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INSTITUT DE RADIOPROTECTION ET DE SÛRETÉ NUCLÉAIRE

DOSE LIMIT VALUES FOR NUCLEAR INSTALLATIONS, RADIOACTIVE RADIATION AND RADIATION PROTECTION

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Report n°IRSN/DAEI/BU-DCI/2022-00044

Ce document relève du contrat commercial n° LW IRSN 2021-0195

This document is covered by commercial contract no

European and International Affairs Division

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			Approbation *(Approval)*	
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Date				
Visa	Yann Billarand Signé numériquement par : Yann Billarand Nom DN : CN = Yann Billarand C = FR Date : 2023.03.06 11:54:31 +02'00'	Yann Billarand Signé numériquement par : Yann Billarand Nom DN : CN = Yann Billarand C = FR Date : 2023.03.06 11:56:36 +02'00'		VALIDATION ÉLECTRONIQUE CERTIFIÉE IRSN Jean-René JOURDAIN 2023.03.06 14:33:15 +01'00'

ABSTRACT

The Swiss regulations (Radiological Protection Ordinance and Nuclear Energy Ordinance) define dose ranges that apply to the probability of an accident, regardless of the type of nuclear facility or facility holding radioactive materials. IRSN undertook a brief survey of international recommendations and national regulatory frameworks in this area, which is only a small part of the overall safety approaches.

With regard to question 1 of Postulate 18.4107 (How does Swiss legislation on radiological protection compare with international best practices?), this study shows that the values specified in the Swiss regulations are in line with practices in other countries. However, the shutdown of a facility if the value of 100 mSv is exceeded for accidents with a probability of more than 10^{-4} per year seems to be specific to the Swiss regulations. The very prescriptive approach in terms of methods for calculating consequences supports this strict provision. IRSN emphasises that the dose values associated with the probabilities alone are not a sufficient criterion for judging the regulatory requirements from one country to another, as the calculation methods may be different (in particular, routes and duration of exposure).

Regarding question 2 (How can we compare the levels of acceptable risk of a nuclear power plant with other sources of radioactivity dissemination and external irradiations?), the regulatory approach in Switzerland is to apply the same criteria (occurrences and consequences) regardless of the type of installation. International practice focuses on NPPs or, more broadly, nuclear industry facilities, and the French practice for small facilities is to eliminate the accident scenario if it could lead to occupational exposure above dose limits without any occurrence calculation. For its next general recommendations, ICRP is considering how to apply tolerability to different exposure categories and exposure situations. IRSN believes that potential exposures, which are closely linked to risk acceptance, should be taken into account in these considerations.

Finally, with regard to question 3 (What are the current discussions in science and research regarding low dose of ionizing radiations?), recent advances in knowledge of the effects of ionizing radiation at low doses are not such as to call into question the exposure levels specified in the Swiss regulations. It should simply be noted that the dose of 100 mSv should no longer be considered as a dose value below which there is no scientifically proven association in exposure and an increased excess risk of cancer.

Key-words: accident probability; NPP; dose range

TABLE OF CONTENTS

TABLE OF FIGURES AND TABLES

Figures

Tables

1 CONTEXT

The Swiss Federal Office of Energy (SFOE[1]) would like to have an opinion on the relevance of the revision of January 10, 2018 of the Swiss nuclear energy ordinance, and in particular on the position that Switzerland thus adopted in relation to other European countries with an operating nuclear power plant.

This office entrusted the mission to three experts in the field, François BOCHUD (Switzerland), Didier GAVILLET (Switzerland) and Patrick MAJERUS (Luxembourg), with the task of drawing up a report on this subject. However, in order to guarantee the independence of their judgment, and given that some of these experts had participated in the drafting of the ordinance, the Swiss Federal Office of Energy asked that this panel of experts to rely on opinions from outside Switzerland. In this context, IRSN was asked to lead this investigation and to provide an external opinion.

2 TECHNICAL BRIEF

2.1 CLIENT EXPECTATIONS

The requirements are specified by the three designated experts in the document entitled “Postulate 18.4107: Dose limit values for nuclear installations, radioactive radiation and radiation protection – Call for tender” (dated March 11, 2021), which is given in Appendix 1. It consists of the 3 main questions:

1) How does Swiss legislation on radiological protection compare with international best practices?
2) How can we compare the levels of acceptable risk of a nuclear power plant with other sources of radioactivity dissemination and external irradiations?
3) What are the current discussions in science and research regarding low dose of ionizing radiations?

In addition, a general opinion on the management of radiological risk in Switzerland is expected on the basis of the answers to the various questions.

Some clarifications have been made by the 3 experts during a dedicated meeting[2] held on March 2, 2021, in the context of the instruction of this proposal and are also taken into account in the present IRSN answer.

The deliverable will be a report, the draft version of which will be presented to the 3 experts before the final version is edited. It will present the differences between a prescriptive system, such as that in Switzerland and a system based more on objectives to be achieved (performance-based approach), such as that in France, in a way that can be understood by a non-expert.

[1] In French, OFEN for Office Fédéral de l'Energie

[2] The minutes, written in French, are available on request

2.2 IRSN SERVICE

The methodology followed by IRSN to respond to the requirements (see § 2.1) has been developed in the technical and financial proposal IRSN 120515 – Index 2, in particular in its section 2.2.

The IRSN service, including this report, aims to meet the requirements of the contract OFEN SI/300326-01 - IRSN LW 2021-0195 signed on February 3, 2022, and based on its technical and financial proposal.

The following sections deal with the 3 initial questions and one additional point beyond the questions 1 and 2.

3 ADDITIONAL INFORMATION CONCERNING THE IRSN RESPONSE BEYOND THE QUESTIONS 1 AND 2

According to the IRSN's technical and financial proposal, beyond the questions 1 and 2, and taking into account the clarifications made during the meeting[3] held on March 2, 2021, in the framework of the instruction of this proposal, IRSN involved nuclear safety experts in order to provide an insight into the approach used for nuclear power plants in France, as described below.

The French practices and regulations regarding the acceptability of the risk of nuclear power plants are based on the assessment of the adequate implementation of safety principles such as defence-in-depth and the justification that the provisions taken by the licensee "in view of the state of knowledge, practices and the vulnerability of the environment, enable the risks and drawbacks mentioned in Article L. 593-1 of the Environment Code to be reduced to the lowest possible level under economically acceptable conditions" (according to the Order of 7 February 2012 establishing the general rules relating to basic nuclear installations). Thus, the French practices and regulations are not based on a quantitative cut-off criterion for radiological doses.

IRSN will summarize the general aspects mentioned in the regulation concerning the safety objectives to be pursued by a nuclear power plant licensee.

It will illustrate them technically by 3 different approaches that are carried out in France:

1. Process and examples of results of the 4th Periodic Safety Review of the 900 MWe series:
    a. The main safety aspects that were considered to define the detailed scope of the assessment of the 900-MWe series Periodic Safety Review,
    b. 3 major examples of improvements and corresponding results in terms of radiological consequences,
2. Position of the radiological consequences assessment within the safety demonstration."

[3] The minutes, written in French, are available on request

3.1 General aspects of regulation regarding safety objectives to be targeted for a nuclear power plant

The French Environment Code requires that it be demonstrated that technical or organizational measures taken or envisaged are capable of sufficiently preventing or limiting the risks or drawbacks presented by the installation.

In addition to this very general objective, more detailed recommendations on the safety objectives to be pursued by each nuclear installation licensee are given in the Order of 7 February 2012 laying down the general rules relating to basic nuclear installations and, for nuclear power plant licensees, in the ASN guide No. 22 relating to the design of pressurized water reactors. This guide was prepared jointly with IRSN[4].

The Order of 7 February 2012 stipulates that "*the licensee ensures that the provisions adopted for exercising the activities in view of the state of knowledge, practices and the vulnerability of the environment, enable the risks and drawbacks mentioned in article L. 593-1 of the environment code to be brought to as low a level as possible under economically acceptable conditions*". In this context, it defines the demonstration of nuclear safety in terms of the objective that the "*risks of an accident - radiological or not – and the scale of their consequences, given the current state of knowledge, practices and the vulnerability of the installation environment, are as low as possible under acceptable economic conditions*". The Order of 7 February 2012 on safety demonstration reflects French practice, according to which this demonstration is based in particular on the application of safety principles such as defence-in-depth, the guarantee of essential safety functions or the implementation of successive and sufficiently independent barriers.

ASN Guide No. 22 contains more detailed recommendations specific to PWRs on safety objectives and safety principles. Without quoting all the relevant articles of this guide, it may be possible to summarize the general aspect of the chapter on safety objectives as follows:

- Exposure of people, effluent discharges and radioactive waste associated with normal operation shall be kept as low as reasonably achievable;
- In the event of an incident or accident, the release of radioactive or hazardous substances or the hazardous effects, and their impact on man and the environment, shall be kept as low as reasonably achievable;
- To prevent radiological incidents and accidents and to mitigate the consequences of those that might occur despite the preventive measures taken. To this end, design choices shall be made in order to:
    - minimise the number of incidents and limit the possibility of accidents occurring,

[4] As this guide applies primarily to the design of new-generation PWRs, its recommendations may also be used, for reference, to seek improvements to be made to reactors in operation, for example during their periodic safety reviews. It may also be used with care for NPP involving other types of reactors.
https://www.irsn.fr/FR/expertise/demarches-de-surete/Pages/Surete-Guide-ASN-22-Conception-des-reacteurs-a-eau-sous-pression.aspx#.Y1jFjbbP3g4

- minimise, as far as is reasonably practicable, the frequency of accidents resulting in fuel meltdown,
- prevent or, failing that, limit the radioactive releases that may result from incidents or accidents, including accidents with fuel meltdown; provisions aim in particular at preventing contamination of the heat sink and of the groundwater or surface water by radioactive substances;

- More in particular:
  - in the case of accidents without fuel meltdown (in the reactor core or in the pool), the radiological consequences shall be as low as reasonably practicable and, whatever the case, they shall not lead to the need to implement population protection measures (no sheltering, no taking of stable iodine tablets, no evacuation),
  - the estimated frequency of fuel meltdown shall be as low as reasonably practicable and, whatever the case, less than 10^{-5} per year and per installation, taking into consideration all types of failures (human, material) and hazards (excluding malicious acts),
  - accident situations with core fuel meltdown which could lead to significant radioactive releases that develop too rapidly to allow deployment of the necessary population protection measures in good due time shall be rendered physically impossible or, failing that, extremely unlikely with a high-level degree of confidence,
  - the population protection measures that would be necessary in the event of the other accidents with fuel meltdown shall be very limited in terms of extent and duration (no permanent relocation, no evacuation outside the immediate vicinity of the site, no sheltering outside the vicinity of the site, no long-term restriction on the consumption of foodstuffs outside the vicinity of the site). To this end, such accidents must not result in widespread contamination and long-term pollution of the environmental media.

3.2 Position of assessment of radiological consequences within the safety demonstration of French NPP

Article 3.7 of the above-mentioned Order of 7 February 2012 requires that the safety demonstration includes an assessment of the radiological consequences of the anticipated incidents and accidents.

The purpose of the safety demonstration of a NPP is to demonstrate that the measures taken by the licensee make it possible to achieve a satisfactory level of safety, based primarily on the adequate design and sizing of the structures, systems and components (SSC) of the NPP and on the implementation of appropriate manufacturing, construction and operating requirements, including those related to organization.

It should be emphasized that the assessment of radiological consequences mentioned below refers only to the assessment of radiological consequences within the safety demonstration. It does not refer to other assessments of radiological consequences such as those carried out in the event of an emergency situation or for emergency preparedness or security studies.

The assessment of radiological consequences contributes essentially to the verification, in fine, of the adequacy and sufficiency of these provisions. It is intended to strengthen the safety demonstration presented in the light of the general safety objectives adopted. Whatever the outcome of the assessment, the licensee is required to demonstrate that the impact of his NPP on people and the environment in the event of an incident or accident will remain as low as reasonably possible. The licensee cannot therefore use predefined dose limit values as acceptance criteria: relevant criteria relate in particular to the state of the barriers between the radioactive material and the environment. “Decoupling criteria” are established for the state of the various barriers and their compliance is verified in accident studies. Compliance with these “decoupling criteria” generally ensures compliance with the radiological objectives for each category of events considered. Nevertheless, the assessment of radiological consequences provides useful appraisal elements based on orders of magnitude of the impact on humans and on the environment of these situations. Within this context, evaluation of radiological consequences consists of the calculation of relevant radiological or “dosimetric” indicators to verify compliance with the objectives with the regard to the consequences of the incident or accidental situations considered in the safety demonstration.

During the initial design of a facility, it provides insight aimed at confirming that the safety provisions planned for a facility are satisfactory. They allow, in addition to the analysis of accident studies, the identification of the dominant contributions (radionuclides, release pathways, exposure pathways) and the search for measures to reduce their impact.

During the periodic safety review, the assessment of the radiological consequences is an input data to be considered for the definition of the orientations of the review and the improvements to be made to the design of the installation with regard to the objective of limiting the consequences of these situations, as far as reasonably possible. Finally, the assessment of the radiological consequences is to be considered, among other elements, to assess the acceptability of a modification to the installation. It is therefore possible that a modification which would lead to an increase in the radiological consequences in certain incident or accident situations could be considered acceptable, in particular if other elements contribute to its safety relevance.

It should be emphasized that the assessments of radiological consequences referred to in this document are conventional in nature, as they result from an agreed approach taking into account their goal in the context of the safety demonstration, and are therefore linked to the assumptions adopted for the studies presented in the safety reports; they are not intended to provide an envelope for the risks associated with a given installation, nor to determine the size of the on-site emergency plans (PUI), the special intervention plans (PPI) or the corresponding post-accident plans, which may be based on different assumptions. Similarly, the nature and use of the radiological consequences assessment referred to in this document are fundamentally different from the radiological consequences assessments carried out elsewhere in the context of security studies; the latter aim to identify the targets to be protected and to define the protective measures to be taken.

3.3 Process and examples of results for the 4th Periodic Safety Review of the French 900 MWe series

3.3.1 French PSR

In accordance with Article L. 593-18 of the French Environment Code, the operator of a nuclear installation must carry out a periodic review of the installation every ten years. Periodic reviews are the ideal opportunity to carry out large-scale inspections and modifications to the installations, designed to improve safety, taking into account changes in requirements, best practices and advances in knowledge as well as operating experience. They include not only a verification of the conformity of the installation, including an assessment of the control of ageing-related degradation phenomena, but also a reassessment of the safety of the installation.

In this respect, the general approach used in France for the ten-yearly safety reviews of PWRs consists of two parts:

- A **compliance review** aims to assess the conformity of the installations with the safety requirements applicable to them, in order to:
    - on the one hand, to verify that the conformity of the standard state of construction and operation of the installations corresponds to that described in the safety report and the general operating rules in force. The studies carried out for this purpose are called "compliance studies",
    - secondly, to verify, by means of on-the-spot inspections, the actual conformity of each nuclear reactor with this standard state of construction and operation;
- A **reassessment of the safety requirements**. The objective is to improve the safety of the installations, by considering changes in the safety requirements applicable to the most recent installations or those being planned, as well as areas where feedback or changes in technical knowledge are likely to lead to changes in the applicable safety requirements. The studies aimed at verifying the satisfactory behavior of installations, taking into account these reassessed requirements, are called "reassessment studies".

This system meets the requirements of the European Nuclear Safety Directive[5].

3.3.2 Process of PSR

A single operator operates the French power plant fleet which has the particularity of being composed of a large number of pressurized water reactors that can be grouped into three types - called series - with very similar general characteristics.

Thus, in order to take account of the common characteristics of each plant series, the periodic review process is therefore divided into two phases:

- a so-called "generic" phase which deals with issues relating to all reactors of a given type. This generic approach makes it possible to pool the studies and modifications that make it possible to achieve the

[5] Europe Council Directive 2014/87/Euratom of 8 July 2014, article 8c, alinéa b

objectives set for the review. At the end of the generic phase, the operator defines all the modifications to be integrated, which are necessary to bring the reactors to the reference state expected at the end of the periodic review;

- a so-called "specific" phase for each reactor in the series concerned. This phase makes it possible to integrate the conclusions of the generic phase (material and intellectual modifications) and to examine the specificities of the reactor (environment, compliance, etc.).

The safety baseline at the end of the review will be considered stable until the next safety review. However, the process of continuous improvement of safety may lead to changes in this baseline in the period between two reviews to take account of the need for significant safety improvements resulting in particular from feedback from major events, such as the Fukushima accident in 2011.

3.3.3 The 4th Periodic Safety Review of the French 900 MWe series

The main objectives for the 4th Periodic Review of 900-MWe reactors are as follows:

- Integration of the "hardened safety core" as a “post-Fukushima” measure;
- Reassessment of the operating conditions of the reactors and the associated radiological consequences of accidents without core meltdown in order to **tend towards the absence of the need to implement measures to protect the population** (no sheltering, no evacuation and no administration of stable iodine during the so-called "short-term" phase of the accident (from a few hours to a maximum of 7 days));
- Reassessment of the management of severe accidents (with core meltdown), **with the objective of reducing the risk of early or large radiological releases** (in the event of a managed severe accident, the measures to protect the population must be very limited in scope and duration);
- Reassessment of the risks associated with the fuel storage in the pool (the objective is to **reduce as far as possible the risk of dewatering of the fuel assemblies stored under water**)
- An improvement of the level 1 probabilistic safety studies on core meltdown and their target (aiming at a residual risk level of the same order of magnitude as the target for third-generation reactors), the scope of which has been extended to include the risks associated with fire, internal flooding, internal explosion and earthquake;
- An improvement in level 2 probabilistic safety studies on radiological releases;
- Reassessment of the risks of internal and external hazards of natural origin (related to climate change, earthquakes, the environment or human activities), verification of the adequacy and effectiveness of protective measures and definition of new measures if necessary;
- Assessment of the behavior of the facility in the event of a natural hazard of extreme severity, with the objective of avoiding large releases and limiting the radiological consequences in space and time;
- Assessment of the behavior of 900 MWe reactors in terms of operator response times and reference plant condition categories (PCC) considered for the Flamanville 3 EPR;

- Improvement of operating conditions in terms of organizational and human factors (FOH);
- Improvement of ageing management and obsolescence considerations.

Following the IRSN review of EDF's file, ASN issued a position statement in April 2016 on the initial generic study program after a public consultation on the draft requests for additions to be sent to EDF, in particular the consideration of certain requirements adopted for the Flamanville 3 EPR reactor. The ASN took a position on the generic studies related to this periodic review at the beginning of 2021, after having received the opinion of the Advisory Committee (GPR) on the basis of IRSN's assessment of the 2020 periodic review, and also after a public consultation.

This position was taken in particular on the methods for verifying the conformity of installations and the management of ageing and obsolescence consideration, and on the mechanical strength of reactor vessels up to 50 years of age, as well as on studies on the safety of spent fuel pools, the limitation of accident consequences for accidents without core meltdown, the improvement of the management of core meltdown accidents, and the ability of installations to withstand internal and external hazards.

Reactor No. 1 at Tricastin was the first to undergo its fourth periodic review in 2019. The last periodic review of a 900 MWe reactor is scheduled for 2030.

3.3.4 Examples of measures taken by the licensee to achieve the objectives

The following illustrations of the French approach cover cases where modifications are directly incepted by radiological consequences calculation but also cases where major modifications do not require such a calculation to justify the importance of their implementation, also in terms of radiological consequences.

3.3.4.1 Design-basis accidents

In order to meet the objective of further reducing the radiological impact of design-basis accidents as far as reasonably possible and to reach levels of radiological consequences that do not require the implementation of countermeasures for the population (no sheltering, no evacuation and no administration of stable iodine), EDF proposed in the safety report to implement measures to significantly reduce the radiological consequences for the most severe scenario in terms of radiological consequences (the SGTR -steam generator tube rupture - accident involving the rupture of a tube in a steam generator as a Category 4 condition).

Indeed, the magnitude of the radiological consequences of an accident of SGTR is linked, on the one hand, to the magnitude of the releases (essentially in the liquid water phase, the fission products of releases being assumed to be released entirely into the atmosphere), and on the other hand, to the degree of contamination of the primary circuit (which contaminates the secondary circuit via the SGTR breach) by fission products or corrosion products.

In this context, EDF has proposed **lowering the reactor shutdown threshold in ^{131}I equivalent** during power transients (from 100,000 MBq/t to 80,000 MBq/t). This reduction allows a significant reduction in the consequences assessed in the safety report for accidents occurring during reactor operation and not leading to fuel cladding rupture.

3.3.4.2 Core-meltdown accidents

A core meltdown accident can lead to short- or longer-term releases into the environment if the integrity of the containment cannot be maintained over time. The various risks associated with core meltdown accidents are analyzed. Where appropriate, measures are implemented to either reduce the likehood of occurrence of the situations concerned or to delay their occurrence and mitigate their consequences.

To meet this objective, EDF has designed a **new system** (EASu/SFu) allowing heat removal from the containment and has taken measures to **stabilize the corium** on the basemat of the reactor pit and of an adjacent room in the reactor building. These new provisions complement the existing provisions (the containment spray system (EAS), the U5 device to filter possible releases into the environment, the hydrogen recombiners to prevent the explosion of H2 in the containment, the ventilation of the control room to keep it habitable), and reinforce the means of long-term management of a core-melt accident, in particular to avoid radioactive releases due to the opening of the containment vent-filtering device (U5) or long-lasting effects in the environment in the event of a penetration of the basemat. These new provisions therefore contribute to reducing the radiological consequences of core-meltdown accidents.

Evacuation of residual power without opening the U5 device

Without power removal from the containment, the vaporisation of water on the corium and the production of non-condensable gases during the corium-concrete interaction lead to slow pressurisation of the containment. The pressure in the containment can reach the design pressure of the containment vessels and require the opening of the U5 device, leading to radiological releases to the environment.

In the context of the 4th review, the implementation of the EASu provision allows the following two functions to be carried out

- flooding and cooling of the corium inside or outside of the vessel,
- evacuation of residual power from the containment.

The EASu system allows residual power to be evacuated from the containment in the event of a severe accident. Its operation is based on the one hand, on an EASu pump, which can operate in direct injection from the safety injection system tank (PTR) or in recirculation from the reactor building sumps, and, on the other hand, on an EASu exchanger, which ensures the cooling of the reinjected water and itself connected to the Ultimate Cold Source (SFu). The SFu consists of a mobile pumping device that is transported and deployed by dedicated teams (see Figure 1).

The EASu provision is designed to prevent core meltdown situations leading to the opening of the U5 containment venting device. It also contributes to reducing the radiological consequences of controlled containment situations.

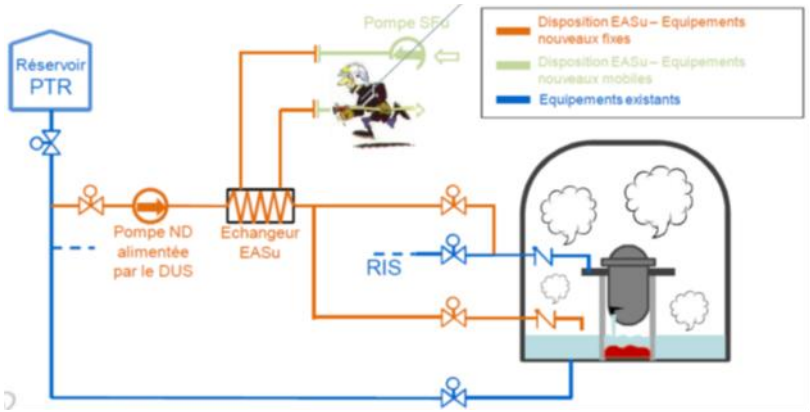

Figure 1 – EASu and SFu systems

Provisions against the risk of loss of containment by erosion and/or penetration of the concrete basemat

In a core meltdown accident situation, the core meltdown can lead to the formation of a corium pool which can eventually break through the vessel and then lead to basemat erosion, thus challenging containment.

In order to limit the risk of loss of containment in an accident situation with core meltdown by erosion of the basemat, a system based on the stabilization of the corium under water after dry spreading is implemented (see Figure 2): the spreading of the corium after the vessel has been breached is carried out in the reactor pit and in an adjacent instrumentation room (RIC room).

The dry spreading of the corium is guaranteed by the prior sealing of the reactor vessel pit and the adjacent RIC room. This is rapidly followed by passive flooding of the corium with water contained in the previously filled sumps at the bottom of the vessel. This water is then cooled by the EASu system.

The corium is reflooded by gravity from the water in the sumps and in the bottom of the reactor vessel, which have been previously filled by the RIS (Safety Injection), EAS (Spray) circuits or by the zero flow line of the EAS-u pump, or, actively, by injecting water into the vessel after the corium has spread, if the sumps in the reactor vessel have not been filled.

The vessel breakthrough detection measurement (thermocouple located in the reactor vessel pit) allows the diagnosis of the vessel breakthrough, thus ensuring that water is injected on the corium via the vessel at the most effective moment which corresponds to the reflooding after dry spreading of the corium.

Gravity flooding of the corium is ensured by redundant coring in the walls of the reactor pit and the adjacent RIC room, sealed by a fusible device ensuring a tightness between the water accumulated at the bottom of the reactor building and the spreading zone. This contributes to guarantee dry spreading of the corium. After the corium has spread, the sealing device is removed by the breaking of the fusible devices.

The cooling of the corium and the evacuation of the residual power from the vessel in the long term are ensured by the EASu arrangement and the SFu ultimate cold source.

This solution, in its principles, is similar to the one implemented on new-generation reactors (core catcher).

In the event of a core meltdown accident, this modification would significantly reduce the release into the environment and thus the radiological consequences.

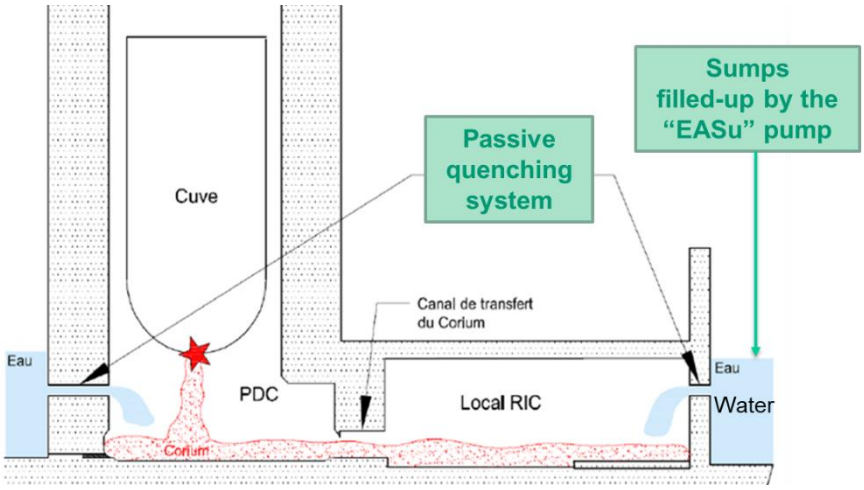

Figure 2 – Stabilisation of the corium under water after dry spreading

Spent Fuel Storage Pool

In addition to the provisions implemented to reduce the radiological consequences of accidents occurring in the reactor, the operator has implemented a provision to reduce the probability of an accident occurring in the pool.

The building housing the spent fuel storage pool does not have a containment system. Therefore, the strategy adopted is to make unlikely any accident situation that would lead to a release into the environment and thus radiological consequences. To do this, it shall be guaranteed with a high degree of confidence that the fuel assemblies remain submerged.

The loss of the ultimate heat sink leads to the loss of cooling of the pool in which the spent fuel assemblies are stored. The planned management of the situation consists in evacuating the residual power of the assemblies by boiling the pool water and making a water refill so as to maintain a sufficient pool water level, i.e., above the assemblies. This strategy requires letting the steam to be vented outside the fuel building by opening an outlet, to avoid a pressure build-up. The water can be replenished either from the demineralized water circuit or from the fire-fighting water circuit.

As early as 2010, EDF had defined specific emergency operating rules for the spent fuel storage pool. The Fukushima-Daiichi nuclear power plants (NPP) accident in 2011 confirmed the relevance of the EDF's strategy, which is now almost fully implemented at all its reactors. However, the Fukushima-Daiichi NPP accident also highlighted the need to ensure the reliability of the water make-up resources to compensate for the loss caused by the boiling of the pool water, while waiting for the pool to be cooled in a closed loop. Thus, as part of phase 2 of EDF's "post-Fukushima" action program, EDF implemented an "ultimate" source of water to make up for the fuel deactivation pool.

Finally, to enable resumption of pool cooling in the event that the cooling provided by the dedicated system is permanently affected, EDF is setting up a diversified mobile cooling system as part of the fourth ten-yearly

periodic safety review for 900 MWe reactors. In this case, this system makes it possible to resume the cooling of the fuel deactivation pool in a closed loop and thus the closure of the fuel building outlet. This system consists of a fixed and a mobile part (see Figure 3).

It represents major step forward in reactor safety, and its deployment at the rate of ten-yearly outage programmes for 900 MWe reactors will enable to reach a safe state (resumption of closed-loop cooling) in the majority of accident situations likely to affect the pools, whether these situations are initiated by an external aggression or an internal event. This system is also planned for the next safety periodic reviews of the 1300 and 1450 MWe reactors.

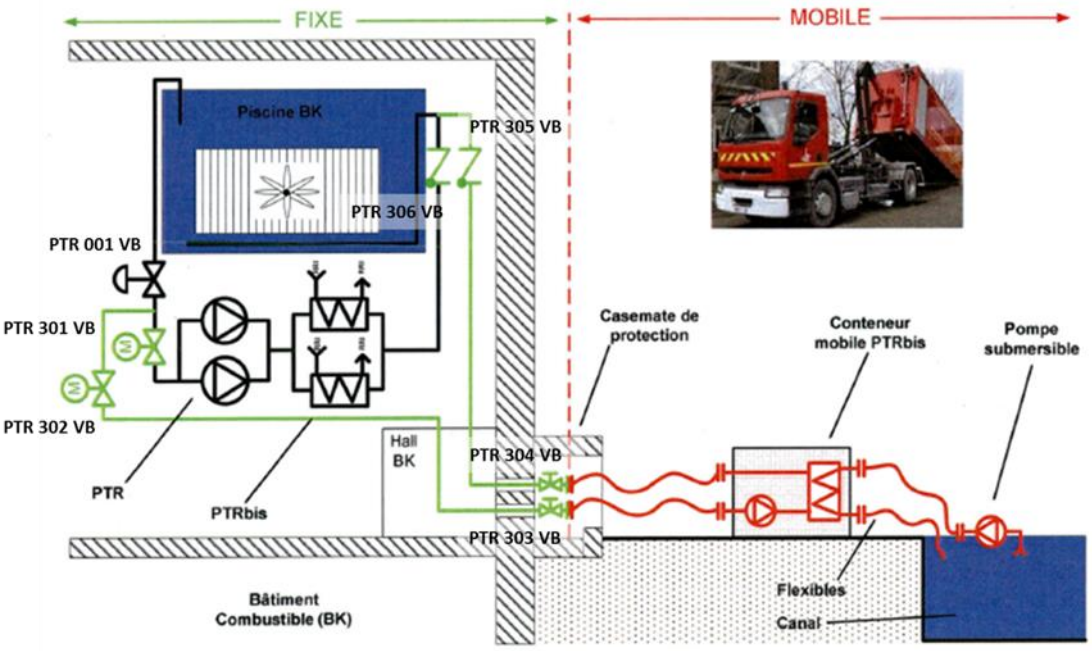

Figure 3 – Mobile cooling system

4 UNDERPINNING RATIONALE BEHIND CRITERIA ASSOCIATED TO PLANNED EXPOSURE SITUATIONS

When a regulation encompasses values or criteria to be respected, it never specifies the reasoning or references that have led to their precise definition, often with the difficulty which is that one is in or out of compliance, with always in a very brutal way. Of course, if this barrier is understandable for certain risks, it is quite difficult to defend it firmly when it comes to exposure to agents recognized as carcinogenic, such as radiation, such as ionizing radiation, or certain chemical substances, the management of which is most often based on a linear model without threshold.

However, in the context of questions about the evolution of the criteria or the consequences of their non-compliance in the regulations, it seemed important to us to redefine, as far as possible, these arguments or these references.

In order to limit our investigations, we considered the scope of application of Article 123 of the Radiation Protection Ordinance and its counterpart in the Nuclear Energy Ordinance. These articles apply to licensed installations, which quite clearly refers to planned exposure situations as defined in ICRP 103. Gradually, the criteria usually associated with this type of situation are:

- Exemption levels and clearance levels,
- Exposure limits for the public and workers applicable during normal operation of an installation,
- Dose constraints for the public and workers,
- The risk constraints that apply in the context of potential exposures. In the system defined by the ICRP, potential exposures are a concept associated with planned exposure situations.

4.1 Exemption levels and clearance levels

In the European Communities' publication RP 65 (Principles and Methods for Establishing Concentrations and Quantities (Exemption values) Below which Reporting is not Required in the European Directive), the exemption is featured as follows: The exemption principle combines the idea of negligibility and control efficiency with the scope of the regulatory provisions. Below a certain level of risk, the pursuance of regulatory supervision proves inefficient or even socially harmful. The ICRP, the IAEA and the European Commission then define this notion of exemption in terms of regulatory consequences rather than in terms of health significance. Nevertheless, it is the GSR Part 3 that is the most precise on this notion, stating:

"The general criteria for exemption of a practice or a source within a practice from some or all the requirements of [GSR Part 3] are that: (a) Radiation risks arising from the practice or from a source within the practice are sufficiently low as not to warrant regulatory control, with no appreciable likelihood of situations arising that could lead to a failure to meet the general criterion for exemption; or (b) Regulatory control of the practice or the source would yield no net benefit, in that no reasonable measures for regulatory control would achieve a worthwhile return in terms of reduction of individual doses or of health risks."

When it was necessary to define operational values for the exemption thresholds (i.e. activity values by radionuclide -. (historically, in France, this was defined anyway, by radiotoxicity group), the question arose as to what requirement in terms of health consequences had to be met. In 1993, the European Commission proposed to use a value of excess cancer risk of 10^{-5}/year to 10^{-6}/year (Radiation Protection -65): Using the detriment coefficient in force at that time (ICRP 60) and the LNT assumption, calculations lead to a rounded value of 100 µSv. Assuming that the same person could be exposed to different sources, the dose value finally used to estimate the exemption levels was 10 µSv per year. This choice was supported by the fact that it on represents a small percentage of the exposure to natural background and by the UNSCEAR 2012 report, which explains that in the range of individual doses below one hundred millisieverts, the excess cancer risk in a population can't be clearly attributed to the exposure. Another constraint is also that the collective dose must remain below 1 Sv/y. It is clear that this criterion is met in most cases by compliance with the individual dose criteria. American

authors, in their analysis of 132 federal regulatory decisions (Environ. Sci. Technol., Vol. 21, No. 5, p415-420 1987) mention a value of 10^{-6} excess cancer risk over a lifetime as a threshold below which it is not worthwhile to regulate a carcinogenic substance when a large part of the population is exposed to it. The WHO, in its guidelines for drinking water (Guidelines for drinking-water quality, 4th edition, incorporating the 1st addendum, 24 April 2017 Guideline) mentions a value of 10^{-6} DALY as an individual target for the consequences of biological or chemical agents in drinking water. Given that one cancer corresponds on average to 10 years of life lost, this value corresponds to an excess risk of about 10^{-5}/year.

Recently, the French association CRIIRAD pointed out that the protection levels for genotoxic substances are more permissive for radioactive substances than for chemicals. Thus, the assumptions of 0.1 mSv/y in the WHO guidelines weren't appropriate, leading to a lifetime cancer excess risk clearly higher than 10^{-5} .

To conclude this very brief analysis, the translation of the acceptable range of values for risk management to the specific field of radiation was a reference dose criterion of 10 µSv/y, without a clear link to the levels of cancer excess risks considered acceptable in the 1980s and 1990s. However, this level is clearly much lower than natural background exposure and there is no clear scientific evidence of excess cancer risk at this level of exposure over a lifetime.

4.2 Annual exposure limits

4.2.1 Occupational exposure.

The annual exposure limit recommended by ICRP 26 published in 1977 is 50 mSv/year. The reasoning at that time was as follows: Occupations known for their high level of protection did not display an annual mortality rate of 10^{-4}. Consequently, the ICRP has calculated an occupational exposure limit value of the order of 5 mSv/year, which at the time of Publication 26 had a detriment coefficient in the order of 1.6 10^{-2} /Sv in terms of mortality. Considering that these are recorded deaths, the ICRP estimated that a limit value of 50 mSv/year would result in an average exposure of 5 mSv/year, based on the UNSCEAR report published in 1977 (Appendix E). This argument, which may seem somewhat weak, illustrates the difference between accidents that can be clearly attributed to a known cause and an inferred cancer risk. By calculating the dose over the entire working life (i.e. 2.4 Sv), the ICRP considered that an individual risk corresponding to this dose was unacceptable, whereas it had previously argued in terms of collective risk, especially since the risk coefficient had increased sharply between the two publications, by a factor of 4 if we refer to the general population (Annals of ICRP 1991 Risks associated with ionizing radiation). Taking into account various characteristics of radiation exposure (e.g. probability of attributable death, aggregated detriment (see Table 5 of ICRP 60)), the ICRP estimated that a dose of 1 Sv received uniformly over the duration of the professional activity was a maximum. Considering an occupational period of 50 years, the average annual dose deducted was therefore 20 mSv/year (100 mSv over 5 years without exceeding 50 mSv/year).

4.2.2 Public exposure

At the time of ICRP 26, it was argued that the exposure limit for the public should be lower than for workers, because of the lower benefit. Surprisingly enough, the same range of acceptable risk levels is given for setting a limit and for setting exemption thresholds. There is probably some confusion about the term “acceptable” here. In the case of exemption thresholds, it is an acceptable risk if no management measure is taken. In the second case, it is a tolerable risk as defined by the ICRP, i.e. an upper limit without prejudice to the application of the optimization principle. Moreover, it is the existence of this principle of optimization that leads the ICRP to state in its Publication 126 that a value of 5 mSv/year calculated for a critical group makes it possible to respect the value of 1 mSv/year on average for the general population. Arithmetically, this value of 1 mSv/year corresponds to an excess risk of 10^{-5}/year, which is the rounded value of the detriment coefficient described in ICRP 26 of 10^{-2} Sv^{-1}.

ICRP 60 has recommended a public exposure limit value of 1 mSv/year. From a health point of view, this value follows the same reasoning as that used in ICRP 26. However, it no longer seems to be linked to an occupational exposure limit value (the ratio between the two values has moreover doubled). This value also has the advantage of being lower than the average exposure from natural radiation sources. If it still meets the same level of protection as in ICRP 26, it is no longer presented as an average but as an individual protection target. Moreover, even r if received by the same person over a lifetime, it remains in the low dose range defined by UNSCEAR (< 100 mGy) UNSCEAR 2012 Annex A, for which the UNSCEAR states that an increase in cancer cases is plausible but not proven. Increasingly, the study of larger cohorts may challenge this conclusion for doses in the order of a few tens of mSv (see Section 6).

4.3 Dose constraints

This concept is presented in ICRP 60 as a useful tool for optimizing practices, essentially to manage possible inequities associated with the exposure of a given source. This concept was reaffirmed in Publication 103 by associating it with planned exposure situations. This concept is used differently in national regulations. The tendency is rather to leave it to the public authorities to define dose constraints for the public. Table 6.2 of the ICRP Publication 103 suggests different values depending on the subject matter. On the other hand, the definition of dose constraint for workers is the responsibility of the employer. It may also be relevant to use this concept by associating it with operations rather than an annual dose, which allows a finer implementation of the optimization principle.

Clearly, this type of value does not carry any health consideration and is part of the toolbox for implementing the optimization principle. When questioned by ASN on the usefulness of translating this concept into regulations for the protection of the public, IRSN had pointed out that the use of the best available techniques is a more powerful tool, which has in fact led to the exposure of the populations to discharges from major nuclear

installations in France being several orders of magnitude lower than the limit of 1 mSv/year (avis IRSN No. 2016-0036[6]).

4.4 Potential exposure

Potential exposure situations are dealt with ICRP Publication 64. This publication clearly mentions the stacking of probabilities between the occurrence of the event on the one hand, and the occurrence of the effect for a given exposure on the other hand to determine an overall risk probability. To assess this effect, ICRP uses the radiological detriment which is a tool that aims to capture all cancer sites associated with radiation exposure, weighted by the severity of each site. This stacking can be qualified as a risk constraint. It emphasizes the fact that the assessment of the probability of an adverse event is often much more uncertain than the assessment of the probability of an adverse effect for a given level of exposure. It also states that for the latter assessment, the range of doses must also be considered with caution, as the relationships between exposure and effect are different, ranging from the LNT model for low doses (< 100 mSv) to a probability estimate with S-curves for deterministic effects at high doses. We add that the effects at high doses do not replace the stochastic effects, but are additional, and that taking these effects into account at these dose levels should no longer consider a reduction factor such as the one currently used by the ICRP to assess the detriment (DDREF = 2). At present, the ICRP does not provide a risk constraint value, but a table of probability recommendations (Table 1).

Table 1. Range of probabilities in a year from which constraint may be selected (ICRP publication 64 (1993))

Table 1. Range of probabilities in a year from which constraint may be selected

Sequence of events leading to doses treated as part of normal exposures	10^{-1} to 10^{-2}
Sequence of events leading to stochastic effects only but above dose limits	10^{-2} to 10^{-5}
Sequence of events leading to doses where some radiation effects are deterministic	10^{-5} to 10^{-6}
Sequence of events leading to doses where death is likely to result	$< 10^{-6}$

Nevertheless, this publication makes a rather fundamental recommendation: The risk from potential exposures (thus including the 2 levels of probability) should be of the same order of magnitude as the risk from exposure in a normal situation. The term “normal” is important because it is not the limit value that is used, but rather the exposure observed by field of application. Taken literally, this means in particular that situations that could lead to deterministic effects should be excluded from the radiation safety demonstration.

In 1997, Publication 76 clarified some elements in the practical application of the risk constraint associated with potential exposures. Using the ICRP 60 risk coefficient for fatal cancer (4.10^{-2}/Sv) and the average dose received by workers (5 mSv/year) used in ICRP 26 para 23 to derive the limit (50 mSv/year), this publication proposes a risk constraint of 2.10^{-4} per year. A similar procedure applied to population exposure leads to a risk constraint

[6] Avis IRSN N° 2016-0036 du 9 février 2016, « Recommandations sur l’utilisation des contraintes de dose pour la protection du public »

value of 5.10^{-6}/year (assuming that 100 µSv/year is the dose constraint corresponding to a limit for the public of 1 mSv/year and that the risk coefficient for fatal cancer for the population is 5.10^{-2}/Sv).

10 years later, ICRP 103 adopted this concept of potential exposure associated with planned exposure situations without updating the value proposed in ICRP 76 for the worker and multiplying the value for the population by 2 (4.10^{-2} and 1.10^{-5} per year, respectively). For the sake of clarity, we believe that these assessments should be made using the detriment-adjusted risk coefficients as proposed by ICRP 103, i.e. 4.2 10^{-2}/Sv and 5.7. 10^{-2}/Sv. The values are not very different, but have a different meaning in that the ICRP 103 coefficients reflect an occurrence, whereas the ICRP 60 coefficients reflect a mortality.

5 OCCURRENCES AND ASSOCIATED RADIOLOGICAL DOSE CRITERIA

IRSN conducted a rapid survey of international recommendations and national regulatory frameworks, regarding the relationship between the estimated frequency of postulated events and the radiological dose criteria that could be associated with them. The results are presented, discussed and compared with the Swiss regulatory framework in this chapter.

However, it should be recalled that this issue is only a small part of the overall safety approach: "S*afety is the result of a set of technical and organizational measures taken at all stage in the lifetime of a facility to ensure that its operation and its very existence present risks that are low enough to be considered acceptable for the workers and staff directly involved, the general public and the environment. The concept of acceptable risk does not refer to defined and absolute criteria*"[7]. Ensuring safety relies in particular on the adequate implementation of fundamental principles such as defence-in-depth, the fulfillment of safety functions and the efficiency of the relevant number of barriers.

As an illustration of the importance of this warning, it could be highlighted that the WENRA reference levels (cf. 5.2.4) which "*areas and issues they address were selected to cover important aspects of nuclear safety where differences in substance between WENRA countries might be expected*" do not mention any estimated frequency of events (except in one reference level related to hazards) and very rarely mention radiological prescribed limits and in a general manner (without any numerical values).

It should be noted that, in order to make its analysis as robust as possible, IRSN convened remote meetings with ENSI and the FOPH to present the technical documents drafted to accompany the implementation of the regulatory framework. In September 2022, face-to-face[8] were held with both regulatory bodies in order to verify the IRSN's understanding of the relationship between the different levels of the regulatory pyramid and to go into the details of the calculations of radiological consequences.

[7] Elements of nuclear safety – Pressurized water reactors – Jean Couturier, EDP Sciences, 2022

[8] The minutes IRSN/PSE-Santé of the meeting held on September 7, 2022, written in English, are available on request

5.1 The Swiss regulation

Swiss nuclear regulation is mainly based on the following two texts: the Nuclear Energy Ordinance (NEO) and the Radiation Protection Ordinance (RPO).

In these two texts, for the design basis accidents foreseen in nuclear installations, links have been established for different scenarios between the occurrence of these events (probability intervals) and dose limits (in mSv).

The NEO (Article 8) distinguishes between design-basis accidents of internal and external origin; among the events of external origin, a distinction is made between non-natural events (aircraft crash, etc.) and natural events (earthquake, flood, etc.).

The categorization of events of internal origin and non-natural events of external origin according to their annual frequency, as well as the associated dose limits, are contained in the RPO (Article 123):

Table 2. Link between estimated event frequencies and dose limits (Swiss regulation, RPO)

Annual frequency	***Associated dose limit for the public***
> 10^{-1}	Dose constraint set in the authorization (yearly)
Between 10^{-2} and 10^{-1}	Dose constraint* (for an event)
Between 10^{-4} and 10^{-2}	Less than or equal to 1 mSv (for an event)
Between 10^{-6} and 10^{-4}	Less than or equal to 100 mSv (for an event)

* equals to 0.3 mSv according to annex 7 of the Swiss RPO

For natural events of external origin, the NEO considers that there is one event with a frequency of 10^{-3} per year and one event with a frequency of 10^{-4} per year. These two frequencies, and the associated dose limits, are specified in the NEO (Article 8):

Table 3. Link between estimated event frequencies and dose limits (Swiss regulation, NEO)

Annual frequency	***Associated dose limit for the public***
10^{-3}	1 mSv
10^{-4}	100 mSv

The value of 1 mSv corresponds to the individual annual dose limit for public exposure resulting from deliberate practices, and the value of 0.3 mSv corresponds to the dose constraint for public exposure.

It should be noted that in the RPO, there may be problems of interpretation in associating the dose limit values with the limits of the probability intervals - this issue is particularly relevant for the value to be associated with

an annual frequency of 10^{-4}. On the other hand, for natural events of external origin (e.g. earthquakes), the NEO clearly states that the dose limit for the public associated with an annual frequency of 10^{-4} is 100 mSv.

The value of 100 mSv is a purely arithmetical value, and used by the plant operators to justify their ability to control a failure within the framework of the design basis rules and to guarantee that such a failure would have only minor radiological consequences. This value is in fact the result of a calculation made for a fictitious person, who would be the most exposed to ionizing radiation.

If the 100-mSv limit is exceeded - for any event, internal or external,- immediate measures must be taken to temporarily shut down and refit the nuclear power plant (see Article 44 of the NEO). For example, if the estimated dose is between 1 and 100 mSv for a natural event of external origin occurring statistically every 1000 years (with an associated dose limit of 1 mSv), a delay is given for refitting.

It should be noted that the value of the constraint dose (0.3 mSv) is consistent with ICRP Publication 103, even though ICRP doesn't use a probability for the dose constraint.

The value of 100 mSv corresponds to the highest reference level defined by the ICRP for emergency situations[9], although the current recommendation recognises that, in some circumstances, the most appropriate reference level may be below 20 mSv.

It should be emphasized that it is difficult to link safety demonstration and radiological crisis; in fact, the levels referred to here are those for the emergency phase, leading to the initiation of measures to protect the population. It is therefore not a safety demonstration objective, but the reference levels defined for the management of radiological emergencies can serve as a first target value in the framework of a technical discussion for a safety assessment.

5.2 International provisions

This chapter presents elements related to the links between the occurrence of a design basis accident and the associated radiological dose criteria, as described in some international texts.

However, it should be remembered (see the introduction to this chapter) that this aspect is only one part of the safety approach.

5.2.1 ICRP

Potential exposures

The ICRP defines potential exposures as those associated with deviations from normal operating procedures, that can be anticipated and should therefore be considered at the design stage[10].

[9] ICRP 146 – Radiological protection of people and the environment in the event of a large nuclear accident

[10] ICRP publication 103 – The 2007 recommendations of the international commission on radiological protection

...

The probability of occurrence of these deviations is assessed, protective devices proportional to that probability are introduced (to reduce the risk of potential exposure), the resulting dose and the detriment associated with that dose are assessed, and the results are finally compared with an acceptance criterion.

As detailed in Section 4.2 of this report, the ICRP introduces the concept of a "risk constraint" associated with potential exposure. This concept is adopted by the IAEA[11] for the final disposal of radioactive waste: "*a final storage facility (considered as a single source) is designed so that the calculated dose or risk to the representative person who may be exposed in the future from possible natural processes affecting the final storage facility is no greater than a dose constraint of 0.3 mSv per year or a risk constraint on the order of 10^{-5} per year*."

It should be noted that this concept is used in several countries, but only in the context of waste storage ("*risk constraints are used for assessment of the safety and radiological protection of a geological disposal facility for long-lived radioactive waste*"[12].

The risk constraint

The risk constraint, associated with potential exposure, is the probability of an unexpected event resulting in a dose multiplied by the detriment resulting from that dose. It represents a constraint set as a (prospective) limit on the individual risk. As a reminder, the detriment has been set at $4.22.10^{-2}$ per Sv for workers and $5.74.10^{-2}$ per Sv for the general population[10].

The ICRP recommends a generic risk constraint of 2.10^{-4} per year for potential exposure of workers (based on the probability of fatal cancer associated with an average annual occupational dose of 5 mSv - referring to "real" doses about 10 times lower than the previous dose limit for workers of 50 mSv/year). The recommended risk constraint value for the public is 10^{-5} per year (i.e., 20 times lower than for workers).

Thus, the product of the probability of an event and the dose associated with that event is constant, equal to $4.74.10^{-3}$ for workers and $1.74.10^{-4}$ for the population (i.e. 27 times less). This means that the more likely an event is, the lower the dose associated with it should be, and vice versa.

If we do the calculation for the values in the Swiss regulation, we see that they are well within (by a factor of 10 or more) of the risk constraint value recommended by the ICRP for the population:

Table 4. Calculation of risk constraint values for the Swiss regulation

Annual frequency	***Associated dose limit for the public***	***Risk constraint***
Event with internal origin and non-natural event with external origin		
Between 10^{-1} and 10^{-2}	Dose contraint of 0.3 mSv	Between 2.10^{-6} and 2.10^{-7}
Between 10^{-2} and 10^{-4}	Less than or equal to 1 mSv	Between 6.10^{-7} and 6.10^{-9}
Between 10^{-4} and 10^{-6}	Less than or equal to 100 mSv	Between 6.10^{-7} and 6.10^{-9}

[11] IAEA n°SSR-5 – Disposal of radioactive waste

[12] ICRP 122 – Radiological protection in geological disposal of long-lived solid radioactive waste

Annual frequency	***Associated dose limit for the public***	***Risk constraint***
Natural event with external origin		
10^{-3}	1 mSv	6.10^{-8}
10^{-4}	100 mSv	6.10^{-7}

5.2.2 IAEA

IAEA defines different plant states:

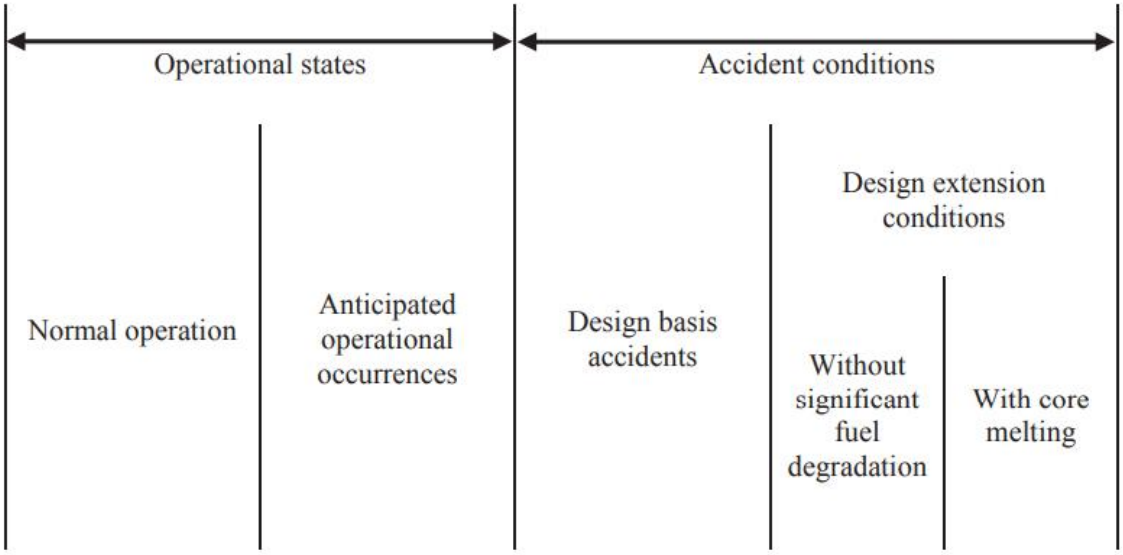

Figure 4 – Plant states[13]

Occurrence of events

With regard to the occurrence of events, the principle is that "*frequently occurring plant states shall have no, or only minor, radiological consequences and plant states that could give rise to serious consequences shall have a very low frequency of occurrence*."[14].

A categorization based on estimated annual frequencies is given to illustrate certain practices of the IAEA:

[13] IAEA safety glossary, Terminology Used in Nuclear Safety, Nuclear Security, Radiation Protection and Emergency Preparedness and Response (2022 (Interim) Edition)

[14] IAEA n°SSR-2/1 Rev.1, IAEA n°SSR-3 and IAEA n°SSR-4

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Table 5. Possible anticipated operational occurrences and design basis accident categories used in some States for new reactors[15]

Plant state	Alternative names used in some States	Indicative frequency range (per year)
Anticipated operational occurrences	Faults of moderate frequency: DBC-2, PC-2	$f > 10^{-2}$
Design basis accidents	Infrequent faults: DBC-3, PC-3 Limiting faults: DBC-4, PC-4	$10^{-2} > f > 10^{-4}$ $10^{-4} > f > 10^{-6}$

Radiological acceptance criteria

"*The design of a nuclear power plant shall be such as to ensure that radiation doses to workers at the plant and to members of the public do not exceed the dose limits, that they are kept as low as reasonably achievable in operational states for the entire lifetime of the plant, and that they remain below acceptable limits and as low as reasonably achievable in, and following, accident conditions*". "*Acceptable limits for purposes of radiation protection associated with the relevant categories of plant states shall be established, consistent with the regulatory requirements*".[16]

It is important to note that IAEA does not give numerical values, but recommends general objectives: "*discharges of radioactive material are then kept within acceptable limits*", "*without unacceptable radiological consequences*", "*a main objective is to manage all design basis accidents so that they have no (or minor) radiological consequences on or off site and do not require protective actions off site*"[17]. Sometimes completed with qualitative elements regarding radiation protection: "*There should be no, or only minor, radiological impact beyond the immediate vicinity of the plant as a result of anticipated operational occurrences or design basis accidents, without the need for any off-site protective actions. The definition of minor radiological impact should be set by the regulatory body […]*"[15].

The IAEA does not give a definition of "*minor radiological impact*" and only provides guidance on the notion of an acceptable limit: "[...] *acceptable limits of effective dose for members of the public beyond the immediate vicinity of the plant are typically in the order of a few millisieverts per event*." [15]

The IAEA also gives some recommendations on the concept of "*radiological consequences*": for example, it can be expressed in terms of effective dose, activity released (in Bq) for the various radionuclides, or health impact.

5.2.3 Euratom

In line with the introduction of the current chapter, Euratom set an overarching safety objective according to which: "*nuclear installations are designed, sited, constructed, commissioned, operated and decommissioned with*

[15] IAEA n°SSG-2 Rev.1

[16] IAEA n°SSR-2/1, requirement 5

[17] IAEA n°SSR-2/1 Rev.1

…

the objective of preventing accidents and, should an accident occur, mitigating its consequences and avoiding: (a) early radioactive releases that would require off-site emergency measures but with insufficient time to implement them; (b) large radioactive releases that would require protective measures that could not be limited in area or time" [18].

As regards the implementation of the objective, the Directive does not set quantitative limits for the radiological consequences in terms of the estimated frequency of events: "*in order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that where defence-in-depth applies, it shall be applied to ensure that: (a) the impact of extreme external natural and unintended man-made hazards is minimised; (b) abnormal operation and failures are prevented; (c) abnormal operation is controlled and failures are detected; (d) accidents within the design basis are controlled; (e) severe conditions are controlled, including prevention of accidents progression and mitigation of the consequences of severe accidents; (f) organisational structures according to Article 8d(1) are in place*".

5.2.4 WENRA

The Western European Nuclear Regulators Association (WENRA) presents[19] a reading grid for levels of defense-in-depth, in which objectives in functional terms are given and indications in terms of qualitatively acceptable radiological consequences.

[18] European nuclear safety directive 2009-71/Euratom (amended by 2014/87/Euratom)

[19] Report Safety of new NPP designs (2013)

Table 6. Events considered to occur and consequences considered in the design[19]

Levels of defence in depth	Objective	Essential means	Radiological consequences	Associated plant condition categories
Level 1	Prevention of abnormal operation and failures	Conservative design and high quality in construction and operation, control of main plant parameters inside defined limits	No off-site radiological impact (bounded by regulatory operating limits for discharge)	Normal operation
Level 2	Control of abnormal operation and failures	Control and limiting systems and other surveillance features		Anticipated operational occurrences
Level 3 (1) 3.a	Control of accident to limit radiological releases and prevent escalation to core melt conditions (2)	Reactor protection system, safety systems, accident procedures	No off-site radiological impact or only minor radiological impact (4)	Postulated single initiating events
3.b		Additional safety features(3), accident procedures		Postulated multiple failure events
Level 4	Control of accidents with core melt to limit off-site releases	Complementary safety features(3) to mitigate core melt, Management of accidents with core melt (severe accidents)	Off-site radiological impact may imply limited protective measures in area and time	Postulated core melt accidents (short and long term)
Level 5	Mitigation of radiological consequences of significant releases of radioactive material	Off-site emergency response Intervention levels	Off site radiological impact necessitating protective measures(5)	-

For existing reactors, as mentioned above, the objectives are presented in a very global and qualitative way in terms of radiological consequences, although this aspect is of course only one part of the objectives: « *The design basis shall have as an objective the prevention or, if this fails, the mitigation of consequences resulting from anticipated operational occurrences and design basis accidents. Design provisions shall be made to ensure that potential radiation doses to the public and the site personnel do not exceed prescribed limits and are as low as reasonably achievable.*"[20].

5.3 National regulatory framework

The regulations of several other countries (Germany, Belgium, Canada, Finland, the Netherlands, the United Kingdom, Sweden, and the United States) have been reviewed to identify some guidelines in the way they relate occurrences of design basis accidents to limit values in connection with the concept of acceptable limit in terms of radiological consequences.

Again, it should be noted that this section **is not exhaustive** in terms of safety approaches - it simply focuses on the quantitative aspects of radiological consequences as presented in the different regulations, not necessarily

[20] Report WENRA Safety Reference Levels for Existing Reactors (2020)

in guides or other application documents. In addition, the use of dose criteria in practice is not well known from this literature review.

5.3.1 Types of installations concerned

When reviewing international documents, some IAEA documents[14] are only relevant to nuclear power plant design. Other IAEA documents concern research reactors[21] or nuclear fuel cycle facilities[22].

The Euratom Directive 2014/87 applies more broadly to all nuclear facilities (nuclear power plant, enrichment plant, nuclear fuel fabrication plant, processing facility, research reactor, spent fuel storage facility, radioactive waste storage facility).

The Swiss regulation applies to all types of nuclear facilities (although the DETEC ordinances make a distinction for nuclear power plants, which must meet additional technical criteria).

In most of the other countries considered here (with the exception of a few countries such as Finland and Belgium), the regulatory elements mentioned apply only to power plants.

5.3.2 Existing and new facilities

The words “new” and “existing” are commonly used to categorize nuclear facilities in order to strengthen one of the pillars of safety: continuous improvement. It is easy to understand that more and more ambitious objectives or requirements have to be applied to nuclear facilities, but that the way they are applied may differ depending on the life phase of the facility when they are established.

Nevertheless, regulation applies to any operating facility (a “new” facility becomes an “existing” one when it is in operation and its requirements are not changed) and “new” and “existing” are generally not used in high-level documents (for example, in Swiss regulations, there is no distinction between existing and new facilities), as but rather in guidance-type documents. This reflects the fact that the objective (or requirement or criteria or…) applies to facilities that will operate in the future and is used as a reference for the timely implementation of reasonably practicable safety improvements at existing facilities.

For example, Euratom specifies[23] that the objective of applies to “installations for which a construction license is granted for the first time after 14 August 2014 and will be used as a reference for the timely implementation of reasonably practicable safety improvements to existing nuclear installations”. The word “new” is not used.

The IAEA points out that, for practical reasons, the new requirements apply mainly to new facilities. However, the IAEA recognizes the difficulties of implementing new requirements to existing installations or to already approved design and considers that “*it is expected that a comparison will be made with the current standards, for example as part of the periodic safety review for the plant, to determine whether the safe operation of the plant could be further enhanced by means of reasonably practicable safety improvements*”[14]… In any case, the

[21] IAEA n°SSR-3

[22] IAEA n°SSR-4

[23] Euratom directive 2014/87

overall objective of having consequences as low as reasonably achievable and below the prescribed limits in the event of an accident applies to both existing and future facilities.

WENRA has set safety objectives for new nuclear power plants, but it also points out "*that these objectives should be used as a reference for identifying reasonably practicable safety improvements for "deferred plants" and existing plants during periodic safety reviews*". Moreover, when wondering if it may be relevant to further revise the Safety Objectives or the Booklet, WENRA-RHWG highlighted that there may be some work to be done on the terminology when saying that "*it should be made clear what is meant with "existing reactors" and "new reactors" or should some other terminology be used*"[24].

Most of the figures in the current report use the terms "new" and "existing" in the same usual way as described above.

5.3.3 Facility states – categorization

In a general way, countries surveyed here start by categorizing the different states of the facilities. For this categorization, most follow the fairly common general approach, although the terminology may differ:

- Normal operation
- Anticipated operational occurrence
- Design basis accident
- Design extension conditions without fuel degradation
- Design extension condition with fuel degradation

Most of the countries reviewed here have the same practice regarding the categorization of facility states, as these categories are clearly defined in international standards.

5.3.4 Events occurrence

Each predefined state is associated with an interval corresponding to the annual frequency of the events considered.

For Canada, these intervals are as follows:

- $> 10^{-2}$ for anticipated operational occurrences
- $[10^{-5} ; 10^{-2}]$ for design basis accidents
- $< 10^{-5}$ for beyond design basis accidents

For Finland:

- $> 10^{-2}$ for anticipated operational occurrences

[24] WENRA Safety Objectives for New Nuclear Power Plants and WENRA Report on Safety of new NPP designs – RHWG position on need for revision September 2020

- [10^{-3}; 10^{-2}] for postulated accidents of Class 1
- < 10^{-3} for postulated accidents of Class 2

For Germany, "guide values" are given to enable the classification of events:

- > 10^{-2} for anticipated operational occurrences
- [10^{-5}; 10^{-2}] for design basis accidents
- < 10^{-5} for beyond design basis accidents

For the Netherlands, the following intervals are given:

- > 10^{-1}
- [10^{-2}; 10^{-1}]
- [10^{-4}; 10^{-2}]
- < 10^{-4}

There are common practices between countries - assigning frequencies of occurrence to each facility state - without however having the same values from one country to another. The value of 10^{-2} seems to have been adopted by all countries for the upper bound of the interval associated with design basis accidents. The value of the other limit of the interval (sometimes there are two) is variable (equal to 10^{-4}, 10^{-5}, 10^{-6} or less than 10^{-3} or 10^{-4}).

As a reminder, Swiss regulations[25] define the intervals [10^{-4}; 10^{-2}] and [10^{-6}; 10^{-4}] for design basis accidents, in accordance with IAEA recommendations.

5.3.5 Dose criteria

For each of the predefined plant states, radiological acceptance criteria for the public are specified (without prejudice to other criteria related to the plant): for frequent events, there are no (or few) radiological consequences, while events that could lead to consequences have a very low probability of occurrence.

For Canada, the radiological acceptance criteria are expressed in terms of whole-body dose likely to be received by the average individual in the most critical risk groups, in the vicinity of the site or beyond, during the 30-day period following an accident. The limit values defined for these criteria are as follows:

- 0.5 mSv for anticipated operational occurrences
- 20 mSv for design basis accidents

For Finland, the radiological acceptance criteria are expressed in terms of annual effective dose to the public. The limit values defined for these criteria are as follows:

- 0.1 mSv/year for anticipated operational occurrences

[25] RPO, art. 123

- 1 mSv/year for postulated accidents of Class 1
- 5 mSv/year for postulated accidents of Class 2
- 20 mSv/year for design extension conditions without fuel degradation

For Belgium, the following limit values are defined for the two postulated events of levels C3a (postulated single initiating events) and C3b (postulated multiple failure events): the effective dose shall be less than 5 mSv per event, and the thyroid dose for infants, children, and adolescents shall be less than 10 mSv per event. It should be noted that other European countries (e.g. Hungary) include thyroid dose i in addition to effective dose in their radiological acceptance criteria.

For Germany, the radiological acceptance criteria for design basis accidents are expressed in terms of effective dose (50 mSv per event) and equivalent dose to various organs or tissues (see table below). It should be noted that the dose constraint value in the German regulations, which applies to normal operation and expected operational incidents, is identical to that used in Switzerland (0.3 mSv/year).

Table 7. Radiological acceptance criteria in German regulations

§	Scope of applicability	Time period	Dose [mSv]
§ 104 StrlSchV	**Accident planning levels for nuclear installations**		
	Effective dose	Event	50
	Organ equivalent dose: thyroid	Event	150
	Organ equivalent dose: skin, hands, forearms, feet and ankles	Event	500
	Organ equivalent dose: eye lens, gonads, uterus, red bone marrow	Event	50
	Organ equivalent dose: bone surface	Event	300
	Organ equivalent dose: great gut, lung, stomach, bladder, breast, liver, gullet, other organs or tissues unless specified above	Event	150

For the Netherlands, the radiological acceptance criteria are expressed in terms of effective dose to the public (for a single event) and are distinguished for the two age groups "over 16 years" and "under 16 years" (values are then divided by 2.5).

Table 8. Radiological acceptance criteria in the Dutch regulations

	Maximum allowed effective dose	
Probability of event (per year)	*Age ≥16*	*Age under 16*
≥ 10^{-1}	*0.1 mSv*	*0.04 mSv*
≥ 10^{-2} & < 10^{-1}	*1 mSv*	*0.4 mSv*
≥ 10^{-4} & < 10^{-2}	*10 mSv*	*4 mSv*
< 10^{-4}	*100 mSv*	*40 mSv*

For Sweden, the radiological acceptance criteria are expressed in terms of annual effective dose, for all nuclear facilities of a site (see table below). It should be noted that the value associated with accident basis design is 100 mSv.

Table 9. Radiological acceptance criteria in Swedish regulations

Event categories (H1-H5) according to Swedish regulations	Design criteria (mSv) for existing reactors (with respect to the general public)	Defence-in depth- level (DiD)	Associated plant condition categories (according to WENRA)
H1	0,1*	1	NO
H2	1	2/3	AOO
H3	10	3	AOO
H4A	100	3	DBA
H4B	100	3	DEC A
H5	**	4	DEC B

*) Per year and for all nuclear facilities at the site
**) No dose criterion is specified. Instead, here is a maximum permissible emission of Cesium-13, which corresponds to 100 TBq.

For the UK, the criteria are also expressed in terms of effective dose. For design basis accidents, the limit value is 100 mSv for a frequency between 10^{-5} and 10^{-4}, 10 mSv between 10^{-4} and 10^{-3} and 1 mSv above 10^{-3}.

Finally, for the USA, the radiological acceptance criteria are expressed both in terms of effective dose (TEDE = total effective dose equivalent) and thyroid equivalent dose:

- 0.25 mSv/year in effective dose and 0.75 mSv/year in thyroid equivalent dose for normal operation
- 250 mSv in effective dose and 3 Sv in thyroid equivalent dose for the duration of the event for design basis accidents. It should be noted that a fraction of these values is used depending on the frequency of occurrence of the events: for example, for events with a "moderately high" frequency of occurrence, this fraction is 10% (i.e., 250 x 10% = 25 mSv in effective dose). For "BWR rod drop accident" events, the fraction is 25% (i.e. 63 mSv in effective dose) (see table below).

Table 10. Radiological Acceptance Criteria in US Regulations

Table 1
Accident Dose Criteria

Accident or Case	EAB and LPZ Dose Criteria	Analysis Release Duration
LOCA	25 rem TEDE	30 days for all leakage pathways
BWR Main Steam Line Break		Instantaneous puff, until MSIV isolation
Fuel Damage or Pre-incident Spike	25 rem TEDE	
Equilibrium Iodine Activity	2.5 rem TEDE	
BWR Rod Drop Accident	6.3 rem TEDE	24 hours
Small Line Break Accident	2.5 rem TEDE	Until isolation, if capable, or until cold shutdown is established
PWR Steam Generator Tube Rupture		Affected SG: time to isolate; Unaffected SG(s): until cold shutdown is established
Fuel Damage or Pre-incident Spike	25 rem TEDE	
Coincident Iodine Spike	2.5 rem TEDE	
PWR Main Steam Line Break		Until cold shutdown is established
Fuel Damage or Pre-incident Spike	25 rem TEDE	
Coincident Iodine Spike	2.5 rem TEDE	
PWR Locked Rotor Accident	2.5 rem TEDE	Until cold shutdown is established
PWR Rod Ejection Accident	6.3 rem TEDE	30 days for containment leakage pathway; Until cold shutdown is established for secondary pathway
Fuel Handling Accident or Cask Drop	6.3 rem TEDE	2 hours

It is interesting to note that a different approach is envisaged in some countries when considering severe accidents.

For instance, Canada does not use dose criteria in relation to its safety goals, which take into account (for new facilities) the frequency of large radioactive releases (maximum 10^{-6}/year) and the frequency of small radioactive releases (maximum 10^{-5}/year). Indeed, a release is considered large (or significant) if it results in a long-term relocation of the population (or a short-term evacuation, but of a large area or with a prolonged evacuation period). And it is considered minor if it requires only temporary sheltering or evacuation. These releases are characterized by the activity released (in Bq): more than 10^{15} Bq of I131 for low releases and more than 100 TBq of ^{137}Cs for high releases.

For Finland, the safety objectives consider, for new facilities, the frequency of significant radioactive releases (maximum 5.10^{-7}/year). These "significant" releases are characterized, as in the Canadian regulations, by the activity released, limited to 100 TBq of Cs137.

For Sweden, the criteria for "H5" events are expressed in terms of the maximum release to the environment, in ^{137}Cs (100 TBq).

5.3.6 Small size facilities

As recalled at the beginning of Chapter 5, international documents and national regulations, when defining accident types, occurrences and associated radiological consequences, are mainly applicable to nuclear power plants and possibly to fuel cycle installations.

The Swiss RPO is fully applicable to small size facilities such as hospitals or industrial facilities using sealed or unsealed radioactive materials. The feedback of experience shared by the FOPH (Federal Office of Public Health) with IRSN during remote and face-to-face meetings is that radiological consequence assessments above 1 mSv or 0.3 mSv are rarely met. Therefore, the calculation of the probability of abnormal situations liable to occur is not really an issue. So far, the radiological consequences assessment is only required for facilities handling unsealed sources.

The requirement to obtain an analysis of potential accidents even in small size facilities is a good practice. However, as another case, the design of the facility may be unique, it's quite difficult for the applicant to carry out a statistical study of the potential accident. We have noted that the FOPH is drafting of a guide to help in this area.

It is therefore difficult to apply an analogous approach to safety for all types of installation. It is therefore important that national regulations clearly identify the families of installations and the regulatory framework applicable to them. In France, a decree clearly defines the activity in radionuclides or the power for electrical devices producing ionizing radiation, beyond which the most restrictive regulatory regime applies. The smallest facilities are covered by the Public Health Code and only recently have studies been carried out by the operators on the radiological consequences of an accident. This is the case for cyclotrons. The French experience with accidents in small installations mainly concerns workers. The approach essentially consists of an engineer's judgment on the plausibility of a situation that could expose the worker beyond the regulatory limit. The operator is then required to take steps to eliminate this situation. It is therefore a deterministic approach that does not require the definition of several accident categories.

However, it would be interesting to consider the public's tolerability to accident situations depending on the type of installation. The TG 114 of ICRP is considering tolerability and reasonableness. The question of the relationship between limits or consequences in the event of an accident and the purpose of the use of ionizing radiation can be pushed to this technical group.

5.3.7 Conclusion

There is a common practice among countries to associate dose criteria for the public with the different facility states, with the willingness to be consistent in the way accidents are pooled.

However, there are differences in the way these criteria are expressed: in all countries in terms of effective dose, either related to the year or to an event, but also in some countries in terms of equivalent dose to the thyroid or to other organs or tissues. The dose criteria do not usually distinguish between age groups, except in the Netherlands.

The dose criteria are not usually accompanied by information on the integration period of the dose, except for some countries which use several values for different phases of the accident. Belgium, for instance, uses the concept of short-, medium- and long-term consequences.

Overall, numerical values are not the same from one country to another. For the effective dose, the dose criteria associated with design basis accidents may be, depending on the country, 1, 5, 10, 20, 40, 50 or 100 mSv (Sweden, UK, the Netherlands), or even 250 mSv (USA).

As a reminder, the following values are defined in the Swiss regulations: 0.3 mSv for events with an annual frequency greater than 10^{-2}, 1 mSv for the interval [10^{-2}; 10^{-4}] and 100 mSv for the interval [10^{-4}; 10^{-6}]) – without taking into account thyroid doses. It should be noted that the 1-mSv criterion is among the lowest values of the dose criteria used in the countries considered, and that the 100-mSv criterion is at the upper limit of the dose criteria found, but is commonly used. An important point to note is that the 100-mSv applies to a dose integrated over 1 year, whereas the lower values often apply to shorter integration times, making the comparison difficult.

On the other hand, Switzerland seems to be the only country with a strict application of dose criteria, non-compliance with could lead to the temporary shutdown of the facility. In other countries, the non-respect of the dose criteria seems to be less strict, although the same logical approach "the higher the occurrence, the lower the associated dose" is in line with what is done internationally. Finally, Switzerland has adopted the approach recommended by the international radiation protection organizations (ICRP and IAEA), followed by many countries, particularly in Europe. Occurrence intervals used in the Swiss regulations are in line with those recommended by international organizations and, overall, with those used in other countries. The dose constraints that can be derived from the intervals bounds are in line with the ICRP recommendations set out in ICRP 103 addressing potential exposures.

5.4 Dose calculation Method

The method used in Switzerland to check compliance with the dose criteria was also investigated, because it may have a strong influence on the result. A large part of the face-to-face meeting with the IRSN and ENSI in Brügg on the 7th of September 2022 was devoted to this issue.

Some countries, such as Switzerland, are very prescriptive: the assumptions and equations to calculate the dose for the safety report are specified in the ENSI guideline G14. The dose calculation method is thus “set in stone” and is the same for all. It should be noted that this guide will soon be updated to take account of the recommendations of the ICRP and the IAEA standards. Other countries, such as France, leave the operator free to choose the method of his its choice as long as it allows a response consistent with regulatory expectations.

Regarding the dose calculation itself, some differences between the methods used in Switzerland and in France were highlighted:

- **The location of the exposed person**, for which the calculation is made in Switzerland, is at the site boundary, whereas the method used in France considers a “representative person” (representative of the most exposed individuals in the population, excluding those with extreme or rare habits) - not necessarily (rarely) located at the site boundary. IRSN notes that the hypothesis used in Switzerland can be very punitive.
- The consideration of **the ingestion pathway** according to the different phases of the accident is not the same in the two countries: only during the first 48 h of release in Switzerland, and after the release period in France. One question is how to consider the actual behavior of the population in the event of an accident in terms of self-protection measures, since this could lead to different assumptions for the

assessment of the radiological consequences, in particular with regard to the ingestion exposure pathway.

- **In France, the concepts of "short", "medium" and "long" term calculations** are used . The short term generally corresponds to the period of the release, the medium term is approximately 1 year after the end of the release, and the long term is the time taken to return to 1 mSv/year. The regulations have introduced these concepts of delay because the radiological consequences are not only felt at the time of release (exposure to the plume and inhalation), but also well beyond this period due to deposition (ingestion). Depending on the radionuclides released, the doses associated with the "medium" or "long" term phases may be higher than those associated with the "short" term phase.

5.5 Synthesis

In order to meet the client's expectation of a comparison between Swiss legislation on radiological protection and international best practices, particularly with regard to accidental situations, the study unavoidably enhances the concept of acceptable limits in term of radiological consequences and the estimated frequency of these accidental situations. Notwithstanding the relevance of the information provided to support the conclusion below, these information and data should be used with caution and should not be assessed outside the current context.

Firstly, the improvement of these information and data could be misinterpreted as if they were the fundamental part of the safety approach. Safety is primarily based on the appropriate application of safety principles such as defence-in-depth, ensuring fundamental safety functions or implementing successive and sufficiently independent barriers. Thus, safety demonstration is not limited to the use of pre-defined dose limit values, the weight of which may vary according to national practice or regulation, but the above principles remain fundamental.

Furthermore, international harmonization is generally aimed at general principles or practices, but cannot reasonably be applied to detailed methodology. In this context, detailed vocabulary or figures should be used with caution when making comparison. In particular, IRSN stresses that the dose values associated with the probabilities alone are not a sufficient criterion for judging the regulatory requirement from one country to another, as the calculation methods may be different (in particular, routes and duration of exposure).

In view of this, the assessment that leads to the conclusion below should not be summarized, for example, by a comparative table gathering different countries with some estimated frequencies of situations and some dose limits: such a summary would be misleading as regards both the safety approach and the effective practices of each country.

The dose criteria used in the two Swiss ordinances, NEO and RPO, are consistent with internal references and with the range of values used by the various countries that IRSN examined for the regulations on the specific issue. The value of 100 mSv used for the lower bound of the [10^{-4} :10^{-6}] range is one of the highest values used by the other countries. However, the value of 100 mSv applies to an exposure period of one year, which is a longer exposure period than those used for dose calculation in other countries. Within the framework of our

analysis, Switzerland is the only nuclear country that imposes strict compliance with a dose criterion: this value is used as a cut-off criterion (reactor shutdown). IRSN considers that the definition of a prescriptive approach square with the use of a cut-off value in a very strict way. During the discussions for the preparation of this report, mention was made of the sudden increase from 1 mSv to 100 mSv when the probability of the accident in question becomes equal to 10^{-4}/year. On this point, it is important to remember that the safety approach is not based on compliance with a dosimetric criterion but is part of a continuous process of improving safety and optimizing radiation protection. The comparison with a dosimetric criterion appearing in the regulations is intended only as a check and not as an a priori objective.

6 HEALTH EFFECTS AT LOW DOSES

A detailed report (in French and German) on the effects of low doses on humans and the risk assessment was published by the Swiss Federal Council on 2 March 2018 in response to Postulate 08.3475 of the Swiss Parliament. This report presented the state of knowledge on the risks associated with ionizing radiation at low doses, for cancers and non-cancerous pathologies (Federal Council 2018). Question 3 concerns information that may have evolved in the years since the publication of this report, and the need for additional data or research to reduce uncertainties at low doses.

This section provides a summary of the findings on risks at low doses that have been published since 2018. It answers Question 3 of the client expectations (see section 2.1). It is not intended to be an exhaustive review, but rather a synthesis of the main epidemiological findings. It focuses on the information elements relevant to the low-dose range, defined according to the UNSCEAR definition as the range of doses below 100 mSv (UNSCEAR 2015).

The content of this section is as follows:

- Analysis of the report on "the state of knowledge on the risks of ionizing radiation at low doses" published by the Federal Council in 2018 in response to Parliament's postulate;
- Review of the most recent epidemiological data on low-dose health risks published in the international literature since 2018;
- Synthesis of key findings, and identification of short-term development perspectives based on ongoing research projects and working groups.

6.1 Analysis of the report on "the state of knowledge on the risks of ionizing radiation at low doses" of 2018

This 26-page report takes stock of the state of knowledge on the risks of low-dose exposure to ionizing radiation at low doses in 2018 (Federal Council 2018). It includes a summary of epidemiological findings, with particular emphasis on studies conducted in Switzerland. Most of the report is devoted to epidemiological studies on the risks of cancer and leukaemia at low doses, but a part is also devoted to the risks of non-cancerous pathologies, and to knowledge of the mechanisms of action at the biological level.

Based on this synthesis, the report concludes that "recent studies confirm the application of the linear model without threshold as a prudent basis for radiation protection in Switzerland". However, it stresses that "the cardiovascular effects at low doses and the mechanisms of action leading to radiation-induced cancer remain insufficiently understood and deserve particular attention" and that "the consideration of recently observed effects such as genomic instability and the bystander effect concerning the induction of cancers as well as the incidence of radiation on cardiovascular diseases in the estimation of radiological risk constitutes a challenge for the years to come". The IRSN's critical analysis of this report highlights the following main points:

- The review carried out in this report is of good quality, not exhaustive but complete and balanced, and provides a good summary of the state of epidemiological knowledge on the effects of low doses in 2018;

- The report provides the main contextual elements necessary for a good understanding of this synthesis (definition of low doses, definition of stochastic effects, summary of the main biological mechanisms involved in the process of carcinogenesis, international context of radiation protection, etc.);
- The conclusions are in line with the summary of the state of knowledge, and their relevance to the radiation protection system are clearly explained.

6.2 Summary of recent epidemiological data published in the international literature since 2018 on the health risks at low doses

This section presents a non-exhaustive summary of the scientific literature over the period 2018-2022 on the health effects of exposure to ionizing radiation at low doses. It particularly details the epidemiological results on the risks of cancer and leukemia. Results relating to biological mechanisms and non-cancerous pathologies are also partially addressed.

6.2.1 Recent results on the risks of cancers and leukemia at low doses

Epidemiological study of survivors of the bombing of Hiroshima and Nagasaki

In recent years, new analyzes of mortality risk and cancer incidence have been published on the cohort of Japanese survivors of the 1945 atomic bombings (the so-called Life Span Study, LSS), with an extended follow-up period and a new dosimetry review. In particular, the risk analysis for specific anatomical sites of cancer has been continued since 2018, with the analysis of breast cancer (Brenner et al. 2018), digestive tract (Sakata et al. 2019; Sugiyama et al. 2020), uterus and ovaries (Utada et al. 2019; Utada et al. 2021), brain cancer (Brenner et al. 2020), liver (French et al. 2020), prostate, kidney and bladder (Mabuchi et al. 2021; Grant et al. 2021).

Analyzes of all solid cancers showed differences in the estimation of the shape of the dose-response relationship between mortality and incidence data or between men and women. In an attempt to explain these differences, Brenner et al. (2022) studied in detail the parameters likely to influence the estimation of the dose-response relationship. Using identical modeling methods for the mortality data and the incidence data, the observed dose-response relationship appears linear-quadratic in men, whether based on mortality data or incidence data. For women, the results are more complex: a linear-quadratic relationship is observed for the mortality data, but the relationship appears linear for the incidence data. These differences could be explained by a different contribution of cancer types according to the time since exposure, and between men and women. In addition, analyzes according to age at the time of exposure show that the curvature of the dose-response relationship is mainly observed in survivors exposed before the age of 20 (Brenner et al. 2022). These results suggest that the grouped analysis of all solid cancers is not the optimal method for assessing the risk of radiation-induced cancer, and that an analysis by site or group of cancer sites now seems preferable. (Cologne et al. 2019). Little et al. also observed evidence of curvature in the mortality data for solid cancers (specifically, the group of solid cancers excluding lung, breast, and stomach cancers) and leukemia, such that for solid cancer and leukaemia, the estimates of excess risk per unit dose almost doubled when the dose was increased from 0.01 to 1.0 Gy, with most of the increase occurring in the range from 0.1 to 1.0 Gy (Little et al. 2020). In a new complementary

analysis, the authors conclude that there is a significant but modest curvature of the dose-risk relationship for all solid cancers, based on mortality and incidence data, but highlight the existence of significant variation between cancer sites (Little and Hamada 2022).

An analysis of solid cancer mortality in Japanese survivors who were in utero in Hiroshima or Nagasaki at the time of the atomic bombings was carried out, with a follow-up to 2012. A dose-risk relationship was observed in women, but not in men. However, only 14% of the survivors exposed in utero had died at the end of follow-up, so most data on these survivors are yet to come (Sugiyama et al. 2021).

Epidemiological studies of medical imaging patients

Since 2018, two new analyzes have been published on the risk of cancer after a childhood CT scan:

- Meulepas et al. analyzed data from a large Dutch cohort of almost 170,000 people who had received a CT scan when they were under 18 years of age. The study found a significant excess relative risk (ERR) per Gy for brain tumors (average cumulative brain dose of 38 mGy) but not for leukaemia (Meulepas et al. 2019).

- A new analysis of the French cohort was published, after the inclusion of new patients, extension of follow-up and collection of information on predisposing factors for childhood cancer. The analysis included more than 103,000 patients, including 3% with cancer predisposing factors. The mean cumulative doses were 28 and 10 mGy for brain and red bone marrow, respectively. The results show statistically significant dose-response relationships for central nervous system tumors and leukaemia, even after excluding patients with cancer predisposing factors (Foucault et al. 2022).

One article reviewed the literature on cancer risks associated with ionizing radiation exposures in childhood medical diagnoses (Abalo et al. 2020). Among the relevant epidemiological studies published between 2000 and 2019, six studies on paediatric CT scans served as the basis for a meta-analysis of the risk of leukaemia and brain tumors . In total, the meta-analysis included more than 11 million patients. The results showed a significant increase in the risk of leukaemia and brain tumors. The authors conclude that "exposure to CT scans during childhood appears to be associated with an increased risk of cancer" (Abalo et al. 2020).

The results of studies on the risk of cancer after paediatric CT scans are always highly criticized, particularly because of the possibility of reverse causality bias and indication bias. However, the possibility of a reverse causation bias is low for leukaemias (because most leukaemias in young people are acute leukaemias), and a recent simulation study shows that the application of an adjusted exclusion period strongly limits the possibility of reverse causality bias for brain cancer (Little et al. 2022a). The collection of information on medical indications and on the presence of predisposing factors for cancer or leukaemia in certain studies should make it possible to answer questions about a possible indication bias (Foucault et al. 2022; Bernier et al. 2019).

A meta-analysis was carried out on the long-term cancer risk in children/adolescents with scoliosis who underwent repeated radiological examinations between 1912 and 1990. A total of 9 studies were retained, including nearly 19,000 patients with of scoliosis. The mean number of full spine radiographs was 23 (range 0 - 618) and the mean cumulative breast dose was 110 mGy. Compared to controls, incidence rates in patients with scoliosis were statistically higher for breast cancer and for all cancers (Luan et al. 2020).

The first evidence that low doses of radiation in utero might increase the risk of cancer later in life was published in the mid-1950s, based on a case-control study (called the Oxford Survey of Childhood Cancers, OSCC) of childhood cancer mortality after radiographic examination of the pregnant mother's abdomen. Since then, the question of cancer risk following in utero exposure has remained much debated, particularly because there was little support outside the OSCC study. In 2021, an analysis of all the available data was carried out. The authors compared the results of all combined studies (excluding OSCC) with those of the OSCC study. Overall, the estimated relative risks were consistent between OSCC and all the other studies combined. This analysis therefore confirms the observation of a significant excess risk following in utero exposure, whether for leukaemia or for all other childhood cancers combined (Wakeford and Bithell 2021). Another recent analysis of the literature confirms the existence of an excess risk of childhood cancer following in utero exposure to radiation for medical diagnosis (Little et al. 2022b).

Epidemiological studies of workers exposed to ionizing radiation

The value of studies of workers exposed to ionizing radiation is that the doses have been accumulated as many low doses of radiation over long periods, often many years. While questions remain about the quality of the recorded doses received during the early years of operation of nuclear facilities, these studies now provide major additional information to the results from the study of survivors of the Japanese atomic bombings, on which the the current radiation protection system is largely based (Wakeford 2018, 2021, 2022a; Rühm et al. 2022).

The INWORKS project is a joint study of nuclear workers, including over 300,000 nuclear workers in France, the UK and the USA. For workers whose cumulative dose was greater than zero, the average cumulative dose over their entire professional life was about 20 mGy. In total, the monitoring covered more than 8 million person-years. Most of the results were published before 2018 and showed a significant dose-response relationship for leukaemia and all solid cancers. The estimated radiation-induced risk remained statistically significant even when the range of cumulative doses was restricted to less than 150 mGy. Since 2018, additional analyzes have aimed to compare the risk estimates from INWORKS with those from the LSS, as accurately as possible. The estimated risk per unit radiation dose for cancer in workers was similar to estimates derived from Japanese atomic bomb survivors (Leuraud et al 2021), suggesting no or little dose rate impact.

The cancer risk analysis was updated in the UK Nuclear Workers Cohort, comprising over 170,000 individuals and over 5 million years of mortality and incidence follow-up. The average cumulative external dose was 25 mSv based on individual dosimeter records. The results showed a significant relationship between the cumulative dose and the risk of solid cancers. This relationship remained significant even when the dose range was restricted to less than 100 mSv. The authors concluded that their study provides direct evidence of cancer risk from occupational exposure to low-dose and low-dose-rate external radiation, with results broadly consistent with LSS risk estimates and those adopted in current ICRP guidelines (Haylock et al. 2018). Recent complementary analyzes have allowed refinement of the estimation of the shape of the dose-risk relationship for solid cancers, and the consideration of certain specific cancer sites (Hunter et al. 2022a). The authors confirm an association between the dose and the risk of leukaemia, but also for chronic myeloid leukaemia (Gillies et al. 2019). A statistically significant dose-risk association was also observed for the incidence of non-Hodgkin's lymphoma and multiple myeloma. (Hunter et al. 2022b).

The first results from the ongoing “Million Person Study” project in the USA were published (Boice et al. 2022a; 2022b; 2022c; 2022d; 2022e). In particular, a study of the risk of leukaemia and cancer was carried out among 135,000 American nuclear power plant workers. The mean cumulative external dose was 49 mSv. Analyzes showed a significant but weak dose-risk relationship for leukaemias other than chronic lymphoblastic leukaemia, but no association for all solid cancers (Boice et al. 2021c).

A review of the literature on studies involving medical personnel exposed to ionizing radiation was published in 2020 (Chartier et al. 2020). In the United States, an analysis of mortality from lung cancer and leukaemia was performed on a cohort of over 109,000 workers. The average cumulative dose was estimated to be 63 mSv. A small but significant dose-risk relationship was observed for lung cancer, but not for leukaemia, breast cancer and brain cancer (Boice et al. 2022e). It should be noted, however, that these studies raise questions about the quality of the individual dose reconstruction.

Cancer incidence and mortality were analyzed in a cohort of Russian liquidators who participated in clean-up procedures in the Chernobyl exclusion zone in 1986-1987. The study includes more than 69,000 individuals, with an average external dose of 133 mGy. The results show a significant positive dose-risk relationship between cumulative dose and solid cancer risk, for both incidence and mortality data. These relationships remain statistically significant when the dose ranges are restricted to 0-200 mGy (Ivanov et al. 2020).

Epidemiological studies of environmental exposures

In France, two ecological studies investigated the potential risks of childhood cancers associated with exposure to ionizing radiation from natural sources. The first study examined the incidence of central nervous system tumors in almost 5,500 cases. No overall association was observed for central nervous system tumors in children, but an association between pilocytic astrocytomas and gamma radiation was suggested (Berlivet et al. 2020). The second study looked at the risk of acute leukaemia in children, considering exposure at the time of birth (complementing an earlier study that had considered exposure at the time of diagnosis). Although based on a population of 6,000 cases of acute leukaemia, the study showed no association between exposure to natural radiation and the incidence of childhood acute leukaemia (Berlivet et al. 2021).

In Switzerland, a study analyzed the association between natural terrestrial gamma radiation, exposure to cosmic rays and exposure due to 137Cs deposits from the Chernobyl accident and childhood cancer incidence. The study focused on nearly 3.5 million children under the age of 16 for whom we had georeferenced data on their place of residence, including more than 3,000 cases of cancer. The median cumulative dose since birth was 8 mSv (range 0 to 31 mSv). The authors observed a significant positive relationship for childhood cancers and leukaemia. They concluded that “these results support that external exposure to naturally occurring radiation may contribute to observed rates of cancer in children, particularly leukaemia and central nervous system tumors” (Mazzei-Abba et al. 2021).

Two review articles considering all the available results on an association between childhood cancer risk and exposure to natural gamma radiation have been published. The authors concluded that it is difficult to draw firm conclusions from the currently available results, in particular because of the difficulties in obtaining precise estimates of individual doses or the small size of some studies (Mazzei-Abba et al. 2020; Kendall et al. 2021).

No results had been published for nearly 10 years on the cohort set up in Kerala, India, which is a region with a high level of natural radioactivity. A new analysis of cancer incidence has been published on a cohort of more than 149,000 adult residents followed for an average of 19 years. The authors obtained a negative but non-significant dose-risk relationship, after adjustment for alcohol consumption, tobacco consumption and level of education. No quantitative results were provided for leukaemia (Jayalekshmy et al. 2021).

Many articles were published in 2021 on the health consequences 35 years and 10 years after the Chernobyl and Fukushima nuclear accidents. A summary article was published, providing an overview of knowledge, whether on radiation-induced effects or not. This summary emphasizes the importance of epidemiological monitoring of the populations affected by a nuclear accident, but it also details the limits to interpretation, linked for example to the quality of dose reconstruction, the difficulty of monitoring the term or the impact of screening for thyroid cancer risk (Cléro et al. 2021).

Syntheses and meta-analyses

In addition to the work related to the exposure situations described in the previous chapters, several general syntheses (reviews, meta-analyses, joint analyses) have been published in recent years on cancer risk at low doses, for all cancers or for specific cancer sites. The most important ones are summarized below.

The PIRATES study is a joint analysis of the risk of thyroid cancer associated with exposure to low doses of radiation (<200 mGy) during childhood (age at exposure <19 years). Data from eight medically exposed cohorts were combined with those from survivors of the atomic bombings in Japan, resulting in a total of more than 107,000 individuals followed for an average of 41 years. The analysis confirmed the existence of a linear dose-risk relationship for thyroid cancer, with greater risk associated with age at exposure and younger attained age (Lubin et al. 2017).

A joint analysis of the risk of leukaemia associated with exposure to low doses of radiation (<100 mSv) in childhood (age at exposure <21 years) was also performed. The study combined data from eight medically exposed cohorts and those of survivors of the atomic bombings in Japan, for a total of more than 262,000 individuals followed for an average of 20 years. The results confirmed the existence of a positive dose-risk relationship below 100 mSv and even below 20 mSv for acute lymphoblastic leukaemia. The authors concluded that their results “imply that the current system of radiation protection is conservative and not overly protective” (Little et al. 2018).

A meta-analysis of the radiation-induced risk of solid cancers was carried out in cohorts exposed to low dose rates (Shore et al. 2017). The analysis focused on 22 epidemiological studies, including data from more than 900,000 individuals. For each low dose rate study, the estimated risks were compared with those derived from the cohort of survivors of the atomic bombings in Japan, in order to assess the effect of dose rate on the risk of radiation-related cancer. The combined analysis of the 22 low-dose rate studies shows a risk estimate similar to that derived from the LSS (in the range of 1 to 2), with the cohort of Mayak workers dominating the overall result. In a sensitivity analysis restricted to studies with mean doses <100 mGy (analysis of 16 mortality studies, excluding in particular the Mayak workers study), the estimated ERR was still statistically significant and the estimated risk ratio between the low-dose rate studies and the LSS was then close to 1, with no evidence of heterogeneity of the risk between the different low-dose rate studies. The authors concluded that their data

provide “an important complement to LSS-derived risk estimates used for radiation protection purposes” (Shore et al. 2017).

The National Council on Radiation Protection and Measurements (NCRP) has reviewed the validity of the Linear No-Threshold (LNT) model. To do this, the authors carried out a critical review of 29 studies or groups of epidemiological studies on occupational, medical and environmental exposures published since 2000. The quality of each study and its level of support for the LNT model were assessed. In total, only five studies provided no support for the LNT model, while four studies were considered inconclusive. The report concluded that the majority of the studies reviewed, including those of the highest quality, showed good consistency with the LNT model, for solid cancers and for leukaemia and that "the LNT model, perhaps with a DREF >1, is conservative and practical for radiation protection”. (NCRP 2018; Shore et al. 2018).

In 2020, the National Cancer Institute in the United States (NCI) published a monograph on epidemiological studies of cancer risk after exposure to low doses of ionizing radiation at low LET (Berrington de Gonzales et al. 2020). The analyses focused on a total of 22 studies published since 2006, with average doses below 100 mSv. The first objective was to assess the potential impact of confounding factors and biases at low doses, such as selection bias, sources of dose errors, study power, loss of tracking and uncertainty in results, or model misspecification (Schubauer-Berigan et al. 2020; Gilbert et al. 2020). This systematic analysis of potential biases showed that recent epidemiological studies have several limitations, but only a few positive studies were potentially biased towards overestimating risk. After excluding these studies, most studies still provide positive risk estimates (Hauptmann et al. 2020). The second objective was to perform a meta-analysis. The authors concluded that "recent epidemiological studies directly confirm the existence of excess cancer risks due to low doses of ionizing radiation. Furthermore, the cancer risks associated with low dose radiation exposures were statistically consistent with the estimated radiation-induced cancer risks in survivors of the atomic bombings” (Hauptmann et al. 2020).

UNSCEAR has carried out an assessment of the uncertainties associated with risk projections for various effects related to exposure to ionizing radiation, in particular the risks of leukaemia, solid cancers and thyroid cancer, based on realistic exposure scenarios (UNSCEAR 2020). A Monte Carlo uncertainty propagation approach was applied to calculate credibility intervals, reflecting both statistical uncertainty and the potential impact of additional sources of uncertainty (selected populations, exposure assessment, health outcome assessment, study design, confounding factors, statistical methods and model uncertainties, other sources of uncertainty). The results showed that, overall, the estimated uncertainties were low (less than a factor of 1.5), and rarely greater than a factor of 2 (UNSCEAR 2020).

UNSCEAR has recently published a comprehensive review of the biological mechanisms relevant for inferring cancer risk from low-dose, low-dose-rate radiation (UNSCEAR 2021). This report aimed to synthesize current knowledge on the biological mechanisms of radiation action at doses predominantly in the low to moderate dose range relevant to the process of carcinogenesis. This report considered mutagenic mechanisms (related to DNA modification, but also other relevant biological mechanisms (stimulation of DNA repair, modifications of gene expression, adaptive response, bystander effects, etc.) The report shows that mutagenic mechanisms are now well known, and their impact on carcinogenesis is compatible with a linear model. On the other hand, although the existence of non-mutagenic mechanisms is now recognized, their contribution to the process of radiation-

induced carcinogenesis remains unclear. Based on their review, the authors point out that "Knowledge of the mechanisms that affect cancer risk at low doses […] suggests that an overall threshold for cancer induction is unlikely and there is evidence that some known mechanisms already operate at a dose level of 10 mGy". They conclude that "there remains good justification for the use of a non-threshold model for risk inference given the robust knowledge on the role of mutation and chromosomal aberrations in carcinogenesis" (UNSCEAR 2021).

Rühm et al. have produced a synthesis of recent epidemiological data on the risks of cancer linked to low doses of radiation. The authors point out that overall, the results available today are based on studies involving several million individuals, many of whom have been followed for more than half a century. They conclude that the epidemiological findings provide substantial evidence that ionizing radiation induces cancer at doses above 100 mGy and increasing evidence for doses below 100 mGy. Results from prolonged exposures (e.g. among nuclear workers) demonstrate that small doses accumulated over many years at low dose rates have stochastic health effects (Rühm et al. 2022).

6.2.2 Recent results on the risk of non-cancer diseases at low doses

Diseases of the circulatory system

Circulatory diseases are a major health burden and cause of death in many countries. It is now well established that high doses of radiation cause damage to the heart and blood vessels and induce an increased incidence of diseases of the circulatory system in humans one or two decades after exposure. ICRP Publication 118 classified diseases of the circulatory system as tissue reactions, with a dose threshold of 0.5 Gy, for radiation protection purposes (ICRP 2012).

An analysis of the lifetime risk of death from diseases of the circulatory system was carried out on the basis of the latest data from survivors of the Japanese atomic bombings (revised dosimetry of 2022, follow-up until 2003). The authors used various linear-quadratic risk models and Bayesian techniques to adjust for errors in dose estimates. The calculations were made for a dose of 0.1 Gy, using background rate data from the UK population. The same approach was applied to solid cancers for comparison. According to these calculations, the lifetime risk of diseases of the circulatory system would be about 40% to 60% of that estimated for solid cancers but associated with wider credibility intervals (Little et al. 2020).

Little et al. performed an analysis of the available data on the risk of circulatory diseases oat low to moderate doses. The authors broadly confirm their previous results, showing a statistically significant excess risk for the main types of diseases of the circulatory system, in particular ischemic heart disease and stroke. However, the authors stress the difficulty of interpreting the results, in particular because of the heterogeneities and inconsistencies of the results and because of evidence of non-linearity of the dose-response for cerebrovascular accidents (Little et al. 2021).

The European MELODI association conducted a review of the evidence on the risks of cardiovascular disease associated with ionizing radiation. This review considered the different clinical, occupational or environmental exposure situations, and addressed epidemiological, biological, risk modelling and systems biology aspects. Over the past decade, evidence indicating increased risk at lower dose and dose rate levels has been accumulated. However, the uncertainties regarding the shape of the dose-response, the dose threshold (if any), and the

contribution of other risk factors for diseases of the circulatory system, are considerable at low doses. The authors highlighted the existing gaps in the available knowledge and proposed future research directions (Tapio et al. 2021). Furthermore, the epidemiological data currently available must be considered with great caution (Wakeford 2022b).

Diseases of the central nervous system

In recent years, questions have been raised about the possible effects of exposure to ionizing radiation at low to moderate doses on cognitive function. A group of experts brought together by the European MELODI association has summarized the state of knowledge on this subject. If at moderate and high doses (above 0.5 Gy), ionizing radiation is an established risk factor for cognitive disorders, the results on the effects of low to moderate doses remain patchy. A better characterization of the considered effects is necessary, as well as a better consideration of the human lifespan and the variations of the risk according to age. Moreover, the mechanisms underlying radiation-induced cognitive effects are unclear and are likely to involve multiple biological pathways and different cell types. The authors conclude that well-conducted research in large epidemiological cohorts and experimental studies in appropriate animal models are needed to improve the understanding of radiation-induced cognitive effects (Pasqual et al. 2021).

Lopez et al. carried out a systematic analysis of the relevant epidemiological literature published between 2000 and 2022. Forty-five publications relating to various exposure situations (atomic bomb, occupational, environmental and medical exposure) were identified. The meta-analysis showed significant dose-risk relationships for the incidence and mortality from cerebrovascular diseases, and Parkinson's disease. The authors conclude that their results “suggest that low to moderate exposure to ionizing radiation in adults may have effects on non-cancer diseases of the central nervous system” (Lopes et al. 2022).

Lens opacities

In 2012, the International Commission on Radiological Protection (ICRP) revised the classification of cataracts as a tissue reaction with a reduced dose threshold to 0.5 Gy. The ICRP indicated that this change was mainly based on epidemiological findings (ICRP 2012).

A synthesis of knowledge on radiation-induced cataracts was recently produced by a group of experts brought together within the framework of the European MELODI association. The objective was to discuss recent epidemiological and clinical studies, ophthalmological examination techniques, biological and mechanistic knowledge, and to identify research gaps. In particular, the authors recommend that the effect of ionizing radiation on the lens be studied in the context of broader systemic effects, including on the retina, brain and other organs (Ainsbury et al. 2021).

Little et al. performed an analysis of recent epidemiological data on the risk of radiation-induced cataract (Little et al. 2021). Their analysis shows evidence of an excess risk of posterior cortical and subcapsular cataracts at low to moderate doses. Furthermore, the other known risk factors for cataracts, such as solar UV radiation exposure, diabetes, overweight, smoking, corticosteroids and ocular trauma do not appear to be likely confounding factors in the dose-response relationship. The authors conclude that “the classification of cataract as a tissue reaction

effect with a threshold dose of 0.5 Gy is borderline incoherent" in view of certain data available today (Little et al. 2021).

The results of the European LDLensRad project on radiation-induced cataracts have recently been published (Ainsbury et al. 2022). This project provided results on the mechanisms of cataract induction by radiation, and on the effects of age and dose rate. The results also suggest that the early lesions induced by ionizing radiation are better described by a deterministic model, while the late manifestations are better described by a stochastic model. These results may be important for the consideration of cataract risk in radiation protection system (Ainsbury et al. 2022).

Hereditary effects

Researchers have reanalyzed old data collected between 1948 and 1954 on pregnancy outcomes in women who survived the Japanese atomic bombings (Yamada et al. 2021). Earlier reports (1956, 1981 and 1990) did not identify a significant association with dose. The authors re-examined the risk of major birth defects and perinatal death in a population of over 71,000 children using revalidated diagnostic data, parent gonadal dose estimates from the 2002 Dosimetry System, and methods of improved statistical analysis. The analyzes show a positive, but not significant, association between parental radiation exposure and an increased risk of major birth defects and perinatal death. The authors emphasize the significant uncertainties associated with their results and recommend great caution in their interpretation (Yamada et al. 2021).

A "trio" family study was carried out in Ukraine among Chernobyl liquidators. The authors investigated whether children born of parents exposed to ionizing radiation were born with more de novo germline mutations (Bazyka et al. 2020). The study included 130 children born between 1987 and 2002 and their parents. The mean gonadal doses before conception were 365 mGy (range 0-4080 mGy) and 19 mGy (range 0-550 mGy) in fathers and mothers, respectively. In each family, whole genome sequencing was performed on blood samples from both parents and one child. The analysis showed no dose-dependent increase in the rates, distributions, or types of de novo germline mutations. The authors concluded that "within this exposure range, there is no evidence of a substantial effect on de novo germline mutations in humans, suggesting minimal impact on the health of subsequent generations" (Yeager et al. 2021).

A second "trio" family study was carried out in the UK veterans who were present during the British nuclear tests in Australia and the South Pacific to investigate a possible transgenerational effect of ionizing radiation. Germline mutations were analyzed in 60 families (30 military control families not involved in the tests and 30 families of nuclear test veterans). The study showed no overall increase in the total number of de novo single mutations, small insertions and deletions, structural variants or cluster mutations in the children of veterans. The authors conclude that their results "provide no evidence for an increase in germline mutations in a group of British nuclear test veterans" (Rake et al. 2022; Moorhouse et al. 2022). However, a major limitation of the study is the lack of reliable dosimetric data on the veterans.

6.3 Ongoing expertise and projects

Several large-scale epidemiological studies are in progress and should provide new results on low-dose risks, both for cancer or non-cancerous pathologies, in the coming years In particular, the European EPI-CT project on the risk of cancer after pediatric CT scans should be mentioned. This project brings together data from cohorts in Belgium, Denmark, France, Germany, the Netherlands, Norway, Spain, Sweden and the United Kingdom. It includes a total of more than one million children who had CT scans before the age of 22 and uses an improved and standardized dosimetric approach. This project will have high statistical power and should also assess the potential impact of reverse causation and indication biases (Bernier et al. 2019; Thierry-Chef et al. 2021). Several projects on workers are underway. The INWORKS project on nuclear workers is currently undergoing an extension of follow-up and should provide additional results on low-dose cancer risks in the near future. Another large-scale project is the “Million Person Study” currently underway in the United States, which should make it possible to quantify the radiation risk on a very large database by bringing together different American studies (Boice et al. 2022d).

A committee of experts appointed by the American Academy of Sciences has recently published a report aimed at identifying research priorities for low-dose health effects in the United States. The recommendations made concern in particular the development of research in epidemiology and radiobiology, and the need to maintain associated research infrastructures (NASEM 2022).

6.3.1 Expertise on the risks of cancer and leukemia

UNSCEAR launched an "Assessment of epidemiological studies carried out on radiation and cancer" in 2019 to update its 2006 report. The objectives are to conduct a systematic review of the literature for each cancer site, to identify the most relevant risk models, and to assess the lifetime risk under different methodological assumptions (base rate, additive or multiplicative transfer, modifying factors such as age or sex). The report is expected in 2025 (UNSCEAR 2022).

Several working groups (TG for taskgroup) of ICRP Committee 1 are directly related to the assessment of cancer risks at low doses (https://www.icrp.org/):

- TG91 " Radiation risk inference at low dose and low dose rate exposure for radiological protection purposes" aims to review the state of knowledge on the effects induced by ionizing radiation at low doses and low dose rates, at the molecular, cellular, experimental and human levels. Ultimately, the objective is to provide a basis for reviewing the validity of the coefficient of reduction of effects at low doses and dose rates (DDREF) introduced in 1991 in the calculation of the detriment. The final report is expected in 2023.
- TG111 “Factors governing the individual response of Humans to ionizing radiation” aims to apply a systematic approach to review the scientific literature on inter-individual variations in response to radiation. Factors considered include, among others, gender, age or genetic characteristics. The TG is mainly interested in cancer risk, but also in tissue reactions and non-cancerous pathologies. The report is expected in 2023.

- TG118 “Relative biological effectiveness (RBE), quality factor (Q) and radiation weighting factor (wR)” aims to review the scientific literature on RBE and to advice on the potential impact on ICRP recommendations. The report is expected in 2025.
- TG122 “Update of detriment calculation for cancer” aims to assess the current knowledge on all aspects of the detriment calculation for cancer, to assess its potential impact and to consider changes to the detriment calculation, if necessary. It has two main components; 1/ the risk of cancer (shape of the dose-risk relationship, variation with age and sex, transfer between populations, projection over lifespan) and 2/ the severity of cancers (lethality, quality of life, years of life lost, disability-adjusted life years (DALYs)). The report is expected in 2028.

6.3.2 Expertise on the risks of non-cancerous pathologies

In 2021, UNSCEAR launched an expert group on the “Assessment of diseases of the circulatory system due to exposure to radiation”. The objectives are to carry out a systematic review of the scientific literature in epidemiology, radiobiology, and radiopathology. The review will cover the risks of diseases of the circulatory system at high doses (post radiotherapy) and at low doses. The report is expected in 2025 (UNSCEAR 2022).

As a continuation of the UNSCEAR work program for the period 2020-2024, an "Assessment of the effects of exposure to radiation on the nervous system" should be set up in 2022. Other expert groups are planned for by 2024, with in particular to assess knowledge on the risk of cataracts, on the effects of ionizing radiation on the immune system, and on other non-cancer pathologies (including heritable effects). These various reports should be published after 2025 (UNSCEAR 2022).

Several TGs of ICRP Committee 1 are directly related to the assessment of the risks of non-cancerous pathologies at low doses (**https://www.icrp.org/**):

- TG119 "Effects of ionizing radiation on diseases of the circulatory system and their consideration in the system of radiological protection " aims to carry out a critical review of the recent scientific literature on epidemiological and radiobiological studies on diseases of the circulatory system, and to provide advice on how this knowledge should be reflected in the radiation protection system. The final report is expected in 2026.
- TG121 “Effects of ionizing radiation exposure on offspring and next generations” aims to review the knowledge on the effects of in utero radiation exposure and on the hereditary effects of exposure to radiation. Ultimately, the work of the TG should make it possible to provide advice on how these effects should be taken into account in the radiological protection system, for human beings and non-human biota. The final report is expected in 2026.
- TG123 "Classification of harmful radiation-induced effects on human health for radiological protection purposes" aims to clarify the justification for the current classification of radiation effects (stochastic effects versus tissue reactions), to assess the reasons calling for an evolution of this classification and, if a change is considered scientifically desirable, to assess the implications for practical radiological risk management, both for the prevention of tissue reactions and for the limitation of stochastic effects. In

particular, the question arises of whether or not to include certain non-cancerous pathologies in the detriment calculation. The final report is expected in 2027.

6.4 Conclusions and prospects

This summary generally supports and consolidates the conclusions of the report on the effects of low doses on humans and risk assessment published by the Swiss Federal Council in 2018 (Federal Council 2018).

The epidemiological results obtained in recent years clearly strengthen the scientific knowledge on the effects of low doses of radiation on the risk of cancer. The results now show excess cancer risks at dose levels of the order of or below 100 mGy, at least for all cancers taken together and also for certain specific types of cancer. Several syntheses or joint analyzes carried out by international consortia (ICRP, NCRP, UNSCEAR, NCI) conclude that there is increasing evidence of the carcinogenic effects of ionizing radiation at low doses, and that the hypothesis of no threshold for radiation protection purposes seems relevant and reasonable.

These results demonstrate the importance of continuing the epidemiological studies currently under way, in order to extend the duration of follow-up and to take account of effects that may be expressed several decades after exposure. They also illustrate the importance of international joint studies, which improve the comparability of results and the ability to detect low to very low risk studies. Finally, the broadening of the exposure situations considered by the various studies conducted clearly improves our knowledge of the effects of exposure to ionizing radiation.

The review of radiobiological results was not the focus of this synthesis, but it is interesting to quote the UNSCEAR report on the biological mechanisms of cancer at low doses and dose rates. While it is clear that certain mechanisms do not follow linear relationships, the overall process of radiation-induced carcinogenesis includes a strong mutagenic component that appears linear and shows effects at doses of the order of 10 mGy. The authors conclude that the existence of an overall cancer induction threshold is unlikely, and that the use of a non-threshold model for risk inference for radiation protection purposes remains warranted (UNSCEAR 2021).

Many new results have also been obtained in recent years for non-cancerous pathologies. Although an increasing number of epidemiological results seem to point to the existence of excess risks at low doses, the uncertainties remain very large and the heterogeneity of the results severely limits the ability to characterize the risks at low doses. As part of the work of UNSCEAR, several expert groups are underway, both on cancer risks and on non-cancer effects. This work should enable our knowledge of low-dose effects to be consolidated in the coming years.

In addition, the ICRP has recently initiated a process to update the radiation protection system (Clement et al. 2022). Several working groups have been set up, for example on improving the classification of radiation health effects, on the factors of variation of the individual response to exposure to radiation, or on the risks of diseases of the circulatory system. These working groups should also provide new syntheses on the effects of low doses in the coming years. Continued research efforts are needed, in radiobiology to improve knowledge of biological mechanisms, and in epidemiology to improve the quantification of dose-risk relationships at low doses (Laurier 2021). The development of multidisciplinary approaches involving radiobiology, epidemiology and modelling,

such as the "Adverse Outcome Pathway (AOP)" approach (Chauhan 2022) or the development of mechanistic models, should allow a better understanding of the discrepancies between experimental results in animals and observational results in humans (NCRP 2020; UNSCEAR 2021). Ultimately, this research should improve risk assessment at low doses.

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6.6 Glossary

AOP: adverse outcome pathway

ASN: French nuclear safety authority

EASu: Ultimate containment spray system

ENSI: Swiss federal nuclear safety inspectorate

FOH: Organizational and Human Factors

FOPH: Swiss federal office for public health

GPR: Advisory committee for reactors

IAEA: international atomic energy agency

ICRP: international commission for radiological protection

LNT: linear no threshold

LSS: life span study

NCI: US national cancer institute

NCRP: US national council on radiation protection and measurements

NEO: Swiss nuclear security ordinance

PSR: Periodic Safety Review

PTR: Safety Injection System Tank

PWR: Pressurized Water Reactor

SFu: Ultimate heat sink

RPO: Swiss radiation protection ordinance

SGTR: Steam Generator Tube Rupture

U5: emergency operating procedure for reactors in the French nuclear power plant leet

UNSCEAR: united nation scientific committee on the effects of atomic radiation

WENRA: western European Nuclear Regulators Association

WHO: World Health Organization

APPENDICES

Annexe 1. Call for tender

	Postulate 18.4107: Dose limit values for nuclear installations, radioactive radiation and radiation protection – **Call for tender**		
Version :	11.03.2021	Authors :	François BOCHUD Didier GAVILLET Patrick MAJERUS

1. Introduction

On March 3, 2019, the Council of States of the Swiss Parliament (Upper House) accepted a postulate asking the Federal Council (Government) to entrust independent experts specialized in the fields of radiological protection and medicine with the mission to prepare a report on the consequences of the revision of January 10, 2018 of the Swiss Nuclear Energy Ordinance. More precisely, an expertise is required on the criteria for provisional taking out of service of nuclear power plants (Art. 44), as well as on risk/hazard assumptions made in that ordinance (Art. 8).

The report will include presenting the relationship between the limit values proposed for the provisional taking out of service of nuclear power plants and the values appearing in the Swiss legislation on radiological protection (Art. 123), as well as the strategies of Switzerland in the field of radiation protection and the emergency measures that are associated with it. A comparison with the recommendations and limits in force at the international level, as well as with the scientific knowledge concerning the management of ionizing radiation at low doses, are also expected.

The report should also address the various contributions of radiation sources to the population. It will have to show whether the measures to protect the population against the harm of ionizing radiation are proportionate to the usefulness for society of the technologies in which they come into play.

The following experts have been designated to pilot an external expertise to perform this task:

1. **Dr François BOCHUD**,
   Director of the Institute of Radiation Physics, Lausanne University Hospital
   - Chair of the Swiss Federal Commission for Radiological Protection.
   - Professor in medical physics at Lausanne University.
   - Member of Committee 4 of the International Commission on Radiological Protection (ICRP).
   - Member of the International Commission on Radiation Units & Measurements (ICRU, since 01.01.2021)
2. **Dr Didier GAVILLET**,
   Deputy Head of the Nuclear Energy and Safety Division of the Paul Scherrer Institut
   - Member of the Swiss Federal Commission for Nuclear Safety.
   - Member of the "groupe permanent usine" of the French Safety Authority (ASN)
3. **Dr Patrick MAJERUS**,
   Head of the Division of Radiation Protection, Health Ministry, Luxemburg
   - Vice-Chair of the European Nuclear Safety Regulators Group (ENSREG) and Chair of its Working Group on Transparency
   - Vice-Chair of the Working Group on Emergencies of the Heads of the European Radiological Protection Competent Authorities (HERCA)
   - Member and national contact point of several other international groups – e.g. EURATOM Art. 37 Group of Experts, Decommissioning Founding Group, Nuclear Decommissioning Assistance Program Committee, Safeguards National Expert Group, Convention on Nuclear Safety (CNS), and the bilateral Commissions on nuclear safety with Belgium and France.

The goal of this document is to define the specific questions necessary to be answered in the report in order to respond to the postulate.

2. Questions

2.1. How does Swiss legislation on radiological protection compare with international best practices?

- The general radiation protection strategy adopted by Switzerland will be put into perspective with international recommendations (e.g. ICRP, EU-BSS).
- The dose criteria used internationally (e.g. dose limits, reference level, numerical protection criteria) will be presented and a critical analysis of how they are applied in Switzerland will be performed.
- The distinction between risk assessment and risk management will be explained and discussed.
- The risk management strategy in at least one country of economic level comparable with Switzerland will be presented; for illustration a selection of accident scenarios for running plants with frequencies of occurrence between 10^{-3} and 10^{-6} will be presented with the resulting estimated emergency exposure situations. A comparison will be made with what is done in Switzerland, with focus on, but not limited to, prescriptive criteria used in decision taking. The implementation of the concept of potential exposure should also be discussed. The discussion should focus on the Radiological Protection Ordinance (in particular Art. 123 on safety analysis of the design) and its transposition for nuclear facilities into the Nuclear Energy Ordinance (in particular Art. 8 on the requirements concerning measures to prevent accidents)[1].

2.2. How can we compare the levels of acceptable risk of a nuclear power plant with other sources of radioactivity dissemination and external irradiations?

- The level of risk, if possible expressed in terms of harm and frequency of occurrence should be compared with different practices and exposure situations. Examples of other sources of radionuclides are hot lab in research facilities, industry in general, inhalation of radon and hospitals.
- The report will also compare the possible doses in the event of a nuclear accident with those delivered annually to the population. This point will be approached from the somatic and psychological point of view.

2.3. What are the current discussions in science and research regarding low dose of ionizing radiations?

- A detailed report (in French and in German) on the effects of low doses on humans and risk assessment was published on March 2, 2018 in response to the Parliament's postulate 08.3475. The question posed in the context of this call for tender should only address information that may have evolved during the last three years that followed the publication of that report, and the need of data or research, for the reduction of uncertainties.

2.4. General opinion

Based on the answers to the present questions, the report will give a general opinion on how the radiological risk is managed in Switzerland.

[1] The practical application can be found in a directive from the Swiss Federal Safety Inspectorate (ENSI-A01). In addition, ENSI also published the seismic evidence in a specific statement. If further documents or explanations are required, ENSI is ready to help.

3. Organization and schedule

The submission is expected to contain the following points:

1. Justification of the tenderer's competence in terms of radiological protection and medicine.
2. References to self publications in the present area of competences.
3. Short presentation of the methodology to Majerus/Gavillet/Bochud and representatives of the federal offices of energy and public health, including clarification of open questions and if necessary adjustment of the assignment.
4. Presentation of the progress at mid-term (approx. 4 months after the start) to Majerus/Gavillet/Bochud.
5. Presentation of the final draft report.
6. Delivery of the final report.
7. Costs.

The final report is expected to be between 50 to 70 pages. It should be written in English.

Date	Milestone
15.04.2021	Financial and technical proposition
30.04.2021	Acceptance of the offer by the Federal Office of Energy
30.04.2021	Start of the project
to be defined	Progress at mid-term
to be defined	Final draft report
to be defined	Feedback from Majerus/Gavillet/Bochud
to be defined	Final report

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