

Processing conformity deviations
*with respect to specified requirements for elements
important for protection (EIP);*

Nuclear power reactors
Radiological accident risks

GUIDE No. 21

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Preamble

The ASN collection of guides is intended for professionals concerned by the nuclear safety and radiation protection regulations (licensees, users or transporters of ionising radiation sources, general public, etc.).

The guides set out recommendations with the aim of:

- explaining the regulations and the rights and obligations of the persons concerned by the regulations;*
- explaining the regulatory objectives and, as applicable, describing the practices considered by ASN to be satisfactory.*
- giving practical tips and information concerning nuclear safety and radiation protection:*

Application of these guides does not in any way reduce the responsibility of a basic nuclear installation licensee with regard to the safety of its installation.



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INTRODUCTION

1.1. Regulatory and para-regulatory references

- ❑ Environment Code;
- ❑ Decree 2007-1557 of 2nd November 2007 amended, relative to basic nuclear installations and to regulation of the transport of radioactive substances in terms of nuclear safety;
- ❑ Order of 7th February 2012 setting the general rules concerning basic nuclear installations;
- ❑ ASN Resolution 2014-DC-0444 of 15/07/2014 relative to the shutting down and restarting of pressurised water nuclear power reactors
- ❑ Basic safety rule RFS 2001-01 concerning the determination of the seismic risk for the safety of surface basic nuclear installations;
- ❑ Basic safety rule RFS-2002-01 concerning the development and utilisation of probabilistic safety assessments for pressurised water nuclear reactors;
- ❑ ASN Guide of 21st October 2005 to the conditions of notification and codification of criteria related to significant safety, radiation protection or environmental events applicable to basic nuclear installations and to radioactive material transport operations

1.2. Glossary

In the remainder of this guide, the terms marked by an asterisk are defined in the appended glossary.

1.3. Purpose of the guide

Article 1.3 of the order of 7th February 2012 defines the notion of deviation*, and sets out in chapter VI of part II the general provisions concerning the management of deviations.

The purpose of this guide is to clarify certain general provisions for the management of deviations*. It establishes recommendations on the actions to be carried out by the nuclear power reactor licensee following the detection of a particular category of deviation* of which the characteristics are defined below.

This guide does not prejudice any more stringent ASN requirements or prescriptions concerning deviations whose implications might be judged particularly significant, or for other types of deviations*.

1.4. Scope of the guide

This guide applies to nuclear power reactors as of their commissioning*. More specifically it applies to deviations* that satisfy the following two characteristics combined:

- deviations* concerning a nuclear power reactor detected as from its commissioning* or, if applicable, its partial commissioning* until publication of the decree authorising its final shutdown and decommissioning,
- deviations* that could call into question compliance with a specified requirement* for an element important for protection* (EIP) when this requirement results from the part of the demonstration of nuclear safety* relative to risks of radiological accidents.

1.5. Document status

The provisions relative to the ways in which the sum of conformity deviations are taken into account are taken from the conclusions of the meeting of the advisory board of experts responsible for nuclear reactors dated 6th March 2014. Changes may be made to this version of the guide in the future depending on the feedback from its application.



2. NOTION OF CONFORMITY DEVIATION

2.1. Definition of a conformity deviation

In this guide, a *conformity deviation* is defined as a deviation* of an element important for protection* (EIP) from a specified requirement* when that requirement results from the part of the demonstration of nuclear safety* relative to risks of radiological accidents.

Deviations* (errors in methodology, calculation or modelling, data or parameter omissions, etc.) can be detected in a substantiating study of the demonstration of nuclear safety* relative to the risks of radiological accidents. The processing of these deviations* may necessitate changing some of the specified requirements* resulting from these studies and thus be the cause of *conformity deviations*.

A deviation* can affect a specified requirement* of an EIP without calling into question compliance with that requirement: such a deviation* in itself alone does not constitute a *conformity deviation*; however, if compliance with that specified requirement* is called into question due to a cumulative effect with other known deviations* affecting the same EIP, then this set of deviations* constitutes a *conformity deviation*.

2.2. Prevention of conformity deviations

Extract from the order of 7th February 2012

Article 2.5.1

II. The EIPs undergo qualification proportionate to the risks, with the aim in particular of **guaranteeing their ability to fulfil their assigned functions** with respect to the stresses and environmental conditions associated with the situations for which they are required. **Provisions [...] for maintenance enable this qualification to be maintained** for as long as necessary. [...]

In order to ensure the long-term maintaining of the EIP qualification required by article 2.5.1 of the order of 7th February 2012, the licensee shall maintain its facility and implement a maintenance policy designed to detect the EIPs affected by phenomena of wear and ageing (corrosion, etc.) and preventively repair them before such phenomena call into question compliance with a specified requirement* and therefore their qualification.

2.3. Statuses of a conformity deviation

Extract from the order of 7th February 2012

Article 2.6.3

I. The licensee shall ensure that deviations are processed within times appropriate for the risks involved, which more particularly involves:

- determining the technical, organisational and human causes of the deviation;
- defining the appropriate curative, preventive or corrective actions;
- assessing the effectiveness of the actions implemented.

The following statuses are attributed to a *conformity deviation* based on the key steps in its processing:

- **"emerging"**: a *conformity deviation* is said to be *emerging* as long as the licensee has not determined all the impacts of the deviation* on compliance of the EIPs concerned with the specified requirements*.
- **"resolved"**: a *conformity deviation* is said to be *resolved* when the licensee has determined the appropriate curative*, preventive* or corrective* actions.
- **"corrected"**: a *conformity deviation* is said to be *corrected* once the licensee has implemented the actions defined above.
- **"closed"**: a *conformity deviation* is said to be *closed* when the result of the licensee's assessment of the effectiveness of the correction actions implemented is positive.



3. REACTIVE MEASURES FOLLOWING DETECTION OF A DEVIATION

Extract from the order of 7th February 2012

Article 2.6.2

The licensee shall examine each deviation as soon as possible in order to determine:

[...]

- whether **protective measures** have been taken **immediately**.

To determine the protective measures to implement in the hours following detection of a *conformity deviation*, which may still be in "*emerging*" status, the licensee shall examine¹ the ability of the EIPs concerned to ensure, at all times and with the required performance levels, their functions necessary for the demonstration of nuclear safety* with respect to the radiological risks.

On the basis of this examination, the licensee decides on the availability of the EIPs within the meaning of the general operating rules (RGE):

- if the licensee considers that the EIPs affected by deviations are unavailable within the meaning of the RGEs, the licensee shall apply the action to take specified in the RGEs for the unavailability in question. Detection of the deviation * is taken as a starting time for the implementation time frame of the action to take.
- if the licensee considers that the EIPs affected by the deviation are available within the meaning of the RGEs, the licensee shall determine any immediate protective measures* it considers appropriate and shall implement them.

The licensee shall supplement this response analysis by determining any compensatory measures* that might be required.

4. DETAILED CHARACTERISATION OF A CONFORMITY DEVIATION

Extract from the order of 7th February 2012

Article 2.6.2

The licensee shall examine each deviation as soon as possible in order to determine:

[...]

- **its significance for the protection of the interests** mentioned in article L. 593-1 of the Environment Code.

Alongside this, and without delaying reactive implementation (see §3) of the protective measures* and compensatory measures*, the licensee shall undertake a detailed characterisation of the *emerging conformity deviation* aiming at determining whether or not it constitutes a *conformity deviation* (see §4.2), and if it does, evaluating its significance (see §4.3).

4.1. Characterisation times

General rule

The detailed characterisation of an *emerging conformity deviation* shall be completed as quickly as possible and within two months at the latest, unless the licensee can justify why this is impossible.

¹ To this end, if the licensee is not yet able to confirm the *conformity deviation*, it postulates the deviation.



Particular rules associated with the management of reactor shutdown periods

Extract of ASN resolution 2014-DC-0444

Article 2.3.1

The licensee may not start loading fuel assemblies into the reactor vessel until it has verified that:

[...]

- b) the state of the installation with respect to the baseline requirements applicable to it is such that there is nothing to prevent loading of the fuel assemblies into the vessel. **More particularly, the licensee shall verify that any deviations that can only be corrected when the core is completely unloaded from the reactor vessel have either been corrected or else it has been proven that they remain acceptable for the time necessary to correct them.**

Before deciding to proceed with loading the fuel assemblies into the vessel, the licensee shall complete the characterisation of any *emerging conformity deviation* which can only be corrected when the reactor core is completely unloaded. Failing this, the licensee shall provisionally postulate the *conformity deviation* and assess its significance before deciding whether or not to proceed with loading.

Extract of ASN resolution 2014-DC-0444

Article 2.4.2

The request for approval of reactor start-up shall be accompanied by the following:

[...]

- e) **The list of deviations affecting the EIPs for which the licensee has not implemented all the curative actions defined in application of Article 2.6.3 of the abovementioned order of 7th February 2012 and a synthesis of the justification**, with respect to the protection of the interests mentioned in Article L. 593-1 of the Environment Code - **for not correcting them**; the corrective action deadline for each deviation shall moreover be specified;

The approval request shall include a demonstration by the licensee that the installation is capable of functioning over the forthcoming cycle under conditions that suitably protect the interests mentioned in Article L. 593-1 of the Environment Code and in compliance with the baseline requirements applicable to the installation.

Before making its request for approval for reactor start-up, the licensee shall complete the characterisation of any *emerging conformity deviation* which it does not plan correcting prior to reactor start-up. Failing this, the licensee shall provisionally postulate the *conformity deviation* and take into account the assessment of its significance in the justification established to support the approval request.

4.2. Confirming the constitution of a conformity deviation

The first characterisation step consists in exhaustively identifying the affected EIPs and the specified requirements* which are called into question by the *emerging conformity deviation*.

As soon as the licensee has completed identifying the affected EIPs and the specified requirements called into question for a given installation, it shall decide whether the protective and compensatory measures already in place are adequate. If necessary, it implements additional or alternative measures to those already in place pending correction of the *conformity deviation*.

During this characterisation step, the licensee can re-examine the grounds for a specified requirement* and revise its specification if necessary. In this case it shall inform ASN of the change in the specification of the specified requirement and the reasons for the change.

If the results lead the licensee to conclude that all the specified requirements* are satisfied, then the deviation* detected does not constitute a *conformity deviation* and therefore shall not be subject to the conditions of application of this guide in its subsequent processing. Conversely, the moment the results confirm noncompliance with at least one specified requirement* of an EIP, the *conformity deviation* exists.



4.3. Assessing the significance of a conformity deviation

The second characterisation step consists in assessing the significance of a *conformity deviation*. To do this, the licensee shall examine more specifically the impact of the *conformity deviation* on:

1. the possibility of inducing an initiating event* that is not addressed in the safety analysis report;
2. the probability of occurrence of the initiating events* addressed in the safety analysis report;
3. the ability of the installation, further to an initiating event* addressed in the safety analysis report, to return to and be maintained in a safe condition* (identification of a safe path*);

NB: with regard to the identification of safe paths, the licensee can use realistic assessment methods, and notably not include additional aggravating factors.

4. the assessments of the radiological consequences presented in the safety analysis report;
5. the increase in the risk of core meltdown (level-1 probabilistic safety assessment) and the risk of radioactive releases (level-2 probabilistic safety assessment).

NB: This probabilistic safety assessment does not have to be carried out in all cases. If the licensee plans not to carry out a probabilistic safety assessment, it shall explain why.

Taking into consideration of the protective and compensatory measures

To assess the significance of a *conformity deviation*, the licensee can take into account the protective and compensatory measures implemented pending corrective action, on condition that the effectiveness of these measures is not affected by other known deviations* as yet not corrected.

Extract from the order of 7th February 2012

Article 2.5.1

I. The licensee shall identify and list the EIPs and related specified requirements and keep the list up to date.

II. II. The EIPs shall undergo **qualification proportionate to the risks** with the aim in particular of guaranteeing the ability of the said EIPs to fulfil their assigned functions with respect to the stresses and environmental conditions associated with the situations for which they are required.

[...]

The elements of the installation which fulfil - as a protective or compensatory measure - a function necessary for implementation of the safe path* or which verify that one of these functions is fulfilled, and which were not previously considered as EIPs, shall be identified as such by the licensee during the period for which they fulfil these functions. The licensee shall identify their specified requirements* and provide proof of their qualification, proportionate to the risks, as required under II of article 2.5.1 of the order of 7th February 2012.

5. CONFORMITY DEVIATION CORRECTION TIME FRAMES

5.1. Principle No. 1: correction as soon as possible

Extract from the order of 7th February 2012

Article 2.3.1

I. The licensee shall establish and undertake to implement a policy for the protection of the interests mentioned in article L. 593-1 of the Environment Code, explicitly asserting:

- **the priority granted to the protection of the abovementioned interests, firstly by the prevention of accidents and the mitigation of their consequences on account of nuclear safety, with respect to the economic or industrial advantages resulting from the operation of its installation** or the progress of the research activities associated with this operation; [...]

Consistently with article 2.3.1 of the order of 7th February 2012 giving priority to nuclear safety over the economic and industrial advantages resulting from the operation of the installation, the licensee



shall give priority to the correction of a *conformity deviation* as soon as it is possible to do so. This first principle aims at not delaying unnecessarily the correction of a *conformity deviation*.

However, in accordance with III of article 2.6.3 of the order of 7th February 2012, the processing of a deviation* constitutes an activity important for protection* (AIP). For application of this first principle, the AIP preparation and performance measures of chapter VI of the above order should be complied with in order to ensure the quality of the correction work and avoid creating new deviations*.

This principle leads to the adoption of the following methods for determining an "as soon as possible" (ASAP) correction time frame:

- **"As soon as possible" (ASAP) correction time frame: correction of a conformity deviation, including at the emerging stage, once the conformity deviation is resolved and the technical and human resources necessary for the correction work can be mobilised, at a time when the installation is in an operating state that allows the work to be carried out.**

More particularly:

- if the work to restore conformity can be carried out when the reactor is operating: correction as soon as possible in compliance with the preparation time necessary to perform the work (AIP) under satisfactory conditions;
- if the work to restore conformity can only be carried out when the reactor is shut down: correction at the next shutdown for refuelling in compliance with satisfactory conditions of preparation of the AIPs for this shutdown, otherwise the work is carried out at the following shutdown;
- the licensee shall take advantage of any opportunity that arises to work on an EIP - either during scheduled or unscheduled maintenance work, or when incorporating a modification - to correct the resolved conformity deviations affecting that EIP.

5.2. Principle No. 2: correction within a time frame appropriate for the risks

Extract from the order of 7th February 2012

Article 2.6.3

I. The licensee shall ensure that the deviations are processed within time frames appropriate for the risks involved, which more particularly consists in:

[...]

- defining the appropriate curative, preventive or corrective actions;
- implementing the defined actions.

The licensee, as the entity responsible for the safety of its installation (see article L. 593-6 of the Environment Code), shall substantiate the acceptability of the correction time frame it is adopting with regard to the risks of the *conformity deviation*, the principle being that the greater the risk, the shorter the time frame adopted.

This part of the guide presents a procedure for determining correction time frames proportionate to the risks the conformity deviation represents and specifies associated maximum indicative times. The risk that the *conformity deviation* represents is to be assessed, as a first approximation, with respect to the results of the characterisation of its significance under the conditions defined in §4.3.

The maximum correction time frame adopted by the licensee should not, save particular cases, exceed the maximum indicative time frames mentioned in tables 1 to 7 of appendices 1 and 2.



The tables are however not relevant for the following particular cases, for which the correction time frames shall be defined on a case-by-case basis:

- *conformity deviations* concerning the conditions of storage in the spent fuel pool;
- *conformity deviations* affecting the part of the nuclear safety demonstration* associated with a hazard other than earthquakes or extreme hazards.

Maximum indicative time frames

Tables 1 to 7 of appendices 1 and 2 make reference to two types of time frame which aim at regulating application of the first principle of "correction as soon as possible" set out earlier while at the same time taking account of the degree of urgency of correcting a conformity deviation in the light of the risk it represents for protection of interests referred to in article L. 593-1 of the Environment Code.

□ **Type-A time frame: risk requiring urgent correction**

- **A1 time frame:** immediate shutdown of the reactor in the most appropriate state for protection of the interests mentioned in article L. 593-1 of the Environment Code, then correction of the deviation before reactor start-up;
- **A2 time frame:**
 - for a reactor under power operation: if the conformity deviation can be corrected in this power operation state, correction within two months; otherwise, shutdown of the reactor in the most appropriate state for protection of the interests mentioned in article L. 593-1 of the Environment Code, then correction of the deviation before reactor start-up;
 - for a shut down reactor: correction before start-up, in the most appropriate state for protection of the interests mentioned in article L. 593-1 of the Environment Code.

□ **Type-B time frame: risk not requiring urgent correction**

- **B1 time frame:** when there is no urgency, the licensee shall apply an "ASAP" correction time frame, in accordance with the first principle, which leads it to schedule correction within two years at the most according to the operating cycle length for the reactor concerned ;
- **B2 time frame:** for low-risk conformity deviations, the licensee shall seek in priority to apply an "ASAP" correction time frame in accordance with the first principle, but can if necessary adopt a correction time frame of 5 years at the most;

For generic deviations* necessitating validation of the correction solution before it is deployed on all the reactors concerned, the type B1 and B2 correction time frames can be slightly extended for installations other than the reactor on which the correction solution is implemented for the first time. Whatever the case, the acceptability of any extended time frames shall be justified by the licensee.

For generic deviations* coming under an A1/A2 time frame, the licensee can stagger the shutting down of the reactors concerned when this is vital to avoid a generalised network incident and thus avoid causing a situation that could jeopardise the nuclear safety of all the reactors. Whatever the case, the need to postpone the immediate shutdown of some of the reactors concerned and the acceptability of the deferred shutdown time frames shall be justified by the licensee.



Additional clarification brought by the probabilistic safety assessments (PSA)

In cases where the licensee has additional clarification brought by the level-1 or level-2 probabilistic safety assessments, the licensee shall define the associated risk increase criteria beyond which the type B time frames mentioned in tables 1 to 7 of appendices 1 and 2 must be revised to type-A time frames.

6. ASSESSMENT OF THE EFFECTIVENESS OF THE CORRECTION ACTIONS

Extract from the order of 7th February 2012

Article 2.6.3

I. The licensee shall ensure that the deviations are processed **within times appropriate for the risks involved**, which more particularly involves:

[...]

- defining the appropriate curative, preventive or corrective actions;
- implementing the defined actions.
- **assessing the effectiveness of the actions implemented.**

Alongside the defining of correction actions, the licensee shall establish the nature of the justifications² and the associated criteria it will use as a basis for declaring closing of the *conformity deviation* as soon as possible after its correction.

When the assessment of the effectiveness of the correction actions implemented requires temporary monitoring to verify that the conformity deviation does not reappear, the licensee has to specify the chosen observation period before it can declare the *conformity deviation* closed.

As the processing of a deviation* constitutes an AIP, the closing of a *conformity deviation* requires that the results of the technical verification actions mentioned in article 2.5.3 of the order of 7th February 2012 be taken into account beforehand.

7. TRACEABILITY AND INFORMING ASN

7.1. List of conformity deviations and state of progress of their processing

Extract from the order of 7th February 2012

Article 2.6.3

III - The licensee shall keep an up-to-date **list of the deviations and the state of progress of their processing.**

The list of deviations* kept up to date by the licensee in application of III of Article 2.6.3 of the order of 7th February 2012 makes it possible to:

- readily extract the *conformity deviations* and, for those whose characterisation (see §4) is completed, have an exhaustive list of the EIPs affected and their specified requirements* which are not satisfied;
- to indicate the state of progress of the processing of each conformity deviation with respect to the following statuses (see §1):
 - *emerging conformity deviation*, indicating the state of progress of its characterisation;
 - *conformity deviation* in the course of being resolved, indicating the targeted date for resolving it;

² Justification by studies or tests, with or without a period observation to see whether the deviation occurs again.



- *conformity deviation resolved*, indicating the planned date of correction;
- *conformity deviation corrected*;
- *conformity deviation closed*.

Drawing up this list also makes it possible to identify those *conformity deviations* which have been notified to ASN as a significant event* in application of article 2.6.4 of the order of 7 February 2012.

7.2. Notification of a significant event

Extracts from the order of 7th February 2012

Article 2.6.2

The licensee shall examine each deviation **as soon as possible** in order to determine: [...] if appropriate, whether it represents a significant event; [...]

Article 2.6.4

The licensee shall notify ASN of each significant event **as soon as possible**. [...]

NB: As the notion of significant event* comes under a wider area of application than that associated with the notion of *conformity deviation*, this guide is not intended to address the broader subject of the criteria and time frames for notifying a significant event*. These aspects are addressed in another guide (see §1.1).

As soon as the *conformity deviation* is confirmed, the licensee shall determine whether it constitutes a significant event*, and if it does, the licensee shall notify ASN of it within the times set by ASN in application of article 2.6.4 of the order of 7th February 2012. In order to comply with the notification deadlines, the licensee shall take confirmation of the *conformity deviation* as being the date of origin of the event, and not detection of the *emerging conformity deviation*.

During the detailed characterisation of the *conformity deviation*, and in any case on completion of the characterisation, the licensee shall reconsider whether the deviation constitutes a significant event* and, in the affirmative and if this has not been done earlier, the licensee shall give notification of it, indicating in what respect the detailed characterisation revealed elements leading it to change its position on the notification of a significant event*. To comply with the notification deadlines, the licensee then takes the date of origin of the event as being the date on which sufficient information became available to conclude that it constitutes a significant event*.

Extracts from the order of 7th February 2012

Article 2.6.3

[...] for deviations confirmed as being of minor significance for protection of the interests mentioned in article L. 593-1 of the Environment Code, the processing can be limited to defining and implementing curative actions.

Article 2.6.5

The licensee shall carry out an in-depth analysis of each significant event [...] including in particular the following elements: [...] the analysis of the technical, human and organisational causes of the event [...].

A *conformity deviation* which is notified as a significant event* cannot be considered by the licensee as a deviation of minor significance in application of article 2.6.3 of the order of 7th February 2012. The licensee therefore cannot, for the processing of this deviation*, simply define and implement curative actions: the licensee shall, in application of article 2.6.5 of the said order, conduct an in-depth analysis of the event including more specifically an analysis of its technical, human and organisational causes.

As part of this in-depth analysis, the licensee shall determine whether the *conformity deviation* that caused the event potentially constitutes a generic deviation*, and if so, it defines the verification programme to conduct on the similar EIPs of its other reactors.



NB: If within the two-month time limit (see §4.1) for performing the detailed characterisation of an *emerging conformity deviation* the licensee does not have sufficient information to decide whether or not it constitutes a *conformity deviation* and hence a significant event*, the licensee shall inform ASN of the ongoing characterisation process. To this end, the licensee shall give ASN the information on the *emerging conformity deviation* at its disposal at this stage and justify the additional time needed to characterise it.

7.3. Informing ASN during reactor shutdown periods

Independently of the significant event* notification procedure, informing ASN of the deviations* and state of progress of their processing relating to a reactor shutdown period is addressed in the articles of ASN resolution 2014-DC-0444 mentioned below.

Extracts of ASN resolution 2014-DC-0444

Article 2.1.2

The order presentation file sets out: [...]

c) a list of any deviations affecting the EIPs, that the licensee has not planned to correct during the shutdown and a synthesis of the justification - with respect to protection of the interests mentioned in Article L. 593-1 of the Environment Code - for not correcting these deviations during the shutdown;

Article 2.4.2

The request for approval for reactor start-up shall be accompanied by the following: [...]

e) The list of deviations affecting the EIPs for which the licensee has not implemented all the curative actions defined in application of Article 2.6.3 of the abovementioned order of 7th February 2012 and a synthesis of the justification - with respect to protection of the interests mentioned in Article L. 593-1 of the Environment Code - for not correcting them; the correction deadline for each deviation shall moreover be specified;

Article 2.5.2

The file giving the shutdown results contains: [...]

c) the list of deviations affecting the EIPs for which the licensee has not implemented all the curative actions defined in application of Article 2.6.3 of the abovementioned order of 7th February 2012 and a synthesis of the justification - with respect to protection of the interests mentioned in Article L. 593-1 of the Environment Code - for not correcting them; the correction deadline for each deviation shall moreover be specified;

Article 3.1.1

When the licensee shuts down a reactor or takes advantage of its shutdown to carry out modifications or preventive or curative maintenance on EIPs without renewing all or part of the fuel assemblies in the reactor vessel, only section 2 of chapter 2.3 of this appendix is applicable. Furthermore, the licensee informs ASN as soon as possible of reactor shutdown and start-up.

Moreover, if the foreseeable duration of reactor shutdown will exceed 240 hours, the licensee shall transmit without delay a file describing the planned activities on the EIPs during the shutdown and, at the end of the shutdown, the results of the activities performed on the EIPs, the list of deviations discovered during the shutdown and the progress of their processing.

These elements are also transmitted if the actual reactor shutdown duration exceeds 240 hours.



8. CONSIDERATION OF CUMULATIVE CONFORMITY DEVIATIONS

Extract from the order of 7th February 2012

Article 2.7.1

In addition to the individual processing of each deviation, the licensee shall periodically review the deviations to assess the cumulative effect of as-yet uncorrected deviations on the installation.

[...]

8.1. Method of analysing cumulative conformity deviations

As part of the review of deviations mentioned in article 2.7.1 of the order of 7th February 2012, the licensee shall examine the cumulative effect of the non-corrected *conformity deviations* which have given rise to a significant event* notification in application of article 2.6.4 of the said order.

8.1.1. Taking into account of compensatory measures

The licensee can exclude a non-corrected *conformity deviation* from the scope of its cumulative deviations analysis on condition that it provides proof that the specific compensatory measures dedicated exclusively to that deviation* (mobile resources, temporary physical modifications, etc.) are sufficiently effective for it to be considered provisionally corrected pending the implementation of lasting curative actions.

The licensee shall therefore maintain within the scope of the analysis the *conformity deviations* for which:

- the effectiveness of the compensatory measures is only partial and therefore does not enable them to be considered as provisionally corrected pending implementation of the lasting solution;
- the compensatory measures implemented involve provisions which are specific and exclusively dedicated to them.

8.1.2. Taking multiple and identical conformity deviations* into account,

§4.3 of this guide stipulates that the significance of a *conformity deviation* considered individually is assessed by examining in particular the ability of the installation, further to an initiating event* addressed in the safety analysis report, to return to and be maintained in a safe condition*; In this context, this guide indicates (see tables 1, 2, 3 of appendices 1 and 2) that the safe path* can be identified without postulating additional aggravating factors.

As long as the EIPs affected by a *multiple and identical conformity deviation** have not been exhaustively identified for a reactor, the licensee shall, in its analysis of cumulative deviations, systematically examine the impact of the potential presence of this *multiple and identical conformity deviation** to ensure that it does not call into question the safe paths* already identified for other *conformity deviations* which may be sensitive to aggravating factors.

8.1.3. Assessment of the significance of the cumulative conformity deviations considered in the analysis

The licensee shall assess the significance of the cumulative conformity deviations considered in this analysis based on the same approach as that set out in §4.3 and if necessary implement complementary or alternative protective and compensatory measures to those already in place.

On the basis of this assessment and of the time frame recommendations of §5, the licensee shall re-examine the relevance of the previously adopted correction time frames and revise them if necessary.



The licensee shall be particularly attentive to the assessment of cumulative *conformity deviations* that directly or indirectly affect:

- a same given function among the functions mentioned in I of article 3.4 of the order of 7th February 2012;
- the fuel cooling function and the radioactive substance containment function in the context of a given accident sequence affecting the fuel assemblies present in the reactor vessel or the spent fuel pool.

Furthermore, for the assessment of the significance of the cumulative *conformity deviations*, the licensee shall look for the probabilistic clarification it can obtain from either the probabilistic studies at its disposal or sensitivity studies.

In particular, for the assessment of conformity deviations relating to seismic qualification, if the licensee does not yet have a probabilistic safety study of the seismic risk, it shall seek this probabilistic clarification by using sensitivity studies of its PSA-1 relative to the accident sequences induced by an earthquake of the Maximum Historically Probable Earthquake (MHPE) or Safe-Shutdown Earthquake (SSE) level.

8.2. Updating of the analysis of the effects of cumulative conformity deviations

The licensee shall regularly update its analysis of the cumulative *conformity deviations* which have been notified as significant events* on the minimum basis of the following three rules:

- R1: the licensee shall update its analysis of the cumulative *conformity deviations* when a significant event* report as mentioned in I. of article 2.6.5 of the order of 7 February 2012 is transmitted to ASN.

Furthermore, the licensee shall update its analysis:

- R2: before unloading the core for the cumulative *conformity deviations* that directly or indirectly affect performance of the fundamental function of cooling the spent-fuel pool;
- R3: before loading the core, then before proceeding with reactor start-up for the cumulative *conformity deviations* that affect the reactor.

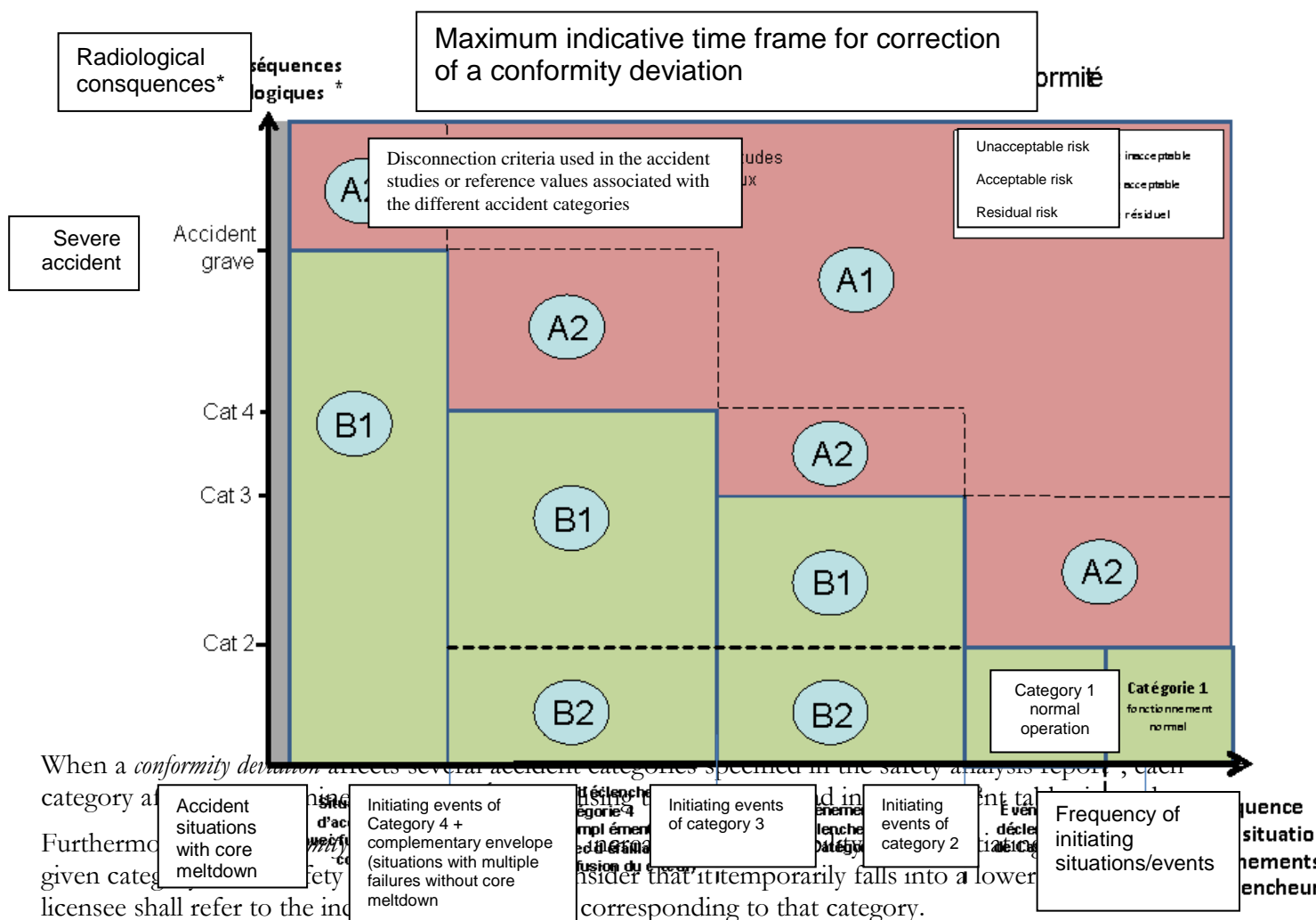


APPENDIX 1: Correction time frames for *conformity deviations* affecting the part of the demonstration of nuclear safety associated with internal failures

Tables 1 to 4 are based on a cross-assessment between the robustness of the demonstration of the installation's ability to reach and maintain a safe state* on the one hand, and on the other hand compliance with the safety objectives associated with the different accident categories addressed in the safety analysis report* for the control of initiating events* relative to internal failures*.

Compliance with the objectives associated with these different accident categories is to be considered with regard to compliance with the disconnection criteria of the accident studies or with regard to the results of the assessments of the radiological consequences of the releases with respect to the reference values associated with the different accident categories.

In this case, determination of the maximum indicative time frames adopted in these tables is based on the result of this assessment with regard to the zones of risk acceptability³ (see figure 1).



³ The notion of risk is associated with a probability-consequence relationship; the acceptability of a risk is then assessed on a two-dimensional diagram where the higher the probability of a risk, the lower shall be its consequence and vice versa, with a serious consequence only being acceptable if its probability of occurrence is low.

□ **Table No. 1: Time frames associated with the control of initiating events of category 2**

Is there a deterministic safe path (reaching and maintaining a safe state) based on qualified EIPs? (lasting or temporary) - without postulated aggravating factor and with realistic hypotheses	No	A1	
	Yes	Consequences not in conformity with the category-2 safety objectives	A2 if cat-3 objectives satisfied, (otherwise A1)
		Consequences in conformity with the category-2 safety objectives	B2

□ **Table No. 2: Time frames associated with the control of initiating events of category 3**

Is there a deterministic safe path (reaching and maintaining a safe state) based on qualified EIPs? (lasting or temporary) - without postulated aggravating factor and with realistic hypotheses	No	A1	
	Yes	Consequences not in conformity with the category-4 safety objectives	A1
		Consequences not in conformity with the category-3 safety objectives but compatible with category 4	A2
		Consequences in conformity with the category-3 safety objectives	B1
		Consequences in conformity with the category-2 safety objectives	B2

□ **Table No. 3: Time frames associated with the control of initiating events of category 4 and the complementary envelope associated with the prevention of core meltdown**

Is there a deterministic safe path (reaching and maintaining a safe state) based on qualified EIPs? (lasting or temporary) - without postulated aggravating factor and with realistic hypotheses	No	A1	
	Yes	Consequences not in conformity with the category-4 safety objectives (while avoiding an accident situation with core meltdown)	A2
		Consequences in conformity with the category-4 safety objectives	B1
		Consequences in conformity with the category-2 safety objectives	B2



□ **Table No. 4: Time frames associated with the control of accident situations with core meltdown**

<p><i>Does the conformity deviation call into question a specified requirement* necessary for demonstrating that the accident situations with core meltdown which could lead to significant radioactive releases off site that develop too rapidly to allow timely deployment of the necessary population protection measures are physically impossible or extremely improbable with a high level of confidence? (see articles 3.9 of the order of 7th February 2012</i></p>	Yes ⁴	time frame A2 for a shut down reactor
	No	B1

⁴ Examples: creation of a containment bypass situation; calling into question the possibility of depressurising the reactor to avoid a meltdown accident under pressure, etc.



APPENDIX 2: Time frames for correcting conformity deviations affecting the part of the nuclear safety demonstration associated with earthquakes

The basic safety rule RFS 2001-01 introduces two levels of earthquake: the maximum historically probable earthquake (MHPE) which is higher than all the known earthquakes having occurred in the vicinity of the power plant in the last thousand years, and the safe-shutdown earthquake (SSE), a hypothetical earthquake of even greater intensity.

A *conformity deviation* with respect to an earthquake resistance requirement can:

- call into question the ability of the installation to be placed and maintained in a safe shutdown state in a situation of prolonged loss of external electrical power supplies induced by an earthquake: this case is addressed in table No. 5;
- in the event of an earthquake, result in the failure of elements of the installation and induce an accident situation: this case is addressed in table No. 6;
- call into question the ability of the installation to cope, in the event of an earthquake, with the unique postulated initiating events of categories 2 to 4 of the safety analysis report: this case is addressed in table No. 7;

- ***Table No. 5: Time frames associated with deviations affecting (directly or indirectly) the ability of the installation to be placed and maintained in a safe shutdown state in a situation of prolonged loss of external electrical power supplies further to an earthquake***

In the event of an earthquake of SSE level, it must be possible to place and maintain the installation in a safe shutdown state⁵, considering more specifically that the earthquake induces a situation of prolonged loss of the external electrical power supplies.

Table No. 5 thus aims at making the *conformity deviation* correction time proportionate to the reduction in the seismic resistance of the safe path enabling this situation to be controlled:

Consequence of the conformity deviation in the seismic resistance to the SSE on the ability of the installation to reach and be maintained in a safe shutdown state in the event of prolonged loss of the external electrical power supplies ⁶	No safe path qualified for the SSE or MHPE	A1
	There is a safe path based on EIPs (lasting or temporary) qualified at least for the MHPE, without postulated aggravating factors and with realistic hypotheses	B1

⁵ See (b) of 2.14 of IAEA safety standard NSG 1.6 "Seismic design and qualification for nuclear power plants"

⁶ Recovery of the failed external electrical power network following an earthquake cannot be considered before 2 weeks.



□ **Table No. 6: Time frames associated with seismic resistance deviations that could lead to an accident situation in the event of an earthquake**

Apart from the preceding particular case concerning the control of a postulated situation of loss of external electrical power supplies induced by the earthquake, a first level of defence in depth against an earthquake more generally consists in ensuring the seismic resistance to the SMS of those elements of the installation whose failure in the event of an earthquake could, directly or indirectly, induce an accident situation⁷.

Table No. 6 thus aims at making the *conformity deviation* correction time proportionate to the weakening of this first level of defence in depth induced by the deterioration in the seismic resistance of the installation.

		Level of reduction of the seismic resistance: seismic resistance maintained for the MHPE	Level of reduction of the seismic resistance: not resistant to the MHPE
Severity of the failure induced in the event of an earthquake by the deviation from the SSE earthquake resistance requirement	event not covered by the initiating events of category 2 to 4, or by the complementary envelope of the safety analysis report	A1	A1
	covered in the safety analysis report by an initiating event of category 4 or of the complementary envelope	A2	A1
	covered in the safety analysis report by an initiating event of category 3	B1 ⁸	A2
	covered in the safety analysis report by an initiating event of category 2	B2	B1
	Management of the event within the limits of the operating conditions provided for in the operating technical specifications of the RGEs (general operating rules)	B2	B2

• Application of table No.6 to loss of primary coolant situations

The situations of loss of primary coolant that cannot be compensated for within the limits specified by the operating technical specifications of the RGEs but which can be isolated (on the understanding that the isolation function that allows loss of the primary coolant to be stopped shall not be affected by a conformity deviation) are considered to be category 2 situations.

□ **Table No. 7: Time frames associated with deviations affecting (directly or indirectly) the seismic resistance of the EIPs involved in the control of initiating events of categories 2 to 4.**

In addition to the first level of defence mentioned above, a second level of defence against earthquakes consists in ensuring the seismic resistance of the elements of the installation that are necessary to

⁷ See (a) of 2.14 of IAEA safety standard NSG 1.6 "Seismic design and qualification for nuclear power plants"

⁸ Criterion B1 adopted in view of the equivalence of the probability of occurrence of an MHPE earthquake with respect to the probability of occurrence of category 3 situations.



control incidents and accidents and in particular the postulated initiating events of category 2 to 4 in the safety analysis report⁹.

ASN considers¹⁰ that the existence of several levels of defence in depth does not justify continuing, over the long term, the operation of an installation on which one level is deficient, and that consequently the licensee shall try to maintain the operability of all the levels of defence in depth at all times.

Consequently, although the correction of a *conformity deviation* from a seismic resistance requirement for an EIP that is necessary to control the postulated initiating events* of category 2 to 4 in the safety analysis report does not necessitate the adoption of an urgent correction time frame (A criteria) as long as the first level of defence in depth is not affected, the licensee shall nevertheless try to correct this deviation as soon as possible (B criteria) in order to restore the second level of defence against an earthquake.

Consequence of the conformity deviation affecting the seismic resistance of the safe path on the postulated initiating events of category 2 to 4 of the safety analysis report	Calling into question the SSE seismic qualification of the two redundant channels of the safety analysis report safe path*	B1
	Maintaining of the SSE seismic qualification of at least one the two redundant channels of the safety analysis report safe path*	B2

□ *Particular case of a seismic resistance conformity deviation coming under several of tables 5 to 7*

General rule: the time frame criterion adopted is the most constraining of the criteria in the tables concerned.

Particular rule: when a seismic resistance *conformity deviation* comes under the tables 6 and 7 for a given initiating event, the chosen correction time frame criterion corresponds to the most constraining of the two tables plus an added penalising factor with a criterion level (B2 > B1; B1 > A2, A2 > A1) in order to take into account the fact that the *conformity deviation* simultaneously affects, in the event of an earthquake, the prevention of that initiating event and the ability of the installation to control that event.

⁹ See (c) of 2.14 and 2.15 of IAEA safety standard NSG 1.6 "Seismic design and qualification for nuclear power plants"

¹⁰ See 4.10 of IAEA safety standard SSR 2/1 "Safety of nuclear power plants: design"



Glossary

Activity Important for Protection (AIP)

See definition given in article 1.3 of the order of 7th February 2012.

Commissioning

5 See definition given in article 20 of decree 2007-1557 of 2nd November 2007.

Compensatory measure

Temporary measure taken to compensate in whole or in part the consequences of a deviation.

Corrective action

Action aiming to eliminate the cause of a detected deviation.

10

Curative action

Action aiming to eliminate a detected deviation.

Demonstration of nuclear safety

See definition given in article 1.3 of the order of 7th February 2012.

Deviation

15 See definition given in article 1.3 of the order of 7th February 2012.

Element important for protection (EIP):

See definition given in article 1.3 of the order of 7th February 2012.

Generic deviation

Conformity deviation affecting several nuclear power reactors operated by the same licensee.

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Initiating event

See definition given in article 1.3 of the order of 7th February 2012.

Internal failure

See definition given in article 1.3 of the order of 7th February 2012.

Preventive action

25 Action aiming to eliminate the cause of a potential deviation.

Multiple and identical conformity deviation

A conformity deviation that could affect a type of component that is present in different items of equipment (example: electrical relays, supports, etc.) and which consequently could affect numerous safety functions in a widespread manner.

30

Partial commissioning

See article 20 of decree 2007-1557 of 2nd November 2007.

Protective measure

Temporary measure taken with the aim of avoiding:

- 35
- either the occurrence of a situation requiring the use of an item of equipment affected by a deviation;
 - or letting a developing deviation get worse.

Safety analysis report

Document mentioned in 1° of II of article 20 of decree 2007-1557 of 2nd November 2007.

Safe path

40 Sequence of operational management actions associated with a list of equipment items whose sufficiency and effectiveness in returning a nuclear power reactor from a defined accident situation to a safe state has been demonstrated.

Safe state

State of a nuclear reactor in which the functions of controlling the nuclear reactions, cooling the fuel and containment of radioactive substances are ensured over the long term.

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Significant event

See definition given in article 1.3 of the order of 7th February 2012.

Specified requirement

See definition given in article 1.3 of the order of 7th February 2012.



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