are evaluating Leadership and Management for Safety aspects.

*QUESTIONNAIRE A:*

**"INSPECTOR'S ROLE IN THE REGULATORY BODY ASSESSMENT OF THE LICENSEE'S HUMAN AND ORGANISATIONAL ASPECTS"**

**COUNTRY: UNITED STATES**

## QUESTIONNAIRE

Note: For this set of questions, the term "inspector" refers to resident or site inspector (or other inspector for a dedicated area, such as electricity, radiological protection, etc.) but NOT to the RB's HOF specialists.

### 1. RB'S FRAMEWORK REGARDING HOF INSPECTIONS

1.1 Does your regulatory framework contain requirements, guidance or compliance criteria related to inspection of HOF considerations? Yes.

If yes, what are the areas covered by this framework (Competence management? Qualification of personnel? Management system? Safety culture? Organisational design?, Staffing?, Change management? etc.…). Please list the covered areas: Safety Culture

### 2. INSPECTOR'S ROLE IN PERFORMING HOF INSPECTIONS

2.1 What are the main HOF areas covered by inspection?
Please list these areas:

Safety Culture and Safety Conscious Work Environment

2.2 Are HOF inspections planned on a regular (yearly, etc.) basis, reactive inspections [e.g. after an event, financial issues, results of periodic safety review (PSR), etc.], another trigger?
Please describe:

Safety Culture inspections happen infrequently. The Reactor Oversight Process (ROP) uses inputs from inspections and performance indicators to determine a licensee's status within the Action Matrix. As licensee performance declines, the NRC will respond with increased regulatory oversight. Once licensee performance has degraded such that they have moved into the furthest column (column 4) in the matrix, the NRC will perform a diagnostic inspection, using Inspection Procedure 95003.02 with an emphasis on safety culture.

During biennial Problem Identification and Resolution inspections, the NRC inspects aspects of safety conscious work environment. This includes interviewing site personnel about willingness to raise nuclear safety concerns; a sampling of the licensee's corrective action program; and a review of the alternative methods for raising concerns available to the site personnel, such as Employee Concerns Programmes.

2.3 What is the inspector's specific role in performing HOF inspections and in the assessment performed by the RB?
Please describe:

During the IP95003 inspections, the safety culture specialists perform focus group interviews with a large cross-section of station personnel, and individual interviews with managers and Senior Leaders. The team will also do a thorough review of the Employee Concerns Programme. The team reviews any third party safety culture assessments, self- assessments, root causes, and other information the licensee has regarding culture at the site.

2.4 Does your organisation have inspectors dedicated to HOF issues? Yes.
Please give details:

The NRC has a training and qualification programme for safety culture assessors. This qualification programme is contained within the Inspection Manual Chapter 1245 suite of Inspector Qualifications. It contains On The Job requirements, including conducting focus groups during an inspection. There are also Individual Study Activities. There are two distinct levels of assessors: Safety Culture Assessors and Senior Safety Culture Assessors. All candidates qualify by participating in an interview with a Senior Safety Culture Assessor and a member of management.

2.5 What kind of support does the inspector receive from HOF specialists (e.g. for inspection preparation, during the inspection, etc.)?
Please describe: See answers above

## 3. INSPECTOR'S RESOURCES FOR PERFORMING HOF INSPECTIONS

3.1 Does your RB specifically train the inspectors in HOF areas? Yes.
Please describe (Training as part of inspector's qualification? Areas covered? Other HOF-related training available):
All inspectors take an on-line course on safety culture which includes history and information on specific events that have had an impact on safety culture in commercial power plants.

3.2 Are there specific tools for supporting the inspector's work regarding HOF inspections (guidance, a template for capturing observations, databases…)? Y/N
Please describe:

There are inspection procedures and guidance documents which are available to inspectors, as well as a group of qualified Safety Culture Assessors and Senior Safety Culture Assessors who can assist with inspection activities.

## 4. INSPECTOR'S IMPACT OF HOF ISSUES WITHIN NUCLEAR INSTALLATIONS

4.1 In which way do RB's processes dedicated to HOF contribute to the improvement of safety within nuclear installations?
Please describe (achievements, outputs, impacts…):

The NRC's final Safety Culture Policy Statement (SCPS) was published on June 14, 2011. The SCPS provides the NRC's expectation that individuals and organisations performing regulated activities establish and maintain a healthy safety culture that recognises the safety and security significance of their activities and the nature and complexity of their organisations and functions. Because safety and security are the primary pillars of the NRC's regulatory mission, consideration of both safety and security issues, commensurate with their significance, is an underlying principle of the SCPS.

## QUESTIONNAIRE B:

## HOW TO INSPECT A LICENSEE'S CORRECTIVE ACTION PROGRAMME

COUNTRY: ……

### NOTES

Only one response per country is required. If more than one person from your country is participating, please co-ordinate the responses accordingly.

Submittals should be sent by e-mail to luc.chanial@oecd.org by 11 February 2018.

### FOREWORD

In 2010, the Working Group on Inspection Practices (WGIP) issued a report titled Inspection of Licensee's Corrective Action Programme [NEA/CNRA/R(2010)7]. The observations, commendable practices and conclusion in this report were developed based on the results of a questionnaire to which fourteen countries responded. In general, the commendable practices are of a broad nature and indicate *what* areas of a licensee's corrective action programme (CAP) should be assessed by the regulatory body (RB).

This workshop topic will build on the 2010 report and examine *what* and *how* RB's assess licensee CAPs, as their effectiveness is the foundation to sustain safe operation of nuclear power plants. CAPs cover a wide range of areas; the scope of this workshop topic is limited to those identified below:

- identification and documentation of the problem;
- actions taken to address the problem;
- prioritisation of corrective actions;
- implementation and execution of corrective actions;
- assessment of the effectiveness of corrective actions;
- trend analysis to identify repetitive problems or repetitive causes;
- apparent cause analysis/root cause analysis.

The purpose of this workshop topic is to identify commendable inspection practices and share information about methods, procedures and criteria used to inspect licensees' corrective action programmes.

A RB should have confidence that a licensee's corrective action program is effective; this includes assessments of the effectiveness of corrective actions as well as apparent cause analysis/root cause analysis, and trend analysis.

This workshop topic excludes physical security.

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

1. What are your RB's definition and understanding of a licensee's CAP?

2. Does your RB have legislative and regulatory requirements that obligate a licensee to implement a CAP?
    a) If not, do your licensees have a self-imposed CAP?
    b) Does your RB approve a licensee's CAP? What are the acceptance criteria used by your RB to conduct this approval (e.g. standard)?
    c) Does your RB give credit (i.e. confidence) to a CAP that is shared amongst different sites within the same parent company? For example, is the CAP inspected at only one NPP or all NPPs that are using the same CAP?

3. How does your RB inspect a licensee's CAP?
    a) What is the frequency at which your RB inspects a licensee's CAP? What are the criteria used to modify the frequency of inspection?
    b) Does your RB have inspection guides to inspect a licensee's CAP?
    c) What areas of the licensee's CAP does your RB inspect?

4. What are the criteria used by your RB to inspect the following areas for compliance?
    a) identification and documentation of the problem including the identification of human and organisational factors issues (e.g. licensee reports, non-conformance reports, etc.)
    b) actions taken to address the problem
    c) prioritisation of corrective actions
    d) implementation and execution of corrective actions
    e) assessment of the effectiveness of corrective actions
    f) trend analysis to identify repetitive problems or repetitive causes
    g) apparent cause analysis/root cause analysis

5. Does your RB inspect how a licensee processes corrective actions? If yes, explain what your RB does in the following areas:
    a) deadlines of corrective actions
    b) safety assessments and reporting to RB
    c) approval process by RB and feedback to the licensee
    d) follow-up of open issues
    e) safety culture requirements, including human and organisational factors

Are there any other important topics that you would like to be considered for the workshop?

*QUESTIONNAIRE B:*

**"HOW TO INSPECT A LICENSEE'S CORRECTIVE ACTION PROGRAMME"**

**COUNTRY: BELGIUM**

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

1. What are your RB's definition and understanding of a licensee's CAP?

In Belgium, there is no such thing as a global licensee's CAP. Corrective actions are defined and monitored on different levels in the organisation and via different processes (e.g. via JCOs, NCRs, etc.).
The corrective actions issued by the RB are monitored by the licensee via a "punch list" database and by the RB by a simple MS Access database. The (self-imposed) corrective actions issued by the licensee are reviewed by the RB in the context of the process (e.g. a JCO).
Personal: I know that in some countries all corrective actions are gathered in and managed via a global database. This is not the case in Belgium.

2. Does your RB have legislative and regulatory requirements that obligate a licensee to implement a CAP?
   There is no such obligation.

   a) If not, do your licensees have a self-imposed CAP?

      The licensee has a "punchlist"' database for this.

   b) Does your RB approve a licensee's CAP? What are the acceptance criteria used by your RB to conduct this approval (e.g. standard)?

      There is no approval of the licensee's "punchlist" database.

   c) Does your RB give credit (i.e. confidence) to a CAP that is shared amongst different sites within the same parent company? For example, is the CAP inspected at only one NPP or all NPPs that are using the same CAP?

      Different sites should be allowed to use the same database for CAP, as long as they can clearly extracted the information for their own site.

3. How does your RB inspect a licensee's CAP?
   No global inspection. Each individual corrective action is followed up.
   a) What is the frequency at which your RB inspects a licensee's CAP? What are the criteria used to modify the frequency of inspection?
      NA
   b) Does your RB have inspection guides to inspect a licensee's CAP?
      No
   c) What areas of the licensee's CAP does your RB inspect?
      NA

4. What are the criteria used by your RB to inspect the following areas for compliance?

a) identification and documentation of the problem including the identification of human and organisational factors issues (e.g. licensee reports, non-conformance reports, etc.)

   Correctness and completeness of the information

b) actions taken to address the problem

   Effectiveness and efficiency, timeliness

c) prioritisation of corrective actions

   Importance to nuclear safety

d) implementation and execution of corrective actions

   Fullness and timeliness

e) assessment of the effectiveness of corrective actions
   Sound (technical) judgement

f) trend analysis to identify repetitive problems or repetitive causes

   See if a process for this is in place and is executed on a regular basis

g) apparent cause analysis/root cause analysis

   See if a process for this is in place and is adequately used

5. Does your RB inspect how a licensee processes corrective actions? If yes, explain what your RB does in the following areas:
   a) deadlines of corrective actions

      A reminder is sent when the deadline has expired with request to explain why and if needed to propose a new deadline.

   b) safety assessments and reporting to RB

      This is closely followed up by the licensee himself and a version upgrade is made of the document if the deadline has expired.

   c) approval process by RB and feedback to the licensee

      By Q/A letters/e-mails and regular meetings

   d) follow-up of open issues

      By regular meetings

   e) safety culture requirements, including human and organisational factors

      By specific observations and interviews

Are there any other important topics that you would like to be considered for the workshop?

*QUESTIONNAIRE B:*

**"HOW TO INSPECT A LICENSEE'S CORRECTIVE ACTION PROGRAMME"**

**COUNTRY: CANADA**

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

1. What are your RB's definition and understanding of a licensee's CAP?

   The CNSC does not have a definition for CAP. But it does impose regulatory requirements on licensees that specify they must put a CAP in place.

   All Canadian NPP licensees are required to follow N286-12 Management System Requirements for Nuclear Facilities, which says:

   Problem identification and resolution
   When problems arise, they shall be
   (a) immediately controlled, if required;
   (b) documented;
   (c) evaluated for significance and for underlying cause if deemed by management to be systemic or having impact on meeting business objectives; and
   (d) accepted.
   Actions employed to resolve problems shall be reviewed for effectiveness.

2. Does your RB have legislative and regulatory requirements that obligate a licensee to implement a CAP?

   Licences issued to NPP licensees stipulate: The licensee shall implement and maintain a management system. A CAP is mandatory as part of the management system.

   a) If not, do your licensees have a self-imposed CAP?

      N/A

   b) Does your RB approve a licensee's CAP? What are the acceptance criteria used by your RB to conduct this approval (e.g. standard)?

      No, the CNSC does not approve licensees' CAPs. These are however part of the license and as such, the CNSC inspects them.

   c) Does your RB give credit (i.e. confidence) to a CAP that is shared amongst different sites within the same parent company? For example, is the CAP inspected at only one NPP or all NPPs that are using the same CAP?

      No. Some NPP licensee's in Canada use the same CAP at more than one site. However, the CNSC conducts CAP inspection at all sites.

3. How does your RB inspect a licensee's CAP?
   a) What is the frequency at which your RB inspects a licensee's CAP? What are the criteria used to modify the frequency of inspection?

      **Frequency of CAP inspections:**

As per the baseline inspection plan, the CNSC inspects self-assessments and CAP four times per year. A more detailed inspection of these is conducted once every 5 years.

In addition, Problem Cause and Resolution Effectiveness is inspected twice every 5 years.

**Criteria used to modify the frequency:**
The CNSC uses a graduated approach to enforcement. If many problems are note during routine monitoring and surveillance, inspectors may recommend to management that a formal reactive inspection be conducted in that area. Also, if too many non-compliances or recurring non-compliances are noted during scheduled inspections, a formal reactive inspection may be necessary.

b) Does your RB have inspection guides to inspect a licensee's CAP?

**Yes. There are four inspection guides covering four areas identified below.**

c) What areas of the licensee's CAP does your RB inspect?

**Problem Identification and Resolution (effectiveness review)**

i. To verify Corrective Actions (CA) are completed and those for safety significant and systemic problems are reviewed for effectiveness for the prevention of recurrence.

**Problem Identification and Resolution (problem resolution)**

ii. To verify that the licensee is effectively maintaining the principle 'Problems are identified and resolved' and the associated clauses from the standard providing the interfacing requirements. The guide covers activities from the problem being identified and documented until completion of corrective actions. It includes the actions taken to address the non-conformance, the implementation and execution of corrective actions.

**Problem Identification and Resolution (trend analysis)**

iii. To determine whether the licensee performs trend analysis to identify repetitive problems or repetitive causes.

**Problem Identification and Resolution (event investigation)**

iv. To verify that the licensees programme for Problem Identification and Resolution addresses event investigation (cause analysis) to meet the requirements of N286-05 clause 5.11 or N286-12 clause 4.9, and associated clauses from the applicable standard which provide interfacing requirements.

4. What are the criteria used by your RB to inspect the following areas for compliance?
   a) identification and documentation of the problem including the identification of human and organisational factors issues (e.g. licensee reports, non-conformance reports, etc.)

| Expected Output | Inspection Activity |
|---|---|
| An SCR/AR/PICA is issued when a problem has been identified. | Verify if an SCR/AR/PICA was raised for an identified problem ( i.e. adverse condition). Review Shift Log, calibration data base, work tracking database, CNSC inspectors e-mails sent to licensees after CNSC work around, SCR/PICA reported by other nuclear stations, CNSC Action items as a result of compliance activities, receiving inspection reports. |
| SCR/PICA/AR shall be valid and traceable to the parts and activities to which they refer. | Verify that the SCR/PICA/AR wording in the description is:<br>- Clear,<br>- Unambiguous, and<br>- Provides sufficient information for the problem to be understood by a third party. |
| The necessary SCR/PICA records are identified, retrievable and complete | Review the records for the SCR/PICA/AR identified in section 2 item 1, and using the SCR/PICA database as necessary, verify that:<br>- All attachments referenced in the SCR/PICA are available,<br>- There are no SCRs/PICAs listed as being closed to the SCR/PICA that are not listed in the applicable field, and<br>- All required analysis data fields are complete and the information is clear, unambiguous and complete. |

b) actions taken to address the problem

| Expected Output | Inspection Activity |
|---|---|
| Actions taken to correct the causes of safety significant events and systematic or serious problems are identified as requiring a review for effectiveness. | From the sample of SCR/PICA/AR records obtained in Section 1, for which effectiveness reviews were not carried out, determine whether the need for an effectiveness review has been properly assessed.<br><br>Verify that:<br>- The SCR/PICA did not meet the criteria for the need of an effectiveness review.<br>- The justification is documented and is adequate. |
| Problems shall be assessed and fixed promptly. The timeliness of the reviews are commensurate with the significance of the problem | Assess management reports for metrics from SCR/AR/PICA Database and verify that the SCR/PICA/AR have been addressed (reviewed) in the required timelines by FLM/MRM/CARB etc. as per procedures requirements. |
| The non-conforming items that are required to be prevented from use are isolated or identified | Select a separate sample of items that are prevented from being used and are not already part of section 2 item 1 above, e.g. in the warehouse or in the field,.<br>Verify that:<br>- The non-conforming items have adequate isolation or identification in the field;<br>or<br>- Are identified and segregated in the warehouse, and<br>- are traceable to the documenting record |
| Problems shall be assessed and fixed promptly | Review the records for the SCR/PICA/AR identified |

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| | in section 2 item 1 above and:<br>a. verify that the problem was corrected or the hazard was controlled immediately<br>b. Assess management reports for metrics from SCR Database and verify that the SCR/PICA/AR was addressed per the timeline in licensee procedures. |
| Records show that safe operation has been demonstrated. | Review the records for the SCR/PICA/AR identified in section 2 item 1 above and verify that any operability concerns (including TOE) are addressed<br><br>Assess the actions taken for completeness, i.e. no gaps. |
| Corrective Actions are taken to eliminate identified root causes for serious or systemic problems and they are clearly documented. | Review the records for the SCR/PICA/AR identified in section 2 item 1, for the corrective actions that are specified, and using the SCR/PICA database as necessary, verify that:<br>- All evaluations have at least one Recurrence Control action (RC) to prevent recurrence for category A and B, or reduce the frequency or risk of recurrence for category C.<br>- If Apparent Cause Evaluation (ACE) of category C shows that RC action is not feasible or cost effective and the evaluation has been approved without RC action, verify that the rationale has been documented in the ACE conclusion.<br>- Any transfer of actions is clearly referenced.<br>- Corrective actions are robust and do not show a dependence on administrative solutions, e.g. coaching.<br>- Corrective actions have clear criteria to enable determination of completion i.e. do not depend on a subjective determination of the adequacy of the action taken (e.g. assignments are specific, measurable, achievable, realistic and timely) |
| Lessons learned from licensee's experiences are considered (OPEX). | Examine the RCA/ACE reports, SCRs/PICAs and REG DOC 3.1.1 preliminary and detailed event for the sample in question 16. Verify that there is evidence that internal OPEX was considered (where applicable). |
| Lessons learned from external sources are considered (OPEX). | Examine the RCA/ACE reports and SCRs/PICAs for the sample in question 16.Verify that there is evidence that external OPEX was considered (where applicable) e.g. COG, WANO, other sites etc. |

c) prioritisation of corrective actions

| **Expected Output** | **Inspection Activity** |
|---|---|
| The SCRs/PICAs were generated and categorised according with the approved procedures. | Using the licensee's procedure for classifying events for their Resolution Category and Significance Level identify a sample of RCAs and ACEs performed over the last two years and verify the following:<br><br>**a.** The appropriate document, or record was generated in accordance with the associated |

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| | approved procedure<br>**b.** The event is correctly categorised<br>*Note:* Criteria to consider when choosing a sample of RCA/ACEs events for the inspection may include:<br>**1)** CNSC site staff experience<br>**2)** Safety significance<br>**3)** Risk<br>**4)** Repeated events<br>**5)** Status of completion of the RCA/ACE |
| Systemic adverse conditions (or those impacting business objectives) have been evaluated for significance | From the sample of SCR/PICAs selected for the inspection, identify those records that triggered a causal analysis.<br>Verify that:<br>• The level of causal analysis assigned matches the criteria specified in licensee governance.<br>• The correct level of casual analysis was assigned to the applicable problem. |

d) implementation and execution of corrective actions

| **Expected Output** | **Inspection Activity** |
|---|---|
| Opportunities for improvements are identified and corrective actions are implemented when necessary. | Request a sample of self-assessments reports concerning Effectiveness Reviews for the last 2 years.<br><br>Verify that all areas for improvement observed during self-assessments are appropriately dispositioned and implemented if required. |
| The Problem Identification and Resolution programme and procedure documentation used for the inspection were controlled | Verify the procedure for Problem Identification and Resolution (including SCR/PICA/AR) for the sample selected:<br>- Is uniquely identified<br>- Meets the defined format and presentation<br>- Documentation status is identified<br>- Was distributed by a controlled method<br>- Is not obsolete<br>For the procedures used for the inspection of the sample, review the content for:<br>- Ease of understanding i.e. non- ambiguous language, e.g. ‘shall’ rather than ’should’ or ‘may’,<br>- Clear criteria for acceptance<br>- Authorised by management |
| Cancelled actions are justified and approved. | Review the records for the SCR/PICA/AR identified in section 2 item 1. For any actions that were cancelled verify that:<br>- The SCR/PICA/AR contains evidence that justifies the rationale for the cancellation.<br>- The cancellation is approved.<br>- The individual who updated the SCR/PICA text and date is identified in the text field. |

| | |
|---|---|
| The record of the completion of the Corrective Actions is complete, traceable and verified by appropriate staff. | Review the records for the SCR/PICA/AR identified in section 2 item 1. Refer to the associated databases where necessary. Verify that:<br>- All actions are recorded on the Action Request against the associated assignment of the in the Completion Notes as specified in the licensee governance.<br>- The identity of the person making the entry is recorded.<br>- The action was approved by personnel authorised to sign the record |
| Actions specified on the SCR/PICA/AR are completed within the timeframe specified. | Review the records for the SCR/PICA/AR identified in section 2 question 1. Refer to the associated databases where necessary. Verify that:<br>- Any extensions to assignment due dates are justified and approved in accordance with licensee governance<br>- The number of extensions is within the limits specified by licensee governance and approved by the required level of management. |

e) assessment of the effectiveness of corrective actions

| **Expected Output** | **Inspection Activity** |
|---|---|
| Licensee staff are qualified to perform corrective action effectiveness reviews. | For the sample of effectiveness review records obtain the training records for the individuals identified as performing the review and verify that the individuals have received the required training. |
| Effectiveness Review activities are carried out using approved documents/practices | Perform analysis of inspection results from Section 3. As the site specific guide uses licensee documents for expected outputs, the deficiencies identified by the inspection provides information regarding procedural adherence. The inspection team will determine:<br>- Procedures are followed<br>- Records are completed as per applicable licensee governance. |
| Records demonstrate corrective action to eliminate systemic and serious problems have been reviewed to assess their effectiveness in preventing recurrence. | From the sample of effectiveness review records obtained in Section 1, verify records show that:<br>- Effectiveness reviews address all corrective actions taken.<br>- Effectiveness reviews are completed within the required timeframe after closeout of the last action as specified by licensee governance/records.<br>- Determination of effectiveness is explicitly stated with supporting data. If necessary obtain records of the supporting data and verify it supports the determination of effectiveness. The completion of effectiveness review is clearly stated.<br>- All failed barriers identified in the cause evaluations have been addressed<br>- There is information regarding measures put in place to prevent recurrence.<br>- The analysis of data regarding recurrence demonstrates the measures are sustainable. |

| | |
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| | - If possible perform a visual check to verify the stated corrective actions have been implemented (e.g. revised document). |
| Effectiveness Review reports have been reviewed and approved by appropriate staff to confirm adequacy and completeness. | Review the sample of Effective Review Reports and verify:<br>- The required information has been addressed in the report.<br>- The report indicates the required review and approval (individuals are identified and are dated) |
| For reviews determined as ineffective, those actions have been identified and recorded as problems | For reviews determined to be ineffective, verify that:<br>- This has been recorded<br>- It is traceable to the original effectiveness reviews<br>- Additional required action has been identified. |
| The programme and procedure documentation applicable to problem resolution effectiveness are adequate to ensure the review is completed properly and safely. | For a sample of the licensee procedures referenced in site specific guides, review their content for:<br>- Clear directions i.e. non- ambiguous language, and appropriate use of 'shall' 'should' or 'may',<br>- Clear review criteria,<br>- Procedure directions support the requirements stated in the programmes |

f) trend analysis to identify repetitive problems or repetitive causes

| **Expected Output** | **Inspection Activity** |
|---|---|
| The problem report contains accurate code trending to identify the problems and their causes | Obtain a sample of the problem reports with a low significance level (i.e. 3, 4 and 5). Review the codes on each report. Verify the following:<br>- Each report has codes for problems and their causes.<br>- The identified code is listed in the procedure<br>- The identified code assigned for the problem is accurate as described in the report.<br>- The identify code that assigned for the cause is accurate as described in the report. When the root cause evaluation report or apparent cause evaluation report are issued, compare the information in these reports with information in the problem report.<br>- Whether multiple codes are necessary to describe the problem and its cause. |
| A structure of information sources is established and controlled. | Review the sample of trending data from section 1. Verify the following<br>- The information that is being gathered for trending matches that stipulated in licensee governance<br>- that sufficient data is available for organising and analysing i.e. is there a minimum requirement for data points<br>- over what time period and how often (daily, weekly, monthly, quarterly) is the data being trended and analysed, and the basis for it<br>- determine whether the time frame is historical (reactive) or dynamic (proactive) and the rationale |
| Data is organised and trended to identify repetitive | For the sample from section 1, review the selected |

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| problems or repetitive causes using established techniques and methodologies. | trend analysis techniques (such as Pareto charts and control charts) and:<br>- determine whether the analytical techniques are being applied in accordance with standard statistical practice to deliver meaningful information for analysis<br>- check that the trend coding level of detail is sufficient to represent the content of data being gathered (as specified in licensee governance)<br>- check that the trend codes are correctly assigned<br>- review what types of trend codes are available and rational for the selected one(s) (as specified in licensee governance)<br>- determine whether the technique is appropriate for the selected data and time frame, i.e. Pareto charts for a snapshot in time to identify the 'big hitters' (or 80/20 rule); control charts for measurements over time with statistically determined upper and lower limits<br>- check that repetitive problems are defined<br>- verify that SCRs/PICAs are raised to identify repetitive problems<br>- Verify that the conclusion for the analysis is supported by results (i.e., why an adverse trending was or was not determined) |
| Trend analysis findings and observations of repetitive problems or repetitive causes have been reviewed and approved by the specified level of management. | Review the reports from the sample of section 1 for evidence of approval. Interview the approving manager(s) to determine what it is they are approving, for what purpose and actions planned. |
| Findings and observations of repetitive problems or repetitive causes are documented and reported to senior management and disseminated to affected groups. | Review appropriate reports for any findings and observations of repetitive problems (if any); attend any meeting, if possible, where reports/trend analysis results are presented and discussed. Verify that:<br>a. Management initiates actions in response to the identified problem.<br>b. The problem or cause is clearly identified and actions are identified to correct the problem and prevent any reoccurrence.<br>c. The actions sufficiently address problems to prevent the occurrence of similar potential problems or causes. |
| Individual performing and having responsibilities for assessing the trending codes for individual reported problem are qualified to do so. | Using the sample of records from question 1, obtain the training records for the individuals identified in the records that performed trend coding and verify that the individuals have received the required training and are qualified to perform problem coding. |
| The licensee programme and procedure documentation for trend analysis followed a procedure controlled process. | Verify the sample of licensee programmes and procedures referenced in the guide are controlled. Review documents for the following:<br>a. They are uniquely identified<br>b. They meet the defined format and presentation<br>c. the document status is identified<br>d. They were distributed by a controlled method<br>e. They are not obsolete |

| | |
|---|---|
| The licensee programme and procedures documents for trending are adequate to ensure work is completed properly. All documentation has clear management authorisation. | For the procedures used for the inspection of the sample in question 1, review the content for:<br>• Clear directions i.e. non- ambiguous language, e.g. appropriate use of 'shall', 'should' or 'may',<br>• Clear review criteria<br>• Procedures directions support the requirements stated in the programmes<br>• Authorisation by management is evident |
| Work activities are authorised and carried out using approved practices | For the sample of records in question 1 which have dedicated procedures:<br>• Verify that procedures which governed the work were followed<br>• Verify that all required records generated by the work were completed and approved as per the applicable licensee governance |
| Records are appropriately maintained | For the records identified within the scope of this inspection, verify they are:<br>• Appropriately and completely filled out,<br>• Complete (all attachments are present/ available)<br>• Clearly identified as permanent or temporary (in the procedure or on the record)<br>• Verify that all requested records have been retrieved. |

g) apparent cause analysis/root cause analysis

| **Expected Output** | **Inspection Activity** |
|---|---|
| The extent of the root cause analysis is based on the significance or extent of the problem | Review the records for the SCR/PICA/AR identified in section 2 item 1 above and assess the adequacy of significance level and Resolution Category assignment.<br><br>Verify that the significance level and Resolution Category are correctly assigned as defined in licensee's procedures.<br><br>Verify that the appropriate root cause analysis methods selected e.g. RCA, ACE are aligned with the assigned Significance and Resolution Categories, as defined in the licensee procedure. |
| Systemic adverse conditions (or those impacting business objectives) have been evaluated for significance and for underlying causes, and corrective actions have been identified | Verify that the causes of the adverse conditions and their corrective actions are stated and are aligned with the facts and evidence. |
| Systemic adverse conditions (or those impacting business objectives) have been evaluated for significance and for underlying causes. | Using the ACEs, verify that each contains the following information:<br><br>**a.** Provides a historical context (i.e. whether it is a repeat of an earlier event)<br>**b.** Clear description of the circumstances, people's actions and the flow of events, including actions taken to control the problem |

| | |
|---|---|
| | **c.** Identification of the categorisation and significance level coding that would trigger a ACE<br>**d.** Actions necessary to identify the scope of the problem<br>**e.** An analysis of the controls and influences that affect, people, plant and procedures<br>**f.** The methodologies used for the analysis<br>**g.** Results that show that analytical techniques are appropriately used<br>**h.** Causes are identified that are appropriate based on the analysis provided (rationale and justification are provided)<br>**i.** Causes are tangible, and appropriate to the level of action that was assigned.<br>**j.** There are no findings which do not have an identified cause<br>**k.** Conclusions are supported and consistent with information in the report. |
| Adverse conditions are evaluated for significance. | For the sample of causal analyses which are classified as ACE, review the records and identify those which contain the items below. Compare those found with licensee governance criteria for RCA/ACE. Verify that the correct level of causal analysis was assigned to the applicable problem.<br><br>Indicators in ACE's that suggest that an incorrect causal analysis level was assigned are:<br><br>**a.** Results which indicated that the corrective action was ineffective<br>**b.** Complex adverse conditions with causes assigned to intangible issues such as:<br>i. Inattention to detail,<br>ii. Poor safety culture<br>**c.** Weak/inappropriate corrective actions, such as:<br>i. The constant use of coaching as a solution rather than making the process more robust,<br>ii. Ineffective administrative solutions<br>iii. Inspecting compliance into a process rather than addressing why the process failed<br>**d.** Recurring adverse conditions such as many trend SCRs for the same issue, etc.<br>**e.** Indications where the ***depth*** of the investigation is inconsistent with the ***breadth*** of the related issues i.e. the resources, scope and instructions provided are adequate to identify the cause |

5. Does your RB inspect how a licensee processes corrective actions? If yes, explain what your RB does in the following areas:

   Yes. The CNSC also inspects the robustness of corrective actions to ensure non-recurrence of problems.

a) deadlines of corrective actions

   CNSC verifies if the deadlines the licensee sets for its corrective actions are met (i.e. The CNSC doesn't have regulatory criteria but verifies if the licensee's own criteria are met).

b) safety assessments and reporting to RB

   REGDOC-3.1.1 outlines reporting requirements for NPPs. As part of some CAP inspections, the CNSC verifies if the licensee reported reportable events to the CNSC.

c) approval process by RB and feedback to the licensee

   The CNSC doesn't approve licensee corrective actions. However, the CNSC looks at the licensee's own approval process.

d) follow-up of open issues

   During inspections, the CNSC examines if corrective actions are closed within the proposed dates. If closure dates are not respected by licensees, it is considered to be a non-compliance to procedural adherence.

e) safety culture requirements, including human and organisational factors

   The CNSC verifies that persons involved in the various steps of the CAP are adequately trained and qualified.

Are there any other important topics that you would like to be considered for the workshop?

*QUESTIONNAIRE TOPIC B:*

**"HOW TO INSPECT A LICENSEE'S CORRECTIVE ACTION PROGRAMME"**

**COUNTRY: CZECH REPUBLIC**

**QUESTIONNAIRE**

For preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

1. What is your RB's definition and understanding of a licensee's CAP?

   No definition. Only OPEX programme was implemented in the Czech Republic and within QMS is set process for solving of discrepancies (resp. non-conformances). Therefore only definition of event is in legislative framework.

2. Does your RB have legislative and regulatory requirements that obligate a licensee to implement a CAP?
   a) If not, do your licensees have a self-imposed CAP?

      No, licensee established only OPEX programme and within QMS process for solving discrepancies.

   b) Does your RB approve a licensee's CAP? What are the acceptance criteria used by your RB to conduct this approval (e.g. standard)?

   c) Does your RB give credit (i.e. confidence) to a CAP that is shared amongst different sites within the same parent company? For example, is the CAP inspected at only one NPP or all NPPs that are using the same CAP.

      Licensee implements similar QMS regarding to both NPPs sides in the Czech Republic.

3. How does your RB inspect a licensee's CAP?
   a) What is the frequency at which your RB inspects a licensee's CAP? What are the criteria used to modify the frequency of inspection?

      RB inspects QMS usually annually, only in case of serious findings semi-annually. Inspection is focused on compliance with requirements of regulation for QMS process and with requirements of Atomic Act.

   b) Does your RB have inspection guides to inspect a licensee's CAP?
      RB developed guide for inspection of licensee QMS and guide for inspection of OPEX.

   c) What areas of the licensees CAP does your RB inspect?

4. What are the criteria used by your RB to inspect the following areas for compliance?
   a) identification and documentation of the problem including the identification of human and organisational factors issues (e.g. licensee reports, non-conformance reports, etc.)

   b) actions taken to address the problem

   c) prioritisation of corrective actions

   d) implementation and execution of corrective actions

e) assessment of the effectiveness of corrective actions

f) trend analysis to identify repetitive problems or repetitive causes

g) apparent cause analysis/root cause analysis

All a/m items are inspected during OPEX inspection usually in regular tree months period regarding to both NPP sides in the CzR.

5. Does your RB inspect how a licensee processes corrective actions? If yes, explain what your RB does in the following areas:
   a) deadlines of corrective actions

   b) safety assessments and reporting to RB

   c) approval process by RB and feedback to licensee

   d) follow-up of open issues

   e) safety culture requirements, including human and organisational factors

   All a/m items are inspected during OPEX inspection usually in regular tree months period regarding to both NPP sides in the CzR.

   Are there any other important topics that you would like to be considered at the workshop?

   No.

*QUESTIONNAIRE B:*

**"HOW TO INSPECT A LICENSEE'S CORRECTIVE ACTION PROGRAMME"**

**COUNTRY: FINLAND**

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

1. What is your RB's definition and understanding of a licensee's CAP?

- STUK understands that CAP is licensees own function, which is used in
  - identification and documentation of the problem
  - actions taken to address the problem
  - prioritisation of corrective actions
  - implementation and execution of corrective
  - assessment of the effectiveness of corrective
  - trend analysis to identify repetitive problems
  - apparent cause analysis/root cause analysis
- STUK inspects licensees CAP based on regulatory requirements

2. Does your RB have legislative and regulatory requirements that obligate a licensee to implement a CAP?

Yes, specific requirements are given in

- Radiation and Nuclear Authority Regulation STUK/1/2016 21 §
- Regulatory Guides: YVL A.3 (Management system for a nuclear facility) chapter 7.5 and YVL A.10 (Operating experience feedback of a nuclear facility)

a) If not, do your licensees have a self-imposed CAP?

b) Does your RB approve a licensee's CAP? What are the acceptance criteria used by your RB to conduct this approval (e.g. standard)?

STUK doesn't approve licensees CAP itself, so there is no acceptance criteria either. However some of the corrective actions in licensees event reports are approved by STUK.

c) Does your RB give credit (i.e. confidence) to a CAP that is shared amongst different sites within the same parent company? For example, is the CAP inspected at only one NPP or all NPPs that are using the same CAP.

In Finland there is currently only two different plant types (VVER and BWR) in operation operated by different licensees, so each licensee has their own CAP. However licensees have co-operation with other countries operating similar plants. IRS reports are also reviewed by licensees.

3. How does your RB inspect a licensee's CAP?

a) What is the frequency at which your RB inspects a licensee's CAP? What are the criteria used to modify the frequency of inspection?

This topic is included in RB's Periodic Inspection Programme: 'Operating experience feedback' and 'Management system' on site inspections are carried out under annual plans every second year. In addition STUK can execute additional inspections, when necessary.

The status of licensee's CAP is one of the main object in these inspections. Additional inspections on licensees CAP were executed in 2017 (Olkiluoto) and 2018 (Loviisa). The purpose of these additional inspections was to explore the effectiveness of licensees corrective actions.

RB follows-up on the implementation of the corrective actions taken by the licensee: independent check, spot check, specific follow-up system for documentation.

b) Does your RB have inspection guides to inspect a licensee's CAP?

In general, the scope of inspections is to verify that licensee met the requirements given in YVL-guide A.3 and A.10.

STUK has internal guide YTV 4.a.2, which consist a basic description how the Periodic Inspection Programme inspection should be executed. More detailed inspection guide which contains list of matters to be verified in inspection.

c) What areas of the licensees CAP does your RB inspect?

The areas are:

- Resources and assessment of the organisation's operating experience
- Operating experience policy, objectives and action plans
- Operating experience instructions and procedures
- Utilising external operating experiences at the power plant
- Reports that the power plant has undergone
- Examination of sample cases selected by STUK
- Inquiries and conclusions about the measures that have been initiated by the power plant and their implementation
- International reporting of recent power company events
- International exchange of information, collaboration and databases

4. What are the criteria used by your RB to inspect the following areas for compliance?

a) identification and documentation of the problem including the identification of human and organisational factors issues (e.g. licensee reports, non-conformance reports, etc.)

Regulatory Guide YVL A.10 requirements 503, 707 + 708 + 710 + B03

503. In order to ensure the availability of adequate expertise and that the organisation is able to draw the required lessons, the following resources shall be made available for the analysis and investigation of operational events:

- representation by the various organisational units;
- competence in the methods of investigation;
- technical expertise;
- expertise related to human and organisational performance.

707. A list of the events to be reported is provided in Annex A. The operational event reports listed under items A01 through A07 shall be submitted to STUK for approval and the operational event reports listed under item A08 for information.

708. The operational event report shall be submitted to STUK within two months of the detection of the event.

710. The content of the operational event reports to be submitted to STUK are presented in Annex B. The report shall address the issues to the level of accuracy consistent with what is essential about the event being reported.

B03. *Causes and contributory causes of the event.* The report shall address direct causes and contributory factors. The analysis of the causes shall identify the issues related to the organisation's activities such as management; staff action; assumptions and skills; co-operation and communications; adequacy of resources; the management of external actors and change management; organisational modi operandi and decision making. Additionally, it is necessary to identify the factors in the organisation's safety culture that contributed to the sequence of events.

b) actions taken to address the problem

Regulatory Guide YVL A.10 requirements 512–513, 707 + 708 + 710 + B05

512. In order to prevent the recurrence of the event and to improve the level of safety where necessary, the licensee shall take corrective and preventive actions in response to the findings of the investigation. Such actions may include technical modifications at the plant, its structures, components and systems; changes to operations and operating instructions, surveillance or inspection activities; and changes in the organisation and in the training provided to personnel.

513. A traceable link shall exist between the uncovered root causes and detected flaws on the one hand and the corrective and preventive actions on the other.

707. A list of the events to be reported is provided in Annex A. The operational event reports listed under items A01 through A07 shall be submitted to STUK for approval and the operational event reports listed under item A08 for information.

708. The operational event report shall be submitted to STUK within two months of the detection of the event.

710. The content of the operational event reports to be submitted to STUK are presented in Annex B. The report shall address the issues to the level of accuracy consistent with what is essential about the event being reported.

B05. *Corrective and preventive actions taken to avoid the recurrence of similar events.* An implementation plan shall be prepared for corrective and preventive actions complete with an advance evaluation of the feasibility and effectiveness of such actions. The actions shall be presented in highly concrete terms, the related responsibilities shall be defined and deadlines established for implementation. All actions shall be traceable to identified causes.

c) prioritisation of corrective actions

Regulatory Guide YVL A.10 requirements 514, 707 + 708 + 710 + B05

707. A list of the events to be reported is provided in Annex A. The operational event reports listed under items A01 through A07 shall be submitted to STUK for approval and the operational event reports listed under item A08 for information.

708. The operational event report shall be submitted to STUK within two months of the detection of the event.

710. The content of the operational event reports to be submitted to STUK are presented in Annex B. The report shall address the issues to the level of accuracy consistent with what is essential about the event being reported.

d) implementation and execution of corrective actions

Regulatory Guide YVL A.10 requirements 516, 517, 707 + 708 + 710 + B05, 712

707. A list of the events to be reported is provided in Annex A. The operational event reports listed under items A01 through A07 shall be submitted to STUK for approval and the operational event reports listed under item A08 for information.

708. The operational event report shall be submitted to STUK within two months of the detection of the event.

710. The content of the operational event reports to be submitted to STUK are presented in Annex B. The report shall address the issues to the level of accuracy consistent with what is essential about the event being reported.
712. The licensee shall submit a follow-up report for information if any changes have taken place in the information presented in the report, or if STUK finds this necessary in order to monitor corrective and preventive actions.

B05. *Corrective and preventive actions taken to avoid the recurrence of similar events.* An implementation plan shall be prepared for corrective and preventive actions complete with an advance evaluation of the feasibility and effectiveness of such actions. The actions shall be presented in highly concrete terms, the related responsibilities shall be defined and deadlines established for implementation. All actions shall be traceable to identified causes.

e) assessment of the effectiveness of corrective actions

Regulatory Guide YVL A.10 requirements 603
603. The licensee shall carry out trend analyses and prepare a range of summaries in order to identify weaknesses and movements in trends at the facility by making use of data significant in terms of operating experience feedback, such as maintenance and non-conformity data and other databases.

f) trend analysis to identify repetitive problems or repetitive causes

Regulatory Guide YVL A.10 requirements 603

603. The licensee shall carry out trend analyses and prepare a range of summaries in order to identify weaknesses and movements in trends at the facility by making use of data significant in terms of operating experience feedback, such as maintenance and non-conformity data and other databases.

g) apparent cause analysis/root cause analysis

Regulatory Guide YVL A.10 requirements 506, 508, 707 – 710, B03

506. All events shall be analysed or investigated on a time scale consistent with the safety significance of the event concerned. The analysis or investigation shall at least address the following:

- the sequence of events, situation control and non-conformities relative to normal operation;
- a safety assessment and potential safety significance;
- the circumstances contributing to the event;
- the recurrence of similar events or frequency of similar causes;
- corrective and preventive actions.

508. An analysis of root causes is required when the event involves circumstances that have, or may have, significant implications for plant safety. The analysis of root causes may identify structural problems in the activities of the organisation so as to provide indications for the determination of direct causes, for example. Possible examples of such indications include complex cause-effect relationships, communications problems, or vaguely defined responsibilities.

707. A list of the events to be reported is provided in Annex A. The operational event reports listed under items A01 through A07 shall be submitted to STUK for approval and the operational event reports listed under item A08 for information.

708. The operational event report shall be submitted to STUK within two months of the detection of the event.

709. The analysis of root causes shall be submitted for information within four months of the detection of the reportable event. Generic investigations shall be submitted for information upon completion in accordance with the timetable defined by the licensee.

710. The content of the operational event reports to be submitted to STUK are presented in Annex B. The report shall address the issues to the level of accuracy consistent with what is essential about the event being reported.

B03. *Causes and contributory causes of the event.* The report shall address direct causes and contributory factors. The analysis of the causes shall identify the issues related to the organisation's activities such as management; staff action; assumptions and skills; co-operation and communications; adequacy of resources; the management of external actors and change management; organisational modi operandi and decision making. Additionally, it is necessary to identify the factors in the organisation's safety culture that contributed to the sequence of events.

5. Does your RB inspect how a licensee processes corrective actions? If yes, explain what your RB does in the following areas:

a) deadlines of corrective actions

STUK evaluates the investigation of events carried out by the licensee based on the operational event reports. Deadlines of corrective actions are included in reports.

STUK does spot checks to verify the implementation of corrective actions. STUK has access to licensees electrical systems where the situation of corrective actions is possible to verify. Possible changes in licensee’s corrective actions and deadlines reported in the event reports is required to inform STUK.

b) safety assessments and reporting to RB

Safety assessments are included in the licensees event reports reported to STUK.

c) approval process by RB and feedback to licensee

STUK evaluates the investigation of events carried out by the licensee based on the operational event reports. RB approval is needed for some reports, criteria is defined in Regulatory Guide YVL A.10.

d) follow-up of open issues

STUK follows open issues and reacts if necessary (eg by requesting situation report)

e) safety culture requirements, including human and organisational factors

Safety culture assessments are included in the event reports reported to STUK.

Are there any other important topics that you would like to be considered at the workshop?

If the effectiveness of licensees corrective actions is observed to be inadequate (eg. recurring events), what methods does RB have to react?

*QUESTIONNAIRE B:*

**"HOW TO INSPECT A LICENSEE'S CORRECTIVE ACTION PROGRAMME"**

**COUNTRY: FRANCE**

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

1. What are your RB's definition and understanding of a licensee's CAP?
   In France, ASN's expectation of CAP has been introduced in the order of 7 February 2012 setting the general rules relative to basic nuclear installations. Our understanding of a licensee's CAP is based on the ability of the licensee to identify, characterise and deal with deviations within times appropriate for the risks involved. Since in France the only licensee is operating a standardised fleet (same technology and technically alike), some deviations may affect several NPPs. Therefore, in addition to local deviation management, ASN expects the licensee to have a general overview of generic deviations and to have dedicated procedures to handle them.

2. Does your RB have legislative and regulatory requirements that obligate a licensee to implement a CAP?

   As mentioned previously, the order of 7 February 2012 sets obligations for the management of deviations (articles of Chapter VI) and for continual improvement (articles of Chapter VII), including operating experience feedback. Therefore, the licensee has set up an organisation in order to fulfil these requirements.

   a) If not, do your licensees have a self-imposed CAP?

      Not concerned.

   b) Does your RB approve a licensee's CAP? What are the acceptance criteria used by your RB to conduct this approval (e.g. standard)?

      No, ASN does not approve the licensee's CAP. However, we do perform inspections in order to evaluate if the organisation set up by the licensee meets the regulatory requirements.

   c) Does your RB give credit (i.e. confidence) to a CAP that is shared amongst different sites within the same parent company? For example, is the CAP inspected at only one NPP or all NPPs that are using the same CAP?

      In France, there are 19 NPPs and 58 reactors operated by only one licensee. The same general organisation for the management of deviations is applied in all NPP, even though there are still some local adaptations. In addition, national department of the licensee also have an organisation to deal with generic deviations.

      Nevertheless, ASN does not give credit to the general organisation that is shared by all the NPPs in France. Indeed, it has been observed noticeable discrepancies amongst French NPPs regarding management of deviations.

3. How does your RB inspect a licensee's CAP?

   a) What is the frequency at which your RB inspects a licensee's CAP? What are the criteria used to modify the frequency of inspection?

      There is no fixed frequency to inspect a licensee's CAP. It will depend on whether there is an evolution of the organisation of the licensee's CAP or a negative feedback on the management of some deviations by the licensee. However, as part of reactor outage control by ASN, part of our mission is to ensure that deviations are well managed by the licensee. Therefore, with 58 reactors in operation, the licensee's CAP is examined quite frequently.

   b) Does your RB have inspection guides to inspect a licensee's CAP?

At the time being, we do not have a dedicated guide to inspect the licensee's CAP.

c) What areas of the licensee's CAP does your RB inspect?

The order of 7 February 2012 sets obligations to the licensee to identify, characterise and deal with deviations within times appropriate for the risks involved, but also to ensure traceability of technical control, the verifications and assessments of the measures taken. The purpose of our inspections is to ensure that the licensee's CAP meets with these obligations. Inspections also focus on the decision-making process related to deviations management and the operating experience feedback process.

4. What are the criteria used by your RB to inspect the following areas for compliance?

a) identification and documentation of the problem including the identification of human and organisational factors issues (e.g. licensee reports, non-conformance reports, etc.)

Regarding the identification, criteria are based on the definition written in the order of 7 February 2012.

**deviation**: non-compliance with a specified requirement, or non-compliance with a requirement set by the licensee's integrated management system that could affect the provisions of the second paragraph of article L. 593-7 of the environment code.

**specified requirement**: requirement assigned to an element important for protection, so that it fulfils - with the required characteristics - the function provided for in the demonstration mentioned in the second paragraph of article L. 593-7 of the environment code, or to an activity important for protection so that it meets its objectives with respect to that demonstration;

**element important for protection**: element important for the protection of the interests mentioned in article L. 593-1 of the environment code (public security, health and safety, protection of nature and the environment), that is to say structure, equipment, system (programmed or not), hardware, component or software present in a basic nuclear installation or placed under the responsibility of the licensee, fulfilling a function necessary for the demonstration mentioned in the second paragraph of article L. 593-7 of the environment code, or checking that this function is ensured;

**activity important for protection**: activity important for protection of the interests mentioned in L. 593-1 of the environment code (public security, health and safety, protection of nature and the environment), that is to say activities participating in the technical or organisational provisions mentioned in the second paragraph of article L. 593-7 of the environment code, or that could affect them;

In order to concertise these concepts, ASN is currently writing a guide to help the licensee and also to clarify our expectations.

As for the documentation is concerned, CAP can be considered as an activity important for protection. Therefore, articles 2.5.2 to 2.5.7 of the order of 7 February 2012 are applicable. In particular, article 2.5.6 sets:
"The activities important for protection, their technical control and the verifications and assessments are documented and tracked such that compliance with the specified requirements can be demonstrated in principle and verified retrospectively. The corresponding documents and records are kept up-to-date, readily accessible and legible, protected, conserved under satisfactory conditions, and archived for an appropriate and justified length of time."

b) actions taken to address the problem

The licensee is responsible for defining the appropriate curative, preventive and corrective actions. However, ASN, with the support of its TSO (IRSN), may question the licensee on the measures taken or considered to address a deviation and require additional information to make our own opinion and eventually requires additional actions from the licensee.

c) prioritisation of corrective actions

The order of 7 February 2012 sets "*that the deviations are handled within times appropriate for the risks involved*". For deviation with a limited importance for the protection of the interests mentioned in article L. 593-1 of the environment code, ASN did not defined specific criteria. However, for the deviation of an element important for protection from a specified requirement when that requirement results from the part of the demonstration of nuclear safety relative to risks of radiological accidents, ASN has published in 2015 the guide n° 21 (*processing conformity deviations with respect to specified requirements for elements important for protection*). This guide sets two principles: correction as soon as possible and correction within a time frame appropriate for the risks. The guide presents a procedure for determining correction time frames proportionate to the risks the conformity deviation represents and specifies associated maximum indicative times.

d) implementation and execution of corrective actions

There is no specific criteria for the implementation and execution of corrective actions. Nevertheless, the management of a deviation is documented and tracked by the licensee. So, it is possible, during an inspection, to verify retrospectively that the corrective actions have been implemented according to the time frame identified by the licensee. It gives also the opportunity to evaluate the licensee's CAP for the management of this specific deviation.

e) assessment of the effectiveness of corrective actions

Article 2.6.3 of the Order of 7 February 2012 sets that the licensee has to assess the effectiveness of the actions implemented.

f) trend analysis to identify repetitive problems or repetitive causes

Article 2.7.2 of the Order of 7 February 2012 sets that "the licensee takes all necessary measures, including with respect to outside contractors, to systematically collect and analyse information that could enable it to improve the protection of the interests mentioned in article L. 593-1 of the environment code, whether the information results from the experience of the activities mentioned in article 1.1 on its own installation or on other installations - similar or not - in France or abroad, or from research and development activities". ASN performs inspection to evaluate the organisation of the licensee to take into consideration operating experience feedback. This point is of particular importance for ASN, since the licensee operates a standardised fleet (same technology and technically alike), with some deviations that may affect several NPPs.

g) apparent cause analysis/root cause analysis

Article 2.6.3 of the Order of 7 February 2012 sets that the licensee determine the technical, organisational and human causes of the deviation. For significant event (articles 2.6.4 and 2.6.5), a detailed description of the causes is expected from the licensee and will be examined by ASN.

5. Does your RB inspect how a licensee processes corrective actions? If yes, explain what your RB does in the following areas:

For deviations as defined in ASN's guide n° 21 or for deviations that result in the notification of the significant event, there will be a systematic review of how the licensee processed corrective actions.

For other deviations, ASN performs inspections dedicated to deviation management during which inspectors will look at different deviations and evaluate the CAP of the licensee.

a) deadlines of corrective actions

For deviations that fall under the ASN's guide n° 21, deadlines are clearly defined.

b) safety assessments and reporting to RB

Article 2.6.2 sets that the licensee examines each deviation as soon as possible in order to determine, in particular, its importance for the protection of the interests mentioned in article L.

593-1 of the environment code (including nuclear safety) and, if appropriate, whether it represents a significant event. So, for each deviation, it is expected to have a safety assessment with actual or potential consequences.

Regarding the reporting to ASN, for deviations that represent a significant event, there are legislative and regulatory obligation to notice these deviations to ASN as soon as possible. Moreover, as part of reactor outage control by ASN, information on deviations are frequently transmitted to ASN or inspected by ASN.

c) approval process by RB and feedback to the licensee

There is no legal or regulatory approval process by ASN regarding deviation management. However, there are technical discussions between ASN and the licensee to agree on the deadlines of corrective actions and to have a general overview of the curative, preventive and corrective actions taken or considered by the licensee.

d) follow-up of open issues

Article 2.6.2 sets that the licensee keeps an up-to-date list of the deviations and the state of progress of their processing. This list can be examined during an inspection.

e) safety culture requirements, including human and organisational factors

This is part of the root causes analysis.

Are there any other important topics that you would like to be considered for the workshop?

No.

*QUESTIONNAIRE B:*

**"HOW TO INSPECT A LICENSEE'S CORRECTIVE ACTION PROGRAMME"**

**COUNTRY: GERMANY**

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

1. What are your RB's definition and understanding of a licensee's CAP?
   See answer 2

2. Does your RB have legislative and regulatory requirements that obligate a licensee to implement a CAP?

   Question 1 and 2 are answered together.

   In Germany there is no requirement for a specific form of CAP. Nonetheless, the requirement KTA 1402 "integrated management for the safe operation of nuclear power plants" states that the licensee of the plant has treat corrective actions via the management system.

   Two essential systems are required and being used:

   1) 1st: failure alarms: Failures, faults and deviations are reported and lead to corrective actions. According to KTA 1402 this process is called "failure alarm". Requirements regarding failure alarms are e.g.:There has be a central database-system for failure alarms. Every employee shall be authorised to be able to initiate or issue failure alarms. This central database-system is usually called "Betriebsführungssystem (BFS)"
      - Each failure alarm shall be classified with regard to its safety relevance in order to be able to prioritise its urgency. In this context, it shall be checked whether the alarm requires reporting in accordance with AtSMV (ordinance regulating reporting of events which are safety relevant).
      - The subsequent activities shall be surveilled until final removal of the cause of failure.
      - The responsible persons and units of the pending failure alarm have to be notified by the BFS. Besides that, failure alarms shall be included and discussed in the systematic information exchange (e.g., morning conference).

   2) 2nd: tracking of improvement-measuresLike failure alarms, also improvement measures need to be planed and supervised via the central database-system. This includes prioritisation and coordination of different measures as well as deadlines for planning and implementation and the assessment of the effectiveness.

      a) If not, do your licensees have a self-imposed CAP?

         The licensees use processes of their management system (especially the two mentioned systems) to keep track of CA.

      b) Does your RB approve a licensee's CAP? What are the acceptance criteria used by your RB to conduct this approval (e.g. standard)?

         Not the CAP itself is approved. But the processes of the management system are inspected.

      c) Does your RB give credit (i.e. confidence) to a CAP that is shared amongst different sites within the same parent company? For example, is the CAP inspected at only one NPP or all NPPs that are using the same CAP?

Since corrective actions are usually plant specific, an inspection at only one site is usually not feasible. Aspects of the management system applicable to several sites can be inspected for all sites at once. The implementation needs to be reviewed for each site.

3. How does your RB inspect a licensee's CAP?

Since there is no CAP as a single process, the CAP itself is not inspected. Nonetheless the corrective actions are part of nuclear oversight. So the following answers apply to the corrective actions rather than the CAP.

a) What is the frequency at which your RB inspects a licensee's CAP? What are the criteria used to modify the frequency of inspection?
   Corrective actions are part of regular inspections. Besides that, there are inspections concerning the safety management system that also include aspects of CAP.
b) Does your RB have inspection guides to inspect a licensee's CAP?
   No.
c) What areas of the licensee's CAP does your RB inspect?
   Inspections concerning the safety management system typically also include aspects of CAP like:
   i. event analyses / root cause analyses
   ii. self-assessments, reviews and audits
   iii. failure alarms
   iv. requirements by the authority resulting from inspections and approvals

Besides that, inspectors review the status of corrective actions according to the topic they inspect. Corrective actions that require hardware changes within the plant typically require an approval for modification by the authority; therefore, the action including its implementation is reviewed and inspected as part of the modification process.

4. What are the criteria used by your RB to inspect the following areas for compliance?

Question 4 and 5 are answered together. Specific information is provided beneath the mentioned items.

Safety relevant deviations are reportable events. Therefore the aspects mentioned in question 4 and 5 are evaluated, reviewed or inspected for each specific event. That means that deadlines, required reports and safety assessment etc. are specified in the frame of the event. E.g. an event involving safety culture issues will require detailed analyses of human and organisational factors while an event regarding technical issues requires technical analyses and in some cases design changes of equipment as a measure to prevent reoccurrence.

The CA resulting from self-assessments, peer reviews, internal reviews, process audits, QA audits etc. are checked during inspections of the management system. These inspections are process-oriented. Thus it is checked how the CA are derived, decided, recorded, implemented and evaluated regarding their effectiveness. In order to review more comprehensive insights like trend analyses for small events, the licensees are required to report to the authority regularly. Results of these reports are addressed e.g. during the annual inspection of the licensees management system.

The acceptance criteria are based on national regulation, requirements of the license, the state of science and technology. The processes are also evaluated according the inspector's expectations. The inspector may give hints for further improvements.

a) identification and documentation of the problem including the identification of human and organisational factors issues (e.g. licensee reports, non-conformance reports, etc.)

In case of reportable events, there is an official form that needs to be filled out for the supervisory authority. Criteria are completeness, correctness and timeliness.

b) actions taken to address the problem.

The deviations have to be removed and appropriate measures against repetition have to be taken.

c) prioritisation of corrective actions.

The priorisation is based on the safety relevance. Actions which are necessary for further safe operation are of highest priority while actions leading only to minor improvements are of lower priority.

d) implementation and execution of corrective actions.

Are the CA performed according to the applying regulation (modification process, maintenance process or integration in training programme)?

e) assessment of the effectiveness of corrective actions.
Is the operator's plan for the assessment of the efficiency appropriate? Are the results of the operator's assessment plausible?

f) trend analysis to identify repetitive problems or repetitive causes.

Is the event related to previous events? Is there an increase or decrease of the number of fault alarms regarding certain topics?

g) apparent cause analysis/root cause analysis.

Are the analyses performed according to the state of the art?

5. Does your RB inspect how a licensee processes corrective actions? If yes, explain what your RB does in the following areas:
   a) deadlines of corrective actions.

   Evaluation if the deadlines are reasonable and met, justification of new deadlines in the case they are not met.

   b) safety assessments and reporting to RB.

   Review of the operator's report (all aspects addressed?).

   c) approval process by RB and feedback to the licensee.

   Information by sending the TSO report and/or a letter of the RB with additional requirements in the case of insufficient evaluation or CA.

   d) follow-up of open issues.

   Review of operator's reports to the fulfilment of open issues.
   e) safety culture requirements, including human and organisational factors.

Evaluation of operator's report about his in-depth event analysis and the CA derived from it, evaluation of the measures to monitor the effectiveness of the CA.

Are there any other important topics that you would like to be considered for the workshop?

*QUESTIONNAIRE B:*

**"HOW TO INSPECT A LICENSEE'S CORRECTIVE ACTION PROGRAMME"**

**COUNTRY: JAPAN**

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

1. What are your RB's definition and understanding of a licensee's CAP?

   A licensee is being required to construct a method of CAP for preventing recurrence of non-conformance in accordance with a law (the Reactor Regulation Act) and ordinances. The licensee provides own rules for CAP, and applies it for operation of their plants.

2. Does your RB have legislative and regulatory requirements that obligate a licensee to implement a CAP?

   Yes, the NRA has. A licensee provides operational safety programmes including CAP. The operational safety programmes are reviewed by the NRA on conformity to regulatory requirements from the perspective of whatever the quality assurance system is established or not. The licensee operates plants in accordance with the operational safety programmes and own procedures. The NRA's inspectors inspect plants to identify actual safety conditions and determine whether there is a violation of safety programmes including CAP.

   a) If not, do your licensees have a self-imposed CAP?

      As described above.

   b) Does your RB approve a licensee's CAP? What are the acceptance criteria used by your RB to conduct this approval (e.g. standard)?

      As shown in above, the NRA permits a licensee's operational safety programmes including CAP. Especially, it is considered that the programmes confirm requirements of JEAC-4111(Quality assurance code for safety in nuclear power plants, based on ISO-9001) at the examination by the NRA, The rules of CAP is also prescribed by the licensee's procedures in detail.

   c) Does your RB give credit (i.e. confidence) to a CAP that is shared amongst different sites within the same parent company? For example, is the CAP inspected at only one NPP or all NPPs that are using the same CAP?

      Basically the CAP is inspected at only one NPP. However, the inspector can inspect the CAP for all NPPs by inspecting the quality management system it is applied for several NPPs in common way when NPPs are operated by the same company.

3. How does your RB inspect a licensee's CAP?

The NRA inspects a licensee's CAP to identify actual safety conditions and determine whether there is a violation of safety programmes. In addition, inspectors patrol plants periodically.

   a) What is the frequency at which your RB inspects a licensee's CAP? What are the criteria used to modify the frequency of inspection?

The NRA inspects a licensee's operational safety programmes including CAP four times a year. To change its frequency, we should ask for revision of ordinances. In addition, inspectors patrol plants periodically. Inspectors can determine the frequency of the patrol freely but the lowest frequency is shown in a guide of the NRA.

a) Does your RB have inspection guides to inspect a licensee's CAP?

Implemental method of operational safety inspection including CAP is provided by rules of the NRA (e.g. the procedure for operational safety inspection). Besides, there is a guide of inspection it describes a point of view for inspection of CAP.

c) What areas of the licensee's CAP does your RB inspect?

- identification and documentation of the problem;
- actions taken to address the problem;
- prioritisation of corrective actions;
- implementation and execution of corrective actions;
- assessment of the effectiveness of corrective actions;
- trend analysis to identify repetitive problems or repetitive causes;
- apparent cause analysis/root cause analysis.

4. What are the criteria used by your RB to inspect the following areas for compliance?

The NRA inspectors usually use procedures and guides shown below for each area. (No.5 is used in area 'g. apparent cause analysis/root cause analysis' especially.)

- The procedure for operational safety inspection.
- The inspector's manual for local offices.
- Licensee's operational safety programmes.
- The guide to the operational safety inspection and examination.
- The guide to the assessment about a licensee's root cause analysis. (RCA)
- The guide to the assessment about a licensee's safety culture and the degradation of the organisational culture.

a) identification and documentation of the problem including the identification of human and organisational factors issues (e.g. licensee reports, non-conformance reports, etc.)

b) actions taken to address the problem

c) prioritisation of corrective actions

d) implementation and execution of corrective actions

e) assessment of the effectiveness of corrective actions

f) trend analysis to identify repetitive problems or repetitive causes

g) apparent cause analysis/root cause analysis

5. Does your RB inspect how a licensee processes corrective actions? If yes, explain what your RB does in the following areas:

Yes.

a) deadlines of corrective actions

Confirm appropriateness of the process of discussion, establishment and implementation of deadlines.

b) safety assessments and reporting to RB

Reporting to the NRA is not required although the NRA can inspect process and results of a licensee's safety assessments.

c) approval process by RB and feedback to the licensee

The NRA doesn't have approval process, although the NRA keeps CAP in under surveillance and takes some administrative action when it is needed.

d) follow-up of open issues

For instance, when a licensee's process has some problems such as delay of the CAP process or overdue, the NRA inspector works to grasp the situation and judges if its reason is acceptable. Inspectors pointed out the problems as necessary.

e) safety culture requirements, including human and organisational factors

An inspector measures a licensee's performance on safety culture once a year. A licensee is notified the result of the evaluation. (The result is also open to public in the NRA's Website.)

Are there any other important topics that you would like to be considered for the workshop?

Nothing in particular.

*QUESTIONNAIRE B:*

**"HOW TO INSPECT A LICENSEE'S CORRECTIVE ACTION PROGRAMME"**

**COUNTRY: MEXICO**

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

1. What are your RB's definition and understanding of a licensee's CAP?

   The Corrective Action Programme (CAP) of the Licensee is one of the programmes of continuous improvement that aims to promote the reporting of unsuitable conditions relating to Nuclear Safety, Radiation Safety, Industrial Security, Physical Security, the compliance with regulations, the reliability of the plant or the commercial concerns, the resolutions of the unsuitable conditions will prevent the recurrence of improper conditions.

   The RB's understanding of a licensee's CAP is:

   Establish guidelines to be followed to assess the effectiveness of the program for the identification and resolution of problems (PI & R), in order to verify:

   1) If the licensee is identifying and introducing into the corrective actions programme (CAP) deficiencies and classifying them properly.

   2) If the licensee is identifying and implementing corrective action effectively.

   3) If the installation personnel have a favourable disposition to the identification and resolution of deficiencies.

   4) If the licensee is following and assessing the effectiveness of the program of corrective actions and the program of independent internal evaluations and self-assessments, and correcting its deficiencies.

   As well as to anticipate the identification of deficiencies before, these values exceeded the Action Matrix thresholds levels and track resolution of these deficiencies.

2. Does your RB have legislative and regulatory requirements that obligate a licensee to implement a CAP?

   Yes, there is the 10CFR Appendix B. 10CFR 50.73 "Reportable events", and License Condition.

   a) If not, do your licensees have a self-imposed CAP?

      No, our licensee has to comply with regulations.

   b) Does your RB approve a licensee's CAP? What are the acceptance criteria used by your RB to conduct this approval (e.g. standard)?

      No, the Regulatory Body doesn´t approve a licensee's CAP.

   c) Does your RB give credit (i.e. confidence) to a CAP that is shared amongst different sites within the same parent company? For example, is the CAP inspected at only one NPP or all NPPs that are using the same CAP?

In Mexico there are only one site.

3. How does your RB inspect a licensee's CAP?

Yes, our Regulatory Body inspects a licensee's CAP.

a) What is the frequency at which your RB inspects a licensee's CAP? What are the criteria used to modify the frequency of inspection?

Our RB inspects a licensee's CAP: the resident's inspectors inspect the licensee's CAP quarterly and annual bases; there is a biannual inspection from the headquarters.

Our RB doesn't have a criterion for modify the frequency of inspections.

b) Does your RB have inspection guides to inspect a licensee's CAP?

Yes, Identification and problems resolution

c) What areas of the licensee's CAP does your RB inspect?

1. External Evaluation

i. Requirements of the operational license,
ii. Commitments to the Regulatory Body,
iii. Findings and actions resulting from inspections of the residence (OR),
iv. Findings and actions derived from programmed inspections (OI),
v. External evaluations as INPO, WANO, IAEA, etc.

2. Internal Independent Evaluations

a. Audits of Quality Assurance
b. Managements assessments

3. Internal assessments and self-assessments

i. Reportable events analysis,
ii. Degraded conditions and non-conformities,
iii. Minor incidents analysis,
iv. External operational experience, analysis,
v. Legislation analysis,
vi. Training analysis,
vii. Materials and spare parts,
viii. Maintenance rule,
ix. Maintenance management,
x. Indicators programme.

4. Routine activities

i. Changes in documents, procedures and plans,
ii. Design modifications,
iii. Temporary modifications,
iv. Degraded conditions or non-conformities,
v. Adverse Conditions to quality,
vi. Work orders,

vii. Monitoring and testing requirements,
viii. Radiological protection incidents: dosimetry, radiological problems, areas contamination,
ix. Incidents in chemical parameters,
x. Non-conformities with the operational condition (inoperabilidades, applications for temporary modifications),
xi. Human errors,
xii. Industrial safety incidents that caused accidents.

4. What are the criteria used by your RB to inspect the following areas for compliance?

a) Identification and documentation of the problem including the identification of human and organisational factors issues (e.g. licensee reports, non-conformance reports, etc.)

The identification and documentation of the problem: must be complete and accurate, in accordance with their importance for the safety and the ease with which it was detected. It will be taken into account aspects relating to operability and reporting, generic implications, common cause and previous occurrences.

b) actions taken to address the problem

The identification of corrective actions focusing on the correction of the problem, to avoid its repetition, the priority is given and the establishment of deadlines for their implementation. If it is requiring a long time to implement, check whether provisional or compensatory actions are required.

c) prioritisation of corrective actions

The inspectors review the categorisation of the deficiency in accordance with their importance for the safety, the need for the analysis of causes: apparent cause and root cause.

d) implementation and execution of corrective actions

The inspectors review and verify that the operator implements and executes corrective actions in a timely manner, keeping focus in the importance for safety. (including within these attributes would be the justification of delays in compliance with the dates of implementation of corrective actions). If permanent corrective actions need an important time to be implemented, verify interim actions or compensatory actions have been identified and implemented to minimise the problem and/or mitigate its effects until the permanent action can be implemented.

e) assessment of the effectiveness of corrective actions

To assessment the effectiveness of corrective actions, the inspectors will take into account the annual programme of self-evaluations, and where applicable, continuous self-evaluations and the time taken will be reviewed. During this review will verify compliance with the annual programme, self-assessment methodology, the definition of expectations, the quality of the evaluation and documentation of the results.

f) trend analysis to identify repetitive problems or repetitive causes

The inspectors review the trend analysis reports looking for significant negative trends associated with the human performance or operation of the equipment. If the inspectors find a

negative trend, they must check the activities of monitoring, control and evaluation of CAP and the programme's internal assessments that the holder is carrying out.

g) apparent cause analysis/root cause analysis

The inspectors review the identification of the apparent cause analysis or root cause analysis and the causes of the deficiency. This attribute will be evaluated only for significant conditions adverse to quality.

5. Does your RB inspect how a licensee processes corrective actions?

Our Regulatory Body doesn’t inspect how a licensee processes corrective actions.

If yes, explain what your RB does in the following areas:

a) deadlines of corrective actions

b) safety assessments and reporting to RB

c) approval process by RB and feedback to the licensee

d) follow-up of open issues

e) safety culture requirements, including human and organisational factors

Are there any other important topics that you would like to be considered for the workshop?

*QUESTIONNAIRE B:*

**"HOW TO INSPECT A LICENSEE'S CORRECTIVE ACTION PROGRAMME"**

**COUNTRY: POLAND**

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

1. What are your RB's definition and understanding of a licensee's CAP?

   In Poland there is no definition of CAP in Polish law or procedures.

2. Does your RB have legislative and regulatory requirements that obligate a licensee to implement a CAP?

   a) If not, do your licensees have a self-imposed CAP?

   b) Does your RB approve a licensee's CAP? What are the acceptance criteria used by your RB to conduct this approval (e.g. standard)?

   c) Does your RB give credit (i.e. confidence) to a CAP that is shared amongst different sites within the same parent company? For example, is the CAP inspected at only one NPP or all NPPs that are using the same CAP?

   In Poland there is no legislative or regulatory requirements that obligate a licensee to implement a CAP. However we have some requirements to do corrective actions during implementation of integrated managements system (IMS) and on the basis of conclusion from operating experience assessment. Apart from this, one of the license condition required from licensee inform RB within 90 days after failure SSC safety class 1 or 2 about the reason of these, making of analyses and implement corrective action which will eliminate this possibility in the future.

3. How does your RB inspect a licensee's CAP?

   a) What is the frequency at which your RB inspects a licensee's CAP? What are the criteria used to modify the frequency of inspection?

   b) Does your RB have inspection guides to inspect a licensee's CAP?

   c) What areas of the licensee's CAP does your RB inspect?

      N/A

4. What are the criteria used by your RB to inspect the following areas for compliance?

   a) identification and documentation of the problem including the identification of human and organisational factors issues (e.g. licensee reports, non-conformance reports, etc.)

   b) actions taken to address the problem

   c) prioritisation of corrective actions
   d) implementation and execution of corrective actions

   e) assessment of the effectiveness of corrective actions

f) trend analysis to identify repetitive problems or repetitive causes

g) apparent cause analysis/root cause analysis

N/A

5. Does your RB inspect how a licensee processes corrective actions? If yes, explain what your RB does in the following areas:

a) deadlines of corrective actions

b) safety assessments and reporting to RB

c) approval process by RB and feedback to the licensee

d) follow-up of open issues

e) safety culture requirements, including human and organisational factors

N/A

Are there any other important topics that you would like to be considered for the workshop?

*QUESTIONNAIRE B:*

**"HOW TO INSPECT A LICENSEE'S CORRECTIVE ACTION PROGRAMME"**

**COUNTRY: SLOVENIA**

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

1. What are your RB's definition and understanding of a licensee's CAP?
   A process which ensure that:
   - all deviations, non-conformances as well as proposals for improvements, are timely identified and documented,
   - deviations are corrected,
   - major deviations and proposals are analysed,
   - all proposed corrective actions to prevent repetition of deviation or actions to implement improvements are effectively implemented.

2. Does your RB have legislative and regulatory requirements that obligate a licensee to implement a CAP?
   Yes.
   a) If not, do your licensees have a self-imposed CAP?
   b) Does your RB approve a licensee's CAP? What are the acceptance criteria used by your RB to conduct this approval (e.g. standard)?
      SNSA does not approve licensee's CAP. CAP is a subject for inspection reviews.
   c) Does your RB give credit (i.e. confidence) to a CAP that is shared amongst different sites within the same parent company? For example, is the CAP inspected at only one NPP or all NPPs that are using the same CAP?
      N/A for Slovenia – We have only one NPP.

3. How does your RB inspect a licensee's CAP?
   a) What is the frequency at which your RB inspects a licensee's CAP? What are the criteria used to modify the frequency of inspection?
      - 4 times per year.
      - We would increase the frequency when
        - significant deviation in number of non-conformances/deviations in time period
        - deviations/non-conformances are not timely analysed
        - many corrective actions are delayed in implementation
        - inadequate classification of deviation

   b) Does your RB have inspection guides to inspect a licensee's CAP?
      No.

   c) What areas of the licensee's CAP does your RB inspect?
      - reporting-identification and documentation of the problem, as well as proposals for improvements (e.g. modifications);
      - analysis of reported problems (or proposals);
      - classification of the problem;

- root cause analysis;
- proposed corrective actions, prioritisation of CAs;
- implementation and execution of CAs;
- assessment of the effectiveness of CAs;
- performance indicators related to CAP (repetitive problems and causes, delayed actions, critical components…).

4. What are the criteria used by your RB to inspect the following areas for compliance?

a) identification and documentation of the problem including the identification of human and organisational factors issues (e.g. licensee reports, non-conformance reports, etc.)

- During inspections on CAP records in licensee's database are reviewed – SNSA can check many of parameters, such as problems related to particular equipment, EQ related problems, safety culture related problems and also HOF.
- Furthermore SNSA inspector are able to review the content of particular records as well as corresponding analysis and defined corrective actions. HOF aspect should be addressed by the licensee.

b) actions taken to address the problem

- Immediate corrective actions to fix the problem are implemented.
- Short and long-term corrective actions with deadlines to prevent repetition are defined based on apparent or root cause analysis.

c) prioritisation of corrective actions

- Records into CAP database have to be classified based on safety importance (1 to 4, 1=serious impact to safety, 4=for trending). For classification 1 and 2, sometimes also 3 root cause analysis have to be done. Corrective actions are defined based on RCA results.
- Furthermore records into CAP database have to be prioritised – U (urgent) -> to be fixed in 24 hours; 1 -> remedy of the problem should be started at least next working day; D (date) – minor deviation, remedy should be finished by the determined date.

d) implementation and execution of corrective actions

- CAs are fully implemented by the given deadline.
- Work orders are prepared and approved.
- Works are executed in accordance to procedures and guidelines.
- Appropriate QA and QC control is carried out. All works are recorded.

e) assessment of the effectiveness of corrective actions

- Operation of the particular equipment is strictly followed – walk-downs, inspection, testing
- Safety important equipment is involved into quarterly System Health reports. System are linked with their performance indicators. In case of effectively defined and implemented CAs corresponding performance indicator should improve in the next periods.
- Records in CAP database for particular equipment is followed. There should be no similar records.

f) trend analysis to identify repetitive problems or repetitive causes

- Performance indicators are in place to follow repetitive problems and causes.
- PI's results a regularly analysed, CA's are defined and implemented.

g) apparent cause analysis/root cause analysis

- ACAs/RCAs are prepared for problems in classification 1, 2 or 3. Results are also sent to the SNSA.
- Content of analysis is in accordance to regulation JV9 (Rules on Operational Safety of Radiation or Nuclear Facilities)

5. Does your RB inspect how a licensee processes corrective actions? If yes, explain what your RB does in the following areas:
Yes.

a) deadlines of corrective actions

- Review of licensee records
- Follow-up inspections
- Licensee reporting to the SNSA

b) safety assessments and reporting to RB

- Reporting in accordance to regulation JV9 (Rules on Operational Safety of Radiation or Nuclear Facilities)
- Follow-up inspections

c) approval process by RB and feedback to the licensee

- SNSA reviews licensee's reports and root cause analysis. Open questions or additional requests are cent tp the licensee.
- If needed additional inspection is performed based on the SNSA review.

d) follow-up of open issues

- Requirements for additional reporting
- Follow-up inspections

e) safety culture requirements, including human and organisational factors

- Inspection reviews on safety culture
- Review of licensee reports
- Follow-up inspections

Are there any other important topics that you would like to be considered for the workshop?

*QUESTIONNAIRE B:*

**"HOW TO INSPECT A LICENSEE'S CORRECTIVE ACTION PROGRAMME**

**COUNTRY: SPAIN**

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

1. What are your RB's definition and understanding of a licensee's CAP?
   A corrective actions programme shall be set up for the integral management of the identification, assessment and resolution of non-conformities and proposals for improvement identified as a result of external assessments, independent internal assessments, self-assessments and the suggestions and findings of the personnel and during the performance of routine plant operation and maintenance activities, and of regulatory requirements and commitments.

2. Does your RB have legislative and regulatory requirements that obligate a licensee to implement a CAP?
   There are regulatory requirements in Nuclear Safety Council (CSN) Instruction number IS-19, of October 22nd 2008, on the requirements of the nuclear facilities management system. Non-conformities shall be categorised depending on their importance for plant safety and reliability.

   a) If not, do your licensees have a self-imposed CAP?

      N/A

   b) Does your RB approve a licensee's CAP? What are the acceptance criteria used by your RB to conduct this approval (e.g. standard)?

      No, the CSN doesn´t approve the licensee's CAP. The CSN has an inspection program.

   c) Does your RB give credit (i.e. confidence) to a CAP that is shared amongst different sites within the same parent company? For example, is the CAP inspected at only one NPP or all NPPs that are using the same CAP?

      It´s not the case in Spain. There is a specific CAP for each site and there are inspections in each site.

3. How does your RB inspect a licensee's CAP?

   a) What is the frequency at which your RB inspects a licensee's CAP? What are the criteria used to modify the frequency of inspection?
      There are some different inspection related to CAP.
      One perform (routine review) by Resident Inspectors with a daily frequency (30 minutes with free access to the database).
      Each baseline inspection (specialist from headquarters) review issues related to the inspection.
      One annual inspection by Resident Inspectors (40 man hours).
      One Triennial team inspection (specialist from quality assurance headquarters, resident inspectors) (200 man hours).

   b) Does your RB have inspection guides to inspect a licensee's CAP?
      Yes, the CSN has an inspection procedure, PA.IV.201," Identification, Resolution& Programme (PI&R)".

c) What areas of the licensee's CAP does your RB inspect?

The CSN inspect the different areas of CAP:

- Identification and documentation problems.
- Resolution problems (prioritising evaluating, and correcting problems)
- Trend analysis.

4. What are the criteria used by your RB to inspect the following areas for compliance?

a) identification and documentation of the problem including the identification of human and organisational factors issues (e.g. licensee reports, non-conformance reports, etc.)
There are some different criteria to inspect these areas depending on the kind of inspection: routine, baselines, annual or triennial.

During the routine review the Resident inspectors screen each item entered into the corrective action programme. After there is a screening of the issue to review the preliminary documentation based on equipment failures, inadequate maintenance work practices, personnel errors, inadequate risk assessments, management and emergent work control problems, procedure deficiencies, or non-compliances with procedures or regulatory requirements.

During the annual inspection, there is a more detailed review of some issues identified on the routine inspection. The issues can be related to non-conforming or degraded conditions, Maintenance Rule Issues.

During the triennial inspection, the issues are related to:

- Licensee audits
- Completed self-assessments/audits
- Quality assurance audits
- CSN inspections (issues identified during baseline, supplemental, and reactive inspections, issues related to violations and documented findings (more than minor safety significance), violations of regulatory requirements).
- Corrective Maintenance incidences
- Repetitive Corrective Maintenance
- Employee concerns.
- Licensee event reports
- Degraded/Non-conforming conditions
- Minor incidents
- Operating experience
- Functional failures of estructures systems and components (SSC)
- Incidences implementation design modifications
- Temporary design modifications
- Incidents in surveillance or post maintenance testing
- Inoperability SSC
- Incidences in reception of materials
- Non-conformance materials
- Incidences on contractor tasks
- Plant observations
- Out of service SSC
- Radiological Incidences

- 10CFR21

In each issue, the identification of the deficiency, it must be complete and accurate, in accordance with its importance and ease of detection. The aspects related to operability/reportability, extension of the condition, generic implications, common cause and previous occurrences will also be taken into account.

b) actions taken to address the problem
Review all the actions of the issues selected.

c) prioritisation of corrective actions
Review prioritisation of the problem's resolution commensurate with the safety significance.

d) implementation and execution of corrective actions
Review that actions are appropriately focused to correct the problem and avoid repetition, and the completion of corrective actions are in a timely manner consistent with the importance for safety. If the permanent corrective actions need an important time to be implemented, verify that the provisional actions and/or compensatory measures have been identified and implemented to minimise the problem and/or mitigate its effects until the permanent action can be implemented.

e) assessment of the effectiveness of corrective actions
Review there is no repetition of the problems.

f) trend analysis to identify repetitive problems or repetitive causes
Inspectors consider emerging or existing cross-cutting themes, SSCs failures. If the problems are repetitive, review if they have been scaled in the categorisation of its importance.

g) apparent cause analysis/root cause analysis
At least the inspectors reviewed all analysis/root cause analysis for Reportable Events, SSCs failures related to Maintenance Rule.

5. Does your RB inspect how a licensee processes corrective actions? If yes, explain what your RB does in the following areas:

a) deadlines of corrective actions

Review open actions with high priority (related to safety significance of the issue), justifications for extending corrective action due dates.

b) safety assessments and reporting to RB

Review in triennial inspection

c) approval process by RB and feedback to the licensee

In Spain, the licensee open special registers in the PAC for these items as "Regulatory requirement".

d) follow-up of open issues

Review in triennial inspection.

e) safety culture requirements, including human and organisational factors

There is a baseline inspection each two year in this area with specialists from headquarters.

Are there any other important topics that you would like to be considered for the workshop?

*QUESTIONNAIRE B:*

**"HOW TO INSPECT A LICENSEE'S CORRECTIVE ACTION PROGRAMME"**

**COUNTRY: SWEDEN**

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

1. What are your RB's definition and understanding of a licensee's CAP?

   This is a programme with the primary goal to learn from experiences, mistakes and shortcomings and to implement this knowledge into the activities at the plant. It's a basic program to develop the plant (structures, systems and components) itself but also to develop routines, procedures and the overlying management system, so that safety is improved or at least maintained
   Input could be from root cause analyses, different types of self-assessment, experiences from other NPPs or other adjacent business as well as observations and remarks from the authority.

2. Does your RB have legislative and regulatory requirements that obligate a licensee to implement a CAP?

   SSM are not mentioning CAP in the requirements but there are still requirements that oblige the licensee develop safety, based on experiences.

   From chapter two in Regulations concerning Safety in Nuclear Facilities, Section 9 states: The licensee shall ensure that Safety in nuclear activities is routinely monitored and followed up. Deviations in nuclear activities affecting safety should be identified and managed so that safety is maintained and continually improved.

   Also, in the same chapter Section 10 states; the safety of a facility shall be continuously analysed and assessed in a systematic manner. There should also be a programme in place for the safety improvement measures, i.e. technical as well as organisational measures arising as a result of this continuous analysis and assessment.

   a) If not, do your licensees have a self-imposed CAP?
      Yes, all three NPP licensees have developed and implemented a CAP.

   b) Does your RB approve a licensee's CAP? What are the acceptance criteria used by your RB to conduct this approval (e.g. standard)?

      No, SSM do not approve licensees CAP.

   c) Does your RB give credit (i.e. confidence) to a CAP that is shared amongst different sites within the same parent company? For example, is the CAP inspected at only one NPP or all NPPs that are using the same CAP?

      This has not yet been an issue in Sweden. However, there are one area where the licensee collaborate in Sweden. They have a database where licensee report root causes from fault reports after repairing SSC's in the plant. This database could be used to gain knowledge regarding for example, a special valve make. The database is also used when doing the PRA's for a plant.

3. How does your RB inspect a licensee's CAP?

SSM do inspections mainly in two areas of the CAP. One is the area of internal audits, and the second is the area of lessons learned from licensee event reports.

a) What is the frequency at which your RB inspects a licensee's CAP? What are the criteria used to modify the frequency of inspection?
Regarding internal audits, we have an inspection programme in two steps. In the first step we every second year do oversight inspections of the programme for internal audits. In step two we do follow-up regarding how the audits remarks have been taken care of, in that special inspection area . For example when inspecting in the area of competence we check if the competence area have been subject to internal audit and also how audit remarks have been taken care of.
Regarding lessons learned from licensee event report SSM once a year inspect how licensee have identified the root cause for reported events. The inspection also cover how licensee prevent these from recurrence. In this inspection, we usually also follow that external experience from other licensees is taken care of.

b) Does your RB have inspection guides to inspect a licensee's CAP?

SSM have general instructions that govern how an inspection shall be carried out. In the preparation of an inspection, you have to develop criteria and questions that cover the inspected area and the relevant section in the regulation's.

c) What areas of the licensee's CAP does your RB inspect?

Se above question 3.

4. What are the criteria used by your RB to inspect the following areas for compliance?
In the process for preparing the inspection criteria's are developed. The criteria are developed in such way that the scope of the inspection are covered and for each paragraph included in the inspection. Each inspection are unique in the scope and content why the criteria will be different from inspection to inspection. SSM has therefore not defined any criteria for areas mentioned below.

a) identification and documentation of the problem including the identification of human and organisational factors issues (e.g. licensee reports, non-conformance reports, etc.)

b) actions taken to address the problem

c) prioritisation of corrective actions

d) implementation and execution of corrective actions

e) assessment of the effectiveness of corrective actions

f) trend analysis to identify repetitive problems or repetitive causes

g) apparent cause analysis/root cause analysis

5. Does your RB inspect how a licensee processes corrective actions? If yes, explain what your RB does in the following areas:

6.

SSM does not inspect the licensee's process for corrective actions. However in some cases we do follow-up on certain cases, typical from a licensee event report. We then follow how licensee have handled the reported event and determine if the root cause analyst is adequate, is the corrective actions enough to prevent a recurrence, is the time frame acceptable are there any safety culture aspects involved and in such case, are they cared for in the same way as any technical issue.

a) deadlines of corrective actions

b) safety assessments and reporting to RB

c) approval process by RB and feedback to the licensee

d) follow-up of open issues

e) safety culture requirements, including human and organisational factors

*QUESTIONNAIRE B:*

**"HOW TO INSPECT A LICENSEE'S CORRECTIVE ACTION PROGRAMME"**

**COUNTRY: SWITZERLAND**

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

1. What are your RB's definition and understanding of a licensee's CAP?

   Non-conformances should be identified and corrected. The operator should implement some sort of CAPs to identify and fix problems. Regulatory bodies should implement inspection programmes to assess the effectiveness of operators CAPs.

2. Does your RB have legislative and regulatory requirements that obligate a licensee to implement a CAP?

   Yes, all our NPPs have Corrective Action Programmes. There is a regulatory requirement for that (KEV, Art. 32, Abs. 2 and others). However, there is no requirement for a specific form of a corrective action programme. Each licensee has its unique CAP.

   a) If not, do your licensees have a self-imposed CAP?

   b) Does your RB approve a licensee's CAP? What are the acceptance criteria used by your RB to conduct this approval (e.g. standard)?

      No, the RB does not approve the licensee's CAP.

   c) Does your RB give credit (i.e. confidence) to a CAP that is shared amongst different sites within the same parent company? For example, is the CAP inspected at only one NPP or all NPPs that are using the same CAP?

      In Switzerland there are no CAPs, which are shared amongst different sites. All NNPs are different.

3. How does your RB inspect a licensee's CAP?

   The RB reviews mainly the process and programmes. The regulator requests in general a description of the process (routines, procedures) and checks if the NPPs act accordingly. If improvements are mandatory, the regulator (ENSI) requires them. Inspections are performed in accordance with the requirements specified in the manuals.
   The resulting measures are inspected mainly during plant walk down inspections. The site inspector performs additional routine inspections.

   a) What is the frequency at which your RB inspects a licensee's CAP? What are the criteria used to modify the frequency of inspection?
      About twice a year. It can be in form of an audit with regard to the correct implementation, appropriate execution and overall effectiveness of the programme. Changes in frequency of inspection are mainly related to reportable events in the affected plant or in other plants.

   b) Does your RB have inspection guides to inspect a licensee's CAP?

      No, but ENSI is conducting inspections according regulatory guidelines.

c) What areas of the licensee's CAP does your RB inspect?

All operator activities could be subject of inspections. The focus is on significant safety related systems. Areas of inspections: Maintenance, non-destructive examinations, fuel management, emergency preparedness, quality assurance, radiation protection, human factors, radioactive waste treatment and emissions, and others.

4. What are the criteria used by your RB to inspect the following areas for compliance?

There are no specific criteria. All licensees are required to perform corrective actions in a timely manner. The licensee should promptly identify and correct safety significant problems. The goal of the CAP is to prevent the reoccurrence of problems. The CAP should be risk-informed (prioritisation).
The inspections by the RB require some amount of subjective determination when deciding if corrective actions are timely and adequate.

a) identification and documentation of the problem including the identification of human and organisational factors issues (e.g. licensee reports, non-conformance reports, etc.)

b) actions taken to address the problem

c) prioritisation of corrective actions

d) implementation and execution of corrective actions

e) assessment of the effectiveness of corrective actions

f) trend analysis to identify repetitive problems or repetitive causes

g) apparent cause analysis/root cause analysis

5. Does your RB inspect how a licensee processes corrective actions? If yes, explain what your RB does in the following areas:

In case of deficiencies in all of the cases mentioned below, the ENSI requires the correct and complete removal of the deficiency.

a) deadlines of corrective actions

b) safety assessments and reporting to RB

c) approval process by RB and feedback to the licensee

d) follow-up of open issues

e) safety culture requirements, including human and organisational factors

Are there any other important topics that you would like to be considered for the workshop?
No

*QUESTIONNAIRE B:*

**"HOW TO INSPECT A LICENSEE'S CORRECTIVE ACTION PROGRAMME"**

**COUNTRY: UNITED KINGDOM (UK)**

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

1. What are your RB's definition and understanding of a licensee's CAP?

   The Office for Nuclear Regulation (ONR) does not define a single "corrective action programme". There are a number of legal obligations in the site licence conditions and other safety legislation which require the licensees to continually improve safety performance. ONR therefore expects to see prioritised and time bound corrective action programmes associated with the following processes:
   - Reporting and investigation of on site incidents.
   - Operating experience feedback (OEF) from other operators.
   - Independent assessment (audit / self-regulation).
   - The resolution of construction or plant defects.
   - Management reviews.
   - Periodic reviews of safety cases or revised safety cases.
   - Emergency exercises.
   - Nuclear safety improvement programmes.
   - Regulatory and enforcement activities.

2. Does your RB have legislative and regulatory requirements that obligate a licensee to implement a CAP?

   Yes, the conditions attached to the nuclear site licence contain requirements for CAPs as follows:

   The UK site licence condition 17 requires licensees to have adequate quality management arrangements. IAEA Safety Standard GSR Part two is used to judge the adequacy of the arrangements and this standard requires all non-conformances from any source or safety related events to be evaluated and corrective action taken in a timely manner. It also requires the status and effectiveness of corrective actions to be monitored and reported to management. This licence condition therefore provides an overarching requirement for corrective action programmes.

   The UK site licence condition 7 requires licensees to have adequate arrangements for notification, recording, investigation and reporting of incidents occurring on the site. ONR's guidance indicates that investigation includes identifying and implementing corrective action to prevent repeat incidents. The guidance also indicates that a licensee's arrangements should include consideration of Operating Experience Feedback from other operators. In UK health and safety law the Management of Health and Safety at Work Regulations also contains similar requirements.

   The UK site licence condition 15 requires licensees to have adequate arrangements for the periodic and systematic review and reassessment of safety cases. ONR's guidance indicates that where shortfalls against modern standards are identified they should be categorised and where appropriate an appropriate programme of work is implemented to resolve the shortfall.

   a) If not, do your licensees have a self-imposed CAP?

      Not applicable

b) Does your RB approve a licensee's CAP? What are the acceptance criteria used by your RB to conduct this approval (e.g. standard)?

The licence conditions do allow ONR to specify that management arrangements need to be approved by ONR. However, in practice the arrangements associated with CAPs are not usually approved. Where individual corrective actions are judged to be of high safety significance, ONR's monitors progress on its "issues" data base, verifies completion and when content, agrees the licensee may close them out. If corrective action involves modifications to plant or processes ONR may also permission (e.g. approve) the implementation of these modifications.

c) Does your RB give credit (i.e. confidence) to a CAP that is shared amongst different sites within the same parent company? For example, is the CAP inspected at only one NPP or all NPPs that are using the same CAP?

Where a parent company operates a number of sites or a licensee has a number of large facilities on a single site ONR will carry out inspections on all the sites until there is confidence that the management arrangements are similar and implemented to a consistent standard. When confidence is attained ONR often chooses to carry out in-depth inspection at two or three of the sites or facilities as a representative sample. An overview of the effectiveness of the CAPs on the other sites or facilities is maintained as part of normal regulatory business.

3. How does your RB inspect a licensee's CAP?

A key feature of ONR's regulation is compliance inspection against the 36 site licence conditions. As described previously some licence conditions require CAPs and therefore the CAPs are inspected during compliance inspections against the criteria set out in ONR's guidance. Each sites compliance inspection programme is periodically reviewed to ensure it is proportionate to the safety significance and risk of the activity.

Where ONR becomes aware, through whatever means, of safety shortfalls which are sufficiently significant to warrant ONR's attention they are categorised and entered into ONR's "Issues Database". This database enables ONR to apply a proportionate level of regulatory control based on safety significance and ensures the licensee's CAP effectively resolves the issue. This process ensures safety significant issues are closed out by the licensee and provides a continual oversight of the effectiveness and suitability of the licensee's CAP processes.

An annual review of safety meeting is held with each licensee, the meeting considers safety performance indicators and an overview of the performance of the CAP programmes.

a) What is the frequency at which your RB inspects a licensee's CAP? What are the criteria used to modify the frequency of inspection?

The annual site licence compliance inspection programme is targeted on activities and processes with the greatest safety significance and proportionate to the risks. The licence conditions associated with the CAPs are significant and therefore each condition is usually inspected at least once every 3 years. A few licence conditions are associated with various CAPs and this effectively means that one or more aspects of the licensees overall corrective programme is inspected annually. This frequency may be increased for licensees with a poor safety performance who are subject to enhanced regulatory attention.

ONR maintains an issues database which tracks significant safety actions resulting from regulatory activities. As part of their normal regulatory business Inspectors maintain continual surveillance of these issues to ensure they are resolved and that the licensees CAP is effective.

b) Does your RB have inspection guides to inspect a licensee's CAP?

ONR has guides on planning, carrying out and reporting licence compliance inspections. Technical inspection guides provide further guidance for inspecting each licence condition. This includes guidance on inspecting corrective action programmes where appropriate. ONR Safety Assessment Principles also recognise the importance of continual improvement and learning. International standards for leadership and management for safety and management systems are also used to provide guidance on relevant good practice.

c) What areas of the licensee's CAP does your RB inspect?

For each CAP ONR adopts a proportionate sampling approach to inspect the areas described below:

- The activities undertaken to identify shortfalls and non-conformances (e.g. event reporting, audit, etc.).
- Corrective action recording, prioritisation, tracking, verification and effectiveness.
- CAP Management.

4. What are the criteria used by your RB to inspect the following areas for compliance?
   a) identification and documentation of the problem including the identification of human and organisational factors issues (e.g. licensee reports, non-conformance reports, etc.)

Technical inspection guides provide criteria on the identification of shortfalls. This includes consideration of human and organisational factors.
International management system standards also provide high level criteria.

b) actions taken to address the problem

Technical inspection guides indicate the factors to be considered when formulating corrective actions and this is used in conjunction with the *inspector's knowledge and experience to judge the adequacy of corrective actions.
International management system standards also provide high level criteria.

c) prioritisation of corrective actions

Technical inspection guides indicate that corrective actions should be prioritised but judging the adequacy of this prioritisation relies on the *inspector's knowledge and experience.

d) implementation and execution of corrective actions

Technical inspection guides indicate that corrective actions should be tracked to completion and verified before being closed out. Judging the adequacy of the tracking and verification of individual actions relies on the *inspector's knowledge and experience.
International management system standards also provide high level criteria.

e) assessment of the effectiveness of corrective actions

Technical inspection guides indicate that a process should be in place to review the effectiveness of corrective actions and provides guidance on sampling and evaluating the effectiveness of previous corrective actions.

International management system standards also provide high level criteria.

f) trend analysis to identify repetitive problems or repetitive causes

Technical inspection guides includes guidance on trend analysis. This includes trend analysis, categorisation, use of databases, reviews, placing corrective action, checking adverse trends are acted upon.

g) apparent cause analysis/root cause analysis

Technical inspection guides includes inspection of root cause analysis during the reporting and investigation of events. Judging the adequacy of root cause analysis relies on the *inspector's knowledge and experience.

*Note: Inspectors are supported by a governance process which provides advice, guidance and may endorse the inspector's decision.

5. Does your RB inspect how a licensee processes corrective actions? If yes, explain what your RB does in the following areas:

Compliance inspections against relevant licence conditions examine how the licensee processes corrective actions.

a) deadlines of corrective actions

ONR allows the licensee to prioritise corrective actions and to set appropriate target dates for completion. For significant actions ONR uses its issues data base to monitor progress and timely completion. For actions with less safety significance ONR samples the licensee's key performance indicators to monitor how actions are managed and closed.
Technical inspection guides and international management system standards indicate that corrective actions shall be taken in "due time" or in "a timely manner". Judging this during inspections relies on the inspector's knowledge and experience.

b) safety assessments and reporting to RB

As part of ONRs permissioning regime it carries out assessment of the licensees safety cases. ONR also carries out assessment of the licensees periodic safety review of their safety cases. Where ONR assessments conclude that an activity may continue/start but some corrective actions are still required the licensee usually develops a "Forward Action Plan" (FAP). Where this plan is considered significant it is raised as an issue in ONR's Issues database and this ensures it is tracked to completion and verified by ONR before it is closed out. The licensee reports completion of the FAP to ONR in order to close out the issue on the database.

c) approval process by RB and feedback to the licensee

Licensees are expected to manage their own corrective action programmes and verify the closure of actions themselves. Therefore ONR does not routinely approve the closure of the licensee's corrective actions. However, where a corrective action is safety significant and is being tracked by ONR on its issues database, ONR confirms the issue is closed before the licensee closes out the corrective action.

d) follow-up of open issues

During compliance inspections ONR examines the licensees' management of the CAPs to ensure the status of corrective actions is known and that actions are being closed out. This includes tracking of open actions and the management of overdue action. The significant actions which have been entered into ONR's issues database are controlled by an internal ONR governance process where the most significant issues are subject to senior regulators scrutiny.

e) safety culture requirements, including human and organisational factors

Compliance inspections check that corrective actions include consideration of safety culture requirements. This is included in ONR guidance but also relies on the knowledge and experience of the inspector. Understanding safety cultural aspects is a specialist role and ONR is currently developing its expertise in this area.

Are there any other important topics that you would like to be considered for the workshop?

1) Senior Management play a key role in developing an organisations safety culture. A key part of this is a culture of continual improvement which relies on successful corrective action programmes. The workshop may wish to consider inspection of senior management's role in the CAP. E.g. senior management's:
    - Commitment to the CAPs.
    - Oversight of the CAPs effectiveness.
    - Review of what insight the CAPs give on the organisations performance.
    - Direction on the organisations overall strategic priorities.

2) The term corrective action is associated with eliminating the cause of a detected non-conformance. Modern management system standards are now requiring the organisation to take actions to address risk and opportunities (replacing the old requirements for preventive action to eliminate potential non-conformance). The workshop may wish to consider if processes for addressing risks and opportunities should be inspected as part of the corrective action programme.

*QUESTIONNAIRE B:*

**"HOW TO INSPECT A LICENSEE'S CORRECTIVE ACTION PROGRAMME"**

**COUNTRY: UNITED STATES**

## QUESTIONNAIRE

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

1. What are your RB's definition and understanding of a licensee's CAP?

   The NRC's principle regulatory basis for defining and understanding licensee CAP is found in Appendix B to Part 50—Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants. Fundamentally, CAP is defined by Criterion XVI. Corrective Action: "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and non-conformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management." Other Appendix B criteria are also important to an effective CAP. These include but are not limited to such as Criterion II. Quality Assurance Programme, IV. Procurement Document Control, V. Instructions, Procedures, and Drawings, VI. Document Control, X. Inspection, XVII. Quality Assurance Records, and XVIII. Audits.

2. Does your RB have legislative and regulatory requirements that obligate a licensee to implement a CAP? Yes

   a) If not, do your licensees have a self-imposed CAP? N/A

   b) Does your RB approve a licensee's CAP? What are the acceptance criteria used by your RB to conduct this approval (e.g. standard)?

      10 CFR 50 Appendix B requires, in part: Every applicant for a construction permit is required by the provisions of § 50.34 to include in its preliminary safety analysis report a description of the quality assurance programme to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Every applicant for an operating licence is required to include, in its final safety analysis report, information pertaining to the managerial and administrative controls to be used to assure safe operation. Every applicant for a combined licence under part 52 of this chapter is required by the provisions of § 52.79 of this chapter to include in its final safety analysis report a description of the quality assurance applied to the design, and to be applied to the fabrication, construction, and testing of the structures, systems, and components of the facility and to the managerial and administrative controls to be used to assure safe operation…

      NUREG-0800, "Standard Review Plan," Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants Review Responsibilities," provides guidance for the quality assurance (QA) staff reviews and evaluates quality assurance program descriptions (QAPDs) submitted by applicants for a design certification (DC), combined license (COL), early site permit (ESP), construction permit (CP), and operating license (OL). The QAPDs submitted by applicants for DC, COL,

ESP CP, and OL are reviewed and evaluated in accordance with the applicable sections of this Standard Review Plan (SRP).

c) Does your RB give credit (i.e. confidence) to a CAP that is shared amongst different sites within the same parent company? For example, is the CAP inspected at only one NPP or all NPPs that are using the same CAP?

No CAP implementation must be inspected inspected at all sites and deficiencies found at one site that reflect programmatic governance issues at the parent company level must be addressed at all affected sites.

3. How does your RB inspect a licensee's CAP?

a) What is the frequency at which your RB inspects a licensee's CAP? What are the criteria used to modify the frequency of inspection?

For licensees performing "nominally" (e.g. Licensees in Column I of the Action Matrix discussed in IMC 0305), CAP inspection frequency is governed by inspection procedure IP 71152, Problem Identification and Resolution, in which PI&R activities are reviewed in four ways: routine reviews; semi-annual trend reviews; annual follow-up of selected issues; and biennial team inspections.

b) Does your RB have inspection guides to inspect a licensee's CAP?

IP 71152, Problem Identification and Resolution, includes an inspection guidance section. It also includes sections addressing the inspection basis, level of effort, objectives, requirements, resource estimates, completion standards, and references.

c) What areas of the licensee's CAP does your RB inspect?

IP 71152 objectives include inspection activities:

- To evaluate the effectiveness of the licensee's corrective action program in identifying, prioritising evaluating, and correcting problems.
- To confirm that licensees are complying with NRC regulations regarding corrective action programmes.
- To help the NRC gauge supplemental response when ROP Action Matrix thresholds are crossed.
- To confirm the licensee's appropriate use of industry and NRC operating experience.
- To evaluate the effectiveness of licensee audits and self-assessments.
- To confirm licensees have established a safety conscious work environment.
- To follow-up on corrective actions for selected previously identified compliance issues (e.g. non-cited violations (NCVs)).
- To verify that licensees are identifying and placing potential 10 CFR 21—REPORTING OF DEFECTS AND NON-COMPLIANCE issues into the
- Corrective Action Programme (CAP) and appropriately evaluating them.

4. What are the criteria used by your RB to inspect the following areas for compliance?

a) Identification and documentation of the problem including the identification of human and organisational factors issues (e.g. licensee reports, non-conformance

reports, etc.)

IMC 0612 establishes criteria that are used across the inspection programme – not just for CAP – to establish a screening threshold for documenting findings of deficient licensee performance (i.e. more than minor instances in which a licensee has failed to satisfy a regulatory requirement or self-imposed standard that it reasonably could- and should have met). Baseline inspection of the licensee CAP relies on inspector experience, training, and IP 71152 requirements and guidance, based on the objectives listed above, to identify issues that are then screened using IMC 0612.
Additionally, inspectors screen all CAP items conduct daily plant-status tours.
IMC 0611Conveys the basic requirements and content for preparing power reactor
inspection reports and provides the requirements for documenting power reactor inspections and findings, violations, and observations. The objectives of this guidance include

- Clearly communicating significant inspection results in a consistent manner to licensees, NRC staff, and the public.
- Documenting the basis for significance determination and enforcement action.
- Documenting inspection results as input into the Operating Reactor Assessment Programme

b) Actions taken to address the problem

See response to 4.a. Additionally, issues of increased safety importance (i.e. findings of greater-than-green significance) receive supplemental inspection in accordance with IPs 95001, -02, or -03, and a notice of violation (NOV) is typically issued when a violation is associated with a finding of greater-than-green significance. Unlike non-cited violations (NCVs) which are typically issued for violations associated with green findings, NOVs require a formal response by the licensee.

c) Prioritisation of corrective actions

See 4.a. and 4.b. above. Inspectors conduct annual follow-up of selected issues to ensure that licensees have planned and/or implemented corrective actions commensurate with the significance of identified issues. In addition, inspectors conduct biennial inspections during which risk insights are used to select issues that have been processed through the licensee's corrective action programme. Selected samples include, to the extent available, significant conditions, cited and non-cited violations of regulatory requirements, other documented findings, issues identified through NRC and industry operating experience, and licensee audits and assessments. Inspectors must review corrective actions related to greater-than-green findings that were not completed by the end of the associated supplemental inspection and were not otherwise reviewed.

d) Implementation and execution or corrective actions See 4.a., 4.b., and 4.c. above.

e) Assessment of the effectiveness of corrective actions

See 4.a. and 4.b. above. As discussed in 3.c., above, the first objective of IP 71152, along with associated requirements and guidance, is to evaluate the effectiveness of the licensee's corrective action programme.

f) Trend analysis to identify repetitive problems or repetitive causes

See 4.a. and 4.b. above. Inspectors perform a semi-annual review to identify trends that might indicate the existence of a more significant safety issue. The scope of this review includes repetitive or closely-related issues that may have been documented by the licensee outside the normal corrective action programme, such as: trend reports or PIs, major equipment problem lists, repetitive and/or rework maintenance lists, departmental problem/challenge lists, issues that challenge operators in performing duties (e.g. workarounds), system health reports, quality assurance audit/surveillance reports, self-assessment reports, maintenance rule assessments, or corrective action backlog lists. Additionally, inspectors consider reviewing corrective action documents which have been dispositioned to identify potential adverse trends in structures, systems, and components (SSCs) as evidenced by acceptance of long-standing non-conforming or degraded conditions. Such indicators could include "use-as-is" determinations, revision of engineering or operational acceptance criteria, reductions in design or operational margin, and repetitive work orders.
Apparent cause analysis/root cause analysis
See 4.a. and 4.b. above. In addition, licensee cause analysis/root cause analysis receives increased attention in supplemental inspection procedures IP 95001, -02, and -03, which are conducted for findings and performance indicators of greater-than-green significance.

5. Does your RB inspect how a licensee processes corrective actions? If yes, explain what your RB does in the following areas: Yes.

a) deadlines of corrective actions

Inspectors evaluate the completion of corrective actions in a timely manner commensurate with the safety significance of the issue (may be deferred to biennial inspection). If permanent corrective actions require significant time to implement, then inspectors will verify that interim corrective actions and/or compensatory actions have been identified and implemented to minimise the problem and/or mitigate its effects, until the permanent action could be implemented.

b) safety assessments and reporting to RB

Inspectors conduct annual follow-up of selected issues to ensure that licensees have planned and/or implemented corrective actions commensurate with the significance of identified issues.

c) approval process by RB and feedback to the licensee

The NRC does not approve specific licensee corrective actions.

d) follow-up of open issues

IP 71152 provides the following guidance:

- Complete and accurate identification of the problem in a timely manner commensurate with its significance and ease of discovery.
- Evaluation and disposition of operability/reportability issues.
- Consideration of extent of condition, generic implications, common cause, and previous occurrences.
- Identification of significant negative trends associated with human or equipment performance.
- Classification and prioritisation of the resolution of the problem commensurate with its safety significance.

e) safety culture requirements, including human and organisational factors

Inspectors review issues that pose challenges to the free flow of information for adequate resolution and to ensure that employees feel free to raise safety concerns, both to their management and to the NRC, without fear of retaliation.
Are there any other important topics that you would like to be considered for the workshop? No

*QUESTIONNAIRE C:*
**"INSPECTION OF THE CURRENT DESIGN BASIS"**

**COUNTRY: ……**

**NOTES**

Only one response per country is required. If more than one person from your country is participating, please co-ordinate the responses accordingly.

Submittals should be sent by e-mail to luc.chanial@oecd.org by 11 February 2018.

**FOREWORD**

The range of conditions and events taken explicitly into account in the design of a facility is known as the design basis [IAEA (NS-G-2.10)]. The regulatory body (RB) may carry out inspections of facilities and activities to verify that the current configurations of and functions performed by safety systems, structures and components (SSCs) will meet the requirements to withstand current design basis conditions and events. Over the lifetime of a facility, the performance of SSCs may change as new technology and new processes are introduced. The licensee may aim to secure improved safety and performance by introducing new components, systems and upgrades. It is the responsibility of the regulatory body to assure that safety is not jeopardised as a result of those decisions.

This workshop topic will focus on the methods, procedures and criteria used by RBs to inspect the design basis of NPP SSCs and will aim to identify relevant commendable inspection practices.
This workshop topic excludes physical security.

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

**1. PURPOSE AND OBJECTIVES OF DESIGN BASIS INSPECTIONS**

1.1 Does your RB undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis? Describe the reasons for undertaking a design basis inspection?
1.2 How often are design basis inspections required to be undertaken? Describe the basis for inspection frequency.
1.3 If your RB does not undertake specific design basis inspections, is this work incorporated in other inspection programmes? Please provide details.
1.4 Does your RB use design basis inspection in the periodic safety review (PSR) or license renewal process? Please provide details.

**2. MANAGEMENT OF CURRENT DESIGN BASIS INSPECTIONS**

2.1 Describe the resources required/deployed to undertake a current design basis inspection (inspection team number, technical specialists – external and/or internal, hours, etc.)?
2.2 Describe the type of information requested/supplied by the licensee to support the inspection. When is this information required/supplied?
2.3 Describe how supply chain issues may be linked to current design basis inspection?
2.4 Describe the scope of a current design basis inspection (e.g. SSCs, equipment configuration, maintenance, plant modification, safety limits/plant parameters, etc.).

2.5 Is there a graded approach used to select SSCs for inclusion in the inspection programme? If yes please specify how the graded approach is applied.
2.6 Describe how human performance is included in current design basis inspection (e.g. licensee training and qualification programme, operating instructions, etc.)

## 3. PERFORMANCE OF CURRENT DESIGN BASIS INSPECTIONS

3.1 Describe your RB guidelines/procedures for inspection of the current design basis.
3.2 What methods of inspection are used (e.g. document review, interview, plant walk down, testing and maintenance observation, etc.) and under what circumstances?
3.3 How does your RB use technical specialists (e.g. for preparation, during the inspection, reviewing the inspection findings, etc.)?
3.4 Describe if there are specific processes for recording and acting upon current design basis inspection findings to improve your regulatory program and plant safety.

## 4. WHAT ISSUE WOULD YOU LIKE TO DISCUSS DURING THE WORKSHOP?

*QUESTIONNAIRE C:*
**"INSPECTION OF THE CURRENT DESIGN BASIS"**

**COUNTRY: BELGIUM**

## QUESTIONNAIRE

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

### 1. PURPOSE AND OBJECTIVES OF DESIGN BASIS INSPECTIONS

1.1 Does your RB undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis? Describe the reasons for undertaking a design basis inspection?

There are no dedicated inspections directly related to the verification of the design basis.
However, there exist some inspections to confirm that SSC's meet the current design basis:

- As the result of the periodic safety review they can be undertaken. (PSR: 10-yearly)
- In the case of modifications, verification that the modification is conform to the design basis is done systematically.
- Experience feedback can be a trigger to do such inspections. E.g. verification if the safety related pumps are still conform the design basis, after that an event showed discrepancy for similar pump.

Other inspections are the verifications that are asked by the regulations like the ASME-code. The verification of compliance with the prescriptions for the in-service-inspections is part of the Bel V inspection program.

1.2 How often are design basis inspections required to be undertaken? Describe the basis for inspection frequency.

See above

1.3 If your RB does not undertake specific design basis inspections, is this work incorporated in other inspection programmes? Please provide details.

See above

1.4 Does your RB use design basis inspection in the periodic safety review (PSR) or licence renewal process? Please provide details.

There exists no license renewal process in Belgium.
For the PSR: it is the opposite that happens: the PSR can trigger design basis inspections

### 2. MANAGEMENT OF CURRENT DESIGN BASIS INSPECTIONS

2.1 Describe the resources required/deployed to undertake a current design basis inspection (inspection team number, technical specialists – external and/or internal, hours, etc.)?

As there is no systematic approach, the resources are those involved in the frame described above.

2.2 Describe the type of information requested/supplied by the licensee to support the inspection. When is this information required/supplied?

For the modifications: it has to be foreseen in the safety evaluation. Other information sources are the SAR or the synthetic qualification files, which document the (environmental) qualification of equipments.

2.3 Describe how supply chain issues may be linked to current design basis inspection?

2.4 Describe the scope of a current design basis inspection (e.g. SSCs, equipment configuration, maintenance, plant modification, safety limits/plant parameters, etc.).

See above

2.5 Is there a graded approach used to select SSCs for inclusion in the inspection programme? If yes please specify how the graded approach is applied.

/

2.6 Describe how human performance is included in current design basis inspection (e.g. licensee training and qualification programme, operating instructions, etc.)

**3. PERFORMANCE OF CURRENT DESIGN BASIS INSPECTIONS**

3.1 Describe your RB guidelines/procedures for inspection of the current design basis.

Non-existing in the frame of dedicated inspections related to the verification of the design basis.

3.2 What methods of inspection are used (e.g. document review, interview, plant walk down, testing and maintenance observation, etc.) and under what circumstances?

- For the modifications: a document review and surveillance of requalification testing results is done.
- In the case of PSR or experience feedback: this is done by document review and follow-up of test results.

3.3 How does your RB use technical specialists (e.g. for preparation, during the inspection, reviewing the inspection findings, etc.)?

The analysis of (modification) documents is done by specialists. The surveillance of the requalification testing is done by the inspector, but the in deep analysis of the test results is done by specialists.

3.4 Describe if there are specific processes for recording and acting upon current design basis inspection findings to improve your regulatory program and plant safety.

See above

**4. WHAT ISSUE WOULD YOU LIKE TO DISCUSS DURING THE WORKSHOP?**

I will like to learn from my colleague's about:

- for which countries exists a design basis inspection program
- on which basis a design basis inspection is executed (for instance, are in-service inspections part of design basis inspections?)
- inspection methods

- scope and difficulties/challenges to perform such inspections

***QUESTIONNAIRE C:***

**"INSPECTION OF THE SSCS CURRENT DESIGN BASIS"**

**COUNTRY: CANADA**

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

## 1. PURPOSE AND OBJECTIVES OF DESIGN BASIS INSPECTIONS

1.1 Does your RB undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis? Describe the reasons for undertaking a design basis inspection?

Yes. Our primary design basis inspection is a System Inspection. A system inspection compares the system equipment in the field to the system design, reviews maintenance activities on the system, and temporary and permanent engineering changes.

We also have an Engineering Change Control inspection (ECC). The ECC inspection looks at the licensee programme for design, construction, and commissioning of engineering changes to SSC.

1.2 How often are design basis inspections required to be undertaken? Describe the basis for inspection frequency.

Currently system inspections are completed on a minimum of two systems important to safety per station per year.

ECC inspections are completed on a five-year cycle per station.

These frequencies are based on a review of the minimum number of inspections and other regulatory activities needed to confirm that the licensee is maintaining an adequate level of safety. Note that NPP undergoing life extension will have an extra set of inspections on maintaining and changing the design basis.

1.3 If your RB does not undertake specific design basis inspections, is this work incorporated in other inspection programmes? Please provide details.

Not applicable. Note that other inspections may look at some aspects of a licensee maintaining a design basis.

1.4 Does your RB use design basis inspection in the periodic safety review (PSR) or license renewal process? Please provide details.

Canada does not formally use design basis inspections to support a PSR review. Staff reviewing a PSR submission will be aware of design basis inspection results.

Design basis inspection results are used to support recommendations for licence renewal decisions.

## 2. MANAGEMENT OF CURRENT DESIGN BASIS INSPECTIONS

2.1 Describe the resources required/deployed to undertake a current design basis inspection (inspection team number, technical specialists – external and/or internal, hours, etc.)?

System inspections are normally completed by a single site inspector and take three person weeks of effort. If required, the inspector can call in specialist support.

Two system inspections (electrical distribution and service water) are completed on a five year cycle and require specialist support on site for the site inspector. Total effort is about eight person weeks.

The engineering change control inspection has specialist support for the site inspector. Specialist support is provided by management system, human factors, and various engineering specialists as required. Total effort is about eight person weeks.

2.2 Describe the type of information requested/supplied by the licensee to support the inspection. When is this information required/supplied?

For a system inspection:

- Station procedures
- Operating documents such as operating manuals
- Design documentation
- System health plans and reports
- Maintenance records and plans
- Problem identification and correction records
- Internal audit and self-assessment reports.

The site inspector has direct access to the above documents in the licensee's systems.
For an engineering change control inspection, a formal letter is issued to the licensee, requesting station procedures and a list of engineering changes in-progress or completed in the last two years. Typically this information is requested to be supplied twenty days before the onsite portion of the inspection. Any other required information is acquired while on site.

2.3 Describe how supply chain issues may be linked to current design basis inspection?

A system inspection does not look at supply chain issues unless they are identified in maintenance or problem identification records.

An engineering change control inspection may look into the supply chain for design or construction services, but not for components. Supply chain is subject to a separate inspection with support from management system specialists.

2.4 Describe the scope of a current design basis inspection (e.g. SSCs, equipment configuration, maintenance, plant modification, safety limits/plant parameters, etc.).

The scope of the design basis inspections is based on confirming that the paper plant (as designed) matches the physical plant in the field (as operated). This includes confirming that design changes consider the impact on the safety analysis, are properly designed and verified, constructed and commissioned according to the design, and the operations documentation and training comply with the completed design.

2.5 Is there a graded approach used to select SSCs for inclusion in the inspection programme? If yes please specify how the graded approach is applied.

Yes.

For system inspections, typically one special safety system (shutdown system, emergency core cooling, or containment) and one system important to safety (defined by the PSA) are inspected each year.

For engineering change control inspections several engineering changes are selected with the more safety significant changes inspected.

2.6 Describe how human performance is included in current design basis inspection (e.g. licensee training and qualification programme, operating instructions, etc.)

Human factors specialists can be involved in engineering change control inspections. The CNSC also has a human performance programme inspection (five year cycle).

Training specialists have an inspection on the licensee's Systematic Approach to Training programme. This inspection includes inspecting the licensee's training programme modifications due to engineering changes.

## 3. PERFORMANCE OF CURRENT DESIGN BASIS INSPECTIONS

3.1 Describe your RB guidelines/procedures for inspection of the current design basis.

Procedures have been written to control the production of inspection guides, conduct of inspections, and writing a compliance verification report.

Each inspection has an approved generic guide that forms the basis for each inspection. For an inspection the generic guide is modified to be used at the specific. Both the system and engineering change control have approved generic guides. These guides are modified to confirm a licensee's specific requirements for the execution of the inspection.

3.2 What methods of inspection are used (e.g. document review, interview, plant walk down, testing and maintenance observation, etc.) and under what circumstances?

A system inspection consists of several design basis checks:

- Review of design and operations documents for the system
- Review of the system engineer's system health monitoring plan and report
- Walkdown of the system in the control room and the field, sometimes with the system engineer
- Review of reliability test results
- Follow-up interview with the system engineer to resolve outstanding questions and issues.

An engineering change control inspection consists of several design basis checks:

- Review of engineering change control procedures
- Review of design documents for the selected changes
- Review of the design change documents
- Review of the construction and installation documents related to the selected changes
- Review of the commissioning documents related to the selected changes
- Walkdown of completed and in-progress engineering changes
- Observation of construction and commissioning work related to the selected changes
- Follow-up interviews with the personnel involved in making the selected changes to resolve outstanding questions and issues.

3.3 How does your RB use technical specialists (e.g. for preparation, during the inspection, reviewing the inspection findings, etc.)?

System inspections generally do not have specialist input unless the inspector finds a problem requiring technical support. The electrical distribution and service water system inspections have considerable specialist input.

Engineering change control inspections have considerable specialist input. The inspector is there to manage the inspection and provide local knowledge of how the station works.

3.4 Describe if there are specific processes for recording and acting upon current design basis inspection findings to improve your regulatory program and plant safety.

Each CNSC power reactor inspection related procedure and inspection guide has a comments copy specifically to support identifying areas for improvement in the conduct of inspections.

The inspection procedure also requires the completion of a lessons learned document after each inspection. The lessons learned are reviewed quarterly by the Power Reactor Site Office Supervisors quarterly (PRSOS). The PRSOS then revise procedures as required.

## 4. WHAT ISSUE WOULD YOU LIKE TO DISCUSS DURING THE WORKSHOP?

N/A

*QUESTIONNAIRE TOPIC 3:*

**"INSPECTION OF SSC CURRENT DESIGN BASIS"**

**COUNTRY: FINLAND**

## QUESTIONNAIRE

For preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

## 1. PURPOSE AND OBJECTIVES OF DESIGN BASIS INSPECTIONS

1.1 Does your RB undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis? Describe the reasons for undertaking a design basis inspection?

- Radiation and Nuclear Safety Authority (STUK) does not undertake inspections specifically aimed at confirming that the SSCs meet the current design basis.

1.2 How often are design basis inspections required to be undertaken? Describe the basis for inspection frequency.

- No specific design basis inspections are undertaken.

1.3 If your RB does not undertake specific design basis inspections, is this work incorporated in other inspection programmes? Please provide details.

- STUK does not carry out specific design basis inspections, but the subject is considered on several different inspections, mainly ones titled "Safety planning", "Plant maintenance" and "Safety functions". These inspections are carried out yearly for every NPP in Finland. Overall goals of these three inspections are the following:
  - Safety planning:
    - To evaluate the methods and practices of the utility on how safety requirements are transferred to the entire design chain. To inspect licensees practices regarding design of plant modifications, including the actions and processes of the designer organisation.
  - Plant maintenance:
    - To evaluate the methods and practices of the utility on how the operability and integrity according to the design bases are ensured.
  - Safety functions:
    - To evaluate the methods and practices of the utility on how the systems performing safety functions fulfil their design basis and the correctness of the basis.
- Additionally, current design bases are evaluated continuously during plant lifetime, e.g. design modifications in SSC, periodic safety reviews and renewals of operating licences.

1.4 Does your RB use design basis inspection in the periodic safety review (PSR) or licence renewal process? Please provide details.

- No specific design basis inspection is undertaken, but the design bases are reviewed in these plant lifecycle phases when evaluating the current plant documentation taking into consideration all the changes to SSC done during operation.
- Nuclear Energy Act (990/1987) demands that the safety of a NPP shall be evaluated as a whole once every 10 years, minimum.

## 2. MANAGEMENT OF CURRENT DESIGN BASIS INSPECTIONS

2.1 Describe the resources required/deployed to undertake a current design basis inspection (inspection team number, technical specialists – external and/or internal, hours, etc.)?

- No specific design basis inspection is undertaken, but the inspections mentioned in item 1.3 are organised typically as follows:
  - Inspection team is led by an appointed STUK inspector. This inspector is responsible for planning the outline for the inspection and gathering the necessary expertize within STUK to undertake the inspection according to the plan outline. Typically the team comprises of 2-5 experts, depending on the scope of the inspection, all of which are usually STUK inspectors. Detailed planning of the inspection (scope = which SSCs are inspected, timetable, inspection criteria, information requests from the licensee, etc.) is done by the inspection team. Typical inspections take two days on site.

2.2 Describe the type of information requested/supplied by the licensee to support the inspection. When is this information required/supplied?

- Licensee may be requested to supply information to STUK before the inspection or to be available for the inspectors during the on site inspections. Documents to be made available may include (for selected SSCs) for example: maintenance instructions, operating instructions, emergency operating procedures, ageing management reports, periodic testing reports and fault histories.

2.3 Describe how supply chain issues may be linked to current design basis inspection?

- One common topic of discussion when on site is the evaluation of availability of necessary spare parts for the inspected SSCs to maintain their operability. Supply chain issues are regularly referred to as a challenge in maintaining a good inventory. If not corrected, unstable supply chains may lead to plant changes to ensure the integrity of the systems is not compromised.

2.4 Describe the scope of a current design basis inspection (e.g. SSCs, equipment configuration, maintenance, plant modification, safety limits/plant parameters, etc.).

- No specific design basis inspection is undertaken, but the scopes of inspections mentioned in item 1.3 are typically selected based e.g. on: recent plant modifications that have been completed, findings on noteworthy increase in inoperability in certain SSCs or other similar findings or any concerns raised in international operating experience.

2.5 Is there a graded approach used to select SSCs for inclusion in the inspection programme? If yes please specify how the graded approach is applied.

- Inspection teams responsible for the planning of the inspections have a lot of room for considering how to set the scope. Graded approach is applied quite informally when setting the scope to give higher priority to SSCs in higher safety classifications, but the inspections need not be limited only on those if there are valid reasons for inspecting non-safety classified SSCs.

2.6 Describe how human performance is included in current design basis inspection (e.g. licensee training and qualification programme, operating instructions, etc.)

- No specific design basis inspection is undertaken. General points on evaluation of human performance is given in STUKs response for questionnaire topic 1.

**3. PERFORMANCE OF CURRENT DESIGN BASIS INSPECTIONS**

3.1 Describe your RB guidelines/procedures for inspection of the current design basis.

- No specific design basis inspection is undertaken.

3.2 What methods of inspection are used (e.g. document review, interview, plant walkdown, testing and maintenance observation, etc.) and under what circumstances?

- For the inspections mentioned in item 1.3 the primary methods of inspections are document review (document types mentioned in item 2.2), discussions with licensee personnel and limited plant walk-downs, for example go-through of e.g. an EOP combined with plant tour to verify local actions in the EOP.

3.3 How does your RB use technical specialists (e.g. for preparation, during the inspection, reviewing the inspection findings, etc.)?

- STUK aims to have as much of the necessary expertize in-house as possible. As such, all inspections listed in item 1.3 are handled by STUK inspectors. Each inspection has a nominated responsible lead, but all inspectors in the team are included in planning of the inspection, participating on site, and making and reporting the findings.

3.4 Describe if there are specific processes for recording and acting upon current design basis inspection findings to improve your regulatory programme and plant safety.

- No specific design basis inspection is undertaken, but the inspections mentioned in item 1.3 are documented as follows:

  – During the on site inspection, the inspection team makes notes on different findings they come across. These can be deviations from regulations or otherwise problematic practices which need corrective actions, neutral but still somehow noteworthy observations, or good practices that the licensee has applied. The findings are collated into minutes of the inspection on site to be shown to the licensee at the end of the inspection. The minutes may include, depending on the findings, requirements and deadlines for corrective actions, or just a list of general observations made during the inspection. Possible requirements are handled in STUKs and licensees requirement management processes as any other requirements, and status of requirements given are checked in the corresponding inspection next year.

  – STUK also has an internal database (separate from requirements tracking) for gathering all such observations that do not warrant a separate requirement and a corrective action, but are still somehow noteworthy. The observations gathered are periodically analysed by STUKs section of Organisations and Management Systems to find if there are any worrisome trends in the findings or common causes for the observations that could warrant a further investigation.

**4. WHAT ISSUE WOULD YOU LIKE TO DISCUSS DURING THE WORKSHOP?**

*QUESTIONNAIRE C:*

**"INSPECTION OF THE SSCS CURRENT DESIGN BASIS"**

**COUNTRY: FRANCE**

## QUESTIONNAIRE

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

## 1. PURPOSE AND OBJECTIVES OF DESIGN BASIS INSPECTIONS

1.1 Does your RB undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis? Describe the reasons for undertaking a design basis inspection?

No, ASN does not carry out specific design basis inspections. Nevertheless, throughout inspections on other topics (maintenance, plant operation, non-conformities management, etc.) the respect of the design basis is assessed.

1.2 How often are design basis inspections required to be undertaken? Describe the basis for inspection frequency.

Not concerned.

1.3 If your RB does not undertake specific design basis inspections, is this work incorporated in other inspection programmes? Please provide details.

Yes, as mentioned above, the respect of the design basis is assessed through inspections on maintenance activities, plant operation, non-conformities management, qualification and obsolescence, walk down inspections.

ASN does not neither perform specific inspections on plant modification. Nevertheless, the impact of this plant modifications on the safety and on the design basis is evaluation through the authorisation process.

1.4 Does your RB use design basis inspection in the periodic safety review (PSR) or licence renewal process? Please provide details.

Yes, ASN may use inputs of inspections in the periodic safety review (that takes place every ten years).

ASN does not perform a "classical" licence renewal process. Instead, ASN delivers authorisation for start-up after each refuelling outage. If inspections performed before this authorisation shows there are issues regarding safety, dealing or no with the respect of design basis, the start-up authorisation will not be delivered until further investigations demonstrate that the problem is resolved.

## 2. MANAGEMENT OF CURRENT DESIGN BASIS INSPECTIONS

2.1 Describe the resources required/deployed to undertake a current design basis inspection (inspection team number, technical specialists – external and/or internal, hours, etc.)?
Typically, an inspection team is conformed by two inspectors sometimes three (at least one of them is a regional inspector). It is possible to have in the inspection team specialists form France TSO (IRSN).

The whole inspection would take two weeks: one whole week for preparing it, one whole day in the installation and four or five days for writing the inspection rapport and finish the inspection file.

2.2 Describe the type of information requested/supplied by the licensee to support the inspection. When is this information required/supplied?

Three weeks before the inspection take place, inspectors may request licensee "organisational documents" (e.g. procedures) concerning the topics they will inspect. Usually the licensee will send these documents two weeks before the date of the inspection. The operational documents (e.g. templates filled) will be required during the inspection.

In other hand, ASN inspectors will use the information that is in the safety file, operational technical specifications, general maintenance programmes, etc…, all of them at the disposal of the inspectors.

2.3 Describe how supply chain issues may be linked to current design basis inspection?

Supply chain issues may be assess mainly throughout inspections on maintenance, qualification & obsolesce and non-conformities management.

2.4 Describe the scope of a current design basis inspection (e.g. SSCs, equipment configuration, maintenance, plant modification, safety limits/plant parameters, etc.).

Not concerned.

2.5 Is there a graded approach used to select SSCs for inclusion in the inspection programme? If yes please specify how the graded approach is applied.

Our inspections scope only SSCs safety related or activities important for safety.

2.6 Describe how human performance is included in current design basis inspection (e.g. licensee training and qualification programme, operating instructions, etc.)

ASN carries out specific inspections on human factors. Nevertheless, aspects as operators training, qualification programme, etc. may also assessed during inspections on maintenance, plant operation, qualification, walk down inspections, etc.

## 3. PERFORMANCE OF CURRENT DESIGN BASIS INSPECTIONS

3.1 Describe your RB guidelines/procedures for inspection of the current design basis.

As ASN does not perform specific inspections on design basis, there is no guidelines on this topic. However, other inspections guidelines are available dealing with safeguards systems, auxiliary systems, maintenance activities, non-conformities management, plant operation, walk down inspections, human factors.

3.2 What methods of inspection are used (e.g. document review, interview, plant walk down, testing and maintenance observation, etc.) and under what circumstances?

All the mentioned methods of inspection are used by French inspectors. During each refuelling outage, one or several walk down inspections are performed, including testing and maintenance observation. Documents reviews and licensee interviews are preferred when not refuelling outage period.

3.3 How does your RB use technical specialists (e.g. for preparation, during the inspection, reviewing the inspection findings, etc.)?

Specialist form IRSN will always participate on the preparation of the inspection (their participation is compulsory). They can participate to the inspection (their participation is not compulsory but sometimes depending on the topic it is recommended).

In case of finding, ASN may require the TSO to participate in the technical analysis of the finding.

3.4 Describe if there are specific processes for recording and acting upon current design basis inspection findings to improve your regulatory program and plant safety.

According to ASN inspection process, each inspection gives rise to a letter to the licensee, through which inspectors will required actions aiming to correct non-conformities/ findings they would note.

In addition, each inspection will be acted by an internal rapport, which is more detailed compared with the letter to the licensee.

- It will mention all the subjects that have been looked out by the inspection team (not only those that have been the subject of requests in the letter but also those for which the inspection team did not find any non-compliances).
- Inspectors will signal the topics that need to be followed up during futures inspection.
- This rapport will gives information with information regarding the interviewed people (name and function), documentation used for preparing the inspection and consulted while the inspection.
- Finally, if photos have been taken during the inspection, they will be joined to this rapport.

Inspections results will feed the installation evaluation made by ASN.

## 4. WHAT ISSUE WOULD YOU LIKE TO DISCUSS DURING THE WORKSHOP?

*QUESTIONNAIRE C:*

**"INSPECTION OF THE SSCS CURRENT DESIGN BASIS"**

**COUNTRY: GERMANY**

## QUESTIONNAIRE

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

## 1. PURPOSE AND OBJECTIVES OF DESIGN BASIS INSPECTIONS

1.1 Does your RB undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis? Describe the reasons for undertaking a design basis inspection?

1.2 How often are design basis inspections required to be undertaken? Describe the basis for inspection frequency.

There are no RB inspections that are specifically aimed at confirming that SSCs meet the current design basis.

1.3 If your RB does not undertake specific design basis inspections, is this work incorporated in other inspection programmes? Please provide details.

The inspection of SSCs important to safety is part of several other areas of inspections. Notably, the RB inspects compliance with the current design basis within the areas:

- modifications,
- in-service inspections,
- maintenance,
- quality assurance,
- ageing management,
- fire protection by system design,
- civil engineering.

In addition to the construction and operation of a nuclear power plant, modifications are an important subject to the RB's nuclear licensing and supervision activities. All modifications to a nuclear power plant that are important to safety may only be implemented after a corresponding review of the RB and its TSO. Within this review, it is verified that the modified plant will still be in accordance with the design basis, the current regulation requirements and the licence. Furthermore, the operator has to declare the planned scope of important checks like as-built checks or acceptance and functional testing. This scope is also reviewed and it is settled to which extent the TSO will inspect the successful completion of these steps on site.

The RB's inspections of single modifications comprise, for example, the implementation of requirements that were stipulated in its letter of approval, or the timely update of documents (e. g. operating manual, technical documentation). In inspecting the operator's modification process the RB additionally checks, that the modifications, for which no applications are filed, are indeed not important to safety.

Other areas of on site inspections that allow to assess the condition of SSCs are in-service inspections and preventive maintenance. During these inspections, the operator's compliance with the corresponding procedures as well as the results of testing or maintenance are observed. The TSO inspects the in-service inspections and maintenance activities with a frequency that is fixed within approved manuals. It is obliged to inform the RB about any abnormal occurrences. The RB observes in-service inspections and

maintenance activities on a random basis several times a year. During these inspections, it is verified, for example, that deviations are recorded and corrected properly.

To ensure the application of the provisions of the quality assurance system, the RB inspects, amongst other things, the compliance with quality assurance instructions and other relevant operating rules at random. The quality assurance system is fundamental to ensure that new or replaced equipment conforms the design basis requirements.

The scope of ageing management inspections comprises plant walk-downs, inspection of records and reports in the fields of electrical engineering, I&C equipment, mechanical and civil engineering.

During inspections of fire protection measures the RB inspects the condition of cable routes and passages, the condition of diesel engine fuel oil systems, the closing function of fire doors, etc.

To control structures, the RB performs civil engineering plant walk-downs with inspection of the condition of steel parts, concrete parts, coatings, seals, etc.

The inspection programme of the regulatory body is complemented by systematic plant surveys (systematic plant walk-downs) which are performed by a TSO.

1.4 Does your RB use design basis inspection in the periodic safety review (PSR) or licence renewal process? Please provide details.

For most of the topics, the review of the PSR is performed on the basis of documents that are submitted by the operator within the PSR process, or that have been provided before in the framework of other licensing/supervision processes. In some special cases, for example within the review of the probabilistic safety analysis that is a mandatory part of the PSR, it can be necessary to verify certain details by going on site.

## 2. MANAGEMENT OF CURRENT DESIGN BASIS INSPECTIONS

2.1 Describe the resources required/deployed to undertake a current design basis inspection (inspection team number, technical specialists – external and/or internal, hours, etc.)?

Since there are no specific RB current design basis inspections, it is difficult to provide numbers. However, the expenditure of time for the RB inspections that are listed above (see No. 1.3) and the systematic plant surveys performed by a TSO (also noted in No. 1.3, for example one generalist and one specialist from the TSO and possibly one inspector of the RB) is extensive.

In addition to these inspections, the nuclear supervision of modifications requires a lot of resources at the RB and its TSO on a permanent basis. At first, all modifications important to safety are reviewed and assessed by technical experts during their office work. Later on, they inspect the licensee's final implementation and pre-service testing of a modified SSC on site in order to verify that it corresponds to the approved construction design.
Additionally, the regular participation of TSO experts in the operator's in service inspection and maintenance activities (as described in answer 1.3) also generates a good deal of inspection work on site.

2.2 Describe the type of information requested/supplied by the licensee to support the inspection. When is this information required/supplied?

In the particular case of TSO plant surveys, the licensee is informed during the preparation of the inspection, which systems or buildings are going to be inspected. In this way the licensee can provide relevant documents in advance (if necessary), he can designate a competent contact person and he may

even compile certain special documentation that is specifically going to be looked at during the inspection (for example notices of malfunctions of certain systems).

With respect to the aforementioned RB inspection activities on modification, in-service inspections, maintenance, etc., there is no big need for special support from the licensee before the inspection, since all relevant documents that describe the normal SSC condition are already at hand from the preceding approval procedure.

2.3 Describe how supply chain issues may be linked to current design basis inspection?

In some cases, supply chain issues may pose a challenge to the licensee in buying new components and spare parts. But, since modifications, maintenance and repair of SSCs important to safety are reviewed, assessed and inspected, the RB can check that the quality of new components or spare parts still meets the requirements of nuclear regulations.

On site, the licensee can have his own workshops, which can manufacture selected parts themselves or carry out repairs, and the licensee has certain stores on spare parts and components. The management of these facilities and the process of replacement of SSCs important to safety is typically a subject of on site inspections that investigate quality assurance processes.

2.4 Describe the scope of a current design basis inspection (e.g. SSCs, equipment configuration, maintenance, plant modification, safety limits/plant parameters, etc.).

Inspections that are related to the design basis can comprise the apparent state of SSCs, their performance during operation or testing, the procedures and final results of their modification, their environmental and operating conditions. For details see also answer 3.2.

2.5 Is there a graded approach used to select SSCs for inclusion in the inspection programme? If yes please specify how the graded approach is applied.

The review and assessment of modifications of the plant or operation procedures by the RB uses a graded approach (3 levels of safety significance).

Inspections of modifications as described above are applied to all items important to safety with a graduation between safety systems and safety related items.

Planned in-service inspection and maintenance activities are observed within a frequency that was fixed based on their safety relevance.

Items not important to safety are usually not inspected.

2.6 Describe how human performance is included in current design basis inspection (e.g. licensee training and qualification programme, operating instructions, etc.)

In the supervision of human performance the expertise of the persons in charge and of the other personnel working at the plant plays a major role. The supervision activities in this field are divided into review and inspection activities. The inspections can take place on site or at the training centre.

On the one hand, the RB requires the submission of documentation that proves the necessary technical education, training and practical experience. Thus, the RB’s checks of compliance with the corresponding nuclear regulation are carried out during office work.

On the other hand, shift personnel in charge have to pass a technical examination. Representatives of the RB and his technical experts attend the oral examination as voting members of the board of examiners at the plant or the German training centre. Apart from that, the qualification of responsible persons and other personnel is verified casually within technical discussions and question on diverse occasions on site. Sometimes, a representative of the RB attends a training course to check if its contents are in accordance with the corresponding regulations.

Another area of inspection is the assessment of the operating management and the overall plant condition. In this context, plant walk-downs and visits to the control room are carried out, which allow to inspect the physical condition of the plant as well as the compliance with the written operating regulations. The correctness of written operating regulations important to safety is not assessed during inspections, because this happens to the full extent before they are put into force. But during inspections, it is checked if such documents are up-to-date, complete, and in accordance with the last approved version, as well as understood and followed by the staff.

## 3. PERFORMANCE OF CURRENT DESIGN BASIS INSPECTIONS

3.1 Describe your RB guidelines/procedures for inspection of the current design basis.

The conceptual design for inspections as well as corresponding processes, regulations and aids are laid down in the RB's management system. In these documents, in particular:

- the functions of on site inspections,
- the areas of inspection (e. g. modification, in-service inspections, quality assurance, etc.) with a corresponding check list for each of them,
- the annual inspection programme,
- participants of inspections/team inspections,
- preparation of an inspection,
- classification of deviations and measures
- benchmarks

are addressed. Since "current design basis" is not an area of inspection of its own (see answer 1.1 to 1.2), there is no individual document for this topic. Nevertheless, many other areas of inspection cover certain aspects of current design basis inspections (see answer 1.3 and 2.6).

3.2 What methods of inspection are used (e.g. document review, interview, plant walk down, testing and maintenance observation, etc.) and under what circumstances?

Elements of on site inspections that are suitable to probe the current design basis are, for example, the following activities:

- verification, that a modification/repair of an SSC has been implemented according to the pre-approved construction design (by visual inspection of dimensions of the construction, material, place of installation, welding seams, equipment configuration, anchorage etc.) and that the pre-approved procedures (e. g. sequence plan) concerning intermediate/final and functional tests are followed
- verification of the proper function of systems and components by
  - observation of planned in-service inspections and maintenance activities
  - on site review of the licensee's documentation that records malfunctions
  - interviewing responsible persons from the licensee about the previous performance of SSCs
- plant walk-downs to watch for obvious defects in SSCs or conditions that might obviously compromise their functions when required (e. g. seismic housekeeping, environmental conditions)

3.3 How does your RB use technical specialists (e.g. for preparation, during the inspection, reviewing the inspection findings, etc.)?

In general, the assigned TSOs perform a large number of tasks in supporting the RB in supervisory procedures. The focus of these activities is on preparing expert reports, supervising the licensee's tests and inspections (qualification tests, materials testing, building inspections, pressure tests, acceptance and performance tests and in-service inspections), controlling maintenance activities and preparing TSO reports on modification projects applied for (design approval). Further advisory and support activities of TSOs include reviewing reportable events, plant surveys including the control of operations management or control of the effectiveness of the licensee's management system. Type and extent of TSO inspection activities are fixed in the corresponding contracts. Most of the TSO inspections are performed without inspectors from the RB being present. Serious inspection findings have to be reported to the RB, who will then decide on further measures.

Typically, the on site inspections of the RB are prepared, carried out and documented without the TSO's technical experts. If the inspection findings require further investigation or a deeper technical assessment (e. g. in the case of reportable events), technical experts are consulted at short notice.

3.4 Describe if there are specific processes for recording and acting upon current design basis inspection findings to improve your regulatory program and plant safety.

Plant safety: The processes that describe how the RB acts upon inspection findings are independent of the area that is inspected. The inspection results are classified and reacted upon accordingly (e. g. giving advice, writing a letter, issuing a direction etc.). There are no specific processes for findings from design basis inspections.

Regulatory program: The planning of the RB's annual inspection programme takes into account the required inspection areas and previous inspection findings. However, since current design basis inspections are not an explicit notion in the management system, none of these processes refers specifically to current design basis inspections.

## 4. WHAT ISSUE WOULD YOU LIKE TO DISCUSS DURING THE WORKSHOP?

*QUESTIONNAIRE C:*

**"INSPECTION OF THE SSCS CURRENT DESIGN BASIS"**

**COUNTRY: JAPAN**

## QUESTIONNAIRE

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

## 1. PURPOSE AND OBJECTIVES OF DESIGN BASIS INSPECTIONS

1.1 Does your RB undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis? Describe the reasons for undertaking a design basis inspection?

The NRA undertake inspection to confirm that SSCs meet the current design basis in two phases:

- Safety review: The NRA Confirm that the design of SSC satisfies regulatory requirements, mainly by documents applied by the licensee.
- Pre-Service Inspection: After the application from the licensee, The NRA facility inspector directly confirms that SSCs has been constructed according to the design confirmed by the safety review and conforms to the technical standards.

These two phases are applied in all cases, such as new plant construction, modification, reinforcement of regulatory requirements. And if necessary, the NRA require to back-fit to the latest design standards. By the law licensee are obliged to adapt SSCs to the latest design standards and shouldn't use SSCs before passing Pre-Service Inspection.

1.2 How often are design basis inspections required to be undertaken? Describe the basis for inspection frequency.

Pre-Service Inspection (is not carried out at regular intervals on a regular basis but) is undertaken every time the design of SSCs that should receive safety review is changed. The scope of SSCs that should receive safety review is stipulated by law and regulations.

1.3 If your RB does not undertake specific design basis inspections, is this work incorporated in other inspection programmes? Please provide details.

The NRA undertake specific design basis inspection in Pre-Service Inspection.

1.4 Does your RB use design basis inspection in the periodic safety review (PSR) or license renewal process? Please provide details.

The NRA don't use design basis inspection in the periodic safety review (PSR) nor license renewal process. The NRA requires for licensee who plans to operate nuclear reactor for more than 40 years to receive NRA approval. Licensee needs to submit application including the evaluation result on the deterioration.

As a result of special inspection for grasping SSC's aged deterioration situation according to the guidelines indicated by NRA, the license holder got the evaluation result on the deterioration situation and the maintenance of the SSC in documents to be submitted for NRA approval. It is necessary to include management policy. Based on the evaluation, if the licensee plans to change the design of SSCs, a safety review and Pre-Service Inspection by the NRA are carried out.

## 2. MANAGEMENT OF CURRENT DESIGN BASIS INSPECTIONS

2.1 Describe the resources required/deployed to undertake a current design basis inspection (inspection team number, technical specialists – external and/or internal, hours, etc.)?

Whole resources necessary for NRA to carry out Pre-Service Inspection is dependent on the scale of SSCs to be inspected and difficulty of the check, etc. In principle, each inspection is carried out with multiple teams as a unit with more than two inspectors as necessary. NRA doesn't utilise the outside personnel to Pre-Service Inspection. When deciding about details of the inspection contents of Pre-Service Inspection, it's possible to receive a review of the inner technical expert, but such example is little.

2.2 Describe the type of information requested/supplied by the licensee to support the inspection. When is this information required/supplied?

Information necessary for conducting the Pre-Service Inspection is basically provided at the time of application or interview from the licensee before conducting the inspection. The information includes details of the design of the SSCs to be inspected, production, and construction schedule. Documents to be submitted by the licensee at the time of application are stipulated by laws and regulations.

2.3 Describe how supply chain issues may be linked to current design basis inspection?

Pre-Service Inspection is conducted by NRA facility inspectors directly to SSC, but as a prerequisite, inspectors confirm the status of QA activities (including procurement management) pertaining to construction and inspection conducted by licensees. In addition, when it is necessary to particularly confirm the items concerning the supply chain, it is possible to inspect the vendor by a system different from the Pre-Service Inspection.

2.4 Describe the scope of a current design basis inspection (e.g. SSCs, equipment configuration, maintenance, plant modification, safety limits/plant parameters, etc.).

The purpose of the Pre-Service Inspection is to confirm on each step of construction whether the SSCs (including the configuration of the facility and parameters, and their modification) is manufactured and installed as designed, and whether the function / performance satisfying the technical standard is demonstrated.

2.5 Is there a graded approach used to select SSCs for inclusion in the inspection programme? If yes please specify how the graded approach is applied.

Yes.
SSCs to be subjected to safety review and Pre-Service Inspection are prescribed by laws and regulations in consideration of safety importance. Furthermore, the degree of involvement of the NRA facility inspector in the Pre-Service Inspection takes into account the safety importance of the SSCs to be inspected.

2.6 Describe how human performance is included in current design basis inspection (e.g. licensee training and qualification programme, operating instructions, etc.)

Pre-Service Inspection is conducted by NRA facility inspectors directly to SSC, but as a prerequisite, inspectors confirm the status of QA activities (Including competence of stakeholders and inspection procedures) pertaining to construction and inspection conducted by licensees.

## 3. PERFORMANCE OF CURRENT DESIGN BASIS INSPECTIONS

3.1 Describe your RB guidelines/procedures for inspection of the current design basis.

Procedures for conducting Pre-Service Inspections are set as internal regulations of the secretariat of NRA, notified to licensee, and published on the NRA website.

3.2 What methods of inspection are used (e.g. document review, interview, plant walk down, testing and maintenance observation, etc.) and under what circumstances?

Pre-Service Inspection is carried out by combining means for directly witness the SSCs and means for utilising the record of the inspection previously obtained by the licensee. The use of the record of the inspection conducted by the licensee is based on the premise that the quality control system of the licensee conforms to the regulation standards established by NRA.

3.3 How does your RB use technical specialists (e.g. for preparation, during the inspection, reviewing the inspection findings, etc.)?

While it is rare to utilise technical experts in Pre-Service Inspection, for example, NRA facility inspectors can utilise internal technical experts in preparation stages to determine detailed inspection content.

3.4 Describe if there are specific processes for recording and acting upon current design basis inspection findings to improve your regulatory programme and plant safety.

Since the criteria of Pre-Service Inspection is that SSCs to be inspected conforms to the latest design standards and satisfies the regulatory requirements, so that the SSCs is not permitted to use until it passes the Pre-Service Inspection. The process of recording the inspection findings and notifying the licensee is set by the internal regulations of the secretariat of NRA.

## 4. WHAT ISSUE WOULD YOU LIKE TO DISCUSS DURING THE WORKSHOP?

Nothing in particular.

*QUESTIONNAIRE C:*

**"INSPECTION OF THE SSCS CURRENT DESIGN BASIS"**

**COUNTRY: KOREA (REPUBLIC OF)**

## QUESTIONNAIRE

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

## 1. PURPOSE AND OBJECTIVES OF DESIGN BASIS INSPECTIONS

1.1 Does your RB undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis? Describe the reasons for undertaking a design basis inspection?

Answer: RB doesn't undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis.

1.2 How often are design basis inspections required to be undertaken? Describe the basis for inspection frequency.

Answer: Refer to Answer 1.1.

1.3 If your RB does not undertake specific design basis inspections, is this work incorporated in other inspection programmes? Please provide details.

Answer: RB doesn't undertake specific design basis inspections, but it is incorporated in several inspection programmes.

- Pre-service Inspection: In accordance with Article 27(Pre-Service Inspections) of ENFORCEMENT DECREE OF THE NUCLEAR SAFETY ACT, the pre-service inspection shall be performed to verify whether the construction works and performance of nuclear reactor facilities are confirm technical criteria. Construction processes subject to pre-service inspections and timing for such inspections shall be as follows: (1) When construction of major structures of nuclear reactor facilities has commenced and any strength test for each major process is possible, (2) When any function test for each system is possible after the construction of nuclear reactor facilities has been completed, (3) When it is possible to conduct water pressure tests at ordinary temperatures and function tests at high temperatures, (4) When it is possible to charge nuclear fuel and run a test for trial operation.
- Periodic inspection: In accordance with Article 35(Regular Inspections) of ENFORCEMENT DECREE OF THE NUCLEAR SAFETY ACT, the pre-service inspection shall be performed to verify whether reactor facilities are operated in conformity with the technical criteria and the performance to withstand pressure and radiation, and other performance of the reactor facilities are maintained. The periodic inspection shall be performed within 20 months of the start of initial commercial operation or inspection in the case of nuclear reactors for power generation purposes.
- Vendor inspection: In accordance with Article 31-2(Inspection of Suppliers) of ENFORCEMENT DECREE OF THE NUCLEAR SAFETY ACT, the vendor inspection shall be performed to verify whether matters concerning the design, manufacture and performance testing of safety related installations comply with the criteria for permits. The methods, procedures and other necessary matters for the inspections shall be determined and publicly notified by RB.

1.4 Does your RB use design basis inspection in the periodic safety review (PSR) or licence renewal process? Please provide details.

Answer: In accordance with Article 36(Timing, etc. for Periodic Safety Reviews) of ENFORCEMENT DECREE OF THE NUCLEAR SAFETY ACT, each operator of a nuclear power reactor shall comprehensively review the safety of the reactor facilities every ten years from the date he/she has obtained an operating license of such reactor facilities, and prepare and submit the PSR report to the RB.

RB review matters regarding design of reactor facilities to check whether the currently valid criteria at the time of review was accurately reflected in the design (including design documents).

RB review an information concerning the actual state of structures, systems, or appliances essential to safety to check whether the actual state of structures, systems, or appliances essential to safety satisfies the design requirements at present until the time of the next periodic safety assessment and the details have been duly documented.

RB review particulars regarding the degradation due to ageing of the structures, systems and equipment of reactor facilities to check whether degradation due to ageing of the structures, systems and equipment of reactor facilities is being effectively controlled to maintain the required safety margin.

## 2. MANAGEMENT OF CURRENT DESIGN BASIS INSPECTIONS

2.1 Describe the resources required/deployed to undertake a current design basis inspection (inspection team number, technical specialists – external and/or internal, hours, etc.)?

Answer: In case of periodic inspection, about 30~40 inspectors (internal technical specialists) of seven field (Reactor system, instrument & electrical system, structure system, etc.) undertake a current design basis inspection for approximately 40 days.

2.2 Describe the type of information requested/supplied by the licensee to support the inspection. When is this information required/supplied?

Answer: Documents (plant parameters, qualification of examiner and equipment, maintaining and testing procedures, past test results, something significant to report, test plan, etc.)

2.3 Describe how supply chain issues may be linked to current design basis inspection?

Answer: Vendor inspections is undertaken by RB to confirm the quality of components and equipment manufactured by vendors (prime contractor, associate subcontractors and including all overseas suppliers).

2.4 Describe the scope of a current design basis inspection (e.g. SSCs, equipment configuration, maintenance, plant modification, safety limits/plant parameters, etc.).

Answer: Integrity, performance and maintenance of the SSCs, plant modification (design change)

2.5 Is there a graded approach used to select SSCs for inclusion in the inspection programme? If yes please specify how the graded approach is applied.

Answer: In accordance with Notice of the Nuclear Safety and Security Commission No. reactor.34 (Regulation on Items and Method of Periodic Inspection for Nuclear Reactor Facilities), the facilities and field subject to periodic inspection are established. Extent and frequency of examination of SSCs are determined in accordance with ASME B&PV Code Sec. XI and long-term plan (LTP). Examinations performed in accordance with ASME B&PV Code Sec. XI that reveal flaws or relevant conditions exceeding the acceptance criteria standards shall be extended to include additional examinations during the current outage. The additional examinations shall include an additional number of welds, areas, or parts included in the inspection item equal to the number of welds, areas, or parts included in the

inspection item that were scheduled to be performed during the present inspection period. The additional examinations shall be selected from welds, areas, or parts of similar material and service.

2.6 Describe how human performance is included in current design basis inspection (e.g. licensee training and qualification programme, operating instructions, etc.)

Answer: In accordance with Article 55 (Qualification and Training) of Regulations on Technical Standards for Nuclear Reactor Facilities, Etc., (1) plant personnel with knowledge and experience required for the performance of duties in the power plant shall be appointed, (2) personnel conduct reactor operations, fuel material handling, and radioisotopes handling shall be qualified or trained personnel under the direction and supervision of qualified personnel, (3) A training program shall be established for the plant personnel to assure that they perform their duties successfully according to operating procedures in normal operation and accident conditions.

## 3. PERFORMANCE OF CURRENT DESIGN BASIS INSPECTIONS

3.1 Describe your RB guidelines/procedures for inspection of the current design basis.

Answer: Inspection guidelines are used for inspection of the current design basis. Scope, content, method, acceptance criteria, reference of inspection are described in the guidelines.

- Inspection guideline:
  Pre-operational Inspection Guidelines for LWR (Construction & Installation)
  Pre-operational Inspection Guidelines for LWR (Functional & Start-up test)
  Periodic Inspection Guidelines for Nuclear Power Reactor and Related Facilities
  Inspection Guidelines for Nuclear Reactor Facility Suppliers, etc.
- Inspection procedure:
  Pre-operational Inspection procedure for Nuclear Power Reactor and Related Facilities
  Periodic Inspection procedure for Nuclear Power Reactor and Related Facilities
  Inspection procedure for Nuclear Reactor Facility Suppliers, etc.

3.2 What methods of inspection are used (e.g. document review, interview, plant walk down, testing and maintenance observation, etc.) and under what circumstances?

Answer: Document review, interview, plant walk down, testing and maintenance observation are used.

3.3 How does your RB use technical specialists (e.g. for preparation, during the inspection, reviewing the inspection findings, etc.)?
Answer: RB use the internal technical specialists for preparation, during the inspection and reviewing the inspection finding.

3.4 Describe if there are specific processes for recording and acting upon current design basis inspection findings to improve your regulatory program and plant safety.

Answer: The specific processes, No. Reactor.10 (Regulation on Control of Inspection Findings of Nuclear Power Utilisation Facilities) of Notice of the Nuclear Safety and Security Commission, are used for recording and acting. (1) Preparation and Issuance of Inspection Findings Form, (2) Control and Exception of Inspection Findings, (3) Control and Utilisation of Inspection Findings, (4) Review and Supplementation of Report on Corrective Actions of Inspection Findings are included in the Notice.

## 4. WHAT ISSUE WOULD YOU LIKE TO DISCUSS DURING THE WORKSHOP?

*QUESTIONNAIRE C:*

**"INSPECTION OF THE SSCS CURRENT DESIGN BASIS"**

**COUNTRY: MEXICO**

## QUESTIONNAIRE

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

## 1. PURPOSE AND OBJECTIVES OF DESIGN BASIS INSPECTIONS

1.1 Does your RB undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis? Describe the reasons for undertaking a design basis inspection?

The Regulatory Body does not undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis.

1.2 How often are design basis inspections required to be undertaken? Describe the basis for inspection frequency.

As it was written above, no specific design basis inspections are undertaken by the Regulatory Body.

1.3 If your RB does not undertake specific design basis inspections, is this work incorporated in other inspection programmes? Please provide details.

The Regulatory Body does not carry out specific design basis inspections, but the subject is considered in other inspections, which are part of the base line inspection programme, mainly in operation, maintenance and engineering. Overall goals of these three inspections are the following: (a) Oversight the testing methods and practices of the utility on how safety requirements are maintained during the entire plant life. To inspect licensee's operation practices regarding to maintain adequate margin design during the implementation of plant modifications, including compliance with Technical Specifications; (b) Oversight the methods and practices of the utility on how the operability and integrity are maintained during maintenance planning and implementation according to plant specific procedures to comply with the design bases, and (c) Oversight the methods and practices of the utility on how the plant systems are performing safety functions to fulfil their design basis and the correctness of the basis.

It is important make emphasis that due to the overall amount of plant systems related and no related to safety the inspectors use the "Risk-Based Inspection Guidelines" as a tool to maintain oversight over the plant systems and components which are the most contributors for core damage frequency.

1.4 Does your RB use design basis inspection in the periodic safety review (PSR) or licence renewal process? Please provide details.

The regulatory Body doesn´t use design basis inspection during the periodic safety review or licence renewal process, because the Assessment Department evaluates the design changes according with the 10CFR50.59 and the Verification Department inspect these changes during the base line inspections.

## 2. MANAGEMENT OF CURRENT DESIGN BASIS INSPECTIONS

2.1 Describe the resources required/deployed to undertake a current design basis inspection (inspection team number, technical specialists – external and/or internal, hours, etc.)?

As mentioned above, no specific design basis inspection is performed, but the inspections mentioned in item 1.3 are organised typically as follows:

The Inspection team is formed by one inspector leader, which is responsible for planning the inspection and outline the Agenda, and another 2-3 inspectors, depending on the scope of the inspection, all of which are usually generalist inspectors. Detailed planning of the inspection is done by the inspection team according with the procedures. Typical inspections take three to five days on site.

2.2 Describe the type of information requested/supplied by the licensee to support the inspection. When is this information required/supplied?

Licensee and the Regulatory Body have an agreement for sharing a digital network named “C97” in which Licensee stored all the design basis information. So, any Regulatory Body staff –including inspectors – have access to the “C97” from their computer in the Regulatory Body Headquarters located in Mexico City. This is a great tool because the inspector can review in advance maintenance procedures, operating procedures, emergency operating procedures, plant modifications packages, documents from the plant vendor, plant drawings as layout, electrical wiring, logic control and flow systems.

On site the inspectors request for some additional information as surveillance testing results, Reactor Oversight Process (ROP) indicators, Operations log, maintenance plan, preventive and corrective maintenance records, ageing management reports, reports on plans systems performance and health report system.

2.3 Describe how supply chain issues may be linked to current design basis inspection?

Inspectors verify supply chain issues; one specific topic is verifying the issues related with fraudulent spare parts. The cause is that for economic reasons it is not possible to have all the necessary spare parts in the storage site in the case of safety related components the licensee has a software which has implemented a component items catalogue, for safety related components the licensee has agreements with plant components suppliers who provided the items requested.

2.4 Describe the scope of a current design basis inspection (e.g. SSCs, equipment configuration, maintenance, plant modification, safety limits/plant parameters, etc.).

As mentioned before, no specific design basis inspection is performed, but the scope of the inspections mentioned in item 1.3 typically included the verification of recent plant modifications that have been fully completed, plant walk-through, verification of risk monitor, verification of thermal limits, verification of condition reports related with deficiencies on SSCs, verification of inoperability records for specific SSCs or other similar findings or any concerns raised in international operating experience.

2.5 Is there a graded approach used to select SSCs for inclusion in the inspection programme? If yes please specify how the graded approach is applied.

The Regulatory Body developed the Risk-Based Inspection Guides (RIG's) for Laguna Verde Nuclear Power Plant Unit 1 (LVNPP U-1) as part of the application of Probabilistic Risk Assessment (PRA) methodology. RIG's are being used by inspectors as a helpful tool to plan and perform inspection activities at LVNPP U-1. The RIG's purpose is to assist the inspectors in establishing a more efficient approach for planning and performing inspections at plant systems and components most important to ensuring public safety.

2.6 Describe how human performance is included in current design basis inspection (e.g. licensee training and qualification programme, operating instructions, etc.)

During the operations inspection the inspectors observe the main control room operator’s performance during the surveillance testing activities.
On the other hand, during the maintenance inspection the inspectors observe the maintenance technician’s performance during the maintenance activities.

Also, during the operational exams applied by Regulatory Body for renewal of SRO and RO licensees the examiners assesses the crew performance for maintaining the plant within the design basis margins.

## 3. PERFORMANCE OF CURRENT DESIGN BASIS INSPECTIONS

3.1 Describe your RB guidelines/procedures for inspection of the current design basis.

No specific design basis inspection is undertaken.

3.2 What methods of inspection are used (e.g. document review, interview, plant walk down, testing and maintenance observation, etc.) and under what circumstances?

For the inspections referred in item 1.3 the methods of inspections are document review, plant walk-through to verify SSCs status, plant personnel performance observations and discussions with licensee personnel.

3.3 How does your RB use technical specialists (e.g. for preparation, during the inspection, reviewing the inspection findings, etc.)?

For the inspections referred in item 1.3 the Regulatory Body has made efforts to recruit technical specialists as much is possible in several disciplines, including to contract temporary technical specialist to cover the gap of specific specialities which are not usually filled by permanent staff.

In this sense, all the technical specialists can provide support to the inspectors as advisers during the inspections mentioned in item 1.3.

3.4 Describe if there are specific processes for recording and acting upon current design basis inspection findings to improve your regulatory programme and plant safety.

The Regulatory Body has two core processes for recording and acting upon current **any** inspection findings to improve our regulatory programme and plant safety.

Inspection process is related with the planning, preparation, performance and documenting of the inspection report. This process is for the inspection base line programme and the findings issued during such inspections are graded by the inspectors mainly by using the SERHE (System of Risk Assessment of Findings and Events) which is a software computer to grade the findings by risk-approach. Depending of the assessment results for the finding –green, white, yellow or red – the ROP Matrix is used to define the "Actions" to be performed by Regulatory Body against Licensee to make the necessary actions to restore a green condition for the finding in a specific time defined by Licensee but agreed by Regulatory Body. In most cases, the green condition is reached when the finding has been corrected by corrective actions and by establishment of preventive actions aimed to avoid recurrence of the finding. This process provides important inputs to improve the regulatory programme and plant safety.

Enforcement process is related with the performance of legal order visit for all the findings with a white, yellow or red colour. This audits are performed with strict adherence to the Federal Law of the Administrative Process. So, inspectors, technical specialists, lawyers and enforcement personnel are the main actors for performing such kind of legal visit orders. As result of these legal visits orders the Regulatory Body should define if: a) It is concluded that it does not exist any violation, b) the violation is of low importance, so, only recommendations are established in writing form to be taken in consideration by Licensee, or c) the violation is of medium or major importance which implicates the payment of penalty fee by Licensee. For cases b and c, the Regulatory Body can take some enforcement actions as partial closure of NPP, issue a reactor shutdown order, temporary suspension of staff or written reprimand from staff. Such regulatory actions are intended to discourage the licensee from violating the

regulations established to maintain and respect the design bases of the plant, and therefore to improve plant safety.

## 4. WHAT ISSUE WOULD YOU LIKE TO DISCUSS DURING THE WORKSHOP?

*QUESTIONNAIRE C:*

**"INSPECTION OF THE SSCS CURRENT DESIGN BASIS"**

**COUNTRY: POLAND**

## QUESTIONNAIRE

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

### 1. PURPOSE AND OBJECTIVES OF DESIGN BASIS INSPECTIONS

PLEASE NOTE THAT POLAND EXPERIENCE IS LIMITED TO INSPECTION PRACTICES WITH RESPECT TO RESEARCH REACTOR

1.1 Does your RB undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis? Describe the reasons for undertaking a design basis inspection?

Yes. This kind of inspections give reasonable assurance that SSCs are performing their safety functions as design and analysed (e.g. in SAR).

1.2 How often are design basis inspections required to be undertaken? Describe the basis for inspection frequency.

This kind of inspections are performed during almost every inspection in research reactor. Moreover this kind of inspections are performed :

- when modification of safety important SSC is implemented by licensee,
- during license renewal or periodic safety review (PSR) is carrying out by licensee,
- when new regulation come into force.

There is no legal basis which describe inspection frequency. Frequency came from annual and five-year inspection plan.

1.3 If your RB does not undertake specific design basis inspections, is this work incorporated in other inspection programmes? Please provide details.

See above.

1.4 Does your RB use design basis inspection in the periodic safety review (PSR) or licence renewal process? Please provide details.

See above.

### 2. MANAGEMENT OF CURRENT DESIGN BASIS INSPECTIONS

2.1 Describe the resources required/deployed to undertake a current design basis inspection (inspection team number, technical specialists – external and/or internal, hours, etc.)?

Normally PAA inspection team consist of four people: 2 inspectors and two technical specialist. In Maria research reactor inspection will take one or two days maximum.

2.2 Describe the type of information requested/supplied by the licensee to support the inspection. When is this information required/supplied?

PAA is requiring design documentation (e.g. drawings, system description), PSR report, or SAR. Depending on the case stated in point 1.2 some documentation is required to be supplied prior to inspection, but some drawings are checked during inspection.

2.3 Describe how supply chain issues may be linked to current design basis inspection?
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2.4 Describe the scope of a current design basis inspection (e.g. SSCs, equipment configuration, maintenance, plant modification, safety limits/plant parameters, etc.).

During design basis inspections PAA verifies: SSCs important to safety, equipment configuration, maintenance, plant modification, safety limits/plant parameters.

2.5 Is there a graded approach used to select SSCs for inclusion in the inspection programme? If yes please specify how the graded approach is applied.

PAA is using graded approach by performing more frequently inspections of SSCs with higher safety class.

2.6 Describe how human performance is included in current design basis inspection (e.g. licensee training and qualification programme, operating instructions, etc.)

When performing e.g. verification of in-core neutron measurement system we are asking operators to use current versions of plant manuals and instructions, to verify if they are updated and accurate.

## 3. PERFORMANCE OF CURRENT DESIGN BASIS INSPECTIONS

3.1 Describe your RB guidelines/procedures for inspection of the current design basis.

PAA has developed set of guidelines for inspectors which are topic/scope oriented. Guides give inspectors quite detailed list of steps to follow during inspection. Basically it describes what and how inspection should be performed, what are reference documents.

3.2 What methods of inspection are used (e.g. document review, interview, plant walk down, testing and maintenance observation, etc.) and under what circumstances?

Normally in most cases all of above mentioned methods are used in every inspection. Inspector starts with document review, then he go for system walk down and if required he will observe testing activities. Less frequently PAA inspectors observe maintenance activities.

3.3 How does your RB use technical specialists (e.g. for preparation, during the inspection, reviewing the inspection findings, etc.)?

PAA uses technical specialist rather rarely, but if that is the case they are engaged in all stages of inspection (preparation, performance, documentation, finding review).

3.4 Describe if there are specific processes for recording and acting upon current design basis inspection findings to improve your regulatory program and plant safety.
No. There is no separate, specific process for such inspections. It goes through standard inspection process.

## 4. WHAT ISSUE WOULD YOU LIKE TO DISCUSS DURING THE WORKSHOP?

*QUESTIONNAIRE C:*

**"INSPECTION OF THE SSCS CURRENT DESIGN BASIS"**

**COUNTRY: SLOVAK REPUBLIC**

## QUESTIONNAIRE

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

## 1. PURPOSE AND OBJECTIVES OF DESIGN BASIS INSPECTIONS

1.1 Does your RB undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis? Describe the reasons for undertaking a design basis inspection?

Specific inspection for design basis are not performed. Before licensee implements a change that might impact nuclear safety, he is obligated by Act. No. 541/2004 Coll. (Atomic Act) to inform the RB of the change. If he wants to implement a change that has influence on nuclear safety (this includes changes in selected equipment, etc.) he needs to ask RB for approval. Only after RB approval the change might be implemented. This also requires all documents to be updated in accordance with the current state of the plant.

1.2 How often are design basis inspections required to be undertaken? Describe the basis for inspection frequency.

As said before NRA does not perform special design basis inspections.

1.3 If your RB does not undertake specific design basis inspections, is this work incorporated in other inspection programmes? Please provide details.

Changes in plant design with impact on nuclear safety are approved by the RB. The current state of the plant is checked during outage inspections and also during inspections of the side inspectors. Also inspectors take part on functional tests of equipment during which the current state of the plant documentation is also checked. Inspections of the compliance of selected equipment with their quality assurance plans are also performed.

1.4 Does your RB use design basis inspection in the periodic safety review (PSR) or license renewal process? Please provide details.

Currently all licences for NPP operation are issued without time restriction. The licensee is obligated to perform PSR every ten years. Also shortly before the planned lifetime of NPP is reached, the licensee is obligated to perform PSR in order to prove that the plant might be operated even after its original planned lifetime. Part of PSR is the evaluation of design basis. NRA performs an inspection of the PSR evaluation which means that it also inspects all the areas of the PSR.

## 2. MANAGEMENT OF CURRENT DESIGN BASIS INSPECTIONS

2.1 Describe the resources required/deployed to undertake a current design basis inspection (inspection team number, technical specialists – external and/or internal, hours, etc.)?
As said before, special inspection to check the design basis. Design basis is inspected during other inspections of NRA. There for it is impossible to provide answer for this question.

2.2 Describe the type of information requested/supplied by the licensee to support the inspection. When is this information required/supplied?

During regular inspection, the licensee provides all documentation requested by the RB. This includes designs, test protocols, quality assurance plans etc. These are then checked by the inspectors. If there has been a change in design and the change itself had impact on nuclear safety, then it had to be approved by the regulatory body.

2.3 Describe how supply chain issues may be linked to current design basis inspection?

Currently the supply chain is not inspected. However, inspections of factory acceptance tests are performed. Suppliers are the responsibility of the licensee and the RB has no influence on their selection if all legislative requirements are met. Also the prime responsibility for nuclear safety cannot be transferred from the licensee, so the licensee is also responsible for the actions of his suppliers.

2.4 Describe the scope of a current design basis inspection (e.g. SSCs, equipment configuration, maintenance, plant modification, safety limits/plant parameters, etc.).

During regular inspection the inspector focuses on the main subject of the inspection. This means that if the inspector is observing a test, he is familiar with the procedure as well as the design. Procedures and design documentation are some of the base documents that are checked during inspection. The performance of test as well as plant configuration is then checked based on the information from documentation.

2.5 Is there a graded approach used to select SSCs for inclusion in the inspection programme? If yes please specify how the graded approach is applied.

NRA uses graded approach for the creation of inspection plan.

2.6 Describe how human performance is included in current design basis inspection (e.g. licensee training and qualification program, operating instructions, etc.)

Inspection of licensee’s training programme are dun periodically. Also all inspections whether it’s an inspection focused on emergency preparedness or a specific test evaluate human performance.

## 3. PERFORMANCE OF CURRENT DESIGN BASIS INSPECTIONS

3.1 Describe your RB guidelines/procedures for inspection of the current design basis.

As said before special inspections of design basis are not performed by NRA. Design basis is checked during other inspections.

3.2 What methods of inspection are used (e.g. document review, interview, plant walk down, testing and maintenance observation, etc.) and under what circumstances?

During RB inspections all above mentioned methods are used (document review, interview, plant walk down, testing and maintenance observation).

3.3 How does your RB use technical specialists (e.g. for preparation, during the inspection, reviewing the inspection findings, etc.)?

Inspectors are qualified to perform technical evaluation. However, if needed during the preparation phase or during the performance of an inspection, the RB might call for external assistance. Also NRA has a division for Safety Analyses and Technical Support, who if needed might be called to assist. This division also performs inspection of NPPs which are focused amongst others on deterministic and probabilistic analyses as well as long-term operation.

3.4 Describe if there are specific processes for recording and acting upon current design basis inspection findings to improve your regulatory programme and plant safety.

Results of all inspections are taken into account when new inspection plan is prepared. However, there are no specific processes that would specify the changes that need to be performed in NRA's inspection programme based on inspection findings.

## 4. WHAT ISSUE WOULD YOU LIKE TO DISCUSS DURING THE WORKSHOP?

*QUESTIONNAIRE C:*

**"INSPECTION OF THE SSCS CURRENT DESIGN BASIS"**

**COUNTRY: SLOVENIA**

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

## 1. PURPOSE AND OBJECTIVES OF DESIGN BASIS INSPECTIONS

1.1 Does your RB undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis? Describe the reasons for undertaking a design basis inspection?

YES.

- Design improvement is a continuous process at the Krško NPP. With that type of inspections the SNSA checks that improvements are prepared in accordance to regulations, standards and best practices.
- Quality of performed works and performance of installed SCCs is verified, as well.
- Design basis inspection is also aimed to check adequacy of existing design in case of new requirements (regulatory req., new standards) or in case of important foreign operational experience.

1.2 How often are design basis inspections required to be undertaken? Describe the basis for inspection frequency.

- Specific inspections are performed after identification of new requirements, results of analysis, operational experience, etc…. Typical such inspection reviews were "seismic design" and "flood protection". Another example is inspection on "SGs forged components" (experience with supplier French Creusot Forge) or inspection on "in-service inspection of RPV" after Doel three experience with hydrogen flaking.
- Continuously during plant outages (every 18 months). Reason: majority of design improvements are implemented during outages.
- Inspections to verify status of safety important SCCs (performance, deviations, maintenance and testing activities, etc…) about four times per year.
- Reactive inspections following abnormal situations.
- PSR every 10 years.

1.3 If your RB does not undertake specific design basis inspections, is this work incorporated in other inspection programmes? Please provide details.

1.4 Does your RB use design basis inspection in the periodic safety review (PSR) or licence renewal process? Please provide details.

- Verification of design basis is a part of ten yearly PSR. Verification, including inspections, are done by the licensee and contractors. SNSA is responsible to review the PSR report with associated action plan. Subject of inspection reviews is implementation of PSR action plan.
- Within LR process main focus is on ageing management of SCCs. Verification of design basis is a separated process.

## 2. MANAGEMENT OF CURRENT DESIGN BASIS INSPECTIONS

2.1 Describe the resources required/deployed to undertake a current design basis inspection (inspection team number, technical specialists – external and/or internal, hours, etc.)?

- SNSA has only three nuclear inspectors. Therefore involvement of experts from nuclear safety division is needed to cover this area. Inspection team typical consists from 3 or 4 members (inspector + experts).
- During outage TSOs are used to supervise activities in their field of expertise. Representatives of TSOs are not part of RB inspection team. They provide their own independent supervision and subsequently report to SNSA inspectors.

2.2 Describe the type of information requested/supplied by the licensee to support the inspection. When is this information required/supplied?

- Documentation on preparation of design modifications. Documentation is required and supplied during SNSA licensing process.
- Documentation on implementation of design modifications. Sometimes required during outages.
- Analysis prepared by supplier or licensee. Usually required and reviewed during inspection review. Sometimes required and supplied in advance.
- Qualification reports. Usually required and reviewed during inspection review.
- Reports of maintenance and testing activities - required and reviewed during inspection review.
- Reports on in-service inspections – supplied to SNSA periodically.

2.3 Describe how supply chain issues may be linked to current design basis inspection?

- Regulation JV5 (Rules on Radiation and Nuclear Safety Factors) include requirements on supervision of subcontractors and suppliers.
- SNSA is not authorised to perform direct inspections of suppliers. SNSA inspectors supervises the licensee's system to control supply chain.

2.4 Describe the scope of a current design basis inspection (e.g. SSCs, equipment configuration, maintenance, plant modification, safety limits/plant parameters, etc.).

2.5

- Preparation and implementation of design modifications
- Design of installed equipment
- Maintenance and testing activities
- In-service inspections
- Status of SCCs
-

2.6 Is there a graded approach used to select SSCs for inclusion in the inspection programme? If yes please specify how the graded approach is applied.

YES. Criteria used are: safety importance, PSA, past performance, OPEX.

2.7 Describe how human performance is included in current design basis inspection (e.g. licensee training and qualification programme, operating instructions, etc.)

- Work instructions, personnel training and qualification programme are part of review done by TSOs.
- Check of procedures is also done by the SNSA in the licensing process.
- During regular inspections on maintenance, testing or in-service activities review of procedures, checking of personnel training and qualifications is done by the SNSA inspectors.

## 3. PERFORMANCE OF CURRENT DESIGN BASIS INSPECTIONS

3.1 Describe your RB guidelines/procedures for inspection of the current design basis.
Currently SNSA does not have procedure/guideline to prepare and implement that type of inspections.

3.2 What methods of inspection are used (e.g. document review, interview, plant walk down, testing and maintenance observation, etc.) and under what circumstances?

- Review of design documentation
- Walk-downs
- Review of modifications implementation
- Observation of maintenance, testing and in-service inspection activities
- Review of maintenance and testing results

3.3 How does your RB use technical specialists (e.g. for preparation, during the inspection, reviewing the inspection findings, etc.)?

- TSOs are used, especially during outages. They review documentation and implementation of modifications of safety related SSCs, preparation and implementation of important maintenance or testing activities or in-service inspection.
- TSOs independently supervise activities in their field of expertise. They regularly report to the SNSA inspectors about results and findings. The SNSA inspectors are authorised to act upon on TSO's findings.

3.4 Describe if there are specific processes for recording and acting upon current design basis inspection findings to improve your regulatory programme and plant safety.

- Findings of SNSA inspectors or TSOs are recorded in inspection report. When minor deviations from regulatory requirements, standards or procedures are found corrective actions are required and recorded in inspection report, as well. In case of major deviations subsequent evaluation is made by inspectors and dedicated SNSA experts. Corrective actions are required by the inspection order.
- All findings and requirements of corrective actions are entered into special SNSA tracking system (IT tool) which allows to follow implementation of required corrective actions.
- Based on ten yearly PSR a report is prepared by the licensee and sent to the SNSA in review and approval. Part of the report a list of deviations found and plan of corrective actions to fix them.

## 4. WHAT ISSUE WOULD YOU LIKE TO DISCUSS DURING THE WORKSHOP?

*QUESTIONNAIRE C:*

**"INSPECTION OF THE SSCS CURRENT DESIGN BASIS"**

**COUNTRY: SPAIN**

**QUESTIONNAIRE**

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

## 1. PURPOSE AND OBJECTIVES OF DESIGN BASIS INSPECTIONS

1.1 Does your RB undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis? Describe the reasons for undertaking a design basis inspection?

CSN undertakes design basis inspections (DBI) that are specifically oriented to confirm that SSCs are maintained within their design basis. These inspections provide monitoring of the capability of the selected components and operator actions to perform their design bases functions. The inspections also evaluate the implementation of modifications to SSCs that may affect the design bases as well as introduce potential common cause failures.

Maintenance and Review of Operating Experience Issues are inspection areas that are also included.

1.2 How often are design basis inspections required to be undertaken? Describe the basis for inspection frequency.

CSN undertakes these inspections on a biennial basis for each NPP.

The inspection frequency is based on past experience with this kind of inspections and CSN resource management.

1.3 If your RB does not undertake specific design basis inspections, is this work incorporated in other inspection programmes? Please provide details.

1.4 Does your RB use design basis inspection in the periodic safety review (PSR) or licence renewal process? Please provide details.

CSN does not use design basis inspections in the PSR or license renewal process. The results of DBI are treated as inspection findings that follow a separate reactor oversight process.

## 2. MANAGEMENT OF CURRENT DESIGN BASIS INSPECTIONS

2.1 Describe the resources required/deployed to undertake a current design basis inspection (inspection team number, technical specialists – external and/or internal, hours, etc.)?

The inspection procedure is estimated to take 475 hours of CSN direct inspection effort every two years for those sites with one reactor, and 500 hours for sites with two reactors.

This is based on a multi-disciplinary team that comprises a team leader (NPP project manager) and five or six specialist inspectors (operation, maintenance, mechanical engineering, electrical and instrumentation engineering, human performance). The resident inspector can also participate in the inspection.

2.2 Describe the type of information requested/supplied by the licensee to support the inspection. When is this information required/supplied?

Information requested before the inspection:

- Safety analysis report
- Systems descriptions
- Design basis documents
- Pipe and instrumentation diagrams
- List of design modifications affecting the selected components
- Significant surveillance requirement procedures
- Pre-operational tests results
- Operating procedures

Information supplied during the inspection:

- Design calculations
- Surveillance requirements tests results
- Vendor´s manuals
- Maintenance programmes
- Work orders

2.3 Describe how supply chain issues may be linked to current design basis inspection?

Supply chain issues (e.g. use of digital components, substitution of certain devices due to plant ageing and obsolescence, vendor´s modifications in safety related SSCs, etc.) should be linked to design basis inspections via design modifications affecting the selected components.

2.4 Describe the scope of a current design basis inspection (e.g. SSCs, equipment configuration, maintenance, plant modification, safety limits/plant parameters, etc.).

The sample selection includes a group of 6-8 components selected based on risk-significance, as well as operator´s actions and operating experiences related to the selected components.

The inspection requirements include the review of the following areas: design, modifications, maintenance, problem identification and resolution, operating experience issues and environmental qualification.

2.5 Is there a graded approach used to select SSCs for inclusion in the inspection programme? If yes please specify how the graded approach is applied.
The sample selection will be based on risk information from the Probabilistic risk assessment (PRA), components with low design margins or operator’s action with high-risk significance.

Additionally, the team leader can establish other selection criteria (e.g. operating experience, engineering judgement, recent design modifications, etc.).

2.6 Describe how human performance is included in current design basis inspection (e.g. licensee training and qualification programme, operating instructions, etc.).

Human performance is included in design basis inspections via the review of topics related to human factors engineering and organisational factors.

## 3. PERFORMANCE OF CURRENT DESIGN BASIS INSPECTIONS

3.1 Describe your RB guidelines/procedures for inspection of the current design basis.

CSN counts on PT.IV.218 rev.1 Inspection Procedure that include the following items: inspection objective, frequency and sample selection, level of effort, inspection requirements and guidance.

3.2 What methods of inspection are used (e.g. document review, interview, plant walk down, testing and maintenance observation, etc.) and under what circumstances?

The procedure above mentioned describes an inspection which is a combination of documental review (in-office and during the inspection) and walk-downs.

3.3 How does your RB use technical specialists (e.g. for preparation, during the inspection, reviewing the inspection findings, etc.)?

In addition to the inspection team described in 2.1, there is an inspection support team that includes a specialist in PRA, a NPP resident inspector, a specialist in operating experience, a specialist in quality assurance and any other technical specialist needed.

Inspection findings are documented by the inspection team that can be advised by other technical specialists.

3.4 Describe if there are specific processes for recording and acting upon current design basis inspection findings to improve your regulatory programme and plant safety.

Design basis inspection findings are treated like any other findings from the CSN Basis Inspection Programme.

## 4. WHAT ISSUE WOULD YOU LIKE TO DISCUSS DURING THE WORKSHOP?

Topics related to plants ageing, environmental qualification and long-term operation should be include in design basis inspections.

*QUESTIONNAIRE C:*

**"INSPECTION OF THE SSCS CURRENT DESIGN BASIS"**

**COUNTRY: SWEDEN**

## QUESTIONNAIRE

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

## 1. PURPOSE AND OBJECTIVES OF DESIGN BASIS INSPECTIONS

1.1 Does your RB undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis? Describe the reasons for undertaking a design basis inspection?

On a system level, SSM undertakes inspections of e.g. performance tests for safety systems. This includes, amongst other things, inspection that applied acceptance criteria meet the performance required with respect to applicable design basis event (for the system in question). This type of system based inspections also includes control of system configuration (e.g. valve basing) during plant walk-downs.

In the case of mechanical components, a programme is incorporated which includes certificate of compliance from accredited bodies (see also answer to 1.3). SSM reviews the design basis while the accredited body inspects and verifies compliance, as well as any other inspections that need to be made.

In the area of environmental qualifications of electrical equipment, SSM has had an increased focus, including inspections, in recent years. As follows from the joint standard IEC/IEEE 60780-323 the main objective of this qualification is to demonstrate that the equipment can perform its safety function before, during, and after applicable design basis event (DBE).

Regarding reasons for undertaking design basis inspections: the concept of design basis can be considered as an important part of the basis for the authorisation to operate the plant. Therefore, inspections of such an approach in turn can be considered justified. Fulfilment of the design basis is essential for the fulfilment of "the Nuclear Promise".

1.2 How often are design basis inspections required to be undertaken? Describe the basis for inspection frequency.

The type of inspection, where a safety system is selected (system based inspections), SSM undertakes once or twice per year and per licensee. The basis for this is mainly the availability of nuclear safety inspectors at SSM and priorities with regard to other duties.

Intervals of inspections for mechanical components are determined based on classification into inspection groups A to C. This classification is in turn determined while taking into consideration the relative risk of nuclear fuel damage, external release of radioactive materials and deficiencies in general safety level owing to damage that might occur in the mechanical components.

1.3 If your RB does not undertake specific design basis inspections, is this work incorporated in other inspection programmes? Please provide details.
As explained under 1.1 a programme is incorporated, regarding mechanical components, which includes certificate of compliance from accredited body. This applies to both periodic in-service inspections and pre-service inspections in connection with plant modifications.

1.4 Does your RB use design basis inspection in the periodic safety review (PSR) or licence renewal process? Please provide details.

As follows from the European Nuclear Safety Directive, article 8c, the intended safety reassessment (i.e. the PSR) aims at ensuring compliance with the current design basis and identifies further safety improvements. However, in the SSM supervision system, inspection is separate from review. Regarding PSR, only review is undertaken.

## 2. MANAGEMENT OF CURRENT DESIGN BASIS INSPECTIONS

2.1 Describe the resources required/deployed to undertake a current design basis inspection (inspection team number, technical specialists – external and/or internal, hours, etc.)?

Usually two to four inspectors undertake the system based inspections; about 10–12 days each. (4–5 days on site and the other for preparation and after work.)

2.2 Describe the type of information requested/supplied by the licensee to support the inspection. When is this information required/supplied?

Information is requested and supplied both in prior and during the inspection on site, for example regarding delegation of responsibilities within the organisation, basis for the OLCs, operating instructions and test procedures, etc.

2.3 Describe how supply chain issues may be linked to current design basis inspection?

Regarding mechanical components, this is incorporated into the programme that includes inspection plans (during both manufacturing and in connection with installation) and certificate of compliance from accredited body.

More generally, SSM inspects that licensees have management systems that handle these aspects.

2.4 Describe the scope of a current design basis inspection (e.g. SSCs, equipment configuration, maintenance, plant modification, safety limits/plant parameters, etc.).

The scope can vary, but typically includes:

- a chosen safety system and its safety function (task) with regard to DBE,
- operating conditions, in the OLCs, for this system,
- requirements and procedures for operational readiness verification,
- acceptance criteria in relation to DBE,
- instructions for required operations of the system
- maintenance intervals,
- control of system configuration,
- check that any plant modification have been handled correctly, etc.

2.5 Is there a graded approach used to select SSCs for inclusion in the inspection programme? If yes please specify how the graded approach is applied.
Yes, graded approach with the main safety functions and assumptions in SAR as a guiding principle.

2.6 Describe how human performance is included in current design basis inspection (e.g. licensee training and qualification programme, operating instructions, etc.)

It is included mainly through inspection of competence and of operating instructions.

## 3. PERFORMANCE OF CURRENT DESIGN BASIS INSPECTIONS

3.5 Describe your RB guidelines/procedures for inspection of the current design basis.

SSM has not yet developed any guidelines or procedures, but an inspection plan is made prior to inspection based on those used earlier.

3.6 What methods of inspection are used (e.g. document review, interview, plant walk down, testing and maintenance observation, etc….) and under what circumstances?
The inspections include document review, interviews, plant walk down and testing observation (so far mainly under operation of the plant).

3.7 How does your RB use technical specialists (e.g. for preparation, during the inspection, reviewing the inspection findings, etc….)?

Sweden has not established any arrangements involving a TSO. In the area of mechanical components, there are technical specialists within the accredited bodies.

3.8 Describe if there are specific processes for recording and acting upon current design basis inspection findings to improve your regulatory program and plant safety.

No specific processes compared to other inspections. An inspection report is completed and if there are shortcomings in relation to applicable requirements, an injunction will be issued for correcting the licensee.

## 4. WHAT ISSUE WOULD YOU LIKE TO DISCUSS DURING THE WORKSHOP?

Inspection practices when it comes to safety features for the category of design bases called Design Extension Conditions (DEC), as shown in figure below. This may include, for example filtered containment venting and other additional safety features to mitigate multiple failure events (CCFs).

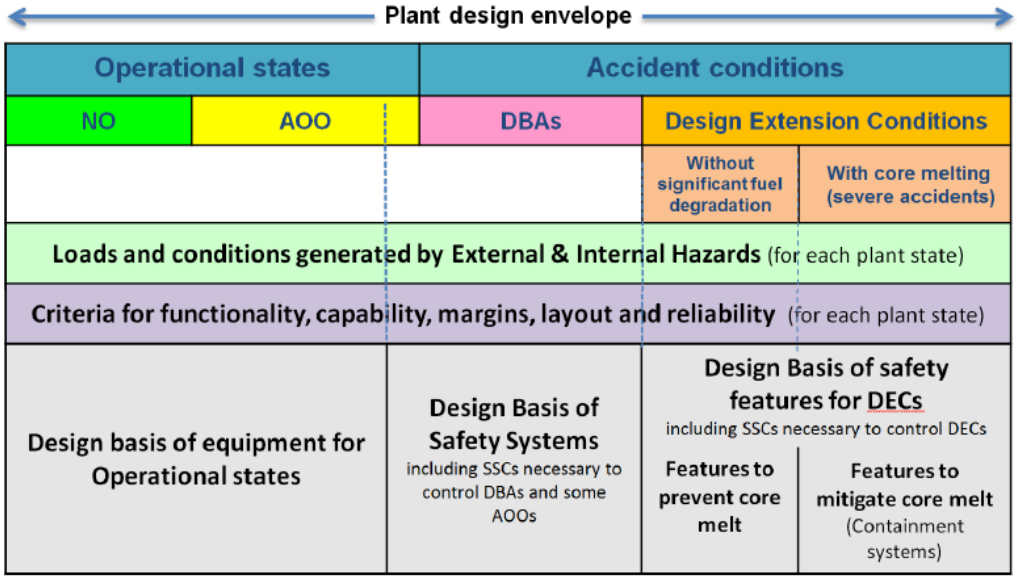


*FIG. 2. Main elements of the design basis of SSCs for different plant states.*

Figure presented in IAEA-TECDOC-1791, *Considerations on the Application of the IAEA Safety Requirements for the Design of Nuclear Power Plants*.

*QUESTIONNAIRE C:*

**"INSPECTION OF THE SSCS CURRENT DESIGN BASIS"**

**COUNTRY: UNITED KINGDOM (UK)**

## QUESTIONNAIRE

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

## 1. PURPOSE AND OBJECTIVES OF DESIGN BASIS INSPECTIONS

1.1 Does your RB undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis? Describe the reasons for undertaking a design basis inspection?

Yes - System Based Inspections (SBIs) are an essential element of ONR's overall intervention on a nuclear site and consist of a series of inspections which are intended to establish that the basic elements of a site/facility safety case as implemented in Safety Systems and Structures (SSS) are fit for purpose and that they will fulfil their safety functional requirements.

1.2 How often are design basis inspections required to be undertaken? Describe the basis for inspection frequency.

The overarching aim is to ensure that all identified Safety Systems and Structures on a site will be inspected twice during the nominal ten year timescale associated with a Periodic Safety Review. Therefore, the SBI inspection programme for each site/facility is such that all the key elements implementing the safety case are checked every 5 years. Having identified the key systems/structures for the site or facility, the inspections should be transposed onto a 5 year plan in an appropriate sequence and aligning with, for example, plant outages as necessary.

1.3 If your RB does not undertake specific design basis inspections, is this work incorporated in other inspection programmes? Please provide details.

N/A

1.4 Does your RB use design basis inspection in the periodic safety review (PSR) or licence renewal process? Please provide details.

ONR does not make specific reference to SBIs in the periodic safety review (PSR) or licence renewal process. However as noted in 1.2 above, SBIs are undertaken twice during the nominal ten year timescale associated with a PSR. Licence renewal process is not predicated on SBIs.

## 2. MANAGEMENT OF CURRENT DESIGN BASIS INSPECTIONS

2.1 Describe the resources required/deployed to undertake a current design basis inspection (inspection team number, technical specialists – external and/or internal, hours, etc.)?

A typical SBI involves the ONR nominated site inspector and support from one or two internal technical specialists (see Note 3.3). The time spent depends on the complexity, size of the SSS and specialists knowledge/ understanding. However typical durations would be:-

- Preparation time 2 to 3 days
- Time on site – 1 to 2 ½ days
- Reporting and follow-up – 1 to 2 ½ days

2.2 Describe the type of information requested/supplied by the licensee to support the inspection. When is this information required/supplied?

Typical documentation provided minimum 2 weeks prior to intervention:

- Station Living Safety Document, Safety Case User Guides
- System Description Document
- System Safety Report
- System Health Reports
- Relevant system operating experience reports
- Relevant engineering change reports
- Relevant Technical Specifications and commentaries
- Maintenance schedule entries

Typical documentation reviewed during intervention on site:

- Training records, training documentation, role profiles, authorisations
- Station Operating Instructions, Plant Operating Instructions, Surveillance routines
- Operational records and logs
- Alarm logs, operator burdens, distractions and work arounds
- Return to service forms, hand over certificates, configuration control records
- Work order cards, safety documentation, permits
- Maintenance records, instrument check sheets, calibration data, condition monitoring data
- Asset management database
- Defect records
- Leak schedules

2.3 Describe how supply chain issues may be linked to current design basis inspection?

Supply chain intervention is not specifically identified as an area for inspection in ONR SBI guidance nor is LC 17 – Management systems one the six mandatory LCs included in an SBI. However ONR has guidance on Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items or Services and Licensee's "Intelligent Customer" capability. If the SSS under consideration is judged to have specific supply chain issues linked to design basis inspection ONR may call on the nominated inspector or specialist inspector to pursue this matter.
Nuclear Safety Technical Assessment Guide:
http://www.onr.org.uk/operational/tech_asst_guides/ns-tast-gd-077.pdf

LC 28 - Examination, Inspection, Maintenance and Testing is one of the mandatory licence conditions specified in ONR SBI guidance. Inspection of this condition may sample the control of stores items.

2.4 Describe the scope of a current design basis inspection (e.g. SSCs, equipment configuration, maintenance, plant modification, safety limits/plant parameters, etc.).

SBIs inspections are structured around sample examination of arrangements made in accordance six standard nuclear site licence conditions:-

- LC 10 – Training - To ensure that the operators and maintainers are adequately trained in the operation/maintenance of the SSS.
- LC 23 - Operating Rules - To ensure that the limits and conditions identified in the safety case are properly implemented.
- LC 24 - Operating Instructions - To ensure that the operators and maintainers of the SSS have adequate written instructions relating to ensuring compliance with the limits and conditions above.
- LC 27 - Safety Mechanisms, Devices and Circuits - To ensure that if there are safety mechanisms as part of the SSS they are properly connected and in good working order.

- LC 28 - Examination, Inspection, Maintenance and Testing - To ensure that the SSS is being adequately maintained.
- LC 34 - Leakage and Escape of Radioactive Material and Radioactive Waste - To ensure that the SSS is not leaking radioactive materials, liquids, sludges, gases etc….

For each of the LCs inspected, a rating is given based on the information sampled and the discussions held with the relevant licensee staff. The ratings given are in accordance with the ONR inspection rating guide provided at Annex 1 below.

In addition and overall judgement of 'YES/ NO' is given that the System/Structure adequately fulfils the requirements of the safety case. The ONR inspector's experience and judgement is crucial in coming to a decision whether the Safety System or Structure will fulfil the requirements of the safety case.

The basis for the intervention is an initial assumption that the extant safety case for the system/structure is robust and the SBI is not intended to challenge the principal safety case claims and arguments, but rather to confirm that the safety case requirements are represented on the plant and within the associated plant documentation.

SBIs involve a 'deep slice' sample into the safety case and its supporting documents, with a view to ascertaining the adequacy of the implementation of the licensee's arrangements as a part of licence condition (LC) compliance. These inspections are generally undertaken with the support of specialists from within ONR and are informed through a review of the safety case (including supporting references and records), discussions with station specialists, plant inspection and from the sampling of documents and records.

Note: that in some cases it is not appropriate to inspect an SBI against all six licence conditions. For example, if a system does not contain radioactive materials, then it will not be necessary to check against LC34 and; therefore, the Intervention Record must record that it was not applicable on this occasion and provide an appropriate justification

2.5 Is there a graded approach used to select SSCs for inclusion in the inspection programme? If yes please specify how the graded approach is applied.

While it is recognised that a SBI approach is appropriate for all nuclear licensed sites, there will be considerable variation between, for example, the number and type of Safety Systems and Structures for an operational reactor site and an intermediate level waste store. Additionally, the approach taken to identify the key Safety Systems and Structures associated with a SBI on a multi-facility site is different to that required for an 'island' reactor site.

For a nuclear power plant there will be around 30 such systems whereas for a simple radioactive waste store there may only be 2 or 3. ONR Guidance is provided for an example of Civil Nuclear Reactor Programmes SSS list (see 3.1).

2.6 Describe how human performance is included in current design basis inspection (e.g. licensee training and qualification programme, operating instructions, etc.)

The licence conditions listed below are mandated in the SBI guidance and relate to human performance. The Technical Inspection Guide associated with each licence condition provides further guidance on their inspection:

- LC 10 – Training - To ensure that the operators and maintainers are adequately trained in the operation/maintenance of the SSS.
- LC 24 - Operating Instructions - To ensure that the operators and maintainers of the SSS have adequate written instructions relating to ensuring compliance with the limits and conditions.

- LC 28 - Examination, Inspection, Maintenance and Testing - To ensure that the SSS is being adequately maintained, including maintenance instructions.

## 3. PERFORMANCE OF CURRENT DESIGN BASIS INSPECTIONS

3.1 Describe your RB guidelines/procedures for inspection of the current design basis.

ONR has detailed Guidance for Intervention Planning and Reporting. The general SBI guidance is as is outlined in section 2.4 above and attached to Annex 1 (ONR-INSP-GD-059).

3.2 What methods of inspection are used (e.g. document review, interview, plant walk down, testing and maintenance observation, etc.) and under what circumstances?

ONR operates on a sampling basis of evidence including:

- Document review
- Interview station and corporate personnel
- Plant walk down
- Testing and maintenance observations
- Review of system health

3.3 How does your RB use technical specialists (e.g. for preparation, during the inspection, reviewing the inspection findings, etc.)?

ONR employs its own technical specialist inspectors for preparation, during inspection, reviewing inspection findings, producing intervention records and pursuing regulatory issues.
Note: That ONR's process allows for the use of external Technical Support Contract organisations to provide technical specialist support. In the year 2015/16 ONR employed a TSC to support ten off SBIs in the operating reactors programme. No regulatory decision making or enforcement is taken by TSC.

3.4 Describe if there are specific processes for recording and acting upon current design basis inspection findings to improve your regulatory program and plant safety.

ONR operates an enforcement policy and management model which takes a graded approach to regulatory issues management. An issues management process with four defined levels of issue (1 - most significant to 4 – low level issues) is used to record and act upon inspection findings. The process and RB organisational structure has appropriate governance in place to ensure lessons are learned and improvements made to programmes and plant safety. (The full detail is too extensive to provide in this questionnaire).

## 4. WHAT ISSUE WOULD YOU LIKE TO DISCUSS DURING THE WORKSHOP?

No Specific Topics

## ANNEX 1 TO QUESTIONNAIRE C

**ONR intervention rating system**

- *Green – No formal action*. ONR is generally content that licensee/duty holder's performance meets relevant good practice (e.g. meets legal requirements) and any identified shortfalls are not significant. ONR feedback (if any) is informal and advisory in nature.

- *Amber – Seek improvement*. ONR inspections have identified significant shortfalls. ONR action is to issue an enforcement communication (letter or e-mail) which is tracked to completion.
- *Red – Demand improvement*. Shortfalls have been identified which are sufficiently serious to merit the use of ONR powers to compel compliance (e.g. IN, direction or withholding of a permission).

ONR-INSP-GD-059

http://www.onr.org.uk/operational/tech_insp_guides/ns-insp-gd-059.pdf

*QUESTIONNAIRE C:*

**"INSPECTION OF THE SSCS CURRENT DESIGN BASIS"**

**COUNTRY: UNITED STATES**

## QUESTIONNAIRE

For the preparation of the workshop, participants are invited to supply their national inspection approaches used according to the following questionnaire:

## 1. PURPOSE AND OBJECTIVES OF DESIGN BASIS INSPECTIONS

1.1 Does your RB undertake inspections that are specifically aimed at confirming that SSCs meet the current design basis? Describe the reasons for undertaking a design basis inspection?

Yes. The U.S. Nuclear Regulatory Commission (NRC) considers the establishment and maintenance of an adequate design basis throughout plant life to be fundamental to safe operation of the plant. This provides assurance that the plant will function as expected during all design basis conditions.

1.2 How often are design basis inspections required to be undertaken? Describe the basis for inspection frequency.

Currently, the NRC performs a Design Basis Assurance (DBA) inspection approximately every three years at each of our facilities. We are on a three year cycle and are required to perform a DBA inspection once per triennial period. We attempt to schedule these inspections as close to every three years as practical but the actual requirement is once per cycle.

1.3 If your RB does not undertake specific design basis inspections, is this work incorporated in other inspection programmes? Please provide details.

As described above, the U.S NRC does undertake a specific design basis inspection at each of our facilities but we also consider the design basis in other inspection activities. For example, we perform a plant modification inspection which examines changes made to the plant to ensure that the changes are consistent with the current design basis. Many of our inspection activities are related to the current design basis in some way which provide additional insight into this aspect of the licensee's activities.

1.4 Does your RB use design basis inspection in the periodic safety review (PSR) or license renewal process? Please provide details.

Yes. The U.S. NRC conducts an annual review of overall licensee performance at each of our facilities. This review includes discussion related to the results of the current design basis inspections that were performed during the assessment period. The End-of-Cycle (EOC) meeting is typically conducted in February and looks at the assessment period of the previous calendar year (January through December). If a specific Design Basis Assurance (DBA) inspection was not performed during the assessment period, other insights into the licensee's maintenance of the design basis documented during other inspection activities are discussed as appropriate. The U.S. NRC has a separate program related to license renewal that includes inspections related to the design basis. Results of these inspections are not typically discussed during the EOC review meetings since they are more forward looking (maintaining the design basis in the future) rather than current performance which is the focus of the EOC assessment meetings.

## 2. MANAGEMENT OF CURRENT DESIGN BASIS INSPECTIONS

2.1 Describe the resources required/deployed to undertake a current design basis inspection (inspection team number, technical specialists – external and/or internal, hours, etc.)?

The Design Basis Assurance (DBA) inspection is a team inspection. The team consists of a team leader, one mechanical inspector, one electrical inspector, and one operations inspector. Each of these are full time NRC inspectors. In addition, two contractors are on the team, one mechanical specialist and one electrical specialist. The contractors are very seasoned individuals that were involved in the design and construction of NPPs in their careers. The inspection is performed beginning with an in-office preparation week, followed by one week on site, one week in-office review, a second on site week, and finally documentation. The number of direct inspection hours is estimated at 312 hours (plus or minus 15 percent). These hours do not include preparation or documentation work.

2.2 Describe the type of information requested/supplied by the licensee to support the inspection. When is this information required/supplied?

Approximately 60 days in advance of the first on site week of the DBA inspection, the team leader will prepare a Request for Information (RFI) letter to be sent to the licensee. This letter details the information required in advance of the inspection to allow for an effective team preparation week. The specific information requested in advance of the inspection includes:

1. An Excel spreadsheet of equipment basic events (with definitions), including importance measures sorted by risk achievement worth and Fussell-Vesely from your internal events probabilistic risk assessment. Include basic events with risk achievement worth value of 1.3 or greater.

2. A list of the top 50 cut-sets from your PRA.

3. Copies of probabilistic risk assessment “system notebooks” and the latest probabilistic risk assessment summary document.

4. An Excel spreadsheet of probabilistic risk assessment human action basic events or risk ranking of operator actions from your site specific PSA sorted by risk achievement worth and Fussell-Vesely. Provide copies of your human reliability worksheets for these items.

5. If you have an external events or fire PSA model, provide the information requested in items 1-4 for external events and fire.

6. A list of high large early release frequency impact events and associated components.

7. Structures, systems, and components in the Maintenance Rule (a)(1) category.

8. A list of high-risk maintenance rule systems/components and functions; based on engineering or expert panel judgement.

9. Site top 10 issues list, if available.

10. Any pre-existing list of components and associated calculations with low design margins.
11. A list of operating experience evaluations for the last 3 years.

12. A list of all time critical operator actions in procedures.

13. A list of current “operator work arounds/burdens.”

14. Procedures, including emergency and abnormal, used to accomplish operator actions

associated with the basic events credited in your PRA.

15. Lists of permanent and temporary modifications performed in the past 5 years to structures, systems, and components sorted by component identified in Item 1.

16. List of root cause evaluations associated with component failures or design issues initiated/completed in the last 5 years.

17. A list of any common cause failures of components in the last 3 years.

18. A copy of any internal/external self-assessments and associated corrective action documents generated in preparation for this inspection.

19. A copy of engineering/operations-related audits completed in the last 2 years.

20. Electronic copies of the Technical Specifications, Technical Specifications Bases, and the Final Safety Analysis Report, as updated.

21. A copy of the Individual Plant Examination of External Events, if available electronically.

22. One-line drawings of emergency core cooling system, ultimate heat sink, emergency feedwater, safety related electrical systems.

23. A list of licensee contacts for the inspection team with phone numbers.

24. A copy of the current management and engineering organisational charts.

In addition, the following information is requested to be provided throughout the inspection:

1. Electronic copies of the design bases documents for selected components and modifications.

2. Electronic copies of the system health notebooks for selected components and modifications.

3. A list of the design calculations that provide the design margin information for selected components. (Calculations for selected components should be available during the information gathering visit.)

4. Calculations and drawings associated with selected components.

5. Modification documentation associated with modifications selected, this includes:

    a. Post-modification testing, including performance characteristics affected, assumptions, and acceptance criteria associated with modifications selected.

    b. Updated maintenance and surveillance procedures associated with modifications.

    c. Updated operation procedures and training plans associated with the modifications.

6. Copies of any corrective action documents generated as a result of the team's questions or queries during this inspection.

7. Copies of the list of questions submitted by the team members and the status/resolution of the

information requested (provide daily during the inspection to each team member).

2.3 Describe how supply chain issues may be linked to current design basis inspection?

The design basis inspection does not specifically examine supply chain issues. The inspection focuses on licensee performance related to maintaining the plant consistent with the current design basis. However, given the realities of obsolescence and availability of replacement parts, inspectors do examine the adequacy of the licensee's programme for procuring parts as part of their inspection activities. This would include commercial grade dedication programmes and reverse engineering efforts. Supply chain issues are specifically examined by the vendor inspection group within the U.S. NRC.

2.4 Describe the scope of a current design basis inspection (e.g. SSCs, equipment configuration, maintenance, plant modification, safety limits/plant parameters, etc.).

The scope of a design basis inspection includes a selection of mechanical and electrical SSCs, a containment related SSC, a review of selected modifications to SSCs, and review of a selection of Operating Experience (OpE) documents related to how these issues were applied to the facility.

Inspection of these SSCs is very detailed and include reviews of component maintenance history and corrective action programme reports to verify monitoring of potential degradation, related engineering calculations and analyses, maintenance and testing procedures, and operating parameters. For selected SSCs, the team will develop and run specific plant scenarios in the plant simulator to demonstrate how these SSCs will function under various conditions, including accident conditions. In addition, throughout the inspection, the inspectors verify that the licensee is identifying engineering design issues and problems and entering them into their corrective action programme.

2.5 Is there a graded approach used to select SSCs for inclusion in the inspection programme? If yes please specify how the graded approach is applied.

Yes, the U.S. NRC does use a graded approach to selecting SSCs for inclusion in the design basis assurance inspection. Specifically, three different approaches can be used to select SSCs. These include the system approach, the risk-significance/low margin approach, and the event scenario- based approach. In the system approach, risk-significant components in the most risk-significant systems are considered for inspection. In the risk-significant/low margin approach, components are selected based on their risk-significance with the use of low margin (either low design margin; low maintenance margin; or operating margins) as an option. In the event scenario-based approach, accident sequences using the licensee's most current probabilistic risk assessment (PRA) model is used to inform the component selection. Details for the application of each of these three approaches are contained in the inspection procedure. Component selection also includes consideration of past inspections, equipment performance issues, and desired focus areas at the specific facility.

2.6 Describe how human performance is included in current design basis inspection (e.g. licensee training and qualification programme, operating instructions, etc.)

As part of the design basis assurance inspection, the team examines how the licensee's training, maintenance, testing, and operating procedures and programmes function to support the safety related components selected for inspection. The focus of this examination is to ensure that the SSC remains within the design basis. Specific to human performance, the team will often develop scenarios to be run in the plant simulator to determine how select SSCs will function during accident or upset conditions. The licensee supplies operating crews to run the scenarios in the simulator. The focus of this activity is on the performance of the SSCs and not necessarily on crew performance. However, some scenarios have related time critical operator actions associated with the SSC that are contained in the design basis. This activity is an opportunity to examine the interface between engineering and operations to ensure that assumed times can be realistically achieved and

are procedurally adequate. These simulator scenarios are conducted much like a licensed operator examination, including confidentiality agreements, to protect the integrity of the exercise but are not used to grade licensee control room operators.

## 3. PERFORMANCE OF CURRENT DESIGN BASIS INSPECTIONS

3.1 Describe your RB guidelines/procedures for inspection of the current design basis.

The specific inspection procedure used by the U.S. NRC for the design basis inspection is Inspection Procedure 71111 Attachment 21M, "Design Bases Inspection (Team)." It provides for a multi-disciplinary team comprised of a team leader and two to three regional inspectors (operations/maintenance and engineering). In addition, the team includes two contractor design specialists in the mechanical and electrical/instrumentation and control disciplines. The inspection is conducted on a triennial cycle.

3.2 What methods of inspection are used (e.g. document review, interview, plant walk down, testing and maintenance observation, etc.) and under what circumstances?

The design basis team inspection is conducted on site to allow for direct interaction with licensee personnel. The inspection is conducted using document review, interviewing licensee engineering, operations, and maintenance personnel involved in the area of design control, extensive plant walk-downs of selected systems and components, observations of activities in-progress including plant simulator scenarios, and regular interaction with station regulatory and management personnel. During the inspection, the licensee assigns a team of station personnel to support the inspectors on a full time basis. This support team includes individuals assigned as counterparts for each NRC team member. Questions and requests for information are made through these counterparts. The licensee records and tracks all requests made from the inspection team and the status of the responses are discussed daily (at a minimum) with the team leader.

3.3 How does your RB use technical specialists (e.g. for preparation, during the inspection, reviewing the inspection findings, etc….)?

Each team member is a technical specialist in their area. They are responsible for preparing for the inspection and communicating inspection status and recommendations to the team leader. Each team member is responsible for researching and developing inspection findings and coordinating with other team members. The team works together to determine the appropriate path forward on potential issues and shares information and knowledge to maximise the effectiveness of the time on site. Questions from the team related to current licence basis or other technical issues can be discussed with U.S. NRC headquarters personnel.

3.4 Describe if there are specific processes for recording and acting upon current design basis inspection findings to improve your regulatory programme and plant safety.

The U.S. NRC's process for developing and documenting inspection findings include identification of a specific performance deficiency, determining whether the finding is minor or more than minor, assigning a safety significance colour based on risk (Green, White, Yellow, or Red), and establishing a cross-cutting aspect. Issues identified as minor are not documented in a report but are entered into the licensee's corrective action programme and compliance is restored. More than minor issues are documented. The majority of findings identified and documented in an inspection report are assigned a colour of Green, meaning that they are considered to have very low safety significance. Issues determined to be Greater-Than-Green have greater risk-significance and are processed using established procedures including extensive discussions between NRC regional and headquarters personnel. Cross-cutting areas assigned to inspection findings include Problem Identification and Resolution (PI&R), human performance, and safety conscious work environments aspects and are

based on the basic cause of the performance deficiency. Also, inspection findings go-through several layers of review by regional management before they are issued.

## 4. WHAT ISSUE WOULD YOU LIKE TO DISCUSS DURING THE WORKSHOP?

Current or emerging issues that could affect the inspection of the design basis. This would include ageing of SSCs and the effect of maintenance. Would be interested in learning best practices on inspection techniques and issue identification. Also, correction of identified issues and how those issues are tracked and followed up on.