Class I Guidances

Guideline - Safety demonstration of new class I nuclear installations:
approach to Defence-in-Depth, radiological safety objectives and the application of a graded approach to external hazards

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List of abbreviations

C1, C2, C3 and C4: Design basis categories 1 to 4

DEC: Design Extension Conditions

DiD: Defence-in depth

Euratom: European Atomic Energy Community

FANC: Federal Agency for Nuclear Control

GRR-2001: General Regulation on the Protection of the Population, the Workers and the Environment Against the Danger of Ionizing Radiation

HL1: Hazard level 1

HL1*: Hazard level associated to the margin assessment of HL1

HL2: Hazard level 2

NPP: Nuclear Power Plant

PIE: Postulated initiating event

RHWG: Reactor Harmonization Working Group

SA: Severe accidents

SO1: Safety objective 1

SO2: Safety objective 2

SO3: Safety objective 3

WENRA: Western European Nuclear Regulators Association
1. Introduction

The basis of the Belgian regulation regarding radiation protection can be found in the royal decree of July 20, 2001 [1] concerning the General Regulation on the Protection of the Population, the Workers and the Environment Against the Danger of Ionizing Radiation (GRR-2001). This royal decree describes in particular the licensing procedure and radiation protection principles (dose limits, dose constraints,...).

The basis of the Belgian regulation regarding nuclear safety can be found in the royal decree of 30 November 2011 [2] which is the transposition into Belgian law of the council directive 2009/71/Euratom ‘Nuclear Safety’ [3] and of the WENRA reference levels for existing reactors [4]. This royal decree contains the following sections: safety management, design, operation, safety verification and emergency planning. It contains a chapter "Generic safety rules" which applies to all new class I nuclear installations.

The recommendations formulated in this guideline aim at providing more detailed information on the expectations of the regulatory authority related to Defence-in-Depth (DiD) and quantitative radiological safety objectives in the context of the safety demonstration of new class I nuclear installations. Implementing the recommendations of this guideline will not automatically lead to the success of the authorization process but should increase the confidence of the applicant in a successful authorization process. In addition, in light of specific risks associated to an installation and its surroundings, additional safety objectives may be defined by the regulatory authority.

2. Scope

This guideline applies (i.e. it should be used as an applicable document) to new class I nuclear installations except disposal installations. A new class I nuclear installation means a nuclear installation that is the subject of a new license application and for which the license application is introduced to the regulatory authority after the date of approval of this document.

It is outside to the scope of this guideline to address aspects related to multi-installation sites (for example the fact that several installations on the site may be challenged at the same time).

The applicant is free to propose an approach (i.e. methodology) that differs from this guideline provided it is fulfilling the regulatory requirements. The quantitative radiological safety objectives (see §6) should however always be met. The regulatory authority will evaluate the proposed approach and its justification against the background of this guideline.

3. Objective

The objectives of this guideline are to:

- present the structure of the levels of Defence-in-Depth;
- present the design basis categories (C1 to C4);
- present nuclear safety objectives associated to the design basis categories;
- present the approach to external hazards and the application of a graded approach for them.

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1 This means that for new class I nuclear installations, it is expected by the regulatory authority that all applicable recommendations of this guideline are implemented in the design. If this is not the case, the regulatory authority will likely ask the applicant to provide justifications for the recommendations that are not implemented.

2 Class II or class III installations located on class I sites do not fall under the scope of this guideline.
4. Approach

This guideline is written in relation to the council directive 2014/87/ Euratom of 8 July 2014 [5] amending directive 2009/71/Euratom establishing a community framework for the nuclear safety of nuclear installations in particular with regards to Article 8a defining the nuclear safety objective for nuclear installations and article 8b on the implementation of the nuclear safety objective for nuclear installations. In addition, to support the requirements already formulated in the Belgian regulation, this guideline is mainly inspired from recent WENRA publications on safe design of new NPPs [6],[7], from safety reference levels [4],[18] as well as from recent IAEA publications [8],[9],[10],[13],[14],[15] and [16].

The regulatory authority considers it relevant to use the WENRA publications [6],[7] as a reference to define a DiD approach and qualitative safety objectives for all new class I nuclear installations because many parts of these publications are written in general terms (i.e. not specific to a certain type of nuclear installation) or can be generalized without difficulty. The final objective is of course the same: to guarantee the safety level of the installation in view to protect the persons on-site, the population and the environment.

For all new class I nuclear installations, the chapter “Generic safety rules” of the Belgian regulation [2] requires establishing a list of postulated initiating events (PIE) to cover all events that could affect the safety of the installation, and to select a subset of design basis events from that list, based on deterministic or on probabilistic methods, or a combination of both. The chapter specific to nuclear power plants of the Belgian regulation [2] specifies that the selected design basis events will be grouped into a limited number of categories according to their probability of occurrence, and requires the definition of acceptance criteria for each category such that there are no or minor radiological consequences for frequent events and that events with potential severe consequences must have a very low probability of occurrence. These general terms can be generalized to new class I nuclear installations. Design basis categories are addressed in section 5, in relation to Defence-in-Depth. Radiological safety objectives to be associated to these categories are discussed in section 6. Guidance on how external hazards are to be included in the safety assessment and expectations on applying a graded approach in light of the potential worst-case radiological consequence associated to an installation are provided in section 7.

The list of references is provided in section 8. All terms written in this guideline and defined in section 9 “Definitions” are written in italic the first time they appear.

5. Defence-in-Depth and design basis categories

5.1. Background

In March 2013 WENRA has published a report [7] on safety of new NPP designs setting out the common positions established by the Reactor Harmonization Working Group (RHWG) of WENRA on selected key safety issues. Position 1 of this document defines a refined structure of DiD as proposed by RHWG. This structure is adopted in Table 1 of section 5.2 with several terms being changed to accommodate its application also to non-NPP nuclear class I installations. The DiD structure is also coherent with Article 8b/1 of the Euratom council directive 2014/87/Euratom [5] on DiD.

5.2. Deterministic approach to Defence-in-Depth (DiD) and associated design basis categories

The structure of the levels of DiD and associated design basis categories recommended by the Belgian regulatory authority is presented in Table 1 below. This table should be read first of all in the context of internal events. Although the approach presented in this section is “deterministic”, C2 and C3a PIEs should be selected using deterministic or probabilistic methods or a combination of both, as well as engineering judgment. C3b, C4a and C4b PIEs should be derived and justified as representative, based on a combination of deterministic and probabilistic assessments as well as engineering judgment.
### Table 1: Structure of the levels of DiD adopted by the Belgian regulatory authority and associated design basis categories for the deterministic approach

<table>
<thead>
<tr>
<th>Levels of DiD Level</th>
<th>Objective of the DiD Level</th>
<th>Qualitative safety objective of the DiD Level (Off-site radiological consequences)</th>
<th>Associated Design Basis Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Prevention of abnormal operation and failures</td>
<td>No off-site radiological impact (bounded by regulatory operating limits for discharge)</td>
<td>C1 “Normal operation” GRR-2001</td>
</tr>
<tr>
<td>Level 2</td>
<td>Control of abnormal operation and detection of failures</td>
<td>No off-site radiological impact or only minor radiological impact (part of WENRA Objective O2)</td>
<td>C2 “Anticipated operational Occurrences” SO1</td>
</tr>
<tr>
<td>Level 3.a</td>
<td>Control of accident to limit radiological releases and prevent escalation to severe accidents</td>
<td>Off-site radiological impact may imply limited protective measures in area and time (part of WENRA Objective O3)</td>
<td>C3a “Postulated single initiating events” SO2</td>
</tr>
<tr>
<td>Level 3.b</td>
<td>Control of severe accidents to limit off-site releases</td>
<td>Reduce the risk further</td>
<td>C3b “Postulated multiple failure events” SO2</td>
</tr>
<tr>
<td>Level 4</td>
<td>Mitigation of radiological consequences of significant releases of radioactive material</td>
<td>Off-site radiological impact necessitating protective measures</td>
<td>C4a3 “Severe Accidents not practically eliminated” SO3</td>
</tr>
<tr>
<td>Level 5</td>
<td>Mitigation of radiological consequences of significant releases of radioactive material</td>
<td></td>
<td>C4b4 “Severe Accidents practically eliminated” Not Applicable</td>
</tr>
</tbody>
</table>

5.2.1. **C2 “Anticipated operational occurrences”**

An anticipated operational occurrence should meet the quantitative safety objective SO1 presented in section 6.2.1 and section 6.3 with a conservative\(^5\) deterministic safety analysis approach.

5.2.2. **C3a “Postulated single initiating events”**

The postulated single initiating events design basis category\(^6\) is constituted of accidents initiated by a single postulated initiating event with all its consequential failures, if any. Based on probabilistic insights, the applicant can propose that a postulated single initiating event is considered in a different design basis category (e.g. C3b) and seek for agreement from the regulatory authority.

The accidents described above should meet the quantitative safety objective SO2 presented in section 6.2.2 and section 6.3 with a conservative deterministic safety analysis approach (which includes the single failure criteria).

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\(^3\) C4a design basis category covers severe accidents not practically eliminated.
\(^4\) C4b design basis category covers severe accident phenomena occurring in situations practically eliminated but not in any other design basis category.
\(^5\) Guidance on the expectations of the regulatory authority for a conservative safety analysis approach will be developed.
\(^6\) In the context of the WENRA safety reference levels [18], C3a accidents are the “design basis accidents”.

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5.2.3. C3b “Postulated multiple failure events”

The postulated multiple failure events design basis category\(^7\) is constituted of accidents to be considered at the design stage caused by one of the following:

- a postulated common cause failure or inefficiency of all redundant trains of a same safety system needed to fulfill a safety function necessary to cope with a postulated anticipated operational occurrences (C2) or a single postulated initiating event (PIE) of C3a, or
- a postulated common cause failure of a same safety system needed to fulfill the safety functions in normal operation (C1).

Not all common cause failures need necessarily to be postulated. The applicant is expected to propose the list of common cause failures postulated and those not postulated (because either enveloped by postulated events or screened out).

The safety systems affected are the safety systems relied on under DiD Level 1 to 3.a. The aim in C3b is to control the selected multiple failure events to limit radiological releases and prevent escalation to severe accident conditions.

The accidents listed above should meet the quantitative safety objectives SO2 presented in section 6.2.2 and section 6.3 with an approach which could be less conservative\(^8\) than the one used for the analysis of C3a events.

5.2.1. C4 “Severe Accidents”

Severe accidents (SA) are a specific set of rare accidents for which the consequences are beyond those of C3b accidents.

Although C3b aims at preventing severe accidents as far as reasonably practicable, severe accidents should nevertheless be considered as part of the DiD approach. Severe accidents which lead to early or large releases need to be practically eliminated (see section 5.3).

C4a accidents\(^9\) are severe accidents (e.g. core melt\(^10\), large releases of radioactive material from the installation, ...) that have not been practically eliminated (see section 5.3).

For these accidents, design measures should be implemented in order to meet safety objective SO3. In addition, the applicant should demonstrate to the regulatory authority that there are no reasonably practicable design measures that could be implemented to meet safety objective SO2.

Quantitative safety objectives are presented in section 6.2.3 and section 6.3 and should be met with an approach which could be less conservative than the one used for the analysis of C3a events.

For SA practically eliminated there are no quantitative safety objectives defined. Any additional reasonably practicable mitigating provisions should be implemented to address SA phenomena that arise in the practically eliminated SA situations and which are not covered under C4a with the aim to reduce the risk further. To meet this objective, “severe accidents” should be postulated (i.e. hypothetical accidents) under C4b. The intention in addressing these additional SA phenomena is to ensure that the DiD Level 4 analysis covers a wide set of severe accident phenomena. The mitigation means for these situations belong to level 4 of the Defence in Depth (DiD).

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\(^7\) In the context of the WENRA safety reference levels \([18]\), C3b accidents are part of the “Design Extension Conditions (DEC)”.

\(^8\) Guidance on the expectations of the regulatory authority for a less conservative safety analysis approach will be developed.

\(^9\) In the context of the WENRA safety reference levels \([18]\), C4a accidents are part of the “Design Extension Conditions (DEC)”.

\(^10\) The scope of the safety demonstration should cover all risks induced by the nuclear fuel, even when stored in the fuel pool. Hence, core melt accidents (severe accidents) have to be considered when the core is in the reactor, but also when the whole core or a large part of the core is unloaded and stored in the fuel pool or stored elsewhere in the installation (e.g. in-vessel fuel storage).
5.3. **Demonstration of practical elimination**

This section addresses the demonstration of practical elimination of a sequence (initiator) which could lead to early or large releases.

The demonstration of practical elimination is considered successful if [7]:

- The sequence (initiator) can be proven to be physically impossible;
- The sequence (initiator) is extremely unlikely to arise with a high level of confidence.

Steps to demonstrate that the sequence (initiator) is extremely unlikely to arise with a high level of confidence are:

- Identify the initiator or the accident sequence that would lead to radiological consequences beyond SO3;11
- The probability of this initiator or accident sequence should be pushed to very low probabilities. If the demonstration applies to the initiator then it is sufficient to agree with the regulatory authority on a cut-off probabilistic value. If the demonstration applies to the accident sequence then the demonstration cannot be claimed successful solely based on compliance with a general cut-off probabilistic value: the demonstration must be robust noting that:
  - If the demonstration of practical elimination relies on the demonstration that the event is “extremely unlikely with a high level of confidence” then, in order to quantify the notion of “extremely unlikely”, it is important to provide an order of magnitude of acceptable reliability for the upstream credited layer(s) of provision(s)12 (also referred to as “line of defence” or “line of protection”) used in the safety demonstration;
  - because of the existence of unforeseen/unexplained common cause failures there is a limit to the reliability that can be allocated to a single layer of provision. It is important to include arguments on reliability of the relevant structures, systems and components;
  - when relevant in the demonstration, the probability of the common cause failure is taken into account;
- the simplicity of the safety architecture or the demonstrated degree of knowledge for the phenomena involved in the accident will contribute to a robust demonstration of the practical elimination.

6. **Radiological Safety objectives**

Article 8a of council directive 2014/87/Euratom of 8 July 2014 [5] defining the nuclear safety objective for nuclear installations, indicates that Member States shall ensure that the national nuclear safety framework requires that nuclear installations are designed, sited, constructed, commissioned, operated and decommissioned with the objective of preventing accidents and, should an accident occur, mitigating its consequences and avoiding:

- early radioactive releases that would require off-site emergency measures but with insufficient time to implement them;
- large radioactive releases that would require protective measures that could not be limited in area or time.

In relation to this, the following sections define radiological safety objectives for the public outside the site limits. Even if a safety objective is met, the applicant should show that the radiological consequences cannot be reduced further with reasonable means (this is referred to as an ALARA optimization).

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11 see §6.2 for the definition of off-site objective SO3 and §6.3 for the definition of on-site objective SO3.
12 The term “layers of provisions” is used in IAEA/SSR-2/1 Ref [16].
6.1. **Radiological safety objectives for normal operation**

For normal operation (C1), the regulatory operating limits for discharge and dose constraints apply. Dose limits are provided in [1].

6.2. **Off-site radiological safety objectives SO1, SO2 and SO3**

The radiological safety objectives are expressed in terms of effective dose and thyroid dose.

In the following sections, dose coefficients should be taken from [1]. If some isotopes or dose coefficients needed for the dose calculations are not listed in [1], values are to be defined in consultation with the regulatory authority.

**6.2.1. Radiological safety objective SO1**

For an anticipated operational occurrence (C2), the quantitative acceptance criteria for safety objective SO1 for an individual of the public off-site are:

- For events at least as frequent as once in a year:
  - Effective dose/event < 0,1 mSv/event;
  - Equivalent thyroid dose/event for the infant, child or adolescent < 0,3 mSv/event.
- For events less frequent than once in a year:
  - Effective dose/event < 0,5 mSv/event;
  - Equivalent thyroid dose/event for the infant, child or adolescent < 1,5 mSv/event.

The doses for the public should be evaluated for the most exposed and vulnerable individual (based on realistic parameters\(^{13}\)) considering the whole time period of the releases or the duration of direct irradiation exposure from a source within the installation. The dose should take into account direct exposure, cloud shine, and inhalation. The thyroid dose should be calculated taken into account inhalation only.

**6.2.2. Radiological safety objective SO2**

Qualitatively, safety objective SO2 is that C3a and C3b accidents induce no off-site radiological impact or only minor radiological impact (in particular, no necessity of iodine prophylaxis, sheltering nor evacuation\(^{14}\)). The objective should be interpreted in such way that for those accidents, releases should be avoided and where it is not possible to completely avoid them, the doses for the public should be below the levels where emergency response protective measures might be considered.

For accidents C3a and C3b, the quantitative acceptance criteria for safety objective SO2 for an individual of the public off-site are:

- Effective dose/event < 5 mSv/event;
- Equivalent thyroid dose/event for the infant, child or adolescent < 10 mSv/event.

The effective dose should take into account direct exposure, cloud shine, and inhalation. The thyroid dose should be calculated taking into account inhalation only. In addition, all paths need to be taken into account in order to ensure that the lifetime effective dose is well below 1 Sv/event [12], [20]. Agricultural products (basket of products to be defined and justified) should be consumable within a time period of one year following the accident. In all cases, no credit can be given to any off-site remediation measure except those related to restriction of food consumption during the first year after the accident.

The doses for the public should be evaluated for the most exposed and vulnerable individual (based on realistic parameters) considering the whole time period of the releases or the duration of direct irradiation exposure from a source within the installation.

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\(^{13}\) More explanations will be provided in the FANC guideline(s) that will be developed on conservative and less conservative safety analyses approaches.

\(^{14}\) However, restriction of food consumption could be needed in some scenarios.
6.2.3. Radiological safety objective SO3

Safety objective SO3 aims at reducing potential releases to the environment from severe accidents, also in the long term\textsuperscript{15}, by following the qualitative criteria below:

- severe accidents which would lead to early\textsuperscript{16} or large\textsuperscript{17} releases have to be practically eliminated (See section 5.3);
- severe accidents which would lead to unacceptable direct irradiation (e.g. in case of criticality accidents without release) have to be practically eliminated (see section 5.3);
- for severe accidents that have not been practically eliminated, design provisions have to be taken so that only limited protective measures in area and time are needed for the public (no permanent relocation, no need for emergency evacuation outside the immediate vicinity of the plant, limited sheltering, no long term restrictions in food consumption) and that sufficient time is available to implement these measures.

To meet the third bullet, the following interpretations of limited protective measures are provided based mainly on [7] (specified zones are not meant to be used for emergency preparedness planning; zones related to emergency planning are provided in [11]):

- Immediate vicinity of the plant: The design should be such that the possible release of radioactive substances in a C4a accident, based on the analyzed consequences of the accident, will not initiate a need for emergency evacuation beyond the immediate vicinity of the plant. The design objective is to have a radius (R) of this immediate vicinity not exceeding 3 to 10 km\textsuperscript{18} (evacuation zone);
- Limited sheltering and iodine prophylaxis: The design objective should be such that the possible release of radioactive substances in a C4a accident, based on the analyzed consequences of the accident, will not initiate a need for sheltering and iodine prophylaxis beyond the zone delimited by a radius (R) not exceeding 5 to 20 km\textsuperscript{18} (sheltering zone);
- No long-term restrictions in food consumption: This is interpreted so that after a C4a accident, based on the analyzed consequences of the accident, agricultural products beyond the sheltering zone should generally be consumable one year after the accident (see section 8.4.1.2 of [11]).

The radii used by the applicant should be agreed with the regulatory authority. The detailed safety objectives and protective measures for the public are summarized in Table 2.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Evacuation zone (R ≤ 3 to 10 km)</th>
<th>Sheltering zone (R ≤ 5 to 20 km)</th>
<th>Beyond sheltering zone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evacuation</td>
<td>Maybe</td>
<td>No: Effective dose/event &lt; 50 mSv/event beyond the evacuation zone. The dose should be integrated over 7 days.</td>
<td>No: Effective dose/event &lt; 50 mSv/event beyond the evacuation zone. The dose should be integrated over 7 days.</td>
</tr>
</tbody>
</table>

\textsuperscript{15} Long term: considering the time over which the safety functions need to be maintained. It could be months or years, depending on the accident scenario.

\textsuperscript{16} Early releases: situations that would require off-site emergency measures but with insufficient time to implement them.

\textsuperscript{17} Large releases: situations that would require protective measures for the public that could not be limited in area or time.

\textsuperscript{18} The radius which is considered as justified is the smallest radius. Exceeding this value towards the upper bound should be justified by the applicant. A radius exceeding the upper bound (which is the value used or planned to be used for the emergency planification zones) are not justified according to the regulatory authority.
<table>
<thead>
<tr>
<th>Sheltering</th>
<th>Maybe</th>
<th>Maybe</th>
<th>No: Effective dose/event &lt; 5 mSv/event, beyond the sheltering zone. The dose should be integrated over 24 hours.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iodine Prophylaxis</td>
<td>Maybe</td>
<td>Maybe</td>
<td>No: Equivalent thyroid dose/event for the infant, child or adolescent &lt; 10 mSv/event during cloud passage, beyond the sheltering zone.</td>
</tr>
</tbody>
</table>

**Long term measures**

| Long-term restrictions in food consumption | Maybe | Maybe | No: Agricultural products should be consumable one year after the accident, beyond the sheltering zone. |

Table 2: Quantitative safety objectives SO3 for areas where limited protective measures may be needed.

The thyroid dose should be calculated taking into account inhalation only. The doses for evacuation and sheltering should take into account direct exposure, inhalation, cloud shine and ground shine. Beyond the sheltering zone, agricultural products (basket of products to be defined and justified) should be consumable within a time period of one year following the accident. For permanent relocation, all paths should be considered.

The doses should be evaluated for the most exposed and vulnerable individual (based on realistic parameters) considering the relevant integration time and the whole released source term\(^{19}\).

### 6.3. On-site radiological safety objectives SO1, SO2 and SO3

This section will be completed in the next revision of this guideline.

### 7. Consideration of external hazards

#### 7.1. General approach

The approach for the safety demonstration of external hazards presented here is consistent with the approach focused on internal hazards presented in section 5. In general, for each type of external hazard, two hazard levels need to be defined: HL1 and HL2, and a margin assessment is to be carried out for the ‘HL1’ hazard. When existing, hazard specific FANC guidelines complement or further precise the general statements presented here.

For the first hazard level ‘HL1’ considered as an initiating event, the safety objective SO2 should be met with the use of a conservative safety analysis. The ‘HL1’ hazard is defined as a C3a initiating event. The annual exceedance frequency should not be higher than \(10^{-4}/y\) for natural hazards and \(10^{-6}/y\) for unintentional man-made hazards with due consideration of uncertainties. This difference between natural hazards and man-made hazards can be explained by the fact that man-made hazards tend to be subject to stronger changes over time\(^{20}\).

A second hazard level ‘HL2’, more severe and less frequent than ‘HL1’ should also be defined. For this second hazard level ‘HL2 considered as a rare initiating event’, safety objective SO3 should be met. If reasonable design measures are available with which SO2 can be met, then they should be implemented. For the ‘HL2’

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\(^{19}\) If the whole released source term is released within a period of time exceeding the relevant integration time (i.e. 24 hours or 7 days), then an equivalent release rate and release time should be defined in order to envelop the whole released source term within the relevant integration time or alternatively, the whole release period should be considered.

\(^{20}\) For example: the hazard posed by aircraft crashes was practically non-existent a century ago. Natural hazards such as earthquake are more stable over time or develop in a more predictable manner.
hazard, the use of a less conservative safety analysis is acceptable to the regulatory authority and the ‘HL2’ hazard is thus categorized as a C4a initiating event or, when SO2 is met, a C3b initiating event.

7.2. Margin assessment

The safety analysis should also demonstrate the sufficiency of conservatism for accidents induced by the ‘HL1’ hazard by a margin assessment. The margin is defined as the difference gap between the ‘HL1’ hazard, and a hazard (typically referred to as HL1*) for which the radiological safety objective SO2 can still be ensured even with use of less conservative methods, assumptions and data. Unless explicitly defined by the regulatory authority in guidelines, the margin assessment should be proposed by the applicant to the regulatory authority and should follow the assessment rules of design basis category C3b (i.e. SO2 and less conservative analysis).

The margin can be measured in a number of ways:

- As a gap in exceedance frequency between the ‘HL1’ hazard and the ‘HL1*’ hazard;
- As a gap in the severity between the ‘HL1’ hazard and the ‘HL1*’ hazard.

In all cases, the selection and severity of external hazards to be considered is subject to the acceptance of the regulatory authority.

To illustrate the relation between HL1 and the margin assessment graphically, an example is provided in Figure 1. In this figure the radiological consequences (y-axis) are given in relation to the hazard severity/exceedance frequency (x-axis). The installation considered meets SO2 for HL1 conservatively (colored area on right side of the figure). The best-estimate radiological consequence corresponding to HL1 is well below SO2, however, this is not the margin that is expected to be determined as part of the margin assessment.

Beyond the HL1 hazard, several (hypothetical) best-estimate curves are shown corresponding to different designs. Do note that such curves do not need to be calculated. These curves are given for 4 cases:

- case 1 shows a steep increase just beyond the HL1 hazard and very little margin: this is not considered to be acceptable;
- case 2 is a case for which the margin is determined explicitly: although the scales are not displayed, this case seems acceptable;
- case 3 is a case for which the margin is not calculated explicitly but, it is shown that a at sufficiently large “distance” from HL1, the best-estimate response is below SO2: again although the scales are not displayed, this case seems acceptable;
- case 4 concerns the situation for which it is shown that SO2 is met for HL2: no margin assessment is needed.
7.3. Application of the graded approach to external hazards

7.3.1. General approach
The graded approach aims to apply safety requirements in a manner commensurate with the characteristics of the installation, practice or source and with the magnitude and likelihood of the exposures. For the application to external hazards, the focus of the graded approach presented here will be on the potential radiological consequences based on which the scope of the safety demonstration of the external hazards will be defined. The general steps in this process are the following:

- Characterize the potential worst-case radiological consequences related to the new installation and, when necessary, in relation to a specific external hazard (see 7.3.2);
- Categorize this potential worst-case radiological consequence in relation to the safety objectives SO2 and SO3 (see 7.3.3);
- Determine the scope of the safety analysis in function of the categorization of the potential worst-case consequences.

The applicant should propose and justify the manner in which the graded approach is applied to the safety demonstration of external hazards. If the potential worst-case consequences are not determined, then by default the new installation should be categorized under the highest graded approach category (i.e. 4).

As will be clarified in the next subsections that provide expectations and guidance on the elements that should or could be part of the graded approach, most effort is necessary to determine the potential worst-case radiological consequence. In some cases an approach that quantifies the potential worst-case radiological consequence independently from the type and/or severity of the external hazard may be sufficient.

7.3.2. Characterisation of the potential worst-case radiological consequences
Two aspects are important for the characterization of the consequences in relation to setting up a safety demonstration:
• At the moment that the scope of the safety demonstration is defined, it is likely that only preliminary and general information is available and not a detailed and final design;
• The characterization should be done conservatively. If the resulting categorization would be underestimating the real consequences, then this would result in an insufficiently elaborate safety demonstration and hence an insufficient – i.e. unacceptable – protection in the final design.

These two aspects call for a simple and conservative approach. In general such an approach should consider the following aspects:
• The source and source term;
• The potential release of the source term;
• The external transport of the released source term;
• The resulting radiological impact.

Several factors should be considered as relevant characteristics of the source and source term, such as:
• Type of radioisotopes, either isotope specific or categorized for instance in groups such as $\alpha$, $\beta\gamma$, noble gasses, tritium, iodine, etc.;
• Mobility and physical form of the source term, e.g. solid, gaseous, liquid;
• Magnitude of the source term. As the main principle, the source present in the entire installation should be considered. However, it may be justified to segment the installation and assess the corresponding source term. Such segmentation could also be specific to an external hazard.

To assess the potential release of the source term(s), consideration should be given to the following aspects:
• Influence of the external hazard. The characteristics of an external hazard may impact differently on the source. For instance: some external hazard may give rise to mechanical forces whereas others give rise to reactivity effect; some external hazard may lead to the loss of the heat sink, whereas others may lead to the loss of electrical supply. For the purpose of applying the graded approach, an elaborate site specific hazard assessment is not considered necessary. Instead the characteristics of the external hazard should be accounted for and some basic knowledge on the potential site specific severity should be included by assuming a severity that can be considered “rare” but not unrealistic$^{21}$.  
• Influence of the installation. The characteristics of the installation may aggravate or alleviate the release of the source. Aggravating characteristics, for instance the potential for chemical reactions or the release of energy, should be included. Taking into account alleviating characteristics such as barriers needs to be justified.

The release fraction of the source(s) should be appropriately justified and otherwise assumed to be 100%.

The external transport medium of the released source term(s) may be external hazard specific (e.g. by water or by air), however, in most cases the transport by air will be the relevant mode of dispersion. In this case the weather and point of release are relevant factors to be described and justified. Methods, assumptions and data to model the external transport of the release source term should not differ from those that are applied in relation to SO2.

Finally, to determine the radiological impact the characteristics of the source term and of the exposed person should be specified and justified. Methods, assumptions and data related to the characteristics of the exposed person should not differ from those that are applied in relation to SO2.

As stated the approach should be detailed and justified. It should be noted that crediting beneficial characteristics of the installation (e.g. segmentation, barriers, etc.) will be subject to a critical review and will also likely lead to additional conditions on the design and/or the safety demonstration. Such additional conditions will aim to ensure the validity of crediting the characteristic.

$^{21}$ For example: without performing a site specific hazard assessment, one can assume that a certain wind-speed can be considered rare. In addition, use can be made of an expert opinion to establish such a level.
7.3.3. Categorization of the potential worst-case radiological consequences

The hazard-specific worst-case consequences will fall into one of the following graded approach categories:

1. Radiological consequences on-site below the SO2 limits\(^{22}\);
2. Radiological consequences on-site larger than SO2 but radiological consequences off-site below the SO2 limits;
3. Radiological consequences off-site larger than SO2 but not larger than SO3 limits;
4. Radiological consequences off-site larger than SO3 limits.

7.3.4. Graded safety demonstration matrix

To determine the scope of the safety demonstration, the following graded safety demonstration matrix should be used:

<table>
<thead>
<tr>
<th>Graded approach category</th>
<th>Include in safety demonstration?</th>
<th>Margin assessment (HL1(^{*}))</th>
<th>HL2</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>3</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>2</td>
<td>yes</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>1</td>
<td>yes(^{*})</td>
<td>no</td>
<td>no</td>
</tr>
</tbody>
</table>

\(^{*}\): For graded approach category 1 the installation should be designed for at least the severity retained in conventional design standards, when existing, according to the national codes for industrial facilities. Unless those standards and codes are more stringent, a HL1 event should be defined and analyzed with a severity set such that the exceedance frequency of the external natural hazard corresponds to a few percent’s probability of exceedance during the lifetime of the facility. Note that for some hazards (e.g. aircraft crashes) a specific definition for the HL1 event for the graded approach category 1 may be provided in dedicated FANC guidelines.

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\(^{22}\) The applicable SO2 limit on-site will defined in the next revision of this guideline.
8. References

[6] WENRA statement on safety objectives for new nuclear power plants, November 2010
[18] WENRA safety reference levels for existing reactors, September 2014
[19] Arrêté AFCN du 17/10/03, Niveaux-guides d’intervention pour les situations d’urgence radiologique
IAEA, Safety Standard Series No. GS-R-2, Preapradness and response for a nuclear or radiological emergency, 2002
9. Definitions

**abnormal operation** [17]: See *anticipated operational occurrence*.

**accident conditions**: Deviations from normal operation that are less frequent and more severe than anticipated operational occurrences, and which include single initiating events accidents, multiple failure events accidents and severe accidents.

**anticipated operational occurrence** [17]: An operational process deviating from normal operation which is expected to occur at least once during the operating lifetime of a facility but which, in view of appropriate design provisions, does not cause any significant damage to items important to safety or lead to *accident conditions*.

**applicable document**: In the context of this guideline, a document that contains recommendations that should be followed in order to meet the expectations of the regulatory authority. (The document remains however a non-legally binding document).

**barrier** [17]: A physical obstruction that prevents or inhibits the movement of people, radionuclides or some other phenomenon (e.g. fire), or provides shielding against radiation.

**direct exposure**: Direct external exposure to a radiation source. The term is used to take into account exposure situations that do not necessarily result from a release (e.g. criticality accidents).

**early releases** [6]: Situations that would require off-site emergency measures but with insufficient time to implement them.

**event** [17]: An event is any occurrence unintended by the operator, including operating error, equipment failure or other mishap, and deliberate action on the part of others, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

**exceedance frequency**: The annual frequency of an event with a severity equal to or larger than a specified value.

**initiating event** [17]: An identified event that leads to *anticipated operational occurrences* or *accident conditions*.

**large releases** [6]: Situations that would require protective measures for the public that could not be limited in area or time.

**normal operation** [17]: Operation within specified *operational limits and conditions*.

**operational limits and conditions** [17]: A set of rules setting forth parameter limits, the functional capability and the performance levels of equipment and personnel approved by the regulatory body for safe operation of an authorized facility.

**postulated initiating event (PIE)** [17]: An event identified during design as capable of leading to anticipated operational occurrences or accident conditions.

**public** [1]: Individuals of the population, with the exception of the persons professionally exposed, trainee(s) and student(s) during their working hours.

**single failure** [18]: A failure and any consequential failure(s) postulated to occur in any component of a safety function in connection with the initiating event or thereafter at the most unfavourable time and configuration.
**safety system**: A system provided to ensure one of the **safety functions**.

**safety functions**: Functions important to safety and to be fulfilled by the design to control transients, prevent accidents and accident escalation or to mitigate the consequences of accidents. The main safety functions are (i) Control of reactivity, (ii) Cooling of radioactive material (iii) Confinement of radioactive material.
Appendix A: Summary table of off-site radiological safety objectives

<table>
<thead>
<tr>
<th>Design Basis Categories</th>
<th>Radiological Safety Objective:</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1 “Normal operation”</td>
<td>GRR-2001: See article 20.1.4 of the GRR-2001</td>
</tr>
<tr>
<td>C2 “Anticipated operational Occurrences”</td>
<td>SO1: For events at least as frequent as once in a year:</td>
</tr>
<tr>
<td></td>
<td>• Effective dose/event &lt; 0.1 mSv/event;</td>
</tr>
<tr>
<td></td>
<td>• Equivalent thyroid dose/event for the infant, child or adolescent &lt; 0.3 mSv/event;</td>
</tr>
<tr>
<td></td>
<td>For events less frequent than once in a year:</td>
</tr>
<tr>
<td></td>
<td>• Effective dose/event &lt; 0.5 mSv/event;</td>
</tr>
<tr>
<td></td>
<td>• Equivalent thyroid dose/event for the infant, child or adolescent &lt; 1.5 mSv/event;</td>
</tr>
<tr>
<td></td>
<td>considering the whole time period of the releases or the duration of direct irradiation exposure. The effective dose should take into account direct exposure, cloud shine, and inhalation. The thyroid dose should be calculated taking into account inhalation only.</td>
</tr>
<tr>
<td>C3a “Postulated single initiating events”</td>
<td>SO2: Effective dose/event &lt; 5 mSv/event;</td>
</tr>
<tr>
<td></td>
<td>Equivalent thyroid dose/event for the infant, child or adolescent &lt; 10 mSv/event;</td>
</tr>
<tr>
<td></td>
<td>considering the whole time period of the releases or the duration of direct irradiation exposure. The effective dose should take into account direct exposure, cloud shine, and inhalation. The thyroid dose should be calculated taking into account inhalation only.</td>
</tr>
<tr>
<td></td>
<td>• Lifetime effective dose/event &lt; 1 Sv/event, beyond the site limits (all paths);</td>
</tr>
<tr>
<td></td>
<td>• Agricultural products should be consumable one year after the accident, beyond the site limits.</td>
</tr>
<tr>
<td>C3b “Postulated multiple failure events”</td>
<td>SO3: Effective dose/event &lt; 50 mSv/event beyond the evacuation zone. The dose should be integrated over 7 days;</td>
</tr>
<tr>
<td></td>
<td>Effective dose/event &lt; 5 mSv/event, beyond the sheltering zone. The dose should be integrated over 24 hours;</td>
</tr>
<tr>
<td></td>
<td>Equivalent thyroid dose/event for the infant, child or adolescent &lt; 10 mSv/event during cloud passage, beyond the sheltering zone;</td>
</tr>
<tr>
<td></td>
<td>considering the whole released source term$^{19}$ The effective dose should take into account direct exposure, inhalation, cloud shine and ground shine. The thyroid dose should be calculated taking into account inhalation only.</td>
</tr>
<tr>
<td></td>
<td>• Lifetime effective dose/event &lt; 1 Sv/event, beyond the site limits (all paths);</td>
</tr>
<tr>
<td></td>
<td>• Agricultural products should be consumable one year after the accident, beyond the sheltering zone.</td>
</tr>
<tr>
<td>C4a “Severe Accidents not practically eliminated”</td>
<td>SO4: Not Applicable</td>
</tr>
<tr>
<td>C4b “Severe Accidents practically eliminated”</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

Table A1: Summary table of off-site radiological safety objectives