

# Swedish Radiation Safety Authority Regulatory Code



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## The Swedish Radiation Safety Authority's Regulations and General Advice Concerning the Protection of Human Health and the Envi- ronment in Connection with the Final Manage- ment of Spent Nuclear Fuel and Nuclear Waste

*Please note that translated versions of the Authority's regulations  
lack legal force and are for information purposes only.*



## The Swedish Radiation Safety Authority's Regulations concerning the Protection of Human Health and the Environment in connection with the Final Management of Spent Nuclear Fuel and Nuclear Waste;<sup>1</sup>

SSMFS 2008:37

Published on 30 January  
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issued on 19 December 2008.

On the basis of Sections 7 and 8 of the Radiation Protection Ordinance (1988:293), the Swedish Radiation Safety Authority hereby issues the following regulations.

### Application and definitions

**Section 1** These regulations apply to the final management of spent nuclear fuel and nuclear waste. The regulations do not apply to landfills for low-level nuclear waste in accordance with Section 19 of the Nuclear Activities Ordinance (1984:14).

**Section 2** In these regulations the following terms and concepts are used with the meanings specified here.

<i>best available technique:</i>	the most effective measure available to limit the release of radioactive substances and the harmful effects of releases on human health and the environment, and which does not entail unreasonable costs
<i>intrusion:</i>	human intrusion into a repository which can affect its protective capability
<i>optimisation:</i>	keeping the radiation doses to humans as low as reasonably achievable while taking economic and societal factors into account
<i>harmful effects</i>	cancer (fatal and non-fatal) as well as hereditary effects in humans caused by ionising radiation, in accordance with paragraphs 47-51 in Publication 60, 1990, of the International Commission on Radiological Protection

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<sup>1</sup> These regulations and the general advice were issued previously in the Swedish Radiation Protection Authority's Regulatory Code (SSI FS 1998:1 and SSI FS 2005:5).

	(ICRP)
<i>protective capability:</i>	the capability to protect human health and the environment from the harmful effects of ionising radiation
<i>final management:</i>	handling, treatment, transport, interim storage prior to, and in connection with, disposal as well as the disposal itself.
<i>risk:</i>	the product of the probability of receiving a radiation dose and the harmful effects of the radiation dose

Terms and concepts used in the Radiation Protection Act (1988:220) and the Act on Nuclear Activities (1984:3) have the same meanings in these regulations.

### **Holistic approach, etc.**

**Section 3** Human health and the environment shall be protected from detrimental effects of ionising radiation during the period of time when the various stages of the final management of spent nuclear fuel and nuclear waste are being implemented as well as in the future. The final management may not cause impacts on human health and the environment outside Sweden's borders that are more severe than those accepted inside Sweden.

**Section 4** Optimisation must be performed and the best available technique shall be taken into consideration in the final management of spent nuclear fuel and nuclear waste.

The collective dose, as a result of the expected outflow of radioactive substances over a period of 1,000 years after closure of a repository for spent nuclear fuel or nuclear waste shall be estimated as the sum, over 10,000 years, of the annual collective dose. The estimate shall be reported in accordance with Sections 10 to 12.

### **Protection of human health**

**Section 5** A repository for spent nuclear fuel or nuclear waste shall be designed so that the annual risk of harmful effects after closure does not exceed  $10^{-6}$  for a representative individual in the group exposed to the greatest risk.<sup>2</sup>

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<sup>2</sup> Facilities in operation are subject to the Swedish Radiation Safety Authority's regulations (SSMFS 2008:23) on protection of human health and the environment in connection with discharges of radioactive substances from certain nuclear facilities as well as the Swedish Radiation Safety Authority's regulations (SSMFS 2008:51) concerning basic provisions for the protection of workers and the general public in practices involving ionising radiation.

The probability of harmful effects as a result of a radiation dose shall be calculated using the probability coefficients provided by Publication 60, 1990 of the International Commission on Radiological Protection.

## **Environmental protection**

**Section 6** The final management of spent nuclear fuel and nuclear waste shall be implemented so that biodiversity and the sustainable use of biological resources are protected against the harmful effects of ionising radiation.

**Section 7** Biological effects of ionising radiation in the habitats and ecosystems concerned shall be described. The report shall be based on available knowledge on the ecosystems concerned and shall take particular account of the existence of genetically distinctive populations such as isolated populations, endemic species and species threatened with extinction and in general any organisms worth protecting.

## **Intrusion and access**

**Section 8** A repository shall be primarily designed with respect to its protective capability. If measures are adopted to facilitate access or to make intrusion more difficult, the effects on the protective capability of the repository shall be reported.

**Section 9** The consequences of intrusion into a repository shall be reported for the different time periods specified in Sections 11 to 12.

The protective capability of the repository after intrusion shall be described.

## **Time periods**

**Section 10** An assessment of a repository's protective capability shall be reported for two time periods of the orders of magnitude specified in Sections 11 to 12. The description shall include a case based on the assumption that the biospheric conditions prevailing at the time when an application for a licence to construct the repository is submitted will not change. Uncertainties in the assumptions made shall be described and taken into account when assessing the protective capability.

### *The first thousand years following closure of a repository*

**Section 11** For the first thousand years following repository closure, the assessment of the repository's protective capability shall be based on quantitative analyses of the impact on human health and the environment.

*Period after the first thousand years following closure of a repository*

**Section 12** For the period after the first thousand years following repository closure, the assessment of the repository's protective capability shall be based on various possible sequences for the development of the repository's properties, its environment and the biosphere.

### **Exemptions**

**Section 13** If there are particular grounds, the Swedish Radiation Safety Authority may grant exemptions from these regulations if this can be done without circumventing the aim of the regulations.

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These regulations shall enter into force on 1 February 2009.

SWEDISH RADIATION SAFETY AUTHORITY

ANN-LOUISE EKSBORG

Carl-Magnus Larsson

## **The Swedish Radiation Safety Authority's general advice on the application of the regulations (SSMFS 2008:37) concerning the protection of human health and the environment in connection with the final management of spent nuclear fuel and nuclear waste;**

**SSMFS 2008:37**

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issued on 19 December 2008.

The Swedish Radiation Safety Authority hereby issues the following general advice.

### **Section 1: Application**

This advice is applicable to final geological disposal of spent nuclear fuel and nuclear waste. The advice covers measures undertaken with a view to developing, siting, constructing, operating and closing a repository, which can have an impact on the protective capability of the repository and the environmental consequences after closure.

The advice is also applicable to measures that are to be undertaken with spent nuclear fuel and nuclear waste before disposal and which can have an impact on the protective capability of a repository and its environmental consequences. This includes activities at installations other than the repository, such as the conditioning of waste that takes place by casting waste in concrete and by encapsulation of spent nuclear fuel, as well as transports between installations and steering of waste to different repositories, including shallow land burials for low-level nuclear waste that are licenced in accordance with Section 16 of the Nuclear Activities Ordinance (1984:14). However, as is the case with the regulations, the advice is not applicable to the installation for land burial.

### **Section 2: Definitions**

Terms and concepts used in the Radiation Protection Act (1988:220), the Act on Nuclear Activities (1984:3) and the Swedish Radiation Safety Authority's regulations (SSMFS 2008:37) on protection of human health and the environment in connection with final management of spent nuclear fuel and nuclear waste have the same meanings in this advice. The following definitions are also used:

<i>scenario:</i>	a description of the potential evolution of the repository given an initial state and specified conditions in the environment and their development
<i>exposure pathway:</i>	the migration of the radioactive substances from a repository to a place where human beings are present, or where an organism covered by the environmental protection regulations is present. This includes dispersion in the geological barrier, transport with water and air flows, migration in ecosystems and uptake in human beings or organisms in the environment.
<i>risk analysis:</i>	an analysis with the aim of clarifying the protective capability of a repository and its consequences with regard to the environmental impact and the risk for human beings

## **Sections 4, 8 and 9: Holistic approach, etc.; intrusion and access**

### *Optimisation and Best Available Technique*

The regulations require optimisation to be performed and the best available technique to be taken into account. Optimisation and best available technique should be applied in parallel with a view to improving the protective capability of the repository.

Measures for optimisation of a repository should be evaluated on the basis of calculated risks.

Application of best available technique in connection with disposal means that the siting, design, construction and operation of the repository and appurtenant system components should be carried out so as to prevent, limit and delay releases from both engineered and geological barriers as far as is reasonably possible. When striking balances between different measures, an overall assessment should be made of their impact on the protective capability of the repository.

In cases where considerable uncertainty is attached to the calculated risks, for instance in analyses of the repository a long time after closure, or analyses made at an early stage of the development work with the repository system, greater weight should be placed on best available technique.

In the event of any conflicts between application of optimisation and best available technique, priority should be given to best available technique.



Experiences from recurrent risk analyses and the successive development work with the repository should be used when applying optimisation and best available technique.

#### *Collective dose*

The regulations require an account of the collective dose from releases taking place during the first thousand years after closure. As far as concerns disposal, the collective dose should also be used in comparisons between alternative repository concepts and sites. The collective dose need not be reported if the repository concept entails a complete containment of the spent nuclear fuel or nuclear waste in engineered barriers during the first thousand years after closure.

#### *Occupational radiation protection*

An account should be given of measures undertaken for radiation protection of workers that may have a negative impact on the protective capability of the repository or make it more difficult to assess.

#### *Future human action and the preservation of information*

When applying best available technique, consideration should also be given to the possibility to reduce the probability and consequences of inadvertent future human impact on the repository, for instance inadvertent intrusion. Increased repository depth and avoidance of sites with extractable mineral assets may, for instance, be considered to reduce the probability of unintentional human intrusion. Preservation of knowledge about the repository could reduce the risk of future human impact. A strategy for preservation of information should be produced so that measures can be undertaken before closure of the repository. Examples of information that should be taken into consideration include information about the location of the repository, its content of radioactive substances and its design.

## **Sections 5 – 7: Protection of human health and the environment**

### ***Risk for the individual from the general public***

#### *The relationship between dose and risk*

Under the regulations, the recommendations of the International Commission on Radiological Protection (ICRP) are to be used when calculating the harmful effects of a radiation dose. According to ICRP Publication 60, 1990, the factor for conversion of effective dose to risk is 7.3 per cent per sievert.

*The regulations' criterion for individual risk*

Under the regulations, the risk for harmful effects for a representative individual in the group exposed to the greatest risk (the most exposed group) shall not exceed  $10^{-6}$  per year. Since the most exposed group cannot be described in an unambiguous way, the group should be regarded as a way of quantifying the protective capability of the repository.

One way of defining the most exposed group is to include the individuals who receive a risk in the interval from the highest risk down to one-tenth of this risk. If a larger number of individuals can be considered to be included in such a group, the arithmetic average of individual risks in the group should be used for demonstrating compliance with the criterion for individual risk contained in the regulations. One example of this kind of exposure situation is a release of radioactive substances into a large lake that can be used as a source of drinking water and for fishing.

If the exposed group only consists of a few individuals, the criterion of the regulations for individual risk can be considered as being complied with if the highest calculated individual risk does not exceed  $10^{-5}$  per year. An example of a situation of this kind might be if consumption of drinking water from a drilled well is the dominant exposure pathway. In such a calculation example, the choice of individuals with the highest risk load should be justified by information about the spread in calculated individual risks with respect to assumed living habits and places of stay.

*Averaging risk over a lifetime*

The individual risk should be calculated as an annual average on the basis of an estimate of the lifetime risk for all relevant exposure pathways for every individual. The lifetime risk can be calculated as the accumulated lifetime dose multiplied by the conversion factor of 7.3 per cent per sievert.

*Averaging risk between generations*

Deterministic and probabilistic calculations can both be used to illustrate how risk posed by the repository develops over time. However, a probabilistic analysis can in certain cases give an insufficient picture of how an individual detrimental event, for instance, a major earthquake, would affect the risk for a particular generation. The probabilistic calculations should in such cases be supplemented as specified in Appendix 1.

*Selection of scenarios*

An assessment of the protective capability of a repository and the environmental consequences should be based on a set of scenarios that together illustrate the most important courses of development of the repository, its surroundings and the biosphere.

### *Dealing with climate evolution*

Taking into consideration the great uncertainties associated with the assumptions concerning climate evolution in a remote future and to facilitate interpretation of the risk to be calculated, the risk analysis should be simplified to include a few possible climate evolutions.

A realistic set of biosphere conditions should be associated with each climate evolution. The different climate evolutions should be selected so that they together illustrate the most important and reasonably foreseeable sequences of future climate states and their impact on the protective capability of the repository and their environmental consequences. The choice of the climate evolutions that serve as the basis for the analysis should be based on a combination of sensitivity analyses and expert judgements. Additional guidance is provided in the section containing advice on Sections 10 to 12.

The risk posed by the repository should be calculated for each assumed climate evolution by summing the risk contributions from a number of scenarios that together illustrate how the more or less probable courses of development in the repository and the surrounding rock affect the repository's protective capability and environmental consequences. The calculated risk should be reported and evaluated separately for each climate evolution in relation to the criterion of the regulations for individual risk. Hence, it should be shown that the repository complies with the risk criterion for each of the alternative climate evolutions. If a lower probability than one (1) is stated for a particular climate evolution, this should be justified, for instance by expert judgements.

### *Future human action*

A number of future scenarios for inadvertent human impact on the repository should be presented. The scenarios should include a case of direct intrusion in connection with drilling in the repository and some examples of other activities that indirectly lead to a deterioration in the protective capability of the repository, for example by changing the hydrological conditions or groundwater chemistry in the repository or its surroundings. The selection of intrusion scenarios should be based on present living habits and technical prerequisites and take into consideration the repository's properties.

The consequences of the disturbance for the repository's protective capability should be illustrated by calculations of the doses for individuals in the most exposed group and be reported separately from the risk analysis for the undisturbed repository. The results should be used to illustrate conceivable countermeasures and to provide a basis for the application of best available technique (see the advice on optimisation and best available technique).

An account need not be given of the direct consequences for the individuals intruding into the repository.

#### *Special scenarios*

For repositories primarily based on containment of the spent nuclear fuel or nuclear waste, an analysis of a conceivable loss during the first thousand years after closure of one or more barrier functions of key importance for the protective capability should be presented separately from the risk analysis. The intention of this analysis should be to clarify how the different barriers contribute to the protective capability of the repository.

#### ***Biosphere conditions and exposure pathways***

The future biosphere conditions for calculations of consequences for human beings and the environment should be selected in agreement with the assumed climate state. Unless it is clearly inconsistent, however, today's biosphere conditions at the repository and its surroundings should be evaluated, i.e. agricultural land, forest, wetland (mire), lake, sea or other relevant ecosystems. Furthermore, consideration should be taken to land uplift (or subsidence) and other predictable changes.

The risk analysis can include a limited selection of exposure pathways, although the selection of these should be based on an analysis of the diversity of human use of environmental and natural resources which can occur in Sweden today. Consideration should also be taken to the possibility of individuals being exposed to combinations of exposure pathways within and between different ecosystems.

#### ***Environmental protection***

The description of exposure pathways as mentioned above should also include exposure pathways to certain organisms in the above-mentioned ecosystems that should be included in the risk analysis. The concentration of radioactive substances in soil, sediment and water should be accounted for where relevant for the respective ecosystem.

When a biological effect for the identified organisms can be presumed, an evaluation should be made of the consequence this may have for the affected ecosystems, with the view to facilitating an assessment of impact on biological diversity and sustainable use of the environment.

The analysis of consequences for organisms in "today's biosphere", carried out as above, should be used for the assessment of environmental consequences in a long-term perspective. For assumed climates, where the present biosphere conditions are clearly unrealistic, for example during a colder climate with permafrost, it is sufficient to conduct a general

analysis based on knowledge currently available about applicable ecosystems. Additional advice is contained in Appendix 2.

### ***Reporting of uncertainties***

Identification and assessment of uncertainties in (for instance) site-specific and generic data and models should take place in accordance with the instructions given in the general advice for the Swedish Radiation Safety Authority's regulations (SSMFS 2008:21) concerning safety in connection with the disposal of nuclear material and nuclear waste. The different categories of uncertainties specified there should be evaluated and reported on in a systematic way and evaluated on the basis of their importance for the result of the risk analysis. The report should also include a motivation of the methods selected for dealing with different types of uncertainties, for instance in connection with the selection of scenarios, models and data. All calculation steps with appurtenant uncertainties should be reported on.

Peer review and expert panel elicitation may be used in cases where the basic data is insufficient to strengthen the credibility of assessments of uncertainties in matters of great importance for assessing the protective capability of the repository.

## **Sections 10 to 12: Time periods**

Two time periods are defined in the regulations: the period up to one thousand years after closure and the subsequent period.

For longer time periods, the result of the risk analysis should be successively regarded more as an illustration of the protective capability of the repository given certain assumptions.

### ***Limitation of the risk analysis in time***

The following principles should provide guidance for the limitation of the risk analysis in time:

1. For a repository for spent nuclear fuel or other long-lived nuclear waste, the risk analysis should at least cover approximately one hundred thousand years or the period for a glaciation cycle to illustrate reasonably predictable external strains on the repository. The risk analysis should thereafter be extended in time for as long as it provides important information about the possibility of improving the protective capability of the repository, although for a maximum time period of up to one million years.
2. For repositories for nuclear waste other than those referred to in item 1, the risk analysis should at least cover the period of time until the expected maximum consequences in terms of risk and environmental impact have taken place, although for a maximum time period of up to

one hundred thousand years. The arguments for the selected limitations of the risk analysis should be presented.

### ***Reporting on the first thousand years after closure***

The period of time of one thousand years should be regarded as the approximate time period for which a risk analysis can be carried out with a high level of credibility with regard to many factors, such as climate and biosphere conditions. For this time period, available measurement data and other knowledge about the initial conditions should be used for a detailed analysis and description of the protective capability of the repository and the evolution of its surroundings.

The conditions and processes during the early evolution of the repository which can affect its long-term protective capability should be described in as much detail as possible. Examples of such conditions and processes include the resaturation of the repository, stabilisation of hydrogeological and geochemical conditions, thermal evolution and other transient events.

Biosphere conditions and known trends in the surroundings of the repository should also be described in detail, partly to be able to characterise “today’s biosphere” (see advice for Section 5), and partly to be able to characterise the possible conditions applicable to a conceivable early release from the repository. Known trends here for instance refer to land uplift (or subsidence), any trends in climate evolution and appurtenant changes in use of land and water.

### ***Reporting on very long time periods***

#### *Up to one hundred thousand years*

Reporting should be based on a quantitative risk analysis in accordance with the advice on Sections 5 to 7. Supplementary indicators of the repository’s protective capability, such as barrier functions, radionuclide fluxes and concentrations in the environment, should be used to strengthen the confidence in the calculated risks.

The given period of time of one hundred thousand years is approximate and should be selected in such a way so that the effect of expected large climate changes, for instance a glaciation cycle, on the protective capability of the repository, and the consequences for the surroundings can be illustrated.

#### *Beyond one hundred thousand years*

The risk analysis should illustrate the long-term evolution of the repository’s barrier functions and the impact of major external disturbances on the repository, such as earthquakes and glaciations. Taking into consideration the increasing uncertainties over time, the calculation of doses to people and the environment should be made in a simplified way with respect to

climate development, biosphere conditions and exposure pathways. The climate evolution may be described as an idealised repetition of identical glaciation cycles.

A strict quantitative comparison of calculated risk with the criterion for individual risk contained in the regulations is not meaningful. The assessment of the protective capability of the repository should instead be based on reasoning on the calculated risk together with several supplementary indicators of the protective capability of the repository, such as barrier functions, radionuclide fluxes and concentrations in the environment. If the calculated risk exceeds the criterion of the regulations for individual risk or if there are other indications of substantial disruptions to the protective capability of the repository, the underlying causes of this should be reported on as well as possible measures to improve the protective capability of the repository.

***Summary of arguments for demonstrating compliance with the requirements of the regulations***

The reporting should include an account of how the principles for optimisation and the best possible technique have been applied in the siting and design of the repository and appurtenant system components, and how quality assurance has been used in the work with the repository and appurtenant risk analyses.

The arguments for the protective capability of a repository should be evaluated and reported on in a systematic way. The reporting should include a logically structured argument for the protective capability of the repository with information on calculated risks, uncertainties in the calculations made and the credibility of the assumptions made. To provide a good understanding of the results of the risk analysis, it should be evident how individual scenarios contribute to the level of risk posed by the repository.

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This general advice applies as of 1 February 2009.

SWEDISH RADIATION SAFETY AUTHORITY

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*Appendix I****Advice on the averaging of risk between generations***

For certain exposure situations, the annual risk, calculated as an average of all conceivable outcomes of a probabilistic risk assessment, provides an insufficient picture of how risk is allocated between future generations. This particularly applies to events which:

- can be assessed as leading to doses during a limited period of time in relation to the time period covered by the risk analysis, and
- if they arise, can be assessed as giving rise to a conditional individual risk exceeding the criterion contained in the regulations for individual risk, and
- can be assessed as having such a high probability of occurring during the time period covered by the risk analysis that the product of this probability and the calculated conditional risk is of the same order of magnitude as, or exceeds, the criterion for individual risk contained in the regulations.

For exposure situations of this kind, a probabilistic calculation of risk should be supplemented by calculating the risk for the individuals who are assumed to live after the event has taken place and who are affected by its calculated maximum consequence. The calculation can for instance be made by illustrating the significance of an event occurring at different points in time ( $T_1$ ,  $T_2$  [...],  $T_n$ ), taking into consideration the probability of the event occurring during the respective time interval ( $T_0$  to  $T_1$ ,  $T_0$  to  $T_2$  [...],  $T_0$  to  $T_n$ , where  $T_0$  corresponds to the time of closure of the repository). The results from these, or similar calculations, can in this way be expected to provide an illustration of the effects of the spreading of risk between future generations and should, together with other risk calculations, be reported on and evaluated in relation to the regulations' criterion for individual risk.



***Advice on the evaluation of environmental protection***

The organisms included in the analysis of environmental impact should be selected on the basis of their importance in the ecosystems, but also in line with their protection value according to other biological, economic or conservation criteria. Other biological criteria refer (among other things) to genetic distinctiveness and isolation (for example, presently known endemic species). Economic criteria refer to the importance of the organisms for establishment of different kinds of livelihood (for instance, hunting and fishing). Conservation criteria refer to possible protection by current legislation or local regulations. Other aspects, such as cultural history, for instance, should also be taken into consideration when identifying such organisms.

An assessment of effects of ionising radiation in selected organisms deriving from radioactive substances that may have spread from a repository can be made on the basis of the general guidance provided by Publication 91 from the International Commission on Radiological Protection (ICRP).<sup>1</sup> The applicability of the knowledge and databases used for the analyses of dispersion and transfer of radioactive substances in ecosystems and for analysing the effects of radiation on different organisms should be assessed and reported on.

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<sup>1</sup>A Framework for Assessing the Impact of Ionising Radiation on Non-human Species, ICRP Publication 91, Annals of the ICRP 33:3, 2003.

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