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Safety Assessments

In connection with use of radiation sources

Guide

Sundhed for alle

Safety Assessments
In connection with use of radiation sources

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Introduction

The purpose of this guide is to provide instructions on how to design a safety assessment in connection with use of sources of ionising radiation (radiation sources). The rules are laid down in the Radiation Protection Act and related executive orders; see Chapter 7. The purpose of the rules is to ensure that use of ionising radiation is justified and optimised, and that the dose limits are not exceeded.

This Guide has been compiled by the Danish Health Authority, which performs the regulatory tasks pertaining to safety and radiation protection where ionising radiation occurs, is used or is generated.

Who is the Guide for?

- The Guide is aimed at all undertakings that use radiation sources to an extent that requires a licence, as a safety assessment is one of the criteria for obtaining and maintaining such a licence.
- The Guide is not aimed at uses of radiation sources that require notification – e.g. intraoral dental X-rays or the use of demonstration sources for teaching purposes.
- The Guide is also not intended for uses of radiation sources subject to neither the licensing nor notification requirement – e.g. use of low-activity sealed sources.
- The Guide is not applicable to existing exposure situations subject to licensing, such as occupational radon exposure.

Obtaining and maintaining a licence for use of radiation sources has at all times been subject to a requirement for the prospective licensee (the undertaking) to document its radiation protection. In the past, this was typically accomplished by a one-off procedure whereby the undertaking submitted documentation to the Danish Health Authority on a case-by-case basis. The safety assessment provides a means of structuring the documentation that the undertaking must in any event submit to the Danish Health Authority in connection with the undertaking's use of radiation sources.

The Guide consists of several elements. The Guide itself reviews the content of a safety assessment based on guidelines compiled by the International Atomic Energy Agency (IAEA). Annex B is a general template for a safety assessment indicating how the majority of undertakings will be able to compile a report that meets the requirements immediately. Finally, Annex C provides a number of specific safety assessment report templates adapted for specific applications.

How to use this Guide

- Chapter 1 describes the background to the requirement for a safety assessment, including the concepts of use and licensing.
- Chapter 2 describes the fundamental radiation protection principles – justification, optimisation and dose limits – which are focal for the safety assessment.
- Chapter 3 indicates the types of undertakings that are required to compile a safety assessment.
- Chapter 4 describes safety assessment fundamentals, and the majority of undertakings should be able to compile a safety assessment based on the recommendations in this chapter.
- Chapter 5 is intended to serve as a reference text for a detailed description of the structure and components of a safety assessment. This chapter is primarily of relevance when establishing irradiators or other large-scale facilities for e.g. particle therapy or cyclotrons, where the risks of use may be very high and hence a more detailed safety assessment is necessary.
- Chapter 6 deals with quality assurance and presents the links that may exist between an undertaking's quality management system and a safety assessment.
- Annexes B and C provide report templates for documentation of safety assessments. Annex B is a general report template for safety assessment, and Annex C refers to report templates adapted for specific applications. See Annex C for a description of the individual templates.

The Radiation Protection Act authorises the Danish Health Authority to set requirements for safety assessment[1], and this Guide explains how the safety assessment can be designed to adequately document radiation protection. If the instructions in the present Guide are followed, the undertaking can expect the safety assessment to be correctly structured and adequate in scope. The instructions in this Guide are not binding upon the undertaking in that it may opt to fulfil a requirement by a procedure other than as indicated, if it results in a safety assessment of adequate content and scope. If a procedure other than the one indicated is adopted, the undertaking must be able to substantiate that its chosen procedure serves to document its safety assessment. The Danish Health Authority may, if necessary, assess whether the content and scope of a safety assessment are adequate.

1 Section 5(2), Act No. 23 of 15 January 2018 on Ionising Radiation and Radiation Protection

The Guide makes reference in footnotes to relevant sections of acts and executive orders. Words in italics are explained in the glossary; see Annex A.

For general information on ionising radiation and its biological effect, occurrence, application, etc. please consult the Danish Health Authority's publication "The Radiation Guide"; see Chapter 7.

The latest version of this Guide is available at www.sis.dk.

1. The terms use, licensing and safety assessment

The radiation protection legislation employs the term "*use*" to describe the contexts in which precautions must be taken from the point of view of radiation protection. The term has a broader meaning compared with the usual sense in that "use" denotes all actions involving *radioactive material* and *radiation generators*.

Use

In the radiation protection legislation, the term "use" means:

a) For radioactive materials (unsealed and sealed sources): ***Manufacture, processing, holding, import, export, transfer, handling, application, control, technical safety inspection, storage, disposal, recycling, reuse, discharge and transport.***

b) For radiation generators: **Manufacture**, in the process of which *ionising radiation* is generated, ***modification of*** radiation generators with implications from the point of view of radiation protection as well as ***installation*****, application, control** and **technical safety inspection**.[2]

As indicated above, "application" comes under the term "use". Thus, while the terms 'application' and 'use' may be construed as synonymous in other contexts, in the context of radiation protection they do not denote the same, since 'application' is just one of many sub-elements of the concept of 'use'.

The radiation protection legislation describes three levels of regulatory control for use of *radiation sources:* licensing, notification and exemption from these requirements – commensurately with the risk posed by a given use.

The licensing requirement is the most restrictive level of regulatory control. A radiation source must not be used until the Danish Healthy Authority has licensed *the undertaking* for that use and has approved registration of the radiation source and/or *facility*.[3]

In cases where use is associated with a low risk, there is no requirement for licensing, and the undertaking must instead notify the Danish Health Authority of the use.

If the risk is so low that there is no need for radiation protection measures, the undertaking's use of radiation sources is exempt from the licensing and notification requirements.

2 Section 10, No. 7a, Executive Order No. 669/2019.
3 Section 51(5), Executive Order No. 669/2019.

In advance of any use of radiation sources subject to the licensing requirement, the undertaking is required to compile a *safety assessment*.[4] A safety assessment is a systematic review of factors of relevance for safety and *radiation protection* entailed by the planned use.[5] A safety assessment typically comprises a cradle-to-grave description of the radiation risks, safety functions, geographical location, radiation protection measures, the design and robustness of the facility or devices as well as human factors.

The requirement for safety assessment was first introduced explicitly in the legislation in early 2018, and undertakings required to compile a safety assessment may therefore be in one of two situations: the undertaking either does not yet hold a licence, and is therefore required to compile a safety assessment in support of its licensing application, or it already holds a licence and is required to compile a safety assessment based on its licence.

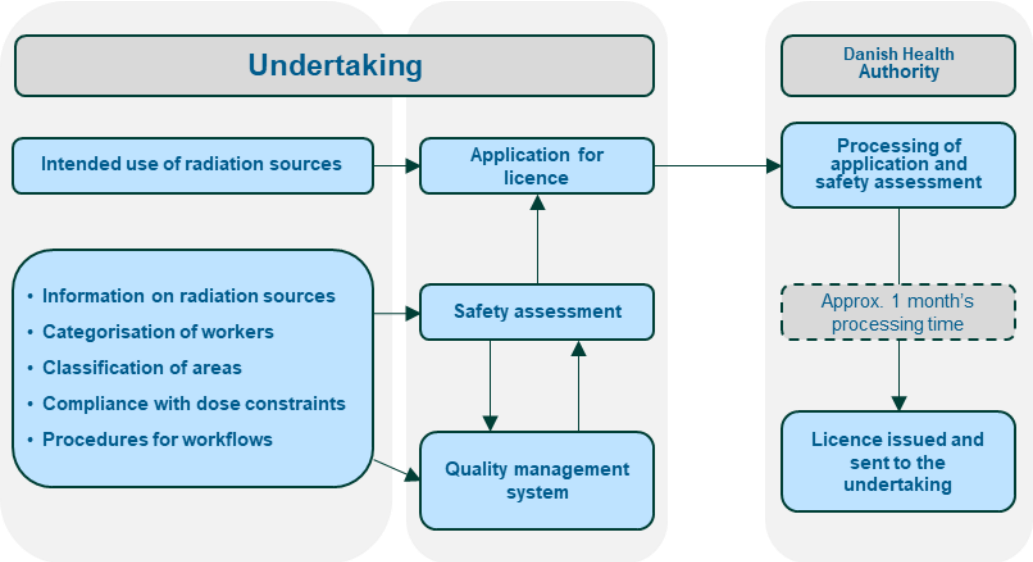
Undertakings not yet licensed to use radiation sources

If the undertaking does not yet hold a licence, it must first decide what types of use and what types of radiation sources it wishes to apply to be licensed for. In support of its application, the undertaking is required to compile a safety assessment covering its intended types of use. This means that the scope of use the undertaking applies to be licensed for must be addressed in the safety assessment; see Figure 1.

Figure 1

A flowchart illustrating the typical process steps in an application for licensing to use radiation sources.

Safety assessment is part of the application for a licence.



4 Section 20(1), Executive Order No. 669/2019.
5 Section 10, No. 49, Executive Order No. 669/2019.

Undertakings licensed to use radiation sources

If the undertaking is licensed to use radioactive materials (i.e. unsealed or sealed sources), the licensed types of use will be stated specifically in the licence. If the undertaking is licensed for use of radiation generators by a licensing document issued under the new legislation, i.e. after 6 February 2018, the licensed types of use will be stated specifically in the licence. If, on the other hand, the undertaking holds a licence issued before 6 February 2018, that licence remains valid in accordance with the transitional provisions, without a new licence document having been issued.[6, 7] In any case, it is the scope of the licence that must be addressed in the safety assessment.

The Danish Health Authority recommends that undertakings engage actively in the assessment of safety, and that each undertaking draws up an overall plan for when and how a safety assessment can be produced. Initially, the Danish Health Authority will only require submission of a report on safety assessment when the undertaking is planning changes in use affecting the scope or terms and conditions of its licence.

6 Section 89, Executive Order No. 670/2019.
7 Sections 58-59, Executive Order No. 671/2019.

2. Radiation protection principles

In Denmark, the system for radiation protection is structured in accordance with the recommendations of the International Commission on Radiation Protection (ICRP)[8] and is based on three fundamental principles: justification, optimisation and dose limitation. The principles have been incorporated into the Danish radiation protection legislation, and their significance for use of radiation sources is described below.

2.1. Justification

The main principle governing use of radiation sources is that the use shall be justified. This means that the use of radiation sources shall take place solely if the health, economic, social or other benefits of that use outweigh the detriment.

The assessment of justification must include consideration of options for employing alternative methods that are either not based on ionising radiation or are based on significantly reduced exposure or risk.

It is the undertaking's duty to assess and document whether a given use is justified, or whether an alternative method, which might not involve the application of radiation sources, would be more justified. That being the case, the alternative method must be chosen. In case of doubt, the alternative method should be trialled first. The undertaking shall also regularly assess whether its use of radiation sources continues to be justified.

The Danish Health Authority may, at any time, assess and determine whether a given use of radiation sources is justified.[9]

2.2. Optimisation

The optimisation principle entails that use of radiation sources may take place solely if the likelihood and magnitude of exposure, including the number of individuals exposed, are as low as reasonably achievable taking into account the current state of technical knowledge and economic and social factors.[10] Economic and social factors are taken into account in the premise underlying the established *dose limits* and *dose constraints*. The undertaking must therefore put in place the radiation protection measures necessary for compliance with the established dose constraints. Such measures would include employing a *quality management system*; see Chapter 6.

“Reasonably” means that the undertaking shall neither invest excessive nor insufficient resources in protective measures. The undertaking must comply with the legislation in the

8 ICRP Publ. 103, 2007.
9 Section 17, Executive Order No. 669/2019.
10 Section 18, Executive Order No. 669/2019.

field of radiation protection and achieve the best level of radiation protection under the given circumstances.

The Danish Health Authority may, at any time, assess and determine whether the use of radiation sources has been optimised, e.g. whether implemented radiation protection measures, protocols for the duration of exposures, etc. are adequate for compliance with dose constraints.[11]

The optimisation procedure shall take into account the exposure of *exposed workers*, *other workers* and *members of the public* in relation to the dose constraints established for these categories of individuals.

A dose constraint must be applied in the design of facilities and in the planning of work procedures and specifies the magnitude of the dose these facilities and work procedures are permitted to cause to each individual. The application of dose constraints shall result in optimisation of the radiation protection, i.e. minimisation of exposure, e.g. by means of access control, restrictions on proximity time and utilisation of shielding. In this way, the actual exposure of workers and members of the public can be expected to be lower than the dose constraint.

As part of the optimisation process, it will typically be relevant to perform a review of the safety assessment if the optimisation gives rise to changes with implications for the scope of the licence. Some optimisation processes, though, are covered by the undertaking's licence (e.g. changes in dose parameters for CT protocols) and hence, these optimisation processes do not change the scope of the licence and will consequently not necessitate a safety assessment update.

2.3. Dose limits

The sum of doses to an individual must not exceed the dose limits.[12,13] The dose limits are set so as to limit the risk of *late effects* and prevent any *acute effects*. The principle of dose limitation protects the right of all individuals to not be subjected to disproportionately high risks as a result of *exposure*. The dose limits apply to exposed workers, other workers and members of the public, but not to patients.

11 Section 19, Executive Order No. 669/2019.
12 Section 23, Executive Order No. 669/2019.
13 Section 31, Executive Order No. 669/2019.

3. Scope

A safety assessment is an internationally recognised method of assessing safety and radiation protection related to use of radiation sources or exposure. The method may be applied to any activity entailing a risk of individual exposure, and is a tool for structuring the documentation that the undertaking shall under any circumstances submit to the competent authority in support of the undertaking's use of radiation sources. In Denmark, this approach was incorporated in the relevant legislation with effect from 1 February 2018. Consequently, any undertaking seeking to be licensed for use of radiation sources is required to submit a safety assessment as part of its licensing application.

3.1. Industries and work involving radiation sources subject to the safety assessment requirement

A large number of industries in Denmark use radiation sources for many different purposes and under very differing conditions. Many of those purposes require a licence from the Danish Health Authority and thus also require the undertaking to compile a safety assessment. If an undertaking is in doubt as to whether its planned use of radiation sources requires a safety assessment, the undertaking may direct its query to the Danish Health Authority, Radiation Protection.

The list below shows examples of industries and work involving radiation sources that require a safety assessment for non-medical and *medical use*, respectively. The list is not exhaustive or presented in any particular or priority order.

- Device testing and calibration
- Borehole logging (well logging)
- Density and moisture measurement
- Radiation generators that are not *self-shielded*
- Industrial radiography (inside and outside of facilities)
- Sterilisation by irradiation
- Research using particle accelerators
- Process control (level measurement, fill-height detection, flow measurement, thickness gauging, belt load weighing, mass-per-unit-area measurement) if the source activity exceeds the exemption values[14]
- X-ray analysis (X-ray fluorescence, X-ray cabinets)
- Use of unsealed sources for research and development
- Handling and storage of NORM
- Veterinary X-ray, certain applications[15]
- Radiopharmaceuticals production using cyclotrons
- Manufacture, installation and modification of radiation generators

14 Annex 3, Executive Order No. 670/2019.
15 Section 5, Executive Order No. 671/2019 and second sentence, Annex 1.

- *Acceptance testing* and *performance testing* of radiation generators and associated *equipment*
- *Brachytherapy* using sealed sources (seeds, plaques, afterloading)
- *Radiotherapy* (using electron accelerators)
- *Particle therapy* (e.g. using protons)
- *X-ray radiation therapy* and *dermatologic therapy*
- Nuclear medicine examinations (SPECT, PET, etc.) and therapies
- Medical diagnostics (conventional X-ray, CT scanning, fluoroscopy, bone scintigraphy, mammography, angiography, etc.)
- Dental X-ray, certain applications.[16]

3.2. Factors that might entail updating of a safety assessment

A safety assessment must be performed or updated for facilities under construction or modification. While this may be prompted by the manufacturer of the radiation source, the contractor for construction of the facility, the undertaking/client or the regulatory authorities, the responsibility for maintaining and documenting safety rests at all times with the undertaking.

Safety assessment update

Depending on the scope of the facility or application, updating of the safety assessment may be required when:

- Evaluating the site and the vicinity in which the facility or the application will be located
- Drafting the design
- Constructing facilities/and or devising procedures for application
- Commissioning facilities or commencing application
- Altering a design or operation
- Performing periodic assessments (e.g. as a result of an audit)[17]
- Extending the life of a facility beyond its original design life
- Planning administrative changes, e.g. changes in the ownership or management of a facility and replacement of personnel critical to safety
- Decommissioning and dismantling facilities
- Releasing facilities from regulatory control.

The safety assessment should state what factors have prompted the safety assessment update.

16 Section 5, Executive Order No. 671/2019 and first sentence, Annex 1.
17 Section 94, Executive Order No. 669/2019.

In the planning phase for large-scale facilities, in addition to assessment of radiation risks, there may be requirements for assessment of environmental impacts and non-radiological risks before construction of the facility may commence. Assessment of the above-stated aspects will generally have many factors in common with the safety assessment performed to address associated radiation risks. The assessment of these aspects should ideally be coordinated in order to save resources and increase the robustness and coherence of the various assessments.

See also Section 5.2 under "cradle-to-grave".

4. Fundamentals of the safety assessment

The purpose of the safety assessment is to ensure the optimisation of radiation protection and the undertaking's compliance with all relevant requirements for safety and radiation protection during normal operations, anticipated operational occurrences (e.g servicing and technical safety inspections) and accident conditions, as well as during decommissioning. The undertakings compilation of the safety assessment is an iterative, but still finite process resulting in a conclusion concerning the radiation protection.

Safety assessment:

An assessment of all aspects of an undertaking's specific use of radiation sources or exposure of relevance for safety and radiation protection.

4.1. Systematic review of safety and radiation protection

In compiling the safety assessment, the undertaking typically maps, adds and upgrades a number of relevant radiation protection measures, such as measures to minimise potential doses. The undertaking then identifies, selects and implements the most appropriate radiation protection solutions, e.g. by implementing dose constraints. The procedure is not concluded until the radiation protection has been sufficiently optimised and compliance with all relevant requirements for safety and radiation protection has been documented.

The safety assessment should:

- Include safety analyses and risk mapping for normal operation, anticipated operational occurrences and accident conditions (see Section 5.2.1 regarding risk assessment and safety analysis)
- Clarify the need for radiation protection of workers, the general public and the environment
- Include validations of calculation methods and model calculations used in the safety analyses
- Determine whether adequate safety measures have been taken to reduce risks, including during the preliminary deliberations regarding the choice of site for a facility as well as for future decommissioning of that facility.

The purpose of the safety assessment is to ascertain whether the safety of a facility or a particular type of use is adequate, including whether requirements for radiation protection have been complied with.

The safety assessment is a dynamic document that must be maintained on an ongoing basis.[18] The safety assessment must therefore be updated:

- periodically as operating experience is amassed
- at a frequency commensurate with the risks
- for changes in operation, construction or work procedures.

4.2. Graded approach

A safety assessment must be of a scope and be carried out at a level of detail commensurate with the radiation risk associated with the given practice.[19]

A graded approach takes into account the number of radiation sources (radiation generators and unsealed and sealed sources alike), their location relative to each other, the scope and type of use as well as the undertaking's competence.

The graded approach can be accomplished by determining the radiation risk based on a hazard categorisation for the given type of source and the specific use.

The Danish Health Authority assesses sealed sources, by means of the IAEA's hazard categorisation.[20] Sources in Categories 1-3 may give rise to exposure to a degree that causes acute effects if improperly managed. This risk will, in principle, not be present for sources in Categories 4-5. The scope of a safety assessment is thus highest for sealed sources in IAEA Category 1 and lowest for Category 5.

The IAEA's categorisation covers sealed sources, but the method can also be applied to unsealed sources. However, in addition, safety assessment must also take into account that unsealed sources can be inhaled and/or ingested, and that they can lead to contamination of e.g. skin and surfaces and can disperse in the environment.

There is currently no equivalent hazard categorisation for X-ray generators and particle accelerators, although there is great variation in the hazard potential of these sources.[21] The hazard potential is special in that these devices can switch the radiation on and off, and the design of the devices also means that there is usually no hazard present when the devices are switched off. The primary safety failure is likely to be caused by improper use of the device (e.g. use outside a shielded room or in non-compliance with distancing requirements) or as a result of activation of components when using high-energy X-rays and particulate radiation. Particle accelerators give rise to high *dose rates* and can potentially cause high radiation doses due to activated components that are radioactive

18 Section 20(2), Executive Order No. 669/2019.
19 Section 20(1), Executive Order No. 669/2019.
20 Safety of Radiation Generators and Sealed Radioactive Sources, Safety Guide No. RS-G-1.10 (2006).
21 The nuclear installations at the Risoe site are handled according to the same principles, but their decommissioning is subject to separate regulation in compliance with the "Operational and Decommissioning Limits and Conditions" (BfDA, Betingelser for Drift og Afvikling), which were likewise drawn up in line with IAEA recommendations.

even when the particle accelerator is switched off. These accelerator components are thus in some instances comparable with radioactive sources in Categories 1-3. This should be taken into account during repairs, maintenance and decommissioning facilities.

Safety assessments for Category 1-3 radioactive sources and particle accelerators should, in addition to general qualitative assessments, include a quantitative assessment of hypothetical exposure scenarios comprising equipment failures, human error and including their likelihood and impact. Safety assessments for routinely applied Category 4-5 sources will generally be relatively simple and include standard data from the manufacturer regarding doses and safety systems, as well as an assessment of local factors such as access, shielding, frequency of use, etc.

The complexity of a safety assessment therefore depends on the nature and scope of the undertaking's use of radiation sources and exposure, and in some cases special circumstances apply that may reduce the requirements regarding complexity. Certain types of use, especially X-ray diagnostics in the field of medical use and *veterinary medical use*, are very well established and are based to a great extent on dedicated training of specific practitioners. The fact that these applications are well-established means that a well-founded convention has been built up over time for practices that result in a high degree of safety for the application, such as shielding and design of X-ray rooms. Similarly, those practices include safety-critical routines in the training of practitioners in these fields, such as in various health worker training programmes. This is also reflected in the training requirements for exposed workers, as stipulated in the executive orders. Safety assessments for these types of use can be designed largely with reference to the already established, standardised requirements in the field.

4.3. Scope of the safety assessment

The safety assessment must reflect the risk entailed by the specific use of radiation sources – in terms of normal use, anticipated operational occurrences and accident conditions. One significant factor is whether the radioactive source at issue always emits radiation or is a radiation generator that can be switched off when not in use.

As stated in Chapter 2, a safety assessment typically comprises a cradle-to-grave description of radiation risks, safety functions, geographical location, radiation protection measures, the design and robustness of the facility or devices as well as human factors.

The safety assessment should ideally be performed in accordance with the IAEA's recommendations[22] – these are detailed in Chapter 5 and form the basis for the instructions in this Guide. An example of the work process in compiling a safety assessment report and of the structure of the safety assessment is provided in Annex B. Annex C also contains examples of standardised safety assessment reports for selected types of radiation source use and exposure.

22 Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), 2016.

4.4. Documenting the safety assessment in a report

Ideally, the undertaking should compile the safety assessment in a report. The report will then serve as the documentation that relevant safety and radiation protection requirements have been addressed, and that the arrangements implemented by the undertaking are deemed sufficient to ensure the optimisation of that radiation protection. The report must be submitted to the Danish Health Authority in support of a licence application.[23] The report may contain references to pre-existing documentation, floor plans, a quality management system, instructions, etc. For this purpose, the Danish Health Authority has produced a number of report templates for the most common types of applications; see Annex C.

Safety assessment is of relevance for the entire lifetime of the licence granted.[24] If major changes are planned regarding safety and radiation protection measures, work procedures, radiation source type and activity volume or the like, a renewed safety assessment must be performed. A renewed assessment must be documented in a separate report for submission to the Danish Health Authority.

A large undertaking with multiple departments, each holding its own licence to use radiation sources, should ideally perform safety assessments for each department documented in independent reports for the departments in question. The individual reports should then be compiled into a consolidated report for the entire undertaking.

An example of large undertakings are the five healthcare governing “Regions” in Denmark. A Region is the top-level undertaking with responsibility for hospitals in its region, and each hospital typically has different departments that apply radiation sources more or less independently of each other. Thus, each hospital department with radiation source applications must perform a safety assessment. In some areas, e.g. discharge of radioactive substances, a need has been identified for performing a consolidated interdepartmental assessment at each geographical location.

4.5. The safety assessment is an iterative process

The compilation of a safety assessment is typically performed in an iterative process, as described in Figure 2.

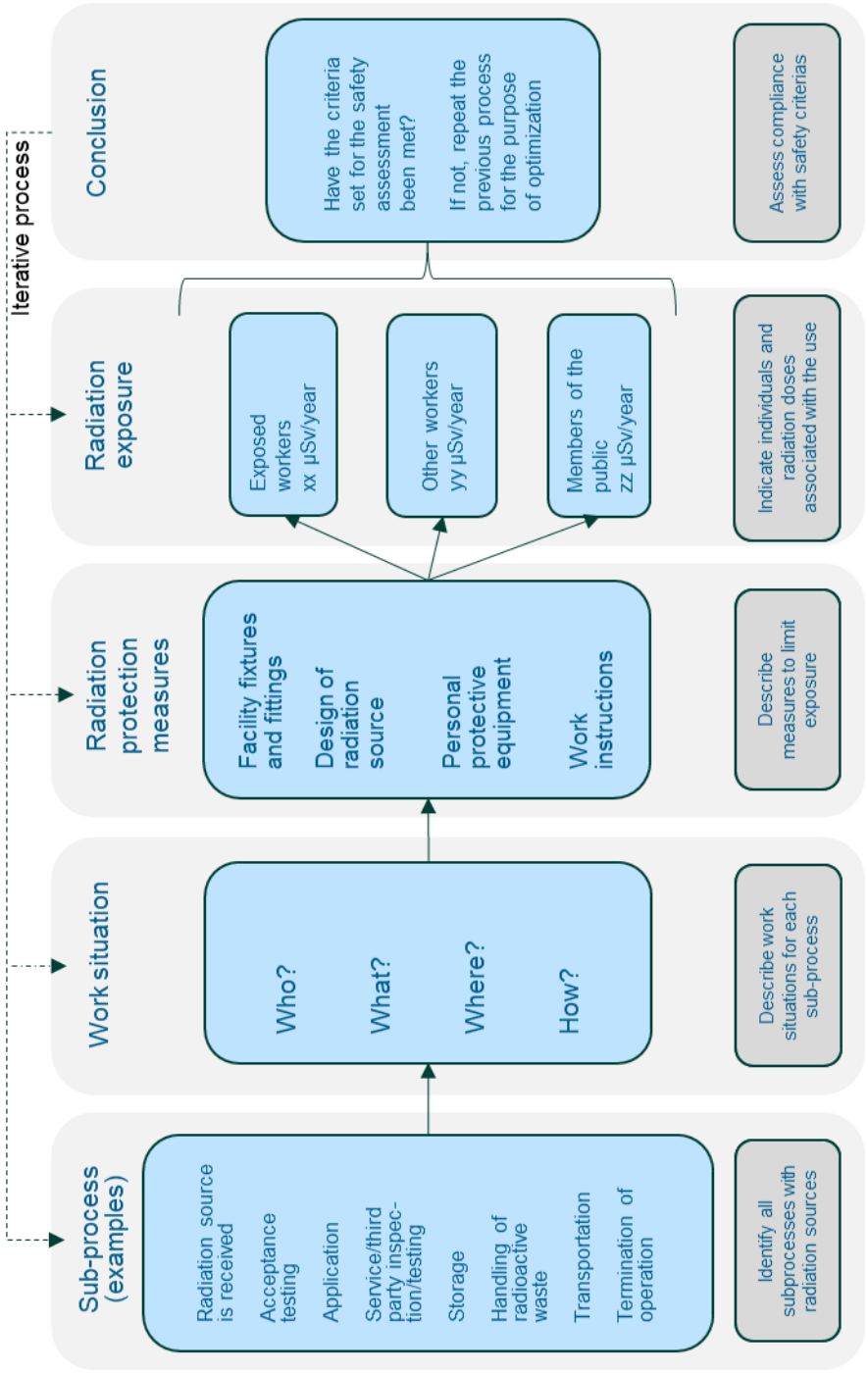
For each type of radiation source, a description must be provided of the individual sub-processes the radiation source undergoes, from when the source is received at the undertaking until the source leaves the undertaking again. The sub-processes depend on the radiation source and the undertaking involved, which is why the first column of Figure 2 provides examples only.

For each sub-process, a description must then be made of situations entailing exposure, and the radiation protection measures taken to minimise those exposures.

23 Section 18, Act No. 23/2018.
24 Section 20(2), Executive Order No. 669/2019.

Figure 2

Schematic of the iterative process typically followed by an undertaking in compiling the safety assessment.



4.6. Regulatory processing

In order to obtain and maintain a licence for use of radiation sources, an undertaking is required to compile a safety assessment, document it and submit it to the Danish Health Authority. Furthermore, any changes and updates with implications for the licence or its terms and conditions must be submitted to the Danish Health Authority.[25]

The safety assessment is reviewed by the Danish Health Authority as part of the licensing procedure. A safety assessment is a prerequisite for the undertaking being eligible for a licence for use of radiation sources. The Danish Health Authority uses the safety assessment to inform its decision regarding the issuance of a licence to the undertaking, and it forms the basis for setting any specific terms and conditions for the licence.

The Danish Health Authority's review of the safety assessment is based on the nature and scope of the undertaking's use of radiation sources. The final review prior to licensing takes into account how the safety aspects at the site, the design, the planned operations, etc. are combined in order to meet the specified safety criteria.

When an undertaking that is already licensed to use radiation sources submits a revised safety assessment or a new safety assessment, that safety assessment will also be reviewed by the Danish Health Authority.

In most cases, an undertaking will submit its safety assessment together with its licensing application. However, it is recommended to compile and submit the safety assessment well in advance of the construction or establishment of large-scale facilities for radiation sources. If the safety assessment is adequate, the Danish Health Authority will notify this to the undertaking in the form of a *pre-licence* confirming that the necessary prerequisites for the establishment (in the form of *barriers*, procedures, competences, etc.) have been assessed as being present. As mentioned above, however, the safety assessment must be periodically updated to reflect the actual conditions. An updated safety assessment will therefore be required once construction or establishment have been completed in order for the updated version to provide the basis for the undertaking's application for a licence for use of radiation sources.

Early contact with, and ongoing dialogue with, the Danish Health Authority are important in ensuring the smooth progress of the project. For the establishment of large-scale facilities, the more extensive recommendations in Chapter 5 will be relevant – see in particular Section 5.2 under "cradle to grave".

25 Section 20, Executive Order No. 669/2019.

5. Detailed recommendations regarding content and compilation

The Danish Health Authority's recommendations regarding safety assessments are in accordance with the international recommendations of the IAEA. The IAEA publication on safety assessments (GSR Part 4 (Rev. 1)) sets out 24 subject matters that should be included in a safety assessment. These include planning, executing, updating, documenting, and verifying of the safety assessment. The recommendations are aimed particularly at relatively complex applications. They are divided into a set of general recommendations for the undertaking and the organisation regarding the safety assessment, followed by a set of specific recommendations for the content of the safety assessment and a set of recommendations relating to *safety analysis*. There are also recommendations for documentation and follow-up of the safety assessment.

As stated in the introduction, the instructions in this Guide are not binding – there is thus methodological freedom for the undertaking in relation to the design of its safety assessment. The 24 IAEA subject matters are referred to in GSR Part 4 as requirements, but in Denmark have the status of recommendations.

5.1. Recommendations for the undertaking and organisation regarding the safety assessment

Graded approach[26]

A safety assessment should be of a scope and be carried out at a level of detail commensurate with the radiation risk associated with the facilities and types of use in question. See also Section 3.2 on the graded approach.

Scope of the safety assessment[27]

The safety assessment should cover all radiation sources, facilities and types of use subject to the licensing requirements that may be of significance in assessing the risk of exposure. If the use of a facility involves the use of multiple individual sources, the risks of use should initially be assessed for each of these before an assessment is made of the overall risks posed by use of the facility as a whole.

Responsibility for the safety assessment[28]

The radiation protection legislation refers to the entity that holds the right of disposal to, or uses, a radiation source as “the undertaking” and to the entity that permits its workers to use or be exposed to ionising radiation as "*the employer*", regardless of whether the

26 GSR Part 4 (Rev. 1), Requirement 1, pp. 7-9.
27 GSR Part 4 (Rev. 1), Requirement 2, p. 9.
28 GSR Part 4 (Rev. 1), Requirement 3, p. 9.

employer is also the undertaking that holds the right of disposal to, or uses, the radiation source.

The undertaking is responsible for ensuring that the safety assessment is performed for all relevant facilities and types of use that are subject to the licensing requirement. The safety assessment should be performed by qualified personnel with experience of all the relevant areas comprised by facilities and types of use. The undertaking's radiation protection officer and medical physics expert (for medical use) together with any *radiation protection expert*, if such exists, will typically be involved.

The following responsibilities should be clarified and specified in the safety assessment:

- Who is responsible for the licence within the undertaking – in other words, which individual has been delegated the responsibility for ensuring compliance with the terms and conditions of the licence
- Who is responsible for the design and approval of the safety assessment within the undertaking – in other words, which individual has been delegated the responsibility for reporting and submitting the safety assessment to the Danish Health Authority
- Who is responsible for ensuring that periodic review and amendment or updating of the safety assessment are carried out – in other words, which individual has been delegated responsibility for updates being carried out and submitted to the Danish Health Authority.

Preparation for the safety assessment[29]

Prior to the compilation of the safety assessment, the undertaking should ideally appoint a group of individuals who will be delegated the task of compiling the safety assessment. This group may include one or more radiation protection experts. Relevant information on the siting, design, structure, operation and decommissioning of facilities should be available to these individuals. In addition, relevant requirements in the radiation protection legislation should be identified.

5.2. Recommendations for the content of the safety assessment

This section reviews the fundamentals that should be included in a safety assessment. These elements correspond to recommendations ("Requirements") 6-12 in IAEA GSR Part 4. For specific types of use, there is also a recommendation regarding structural and organisational security, covered in recommendation 13 in GSR Part 4.

29 GSR Part 4 (Rev. 1), Requirement 5, p. 14.

Assessment of safety functions[30]

Safety functions consisting of, e.g. shielding, interlocks, built-in dosimetry systems and procedures during normal operation, anticipated operational occurrences (e.g. servicing or technical safety inspections) and accident conditions should be addressed in the safety assessment.

Examples of safety functions

Engineered structures

- Radiation shielding inside facilities
- Containers for sources
- Access control to facilities
- Facility surveillance.

Systems and components

- Interlocks
- Access controls
- Dosimetry systems
- Motors and circuits
- Computer systems and software
- Physical ancillary appliances.

Procedures

- Workflows
- Guides and instructions.

The reliability, redundancy and independence of the security functions should also be assessed. The assessment of safety functions should be performed for all the physical locations (facilities) and all the sub-processes where work involving radiation sources takes place. The review is illustrated in Figure 2, as part of the iterative process of compiling the safety assessment.

The safety functions and their effectiveness may depend on the engineered structures, systems, and components of which the safety functions form a part. Therefore, these structures, systems and components should be assessed independently, as described in the next recommendation.

Assessment of structures, systems and components[31]

Structures, systems and components comprised by safety functions as described above should be assessed for their stability and reliability. This recommendation relates to the previous recommendation regarding assessment of safety functions, as there may be

30 GSR Part 4 (Rev. 1), Requirement 7, p. 15.
31 GSR Part 4 (Rev. 1), Requirement 10, pp. 17-19.

factors concerning engineered structures, systems and components with implications for the capability of the safety functions.

Assessment of the stability and reliability of structures, systems and components includes the following:

- Consistency between design and execution
- Impact of any failure and need for sustained functioning
- Protection against external impacts
- Protection against internal impacts
- Materials used
- Protection against failures caused by design flaws (built-in, "fail-safe")
- Operational reliability of critical equipment
- Safety factors during decommissioning and dismantling after final use of a facility or a concluded work process.

Site assessment[32]

Physical, chemical and radiological factors with implications for exposure to ionising radiation (including dispersion of radioactive material) should be identified and assessed during normal operation, anticipated operational occurrences or accident conditions. Natural and human factors with implications for safety should be identified.

Assessment of radiation protection measures[33]

The safety assessment should include an assessment of the adequacy of the radiation protection for protecting people and the environment. Radiation protection should be assessed for normal operation, anticipated operational occurrences and accident conditions.

Assessment of human factors[34]

The safety assessment should include an assessment of whether radiation protection measures in the form of procedures as well as training, maintenance and further development of personnel competences are adequate to ensure radiation protection during normal operation, anticipated operational occurrences and accident conditions.

32 GSR Part 4 (Rev. 1), Requirement 8, pp. 15-16.
33 GSR Part 4 (Rev. 1), Requirement 9, pp. 16-17.
34 GSR Part 4 (Rev. 1), Requirement 11, pp. 19-20.

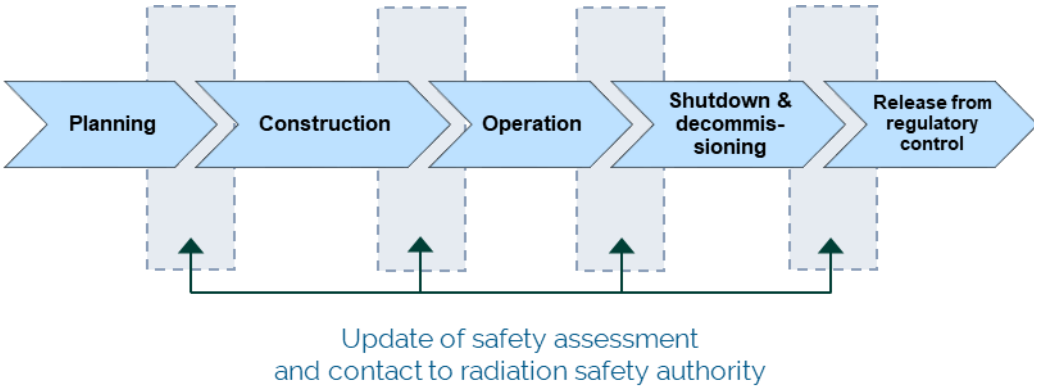
Cradle-to-grave assessment[35]

The safety assessment should cover the entire lifetime of the facility, or the entire period in which a given use is expected to continue. The safety assessment should take into account the ageing of installations and apparatus, appliances or devices, including the specific situation in which it has been decided that an undertaking or activity is to be terminated. If this situation arises and it is acknowledged that the undertaking or the work processes are to be terminated, the safety assessment should be reassessed and, if necessary, updated. At the design stage of the establishment of large-scale facilities, ageing, decommissioning, etc. should be addressed in advance and included in the safety assessment. At the transition between the different stages, the authorities should be involved; see Figure 3.

Figure 3

Phases in the cradle-to-grave assessment.

At the transition between the stages, the safety assessment should be updated and submitted to the Danish Health Authority, Radiation Protection.



Structural and organisational security, defence-in-depth (for special types of use)[36]

For special types of use (particle therapy facilities, cyclotron facilities for radiopharmaceuticals production, industrial irradiation), in the safety assessment, the undertaking should report on its measures to ensure structural and organisational safety.

Structural safety
Identification of physical barriers and their function as radiation protection.

Organisational safety
Identification at each organisational level of the options and ability of individuals responsible to take action on safety issues.

Structural safety pertains to, e.g.:

- Limitation in the functioning of barriers and the cause of this
- Measures to counteract these limitations
- Precautions in case of any safety function failure.

35 GSR Part 4 (Rev. 1), Requirement 12, pp. 20-21.
36 GSR Part 4 (Rev. 1), Requirement 13, pp. 21-23.

Organisational safety pertains to, e.g.:

- Addressing deviations from normal operation
- Detecting and terminating safety-related deviations
- Controlling emergencies comprised by the design parameters for the facility/work process
- Specifying measures to address the consequences of emergencies that exceed design parameters
- Limiting radiation risks
- Making arrangements to prevent loss of competences as a result of, e.g. a radiation protection officer's dismissal or resignation.

Examples of measures to demonstrate organisational safety would include periodic testing, external audits, instructions, procedures and checklists for use by relevant personnel.

5.2.1. Risk assessment and safety analysis

In a *risk assessment* all radiation sources are assessed and listed in order of priority.[37] The risk assessment can be used as a tool for identifying the sources or types of use that should be prioritised in the safety assessment. The risk assessment includes the probability and consequence of exposure of workers and members of the public as well as potential impact on the environment resulting from anticipated operational occurrences or accident conditions.

For applications involving different sources and involving multiple personnel groups, it is often helpful to employ a risk matrix to indicate the level of risk. In a risk matrix, the consequence/severity and the probability of radiation exposure in a given (potential) work scenario are assessed. The assessment can be performed for different categories of people, e.g. a worker or members of the public. Assessment of probability and severity can serve as an aid to determining the overall risk assessment of this scenario.

Figure 4

Example of a risk matrix in which the hazard categorisation is colour-coded to reflect the relationship between consequence and probability.

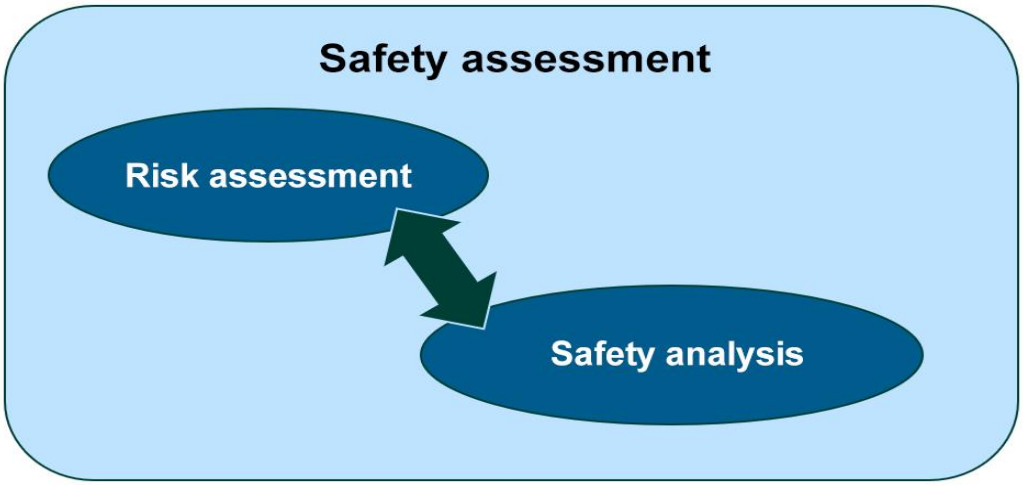
	High probability	Moderate probability	Improbable
Major consequence			
Moderate consequence			
Minor consequence			

37 GSR Part 4 (Rev. 1), Requirement 6, pp. 14-15.

The safety analysis is a quantitative investigation of and conclusion as to whether relevant quantitative requirements in the radiation protection legislation have been complied with, e.g. compliance with dose constraints. The outcome of the safety analysis is thus what decides whether the undertaking is able to demonstrate its compliance with regulatory requirements and other objectives of the safety assessment.

Figure 5

The risk assessment and safety analysis are integral to the safety assessment and may be mutually complementary.



A safety analysis includes mapping of potential exposures of workers, members of the public and the environs during normal operation, anticipated operational occurrences and accident conditions.

The safety analysis should address recommendations ("Requirements") 15-19 of IAEA GSR Part 4, where appropriate. These recommendations are described below.

Deterministic and probabilistic methods[38]

The safety analysis may include a number of calculation parameters and assumptions regarding radiation risks. In order for the parameters and assumptions to translate into an actual assessment of radiation risks, the numerical magnitude of these parameters and assumptions must be determined. The methods employed may be either deterministic or probabilistic.

Conservative estimates, based on operational experience, may provide the basis for a deterministic analysis. A probabilistic analysis can be used to identify radiation hazards in selected sub-processes of the undertaking's use of radiation sources, where the causes, consequences and probabilities of hazardous situations can be mapped and form the basis for ranking radiation hazards. This is especially relevant for types of use for which no operational experience has been amassed yet. A Failure Mode and Effects Criticality Analysis (FMECA) is an example of a probabilistic method in which consequence and probability can be assigned a numerical value and used to calculate the total risk or

38 GSR Part 4 (Rev. 1), Requirement 15, pp. 24-25.

ranking of the radiation hazard. This method can be combined with a risk matrix in order to assess and rank risks in the risk assessment; see Figure 4.

Criteria for assessing safety[39]

Explicit criteria for how safety is to be assessed should be set out in the safety analysis, for example, requirements in executive orders, reference to guides, principles and optimisation methods.

Assessment of uncertainties[40]

Known sources, types and the extent of uncertainties should be mapped using quantitative methods and/or expert assessments.

When compiling a safety analysis, in many cases it is necessary to include values and estimates that are very uncertain. When using unsealed sources, uncertainties would include the magnitude of the risk of spillage of a radioactive source, and the magnitude of any activity volume that might land on the skin in a given situation. An example of such a scenario would be if an FDG syringe were dropped on the floor or a Tc-99m eluate were spilt inside an LAF bench.

Consequently, in assessing uncertainties, the sensitivity of the safety analysis to those uncertainties must be determined.

Verification and validation of computer models[41]

Computer modelling and calculations included in the safety analysis should be verified and validated. Uncertainties, approximations and the limitations of modelling and calculations should be stated in the validation. It should also be ensured that users have the requisite competences for applying the modelling results and calculations.

Computer models based on commercially available standard software may be considered sufficiently validated.

Operational experience[42]

Experiences (empirical data) regarding operational safety should be included in the safety analysis. Empirical data may relate to human error, safety systems, exposure, *radioactive waste*, discharges, etc.

5.3. Recommendations for documentation and follow-up of the safety assessment

Documentation[43]

The results of the safety assessment should be recorded in a report containing documentation of compliance with requirements in the radiation protection legislation, the rationale for data collection, radiation risks, and an assessment as to whether objectives

39 GSR Part 4 (Rev. 1), Requirement 16, p. 25.
40 GSR Part 4 (Rev. 1), Requirement 17, pp. 25-26.
41 GSR Part 4 (Rev. 1), Requirement 18, pp. 26-27.
42 GSR Part 4 (Rev. 1), Requirement 19, p. 27.
43 GSR Part 4 (Rev. 1), Requirement 20, pp. 27-28.

have been met. The report should be updated on a regular basis. See also Section 3.4 on compiling a report on the safety assessment. The safety assessment and the resulting report should ideally refer to procedures and instructions in the undertaking's quality management system, as described in Section 6.2.

Independent verification[44]

For particular types of use (facilities for particle therapy, cyclotron systems for radiopharmaceuticals production, sterilisation by irradiation), the undertaking should ideally arrange for third-party verification of the safety assessment before submission to the Danish Health Authority.[45] The verification should be carried out by individuals with pertinent competences, but who are not responsible for the relevant components of the safety assessment – e.g. a radiation protection expert.

Administration of the safety assessment[46]

The compilation and maintenance of the safety assessment should be planned, organised, implemented, audited and evaluated. See also Section 5.1 concerning responsibility for the safety assessment.

Maintenance of the safety assessment[47]

The safety assessment must be evaluated and updated periodically at an interval commensurate with the nature and scope of the use of radiation sources, as well as in the event of significant changes from a radiation protection point of view[48]. All changes of significance from a radiation protection point of view or that require amendment to the scope of the licence must be described, e.g. any change in the number of sources, intensity, activity volume, activity concentration and application, among users, in designated responsibility and any alterations to buildings/facilities.

In the event of changes with implications for the basis for a licence or its terms and conditions, these changes must form the basis for an updated safety assessment.[49]

Licence terms and conditions[50]

Based on the safety assessment, the Danish Health Authority may set terms and conditions for the undertaking's licence. The terms and conditions may include specific requirements regarding safety maintenance procedures, based on, e.g. intervals for maintenance, monitoring and inspections. In addition, specific requirements may be made regarding specification of procedures for maintaining safety during normal operation, anticipated operational occurrences and accident conditions as well as necessary personnel/requisite competences for maintaining those procedures.[51]

44 GSR Part 4 (Rev. 1), Requirement 21, pp. 28-29.
45 Section 20, Act No. 23 of 15 January 2018 on Ionising Radiation and Radiation Protection.
46 GSR Part 4 (Rev. 1), Requirement 22, p. 30.
47 GSR Part 4 (Rev. 1), Requirement 24, pp. 30-32.
48 Section 20(2), Executive Order No. 669/2019.
49 Section 17, Act No. 23/2018.
50 GSR Part 4 (Rev. 1), Requirement 23, p. 30.
51 Section 20, Act No. 23/2018.

6. Quality assurance

Quality assurance denotes all planned and systematic actions, including quality control, necessary to provide adequate assurance that radiation sources, facilities, equipment, systems or components and procedures will perform satisfactorily in compliance with agreed standards. In order to achieve satisfactory quality assurance, the Danish Health Authority requires that use of radiation sources is supported by utilisation of a quality management system.[52] The overall purpose is to maintain and optimise the radiation protection.

The quality management system must reflect the undertaking's current use of radiation sources. It must therefore serve to substantiate that relevant documents such as the safety assessment, inventories, registries, protocols, instructions and the like are updated and available. These documents must also be available for submission to the Danish Health Authority upon request.[53]

6.1. System fundamentals

Table 1 lists a number of key radiation protection legislation requirements which the quality management system must serve to ensure compliance with at all times. These requirements are all relevant to address in the safety assessment, and the table thus illustrates the various links that may exist between the quality management system and the safety assessment. Note that the listing in the table is not exhaustive.

52 Section 93, Executive Order No. 669/2019.
53 Section 18, Act No. 23/2018.

Table 1

List of key topics to be covered by the quality management system and that the safety assessment is expected to address.

Additional requirements may be applicable.[54,55]

Topics and content	Reference to sections in Executive Order No. 669/2019
Safety assessment	
Must be updated to reflect current use	§ 20(2)
Instructions	
Safety measures in the event of emergencies, accidents and incidents	§ 57
Procedures	
Classification of areas and facilities	§§ 49-50
Categorisation of workers	§ 38
Testing of measuring equipment	§ 56
Individual dose monitoring	§§ 78-79
Medical use: all sub-processes involving use of radiation sources	§ 95(1)
Medical use, radiation therapy: risk assessment of the course of treatment	§ 95(2)
Documentation	
Records of doses to exposed worker (retained for at least 5 years)	§ 86
Results of all tests	§ 94
Inventories	
Designated expert individuals	§ 34
Exposed workers, their qualifications and maintenance of same	§ 45(2)-(3)

54 Section 16.1, Danish Health Authority guide on use of unsealed sources.
55 Section 15.1, Danish Health Authority guide on use of sealed Sources.

6.2. Coherence between the safety assessment and the quality management system

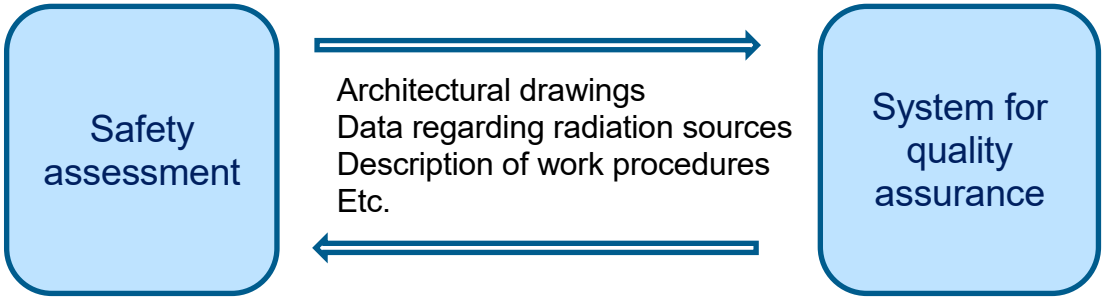
The statutory requirement that an undertaking shall compile a safety assessment is set out in Section 20, Executive Order no. 669/2019. Similarly, the statutory requirement for an undertaking to have a quality management system is set out in Section 93, Executive Order no. 669/2019.

The two provisions are mutually complementary, as many of the elements of the safety assessment are also included in the quality management system. The data that form the basis for the safety assessment (plant drawings, specifications for radiation sources, procedural descriptions of work processes, etc.) will often be data that are also recorded in the undertaking's quality management system.

Safety assessment and quality management system are therefore closely linked and are both dynamic – any update to the safety assessment will most certainly entail changes to documents in the quality management system, and certain changes in the quality management system may entail a need to update the safety assessment; see Figure 6.

Figure 6

The safety assessment and quality management system contain many of the same basic data and information.



7. Statutes, executive orders, guides, etc.

The original Danish governing act and the executive orders in force at any time are available to download from www.retsinformation.dk. Other publications from the Danish Health Authority, Radiation protection are available to download from www.sis.dk.

Governing act and executive orders

- Ministry of Health Act No. 23 of 15 January 2018 on Ionising Radiation and Radiation Protection (Radiation Protection Act).
- Danish Health Authority Executive Order No. 669 of 1 July 2019 on Ionising Radiation and Radiation Protection.
- Danish Health Authority Executive Order No. 670 of 1 July 2019 on Use of Radioactive Substances.
- Danish Health Authority Executive Order No. 671 of 1 July 2019 on Use of Radiation Generators.
- Ministry of Health Executive Order No. 967 of 30 August 2019 on Fees Charged for the Danish Health Authority's Inspection, Advisory and Assistance Services.
- Danish Working Environment Authority Executive Order No. 10 of 5 January 2018 on Medical Examinations Pertaining to Potential Occupational Exposure to Ionising Radiation.

Guides

- Danish Health Authority guide on use of unsealed sources (2020).
- Danish Health Authority guide on use of sealed sources (2020).
- Danish Health Authority guide on intraoral radiography (2019).
- Danish Health Authority guide on radiation generators – for service providers (2019).
- Danish Health Authority guide on veterinary use of portable X-ray equipment (2016).
- Danish Health Authority guide on industrial radiography (2006).
- Danish Working Environment Authority guide on medical examinations pertaining to potential occupational exposure to ionising radiation (2002, updated 2019).

Other relevant publications

- Danish Health Authority publication: The Radiation Guide – Ionising Radiation (2013).
- Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev 1) (2016).
- Radiation Safety in Industrial Radiography, IAEA Specific Safety Guide No. SSG-11 (2011).
- Radiation Protection and Safety in Medical Uses of Ionizing Radiation, IAEA Specific Safety Guide No. SSG.46 (2018).
- Decommissioning of Medical, Industrial and Research Facilities, IAEA Specific (Safety Guide No. SSG-49 (2019).

Annex A: Glossary

In this Guide, the following definitions apply:

Acceptance testing:	Testing carried out for the purposes of medical use of radiation sources prior to their acceptance into clinical service, and after any modifications and repairs, to ensure that the radiation source and equipment conform to the pre-defined specifications and applicable operational limits and conditions.
Acute adverse effect of radiation:	An injury for which a threshold dose has been defined as the cause of the adverse effect, and where the extent of that effect increases proportionally with the magnitude of the dose. Examples of acute effects are radiation cataract, sterility, and inhibition of the formation of white blood cells and other cells.
Alteration:	Alterations to radiation generators in any context, including during including cleaning, maintenance and repairs where the alteration might have implications from the point of view of radiation protection.
Application:	Specific type of use of a radiation generator. A subcategory of this is medical use involving medical exposure.
Barrier:	A physical obstruction that prevents or inhibits the movement of people, radionuclides or any other phenomenon (such as fire) or provides shielding against radiation.
Brachytherapy:	Treatment of cancer by the application of sealed sources placed inside or on the patient.

Carers and comforters:	Individuals who knowingly and voluntarily, other than in the course of their occupation, incur an exposure to ionising radiation by helping in attending to and comforting individuals undergoing or having undergone medical exposure. This includes the next of kin, including children, of individuals undergoing or having undergone medical exposure.
Carriage:	Relocation and any operation involving loading, unloading, in-transit storage and handling on Danish territory. Carriage therefore includes shipments to and from Danish consignees and consignors, and shipments transiting Danish territory.
Constancy testing:	Regular testing performed in the case of medical use of radiation sources to ensure that selected parameters for the radiation source and equipment constantly remain within the determined tolerances.
Dermatologic therapy:	The treatment of skin disorders, excluding cancer, through use of radiation generators.
Discharge:	Dispersion of unsealed sources to the environment e.g. via a sewer or chimney.
Disposal:	Discharge of radioactive waste from the application of unsealed sources or *disposal* of radioactive waste at an undertaking specially designated for this purpose.
Dose constraint:	An upper limit on the individual dose permitted to be delivered by an undertaking's aggregate use of radiation sources in a planned exposure situation and which provides a baseline for optimisation of radiation protection.
Dose limit:	The size of the effective dose or the equivalent dose in a specified period which shall not be exceeded for an individual.

Dose rate:	Dose per unit of time. Dose rate is typically expressed in microsieverts per second (µSv/s), or microsieverts per hour (µSv/h).
Effective dose:	The sum of the weighted equivalent doses in all the tissues and organs of the body from internal or external exposure.
Employer:	A natural or legal person which allows its workers to engage in use of radiation generators or allows its workers to be exposed to ionising radiation.
Equipment:	The supplementary apparatus, appliances or devices necessitated by the use of radiation sources or exposure, including containers, measuring instruments and other measuring equipment, imaging systems and apparatus, appliances or devices for radiation protection.
Equivalent dose:	The average absorbed dose in any tissue or organ weighted for the type and quality of ionising radiation.
Export:	Transfer of unsealed or sealed sources from Denmark to another country.
Exposed worker:	A worker in an undertaking that uses radiation sources, where the worker is directly involved in or performs work necessary for that use.
Facility:	Interiors, including laboratories, radiography rooms and storage and waste storage rooms and their associated structural elements constructed and fitted out to provide radiation protection from the use of radiation sources, and vehicles designed and fitted out to provide radiation protection during application of radiation sources.

Final disposal:	Emplacement without the intention of subsequent retrieval of radioactive waste in a natural or engineered barrier system, including in a facility, for the purpose of providing radiation protection.
Handling:	The practical operations associated with manufacture, application, storage, etc. of sealed or unsealed sources and devices containing sources. Handling includes, e.g. operations associated with receiving a source, work involving a source, and transferring a source.
Holding:	Ownership of, or right of use to, unsealed or sealed sources.
Import:	Transfer of unsealed or sealed sources to Denmark from another country.
Incident:	Any failure of a barrier resulting in a risk of unintended exposure.
Individual dose monitoring:	Determination of the *effective dose* or *equivalent dose* incurred by an individual, by means of a personal dosimeter or based on a dose monitoring programme.
Industrial radiography:	Radiography for industrial or research purposes, in which sealed sources or radiation generators are used inside or outside of facilities, e.g. for weld inspection. Industrial radiography does not comprise use of radiation generators in which the requisite shielding and safety features are built into the structure housing the radiation source.
Installation:	Assembly, fitting, setting up and connecting of a radiation generator and equipment to the responsible undertaking's utilities (e.g. electricity and water) so that radiation can be generated.

Ionising radiation:	Particles, including photons, capable of causing ionisation in substances directly or indirectly, but in the case of electromagnetic radiation only of a wavelength of 100 nm or less.
Late effect:	An injury for which no proven threshold dose has been defined as potentially causing that injury and where the risk of injury being caused increases proportionally to the magnitude of the dose. Examples of late effects are leukaemia and other types of cancer and genetic effects. Late effects may arise many years after exposure.
Manufacture:	The production or construction of radiation sources.
Medical exposure:	Exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment and intended to benefit their health, as well as exposure incurred by *carers and comforters* and by volunteers in medical or biomedical research.
Medical physics expert:	An individual, who within their field of expertise, is tasked with advising on matters relating to medical radiation physics and radiation sources, etc., and ensuring the performance of dosimetry, including measurements for evaluation of doses incurred by patients and individuals incurring medical exposure. The medical physics expert must be approved by the Danish Health Authority.
Medical use:	Application of radiation sources for *medical exposure*.
Member of the public:	An individual in the general population who may be subject to exposure.
Operational limits and conditions:	A set of rules specifying an acceptable range for critical parameters in order thereby to indicate when remedial action is required.

Other worker:	Worker who is not an exposed worker in an undertaking that uses radiation sources or is responsible for exposure.
Particle therapy:	Treatment of cancer using radiation generators that accelerate particles heavier than electrons, e.g. protons.
Performance testing:	Regular testing carried out for the purposes of medical use of radiation sources to ensure that the radiation source and equipment continue to conform to the pre-defined specifications and applicable operational limits and conditions.
Pre-licence:	The Danish Health Authority's confirmation that the documentation submitted substantiates that the requisite preconditions are present for the undertaking to proceed with the process leading up to acceptance into service and commissioning of radiation sources and/or facilities. May, for example, be granted if an undertaking submits a preliminary safety assessment prior to the start of construction works.
Quality assurance:	All planned and systematic actions, including quality control, necessary to provide adequate assurance that a radiation source, a facility, equipment, a system or component or a procedure will perform satisfactorily in compliance with agreed standards.
Quality management system:	A coherent and documented management system to assure the quality of the organisation's processes in a systematic and effective manner with a view to achieving the organisation's safety and radiation protection objectives. The system typically comprises organisational structure, resources and processes, workers and equipment as well as policies, procedures and instructions.
Radiation:	Ionising radiation.

Radiation generator:	A device capable of generating ionising radiation.
Radiation protection:	Arrangements for protection against ionising radiation, including prevention of emergencies, accidents and incidents and mitigation of the consequences thereof.
Radiation protection expert:	An individual who shall advise the undertaking to ensure effective radiation protection of workers and members of the public concerning the undertaking's use of radiation sources or exposures. The radiation protection expert must be approved by the Danish Health Authority.
Radiation protection officer:	An individual tasked with monitoring and assisting in maintaining the radiation protection of workers and members of the public in connection with the undertaking's use of radiation sources or exposures. The radiation protection officer must be approved by the Danish Health Authority.
Radiation source:	A radioactive substance or a radiation generator.
Radiotherapy:	Treatment of cancer using radiation generators operating with energies greater than or equal to 1 MeV.
Radioactive material:	A radioactive substance, the activity volume or activity concentration of which cannot be disregarded from a radiation protection point of view.
Radioactive substance:	A substance containing one or more radionuclides.
Radioactive waste:	Radioactive material for which no further use is foreseen.
Radionuclide:	Unstable atomic nucleus that undergoes decay as it emits ionising radiation.

Risk assessment:	Important part of a safety assessment. Assessment of the consequence and probability of exposure of workers and members of the public as well as potential impact on the environment resulting from anticipated operational occurrences or accident conditions. Can be used as a tool for prioritising risks. Used in conjunction with the safety analysis.
Safety analysis:	Important part of a safety assessment. Quantitative investigation to ascertain compliance with regulatory requirements and other objectives, e.g. dose constraints. Used in conjunction with the risk assessment.
Safety assessment:	An assessment of all aspects of an undertaking's specific use of radiation sources of relevance for safety and radiation protection.
Self-shielded radiation generator:	A radiation generator permanently integrated inside a shielding, which offers sufficient protection to permit the radiation generator to be operated outside of facilities, with no restrictions on human proximity to the radiation generator.
Storage:	Storage of radioactive material or radioactive waste in facilities specially designed for that purpose.
Technical safety inspection:	Regular inspection to ensure that a radiation generator and associated facilities and equipment are in a satisfactory technical state from the point of view of safety.
Testing:	See *constancy testing*, acceptance testing and performance testing.
Transfer (non physical):	Change of ownership of a sealed source from one undertaking to another. If an undertaking returns a disused source to the manufacturer or to Danish Decommissioning, this is also termed a transfer.

Undertaking:	Natural or legal person responsible for use of a radiation source.
Unintended exposure:	Exposure that significantly exceeds that incurred by persons and the environment through correct use of radiation sources, and medical exposure that is significantly different from the medical exposure intended for a given purpose.
Use:	Radioactive sources: Manufacture, processing, holding, import, export, transfer, handling, application, control, technical safety inspection, storage, disposal, recycling, reuse, discharge and carriage. Radiation generators: Manufacture in the process of which ionising radiation is generated, and alterations to radiation generators that might have implications from the point of view of radiation protection, and installation, application, testing and technical safety inspection.
Veterinary medical use:	The application of radioactive material or radiation generators for veterinary medical examinations, treatment or research within this domain, and for radiation generators, the exposure of animals for the purpose of research for advancing human diagnostics and treatment.
Worker:	Any person who, regardless of any underlying contractual relationship, is engaged in a worker-like relation.
X-ray radiation therapy:	Treatment of cancer using radiation generators operating with a voltage less than or equal to 100 kV.

Annex B: General Report Template

The present report template is based on IAEA Safety Standard GSR Part 4 (Rev. 1): Safety Assessment for Facilities and Activities. As described in Section 4.2, the safety assessment should follow a graded approach commensurate with the nature and scope of the use of radiation sources.

The complexity of a safety assessment depends first and foremost on the nature and scope of the undertaking's use of radiation sources and exposure, but for some specific applications special circumstances apply that may reduce the requirements regarding complexity. These special circumstances reduce the number of areas that specifically need to be addressed in the safety assessment, which in turn can be based on a simpler template. This applies e.g. to the templates for use of radiation generators by chiropractors and in veterinary medical examinations.

The template in this Annex B is therefore a general template covering most types of use. Annex C refers to adapted templates for a number of very specific applications.

1. Introduction

The introduction should include a brief description of the background to the safety assessment. The introduction might, for example, state that the purpose of the safety assessment is to systematically describe the undertaking's use of radiation sources and the nature of the radiation protection measures employed to address the risks entailed by the use of the radiation sources. The safety assessment is structured on the basis of a graded approach and thus covers all aspects necessary for documenting that relevant requirements from a radiation protection point of view have been complied with, and that the radiation protection has been optimised.

In addition, the introduction may include captions such as purpose, scope and responsibility:

Purpose

- A brief description of the undertaking's use of radiation sources subject to the licensing requirement (e.g. use of sealed sources for density and moisture measurement for purposes of contracting works, or use of radiation generators for the treatment of cancer patients).
- Objective – what requirements for radiation protection are complied with?
- Requirements in executive orders, instructions in guides, principles of radiation protection and methods of optimisation should be listed as bulleted items with reference, as applicable, to relevant executive orders, etc. In addition, the undertaking may present its own additional safety objectives, e.g. by establishing dose constraints.

Scope

- What use is covered, how is the graded approach employed?
- Coherence with the undertaking's quality assurance system
- A brief description of radiation sources and facilities
- A brief description of the undertaking's use of radiation sources.

Responsibility

- Indication of who is responsible for the licence within the undertaking. In other words, which individual has been delegated the responsibility for ensuring compliance with the terms and conditions of the licence.
- Indication of who is responsible for the design and approval of the safety assessment within the undertaking. In other words, which individual has been delegated the responsibility for reporting and submitting the safety assessment to the Danish Health Authority.
- Indication of who is responsible for ensuring that periodic review and amendment or updating of the safety assessment are carried out. In other words, which individual has been delegated responsibility for updates being carried out and submitted to the Danish Health Authority.

- Under what circumstances will the safety assessment be reviewed to assess the need for changes? Any changes of significance from a radiation protection point of view or that require amendment to the scope of the licence should be described, e.g., any change in the quantity of sources, intensity, activity volume, activity concentration and application, among users, in designated responsibility and any alteration to buildings/facilities; see Section 3.2 of the Guide.

- When must the Danish Health Authority be notified of changes? As soon as there is any intention to change the basis for a licence or its terms and conditions and before any such change is implemented.

The safety assessment should also be version-controlled.

2. Description of the undertaking's/department's use of radiation sources
This section is for describing the undertaking's physical conditions, processes and sub-processes for use of radiation sources.

Facilities

- Description of the rooms, buildings, etc. used, e.g. by means of floor plans incl. adjoining rooms and floors, the location of radiation sources, indication of workplaces, general occupancy, shielding, etc.

- Floor plans showing distances, the dimensions of shielding, walls, floors, windows and descriptions of structural materials. Reference may be made to appendices showing floor plans, etc.

- Classification of areas and facilities (supervised or controlled).

Radiation sources and equipment

- Information on radiation sources and equipment of relevance for safety. Reference may be made to appendices containing technical specifications, etc.

Use

- Description of the undertaking's use of radiation sources in sub-processes. The use may be broken down into relevant sub-processes, e.g.:
  - Source receipt
  - Manufacture
  - Acceptance testing
  - Application
  - Testing
  - Technical safety inspection/servicing
  - Storage
  - Handling of activated components
  - Handling of radioactive waste
  - Discharge
  - Carriage
  - Change in use due to termination of operation.
- The undertaking may at its option describe other sub-processes for this purpose on condition that all sub-processes during which members of the public or workers might incur exposure are described. It may be helpful to provide a flowchart illustrating the undertaking's use of radiation sources.

3. Description of radiation protection, optimisation, personnel competences

This section is for describing radiation protection and optimisation within the undertaking on the basis of the information on physical conditions (facilities, other premises, surroundings, etc.), radiation sources and their use, as described in Section 2, with reference, as applicable, to the role of the quality system in maintaining radiation protection. In addition, the personnel competences required for the work with the radiation sources should be described.

Radiation protection and optimisation should be described for each sub-process identified in Section 2:

- How do, e.g. distance from radiation sources, restrictions on proximity time, access control, use of shielding, work procedures, etc. serve to reduce exposure and thereby optimise the radiation protection?

Examples of radiation protection measures that may be of relevance are listed below.

Monitoring and control: a) Dose rate monitoring, b) Access to measuring instruments, c) Test measurements after use, d) Visual or acoustic alarms, e) Product inspection, f) Technical safety inspection.

Other dose limitation: a) Proximity time, b) Shielding, c) Facility design, d) Use of a collimator.

Facilitation of planned exposure: a) For medical exposures: correct prescribing/referral (justification), b) Use of exposure protocols, c) Verification measurement of output, d) If exposure (dose) is calculated individually for each exposure, then verification of the calculation.

Access restriction: a) Access control, b) Video surveillance, c) Special keys or access cards, d) Interlocks for automatic termination of exposure e) Containment.

See also the annexes setting out requirements and special requirements for specific applications in the Executive Order on Ionising Radiation and Radiation Protection (Executive Order No. 670/2019) and in the Executive Order on Use of Radiation Generators (Executive Order No. 671/2019).

Specifically for radiation generators: Compliance with *operational limits and conditions*, access to lead aprons and lead gloves, cassette holders, screen/tube head, exposure indicators (audiovisual), easily accessible emergency stop switches, permanently installed dose rate meters.

Specifically for radioactive material: Activity volume limitation, activity concentration limitation, radiation safety cabinet, ventilation/air exchange, interlocks and air pressure, protective suit, gloves and respiratory protection, access to washbasin, emergency shower and isotope drain, easy-to-clean surfaces, containers for storage or carriage, waste management and emergency response functions.

Staff competences: Education and training programmes.

Other radiation protection measures may be relevant for the undertaking.

4. Assessment of safety throughout the lifetime of the undertaking

A complete safety assessment should cover the entire life cycle of the undertaking, from the initial planning of a new use of radiation sources to the final phase-out – especially when using radioactive sources or in the presence of the possibility of activation. The safety assessment should include a section specifically addressing factors ensuing from major changes over the lifetime of the undertaking. This should include how the ageing of installations and apparatus, appliances or devices is addressed, including the specific situation in which it has been decided that an undertaking or activity is to be terminated. The safety assessment may in this case form part of the undertaking's decommissioning/closure plan and should describe the radiation hazards entailed (e.g. the nature and volume of activated building components) and what measures need to be implemented to optimise radiation protection during the decommissioning/closure (e.g. how the building components will be dismantled).

5. Calculation of optimised doses during routine operation and maximum doses in the event of an accident

This section is for specifying the radiation doses that may be incurred from the undertaking's use of radiation sources described in Section 2, taking into account the radiation protection and optimisation described in Section 3. In addition, a description should be provided of realistic accident scenarios and the maximum doses that such accidents might cause.

Radiation doses for work processes that may cause exposure, incl. testing, service and technical safety inspection

Doses should be estimated on the basis of calculations, with reference, if applicable to dose rates, proximity times and distances (e.g. indicated on floor plans), duration of exposures, number of annual exposures, etc. The calculations should be performed on the basis of estimated upper bounds on exposure times, dose rates, etc., and the realistic interval of doses corresponding to the variation in bounds for exposure time, dose rate, etc. should be indicated, if applicable. The specific numerical values and other assumptions forming the basis for the calculations should be stated.

Doses should be calculated for each sub-process, and exposure of members of the public or workers described, if applicable. For descriptions of the basis and assumptions for calculations, reference may be made to documentation in appendices.

Workflows, procedures and sub-processes that can be expected to result in the highest doses of radiation, as well as which categories of individuals would incur those doses (exposed workers, other workers, members of the public) may be described in a table.

For each sub-process, a table should ideally be provided to show specific radiation scenarios, measures to limit exposure as well as the estimated or calculated doses different categories of individuals might incur in those scenarios. An example of such a table is seen in Table B1.

Table B1

Example of a table presenting specific exposure scenarios, measures to limit the exposure, and the estimated annual dose potentially caused by a given exposure scenario. Reference may be made to procedures, floor plans, calculations, etc. in the appendices to the safety assessment.

Scenario	Relevant protective measures	Estimated annual dose to exposed workers, other workers and/or members of the public
E.g. moving a logging source from its container to a borehole.	E.g. handling instructions, presence of two qualified workers, handling equipment, dose rate meter, site containment.	Doses must be calculated on the basis of the radionuclide, activity volume, distance, etc. Calculation should be performed under the supervision of a radiation protection expert. Reference should be made to calculations in appendices, as applicable.
E.g. sampling of unsealed source from stock solution.	E.g. instructions on handling, facility fixtures and fittings, radiation safety cabinet, additional mobile shielding, lead shield for syringe, gloves.	Doses must be calculated on the basis of the radionuclide, activity volume, distance, etc. Calculation should be performed under the supervision of a radiation protection expert. Reference should be made to calculations in appendices, as applicable.

Determination of doses incurred from incidents or accidents

Incidents: Based on the sub-processes and own operating experience, the undertaking should identify realistic scenarios in which *unintended exposure* could occur, e.g. due to non-compliance with procedures, and estimate the dose that would be incurred. The undertaking may refer to appendices documenting and describing the basis and assumptions for calculations.

Accidents: Based on the sub-processes and own operating experience, the undertaking should identify realistic scenarios in which technical failures, external adverse events (e.g. flooding, lightning strike, fire) or ordinary spillage might cause exposure or dispersion of radioactive material, and estimate the dose that would be incurred. The assessment may be limited to one or a few scenarios in which a technical failure or fault occurs. For descriptions of the basis and assumptions for calculations, reference may be made to documentation in appendices. Doses from potential incidents and accidents should ideally be presented in a table, as shown in Table B2.

Table B2

Example of a table presenting specific incidents or accidents, their causes, who is at risk, measures to limit exposure, and the consequences and doses of radiation the exposure scenario might result in. Reference may be made to procedures, floor plans, calculations, etc. in the appendices to the safety assessment.

Incident or accident	Cause	Who is at risk	Measures to limit exposure	Consequence, incl. radiation doses
E.g. exposure of workers from a logging source.	Loss of sealed source during transfer from tank to borehole due to defective equipment.	Exposed workers.	Site containment, instruction of workers in accident procedure.	Dose calculated on the basis of the radionuclide, activity volume, distance, etc. Calculation should be performed under the supervision of a radiation protection expert.
E.g. contamination of the skin by unsealed source.	Touching of contaminated surface.	Exposed workers. Cleaning staff.	Test measurement after handling completed. Thorough hand washing.	May pose risk of ingestion as well as doses to the skin. Dose calculated on the basis of the radionuclide, activity volume, distance, etc. Calculation should be performed under the supervision of a radiation protection expert.

Summary (see also "Conclusion" in Figure 2, Section 4.5 of the Guide)

Here, the undertaking should indicate the aggregate assessed doses to exposed workers, other works and members of the public during operation, incidents and accidents. The results should be used to categorise workers and assess the need for individual dose monitoring.

6. Any measures to supplement the above

This section is used for describing additional measures that are deemed necessary on the basis of regulatory requirements or the undertaking's own requirements.

Insofar as these have not already been included in the description of radiation protection and optimisation (Section 3), supplementary radiation protection measures might include:

- Categorisation of workers (Categories A, B, C), including individual dose monitoring (1- or 3-month period, passive or active radiological monitoring), as well as medical examinations of Category A exposed workers.
- Quality assurance by means of a quality management system
- Competence maintenance (procedures, recruitment, training, drills, courses, etc.)
- Further optimisation (dose constraints, etc.)
- Compliance with general occupational health and safety requirements conducive to radiation protection.

7. Compliance with requirements for radiation protection

In this section, the undertaking should assess whether the objective it established in Section 1 has been complied with.

- Compliance with statutory requirements should be described, with reference, as applicable, to relevant appendices covering classification of areas, responsibility and competence factors, etc.
- Compliance with the undertaking's own requirements and objectives for radiation protection, including optimisation, should be described.

Annex C: Report templates for selected types of use and facilities

This Annex makes reference to a number of specific safety assessment report templates for selected applications. While the templates match the general report template in Annex B, they have been revised to embody the graded approach for the specific type of use.

The application-specific templates cover the following types of use:

- Process control by means of sealed sources
- Industrial radiography inside facilities
- Radiation generators for chiropractic examinations
- Radiation generators for veterinary medical examinations.

Additional report templates are expected to be published.

Safety assessment for process control by means of sealed sources

This template may be used for safety assessment of the application and technical safety inspection of sealed sources in connection with the following types of process control:

- Level measurement
- Fill-height detection
- Flow measurement
- Thickness gauging
- Belt load weighing
- Mass-per-unit-area measurement
- Moisture measurement.

The following radionuclides are covered:

- Co-60
- Cs-137
- Ba-133
- Am-241.

If the use of sealed sources is not subject to the licensing requirement; see Annex 1, Executive Order No. 670/2019, the undertaking is not required to perform a safety assessment.

The safety assessment must document fulfilment of general requirements for radiation protection in accordance with Danish Health Authority Executive Orders No. 669/2019 and No. 670/2019. In addition, the safety assessment should meet the relevant requirements set out in IAEA Safety Standard, GSR Part 4 (Rev. 1).

The safety assessment template for process control by means of sealed sources is available here.

The template should be filled in by the undertaking and submitted to the Danish Health Authority, Radiation Protection at sis@sis.dk.

All the Danish Health Authority templates for safety assessments are available from the Guidelines section on the Danish Health Authority's website, www.sst.dk/da/viden/straaling/vejledninger.

Safety assessment for industrial radiography inside facilities

This template may be used for safety assessment of the use and inspection of radiation generators and sealed sources employed for *industrial radiography* inside facilities.

Sealed sources and radiation generators employed for industrial radiography outside facilities are subject to additional safety requirements and are not covered by this Annex.

The safety assessment must ensure compliance with general requirements for radiation protection in accordance with the Danish Health Authority's Executive Orders No. 669/2019, No. 670/2019 and No. 671/2019 and also comply with supplementary requirements for industrial radiography inside facilities (Annex 12, Executive Order No. 670/2019; Annexes 14 and 15, Executive Order No. 671/2019). In addition, the safety assessment should meet the relevant requirements set out in IAEA Safety Standard, GSR Part 4 (Rev. 1). The undertaking is also recommended to follow the guidelines set out in the Danish Health Authority's current guide on industrial radiography.

The safety assessment template for industrial radiography inside facilities is available here.

The template should be filled in by the undertaking and submitted to the Danish Health Authority, Radiation Protection at sis@sis.dk.

All the Danish Health Authority templates for safety assessments are available from the Guidelines section on the Danish Health Authority's website, www.sst.dk/da/viden/straaling/vejledninger.

Safety assessment for radiation generators for chiropractic examinations

This template may be used for safety assessment for the use of radiation generators for conventional medical diagnostics by chiropractors.

The safety assessment must ensure compliance with requirements for radiation protection in accordance with the Danish Health and Medicines Authority's Executive Orders No. 669 and No. 671 and should comply with relevant recommendations stated in the IAEA Safety Standard, GSR Part 4 (rev. 1).

The safety assessment template for radiation generators for chiropractic examinations is available here.

The template should be filled in by the undertaking and submitted to the Danish Health Authority, Radiation Protection at sis@sis.dk.

All the Danish Health Authority templates for safety assessments are available from the Guidelines section on the Danish Health Authority's website, www.sst.dk/da/viden/straaling/vejledninger.

Safety assessment for radiation generators for veterinary medical examinations

This template may be used for safety assessment of use of radiation generators for the following types of veterinary medical examinations:

- Conventional X-ray (application outside the undertaking)
- Dental X-ray (application outside the undertaking)
- X-ray by means of hand-held X-ray devices (requires special justification)
- CT
- Fluoroscopy.

Here it should be noted that conventional veterinary medical radiography and dental radiography performed at the undertaking's own premises are not subject to the radiation protection legislation's licensing requirement and that a safety assessment is thus not required.[56]

The safety assessment must ensure compliance with requirements for radiation protection in accordance with the Danish Health and Medicines Authority's Executive Orders No. 669 and No. 671 and should comply with relevant recommendations stated in the IAEA Safety Standard, GSR Part 4 (rev. 1). Veterinarians providing roving services (using portable devices outside their own premises) are also recommended to follow the Danish Health Authority guide fro 2016 on veterinary use of portable X-ray appliances as regards compilation of the safety assessment.

The safety assessment template for radiation generators for veterinary medical examinations is available here.

The template should be filled in by the undertaking and submitted to the Danish Health Authority, Radiation Protection at sis@sis.dk.

All the Danish Health Authority templates for safety assessments are available from the Guidelines section on the Danish Health Authority's website, www.sst.dk/da/viden/straaling/vejledninger.

56 Annex 1, 2, Executive Order No. 671/2019.

Radiation protection advice

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