Swedish Radiation Safety Authority

Appendix 1
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Working group: Tomas Andersson, Ulf Andersson, Karin Aquilonius, Anna Maria Blixt Buhr, Erica Brewitz, Simon Carroll, Pia Eriksson, Peter Frisk, Fredrik Forsberg, Christian Karlsson, Charlotte Lager, Christian Linde, Tor Löfström Johnsson, Stefan Persson, Steve Selmer, Ingela Thimgren, Annika Åström.

Consulted: Annelie Bergman, Catarina Danestig Sjögren, Anne Edland, Svante Ernberg, Charlotta Fred, Jan Hanberg, Ove Nilsson, Nina Persson, Jonas Sjöström.

Approved: Helene Jönsson

Special conditions for the ESS facility in Lund

Temporary table for tracking review of translation

Section	Translation reviewed, by / date	Comment
Chap 1, section D. Chap 1, App 2. Chap 1, App 3.	Carl Tillman / 2018-10-26	
Chap 1, App 1.	Carl Tillman / 2018-10-26	Not reviewed, but added comment that identical text (SSMFS 2008:1, app 2.) is already available at SSM web site, i.e. could be basis for translation.
Chap 5	Cecilia Lowe / 2018-11-01	
Ch 1 (A-F) plus appendix 1-5, Ch 2	Peter Jacobsson, 2018-11-14	I have not looked at the Rad Waste/Decommissioning part
Chap 4	Per Nilsson / 2018-11-15	Minor changes. Some systematic rephrasing: reasonably possible -> possible and reasonable manual measures -> manual actions accredited -> credited ambient -> environemental
Chap 6	Ulrika Agnvik Oct 24	Minor Changes. Supervised area replaced with Protected area Alarm central replaced with Security Monitor

		Room

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Introduction

In addition to directly applicable regulations for practices with ionising radiation, the Swedish Radiation Safety Authority (SSM) has identified a need to expand the specification of requirements for the ESS facility in Lund. With the support of section 26 of the Swedish Radiation Protection Act (1988:220), ESS AB was notified on permit conditions in several specialised areas on 17th July 2014, in conjunction with an initial decision. A revised version of these conditons has subsequently been issued to European Spallation Source ERIC (ESS) through documents 15-36 and 15-2919 (only physical protection).

In conjunction with the new Swedish Radiation Protection Act (2018:396), new Swedish Radiation Protection Ordinance (2018:506) and new regulations entering into force in 2018, a revision of the above-mentioned appendix to the conditions has been necessary. The scope of the review is broadly summarised below.

Definitions and requirements contained in the Swedish Radiation Safety Authority's regulations on basic provisions for practices with ionising radiation subject to licence (SSMFS 2018:1) have been removed from the appendix to the conditions. Conditions in chapter 1 relating to operations have formed a separate chapter (chapter 8). The structure of chapter 1 has been amended to the same structure as in SSMFS 2018:1. In chapters 2-6, adjustments have been made partly as an adaptation to the authority's increased knowledge of the ESS facility and partly as an adaptation to the changes made in the authority's regulatory project. For chapter 7, the authority has carried out a comprehensive revision of the conditions as a result of increased knowledge of the facility.

In future, the conditions may also need to undergo further revisions in the incremental licencing process in line with ESS presenting more complete technical solutions and more detailed accounts with regard the facility.

Chapter 1: Radiation Safety

A. Scope and Definitions

1. The conditions apply to measures necessary to maintain and develop radiation safety during the construction, ownership, and operation, including the decommissioning, of the ESS facility in order to, as far as reasonably possible and taking into account the best available technology, prevent harmful effects of radiation and prevent unlawful handling of radiation sources. The conditions comprise provisions on technical, organisational, and administrative measures.

2. In these conditions the following terms mean

Facility:	Relevant technical devices and produced radioactive substances, including all structures, systems and components necessary for the handling of radioactive substances and radioactive waste,
Decommissioning:	Measures taken by the licensee after the final shutdown of a facility in order to dismantle and demolish all or part of the facility, and to reduce the amount of radioactive substances in the ground and remaining buildings to levels that enable clearance of the facility,
Normal operations:	Events and circumstances within established conditions and restrictions, which include all operating conditions,
Final shutdown:	Cesssation of the practices for which a facility is built without the intention to resume them,
Radiation source:	Materials or objects which may emit ionising radiation or radioactive substances,
Safety function:	A function that is of importance to the safety of a facility.

B. Reporting of the Facility's Radiation Safety

Safety analysis report

1. A safety analysis report shall describe how the facility's safety, radiation protection, and physical protection are arranged in order to protect people's health and the environment from harmful effects of ionising radiation. The report shall reflect the facility as it is built, analysed and verified, and demonstrate how the applicable requirements on its design, function, organisation and practices are fulfilled. The safety analysis report shall contain, as a minimum, the information stated in appendix 1, and the operational limits and conditions set out in the first paragraph in chapter 8 of condition B1. Changes in the facility shall be evaluated on the basis of the circumstances specified in the safety analysis report. The safety analysis report shall be handled with consideration to the need for confidentiality.

There shall be adequate traceability of the safety analysis report's data relating to requirements, the description of how the requirements are interpreted and enforced, as well as the investigations and analyses that confirm the requirements are fulfilled.

Before the facility may be constructed and before major renovations or major modifications to the existing facility are carried out, a preliminary safety analysis report shall be compiled. Before trial operations of the facility with intentional neutron production may commence, the safety analysis report shall be renewed to reflect the facility as it is built. Before the facility subsequently commences routine operations, the safety analysis report shall be supplemented with an account of the experiences from trial operations.

Both the preliminary safety analysis report and the updated and supplemented safety analysis report shall be safety reviewed at each stage, in accordance with condition 2, and shall be examined and approved by the Swedish Radiation Safety Authority. The safety analysis report shall then be kept up to date.

Safety review

2. A safety review shall be conducted to verify that the appropriate aspects within radiation safety are taken into account, and that the applicable safety requirements on the facility's design, function, organisation and practices are fulfilled. The review shall be conducted in a comprehensive and systematic way, and shall be documented.

The safety review shall be carried out in two steps. The first step, the primary safety review, shall be done within the parts of the facility's organisation responsible for the relevant specialised issue or function. The second step, the stand-alone safety review, shall be done within a review function established for the purpose, and which shall have an independent standing in relation to the speciailised responsible parts of the organisation.

Modifications

3. Modifications of the facility that affect the circumstances specified in the safety analysis report and fundamental changes to the safety analysis report shall, before they may be applied, be safety reviewed in accordance with condition 2 and submitted to the Swedish Radiation Safety Authority. A change notification shall contain a description of the planned modification in relation to the previous design, the reasons for the modification, the assessed consequences of importance to radiation safety, and the documented safety review.

A notification concerning a modification to the facility design shall also include the corresponding change to the safety analysis report, in accordance with condition 1.

C. General Conditions

Physical protection

1. A facility shall have a physical protection, in accordance with section 3 in chapter 2 of SSMFS 2018:1. The design of the protection shall be based on analyses which are taken from the national design-basis threat description and shall be documented in a plan, which shall describe the design, organisation, management and staffing of the protection. The threat analysis and the plan shall be kept up to date and the plan's effectiveness be tested in the form of regular exercises.

Before the facility may be commissioned, the plan for the physical protection shall be safety reviewed in accordance with condition B2, and examined and approved by the Swedish Radiation Safety Authority. Modifications to the plan that affect the physical protection shall be safety reviewed in accordance with condition B2. Modifications shall be submitted to the Swedish Radiation Safety Authority before they may be applied.

Further provisions on the physical protection can be found in chapter 6. Conditions on information security can be found in chapter 7, and on emergency preparedness in chapter 3.

Design

1. The facility shall be designed so that radiation safety is maintained and developed as far as is reasonably possible. The design shall be adapted in part to the functions and tasks that will be performed, and in part to people's abilities and limitations.

Further conditions on design can be found in chapter 4, on mechanical devices in chapter 5, and on physical protection in chapter 6.

D. Organisation, Management and Governance of the Practices

1. The organisational conditions necessary to maintain radiation safety shall be ensured in a systematic and traceable manner, with the support of the management system set out in sections 4 and 5 in chapter 3 of SSMFS 2018:1.

2. In addition to what is stated in section 5 in chapter 3 of SSMFS 2018:1, objectives and guidelines for the practices shall be formulated so that they can be monitored. The management system shall describe how goals and guidelines are developed.

3. Practices shall be planned so that sufficient time and adequate resources are allocated for the safety measures and safety reviews that need to be carried out.

4. Decisions on radiation safety issues shall be preceded by adequate preparation and guidance to ensure a comprehensive promotion and prioritisation of radiation safety. When deciding on radiation safety issues, a documented decision support tool shall be used.

5. The licensee shall appoint a person in the organisation with the task of being the contact person with the Swedish Radiation Safety Authority. The contact person shall have good knowledge of the practices and thereby the associated radiation protection issues. Nothing prevents the radiation protection expert function from being the contact person. The Swedish Radiation Safety Authority shall be kept informed of the contact's name.

Management system

6. Systematic monitoring and evaluation of practices shall be carried out continuously to identify and manage deviations of importance to radiation safety, and to ensure continuous development of the practices in accordance with established objectives and guidelines.

Expertise and suitability in general

7. The training programmes for different categories of personnel shall be documented. Information on the scope and time of each completed training course shall be documented for each person.

Documentation and Archiving

8. Technical facility documentation and safety review reports prepared in accordance with condition B1 shall be stored as long as practices are conducted at the facility.

9. Documentation of the operational activities and other practices of importance to the safety of the facility shall be stored for the time needed to be able to clarify and analyse the causes of events in the facility.

10. An archive shall be maintained in which documentation relating to the practices from a radiation protection perspective is kept. The documentation shall, as a minimum, include that stated in appendix 2. Disposal of the archive, in addition to that stated in appendix 2, shall be in consultation with SSM.

With regard to documentation that is subject to revision, this refers to the last applicable revision, unless otherwise specified.

11. The archive shall be handled and taken care of so that all information can be read and, if necessary, transferred to another data carrier. In matters on the preparation of documents, the choice of materials and methods shall be in accordance with the relevant regulations from the

Swedish National Archives. At present, regulations (RA-FS) are applicable, in accordance with appendix 3.

Documentation that can be hard to read due to age shall be transferred to new data carriers before defects occur. When transferring, it shall be ensured that the information is reproduced correctly.

12. The documentation shall be stored in cabinets or archive premises that fulfil the requirements of the Swedish National Archives regulations on archive premises.

13. When the practices cease and have been decommissioned, the organised and registered archives shall be handed over to the Swedish National Archives.

Safety programme
14. Once a facility has been routinely commissioned, radiation safety shall be continuously analysed and assessed in a systematic manner. This analysis and assessment shall also encompass the applicable rules for the design, construction and operation, as well as design criteria that have been added after the commissioning of the facility. An established safety programme shall be in place for the safety improvement measures, both technical and organisational, resulting from this continuous analysis and assessment. The safety programme shall be evaluated and updated annually.

E. Protection of Workers

Measurement of intake of radioactive substances in the body
1. Measurement of intake of radioactive substances in the body shall be carried out on the affected worker in the event of suspicion of or ascertained intake.

Measurements shall also be carried out on a selection of workers who, in conjunction with their work, have been located in environments with specific risk of intake of radioactive substances.

For measurement according to the second paragraph, the following applies:

a. at least one worker from each work team shall undergo measurement after completion of the work,
b. measurements shall be carried out at least once a month for the work ongoing for a longer period, and
c. if the committed effective radiation dose to a worker is estimated to a total value of 0.25 millisievert or above, all workers who have participated in the relevant work shall be measured.

Results from the measurements shall be evaluated and documented.

2. Measurement of intake of radioactive substances in the body shall be carried out according to a documented procedure approved by the Swedish Radiation Safety Authority. The documentation shall contain an account of the:

a. choice of method,
b. measuring equipment and procedures for the measurement process,
c. expertise of the personnel performing the measurements,
d. methods used to calculate intake and committed effective doses,
e. procedures for evaluating and assessing the obtained measurement results, and
f. procedures for calibration and inspection of the measuring equipment.

F. Protection of the General Public and the Environment: Emmission of Radioactive Substances during Normal Operations

Protection of the general public and the environment
1. The radiological impacts of the practices on the general public and the environment shall be investigated, based on the assessment of events and circumstances carried out in accordance with section 1 in chapter 2 of SSMFS 2018:1. Appendix 4 states what the investigation shall include.

The investigation shall be documented and kept relevant.

2. The radiation dose to members of the general public, in accordance with sections 2 and 3 in chapter 5 of SSMFS 2018:1, shall be calculated using realistic dose models. The licensee shall include the exposure pathways and aspects stated in appendix 5 in the dose calculation.

Uncertainties in assumptions and parameter selection shall be analysed and quantified.

Parameter and method selection shall be based on documented sensitivity analyses.

The annual dose calculation shall consider and integrate each year's emission of radioactive substances calculations over 100 years.

Further conditions on the protection of the general public and the environment with regard emissions of radioactive substances and direct and indirect external exposure during normal operations are found in chapter 2, and for anticipated events with coherent conditions in event classes H2 to H5 in chapter 4.

G. Protection of the General Public and the Environment: Radioactive Waste

Storage of radioactive substances and radioactive waste
1. Storage of radioactive substances or radioactive waste shall take place in installations or areas that are appropriate and adapted for this purpose, and in the manner specified in the safety analysis report, in accordance with condition B1.

Installations or areas for storage of radioactive substances or radioactive waste shall be designed, and the activites in these shall be conducted, taking into consideration the planned storage duration, the storage environment, and the characteristics of the stored radioactive substances or radioactive waste, and how these may change during storage.

When designing and operating an installation or an area for storage of radioactive substances or radioactive waste, the need to inspect the stored material shall be met, as well as the need for a back-up area for the relocation of material.

Waste plan
2. A waste plan, in accordance with section 9 in chapter 5 of SSMFS 2018:1, shall, for radioactive waste expected to arise during trial operations with intentional neutron production, during operations, and during decommissioning, contain information on:

a. how the material is divided into different waste categories,
b. the estimated amounts of the different waste categories,
c. the estimated nuclide content,
d. all of the steps in the handling chain, from when the waste arises through to its clearance, alternatively until it is reused, recycled, or placed in final repository,
e. the timelines for the steps in d,
f. how the selection of methods for disposal of the different waste categories is justified with regard to safety and radiation protection, and

g. the measures taken in order to limit the amount of radioactive waste and the radioactive substances contained therein.

Before the facility is put into trial operations with intentional neutron production, a plan, in accordance with the first paragraph, shall be prepared and included in or attached to the safety analysis report, in accordance with condition B1, and agreements with authorised waste management companies shall be reported if handling and final repository, in accordance with condition d, is not planned to take place in-house.

3. For radioactive waste, including radioactive waste transferred to another facility, procedures shall be in place for verifying that disposal takes place according to the respective plans in condition 2.

Reporting measures

4. For radioactive waste, the measures taken for handling at the facility shall be stated in the safety analysis report for the facility, in accordance with condition B1.

For radioactive waste that is routinely handled at the facility, and which shall not be cleared or transferred to surface repository or landfill, the type description specifications for the types of waste packages intended for storage of the waste for more than five years, or for final repository, shall be attached to the safety analysis report.

Determining the radioactive substances in radioactive waste

5. The content of radioactive substances in radioactive waste to be transferred to final repository without further handling at the facility, or is intended to be stored for longer than two years, shall be determined by a nuclide specific measurement. In those cases where this is not reasonable or possible, the content of radioactive substances shall be determined by other means.

Register of radioactive waste

6. With regard the documention that is required in accordance with section 12 in chapter 5 of SSMFS 2018:1, there shall be access at the facility to a register of items with the radioactive waste that has arisen at the facility or which is located at the facility. The register shall be kept up to date to the extent this is reasonably possible. Each registered waste item shall be clearly labelled for identification. The register shall also contain information on how each waste item that left the facility has been disposed of.

For each waste item, the register shall contain information on:

a. the waste item's identity (labelling),
b. the corresponding type description specification,
c. the origin of the waste, or from which part(s) of the facility the waste comes,
d. any prior processing of the waste and its current physical and chemical form,
e. the quantity,
f. the nuclide-specific content of radioactive substances, with a reference date and uncertainty in the nuclide content,
g. an external radiation level, with distance and reference date,
h. the storage location or final repository, and
i. the date of completed processing - for radioactive waste which is intended to be kept at the facility for longer than two years, the register shall also contain information on the schedule for further handling.

Acceptance criteria for radioactive waste

7. Documented requirements (acceptance criteria) on the properties of the material that may be received for storage or other handling shall be in place. Acceptance criteria shall, as far as reasonably possible, be designed taking into account radiation safety in all stages of continued disposal. The acceptance criteria shall be included in the safety analysis report, in accordance with condition B1.

H. Protection of the General Public and the Environment: Decommissioning

Decommissioning Plan

1. A decommissioning plan, in accordance with section 14 in chapter 5 of SSMFS 2018:1, shall contain information as stated in appendix 6. Fundamental changes to the plan shall be notified to the Swedish Radiation Safety Authority.

Measures relating to final shutdown and service operations

2. When a decision has been made on final shutdown within a specified period at the facility, a comprehensive analysis and assessment of how radiation safety is maintained during the time remaining until the final shutdown shall be made without delay. An analysis and assessment of the need for organisational changes during the shutdown and the staffing requirements during the decommissioning shall also be made.

The analyses, assessments and measures resulting from this process shall be documented and submitted to the Swedish Radiation Safety Authority.

3. Within one year of the final shutdown of the facility, the decommissioning plan shall, in accordance with condition 1, be renewed and submitted to the Swedish Radiation Safety Authority.

The renewed plan, according to the first paragraph, shall include, among other things, an account of which facility areas and equipment will be needed during decommissioning, as well as the preparatory measures that need to be taken prior to dismantling and demolition.

Measures that are required in order to maintain radiation safety during any service operations, and to retain the functions necessary in order to maintain radiation safety during the subsequent stages of decommissioning, shall, during service operations, be described in the safety analysis report, in accordance with condition 2.

Measures in conjunction with dismantling and demolition

4. A written report containing the information referred to in Article 37 of the treaty of 25th March 1957 establishing the European Atomic Energy Community (Euratom) shall be issued to the Swedish Radiation Safety Authority no later than one year before the dismantling and demolition of the facility commences.

5. Before dismantling and demolition of the facility commences, the renewed decommissioning plan, in accordance with condition 3, shall be supplemented and reported to the Swedish Radiation Safety Authority. The facility's safety analysis report shall be revised with regard to the activities planned at the facility. The revised safety analysis report shall be safety reviewed, in accordance with condition B3, and examined and approved by the Swedish Radiation Safety Authority before dismantling and demolition commences.

6. Before the implementation of a subsection, according to the decommissioning plan, may start, a report of the planned measures shall be submitted to the Swedish Radiation Safety Authority. The report shall also include any protective measures planned, in addition to those specified in the facility's safety analysis report, in accordance with condition 5. The choice of methods for

decontamination, dismantling and demolition shall be justified. The report shall include an analysis and assessment of the risks and consequences of importance to radiation safety, and whether these are contained in the facility's safety analysis report.

As per the first paragraph, the report shall be safety reviewed prior to submission, in accordance with condition B2.

After the implementation of a subsection, a report of performed measures shall be issued to the Swedish Radiation Safety Authority.

Documentation and decommissioning report

8. Completed assessments, implemented measures and the results of measurements and calculations shall be continuously documented during the decommissioning.

9. Once dismantling and demolition is completed, a decommissioning report on the implementation of the decommissioning, with descriptions of past experiences and the facility's end state, shall be compiled and submitted to the Swedish Radiation Safety Authority.

I. Protection of the General Public and the Environment: Costs and Funding

1. Before trial operations with intentional neutron production, ESS shall report how the funding is ensured for the costs associated with radiation-safe handling and final repository of radioactive waste, and for a radiation-safe decommissioning and demolition of the facility. The report shall contain:

a. all measures which ESS intends to implement in conjunction with the handling and final repository of radioactive waste that arises during trial operations with intentional neutron production and during routine operations, reported in accordance with conditions G2,

b. all measures that ESS intends to implement in conjunction with the decommissioning and demolition of the facility, including handling and final repository of all decommissioning waste, clearance and land reclamation, reported in accordance with conditions G2 and H1,

c. a calculation of the expected costs for measures referred to in a and b, and

d. an account of how ESS ensures funding for measures referred to in points a and b.

2. When renewing a permit, ESS shall prepare and present:

a. a revised cost estimate that shall contain
   i. the expected costs for measures in accordance with conditions I1a-b and
   ii. an analysis of changes in relation to the previous cost calculation.

b. an account of any changes to how funding is secured for costs of the measures, in accordance with conditions I1a-b.

3. ESS shall notify the Swedish Radiation Safety Authority of significant changes in the statutes that are presented to the ESS Council and which have a bearing on conditions I1-2.

Appendix 1 to Chapter 1

Information in the safety analysis report

In accordance with condition B1, the safety analysis report shall, as a minimum, contain the information listed below. In addition, the report shall, in an appropriate manner and taking into account the need for confidentiality, contain information on the design criteria and layout of the physical protection.

Introduction
A table of contents, reading instructions, definitions, description of the relationship to other safety documentation, and the principles for the handling of the safety analysis report.

Facility site
An account of how, from a safety perspective, the site of the facility and the surrounding area can affect the facility; for example, with regard to population density, air traffic, hydrology, geology and seismic activities, as well as ongoing activities in the surrounding area.

Design rules
An account of the requirements with design principles, as well as the design criteria and design rules, which have governed the facility's design and construction. An account of how the facility meets the specified rules and criteria, as well as how structures, systems and components in the facility have been divided into classes indicating their safety significance.

Facility and function description
A description of the facility's construction and its systems, function and performance during normal operations, including storage and other handling of radioactive substances and radioactive waste. Detailed descriptions of the facility's barriers and safety functions, with the included safety systems. Descriptions of the systems and equipment that, in addition to the safety systems, have proved to be of vital importance to the defence in depth. An account of the principles for the design of control rooms, and other monitoring and control devices, where the interface between personnel and the facility is of importance to safety.

An account of the criteria in order to include equipment in the operational limits and conditions, as well as the principles for determining which functional tests and testing intervals are necessary to verify that the facility is operated within specified limits (operational readiness).

Source terms
An account of supporting documentation for determining the amounts and types of radioactive substances that can be cleared during events and circumstances, so-called source terms.

Emissions
An account of expected nuclide-specific emissions to the environment during normal operations and expected operational disruptions, as well as the measures taken to prevent and minimise the emissions.

Radioactive substances and radioactive waste
An account of handling plans at the facility and the continued disposal of radioactive substances and radioactive waste, in accordance with condition G3. A description of how the handling of radioactive substances and radioactive waste takes place at the facility, taking into account safety and radiation protection, as well as during subsequent handling or disposal, in accordance with the conditions in section G . An account of the measurement methods for determining the amounts and types of radioactive substances in radioactive waste, in accordance with condition G6.

Radiation protection
An account of the

- requirements, prerequisites and control of the practices,
- expected radiation doses during normal operations and measures taken to prevent and limit radiation doses.

Operation of the facility
An account of the organisation and principles for the management and governance of

- operational activities, including control room work,
- maintenance activities, continuous supervision and controls, as well as the management of age-related deterioration and damage,
- the handling of radioactive substances and radioactive waste,
- the radiation protection and safety work at the facility, and
- emergency preparedness for events and circumstances that may have radiological consequences.

A description of the instruction packages used for normal operations, as well as for events that may have radiological consequences.

An account of the principles for the facility's experience feedback system.

An account of the principles for the facility's staffing system, as well as training and expertise evaluation of personnel with tasks of importance to the safety in the practices.

Assessment of operating conditions
An account of the safety assessments in accordance with section 1 in chapter 2 of SSMFS 2018:1, and of the investigations that have been carried out in relation to the facility's performance and environmental impact during normal operations and during events that may have radiological consequences.

Supporting reports
The investigations, assessments and other supporting reports of relevance in demonstrating how the requirements are fulfilled.

Plans
Overview drawings of the facility and its systems, plus flowcharts.

Appendix 2 to Chapter 1

Documentation to be saved and that which may be disposed of

The disposal limitation period indicates the number of years the document shall be saved after it has been archived. The term long-term storage means archiving far into the future; i.e. archiving for a considerably longer period than 100 years.

Type of documentation	**Disposal limitation period**
Applications for permits and all supporting Documentation, as well as issued permits	Long-term storage
Design criteria, facility description	Long-term storage
Operating instructions and disruption instructions related to radiation protection	50 years
Event registration or reporting, and report-worthy events with respect to radiation protection	50 years
Radiation protection instructions	50 years
Data on individual doses in accordance with SSMFS 2008:1	Until the affected individual turns 75, but for at least 30 years after work with ionising radiation ceases
Accident instructions/emergency preparedness plan	25 years
Annual reports in accordance with chapter 2	25 years
Results of measurements of samples in the local environmental monitoring	Long-term storage
Documentation on the properties, treatment and final disposal of generated waste	Long-term storage
Documentation on generated waste at the facility shall be saved there for as long as the waste is located there. When the waste is transferred to other facilities for treatment prior to final repository or for final repository, the responsibility for documentation also transfers to these facilities.	Long-term storage
Meteorological data	5 years

Appendix 3 to Chapter 1

Regulations and general advice published in the Swedish National Archive's statute book (RA-FS) that may be applicable.

2006:1
The Swedish National Archive's regulations and general advice for documents on paper

2010:2
Regulations on amendment to the Swedish National Archive's regulations and general advice (2006:1) for documents on paper

2006:3
The Swedish National Archive's regulations and general advice for documents on drawing film and reprographic film

2006:4
The Swedish National Archive's regulations and general advice on technical requirements and certification

2008:1
Regulations on amendment to the Swedish National Archive's regulations and general advice (RA-FS 2006:4) on technical requirements and certification

2009:1
The Swedish National Archive's regulations and general advice on electronic documents (recordings for automated processing)

2009:2
The Swedish National Archive's regulations and general advice on technical requirements for electronic documents (recordings for automated processing)

2013:4
The Swedish National Archive's regulations and general advice on archive premises

Appendix 4 to Chapter 1

Investigation of the radiological consequences to the general public and the environment

The investigation shall, where relevant, include the following:

1. A description of emission pathways to air and water, including permanent sewer systems and district heating networks.
2. A description of the monitoring systems' design.
3. The expected size and composition of the emission: to be reported nuclide specifically.
4. The expected doses to members of the general public during normal practices and during events, as well as the effective dose to the representative person and the equivalent dose to the representative person in cases deemed relevant.
5. A description of the methods used to calculate the dose, according to point 4.
6. A description of the types and quantities of radioactive waste generated in the practices, as well as the methods for how they shall be disposed of.

A radiological survey of the environment shall be carried out before practices commence, and the effects of the practices on the environment shall be described.

Appendix 5 to Chapter 1

Calculating the dose to the general public

When calculating the annual effective dose to members of the general public, the dose shall be calculated for the representative person, and the following exposure pathways shall be considered:

- External exposure
  - directly from the practices and indirectly from activation of the surrounding environment
  - caused by the year's emission of radioactive substances
  - cause by radioactive substances from previous years' emissions that have accumulated in the environment
- Internal exposure from intake of radioactive substances
  - emitted during the year
  - from previous years' emissions that have accumulated in the environment
- Internal exposure from previous years' intake of radioactive substances from emissions

During calculations for ESS, consideration shall, as a minimum, be given to:

1. relevant radionuclides, taking into account the physical and chemical form,
2. emissions pathways, emission points,
3. other routes of exposure,
4. hydrological and meteorological dispersion conditions,
5. landscape variations,
6. variations in the seabed (for aquatic modeling),
7. geological conditions relevant to grain size,
8. sensitive species and biotopes,
9. ecological conditions,
10. land use in the immediate area,
11. seasonal variations that may affect radiation doses,
12. demographics (population density and age distribution),
13. living habits,
14. consumption patterns,
15. other local conditions that affect the the emissions' form, composition or dispersion in the environment.

Appendix 6 to Chapter 1

Information in the decommissioning plan

In accordance with condition H5, the complete decommissioning plan for a facility shall contain the following information. Other decommissioning plans prepared in accordance with the conditions in section H shall include the information below that can reasonably exist at the relevant time points. Where corresponding information is found in the facility's safety analysis report, or any other documentation, it is sufficient to make reference to this in the form of a summary account in the decommissioning plan. The decommissioning plan shall also include a description of how the facility's safety analysis report will be revised prior to the various stages of decommissioning. This description shall be based on a review of how the Swedish Radiation Safety Authority regulations will be implemented in these stages.

Documentation of the facility

- A current facility description with drawing documentation. The facility description shall be based on a description of the entire facility site, where it clearly states which parts are included in the facility that will be decommissioned.
- A summary of operational data, operational experiences and events that may be of importance to safety and radiation protection during decommissioning.
- A description of the prescence of radioactive substances in the facility after final shutdown.

Scheduling prerequisites

- An account of available or planned systems for the disposal of radioactive wastes and other radioactive materials that need to be disposed of in conjunction with the decommissioning.
- An account of the ultimate objective of the decommissioning.
- An account of planned dates for the start and completion of the different stages of decommissioning. These times shall be justified, among other things, taking into account the presence of radioactive substances in the facility, and access to personnel with experience of the facility's operations and experience in decommissioning activities.

Decommissioning activities

- A description of the planned activities from final shutdown until the decommissioning is completed. This description shall indicate the main sub-elements or sub-projects planned and when these are intended to be implemented. The planning shall be based on an analysis of various approaches for the decommissioning.
- A description of the planned organisation, as well as the management and governance of the decommissioning activities, and the estimated personnel and expertise needs for the different stages.
- An analysis and assessment of the risks and consequences of importance from a safety and radiation protection perspective for the planned activities.
- An account of the estimated radiation doses to personnel and emission of radioactive substances into the environment.
- An account of the estimated quantities of radioactive materials and their activity content, as well as a description of how the materials will be disposed of.
- An account of how the facility's end state will be verified.

Chapter 2: Protection of the General Public's Health & the Environment from Emissions of Radioactive Substances during Normal Operations

A. Scope and Definitions

1. The purpose of these conditions is to protect people's health and the environment from harmful effects of ionising radiation from the ESS facility during operations, when it is decommissioned, and beyond.

Emissions of radioactive substances from the ESS facility may not cause more severe effects on people's health and the environment outside Sweden's borders than those that are accepted within Sweden.

The conditions supplement what is said on the protection of the general public and the environment in section F in chapter 1.

2. These conditions are applicable in the event of emissions of radioactive substances, and direct and indirect external exposure from the ESS facility, both in operation and during decommissioning.

3. Terms and concepts used in these conditions have the same meaning as in the Environmental Code. Otherwise, in these conditions the meanings of the following are:

Local environmental monitoring:	emission controls and monitoring of radioactive substances in the environment in the area surrounding the facility,
Target value:	the level which the emissions of radioactive substances can be reduced to during a certain given period of time, with regard to emitted activity of individual radioactive substances or groups of radioactive substances.

B. General Conditions

1. The provisions in section 7 in chapter 5 of SSMFS 2018:1 shall not be applied by ESS. By optimising radiation protection, the dose to members of the general public shall be limited. The optimisation shall encompass all parts of the facility and a dose constraint of 0.1 mSv per year shall be used as the starting value for radiation protection optimisation, in accordance with section 4 in chapter 5 of SSMFS 2018:1. When limiting the emission of radioactive substances and direct and indirect external exposure from the facility, in accordance with section 5 in chapter 5 of SSMFS 2018:1, the principle of Best Available Technique (BAT) shall be applied. The requirement applies even when the practices, facility, premises, or workplaces are modified. In the event of modifications, measures shall be taken to improve, or at least maintain, the same level of protection for the general public and the environment.

2. An integrated effective dose to members of the general public caused by one year's emission of radioactive substances, and of direct or indirect external exposure from the facility, may not exceed 0.1 millisievert (mSv).

3. The licensee shall show that the dose limit in condition 2 above is met through calculations. See also conditions F1 and F2 in chapter 1.

4. Target values shall be produced for emissions of individual radioactive substances or groups of radioactive substances from the facility.

The Swedish Radiation Safety Authority shall be notified of the produced target values. The supporting documentation for the target values shall be enclosed with the notification.

5. Possible effects on the environment from emissions of radioactive substances, and direct or indirect external exposure from the facility, shall be investigated and documented; see also condition F1 in chapter 1. The investigation shall be based on measured and calculated activity concentrations in the environment and shall be kept relevant.

6. Local environmental monitoring of radioactive substances shall be carried out at the facility.

7. Local environmental monitoring shall be quality assured and documented. The measurement laboratories which ESS uses for environmental monitoring shall, upon request from the Swedish Radiation Safety Authority, participate in comparative measurements.

The requirements relating to organisation, management, and governance, as stated in section D in chapter 1 of SSMFS 2018:1, also apply to environmental monitoring.

8. Representative sub-samples shall be taken annually during spring and autumn from:

a. the main stack's particle filter, in accordance with C2b,
b. the respective emission pathways to water, in accordance with C3, and
c. the surrounding environment, in accordance with the programme referred to in D2.

The samples, together with data on measurement results, detection limits, and measurement uncertainties, shall be sent to the Swedish Radiation Safety Authority as soon as reasonably possible after the samples have been collected.

In addition, representative sub-samples from the particle filter in the main stack, as well as for the respective emission pathways to water, for the month which showed the highest emissions during the calendar year shall be sent to the Swedish Radiation Safety Authority no later than 31st January of the following year.

9. Before the practices are altered so that new radiation sources, emission pathways, or other exposure pathways arise, or an existing exposure pathway is affected, the licensee shall investigate:

a. the size and composition of the emission,
b. environmental and dispersion conditions,
c. anticipated doses to representative members of the general public, and
d. anticipated exposure of other organisms.

The investigation shall be attached to the notification made in accordance with condition B3 in chapter 1. See also condition F1 in chapter 1.

C. Emission Control of Radioactive Substances

1. Emissions of radioactive substances to air and water during operations and during decommissioning shall be monitored through measurement, as far as this is reasonably possible. Each emission location for radioactive substances shall be well marked and the number of emission locations shall be limited.

Detection limits of the measuring instruments shall be selected so that comparisons can be made with the values specified in conditions B2 and B4, and so the conditions in appendix 1 are fulfilled.

2. Emissions to the air from the facility shall be checked by

a. continuous nuclide specific measurements of volatile radioactive substances, e.g. noble gases, and

b. measurement of continuously collected samples of particle-bound radioactive substances, as well as of iodine and tritium.

3. Emissions to water from the facility shall be checked by measuring representative samples for each controlled emission pathway. The checks shall include nuclide-specific measurements of gamma- and alpha-emitters, as well as tritium and total beta.

4. Diffuse leakage from the facility shall be avoided as far as reasonably possible. The prescence of diffuse leakage shall be periodically analysed and evaluated with regard the extent and consequences to the public and the environment. Investigation and analysis documentation shall be documented and kept up to date.

5. The function of the measuring equipment and emission control systems shall be checked on a regular basis, and when there is suspicion of malfunction of these. Written instructions shall be in place for the maintenance of the equipment and systems.

6. When regular measuring equipment is out of service, a compensatory measurement or calculation shall be carried out to such an extent that emission levels can be determined. Scheduled shutdown may only be carried out if operating conditions are deemed stable.

7. The licensee shall, regularly and with appropriate frequency, analyse radioactivity in systems that may affect emissions.

D. Monitoring Radioactive Substances in the Environment

1. Monitoring of radioactive substances in the environment shall be carried out around the facility.

2. The licensee shall develop a proposal on a programme for monitoring of radioactive substances in the environment, which the Swedish Radiation Safety Authority review and approve.

The programme shall specify methods and performance with regard sampling, sample preparation, measurement, analysis, evaluation, and reporting, as well as which sample types and sampling locations shall be used.

Sampling shall be performed by staff with documented expertise for the task.

3. In case of an event that resulted in increased emissions of radioactive substances, or increased direct or indirect external exposure, separate monitoring of radioactive substances in the environment shall be carried out. The evaluation of this shall include an assessment of the radiological consequences for the exposed area.

E. Reporting

1. Emissions of radioactive substances to air and water, in accordance with conditions C1-C3, that are reported as activity emissions, and doses to members of the general public, calculated in accordance with conditions B2 and B3, as well as which measures, with the aim of achieving the target value in accordance with condition B4, that have been taken or are planned in order to limit emissions of radioactive substances, shall be reported to the Swedish Radiation Safety Authority, in accordance with appendix 2.

2. If deviations from conditions C1-C3 occur, or when measurements have been made in accordance with condition C6, reporting of emissions, in accordance with condition E1 shall state which measurement systems have been used during the period in which the report refers, and in what way and how often the measurements have been carried out.

3. Results of monitoring of radioactive substances in the environment shall be reported to the Swedish Radiation Safety Authority in accordance with appendix 3.

4. Events of significance to the general public's exposure shall be reported promptly to the Swedish Radiation Safety Authority, together with an account of the measures that have been taken or are planned to be taken.

F. Archiving and Preservation of Emission and Ambient Samples

1. Provisions on archiving of measurement data and reports that are part of, or are a result of, environmental monitoring can be found in conditions D10-D13 in chapter 1.

Emission and ambient samples shall, as a minimum, be preserved to the extent stated in appendix 4.

The samples shall be clearly marked and stored in a location that prevents theft, other loss, or damage by external influences or fire.

2. When the practices cease, the organised and registered emission and ambient samples shall be handed over to the Swedish Radiation Safety Authority.

Appendix 1 to Chapter 2

Requirements on detection limits

Measurements shall be made with measuring instruments that, **as a minimum**, fulfil the following requirements:

Nuclide	Detection limit requirement (Bq/m^3)
Emissions to air	
Kr-85	1E+4
Xe-133	1E+4
S-35	1E+1
Co-60	1E-2
Sr-90	2E-2
Ru-106	3E-2
Cs-137	3E-2
Pu-239+Pu-240	1E-3
Am-241	5E-3
Cm-242	1E-3
Total-alpha	1E-2
I-129	2E+0
I-131	2E-2
H-3	1E-3
C-14	1E-1
Emissions to water	
H-3	1E+5
S-35	3E+4
Co-60	1E+4
Sr-90	1E+3
I-129	5E+4
Cs-137	1E+4
Pu-239+Pu-240	6E+3
Am-241	5E+1
Cm-242	6E+3
Total-alpha	1E+3

This table will be amended and adapted later in the incremental process. The requirements on detection limits at present come from 2004/2/Euratom, which apply to nuclear power reactors and reprocessing facilities during normal operations.

Appendix 2 to Chapter 2

Reporting of emissions

Reporting of emissions shall be done annually to the Swedish Radiation Safety Authority, and the results shall be summarised by month.

Emissions of radioactive substances to air and water shall be reported in accordance with conditions C1-C3.

Measures which, with the aim of achieving the target value in accordance with condition B4, have been taken or are planned in order to limit emissions of radioactive substances shall be reported.

The following apply for all reporting:

- detection limits shall be specified for each radionuclide that are included in the source term
- measured results of an approved quality shall always be reported
- every radionuclide where at least one measurement result is over half the detection limit during the current reporting period shall be reported
- the reporting period normally used is one month, unless otherwise specified and justified
- measurement results that are below half the detection limit shall be reported as a quarter of the detection limit
- all measurement results that are above half the detection limit shall be reported with a measured value
- zero results can only be reported if approved analysis results are missing and if it has not been possible to detect the nuclide at any time during the reporting period
- where measurements of a radionuclide have not been technically feasible, calculation-based estimates shall be made.

An annual report covering the previous calendar year shall be submitted to the authority on an annual basis, no later than 31st March. The annual report shall summarise:

- all emissions to air and water from the facility during the year,
- an integrated effective dose to the representative person,
- diffuse emissions,
- uncertainties in the measurements and detection limits,
- any calculation-based estimates and uncertainties,
- all results, as well as a discussion on the outcome and evaluation of the trends and events with regard to the emissions, and
- measures which, with the aim of achieving the target value in accordance with condition B4, have been taken or are planned in order to limit emissions of radioactive substances.

The annual reports shall also contain a summary of all the occasions regular measurement systems for control of emissions to air have been out of order. The period the system has been out of order, the cause, the estimated size of the emission during the shutdown period, and method for determining the size of the emission shall be specified for each occasion.

Appendix 3 to Chapter 2

Reporting of monitoring of radioactive substances in the environment

Results from monitoring of radioactive substances in the environment shall be reported to the Swedish Radiation Safety Authority no later than 31st March of the year following the year covered by the report.

The annual report shall summarise

- measurements performed during the year,
- major deviations from the sampling programme,
- uncertainties in the measurements and detection limits.

The annual report shall contain an analysis of the controls performed and the results obtained.

Appendix 4 to Chapter 2

Preservation of emission and ambient samples

Sample type	Preservation period	Sample form
Air filter - aerosol	10 years	Paper filter
Air filter - iodine	3 months	Carbon cartridge
Emissions water - monthly sample	2 years	Representative monthly samples for each controlled emission pathway per year. The samples shall be stabilised and a sufficient amount shall be preserved to be able to perform complementary measurements.
Emissions water - sample from the month that showed the highest emission during a calendar year	10 years	
Other ambient samples	10 years	

Chapter 3: Emergency Preparedness

Basic provisions regarding emergency preparedness and crisis management can be found in sections 4 and 5 in chapter 2 of SSMFS 2018:1. For practices with ionising radiation subject to licence, emergency preparedness and crisis management shall be adapted to the emergency preparedness category in which the practices are placed. Emergency preparedness and crisis management shall be described in an emergency preparedness plan. The aim of the conditions is, among other things, to clarify the importance of maintaining and developing emergency preparedness.

A. Scope and Definitions

1. These conditions are applicable to emergency preparedness activities at ESS, classified as a facility in emergency preparedness category II (SSM2018-1037-5) in accordance with the Swedish Radiation Safety Authority's regulations on basic provisions for practices with ionising radiation subject to licence (SSMFS 2018:1).

2. In these conditons, the following terms mean:

Severe deterministic health effects:	deterministic health effects that are life threatening or result in permanent damage,
Deterministic health effects:	damage from ionising radiation that occurs when the radiation dose exceeds a threshold value, which is different for different health effects, and where the severity increases with an increasing radiation dose,
Crisis management:	measures and methods that are taken in order to manage an arising radiological emergency,
Crisis organisation:	an organisation that manages and limits the consequences of an emergency, until its activities transfer into an organisation for continued care of the facility,
Criteria for information:	event descriptions established by the facility and which are adapted to a level for information,
Criteria for alarm level:	detailed technical or radiological conditions or event descriptions established by the facility and which are adapted to the level for alarms,
Source term assessment:	an estimation of the quantity and composition of radioactive substances that have been released or may be released into the surrounding area in the event of emission of radioactive substances from the facility,
Emergency lighting:	lighting equipment that starts automatically, or continues to illuminate, in the event of a interruption in the normal lighting,
Radiological emergency:	a situation that arises as a result of a sudden occurred event involving a radiation source, which has caused or may be feard to cause harm and which requires immediate measures,
Stochastic health effects:	damage from ionising radiation that may occur without a threshold value being exceeded, where the probability of damage increases with an increased radiation dose and whose severity is independent of the radiation dose,
Access restricted area:	an area where the general public does not have access.

B. Emergency Preparedness Planning

1. The facility's emergency preparedness and crisis management shall be based on scenarios founded on events and circumstances in event class H1-H5, but is not limited to these.

2. The licensee's management system shall state where in the regular organisation the tasks, responsibilities and authorities for emergency preparedness planning are found. The licensee shall allocate sufficient resources for emergency preparedness activities. Experience from occurred events and discovered conditions that have occurred at similar facilities shall be taken into account when planning the crisis management.

3. A prepared crisis organisation shall be in place which is set up when there is a risk of, or in conjunction with, a radiological emergency at the facility.

4. The licensee shall prepare a comprehensive document, an emergency preparedness plan, which:

a. describes the scenarios on which the emergency preparedness and crisis management are based,
b. describes the crisis organisation and its main tasks, responsibilities, premises, resources and collaboration, as well as the foreseen activities in order to manage a radiological emergency at the facility, and
c. gives references to the documentation that provides operational support for the crisis organisation.

5. The emergency preparedness plan and documents for operational support to personnel shall be kept up to date and tested, in the form of regular exercises.

6. The capability of the crisis organisation shall be verified via a full-scale drill before trial operations with intentional neutron production may commence.

7. The emergency preparedness plan shall be coordinated with procedures for operational service which are applied in the event of radiological emergencies, procedures for physical protection, and with other concerned parties' emergency preparedness plans.

8. The emergency preparedness plan shall be safety reviewed, in accordance with condition B2 in chapter 1, and approved by the Swedish Radiation Safety Authority before the facility may be taken into trial operations with intentional neutron production.

9. Alterations to the emergency preparedness plan of importance to radiation safety shall be safety reviewed in accordance with condition B2 in chapter 1. Before the alterations may be applied, they shall be submitted to the Swedish Radiation Safety Authority.

10. The crisis organisation shall, with regard staffing, response time, sustainability, equipment, tools, appropriate premises and collaboration with concerned parties, be configured to be able to manage and limit the consequences of the scenarios which, in accordance with condition 4a, shall be described in the emergency preparedness plan.

11. The licensee shall take the measures necessary so that emergency services, the police, and other concerned parties that can be expected to arrive at the facility during a radiological emergency, are able to use their regular radio communication systems. The measures shall encompass the access restricted area, as well as the buildings and areas prioritised for access.

12. The crisis organisation shall be able to manage a long-term radiological emergency until its activities transfer to an organisation for the continued care of the facility.

C. Alarms and Summoning of Personnel

1. The licensee shall develop criteria for decisions on alarm levels and levels for information that are adapted to the levels:

a. Alarm level area alarm
   Event or circumstance where emissions of radioactive material, which call for protective measures for the general public, have taken place, are ongoing, or cannot be ruled out.

b. Information on the incident
   Event or circumstance that cause damage or risk of injury to workers or facility has occurred. Specific support is needed in order to manage the event or the circumstance. No protective measures for the general public need to be taken.

The criteria for alarms shall be safety reviewed, in accordance with condition B2 in chapter 1, and approved by the Swedish Radiation Safety Authority before the facility may be taken into trial operations with intentional neutron production. Changes in the criteria for alarms that are of importance to radiation safety shall be submitted to the Swedish Radiation Safety Authority.

2. If a criterion for an alarm has been met, then:

a. An alarm shall be triggered, in accordance with condition C1a, and
b. the Swedish Radiation Safety Authority shall be notified within one hour with the information pertinent to condition C1 in chapter 8.

3. If a criterion for information has been met, the Swedish Radiation Safety Authority shall be notified as soon as possible.

4. The licensee shall have equipment, as well as documented procedures, for triggering area alarms.

5. The licensee shall have documented procedures and access to systems in order to summon the crisis organisation. Recurring verification of contactability and response time for workers in the crisis organisation shall be implemented and documented.

6. It shall be possible to give an alarm signal inside buildings, as well as outdoors throughout the access restricted area where immediate protective measures may be relevant. It shall be possible to give announcements at each meeting point in conjunction with an alarm signal.

7. It shall be possible to trigger an alarm signal from at least two, entirely separate, locations at the facility.

8. The alarm signalling system shall be regularly tested. The licensee shall have documented procedures for testing and inspecting the alarm signalling system.

9. During practices that involve the central control room being manned, there shall be workers in the staff who have the expertise to independently assess whether a criterion for alarm is met, and who has the authority to immediately decide on triggering an alarm at the appropriate level. In the event practices at the facility do not involve a need for staffing of the central control room, there shall be workers who are always reachable and have the power to immediately decide on triggering an alarm at the appropriate level. The worker shall be able to arrive at the facility within one hour.

10. The starting point for activating and setting up the crisis organisation shall be the conditions which, in accordance with condition B4a, shall be described in the emergency preparedness plan.

D. Permanent and Alternate Command Centre

1. The licensee shall have a permanent command centre within or directly adjacent to the facility site, from where the crisis organisation normally can govern activities in the event of a radiological emergency.

2. The licensee shall have an alternate off-site command centre, to which the management function can be relocated if the permanent command centre cannot be used. A documented instruction for the relocation shall be in place.

3. The licensee shall have documented procedures and equipment available to prevent contamination by radioactive substances in connection with entry into the permanent command centre, the alternate command centre, and the central control room.

4. The permanent command centre shall have access to back-up power.

5. An intercom system, which is independent of public communication systems and enables continuous verbal two-way communication, shall be located in the permanent and the alternate command centres.

6. A workstation for a representative from the Swedish Radiation Safety Authority shall be available in the permanent and the alternate command centres. This workstation shall have access to the Internet and telephony, as well as radio coverage for the Rakel communications system.

E. Meeting Point

1. The licensee shall ensure that there are clearly marked meeting points at the facility, to which those people without designated tasks within the emergency preparedness organisation shall go in the event of an emergency.

2. At each meeting point, there shall be
   a. documented instructions on which measures shall be taken at the meeting point,
   b. communication devices that enable contact with both the permanent and the alternate command centres, and
   c. emergency lighting.

F. Iodine Tablets

1. If there is a risk of emission of radioactive iodine, the licensee shall ensure that there are enough iodine tablets for those people located within the facility site.

2.There shall be documented instructions on how the tablets shall be stored, distributed and consumed.

G. Personal Protective Equipment

1. The licensee shall ensure that personal protective equipment is available at, or in close proximity to, the facility for all personnel involved in, or called in to support, the crisis organisation.

2. The licensee shall have a documented action plan on how additional protective equipment can be supplied to personnel at the facility.

3. The licensee shall have documented procedures for individual dosimetry in the event of a radiological emergency. The procedures shall include how the dosimeters and associated evaluation equipment shall be handled, and how doses to personnel shall be registered and monitored.

H. Protective Measures

1. In the event of a radiological emergency, the llicencee shall:

a. take urgent protective measures according to a documented and tested plan,
b. in conjunction with an evacuation, as far as reasonably possible, verify that relevant areas and spaces have been evacuated;
c. carry out contamination checks of individuals that are suspected of having been externally contaminated with radioactive substances. If contamination is ascertained, individual decontamination shall take place, in accordance with documented procedures, and
d. take measures according to documented procedures in case of suspected acute radiation damage or suspected internal contamination.

I. Expertise, Training and Drills

1. The licensee shall ensure that all individuals at the facility are informed on what alarm signals mean, where the meeting points are located, and which urgent protective measures may need to be implemented.

2. The licensee shall have specified expertise requirements, as well as short- and long-term training and drill plans, for workers within the crisis organisation.

3. The participation of workers in training courses and drills shall be documented and preserved for each individual. Documented procedures shall be in place to monitor the expertise of workers in each position within the crisis organisation.

4. Experiences from completed drills shall be documented and form the basis for developing the crisis organisation.

5. All individuals who, during or after an emergency, may possibly carry out responses in places where there is risk of high radiation doses or extensive personal contamination by radioactive substances, shall have knowledge of the working methods and radiation protection measures that apply in such an environment.

J. Contact with the Swedish Radiation Safety Authority

1. In the event of an emergency when the crisis organisation has been set up, the licensee shall ensure that there are designated workers who are responsible for being in contact with the Swedish Radiation Safety Authority on matters concerning radiation protection.

K. Meteorological Data

1. The facility shall be designed with equipment so that, as far as reasonably possible, measurement and monitoring of relevant meteorological data that is representative of the facilicty can occur.

2. Current relevant meteorological data representative of the facility shall be continuously measured, recorded and transferred to the Swedish Radiation Safety Authority in the format and with the method determined by the Swedish Radiation Safety Authority. Appendix 1 specifies the

requirements that meteorological equipment shall fulfil and how notification prior to interruptions, and reporting and documentation during and after interupptions, shall be done.

3. It shall be possible to read registered meteorological data for the last 24 hours from the permanent surveillance centre, the permanent command centre, and from the central control room.

L. Source Term Assessment and Dose Calculation

1. The licensee shall ensure that expertise, tools and documented instructions are in place in order to be able to:

a. perform a source term assessment during a radiological emergency at the facility, and
b. calculate and assess radiation doses in the event of emission of radioactive substances before, during and after a radiological emergency. It shall be possible to calculate and assess radiation doses within the access restricted area.

M. Radiation Monitoring

1. The licensee shall ensure that there is stationary measuring equipment, so that continuous radiation monitoring can take place in:

a. the permanent command centre, the central control room, the surveillance centre and other areas that are expected to be manned long-term in conjunction with a radiological emergency.
b. spaces and areas that are prioritised during evacuation from the facility in conjunction with a radiological emergency, and
c. expected emission pathways for radioactive substances to the surrounding area of the facility in conjunction with a radiological emergency. Measurement values shall be recorded and be possible to read centrally from any location in the facility.

2. Measurement equipment, in accordance with condition 1a, shall also be designed with an alarm so that workers in the relevant area can be made aware of a radiation level above the set alarm limit.

N. Ventilation

1. The facility shall be designed with filters which absorb radioactive substances in the ventilation pathways for the air supply to the central control room, permanent command centre, and surveillance centre.

O. Quality Assurance of Equipment

1. The licensee shall, in addition to what is stated in condition C8, ensure that equipment and tools which are part of the crisis organisation are subject to condition B8 in chapter 9 with regard maintenance, continuous supervision, and inspection.

Appendix 1 to Chapter 3

Meteorological data

1. Requirements for certain meteorological equipment

The equipment shall measure the:

1. wind direction and wind speed at a height of approximately 10 metres above ground level,

2. temperature at a height of approximately two metres and approximately 10 metres, and

3. temperature, wind direction and wind speed at a height which, as a minimum, corresponds to the facility's highest point of emission.

2. Notification and documentation

- Equipment to be used for measuring meteorological data , in accordance with condition K1, may, without special notification to the Swedish Radiation Safety Authority, be out of operation for a maximum period of 24 hours for maintenance of the equipment.
- Faults in the equipment that are not addressed within 24 hours shall be reported to the Swedish Radiation Safety Authority
- When regular equipment is out of service, meteorological data representative for the facility shall be collected in other ways.
- Shutdown which is planned and intended to last longer than 24 hours shall be notified in advance to the Swedish Radiation Safety Authority. The notification shall state the reasons for the shutdown and which method of compensatory collection of meteorological data shall be used.
- Maintenance or malfunction causing disruptions, regardless of the length of the disruption, shall be documented.

Chapter 4: Design and Construction, and Safety Assessment

A. Scope and Definitions

1. The conditions apply to measures necessary to maintain and develop safety in the design and construction of the ESS facility, and shall apply from when the licensee has received its first permit until the facility is permanently shut down. The conditions shall also apply to new designs and modifications of the ESS facility. Furthermore, the conditions deal with safety analysis and its prerequisites.

2. In these conditions, the following terms mean:

Acceptance criteria: specified threshold values for a functional or conditional indicator used to assess whether a structure, a system, or a component fulfils the requirements on safety,

Operational group: a specific composition of the structures, systems and components, including manual actions, required to perform all the safety tasks necessary to manage a specific event or a specific circumstance so that this does not lead to increased radiation levels, as well as limiting the dispersion of radioactive substances within the facility and enabling the facility to return to normal operations,

Fundamental safety functions: safety functions necessary to fulfil the facility's safety requirements during all events and circumstances,

Event class: a class of events and circumstances used during the design and deterministic analysis. In these conditions, the following event classes are used, based on frequencies:

Normal operations (H1):
events and circumstances within the defined conditions and restrictions, which include all operating conditions,

Anticipated events (H2):
events and circumstances outside the defined conditions and restrictions that can be expected to occur during the facility's lifetime. The frequency range is greater than or equal to 10^{-2} per year,

Unanticipated events (H3):
events and circumstances outside the defined conditions and restrictions that are not expected to occur during the facility's lifetime. The frequency range is greater than or equal to 10^{-4} but less than 10^{-2} per year,

Improbable events (H4A):
events and circumstances outside the defined conditions and restrictions that are not expected to occur. The frequency range, excluding external sources of risk, is greater than or equal to 10^{-6} but less than 10^{-4} per year. For external sources of risk, the frequency range is greater than or equal to 10^{-5} but less than 10^{-4} per year,

Events with multiple failures (H4B):
events and circumstances outside the defined conditions and restrictions in the frequency range greater than or equal to 10^{-4}

	per year, in combination with common cause failures in a safety group, Highly improbable events (H5): events and circumstances outside the defined conditions and restrictions in the frequency range greater than or equal to 10^{-7} but less than 10^{-6} per year. The event class shall include events and circumstances with extensive release of radioactive substances,
Mitigating group:	a specific composition of the structures, systems and components, including manual actions, required to perform all the safety tasks necessary to manage a specific event or a specific circumstance with extensive damage to the radiation sources, so that radioactive emissions to the surrounding area are as low as is possible and reasonable,
Hazards:	internal and external events and circumstances, the consequences of which threaten to knock out part or all of the fundamental safety functions,
Respite:	the period of time necessary to identify and analyse a situation, carry out assessments and make decisions, as well as implement actions, in any given situation,
Structures, systems and components (referred to in Swedish as SSK):	a general term that covers all physical parts of the facility,
Structures, systems and componentsof importance to safety:	all structures, systems and components that contribute to the management of events and circumstances in event classes H1-H5,
Safety function:	a function that is of importance to the safety of a facility,
Safety group:	a specific composition of the structures, systems and components, including manual actions, required to perform all the safety tasks necessary to handle a specific event or a specific circumstance so that the consequences, in the form of increased radiation levels or dispersion of radioactive substances, are minimised, and extensive damage to radiation sources is counteracted,
Safety-related systems, structures and components:	all structures, systems and components that contribute to the management of an event or circumstance, and which are not a safety structure, safety system, or safety component,
Safety structure, safety systems and safety components:	all structures, systems and components that contribute to the management of events and circumstances in event classes H2-H4A so that the consequences, in the form of increased radiation levels or dispersion of radioactive substances, are minimised, and extensive damage to radiation sources is counteracted.
Safe state:	a condition where the fundamental safety functions can be ensured and maintained for a long time following all events and circumstances in the event classes ‘anticipated events’,

‘unanticipated events’, ‘’improbable events’, ‘events with multiple failures’, or ‘highly improbable events’ (H2-H5).

B. Overall Conditions for the Design

Radiation doses and design criteria

1. The facility shall be designed so that radiation doses to people and the environment are as low as is possible and reasonable during events and circumstances that may arise. Radiation doses may not exceed prescribed dose limits and conditional design criteria in accordance with condition D10.

Defence in depth, including barriers

2. The facility shall be designed to maintain an adapted defence in depth for all aspects of the practices, including handling and storage of all radioactive materials, as well as organisation, management and governance, which prevent events and circumstances that may result in radiation protection-related consequences. The design shall consist of physical barriers to prevent the emission of radioactive substances and direct irradiation into the surrounding area.

3. Measures for the facility’s safety shall be divided into defence in depth levels with the following objectives, or their equivalent:

a. to prevent deviations from normal operations and faults in structures, systems and components (defence in depth level 1),
b. to detect deviations from normal operations and verify that the deviations do not lead to increased radiation levels or dispersion of radioactive substances within the facility (defence in depth level 2),
c. to minimise the consequences of events and circumstances that lead to increased radiation levels and limit the dispersion of radioactive substances, as well as counteract extensive damage to radiation sources (defence in depth level 3),
d. to ensure that radioactive emissions to the surrounding area as a result of events and circumstances with extensive damage to radiation sources are as low as is possible and reasonable (defence in depth level 4), and
e. to mitigate the radiological consequences of emissions to the surrounding area that may result from events and circumstances with extensive damage to radiation sources (defence in depth level 5).

C. The Defence in Depth Principle and Safety Principles

Fundamental safety functions and implementation of defence in depth, including barriers

1. During the design of the facility, specific design solutions, as well as measures and administrative procedures for the operation, shall be developed so that the fundamental safety functions can be maintained to the extent necessary, depending on the state of the facility, for all levels of defence in depth, events and circumstances.

2. The structures, systems and components of importance to safety which are needed to maintain the fundamental safety functions, and the integrated features that contribute to or affect the maintenance of these fundamental safety functions, shall be identified in a systematic manner for all events and circumstances.

3. It shall be possible to monitor the facility in such a way so it can be ensured the necessary safety functions are maintained.

4. The facility shall be designed so that all barriers and all parts of the defence in depth can be in service when the facility is operational, and so that compensatory measures can be taken when any barrier or any part of the defence in depth has been put out of service.

5. The facility shall be designed so that events and circumstances that are anticipated to occur during the facility's lifetime can, as far as possible and reasonable, be managed through the measures and the structures, systems and components that maintain the fundamental safety functions in defence in depth levels 1 and 2.

6. The facility shall be designed so that structures, systems and components that maintain the fundamental safety functions in defence in depth levels 2, 3 and 4 respectively can take the facility to a safe state in conjunction with relevant events or circumstances.

7. A failure of a structure, system, or component of importance to safety, a wrongdoing at a level in the defence in depth, or combinations of failures that simultaneously occur at different levels, shall not be able to jeopardise the function at subsequent levels. An additional strength in a barrier or defence in depth level may not be credited in order to accept weaknesses in another barrier or defence in depth level.

Structures, systems and components of importance to safety shall, as far as possible and reasonable, be independent from the structures, systems and components of importance to safety in other defence in depth levels, as follows:

a. defence in depth level 4 shall be independent of defence in depth levels 1-3, and
b. defence in depth level 3 shall be independent of 1 and 2.

Safety classification

8. All structures, systems and components of importance to safety shall be classified based on their function and safety significance.

9. The assessment of safety significance shall primarily be based on deterministic methods supplemented, in cases where it may be considered appropriate, with probabilistic methods or engineering considerations.

The assessment shall take into account such factors as the frequency of how often a safety function will be required, the potential consequences of malfunctions, as well as the time available for the activation of a safety function in conjunction with an event or circumstance.

For structures, systems and components of importance to safety that perform multiple functions, the function that has the greatest importance to safety shall be decisive during classification.

10. Structures, systems and components of importance to safety shall be designed, constructed and maintained in such a way that their quality and reliability are consistent with their importance to safety.

Event classification

11. The facility shall be designed so that events and circumstances with a high occurrence frequency have no or only minor safety-related consequences, while events and circumstances that may result in serious consequences shall have a very low anticipated occurrence frequency.

12. Identified events and circumstances that affect the facility shall be divided into the following event classes:

- Normal operations (H1)
- Anticipated events (H2)
- Unanticipated events (H3)

- Improbable events (H4A);
- Events with multiple failures (H4B) and
- Highly improbable events (H5).

Design availability, reliability and durability against failure

13. Structures, systems and components of importance to safety shall be based on proven technologies and proven methods, and be tested before use.

If parts of structures, systems and components of importance to safety are based on lesser proven technologies or methods, these shall be compensated with research and increased testing of the technologies or methods.

14. Facility structures, systems and components of importance to safety shall be designed with a high quality and reliability so that their function, at the environmental conditions, loads, and other effects that may arise can be ensured during the events and circumstances in which they shall contribute to the fulfilment of the fundamental safety functions.

A high quality in structures, systems and components of importance to safety shall be obtained through the appropriate selection of standards, materials, and manufacturing, installation and qualification processes.

15. The time during which the facility's structures, systems and components of importance to safety can be used in a safe manner shall be determined in the design.

Sufficient margins shall be in place against aging and other degradation to ensure functionality and integrity during the designed lifetime.

16. Facility structures, systems and components of importance to safety shall be designed so that sufficiently high quality can be maintained throughout the intended lifetime.

It shall be possible to maintain quality by structures, systems and components of importance to safety by that they are, inspected, tested, monitored, maintained, calibrated, repaired and replaced to the extent necessary in order to ensure proper function and maintain integrity during the facility's lifetime in a manner that ensures radiation protection for workers.

17. If structures, systems and components of importance to safety are not of, or cannot be maintained to, a sufficiently high level, conservative safety margins, indirect control methods, and other precautionary measures shall be applied which can compensate for unforeseen failures.

18. Safety groups credited for events and circumstances in event class H2- H4A and mitigating groups shall, as far as possible and reasonable, be designed so that the fundamental safety functions can be maintained when an arbitrary independent failure occurs in a random structure, system or component, regardless of operating conditions.

19. The facility's safety groups shall be designed so that the redundant parts within each safety group have sufficient physical and functional separation to prevent the safety group's function from being knocked out directly or as a result of the same event or circumstance.

Separation within the safety groups shall, to a sufficient extent, be possible to maintain at all times and in all operating conditions, and in all other circumstances that are anticipated to possibly arise at the facility during maintenance, testing, repair or shutdown.

20. During the design, construction and operation of the facility's fundamental safety functions, technical and administrative measures shall be taken that can counteract common cause failures as far as possible and reasonable.

21. Safety groups credited for events and circumstances in event class H4B shall, as far as possible and reasonable, be designed so that the fundamental safety functions can be maintained when an arbitrary, independent common cause failure occurs in two or more safety structures, safety systems, or safety components, regardless of operating conditions.

22. In the event of a failure in structures, systems and components of importance to safety, an acceptable and preferential state that for the safety of the facility is beneficial shall be adopted for these, as far as this is possible and reasonable.

23. The design of the facility shall ensure that structures, systems and components belonging to a higher safety class are protected against the effects of possible malfunctions of the structures, systems and components belonging to a lower safety class.

Passive functionality, automation and respite
24. The function of the facility's safety and mitigating groups shall be passive or designed so that the necessary operational state change of these occurs automatically, as far as is possible and reasonable.

25. The design shall allow, if manual operational state change of a safety or mitigating group is necessary, that the following prerequisites are fulfilled:

a. Respite exists for detection, analysis, decision and action.
b. Instructions are in place that stipulate prerequisites in order for measures to be implemented within the time available, which also take into account the performance-influencing factors and other simultaneous tasks.
c. The measure is supported with instrumentation necessary to monitor the facility's status, in order to be able to deduce the effects of automatically controlled activations, and which gives a clear indication and information on the need for manual actions.
d. All of the equipment necessary for operator actions is positioned so that it is accessible and so that access to it is safe with regards the environmental changes that may arise.
e. An evaluation is made of the risk that an incorrect measure or wrong conclusion regarding the appropriate way to bring the facility to a safe state exacerbates a sequence of events.

Design limits and operational limits
26. A set of conditions for operations adapted to the facility, which ensure that the design limits are included, shall be established and form the basis of the operational limits and conditions.

Man, technology and organisation
27. The facility's design shall be adapted to the personnel's ability to be able to monitor and manage the facility in all events and circumstances.

This shall be done by that systematic consideration of the man-technology-organisation interaction have been included throughout the entire design process. Proven systematic methods and appropriate standards shall be used to address these factors in the design process.

28. The facility shall be adapted to the ability of the personnel by:

a. premises, workplaces and equipment following established and appropriate standards and guidelines for ergonomic design,
b. interaction between personnel and the facility being encouraged in all events and circumstances,
c. the need for collaboration and communication in the work being satisfied,

d. personnel being able to perform their tasks in a reliable manner with regard to performance-impacting factors, such as available time, expected surrounding conditions and cognitive demands on the personnel,
e. other prerequisites of importance to radiation protection and safety having been identified and captured in the design.

29. A control room shall be in place at the facility so that the fundamental safety functions and the protection of these can be monitored and governed during all events and circumstances.

D. Prerequisites for Safety Assessment

Dimensioning and verification of the facility's design
1. Deterministic and probabilistic methods shall be used to analyse and evaluate the facility's defence in depth, with the associated barriers, and the facility's ability to fulfil the fundamental safety functions.

The analyses shall be facility-specific and include all radiation sources in the facility.

Identification of events and circumstances
2. Events and circumstances that can affect safety shall be identified. The identification shall be based on:

a. the circumstances at the facility site and its surroundings,
b. experiences from the current facility, as well as other complex facilities
c. results of deterministic analyses,
d. results of analyses with probabilistic methods, and
e. other circumstances, analysis results or experience of importance to safety.

This identification process shall take into account the appropriate standards, engineering-related assessments and other applicable evaluation of the facility.

3. The impact of events shall be considered as being part of the sequence of events in the identification.

4. During the identification of events and circumstances, reasonable combinations of individual, independent events and circumstances shall be taken into account.

5. Events and circumstances not specified as postulated may be excluded from further evaluation if it can be shown that they result in a negligible risk contribution or that any negative effect on safety cannot reasonably occur.

Event classification and reference values
6. Events and circumstances shall be assumed to occur during those circumstances that involve the greatest negative consequence for safety.

7. When an event or circumstance is only assumed possible to take place during given normal operating conditions, the time-scale of these may be taken into account in the frequency determination.

8. If the frequency of a certain event or a certain circumstance is uncertain, or if it is on the border between two event classes, it shall be placed in the event class with the higher frequency range.

9. For events and circumstances that have the potential to affect various safety parameters in the facility, the most challenging acceptance criteria shall be identified for each event class.

10. For the event classes 'anticipated events', 'unanticipated events', 'improbable events', 'events with multiple failures' and 'highly improbable events' (H2-H5), the design criteria according to the following shall be contained.

a. Design criteria with regard the effective dose to members of the general public

Event class	Design criterion (mSv)
Anticipated events (H2)	0.1
Unanticipated events (H3)	1
Improbable events (H4A)	20
Events with multiple failures (H4B)	20
Highly improbable events (H5)	100

b. For a worker with a credited manual task, motivated and substantiated design criteria with regard effective dose shall be applied.

c. Design criteria with regard the effective dose from iodine to the thyroid gland of a one-year old child from the general public

Event class	Design criterion (mSv)
Anticipated events (H2)	1
Unanticipated events (H3)	10
Improbable events (H4A)	100
Events with multiple failures (H4B)	100

Acceptance criteria

11. For the event classes 'anticipated events', 'unanticipated events', 'Improbable events', and 'events with multiple failures' (H2-H4B), qualitative acceptance criteria shall be derived from the design criteria and established in order to verify the barrier's integrity against the emission of radioactive substances.

To demonstrate that these qualitative acceptance criteria are met, quantitative acceptance criteria shall be identified. Such quantitative acceptance criteria shall be based on the identified physical phenomena, and supported by experimental data.

12. To ensure that the derived qualitative and quantitative acceptance criteria are not exceeded, and, by extension, that the reference values can be included, the acceptance criteria for structures, systems, and components shall be specified based on the most challenging events, in accordance with conditions C11-C12.

Once the acceptance criteria are defined, conservatism shall be incorporated in order to include the uncertainties.

E. Safety Assessment

General conditions for safety assessment

1. All identified events and circumstances, in accordance with condition D2, shall be assessed. Events and circumstances may be omitted from the assessment it it can be justified by that other events and circumstances in the same event class are covering these. The assessments shall be kept up to date.

2. During a safety assessment, the following aspects shall be taken into account:

a. that assumptions, limitations, and selection of input data for analyses are justified and reasonable, and

b. that analyses are documented.

General conditions for deterministic analyses

3. Deterministic analyses shall show how design criteria for events and circumstances in event class H2-H5 are included, by referring to quantitative acceptance criteria.

4. The deterministic analyses shall be used as supporting documentation for:

a. dimensioning of the facility design,
b. verification that the facility design meets the developed design limits and requirements,
c. development and verification of operating limits and operating conditions so that they are consistent with the facility design,
d. identification of necessary manual actions and assessment of the degree to which instructions, instrumentation, and anything else governing these actions are appropriate, and
e. other relevant areas.

5. Models and calculation software used for deterministic analyses of safety and environmental consequences shall be verified and validated. If analytical methods are applied outside the area they are verified and validated for, this shall be evaluated and the increased uncertainty taken into account.

6. Data shall be quality assured and uncertainties shall be considered in the results of analyses. The uncertainties shall be taken into account by using either:

a. conservative analyses,
b. realistic methods and conservative assumptions combined with sensitivity analyses, or
c. realistic methods and realistic assumptions combined with statistical uncertainty analysis.

For all options, system availability shall be conservatively assumed.

Deterministic analyses of safety

7. Assumptions made to simplify the analysis, as well as assumptions regarding the facility's normal operating conditions, the availability and performance of different structures, systems, and components, as well as manual actions, shall be justified.

Manual actions credited in the analyses shall be prepared and governed by instructions.

8. The duration of the analysis shall be of sufficient length to determine the consequences of the event or circumstance.

9. For events and circumstances in the event classes 'anticipated events' up to and including 'highly improbable events' (H2-H5), it shall be shown that the facility can be brought to a safe state.

10. In the analysis of events and circumstances in event classes 'anticipated events', 'unanticipated events', and 'improbable events' (H2- H4A), the most adverse single failure shall be applied in the safety group. A single failure in active structures, systems, and components shall be applied at the most adverse time. A single failure in passive structures, systems, and components shall be applied at the most adverse time, but no earlier than 12 hours after the event and circumstance occurred.

Furthermore, unavailability due to preventive maintenance during operations shall be presumed if it is permitted in the facility's operational limits and conditions.

To demonstrate independence between defence in depth levels 2 and 3, events and circumstances in event class 'anticipated events' (H2) shall only use safety-related structures,

systems, and components in operating groups to protect the barriers, and only structures, systems, and components in safety groups to limit the consequences of the event.

11. Within the event class 'events with multiple failures' (H4B), common cause failures in a safety group shall be applied instead of a single failure, in the same way as in condition E10.

In the analysis of the event class 'events with multiple failures', realistic methods and input data may be used without a statistical uncertainty analysis.

12. Postulated events in the event class 'highly improbable events' shall be analysed to show that defence in depth level 4 can be maintained. For such events, an analysis shall be performed that shows how additional aggravating factors can be managed.

In the analysis of postulated events within the event class 'highly improbable events', realistic methods and input data may be used without analysis with statistical processing of uncertainties. The analyses shall be supplemented with sensitivity analyses to demonstrate the facility's durability and reliability.

For analyses within the event class 'highly improbable events', credited manual actions shall be simple to implement, well prepared, and governed by instructions.

Deterministic analyses of environmental consequences

13. Events and circumstances within event classes H2-H5 that can lead to environmental radiological consequences shall be analysed. For these events and circumstances, the projected effective dose to members of the general public shall be calculated and include all relevant exposure pathways contributing to the radiation dose for one year from the beginning of the event or circumstance.

In addition, the committed equivalent dose to the thyroid gland shall to be calculated for a one-year child who have inhaled radioactive iodine.

14. The parameters of atmospheric and aquatic dispersion calculations shall be statistically developed based on historical weather data and hydrological data from the facility or nearby, and include 95 per cent of all occurring situations.

Analysis with probabilistic methods

15. The analysis with probabilistic methods shall be based on events and circumstances identified in accordance with condition D2 on identification. Limitations shall be justified.

16. The analysis with probabilistic methods shall reflect the facility's interoperability, including possible dependencies, in order to demonstrate a balanced risk profile without threshold effects.

17. The analysis with probabilistic methods shall, as far as possible and reasonable, be realistic and use the best available methods and data. When using conservative methods and data, the impact on results shall be evaluated.

The analysis shall, as far as possible and reasonable, reflect the facility's current design and operation.

Chapter 5: Mechanical Equipment

A. Scope and Definitions

1. These conditions apply to the design and construction, as well as periodic inspection, of mechanical equipment which forms part of a safety function, see definition in chapter 1, and whose failure or malfunction can cause radioactive emissions. However, the conditions do not apply to:

- lifting devices and equipment,
- integrated steel components in a concrete structure, such as density plates, tension and slack reinforcement,
- fully or partially embedded steel components in concrete responsible for receiving loads to be transferred from different anchorages, and
- surface-mounted fixing plates with or without injection, cast fixing plates, and associated retaining bolts, nuts and washers.

2. In these conditions the following terms mean

Qualification:	examination and demonstration to show that a person or a testing, treatment, or assembly process can fulfill their specified tasks,
Mechanical equipment:	generic term for equipment or components that serve to – carry external or internal pressure – bear mechanical load – protect such pressure- and load-bearing equipment referred to in the two points above – hold or control components in the intended manner

B. General Conditions

Application

1. In order to be put into use, mechanical equipment shall be designed, manufactured, installed and inspected to ensure that safety is maintained during all events, including the event class 'improbable events' (H4A). Further provisions for the design and construction, as well as safety assessment, can be found in chapter 4.

2. Before modifications to a facility's design or its operating conditions may be applied, a renewed inspection shall be made to ensure the provisions under condition 1 are fulfilled for mechanical equipment that may be affected by the modification.

3. Before equipment may be put into use for the first time, or after measures according to conditions D2-4 have been taken, or following periodic inspection, or after modification to the facility's design or its operating conditions, a certificate of compliance shall be in place, in accordance with conditions E1 and E2.

Operational restrictions

4. Pressure equipment shall not be subject to higher or lower pressures and/or temperatures than those for which they are designed.

5. Mechanical equipment may not be subject to more or greater pressure variations, or mechanical or thermal load variations, than those that form the basis for the design. Should the

number of such load variations be exceeded, or if large load variations of another kind occur, the safety measures deemed necessary shall be taken without delay.

6. Mechanical equipment may not be exposed to internal or external environments or other influences that have been shown can lead to severe corrosive effects for which the device is not designed. Should such unforeseen changes occur in the internal or external environment that may lead to harmful effects, measures shall promptly be taken to eliminate the cause.

Measures in the event of damage

7. Damage in mechanical equipment that can be caused by, or have developed due to, operating conditions shall be assessed, classified, and investigated in accordance with conditions B5 and B9 in chapter 8, as well as addressed according to the conditions in chapter 5, and reported to the Swedish Radiation Safety Authority in accordance with conditions C1-3 in chapter 8.

8. Equipment in which damage has occurred may be kept in operation without repair or replacement measures being taken, according to conditions D1-13, when it has been shown that adequate safety margins exist against break and against such leakage and other deficiencies that may affect safety during the intended operating time.

Accredited bodies

9. Bodies performing certification or inspection tasks, and laboratories performing testing tasks, according to these regulations, shall have a third party position and be accredited for the tasks in question in accordance with sections 4-5 of the Swedish Act on Accreditation and Technical Inspection (2011:791).

In the case of manufacture of mechanical equipment in another country, overseas certification and inspection bodies, as well as laboratories, may carry out certification, inspection, and testing tasks, in accordance with conditions D6 and D10, if they have been accredited in accordance with provisions equivalent to those applicable for a Swedish body, in accordance with the first paragraph.

C. Conditions on Periodic Inspection

Inspection group classification

1. Mechanical equipment in the facility that performs a safety function or forms part of a safety system shall be divided into inspection groups A-C in order to govern the scope and focus of periodic inspections, in accordance with conditions 5, 7 and 8. The classification shall be determined by taking into account the relative risks of emission of radioactive substances, and deficiencies in the level of safety in general, as a result of damage that can occur in the mechanical equipment. Assignments to inspection groups are as follows:

- A for equipment components where the relative risks are deemed to be highest,
- B for equipment components where the relative risks are deemed to be lower than that for group A, but not minor,
- C for equipment components where the relative risks are deemed to be minor.

These classification principles are based on division into the inspection groups A-C, on the basis of a damage index and a consequence index. A damage index represents a qualitative measure of the likelihood that fracturing or other degradation shall occur in the relevant equipment, and is determined by the probable loads and environment in relation to the design and material properties. A consistency index represents a qualitative measure of the likelihood that fracturing or other degradation shall cause damage that can lead to the emission of radioactive substances, and other damage that can lead to ill health and accidents.

Consequence index / Damage index	1	2	3
I	A	A	B
II	A	B	C
III	B	C	C

Classification in inspection groups shall be reviewed annually, based on experience gained, modifications in the design of the facility or in its operating conditions.

Fundamentals of the inspection

2. The principles, methods, and approach for classification into inspection groups, in accordance with condition C1, and the determination of the scope of inspection and inspection intervals, in accordance with conditions C4, C5, C7 and C8, shall be safety reviewed in accordance with condition B2 in chapter 1. Before inspection programmes, in accordance with condition C5, may be applied, the Swedish Radiation Safety Authority shall be notified of these fundamentals.

Scope of inspection and inspection intervals

3. Mechanical equipment shall be inspected, examined, and monitored on a regular basis to check that no leaks have arisen and that no evidence exists of harmful impact in general. Mechanical equipment attributed to inspection groups A and B shall also be subject to periodic inspections, in accordance with condition C4.

Pressure equipment not subject to inspection according to condition C4, and whose integrity is of importance to the protection of personnel against ill health and accidents, shall be subject to periodic inspections that correspond to the provisions of the Swedish Work Environment Authority on inspection of pressure equipment[1].

4. Mechanical equipment with an active or passive function attributed to inspection groups A and B shall be subject to periodic inspections to the extent and at such intervals necessary with regard to the determined relative risks, in accordance with condition 1, to ensure that the equipment functions as intended. Inspections may be postponed for a maximum of six months.

Inspection programme and execution

5. Inspections, periodic inspections and other examinations of equipment shall be performed in accordance with an inspection programme, in which the provisions in conditions C1-4 have been adapted to the prevailing conditions at the particular facility. The inspection programme shall specify:

- equipment and components to be inspected and subject to periodic inspections,
- the timing for inspections and testing,
- the scope of inspections and testing,
- instructions and procedural descriptions to be used to govern the execution of tests.

The inspection programme shall also include guidelines for extended inspections when such damage is found that may also have affected other similar equipment not covered by the inspection programme.

[1] Latest version is available in the Swedish Work Environment Authority regulations on inspection of pressure equipment. AFS 2017:3

6. The licensee shall ensure that testing in conjunction with periodic inspections, in accordance with condition C4, is performed by an accredited laboratory.

7. Non-destructive testing of mechanical equipment belonging to inspection groups A and B shall be performed with test systems that are qualified to detect and characterise, as well as determine the size of, the damage that can occur in the relevant type of equipment. Determining the sizing of the damage need not be included if repair or replacement measures are taken where there is evidence of damage without prior analyses of the safety margins, in accordance with condition B8. The licensee shall ensure that such qualification is supervised and assessed by an accredited body that has an independent and impartial position, an appropriate organisation with the necessary expertise for the tasks in question, as well as appropriate quality systems.

Measures following periodic inspections
8. Before mechanical equipment may be put into operation after shutdown for periodic inspection, or after measures in accordance with conditions D1-13, interlocks of importance to safety in the facility shall be checked to ensure they are set correctly and locked in accordance with the facility's interlock list.

D. Conditions on Design, Manufacture, Installation and Repair

Classification
1. Mechanical equipment shall be divided into classes to govern the design requirements and quality assurance measures in the design, manufacture and installation, and repair of equipment intended for use at the facility. Division into classes shall be determined by taking into account the significance of the equipment's mechanical integrity for facility safety in all events up to and including the event class 'improbable events' (H4A).

2. Mechanical equipment shall be designed, manufactured, installed, and inspected, in accordance with conditions D3-6 and D9-13.

Design, construction, manufacture, and installation
3. The design and construction shall be based on current design specifications, which shall be safety reviewed in accordance with condition B2 in chapter 1. Before the design specifications may be applied, the Swedish Radiation Safety Authority shall be notified of the design basis contained therein.

4. The design and layout shall be carried out according to well-proven design solutions that have been shown to provide sufficient margins in order for equipment to meet the basic conditions for use, in accordance with condition B1.

Design solutions shall be tailored to the maintenance and inspection requirements that may be relevant during the time equipment is expected to be in use.

5. Equipment shall be manufactured from materials with well-documented properties, the necessary strength at the maximum working temperature, the necessary impact resistance at the minimum working temperature, high durability and good resistance to the ambient environment, as well as good weldability in those cases where welding shall occur.

6. Welding and other joining processes shall be governed and performed according to procedures and by personnel who are qualified for the purpose. The licensee shall ensure that the qualification of procedures and of personnel is supervised and assessed by an accredited body.

Repairs, replacements, etc.

7. Cracks and corrosion that can affect the safety margins may be removed without subsequent repair of material or weld metals, provided that:

- the necessary strength and functional margins are maintained,
- the probable cause of the occurrence has been clarified,
- the necessary measures have been taken to prevent new damage from occurring.

Measures taken to remove such damage without subsequent repair shall be carried out and checked using methods that are qualified for the purpose.

8. If the damage is to such an extent that the necessary strength and functional margins cannot be maintained, the device or component shall be replaced or repaired. Before repair or replacement measures begin, the probable cause of the occurrence shall be clarified and the necessary measures taken to prevent new damage from occurring. Repairs shall be carried out according to repair programmes which have been qualified for the purpose, and which, with sufficient margins, restore the necessary properties for the equipment to be able to fulfil the basic conditions for use, in accordance with condition B1. The licensee shall ensure that the qualification of repair programmes is supervised and assessed by an accredited body where the repair measures involve equipment that forms part of a safety system or performs a safety function.

Inspection during design, manufacture and installation, and repair

9. Materials, shaped products, and welded joints shall be subject to the inspection necessary to ensure no faults or general deviations persist that are of importance to safety. Inspections shall be performed in accordance with the current design, repair and manufacturing methods, as well as class-adapted inspection documentation. This shall include:

- inspection plans, which shall specify the type and extent of inspection at different stages, and during repair, manufacture, and installation in the facility,
- the instructions and procedure descriptions necessary to govern the performance of inspections, non-destructive tests, and other examinations.

10. The licensee shall ensure that testing in conjunction with:

- manufacturing is performed by an accredited laboratory or by the manufacturing organisation under the supervision of an accredited body, in the form of spot checks.
- installation and repair of installed equipment is performed by an accredited laboratory.

Testing in conjunction with manufacturing of materials and shaped products may, however, be performed by the manufacturing organisation if it applies a quality system for governing the testing activities that is certified by an accredited body.

11. Non-destructive testing in conjunction with inspections, in accordance with condition 9, shall be performed with either:

- well-proven test systems, which experience has shown can reliably detect and characterise the defects and deviations that the repair, manufacturing, and installation processes can cause, or
- test systems which, to the extent applicable, have been qualified and evaluated in accordance with condition C7.

Measures after installation

12. After the installation of mechanical equipment in the facility, the following shall apply:

- verification shall be obtained that the equipment has been installed in accordance with applicable drawings and flow diagrams, and that performance meets safety-related requirements,
- an operational test shall be carried out to show that safety valves and other safety equipment function satisfactorily, and that the equipment is not exposed to harmful vibrations or other loads which were not taken into account during the design inspection.

13. Before equipment is put into service it shall be fitted with a permanent identification mark. The identification mark shall contain the information necessary to be able to ensure a unique identification against the design, manufacture and inspection documentation. Such documentation shall be stored in accordance with conditions D8-9 in chapter 1.

E. Conditions for the Verification of Compliance and Annual Reporting

1. In the case of periodic inspections, the licensee shall ensure that an accredited inspection body is engaged which

- reviews the documentation, in accordance with condition C5, to verify that the scope and focus have followed the appropriate programmes, based on principles and methods which have been notified to the Swedish Radiation Safety Authority, and that consideration was given to the decisions which the Swedish Radiation Safety Authority has taken in response to the notifications made,
- supervises the visual checks of equipment in accordance with condition C3, functional tests in accordance with condition C4, and inspection of interlocks in accordance with condition C8,
- checks that tests and other examinations are performed in accordance with conditions C6-7,
- reviews investigations of the prerequisites for continued operations with damaged equipment to verify that adequate safety margins, in accordance with condition B8, exist during the time the equipment is intended to be kept operational without repair or replacement measures being taken.

If these reviews, supervisory occasions, and checks show that the set requirements are fulfilled, the inspection body issues a certificate of compliance in accordance with the provisions in SWEDAC's (the Swedish Board for Accreditation and Compliance) general regulations for accredited inspection bodies[2].

2. In the event of modifications to a facility, in accordance with condition D3, or changes in its operating conditions, the licensee shall ensure that an accredited inspection body is engaged to review the design specifications and other design documentation to verify that:

- the classification used is based on principles which have been notified to the Swedish Radiation Safety Authority, and that consideration has been given to the decisions taken by the Swedish Radiation Safety Authority in response to the notifications made,
- the applied design criteria are notified to the Swedish Radiation Safety Authority, and that consideration has been given to the decisions taken by the Swedish Radiation Safety Authority in response to the notifications made.

[2] The latest version is available in the Swedish Board for Accreditation and Compliance's overall requirements for accredited inspection bodies, STAFS 2011:18

In the event of modifications, exchanges and other measures relating to mechanical equipment, the licensee shall also ensure that an accredited inspection body:

- reviews load data, strength analyses, and other inspection documentation to verify that condition D2 has been fulfilled.
- performs visual checks during and after installation, supervises operational tests in accordance with condition D12, and checks identification marks in accordance with condition D13.

If these reviews, supervisory occasions, and checks show that the set requirements are fulfilled, the inspection body issues a certificate of compliance in accordance with the provisions in SWEDAC's (the Swedish Board for Accreditation and Compliance) general regulations for accredited inspection bodies.

3. In cases of mass production that take place in a controlled manner and, according to supporting documentation, fulfil conditions D3-6 and D9-11, the licensee may request that the accredited body that assessed the manufacturing organisation issue a type-examination certificate, instead of the individual product-examination certificates that form the basis for a certificate of compliance in accordance with condition 2.

The licensee shall ensure that the accredited body performs spot checks to verify that the prerequisites for the type-examination certificate continue to be met during the period manufacturing is ongoing.

4. Every year the licensee shall submit a report (annual report) containing information on the experiences gained during the calendar year and the conclusions reached in response to observations made during visual checks, supervisory occasions, and periodic inspections, and which may be significant for assessing the safety of a certain type of equipment, structure, or construction material. This report shall also contain information on how experiences gained in general affect the safety assessment of the mechanical equipment and the inspection programmes applied. The Swedish Radiation Safety Authority shall receive the annual report no later than 1st March of the following year.

Chapter 6: Physical Protection

A. Scope and Definitions

1. The conditions constitute a clarification of the adapted physical protection that shall be in place, in accordance with section 3 in chapter 2 of SSMFS 2018:.1, the Swedish Radiation Safety Authority's regulations on basic provisions for practices with ionising radiation subject to licence.

2. Additional conditions on information security can be found in chapter 7.

3. In these conditions the following terms are used with the meanings given below:

Guarded area:	an area into which it is verified that only those authorised are given access,
Design basis threat description:	a description in threat levels of an antagonist's capability, equipment and approach,
Simple area protection:	protection consisting of at least one barrier that limits access to the area,
Reinforced area protection:	protection that consists of several barriers, combined with monitoring technical structures or other measures that delay, detect and alarm in the event of ongoing intrusion into an area,
Controlled access:	measures to ensure that only authorised persons are given access to a space or area,
Area protection:	protection of an area so that intrusion is hindered and delayed,
Registered access:	measures to ensure registration of persons entering a space or an area,
Perimeter protection:	protection consisting of enclosing barriers and structures, systems and compnents that can detect, alarm and delay ongoing intrusion into an area,
Protected area:	an area that is surrounded by a perimeter proctection,
Specific design criteria for physical protection:	design documentation issued by the Swedish Radiation Safety Authority for the design of the physical protection, including the design basis threat description and response times,
Access restricted area:	an area where the general public does not have access,
Vital area:	an area containing safety groups that are accredited in order to achieve a safe state in the event of an antagonistic event,
Monitored alarm transmission:	a function that triggers an alarm when an error in an alarm transmission occurs.

B. Analysis of the Physical Protection

1. The licensee shall analyse, verify and document that the physical protection has been ensured in accordance with the conditions:

a. before facilities and buildings are constructed,
b. when new areas/spaces in these are established,
c. when a facility is put into operation,

d. in case of organisational, administrative or technical modifications of the practices in these, and

e. in case of changes of the threat scenario for the facility.

C. Documentation of the Physical Protection

The plan for the physical protection referred to in condition C1 in chapter 1 shall:

1. include as a minimum:
   a. a description of the physical protection's construction and function, as well as man-technology-organisation aspects,
   b. references to detailed system descriptions,
   c. a description of the areas/spaces where radioactive materials subject to licence are stored or handled,
   d. an overall description of processes and procedures,
   e. a description of the organisation; including roles, responsibilities, tasks and competence requirements,
   f. a description of training courses and exercises, and
   g. a description of service providers and suppliers of products and services,
2. be revised based on experience, in accordance with conditions K1 and 2, and
3. be kept relevant and updated.

D. Design and Construction of the Physical Protection

Physical protection in the facility design

1. The licensee shall ensure that physical protection is included in the facility design, taking into account:
   a. the adaptation between the facility's site and its surroundings,
   b. the design basis threat description,
   c. the specific design criteria which the Swedish Radiation Safety Authority decides on,
   d. the defence in depth principle, and
   e. another circumstance of importance to the physical protection.

Protection of access restricted areas

2. The facility shall be located within an access restricted area that is demarcated by a simple area protection.

Protection of guarded areas

3. Guarded areas shall be demarcated by a reinforced area protection.

4. Measures shall be taken to prevent motorised vehicles from forcing the area protection to a guarded area.

Protection of protected areas

5. Protected areas shall be sectioned as far as reasonably possible.

Protection of the security monitor room and vital areas

6. The security monitor room and vital areas shall be located in protected areas which shall be designed so that they withstand antagonistic capacities up to threat level 1, for at least as long as

it takes the police to arrive at the access restricted area, in accordance with the specific design criteria for physical protection, or until safety groups perform their function so that the area is no longer considered to be vital.

The overall physical protection (defence in depth principle)
7. The overall physical protection of vital areas shall be designed to withstand antagonists up to and including threat level 2, for at least as long as it takes the police to arrive at the access restricted area, in accordance with the special design criteria for physical protection, or until safety groups perform their function so that the area is no longer considered to be vital.

Protection of areas for handling, processing or storage of radiation sources
8. Areas used for the handling, processing or storage of radiation sources shall be located in protected areas which shall be designed so that the overall protection of radiation sources withstands antagonistic capacities, in accordance with table 1 in chapter 6, for at least as long as it takes the police to arrive at the facility, according to the specific design criteria for physical protection.

Area for the handling, processing and storage radiation cources in category	**4**	**3**	**2**	**1**
Antagonsitic capacity according to threat level	0	1	2	3

Table 1 in chapter 6

Protection of openings and weaknesses in the perimeter protection
9. The protection level with regard openings and weaknesses in the perimeter protection shall correspond to the design protection level of the perimeter protection in general. The term openings also includes ventilation and cooling ducts, as well as culverts.

Locking systems
10. The facility's locking system shall have a protection level that corresponds to the design protection level of the physical protection in general.

Communication system
11. An intercom system shall be in place that enables communication both within the facility and between the facility and the police authority or other relevant authorities. The intercom system shall consist of at least two systems for communication that enable uninterrupted two-way verbal communication, one of which shall be independent of the public communication systems.

Alarm transmission
12. For alarm transmission to the alarm centre, there shall be at least two independent and diversified communication systems, of which at least one meets the Swedish Anti-Theft Standard SSF 114:2, lowest alarm class 3. The facility's locking system shall have a security level that equal to the design protection level for physical protection in general.

During construction
13. In conjunction with construction of the facility, the facility shall be separated from the surrounding area for surveillance, and for control of access for people and vehicles. The protection of protected and vital areas shall subsequently be adapted as needed.

E. Security Clearance and Positions with Special Responsibility

Security clearance

1. People who are employed, or by other means participate in the practices, at the facility shall be reliable and appropriate from a security standpoint. The licensee shall decide which individuals shall be authorised to gain access to the facility and its systems. The licensee is responsible for ensuring that security clearance of these individuals is carried out. The scope of the security clearance shall be analysed and adapted based on the respective individuals' opportunity to commit antagonistic actions in relation to the areas and the systems to which they are intended to have access.

An approved security clearance shall be a prerequisite to gain independent access to the facility and its systems.

2. Notwithstanding condition 1, where, because of time constraints or another acceptable reason, it is clearly unreasonable to carry out sufficient security clearance, a person may, in exceptional circumstances, participate in the practices at the facility, provided adequate measures are taken to monitor them.

That specified in condition 1 does not apply to people who by law have the authority to gain access to the facility.

Positions with special responsibility for physical protection

3. At least one position with responsibility for the physical protection shall exist at the facility. The position shall have an independent standing in the organisation with the authority to report directly to the facility's highest manager.

4. Positions with responsibility for the physical protection shall have the resources and authority to operate, monitor, evaluate and develop the physical protection.

F. Protection of the Facility

Guarding the facility

1. The licensee shall ensure that the facility is guarded by specially trained personnel (security personnel). There shall be responsible work management for the security personnel.

Security personnel shall be in place in the number needed to be able to:

a. check the authorisation of the persons located within the facility,
b. check vehicles and their authorisations,
c. check that devices for physical protection are functioning,
d. alarm in the event of intrusion,
e. activate prepared measures, and
f. impede, delay and, if possible, prevent intrusion, as well as preparations and attempts to intrude.

2. The seccurity personnel shall, where necessary and with short notice, be possible to reinforce with extra security personnel.

Locks, alarms, and surveillance

3. Intrusion into guarded and supervised areas shall immediately be able to be detected and verified.

4. If cameras are used for verification, each camera's intended function and purpose shall be defined in accordance with SSF 1060:2, SS-EN 50132-1:1 and SS-EN 50132-7:2 in order to ensure picture quality.

5. Information on events and circumstances in the physical protection shall be registered and stored to such an extent that a sequence of events can be investigated retrospectively.

Locking systems and issue of keys
6. Issue of keys and code carriers shall take place against a receipt and be registered.

Security monitor room
7. The facility shall ha a security monitor room. Furthermore,

a. access to the security monitor room shall take place via controlled access,
b. the entrance to the security monitor room shall have two consecutive locked doors so that an interlock is formed, which is designed so that the operator inside the security monitor room approves the passage before access takes place, and
c. the security monitor room shall be equipped with assault alarms, with monitored alarm transmission to a certified alarm centre, in accordance with the Swedish Anti-theft Association's SSF 136 standard.

8. The security monitor room shall be constantly manned by specially trained personnel, and equipped and designed so that the following functions can be continuously maintained:

a. monitoring of alarms from technical surveillance equipment, including verification of alarms,
b. logging and documentation of events,
c. alerting personnel and appropriate authorities in the event of threats to the facility,
d. maintaining internal and external communication as specified to in condition D12, and
e. operating the access control system.

Access for individuals to the facility, areas and spaces
9. Documented procedures for access to the facility shall be in place, as well as a list that, as a minimum, includes:

a. the indivduals who have the right to grant access to the facility, and
b. the indviduals who have been granted access.

The list according to item b shall be preserved for at least seven years.

10. Individuals who are granted access to the access restricted area shall be allocated an authorisation document, which shall be worn visibly.

11. Authorisation documents shall be of limited duration.

12. Access to the guarded area shall be via controlled access.

13. Access to the protected area shall take place via controlled and registered access. Information on registered access shall be saved for at least seven years.

Access for vehicles to the facility, areas and spaces
14. The licensee shall decide which vehicles shall be given access to the facility. Vehicle access to the guarded and protected areas shall take place in a controlled conditions, and only vehicles there on business may be granted access.

G. Categorisation of Radiation Sources

1. Radiation sources which do not constitute permanently fixed components shall be divided into categories in accordance with appendix 3 to SSMFS 2018:1.

2. Radiation sources consisting of non-fixed components in or from targets shall be divided into category 1.

Replacement components that have not been activated do not need to be divided into a category if no natural radioactivity exists (categorisation then takes place in accordance with item 1).

3. For radiation sources that are stored together, the following shall be considered when calculating and categorising the volume of these:

Where radiation sources in individual containers, individual packages or in the form of individual components whose volumes are less than 50 dm^3 and which have been classified in category 2 in the calculation of A/D are stored together, the calculated ratios (A/D) shall be totalled for those units whose volume are less than 50 dm^3. If the sum of A/D is greater than 1000 for these units, the radiation sources should be divided into category 1.

H. Protection of Radiation Sources in Category 1-4

Handling, processing or storage within a protected area
1. The handling, processing or storage of radiation sources that are divided into category 1-3, in accordance with condtion G1, shall take place within protected areas that are designed in accordance with condition D8.

Storage within a guarded area
2. Storage may, if warranted, take place n a clearly marked location in a guarded area with a time restriction and requirements in accordance with table 2 in chapter 6.

The protection shall withstand antagonists with a capacity in accordance with table 2 in chapter 6, for as long as it takes the police, according to the specific design criteria, to arrive at the access restricted area.

The surface covering of containers or packages containing a source of radiation shall consist of a technical design that shall be configured in according to proven design solutions.

Containers, packages or components which constitute or contain a source of radiation shall have a minimum total mass in accordance with table 2 in chapter 6.

Measures, in accordance with table 2 in chapter 6, shall be taken to immediately detect, alarm and promptly verify the cause of the alarm if someone is located by, or in the immediate vicinity of, a container, package or component without authorisation.

Protection of radioactive material category	**4**	**3**	**2**	**1**
Time restriction (h)	-	-	-	24
Antagonistic capacity in accordance with design basis threat description	0	1	2	2
Minimum total mass (kg)	150	250	250	250
Requirements on alarm measures	No	No	Yes	Yes

Table 2 in chapter 6

Movement within a guarded area
3. Radiation sources may be moved in a guarded area. Movement shall be justified by a need to change the material's location and shall be done in the shortest reasonable time.

The protection of radiation sources in category 1-3 shall withstand antagonists with a capacity in accordance with threat level 1, for as long as it takes the police, according to the specific design criteria for physical protection, to arrive at the access restricted area.

I. Identifying and Addressing Deficiencies and Deviations

1. Faults and deficiencies in the physical protection shall be systemastically and continuously prevented, identified and addressed.

Deficiency in category 1
2. If a deficiency in category 1 has been observed, or if there is reasonable suspicion of such a deficiency, prepared measures for physical protection shall be taken without delay.

The following circumstances shall always be assigned to category 1, in accordance with point 1.5 in appendix 2 to chapter 8:

a. a deficiency in a technical, administrative or organisational measure for the physical protection that is of such a nature or extent that it is not possible to maintain the functions for physical protection, in accordance with the conditions in sections D-H, during a potential action up to and including threat level 1, and
b. a deficiency or deviation in the physical protection of such a serious nature or extent that it gives reason to question the plan for physical protection or descriptions of the physical protection in the safety analysis report.

Further measures to be taken in the case of a deficiency of category 1 are specified in condition B4 in chapter 8.

Deficiency in category 2
3. If a deficiency in category 2 has been observed, or there is reasonable suspicion of such a deficiency, the measures necessary to maintain the protection shall be taken.

The following circumstances shall always be assigned to category 2, in accordance with point 2.10 in appendix 2 to chapter 8:

a. a deficiency in a technical, administrative or organisational measure for the physical protection that is of such a nature or extent that it is not possible to maintain the functions for physical protection, in accordance with the conditions in sections D-H, during a potential action up to and including threat level 2,
b. a deviation from a standard, procedure, arrangement, or rule described in the plan for physical protection or in descriptions of the physical protection in the safety analysis report,
c. a deviation from the specified performance of a system or equipment in the physical protection in relation to the rules specified in the plan for physical protection or in descriptions of the physical protection in the safety analysis report,
d. a circumstance which results in the limitation of the physical protection, with the exception of planned interventions,
e. a circumstance which prevented or could have prevented the intended function of equipment of importance to the physical protection,
f. a deficiency in an individual analysis for the physical protection, or a method used for such analysis, of importance to the physical protection,

g. another technical, administrative or organisational circumstance that could affect the physical protection.

4. Further measures to be taken in the case of a deficiency of category 2 are specified in condition B5 in chapter 8.

J. Response Plans and Measures in Case of Antagonistic Actions

Response plans

1. Documented response plans shall be in place for the management and measures for the physical protection in the case of, or threat of, antagonistic actions.

2. Response plans shall be coordinated with other response plans that affect the facility, as a minimum in relation to emergency preparedness, the police and emergency services.

Measures

3. If antagonistic actions are detected, or if there is a suspicion of such, prepared and adapted measures for physical protection shall immediately be taken and shall include:

a. measures against sabotage or attempted sabotage of technical systems and devices for physical protection, radiation protection or safety,
b. measures against sabotage or attempted sabotage of radioactive materials,
c. measures to prevent unauthorised handling and wrongful removal of radioactive materials, and
d. communication, alarms and management of responses.

4. Planned and prepared measures shall be in place to temporarily reinforce the physical protection in the case of an increased threat scenario.

K. Exercise and Evaluation of Experiences and Events

1. The licensee shall have regular exercise activities within physical protection. The experiences from these exercises shall be used in the evaluation of the physical protection.

2. Following occurred antagonistic actions, the physical protection and the plan for physical protection shall be evaluated to identify the need for measures to reduce possible vulnerabilities.

Chapter 7: Information Security

A. Scope and Definitions

1. The conditions apply to measures necessary to maintain and develop information security during the design, construction, operation, and decommissioning of the ESS facility, and shall apply from when the facility has received its first permit until the facility is permanently closed.

2. Terms and expressions used in these conditions mean:

Authorised:	a person or system with the right to use information assets in a specified manner,
Information security:	security of information assets related to the ability to maintain the desired confidentiality, integrity, accessibility, and traceability,
Information worthy of protection:	data and information of crucial importance to the practices, safety and physical protection,
Information assets worthy of protection:	resources that handle information worthy of protection.

B. Organisation, Management and Governance of Information Security

Management system for information security

1. A management system for information security shall be in place that is well adapted to the practices. The management system for information security shall be part of the practice's coordinated and uniform management system. The management system shall clearly state how information security shall be handled within the practices.

2. The management system for information security shall contain:

a. objectives and guidelines for information security,
b. overall principles that apply to how activities within information security work shall be designed and how it shall be maintained and developed,
c. information security policies with descriptions of the overall principles that apply to how the practices shall be designed, maintained and developed,
d. the activities, processes and procedures necessary to maintain information security.

Organisational functions, expertise, authorities and suitability in general

3. Responsibilities and authorities relating to information security shall be clearly defined and documented.

4. An organisational function with responsibility for information security shall be in place. It shall have an independent position in relation to the organisation's functions for operations, engineering and maintenance.

Resources and authorities to operate, monitor, evaluate, and develop information security shall be found within the function. Roles and authorisations within the function shall be documented.

C. Analysis and Identification of Information Assets and Information Worthy of Protection

1. The licensee shall take the measures necessary to maintain information security. These measures shall be based on analyses that identify and classify:

a. information assets worthy of protection,
b. threats to information assets worthy of protection, and
c. vulnerabilities in information assets worthy of protection.

The analyses shall be documented and kept up to date.

2. Information worthy of protection shall be graded and classified based on the identified protection value and the consequences if information is disclosed to unauthorised persons, is modified, made unaccessible or is exposed to other unauthorised handling. The classification of information worthy of protection shall be the basis for the measures taken to maintain information security.

3. Information worthy of protection shall have protection against alteration and unauthorised access. The use of information worthy of protection shall be traceable and regularly monitored. Documented procedures shall be in place for the handling of information worthy of protection.

4. Authorisation for and in technical systems and equipment that handle information worthy of protection shall be documented. The authorisations shall be regularly monitored and any authorisation changes traceable. Documented procedures shall be in place for allocating, managing, and revoking authorisations for and in the technical systems or equipment. When personnel are assigned authorisations for the first time then the authorisation process itself shall be documented.

Monitoring

5. Technical information assets worthy of protection shall be monitored in a manner that ensures unauthorised access can be detected as soon as possible.

13. A log history shall be collected and stored in a manner that ensures the traceability of handling and use of information worthy of protection. The log history shall be:

a. checked and analysed with a regularity necessary to ensure that anomalies can be identified,
b. stored in such way that it cannot be modified,
c. stored for the time necessary so that it can be analysed, and
d. based on current information.

D. Security Measures for the Maintenance of Information Security

Zoning

1. Information worthy of protection shall be protected with an information security-technical defence in depth, which shall be based on zoning. For information management in and between zones, the following apply:

a. a zone may only contain information with the same or a lower protection value,
b. the functions which separate zones shall be configured, parameterised, and managed from the zone that has the highest protection value, or alternatively from their own independent administration point,
c. communication between zones shall be limited and controlled so that the information flow is controlled, structure, and minimal,

d. only one-way communication may occur from the innermost zone to that outside, and
e. communication between zones may only occur between adjacent zones.

Information and control systems of importance to security or physical protection
2. Information security shall be taken into account throughout the lifecycle, from planning to destruction, for information and control systems of importance to safety or the physical protection.

3. Functions that maintain information security included in information and control systems of importance to security or the physical protection shall be developed in accordance with the rules for the system in which the functions are used and be qualified to the same level.

4. The licensee shall ensure that measures which maintain information security do not adversely affect functions of systems and components of importance to safety or the physical protection.

5. Only authorised persons shall have physical and logical access to information and control systems of importance to safety or the physical protection. This restriction shall be made both in terms of duration and number of systems.

6. Configuration and modifications in information and control systems of importance to safety or the physical protection shall take place in a traceable manner and according to documented processes.

7. Equipment used for changes in information and control systems of importance to safety and the physical protection shall be protected on least the same level as the system to which it is used.

8. Information and control systems of importance to safety and the physical protection shall be designed to minimise the system's vulnerability to cyber-attacks or improper use.

9. Systems and components that are vital for maintaining the information security of information and control systems that are of importance to safety or the physical protection shall be physically protected.

10. Data connections on information and control systems of importance to safety or the physical protection which are not used shall be deactivated where this is technically possible.

11. The licensee shall, individually and with the help of suppliers of information and control systems of importance to safety or the physical protection, identify and address vulnerabilities.

E. Antagonistic Actions, Deficiencies and Deviations

1. The licensee shall describe the division of responsibility, have processes, and prepare measures that ensure information security in the event of antagonistic actions.

2. The licensee shall develop a plan for the handling of antagonistic actions and threats to information assets worthy of protection. The plan shall include:

a. a description of the scenarios in the event of an antagonistic action or threat,
b. a description of prepared measures in order to maintain information security,
c. a description of the prepared compensatory measures in order to maintain information security,
d. a description of measures to prevent sabotage or attempted sabotage of
   i. information assets worthy of protection,
   ii. technical systems and devices for radiation safety,

e. a description of communications planning, alarm routes, and management of responses,
f. how action plans are coordinated with society's envisaged responses, and
g. other documentation necessary for the management of antagonistic actions and threats from an information security perspective.

Identified measures and action plans shall be evaluated and kept up to date.

Handling deficiencies and deviations

3. The following circumstances shall always be assigned to category 2 in accordance with point 2.11 in chapter 8, appendix 2:

a. the inability to withstand a potential threat to and in an information security asset worthy of protection,
b. a deviation from standards, procedures, and arrangements, or a rule, described in the management system for information security,
c. a deviation from specified system or equipment performance within information security in relation to the specified requirements,
d. circumstances that result in a limitation in information security, with the exception of planned interventions,
e. circumstances which prevented or could have prevented the intended function of equipment relevant to information security,
f. a deficiency of importance to information security in an individual analysis of the physical protection, or in methods used for such analysis,
g. another circumstance of a technical, administrative, or organisational nature which could affect information security.

Chapter 8: Operation of the Facility

A. Scope and Definitions

Safe state:	condition where the fundamental safety functions can be ensured and maintained for a long time following all events and circumstances in the event classes 'anticipated events', 'unanticipated events', ''improbable events', 'events with multiple failures', or 'highly improbable events' (H2-H5).

B. Overall Conditions for Operations and Daily Operational Activities

Operational limits and conditions

1. The licensee shall establish operational limits and conditions as guidance for the operation of a facility. The operational limits and conditions shall include the information stated in appendix 1. The operational limits and conditions shall, together with the instructions specified in condition 7, provide personnel with the guidance required in order for the operation of the facility to be carried out in accordance with the conditions specified in the facility's safety analysis report. The derivation of the operational limits and conditions shall be clearly stated in the safety analysis report , in accordance with condition B1 in chapter 1.

Before the facility may be taken in trial operations or routine operations, the operational limits and conditions shall be presented in a safety analysis report that has been approved in accordance with condition B1 in chapter 1.

The operational limits and conditions shall be kept up to date. Modifications to, or planned temporary deviation from, the conditions shall be subject to a security review, in accordance with conditon B2 in chapter 1. Before modified limits and conditions or planned temporary deviations from operational limits and conditions may be applied, they shall be notified to the Swedish Radiation Safety Authority.

Management of deficiencies in defence in depth and associated barriers

2. The facility shall promptly be brought to a safe state if it is not possible to ensure that it is being operated in accordance with the operational limits and conditions, or it appears to be working in an unexpected manner.

3. In case of an identified deficiency or grounds for suspicion of a deficiency in a barrier or the defence in depth, measures shall be taken to the extent and within the time necessary, taking into account the severity of the deficiency. The deficiencies shall promptly be assessed and classified, in accordance with appendix 2, and investigated.

4. When a deficiency of **category 1,** according to appendix 2, has been detected, or there is reasonable suspicion of such a deficiency, the facility shall promptly be brought to a safe state. Before the facility is put back into operation without special restrictions, the investigations carried out and the measures taken in response to the deficiency shall be safety reviewed in accordance with condition B2 in chapter 1, and shall be examined and approved by the Swedish Radiation Safety Authority.

5. When a deficiency of **category 2,** according to appendix 2, has been detected, or there is reasonable suspicion of such a deficiency, the restrictions and controls needed to maintain radiation safety shall be implemented.

If the deficiency can be addressed within the conditions specified in the operational limits and conditions, the facility may return to operations without restrictions when corrective measures have been taken and the operational readiness has been verified.

If conditions for corrective measures are not specified in the operational limits and conditions, the facility may only return to operations without special restrictions once the deficiency has been investigated or addressed and a safety review, in accordance with condition B2 in chapter 1, has confirmed that the safety margins are sufficient.

6. In case of a deficiency of **category 3**, according to appendix 2, the facility may, with the restrictions necessary to maintain radiation safety, retain its operating mode while remedial measures are taken. Before any part of the facility subject to the requirements of operational readiness, according to the operational limits and conditions, may be shut down for such measures, the time and manner of implementation of the measures shall be safety reviewed, in accordance with condition B2 of chapter 1.

Instructions and guidelines

7. The licensee shall establish instructions for the measures to be taken at a facility during normal operations, and those events and circumstances that are taken into account in the facility's design.

Instructions and guidelines shall be appropriate, documented and kept up to date. Relevant personnel shall be familiar with the instructions and guidelines.

Instructions, and amendments to such instructions, relating to the control of operational readiness, as well as instructions and guidelines that are intended to be applied during events and circumstances that may have radiological consequences, according to the first paragraph, shall be safety reviewed, in accordance with condition B2 in chapter 1, before they may be applied.

Maintenance, continuous supervision and inspection

8.a. Structures, systems, components and devices of importance to the safety of a facility shall be continuously inspected and maintained in such a way that they fulfil the set safety requirements. In order to do this, programmes for maintenance, continuous supervision and inspection, as well as the management of age-related deterioration and damage, shall be in place.

The programmes shall be implemented with methods validated for their purpose. Measuring and testing equipment shall be kept calibrated in accordance with established instructions.

The programmes shall be documented, as well as reviewed and updated with regard experience acquired and developments in science and technology.

Further provisions on periodic inspection of mechanical devices can be found in chapter 5.

b. To ensure that maintenance, as well as continuous supervision and inspection, is carried out in accordance with the set safety requirements, established and documented procedures shall be in place for work preparation, governance and control of the implementation of the measures.

c. Before facility parts and equipment referred to in condition 8a become operational following maintenance work or other interventions, a functionality check shall be carried out to verify the operational readiness of the facility. The functionality check shall reflect the circumstances expected to previal when the safety function concerned is to be used. Where a full functionality check is not possible or reasonable, an analysis showing that adequate verification of the safety function exists, despite the limited ability to perform a functionality check, shall be in place before commissioning.

Investigation of events and circumstances

9. An investigation of the kind referred to in condition B3, or done for other safety reasons, shall be carried out in accordance with sections 18 and 19 in chapter 3 of SSMFS 2018:1.

The results of the investigation shall be communicated to the relevant personnel at the facility and used to develop the facility's radiation safety. The results shall also be reported to the Swedish Radiation Safety Authority, in accordance with that stated in conditions C1-3.

C. Reporting of Events and Circumstances to the Swedish Radiation Safety Authority

1. Occurred events and discovered circumstances of importance to radiation safety at the facility shall be reported to the Swedish Radiation Safety Authority in accordance with appendix 3:1-3.

2. Occurred events and discovered circumstances which are less severe than those mentioned in condition 1, but of importance to the safety of the facility, shall be reported to Swedish Radiation Safety Authority in accordance with appendix 3:4.

3. Routine reports on practices that are of importance to the safety of the facility shall be submitted in accordance with appendix 3:5.

Appendix 1 to Chapter 8

Information in the operational limits and conditions

In accordance with condition B1, the operational limits and conditions shall, as a minimum, include:

a. the threshold values necessary to protect the target system's integrity,

b. other threshold values necessary to ensure that the design limits are not exceeded at the facility,

c. other conditions and restrictions necessary to ensure that specified values are not exceeded or do not fall short during the required time period for the respective operational modes for systems and components of importance to safety,

d. the technical safety functions in place, and other equipment of vital importance to the facility's defence in depth, with
   i. information on the systems and components that are accredited,
   ii. the requirements on operational readiness laid down for the relevant operating modes, with regard to the minimum number of available components and their performance,
   iii. the measures taken when operational readiness does not prevail,

e. the requirements placed on inspection and testing to ensure the facility fulfils the requirements in the safety analysis report,

f. the general rules applicable to the management and governance of the facility's operations, including modification of the operating mode, performance of tests, management of malfunctions and disruptions, and implementation of preventive and corrective maintenance,

g. the staffing required for safe operations in the relevant operating modes.

Appendix 2 to Chapter 8

Classification of Deficiencies in Barriers and defence in depth

Category 1
Detected serious deficiencies in one or more barriers or the defence in depth, or grounds for suspicion that radiation safety is seriously threatened, shall be classified in category 1. The following events or circumstances shall always be assigned to category 1

1.1 exceeding a threshold value of importance to the target system's integrity, as specified in the operational limits and conditions,

1.2 deterioration of the integrity of any of the barriers for containment of radioactive substances,

1.3 a deficiency in the practices, management or governance to such an extent that it poses a serious threat to radiation safety,

1.4 a deficiency or deviation of such a serious nature or extent that it gives reason to question the the facility's safety analysis report,

1.5 an event or deficiency in the physical protection which is of such a nature or extent that it poses a serious threat to radiation safety.

Category 2
Detected deficiencies in a barrier or defence in depth of a less severe nature than that assigned to category 1, or grounds for suspicion that radiation safety is threatened, shall be classified in category 2. Category 2 shall always include attributable deviations from the operational limits and conditions which lie within assumptions and conditions of the safety analysis report

2.2 a deviation from the specified system or component performance,

2.3 a circumstance that results in operational restrictions or time-limited operations, with the exception of planned procedures specified in the operational limits and conditions,

2.4 a circumstance which prevented or could have prevented the intended function in equipment of importance to safety,

2.5 a threshold value for activating the safety function is found to give a lesser margin than the permitted threshold value indicated in the safety analysis report,

2.6 damage to the monolith protecting the target, which involves damage that results in, or may result in, activity emission, or mechanical damage, or geometric deformation, or another circumstance that may make continued operation inappropriate,

2.7 a circumstance in a facility that results in radioactive substances being present in equipment not approved for such,

2.8 a deficiency of importance to radiation safety in an individual analysis included in the safety analysis report or in a method used for such an analysis,

2.9 another circumstance of a technical or organisational nature which is a threat to radiation safety,

2.10 an event or deficiency in the physical protection that poses a threat to radiation safety, and

2.11 an event or deficiency in the information security that poses a threat to radiation safety.

Category 3
Temporary deficiencies in the defence in depth that arise when addressing events or circumstances which, without measures, could lead to more serious conditions, and which are documented in the operational limits and conditions, in accordance with condition B1, shall be classified in category 3.

Events or circumstances which are assigned to category 3 may not impede the facility's function, but indicate the need for measures or tests because a component or system risks not fulfilling requirements on operational readiness in accordance with the operational limits and conditions.

In order for category 3 to be considered, the event or circumstance shall be of such a nature that immediate measures are not warranted.

Appendix 3 to Chapter 8

Reporting

Reporting in accordance with condition C1

1. Within an hour, the following shall be reported:

- events or circumstances that give rise to an area alarm, according to the alarm criteria determined by the Swedish Radiation Safety Authority,
- events or circumstances which, according to appendix 2, fall within category 1,

Information to be reported to the Swedish Radiation Safety Authority:

- what has occurred,
- when it occurred,
- the immediate consequences that have ensued,
- which measures have been taken,
- which measures are planned,
- an assessment of further developments.

If the report relates to events or circumstances that give rise to an alarm, according to the first paragraph, the following shall also be reported:

- an initial assessment of a containment and ambient source term,
- the current local weather.

Follow-up reports shall be submitted where there is a substantial change in the safety situation or when a new assessment of further developments is made.

2. Within 16 hours, the following shall be reported:

- events or circumstances which, according to the applicable technical criteria, are assigned to level 2 or higher on the international INES scale (International Nuclear and Radiological Event Scale).

3. Within seven days, the following shall be reported:

- a preliminary report on events or circumstances that gave rise to an alarm, in accordance with point 1 above, or which have been assigned to category 1 in appendix 2. Such a report shall contain:
  - a description of the event and the sequence of events,
  - a preliminary analysis of the causes and consequences, as well as an assessment of the safety-related significance of the event or circumstance,
  - measures taken or planned in order to restore the safety margins and to prevent a recurrence.

A final report shall be submitted to the Swedish Radiation Safety Authority as soon as is reasonably possible.

Minutes or equivalent documentation of completed safety reviews, in accordance with condition B2 in chapter 1, shall be attached to both the preliminary and final reports.

Reporting in accordance with condition C2

4. Within 30 days, the following shall be reported:

- a final report on the events or circumstances which have been assigned to category 2, in accordance with appendix 2.

Minutes or equivalent documentation of completed safety reviews, in accordance with condition B2 in chapter 1, shall be attached to the final report.

If special reasons exist whereby a final report, according to the first paragraph, cannot be submitted within 30 days, the Swedish Radiation Safety Authority shall be provided with a preliminary report, which shall also contain a justification of the specific reasons and a fixed timetable for when a final report can be anticipated. Said justification and timetable shall be safety reviewed, in accordance with condition B2.

In addition to the above-mentioned reporting of events and circumstances, requirements on specific reporting of incurred damage can be found in chapter 5.

Reporting in accordance with condition C3

5. Every year, the following shall be reported (annual report):

- a consolidated report of activities at the facility during the calendar year, with experiences gained and conclusions drawn in relation to radiation safety. The report shall also include a summary of events or circumstances which have been assigned to categories 1, 2 or 3. The summary shall include trends and an analysis of the underlying causes, as well as the measures taken or planned. Circumstances that have been assigned to category 3 shall also be described in terms of the purpose of the measures and the time used to implement the measures (down time).
- Further information on reporting can be found in condition E4 in chapter 5.

The annual report shall be submitted to the Swedish Radiation Safety Authority no later than 31st March of the following year.