QUESTIONNAIRE FOR PREPARING THE REGULATORY BODY MEETING in conjunction to the ISOE-Symposium in Cambridge 2010

INVITATION

In conjunction with the 2010 ISOE Symposium, 17-19 November 2010, we are preparing a 4rd Senior Regulatory Body Representatives meeting, to be held 16. November 2010 in Cambridge (UK). We hope to encourage your participation in this meeting which follows on from the very successful Regulatory Body representatives meetings in 2004 (Lyon), 2006 (Essen) and 2008 (Turku). The purpose of the meeting is to provide a forum for open exchange and discussion within specialised regulatory audience concerned with occupational radiation protection. Subsequent to the ISOE-Symposium 2009 in Vienna several representatives of regulatory bodies expressed their interest on the exchange of information about: "**How Lessons Learned from Radiological Events** are drawn up, reported and distributed among RP-responsibles in NPP, training facilities, companies and countries".

MOTIVATION

The feedback from events is highly valuable, because the lessons learned show necessary improvements on actual weak points in the Radiation Protection Program. Lessons learned from events may show aspects, which are not considered either in legal regulations, company rules, RP-planning nor in RP training courses. These weak points may exist also in other units, plants, companies or countries. Therefore lessons learned have to reach all persons who may be concerned, so the repetition of similar events will be prevented.

About the distribution of information about radiological events on an international level, see the instructive presentation from Helena Janzekovic "Use of IRS and OSMIR Database – Lessons Learned" at the last ISOE 2009 Symposium. It is shown that both databases can be successfully used complementary to the ISODATA. These international reporting systems shall not be the main topic of this RB information exchange.

OBJECTIVES OF THE MEETING

The main objectives of the meeting are:

- To meet with regulators from other organisations to exchange information regarding regulatory standards and rules on
  - the criteria defined for nomination a deviation or departures from standard operational parameters, faults, defects, finding, malfunction, incident or accident as a radiological event of interest,
  - the company procedure on reporting internal, analysing the direct causes, the root causes, the increasing or decreasing factors, the radiological consequences, determining the lessons learned and package of measures (the common expression for this procedure is "Operational Experience Feedback" OEF, see for example NEA Committee on Nuclear Regulatory Activities/ Working Group on Operating Experience)
  - the criteria and the way for reporting the information about event to the regulatory body
  - the way how the information are distributed among RP-responsibles in other NPP, training facilities, companies and countries
- The focus should be on events, which have or may have radiological consequences on the staff or which occurred in the area of responsibility of the NPP Radiation Protection Organisation (this may include also uncontrolled releases inside and outside the NPP)

- This meeting will not deal with aspects of events in other fields of nuclear safety (loss of control on criticality, loss control on fuel cooling, deviation from transportation rules, …) will not be considered.
- To help to improve national regulatory effectiveness on occupational radiation protection by comparing national reality versus international context

AGENDA OF THE REGULATORY BODY MEETING

- Introduction of the different representatives
- Brief presentation on national requirements to support feedback from radiological events. Additional some interesting examples of lessons learned may be shown (around 15 min)
- Discussion of terms, differences, special approaches and innovative ideas to support the feedback
- Conclusions: Collection of exemplary approaches to get and distribute lessons learned

OBJECTIVES OF THE QUESTIONNAIRE

In order to introduce the Regulatory Body representatives meeting it is expected to draw an overview of **regulatory control on feedback from radiological events in NPPs from an occupational perspective** in the different ISOE member countries with their similarities and differences.

Therefore we would like you to answer, briefly, the following questionnaire to stimulate information exchange and discussions. Only one response per country is necessary.

Please do not go into the details, just describe a few “objective data”.

Even in case you will not be able to attend the meeting the information you can provide is precious. If you agree, questionnaires filled in by national authorities will be sent to all contacts participating in ISOE.

Yes, I agree X
No, the information should be sent only sent only to the RB participating in ISOE
No, the information should be used only in the RB-meeting

COUNTRY AND REPRESENTATIVE IDENTIFICATION

- **Country**: **France**
- **Name of the Regulatory Body: ASN (Nuclear Safety Authority)**
- **Name and post of the person(s) who fill in the questionnaire: Sophie Chevalier, Head manager, Olivier Couasnon and Xavier Niel, project managers in the Nuclear power plant department**

REGULATORY RIQUIREMENTS ABOUT REPORTING RADIOLOGICAL EVENTS

In the following questionnaire some possible answers are marked in blue color. Please cut of, change or complete (also if there are quantitative levels specified in the legislation)

- **Criteria**

  - Does your legislation specify criteria for nomination a near miss event, a minor damage, a deviation, a finding, an incident or an accident as a radiological event of interest

French regulation does not specify different criteria for nomination of the events. However, there are three rules defining significant events, i.e. the ones which must be declared to the nuclear safety authority :

1. *The so called "TSN law" (which applied to all NPP responsible persons) specifies in the article 54 that once there is an event (nuclear or not), "having or risking to be of significant consequences on the safety of the plant or the transport, or that endangers with significant exposure to ionizing radiation, to persons, or to goods or to the environment", the licensee must declare the event to the Nuclear Safety Authority (ASN) without delay.*
2. *The public health code (enforceable to all responsible persons of the nuclear activity) in its article L. 1333-3 specifies that () "once a responsible person of nuclear activity is faced to an event on the activity on which he is authorised, he must declare without delay the event to the Nuclear Safety Authority (ASN)".*
3. *The labour code defines measures related to working environment and in particular radiation protection, that each employer shall apply (as mentioned in the R. 4451-1). It emphasizes the obligation for the employer to declare every significant event which has led or being likely to carry out the overtaking of one of the limited values (according to the R. 4451-99 of the labour code).*

ASN issued a guide in 2005 which precises the details of the declaration and codification. This guide, and the criteria that it defines, will be soon revised.

One section of this guide is dedicated to radiological events, with 10 different notification criteria related. Those ten criteria concerning radiological protection are :

Criteria RAD1 : Exceeding or risk of exceeding of the annual dose limit

Criteria RAD2 : Exceeding one fourth of the annual dose limit

Criteria RAD3 : Events linked with radioactive contamination

Criteria RAD4 : Job realized without a proper radiation protection pre-analysis (taking into account ALARA principle), or without fully respecting the measures of this pre-analysis.

Criteria RAD5 : Malicious acts affecting occupational radiation protection

Criteria RAD6 : Any unexpected situation involving radioactive source

Criteria RAD7 : Failing signalisation or disrespect of technical conditions for access or stay in a classified area.

Criteria RAD8 : Failing detection and/or monitoring systems, that no more guarantee occupational radiation protection

Criteria RAD9 : Exceeding periodicity of control of monitoring systems

Criteria RAD10 : Other events concerning radiological event

  - If no, does some official document of the licensee specify these criteria?

The licensee (EDF) has produced an internal prescriptive notice (called DI 100), consistent with the ASN's guide, to give practical prescriptions to declare significant events (SE).

In addition, in order to promote experience feedback, this internal prescriptive notice is more demanding than the ASN's guide and defines some criteria of lower levels than those used to declare significant events. This way, events between the DI 100 levels and the ASN ones are called EI (interesting events).

- What are the most important radiological criteria?

The guide defined by the ASN does not classify events in ascending significance order. However, an event declared under criteria 2 (exceeding one fourth of the annual dose limit) shows an immediate and notable effect on the person (that is not obvious for example in the case of an event declared at criteria 7).

When an event is declared to ASN, it is considered to be significant and its significance (importance) will be deduced from INES levels.

ASN Criteria	**Corresponding form criteria**
Criteria RAD1 Exceeding or risk of exceeding of the annual dose limit	a)
Criteria RAD2 Exceeding one fourth of the annual dose limit	a)
Criteria RAD3 Events linked with radioactive contamination	b), Only one part of the case c) depending of the level of contamination, d) ; i); m)
Criteria RAD4 Job realized without a proper radiation protection pre-analysis (taking into account ALARA principle), or without fully respecting the measures of this pre-analysis.	n)
Criteria RAD5 Malicious acts affecting occupational radiation protection	n)
Criteria RAD6 Any unexpected situation involving radioactive source	g)
Criteria RAD7 Failing signalisation or disrespect of technical conditions for access or stay in a classified area.	h) j)
Criteria RAD8 Failing detection and/or monitoring systems, that no more guarantee occupational radiation protection	n)
Criteria RAD9 Exceeding control periodicity of monitoring systems	n)
Criteria RAD10 other events	b), Only one part of the case c) n)

a) Exceeding the annual exposure limit or any other dose constraints of persons (dose limits may be different depending on the category of persons, organs and tissues)

b) Investigation of an unexpected incorporation of activity above the minimum detectable level

c) Investigation of a fixed contamination of skin or wound

d) Exceeding the maximum permitted activity of a facility, room, storage or compartment : not concerned in PWR

e) Not expected increase of coolant activity, air contamination or surface contamination showing a leakage of fuel cladding, of transport cask, of waste container, of sealed source, of glove box or of hot cell → considered as Safety Significant Event (Technical Specifications in operation)

f) Not expected increase of coolant activity or dose rate at primary circuit showing unintended activation of impurities → classified as Safety Significant Event (disrespect of the Technical Specifications in operation)

g) Loss of a radioactive source

h) Unexpected exceeding the maximum permitted level for fixed (= not easily decontaminable) contamination or maximum permitted dose rate inside controlled zones (levels may be different depending on the category of zone)

i) Exceeding the maximum permitted contamination or dose rate outside of controlled zone inside the supervised plant area

j) Exceeding the maximum permitted activity released via the controlled exhaust air stack or waste water → Safety Significant Event

k) Uncontrolled release of activity → Safety Significant Event loss of containment measure 3

l) Exceeding the maximum permitted contamination or dose rate outside of the supervised plant area in the

environment → not concerned in PWR (crisis)

m) Exceeding the clearance levels (activity, dose rate, contamination) for material transported out of supervised plant area declared to be free of radioactivity or below levels for qualified disposal

n) *others …*

o) *others…*

p) *others …*

q) any event which may easily fulfil one of the listed criteria above, but missed fortunately

- Does your legislation specify criteria for reporting

a) only to company internal,

No, but the licensee has organised a system to collect and share significant and interesting events. The licensee issues press release(s) when events may be covered by the media.

b) to the regulatory body,

Yes, for the NPP's licensee according to the following criteria :

The article 54 of the act of 13th June 2006 on Transparency and Security in the nuclear field (TSN Law) indicates that "in the event of an incident or an accident whether nuclear or not, that has or is likely to have significant consequences on the safety of the installation or the transport or endangers, by significant exposure to ionising radiation, persons, goods or the environment, the licensee of a basic nuclear installation[1] or the person responsible for the transport of radioactive substances is obliged to declare it without delay to the Nuclear Safety Authority and to the State representative in the department of the place of the incident or the accident and, where applicable, to the State representative at sea.

One of the assignments of ASN is to inform the public. Thus, ASN puts on its website notices related to all events higher or equal to INES level 1 (as well as some events of interest of INES level 0). For events higher or equal to INES level 2, ASN gives additional information to the Prime Minister and to the Ministers of Industry, Health, Environment and Labour.

c) to international information platforms as INES, IRS and so on?

All significant events are classified according to INES criteria (for events concerning environment, only radioactive releases are classified). Events classified higher than one are reported to IAEA.

- If yes, do the criteria for nomination (for NPP internal analysis and feedback) differ from those criteria for reporting to the regulatory body?

In order to promote experience feedback, the licensee uses the criteria of the ASN's guide with a lower level (it considers the so-considered events are "interesting events"). For instance, events fitting the criteria n°3 have to be declared to ASN for a clothing contamination higher than 10 kBq detected in a plant outside the controlled area. As for the licensee, it retains a level of 800 Bq to register and analyse the events in its experience feedback process.

❑ **Differentiation of types/categories of radiological events?**

- Do the legislation/company rule define different types/category of radiological events?

Even if it makes the declaration of events compulsory, the legislation does not specify the types of radiological events, except to distinguish :

- the events leading or likely to lead to exceeding occupational exposure limits (with specific declaration measures in Public Health Code and Labour Code) ;
- the events leading or likely to endanger the public or the environment (with exceeding regulatory limits), which are considered as radiological emergency situations.

[1] Each NPP is a nuclear basic installation

The objective is to cover all types of events (safety, transport, environment, radiological protection inside and outside nuclear power plants).

Furthermore, emergency situations are handled according to a specific regulatory framework. Once the crisis is under control, the event will be declared by the licensee according to the criteria of the ASN's guide (that does not prevent AIEA notifications in case of emergency).

- Do the legislation use another categorisation instead of INES?

  No

- Which categories are defined in your legislation?

  See above.

❑ **Legislation concerning different aspects or steps for management of radiological events**

- Does your legislation specify different aspects or steps for management of radiological events?

  Yes but mainly when an event is significant enough to set off the on-site emergency plan (emergency situations)

- If so, which aspects or steps are specified in the legal framework?

  Legal framework for radiological events - criteria 1 to 10 :

  Obligations :

  - of declaration (as mentioned above),

  - for the *employer* to lead an analysis of the significant events to avoid their repetition (Labour Code- Article R4455-7).

  Guidance :

  Licensee has to declare the event within 2 days and to send the report to ASN within the two following months. The next updated versions of this report, particularly the final report which takes into account the implementation of preventive and corrective actions, are sent to ASN without delay.

  Legal framework for emergency situations (radiological events with potential high consequences on population or the environment) :

  The Decree 2007-1557 of 2 November 2007 concerning Basic Nuclear Installations and the supervision of the transport of radioactive materials with respect to nuclear safety, requires that each licensee of an NPP, before the commissioning of its installation, sends ASN a file including an on-site emergency plan.

  This plan defines the organisational measures, the response methods and the necessary resources for the handling of emergency situations, in order to protect the employees, the public and the environment from ionising radiation, and to preserve or restore the safety of the installation. If there is an off-site emergency plan, pursuant to the decree of 13 September 2005, the on-site emergency plan states how the licensee shall implement the measures described in the off-site emergency plan.

  The way the licensee shall handle a radiological event (covering b) to e)) is described in the on-site emergency plan. The ASN assesses it at the same time that it analyses the rest of the file required for the commissioning of the installation.

b) Analyse the direct cause, root causes, increasing and decreasing factors

c) Analyse the radiological consequences (really happened or probably could happened)

d) Analyse the lessons learned

e) Determination of measures to improve the RP

❑ **Legal framework on experience feedback from radiological events**

- Does your legal framework have requirements on the operational experience feedback (OEF) from radiological events?

Regulations do not foresee explicitly the implementation of a feedback experience process.

If so, give a short description of the content of references:

However, general requirements in the labour code and the order of the 10th of august of 1984 request the licensee to establish organizational measures to ensure incident and accident prevention. Regulation drafts (work-in-process at ASN) integrate those requirements in a more detailed way.

- Does your legislation specify different aspects or steps of operational experience feedback?

No

If so, which aspects or steps of OEF are specified in the legal framework?

Licensee shall provide promptly a detailed analysis of any important event.

For this purpose, in case of event, the licensee establishes and keeps up to date a report including the following elements :

- an analysis of technical, human and organizational causes of the event;

- an analysis of the real and potential consequences on the installation safety;

- the lessons learned as well as the preventive and corrective actions defined and the schedule for their implementation.

Licensee sends this report to ASN within the two following months after the declaration of the significant event. The next updated versions of this report, particularly the final report which takes into account the implementation of preventives and correctives actions, are sent to the ASN without delay.

❑ **Ways and tools to support the operational experience feedback OEF from radiological events?**

- Which ways or tools exist or are described in the legislation, guidelines or company instruction to support the OEF from radiological events within companies, among other NPP or country wide?

ASN and IRSN (the ASN's main technical support organization) analyse the most significant events and ensure that operation experience feedback is correctly shared.

EDF runs a database (Saphir) which collects all the significant events. ASN and IRSN have also some dedicated databases collecting RP events.

The operational experience feedback is dealt through different meetings :

- on a quarterly basis : meetings of ASN and IRSN with the licensee

- yearly : ASN evaluates the whole RP policy of the licensee and has a meeting with the licensee to present its conclusions ; ASN and IRSN take this review into account when they write their annual reports.

- every 3 years : the permanent group of experts analyses the experience feedback process of the licensee ; an ASN's letter presents its review of the RP system of the licensee for the past 3 years.

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Do you have some additional topics, which you would like to discuss during this or on the next RB meeting:

1/ In case there is a specific significant event, for example, when there is a suspicion of an event of level 2 on the INES scale, an inspection/control on-site is done by ASN (followed by an investigation).

2/ NPP's radiologicals' significant events overview for 2009 (in French) :