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Use of sealed sources

Non-medical purposes

Guide

Sundhed for alle

Use of sealed sources

Danish Health Authority
Islands Brygge 67
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Introduction

The purpose of this Guide is to contribute to correct interpretation and application of the rules regarding *use* of *sealed sources*. The rules are laid down in the Radiation Protection Act and related executive orders (the radiation protection legislation); see Chapter 16. The purpose of the rules is to ensure that the use of sealed sources 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.

This Guide is aimed at *undertakings* that use sealed sources for *non-medical purposes*, for example, manufacture devices containing sealed sources or use sealed sources for testing *equipment*, etc., *process control*, *moisture and density measurement*, *borehole logging*, *blood irradiation* or *industrial irradiation,* etc. The Guide does not include *application* of sealed sources for educational purposes at lower and upper secondary educational institutions, *industrial radiography*, *medical exposure* and *veterinary medical application* or *consumer products*. Furthermore, this Guide does not include information for undertakings that perform *technical safety inspection* and servicing of sealed sources.

The Guide reiterates the requirements of the radiation protection legislation regarding use of sealed sources and contains the Danish Health Authority's guidelines for achieving compliance with those requirements. The undertaking can expect that its use of sealed sources is compliant with the requirements if it follows the instructions of this Guide. The instructions in the Guide are not binding upon the undertaking in that it may, in some cases, opt to fulfil a requirement by a procedure other than as instructed if it provides the same degree of radiation protection. If an alternative procedure is followed, the undertaking must be able to document that its chosen procedure satisfies the requirements. A final decision concerning this may, if necessary, be made by the Danish Health Authority.

Footnotes, italics and formulas

The Guide makes reference in footnotes to relevant sections of the radiation protection legislation, etc. Italicised terms are explained in the glossary in Annex A. Relevant formulas, units and conversion factors can be found in Annex B.

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

1. The term use

The radiation protection legislation employs the term use. The term has a broader meaning compared with the usual sense in that use denotes all actions involving *radioactive substances*.

The term use

In the radiation protection legislation, use of radioactive substances means:

Manufacture, processing, *holding*, *import*, *export*, *transfer*, *handling*, application, control, technical safety inspection, *storage*, *disposal*, recycling, reuse, discharge and *carriage* of radioactive substances.[1]

Thus, while the terms use and application may be construed as synonymous in other contexts, in the context of radiation protection they do not denote the same thing, since application is just one of many sub-elements of the concept of use.

For the areas of use and application covered by this Guide, the following sub-elements of the term use are of relevance: manufacture, holding, import, export, transfer, handling, application, technical safety inspection, storage and carriage. The following describes how these sub-elements are to be understood in relation to sealed sources.

Manufacture
Manufacture means construction and production of sealed sources and devices containing sealed sources. The process does not include manufacture of the *radionuclides* contained in the sealed sources, as this procedure would usually be considered as an operation involving *unsealed sources*. For the manufacture of radionuclides please refer to the Danish Health Authority's Guide on the Use of Unsealed Sources; see Chapter 16.

Holding
Holding means ownership or right of use of sealed sources.

Import
Import means *shipment* of sealed sources to Denmark from another country.

[1] Section 10, No. 7a, Executive Order No. 669/2019.

Export
Export means shipment of sealed sources from Denmark to another country.

Transfer
Transfer means the 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.

Handling
Handling means the practical operations associated with manufacture, application, storage, etc. of sealed sources and devices containing sources. Handling includes, for example, operations associated with receiving a source, work involving a source, and shipment of a source.

Application
Application means utilisation of a sealed source for its intended purpose, such as for testing equipment, process control, moisture and density measurement, borehole logging, blood irradiation and industrial irradiation.

Technical safety inspection
Technical safety inspection means a review to ensure that sealed sources, including devices containing sources and, where relevant, *facilities* and equipment, are in a satisfactory technical state from a safety perspective.

Storage
Storage means any storing of sealed sources, for example, in specially-equipped storage locations inside the facilities where the sources are utilised, or inside facilities dedicated to storage of sealed sources or *radioactive waste*.

Carriage
Carriage means the transportation of a sealed source from one location to another by public road, rail, sea or air.

2. Radiation protection principles

Radiation protection in Denmark is based on a globally recognised system for that purpose. The system follows the recommendations of the International Commission on Radiological Protection (ICRP); see Chapter 16, and is based on three fundamental principles: justification, optimisation and dose limitation. The principles have been incorporated into the Danish radiation protection legislation. The significance of the principles to use of sealed sources is described below.

2.1. Justification

The main principle governing the use of sealed sources is that such use shall be justified. This means that use of sources shall take place solely if the health, financial, societal or other benefits of that use outweigh the detriment.[2]

If possible, an alternative method shall be used

Assessment of the justification shall include consideration of the options for using an alternative method, such as a method

- not based on *radiation*,
- which is based on radiation from a *radiation generator* rather than radiation from a sealed source[3], or
- which involves significantly reduced *exposure* or risk.

Assessment of the justification shall be based on factors such as the radionuclide, the activity, encapsulation and the sensitivity of any detection systems.[4]

It is the undertaking's duty to assess whether a given use is justified or whether an alternative method, which might not involve sealed 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 regularly assess whether its use of sealed sources continues to be justified.[5] This may be ensured by utilising, inter alia, a *quality management system*; see Chapter 15.

The Danish Health Authority's assessment is that use of sealed sources comprised by the present Guide will usually be justified provided that it takes place in accordance with

2 Section 16(1), Executive Order No. 669/2019.
3 Section 16(3), Executive Order No. 669/2019.
4 Section 16(4), Executive Order No. 669/2019.
5 Section 16(7), Executive Order No. 669/2019.

the requirements of the radiation protection legislation and the instructions in the Guide. The undertaking shall, however, always make its own assessment of whether its specific use of sealed sources is justified. In case of doubt, the undertaking is welcome to consult the Danish Health Authority. The Danish Health Authority may, at any time, assess and determine whether an undertaking's use of sources is justified.[6]

2.2. Optimisation

The optimisation principle entails that use of sealed sources shall take place solely if the likelihood and magnitude of the exposure, including the number of individuals exposed, are as low as achievable taking into account the current state of technical knowledge and financial and societal factors.[7]

Achieving optimisation

Optimisation is achieved by means of a continuous process involving the following sub-procedures:

1. Assessment of the exposure situation, including potential exposure from any emergency, accident or incident.
2. Application of appropriate *dose constraints*
3. Identification of potential options for radiation protection
4. Selection of the best option for radiation protection under the given circumstances
5. Implementation of the best option for radiation protection in practice.

The Danish Health Authority may, at any time, assess and determine whether the use of sealed sources has been sufficiently optimised.[8]

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

6 Section 17, Executive Order No. 669/2019.
7 Section 18, Executive Order No. 669/2019.
8 Section 19, Executive Order No. 669/2019.

Dose constraints

The maximum dose constraint applicable to an undertaking's combined use of sealed sources is 0.1 mSv/year for members of the public.[9]

Dose constraints for the undertaking's *exposed workers* shall be established, if necessary, by the undertaking.

The maximum dose constraint applicable to the undertaking's *other workers* is 0.3 mSv/year.[10]

The dose constraints shall be included in the planning of the undertaking's use of sealed sources. The application of dose constraints shall result in optimisation of the radiation protection, i.e. the minimisation of exposure, for example by means of access control, restrictions on duration of exposure and by utilisation of shielding to ensure that the actual exposure of workers and members of the public can be expected to be lower than the dose constraint. For use of sealed sources subject to licensing requirements, the optimisation process shall commence with a basic *safety assessment*; see Chapter 6.[11]

2.3. Dose limitation

The sum of doses to an individual must not exceed the dose limits.[12] The dose limits are determined in order to limit the risk of incidence of *late effects* and prevent the incidence of *acute effects*. The dose limits applicable to *occupational exposure* and *public exposure* from use of all types of *radiation sources* by undertakings are shown in Table 1.

9 Section 21(1), Executive Order No. 669/2019.
10 Section 22, Executive Order No. 669/2019.
11 Section 20(1), Executive Order No. 669/2019.
12 Sections 23 and 31, Executive Order No. 669/2019.

Table 1
Dose limits[13]

Category of individual	Limit *effective dose* [mSv/year]	Limit *equivalent dose* [1] [mSv/year]		
		Lens of the eye	Skin[2]	Extremities[3]
Exposed worker, aged 18 years or over	20	20	500	500
Individual aged between 16 and 18 years[4]	6	15	150	150
Member of the public	1	15	50	-

[1] No dose limits have been established for organs and tissues other than the lens of the eye, skin and extremities, as the dose limit applicable to the effective dose sufficiently limits the dose to other organs and tissues.

[2] The dose limit for the skin applies to any surface of 1 cm^2.

[3] Extremities means the hands, forearms, feet and ankles.

[4] Individual aged between 16 and 18 years who is pursuing a programme of vocational education of at least two years' duration, which is governed by or pursuant to legislation, and where use of radiation sources is a necessary component of that programme.

Further, the equivalent foetal dose incurred from maternal occupational exposure is required to be kept as low as reasonably achievable and must not exceed 1 mSv following notification of the pregnancy to the *employer*.[14]

In the event that a dose limit for occupational exposure is exceeded, the worker may not perform any additional work entailing radiation exposure without approval from the Danish Health Authority.[15]

See Chapter 8 for information on radiological monitoring.

13 Annex 1, Executive Order No. 669/2019.
14 Section 24, Executive Order No. 669/2019.
15 Section 25, Executive Order No. 669/2019.

3. Responsibility

Responsibility for compliance with the requirements of the radiation protection legislation rests with the undertaking that uses sealed sources. However, if the undertaking utilises *outside workers*, the employer of those workers has an independent responsibility for compliance with certain parts of the legislation.

3.1. The undertaking's responsibility

The undertaking that uses sealed sources generally has the full responsibility for compliance with all the requirements of the radiation protection legislation.

In cases where undertaking A borrows, hires or leases a sealed source from undertaking B, it is undertaking A that is responsible for compliance with the requirements of the legislation. This means, for example, that it is undertaking A that is responsible for obtaining a licence from the Danish Health Authority for use of the source, or for notifying the Danish Health Authority of such use and for arranging for registration of the source.

An undertaking's *radiation protection officer*; see Subsection 4.1, is not personally liable for the undertaking's compliance, but shall assist the undertaking in this regard.

A *radiation protection expert*, see Subsection 4.2, acts as an advisor to the undertaking and thus has no personal liability for the undertaking's compliance.

3.2. Allocation of responsibilities and requirements associated with outside workers

When an undertaking that uses sealed sources hires outside workers for work, the employer of such workers has an independent responsibility for compliance with certain parts of the radiation protection legislation.[16] This will be the case, for example, if a worker performs a technical safety inspection of a device containing a sealed source or performs servicing at a facility for an undertaking in which the worker is not employed.

The following sets out the compliance requirements for which an employer of outside workers assumes sole responsibility, and the compliance requirements for which the undertaking and the employer are responsible independently of each other. Responsibility for compliance with the remaining requirements of the radiation protection legislation rests solely with the undertaking.

16 Sections 12 and 13, Executive Order No. 669/2019.

Employer's responsibility – outside workers

The employer assumes responsibility for compliance with the following:

- The requirement for categorisation of exposed workers[17]; however, the undertaking shall verify that the categorisation is appropriate to the doses that the worker is likely to incur from working for the undertaking[18]
- The requirement regarding who may be employed as exposed workers[19]
- The requirement for exposed workers to be instructed on the necessity of early notification of pregnancy in order to establish measures to ensure that the foetal dose becomes as low as reasonably achievable.[20]
- The requirement for exposed workers to be informed of the result of radiological monitoring as soon as possible after the result becomes available[21]
- The requirement for the Danish Health Authority to be notified immediately of doses exceeding the established dose values[22]
- The requirement for doses to exposed workers for the past five calendar years to be documentable[23]
- The requirement for the results of *individual radiological monitoring* to be notified to the Danish Health Authority's Personal Dose Registry no later than four weeks after the results become available.[24]

17 Sections 38-41, Executive Order No. 669/2019.
18 Section 12(2), Executive Order No. 669/2019.
19 Sections 42 and 43, Executive Order No. 669/2019.
20 Section 45(1), No. 6, Executive Order No. 669/2019.
21 Section 84(1), Executive Order No. 669/2019.
22 Section 85, Executive Order No. 669/2019.
23 Section 86, Executive Order No. 669/2019.
24 Section 87, Executive Order No. 669/2019.

Joint responsibility for the undertaking and the employer – outside workers

The undertaking and the employer are jointly responsible for compliance with requirements, including:

- The requirements for justification, optimisation and dose limitation[25]
- The requirements for information, training, instruction, knowledge, skills and competences of and for workers[26]
- The requirements for radiological monitoring of exposed workers[27]
- The requirement for informing other workers about the undertaking's use of sealed sources and the precautions that shall be taken by those workers[28].

The undertaking's responsibility for compliance with the above-mentioned requirements solely pertains to aspects directly related to the outside worker's specific work within the undertaking.[29]

If an undertaking hires category A outside workers; see Chapter 7, the undertaking has a duty to obtain the outside worker's dose history from the employer before the worker is assigned to work involving use of sources.[30]

Undertakings that hire an outside worker shall, if the result of radiological monitoring is not sent to the employer automatically, disclose the result to that employer as soon as possible.[31]

The remainder of this Guide assumes that the undertaking does not hire outside workers.

25 Chapters 4-6, Executive Order No. 669/2019.
26 Section 45(1), Nos. 1-4, and Section 46, Executive Order No. 669/2019.
27 Sections 78-79 and Section 81, Executive Order No. 669/2019.
28 Section 46, Executive Order No. 669/2019.
29 Section 13(2), Executive Order No. 669/2019.
30 Section 44, Executive Order No. 669/2019.
31 Section 83, Executive Order No. 669/2019.

4. Designated expert individuals

The radiation protection legislation distinguishes between two different professional roles of relevance to use of sealed sources for non-medical purposes subject to licensing or notification requirements; see Chapter 5. The titles of these roles are: radiation protection officer and radiation protection expert.

The duties of a radiation protection officer and a radiation protection expert must be carried out by individuals who possess special knowledge, skills and competences regarding use of sealed sources.[32] The roles may each be performed by a single individual or by a group of individuals who jointly have the requisite expertise.[33] In certain cases, the nature, scale or complexity of use may entail that the Danish Health Authority imposes requirements for multiple radiation protection officers or radiation protection experts for an undertaking's use of sources.

These expert individuals shall cooperate to the relevant extent in the performance of their respective duties.[34]

4.1. Radiation protection officer

When using sealed sources subject to licensing or notification requirements, the undertaking shall at all times have a radiation protection officer at its disposal.[35] The radiation protection officer shall assist the undertaking with activities such as monitoring and maintaining the radiation protection of workers and members of the public in connection with the undertaking's use of sources.

When an undertaking needs to have a radiation protection officer "at its disposal", this means that the undertaking and its workers must be able to contact the radiation protection officer readily without delay. It is therefore recommended that the radiation protection officer is present daily on-site at the undertaking's premises. The radiation protection officer shall, as a minimum, have knowledge of radiation and radiation protection and the legislation in this area as well as possess the necessary competences for monitoring or overseeing operation of the radiation protection arrangements that are of relevance in relation to the undertaking's use of sealed sources.[36] Certain uses and applications of sources are subject to special requirements regarding the knowledge, skills and competences (qualifications) to be possessed by the radiation protection officer. These requirements are set out in Annex C.

32 Section 34(2), Executive Order No. 669/2019.
33 Section 33(4), Executive Order No. 669/2019.
34 Section 37, Executive Order No. 669/2019.
35 Section 33(1), Executive Order No. 669/2019.
36 Subsection 1, Annex 7, Executive Order No. 670/2019.

The Danish Health Authority must approve the radiation protection officer.[37] Approval is granted upon application by the undertaking. The application must include documentation of the radiation protection officer's knowledge, skills and competences.[38] The radiation protection officer is required to confirm by his/her signature, his/her performance of the professional role within the undertaking.[39] The radiation protection officer's knowledge, skills and competences shall be updated as needed, for example, when introducing new types of sealed sources or techniques. When using *high-activity sealed sources* updating shall be completed at intervals of no more than five years.[40]

The radiation protection officer's tasks

The tasks of the radiation protection officer will vary according to the nature, extent and complexity of the use of sealed sources, but the radiation protection officer will typically assist with the following tasks:[41]

- Ensuring that use of sources is compliant with the undertaking's instructions
- Maintenance of records
- Carrying out regular assessments of the condition of relevant safety and warning systems.
- Providing workers with information, training and instruction concerning use of sources
- Supervising the performance of individual radiological monitoring
- Reporting to local management
- Implementing procedures for prevention, emergency preparedness and response in the event of incidents, accidents or emergencies, including *emergency exposure situations*.

37 Section 34(1), Executive Order No. 669/2019.
38 Section 34(2), Executive Order No. 669/2019.
39 Section 35(1), Executive Order No. 669/2019.
40 Section 34(4), Executive Order No. 669/2019.
41 Section 33(1), Executive Order No. 669/2019.

The radiation protection officer has a duty to

- inform the Danish Health Authority if the undertaking fails to implement the measures necessary for compliance with the rules in the radiation protection legislation and any additional requirements stipulated by the Danish Health Authority.[42]
- notify the Danish Health Authority when he/she resigns or is absent from work beyond the norm, for example, due to a leave of absence.[43]

Before a radiation protection officer resigns, the undertaking must have obtained the Danish Health Authority's approval of a new radiation protection officer, otherwise the licence to use sealed sources or a notification of such use will be rendered invalid.

4.2. Radiation protection expert

For any use of sealed sources subject to licensing, the undertaking shall, commensurately with the nature, scale and complexity of the use, consult a radiation protection expert on matters of relevance from a radiation protection point of view.[44] “Consult” means that the expert shall be involved in specific matters from the point of view of radiation protection.

Use subject to the requirement for a radiation protection expert

The Danish Health Authority normally requires the undertaking to consult a radiation protection expert on matters of manufacture, application, storage, etc. of high-activity sealed sources and devices containing such sources.

Use not subject to the requirement for a radiation protection expert

For the following uses of sealed sources, the Danish Health Authority does not normally require the undertaking to consult a radiation protection expert:

- Standard application of devices for process control, for example, permanently installed density, moisture, level or thickness gauges containing sources
- Standard application of mobile moisture and density measurement devices containing sources, in connection with road-grading surveys.

42 Section 35(2), Executive Order No. 669/2019.
43 Section 35(3), Executive Order No. 669/2019.
44 Section 33(2), Executive Order No. 669/2019.

If the undertaking is in doubt as to whether its use of sealed sources is subject to the requirement to consult a radiation protection expert, an enquiry shall be made with the Danish Health Authority, which on the basis of an assessment of the nature, scale and complexity of a specific use or application of sources as well as the associated risk, will determine if it is required to consult a radiation protection expert.

The Danish Health Authority must approve the radiation protection expert.[45] The application for approval must be made by the expert personally. The undertaking is not responsible for approval of the radiation protection expert, but it must ensure that the radiation protection expert it consults holds approval to serve as a radiation protection expert for use of sealed sources.

As the professional role of radiation protection expert is not usually associated with extensive personal attendance on-site, the radiation protection expert typically advises the undertaking as an external consultant.

The radiation protection expert's duties

The radiation protection expert's advice shall, as a minimum, comprise the following aspects: [46]

- Optimisation and the establishment of dose constraints
- Preparation of safety assessments and instructions
- Plans for commissioning new types of sources and new or modified facilities
- Classification of areas
- Information, training, instruction and further education for exposed workers
- Categorisation of exposed workers
- Employment conditions for pregnant exposed workers
- Individual radiological monitoring
- Dose rate monitoring equipment
- Environmental monitoring programme

45 Section 34(1), Executive Order No. 669/2019.
46 Section 33(2), Executive Order No. 669/2019.

- Guidelines for handling, storage, transfer, etc. of radioactive waste
- Procedures for prevention, emergency preparedness and response in the event of incidents, accidents or emergencies, including emergency exposure situations.
- Investigation and analysis of incidents, accidents and emergencies
- Quality management system for use of sources.

The radiation protection expert shall document his/her advice to the undertaking and issue a copy of the signed documentation to the undertaking.[47]

47 Section 36, Executive Order No. 669/2019.

5. Licensing, notification, registration, etc.

The radiation protection legislation applies three levels of regulatory control for the use of sealed sources commensurate with the risk posed by that use: licensing, notification and exemption from licensing and notification.

In principle, any use of radiation sources is subject to licensing, which is the most restrictive level of regulatory control. In cases where use is associated with a low risk, there is no requirement for licensing, and the undertaking shall instead notify the Danish Health Authority of the use. If the risk is so low that there is no need for radiation protection arrangements, the undertaking's use of sources is exempt from licensing or notification requirements.

5.1. Licensing

A licence is always required for certain types of use of sealed sources.

Uses of sealed sources that are always subject to licensing

Manufacture of sources as well as the assembly and dismantling of sources in connection with the production, etc. of devices containing sources always requires a licence.[48]

In addition, a licence is always required for application, storage, etc. of sealed sources if the combined activity of the undertaking's sources exceeds 100 times the *exemption value*.[49] Exemption values for commonly used radionuclides are listed in Annex D.

If the undertaking engages in application, storage, etc. of sealed sources with different radionuclides, it is the size of the activity index value, I_{A}, that determines whether the undertaking is subject to licensing requirement. The activity index is calculated by means of the following formula:

$$I_{\mathrm{A}} = \sum_{k} \frac{A_{\mathrm{k}}}{A_{\mathrm{U,k}}} \qquad (1)$$

48 Section 6, No. 2, Executive Order No. 670/2019.
49 Section 5(1), Executive Order No. 670/2019.

where A_{k} is the total activity of radionuclide k, and $A_{\mathrm{U,k}}$ is the exemption value for that radionuclide. If the calculated activity index value is greater than 100, the undertaking is subject to licensing requirement.

Example of determination of the level of regulatory control level based on activity index

An undertaking engages in application and storage of sealed sources containing Co-60, Se-75 and Cs-137. The total activities held by the undertaking are indicated below.

Radionuclide	Activity [Bq]
Co-60	5×10^6
Se-75	4×10^7
Cs-137	5×10^5

To assess whether the undertaking's application and storage are subject to licensing or notification requirements, or are exempt from them, the activity index is calculated by means of Formula 1. The exemption values for Co-60, Se-75 and Cs-137 are listed in Annex D.

Activity index:

$$I_{\mathrm{A}} = \sum_{k} \frac{A_{\mathrm{k}}}{A_{\mathrm{U,k}}} = \frac{A_{\text{Co-60}}}{A_{\mathrm{U,Co\text{-}60}}} + \frac{A_{\text{Se-75}}}{A_{\mathrm{U,Se\text{-}75}}} + \frac{A_{\text{Cs-137}}}{A_{\mathrm{U,Cs\text{-}137}}}$$

$$I_{\mathrm{A}} = \frac{5 \times 10^6 \mathrm{Bq}}{1 \times 10^5 \mathrm{Bq}} + \frac{4 \times 10^7 \mathrm{Bq}}{1 \times 10^6 \mathrm{Bq}} + \frac{5 \times 10^5 \mathrm{Bq}}{1 \times 10^4 \mathrm{Bq}} = 50 + 40 + 50 = 140$$

The activity index is greater than 100, and the undertaking's application and storage of sealed sources are therefore subject to licensing requirement.

A licence for application, storage, etc. of sealed sources must be obtained from the Danish Health Authority which must have acknowledged the registration of the sources before work may commence.[50]

An application for a licence to use sealed sources must be submitted by completing the relevant online form at www.sis.dk. The online application form is available under

50 Section 51(5), Executive Order No. 669/2019.

"Selvbetjening", which also contains a guide for completing the form. The registration of sources and facilities must be done separately; see Subsection 5.4.

The application for a licence to store sealed sources must be supported by an attachment describing the layout and location of the storage site on the premises of the undertaking. An application may be made for a licence to store sources at an *external storage site*, if the source will be applied only for a limited period of time, such as during construction site works. When applying for a licence for storage at an external storage site, information about the address and a description of the external storage site's layout and location must be submitted as an attachment.

5.2. Notification

The Danish Health Authority must be notified of application, storage, etc. of sealed sources if the total activity of the undertaking's sources exceeds the exemption value, but is less than or equal to 100 times the exemption value.[51]

If the undertaking engages in application, storage, etc. of sealed sources with different radionuclides, the activity index shall be determined as specified in Subsection 5.1. If the activity index is greater than 1 but less than or equal to 100, the undertaking is subject to notification requirement.

Example of determination of the level of regulatory control level based on activity index

An undertaking engages in application and storage of sealed sources containing Ba-133 and Am-241. The total activities held by the undertaking are indicated below.

Radionuclide	Activity [Bq]
Ba-133	4×10^6
Am-241	4×10^5

To assess whether the undertaking's application and storage are subject to requirements for licensing or notification, or are exempt from these requirements, the activity index shall be determined by means of Formula 1 in Subsection 5.1. The exemption values for Ba-133 and Am-241 are provided in Annex D.

Activity index:

51 Section 5(1), Executive Order No. 670/2019.

$$I_{\mathrm{A}} = \sum_{k} \frac{A_{\mathrm{k}}}{A_{\mathrm{U,k}}} = \frac{A_{\mathrm{Ba\text{-}133}}}{A_{\mathrm{U,Ba\text{-}133}}} + \frac{A_{\mathrm{Am\text{-}241}}}{A_{\mathrm{U,Am\text{-}241}}}$$

$$I_{\mathrm{A}} = \frac{4 \text{ x } 10^{6}\mathrm{Bq}}{1 \text{ x } 10^{6}\mathrm{Bq}} + \frac{4 \text{ x } 10^{5}\mathrm{Bq}}{1 \text{ x } 10^{4}\mathrm{Bq}} = 4 + 40 = 44$$

The activity index is greater than 1 but less than 100, and the undertaking's application and storage of sealed sources are therefore subject to notification requirement.

Notification is done by completing the designated online form at www.sis.dk. The online application forms are available under "Selvbetjening", which also provides a guide for completing the form.

5.3. Exemption

Application, storage, etc. of sealed sources, the total activity of which is less than or equal to the exemption value, are exempt from licensing or notification requirements.[52] In such cases, there is no requirement to obtain a licence from or submit a notification to the Danish Health Authority.

If the undertaking engages in application, storage, etc. of sealed sources with different radionuclides, the activity index shall be determined as specified in Subsection 5.1. If the activity index is less than or equal to 1, the undertaking is exempt from licensing or notification requirements.

A condition for exempting the use of sealed sources from licensing or notification requirements is that the use conforms to the principle of justification. The radiation protection requirements in the legislation are not applicable to use of sources exempt from licensing and notification requirements.

5.4. Registration of sealed sources and facilities

Sealed sources and facilities must, in the majority of cases, be registered with the Danish Health Authority's Registry of Radiation Sources and Facilities.

52 Section 5(1), Executive Order No. 670/2019.

Facility

A facility for use of sealed sources means, for example:

- Rooms for handling sources
- Storage rooms
- Waste storage rooms.

A sealed source must be registered if the activity is greater than 100 times the exemption value[53]; see Annex D. A facility shall be registered if the use of sources in the facility requires a licence.[54]

Sources and facilities are registered by filling in the designated online form at www.sis.dk. The online application forms are available under "Selvbetjening", which also provides a guide for completing the form.

The duty of registration rests with the undertaking that uses the sealed source or facility.[55]

If the use is subject to licensing requirement, the registration must be confirmed by the Danish Health Authority before the source and/or facility is commissioned. If the use is subject to a notification requirement, it is sufficient for the Danish Health Authority to have acknowledged receipt of the notification of use.[56]

5.5. Import, export and transfer of sealed sources

In case of import from a non-EU country of a sealed source with an activity greater than the exemption value; see Annex D, the consignee (the undertaking that will be receiving the source) must obtain advance approval to do so from the Danish Health Authority.[57]

In case of export to a non-EU country of a sealed source with an activity greater than the exemption value, the consignor (the undertaking that will be transferring the source) must obtain advance approval to do so from the Danish Health Authority.[58] The undertaking shall also ensure that the consignee is entitled to receive the source under the recipient country's legislation.[59]

53 Section 15(1), No. 1, Executive Order No. 670/2019.
54 Section 15(2), No. 1, Executive Order No. 670/2019.
55 Section 51(2), Executive Order No. 669/2019.
56 Section 51(5), Executive Order No. 669/2019.
57 Section 19(1), No. 3, Executive Order No. 670/2019.
58 Section 19(1), No. 2, Executive Order No. 670/2019.
59 Section 21, Executive Order No. 670/2019.

For a transfer within Denmark of a sealed source with an activity greater than the exemption value, the transferring undertaking shall notify this to the Danish Health Authority.[60] The notification must be made within 21 days of the end of the quarter in which the transfer took place.[61] If transferring a high-activity sealed source within Denmark, the undertaking to which the source will be transferred must also obtain advance approval for this from the Danish Health Authority.[62]

For a shipment of a sealed source to an EU Member State, the rules set out in the Council Regulation on shipment of radioactive substances between Member States must be complied with[63]; see Chapter 16.

Before a high-activity sealed source within *security category* A is acquired, a written agreement shall be executed with the manufacturer on the return of the source once it is disused.[64] This agreement should cover aspects such as the financial specifics of any fee for transferring the source back to the manufacturer.

5.6. De-registration of sealed sources and facilities

If a registered sealed source is no longer held by the undertaking or a registered facility is not being used, the source or the facility must be de-registered from the Danish Health Authority's Registry of Radiation Sources and Facilities.[65] Similarly, a licence or notification should be cancelled if the undertaking ceases to use sealed sources.

If a licence is to be cancelled, all registered sealed sources and facilities must be de-registered first. Furthermore, a declaration must be submitted, stating that all sources have been transferred. Likewise, if a notification is to be cancelled, a declaration must be submitted, stating that all sources have been transferred.

De-registration of sealed sources and facilities, and cancellation of a licence or notification are performed by completing the designated online form at www.sis.dk. The online form is available under "Selvbetjening", which also provides a guide for completing the form.

5.7. Inspection

The Danish Health Authority conducts inspections of use of sealed sources according to a graded approach. This means that the type, scope and frequency of inspections are commensurate with the likelihood and impact of any exposure entailed by use of the

60 Section 20(1), Executive Order No. 670/2019.
61 Section 20(3), Executive Order No. 670/2019.
62 Section 19(1), No. 1, Executive Order No. 670/2019.
63 Section 5(1), Executive Order No. 669/2019.
64 Section 23(2), Executive Order No. 670/2019.
65 Section 15(2), Executive Order No. 670/2019.

sources.[66] A distinction is made between administrative inspections and on-site inspections at the undertaking's premises.

Administrative inspections are initiated by a written request from the Danish Health Authority for submission of relevant elements of the undertaking's *quality assurance* and any other relevant documentation by a specified deadline. For on-site inspections, observations will also be made of facilities, working conditions, etc. and interviews will be conducted with relevant workers.

The Danish Health Authority may at any time, regardless of the type of use and level of regulatory control, demand access to sealed sources, facilities, equipment, registries and other records relating to quality assurance, etc. Upon request, the documentation shall be sent to the Danish Health Authority or submitted in person during an on-site inspection.[67]

Upon completion of an inspection and if relevant, the undertaking will receive a statement of requirements from the Danish Health Authority specifying all identified deficiencies and the deadline for remedying them. The inspection will not be regarded as concluded until all requirements have been met. The Danish Health Authority may prohibit the use of sealed sources until the specified requirements have been met.[68]

5.8. Fees

Pursuant to the Ministry of Health's Executive Order No. 1111/2019; see Chapter 16, the Danish Health Authority charges an annual fee to cover the costs of regulatory inspection, advice, assistance and administration incurred from use of sealed sources subject to licensing or notification requirements. The specific fee tariffs are set in relation to the risk posed by the type of source and the complexity of the use or application.

Fees

A fee is charged per:

- Licence or notification pertaining to use of sealed sources
- Registered sealed source
- Facility for external storage of sealed sources
- Facility approved for use of high-activity sealed sources.

66 Section 18(1), Act No. 23/2018.
67 Section 18(2), Act No. 23/2018.
68 Section 19, Act No. 23/2018.

The fee tariffs are adjusted once a year on 1 January. For more information, please consult www.sis.dk.

6. Safety assessment

In advance of any use of sealed sources subject to licensing requirement, the undertaking shall conduct a safety assessment.[69] A safety assessment is a systematic review of all factors of relevance for safety and radiation protection entailed by the planned use.

6.1. Systematic review of safety and radiation protection

The purpose of the safety assessment is to ensure the optimisation of radiation protection at all times and the undertaking's compliance with all applicable requirements for safety and radiation protection during normal operations and in the event of emergencies, accidents and incidents.

The safety assessment comprises a cradle-to-grave description of radiation risks, safety functions, radiation protection arrangements, site, the design and robustness of the facility as well as human factors. The safety assessment must be initiated as early as the planning phase of the use of sealed sources and shall comprise all stages from facility construction through application, storage, etc. of sources to decommissioning.

The safety assessment must be reviewed and updated periodically at intervals commensurate with the nature and scale of the use of sealed sources so that the assessment at all times reflects the current use and application.[70] If changes are planned regarding safety or radiation protection arrangements, operational conditions, work procedures, radionuclides, activities or other conditions with safety and radiation protection implications, a renewed safety assessment shall be performed.

6.2. Scope

The scope of the safety assessment shall be commensurate with the risk associated with the particular use of sealed sources. This typically depends on the quantity and types of sources; their siting relative to each other; whether use takes place inside or outside a facility; the mode and frequency of source application; the reliability and complexity of systems and components; source accessibility for the purposes of maintenance, technical safety inspection, servicing, etc.; and the risk of handling the sources.

The Danish Health Authority's guide to safety assessments; see Chapter 16, provides detailed instructions on performing safety assessments in accordance with the recommendations of the International Atomic Energy Agency (IAEA)[71].

69 Section 20(1), Executive Order No. 669/2019.
70 Section 20(2), Executive Order No. 669/2019.
71 IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), 2016.

6.3. Report

The undertaking should describe the safety assessment in a version-controlled report. The Danish Health Authority will demand submission of the safety assessment for review when an undertaking applies for a licence. The safety assessment will form part of the basis for stipulating any special terms of licensing and will be used as a starting point for inspections.

When the safety assessment in connection with periodic reviews or as part of planned changes is updated, the updated report shall be submitted to the Danish Health Authority if there is basis for amending the licence or its terms.

Safety assessment update

The undertaking's safety assessment shall, as a minimum, be updated in the event of:

- Change in radionuclides and types of sources in use
- Increase in activity
- Commissioning of new facilities
- Implementation of new work procedures that may impact exposure
- Planning of facility decommissioning.

7. Workers

The radiation protection legislation draws a distinction between two types of workers at an undertaking that uses sealed sources: exposed workers and other workers. Exposed workers are those whose work involves sources[72], while other workers are the remainder of the undertaking's workforce[73].

Before an exposed worker is assigned to work involving use of sealed sources, the worker must be categorised.[74] If the undertaking is subject to the requirement to be advised by a radiation protection expert, the categorisation of exposed workers will typically be one of the tasks of that expert.

Exposed workers shall be adequately informed, trained and instructed in the performance of their assigned tasks, and they must possess adequate knowledge, skills and competences for independent work involving sealed sources.[75]

7.1. Categorisation of exposed workers

The categorisation of an exposed worker must be based on an assessment of the effective dose and equivalent doses that might be incurred by the worker during performance of his/her work. That assessment shall include both the doses incurred from work involving sealed sources under routine conditions and the potential doses incurred from incidents and accidents.

[72] Section 10, No. 53, Executive Order No. 669/2019.
[73] Section 10, No. 65, Executive Order No. 669/2019.
74 Section 38, Executive Order No. 669/2019.
75 Section 45(1), Executive Order No. 669/2019.

Categorisation of an exposed worker

Below is a list of factors to be addressed in the assessment of effective dose and equivalent doses in order to categorise an exposed worker.

Sealed sources

- What sources will the work involve?
- What parts of the worker's body (whole body, eye lens, extremities) will be exposed to radiation during normal routines?

Physical organisation

- Where are the sources handled?
- Are the sources stored in the same facility where they are handled?
- Under what conditions are the sources handled?
- Does any other work involving radiation sources take place in the facility?
- Is shielding used?

Routines

- How often (e.g. daily, weekly, monthly) are the sources handled?

Occupancy factors

- For what duration is the worker exposed to radiation?

Dose

- What doses have previously been incurred from the same work?

Unforeseen accidents and incidents

- What are the likely scenarios for accidents and incidents?

Exposed workers shall be categorised into one of the categories A, B or C depending on the magnitude of the assessed effective and equivalent doses to each worker; see Table 2. If just one of the lower limits of effective or equivalent dose for a worker category could potentially be exceeded, the worker must be assigned to the corresponding category.

Table 2

Categorisation of exposed workers

		Effective dose (E) [mSv/year]	Equivalent dose (H_T) [mSv/year]	
			Lens of the eye	Skin/Extremities
Category of worker	A[76]	$E > 6$	$H_T > 15$	$H_T > 150$
	B[77]	$1 < E \leq 6$	-	$50 < H_T \leq 150$
	C[78]	$E \leq 1$	-	$H_T \leq 50$

The categorisation must always be reassessed in the event of changes to the worker's tasks or altered procedures. Further, the categorisation is subject to continuous reassessment.[79]

Examples of categorisation of exposed workers

The following provides examples of typical worker categorisations.

Category A

- Workers engaged in borehole logging using sources.

Category B

- Workers who have access to the irradiation chamber in an industrial irradiation facility.

Category C

- Workers whose work involves application of sources for testing equipment
- Workers who work in proximity to permanently installed sources for process control.

However, the undertaking shall always perform its own assessment of worker doses, as these depend on factors such as the sources used and the undertaking's site conditions.

76 Section 39(1), Executive Order No. 669/2019.
77 Section 40, Executive Order No. 669/2019.
78 Section 41, Executive Order No. 669/2019.
79 Section 38, Executive Order No. 669/2019.

Tasks requiring categorisation as an exposed worker must be performed solely by individuals over the age of 18. However, trainees between the ages of 16 and 18 are permitted to undertake work as category B or C exposed workers provided that use of sealed sources is an essential component of their education.[80]

7.2. Requirements for medical examination of category A exposed workers

The Danish Working Environment Authority requires category A exposed workers to undergo a medical examination before starting any work involving sealed sources and, subsequently, a routine examination at least once a year for as long as they continue to perform that work.[81] In case of doubt, the Danish Working Environment Authority will decide whether a specific use or application necessitates medical examinations. The decision will be made in consultation with the Danish Health Authority. Only a minority of the exposed workers assigned to work involving use of sealed sources within the areas of use and application covered by the present Guide will be subject to the requirement for medical examinations. The requirements will, for example, be applicable to workers who perform borehole logging using sources; see Section 7.1.

7.3. Requirements regarding worker information, training, instruction and qualifications

Exposed workers shall be made aware of the risks associated with the use of sealed sources and shall be educated, trained and instructed in accordance with the following.

Requirements for educating, training and instructing exposed workers

Exposed workers shall[82]

- be instructed on the safety measures to be put in place for prevention of the risks associated with use of sources
- be trained and instructed in use of sources and in measures to limit the consequences of any accident or incident.
- have attained sufficient knowledge, skills and competences before they are permitted to perform independent work involving sources
- be informed of the name and contact details of the radiation protection officer

80 Sections 39 and 42, Executive Order No. 669/2019.
81 Sections 2 and 3, Executive Order No. 10/2018, and WEA Guideline No. 9093/2019.
82 Section 45(1), Executive Order No. 669/2019.

- be instructed regarding the necessity of early notification of pregnancy so that their work may be organised so as to take into account the foetal dose.

Additional special requirements regarding the knowledge, skills and competences of exposed workers apply for certain applications of sealed sources.[83]

Special requirements regarding knowledge, skills and competences

- For application of sealed sources for industrial irradiation exposed workers are required to have completed a training course for operators of industrial irradiation facilities accredited by the Danish Health Authority. They are also required to have completed a training course in fundamentals of radiation protection accredited by the Danish Health Authority.

- For application of sealed sources for borehole logging, exposed workers are required to have completed a relevant higher scientific education and to have completed a training course in the fundamentals of radiation protection accredited by the Danish Health Authority.

An exposed worker's knowledge, skills, competences, information, training and instruction shall be maintained on a continuous basis and, as a minimum, must be updated when new or updated technologies and methods are introduced.[84] When using high-activity sealed sources; see Chapter 12, the maintenance and updating of worker qualifications shall be accomplished at intervals of no more than five years.[85]

A list shall be kept of the exposed workers, with information on each individual's knowledge, skills, competences, information, training and instruction. This list shall be available to all relevant workers at the undertaking.[86] Other workers shall be informed regarding the use of sealed sources at the undertaking and regarding the precautions they are required to take.[87]

83 Section 31(1), Executive Order No. 670/2019.
84 Section 45(2), Executive Order No. 669/2019.
85 Section 31(2), Executive Order No. 670/2019.
86 Section 45(3), Executive Order No. 669/2019.
87 Section 46, Executive Order No. 669/2019.

8. Radiological monitoring

Requirements for radiological monitoring depend on assessment of the dose a worker might potentially incur during routine conditions and in the event of incidents and accidents. The purpose of radiological monitoring is to ensure compliance with the dose limits; see Section 2.3, while serving as a means of optimising radiation protection; see Sections 2.2 and 8.4.

Doses to individual organs, tissues, etc. are termed equivalent doses. The dose limits for the lens of the eye, skin and extremities have been established to prevent the incidence of acute effects, such as cataract. The whole-body dose is termed effective dose. The dose limit for the effective dose has been established to limit the incidence of late effects, such as cancer.

The effective dose, together with the risk factors established by the ICRP, may be used to assess the risk of developing cancer in later life as a result of the harmful effects of exposure to radiation. The ICRP publishes risk factors for late effects, based on e.g. historical cohort studies. A risk factor of approx. $4 \cdot 10^{-5}$ mSv^{-1} is applied in calculating effective doses to exposed workers.[88]

More information about acute and late effects is provided in "The Radiation Guide"; see Chapter 16.

8.1. Requirement for individual radiological monitoring

The requirement for individual radiological monitoring depends on the categorisation of the exposed workers; see Section 7.1. Individual radiological monitoring is required for category A and B workers.[89]

If individual radiological monitoring using a *personal dosemeter* is not expedient or feasible, then individual radiological monitoring shall be performed in accordance with a *radiological monitoring programme* approved by the Danish Health Authority.[90]

If the undertaking is in doubt as to whether its use of sealed sources requires radiological monitoring, the Danish Health Authority should be contacted for advice.

8.2. Requirement to individual radiological monitoring

Radiological monitoring shall ensure determination of the effective dose and, as appropriate, determination of equivalent doses to the lens of the eye, skin and extremities.

88 ICRP Publ. 103, p. 53, 2007.
89 Section 78(1), Executive Order No. 669/2019.
90 Section 78(6), Executive Order No. 669/2019.

Determination of effective dose

Determination of effective dose shall be obtained by means of a personal dosemeter designed to determine the whole-body dose.

Determination of equivalent doses

If there is a risk of significant exposure to the lens of the eye, hands and fingers, etc. a special personal dosemeter shall be used, such as a finger ring dosemeter.

Requirement for radiological monitoring

A worker subject to the requirement for individual radiological monitoring shall be dose-monitored, meaning that they shall wear a personal dosemeter during all work involving sealed sources.

Personal dosemeters, including finger ring dosemeters, are for personal wear only, and must not be shared by multiple workers. If a personal dosemeter is damaged or lost, the worker must not perform work involving sources until a new personal dosemeter has been obtained.

Monitoring period

The monitoring period for personal dosemeters worn to determine effective dose is one month for category A workers and three months for category B workers.[91] For pregnant exposed workers subject to dose monitoring requirement, the monitoring period is one month.[92] The monitoring period for a finger ring dosemeter is typically 14-30 days.

Dosemeter positioning

A personal dosemeter for determining effective dose shall be positioned on the front of the trunk of the body (torso). Pregnant workers must wear their personal dosemeter at belt height at all times.

If finger ring dosemeters are worn, it is important to bear in mind that the positioning of the dosemeter is critical for accurate monitoring of the dose, as the position of the dosemeter is typically some distance away from the most exposed area of the skin. This means that the monitored dose will often be less than the actual dose to the most exposed area of the skin. Given this fact, the undertaking should always take a critical approach to the monitored dose, and, if in doubt, consult a radiation protection expert.

Storage of dosemeters

After working hours, during holidays, etc., dosemeters must be stored in a location where they will not be exposed to radiation. This means that dosemeters should not be stored in proximity to storage locations for sealed sources or other types of radiation sources.

91 Section 78(2) and (3), Executive Order No. 669/2019.
92 Section 79(2), Executive Order No. 669/2019.

8.3. Determination, reporting and notification of doses

Determination of doses from individual radiological monitoring shall be performed by a *dosimetry service* approved by the Danish Health Authority. The dose shall be determined as soon as possible after the monitoring period has expired. Upon suspicion of an unusually large personal dose, the dose shall be determined without undue delay.[93]

Workers who have undergone radiological monitoring shall be informed of the result of the monitoring as soon as possible after the result becomes available.[94] If the dose is determined by other means than a personal dosemeter, the worker who underwent radiological monitoring shall have access to all the factors upon which the dose determination was based.[95] At any time, the undertaking shall be able to document doses to workers for the last 5 calendar years.[96] In the event of any *accidental exposure*, a record shall also be retained of the circumstances of such exposure and of the countermeasures taken.[97]

The results of the individual radiological monitoring, including data on irregularities, shall within 4 weeks of the results becoming available, be notified to the Danish Health Authority's Personal Dose Registry (SRP). The notification shall contain the relevant data and be submitted as directed by SRP.[98] Subject to agreement, notification may also be done by the dosimetry service.

If the effective dose or an equivalent dose exceeds the value in Table 3, the undertaking shall immediately notify the Danish Health Authority.[99] The values are based on category A workers and are thus based on a monitoring period of one month. In case of a shorter monitoring period, it may be necessary to lower the value correspondingly.

Table 3
Values for immediate notification of the Danish Health Authority[100]

Type of dose	Dose value [mSv]
Effective dose	5
Equivalent dose to lens of eye	5
Equivalent dose to skin and/or extremities	50

8.4. Facilitation and optimisation by means of dosemeters

Finger ring dosemeters and electronic dosemeters serve as useful means of facilitating and optimising procedures for handling sealed sources.

93 Section 81, Executive Order No. 669/2019.
94 Section 84(1), Executive Order No. 669/2019.
95 Section 84(2), Executive Order No. 669/2019.
96 Section 86(1), Executive Order No. 669/2019.
97 Section 86(3), Executive Order No. 669/2019.
98 Section 87, Executive Order No. 669/2019.
99 Section 85, Executive Order No. 669/2019.
100 Annex 5, Executive Order No. 669/2019.

Unlike passive personal dosemeters that store dose information for later readout, active electronic dosemeters record and display the measured dose continuously and can be configured to sound an alarm if a given dose is exceeded. In addition, an electronic dosemeter records and displays the dose rate and can be configured to sound an alarm when a given dose rate is exceeded.

Facilitation and optimisation of procedures by means of a dosemeters

Finger ring dosemeters

Finger ring dosemeters are used to determine the equivalent dose to hands and fingers. If the use of a finger ring dosemeter indicates large doses to the hands and fingers, it may be appropriate to determine the doses associated with individual procedures involving handling of sealed sources by replacing the dosemeter between handling procedures. This may indicate which handling procedure results in the highest dose so that measures to optimise these procedures may be implemented, such as utilising distancing tools and shielding.

Electronic dosemeters

The use of an electronic dosemeter makes it possible to determine the dose and dose rate from different work procedures and, on that basis, optimise radiation protection. An electronic dosemeter might, for example, be used as a tool for optimising shielding when handling sources.

9. Classification of areas and signage

Areas where workers might incur effective or equivalent doses exceeding specific levels shall be classified as either supervised or controlled. Prior to use of sealed sources, an assessment shall be made as to whether classification is required for areas in which sources are handled, stored, etc. and adjacent areas.

Signage is required in any location where sealed sources with a total activity exceeding the exemption value are stored; see Annex D,, as well as at all entrances to areas where sources with a total activity exceeding
100 x the exemption value. In addition, supervised and controlled areas are subject to supplementary signage requirements.

9.1. Classification of areas

Classification of an area must be made on the basis of the potential doses that might be incurred in that area, including as a result of incidents and accidents. The scenarios for incidents and accidents must be realistic even if improbable. However, highly improbable scenarios should only be included if their consequences would be very severe. The classification shall be based on the risk in the area without taking into account any radiation protection measures, such as compliance with procedures, use of shielding and access restriction. The classification must therefore be based on the doses that could be incurred in the area if procedures and access restrictions are not complied with.

Two levels of classification are applied: supervised area and controlled area, where supervised area is the lowest classification.

Classification as a supervised area

An area shall be classified as supervised if a worker is assessed as potentially incurring

- an effective dose exceeding 1 mSv/year, but not exceeding 6 mSv/year, or
- an equivalent dose to skin or extremities exceeding 50 mSv/year, but not exceeding 150 mSv/year.[101]

101 Section 49(1), Executive Order No. 669/2019.

Classification as a controlled area

An area shall be classified as controlled if a worker is assessed as potentially incurring

- an effective dose exceeding 6 mSv/year or
- an equivalent dose to the lens of the eye exceeding 15 mSv/year or
- an equivalent dose to the skin or extremities exceeding 150 mSv/year.[102]

The classification of an area depends on several factors, including the total number of sealed sources, the activity, shielding, source siting and worker positions.

Examples of typical classification of areas

Below are examples of typical classification of areas related to specific types of use of sealed sources.

Supervised area

Areas typically classified as supervised:

- Areas for storing mobile devices containing sources for moisture and density measurement.

Controlled area

Areas typically classified as controlled:

- Storage sites for sources for borehole logging, as well as the area for application of those sources during borehole logging
- The radiation chamber in an industrial irradiation facility.

Note that the examples mentioned above are for guidance only. The undertaking shall always perform an individual classification of all relevant areas based on an assessment of the sources concerned and the local conditions associated with the use.

Areas where the exposure is assessed as being less than in a supervised area are not subject to classification. This means that not all areas where sealed sources are handled or stored are to be classified.

102 Section 50(1), Executive Order No. 669/2019.

Areas not normally requiring classification

Below are examples of typical areas related to use of sealed sources which do not normally require classification.

- Areas where only a very limited number of sources for testing equipment are applied or stored
- Areas where permanently installed devices containing sources are applied for process control
- Areas where application of mobile devices containing sources is performed for moisture and density measurement
- Areas where handheld devices for analysis, etc. containing sources are applied or stored.

Note that the examples mentioned above are for guidance only. The undertaking shall always perform an individual classification of all relevant areas based on an assessment of the sources concerned and the local conditions associated with use.

9.2. Signage

Requirements for demarcation and signage for sealed sources are laid down in the radiation protection legislation. In addition, the Danish Working Environment Authority has established general requirements for the appearance, accessibility and durability of safety signage.[103] The instructions in the Guide meet the requirements of both the Danish Health Authority and the Danish Working Environment Authority for radiation safety signage.

Use of sealed sources is subject to a requirement for signage of storage sites and facilities and also supplementary requirements for signage of classified areas.

It is important to note that where sealed sources are used inside facilities, all entrance doors are subject to signage requirements, i.e. including doors that are generally kept shut, such as fire doors. This is because, regardless of which entrance door is used, the risks related to being inside the facility shall be clearly conveyed. For example*, emergency workers* might, when responding to an *emergency,* need to gain access by entrances other than those ordinarily used, which makes it necessary for all entrance doors to bear signage.

103 Executive Order No. 518/1994.

General requirements

For all safety signage, the signage must be legible and durable.[104] If sealed sources are only present occasionally, it would be a good idea to use signs that can be reversed or covered over when no signage is required.

Requirements have been established for the wording on pictograms for safety signage associated with use of sealed sources (see below), but it is generally acceptable to add supplementary text beneath the pictogram, including in languages other than Danish, provided that the requirements stipulated in relevant executive orders for supplementary wording in Danish have also been met.

Storage sites and facilities that are not concurrently classified areas

At all sites where there is storage of sealed sources, with a total activity greater than the exemption value; see Annex D, and at all entrances to facilities or areas where there is storage or handling, etc. of sources with a total activity greater than 100 times the exemption value, ionising radiation warning signs must be in place, in accordance with the prevailing standard[105] and supplemented by the text "*Radioaktivt materiale*" (Radioactive Material).[106] For storage of sources containing different radionuclides, Formula 1 in Section 5.1 must be used to determine if signage is required. Figure 1 shows the signage to be displayed at storage sites and facilities that are not simultaneously classified areas.

Figure 1
Signage at storage sites and facilities that are not concurrently classified areas

If a sealed source is stored in a locked cabinet or the like, the sign shall be placed on the cabinet door. Alternatively, the sign may be mounted on the entrance door to the storage site. If sources are located in a large hall, the sign shall be mounted in an appropriate and conspicuous location near the source.

104 Section 37, Executive Order No. 670/2019.
105 DS/EN ISO 7010:2012.
106 Sections 37 and 38(1), Executive Order No. 670/2019.

Supervised and controlled areas

Both supervised and controlled areas are required to be legibly and durably marked with the text "Radioaktivt materiale" (Radioactive material), information about the classification and the text "Risiko for *ekstern bestråling*" (Risk of external exposure).[107] Figure 2 shows the signage to be displayed for a supervised and a controlled area, respectively.

Figure 2
Signage of classified areas

9.3. Additional requirements for controlled areas

For controlled areas, there must be physical delineation of the area or, if this is not feasible, other security measures or demarcation.[108] Measures shall be in place to ensure that only workers who are needed for use of the sealed sources have access to the controlled areas.[109]

107 Sections 49(2) and 50(2), No. 4, Executive Order No. 669/2019, and Section 38(2-4), Executive Order No. 670/2019.
108 Section 50(2), No. 1, Executive Order 669/2019.
109 Section 50(2), No. 3, Executive Order 669/2019.

10. Radiation protection when using sealed sources

Sealed sources may be permanently installed on production lines at the undertaking's premises or may be mobile and applied at work sites within or outside the undertaking's premises. The sources may be fitted inside devices with integrated shielding or may be loose without integrated shielding. Depending on the type of source, shielding, application, etc. sealed sources can cause varying degrees of personal injury and, for certain sources, even life-threatening injury. It is therefore important that work involving sealed sources is performed in a manner appropriate from the point of view of radiation protection for the safety of both workers and the surroundings.

10.1. Instructions

Precautions for optimisation of radiation protection shall be incorporated into instructions with the aim of limiting exposure.

Instructions for using sealed sources

When using sealed sources, the following written instructions must be provided:[110]

- Instructions regarding application, handling, storage, etc. of the undertaking's sources
- Instructions on precautions in the event of emergencies, accidents and incidents.

The instructions shall be easy to understand and readily available during work.

10.2. Storage

The number of sealed sources kept in storage shall at all times be kept as low as reasonably achievable.[111] Sources with a total activity greater than the exemption value in Annex D shall be stored so as to protect them against fire, theft, vandalism and environmental impacts, meaning that the sources must not be stored together with explosive, flammable or corrosive substances or other substances that pose a risk to safety while being kept in storage.[112]

110 Section 57, Executive Order No. 669/2019.
111 Section 18(1), Executive Order No. 669/2019.
112 Section 36, Executive Order No. 670/2019.

Sources with a total activity greater than the exemption value in Annex D shall be stored in specially-designed storage sites inside the facilities where their application takes place or in a special storage facility.[113] To the extent necessary for their application, sources may be kept in short-term storage outside the specially-designed storage sites or special storage facilities. However, such short-term storage may only give rise to negligible exposure.[114]

If application of a sealed source takes place outside of the undertaking's premises, for example, if application of the source takes place at a construction site, the undertaking is permitted to store the source at an external storage site on condition that the requirements for storage of sources are complied with.

Sealed sources that are disused and to be regarded as radioactive waste and with a total activity which exceeds the exemption value in Annex D shall be stored inside facilities that are not be used for other purposes. The Danish Health Authority may, however, authorise storage of materials other than radioactive waste inside the facility if the exposure from the waste is negligible. In such cases, the radioactive waste shall be stored inside a locked unit within the facility.[115]

When storing sources with different radionuclides, Formula 1 in Section 5.1 shall be used to determine whether the above storage requirements apply.

Storage in connection with carriage

Storage of sealed sources inside vehicles is normally prohibited, as the requirements for storage of radioactive material will be difficult to comply with.[116] An exception would be storage when taking breaks or during overnight stays during carriage. In these cases, the vehicle's cargo space shall be kept locked at all times, or the *packages* conveyed shall be otherwise protected against unlawful unloading, and the dose rate on the exterior of the vehicle must not exceed 5 µSv/h. If these requirements are not met, the vehicle must be kept under constant supervision.[117] During transport storage, the vehicle shall be marked in accordance with the Regulations for the Safe Transport of Radioactive Material; see Chapter 13.

113 Section 35(1), Executive Order No. 670/2019.
114 Section 35(3), Executive Order No. 670/2019.
115 Section 35(2), Executive Order No. 670/2019.
116 Section 36(1), Executive Order No. 670/2019.
117 8.5, S21, ADR 2019.

10.3. Minimisation of exposure during handling

In order to achieve an optimum level of safety, it is essential for the exposed workers to be adequately informed, trained and instructed and to possess the requisite knowledge, skills and competences for use of sealed sources.[118] Further, radiation protection of the other workers as well as members of the public who might be exposed as a result of the use shall at all times be optimised.

The dose depends on the radionuclide, activity, duration of exposure, shielding and distance from the sealed source. The dose rate decreases the greater the distance from the source – doubling the distance from a source quarters the dose rate; see Annex B. The following precautions can therefore be taken immediately in order to reduce the dose.

Distance, time, shielding

- Keep distance from the source.
- Handle the source for the shortest possible time.
- Use shielding if practicable.

Use of sealed sources shall be facilitated and performed utilising suitable equipment to ensure appropriate optimisation.[119] Depending on the source as well as the area of use and application, radiation protection equipment, such as measuring instruments, collimators, shielding and handling equipment, signage and barrier equipment shall be employed. Measuring instruments should always be checked before use and tested at suitable intervals to ensure accurate data display.[120]

Servicing of sealed sources and devices containing sources, involving for example, replacement of sources or removal of permanently-installed shielding from devices may only be carried out by an undertaking holding a licence for such work by the Danish Health Authority.[121]

10.4. General requirements for work involving sealed sources

The application or handling of sealed sources shall be performed in such a way as to avoid touching the source directly with the hands.[122] For example, it is not permitted to touch the measuring rod in mobile gauges for moisture and density measurement, and the base plate should not be touched unless the source probe is in the secured position and, if that is the case, only for cleaning purposes.

118 Section 45(1), Executive Order No. 669/2019.
119 Section 53, Executive Order No. 669/2019.
120 Section 56, Executive Order No. 669/2019.
121 Section 6, No. 8, Executive Order No. 670/2019.
122 Section 47, Executive Order No. 670/2019.

It is not permitted to enter any part of the body in a collimated radiation field.[123] I.e., the worker must not be exposed to direct radiation. In addition, when using and handling sealed sources, workers must at all times ensure that they are protected against scatter radiation.[124]

Sealed sources with an activity exceeding the exemption value; see Annex D, that are outside of their storage site, must not be accessible to unauthorised parties.[125] For mobile sources at work locations to which the public do not have access, the Danish Health Authority considers this requirement as being met if the source is briefly left in a locked container that is securely locked to a stable machinery component or building structure.

The application and handling, etc. of sealed sources shall, as general rule, be performed inside facilities.[126] Exceptions to this are application of non-high-activity sealed sources constructed with adequate integrated shielding for the purpose of application outside facilities[127], for example, application of gauges containing sources for moisture and density measurement. Similarly, the application of sources may be undertaken outside facilities if the dimensions or other factors of the test objects do not permit application to be undertaken inside a facility[128], for example, the application of sources for borehole logging.

10.5. Special requirements for work involving high-activity sealed sources

Any application of a high-activity sealed source outside a facility shall be undertaken with two workers in attendance, one of whom must meet the special requirements for knowledge, skills and competences.[129] For exposed workers engaged in borehole logging, at least one worker in attendance must have a relevant higher scientific education and have completed a training course in fundamentals of radiation protection accredited by the Danish Health Authority.

For any application and handling of high-activity sealed sources outside of their container, i.e. unshielded sources, an *acoustic dose rate alarm* must be used, and where appropriate, the device must be worn on the body.[130] For work at sites where an acoustic dose rate alarm would be difficult to hear, alternative solutions must be employed, such as a vibrating dose rate alarm.[131]

Following any application or handling of a high-activity sealed source, measuring equipment shall be employed to verify that the source has been secured in the shielded position.[132]

123 Section 48(1), Executive Order No. 670/2019.
124 Section 48(2), Executive Order No. 670/2019.
125 Section 49, Executive Order No. 670/2019.
126 Section 50(1), Executive Order No. 670/2019.
127 Section 50(2), Executive Order No. 670/2019.
128 Section 50(3), Executive Order No. 670/2019.
129 Section 61, Executive Order No. 670/2019.
130 Section 62(1), Executive Order No. 670/2019.
131 Section 62(2), Executive Order No. 670/2019.
132 Section 63, Executive Order No. 670/2019.

10.6. Transfer and storage of disused sealed sources

Sealed sources that are no longer in use by the undertaking shall be transferred as soon as reasonably achievable to[133] either another undertaking that has a use for the source, to the manufacturer of the source or to Danish Decommissioning.

A disused sealed source is regarded as radioactive waste and must be stored for no more than one year at the undertaking before it is transferred, unless otherwise approved by the Danish Health Authority.[134] The Danish Health Authority does not normally deem storage for more than one year of disused sources for purposes such as testing equipment at hospitals, etc. justified, meaning that the Danish Health Authority is unlikely to approve such storage.

The undertaking shall maintain a record of the last five years' storage and transfer of sealed sources in the form of radioactive waste.

Record of storage and transfer of sealed sources in the form of radioactive waste

The record shall contain at least the following data on storage and transfer, respectively:[135]

Storage

- Radionuclide
- Date and activity up to that date
- Storage site
- Name of contact.

Transfer

- Date of transfer
- Activity on transfer date
- Name of the undertaking to which the transfer was made.

133 Section 22(1), Executive Order No. 670/2019.
134 Section 22(2), Executive Order No. 670/2019.
135 Section 18(1), Executive Order No. 670/2019.

11. Requirements for sealed sources, facilities and equipment

11.1. Common requirements for sealed sources, facilities and equipment

Sealed sources, facilities and equipment shall conform to national and international technical standards in force at any time that pertain to aspects of the undertaking's use of sources from the point of view of radiation protection.[136]

Sealed sources, facilities and equipment shall at all times be kept in a sound, orderly and technically satisfactory state and must comply with all safety regulations. Any defect or deficiency discovered in any source, facility or equipment shall be notified to the undertaking immediately. Observed defects and deficiencies that might cause *unintended exposure* shall be remedied before further use of a source.[137]

11.2. Requirements regarding sealed sources

Sealed sources shall be certified and tested, including leak tested, in accordance with the prevailing standard in force for their application.[138] As a general principle, certification and testing should be performed in conformance with the latest version of ISO 2919, and leak testing should be performed in conformance with ISO 9978.

The undertaking shall keep a record of its sealed sources if the activity is greater than the exemption value; see Annex D.[139]

Record of sealed sources

The record of the undertaking's sealed sources shall contain the following information:[140]

- Radionuclide
- Activity on a stated date
- Source serial number, if any

136 Section 54, Executive Order No. 669/2019.
137 Section 55, Executive Order No. 669/2019.
138 Section 45, Executive Order No. 670/2019.
139 Section 16(1), Executive Order No. 670/2019.
140 Section 16(2), Executive Order No. 670/2019.

- Source type identification, if any
  (A unique name or number denoting type of source)
- The source's capsule identification, if any
  (A unique name or number denoting the source capsule)
- Source classification according to ISO 2919, if any
- *Special form certificate* for the source, if any
- Container's serial number, if any
- Container's type designation, if any
- Manufacturer of any container
- Application of the source
- Whether source application is stationary or mobile.

Special requirements regarding high-activity sealed sources

The manufacturer or supplier of a high-activity sealed source shall ensure that the source has been identified and marked. Identification and marking shall be legible and durable and shall consist of a unique number engraved or embossed on the source, if feasible. The source shall furthermore bear a radiation hazard warning label if feasible.[141] This means that upon taking receipt of a source, the undertaking should verify that the source has been identified and marked in accordance with the above.

The undertaking shall ensure that a high-activity sealed source is accompanied by documentation comprising photographs of the source type, container and other equipment, including transportation packaging.[142]

11.3. Requirements regarding facilities

The undertaking shall keep an record of facilities utilised for use of sealed sources subject to licensing or notification requirements.[143]

141 Section 58, Executive Order No. 670/2019.
142 Section 60, Executive Order No. 670/2019.
143 Section 17, Executive Order No. 670/2019.

Record of facilities

The record of the undertaking's facilities shall contain the following information:

- Unique identification of the facility (premises designation).
- Facility type (e.g. storage room)
- A floor plan of the facility with information on its design and the capacity of its features to provide radiation protection, and on any limitations
- Classification as a controlled or supervised area, if relevant
- For facilities subject to requirements for technical safety inspection, the date of the last inspection and latest date for the next inspection.

Specific requirements for blood irradiation facilities

The room in which a blood irradiation facility is sited must be constructed to bear the weight of the facility and must be fitted out to reduce the risk of fire. The blood irradiation facility must also be equipped with a device that emits an acoustic alarm in the event of any dose rate increase.[144]

11.4. Requirements for equipment

Requirements for containers

Containers for sealed sources are subject to marking requirements.

Marking of containers

Containers for sealed sources must be legibly and durably marked with: [145]

- The symbol for ionising radiation according to the prevailing standard, supplemented by the text "Radioactive".
- Radionuclide and activity on a stated date
- For high-activity sealed sources, if possible, the source's unique serial number
- The container's type designation and serial number

144 Subsection 3, Annex 12, Executive Order No. 670/2019.
145 Section 46, Executive Order No. 670/2019.

- Manufacturer.

For sources that do not have a specific associated container, the container in which the source is stored shall be legibly and durably marked with the information specified by the first two items above.

Requirements for measuring equipment

Measuring equipment shall be checked for correct display, as a rule, annually or more frequently, as stipulated by the manufacturer. It must be possible at all times to see when the measuring equipment was last checked and when the next check should take place.[146]

11.5. Technical safety inspection of sealed sources, facilities and equipment

Sealed sources with an activity greater than 100 times the exemption value; see Annex D, as well as associated facilities and equipment shall undergo technical safety inspection at fixed intervals.[147]

High-activity sealed sources in security category A or B shall undergo technical safety inspection at no more than 13-month intervals.[148] Sources in blood irradiation facilities will normally be subject to this requirement.

High-activity sealed sources in security category C as well as non-high-activity sealed sources for application outside of facilities shall undergo technical safety inspection at intervals of no more than 25 months.[149] Sources for borehole logging and sources incorporated in devices for moisture and density measurement will normally be subject to this requirement.

Other non-high-activity sealed sources subject to licensing or notification requirements shall undergo technical safety inspections at intervals of no more than 61 months.[150] Sources incorporated in process control devices will usually be subject to this requirement.

There is no requirement for sealed sources declared as radioactive waste to undergo technical safety inspection, but the Danish Health Authority may determine that facilities and equipment used for storage of radioactive waste shall undergo technical safety inspection.[151]

146 Section 56, Executive Order No. 669/2019.
147 Section 52(1), Executive Order No. 670/2019.
148 Section 52(2), Executive Order No. 670/2019.
149 Section 52(3) and (4), Executive Order No. 670/2019.
150 Section 52(5), Executive Order No. 670/2019.
151 Section 52(6), Executive Order No. 670/2019.

Technical safety inspections may be performed solely by undertakings licensed to do so by the Danish Health Authority.[152]

Requirements for technical safety inspection

Technical safety inspections shall ensure that sealed sources, facilities and equipment are in a sound and technically satisfactory state and compliant with the safety regulations.[153] Compliance with the following should be verified:

- That the source, including any associated container, facility and equipment are in technically satisfactory state and show no significant signs of ageing or corrosion.
- That shutter, safety and coupling mechanism, guide tube and drive cable system and shutter status indication systems work flawlessly.
- That warning lights, door switches, etc. work flawlessly.
- That the dose rate at the source does not differ significantly from what is expected. If the container is equipped with a shutter, the measurements should be performed with the shutter in both the open and shut position.
- That signage and marking are correct and legible.

For high-activity sealed sources, technical safety inspections shall include leak testing by means of wipe-tests.[154] For blood irradiation facilities, it is not feasible to conduct wipe-test sampling of the source itself; the wipe-test sampling is instead performed inside the room where the blood products are introduced. Further, for technical safety inspection of high-activity sealed sources, the undertaking shall submit a copy of the inspection report to the Danish Health Authority immediately after the inspection.[155]

Once the inspection has been completed, the sealed source or source container[156] as well as facilities and equipment[157] shall be equipped with legible and durable information regarding the date of the inspection and the latest deadline for the next one. If marking of the source or container with technical safety inspection dates is not expedient, for example if the source container is subject to wear and tear, the dates shall be recorded by other means and in such a way as to make the information readily available to anyone involved in using the source.[158]

152 Section 6, No. 7, Executive Order No. 670/2019.
153 Section 53(1), Executive Order No. 670/2019.
154 Section 53(2), Executive Order No. 670/2019.
155 Section 55(2), Executive Order No. 670/2019.
156 Section 56(1), Executive Order No. 670/2019.
157 Section 57, Executive Order No. 670/2019.
158 Section 56(2), Executive Order No. 670/2019.

An inspection report shall be prepared. The name of the technical safety inspection undertaking and of the individual who conducted the inspection shall be stated in the report. The inspection report for the last three inspections shall be retained at the undertaking.[159]

If, during inspection, defects are discovered that could cause unintended exposure, the inspection undertaking shall immediately notify the Danish Health Authority. Any defect shall be remedied as quickly as possible, and the source must not be utilised in the intervening time.[160]

159 Section 55, Executive Order No. 670/2019.
160 Section 54, Executive Order No. 670/2019.

12. High-activity sealed sources – security measures and emergency response

High-activity sealed sources may be associated with a particular risk of radiation injury and are therefore subject to additional requirements regarding *security measures*. For these types of sources, a *security plan* and an *emergency response plan* shall be prepared and implemented.

12.1. Security categories

High-activity sealed sources shall be categorised into one of the security categories A, B or C, depending on the radionuclide and activity.[161] The activity limits for the three security categories are provided in Annex E.

Security categories – examples

Below are examples of typical security categories for high-activity sealed sources for specific applications:

- Sources utilised in industrial irradiation facilities: security category A.
- Sources utilised in blood irradiation facilities: security category B.
- Sources for borehole logging: security category C.

The activity in sealed sources for application in testing equipment, process control and moisture and density measurement is usually so low that the sources are not required to be assigned to a security category. It is the duty of the undertaking to ensure that its sources are correctly categorised.

Based on its assessment of a high-activity sealed source and the type of use and application, the Danish Health Authority may assign a given source to a different security category.[162] Consequently, the Danish Health Authority has determined that sources in industrial irradiation facilities and blood irradiation facilities shall be assigned to security category A even though the majority belong to security category B in terms of activity.

161 Section 74(1), Executive Order No. 670/2019.
162 Section 74(2), Executive Order No. 670/2019.

12.2. Security officer

Undertakings that use high-activity sealed sources shall appoint a security officer. The security officer shall monitor and assist in implementing the security measures established in the security plan; see Sections 12.3 and 12.4. The security officer shall possess knowledge, skills and competences within radiation protection and security measures commensurate with the nature and magnitude of the risk associated with the undertaking's use of high-activity sealed sources. The security officer's knowledge, skills and competences shall be updated as - and when - needed, but at intervals of no more than five years.[163] The roles of radiation protection officer and security officer may be performed by the same person, but this is not mandatory. A security officer shall be at the service of the undertaking at any time.

12.3. Vulnerability assessment and security plan for sources in security categories A and B

For sealed sources in security categories A and B, a *vulnerability assessment* shall be prepared for approval by the Danish Health Authority before a source is acquired.[164] A vulnerability assessment shall include a description of all threats, weaknesses and potential incidents with implications for source security. The vulnerability assessment shall form the basis for planning and implementing preventive and injury and damage mitigation measures and shall be used for compiling security and emergency response plans. Incidents that might impact source security include fire, flooding, power failure, theft, vandalism, sabotage or acts of terrorism. The vulnerability assessment must be updated on a continuous basis.[165]

Based on the approved vulnerability assessment and prior to acquiring a source in security category A or B a security plan must be prepared and implemented.[166] The security plan is expected to address the scenarios identified in the vulnerability assessment. The security plan shall be approved by the Danish Health Authority[167], and the security plan shall be maintained on a continuous basis[168]. If changes with security implications are made to the security plan, the Danish Health Authority must approve the amended security plan. The security plan must not be disclosed to the public or become known to unauthorised parties.[169]

163 Section 75, Executive Order No. 670/2019.
164 Section 76, Executive Order No. 670/2019.
165 Section 84, Executive Order No. 670/2019.
166 Sections 77(1)and 78(1), Executive Order No. 670/2019.
167 Section 81(1), Executive Order No. 670/2019.
168 Section 84, Executive Order No. 670/2019.
169 Section 81(3), Executive Order No. 670/2019.

Security plan for sources in security categories A and B

The security plan shall as a minimum comprise the following:

- Procedures for checking at least once daily, including on weekends and public holidays for sources in security category A and weekly for sources in security category B, that the source is in the possession of the undertaking and has not been tampered with by unauthorised parties. The Danish Health Authority regards this requirement as being met if a physical check is performed once daily or weekly, respectively. Protocols shall be kept of these checks.[170] An acceptable alternative to physical check is indirect monitoring by means of equipment for dose rate measurement installed at the source's storage site which sounds an alarm if the source is moved or tampered with and the dose rate changes accordingly.

- Access control to ensure that intruders cannot gain access to the area where the source is held. For sources in security category A, the access control shall include at least two different identity checks. For sources in security category B, the access control shall include at least one identity check.[171] An identity check is, for example, a system requiring a personal pin code to be entered in order to gain access to the area where the source is held.

- A system for ensuring that any intruders in the area where the source is held and, for sources in security category A, unlawful removal of the source are detected and assessed immediately. The system shall ensure that in the event of intrusion, resources are deployed immediately, which, for sources in security category A, are sufficient and, for sources in security category B, are highly likely to be sufficient to deter further intrusion or unlawful removal of the source.[172] The Danish Health Authority regards this requirement as met if an alarm system that is ID-based and encrypted is used which indicates where in the building the alarm has been activated, and if there is constant alarm surveillance of the storage room, and that response personnel are able to reach the scene within 35 minutes of the alarm being activated.

- At least two different technical security barriers which, for sources in security category A, deter and, for sources in security B, with great likelihood deter removal of the source before the response personnel arrive on the scene.[173] A technical security barrier is, for example, that the source is kept in a room with a locked door or that the source itself is secured, for example by fixing it mechanically to a stable building component. Locked doors should have locks in security class red, main group 1, and a patented copy-protected keying system should be in operation.

170 Section 77(2), No. 2, and Section 78(2), No. 1, Executive Order No. 670/2019.
171 Section 77(2), No. 2, and Section 78(2), No. 2, Executive Order No. 670/2019.
172 Section 77(2), No. 3, and Section 78(2), No. 3, Executive Order No. 670/2019.
173 Section 77(2), No. 4, and Section 78(2), No. 4, Executive Order No. 670/2019.

- Procedures for selection and screening of workers with independent access to the source and sensitive information.[174] A sub-element of the procedure may, for example, be a requirement for candidates to have no criminal record.

- Measures to ensure that sensitive information concerning the source and security aspects is not disclosed to unauthorised parties[175] and procedures for obtaining non-disclosure agreements from relevant workers[176].

- For sources in security category A, a communication system for ensuring that relevant officers from the undertaking are contacted immediately in the event of theft, unwarranted access, misuse or the like. The system shall contain at least two different types of communication, for example, by mobile phone and online.[177]

- Different security levels that can be activated based on the threat environment at any given time.[178]

Security measures must at no time compromise radiation protection and must not constitute a barrier to emergency response.[179]

12.4. Security plan for sources in security category C

For sealed sources in security category C, a security plan shall be prepared and implemented before a source is acquired.[180] The security plan shall be maintained on a continuous basis[181] and must not be disclosed to the public or become known to unauthorised parties[182].

Security plan for sources in security category C

The security plan shall as a minimum comprise the following:

- Procedures for checking at least monthly that the source is in the possession of the undertaking and has not been tampered with by unauthorised parties. Protocols shall be kept of these checks.[183]

174 Section 77(2), No. 5, and Section 78(2), No. 5, Executive Order No. 670/2019.
175 Section 77(2), No. 6, and Section 78(2), No. 6, Executive Order No. 670/2019.
176 Section 77(2), No. 7, and Section 78(2), No. 7, Executive Order No. 670/2019.
177 Section 77(2), No. 8, Executive Order No. 670/2019.
178 Section 77(2), No. 9, and Section 78(2), No. 8, Executive Order No. 670/2019.
179 Section 82, Executive Order No. 670/2019.
180 Section 79, Executive Order No. 670/2019.
181 Section 84, Executive Order No. 670/2019.
182 Section 81(3), Executive Order No. 670/2019.
183 Section 79(2), No. 1, Executive Order No. 670/2019.

- Access control consisting of at least one identity check to prevent unauthorised parties from gaining access to the area where the source is held.[184]
- At least one technical barrier to reduce the likelihood of the source being removed.[185]
- A procedure for selection and screening of workers with independent access to the source and sensitive information.[186] A sub-element of the procedure may, for example, be a requirement for candidates to have no criminal record.
- Measures to ensure that sensitive information concerning the source and security aspects is not disclosed to unauthorised parties.[187]

The security plan is not subject to the Danish Health Authority's approval. Security measures must at no time compromise radiation protection and must not constitute a barrier to emergency response.[188]

12.5. Compensatory measures

Security plans comprising sealed sources used outside of facilities and other secured work sites on the undertaking's premises shall contain compensatory measures, which shall be implemented when it is not feasible during application, storage, carriage, etc. of the sources to comply with the security requirements otherwise stipulated by the security plan.[189] For sources in security categories A and B, the compensatory measures shall be approved by the Danish Health Authority.[190]

The Danish Health Authority deems that for use of high-activity sealed sources outside of facilities and other secured work sites on the undertaking's premises, sufficient compensatory measures will be for the sources to be kept under supervision by workers approved for that task, and for the sources to be mechanically fixed to a stable building component or equivalent when not in use.

For the storage of a high-activity sealed source in connection with stopovers during transport, the Danish Health Authority deems that locking the source to the vehicle's frame and parking the vehicle in a locked garage kept under surveillance constitute acceptable compensatory measures.

184 Section 79(2), No. 2, Executive Order No. 670/2019.
185 Section 79(2), No. 3, Executive Order No. 670/2019.
186 Section 79(2), No. 4, Executive Order No. 670/2019.
187 Section 79(2), No. 5, Executive Order No. 670/2019.
188 Section 82, Executive Order No. 670/2019.
189 Section 80, Executive Order No. 670/2019.
190 Section 81(1), Executive Order No. 670/2019.

12.6. Emergency response plan

For high-activity sealed sources, an emergency response plan shall be prepared and implemented.[191] The emergency response plan for sources in security category A shall be approved by the Danish Health Authority before acquisition of a source.[192] If substantive amendments from the point of view of radiation protection are made to the emergency response plan, the Danish Health Authority shall approve the amended plan. The emergency response plan is expected to address the scenarios identified in the vulnerability assessment. A person should be appointed to be responsible for the emergency response plan.

191 Section 83(1), Executive Order No. 670/2019.
192 Section 83(2), Executive Order No. 670/2019.

Emergency response plan

The emergency response plan shall as a minimum contain the following:[193]

- Precautions in the event of emergencies, accidents and incidents involving a high-activity sealed source, including loss of the source
- Precautions in case of fire, flooding, power failure, etc.
- Precautions in the event of threatened or actual criminal acts
- Alerting plan, including notification to the police and the Danish Health Authority.

Precautions may include plans for evacuation, alerting and follow-up of emergencies, accidents and incidents. The alerting plan typically comprises a sequence of contacts (alerts) to be initiated immediately after an alert is issued. Responsibility for alerting procedure should be lodged with designated individuals who can be contacted at any time.

Emergency response plans must be regularly maintained, including contacts and telephone numbers – it must be kept up to date and a schedule for the maintenance of the plan must be established.[194]

193 Section 83(1), Executive Order No. 670/2019.
194 Section 84, Executive Order No. 670/2019.

13. Transport

The general rules for the transport of radioactive materials are laid down in Executive Order No. 993/2001; see Chapter 16. In addition, specific provisions exist for each mode of transport (road, rail, sea and air) which are applicable to national and international transport of radioactive material.[195]

Transport of sealed sources

The rules on the transport of sealed sources comprise all the functions and conditions associated with such transport. These include preparation, consigning, loading, carriage, including *transit storage*, unloading and receipt at the destination of the sealed sources.[196]

Sealed sources packaged and ready for consigning to a carrier are called packages.[197] Packages for carriage of sealed sources shall be designed so as to achieve commensurate safety for preventing dispersal of radioactive material during carriage.[198]

A package containing radioactive material is classified on the basis of radionuclide, activity concentration and activity and state (solid, liquid or gas).[199] Sealed sources typically contain concentrated radioactive material in a solid form, which is why, in practice, the radionuclide and activity determine the classification.

The consignor is responsible for ensuring that the package is correctly packed and marked and accompanied by a correctly completed transport document.[200] The carrier is responsible for ensuring that all requirements for the carriage of radioactive material are met, including that the package is correctly marked by the consignor.[201] By carrier is meant any undertaking that transports its own or other undertakings' radioactive material.

13.1. Radiation protection programme and quality management system

Transport of sealed sources shall be carried out in conformance with a radiation protection programme and a quality management system – in the specific regulations on transport of radioactive substances referred to as "management system" – which are graded in proportion to the risk associated with such transport.[202]

Undertakings subject to requirements for licensing or notification of use of sealed sources and hence subject to the requirement for a quality management system (see Chapter 15)

195 Subsection 2, Annex 2, Executive Order No. 993/2001.
196 1.7.1.3, ADR 2019, 1.7.1.3, RID 2019, 1.5.1.3 IMDG 2018 and 1;6.1.3, ICAO-TI.
197 1.2.1, ADR 2019, 1.2.1, RID 2019, 1.2.1, IMDG 2018 and 1;3.1.1, ICAO-TI.
198 1.7.1.2-1.7.1.3, ADR 2019, 1.7.1.2-1.7.1.3, RID 2019, 1.5.1.2-1.5.1.3, IMDG 2018, and 1;6.1.2-1;6.1.3, ICAO-TI.
199 2.2.7, ADR 2019, 2.2.7, RID 2019, 2.7, IMDG 2018, and 2;7, ICAO-TI.
200 Section 16, Executive Order No. 993/2001.
201 1.4.2.2, ADR 2019, 1.4.2.2, RID 2019, and 1;1.2, ICAO-TI.
202 1.7.2-1.7.3, ADR 2019, 1.7.2-1.7.3, RID 2019, 1.5.2-1.5.3, IMDG 2018, and 1;6.2-1;6.3, ICAO-TI.

can integrate their radiation protection programme and quality management system for transport of sealed sources into their general quality management system.

Radiation protection programme

A radiation protection programme shall describe the measures that have been implemented in order to optimise the radiation protection associated with the transport of sealed sources.[203] The nature and scope of the measures shall be graded according to the magnitude and likelihood of exposure.[204]

The radiation protection programme shall ensure that the doses that might be incurred by workers and members of the public from the transport of sealed sources are optimised and below the dose limits. The programme shall comprise all stages of transport and equally any interfaces between carriage and other handling of sources.[205]

The radiation protection programme shall be instrumental in ensuring that workers are adequately trained in radiation protection and relevant precautions to be taken to minimise the exposure of workers and members of the public in connection with transport of sealed sources.[206]

Quality management system

The quality management system shall ensure compliance with the rules on the transport of sealed sources. The quality management system shall, as a minimum, comprise instructions to ensure compliance with the requirements for package design, including maintenance, preparation for carriage, transport documents and other required documentation. To that end, the quality management system shall contain instructions on the transport operations carried out such as loading, unloading and carriage as well as requirements for worker competences and maintenance of those competences.[207]

13.2. Transport by road

The specific rules for transport by road of radioactive material are laid down in ADR; see Chapter 16.

Transport by road within Denmark

The ADR has been implemented in Danish legislation in the Danish Transport, Construction and Housing Authority's Executive Order No. 828/2017; see Chapter 16. The ADR is updated every two years and published on the Danish Road Safety Agency's website (www.fstyr.dk).

A *consignment* containing one or more sealed sources with a total activity less than or equal to the exemption value; see Annex D, is regarded, for transport purposes, as non-radioactive, and its transport may be undertaken as an exempt consignment.[208]

203 1.7.2.1, ADR 2019, 1.7.2.1, RID 2019, 1.5.2.1, IMDG 2018, and 1;6.2.1, ICAO-TI.
204 1.7.2.3, ADR 2019, 1.7.2.3, RID 2019, 1.5.2.3, IMDG 2018, and 1;6.2.3, ICAO-TI.
205 1.7.2.2, ADR 2019, 1.7.2.2, RID 2019, 1.5.2.2, IMDG 2018 and 1;6.2.2 ICAO-TI.
206 1.7.2.5, ADR 2019, 1.7.2.5, RID 2019 and 1;6.2.7, ICAO-TI.
207 1.7.3.1, ADR 2019, 1.7.3.1, RID 2019, 1.5.3.1, IMDG 2018 and 1;6.3, ICAO-TI.
208 For other radionuclides, see ADR Table 2.2.7.2.2.1.

Transport of an exempt consignment is not subject to the rules on transport of radioactive material, and the transport is consequently not subject to any special requirements.

Sealed sources with an activity greater than the exemption value may not be carried as exempt consignments and must normally be carried as excepted packages, Type A or Type B(U) packages, depending on the radionuclide and activity. Different requirements apply to each type of package based on the risk associated with emergencies, accidents and incidents during carriage. Table 4 shows the most common types of package associated with transport of sealed sources within Denmark.

Table 4
The most common package types associated with transport of sealed sources

Package type	Activity	Requirement
Excepted package	Small	Excepted from the majority of requirements for transport
Type A package	Medium	Subject to many requirements for transport
Type B(U) package	Large	Subject to many requirements for transport Regulatory approval of package design

This subsection reiterates the rules regarding transport by road within Denmark of excepted packages, and outlines the rules regarding transport by road of the other types of packages

Requirements for transport of excepted packages

Sealed sources may be carried as excepted packages if the activity of each consignment is below the limit in Table 5.

Table 5
Activity limits for excepted packages not having certificates for special form radioactive material for the most frequently carried sealed sources in solid form.

Radionuclide	Activity limit for excepted packages [MBq]
Co-60	400
Sr-90	300
Cs-137	600
Am-241	1
Am-241/Be	1

The activity limit per package for other radionuclides and for mixtures of radionuclides are stipulated in the ADR.[209, 210]

209 Table 2.2.7.2.4.1.2, ADR 2019.
210 2.2.7.2.2.4–2.2.7.2.2.6, ADR 2019.

Requirements for excepted packages

An excepted package shall meet the general requirements for packages set out in the ADR.[211] In addition, the following requirements apply to excepted packages.

Requirements for excepted packages

- The package shall be designed to contain its contents under routine conditions of transport.[212] In addition, the package shall be designed so that it can be properly secured inside the vehicle.[213]
- At the request of the Danish Health Authority, the consignor shall be able to document that the package design meets all relevant requirements.[214]
- The package must not contain any items other than those that are necessary for the use of the radioactive material or items that could jeopardise the safety of the package during carriage under routine conditions.[215]
- The non-fixed contamination on the external surface of any packaging shall be kept to a minimum and, under routine conditions of carriage, shall not exceed 4 Bq/cm^2 for radionuclides that emit beta and gamma radiation and radionuclides that emit low-toxicity alpha radiation[216], and 0.4 Bq/cm^2 for all other radionuclides emitting alpha radiation.[217]
- The maximum dose rate on the surface of the package must not exceed 5 µSv/h.[218]
- The package shall be marked on the exterior with:[219]
  - Consignor and/or consignee
  - *UN number*: UN 2908, UN 2910 or UN 2911
  - Gross weight (if exceeding 50 kg).
- The interior of the package shall be labelled with the text "Radioaktiv" (Radioactive) clearly visible when the packaging is opened, regardless of whether it is opened as planned or accidentally. If interior labelling is not feasible, the labelling shall be placed on the exterior of the package.[220]
- When using an overpack where the required particulars and hazard labels are not visible, the exterior packaging shall be marked with the word "OVERPACK", the letters of which must be at least 12 mm in height as well as the relevant particulars and UN number.[221]

211 6.4.2, ADR 2019.
212 6.4.2.7, ADR 2019.
213 6.4.2.1, ADR 2019.
214 5.1.5.2.3, ADR 2019.
215 4.1.9.1.3, ADR 2019.
216 2.2.7.1.3, ADR 2019.
217 4.1.9.1.2, ADR 2019.
218 2.2.7.2.4.1.2, ADR 2019.
219 5.1.5.4.1, ADR 2019.
220 2.2.7.2.4.1, ADR 2019.
221 5.1.2.1, ADR 2019.

Requirements for transport documents

Vehicles carrying excepted packages shall carry a transport document declaring the contents by the proper shipping name and associated UN numbers[222] and states the consignor's and consignee's address.[223] Table 6 lists the UN numbers and associated proper shipping names applicable to excepted packages containing sealed sources.

Table 6
UN numbers for excepted packages

UN number	Proper shipping name and description
UN 2908	RADIOAKTIVT MATERIALE, UNDTAGELSESKOLLI – TOM EMBALLAGE (RADIOACTIVE MATERIAL, EXCEPTED PACKAGE – EMPTY PACKAGING)
UN 2910	RADIOAKTIVT MATERIALE, UNDTAGELSESKOLLI – BEGRÆNSET MÆNGDE (RADIOACTIVE MATERIAL, EXCEPTED PACKAGE – LIMITED QUANTITY OF MATERIAL)
UN 2911	RADIOAKTIVT MATERIALE, UNDTAGELSESKOLLI – INSTRUMENTER eller FORARBEJDEDE GENSTANDE (RADIOACTIVE MATERIAL, EXCEPTED PACKAGE – INSTRUMENTS or ARTICLES)

Requirements for the transport document

Special requirements for design and retention of the transport document are outlined below.

- The transport document shall state the UN number preceded by the letters "UN" and the consignor's and consignee's name and address.[224]
- The consignor and carrier shall retain a copy of the transport document for a period of at least three months.[225]
- If the transport document is available electronically or in a computer system, the consignor and carrier shall be able to recreate it in printed format.[226]

Examples of transport documents for transport by road of sealed sources are available at www.sis.dk under "Legislation" → "Radioactivity" → "Transport".

222 2.2.7.2.1.1, ADR 2019.
223 5.1.5.4.2, ADR 2019.
224 5.1.5.4.2, ADR 2019.
225 5.4.4.1, ADR 2019.
226 5.4.4.2, ADR 2019.

Requirements for driver, vehicle, equipment, etc.

The driver of the vehicle shall have received instruction in the requirements made for transport of sealed sources, and specific instructions in relation to that individual's tasks, including in safety commensurate with the risk posed by those tasks.[227]

Consignments shall be securely stowed in the vehicle.[228]

The vehicle's cargo space must be kept locked at all times or the packages carried must otherwise be protected against unlawful unloading. The dose rate at the exterior surface of the vehicle must not exceed 5 µSv/h. If these requirements cannot be met, the vehicle must be kept under constant supervision.[229]

If no other types of packages are carried in the vehicle than excepted packages, an unlimited number of excepted packages may be carried in each vehicle as long as the dose rate limit on the exterior of the vehicle is otherwise complied with.[230]

No marking of the vehicle is required for carriage of excepted packages.[231]

The vehicle shall be equipped with a handheld extinguisher with a capacity of at least 2 kg that meets the applicable safety equipment requirements.[232, 233]

Vehicles and equipment regularly used for carriage of sealed sources shall be inspected periodically inspected for contamination. The frequency shall be adapted to the scale of transport of radioactive material and the probability of contamination.[234]

If a package is damaged or leaking or on suspicion that it is, access to the package shall be restricted and the magnitude of the contamination and the entailed radiation level shall be assessed as rapidly as possible by a qualified individual. Furthermore, the Danish Health Authority; see Subsection 14.4, and other authorities concerned shall be notified as quickly as possible.[235]

Transport of other types of packages

Consignors and carriers of consignments containing sealed sources that do not conform to the activity limit for excepted packages shall consult a *dangerous goods safety advisor*.[236] The tasks of the dangerous goods safety advisor include advising on transport of sealed sources, supervising transport of sealed sources and preparing an annual report for the consignor and/or carrier on all transportation activities.[237]

227 8.5, S12 and 8.2.3, ADR 2019.
228 7.5.11, CV33 (3.1), ADR 2019.
229 8.5, S21, ADR 2019.
230 1.1.3.6.2, ADR 2019.
231 5.3.1.1.3, ADR 2019.
232 8.1.4.2, ADR 2019.
233 8.1.4.4-8.1.4.5, ADR 2019.
234 7.5.11, CV 33 (5.3), ADR 2019.
235 Section 18, Executive Order No. 993/2001.
236 Sections 1 and 2, Executive Order No. 543/2012, and 1.8, ADR 2019.
237 1.8.3.3, ADR 2019.

Most of the requirements applicable to excepted packages also apply to transport of Type A and Type B(U)) packages. In addition, a number of other requirements shall be complied with, the most important of which are specified below.

Requirements for transport

- The package must be designed and tested to ensure that it will retain the radioactive content during routine conditions of transport and in the event of an accident.[238]
- In addition to the requirements for excepted packages, the package shall be marked with:
  - Type of package and identification mark[239]
  - Serial number for package types subject to regulatory approval[240]
  - Ionising radiation symbol for certain types of packages[241]
  - Correctly completed hazard labels[242].
- Packages with a dose rate greater than 2 mSv/h on the exterior surface or more than 100 µSv/h one metre from the exterior shall be carried under *exclusive use*.[243]
- In addition to the transport document, transport documentation shall include:
  - Written instructions[244]
  - Photo ID for the driver[245]
  - Driver's course certificate, if required[246]
  - Certificates, if required[247].
- The vehicle must be marked with placards[248] and orange color plates[249].
- The vehicle shall carry required safety equipment.[250]
- The driver and other personnel shall have received training in transport of radioactive material.[251]
- Only essential personnel may accompany the vehicle.[252]

238 Chapter 6.4, ADR 2019.
239 5.2.1.7.4–5.2.1.7.6, ADR 2019.
240 5.2.1.7.5, ADR 2019.
241 5.2.1.7.6, ADR 2019.
242 5.2.2.1.11.2, ADR 2019.
243 4.1.9.1.10–4.1.9.1.11, ADR 2019.
244 5.4.3.1, ADR 2019.
245 1.10.1.4, ADR 2019.
246 8.2.1.1, ADR 2019.
247 5.4.1.2.5.4, ADR 2019.
248 5.3.1.1.3, ADR 2019.
249 5.3.2.1.1, ADR 2019.
250 8.1.4 and 8.1.5, ADR 2019.
251 1.3.1, 8.2.1, 8.2.3 and 8.5, S21, ADR 2019.
252 Chapter 7, CV 33 (1.3), ADR 2019.

International transport by road

For international transport by road of sealed sources, the rules of the country in question shall be complied with. In addition, the transport document shall be available in Danish and either English, German or French.[253]

13.3. Transport by rail

The rules for transport of sealed sources by rail are prescribed by RID; see Chapter 16. The rules on transport by rail are generally the same as those for transport by road; see Subsection 13.2, with the exception of the requirements for the driver, vehicle and equipment etc. which are not applicable to transport by rail.

Transport of sealed sources by rail requires regulatory approval of the *rail freight carrier* and the *infrastructure administrator* from the Danish Transport, Construction and Housing Authority.

13.4. Transport by sea

According to the Memorandum of understanding; see Chapter 16, which may be applicable to all ferry routes in Denmark and in the Baltic Sea Region, no special transport document is necessary for carriage by sea of sealed sources. This means that the transport document prepared in accordance with regulations for road transport are sufficient. The Memorandum of understanding, however, requires that vehicles carrying packages containing sealed sources, including excepted packages, shall be marked with orange placards on the front and rear of the vehicle for the duration of the voyage starting from the time of check-in with the shipping company.[254] Shipping companies are free to choose whether they wish to adhere to the Memorandum of understanding on a specific ferry route.

Transport by sea of sealed sources not subject to the Memorandum of understanding is subject to the specific regulations for transport by sea set out in the IMDG Code; see Chapter 16, and is regulated according to the vessel's flag state. For carriage by sea on board foreign-flagged vessels, the authorities in the country in question should be consulted for guidance on the rules.

For ferry crossings, the ferry crew shall be informed that sealed sources will be carried on board. It is advisable to bring copies of the transport document, as a copy usually has to be submitted at ticket issuance.

253 5.4.1.4.1, ADR 2019.
254 https://www.soefartsstyrelsen.dk/SikkerhedTilSoes/Skibssikkerhed/FarligtGods/FarligtGodsEmballeret

13.5. Transport by air

Transport by air of sealed sources is regulated by the provisions of ICAO-TI; see Chapter 16. The airlines also apply their own rules, as prescribed in IATA-DRG; see Chapter 16, which is published annually. IATA-DRG is based on the regulations in ICAO-TI.

Transport by air of sealed sources is usually subject to more restrictive requirements regarding, for example, package design and the radiation protection programme, than for the other modes of transport.

14. Emergencies, accidents and incidents

Before using sealed sources, the undertaking shall identify potential emergencies, accidents or incidents. Based on this, a set of instructions shall be prepared for workers on the precautions to be taken in such situations.

In the event of an emergency, accident or incident, including theft involving sealed sources, the undertaking shall promptly take all relevant measures to avert or mitigate serious adverse consequences for human health, safety, quality of life, property or the environment.[255] The Danish Health Authority shall be notified promptly of any such event.[256]

14.1. Instructions regarding precautions

The undertaking shall ensure that clear set of instructions is available to workers on precautions to be taken in the event of an emergency, accident or incident, including theft.[257]

The instructions shall be readily available during work. All relevant precautionary measures should be described in the instructions, including evacuation and containment if applicable. The instructions should also include information about notification of the Danish Health Authority and of the undertaking and its radiation protection officer.

14.2. Procedure in the event of emergencies, accidents and incidents

The following procedure should be followed in the event of emergencies, accidents and incidents, depending on the magnitude of the event.

Procedure in the event of emergencies, accidents and incidents

- Assess the magnitude
- Evacuate unauthorised parties
- Summon assistance
- Cordon off the area if the dose rate exceeds 60 µSv/h
- Keep the area under continuous surveillance
- Notify the radiation protection officer and the undertaking
- Notify the Danish Health Authority; see Subsection 14.4.

255 Section 91, Executive Order No. 669/2019.
256 Section 92(1), Executive Order No. 669/2019.
257 Section 57, Executive Order No. 669/2019.

14.3. Systematic factors

Faulty sealed sources or faulty devices containing sources, faults in facilities or equipment, faulty procedures pertaining to application, etc. of sources - or testing of measuring equipment or equipment with recurring defects may result in unintended exposure. These are referred to as systematic factors. Examples of systematic factors would include a defect propagated to multiple sources or devices containing sources or if an incorrect procedure is reiterated. Dissemination of information on systematic factors can have a significant radiation protection effect, since emergencies, accidents and incidents may be averted for a large number of users of the same type of source or device, facility or equipment, or for users employing the same procedure. Systematic factors shall therefore be notified to the Danish Health Authority as soon as possible[258]; see Subsection 14.4.

14.4. Notification to the Danish Health Authority

Notification to the Danish Health Authority

The Danish Health Authority shall be notified promptly of the following: [259]

- Emergencies, accidents or incidents causing in unintended exposure
- Any discovery, theft, loss, fire, flooding or the like of significance from a radiation protection point of view involving sealed sources
- Incidents that might have resulted in the above.

Notification shall be to the Danish Health Authority, Radiation Protection's 24-hour hotline

tel. +45 44 94 37 73.

In addition, the Danish Health Authority shall be informed as soon as possible of any systematic factors that might result in unintended exposure.[260]

14.5. After an emergency, accident or incident

The cause of an emergency, accident or incident shall be identified and necessary measures shall be taken to prevent recurrence. In the event of accidental exposure, the undertaking shall ensure an adequate analysis is performed of the circumstances and consequences of the exposure, including determination of relevant doses.[261]

258 Section 58, Executive Order No. 669/2019.
259 Section 92(1), Executive Order No. 669/2019.
260 Section 58(1), Executive Order No. 669/2019.
261 Section 59, Executive Order No. 669/2019.

15. Quality assurance

Quality assurance denotes all planned and systematic actions, including quality control, necessary to provide adequate assurance that sealed source, devices containing sources, facilities, equipment, systems or subcomponents or procedures function properly in compliance with agreed standards. In order to achieve quality assurance, the Danish Health Authority requires the utilisation of a quality management system in connection with any use of sealed sources.[262] The overall aim of quality assurance is to maintain radiation protection, for example, by preventing or detecting incorrect handling or storage of sources and defects in sources and source-containing devices, and facilities and equipment. An effective quality management system also enables the undertaking to demonstrate that the continuous use of sealed sources is compliant with the provisions of the radiation protection legislation.

Undertakings shall establish and maintain a quality management system commensurate with the nature and scale of the undertaking's use of sealed sources.[263] This means that the higher the risk associated with the use of sources, the stricter the requirements for the quality management system to reflect all the details of their use, and for the system to address, as a minimum, the risks described in the associated documentation, such as in a safety assessment. The risk shall be assessed based on factors such as radionuclide, activity, security category, shielding, mobility, complexity of application and risk of chemical or mechanical ageing and wear.

The quality management system shall reflect the undertaking's current use of sealed sources. It shall therefore serve to substantiate that relevant documents such as the safety assessment, security plan, emergency response plan, records, registries, protocols, instructions and the like are updated and available.

As part of quality assurance, all radiation protection measures shall be checked at suitable intervals and written instructions shall be available for performing such checks. The results shall be documented in a systematic manner.[264]

15.1. Basic elements of the system

Table 7 provides an overview of a number of significant regulatory requirements with which the quality management system shall serve to ensure compliance. In addition, the quality management system shall ensure that documents such as instructions are complied with and that records and protocols are duly kept.

262 Section 93, Executive Order No. 669/2019.
263 Section 93, Executive Order No. 669/2019.
264 Section 94, Executive Order No. 669/2019.

Table 7
Overview of significant requirements with which the quality management system shall serve to ensure compliance, the overview is not exhaustive

Topics and content	Citing this Guide	Citing the Executive Order
Safety assessment		
Updated to reflect current use	Subsection 6.1	Section 20(2), Executive Order No. 669/2019.
Instructions		
Use of sealed sources	Subsection 10.1	Section 57, Executive Order No. 669/2019.
Precautions in the event of emergencies, accidents and incidents	Subsection 10.1	Section 57, Executive Order No. 669/2019.
Procedures		
Classification of areas	Subsection 9.1	Section 49 and Section 50, Executive Order No. 669/2019.
Categorisation of workers	Subsection 7.1	Section 38, Executive Order No. 669/2019.
Checks of measuring equipment	Subsection 10.3	Section 56, Executive Order No. 669/2019.
Radiological monitoring	Chapter 8	Section 78 and Section 79, Executive Order No. 669/2019.
Selection and screening of workers with independent access to high-activity sealed sources	Sections 12.3 and 12.4	Section 77(2), Section 78(2), Section 79(2), Executive Order No 670/2019.
Documentation		
Doses to exposed workers	Subsection 8.3	Section 86, Executive Order No. 669/2019.
Technical safety inspection reports	Subsection 11.5	Section 55, Executive Order No. 670/2019.
High-activity sealed sources	Subsection 11.2	Section 60, Executive Order No. 670/2019.
Transport documents	Chapter 13	
Protocols		
Checks for the presence of high-activity sealed sources	Sections 12.3 and 12.4	Section 77(2), Section 78(2), Section 79(2), Executive Order No. 670/2019.

Records		
Exposed workers, their qualifications and maintenance of same	Subsection 7.3	Section 45(3), Executive Order No. 669/2019.
Sealed sources	Subsection 11.2	Section 16(1) and (2), Executive Order No. 670/2019.
Facility	Subsection 11.3	Section 17, Executive Order No. 670/2019.
Storage and transfer of sealed sources, including radioactive waste	Subsection 10.6	Section 18(1), Executive Order No. 670/2019.
Vulnerability Assessment		
Updated to reflect current use	Subsection 12.3	Section 76 and Section 84, Executive Order No. 670/2019.
Security plan		
Updated to reflect current use	Sections 12.3 and 12.4	Section 77(1), Section 78(1), Section 79(1), Section 84, Executive Order No. 670/2019.
Emergency response plan		
Updated to reflect current use	Subsection 12.6	Section 83 and Section 84, Executive Order No. 670/2019.

16. Acts, executive orders, guides, etc.

16.1. Acts, executive orders, etc.

- 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. 993 of 5 December 2001 on Transport of Radioactive Material.
- Council Regulation (Euratom) No. 1493/93 of 8 June 1993 on the shipments of radioactive substances between Member States.
- Ministry of Health Executive Order No. 1111 of 7 November 2019 on Fees for the Danish Health Authority.
- Danish Working Environment Authority Executive Order No. 10 of 5 January 2018 on Medical Examinations Pertaining to Potential Occupational Exposure to Ionising Radiation.
- Danish Working Environment Authority Executive Order No. 518 of 17 June 1994 on Safety Signage and other forms of Signalling.
- ADR (Agreement, Dangerous, Road). European Agreement concerning the International Carriage of Dangerous Goods by Road (2019).
- Danish Transport, Construction and Housing Authority Executive Order No. 828 of 10 June, 2017 on Transport by Road of Dangerous Goods.
- Danish Transport, Construction and Housing Authority Executive Order No. 543 of 12 June 2012 on Dangerous Goods Safety Advisors.
- RID (Regulation concerning the International Carriage of Dangerous Goods by Rail) (2019).
- IATA-DRG (International Air Association, Dangerous Goods Regulations) (2019).

- ICAO-TI (International Civil Aviation Organization, Technical Instructions) (2018).
- IMDG (International Maritime Dangerous Goods) Code (2018).
- Memorandum of Understanding for the Transport of Packaged Dangerous Goods on Ro-Ro Ships in the Baltic Sea" (2018).
- Danish Safety Technology Authority Executive Order No. 1229 of 11 December, 2009 on the International System of Units, SI, and other legal units.

16.2. Guides

- Danish Health Authority Guide to Use of Unsealed Sources for Non-Medical Purposes (2020).
- Danish Health Authority Guide to Safety Assessment (2020).
- Danish Working Environment Authority Guide No. 9093 of 31 January 2019 to Medical Examinations Pertaining to Potential Occupational Exposure to Ionising Radiation.

16.3. Other relevant publications

- Danish Health Authority publication: The Radiation Guide – Ionising Radiation (2013).
- ICRP, 2007. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37 (2-4).
- Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev 1), (2016).

The Act and the executive orders in force at any time are available at www.retsinformation.dk. Other publications from the Danish Health Authority are available at www.sis.dk.

Annex A: Glossary

Accidental exposure:	An exposure of individuals as a result of an emergency, accident or incident, excluding the exposure of emergency workers providing emergency response.
Acoustic dose rate alarm:	A device that emits audible signals at dose rate dependent time intervals.
Acute effect:	An injury for which a threshold dose has been defined as the cause of the injury, and where the extent of the injury increases proportionally with the magnitude of the dose. Examples of acute effects are cataract, sterility, and inhibition of the formation of white blood cells and other cells.
Application:	Utilisation of a sealed source for its intended purpose, for example: testing equipment, process control, moisture and density measurement, borehole logging, blood irradiation and industrial irradiation.
Blood irradiation:	Treatment using ionising radiation of a) blood in order to kill bacteria, viruses, etc. and b) cells, tissues, experimental animals, etc. in order to prevent cell division. The device in which the irradiation takes place is a self-shielding irradiation facility. The radiation source in the facility is either a radiation generator or a high-activity sealed source typically containing Cs-137.
Borehole logging:	Geophysical measurement performed by means of a sealed source lowered into a borehole.
Carriage	The change of place of radioactive material, including stops made necessary by transport conditions and including any period spent by the radioactive material in vehicles, tanks and containers made necessary by traffic conditions before, during and after the change of place.

Consignment:	Any package or load of radioactive material presented by a consignor for transport.
Consumer product:	A device or manufactured item into which one or more radionuclides have intentionally been incorporated or produced by intentional activation, or which generates ionising radiation, and which is manufactured for the purpose of making the device or item available to, or marketing the device or item to, consumers.
Dangerous goods safety advisor:	A transportation advisor who shall be contracted to serve undertakings that transport radioactive material other than that in exempt consignments and excepted packages.
Danish Decommissioning:	A state-owned company responsible for receiving and storing radioactive waste from users of radioactive material in Denmark. Danish Decommissioning is also tasked with developing a Danish repository for radioactive waste.
Discharge and disposal:	The discharge, injection into geological layers or the *disposal* of radioactive waste.
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.
Dose constraint:	An upper value of individual dose delivered by a radiation source in a *planned exposure situation* and which provides a basis for optimisation of radiation protection.
Dose limit:	The value of the effective dose or the equivalent dose in a specified period which may not be exceeded for an individual.

Dosimetry service:	A body or an individual with the competence to calibrate, read or interpret personal dosemeters, and make a dose determination based on a personal dosemeter or to measure radioactivity in the human body or in biological samples, or to assess doses.
Effective dose:	The sum of the weighted equivalent doses in all the tissues and organs of the body from internal or external exposure.
Emergency:	A non-routine situation involving a radiation source and necessitating prompt action primarily to mitigate: a) serious adverse consequences for human health and safety, quality of life, property or the environment, or b) a hazard that could give rise to such serious adverse consequences.
Emergency exposure situation:	A situation of exposure due to an emergency.
Emergency response plan:	Arrangements for planning an adequate reaction to an emergency exposure situation on the basis of hypothetical incidents and related scenarios.
Emergency workers:	Any individual having a defined role in an emergency and who might be exposed to radiation as a result of taking action in response to the emergency, including volunteers who have been instructed on their role in advance.
Employer:	A natural or legal person who allows its workers to engage in the use of radiation sources or allows its workers to be exposed to ionising radiation.

Equipment:	The supplementary material necessitated by the use of radiation sources or exposure, including containers, measurement instruments and other measuring equipment, imaging systems and material for radiation protection, including personal protective equipment.
Equivalent dose:	The average absorbed dose in any tissue or organ weighted for the type and quality of ionising radiation.
Exclusive use:	A single consignor´s use of a vehicle. Carriers transporting packages under exclusive use must be approved by the Danish Health Authority. Loading or unloading may not be carried out between the place of dispatch and the destination.
Exemption value:	Value for activity concentration or activity that may be applied as standard for exemption of limited quantities of any type of material.
Existing exposure situation:	An exposure situation that already exists when a decision on its control has to be taken and which does not call or no longer calls for urgent measures to be taken.
Export:	The shipment of 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, or a worker who is subjected to planned exposure to ionising radiation in an existing exposure situation and whose presence is necessary.
Exposure:	Exposure to ionising radiation.
External exposure:	Exposure of the body to radiation sources outside the body.
External storage site:	A storage site outside the registered address of the undertaking.

Facility:	Interiors, including laboratories, radiography rooms and storage and refuse rooms and their associated structural elements constructed and fitted out to provide radiation protection from the use of radiation sources, and vehicles constructed and fitted to provide radiation protection from the application of radiation sources.
Freight operator:	A railway undertaking whose main activity consists of the transport of goods by rail.
Handling:	The practical operations associated with manufacture, application, storage, etc. of sealed sources and devices containing sources. Handling includes, for example, operations associated with receiving a source, application of a source, and shipment of a source.
High-activity sealed source:	A sealed source in which the activity exceeds or is equal to the lower activity limit for security category C in Annex E.
Holding:	*Ownership of, or right of use to, sealed sources.*
Humidity and density measurement:	Measurement of density and/or moisture in soil. Usually performed with a mobile device that most often contains one or two sealed sources consisting of Am-241/Be and/or Cs-137.
Import:	The shipment of sealed sources to Denmark from another country.
Individual radiological monitoring:	Determination of the effective or equivalent dose incurred by an individual by means of a personal dosemeter or based on a radiological monitoring programme.
Industrial irradiation:	Sterilisation, etc. of medical and other equipment by means of ionising radiation. An industrial irradiation facility may also be referred to as an irradiator. The radiation source in the facility is either a radiation generator or a high-activity sealed source typically containing Co-60.

Industrial radiography:	Radiography for industrial or research purposes, e.g. for weld inspection, in which high-activity sealed sources are used inside or outside of facilities, and where the radiation source is moved outside the container.
Infrastructure administrator:	Body or undertaking responsible for facilities, maintenance and administration, including traffic management of railway infrastructure.
Ionising radiation:	Particles, including photons, capable of causing ionisation in substances directly or indirectly, but in the case of electromagnetic radiation, only radiation of a wavelength of 100 nm or less.
Late effect:	An injury for which no proven threshold dose has been identified and where the risk of injury increases with increasing dose. Examples of late effects are leukaemia and other types of cancer and genetic effects. Late effects may arise many years after exposure.
Manufacture:	Manufacture and construction of sealed sources and devices containing sealed sources. The manufacture of the radionuclides included in the sealed sources is not covered by this term.
Medical exposure:	Exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment which is intended to benefit their health, exposure incurred by carers and comforters in connection with this as well as the exposure incurred by volunteers in connection with medical or biomedical research.
Member of the public:	An individual who may be subject to public exposure.
Non-medical purposes:	Purposes that do not include medical exposure. Testing of equipment at hospitals, etc. during application of sealed sources is comprised by this term.

Occupational exposure:	The exposure incurred by a worker from the use of radiation sources or from exposure in the undertaking that worker performs work for. For an individual pursuing a programme of vocational education of at least two years' duration which is governed by or pursuant to legislation and in which the use of radiation sources or exposure is an essential component of that programme, the exposure which that individual incurs from the use of radiation sources or exposure during the education or training is regarded as occupational exposure.
Other worker:	A worker who is not an exposed worker in an undertaking that uses radiation sources or is responsible for exposure.
Outside worker:	An exposed or other worker who performs work for an undertaking that is not that worker's employer.
Package:	Transport packaging with radioactive content.
Personal dosemeter:	A device worn by an individual worker for determination of the effective dose or equivalent dose incurred by that individual.
Planned exposure situation:	An exposure situation that arises from the planned use of a radiation source or the planned exposure to ionising radiation in an *existing exposure situation*. A planned exposure situation may include both normal and potential exposures.
Process control:	Measurement of level, density, flow or other parameters associated with production/operation by means of a device containing a sealed source. The device is usually permanently installed and shielded, and operates without handling by workers.
Public exposure:	The exposure of individuals, excluding any occupational or medical exposure.

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 remediation of the consequences hereof.
Radiation protection expert:	An individual who shall advise the undertaking to ensure effective radiation protection of workers and members of the public in connection with the undertaking's use of radiation sources or exposures. The radiation protection expert shall 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 shall be approved by the Danish Health Authority.
Radiation source:	A radioactive substance or a radiation generator.

Radioactive material:	A radioactive substance, the activity 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.
Radiological monitoring programme:	Individual radiological monitoring that is not based on the use of a personal dosemeter, including measurement of biological specimens from the individual, measurement of the individual in a whole body counter or for assessment of doses based on an estimate made on the basis of individual measurements obtained from other exposed workers, based on the results of workplace monitoring or on the basis of calculation methods.
Radionuclide:	Unstable atomic nucleus that undergoes decay as it emits ionising radiation.
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.
Sealed source:	Radioactive material that is permanently sealed in a capsule or incorporated in a solid form with the objective of preventing, under normal conditions, any dispersal of the radioactive material.
Security category:	A class of high-activity sealed sources, which based on their activity and the potential for radiation injury from theft, unintended access or misuse, are subject to the same requirements regarding security measures.
Security measures:	Arrangements or precautions for the purpose of preventing, detecting and responding to theft, unintended access to, or misuse of radioactive material.

Security plan:	Arrangements for planning precautions for the purpose of preventing, detecting and responding to theft, unintended access to, or misuse of, high-activity sealed sources.
Shipment between countries:	All measures necessary for the physical relocation of radioactive material from one country to another country.
Special form certificate:	A certificate documenting that the source type has been tested in conformance with the associated safety standard.
Storage:	Any storing of sealed sources, such as at specially-equipped storage locations inside the facilities where the sources are handled or inside facilities dedicated to storage of sealed sources or radioactive waste.
Technical safety inspection:	Inspection to ensure that sealed sources, including devices containing sources and, where relevant, facilities and equipment, are in a satisfactory technical state from a safety perspective.
Transfer:	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 a transfer.
Transit:	The shipment via Denmark of radioactive material from a country outside the European Union to another country outside the European Union.
Transport:	Transportation and any operation involving loading, unloading, transit storage and handling on Danish territory. Transport therefore includes transportation to and from Danish consignors and consignees and transportation transiting via Danish territory.
UN number:	Numbering of official proper shipping names for dangerous goods defined by the UN.

Undertaking:	A natural or legal person who owns, rents, leases, borrows or otherwise holds right of use of a radioactive substance or is responsible for an area exposed to ionising radiation or who is responsible for the 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.
Unsealed source:	Radioactive material in the form of a gas, aerosol, fluid or solid that is not sealed in a capsule, where contact with or dispersal of the material may occur during use.
Use:	Manufacture, processing, holding, import, export, transfer, handling, application, control, technical safety inspection, storage, disposal, recycling, reuse, discharge and transport of radioactive substances.
Veterinary medical application:	The application of radioactive material for veterinary medical diagnostics, treatment or research within these domains.
Vulnerability assessment:	The identification of threats and security weaknesses during the use of radioactive material.
Worker:	Any person who, regardless of any underlying contractual relationship, is engaged in a worker-like relation.

Appendix B: Formulas, units and conversion factors

Formulas

Basic formulas*	
Description	**Formula**
Activity, A, to time, t	$A_t = A_0 \cdot e^{-\ln 2 \cdot t / t_{½}}$
Dose rate ** of a given activity at distance, x, from unshielded source	$\dot{D} = A \cdot \Gamma / x^2$
Dose rate ** at a given activity at distance, x, from a shielded source attenuated by a material with a linear absorption coefficient, μ and thickness, d	$\dot{D} = \left(\frac{A \cdot \Gamma}{x^2}\right) \cdot e^{-\mu \cdot d}$
Dose rate** at a given distance (inverse-square law) *When the dose rate D_1, is known at distance, x_1, from a radiation source, the dose rate, D_2, at a given distance, x_2, is determined from the relationship*	$\dot{D}_2 = \dot{D}_1 \cdot (x_1/x_2)^2$
Distance** resulting in a given dose rate (inverse-square law) *When the dose rate, D_1, is known at distance, x_1, from a radiation source, distance, x_2, at a given dose rate, D_2, is determined from the relationship*	$x_2 = x_1 \cdot \sqrt{\dot{D}_1/\dot{D}_2}$
Calculation of transmission factor (with and without shielding)	$T = \dot{D}_m/\dot{D}_u$
Dose after a given period of time, t (valid when $t << t_{½}$)	$D = \dot{D} \cdot t$

* All quantities in these formulas should be considered operational quantities such as the ambient dose equivalent, $H^*(10)$, as defined by ICRP[265].

** Where the radiation source emits electromagnetic radiation, e.g. gamma rays, and can be considered a point source.

265 ICRP Publ. 116, 2010.

Formulas for determining the level of regulatory control[266]	
Description	**Formula**
Activity index for radionuclide, *k*	$I_A = \sum_k \frac{A_k}{A_{U,k}}$
Activity concentration index for radionuclide, *k*	$I_{AK} = \sum_k \frac{AK_k}{AK_{U,k}}$

Definitions and symbols

Definitions		
Description	**Formula**	**Unit**
Absorbed dose *Where dε is the energy from ionising radiation which is deposited in an infinitesimal volume of mass, dm*.	$D = \frac{d\varepsilon}{dm}$	[gray, Gy]
Equivalent dose *The quantity, equivalent dose, takes into account the biological effect of ionising radiation in relation to radiation type and energy.*	$H_T = \sum_R w_R \cdot D_{T,R}$	[sievert, Sv]
Effective dose *The effective dose quantity takes into account differentiated organ and tissue sensitivity to radiation for instance where only part of the body is exposed or is subjected to inhomogeneous exposure.*	$E = \sum_T w_T \cdot H_T$	[Sv]

Symbols		
Symbol	**Description**	**Unit**
A	Activity	[becquerel, Bq]
A_t	Activity to time, *t*	[Bq]
A_0	Original activity to time = 0	[Bq]

266 Annex 1, Executive Order No. 670/2019.

A_k	Activity of radionuclide, *k*	[Bq]
$A_{U,k}$	Activity for radionuclide, *k*, for exemption[267]	[Bq]
AK_k	Activity concentration of radionuclide, *k*	[Bq/g]
$AK_{U,k}$	Activity concentration for radionuclide, *k*, for exemption and clearance[268]	[Bq/g]
d	Thickness	[meter, m]
D	Dose	[Sv] *Is typically in units of µSv or mSv*
$\dot{D}$	Dose rate	[Sv/h] *Is typically in units of µSv/h or mSv/h*
$D_{T,R}$	Average absorbed dose deposited in the organ/tissue, *T*, as a result of the radiation, *R*	[Gy]
Γ	Gamma Constant *Constant for calculating dose rate for a given activity and distance*	[Sv·m^2/(Bq·s)]
µ	Linear absorption coefficient *Probability of attenuation per unit length*	[m^{-1}]
t	Time	[second, s]
$t_{½}$	Half-life *Time elapsing before the activity has been reduced by half*	[s]
T	Transmission factor	Dimensionless

267 Annex 3, Executive Order No. 670/2019.
268 Annexes 3 and 4, Executive Order No. 670/2019.

	The ratio of dose rate after radiation has passed the shielding to dose rate before passing the shielding	
w_R	Radiation Weighting Factor[269] *Used to weight the absorbed dose to organ or tissue for the type and energy of the radiation (radiation, R) and thereby transition from physical effect [gray] to biological effect [sievert]*	[Sv/Gy]
w_T	Tissue weighting factor[270] *Used to weight equivalent dose in organ or tissue (tissue, T) for its radiation sensitivity*	Dimensionless
x	Distance	[m]

Conversion factors

Activity

- 1 becquerel [Bq] = 1 decay per second [s^{-1}]
- 1 curie [Ci] = 37 GBq
- 1 mCi = 37 MBq

The SI unit for activity is the becquerel[271], the curie being an obsolete unit.

Absorbed dose

- gray [Gy] = J · kg^{-1}
- 1 Gy = 100 rad
- 1 rad = 10 mGy

The SI unit for absorbed dose is the gray[272], the rad being an obsolete unit.

269 Annex 4, Table 1, Executive Order No. 669/2019.
270 Annex 4, Table 2, Executive Order No. 669/2019.
271 Annex 1, Executive Order No. 1229/2009.
272 Annex 1, Executive Order No. 1229/2009.

Equivalent and effective dose

- sievert [Sv] = J · kg^{-1}
- 1 Sv = 100 rem

The SI unit for equivalent dose is the sievert[273], the rem being an obsolete unit.

Energy

- joule [J] = N · m
- 1 electron volt [eV] = 1.602 · 10^{-19} J

Prefixes

pico	nano	micro	milli	kilo	mega	giga	tera	peta	exa
p	n	µ	m	k	M	G	T	P	E
10^{-12}	10^{-9}	10^{-6}	10^{-3}	10^{3}	10^{6}	10^{9}	10^{12}	10^{15}	10^{18}

273 Annex 1, Executive Order No. 1229/2009.

Annex C: Special requirements for the qualifications of radiation protection officers

Manufacture of sealed sources

- Passed an examined course on isotopes accredited by the Danish Health Authority.

Manufacture of devices incorporating sealed sources

- Course in the fundamentals of radiation protection accredited by the Danish Health Authority.

Application of sealed sources for radiation sterilisation, etc. in industrial irradiation facilities

- Radiation protection course at industrial irradiation facility accredited by the Danish Health Authority, and
- Course in the fundamentals of radiation protection accredited by the Danish Health Authority.

Application of sealed sources for blood irradiation

- Course in the fundamentals of radiation protection accredited by the Danish Health Authority.

Application of sealed sources for borehole logging

- Relevant higher scientific education, and
- Course in the fundamentals of radiation protection accredited by the Danish Health Authority.

Application of sealed sources in moisture and density measurement (mobile devices)

- Course in the application of moisture and density meters accredited by the Danish Health Authority.

Application of hand-held devices incorporating sealed sources

- Training in application of the specific types of sealed sources and devices. The training shall be provided by the manufacturer or other competent individual familiar with the specific types of sealed sources and devices.

Annex D: Exemption values for commonly used radionuclides

Radionuclide	Exemption value for activity ($A_{U,k}$), [Bq]
H-3	1×10^{9}
Co-57	1×10^{6}
Co-58	1×10^{6}
Co-60	1×10^{5}
Ni-63	1×10^{8}
Ge-68	1×10^{5}
Se-75	1×10^{6}
Kr-85	1×10^{4}
Sr-90	1×10^{4}
Ru-106	1×10^{5}
Cd-109	1×10^{6}
I-125	1×10^{6}
Cs-137	1×10^{4}
Ba-133	1×10^{6}
Gd-153	1×10^{7}
Ir-192	1×10^{4}
Po-210	1×10^{4}
Ra-226	1×10^{4}
Am-241	1×10^{4}
Cm-244	1×10^{4}
Cf-252	1×10^{4}

For other radionuclides, the exemption value is provided in Annex 3 of Executive Order No. 670/2019; see Chapter 16.

Annex E: Security categories

The activity limits for security categories A, B and C are shown below: [274]

Radionuclide	Lower activity limit for security categories		
	A [TBq]	B [TBq]	C [TBq]
Fe-55	800,000	8,000	800
Co-60	30	0.3	0.03
Se-75	200	2.0	0.2
Kr-85	30,000	300	30
Sr-90 (Y-90)	1,000	10	1.0
Pd-103	90,000	900	90
I-125	200	2	0.2
Cs-137	100	1.0	0.1
Pm-147	40,000	400	40
Gd-153	1,000	10	1.0
Yb-169	300	3.0	0.3
Tm-170	20,000	200	20
Ir-192	80	0.8	0.08
Tl-204	20,000	200	20
Ra-226	40	0.4	0.04
Pu-238	60	0.6	0.06
Pu-239/Be	60	0.6	0.06
Am-241	60	0.6	0.06
Am-241/Be	60	0.6	0.06
Cm-244	50	0.5	0.05
Cf-252	20	0.2	0.02

274 Annex 6, Executive Order No. 670/2019.

Sealed sources in which the activity is lower than the lower limit for activity for sources in security category C are not assigned to security categories.

The limits applicable to security categories are for guidance purposes only. Based on a specific assessment of a high-activity sealed source and its area of use and application, the Danish Health Authority may assign a radiation source to a different security category.[275]

For radionuclides not listed, the Danish Health Authority determines suitable values as and when required.

275 Section 74(2), Executive Order No. 670/2019.

Radiation protection advice

Danish Health Authority
Radiation Protection
Knapholm 7
DK-2730 Herlev

Tel: 44 54 34 54
Tel: 44 94 37 73 (24/7)
Fax: 72 22 74 17
E-mail: sis@sis.dk
Website: www.sis.dk

Questions concerning personal dosimetry

Danish Health Authority
Radiation Protection
Personal dosimetry
Knapholm 7
DK-2730 Herlev

Tel: 44 54 34 56
Fax: 72 22 74 21
E-mail: pl@sis.dk
Website: www.sis.dk