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Use of unsealed sources

Non-medical purposes

Guide

Sundhed for alle

Use of unsealed sources
Non-medical purposes

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Introduction

The purpose of this Guide is to contribute to correct interpretation and application of the rules regarding *use* of *unsealed sources*. The rules are laid down in the Radiation Protection Act and related executive orders (the radiation protection legislation); see Chapter 17. The purpose of the rules is to ensure that the use of unsealed 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.

The Guide is intended for anyone who uses unsealed sources for *non-medical purposes.* However, the Guide does not include the *application* of unsealed sources for educational purposes at primary and secondary educational institutions*, leak detection*, *veterinary medical* application and *NORM.*

The Guide reiterates the requirements of the radiation protection legislation regarding use of unsealed sources for non-medical purposes and contains the Danish Health Authority's guidelines for achieving compliance with those requirements. *The undertaking* can expect that its use of unsealed sources is compliant with the rules if it follows the instructions in 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.

Words in italics are explained in the glossary; see 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 17. 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, the term use 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, 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, storage, disposal, discharge and carriage. The following describes how the individual sub-elements are to be understood in relation to unsealed sources.

Manufacturing
Manufacturing means the production of *radionuclides* for example, using a cyclotron.

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

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

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

Transfer
Transfer means the change of ownership of an unsealed source from one undertaking to another. If an undertaking sends *radioactive waste* for incineration at an incineration plant or to *Danish Decommissioning*, it is also termed a transfer.

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

Handling

Handling means the practical operations associated with the application, storage, etc. of unsealed sources. Handling includes, for example, operations associated with receiving a source, laboratory work with sources, packaging of radioactive waste from the application of sources and the transfer of sources.

Application

Application means utilisation of an unsealed source for its intended purpose, e.g. research and development, animal experiments or experiments in nature.

Storage

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

Disposal

Disposal means discharge of radioactive waste from the application of unsealed sources, see below, or to *deposit* radioactive waste at an undertaking specially designated for this purpose.

In this Guide, the term disposal also means the discard of non-radioactive waste via normal waste disposal.

Discharge

Discharge means the dispersion of radioactive waste to the external environment, for example via drains or chimneys.

Carriage

Carriage means the transportation of an unsealed 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 17, 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 the use of unsealed sources is described below.

2.1. Justification

The main principle governing the use of unsealed 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]

The assessment of justification must include consideration of options for employing alternative methods that are either not based on ionising radiation (for example fluorescent or photometric methods) or involve significantly reduced *exposure* or risk.[3] The assessment must, inter alia, be based on radionuclide, activity and the possibility of radiological monitoring.[4]

It is the undertaking's duty to assess whether a given use is justified or whether an alternative method, which might not involve unsealed 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 unsealed sources continues to be justified.[5] This may be ensured by utilising, inter alia, a *quality management system*; see Chapter 16.

It is The Danish Health Authority's assessment that use of unsealed sources comprised by the present Guide will usually be justified provided that it takes place in accordance with the rules 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 unsealed sources is justified. The Danish Health Authority may, at any time, assess and determine whether an undertaking's use of unsealed sources is justified.[6]

[2] Section 16(1), Executive Order No. 669/2019.
[3] Section 16(2) and (3), Executive Order No. 669/2019.
[4] Section 16(4), Executive Order No. 669/2019.
[5] Section 16(7), Executive Order No. 669/2019.
[6] Section 17, Executive Order No. 669/2019.

2.2. Optimisation

The optimisation principle entails that use of unsealed 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 as well as 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 constraint*s
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 unsealed 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.

Dose constraints

The maximum dose constraint applicable to an undertaking's combined use of *radiation*, including unsealed 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 and should be based on the dose history of the undertaking and similar companies; see Subsection 13.3.

[7] Section 18, Executive Order No. 669/2019.
[8] Section 19, Executive Order No. 669/2019.
[9] Section 21(1), Executive Order No. 669/2019.

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 unsealed 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 unsealed sources subject to licensing requirements, the optimisation process shall commence with a basic *safety assessment*, se Chapter 6.[11]

2.3. Dose limitation

The sum of doses to an individual must not exceed the dose limits.[12,13] The dose limits are determined in order to limit the risk of the occurrence 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 Table 1.

Table 1
Dose limits[14]

Category of individual	**Effective *dose limit* [mSv/year]**	**Equivalent *dose* limit[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.

[10] Section 22, Executive Order No. 669/2019.
[11] Section 20(1), Executive Order No. 669/2019.
[12] Section 23, Executive Order No. 669/2019.
[13] Section 31, Executive Order No. 669/2019.
[14] Annex 1, Executive Order No. 669/2019.

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*.[15]

In the event that a dose limit for occupational exposure is exceeded, the worker may not perform any additional work entailing exposure without approval from the Danish Health Authority.[16] For information on radiological monitoring, see Chapter 13.

[15] Section 24, Executive Order No. 669/2019.
[16] 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 unsealed 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 holds, applies and stores etc. unsealed sources generally has the full responsibility for compliance with all the requirements of the radiation protection legislation.

In cases where undertaking A borrows an unsealed source from undertaking B, it is undertaking A that is responsible for compliance with the requirements of the legislation, including those that fall under the requirement for licensing or notification.

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 unsealed 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.[17] This will for example be the case if a worker performs service on *equipment* at an undertaking in which the person is not employed.

The following sets out the compliance requirements for which the employer 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.

[17] 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[18], 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[19]
- The requirement regarding who may be employed as exposed workers[20]
- The requirement for exposed workers to be instructed on the necessity of early notification of pregnancy and breastfeeding with a view to putting in place measures to ensure that the dose to the foetus or nursing infant is as low as reasonably achievable[21]
- The requirement for exposed workers to be informed of the result of radiological monitoring as soon as possible after the result becomes available[22]
- The requirement for the Danish Health Authority to be notified immediately of doses exceeding the established dose values[23]
- The requirement for doses to exposed workers for the past five calendar years to be documentable[24]
- The requirement for the results of individual radiological monitoring to be notified to the Danish Health Authority's Personal Dose Registry ("SRP") no later than four weeks after the results become available.[25]

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[26]

[18] Sections 38-41, Executive Order No. 669/2019.
[19] Section 12(2), Executive Order No. 669/2019.
[20] Sections 42-43, Executive Order No. 669/2019.
[21] Section 45(1), No. 6, Executive Order 669/2019.
[22] Section 84(1), Executive Order No. 669/2019.
[23] Section 85, Executive Order No. 669/2019.
[24] Section 86, Executive Order No. 669/2019.
[25] Section 87, Executive Order No. 669/2019.
[26] Chapters 4-6, Executive Order No. 669/2019.

- The requirements for information, training, instruction, knowledge, skills and competences of and for workers[27]
- The requirement for radiological monitoring of exposed workers[28]
- The requirements for informing other workers about the undertaking's use of unsealed sources and the precautions that shall be taken by those workers.[29]

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.[30]

If an undertaking hires Category A outside workers; see Chapter 9, the undertaking has a duty to obtain the outside worker's dose history from the employer before a worker is assigned to work involving use of sources.[31]

Undertakings that hire outside workers shall, if the result of radiological monitoring is not sent to the employer automatically, disclose the result to that employer as soon as possible.[32]

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

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

4. Designated expert individuals

The radiation protection legislation distinguishes between two different professional roles of relevance to the use of unsealed 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 unsealed sources.[33] The roles may each be performed by a single individual or by a group of individuals who jointly have the requisite expertise.[34] 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.[35]

4.1. Radiation protection officer

When using unsealed sources subject to licensing or notification requirements, the undertaking shall at all times have a radiation protection officer at its disposal.[36] 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.

The 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 unsealed sources.[37] For the use of unsealed sources covered by licensing requirements, there will normally be a requirement that the radiation protection officer has passed an isotope course[38] approved by the Danish Health Authority.[39] For use covered by the notification requirement, it will be possible to obtain approval as a

[33] Section 34(2), Executive Order No. 669/2019.
[34] Section 33(4), Executive Order No. 669/2019.
[35] Section 37, Executive Order No. 669/2019.
[36] Section 33(1), Executive Order No. 669/2019.
[37] Subsection 1, Annex 7, Executive Order No. 670/2019.
[38] The Danish Health Authority publication *Approved isotope courses for non-medical use of unsealed sources.*
[39] Subsection 4.10, Annex 7, Executive Order No. 670/2019.

radiation protection officer on the basis of documented knowledge of radiation and radiation protection.[40]

The Danish Health Authority must approve the radiation protection officer.[41] Approval is granted upon application by the undertaking. The application must include documentation of the radiation protection officer's knowledge, skills and competences.[42] Radiation protection officers are required to confirm by their signature their performance of the professional role within the undertaking.[43] The radiation protection officer's knowledge, skills and competences must be updated as needed, for example, when introducing new methods or new radionuclides.[44]

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 unsealed sources, but the radiation protection officer will typically assist with the following tasks:[45, 46]

- Ensuring that use of unsealed 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 unsealed 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*.

[40] Subsection 4.11, Annex 7, Executive Order No. 670/2019.
[41] Section 34(1), Executive Order No. 669/2019.
[42] Section 34(2), Executive Order No. 669/2019.
[43] Section 35(1), Executive Order No. 669/2019.
[44] Section 34(4), Executive Order No. 669/2019.
[45] Section 33(1), Executive Order No. 669/2019.
[46] Subsection 1, Annex 2, 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[47]
- notify the Danish Health Authority when resigning or having other than normal absence, for example due to a leave of absence.[48]

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 unsealed sources or a notification of such use will be rendered invalid.

4.2. Radiation protection expert

For any use of unsealed sources subject to the licensing requirement, 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.[49] “Consult” means that the radiation protection 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 that the undertaking consult a radiation protection expert for the following types of use:

- Manufacture of radionuclides
- Handling that involves risk of internal doses
- Handling of radionuclides that emit alpha radiation.

Note that the examples above are for guidance only. The undertaking must always make an individual assessment of the need to consult a radiation protection expert.

[47] Section 35(2), Executive Order No. 669/2019.
[48] Section 35(3), Executive Order No. 669/2019.
[49] Section 33(2), Executive Order No. 669/2019.

If the undertaking is in doubt as to whether its use of unsealed 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, will determine if it is required to consult a radiation protection expert.

The radiation protection expert shall possess adequate education, knowledge, skills and competences for advising on the implementation or modification of the radiation protection arrangements that are relevant for the undertaking's use of unsealed sources.[50] Requirements for radiation protection experts' knowledge, skills and competences are indicated in Annex 9 of Executive Order No. 670/2019.

The Danish Health Authority must approve the radiation protection expert.[51] The application for approval must be made by the expert personally and will apply to specific types of use and applications of unsealed sources. The radiation protection expert will therefore only be able to advise the undertaking on the types of use and applications covered by the approval. Approval takes place for a period of 5 years, after which it is the responsibility of the radiation protection expert to apply for renewed approval.[52]

As the professional role of radiation protection expert is not associated with extensive personal attendance on-site, the radiation protection expert typically advises the undertaking as an external consultant. The radiation protection expert shall document their advice to the undertaking and issue a copy of the signed documentation to the undertaking.[53]

The radiation protection expert's duties

The radiation protection expert's advice shall, as a minimum, comprise the following aspects:[54, 55]

- Optimisation and the establishment of dose constraints
- Preparation of, for example, safety assessments and instructions
- Plans for new or modified facilities and commissioning new radionuclides
- Classification of areas
- Training and further education programmes for exposed workers
- Categorisation of exposed workers

[50] Annex 9, Executive Order No. 670/2019.
[51] Section 34(1), Executive Order No. 669/2019.
[52] Section 34(3), Executive Order No. 669/2019.
[53] Section 36, Executive Order No. 669/2019.
[54] Section 33(2), Executive Order No. 669/2019.
[55] Subsection 1, Annex 2, Executive Order No. 669/2019.

- Employment conditions for pregnant and breastfeeding exposed workers
- Individual radiological monitoring
- Measuring equipment
- Environmental monitoring programme
- Guidelines for handling, storage, transfer and disposal of radioactive waste
- Arrangements for the prevention of emergencies, accidents and incidents
- Investigation and analysis of emergencies, accidents and incidents
- Quality management system for use of unsealed sources.

5. Licensing, notification, registration, etc.

The radiation protection legislation describes three levels of regulatory control for the use of unsealed sources commensurate with the risk posed by that use: licensing, notification and exemption from licensing and notification. The risk is assessed on the basis of the activity concentration (*AC*) and the activity (*A*) of the unsealed sources.

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

Use of unsealed sources shall, as a general rule, take place inside facilities.[56] Facilities associated with the use of unsealed sources that are covered by the licensing requirement must be registered in the Danish Health Authority's Registry of Radiation Sources and Facilities, see Subsection 5.5.[57] The Danish Health Authority may in certain cases approve the application of unsealed sources outside facilities, e.g. for tracer studies in nature or flow measurements in pipes. In these cases, the Danish Health Authority determines individual requirements in relation to the specific application, unless the application is exempt from the requirement for licensing or notification.[58]

5.1. Licensing, notification and exemption from requirements

For the use of unsealed sources, a distinction is made between two forms of regulatory control: regulatory control for holding, application, storage, etc. of unsealed sources and regulatory control for the discharge of *radioactive material*. See Chapter 1 for the definition of the term "use".

In the case of holding, application, storage, etc., the level of regulatory control is based on the maximum activity concentration and the activity that the undertaking expects to have at its disposal at all times.

The level of regulatory control for discharge is calculated on the basis of the monthly discharge, i.e. the total activity discharged per month. The activity concentration at *the point of discharge* is calculated as the total activity per month divided by the total amount of discharged air or wastewater per month.

[56] Section 52(1), Executive Order No. 669/2019.
[57] Section 15(1), No. 2, Executive Order 670/2019.
[58] Section 64(2), Executive Order No. 670/2019.

If an undertaking has several departments in the same geographical location that discharge radioactive material via the same point of discharge, the total activity per month from all departments at the site forms the basis of the activity concentration.

For determination of the level of regulatory control index values for activity concentration (I_{AC}) and activity (I_A) are employed, where the index values are calculated as the activity concentration or the activity divided by the corresponding *exemption value* or *exemption and clearance value*. The index values are given by:

$$I_{\mathrm{AC}} = \sum_{\mathrm{k}} \frac{AC_{\mathrm{k}}}{AC_{\mathrm{U,k}}} \quad (1)$$

$$I_{\mathrm{A}} = \sum_{\mathrm{k}} \frac{A_{\mathrm{k}}}{A_{\mathrm{U,k}}} \quad (2)$$

where AC_k is the activity concentration of radionuclide *k*, A_k is the activity of radionuclide *k,* and $A_{U,k}$ and $AC_{U,k}$ are the corresponding exemption values and exemption and clearance values. The formulas (1) and (2) should in principle be used in all places where several radionuclides are used. In cases where $I_{AC,annex\ 4}$ equals $I_{AC,annex\ 3}$, then $I_{AC,annex\ 4}$ can be regarded as deciding.

Annex C provides examples of the determination of the level of regulatory control.

The exemption values and the exemption and clearance values for the most frequently used radionuclides are indicated in Table 2. For other radionuclides, the values can be found in Annex 3 and Annex 4 of Executive Order No. 670/2019.

Table 2
Exemption values and exemption and clearance values for the most frequently used radionuclides

Radionuclide	Activity concentration [Bq/g]	Activity [Bq]	Activity concentration [Bq/g]
	Exemption value Executive Order No. 670/2019, Annex 3	Exemption value Executive Order No. 670/2019, Annex 3	Exemption and clearance value Executive Order No. 670/2019, Annex 4
H-3	10^6	10^9	10^2
C-14	10^4	10^7	10^0
P-32	10^3	10^5	10^3
S-35	10^5	10^8	10^2
I-125	10^3	10^6	10^2

5.1.1. Holding, application in facilities, storage, etc.

The level of regulatory control for holding, application, storage, etc. of unsealed sources as a function of the activity concentration and activity is indicated in Table 3.

Table 3
Level of regulatory control for holding, application, storage, etc. of unsealed sources[59]

		Activity index I_A		
		$I_{A,annex\ 3} \leq 1$	$1 < I_{A,annex\ 3} \leq 10$	$10 < I_{A,annex\ 3}$
Activity concentration index I_{AC}	$1.000 < I_{AC,annex\ 3}$	Licensing	Licensing	Licensing
	$1 < I_{AC,annex\ 3} \leq 1.000$	Notification	Licensing	Licensing
	$I_{AC,annex\ 3} \leq 1$ and	Exempt from the notification requirement*	Notification	Licensing
	$I_{AC,annex\ 4} \leq 1$	Exempt from requirements	Exempt from requirements	Exempt from requirements

* However, if the total activity per month exceeds an activity index greater than 10, notification is required.

As is indicated in Table 3, there is no licensing or notification requirement when the activity concentration index and the activity index, based on the exemption values[60], are less than or equal to 1. For holding, application, storage, etc. of a single radionuclide, this will correspond to the activity concentration and the activity being less than or equal to the exemption value. If the total activity per month exceeds an activity index of 10, the use will, however, be subject to the requirement for notification.

Note that the level of regulatory control applies to the total holding of unsealed sources, e.g. stock solutions, radioactive waste and radionuclides *administered* to experimental animals.

5.1.2. Discharge of radioactive waste

The level of regulatory control for discharge as a function of the activity concentration and activity is indicated in Table 4. See Subsection 5.1 for calculation of activity concentration at discharge. An example of determining the level of regulatory control for the discharge of radioactive material is specified in Annex C.

[59] Annex 1, Executive Order No. 670/2019.
[60] Annex 3, Executive Order No. 670/2019.

Table 4
Regulatory control level for discharge of radioactive material

		Activity index I_A**		
		$I_{A,annex\ 3} \leq 1$	$1 < I_{A,annex\ 3} \leq 10$	$10 < I_{A,annex\ 3}$
Activity concentration index I_{AC}*	$100 < I_{AC,annex\ 3}$	Licensing	Licensing	Licensing
	$1 < I_{AC,annex\ 3} \leq 100$	Notification*	Licensing	Licensing
	$I_{ACannex\ 3} \leq 1$ and $1 < I_{AC,annex\ 4}$	Exempt from the notification requirement	Notification	Licensing
	$I_{AC,annex\ 4} \leq 1$	Exempt from requirements	Exempt from requirements	Exempt from requirements

* The activity concentration immediately after the point of discharge must not be greater than 10 times the exemption value[61]

** Calculated on the basis of the discharged activity per month

*** At the point of discharge

5.2. Licence application

Licence to use unsealed sources, see Subsection 5.1, must be obtained from the Danish Health Authority before holding, discharge, etc. of unsealed sources.[62]

Licences issued for the use of unsealed sources are valid until otherwise announced by the Danish Health Authority.

5.2.1. Holding, application in facilities, storage, etc.

Licences for holding, application in facilities, storage, etc., are applied for by completing the relevant online form at www.sis.dk. The online application form is available under "Self-service", where you also find a guide to completing the form.

Application for a licence for possession, application in facilities, storage, etc.

The application must be accompanied by relevant information and documentation, including:

- Expected radionuclides, activities and activity concentrations – information must be submitted on both the total holding and the maximum activitiesthat are expected to be handled at a time

[61] Section 26, Executive Order No. 670/2019.
[62] Section 9(1), Executive Order No. 670/2019.

- Facilities for registration and documentation that these facilities meet the applicable requirements, cf. Subsection 8.2
- Documentation of the radiation protection officer's knowledge, skills and competences, see Subsection 4.1
- Safety assessment, see Chapter 6
- Copy of documentation for advice from a radiation protection expert, where applicable
- Relevant instructions, see Subsection 10.1
- Relevant lists and protocols, see Chapter 16.

5.2.2. Discharge

Licenses for discharge are applied for by completing the relevant online form at www.sis.dk. The online application form is available under "Self-service", where you also find a guide to completing the form.

Application for a licence for discharge

The application must be accompanied by relevant information and documentation, including:

- Radionuclides, total activity expected to be discharged per month and the activity concentration at the point of discharge, see Subsection 5.1
- Indication of whether there is discharge through drainage or to the atmosphere, see Chapter 12
- Documentation of the radiation protection officer's knowledge, skills and competences, see Subsection 4.1
- Safety assessment, in which special precautions and doses associated with the discharge are described, see Chapter 6
- Copy of documentation for advice from a radiation protection expert, where applicable
- Relevant instructions, see Subsection 10.1
- Relevant lists and protocols, see Chapter 16.

5.2.3. Application of unsealed sources outside facilities

Licences for the application of unsealed sources outside the facility are applied for by completing the appropriate online form at www.sis.dk. The online application form is available under "Self-service", where you also find a guide to completing the form.

Application for a licence for the application of unsealed sources outside facilities

The application must be accompanied by relevant information and documentation, for example:

- Description of the application and its purpose and justification
- Location and time of the experiment or project execution
- The radionuclide(s) used, including maximum activity concentration and activity as well as chemical form – the number of planned measurements and the activity and activity concentration in each measurement must be specified.
- The transport and movement of the radionuclide(s) in water, soil and air
- The access conditions to the area where the experiment is to be performed
- Documentation of the radiation protection officer's knowledge, skills and competences, see Subsection 4.1
- Safety assessment, see Chapter 6
- Copy of documentation for advice from a radiation protection expert, where applicable
- Radiation protection precautions for the experiment, including precautions regarding incidents
- Plan for discharge and transfer, see Subsection 12.3
- Process for control of and terms for *clearance* of the area after completion of experiments
- Relevant instructions, see Subsection 10.1.

5.3. Notification

The Danish Health Authority must be notified of holding, application, storage, discharge, etc. of unsealed sources subject to notification requirements, see Subsection 5.1, before holding, discharge, etc. of unsealed sources.[63] The notification is only valid when the undertaking has received an acknowledgement from the Danish Health Authority.

A notification is valid until otherwise notified by the Danish Health Authority. However, the undertaking must notify again before new radionuclides are used. Changes in activity concentrations and activities do not require a new notification as long as the level of regulatory control remains unchanged.

5.3.1. Holding, application in facilities, storage, etc.

Notification is done by completing the designated online form at www.sis.dk. The online application form is available under "Self-service", where you also find a guide to completing the form.

Notification on holding, application in facilities, storage, etc.

The notification must be accompanied by relevant information and documentation, for example:

- Radionuclides, activity concentrations and activities – information must be submitted on both the total holding and the maximum activities that are expected to be handled at a time
- Confirmation that all facilities meet the requirements for design; see Chapter 8.2
- Documentation of the radiation protection officer's knowledge, skills and competences; see Subsection 4.1
- Information on radiological monitoring of exposed workers, where relevant; see Chapter 13
- Confirmation that relevant instructions are available; see Subsection 10.1
- Confirmation that relevant records and protocols are kept; see Chapter 16
- Confirmation that the undertaking has relevant and well-functioning measuring equipment, see Chapter 11.

[63] Section 9(1), Executive Order No. 670/2019.

5.3.2. Discharge

Notification is done by completing the designated online form at www.sis.dk. The online application form is available under "Self-service", where you also find a guide to completing the form.

Notification of discharge

The notification must be accompanied by relevant information and documentation, for example:

- Radionuclides, total activity expected to be discharged per month and the activity concentration at the point of discharge, see Subsection 5.1
- Information on whether discharge occurs through drainage or to the atmosphere, see Chapter 12
- Documentation of the radiation protection officer's knowledge, skills and competences, see Subsection 4.1
- Confirmation that relevant instructions are available, see Subsection 10.1
- Confirmation that relevant records and protocols are kept, see Chapter 16.

5.3.3. Application of unsealed sources outside facilities

Notification is done by completing the designated online form at www.sis.dk. The online application form is available under "Self-service", where you also find a guide to completing the form.

Notification of the application of unsealed sources outside facilities

The notification must be accompanied by relevant information and documentation, for example:

- Description of the application and its purpose and justification
- Location and time of the performance of the experiment, including whether the experiment will be performed repeatedly
- The radionuclide(s) used, including maximum activity concentration and activity as well as chemical form
- Information on the transport and movement in water, soil and air of the radionuclides

- Confirmation that unauthorised persons will not be able to access the area where the experiment is performed
- Documentation of the radiation protection officer's knowledge, skills and competences; see Subsection 4.1
- Information on radiological monitoring of exposed workers, where relevant; see Chapter 13
- Plan for discharge; see Subsection 12.3
- Confirmation that relevant instructions are available; see Subsection 10.1
- Confirmation that relevant records and protocols are kept, see Chapter 16
- Confirmation that the undertaking has relevant and well-functioning measuring equipment; see Chapter 11.

5.4. Exempt from the licensing and notification requirements

Holding, application, storage, etc. of unsealed sources are exempt from the licensing or notification requirement when the criteria in Table 3 have been complied with. Discharge is exempted from the licensing and notification requirements when the criteria in Table 4 are met.[64] In such cases, there is no requirement to obtain a licence from or submit a notification to the Danish Health Authority. However, it is a precondition that the use of unsealed sources complies with the principle of justification. The Radiation Protection Act's radiation protection requirements, the provisions in the associated executive orders and in the other rules laid down pursuant to the Act do not apply to the use of unsealed sources that are exempt from the requirements for licensing and notification.

5.5. Registration of facilities

Companies covered by requirements for licensing for holding, application, storage, etc. of unsealed sources must register their facilities in the Danish Health Authority’s Registry of Radiation Sources and Facilities.[65] Examples of facilities for non-medical purposes are presented below.

[64] Section 5(1-2), Executive Order No. 670/2019.
[65] Section 15(1), No. 2, Executive Order 670/2019.

Facilities

Facilities for the use of unsealed sources for non-medical purposes are, for example:

- Isotope laboratories
- Storage rooms
- Waste storage rooms
- Stables.

The facility must live up to the requirements described in Chapter 8. The facility may only be applied for the use of unsealed sources when the Danish Health Authority has confirmed the registration.[66]

The registration obligation is the responsibility of the undertaking that uses the facility.[67]

Any changes to facilities that concern information included in the Danish Health Authority's Registry of Radiation Sources and Facilities must be reported to the Danish Health Authority. In the event of changes, the continued utilisation of the facility for the use of unsealed sources presupposes that the Danish Health Authority has confirmed the changes.[68]

Facilities are registered by filling in the designated online form at www.sis.dk. The online application form is available under "Self-service", where you also find a guide to completing the form.

Registration of facilities

The registration must be accompanied by relevant information and documentation, for example:

- Facility type (e.g. type C/B/A isotope laboratory, storage room, waste storage room)
- Facility name, e.g. room number, for unique identification of the facility

[66] Section 51(5), Executive Order No. 669/2019.
[67] Section 51(2), Executive Order No. 669/2019.
[68] Section 51(6-7), Executive Order No. 669/2019.

- Information on which radionuclides are handled in the facility, including the maximum activity handled per operation for all types of operations, see Subsection 8.2.2
- Floor plans showing the layout of the facility and the location of the facility at the undertaking
- Description of the design, including ventilation and drainage conditions
- Shielding in and of the facility
- Documentation for control of fume hoods etc.
- Documentation for control of ventilation system (including pressure conditions).

5.6. Import and transfer

The following rules apply to the import of unsealed sources from countries outside the EU and to the transfer of unsealed sources in general.

Rules for import, export and transfer of unsealed sources

Import

In case of import from a non-EU country of an unsealed source, with an activity and activity concentration greater than the exemption value[69], the undertaking that will be receiving the source must obtain approval to do so from the Danish Health Authority in advance.[70]

Transfer within Denmark

For a transfer within Denmark of an unsealed source, with an activity and activity concentration greater than the exemption value, the transferring undertaking shall notify this to the Danish Health Authority.[71] The notification must be made within 21 days of the end of the quarter in which the transfer took place.[72]

Transfer to countries within the EU

[69] Annex 3, Executive Order No. 670/2019.
[70] Section 19 (1), No. 3, Executive Order No. 670/2019.
[71] Section 20(1), Executive Order No. 670/2019.
[72] Section 20(3), Executive Order No. 670/2019.

For a transfer of an unsealed source to an EU Member State, the rules set out in the Council Regulation on transfer of radioactive substances between Member States must be complied with; see Chapter 17.[73]

Import of unsealed sources from a country within the EU or receipt of unsealed sources from a Danish undertaking is not covered by special rules, but the Danish Health Authority must have given permission for the use or have received notification of the use beforehand, cf. Chapter 5.2.1 and 5.3.1.

5.7. Record of receipt, production and transfer

Companies that use unsealed sources must keep a record of the least 5 years of receipt, production and transfer to another undertaking of unsealed sources with an activity concentration or activity per storage unit greater than the exemption values[74].[75]

Record of receipt, production and transfer

The record for receipt, production and transfer to another undertaking of unsealed sources with an activity concentration or activity per storage unit greater than the exemption values[76] must contain the following information:[77]

- Radionuclide
- State and chemical form
- Date, activity at the time of reception or production, and when applicable, activity concentration.
- In case of transfer: date of the transfer, activity and, when applicable, activity concentration and the name of the undertaking to which the transfer was made
- Storage location
- Relevant contact name.

[73] Section 5(1), Executive Order No. 669/2019.
[74] Annex 3, Executive Order No. 670/2019.
[75] Section 16(1), No. 2, Executive Order 670/2019.
[76] Annex 3, Executive Order No. 670/2019.
[77] Section 16(3), Executive Order No. 670/2019.

5.8. Deregistration of facilities, licences or notifications

The undertaking may deregister one or more facilities associated with a licence or deregister an entire licence or notification. Before a facility can be deregistered and granted clearance for other purposes, control measurements of surfaces must be performed as described in Chapter 11. Documentation for the control measurements performed must be attached to the deregistration, the documentation must be in reasonable proportion to the unsealed sources that have been applied and stored, etc.[78]

Deregistration is done by completing the designated online form at www.sis.dk. The online application form is available under "Self-service", where you also find a guide to completing the form.

Deregistration of facilities

The deregistration must be accompanied by relevant information and documentation and must, at minimum, contain information on:

- Facility name
- All radionuclides that have been used in the facility
- Measuring equipment used in control measurement of surfaces etc.
- The result of the performed control measurements incl. background measurement
- Indication of where the individual control measurements were performed
- Name/initials of the exposed worker who performed the control measurements and date of execution.

If a licence is to be cancelled, all registered facilities must be deregistered first. In addition, a declaration must be submitted that all radioactive material has been disposed or transferred.

If a notification is to be deregistered, a declaration must be submitted that control measurements of all facilities and other interiors have been performed and that they meet the criteria for clearance[79] and that all radioactive material has been disposed or transferred.[80]

[78] Section 13, Executive Order No. 670/2019.
[79] Annex 5, Executive Order No. 670/2019.
[80] Section 11(1), Executive Order No. 670/2019.

5.9. Inspection

The Danish Health Authority conducts inspections of use of unsealed 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 the use of the unsealed sources.[81] 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 possibly other 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 unsealed 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.[82]

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 unsealed sources until the specified requirements have been met.[83]

5.10. Fees

Pursuant to the Ministry of Health's Executive Order No. 1111/2019, see Chapter 17, the Danish Health Authority charges an annual fee to cover the costs of regulatory inspection, advice, assistance and administration incurred from use of unsealed sources subject to the licensing or notification requirements. The fee is determined in relation to the complexity of the use as well as the risk associated with the use.

Fees

A fee is charged per:

- Licence or notification pertaining to use of unsealed sources
- Facilities approved for use of unsealed sources.

[81] Section 18(1), Act No. 23/2018.
[82] Section 18(2), Act No. 23/2018.
[83] Section 19, Act No. 23/2018.

The fees are adjusted once a year on the 1st of January. More information can be found at www.sis.dk under "Legislation".

6. Safety assessment

In advance of any use of unsealed sources subject to the licensing requirement, the undertaking shall conduct a safety assessment.[84] A safety assessment is a systematic review of all factors of relevance for safety and radiation protection entailed by the planned use.[85]

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, the site, the design and robustness of the facility as well as human factors. The safety assessment should be initiated as early as the planning phase of the use of unsealed sources and shall comprise all stages from facility construction and application of unsealed sources to decommissioning.

The safety assessment must be evaluated and updated periodically at intervals commensurate with the nature and scale of the use of unsealed sources so that the assessment at all times reflects the current use and application.[86] If changes are planned regarding safety or radiation protection arrangements, operational conditions, work procedures, radionuclides, activity, state form 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 unsealed sources. This typically depends on the radionuclide, activity, state form, how and how often they are used, whether the use takes place in a facility, including an isotope laboratory, as well as the working procedures that control the use of unsealed sources. An example of the work process for preparing a safety assessment using unsealed sources and the structure of the safety assessment is presented in Annex D.

[84] Section 20(1), Executive Order No. 669/2019.
[85] Section 10, No. 49, Executive Order No. 669/2019.
[86] Section 20(2), Executive Order No. 669/2019.

The Danish Health Authority's guide to safety assessments; see Chapter 17, provides detailed instructions on performing safety assessments in accordance with the recommendations of the International Atomic Energy Agency (IAEA)[87].

6.3. Report

The undertaking should describe the safety assessment in a version-controlled report. The Danish Health Authority will ask for submission of the safety assessment for review when an undertaking applies for a licence, and this will constitute part of the basis for formulating any specific conditions in connection with the licence and a starting point for inspection.

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 grounds exist 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 concerning which radionuclides are being worked with
- Change concerning the state of the radioactive material
- Increase in activity
- Commissioning of new facilities
- Implementation of new work procedures that may impact exposure
- Planning of facility decommissioning
- Change concerning discharge of radioactive material.

[87] IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), 2016.

7. 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.[88] Prior to use of unsealed sources, an assessment shall be made as to whether classification is required for areas in which unsealed sources are handled, stored, etc. and adjacent areas.

Signage is required in any location where unsealed sources with aggregate total activity exceeding the exemption value[89] are stored as well as at all entrances to areas where unsealed sources with an aggregate activity exceeding 100 x the exemption value are being handled. In addition, supervised and controlled areas are subject to supplementary signage requirements.

7.1. Classification of areas

Classification of areas 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, accidents and emergencies 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, utilisation of personal protective equipment 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.[90]

[88] Sections 49-50, Executive Order No. 669/2019.
[89] Annex 3, Executive Order No. 670/2019.
[90] Section 49(1), Executive Order No. 669/2019.

Classification as a controlled area

An area shall be classified as supervised 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.[91]

Classification of an area depends on several factors, e.g. radionuclides, state and chemical form, activity, activity concentration, location of unsealed sources and worker whereabouts and the risks associated with individual handling. Operations with moderate or high risk, e.g. *iodination* with volatile iodine or working with unsealed sources in powder form, will typically result in the facility being classified as either a supervised or controlled area.

Examples of typical classification of areas

When using unsealed sources, the areas to be classified will most often be entire facilities. Below are examples of typical classification of facilities related to specific types of use of unsealed sources.

Supervised area

Areas typically classified as supervised:

- Type C isotope laboratories.

Controlled area

Areas typically classified as controlled:

- Type B isotope laboratories
- Type A isotope laboratories.

[91] Section 50(1), Executive Order No. 669/2019.

Note that the examples above are for guidance only. The undertaking shall at all times perform an individual classification of all relevant areas based on an assessment of the unsealed sources concerned and the local conditions associated with 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 unsealed sources are handled etc. are to be classified.

Areas not normally requiring classification

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

- Areas where the activities are below the limits in Table 6 in Subsection 8.2.2
- Areas where unsealed sources are not handled or stored.

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

Larger facilities may contain both classified areas and areas that do not need to be classified, or areas with different classification. For example, this may apply if, in a larger isotope laboratory, unsealed sources are only handled in a fume hood that is placed in such a way that it is demarcated from other work in the facility. In this case, it is possible that the fume hood should be classified without having to classify the facility itself.

7.2. Signage

Requirements for signage and demarcation for unsealed 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.[92] 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 unsealed sources is subject to a requirement for signage of storage locations and facilities and also supplementary requirements for signage of classified areas.

[92] Executive Order No. 518/1994.

It is important to note that where unsealed sources are used inside facilities, all entrance doors are subject to signage requirements, i.e. including doors that are normally kept shut, such as fire doors. This is because, regardless of which entrance door is normally used, the risks of being present inside the facility must 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.

7.2.1. General requirements

For all safety signs, the signage must be legible and durable.[93] If radioactive material is 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 unsealed sources, see Subsection 7.2.2 and 7.2.3, 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.

7.2.2. Storage locations and facilities that are not concurrently classified areas

At all locations where there is storage of unsealed sources with a total activity greater than the exemption value[94] and at all entrances to facilities or areas where there is storage or handling, etc. of unsealed 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[95] and supplemented by the text ”Radioaktivt materiale” (Radioactive material).[96] When storing multiple radionuclides, formulas (1) and (2) in Subsection 5.1 must be used to determine whether there is a signage requirement. Figure 1 shows the signage that must be used at storage locations and facilities that are not concurrently classified areas.

[93] Section 37, Executive Order No. 670/2019.
[94] Annex 3, Executive Order No. 670/2019.
[95] DS/EN ISO 7010:2012.
[96] Section 38(1), Executive Order No. 670/2019.

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

If an unsealed source is stored in a locked cabinet, refrigerated cabinet or the like, the sign shall be placed on the cabinet door. Otherwise the sign must be mounted on the entrance door to the storage location.

7.2.3. Supervised and controlled areas

Both supervised and controlled areas must be legibly and durably marked with the text "Radioaktivt materiale" (Radioactive material), information on classification, and the text "Risiko for *intern* og *ekstern bestråling*" (Risk of internal and external exposure).[97, 98, 99] Figure 2 shows the signage to be displayed for supervised and controlled areas, respectively.

[97] Section 49(2), Executive Order No. 669/2019.
[98] Section 50(2), No. 4, Executive Order 669/2019.
[99] Section 38(2-4), Executive Order No. 670/2019.

Figure 2
Signage of classified areas

7.3. 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 of the area.[100] In addition, measures must be taken to ensure that only workers necessary for the use of unsealed sources have access to the controlled areas and that measures have been taken to prevent the spread of radioactive material, where appropriate.[101] As a rule, there should be a wash basin with hands-free operation as well as other relevant equipment within the controlled area, so that contamination of surrounding areas is avoided as far as possible.

[100] Section 50(2), No. 1, Executive Order 669/2019.
[101] Section 50(2), No. 2-3, Executive Order 669/2019.

8. Requirements for facilities etc.

The construction and layout of facilities must be adapted to the radionuclides that are handled, stored, etc. and the associated risk. Construction and layout of a facility must be planned using the dose constraints for occupational and public radiation, see Subsection 2.2.[102] There may be a need for integrated shielding in the structural elements of a facility in order for the radiation protection to be regarded as sufficiently optimised. In addition, there are requirements for the design of facilities and other interiors that must be met.[103]

8.1. Shielding

The shielding effect of a facility's building materials and any additional integrated shielding in facilities must provide adequate protection for exposed workers, other workers as well as members of the population.

Shielding calculations for the above shielding in facilities must, if relevant, be included in the documentation for compliance with dose constraints and optimisation of radiation protection, see Subsection 2.2.

The shielding calculations are made on the basis of the expected *dose rates* in the facility and in relevant interiors and areas around the facility. Based on the length of stay in the relevant facilities, interiors and areas for exposed workers, other workers and members of the public, the dose for these categories of people can be calculated. The dose is compared with the given dose constraints for other workers and members of the public as well as the dose constraints that the undertaking has established for its exposed workers, see Subsection 2.2. The estimated doses should always be lower than the dose constraints, and it must be assessed whether the construction of the facility can be optimised, e.g. by adjusting the shielding. When using unsealed sources subject to licensing requirements, the safety assessment must include documentation of calculations, considerations and conclusions, see Chapter 6.

Shielding calculations for facilities

When assessing and calculating the need for additional integrated shielding in a facility for the use of unsealed sources, the following factors must be taken into account:

- Which radionuclides should be handled and stored in the facility?

[102] Section 52(2), Executive Order No. 669/2019.
[103] Section 64(1), Executive Order No. 670/2019.

- What is the total activity that is to be handled and stored in the facility at one time?
- What is the shielding effect of building materials in walls, floor separations, etc.?
- What rooms and areas (other laboratories, offices, corridors, staff rooms, etc.) are located around (including above and below) the facility, and how far away are they?
- Who is staying in the surrounding interiors and areas (exposed workers, other workers or members of the public)?
- How long can a single person in the mentioned person categories be expected to stay in the facility and the surrounding interiors and areas?

8.2. Requirements concerning design as well as the utilisation of facilities and other interiors

Handling of unsealed sources subject to licensing requirements must normally take place in facilities that meet the requirements for design for type C, B or A isotope laboratories.

If faults or defects are found in a facility, the undertaking must be notified immediately, and when these faults or defects may result in *unintended exposure*, they must be remedied before further use of unsealed sources occurs.[104]

In special cases, the Danish Health Authority may approve the handling of unsealed sources outside facilities, see Subsection 5.2.3 and 5.3.3. In these cases, the Danish Health Authority sets the requirements for handling.[105]

8.2.1. Requirements for facilities consisting of isotope laboratories

Facilities for handling unsealed sources will normally be isotope laboratories. Requirements for the design of an isotope laboratory depend on the activity to be handled in the laboratory. Isotope laboratories are classified as type C, B or A. In Subsection 8.2.2 the activities that may be handled in type C and B isotope laboratories are listed, and below you can find the most important requirements for the design of type C and B isotope laboratories.

[104] Section 55(2-3), Executive Order No. 669/2019.
[105] Section 64(1-2), Executive Order No. 670/2019.

Requirements for type C isotope laboratories[106]

Access conditions

- Unauthorised persons must not have access to facilities and storage locations.

Design

- The facility shall be fitted out and designed so as to minimise worker exposure and the risk and consequences of unintended exposure.*
- Facilities must be tidy and have sufficient space, as superfluous objects and too little space increase the risk of accidents.[107] *
- The facility shall be fitted out so as to prevent the dispersion of radioactive material to the surroundings as far as reasonably achievable.*
- Any areas and objects inside the facility liable to become contaminated with radioactive material shall be kept to a minimum and shall be easy to clean. There should be a sufficient number of cabinets for storing folders, documentation, instructions, etc.*
- All surfaces (walls, doors, floors, table tops, chair seats, etc.) must be smooth, intact and easy to clean. Wooden table tops and fabric chair seats are therefore not acceptable. Surfaces must be resistant to heat, physical and chemical influences as well as the application of chemicals that can corrode the surface.*
- There must be no gaps between fixed furniture, e.g. between tables or between tables and walls, that are difficult to clean. If gaps cannot be completely avoided, these must be sealed with sealant and, as a rule, they must be placed in the places in the facility where there is no handling of unsealed sources. *
- All areas must be easy to clean. Exposed piping, wiring, etc. must be avoided as far as possible, e.g. cable rails can be applied. All floor surfaces must be easily accessible.*

[106] Subsection 1.1, Annex 13, Executive Order No. 670/2019.
[107] Section 55(1), Executive Order No. 669/2019.

Wash basins and drain

- There must be at least one wash basin in the facility that can be operated hands-free. If the application does not permit a wash basin inside the facility, there must be access to washing in an adjacent facility, and access to this facility must be hands-free.
- If discharge of radioactive material with concentrations greater than the exemption values[108] occurs via the drains, the discharge must generally take place via an isotope drain. The collector pipe must be marked as "Isotopafløb" (Isotope drain) at point of access.*
- Isotope drains must have a separate collector pipe or technically equivalent solution that ensures that the waste is not spread to other rooms, e.g. during return flow, before approaching the point of discharge.*

Exhaust

- If *airborne radioactive material* may occur in the facility, a ventilation solution commensurate to the nature and extent of the radioactive material must be in place.*
- If radioactive material might become airborne to any extent of significance from a radiation protection point of view, the facility shall have a sufficient quantity *of radiation safety cabinets*, e.g. fume hoods or LAF benches. LAF benches with horizontal flow, where the air is blown in towards the workers, are not acceptable. An air velocity in the opening of the radiation protection cabinet of 0.5 m/s is normally considered appropriate.*
- The radiation safety cabinet must be provided with a control device that can notify if it is not functioning adequately.*
- Prior to its acceptance into service, the radiation safety cabinet must be tested according to the relevant standard. A relevant standard for control of fume hoods is DS-EN 14175.*
- Extraction from radiation safety cabinets should be even and without air vortices. The radiation safety cabinets must be checked by a testing undertaking or equivalent at least once a year and in the event of significant changes. Date of last third-party inspection should be visible on the radiation safety cabinet.*

[108] Annex 3, Executive Order No. 670/2019.

- If it is necessary to filter the extract air, the filter must be placed so that any exposure is minimised. This will most often mean that the filter must be placed in the part of the exhaust duct located in the laboratory.*
- Airborne radioactive material inside a radiation safety cabinet must not be dispersible to ambient laboratory air or to the air in other interiors.*
- Emission of air from radiation safety cabinets must ensure effective dilution with ambient air. The discharge must take place far enough from the intake ducts to ensure that recirculation cannot take place.*
- Incubators and other special cabinets must be connected to the extraction unit if there is a risk of formation of gaseous radioactive material.[109]

* These requirements must be complied with when stabling animals, see also Subsection 8.2.3.

Requirements for type B isotope laboratories[110]

In addition to the requirements for type C isotope laboratories, the following requirements apply to type B isotope laboratories:

- Where the risk exists of significant contamination, the laboratory shall have a forelab or transitional zone with a wash basin that can be used hands-free, an emergency shower, a drain and space for changing and keeping protective clothing. A type C isotope laboratory can be approved as a forelab.
- Transitions between the flooring and vertical surfaces, e.g. walls, plinths and piping lead-in, shall be rounded and extend at least 10 cm up the vertical surface. This also applies in the forelab.
- There must be suitable negative pressure in relation to the surroundings, so that the risk of contamination of the surroundings is minimised. If the laboratory is subject to a requirement for positive pressure, in accordance with other legislation, access to this shall be via a forelab or interlock ensuring suitable negative pressure in relation to the surroundings. A pressure difference of at least 10 Pa between the isotope laboratory and the forelab and between the vestibule and the surroundings is considered suitable. It is recommended that windows and unused doors be sealed so that they can only be used in emergencies.

[109] Section 67(3), Executive Order No. 670/2019.
[110] Subsection 1.2, Annex 13, Executive Order No. 670/2019.

- Testing devices shall be installed to indicate whether the ventilation system is operating. It is recommended to keep a protocol of the pressures.
- At least once a year and in the event of significant rearrangements, the ventilation system shall undergo performance testing.

Requirements for type A isotope laboratories

The Danish Health Authority lays down requirements for design of type A isotope laboratories on a case-by-case basis.[111]

8.2.2. Activity limits

The maximum activity that may be handled in an isotope laboratory depends on the operations performed. Three categories of operations are used: operations associated with low risk, operations associated with moderate risk and operations associated with significant risk.[112]

Types of operations

When handling unsealed sources, a distinction is made between the following types of operation:

Operations associated with low risk, e.g.

- sampling from stock solution which is not associated with the risk of inhalation of radioactive material or significant external exposure;
- dilution.

Operations associated with moderate risk, e.g.

- synthesis
- marking work (e.g. iodination)
- *administration* in animals.

Operations associated with significant risk, e.g.

- handling of unsealed sources in gaseous, aerosol or powder form.

[111] Subsection 1.3, Annex 13, Executive Order No. 670/2019.
[112] Subsection 1.4, Annex 13, Executive Order No. 670/2019.

In Table 5 you can find the maximum activity that can, as a rule, be authorised for use or handling at any one time in a type C and a type B isotope laboratory. By e.g. sampling from stock solutions, it is the activity of the stock solution that must be stated as the activity handled at any time. In Table 2 you can find a list of the exemption values for the most commonly used radionuclides.

Table 5
Maximum activitiesin type C and B isotope laboratories

Type C isotope laboratory	
Type of operation	Maximum activity (per application or handling)
Operation associated with low risk	10^2 x the exemption value[113]
Operation associated with moderate risk	10^1 x the exemption value
Operation associated with significant risk	10^0 x the exemption value
Type B isotope laboratory	
Type of operation	Maximum activity (per application or handling)
Operation associated with low risk	10^5 x the exemption value
Operation associated with moderate risk	10^4 x the exemption value
Operation associated with significant risk	10^3 x the exemption value

For example, there will be a requirement that the handling takes place in a type B isotope laboratory by iodination work with more than 10 MBq I-125 or by sampling from stock solution of more than 10 MBq P-32.

If the total activity handled at any time does not exceed the maximum activity in Table 6, there is no requirement for the work to take place in a facility. Interiors in which such operations take place must, as a minimum, have a good laboratory standard and all surfaces must be of such a material and of such a design that they are easy to clean and do not retain radioactive material.[114]

[113] Annex 3, Executive Order No. 670/2019.
[114] Subsection 1.1.4, Annex 13, Executive Order No. 670/2019.

Table 6
Maximum activity in other interiors

Other interiors	
Type of operation	Maximum activity (per application or handling)
Operation associated with low risk	10^1 x the exemption value[115]
Operation associated with moderate risk	10^0 x the exemption value
Operation associated with significant risk	10^{-1} x the exemption value

8.2.3. Facilities for stabling and animal experiments

Facilities for stabling animals must comply with the requirements for type C isotope laboratories marked with * in Subsection 8.2.1. Unauthorised persons should not be able to gain access to these facilities. If the application does not allow a wash basin in the facility, there should be access to a wash basin in an adjacent facility.

Stables for large animals must have floor drains with the possibility of rinsing the floor.[116] If radioactive material is administered to animals during an animal experiment, this must take place in an isotope laboratory or another facility approved for this purpose.

8.2.4. Storage and security measures

Unsealed sources with a total activity greater than the exemption values[117] must be stored so as to be secured against theft and vandalism as well as fire, flooding and similar environmental impacts.[118] If there is a risk of formation of airborne radioactive material, storage must take place in facilities with adapted air exchange or in airtight containers.[119] This also applies if there is a risk that the radioactive material may develop positive pressure.

Surfaces in facilities for the storage of radioactive material, including radioactive waste,must be easy to clean and should not retain radioactive material.[120] The storage must be orderly, so that the individual storage units can be easily identified and the exposure thereby minimised.[121] Unauthorised persons must not gain access to the facility.[122]

The specific requirements for signage and marking of storage locations are described in Subsection 7.2.2.

[115] Annex 3, Executive Order No. 670/2019.
[116] Subsection 4.2.2, Annex 13, Executive Order No. 670/2019.
[117] Annex 3, Executive Order No. 670/2019.
[118] Section 36(1), Executive Order No. 670/2019.
[119] Section 35(5), Executive Order No. 670/2019
[120] Subsection 4.1, Annex 13, Executive Order No. 670/2019.
[121] Section 35(6), Executive Order No. 670/2019.
[122] Subsection 1.1.5, Annex 13, Executive Order No. 670/2019.

8.3. Record of facilities

A record must be kept of all the facilities in which unsealed sources or radioactive waste are used, stored, etc. to an extent that is subject to the requirement for licensing or notification.[123]

Record of facilities

Record of facilities must contain:

- Information for unique identification of the facility
- Facility type (e.g. type C/B/A isotope laboratory, stable, storage room, waste storage room)
- A drawing of the facility with information on the ability of the construction and interior design to provide radiation protection
- Classification as a controlled or supervised area, if relevant
- Date of the latest performance test and date of the next performance test for facilities where there is a requirement for a performance test, etc., e.g. performance test of radiation safety cabinet or ventilation system.

[123] Section 17, Executive Order No. 670/2019.

9. Workers

The radiation protection legislation draws a distinction between two types of workers at an undertaking that uses unsealed sources: exposed workers and other workers. Exposed workers[124] are those who are engaged in the work involving unsealed sources, while other workers[125] are the remainder of the undertaking's workforce.

Before an exposed worker is assigned to work involving the use of unsealed sources, such a worker must be categorised.[126] 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 unsealed sources.[127]

9.1. 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 their work. The assessment shall include both the doses incurred from work involving unsealed sources under routine conditions and the potential doses incurred from incidents and accidents.

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.

Unsealed sources

- Which radionuclides are being worked with?
- Which types of radiation (e.g. α, β, γ) are the worker exposed to?
- What is the state and chemical form of the radioactive material?
- What parts of the worker's body (whole body, eye lens, extremities) will be exposed to radiation during normal routines?

[124] Section 10, No. 53, Executive Order No. 669/2019.
[125] Section 10, No. 65, Executive Order No. 669/2019.
[126] Section 38, Executive Order No. 669/2019.
[127] Section 45(1), Executive Order No. 669/2019.

Physical organisation

- Where are the radionuclides handled?
- Are the radionuclides stored in the same facility where they are handled?
- Under what conditions are the radionuclides handled?
- Is there any other work with unsealed sources or other radiation sources going on in the facility?
- Is additional shielding used?

Operations

- Is there sampling from stock solutions?
- Is there administration to experimental animals?
- Is airborne radioactive material handled?

Routines

- How large activities are handled per operation?
- How often (e.g. daily, weekly, monthly) are the operations carried out?

Occupancy factors

- For what duration is the worker exposed to radiation?

Dose

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

Unforeseen accidents and incidents

- What are likely scenarios for emergencies, accidents and incidents (spill-age, intake, etc.)?
- What parts of the worker's body (whole body, eye lens, extremities) will be exposed to radiation during unforeseen incidents and accidents?

Exposed workers are categorised into one of the categories A, B or C, depending on the size of the assessed effective and equivalent doses to the individual worker, see Table 7. If just one of the lower limits of the effective or equivalent dose for a worker category can be exceeded, the worker must be categorised into that category.

Table 7
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[128]	$E > 6$	$H_T > 15$	$H_T > 150$
	B[129]	$1 < \mathrm{E} \leq 6$	-	$50 < \mathrm{H_T} \leq 150$
	C[130]	$\mathrm{E} \leq 1$	-	$\mathrm{H_T} \leq 50$

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.[131]

Examples of categorisation of exposed workers

Listed below are examples of typical categorisations of workers handling unsealed sources for non-medical purposes.

Category A

- Workers performing iodination with volatile iodine and who may accidentally ingest or inhale the volatile iodine in large activities.

Category B

- Workers working with radionuclides that emit beta radiation with medium or high energy (e.g. P-32) and who may receive larger doses to the fingers.

Category C

- Workers working with radioimmunoassays (*RIA kit*).

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

[128] Section 39(1), Executive Order No. 669/2019.
[129] Section 40, Executive Order No. 669/2019.
[130] Section 41, Executive Order No. 669/2019.
[131] 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 unsealed sources is an essential component of their education.[132]

Category A and B workers are subject to individual radiological monitoring requirements as described in Chapter 13.

An exposed worker who is breastfeeding must not be employed under conditions posing a significant risk of internal or external bodily contamination with radioactive material.[133] This may, for example, involve the handling of radioactive material, which in the event of accidental intake may be absorbed into the breast milk and cause the dose to the nursing child to exceed the dose constraint for members of the public, see Subsection 2.2.

9.1.1. Requirement for medical examination of Category A workers

The Danish Working Environment Authority's Executive Order No. 10/2018, see Chapter 17, requires that exposed workers in category A must have a medical examination before starting work with radiation sources and a routine examination at least once a year for as long as the work continues.[134, 135] In case of uncertainty, the Danish Working Environment Authority decides whether medical examinations are necessary for the specific use or application. The decision will be made in consultation with the Danish Health Authority. Only a few of the exposed workers working with the use of unsealed sources for non-medical purposes will be subject to medical examinations.

9.2. Requirements for information, training, instruction and qualifications for workers

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

Requirements for information, training and instruction of exposed workers

Exposed workers shall[136]

- be instructed on the safety measures to be put in place for prevention of the risks associated with use of unsealed sources
- be trained and instructed in use of unsealed sources and in measures to limit the consequences of any accident or incident

[132] Section 42, Executive Order No. 669/2019.
[133] Section 43, Executive Order No. 669/2019.
[134] Sections 2-3, Executive Order No. 10/2018.
[135] AT Guide No. 9093/2019.
[136] Section 45(1), Executive Order No. 669/2019.

- 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
- be instructed regarding the necessity of early notification of pregnancy and breast-feeding, so that their work may be organised so as to take into account the dose to the foetus or nursing child.

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.[137] A record shall be kept of 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.[138]

Other workers shall be informed regarding the use of unsealed sources at the undertaking and regarding the precautions they are required to take.[139]

[137] Section 45(2), Executive Order No. 669/2019.
[138] Section 45(3), Executive Order No. 669/2019.
[139] Section 46, Executive Order No. 669/2019.

10. Radiation protection when using unsealed sources

The use of unsealed sources must be planned and carried out to ensure that at all times the radiation protection is optimised in order to keep the exposure as low as reasonably achievable.[140] Use of unsealed sources shall take place in such a way that any risk of contamination of persons, surfaces, objects, surroundings and the environment is kept as low as reasonably achievable.[141]

When using unsealed sources, it is important to be aware of both the external exposure and the risk of internal exposure caused by intake of radioactive material through the mouth, inhalation of air contaminated with radioactive material or absorption of radioactive material through undamaged skin or wounds.

10.1. Instructions

Precautions for optimising radiation protection must be incorporated into instructions for the purpose of limiting external exposure and preventing internal exposure.

Instructions for using unsealed sources

For use of unsealed sources, the following instructions shall be available:[142]

- Instructions on the use, handling, storage etc. of unsealed sources
- Instructions on transfer and disposal of radioactive waste
- Instructions for cleaning, including where applicable, instructions for cleaning staff
- Instructions on precautions in the event of emergencies, accidents and incidents.

The instructions shall be easy to understand and readily available during work.[143]

[140] Section 18(1), Executive Order No. 669/2019.
[141] Section 67(1), Executive Order No. 670/2019.
[142] Section 65, Executive Order No. 670/2019.
[143] Section 57, Executive Order No. 669/2019.

10.2. Reception of unsealed sources

The workflow of receiving unsealed sources must be structured so that exposure and the risk of contamination are limited as much as possible. The instructions for application, handling, storage, etc. described in Subsection 10.1 should include information on how *consignments* must be received and handled as well as what workers should do in the event of damaged consignments.[144]

Reception of unsealed sources

- Reception should take place as close as possible to the place where the unsealed sources are to be stored. Reception in receptions and similar is not appropriate.
- Upon receipt, it must be checked whether the consignments is intact.
- Upon receipt, it must be ensured that the received activity corresponds with the ordered one.
- Consignments may only be handled by workers who have received instruction.
- As there is a risk that consignments are contaminated, handling must always take place while wearing gloves and possibly lab coats or coveralls. Consignments must be unpacked in suitable areas; for example, in the storage facility, in the isotope laboratory or in a forelab/transition zone allocated to this purpose.
- A control measurement must always be taken of empty packaging from consignments before disposal to ensure that the packaging is not contaminated.

10.3. Storage

The unsealed sources, including radioactive waste, must always be stored in suitable containers or packaging that protects against dispersion.[145] If there is a risk of formation of airborne radioactive material, storage must take place in airtight containers or in facilities with adapted air exchange.[146] The containers must be clearly and durably marked.

[144] Section 57, Executive Order No. 669/2019.
[145] Section 35(4), Executive Order No. 670/2019.
[146] Section 35(5), Executive Order No. 670/2019

Marking of containers

The individual storage containers must be clearly and durably marked with:[147]

- The symbol for ionising radiation according to the prevailing standard, supplemented by the text "Radioaktivitet" (Radioactivity)
- Radionuclide, activity and, as applicable, the activity concentration on a given date.
- State and chemical form
- Relevant contact name.

It is not permitted to store unsealed sources, including radioactive waste, together with explosive, corrosive or highly flammable substances or other substances that may compromise storage safety.[148]

10.3.1. Storage of unsealed sources

The quantity of unsealed sources kept in storage shall at all times be kept as low as reasonably achievable.[149]

Storage of unsealed sources with a total activity that exceeds the exemption values[150] must take place in specially-designed storage locations, e.g. refrigerated cabinets or freezers in the facilities where the unsealed sources are handled or in a special facility for the storage of radioactive material.[151] When storing multiple radionuclides the formula (2) in Subsection 5.1 applies.

To the extent necessary for their application, short-term storage may take place outside the specially-designed storage sites or special storage facilities. However, such short-term storage may only give rise to negligible exposure.[152] This can, for example, apply during ongoing procedures where it is not always appropriate to move a stock solution between the storage location and the handling site several times during the procedure since, in certain cases, it may result in greater exposure than temporary storage at the handling site.

[147] Section 66, Executive Order No. 670/2019.
[148] Section 36(2), Executive Order No. 670/2019.
[149] Section 18(1), Executive Order No. 669/2019.
[150] Annex 3, Executive Order No. 670/2019.
[151] Section 35(1), Executive Order No. 670/2019.
[152] Section 35(3), Executive Order No. 670/2019.

10.3.2. Storage of radioactive waste

Waste with a total activity greater than the exemption values[153] must be stored in facilities that are not normally used for other purposes. The Danish Health Authority may, however, authorise storage other than that of radioactive waste inside the facility if exposure from the radioactive waste would be negligible. In such cases, the radioactive waste shall be stored inside a separate locked unit within the facility.[154] When storing multiple radionuclides the formula (2) in Subsection 5.1 applies.

Biological radioactive waste containing radioactive material, e.g. experimental animals that have been given unsealed sources, should be stored in a freezer until they can be sent for incineration. In this context, the freezer is considered to be a specially-designed facility for storing radioactive waste.

10.4. Minimisation of exposure during handling

Relocation of radioactive material internally in the undertaking, e.g. between isotope laboratories and storage facilities or waste facilities must not give rise to unnecessary exposure and the risk of accidents during relocation must be minimised.[155] The movement of radioactive material in areas where many people are staying should therefore be avoided.

The manufacture of radionuclides, the holding of radioactive material and the production of radioactive waste must be limited to the minimum necessary for application.[156, 157]

Exposure and the risk of spillage and contamination can be minimised through thorough prior planning of the handling of the unsealed sources. The work should be planned as a series of independent steps that can be performed quickly and safely. All relevant safety measures should always be reviewed in detail as part of the planning. The work area and the necessary equipment should be prepared prior to handling, and only the objects necessary for handling should be present at the work area.[158] Equipment should be placed so that it does not complicate the work. It is recommended, as far as possible, to carry out all handling on a waste tray with absorbent paper with a plastic backing, so that any spillage of radioactive material is collected in a confined area. When introducing new procedures, it is advisable to practice such procedures ahead of time without the utilisation of unsealed sources.

Both during and after the handling of unsealed sources, the facility must be kept tidy, as this minimises the risk of spillage and contamination. The facility must also be kept clean. The worker should remove jewellery on exposed body parts prior to handling unsealed sources. During and after handling, control measurements must be taken as described in Subsection 11.1.

[153] Annex 3, Executive Order No. 670/2019.
[154] Section 35(2), Executive Order No. 670/2019.
[155] Section 33, Executive Order No. 670/2019.
[156] Section 32, Executive Order No. 670/2019.
[157] Section 34, Executive Order No. 670/2019.
[158] Section 53, Executive Order No. 669/2019.

Cleaning of contaminated surfacess and skin shall be performed as described in the Subsection 11.4 and 14.4. Used surfaces and equipment, including glassware, should be cleaned immediately after handling, as dry contaminants can be difficult to remove. However, in case of spillage of unsealed sources with a short half-life and high dose rate, it may be appropriate to allow the contamination to decay before cleaning. The cleaning shall continue for as long as it results in effective activity reduction. The cleaned equipment must be checked as described in Chapter 11 and must not be put back in place until the contamination is below the limit value[159], see Subsection 11.2. Control measurement must be performed on the cleaned work area before leaving the facility. Hands must be washed thoroughly and a control measurement must be performed on the exposed worker before leaving the facility or interior.

Extensive control measurements of surfaces and objects in facilities and other interiors should be carried out at appropriate intervals so that undetected contaminants can be detected and cleaned. This procedure should be described in a control measurement schedule, see Subsection 11.3.

Minimisation of exposure

The following precautions should be taken to reduce external and internal exposure:

- Plan the work and prepare the work area.
- Keep the facility tidy both during and after work.
- Remove exposed jewellery before handling commences.
- As far as possible, perform regular control measurements during handling.
- Clean surfaces after each handling.
- Clean equipment, including glassware, immediately after handling, and perform control measurements before putting equipment in place.
- Remove lab coat, footwear, gloves, etc. before leaving the facility.

10.4.1. Minimisation of external exposure

The dose from external exposure depends on the activity, the duration of exposure, the shielding and the distance to the radioactive material.

Activity and duration of exposure

It is not appropriate to initiate a new operation in which unsealed sources are handled before the current operation is completed, as this will result in greater exposure. In addition,

[159] Annex 5, Executive Order No. 670/2019.

the unsealed sources must be handled in the shortest possible time, and the activity must be limited as much as possible.

Additional mobile shielding

If relevant for the radionuclide and type of radiation, and if possible in practice, shielding between the unsealed source and the exposed worker should always be used to minimise exposure. In each individual case, it should be assessed which type and thickness of shielding is most appropriate. Shielding must be adapted to the specific handling of unsealed sources, and no more shielding should be used than necessary, as inappropriate shielding can complicate handling and increase the risk of accidents.

By shielding radionuclides that emit beta radiation, formation of *braking radiation* can occur. This is especially a problem with high-energy beta radiation. The amount of braking radiation increases with increasing atomic number of the absorbent material. It is therefore appropriate that the primary shield is of a material with a low atomic number, e.g. plastic shield (*PMMA*), which also has the advantage of being transparent. It may be beneficial to use additional lead shielding on the outside of the plastic shielding so as to weaken the braking radiation formed in the plastic shielding.[160] When handling radionuclides that emit very weak beta radiation, e.g. H-3, it is, however, not necessary to use shielding.

To reduce the exposure of fingers, it is recommended to shield glasses or syringes containing larger activities of a radionuclide that emits beta radiation or gamma radiation.

Radionuclides that emit gamma radiation cannot be completely shielded, only weakened. Lead shielding is most effective, and it is recommended to use a transparent lead glass shield to better see and perform the handling of the unsealed source. It may be a good idea to use syringe shields, for example of lead, when handling syringes containing larger activities.

Additional mobile shielding

Before commencing the handling of unsealed sources, shielding calculations must be made, which shall be verified during the work by means of control measurements of the work setup, including the unsealed source and the mobile shielding.

Radionuclides that emit beta radiation

- Beta radiation is best shielded with a plastic shield (PMMA).
- Be aware that shielding, especially lead shielding, can generate braking radiation.
- A lead shield can be used on the outside of the plastic shield, if relevant.

[160] Health Physics, Per Hedemann Jensen, 2012, p 406-408.

- When handling syringes containing larger activities, syringe shields can be used.

Radionuclides that emit gamma radiation

- Gamma radiation cannot be completely shielded, only weakened.
- Gamma radiation is most effectively shielded with lead.
- If necessary, lead shielding around the container with the radioactive material can be used.
- A transparent lead glass shield is recommended.
- When handling syringes containing larger activities, syringe shields can be used.

At www.sis.dk you can find data sheets for frequently used radionuclides. Among other things, the data sheets specify the thickness of selected materials for complete shielding of beta radiation and for halving of gamma radiation. Other radionuclides can be found in the radionuclide handbook.[161]

Distance to the radioactive material

The distance to the radioactive material greatly affects the exposure of the worker, as the dose rate will generally decrease with increased distance to the radioactive material. For a point source that emits electromagnetic radiation, e.g. gamma radiation, the dose rate will decrease with the square of the distance. This means that if the distance to the unsealed source is doubled, the dose rate will be reduced to a quarter, see Annex B. Therefore, the greatest possible distance to the radioactive material must be kept. Unsealed sources that are not to be used immediately must be placed in the rear of the radiation safety cabinet or at the storage location. The exposure of the worker can also be reduced by using tools that provide distance to the radioactive material, e.g. pliers or tweezers.

Minimisation of external exposure

The following precautions should be taken to reduce external exposure:

- Handle the radioactive material for the shortest possible time.
- Use as little activity as possible.

[161] Radionuclide and Radiation Protection Data Handbook 2002.

- Do not start a new operation until the current operation is completed.
- Use shielding if relevant for the radionuclide and radiation type and if possible in practice.
- Keep as much distance to the radioactive material as possible, if necessary using distancing tools, e.g. pliers or tweezers.

10.4.2. Minimisation of risk of internal exposure

Use of unsealed sources entails a risk of internal exposure caused by intake through the mouth, inhalation or absorption of radioactive material through undamaged skin or wounds. The reason for the absorption of radioactive material in the body is most often undetected contamination of the skin from spillage.

Intake by mouth

Intake of food or beverages, applying cosmetics, smoking, etc. is prohibited in areas with radioactive material, as this can lead to intake of radioactive material. Also, be careful not to touch the mouth region with fingers, pens, etc. Utilisation of mask, goggles, etc. can prevent intake due to splashes, contact with the mouth region, etc.

Inhalation

Inhalation of radioactive material is minimised by storing the radioactive material in sealed containers when not handled. All bottles, flasks or other containers containing unsealed sources must be tightly closed.[162] When airborne radioactive material is to be handled, this must be done in a radiation safety cabinet.[163] Unsealed sources and equipment should be stored in the rear of the radiation safety cabinet, and the work area should be placed at a suitable distance from the cabinet opening. During work, the cabinet opening should be kept as small as possible to avoid inhalation of airborne radioactive material. Before handling and storage in radiation safety cabinets, check that the extraction unit works optimally. In case of work processes that may involve inhalation of radioactive material, respiratory protection can also be used.

Absorption

Absorption through the skin is avoided by using tools that prevent skin contact with the radioactive material and by avoiding airborne radioactive material. Additional protection is obtained by using relevant personal protective equipment, e.g. lab coats and gloves, as described in Subsection 10.6. Gloves should be changed regularly since they can easily become permeable with prolonged contact with chemical compounds, and the gloves should be changed immediately in case of spillage or suspected contamination. In case of skin damage, it should be considered whether the work with unsealed sources can be postponed until the skin is healed. If this is not possible, wounds and tears must be covered before applying gloves and initiating work.

[162] Section 35(5), Executive Order No. 670/2019
[163] Section 67(3), Executive Order No. 670/2019.

The utilisation of sharp objects should be avoided, and syringes should be handled with care to avoid puncture damage.

Minimisation of risk of internal exposure

The following precautions should be taken to reduce internal exposure:

- Do not intake beverages or food, do not apply cosmetics and do not smoke in areas with radioactive material.
- Avoid touching the mouth region, for example with fingers, pens or pencils.
- Handle airborne radioactive material in a suitable radiation safety cabinet.
- Always wear appropriate personal protective equipment.
- Change gloves regularly.
- Cover wounds and tears.

10.5. Animal experiments

Animal experiments must be planned to minimise contamination. This can be done by covering e.g. tables, scales and surfaces that may become contaminated.[164] Consider anaesthetising the animals during the administration to minimise the risk of accidents and contamination. When working with animals that have been administered with unsealed sources, it is important to be aware that radioactive material is excreted via faeces, urine and possibly exhaled air. Therefore, dust-free material should always be chosen as bedding to minimise the risk of inhalation or intake of radioactive material. In case of significant activities of e.g. H-3 and C-14 in the animals' exhalation, the animal cages should placed in suitable radiation safety cabinets.[165] There is a risk of contaminating the skin through contact with the animals' excrement, therefore gloves and lab coats or coveralls must always be used in animal experiments.[166] Contamination via wounds, bites or tears must also be avoided by using personal protective equipment, see Subsection 10.6.

The animals must only be out of the cages in the time necessary for handling. In order to avoid contamination of non-radioactive animals, these must be kept separate from animals administered with radioactive material, e.g. by using separate cages.[167] The cages must be control measured and cleaned regularly and after each application.[168] It must be assessed whether contaminated bedding, excrement and water from washing cages as

[164] Section 67(1), Executive Order No. 670/2019.
[165] Section 67(3), Executive Order No. 670/2019.
[166] Section 67(2), Executive Order No. 670/2019.
[167] Section 67(4), Executive Order No. 670/2019.
[168] Section 71, Executive Order No. 670/2019.

well as euthanised animals should be treated as radioactive waste. The assessment is estimated on the basis of the activity in bedding, euthanised animals, etc.

Marking of cages or stalls

Cages or stalls containing animals which have been administered with radioactive material with a total activity exceeding the exemption values[169] must be marked with:

- A symbol for ionising radiation
- The text "Radioaktivitet" (Radioactivity)
- Radionuclide
- Activity
- Date
- Name of contact person.

10.6. Utilisation of personal protective equipment

To minimise the risk of contamination of the skin when working with unsealed sources, closed lab coats or coveralls with long sleeves and closed footwear should always be worn.

In addition, gloves must always be worn if there is a risk of contamination of the hands.[170] Many chemicals can penetrate the skin. A contamination directly on the skin thus causes not only external exposure, but can be absorbed into the body and lead to internal exposure. Rubber or plastic gloves that are resistant to the chemical compounds being worked with should thus be chosen. Follow the glove manufacturer's recommendations when choosing gloves. Gloves should be changed frequently since they can easily become permeable when in prolonged contact with chemical compounds, and the gloves should be changed immediately in case of spillage or suspected contamination. To reduce the risk of contamination, a plan should be made about where gloves should and should not be used in the facility. For example, keyboards, taps, switches, handles, etc. should not be touched with gloves unless this is clearly stated.

When appropriate, use shoe covers, goggles, masks, respirators, face shields, etc. Personal protective equipment must be removed before leaving the facility. Both before and

[169] Annex 3, Executive Order No. 670/2019.
[170] Section 67(2), Executive Order No. 670/2019.

after sojourns in type A or type B isotope laboratories, laboratory coats and footwear must be changed in the forelab or the transitional zone to the facility.[171]

[171] Section 68, Executive Order No. 670/2019.

11. Control measurement, cleaning and decommissioning

When working with unsealed sources, suitable measuring equipment must be available, e.g. contamination monitors, for detecting contamination of workers, surfaces and objects with radioactive material and for the assessment of the extent of the contamination. If relevant, dose rate measurement equipment must also be provided to monitor the working environment.

In case of spillage, cleaning should be performed as soon as possible and should be continued as long as an effective activity reduction is achieved, see Subsection 11.4. However, in case of spillage of unsealed sources with a short half-life and high dose rate, it may be appropriate to allow the contamination to decay before cleaning.

Buildings, facilities and other interiors that have been applied for the use of unsealed sources must be decommissioned when use is complete, as described in Subsection 11.5.

11.1. Control measurements

In order to be able to detect any contaminants, it is important that there is measuring equipment that can detect the radionuclides involved in the work. If several types of radionuclides are used, several types of measuring equipment may be required.

Regular control measurements must be performed, as much as possible, during handling so that contamination of the body, surfaces and objects is detected as soon as possible and exposure is minimised. To avoid the dissemination of any contamination, lab coats, coveralls, hands, surfaces and objects must be inspected after each completed handling. In addition, control measurements must be carried out on workers and objects leaving or being removed from a facility in which unsealed sources have been used above the exemption values[172].[173] When working with H-3, it is not possible to detect contamination by direct measurement, and in this case, wipe tests must instead be performed after handling, see Subsection 11.1.2.

11.1.1. Measuring equipment

Measuring equipment must be in good and technically sound condition and must be checked for correct display at appropriate intervals, generally annually or as prescribed by the manufacturer.[174] Often the control for correct display can be performed as a performance test, where for example, the user systematically checks the measurement result for a known source with known activity, the sound of the measuring equipment and

[172] Annex 3, Executive Order No. 670/2019.
[173] Section 71(1), Executive Order No. 670/2019.
[174] Section 55(1), Executive Order No. 669/2019.

its battery level. In addition, the performance test can be supplemented with a background measurement at a known location with primarily natural background radiation, to ensure that the measuring equipment does not show an unexpected measurement result, e.g. due to contamination of the measuring equipment. The measurement results should be compared with previous measurement results to confirm that the measuring equipment is in good condition and shows an expected result. At appropriate intervals, e.g. every 5 years, the performance test should be performed as a control in a traceable laboratory. In addition, a performance test should be performed before using the measuring equipment for the first time.[175] Performance testing of measuring equipment should be described in a procedure, see Chapter 16.

In the event of incorrect display, it may be necessary to perform a traceable calibration of the measuring equipment. It must at all times be possible to see when a control was performed on the measuring equipment and when the next one is scheduled.[176]

If faults are found in measuring equipment, the undertaking (radiation protection officer) must be notified immediately.[177] Work with unsealed sources must not take place if there is no suitable equipment for detecting contamination.

For control measurements, contamination monitors suitable for the used radionuclides should be applied. A contamination monitor typically determines the surface-specific activity concentration with the unit Bq/cm^2, and the measurement result can thus be used for comparison with the limit values for residual contamination set by the Danish Health Authority, see Subsection 11.2.

Dose rate meters can be used as a supplement to assess the radiation level and can for some radionuclides indicate whether a surface or object, e.g. gloves, is contaminated as well as the location of this contamination. Dose rate meters are also suitable for monitoring the working environment during handling.

Contamination monitors

Since contamination monitors have very different sensitivities depending on whether one is dealing with alpha, beta or gamma radiation and the associated energy, care must be taken when choosing and configuring a contamination monitor. Multiple contamination monitors may be required.

When measuring surface-specific activity concentrations on areas that do not correspond to the size of the monitoring window, an overestimation or underestimation of the measurement result will often be obtained. This is partly because contamination monitors generally take the average of the entire area of the monitoring window. For point contaminants, e.g. splashes or droplets, this will basically lead to an underestimation of the surface-specific activity concentration. Measurements with contamination monitors should therefore be used as indication measurements and not precision measurements.

[175] NPL, Good Practice Guide No. 14.
[176] Section 56, Executive Order No. 669/2019.
[177] Section 55(2), Executive Order No. 669/2019.

Contamination monitors must be fixtures or, as a minimum, readily available in type C isotope laboratories. It may be sufficient for adjacent laboratories to share a contamination monitor. In type B isotope laboratories, a contamination monitor must be accessible. There should be a contamination monitor in both the facility and the forelab/transition zone, where relevant, so that control measurements of the workers can easily be carried out. When handling unsealed sources in other interiors than facilities, a contamination monitor must also be available.[178]

11.1.2. Wipe tests

H-3 emits very weak beta radiation, and it is therefore not possible to detect contamination of H-3 with a contamination monitor or dose rate meter. Contamination is instead detected by measurement with wipe tests. A wipe test is performed by wiping an area with a glass filter paper moistened with a solvent, such as water. It is advisable to choose the same area size when wiping areas, e.g. 10 cm x 10 cm. The glass filter paper is then transferred to a counting tube, to which scintillation liquid is added, and measured in a liquid scintillation counter. A background count must always be made as a reference.

In facilities where there is a high level of radiation from the radioactive material being handled and stored, it can be difficult to detect contamination of surfaces with other radionuclides by direct control measurements. In such situations, it is possible to obtain an indication of non-fixed contamination by means of wipe tests, which are brought to a contamination monitor located in a place with low background radiation. In the event of suspected fixed contamination, it is necessary to remove or shield all radioactive material in the facility prior to the control measurement.

11.2. Limit values for residual contamination

Limit values have been set for residual contamination in buildings and facilities as well as on surfaces and objects. These limit values are given as surface-specific activity concentrations with the unit Bq / cm^2.

A distinction is made between limit values for the clearance of buildings, facilities and objects for other purposes and the limit values for residual contamination of surfaces and objects in connection with the use of unsealed sources.[179] The limit values for residual contamination of surfaces and objects depend on whether the use of unsealed sources takes place in a controlled area or in an area that is either supervised or non classified. The limit values for the most frequently used radionuclides are indicated in Table 8. Please note that the limit values for clearance are identical to the limit values for residual contamination in supervised areas and areas which are not classified.

[178] Section 69, Executive Order No. 670/2019.
[179] Annex 5, Executive Order No. 670/2019.

Table 8
Limit values for surface-specific activity concentration of contamination for the most frequently used radionuclides

Radio-nuclide	Clearance of buildings, facilities and objects for other purposes [Bq/cm²]	Surfaces and objects in supervised areas and areas, which are not classified [Bq/cm²]	Surfaces and objects in controlled areas [Bq/cm²]
H-3	1,000	1,000	100,000
C-14	1,000	1,000	10,000
P-32	100	100	1,000
S-35	1,000	1,000	5,000
I-125	50	50	500

In case of mixtures of radionuclides, the above criteria for permissible residual contamination are met when the activity concentration index (I_{AC}) is less than or equal to 1. I_{AC} is calculated using formula (1) in Subsection 5.1, where $AC_{U,k}$ refers to the limit values for clearance and contamination for contamination of facilities, surfaces and objects[180].

No limit values for skin contamination have been set. In case of skin contamination, cleaning must be performed as long as it provides an effective activity reduction, see Subsection 14.4. The values in Annex E can be used to assess the dose from residual skin contamination.

11.3. Programme for control measurements

The required instructions for application, handling, storage, etc. of unsealed sources; see Subsection 10.1, should include a programme for carrying out control measurements ensuring, on one hand, that workers, exposed surfaces and objects are checked after each handling and, and on the other hand, that comprehensive control measurements are performed regularly, e.g. quarterly, of both exposed and non-exposed surfaces and objects in all facilities and interiors in which radioactive material is handled or stored. Control measurements in connection with the clearance of buildings, facilities and other interiors are described in Subsection 11.5.

[180] Annex 5, Executive Order No. 670/2019.

Often contaminated surfaces and objects

Below are examples of surfaces and objects on which contamination is often found after the use of unsealed sources.

- Wash basins, fixtures, walls behind and floor areas around wash basins and the upper part of the drain
- Work tables, trolleys and radiation safety cabinets
- Centrifuges, incubators, magnetic stirrers, pipe holders, pipettes, pipette racks, heating blocks and baths
- Storage facilities for unsealed sources and radioactive waste, such as refrigerators and freezers
- Light switches, sockets, keyboards, computer mice and work folders
- Handles on doors and cabinets.

It must be possible to document the performed control measurements, and they should therefore be recorded in a protocol. Documentation for performed control measurements must be kept for a minimum of 5 years.[181]

Protocol of control measurements

The protocol of control measurements should include the following information:

- Radionuclide
- When and where the measurement has been performed
- Measurement result and result of background measurement
- What measuring equipment was used
- Name of the person who performed the measurement.

[181] Section 72, Executive Order No. 670/2019.

11.4. Cleaning of contaminated surfaces etc.

As a rule, any contamination must be removed as soon as possible, as contamination increases exposure and old contaminants can be difficult to remove. However, in case of spillage of unsealed sources with a short half-life and high dose rate, it may be appropriate to allow the contamination to decay before cleaning.

Spillage of radioactive material on surfaces or objects must be absorbed with absorbent paper. Wiping must be done towards the centre of the contamination to avoid spreading – use gloves and possibly a pair of pliers or tweezers. To facilitate cleaning, a detergent or "carrier" can be used, i.e. a non-radioactive solution of the same chemical compound as the contaminant. The cleaning procedure shall continue for as long as it results in effective activity reduction.[182] Contaminants should always be completely removed, but as this can be difficult in practice, it applies to surfaces and objects that the remaining contamination must not exceed the surface-specific limit value[183].[184] The limit values for contamination of surfaces and objects inside and outside controlled areas of the most frequently used radionuclides are specified in Table 8 in Subsection 11.2.

For a mixture of radionuclides, the formula (1) in Subsection 5.1 must be used. Measurement methods, that makes it possible to distinguish between individual radionuclides, must be used as far as possible. It may be advisable to seek the advice of a radiation protection expert.

Contamination of surfaces

The cleaning procedure must at minimum include the following:

- Make sure that the contaminants remain in the facility and avoid dissemination to other surfaces or clothing, skin, etc.
- Lay absorbent paper or granules over the spilled substance.
- Always wear gloves, and use pliers where appropriate, and wipe the area with absorbent paper. If relevant, use a "carrier" solution.
- Always wipe towards the centre of the contamination to minimise spreading.
- Wash with soap solution.
- Perform control measurements of the cleaned area. If contamination is still found, continue cleaning as long as it provides an effective activity reduction.

[182] Section 11(1)(3), Executive Order No. 670/2019.
[183] Annex 5, Executive Order No. 670/2019.
[184] Section 71(3), Executive Order No. 670/2019.

- Dispose of contaminated cleaning articles (cloths, paper, etc.) as radioactive waste.

If the contamination of surfaces and objects cannot be completely removed, the remaining contamination must not exceed the limit value for contamination[185].[186]

If the contamination cannot be brought below the limit value, the contaminated surface or object must be shielded or replaced and, if applicable, disposed of as radioactive waste.[187]

Precautions in case of contamination of persons are described in Subsection 14.4.

11.5. Decommissioning of buildings, facilities and other interiors

Clearance of buildings and facilities requires the prior approval from the Danish Health Authority, except for the clearance of facilities that are not subject to registration.[188] Prior to the decommissioning, the undertaking should prepare a plan that must ensure that the decommissioning can be carried out in a responsible way from a radiation protection point of view for all workers involved. If the use of unsealed sources in connection with the decommissioning is subject to licence requirements, see Subsection 5.1, the decommissioning must be described in a safety assessment. The IAEA has prepared a guide describing the process for decommissioning, the content of a decommissioning plan and a safety assessment for decommissioning[189], which it is recommended to follow.

Buildings, facilities, other interiors and objects may be cleared if the surface-specific or mass-specific activity concentration is less than or equal to the clearance limit value[190]. Limit values for clearance are stated in Table 8 in Subsection 11.2 for the most frequently used radionuclides.

For a mixture of radionuclides, the formula (1) in Subsection 5.1 must be used. Measurement methods, that makes it possible to distinguish between individual radionuclides, must be applied as far as possible. It may be advisable to seek the advice of a radiation protection expert.

Regardless of whether the level of contamination is below the limit value, non-fixed contaminants should, if possible, be removed before clearance. The cleaning shall continue for as long as it results in effective activity reduction.[191]

Once all unsealed sources and radioactive waste have been disposed of or transferred and the facility has been cleaned, control measurements must be carried out to ensure

[185] Annex 5, Executive Order No. 670/2019.
[186] Section 71(3), Executive Order No. 670/2019.
[187] Section 71(4), Executive Order No. 670/2019.
[188] Section 11(2), Executive Order No. 670/2019.
[189] IAEA Specific Safety Guide No. SSG-49.
[190] Annex 5, Executive Order No. 670/2019.
[191] Section 11(1)(3), Executive Order No. 670/2019.

that all surfaces and objects are free from contamination with radioactive material. Control measurements are not necessary if it is documented by calculation that any contamination will decay to below the clearance level[192] within the decommissioning period.

Control measurement when deregistering facilities

When deregistering facilities, it must be ensured that all surfaces, including those that are not immediately accessible, are free from non-fixed contamination, and that any residual contamination is below the clearance limit value[193]. Surfaces in drainage and ventilation systems can be particularly exposed to contamination, and if relevant, control measurements should thus be carried out in these places.

Water trap

- Control measurements for contamination with radionuclides that emit gamma radiation in the water trap can usually be performed directly on the outside of the water trap.
- Control measurement for contamination with radionuclides that do not emit gamma radiation but emit weak beta radiation or alpha radiation requires wipe tests to be performed inside the water trap.
- In case of doubt as to whether the contamination of a water trap exceeds the limit value, it should be disposed of as radioactive waste.

Ventilation duct

- Control measurements for contamination with radionuclides that emit gamma radiation in the ventilation duct can usually be performed directly on the outside of the ventilation duct.
- Control measurements for contamination with radionuclides that do not emit gamma radiation but emit weak beta radiation are performed by measuring wipe tests from the interior of the ventilation duct.
- Control measurements must be performed on any filters on radiation safety cabinets. If contamination of filters is found, these must be disposed of as radioactive waste.

Control measurement on filters or performance of wipe tests inside water traps and ventilation ducts that require disassembly of parts of the drain or ventilation duct will often require the assistance of a technician. The technician must beforehand be instructed in the

[192] Annex 5, Executive Order No. 670/2019.
[193] Annex 5, Executive Order No. 670/2019.

precautions of the work, e.g. on the utilisation of personal protective equipment, as well as information about the risks associated with the work.

Registered facilities may not be used for other purposes until control measurements have been performed and they have been deregistered from the Danish Health Authority's Registry of Radiation Sources and Facilities, see Subsection 5.8. Please note that a facility can only be cleared for another purpose once the Danish Health Authority has acknowledged the deregistration.

The time period for the decommissioning depends, inter alia, on the radionuclides that have been handled, the application, the layout of the facility and the chosen decommissioning method. The period can range from a few weeks for decommissioning of smaller isotope laboratories where radionuclides with a short half-life have been handled, and up to several years for decommissioning of large research laboratories where large activities have been handled which may have resulted in contamination of both the facility and the ventilation system.

12. Radioactive waste

Radioactive waste is radioactive material for which there no further use is. Radioactive waste must be disposed of as soon as reasonably possible and must be left to decay for a maximum of 1 year.[194] The undertaking can dispose of radioactive waste by discharge. Radioactive waste that is not discharged by the undertaking must be transferred to another undertaking which can process and discharge the radioactive waste or deposit it. The deposit must be made by undertakings specially designated for this purpose.[195]

From an undertaking's perspective, the disposal and transfer of radioactive waste has the same function – i.e. to remove the radioactive waste from the undertaking. However, disposal and transfer are different forms of use, which are subject to different regulatory requirements, see Subsection 5.1. When an undertaking transfers radioactive waste, the radioactive waste is not disposed of (discharged) by the undertaking.

The radioactive waste must be suitable for the chosen disposal method.[196] If the radioactive waste is not suitable for discharge or if activity concentrations and/or activities are too high, the radioactive waste must be deposited.[197]

12.1. Waste routes in Denmark

Disposal of radioactive waste may require several steps and follow several routes. An undertaking can either discharge radioactive waste or transfer it to another undertaking that can process and discharge the radioactive waste or deposit it. Undertakings that can treat and discharge radioactive waste include waste incineration facilities, while Danish Decommissioning has been assigned the task of storing radioactive waste before deposit. The undertaking can also store radioactive waste for up to 1 year with a view to its decay and subsequent clearance.

In connection with the transfer, there should be an agreement between the undertaking and the recipient, e.g. an incineration plant, that it will receive the radioactive waste. When transporting the radioactive waste, rules for carriage must be observed, see Chapter 15.

Figure 3 shows an overview of routes for disposal or transfer of radioactive waste from a typical undertaking's use of unsealed sources.

[194] Section 24(1-2), Executive Order No. 670/2019.
[195] Section 28(1), Executive Order No. 670/2019.
[196] Section 25, Executive Order No. 670/2019.
[197] Section 27(1), Executive Order No. 670/2019.

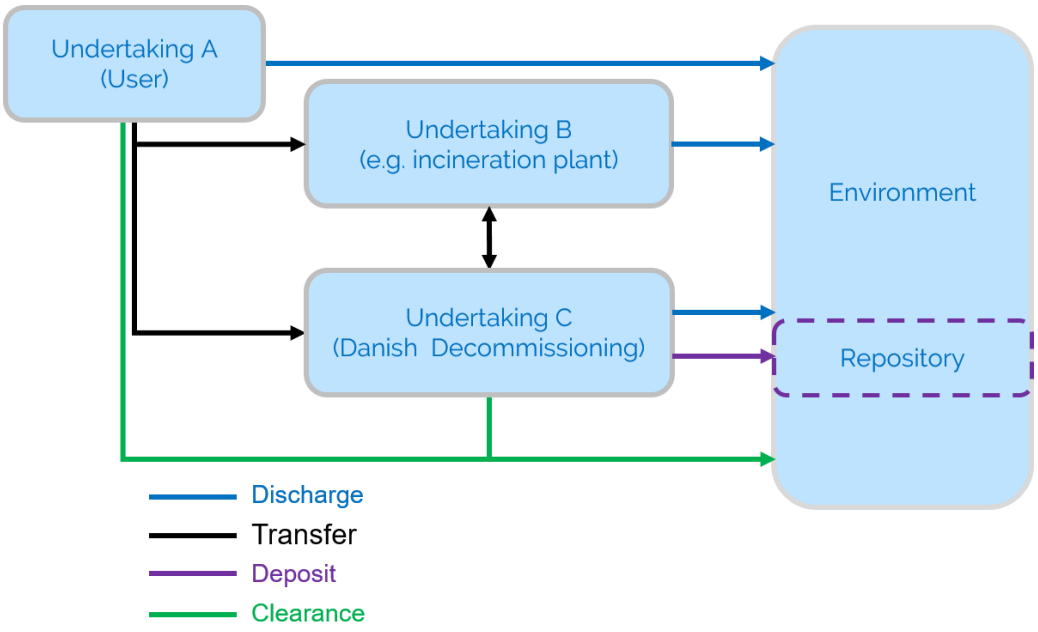


Figure 3
Overview of radioactive waste disposal and transfer of radioactive material

12.2. Discharge

When discharging radioactive waste, liquid or gaseous radioactive waste is led to the surrounding environment at a point of discharge e.g. at the entrance to the public sewer or at the end of a ventilation exhaust duct.

Gaseous radioactive waste can be discharged via ventilation exhaust at the undertaking. In addition, both solid and liquid radioactive waste can be discharged as gaseous radioactive waste after incineration at incineration plants. Incineration of radioactive waste should in principle only be carried out if the incineration ensures that the radioactive material becomes gaseous and can thus be discharged.

Liquid radioactive waste can be discharged via drains to public sewers. Liquid radioactive waste may be unsuitable for discharge if it contains substances which, according to other legislation, prohibit discharge or if the content of radionuclides can be expected to precipitate in the aquatic environment. This could involve radioactive waste from liquid scintillation measurement containing organic solvents.

12.3. Plan for radioactive waste

The undertaking should prepare a plan for the discharge or transfer of the radioactive waste before the acquisition of unsealed sources. The plan should include the characterisation of the radioactive waste, and it should describe how the individual types of radioactive waste are discharged or transferred.[198]

Characterisation of radioactive waste

The characterisation should i.a. include:

- General description of the waste (constituents, state)
- Radionuclide composition in the radioactive waste
- Activity concentration of the various radionuclides in the radioactive waste
- Activity of the various radionuclides in the radioactive waste
- Description, where applicable, of *waste units* (shape, size, bags, containers, weight).

Discharge or transfer

The description of discharge or transfer should include:

- Waste routes (normal refuse collection, discharge, storage with a view to decay, transfer)
- Points of discharge (sewer, chimney), where applicable
- Discharge frequency, where applicable.

The plan may include storing radioactive waste in order to reduce the activity through decay. However, radioactive waste may be left to decay for no more than 1 year.[199] Storage with a view to decay is mainly relevant for radionuclides with a short half-life, e.g. P-32.

[198] IAEA, General Safety Guide No. GSG-9, A-22.
[199] Section 24(2), Executive Order No. 670/2019.

12.4. Treatment of radioactive waste at the undertaking

The treatment of the radioactive waste must ensure that the radioactive waste can be discharged or transferred as specified in the undertaking's plan for radioactive waste. Instructions, that describe the treatment of radioactive waste in connection with discharge and transfer, must be available, see Subsection 10.1.[200]

As part of the treatment of radioactive waste, it is important that the waste is already sorted in the facility. Waste units (bags, containers) can be sorted on the basis of activity concentrations, activities, physical and chemical properties and planned waste routes. The undertaking may transform the waste, e.g. by converting liquid waste into solid form, if it promotes the further process.

In Annex F a decision diagram for discharge and transfer of waste suitable for discharge and solid waste, respectively, is to be found. Liquid and gaseous radioactive waste that is not suitable for discharge is not included in Annex F. This type of radioactive waste as well as solid radioactive waste must be transferred. The requirements set out in Annex F and examples of their use are indicated below.

12.4.1. Disposal exempt from requirements

Radioactive waste with very limited activity concentrations and activities can be disposed of or discharged without requiring radiation protection measures. Disposal of this type of radioactive waste is exempt from permit or notification requirements.[201] Furthermore, radioactive waste can be disposed of without radiation protection measures if the overall criteria for clearance are met. This requires preceding approval from the Danish Health Authority.[202]

The radioactive waste in question can be disposed of via the ordinary waste routes, e.g. normal refuse collection, discharge to sewers or discharge to the atmosphere if the waste is suitable for this. Radioactivity warning labels must be removed or cancelled on empty containers prior to disposal.

Solid waste

Solid waste with activity concentrations and activities as indicated in Table 9 can be disposed of without radiation protection requirements. For waste units containing multiple radionuclides, the formulas (1) and (2) in Subsection 5.1 apply. In cases where $I_{AC,Annex\ 4}$ equals $I_{AC,Annex\ 3}$, $I_{AC,Annex\ 4}$ can be regarded as deciding, as described in Annex F.

[200] Section 65, Executive Order No. 670/2019.
[201] Section 10(1), Executive Order No. 670/2019.
[202] Section 10(2), Executive Order No. 670/2019.

Table 9
Disposal of solid waste that is not subject to radiation protection requirements

	Activity concentration index	Total activity index per month*	Disposal method	Requirement
1)	$I_{\mathrm{AC,annex\ 4}} \leq 1$	unlimited	Normal refuse collection	No requirements
2)	$I_{\mathrm{AC,annex\ 3}} \leq 1$	$I_{\mathrm{A,annex\ 3}} \leq 1$	Normal refuse collection	No requirements

* per licence

Disposal of solid waste that is not subject to radiation protection requirements

The points below refer to the row numbers in Table 9.

1) Solid waste with an activity concentration less than or equal to the exemption and clearance value[203] can be disposed of via normal refuse collection in unlimited activities. This may include empty packaging, laboratory equipment, gloves and paper.

   An undertaking can, for example, dispose of an unlimited number of waste units of 1 kg as long as they do not contain more than 100 kBq H-3 or 1 kBq C-14.

2) Solid radioactive waste with an activity concentration greater than the exemption and clearance value but less than or equal to the exemption value[204] may be disposed of via normal refuse collection when the total activity disposed of per month per licence is less than or equal to the exemption value.

   For example, an undertaking may at most dispose of 1 MBq I-125 per month per licence, where the number of waste units is determined by the activity concentration, which must not exceed 1 MBq/kg. In this case, the undertaking can dispose of, for example,10 waste units of 1 kg each with an activity concentration of 0.1 MBq/kg via normal refuse collection. Similarly, the undertaking can dispose of 100 waste units of 1 kg each per month per licence if the activity concentration is 0.01 MBq/kg.

Liquid or gaseous radioactive waste

Liquid or gaseous radioactive waste with activity concentrations and activities as indicated in Table 10 can be disposed of without radiation protection requirements. For waste containing multiple radionuclides, the formulas (1) and (2) in Subsection 5.1 apply. In cases where $I_{\mathrm{AC,Annex\ 4}}$ equals $I_{\mathrm{AC,Annex\ 3}}$, $I_{\mathrm{AC,Annex\ 4}}$ can be regarded as deciding, as described in Annex F.

[203] Annex 4, Executive Order No. 670/2019.
[204] Annex 3, Executive Order No. 670/2019.

Table 10
Disposal of liquid and gaseous radioactive waste that is not subject to radiation protection requirements

	Activity concentration index	Total activity index per month*	Disposal method	Requirement
1)	$I_{\mathrm{AC,annex\,4}} \leq 1$	unlimited	Discharge to public sewer via drain Emissions to the atmosphere via emission	No requirements
2)	$I_{\mathrm{AC,annex\,3}} \leq 1$	$I_{\mathrm{A,annex\,3}} \leq 1$	Discharge to public sewer via drain Emissions to the atmosphere via emission	No requirements

* per geographical unit in the same point of discharge

Discharge of liquid or gaseous radioactive waste may involve solutions that are poured into the drain or discharged via ventilation exhaust into the atmosphere.

Disposal of liquid or gaseous radioactive waste that is not subject to radiation protection requirements

The points below refer to the row numbers in Table 10.

1) Liquid or gaseous radioactive waste with an activity concentration less than or equal to the exemption and clearance value[205] can be discharged in unlimited activities.[206]
2) Liquid or gaseous radioactive waste with an activity concentration greater than the exemption and clearance value but less than or equal to the exemption value[207] may be disposed of via normal waste routes when the total activity discharged per month per licence is less than or equal to the corresponding exemption value.

12.4.2. Disposal subject to notification requirements

Solid waste

The level of regulatory control "notification" does not apply to solid radioactive waste, see Annex F.

Liquid or gaseous radioactive waste

Discharge of liquid and gaseous radioactive waste with activity concentrations and activities as indicated in Table 11 is subject to a notification requirement. These can be solutions that are poured into drains from wash basins in the isotope laboratory or discharged

[205] Annex 4, Executive Order No. 670/2019.
[206] Annex 1, Executive Order No. 670/2019.
[207] Annex 3, Executive Order No. 670/2019.

via ventilation exhaust to the atmosphere from the radiation safety cabinet. The undertaking's total monthly discharge of radioactive waste determines whether there is a requirement for notification. For the discharge of radioactive waste containing multiple radionuclides, the formulas (1) and (2) in Subsection 5.1 apply. In cases where $I_{AC,Annex\ 4}$ equals $I_{AC,Annex\ 3}$, $I_{AC,Annex\ 4}$ can be regarded as deciding, as described in Annex F.

Table 11
Liquid and gaseous radioactive waste subject to notification requirements

	Activity concentration index	Total activity index per month*	Disposal method	Requirement
1)	$I_{AC,annex\ 3} \leq 100$	$I_{A,annex\ 3} \leq 1$	Discharge to public sewer via drain Emissions to the atmosphere via emission	$I_{AC,annex\ 3} \leq 10$ right after the point of discharge
2)	$I_{AC,annex\ 3} \leq 1$	$I_{A,annex\ 3} \leq 10$	Discharge to public sewer via drain Emissions to the atmosphere via emission	No requirements

* per geographical unit for the same point of discharge

Disposal of liquid or gaseous radioactive waste that is subject to notification requirement

The points below refer to the row numbers in Table 11.

1) Liquid or gaseous radioactive waste with an activity concentration at the point of discharge less than or equal to 100 times the exemption value[208] can be discharged without radiation protection requirements if dispersion in the environment immediately after the point of discharge results in an activity concentration less than or equal to 10 times the exemption value[209] and the total activity discharged per month is less than or equal to the corresponding exemption value.

   Dilution immediately after the point of discharge must ensure that the activity concentration is reduced by a factor of 10. 10 MBq C-14 can be discharged per month, as long as it is ensured that the activity concentration immediately after the point of discharge does not exceed 0.1 MBq/g.

2) Liquid or gaseous radioactive waste with an activity concentration at the point of discharge less than or equal to the exemption value can be discharged without radiation protection requirements when the total activity discharged per month is less than or equal to 10 times the exemption value.

   100 MBq C-14 can be discharged per month, as long as the activity concentration at the point of discharge does not exceed 0.01 MBq/g.

[208] Annex 3, Executive Order No. 670/2019.
[209] Section 26, Executive Order No. 670/2019.

If the activity concentration of liquid poured into the sink in the facility is greater than the exemption value, the liquid must be poured into an isotope drain, see Subsection 8.2.1.

If the monthly discharge exceeds the activity concentration and/or activity limits set out in Table 11, the undertaking must have a licence for the discharge.[210]

12.4.3. Disposal subject to licensing requirements

Solid waste

Solid radioactive waste must be transferred to another undertaking that can process and discharge the radioactive waste or deposit it, see Subsection 12.1.

Liquid and gaseous radioactive waste

Discharge of liquid and gaseous radioactive waste with activity concentrations and activities exceeding the limits for the notification requirement is subject to the licensing requirements.[211]

The conditions for a licence for the discharge of radioactive waste are determined by the Danish Health Authority on a case by case basis.[212] The terms are determined on the basis of the undertaking's safety assessment, which must contain documentation of compliance with dose constraints for the undertaking's total use of radioactive material, incl. discharge.[213] The documentation must contain descriptions of exposure scenarios and assessed doses associated with normal operation, incidents and accidents, see Chapter 6.

12.5. Record

A record of the last 5 years' discharge, storage and transfer of radioactive waste must be kept.[214]

Record of discharge, storage and transfer of radioactive waste

The record must contain the following information:

Storage of radionuclides with a half-life longer than 24 hours:

- Radionuclide
- State and chemical form
- Date

[210] Annex 1, Executive Order No. 670/2019.
[211] Annex 1, Executive Order No. 670/2019.
[212] Section 17, Act No. 23/2018.
[213] Sections 21-22, Executive Order No. 669/2019.
[214] Section 18, Executive Order No. 670/2019.

- Estimated activity and, where relevant, activity concentration when stored as radioactive waste
- Storage location
- Relevant contact name.

Discharge and transfer:

- Date
- Estimated activity and activity concentration for discharge and transfer, respectively
- For discharge: discharge method
- For transfer: the name of the undertaking to which the transfer took place.

Discharge from patients and animals in connection with the administration of radionuclides:

- Documentation based on model calculations that include a statistical estimate of discharges based on number of patients and number of animals, respectively. It may be advisable to seek the advice of a radiation protection expert.

13. Radiological monitoring

The use of unsealed sources will usually involve some degree of exposure of workers. The exposed worker can be exposed either through external exposure caused by an unsealed source located outside the body or by internal exposure caused by radioactive material that has been absorbed into the body by accident. Absorption into the body can take place via intake through the mouth, inhalation or absorption through undamaged skin or wounds; see also Subsection 10.4.2.

Requirements for radiological monitoring depend on the 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 Table 1 in Subsection 2.3, while serving as a means of optimising radiation protection; see Subsections 2.2 and 13.4.

Doses to individual organs, tissues, etc. are termed equivalent doses. The dose limits for the lens of the eye, skin and extremities, see Table 1 in Subsection 2.3, have been established to prevent the incidence of acute localised injury, such as cataract. The whole-body dose is termed effective dose. The dose limit for the effective dose has been established to limit the risk of incidence of late effects, such as cancer.

The effective dose, together with the risk factors established by the ICRP, may be used to generally assess the risk of developing a given type of cancer in later life as a result of the harmful effects of exposure to radiation (late effects). The ICRP publishes risk factors for late effects, for example based on historical cohort studies. For calculating effective doses to exposed workers, a risk factor of approx. $4 \cdot 10^{-5}$ mSv^{-1} is applied.[215]

More information about acute and late effects is provided in "The Radiation Guide"; see Chapter 17.

13.1. Requirement for individual radiological monitoring

The requirement for individual radiological monitoring depends on the categorisation of the exposed workers; see Subsection 9.1. Individual radiological monitoring is required for Category A and B workers.[216] A pregnant exposed worker must furthermore be subject to radiological monitoring, unless it can be ruled out with certainty that the effective dose to the foetus after notification of pregnancy to the undertaking may exceed 1 mSv.[217]

[215] ICRP Publ. 103, p. 53, 2007.
[216] Section 78(1), Executive Order No. 669/2019.
[217] Section 79(1), Executive Order No. 669/2019.

Radiological monitoring of the equivalent dose to the eye lens, skin and extremities is required if an exposed worker, under normal conditions or in the event of an incident or accident, is able to receive equivalent doses exceeding the upper limits in Table 7 in Subsection 9.1.[218]

When individual radiological monitoring using a *personal dosemeter* is not appropriate or feasible, then individual radiological monitoring shall be performed in accordance with a *radiological monitoring programme* approved by the Danish Health Authority.[219]

If an exposed worker under normal conditions or in the event of an incident or accident may receive an effective dose greater than 1 mSv/year from internal exposure or if a foetus may receive an effective dose from internal exposure of an exposed worker in excess of 1 mSv, individual radiological monitoring must be performed in accordance with a radiological monitoring programme approved by the Danish Health Authority. [220, 221] Undertakings which are subject to individual radiological monitoring requirements under a radiological monitoring programme should consult a radiation protection expert.

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

13.1.1. Requirements for individual radiological monitoring for external exposure

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

Determination of effective dose

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

Radionuclides that emit only short-range beta radiation (e.g. H-3, C-14 and S-35) will not normally lead to external exposure of the body. Due to the short range, a personal dosemeter is therefore not usable for determining a possible dosage.

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 utilised, such as a finger ring dosemeter. A finger ring dosemeter can, for example, be relevant when handling large activities of radionuclides that emit beta radiation with medium or high energy, e.g. P-32.

Requirement for radiological monitoring

A worker subject to the requirement for individual radiological monitoring for external exposure shall be radiologically monitored, meaning that they shall wear a personal dosemeter during all work involving unsealed sources. Personal dosemeters, including finger ring dosemeters, are for personal wear only and must not be shared by multiple workers.

[218] Section 78(4-5), Executive Order No. 669/2019.
[219] Section 78(6), Executive Order No. 669/2019.
[220] Section 78(7), Executive Order No. 669/2019.
[221] Section 79(3), Executive Order No. 669/2019.

If a radiologically monitored worker works for several undertakings, a personal dosemeter must be applied to each undertaking, as it must be possible to identify the undertaking at which the measured doses have been received. If a radiologically monitored worker is to perform work at an undertaking where the worker is not employed, the worker must, as a rule, bring the worker's own dosemeter to the undertaking in question.

If a personal dosemeter is damaged or lost, the worker must not perform work involving unsealed sources until a new personal dosemeter has been obtained.

Measuring period

The measuring period for personal dosemeters worn to determine effective dose is one month for Category A workers and three months for Category B workers.[222] For pregnant exposed workers subject to the requirement of radiological monitoring of external exposure, the measuring period is one month.[223] The measuring period for a finger ring dosemeter is typically 14-30 days.

Personal dosemeters must be sent for reading at the *dosimetry service* immediately after the end of the measuring period.[224]

Dosemeter positioning

Personal dosemeter for determining the effective dose should be placed in front of the body at chest height, as the upper part of the body is often not fully covered by any shielding set up on the work table. 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 the measured dose, as the position of the dosemeter is typically some distance away from the most exposed area of the skin. This means that the measured dose will often be an underestimate of the actual dose. Given this fact, the undertaking should always take a critical approach to the measured 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. Even modest increases in radiation levels relative to the background level can affect the dosemeter's measurement result. This means that dosemeters should not be stored in proximity to storage locations for unsealed sources or other types of radiation sources.

13.1.2. Requirements for individual radiological monitoring for internal exposure

Radiological monitoring of internal exposure cannot be performed with a personal dosemeter, but must be based on measurements on biological samples or on direct measure-

[222] Section 78(2-3), Executive Order No. 669/2019.
[223] Section 79(2), Executive Order No. 669/2019.
[224] Section 81(2), Executive Order No. 669/2019.

ments on the body. Biological samples can typically be urine samples, while direct measurements on the body could be measurement on the outside of the neck region by the thyroid gland or measurement in a whole body counter.

If a worker is breastfeeding during a period when working with unsealed sources, precautions must be taken to ensure that there is no significant risk of internal or external contamination of the body with radioactive material.[225] If radioactive material has accidentally entered the body of the breastfeeding worker, some of the radionuclides, depending on the chemical compound they are part of, could be transferred to the baby via breast milk.

The radiological monitoring programme must be adapted to the properties of the current radionuclides and must contain instructions on, for example, measurement method and times for sampling or direct measurement.

Handling of airborne material, e.g. tritiated water, volatile iodine or unsealed sources in powder form, and handling associated with high risk of spillage will often require individual radiological monitoring of internal exposure.

Methods for the detection of internal exposure

Below, for each of the mentioned measurement methods for radiological monitoring for internal radiation, areas of application are stated, where the measurement methods can advantageously be used as part of the individual radiological monitoring.

Urine samples:

- Handling large activities of H-3, C-14 and S-35
- Iodination with volatile iodine.

External measurement on the neck region by the thyroid gland:

- Iodination with volatile iodine.

Whole body counter:

- Handling of radionuclides that emit gamma radiation (e.g. Ra-223 and Th-227).

Gamma camera:

- Handling of radionuclides that emit gamma radiation (e.g. Ra-223).

When taking a biological sample, e.g. urine, it must be assured that the sample does not become contaminated with radioactive material from the environment. Samples and test

[225] Section 43, Executive Order No. 669/2019.

tubes should therefore only be handled outside the work area and hands should be washed thoroughly.

13.2. Determination, reporting and notification of doses

Determination of external 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 measuring period has expired. Upon suspicion of an unusually large personal dose, the dose shall be determined without undue delay.[226]

Workers who have undergone radiological monitoring shall be informed of the result of the monitoring as soon as possible after the result becomes available. 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.[227] At any time, the undertaking shall be able to document doses to workers for the last 5 calendar years, including the current year. In the event of any *accidental exposure*, a record shall also be retained of the circumstances of such exposure and of the countermeasures taken.[228]

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[229] and be submitted as directed by SRP.[230] Subject to agreement, notification may also done by the dosimetry service.

If doses from external exposure exceed the values in Table 12, the undertaking must immediately notify the Danish Health Authority.[231] The values are based on Category A workers and are thus based on a measuring period of one month. In case of shorter measuring periods, it may be necessary to lower the value correspondingly. However, the dose values shall not be increased when using longer measurement periods.

Table 12
Dose values for immediate notification of external exposure to the Danish Health Authority[232]

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

[226] Section 81, Executive Order No. 669/2019.
[227] Section 84, Executive Order No. 669/2019.
[228] Section 86, Executive Order No. 669/2019.
[229] Annex 3, Executive Order No. 669/2019.
[230] Section 87, Executive Order No. 669/2019.
[231] Section 85, Executive Order No. 669/2019.
[232] Annex 5, Executive Order No. 669/2019.

For doses from internal exposure, the dose values for immediate notification of the Danish Health Authority are determined in each specific case.

13.3. Dosestatistics

The dose history of an undertaking and similar undertakings should be used to establish dose constraints for exposed workers, see Subsection 2.2.

In 2017, 172 exposed workers were radiologically monitored as a result of their work using unsealed sources in connection with research and development (this does not include work with accelerator facilities and biomedical research). The total average annual effective dose for these workers was 0.02 mSv.

156 of the workers received less than 0.1 mSv and only one received more than 0.5 mSv. None of the workers received more than 1 mSv.

By comparison, the average dose in 2017 was for all radiologically monitored workers in Denmark was 0.11 mSv.

13.4. Facilitation and optimisation by means of dosemeters

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

An electronic dosimeter registers and indicates, unlike a personal dosimeter, the measured dose continuously and can be set to sound an alarm when a given dose is exceeded. In addition, it can detect and set the dose rate and be set 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 it is found when using a finger dosimeter that large doses are received for hands and fingers, it may be relevant to determine the doses associated with the individual operations by changing the dosimeter between the operations. This may indicate which procedures results in the highest dose so that measures to optimise these procedures may be implemented, such as utilising pliers, tweezers and mobile shielding.

Electronic personal dosemeters

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

14. Emergencies, Accidents and Incidents

Before using unsealed 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 unsealed sources, the undertaking shall promptly take all the relevant measures to avert or mitigate serious adverse consequences for human health and safety, quality of life, property or the environment.[233] The Danish Health Authority must be notified as soon as possible.[234]

14.1. Instructions regarding precautions

The undertaking shall ensure that an easily understood set of instructions is available to workers on precautions to be taken in the event of an emergency, accident or incident, including theft, see Subsection 10.1.[235] The undertaking must therefore prepare for the possibility that the unsealed source may, for example, be stolen or that their container may be damaged.

The instructions shall be readily available during work. All relevant measures should be described in the instructions, including evacuation and closure, decontamination of persons, cleaning of contaminated surfaces and use of "carrier" solutions, as well as stopping ventilation or discharge. The instructions should also include information about notification of the Danish Health Authority and of the undertaking and its radiation protection officer.[236]

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 extent
- Call for help

[233] Section 91, Executive Order No. 669/2019.
[234] Section 92, Executive Order No. 669/2019.
[235] Section 57, Executive Order No. 669/2019.
[236] Section 92(3), Executive Order No. 669/2019.

- Stop the spread of any contamination
- Immediately remove contaminated clothing and set aside for control measurement
- Clean contaminated persons and surfaces; see Subsections 14.4 and 11.4 respectively
- Perform control measurements; see Chapter 11
- Notify the radiation protection officer and the undertaking
- Notify the Danish Health Authority; see Subsection 14.5
- Evacuate unauthorised persons
- Keep the area under constant surveillance.

14.3. Systematic factors

Improperly designed facilities or equipment, improper procedures when using unsealed sources, when controlling measuring equipment, or equipment with recurring defects can lead to unintentional exposure. These are referred to as systematic factors. A systematic factor would, for example, be if a defective procedure is reiterated or if a defect has been propagated to several pieces of equipment of the same type as a result of a manufacturing defect. 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 procedure, equipment or type of unsealed source. Systematic factors shall therefore be notified to the Danish Health Authority as soon as possible; see Subsection 14.5.[237, 238]

14.4. Decontamination of persons

In the event of emergencies, accidents and incidents, contaminated persons must be cleaned as soon as possible.[239] Small contaminants of the skin are removed with soap and water. In case of major contamination of the body, contaminated clothing must be removed immediately and the body must be washed under the emergency shower. The cleaning shall continue for as long as it results in effective activity reduction.[240] Perform ongoing control measurements. The cleaning process should not cause damage to the

[237] Section 58, Executive Order No. 669/2019.
[238] Section 14(2), Act No. 23/2018.
[239] Section 71(2), Executive Order No. 670/2019.
[240] Section 71(2), Executive Order No. 670/2019.

skin, as it may lead to increased uptake of radioactive material through the wound resulting in internal exposure.

In the event of major contamination of persons, the Danish Health Authority must be contacted. In addition, the radiation protection officer or radiation protection expert and the undertaking can be contacted.

The following procedure must be followed when decontaminating persons, depending on the extent.

Decontamination of persons

1. In case of skin contamination: Wash with soap and water until the contamination is removed, but without damaging the skin.
2. In case of damage to the skin with simultaneous contamination: Rinse with plenty of water and, if necessary, pull the wound edges apart to increase bleeding and flushing.
3. In case of contamination of eyes: Immediately use an eye rinser.
4. In case of major external contaminants: Remove contaminated clothing and rinse body under emergency shower, then perform control measurements. The washing shall continue for as long as it results in effective activity reduction. Check the contaminated clothing and, if necessary, set it aside for decay or dispose of it directly as radioactive waste.
5. If the contamination cannot be completely removed: Consult a doctor or radiation protection expert and the Danish Health Authority.
6. If radioactive material is ingested through the mouth: Consult a doctor, radiation protection expert and the Danish Health Authority immediately.

14.5. Notification to the Danish Health Authority

The Danish Health Authority shall be notified promptly during the following situations:[241]

Notification to the Danish Health Authority

The Danish Health Authority shall be notified promptly in the event of:

[241] Section 14, Act No. 23/2018.

- Emergencies, accidents or incidents that have resulted in unintended exposure or significant contamination with radioactive material
- Any discovery, theft, loss, fire, flooding or the like of significance from a radiation protection point of view involving unsealed sources [242]
- Incidents that might have resulted in the above.

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

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 or significant contamination.[243]

14.6. 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.[244]

[242] Section 92(1), Executive Order No. 669/2019.
[243] Section 58(1), Executive Order No. 669/2019.
[244] Section 59, Executive Order No. 669/2019.

15. Carriage

The general rules for the carriage of radioactive material are laid down in Executive Order No. 993/2001; see Chapter 17. In addition, there are specific regulations for each mode of transport (road, rail, sea and air) that apply to national and international carriage of radioactive material.[245] For international carriage of unsealed sources, the rules of the country in question shall be complied with.

Carriage of unsealed sources

The rules on the carriage of unsealed sources comprise all the functions and conditions associated with such carriage. These include among other preparation, consigning, loading, carriage, including *transit storage*, unloading and receipt at the destination of the unsealed sources.[246]

Unsealed sources packaged and ready for consigning to a carrier are called *packages*.[247] Packages for carriage of unsealed sources shall be designed to achieve commensurate safety for preventing dispersal of radioactive material during carriage.[248]

A package containing radioactive material is classified on the basis of radionuclide, activity concentration, activity and state (solid, liquid or gas).[249]

Carriage of unsealed sources that possess secondary hazardous properties is subject to additional transport restrictions.[250] However, these are not described in this Guide, and reference is instead made to the Danish Road Safety Agency, the Danish Emergency Management Agency and the Danish Transport, Construction and Housing Authority.

The consignor is responsible for ensuring that the package is correctly packed and marked and accompanied by a correctly completed transport document.[251] The carrier is responsible for ensuring that all requirements for the carriage of radioactive material are met, including that packages are correctly marked by the consignor.[252] By carrier is meant any undertaking that transports its own or other undertakings' radioactive material.

[245] Subsection 2, Annex 2, Executive Order No. 993/2001.
[246] 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.
[247] 1.2.1, ADR 2019, 1.2.1, RID 2019, 1.2.1, IMDG 2018 and 1;3.1.1, ICAO-TI.
[248] 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.
[249] 2.2.7, ADR 2019, 2.2.7, RID 2019, 2.7 IMDG 2018 and 2.7, ICAO-TI.
[250] 1.7.5, ADR 2019, 1.7.5, RID 2019, 1.5.5 IMDG 2018 and 1;6.5, ICAO-TI.
[251] Section 16, Executive Order No. 993/2001.
[252] 1.4.2.2, ADR 2019, 1.4.2.2, RID 2019 and 1;1.2, ICAO-TI.

15.1. Radiation protection programme and quality management system

Carriage of unsealed sources shall be carried out in conformance with a radiation protection programme and a quality management system – in the specific regulations on carriage of radioactive substances referred to as a "management system" – which are graded in proportion to the risk associated with such carriage.[253]

Undertakings subject to requirements for licensing or notification of use of unsealed sources and hence subject to the requirement for a general quality management system; see Chapter 16, can integrate their radiation protection programme and quality management system for carriage of unsealed sources into the 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 carriage of unsealed sources.[254] The nature and scope of the measures shall be graded according to the magnitude and likelihood of exposure.[255]

The radiation protection programme shall ensure that the doses that might be incurred by workers and members of the public from the carriage of unsealed sources are optimised and below the dose limits. The programme shall comprise all stages of carriage and equally any interfaces between carriage and other handling of sources.[256]

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 carriage of unsealed sources.[257]

Quality management system

The quality management system shall ensure compliance with the rules on the carriage of unsealed 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 driving as well as requirements for worker competences and maintenance of those competences.[258]

[253] 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.
[254] 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.
[255] 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.
[256] 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.
[257] 1.7.2.5, ADR 2019, 1.7.2.5, RID 2019, 1.5.2.5 IMDG 2018 and 1;6.2.7, ICAO-TI.
[258] 1.7.3.1, ADR 2019, 1.7.3.1, RID 2019, 1.5.3.1 IMDG 2018 and 1;6.3, ICAO-TI.

15.2. Carriage by road

The specific rules for carriage by road of radioactive material are laid down in ADR; see Chapter 17. ADR is implemented in Danish legislation through the Danish Transport, Construction and Housing Authority's Executive Order No. 828/2017. ADR is updated every two years and published on the Danish Road Safety Agency's website (www.fstyr.dk).

Unsealed sources will in most cases be able to be transported as either an exempt consignment, excepted packages or type A package. This Guide focuses on the rules governing the carriage of radioactive material by road as an excepted consignment or excepted package. For transport as a type A package, there is a requirement for the affiliatin of a *dangerous goods adviser*, who will guide the undertaking on the rules for this type of package.[259, 260]

15.2.1. Exempt consignment

Exempt consignments are used for consignments that contain radioactive material in such small activities or activity concentrations that no special precautions or radiation protection measures must be taken in connection with carriage.

A consignment with one or more unsealed sources may take place as an exempt consignment if the total activity concentration is below the limit for exempted substances or if the total activity is below the activity limit for exempt consignments and is then considered non-radioactive within the context of carriage. Carriage of exempt consignments is not subject to the rules on carriage of radioactive material, and the carriage is consequently not associated with fulfilment of special requirements.

The activity concentration limits for selected exempted substances and the activity limits for exempt consignments are specified in Table 13. For other radionuclides, see ADR.[261] If an exempt consignment contains a mixture of radionuclides, e.g. if several unsealed sources are transported in the same consignment, it must be ensured that the total activity concentration or activity is below the limits for exempt consignments.[262]

[259] Executive Order No. 543/2012.
[260] Chapter 1.8, ADR 2019.
[261] Table 2.2.7.2.2.1, ADR 2019
[262] 2.2.7.2.2.4–2.2.7.2.2.6, ADR 2019.

Table 13
Limits for exempted substances and exempt consignments for the most frequently transported radionuclides

Radionuclide	Activity concentration limit for exempted substances [Bq/g]	Activity limit for an exempt consignment [MBq]
H-3	1,000,000	1000
C-14	10,000	10
F-18	10	1
P-32	1000	0.1
S-35	100,000	100
Cr-51	1,000	10
Tc-99m	100	10
I-125	1,000	1
I-131	100	1

15.2.2. Excepted package

Excepted packages contain radioactive material in activities that require precautions to be taken in order to ensure adequate radiation protection. Activity limits for excepted packages for frequently transported radionuclides are specified in Table 14.

Table 14
Maximum activity in excepted packages for the most frequently transported radionuclides

Radionuclide	Gas [MBq]	Solid [MBq]	Liquid [MBq]
H-3	800,000	40,000	4,000
C-14	-	3,000	300
F-18	-	600	60
P-32	-	500	50
S-35	-	3,000	300
Cr-51	-	30,000	3,000
Tc-99m	-	4,000	400
I-125	-	3,000	300
I-131	-	700	70

The activity limit per package for other radionuclides and for mixtures of radionuclides are stipulated in the ADR.[263, 264]

Requirements for packages

Excepted packages shall meet the general requirements for packages set out in the ADR.[265] In addition to the general requirements for packages, the following requirements apply to excepted packages.

Requirements for excepted packages

- The package shall be designed so that it can keep the contents contained under the conditions of routine carriage.[266] In addition, the package shall be designed so that it can be firmly secured inside the vehicle.[267]
- At the request of the Danish Health Authority, the consignor of an excepted package shall be able to document that the package design meets all relevant requirements.[268]
- The package must not contain elements or items that could jeopardise the safety of the package during carriage under routine conditions. [269]
- The maximum dose rate on the surface of the package must not exceed 5 µSv/h.[270]
- The package shall be marked on the exterior with:[271]
  - Consignor and/or consignee
  - *UN number*
  - Gross weight (if exceeding 50 kg).
- The interior of the package shall be labelled with the text "Radiaktiv" (Radioactive) so that this is legible when the packaging is opened, regardless of whether it is opened as planned or accidentally. If interior marking is not feasible, the labelling shall be laced on the exterior of the package.[272]

[263] Table 2.2.7.2.4.1.2, ADR 2019.
[264] 2.2.7.2.2.4–2.2.7.2.2.6, ADR 2019.
[265] 6.4.2, ADR 2019.
[266] 6.4.2.7, ADR 2019.
[267] 6.4.2.1, ADR 2019.
[268] 5.1.5.2.3, ADR 2019.
[269] 4.1.9.1.3, ADR 2019.
[270] 2.2.7.2.4.1.2, ADR 2019.
[271] 5.1.5.4.1, ADR 2019.
[272] 2.2.7.2.4.1, ADR 2019.

- When relevant, the package must be provided with directional arrows on two opposite vertical sides, and the arrows must point upwards in the correct direction.[273]
- When using an overpack where the required marking 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.[274]
- 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[275] and 0.4 Bq/cm^2 for all other radionuclides emitting alpha radiation.[276]
- Packaging used for the transport of radioactive material must not be used for the storage or transport of other goods unless it has been cleaned. The cleaning must ensure that the contamination level of radionuclides that emit beta and gamma radiation as well as radionuclides that emit alpha radiation with low toxicity[277] is below 0.4 Bq/cm^2 and that the contamination level of all other radionuclides emitting alpha radiation is below 0.04 Bq/cm^2.[278]

Requirements for transport documents

Vehicles carrying excepted packages shall travel with a transport document declaring the contents by citing the proper shipping names and associated UN numbers[279] and contains the consignor's and consignee's address.[280] In Table 15 you can find the UN numbers and associated proper shipping names applicable to excepted packages containing unsealed sources.

Table 15
UN numbers for excepted packages relevant to the scope of this Guide

UN number	Official proper shipping name and description
UN 2908	RADIOACTIVE MATERIAL, EXCEPTED PACKAGE – EMPTY PACKAGING
UN 2910	RADIOACTIVE MATERIAL, EXCEPTED PACKAGE – LIMITED QUANTITY OF MATERIAL

[273] 5.2.1.10.1, ADR 2019.
[274] 5.1.2.1, ADR 2019.
[275] 2.2.7.1.3, ADR 2019.
[276] 4.1.9.1.2, ADR 2019.
[277] 2.2.7.1.3, ADR 2019.
[278] 5.1.3.2, ADR 2019.
[279] 2.2.7.2.1.1, ADR 2019.
[280] 5.1.5.4.2, ADR 2019.

Requirements for the transport document

The following reproduces the special requirements for storage and design of the transport document.

- The transport document shall state the UN number preceded by the letters "UN" and the consignor's and consignee's name and address.[281]
- The consignor and carrier shall retain a copy of the transport document for a period of at least three months.[282]
- 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.[283]
- For international carriage of unsealed sources, the transport document must be prepared in Danish as well as either English, German or French.[284]

Examples of transport documents for carriage by road of radioactive material are available at www.sis.dk under "Legislation" → "Radioactivity" → "Carriage".

Requirements for driver, vehicle, equipment, etc.

The driver of the vehicle shall have received instruction in the requirements made for carriage of unsealed sources, and specific instructions in relation to that individual's tasks, including in safety commensurate with the risk posed by those tasks.[285,286]

Consignments shall be securely stowed in the vehicle.[287]

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.[288]

If no other types of packages are transported 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.[289]

No marking of the vehicle is required for carriage of excepted packages.[290]

[281] 5.1.5.4.2, ADR 2019.
[282] 5.4.4.1, ADR 2019.
[283] 5.4.4.2, ADR 2019.
[284] 5.4.1.4.1, ADR 2019.
[285] 8.2.3, ADR 2019.
[286] 8.5, S12, ADR 2019.
[287] 7.5.11, CV33 (3.1), ADR 2019.
[288] 8.5 P 21 ADR 2019.
[289] 1.1.3.6.3, ADR 2019.
[290] 5.3.1.1.3, ADR 2019.

The vehicle shall be equipped with a handheld extinguisher with a capacity of at least 2 kg that meets the applicable safety equipment requirements.[291, 292]

Vehicles and equipment regularly used for carriage of unsealed sources shall be periodically inspected for contamination. The frequency shall be adapted to the scale of carriage of radioactive material and the probability of contamination.[293]

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 14.5, and other authorities concerned shall be notified as quickly as possible.[294]

15.3. Carriage by rail

The rules for the carriage of unsealed sources by rail are regulated in RID; see Chapter 17. The rules for carriage by rail are basically the same as for carriage by road; see Subsection 15.2, however, with the exemption of the requirements for drivers, vehicles, equipment, etc. which do not apply to carriage by rail.

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

15.4. Carriage by sea

Under the Baltic Sea Agreement, see Chapter 17, which may be applicable to all ferry routes in Denmark and in the Baltic Sea Region, no special transport documents are necessary for carriage by sea of unsealed sources. This means that the transport documents prepared in accordance with rules applicable to carriage by road are sufficient. The Baltic Sea Agreement, however, requires that vehicles carrying packages containing unsealed 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.[295] Shipping companies are free to choose whether they wish to adhere to the Baltic Sea Agreement on a specific ferry route.

Carriage by sea of unsealed sources not subject to the Baltic Sea Agreement is subject to the specific rules for carriage by sea set out in the IMDG Code, see Chapter 17, 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.

[291] 8.1.4.2, ADR 2019.
[292] 8.1.4.4 – 8.1.4.5, ADR 2019.
[293] 7.5.11 CV33 (5.3), ADR 2019.
[294] Section 18(3), Executive Order No. 993/2001.
[295] https://www.soefartsstyrelsen.dk/SikkerhedTilSoes/Skibssikkerhed/FarligtGods/FarligtGodsEmballeret

For ferry crossings, the ferry crew shall be informed that unsealed 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 issue.

15.5. Carriage by air

Carriage by air of unsealed sources is regulated by the provisions of ICAO-TI, see Chapter 17. The airlines also have their own rules laid down in IATA-DRG, see Chapter 17, which are published every year. IATA-DRG is based on the regulations in ICAO-TI.

Carriage by air of unsealed 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.

16. Quality assurance

Quality assurance denotes all planned and systematic actions, including quality control, necessary to provide adequate assurance that unsealed sources, facilities, equipment, systems, components or procedures will perform satisfactorily 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 unsealed sources.[296] By quality assurance means all the necessary measures, such as regular control, which must be carried out in order to ensure that the use of unsealed sources proceeds in conformity with agreed standards. The overall aim of quality assurance is to maintain radiation protection, for example by preventing or detecting incorrect handling or storage of unsealed sources as well as defects in facilities and equipment. An effective quality management system also enables the undertaking to document that its ongoing use of unsealed sources is in compliance with the rules.

To that end, undertakings shall establish and maintain a quality management system commensurate with the nature and scale of the undertaking's use of unsealed sources.[297] That is, the higher the risk associated with the use, the stricter the requirements for the quality management system to reflect all the details of the use, and that the system should address, as a minimum, the risks described in the associated documentation, e.g. in a safety assessment are. The risk is assessed on the basis of radionuclide, activity, state (gas, liquid or solid form), possibility for shielding, probability of absorption into the body, complexity of handling and so on.

The quality management system shall reflect the undertaking's current use of unsealed sources. It must therefore serve to substantiate that relevant documents such as the safety assessment, 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.[298]

16.1. System fundamentals

In Table 16 you can find an overview of a number of key radiation protection legislation requirements for which the quality management system must serve to ensure compliance with at all times. In addition, the quality management system shall ensure that, for example, instructions are complied with and that protocols are duly kept. Note that the listing in the table is not exhaustive.

[296] Section 93, Executive Order No. 669/2019.
[297] Section 93, Executive Order No. 669/2019.
[298] Section 94, Executive Order No. 669/2019.

Table 16
Overview of significant requirements with which the quality management system shall serve to ensure compliance

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		
Receipt of consignments	Subsection 10.1	Section 65, No. 1, Executive Order No. 670/2019.
Application, handling, storage, etc.	Subsection 10.1	Section 65, No. 1, Executive Order No. 670/2019.
Transfer and disposal of radioactive waste	Subsection 10.1	Section 65, No. 2, Executive Order No. 670/2019.
Cleaning staff, where applicable	Subsection 10.1	Section 65, No. 3, Executive Order No. 670/2019.
Precautions in the event of emergencies, accidents and incidents	Subsection 10.1	Section 65, No. 4, Executive Order No. 670/2019.
Procedures		
Classification of areas	Subsection 7.1	Sections 49-50, Executive Order No. 669/2019.
Categorisation of workers	Subsection 9.1	Section 38, Executive Order No. 669/2019.
Control measurement and surface cleaning	Chapter 11	Section 71(1-2), Executive Order No. 670/2019.
Control of measuring equipment	Subsection 11.1.1	Section 56, Executive Order No. 669/2019.
Radiological monitoring	Chapter 13	Section 78-79, Executive Order No. 669/2019.
Documentation		
Clearance of objects and facilities	Chapter 11.2 and 11.5	Sections 11 and 13, Executive Order No. 670/2019.

Control of the radiation safety cabinet	Subsection 8.2.1	Subsection 1.1.11.2-1.1.11.3, Annex 13, Executive Order No. 670/2019.
Performance testing of ventilation system (type B and A isotope laboratories)	Subsection 8.2.1	Subsection 1.2.6, Annex 13, Executive Order No. 670/2019.
Performes control measurements (stored for at least 5 years)	Subsection 11.3	Section 72, Executive Order No. 670/2019.
Doses to exposed workers (stored for at least 5 years)	Subsection 13.2	Section 86, Executive Order No. 669/2019.
Transport documents, where applicable (kept for at least 3 months)	Subsection 15.2.2	
Protocols		
Pressure conditions (type B and A isotope laboratories)	Subsection 8.2.1	Subsection 1.2.4, Annex 13, Executive Order No. 670/2019. Section 67(3), Executive Order No. 670/2019.
Control of measuring equipment	Subsection 11.1.1	Section 56, Executive Order No. 669/2019.
Records		
Designated expert individuals	Chapter 4	Section 34, Executive Order No. 669/2019.
Exposed workers, their qualifications and maintenance of same	Subsection 9.2	Section 45(2-3), Executive Order No. 669/2019.
Facilities	Subsection 8.3	Section 17, Executive Order No. 670/2019.
Receipt, production and transfer of unsealed sources above the exemption values[299]	Subsection 5.7	Section 16(3), Executive Order No. 670/2019.
Discharge, storage and transfer of radioactive waste	Subsection 12.5	Section 18, Executive Order No. 670/2019.

[299] Annex 3, Executive Order No. 670/2019.

17. Acts, executive orders, guides, etc.

17.1. Acts, executive orders, etc.

- Ministry of Health Act No. 23 of 15 January 2018 on Ionising Radiation and Radiation Protection (Radiation Protection Act).
- Ministry of Health Executive Order No. 1111 of 7 November 2019 on Fees Charged for the Danish Health Authority's Inspection, Advisory and Assistance Services.
- 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 Executive Order on Transport of Radioactive Material.
- Danish Safety Technology Authority Executive Order No. 1229 of 11 December, 2009 on the International System of Units, SI, and other legal units.
- 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.
- Danish Transport, Construction and Housing Authority Executive Order No. 543 of 12 June 2012 on Dangerous Goods Safety Advisors.
- Danish Transport, Construction and Housing Authority Executive Order No. 828 of 10 June, 2017 on Carriage by Road of Dangerous Goods.
- Council Regulation (Euratom) No 1493/93 of 8 June 1993 on the Transfer of Radioactive Substances Between Member States.
- ADR (Agreement, Dangerous, Road). European Agreement concerning the International Carriage of Dangerous Goods by Road (2019).
- RID (Regulation concerning the International Carriage of Dangerous Goods by Rail) (2019).
- Baltic Sea Agreement. Memorandum of Understanding for the Transport of Packaged Dangerous Goods on Ro-ro Ships in the Baltic Sea (2018).
- IMDG (International Maritime Dangerous Goods) Code (2018).

- ICAO-TI (International Civil Aviation Organisation, Technical Instructions) (2018).
- IATA-DRG (International Air Transport Association, Dangerous Goods Regulations) (2019).

17.2. Guides

- Danish Health Authority Guide to Safety Assessment (2020).
- Danish Health Authority Guide on Approved Isotope Courses (2020).
- Danish Working Environment Authority Guide No. 9093 of 31 January 2019 to Medical Examinations Pertaining to Potential Occupational Exposure to Ionising Radiation.

17.3. Other relevant publications

- Danish Health Authority publication: The Radiation Guide – Ionising Radiation (2013).
- The Danish Health Authority's publication "Datablade" (2020).
- Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev 1) (2016).
- Regulatory Control of Radioactive Discharges to the Environment, IAEA, General Safety Guide No. GSG-9 (2018).
- Decommissioning of Medical, Industrial and Research Facilities, IAEA Specific Safety Guide No. SSG-49 (2019).
- ICRP, 2007. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37 (2-4).
- ICRP, 2010. Conversion Coefficients for Radiological Protection Quantities for External Radiation Exposures. ICRP Publication 116. Ann. ICRP 40 (2-5).
- PH Jensen, Health Physics, Radioactivity, ionizing radiation, biological effects and radiation protection, Praxis - Nyt Teknisk Forlag (2012).
- D. Delacroix, J. P. Guerre, P. Leblanc, C. Hickman, RADIONUCLIDE AND RADIATION PROTECTION DATA HANDBOOK 2002, Radiation Protection Dosimetry, Volume 98, Issue 1, 1 January 2002.
- Measurement Good Practice Guide No. 14, The examination, testing and calibration of portable radiation protection instruments, National Physical Laboratory (NPL), Issue 2, Rev. August 2014.

The original Danish Act and the executive orders in force at any time are available to download from www.retsinformation.dk. Other publications from the Danish Health Authority are available to download from 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.
Acute adverse effect of radiation:	An injury for which a threshold dose has been defined as the cause of the adverse effect, and where the extent of that effect increases proportionally with the magnitude of the dose. Examples of acute effects are radiation cataract, sterility, and inhibition of the formation of white blood cells and other cells.
Administered:	See "administration".
Administration:	Administration of radioactive material on/in humans and animals.
Airborne radioactive material:	Radioactive material in gas, aerosol or powder form.
Application:	Utilisation of unsealed sources for the intended purpose, e.g. research and development, animal experiments or experiments in nature.
Braking radiation:	Electromagnetic radiation generated by deceleration of beta particles in material also known as Bremsstrahlung.
Carriage:	Transportation and any operation involving loading, unloading, transit storage and handling on Danish territory. Carriage therefore includes shipments to and from Danish consignees and consignors, and shipments transiting Danish territory.
Clearance:	A change in regulatory status entailing that requirements from the point view of radiation protection in the Radiation Protection Act and the provisions in the rules laid down pursuant to the Act are no longer in force.

Dangerous goods safety advisor:	A transportation advisor who shall be contracted to serve undertakings that transport radioactive material other than that in excepted consignments and excepted packages.
Danish Decommissioning:	A state-owned undertaking 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.
Deposit:	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.
Discharge:	Dispersion of unsealed sources to the environment e.g. via a sewer or chimney.
Disposal:	Discharge of radioactive waste from the application of unsealed sources or the deposit of radioactive waste at an undertaking specially designated for this purpose. In this Guide, the term disposal also means the discard of non-radioactive waste via normal refuse collection.
Dose constraint:	An upper value for the individual dose permitted to be delivered by a radiation source in a *planned exposure situation* and which provides a baseline for optimisation of radiation protection.
Dose limit:	The size of the effective dose or the equivalent dose in a specified period which shall not be exceeded for an individual.

Dosimetry service:	A body or an individual competent 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 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 apparatus, appliances or devices necessitated by the use of radiation sources or exposure, including containers, measuring instruments and other measuring equipment, imaging systems and apparatus, appliances or devices for radiation protection, including personal protective equipment.

Equivalent dose:	The average absorbed dose in any tissue or organ weighted for the type and quality of ionising radiation.
Exemption and clearance value:	Values for activity concentration that may be applied as standard for exemption or clearance of limited quantities of any activity and type of material, see Annex 4 in Executive Order no. 670/2019.
Exemption value:	Values for activity concentration and activity that may be applied as standard for exemption of limited quantities of any type of material, see Annex 3 in Executive Order no. 670/2019.
Existing exposure situation:	An exposure situation that already exists when a decision on its control has to be made and which does not call or no longer calls for urgent measures to be taken.
Export:	Carriage of unsealed 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.
Facility:	Interiors, including laboratories, radiography rooms and storage and waste storage rooms and their associated structural elements constructed and fitted out to provide radiation protection from the use of radiation sources, and vehicles designed and fitted out to provide radiation protection during application of radiation sources.

Freight Operator:	A railway undertaking for which the main activity consists of the transport of goods by rail.
Handling:	The practical operations associated with the application, storage, etc. of unsealed sources. Handling includes operations related to receiving an unsealed source, laboratory work with unsealed sources and packaging of radioactive waste from the application of unsealed sources.
Holding:	Ownership of, or right of use to, unsealed sources.
Import:	Carriage of unsealed 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.
Infrastructure administrator:	Any body or undertaking responsible for the construction, maintenance and management, including traffic management of railway infrastructure.
Internal exposure:	Exposure of the body to radiation sources within the body.
Iodination:	Handling using volatile iodine, typically I-125.
Ionising radiation:	Particles, including photons, capable of causing ionisation in substances directly or indirectly, but in the case of electromagnetic radiation only of a wavelength of 100 nm or less.
Late effect:	An injury for which no proven threshold dose has been 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.

Leak detection:	Leak detection on concealed pipelines using radioactive material.
Manufacture:	Production of radionuclides, e.g. using a cyclotron.
Medical exposure:	Exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research.
Member of the public:	An individual who may be subject to public exposure.
Non-medical purposes:	Purposes that do not include medical exposure.
NORM:	Naturally Occurring Radioactive Material.
Occupational exposure:	The exposure incurred by a worker from the use of radiation sources or from exposure in the undertaking that the 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 a necessary 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.
PMMA:	Polymethyl methacrylate, also called acrylic.
Point of discharge:	The site where discharged radioactive waste is dispersed unsupervised to the external environment, for example, via drains to public sewers, chimney emission or ventilation ducts into the atmosphere.
Public exposure:	The exposure of individuals, excluding any occupational or *medical exposure*.
Quality assurance:	All the 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 accordance 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 safety cabinet:	A cabinet providing protection during the use of radioactive material capable of causing external or internal exposure, e.g. a hot cell, glove box, fume cupboard or ducted laminar air flow bench.

Radiation source:	A radioactive substance or a *radiation generator*.
Radioactive material:	A radioactive substance with an activity or activity concentration 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 application is foreseen.
Radiation:	Ionising radiation.
Radiation generator:	A device capable of generating ionising radiation.
Radiation protection:	Arrangements for protection against ionising radiation, including prevention of emergencies, accidents and incidents and mitigation of the consequences thereof.
Radiation protection expert:	An individual who shall advise the undertaking to ensure effective radiation protection of workers and members of the public concerning the undertaking's use of radiation sources or exposures. The radiation protection expert must be approved by the Danish Health Authority.
Radiation protection officer:	An individual tasked with monitoring and assisting in maintaining the radiation protection of workers and members of the public in connection with the undertaking's use of radiation sources or exposures. The radiation protection officer must be approved by the Danish Health Authority.

Radiological monitoring programme:	Individual radiological monitoring that is not based on the use of a personal dosemeter, for instance 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.
RIA Kit:	Kit for binding analysis; most of these kits contain very small activities of H-3 or I-125.
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.
Security measures:	Arrangements or precautions for the purpose of preventing, detecting and responding to theft, unintended access to, or misuse of radioactive material.
Shipping:	Any package or load of radioactive material presented by a consignor for transport.
Storage:	Any storing of unsealed sources, such as at specially-equipped storage locations inside the facilities where the unsealed sources are handled or storage of radioactive material or radioactive waste inside facilities specially constructed for this purpose.
Transfer (non physical):	Change of ownership of an unsealed source from one undertaking to another. When an undertaking sends radioactive waste for incineration at an incineration plant or to Danish Decommissioning, this is also a transfer.

Transfer:	Any measures necessary for the physical relocation of radioactive material from one country to another country.
Transit:	The transfer via Denmark of radioactive material from a country outside the European Union to another country outside the European Union.
Undertaking:	A natural or legal person who owns, leases, borrows or otherwise holds right of use of a radioactive substance, is responsible for an area exposed to ionising radiation or is responsible for use of a radiation source.
Unintended exposure:	Exposure that significantly exceeds that incurred by persons and the environment through correct use of radiation sources, and medical exposure that is significantly different from the medical exposure intended for a given purpose.
UN number:	Numbering of official proper shipping names for dangerous goods defined by the UN.
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 carriage of radioactive substances.
Veterinary medical application:	The application of radioactive material for veterinary medical examinations, treatment or research within these domains.
Waste unit:	Any bag, container or packaging that encloses radioactive waste.
Worker:	Any person who, regardless of any underlying contractual relationship, is engaged in a worker-like relation.

Annex 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, $\dot{D}_2$, 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, $\dot{D}_2$, 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 in ICRP[300].

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

[300] ICRP Publ. 116, 2010.

Formulas for determining the level of regulatory control[301]	
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 instances 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 activityto time = 0	[Bq]

[301] Annex 1, Executive Order No. 670/2019.

A_k	Activity of radionuclide, *k*	[Bq]
$A_{U,k}$	Activity for radionuclide, *k,* for exemption[302]	[Bq]
AK_k	Activity concentration of radionuclide, *k*	[Bq/g]
$AK_{U,k}$	Activity concentration for radionuclide, *k,* for exemption and clearance[303]	[Bq/g]
d	Thickness	[metres, m]
D	Dose	[Sv] *The metric is typically units of µSv or mSv*
$\dot{D}$	Dose rate	[Sv/h] *The metric is typically 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

[302] Annex 3, Executive Order No. 670/2019.
[303] Annex 3-4, Executive Order No. 670/2019.

	The ratio between the dose rate after radiation has passed the shielding and dose rate before passing the shielding	
w_R	Radiation Weighting Factor[304] *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 [grays] to biological effect [sieverts]*	[Sv/Gy]
w_T	Tissue weighting factor[305] *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[306], 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[307], the rad being an obsolete unit.

[304] Annex 4, Table 1, Executive Order No. 669/2019.
[305] Annex 4, Table 2, Executive Order No. 669/2019.
[306] Annex 1, Executive Order No. 1229/2009.
[307] 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[308], 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}

[308] Annex 1, Executive Order No. 1229/2009.

Annex C: Examples of the determination of the level of regulatory control.

Below you can find examples of the determination of the level of regulatory control for the holding, application, storage, etc. of unsealed sources as well as the discharge of radioactive material.

Example 1: Holding, application, storage, etc.

An undertaking holds, applies, stores, etc. unsealed sources containing C-14, P-32 and I-125. The undertaking does not discharge radioactive material. The maximum activity concentrations and activities that the undertaking holds at any given time are stated below.

Radionuclide	Activity concentration [Bq/ml]	Activity [Bq]
C-14	3×10^4	5×10^6
P-32	5×10^3	5×10^4
I-125	10×10^3	5×10^6

In order to assess whether the undertaking's holding, application, storage, etc. are subject to licensing or notification requirements or are exempted from this, the index values for activity concentration and activity are calculated, cf. formula (1) and formula (2) in Subsection 5.1. The exemption values for C-14, P-32 and I-125 are indicated in Table 2 in Subsection 5.1. For aqueous solutions, it can typically be assumed that Bq/g corresponds to Bq/ml, which is used in the calculation below, where the exemption values are stated with the unit Bq/ml.

Activity concentration index:

$$I_{\mathrm{AC}} = \sum_{\mathrm{k}} \frac{AC_{\mathrm{k}}}{AC_{\mathrm{U,k}}} = \frac{AC_{\mathrm{C\text{-}14}}}{AC_{\mathrm{U,C\text{-}14}}} + \frac{AC_{\mathrm{P\text{-}32}}}{AC_{\mathrm{U,P\text{-}32}}} + \frac{AC_{\mathrm{I\text{-}125}}}{AC_{\mathrm{U,I\text{-}125}}}$$

$$= \frac{3 \times 10^4 \ \frac{\mathrm{Bq}}{\mathrm{ml}}}{1 \times 10^4 \ \frac{\mathrm{Bq}}{\mathrm{ml}}} + \frac{5 \times 10^3 \ \frac{\mathrm{Bq}}{\mathrm{ml}}}{1 \times 10^3 \ \frac{\mathrm{Bq}}{\mathrm{ml}}} + \frac{10 \times 10^3 \ \frac{\mathrm{Bq}}{\mathrm{ml}}}{1 \times 10^3 \ \frac{\mathrm{Bq}}{\mathrm{ml}}} = 3 + 5 + 10 = 18$$

Activity index:

$$I_A = \sum_k \frac{A_k}{A_k} = \frac{A_{C\text{-}14}}{A_{U,C\text{-}14}} + \frac{A_{P\text{-}32}}{A_{U,P\text{-}32}} + \frac{A_{I\text{-}125}}{A_{U,I\text{-}125}}$$

$$= \frac{5 \times 10^6 \text{Bq}}{1 \times 10^7 \text{Bq}} + \frac{5 \times 10^4 \text{Bq}}{1 \times 10^5 \text{Bq}} + \frac{5 \times 10^6 \text{Bq}}{1 \times 10^6 \text{Bq}} = 0.5 + 0.5 + 5 = 6$$

The activity concentration index is greater than 1 but less than 1,000, and therefore the second row in Table 3 in Subsection 5.1.1 covers the activity concentration (blue marking in Figure 4).

The activity index is greater than 1 but less than 10, and therefore the second column in Table 3 in Subsection 5.1.1 covers the activity (red marking in Figure 4).

The common quantity for the two markings indicates the level of regulatory control for the undertaking's holding, application, storage, etc. I.e. that in this example a licence is required.

Figure 4 Level of regulatory control for holding, application, storage, etc. described in Example 1

		Activity index I_A		
		$I_{A,annex\ 3} \leq 1$	$1 < I_{A,annex\ 3} \leq 10$	$10 < I_{A,annex\ 3}$
Activity concentration index I_{AC}	$1{,}000 < I_{AC,bilag\ 3}$	Licensing	Licensing	Licensing
	$1 < I_{AC,annex\ 3} \leq 1{,}000$	Notification	Licensing	Licensing
	$I_{AC,annex\ 3} \leq 1$ and $1 < I_{AC,annex\ 4}$	Exempt from the licensing and notification requirements*	Notification	Licensing
	$I_{AC,annex\ 4} \leq 1$	Exempt from requirements	Exempt from requirements	Exempt from requirements

* However, if the activity per month exceeds an activity index of 10, notification is required.

Example 2: Holding, application, storage, discharge, etc.

An undertaking holds, applies, stores, etc. unsealed sources containing H-3 and C-14. The undertaking also discharges radioactive material via sewers.

Holding, application and storage

The level of regulatory control for the holding, application, storage, etc. of unsealed sources as well as the discharge of radioactive material must be determined. The maximum activity concentrations and activities that the undertaking holds at any given time are stated below.

Radionuclide	Activity concentration [Bq/ml]	Activity [Bq]
H-3	10×10^6	3×10^8
C-14	3×10^4	5×10^6

In order to assess whether the undertaking's holding, application, storage, etc. are subject to licensing or notification requirements or are exempted from this, the index values for activity concentration and activity are calculated, cf. formula (1) and formula (2) in Subsection 5.1. The exemption values for H-3 and C-14 are indicated in Table 2 in Subsection 5.1. For aqueous solutions, it can typically be assumed that Bq/g corresponds to Bq/ml, which is used in the calculation below, where the exemption values are stated with the unit Bq/ml.

Activity concentration index:

$$I_{\mathrm{AC}} = \sum_{\mathrm{k}} \frac{AC_{\mathrm{k}}}{AC_{\mathrm{U,k}}} = \frac{AC_{\mathrm{H\text{-}3}}}{AC_{\mathrm{U,H\text{-}3}}} + \frac{AC_{\mathrm{C\text{-}14}}}{AC_{\mathrm{U,C\text{-}14}}}$$

$$= \frac{10 \times 10^6 \frac{\mathrm{Bq}}{\mathrm{ml}}}{1 \times 10^6 \frac{\mathrm{Bq}}{\mathrm{ml}}} + \frac{3 \times 10^4 \frac{\mathrm{Bq}}{\mathrm{ml}}}{1 \times 10^4 \frac{\mathrm{Bq}}{\mathrm{ml}}} = 10 + 3 = 13$$

Activity index:

$$I_{\mathrm{A}} = \sum_{\mathrm{k}} \frac{A_{\mathrm{k}}}{A_{\mathrm{k}}} = \frac{A_{\mathrm{H\text{-}3}}}{A_{\mathrm{U,H\text{-}3}}} + \frac{A_{\mathrm{C\text{-}14}}}{A_{\mathrm{U,C\text{-}14}}}$$

$$= \frac{3 \times 10^8 \mathrm{Bq}}{1 \times 10^9 \mathrm{Bq}} + \frac{5 \times 10^6 \mathrm{Bq}}{1 \times 10^7 \mathrm{Bq}} = 0.3 + 0.5 = 0.8$$

The activity concentration index is greater than 1 but less than 1,000, and therefore the second row in Table 3 in Subsection 5.1.1 covers the activity concentration (blue marking in Figure 5).

The activity index is less than 1, and therefore, the first column in Table 3 in Subsection 5.1.1 covers the activity (red marking in Figure 5).

The common quantity for the two markings indicates the level of regulatory control for the holding, application, storage, etc. I.e. that the holding, etc. described in this example requires notification.

Figure 5 Level of regulatory control for holding, application, storage, etc. described in Example 2

		Activity index I_A		
		$I_{A,annex\ 3} \leq 1$	$1 < I_{A,annex\ 3} \leq 10$	$10 < I_{A,annex\ 3}$
Activity concentration index I_{AC}	$1{,}000 < I_{AC,bilag\ 3}$	Licensing	Licensing	Licensing
	$1 < I_{AC,annex\ 3} \leq 1{,}000$	Notification	Licensing	Licensing
	$I_{AC,annex\ 3} \leq 1$ and $1 < I_{AC,annex\ 4}$	Exempt from the licensing and notification requirements*	Notification	Licensing
	$I_{AC,annex\ 4} \leq 1$	Exempt from requirements	Exempt from requirements	Exempt from requirements

* However, if the activity per month exceeds an activity index of 10, notification is required.

Discharge

The undertaking discharges a monthly activit of 10 MBq H-3 and 1 MBq C-14 in a total volume of wastewater of 10,000 l.

The activity concentration at the point of discharge is calculated as:

$$I_{AC} = \sum_k \frac{AC_k}{AC_{U,k}} = \frac{AC_{H\text{-}3}}{AC_{U,H\text{-}3}} + \frac{AC_{C\text{-}14}}{AC_{U,C\text{-}14}}$$

$$= \frac{\frac{10\ \text{MBq}}{10{,}000\ \text{l}}}{1 \times 10^6 \frac{\text{Bq}}{\text{ml}}} + \frac{\frac{1\ \text{MBq}}{10{,}000\ \text{l}}}{1 \times 10^4 \frac{\text{Bq}}{\text{ml}}} = \frac{\frac{10 \times 10^6\ \text{Bq}}{10{,}000 \times 10^3 \text{ml}}}{1 \times 10^6 \frac{\text{Bq}}{\text{ml}}} + \frac{\frac{1 \times 10^6\ \text{Bq}}{10{,}000 \times 10^3 \text{ml}}}{1 \times 10^4 \frac{\text{Bq}}{\text{ml}}}$$

$$= \frac{1\,\frac{\mathrm{Bq}}{\mathrm{ml}}}{1\times10^{6}\,\frac{\mathrm{Bq}}{\mathrm{ml}}} + \frac{0.1\,\frac{\mathrm{Bq}}{\mathrm{ml}}}{1\times10^{4}\,\frac{\mathrm{Bq}}{\mathrm{ml}}} = 1\times10^{-6} + 1\times10^{-5} = 11\times10^{-6}$$

Since the activity concentration index based on the exemption values[309] is less than 1, the activity concentration index based on the exemption and clearance values[310] must also be calculated.

$$I_{\mathrm{AC,annex\ 4}} = \frac{1\,\frac{\mathrm{Bq}}{\mathrm{ml}}}{100\,\frac{\mathrm{Bq}}{\mathrm{ml}}} + \frac{0.1\,\frac{\mathrm{Bq}}{\mathrm{ml}}}{1\,\frac{\mathrm{Bq}}{\mathrm{ml}}} = 0.11$$

Activity index:

$$I_{\mathrm{A}} = \sum_{\mathrm{k}} \frac{A_{\mathrm{k}}}{A_{\mathrm{U,k}}} = \frac{10\times10^{6}\mathrm{Bq}}{1\times10^{9}\mathrm{Bq}} + \frac{1\times10^{6}\mathrm{Bq}}{1\times10^{7}\mathrm{Bq}} = 0.01 + 0.1 = 0.11$$

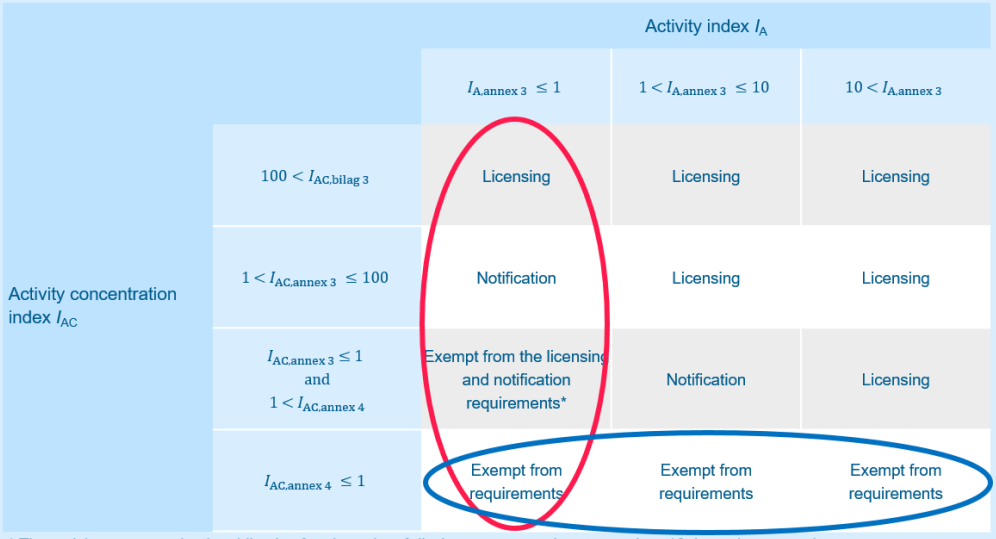
Since the activity concentration index based on the exemption and clearance values is less than 1, the last row in Table 4 in Subsection 5.1.2 covers the activity concentration (blue marking in Figure 6).

The activity index is less than 1, and therefore, the first column in Table 4 in Subsection 5.1.2 covers the activity (red marking in Figure 6).

The common quantity for the two markings indicates the level of regulatory control of the discharge. I.e. that the discharge described in this example is exempt from requirements.

[309] Annex 3, Executive Order No. 670/2019.
[310] Annex 4, Executive Order No. 670/2019.

Figure 6 Level of regulatory control for discharge described in Example 2



* The activity concentration immidiately after the point of discharge must not be greater than 10 times the exemption value.
** Calculated on the discharged activity per month.
*** At the point of discharge.
.

Example 3: Holding, application, storage, etc.

An undertaking holds, applies, stores, etc. unsealed sources containing C-14. The undertaking does not discharge radioactive material. The undertaking holds just one stock solution at any given time, but acquires a total of 15 stock solutions per month. The maximum activity concentration and activity that the undertaking holds at any given time are stated below.

Radionuclide	Activity concentration [Bq/ml]	Activity [Bq]
C-14	1×10^3	10×10^6

In order to assess whether the undertaking's holding, application, storage, etc. are covered by the licensing or notification requirements or are exempted from this, the index values for activity concentration and activity are calculated, cf. formula (1) and formula (2) in Subsection 5.1. The exemption values for C-14 are indicated in Table 2 in Subsection 5.1. For aqueous solutions, it can typically be assumed that Bq/g corresponds to Bq/ml, which is used in the calculation below, where the exemption values are stated with the unit Bq/ml.

Activity concentration index:

$$I_{\mathrm{AC,annex\ 3}} = \sum_{\mathrm{k}} \frac{AC_{\mathrm{k}}}{AC_{\mathrm{U,k}}} = \frac{AC_{\mathrm{C\text{-}14}}}{AC_{\mathrm{U,C\text{-}14}}} = \frac{1 \times 10^{3}\ \frac{\mathrm{Bq}}{\mathrm{ml}}}{1 \times 10^{4}\ \frac{\mathrm{Bq}}{\mathrm{ml}}} = 0.1$$

The activity concentration index based on the exemption values[311] is less than 1, and therefore, the activity concentration index based on the exemption and clearance values[312] must also be calculated.

$$I_{\mathrm{AC,annex\ 4}} = \sum_{\mathrm{k}} \frac{AC_{\mathrm{k}}}{AC_{\mathrm{U,k}}} = \frac{AC_{\mathrm{C\text{-}14}}}{AC_{\mathrm{U,C\text{-}14}}} = \frac{1 \times 10^{3}\ \frac{\mathrm{Bq}}{\mathrm{ml}}}{1\ \frac{\mathrm{Bq}}{\mathrm{ml}}} = 1{,}000$$

Activity index:

$$I_{\mathrm{A}} = \sum_{\mathrm{k}} \frac{A_{\mathrm{k}}}{A_{\mathrm{k}}} = \frac{A_{\mathrm{C\text{-}14}}}{A_{\mathrm{U,C\text{-}14}}} = \frac{10 \times 10^{6}\mathrm{Bq}}{1 \times 10^{7}\mathrm{Bq}} = 1$$

The index values calculated above indicate, cf. Table 3 in Subsection 5.1.1, that the holding, etc. is exempt from the licensing or notification requirement.

However, in case of exemption from the licensing or notification requirements, it is important to be aware that the undertaking's total activity index per month must be less than or equal to 10. If the activity index per month is greater than 10, notification is required.

The undertaking acquires 15 stock solutions per month, which means that the undertaking's activity index per month is 15 times higher than the activity index calculated above.

The activity index per month thus becomes:

$$I_{\mathrm{A,month}} = \sum_{\mathrm{k}} \frac{A_{\mathrm{k,month}}}{A_{\mathrm{k}}} = \frac{15 \times A_{\mathrm{C\text{-}14}}}{A_{\mathrm{U,C\text{-}14}}} = \frac{15 \times 10 \times 10^{6}\mathrm{Bq}}{1 \times 10^{7}\mathrm{Bq}} = 15$$

Since the total activity per month corresponds to an activity index greater than 10, the holding, etc. described in this example will require notification.

[311] Annex 3, Executive Order No. 670/2019.
[312] Annex 4, Executive Order No. 670/2019.

Annex D: Preparation of safety assessment

Basis for designing a safety assessment

Before using unsealed sources subject to licensing requirements, the undertaking must carry out a safety assessment adapted to the nature, scope and complexity of the undertaking's use of sources.[313] The safety assessment must be structured on the basis of a graded approach and cover all factors necessary for documenting that relevant requirements from a radiation protection point of view have been complied with and that the radiation protection has been optimised.

The safety assessment template in this document is structured with reference to the IAEA Security Standard GSR part 4 (Rev. 1), see Chapter 17.

In order to conclude whether an undertaking's radiation protection arrangements are sufficient, it is often appropriate to review an iterative process that includes the sub-processes of the undertaking. Figure 7 shows typical phases of this iterative process.

[313] Section 20(1), Executive Order No. 669/2019.

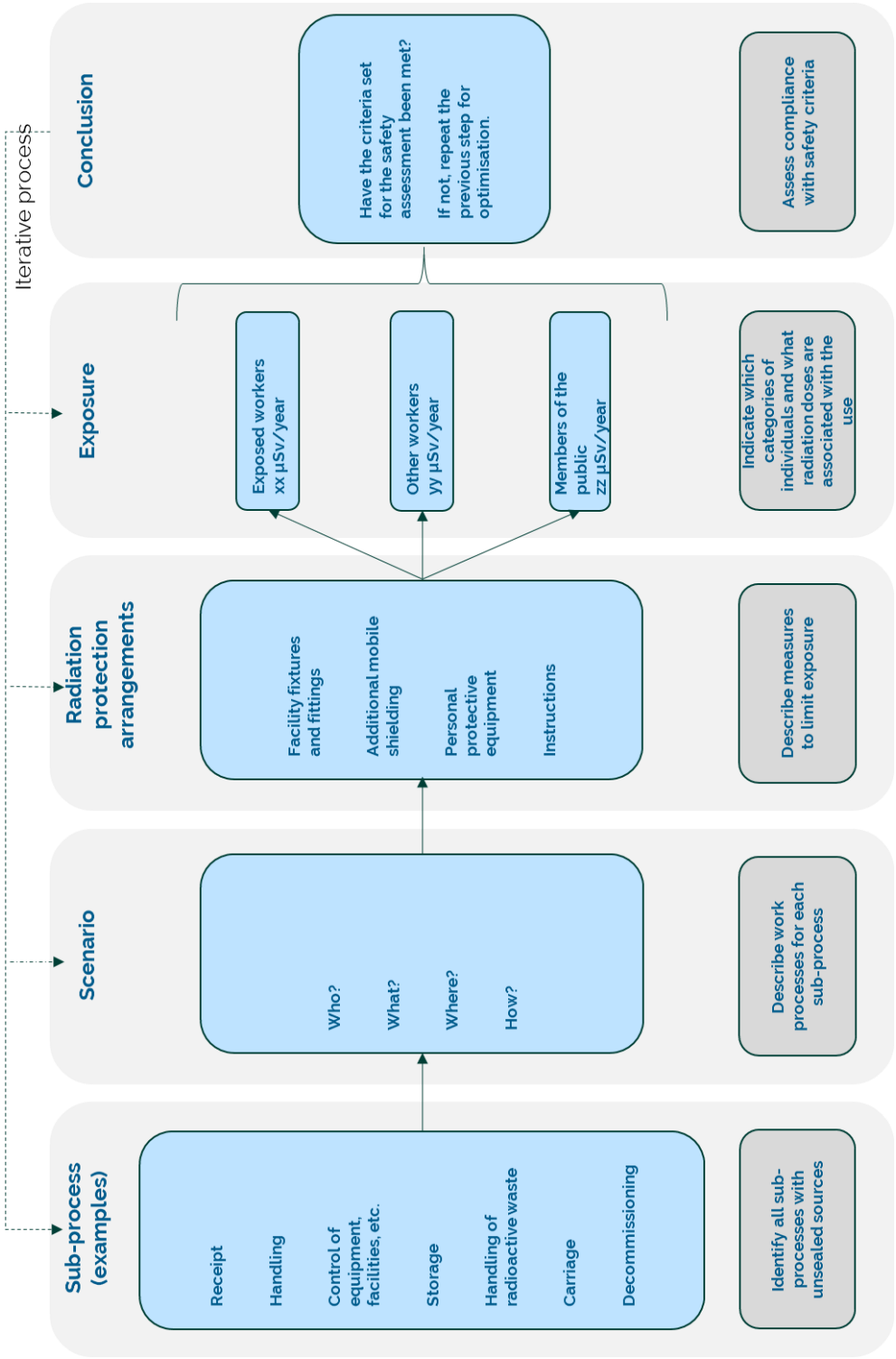


Figure 7
The iterative process that is reviewed when preparing a safety assessment

Safety assessment template

To ensure that all relevant parts of the safety assessment are affected, the safety assessment should be structured according to the instructions below in a version-controlled report. If there are parts of the instructions that are not applicable to the current use, they should be stated and justified. It is possible to refer to already-prepared documents if these cover one or more requirements.

1. Introduction

The purpose of the introduction is to systematically describe the undertaking's use of unsealed sources and the nature of the radiation protection arrangements employed to address the risks entailed by the use of the unsealed sources. In addition, the undertaking's overall set of rules and objectives for radiation protection must be described.

Purpose, scope and responsibilities must be described in the introduction.

Purpose

The use of unsealed sources subject to licensing requirements must be briefly described, e.g. "Handling, storage and discharge of I-125 in connection with animal experiments". See Chapter 1 for the definition of the term use.

In addition, it must be described which requirements for radiation protection must be complied with. These include:

- Dose constraint for members of the public and other workers, see Subsection 2.2.
- Dose limits for exposed workers, see Subsection 2.3.
- Requirements in executive orders, instructions in guides, principles of radiation protection and methods of optimisation (should be listed as bulleted items with reference, as applicable, to relevant executive orders, etc.)
- Additional safety objectives, e.g. constraints for exposed workers, see Subsection 2.2, and definition of procedures for safe use.

Scope

Description of the scope of the safety assessment and how the graded approach is applied. The description must, as a minimum, address the following points:

- Indication of unsealed sources included in the safety assessment
- The basis for the level of regulatory control and its calculations, see Subsection 5.1

- Brief description of facilities, see i.a. Chapter 8 for requirements for facilities
- Delimitation of the safety assessment, e.g. if the use takes place in already-approved facilities
- The connection with other parts of the undertaking's quality assurance system, see Chapter 16.

Responsibility

Description of the responsibility for the licence for the use of unsealed sources and the associated safety assessment. The points below must, as a minimum, address:

- General responsibility for the licence, including a description of the organisation and the department's organisational location, if applicable, see Chapter 3. References can be made to annexes with an organisation chart.
- Responsibility for preparation and approval of the safety assessment at the undertaking/department, see Chapter 4.
- Responsibility for periodic review, alteration or updating of the safety assessment, see Chapter 6.
- Description of the situations that will result in updating the safety assessment. All alterations that may be of significance from a radiation protection point of view or that require an alteration to the scope of the licence shall be described, e.g. alteration in radionuclides, alteration in the state of the radionuclides, activity, activity concentration, facilities and procedures.
- Indication of which updates entail that the Danish Health Authority, Radiation Protection must be informed. The Danish Health Authority must, as a minimum, be informed of changes when the basis for a licence or conditions therein are changed.

2. Description of the undertaking's/department's use of unsealed sources

This part is for describing the undertaking's physical conditions, processes and sub-processes for use of unsealed sources.

The unsealed sources used, their use and facilities must be described in detail.

Unsealed sources

For each unsealed source, the following must be stated as a minimum:

- Radionuclide
- Radiation type (α, β, γ)
- State and chemical form
- Relevant routes of exposure (internal and/or external, including exposure of the eye lens, extremities, etc.), see Subsection 10.4
- Types of operations, including the activity handled per operation and how often the operations are performed, see Subsection 8.2.2.

Use

Detailed description of the undertaking's use of unsealed sources divided into sub-processes. It may be helpful to provide a flowchart illustrating the undertaking's use of unsealed sources. Below are examples of sub-processes in connection with the use of unsealed sources.

- Reception, see Subsection 10.2
- Storage, see Subsection 10.3
- Handling, see Subsection 10.4
- Control of equipment, see Subsection 11.1.1
- Control of radiation safety cabinets, ventilation systems and facilities, see Subsection 8.2.1
- Handling of radioactive waste, including discharge, see Chapter 12
- Carriage of radioactive material, see Chapter 15
- Decommissioning, see Subsection 11.5

Facilities, other interiors, etc.

Description of the facilities applied, etc. must as a minimum include the following points:

- General description of the location of facilities, etc., including adjoining interiors (both above and below) and surroundings, as well as an indication of storage locations, workplaces, worker whereabouts, shielding, etc. Reference may be made to annexes containing relevant layout drawings.

- Description of the design of facilities, etc. Reference can be made to annexes with floor plans showing distances, the dimensions of shielding, walls, floors and windows as well as descriptions of structural materials.
- Description of the ventilation and drainage situation, if applicable.
- Classification of areas based on the above-mentioned description of the unsealed sources and their use, see Subsection 7.1.

Requirements for facilities are described in Chapter 8.

3. Description of radiation protection and optimisation

In this part, radiation protection and optimisation must be explained on the basis of the description of the unsealed sources used, their use, facilities, etc. which are described in Part 2. This can, among other things, be based on the classification of the relevant areas of the undertaking.

Radiation protection arrangements

For each sub-process identified in Part 2, it must be described how distance to the unsealed sources, restrictions on proximity time, access control, use of shielding, work procedures, etc. contribute to reducing exposure and thus optimise radiation protection.

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

Facility construction, see Chapter 8
- Radiation safety cabinet
- Ventilation system (including air exchange)
- Forelab or transitional zone
- Pressure conditions
- Wash basin
- Isotope drain
- Easy to clean surfaces
- Design of facilities, furniture, etc.

Access restriction, see Chapter 7 and 8
- Access control, e.g. access card or guard/staff
- Signage
- Interlock
- Barriers.

Equipment, see Chapter 10
- Personal protective equipment, e.g. gloves, respiratory protection and lab coat
- Additional mobile shielding

- Distancing tools, e.g. pliers or tweezers
- Storage and transport containers.

Dose limitation, see Subsection 10.4

- Distance
- Proximity time
- Shielding
- Limitation of activity and activity concentration.

Monitoring and control, see Chapter 8

- Access to relevant measuring equipment e.g. dose rate meter and contamination monitor
- Programme for control measurements for contamination
- Visual or acoustic alarm on, for example, the radiation safety cabinet and ventilation system
- Third-party inspection of radiation safety cabinet, ventilation system, etc.

4. Cradle-to-grave assessment

The safety assessment should cover the entire period in which a given use is expected to continue. The safety assessment should take into account the aging of installations and equipment, including the specific situation in which it has been decided that an undertaking or activity ceases. If this situation arises and it is acknowledged that the undertaking or the activity is to be terminated, the safety assessment should be reassessed and, if necessary, updated. At the design stage of the establishment of large-scale facilities, ageing, decommissioning, etc. should be addressed in advance and included in the safety assessment. At the transition between the different stages, the Danish Health Authority, Radiation Protection should be involved; see Figure 8.

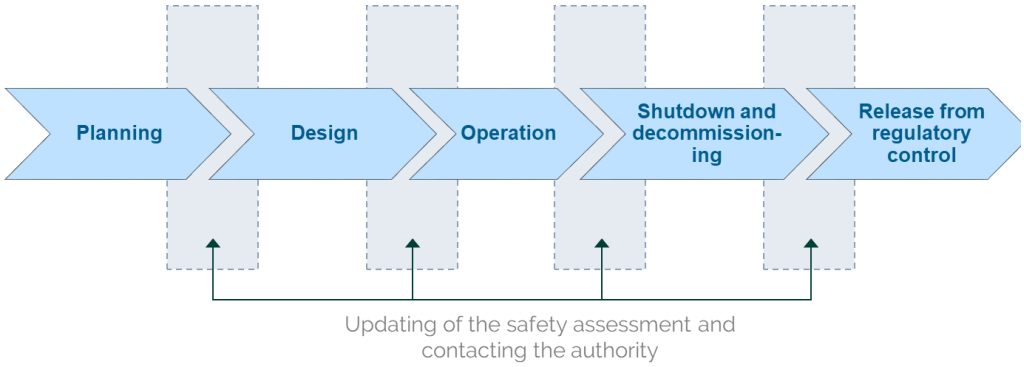


Figure 8
Phases in the cradle-to-grave assessment.

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

5. Calculation of optimised doses during ordinary operation and maximum doses in the event of incidents and accidents

This part lists the radiation doses that may occur in connection with the undertaking's use of unsealed sources described in Part 2, taking into account the radiation protection and optimisation as described in Part 3. In addition, doses due to incidents and accidents are

described. The scenarios for incidents, accidents and emergencies must be realistic even if improbable.

In a safety assessment for the use of unsealed sources, the undertaking must specifically map out when there is a risk of external exposure (including to the hands and eyes), internal contamination of the body and contamination of the environment, respectively. The mapping must include all steps in the management of unsealed sources from acquisition to disposal.

Radiation doses for relevant work processes, incl. control, service and third-party inspection

Doses should be estimated on the basis of calculations, if relevant with references to dose rates, distances (e.g. indicated on floor plans), proximity times, etc. The calculations should be performed on the basis of estimated upper values for proximity times, dose rates, etc. The specific numerical values and other assumptions forming the basis for the calculations should be stated.

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

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

For each sub-process, a table should ideally be provided to show specific radiation scenarios, measures to limit exposure as well as the estimated or calculated doses which different categories of individuals might incur in those scenarios. Example of a table can be found in Table 17.

Table 17
Example of a table presenting specific exposure scenarios, measures to limit the exposure, and the estimated annual dose potentially caused by a given exposure scenario

Scenario	Relevant protective measures	Estimated annual dose to exposed workers, other workers or members of the public
For example sampling from stock solution	E.g. handling instructions, facility design, radiation safety cabinet, additional mobile shielding, shield for syringe, gloves.	Doses are calculated based on radionuclide, activity, distance, etc. The calculation should be done with the guidance of a radiation protection expert. Reference should be made to calculations in appendices, as applicable.

The table is expanded with the number of rows relevant to the use

Determination of doses incurred from incidents or accidents

Incidents: Based on the sub-processes and operating experience, the undertaking identifies realistic, but possibly unlikely, scenarios where unintended exposure may take place. A scenario could be non-compliance with procedures. The dose is assessed on the basis of the presented scenarios. Reference may be made to documentation in annexes for descriptions of the basis and assumptions for calculations.

Accidents : Based on the sub-processes and operating experience, the undertaking identifies realistic, but possibly unlikely, scenarios where unintended exposure may take place. A scenario could be technical failure, common spillage or external influences, e.g. water damage, lightning strike or fires causing exposure or dispersion of radioactive material. The dose is assessed on the basis of the presented scenarios. The assessment may be limited to one or a few scenarios in which a technical failure or fault occurs. Reference may be made to documentation in annexes for descriptions of the basis and assumptions for calculations.

Doses from potential incidents and accidents should ideally be presented in a table, as shown in Table 18.

Table 18
Example of a table presenting specific incidents or accidents, their causes, who is at risk, measures to limit exposure, and the consequences and doses of radiation the exposure scenario might result in

Incident or accident	Cause	Who is at risk	Measures to limit exposure	Consequence incl. radiation doses
Contamination of the skin	Touching contaminated surfaces	Workers Cleaning staff	Control measurement when handling is completed Thorough hand washing	May pose risk of intake as well as doses to the skin Dose is calculated on the basis of the radionuclide, activity, distance, etc. Calculation should be performed under the supervision of a radiation protection expert (See Annex E for assessment of skin dose, if relevant)

The table is expanded with the number of rows relevant to the use

Summary

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

6. Any additional radiation protection measures

In this part, any supplementary radiation protection measures are described which are deemed necessary on the basis of regulatory requirements or the undertaking's own requirements.

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

- Classification of areas, if not already assessed in Part 2, see Chapter 7
- Categorisation of workers, if not already assessed in Part 5, see Chapter 9
- Radiological monitoring, including measuring period, radiological monitoring type and any medical examinations, if not already assessed in Part 5, see Chapter 13
- Quality assurance by means of a quality management system, see Chapter 16
- Competence maintenance, including procedures, recruitment, training, drills, courses, etc., see Chapter 9.2
- Further optimisation, including dose constraints etc., see Subsection 2.2
- Compliance with general occupational health and safety requirements conducive to radiation protection.

7. Conclusion of the safety assessment

In this Part, the undertaking should assess whether there is compliance with the objective established in Part 1.

Compliance with statutory requirements should be described, with reference, as applicable, to relevant annexes covering classification of areas, responsibility and competence factors, etc.

Compliance with the undertaking's own requirements and objectives for radiation protection, including optimisation, should be described.

8. The undertaking's declaration

The safety assessment concludes with the undertaking's declaration that the safety assessment has been carried out thoroughly and adequately and that the safety assessment documents that the undertaking's use of unsealed sources is within the law.

Annex E: Values for assessment of doses from skin contamination

In case of skin contamination, cleaning must be performed as long as it provides an effective activity reduction, see Subsection 14.4. The values in Table 19 can be used to assess the dose from a residual skin contamination, but they do not constitute a criterion for when cleaning can be considered adequate.

The values indicate activity concentrations for residual skin contamination, which are calculated to give a skin dose of 50 mSv. This corresponds to 1/10 of the annual dose limit for exposed workers and is equal to the dose limit for members of the public.[314]

The values are calculated on the basis of an assumption that the contaminant is evenly distributed and remains fixed to the skin for 30 days. Detailed dose assessments should be made in consultation with a radiation protection expert.

For contamination of the skin on smaller areas, e.g. in the form of droplets, where measurement of the activity concentration with a contamination monitor can be difficult, a conservative dose assessment shall be made based on the assumption of the total activity on the skin and the area of contaminated skin.

H-3 is not included in the table as this radionuclide emits only very weak beta radiation, which does result in skin doses.

[314] Annex 1, Executive Order No. 669/2019.

Table 19
Values for assessing doses from skin contamination for the most frequently-used radionuclides

Radionuclide	Remaining skin contamination corresponding to a skin dose of 50 mSv [Bq/cm^2]
C-14	100
F-18	5,000
P-32	50
P-33	100
S-35	100
Cu-64	1,000
Ga-68	10,000
Br-82	500
Zr-89	1,000
Y-90	100
Tc-99m	10,000
I-123	5,000
I-125	1,000
I-131	100
In-111	1,000
Lu-177	100

Annex F: Decision diagram for disposal and transfer

Figure 9
Decision diagram for disposal and transfer of solid radioactive waste

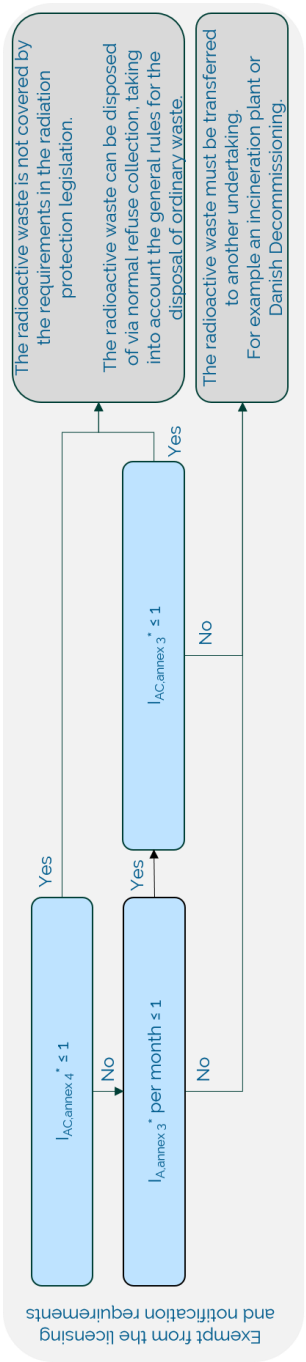
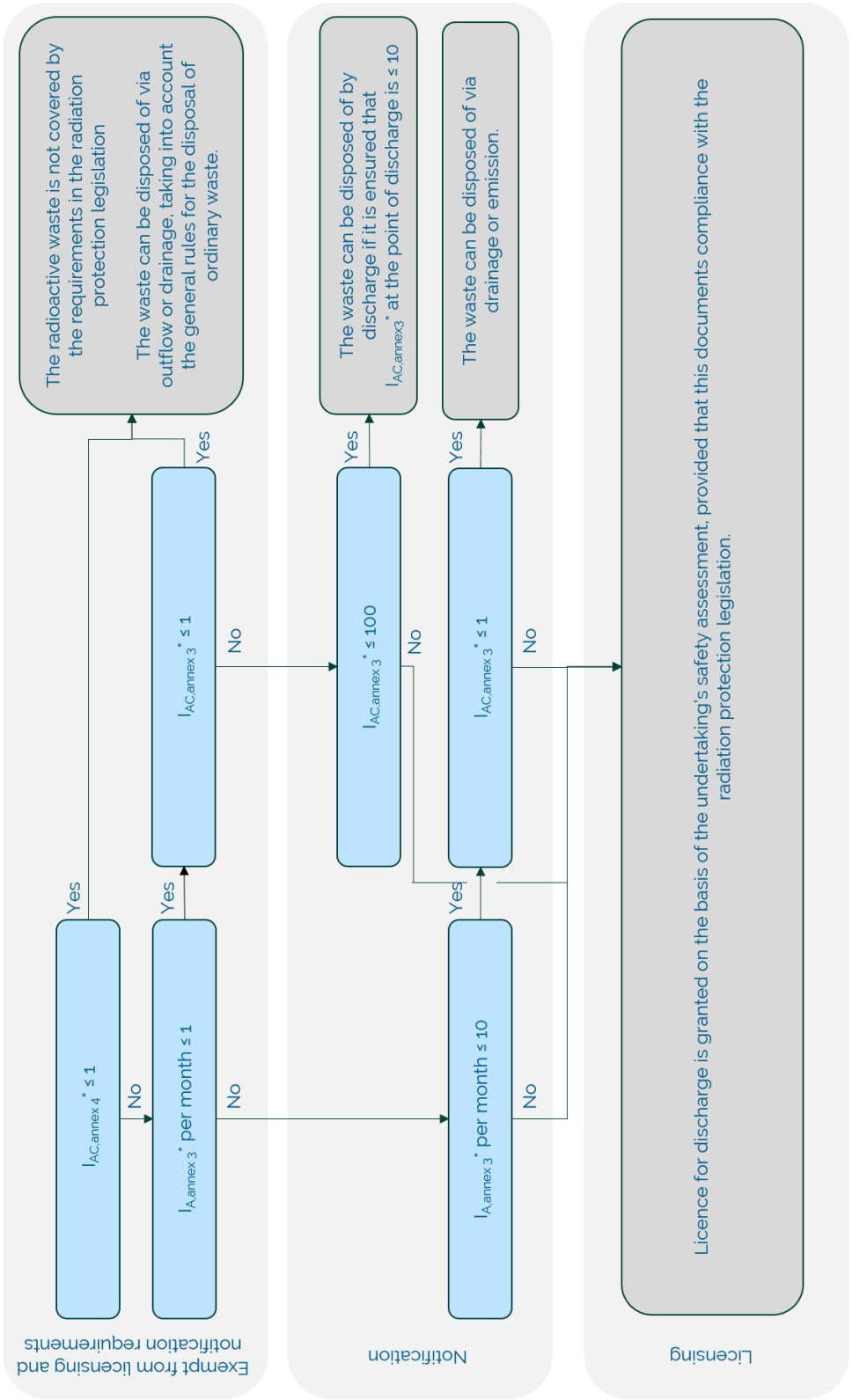


Figure 10
Decision diagram for disposal and transfer of liquid or gaseous radioactive waste



* In Executive Order No.. 670/2019

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