



# Radiation generators

For service companies

Guide



## **Radiation generators**

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# Introduction

The purpose of this Guide is to contribute to correct interpretation and application of the rules regarding use of radiation generators. The rules are laid down in the Radiation Protection Act and related executive orders, which are listed in Chapter 11. The purpose of the rules is to ensure that the use of radiation sources is justified and optimised, and that the dose limits are not exceeded.

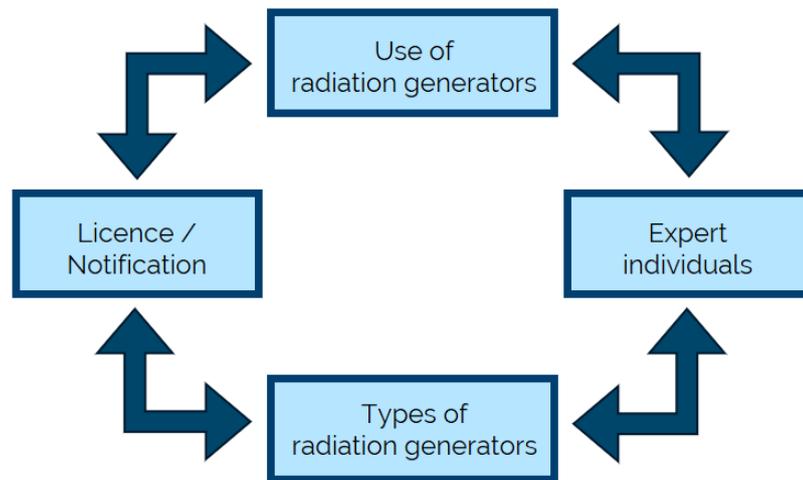
This Guide is aimed specifically at companies that install and perform service on radiation generators. In the Danish legislation on radiation protection the term *undertaking* is used as a general term for any type of company. In this Guide it is convenient to distinguish between different undertakings, and hence, in this guide undertakings or companies that perform service on radiation generators will be referred to as "service companies". Any company responsible for the utilization or application of a radiation generator is also a undertaking in the legal sense, even if that company is, for example, a hospital department. In this Guide, any such company will be termed an "application company" and the Guide is aimed to a lesser extent at these application companies. The terms "*service company*" and "application company" are used in this Guide to distinguish between the two types of undertakings.

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 reiterates the requirements of acts and related executive orders on use of radiation generators and contains the Danish Health Authority's guidelines for achieving compliance with those requirements. Both a service company and an application company can expect to be acting in compliance with the rules if the instructions in this Guide are followed. In the Guide, the focus is particularly on the link between four important areas in the executive orders governing radiation protection and radiation generators, as illustrated in Figure 1.

Figure 1

The four areas in the executive orders addressed by this Guide.



The Guide makes reference in footnotes to relevant sections of acts and executive orders. In the Guide, italicised words and phrases are explained in the glossary in Annex A. For general information on *ionising radiation* and its biological effect, occurrence and *application*, etc., please consult the Danish Health Authority's publication 'Ionising Radiation', as listed in Chapter 11.

The latest version of this Guide is available on the website of the Danish Health Authority, Radiation Protection, [www.sis.dk](http://www.sis.dk).

# 1. 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) and is based on three fundamental principles: justification, optimisation and dose limitation. These principles, which are integral to the Radiation Protection Act, are described below:

## 1.1. Justification

The main principle governing the *use of radiation sources* is that such use shall be justified. This means that the use of radiation sources shall take place solely if the health, financial, societal or other benefits of that use outweigh the detriment.<sup>1</sup>

Assessment of the justification shall include consideration of the options for using alternative methods, which are either a) not based on *radiation*, or b) are based on substantially reduced radiation or risk, or c) are based on radiation from *radiation generators* as instead of radioactive material. The Danish Health Authority's assessment is that any use comprised by this Guide is justified if it complies with the instructions contained herein.

It is the *application company's* duty to assess whether a given use is justified or whether an alternative method, which might not involve radiation, would be more justified to use. In that case, the alternative method must be chosen. In case of doubt, the alternative method shall be trialled first. The application company shall also regularly assess whether its application of radiation sources continues to be justified. This shall be ensured by various means, including the application of a quality management system.

## 1.2. Optimisation

The optimisation principle entails that use of radiation generators shall take place solely if the likelihood and magnitude of exposure, including the number of individuals exposed, are as low as reasonably achievable, taking into account the current state of technical knowledge and financial and societal factors.<sup>2</sup>

"Reasonably" means that *the company* (whether a service company or an application company) shall employ neither too many nor too few protective measures. Instead, the company shall achieve an optimal level of protection under the given circumstances. This will be achieved by means of a continuous process involving 1) assessment of the exposure situation, including potential exposure (accidents), 2) the application of appropriate

<sup>1</sup> Section 16, Executive Order No. 669/2019.

<sup>2</sup> Section 18, Executive Order No. 669/2019.

*dose constraints or reference levels*, 3) identification of potential options for protection, 4) selection of the best option under the given circumstances and 5) implementation of the best option in practice.

In the optimisation process, the company shall take into consideration the exposure of both *workers* and *members of the public*. For use of radiation sources subject to a licensing requirement, the process shall commence with the establishment of a basic *safety assessment* in advance of the company's first use of radiation generators.<sup>3</sup> Regardless of whether the company is a service company or an application company, a safety assessment must be established; see Chapter 7.

### 1.3. Dose limitation

The sum of doses to an individual must not exceed the *dose limits*.<sup>4</sup> The dose limits are set with the purpose to limit the incidence of *late effects* and to prevent the incidence of *tissue effects*. The principle of dose limitation protects the right of all individuals not to be subjected to disproportionately high risks as a result of radiation. The dose limits for *occupational exposure* and *public exposure* from use of radiation sources are shown in Table 1:

Table 1.

Dose limits for occupational and public exposure.

Category of individual	Effective dose limit [mSv/year]	Equivalent dose limit [mSv/year]		
		Lens of the eye	Skin <sup>1)</sup>	Extremities <sup>2)</sup>
<i>Exposed worker, aged 18 years or over</i>	20	20	500	500
Individual aged between 16 and 18 years <sup>3)</sup>	6	15	150	150
<i>Member of the public</i>	1	15	50	-

<sup>1)</sup> The dose limit for the skin applies to any surface of 1 cm<sup>2</sup>.

<sup>2)</sup> Extremities means the hands, forearms, feet and ankles.

<sup>3)</sup> 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 in which the use of radiation sources is a necessary component of that programme.

<sup>3</sup> Section 20, Executive Order No. 669/2019.

<sup>4</sup> Section 23, Executive Order No. 669/2019 (principle not applicable to patients).

## 2. Use of radiation generators

### 2.1. The term "use"

The term "use", in the context of radiation generators, is defined in the Radiation Protection Act<sup>5</sup> and includes any situation in which radiation occurs, regardless of whether or not that radiation is utilized. The use of radiation generators is generally subject to licensing by the Danish Health Authority (for more information about licences, see Chapter 5). The following describes what is meant by use of radiation generators.

#### Use of radiation generators

Pursuant to Section 4 of Executive Order No. 671 of 1 July 2019, use of radiation generators includes the following:

- Manufacture
- Installation
- Application
- Alteration
- Technical safety inspection
- Testing

#### Manufacture of radiation generators

*Manufacture* means production and construction of radiation generators, where radiation is generated in the process.

#### Installation of radiation generators

*Installation* means the assembly, fitting, setting up and connecting of a radiation generator and *equipment* to the application company's utilities (e.g. electricity and water) so that radiation can be generated. Installation involves addressing factors from a radiation protection point of view and thus entails more than simply connecting the device to the power grid by plugging it into an electrical socket. The setting up of, for example, an *X-ray radiation therapy* unit is an installation, whereas the setting up of a *self-shielded radiation generator*, such as an airport luggage scanner, is not considered an installation.

<sup>5</sup> Section 3, No. 2, Act No. 23/2018.

## Application of radiation generators

*Application* means utilization of the equipment for its intended purpose, e.g. imaging, scanning, treatment, etc. Thus, while the terms 'use' and 'application' may be construed as synonymous in other contexts, in this context they do not denote the same. In the legislation on radiation generators, the meaning of 'use' and 'application' is defined differently. Use is broader than application, since use also includes installation, *testing* and *technical safety inspection*. Application is thus a specific type of use. In this Guide, the two terms will be used according to these specific definitions.

In the legislation, application is divided into *medical application* and other types of application. The medical application of radiation generators is the application of such devices for human healthcare. The type of licence required for the different uses and applications differs, as explained in more detail in Chapter 5.

## Alterations to radiation generators

*Alteration* means any work, including cleaning, maintenance and repairs, where that work might have implications from a radiation protection point of view in that it entails, for example, disassembling shielding, disconnecting an interlock system and other manipulation of a radiation generator. Furthermore, alteration in the context of radiation generators for medical application also includes switching between clinical mode and service mode.

## Technical safety inspection of radiation generators

Technical safety inspection means physical checking of the radiation generator's and the equipment's general condition and general safety aspects with regard to radiation protection. This includes examining whether it is safe for users to work with the equipment.

In some instances, these technical safety inspections require separate licensing, while in other instances this is not required.<sup>6</sup> The service company that installs a radiation generator is often also involved in the subsequent task of conducting periodic technical safety inspection and, in some cases, also testing of the radiation generator. The rules regarding the scope and frequency of technical safety inspections are laid down in the legislation<sup>7</sup>, and if the service company performs technical safety inspection, this will typically be planned in consultation with the application company's designated expert individuals. The designated expert individuals are described in Chapter 4.

## Testing of radiation generators

Testing means *acceptance testing* and *performance testing* of the equipment to verify its conformity with pre-defined specifications and applicable *operational limits and conditions*, including whether the equipment operates within given tolerances. Acceptance

<sup>6</sup> Sections 5, 6 and Annex 1, Executive Order No. 671/2019.

<sup>7</sup> Section 19, Executive Order No. 671/2019.

testing and performance testing are solely required for medical application. Acceptance testing is carried out during commissioning, as well as after alterations and repairs. Performance testing is performed at regular intervals to ensure continued conformity with specifications.

## 3. Allocation of responsibilities

### 3.1. Allocation of responsibilities between the company and the employer

Regardless of the type of company concerned, whether it is a service company or an application company, the company has a number of obligations regarding radiation protection in general. Similarly, an *employer* has certain specific obligations in relation to the radiation protection of its workers. The Radiation Protection Act and related executive orders stipulate that the following have a statutory responsibility for compliance:<sup>8</sup>

- The company that is responsible for any use of the radiation generator
- The employer that allows its workers to engage in the use of a radiation generator.

Usually, the same company has all the obligations, as the company will typically be responsible for use of the radiation generator as well as allowing its workers to use the radiation generator. Consequently, in its role as both “company” and “employer”, the company is responsible for compliance with all statutory requirements.

In certain situations, multiple companies may assume a responsibility, for example, if an application company owns a radiation generator, which is serviced by a service company leading to the possibility of exposure of workers from the service company (*outside employer*). In this situation, the service company's workers are to be considered *outside workers* at the application company, and in such cases the application company and the service company each bear their own responsibility and must jointly ensure overall compliance with all requirements.<sup>9</sup>

Thus, a service company installing or performing technical safety inspection of a radiation generator belonging to a client (application company) will be operating as an outside employer at the application company, and the service company's workers could potentially be exposed to radiation at the premises of the application company. The service com-

<sup>8</sup> Section 2(1), Nos. 2-3, Act No. 23/2018.

<sup>9</sup> Sections 11-13, Executive Order No. 669/2019.

pany, as an employer, is consequently responsible for compliance with requirements regarding the training, radiological monitoring, knowledge, skills and competences of its workers, etc.<sup>10</sup>

### 3.2. Allocation of responsibilities within the company

Whether a company is a service company or an application company, it is responsible for regulatory compliance. The company is the legally entity that is responsible for the use of a radiation source, where the company is often registered in a national register with a unique registration number like the Danish central register for companies, CVR. The company can have subsections or departments that use company's radiation sources, but it is the company that is ultimately responsible for complying with the requirements of the Radiation Protection Act and related executive orders.<sup>11</sup>

A service company's or application company's *radiation protection officer* (see Chapter 4) is not personally liable for the service company's or the application company's compliance, but shall assist the company with its compliance. If the radiation protection officer is unable to perform his or her designated duties, or if the company fails to implement the radiation protection arrangements necessary for compliance, the radiation protection officer and, when applicable, the *medical physics expert* shall ensure that the Danish Health Authority is notified.<sup>12</sup>

<sup>10</sup> Section 13, Executive Order No. 671/2019.

<sup>11</sup> Section 11, Executive Order No. 669/2019.

<sup>12</sup> Section 35(2) and (3), Executive Order No. 669/2019.

## 4. Designated expert individuals

The Radiation Protection Act and related executive orders distinguish between three different professional roles pertaining to use of radiation generators subject to the national licensing or notification requirements. These professional roles are termed: the radiation protection officer (RPO), the *radiation protection expert* (RPE) and the medical physics expert (MPE).

Regardless of whether the company is a service company or an application company, the company's radiation protection officer shall monitor or assist in operation of the radiation protection arrangements that are of relevance in relation to the company's use of radiation generators. The radiation protection expert shall advise the company on establishment of the radiation protection arrangements relevant for the company's planned and ongoing use of radiation generators. The medical physics expert shall assist application companies who carry out *medical exposure* within the areas of technology and dosimetry of medical exposure. The duties of designated expert individuals are laid down in the Executive Order on Ionising Radiation and Radiation Protection.<sup>13</sup>

These professional roles shall be performed by individuals with special expertise concerning radiation protection and use of radiation generators. They may each be performed by a single individual or by a group of individuals who collectively possess the needed expertise.<sup>14</sup> In certain cases, based on the nature, scale or complexity of use, the Danish Health Authority may impose requirements for multiple radiation protection officers, radiation protection experts or medical physics experts.

In any event, the designated expert individuals shall be approved by the Danish Health Authority.

### 4.1. Radiation protection officer

For use of radiation generators subject to licensing or notification requirements, the company shall at all times have a radiation protection officer at its disposal.<sup>15</sup> "At its disposal" means that the company and its employees can get in contact with the radiation protection officer rapidly and easily. As this role is usually associated with extensive personal attendance on site, the radiation protection officer will typically be an employee of the company. The radiation protection officer may, however, be contracted as an external consultant, and there is no requirement per se for permanent physical attendance.

<sup>13</sup> Annex 2, Executive Order No. 669/2019.

<sup>14</sup> Section 33(4), Executive Order No. 669/2019.

<sup>15</sup> Section 33(1), Executive Order No. 669/2019.

The approval of a radiation protection officer is granted in response to an application from the company and usually in connection with an application for a licence to use, or a notification of use of, a radiation generator. After approval, radiation protection officers are required to confirm by signature their acceptance of assuming the professional role within the company.<sup>16</sup>

The radiation protection officer shall possess the requisite knowledge, skills and competences for monitoring or overseeing operation of the radiation protection arrangements that are of relevance in relation to the company's use of radiation generators. The radiation protection officer's duties may vary depending on the nature, scale and complexity of that use.

For service companies manufacturing, installing, altering, testing or performing technical safety inspection of radiation generators, the following tasks in particular are relevant for the radiation protection officer to assist with:

- ensuring that use of radiation generators complies with the requirements in the service company's instructions, including introducing workers to the instructions for use of radiation generators;
- ensuring that the service company's instructions for workers comply with applicable regulatory requirements;
- setting up precautions in the event of accidents and incidents; and
- supervising implementation of the *individual dose monitoring* programme.

The service company's radiation protection officer shall also assist in assessing the competences of the service company's workers who use radiation generators. Such assessment shall incorporate the requirements for the competences of exposed workers as prescribed by legislation.<sup>17</sup>

The radiation protection officer shall notify the Danish Health Authority immediately if he/she resigns.<sup>18</sup> Before such resignation, the company shall have obtained the Danish Health Authority's approval of a new radiation protection officer; otherwise, the company loses the right to use radiation generators.

<sup>16</sup> Section 35(1), Executive Order No. 669/2019.

<sup>17</sup> Annex 6, Executive Order No. 671/2019.

<sup>18</sup> Section 35(3), Executive Order No. 669/2019.

## 4.2. Radiation protection expert

For any use of radiation generators subject to the licensing requirement, the company 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.<sup>19</sup> This may be relevant for both a service company and an application company depending on the types of radiation generators at issue. "Consult" means that the expert shall be involved in specific radiation protection issues, such as the format of the safety assessment and any physical or operational alterations with implications for radiation protection. Since this role is not associated with extensive personal attendance on site, the radiation protection expert will typically not be employed by the company, but contracted as an external consultant to deal with a specific issue.

A radiation protection expert must be approved by the Danish Health Authority and any company contracting a radiation protection expert should therefore verify that the radiation protection expert holds valid approval. Radiation protection experts are approved based on personal application by the expert for specific types of use, and the radiation protection expert will thus solely be permitted to advise companies practising the types of use for which approval has been granted. Approval is granted for a term of 5 years<sup>20</sup>, after which the radiation protection expert must apply for a renewal.

The contracted radiation protection expert shall possess the requisite knowledge, education and experience for advising on the implementation or modification of the radiation protection arrangements that are relevant for the company's use of radiation generators.<sup>21</sup> The radiation protection expert's duties are laid down in the Executive Order on Ionising Radiation and Radiation Protection.<sup>22</sup>

## 4.3. Medical physics expert

A medical physics expert is solely required for application companies licensed for medical application of radiation and is thus not relevant for service companies that solely manufacture, install, alter, test or perform technical safety inspections of radiation generators. For medical applications of most types of radiation generators, an application company shall, in addition to a radiation protection officer, have a medical physics expert at its disposal.<sup>23</sup>

<sup>19</sup> Section 33(2), Executive Order No. 669/2019.

<sup>20</sup> Section 34(3), Executive Order No. 669/2019.

<sup>21</sup> Section 34(2), Executive Order No. 669/2019.

<sup>22</sup> Section 33(2), Executive Order No. 669/2019.

<sup>23</sup> Section 33(3), Executive Order No. 669/2019.

## 5. Licensing, notification and exemption

The Danish Health Authority applies three levels of regulatory control: licensing, notification and exemption – commensurately with the risk posed by a given use. By default, use of any radiation generator is subject to licensing, which is the highest level of regulatory control.

In cases where use is associated with a low risk, there is no requirement for licensing, and the company shall instead notify the Danish Health Authority of the use. In cases where the risk is so low that there is no need at all for radiation protection arrangements, the company is exempt from the licensing or notification requirements.

### 5.1. Licensing

Any use of radiation generators, as described in Chapter 2, is generally subject to licensing<sup>24</sup>. However, certain exceptions apply.<sup>25</sup> These exceptions are described in Section 5.3.

A service company intending to perform any of the tasks defined as 'use' shall apply for a licence for such use, regardless of whether or not the service company is responsible for the radiation generator. See Chapter 3 on allocation of responsibilities.

However, solely the company responsible for the radiation generator may apply for a licence for the specific type of use that is termed 'application'. A licence for application, like for any other use, requires the application company to retain the services of a radiation protection officer. For medical application of most types of radiation generators, the application company shall also have a medical physics expert at its disposal in addition to a radiation protection officer.

Consequently, a licence for application is, as a rule, not needed for manufacturers and service companies that solely manufacture, install, alter, test or perform technical safety inspection of radiation generators.

When a service company applies for a licence to use of radiation generators from the Danish Health Authority, it must provide information on

- what types of use it is applying to be licensed for
- what types of radiation generators it is applying for a licence to use

<sup>24</sup> Section 4 and Annex 1, Executive Order No. 671/2019.

<sup>25</sup> Section 5, Executive Order No. 671/2019.

- the name and birthdate (or CPR-number if Danish citizen) of the individual seeking to be approved as a radiation protection officer. Since the individual performing that particular role must be approved by the Danish Health Authority, it is helpful to attach relevant course certificates and possibly a signed CV to substantiate the qualifications of the proposed radiation protection officer.

The service company's workforce shall possess the requisite technical and practical skills for all the types of radiation generators for which it is seeking a licence. If the service company's portfolio of radiation generators is extensive and diversified from a radiation protection point of view, it is recommended that the service company retain multiple radiation protection officers, each of whom have expertise in specific types of radiation generators, but who jointly cover the entire portfolio.<sup>26</sup>

### Application for a licence for use

The application for a licence for use shall contain the following:

- The types of use to be covered by the licence; cf. Section 4, Executive Order No. 671/2019
- The types of radiation generators that are to be used, e.g. dental, *veterinary application*, *industrial radiography* or medical diagnostics
- The name, birthdate (or CPR-number if Danish citizen) and contact details of the radiation protection officer.

Applicants are recommended to submit relevant course certificates and a signed CV substantiating the radiation protection officer's qualifications.

Types of radiation generators and their use must be indicated in the application in terms of generic categories. For applicants using the standard form at [www.sis.dk](http://www.sis.dk), these categories are presented in a list as e.g. dental, veterinary, medical diagnostics, *radiotherapy*, industry, etc.

### Licence for manufacture

Any manufacturing of radiation generators requires a licence if radiation is generated during any stage of manufacturing. A licence is required solely if manufacture and construction take place in Denmark. Thus, a company that manufactures radiation generators where that manufacturing takes place outside Denmark is not required to hold a manufacturing licence in Denmark.

<sup>26</sup> Section 33(4), Executive Order No. 669/2019.

### Licence for installation

A service company must hold a licence for installation of radiation generators if it undertakes installation in Denmark. A typical situation would be that a service company (e.g. a supplier) installs a radiation generator at a client's site, and in this situation, it is the service company that must be licensed for installation, not the client. This means that a manufacturer/supplier from outside Denmark that installs radiation generators in Denmark is required to hold a licence for installation.

### Licence for alterations

A licence is required for alterations that might have implications for radiation protection. Alteration covers any manipulation of the radiation generator that might render it into a state of non-conformity with the technical requirements, even if the alteration is only temporary in nature. This would include the mounting and demounting of shielding, bypassing of security switches or making an alteration of an emergency stop. It is important to take note of the expression "might have", since alterations comprise not only those that would impact radiation protection with absolute certainty, but also any alterations that would only potentially affect radiation protection. Following any alteration of a radiation generator, the service company responsible for that alteration shall ensure that the radiation generator is in a satisfactory technical state from the point of view of safety before any application of the radiation generator.<sup>27</sup>

Radiation generators for medical application typically have a clinical mode of operation in which a number of built-in safety features ensure that irradiation is delivered exactly as prescribed for a given patient. If the equipment permits switch of mode of operation from clinical to a service-only mode in which such safety features are disabled but in which the radiation generator can still emit radiation, then the act of setting the radiation generator to run in its service-only mode is regarded as an alteration requiring a licence.

Conversely, the application company's ordinary alterations of examination protocols such as adjusting kV, mA and exposure time fall under optimisation<sup>28</sup> and are thus not regarded as being alterations subject to the licensing requirement. If alterations are made to the configuration or examination protocols during technical safety inspection, testing or any other service, the individual making such alterations shall immediately communicate those alterations to all relevant individuals with a 'need to know' in the application company.<sup>29</sup>

### Licence for technical safety inspection

All radiation generators shall periodically undergo technical safety inspection to assess their status.<sup>30</sup> The application company licensed for applications of each radiation generator is responsible for ensuring that technical safety inspection is duly carried out, and the task of performing the technical safety inspection can, on request from the application

<sup>27</sup> Section 53, Executive Order No. 671/2019.

<sup>28</sup> Section 18, Executive Order No. 669/2019.

<sup>29</sup> Section 26, Executive Order No. 671/2019.

<sup>30</sup> Section 19, Executive Order No. 671/2019.

company, be carried out by a third party (a service company) licensed to perform technical safety inspection.

The technical nature of most types of radiation generators entails that technical safety inspection requires a licence from the Danish Health Authority. It is the company that performs the technical safety inspection that is required to hold a licence. If an application company hires a service company to perform technical safety inspection, the service company must hold a licence for technical safety inspection. If the application company performs the technical safety inspection itself, the application company must be licensed for technical safety inspection. As a special case, for radiation generators for medical examinations, the licence for technical safety inspection is part of the licence for application.<sup>31</sup>

For certain other types of radiation generators, the nature of the technical safety inspection is such that performing the inspection does not require a licence from the Danish Health Authority. Such a technical safety inspection is subject solely to a requirement for notification of technical safety inspection, which will typically be made under the notification of application. The types of radiation generators exempt from the requirement for licensing for technical safety inspection but subject to the requirement for notification of technical safety inspection are identified in the legislation<sup>32</sup> as well as in Section 5.2.

#### **Licence for acceptance testing and performance testing**

Acceptance testing and performance testing are a statutory requirement solely for radiation generators for medical application. The application company is the company responsible for ensuring that acceptance and performance testing is performed, but the testing may be performed by a third party (service company) licensed to perform acceptance and performance testing of the given type of radiation generator.

The company that performs the tests is the one that must hold a licence for performing acceptance and performance testing from the Danish Health Authority and therefore must retain the services of a radiation protection officer possessing the requisite knowledge, skills and competences.<sup>33</sup>

The employees who perform acceptance testing and performance testing shall likewise possess competences suited for the tasks performed for the given type of radiation generator.<sup>34</sup>

#### **Application processing**

Upon submission of an application for a licence for use to the Danish Health Authority, the service company will be sent a draft licence and a signature sheet to be signed by the service company's expert individuals. Upon submission of the signature sheets, the service company will be sent the final licence from the Danish Health Authority. The service

<sup>31</sup> Section 6, Executive Order No. 671/2019.

<sup>32</sup> Annex 1, Executive Order No. 671/2019.

<sup>33</sup> Annex 2, Item 5, Executive Order No. 671/2019.

<sup>34</sup> Annex 6, Item 1, Executive Order No. 671/2019.

company must be in receipt of the final licence before it commences any use of radiation generators.

## 5.2. Notification

Some types of use of certain types of radiation generators are exempt from the licensing requirement but are subject to a notification requirement.<sup>35</sup>

### Types of radiation generators and their use which are exempt from the licensing requirement but subject to the notification requirement

- **Radiation generators for medical use**
  - Radiation generators for intraoral radiography with a voltage of up to 70 kV – except for hand-held radiation generators: **Application** is exempt from the licensing requirement, provided that such application is confined solely to the application company's own premises.
  - Dental panoramic radiography equipment and cephalostats: **Application** is exempt from the licensing requirement, provided that it is confined solely to the application company's own premises.
- **Radiation generators for veterinary medical use**
  - Radiation Generators for veterinary examinations – except CT Scanners, hand-held radiation generators and radiation generators for fluoroscopy: **Application** is exempt from the licensing requirement, provided that it is confined solely to the application company's own premises.
  - **Technical safety inspection**, except for testing of conformity with operational limits and conditions, is exempt from the licensing requirement for radiation generators for veterinary intraoral radiography up to 70 kV.
- **Radiation generators for industrial use**
  - Hand-held radiation generators and self-shielded radiation generators except for radiation generators for blood irradiation and sterilisation purposes: **Application and technical safety inspection** are exempt from the licensing requirement.

The Danish Health Authority must be notified before use commences.<sup>36</sup> As it is stated in the information box above, notification is specifically for application and technical safety

<sup>35</sup> Annex 1, Executive Order No. 671/2019.

<sup>36</sup> Section 7, Executive Order No. 671/2019.

inspection of the mentioned types of radiation generators. I.e. the application of the radiation generator is not allowed to commence before the notification is sent to the Danish Health Authority. Notification must be carried out in accordance with the procedures published at [www.sis.dk](http://www.sis.dk). When the notification is sent to the Danish Health Authority, the web-form automatically returns a confirmation of reception of the notification, and the use of the radiation generator can now commence.

### 5.3. Exemption

Use of radiation generators operating with a voltage less than or equal to 5 kV is exempt from both licensing and notification requirements.<sup>37</sup> This use is not subject to any requirements in relation to licensing by or notification to the Danish Health Authority, and the radiation generator is not subject to any registration requirement. Although the use is exempt from the licensing and notification requirements, the use must still be justified. Similarly, the application of electron microscopes is exempt<sup>38</sup>, however, the exemption for electron microscopes does not apply to their manufacture or alteration.<sup>39</sup>

<sup>37</sup> Section 1(1), Item 2, Executive Order No. 669/2019.

<sup>38</sup> Section 2(1), Item 3, Executive Order No. 669/2019.

<sup>39</sup> Section 2(4), Executive Order No. 669/2019.

## 6. Radiation generators' operational cycle

During the operational cycle of a radiation generator, periodic technical safety inspections and tests shall be carried out and the associated records updated.

### 6.1. Acceptance and performance testing (medical application only)

Acceptance testing must be performed after installation of a new radiation generator and after the repair of or alterations to an existing radiation generator if the alterations might have had implications for radiation protection.

Performance testing is a periodic verification that the radiation generator conforms to the pre-defined specifications and applicable operational limits and conditions, including whether the equipment operates within given tolerances. The interval between the periodic performance tests must not exceed 13 months.<sup>40</sup> However, for radiation generators for intraoral radiography, the interval is extended so that performance testing for these shall be carried out at intervals not exceeding 10 years. Performance testing typically requires special measuring equipment and special technical skills, and the application company can therefore contract a service company to carry out the performance testing.

In addition, for some radiation generators there is a need to carry out routine *constancy testing* to ensure that selected parameters for the radiation source and equipment constantly remain within the established tolerances.<sup>41</sup> The measurements may be either of the same type as the performance tests or supplemental to the performance tests and conducted by means of other measuring equipment. For the majority of radiation generators for examinations, the nature of the constancy testing is such that it may be carried out by the application company itself. Constancy testing must be carried out more frequently than performance testing, for example monthly, weekly, or maybe even daily in order to rapidly detect and rectify any anomalies. There are no specific regulatory requirements for the interval between constancy tests, but recommendations are provided in guides for certain types of use, or intervals may be agreed upon in consultation with the medical physics expert.

Figure 2 is a flowchart illustrating the typical operational cycle for a radiation generator for medical application. The figure shows the relationship between acceptance testing and performance testing, and the situations in which each test is to be conducted.

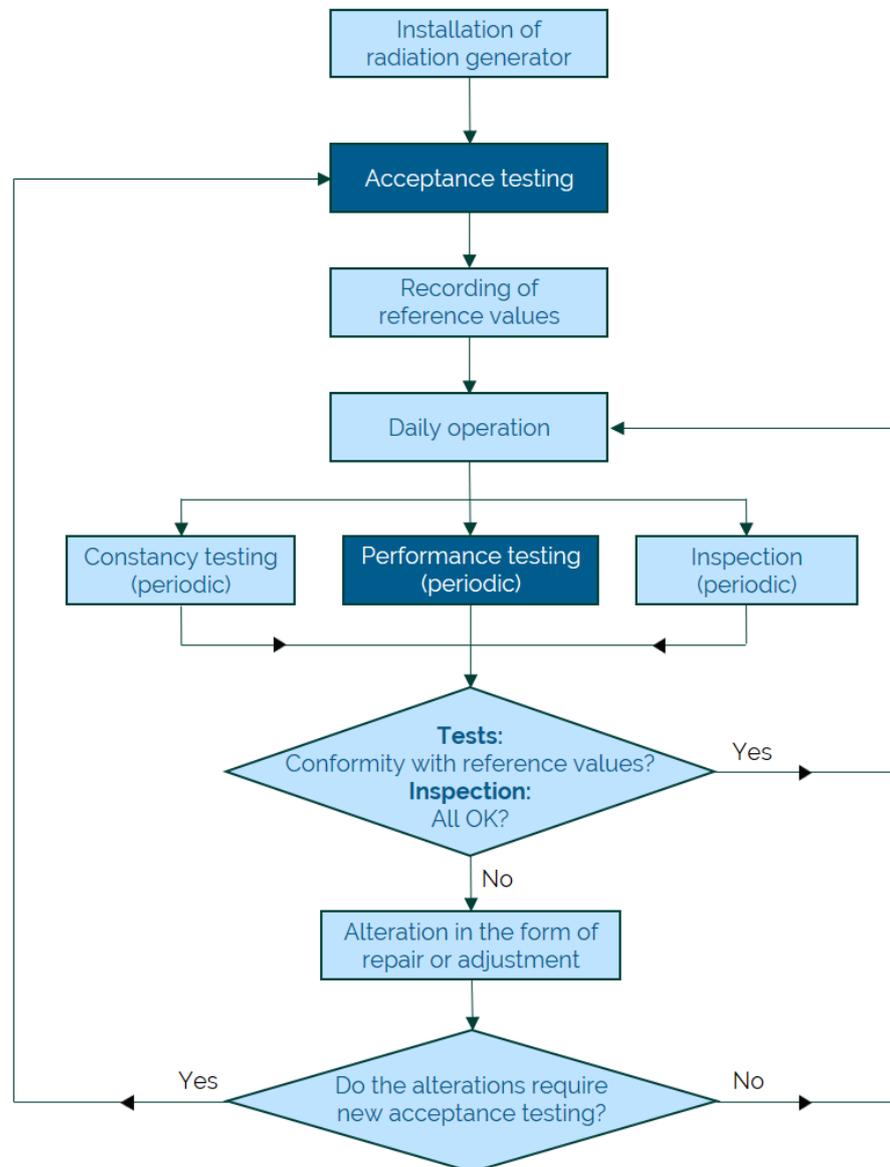
<sup>40</sup> Section 25, Executive Order No. 671/2019.

<sup>41</sup> Section 71(1), Executive Order No. 669/2019.

Figure 2

Flowchart for a typical operational cycle for a radiation generator for medical application.

The acceptance testing and performance testing boxes are colour-coded to highlight their mutual position in the operational cycle, in order thereby to illustrate the difference between the two types of tests.



For each acceptance or performance test, the service company that performs the test shall issue a test report presenting the results of the test to the application company that owns the radiation generator.<sup>42</sup> The results of acceptance tests shall be retained by the application company throughout the lifetime of the radiation generator. For performance tests, a record shall be retained so that the results of the performance tests may be compared over time in order to assess any trends in the measurements. The results of the last five performance tests shall be retained by the application company.<sup>43</sup>

<sup>42</sup> Section 70(4), Section 71(5), Executive Order No. 669/2019.

<sup>43</sup> Section 71(6), Executive Order No. 669/2019.

Recommendations regarding testing of selected types of radiation generators are provided in separate guides for the different applications and are available for download at [www.sis.dk](http://www.sis.dk).

## 6.2. Technical safety inspections and technical safety inspection reports

Application companies shall keep an inventory of the radiation generators they use, which shall state the date of the latest technical safety inspection and the latest date for the next one.<sup>44</sup> The last three technical safety inspection reports shall be retained by the application company. The name of the service company and of the individual who performed the technical safety inspection shall be stated in the inspection report. The service company that performed the inspection is thus required to submit an inspection report to the application company, stating the results of the technical safety inspection.

The technical safety inspection report shall, as a minimum, also state the following:

- Date of the technical safety inspection
- Radiation generator, room and department
- The items assessed during the technical safety inspection
- The result of assessment against criteria (e.g. OK/not OK)
- Where quantitative measurements are included, a record of
  - measurement data expressed in a sufficient number of significant digits
  - tolerances
- Any remarks/corrective actions
- Name or initials of the individual who performed the technical safety inspection.

The above data shall be specifically stated in the report and must not be conveyed by the file name alone.

Any built-in self-tests (the device's integral program for testing the condition of the device) shall be assessed against minimum requirements in applicable national and international technical standards of relevance to the specific use from a radiation protection point of view.

The interval between technical safety inspections must not exceed 13 months.<sup>45</sup> The radiation generator must be labelled with information of the date of the latest technical safety inspection as well as the latest date for the next technical safety inspection, or the information shall be made easily accessible by other means to anyone using or handling the radiation generator.<sup>46</sup>

<sup>44</sup> Section 9(6), Executive Order No. 671/2019.

<sup>45</sup> Section 19(1), Executive Order No. 671/2019.

<sup>46</sup> Section 14, Executive Order No. 671/2019.

### 6.3. Registration and de-registration of radiation generators and facilities

#### Registration

Radiation generators and *facilities* shall be registered with the Danish Health Authority – except, however, for the radiation generators mentioned in Section 5.3. The responsibility for registration rests with the company responsible for the radiation generator or the *facility* (the application company). However, it is not of specific importance who submits the registration, and this task may thus be delegated to the distributor/supplier (the service company).

The registration of a new radiation generator and associated facilities shall be performed by completing the Danish Health Authority's online form at [www.sis.dk](http://www.sis.dk) and attaching the required documentation. A guide to completing the form is also available at the website.

The requirement for registration applies to any radiation generator for which the use is subject to the licensing or notification requirements. Moreover, all facilities shall be registered. For any radiation generator in regular use at the same facility, registration of the facility shall be carried out as part of the registration of the radiation generator. Note that a facility is defined as: 'interiors, including laboratories, radiography rooms as well as storage and waste storage rooms and their associated structural elements constructed and furnished to provide radiation protection during use of radiation sources, and vehicles constructed and furnished to provide radiation protection during use of radiation sources'. The registration of 'stand-alone facilities' without a radiation generator is not addressed in this Guide. Questions regarding this may be addressed to the Danish Health Authority.

For the purpose of registering a radiation generator, it is assigned a unique Danish Health Authority ID number; the *SST-id*. The *SST-id* must be quoted in any subsequent correspondence with the Danish Health Authority concerning the radiation generator in question.

#### De-registration

Radiation generators and facilities that are decommissioned shall be de-registered with the Danish Health Authority.<sup>47</sup> The responsibility for de-registration rests with the company that owns the radiation generator/facility, i.e. the application company, but the de-registration task may be delegated to the service company (which may be a distributor or supplier), for example when replacing a radiation generator. In the event of a replacement, de-registration may be done using the same online form that is used for registering the new radiation generator, and in other cases, for example where a company is closed,

<sup>47</sup> Section 8(3), Executive Order No. 671/2019.

the de-registration may be done by emailing [sis@sis.dk](mailto:sis@sis.dk). Any de-registration must quote the radiation generator's SST-id.

Before any final disposal of a radiation generator it shall be ensured that the radiation generator is no longer capable of generating radiation.<sup>48</sup> Prior to final disposal, any radiation warning sign on the radiation generator should be removed or struck out to prevent the warning sign from subsequently causing uncertainty concerning the risk of exposure. In addition, the radiation generator may contain environmentally hazardous substances which must be disposed of safely, in accordance with other relevant legislation.

#### 6.4. Fee for use of a radiation generators

Pursuant to the Ministry of Health's Executive Order No. 1111/2019, the Danish Health Authority charges an annual fee to cover the costs of *regulatory inspection*, advice, assistance and administration incurred from the use of radiation generators subject to the licensing or notification requirements. The fee is charged to owners of radiation generators and the specific tariffs for the different types of radiation generators are set in relation to the complexity of the application as well as the risk posed by the radiation generator, for example whether it is movable and the magnitude of the dose it is capable of delivering.

The fee is charged for one calendar year at a time. A company is required to pay the fee for the whole year, regardless of how many days of that year the radiation generator has been registered.

The fee tariffs are adjusted once a year and the current tariffs are published on the Danish Health Authority's website.

<sup>48</sup> Section 21, Executive Order No. 671/2019.

# 7. Safety assessment

## 7.1. Systematic review of safety and radiation protection

The use of radiation generators subject to the licensing requirement requires a safety assessment.<sup>49</sup> The safety assessment is a general document concerning the company's aggregate use, as opposed to its use of a specific piece of equipment. Both the service company and the application company shall perform a safety assessment in relation to their respective use. The safety assessment is a systematic review of all factors of relevance for safety and radiation protection entailed by the planned use. It typically comprises a cradle-to-grave description of the radiation risks, safety functions, siting, radiation protection arrangements, the design and robustness of the radiation generator or facility as well as human factors. The safety assessment involves factors concerning facilities and radiation generators as well as work procedures, and the application company's safety assessment may therefore include inputs from the manufacturer or the service company.

The purpose of the service company's safety assessment is to ensure the optimisation of radiation protection and the service company's compliance with all relevant requirements for safety and radiation protection during normal service tasks, anticipated operational incidents and in the event of accidents. In the process of carrying out the safety assessment, the service company typically identifies, elaborates on and improves a number of relevant circumstances, features and arrangements, e.g. procedural descriptions and safety equipment for specific service tasks. The service company then identifies and selects the most appropriate radiation protection solutions to be implemented for the purpose of service tasks. The process is not complete until the necessary radiation protection measures have been adequately identified so as to ensure compliance with all relevant safety and radiation protection requirements during the performance of service tasks.

For the application company, the purpose of the safety assessment is to ensure the optimisation of radiation protection and the company's compliance with all relevant requirements for safety and radiation protection in normal operations, anticipated operational incidents and in the event of accidents. When the safety assessment is initiated, the application company typically identifies, elaborates on and improves a number of relevant circumstances, features and arrangements such as potential doses and appropriate dose constraints. The application company then identifies, selects and implements the most appropriate radiation protection solutions. The procedure is not concluded until the radiation protection has been sufficiently optimised and compliance has been achieved with all relevant requirements for safety and radiation protection.

<sup>49</sup> Section 20(1), Executive Order No. 669/2019.

## 7.2. Report

The service company shall describe the safety assessment in a report. The report constitutes the documentation that relevant requirements for safety and radiation protection have been addressed and that the arrangements implemented by the service company are deemed sufficient to ensure the optimisation of radiation protection. The report shall be submitted to the Danish Health Authority as part of the licence application.

Assessment and updating of safety arrangements remain relevant for as long as the company is licensed to use radiation generators.<sup>50</sup> Where major changes are planned regarding safety and radiation protection arrangements, work procedures, radiation generator type and magnitude or the like, a renewed safety assessment shall be performed. A renewed assessment shall be documented in a separate report for submission to the Danish Health Authority.

## 7.3. Scope

The safety assessment shall be of a suitable scope commensurate with the risk associated with the particular use of radiation generators. For service companies, this typically depends on the types of radiation generators the service provision involves, by what means and how often the service is provided, the reliability and complexity of systems and components as well as their accessibility for maintenance, technical safety inspection, testing and repair.

The Danish Health Authority's recommendations for conducting safety assessments are in accordance with the IAEA's recommendations.<sup>51</sup>

<sup>50</sup> Section 20(2), Executive Order No. 669/2019.

<sup>51</sup> Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev 1), 2016.

## 8. Quality assurance

*Quality assurance* denotes all planned and systematic actions, including quality control, necessary to provide adequate assurance that a radiation source, a facility, equipment, a system or component or procedure will perform satisfactorily in compliance with agreed standards. In order to achieve quality assurance, the Danish Health Authority requires the use of radiation generators to proceed in accordance with a *quality management system*.<sup>52</sup> Quality assurance is taken to mean all the necessary measures, such as regular testing, to be carried out in order to ensure that the use of radiation generators proceeds in conformity with agreed standards. The purpose is to maintain radiation protection, for example by preventing or detecting incorrect use of radiation generators or defects in radiation generators, equipment and facilities. An effective quality management system enables both the application company and the service company to document that its ongoing use of radiation generators is in compliance with the rules.

To that end, service companies shall establish and maintain a quality management system commensurate with the nature and scale of their use of radiation generators. This means that the greater the risk associated with their use, the stricter the requirement for the quality management system. The risk is assessed on the basis of, for example, shielding, mobility, complexity of use and risk of wear.

The quality management system shall reflect the service company's current use of radiation generators, i.e. the types of service tasks performed. The quality management system shall consequently substantiate that relevant documents such as procedures, safety assessments, security and *emergency response plans* and other relevant plans, inventories, registers, protocols and the like are up-to-date and available and can be submitted to the Danish Health Authority upon request.<sup>53</sup>

### 8.1. The basic elements of the system

The quality management system shall, where relevant, ensure and/or, by means of inventories, protocols, registers and the like, document that<sup>54</sup>

- the safety assessment is up-to-date
- workers have received relevant information, training and instruction
- the listing of exposed workers is up-to-date
- the knowledge, skills and competences of exposed workers are appropriate
- exposed workers have the requisite qualifications
- exposed workers have been correctly categorised

<sup>52</sup> Section 93, Executive Order No. 669/2019.

<sup>53</sup> Act No. 23/2018, Section 18(2).

<sup>54</sup> Section 3, Executive Order No. 10/2018; Sections 20, 38, 45, 57, 86, 93, 94, Executive Order No. 669/2019; Sections 9 and 19, Executive Order No. 671/2019.

- the date of the most recent annual health review of Category A workers has been recorded
- exposed workers' dose records are available and retained for 5 years
- instructions concerning use and precautions in the event of accidents are up-to-date
- all radiation protection, security and emergency procedures are revised at suitable intervals
- all reviews are performed in accordance with written instructions for that purpose, and that the results are retained and recorded systematically and initialled by the reviewer
- all the company's radiation generators and facilities have been inventoried in accordance with the specific requirements for such records.

## 9. Emergencies, accidents and incidents

In the event of an emergency, accident or incident involving a use of a radiation generator, the company shall promptly take all the relevant measures to avert or limit serious adverse consequences to human health and safety and quality of life.<sup>55</sup> Relevant measures would typically be to

- suspend operation
- notify the radiation protection officers within both the service company's own organisation and that of the application company
- notify the Radiation Protection Unit of the Danish Health Authority.

If operation cannot be suspended immediately, additional appropriate measures would be to

- evacuate all persons from the site
- prevent access to the site where the *dose rate* exceeds 60  $\mu\text{Sv/h}$
- keep the site under continual surveillance.

### 9.1. Systematic factors

Incorrectly constructed radiation generators, facilities or equipment, insufficient procedures for use and calibration, or equipment with recurring defects may result in *unintended exposure*. These are referred to as systematic factors. A systematic factor would,

<sup>55</sup> Section 91, Executive Order No. 669/2019.

for example, be if an insufficient procedure is repeated or if defects extend to multiple radiation generators or appliances of the same type as a result of a manufacturing defect. Information about systematic factors may be of substantial value from a radiation protection point of view, since it will permit accidents to be averted for a greater number of users of the same type of radiation generators or equipment both nationally and internationally.

## 9.2. Instructions regarding precautions

The service company shall ensure that readily comprehensible instructions are available for its workers on precautions to be taken in the event of an emergency, accident or incident.<sup>56</sup> The instructions shall be readily available during the work and should comprise all relevant measures as well as a description of how they are to be implemented. The instructions should also include notification of the Danish Health Authority and of the service company and the application company and their radiation protection officers.

## 9.3. Notifying the Danish Health Authority

The Danish Health Authority shall be notified promptly<sup>57</sup> in the event of:

- emergencies, accidents or incidents that have resulted in unintended exposure
- any discovery, theft, loss, fire, flooding or the like of significance from a radiation protection point of view
- incidents that could have resulted in the above – the service company and the application company shall both determine the likelihood that an incident might have resulted in unintended exposure, and whether the service company and the application company are thereby subject to the notification requirement. In case of doubt, they should contact the Danish Health Authority.
- cases in which the design or functioning of a radiation generator, including any serious defect or deficiency or repeated incorrect use or a work procedure, might result in unintended exposure.

Notify the 24-hour Emergency Service, Radiation Protection Unit, Danish Health Authority by calling 44 94 37 73.

<sup>56</sup> Section 57, Executive Order No. 669/2019.

<sup>57</sup> Section 14, Act No. 23/2018.

## 10. Regulatory inspection

*Regulatory inspection* is a process, where the authorities supervise the companies to ensure, that they comply with the legislation. This type of inspection is therefore not to be confused with the technical safety inspection of a radiation generator (see Chapter 6.2).

The Danish Health Authority conducts regulatory inspections of companies that use radiation generators, their facilities and equipment.<sup>58</sup>

Regulatory inspections are conducted either by on-site inspection of the service company or application company or by administrative inspection off-site where documentation must be submitted to the Danish Health Authority.

Any changes required by the Danish Health Authority following a regulatory inspection shall be carried out before expiry of the deadline set by the Authority. The Danish Health Authority may prohibit use of radiation generators, facilities and equipment until such changes have been carried out.<sup>59</sup>

The Danish Health Authority may at any time and without a court order demand access to radiation generators, facilities and equipment together with relevant information and materials, such as quality management systems, tests, documentation, etc.<sup>60</sup>

The Danish Health Authority will summarise and publish the most important results of its regulatory inspections.<sup>61</sup>

<sup>58</sup> Section 18, Act No. 23/2018.

<sup>59</sup> Section 19, Act No. 23/2018.

<sup>60</sup> Act No. 23/2018, Section 18(2).

<sup>61</sup> Section 22, Act No. 23/2018.

# 11. Acts, executive orders, etc.

The governing act and the executive orders in force at any time are available for download at [www.retsinformation.dk](http://www.retsinformation.dk). Publications by the Danish Health Authority are available for download at [www.sis.dk](http://www.sis.dk).

## Governing act and executive orders

- Ministry of Health Act No. 23 of 15 January 2018 on Ionising Radiation and Radiation Protection (Radiation Protection Act).
- Danish Health Authority Executive Order No. 669 of 1 July 2019 on Ionising Radiation and Radiation Protection.
- Danish Health Authority Executive Order No. 671 of 1 July 2019 on Use of Radiation Generators.
- Ministry of Health Executive Order No. 1111 of 7 November 2019 on Fees Charged for the Danish Health Authority's Regulatory Inspection, Advisory and Assistance Services. (In Danish only).
- Ministry of Employment Executive Order No. 10 of 5 January 2018 on Medical Examinations Pertaining to Potential Occupational Exposure to Ionising Radiation.

## Other literature

- Danish Health Authority publication: Ionising Radiation – Exposure Pathways in Denmark (2019).
- Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev 1), 2016.

## Annex A: Glossary

In this Guide, the following definitions shall apply:

<i>Absorbed dose:</i>	The quantity of ionising radiation absorbed by a body, measured (usually in grays) as the energy absorbed per unit mass.
<i>Acceptance testing:</i>	Testing carried out for medical applications, prior to clinical commissioning and after any alterations and repairs, to ensure that the radiation generator and equipment conform to the pre-defined specifications and applicable operational limits and conditions.
<i>Alteration:</i>	Any type of work including cleaning, maintenance and repairs where the alteration might have implications from the point of view of radiation protection.
<i>Application:</i>	Specific type of use of a radiation generator. A subcategory of this is medical application involving medical exposure.
<i>Application company:</i>	A company whose use of radiation generators includes application.
<i>Carers and comforters:</i>	Individuals who knowingly and voluntarily, other than in the course of their occupation, incur an exposure to ionising radiation by helping in attending to and comforting individuals undergoing or having undergone <i>medical exposure</i> . This includes the next of kin, including children, of individuals undergoing or having undergone medical exposure.
<i>Company:</i>	Physical or legally person who is responsible for the use of a radiation source.

<i>Constancy testing:</i>	Regular testing carried out for radiation generators for medical use to ensure that selected parameters for the radiation generator and equipment remain within established tolerances.
<i>Dose constraint:</i>	An upper value for the individual dose permitted to be delivered by an company's aggregate use of radiation sources in a planned exposure situation and which provides a baseline for optimisation of radiation protection.
<i>Dose rate:</i>	Dose per unit time. Dose rate is typically expressed in microsieverts per second ( $\mu\text{Sv/s}$ ), or microsieverts per hour ( $\mu\text{Sv/h}$ ).
<i>Effective dose:</i>	The sum of the weighted equivalent doses in all the tissues and organs of the body from internal or <i>external exposure</i> .
<i>Emergency response plan:</i>	Arrangements for planning an adequate reaction to an emergency exposure situation on the basis of hypothetical incidents and related scenarios.
<i>Employer:</i>	A natural or legal person which allows its workers to engage in use of radiation generators or allows its workers to be exposed to ionising radiation.
<i>Equipment:</i>	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.
<i>Equivalent dose:</i>	The average <i>absorbed dose</i> in any tissue or organ weighted for the type and quality of ionising radiation.
<i>Exposed worker:</i>	A worker in a company that uses radiation sources, where the worker is directly involved in or performs work necessary for that use.

<i>External exposure:</i>	Exposure of the body to radiation sources outside the body.
<i>Facility:</i>	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 constructed and fitted out to provide radiation protection from the use of radiation sources.
<i>Individual dose monitoring:</i>	Determination of the effective dose or equivalent dose incurred by an individual, by means of a personal dosimeter or based on a dose monitoring programme.
<i>Industrial radiography:</i>	Radiography for industrial or research purposes in which radiation generators are used within or outside of facilities, e.g. for weld inspection. Industrial radiography does not comprise use of radiation generators in which the requisite shielding and safety features are built into the structure that houses the radiation source.
<i>Installation:</i>	Assembly, fitting, setting up and connecting of a radiation generator and equipment to the application company's utilities (e.g. electricity and water) so that radiation can be generated.
<i>Ionising radiation:</i>	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.
<i>Late effect:</i>	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.
<i>Manufacture:</i>	The manufacture or construction of a radiation generator.

<i>Medical application:</i>	Application of radiation generators for medical exposure.
<i>Medical exposure:</i>	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 <i>carers and comforters</i> and by volunteers in medical or biomedical research.
<i>Medical physics expert (MPE):</i>	An individual having the knowledge to advise on matters relating to medical radiation physics and radiation sources, etc., and to ensure the performance of dosimetry, including measurements for evaluation of doses incurred by patients and individuals subject to medical exposure.
<i>Member of the public:</i>	An individual who may be subject to <i>public exposure</i> .
<i>Operational limits and conditions:</i>	A set of rules specifying an acceptable range for critical parameters in order thereby to indicate when remedial action is required.
<i>Occupational exposure:</i>	The exposure incurred by a worker from the use of radiation sources or from exposure in the company that worker performs work for. For an individual pursuing a programme of vocational education of at least two years' duration which is governed by or pursuant to legislation and in which the use of radiation sources or exposure is 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.
<i>Other worker:</i>	A worker who is not classified as an exposed worker in a company that uses radiation sources or is responsible for exposure.
<i>Outside employer:</i>	Employer of an outside worker.

<i>Outside worker:</i>	An exposed or <i>other worker</i> who performs work for a company that is not that worker's employer.
<i>Performance testing:</i>	Regular testing carried out for radiation generators for medical use to ensure that the radiation source and equipment continue to conform to the pre-defined specifications and applicable operational limits and conditions.
<i>Public exposure:</i>	The exposure of individuals, excluding any occupational or medical exposure.
<i>Quality assurance:</i>	All planned and systematic actions, including quality control, necessary to provide adequate assurance that a radiation source, a facility, equipment, a system or component or a procedure will perform satisfactorily in compliance with agreed standards.
<i>Quality management system:</i>	A coherent and documented management system that ensures 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, personnel and equipment, as well as policies, procedures and instructions.
<i>Radiation:</i>	Ionising radiation.
<i>Radiation generator:</i>	A device capable of generating ionising radiation.
<i>Radiation protection:</i>	Arrangements for protection against ionising radiation, including prevention of emergencies, accidents and incidents and remediation of the consequences hereof.

<i>Radiation protection expert (RPE):</i>	An individual or a group of individuals possessing the knowledge, skills and competences needed to give radiation protection advice in order to ensure the effective protection of workers and members of the public, and whose competence in this respect is recognised by the Danish Health Authority.
<i>Radiation protection officer (RPO):</i>	An individual, who within their field of expertise, is tasked with monitoring and assisting in maintaining the radiation protection of workers and members of the public in connection with the company's use of radiation sources or exposure.
<i>Radiation source:</i>	A radioactive substance or a radiation generator.
<i>Radiotherapy:</i>	The treatment of cancer by means of radiation generators operating with energies greater than or equal to 1 MeV.
<i>Reference level:</i>	The level of effective dose or equivalent dose above which it is judged inappropriate, in an emergency exposure situation, to allow exposures to occur as a result of that exposure situation, even though it is not a limit that may not be exceeded.
<i>Regulatory inspection:</i>	A process, where the authorities supervise the companies to ensure, that they comply with the legislation. (Not to be confused with technical safety inspection).
<i>Safety assessment:</i>	An assessment of all aspects of a company's specific use of radiation generators of relevance for safety and radiation protection.
<i>Self-shielded radiation generator:</i>	A radiation generator permanently integrated inside a shielding, which offers sufficient protection to permit the radiation generator to be operated outside of facilities, with no restrictions on human proximity to the generator.

<i>Service company:</i>	A company whose primary use of radiation generators includes installation, technical safety inspection, alteration, or acceptance/performance testing. The use does not include application.
<i>SST-id:</i>	Unique number for identification in the Danish Health Authority's Registry of Radiation Sources and Facilities. An SST-id is issued by the Danish Health Authority in connection with registration.
<i>Technical safety inspection:</i>	Regular look-over of a radiation generator and associated facilities and equipment to ensure that they are in a satisfactory technical state from the point of view of safety. (Not to be confused with regulatory inspection).
<i>Testing:</i>	See acceptance testing, constancy testing and performance testing.
<i>Tissue effect:</i>	An injury for which a threshold dose is observed, and where the extent of the injury increases with the magnitude of the dose. Examples of tissue effects are cataract, sterility and inhibition of the formation of white blood cells and other cells.
<i>Undertaking:</i>	Natural or legal person responsible for use of a radiation source. In this Guide also called company.
<i>Unintended exposure:</i>	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.
<i>Use:</i>	Manufacture of radiation generators, where ionising radiation is generated in the process; alterations to radiation generators that might have implications from the point of view of radiation protection; installation; application; testing and technical safety inspection of radiation generators.

<i>Veterinary medical application:</i>	The application of radiation generators for veterinary medical diagnostics, treatment or research within these domains, and the exposure of animals for the purpose of research for advancing human diagnostics and treatment.
<i>Worker:</i>	Any person who, regardless of any underlying contractual relationship, is engaged in a worker-like relation.
<i>X-ray radiation therapy:</i>	The treatment of cancer through use of radiation generators operating with a voltage less than or equal to 100 kV.

## Annex B: Formulas, units and conversion factors

Commonly used formulas	
Description	Formula
<p>Dose rate at a given current</p> <p><i>When the dose rate <math>\dot{D}_1</math> is known at current <math>I_1</math> the dose rate <math>\dot{D}_2</math> at a given current, <math>I_2</math>, is determined from the relationship</i></p>	$\dot{D}_2 = \dot{D}_1 \frac{I_2}{I_1}$
<p>Dose rate* at a given distance (inverse-square law)</p> <p><i>When the dose rate <math>\dot{D}_1</math> is known at distance <math>x_1</math> from a radiation source, the dose rate <math>\dot{D}_2</math> at a given distance, <math>x_2</math>, is determined from the relationship</i></p>	$\dot{D}_2 = \dot{D}_1 \left( \frac{x_1}{x_2} \right)^2$
<p>Distance* at a given dose rate (inverse-square law)</p> <p><i>When the dose rate <math>\dot{D}_1</math> is known at distance <math>x_1</math> from a radiation source, distance <math>x_2</math> at a given dose rate <math>\dot{D}_2</math>, is determined from the relationship</i></p>	$x_2 = x_1 \cdot \sqrt{\frac{\dot{D}_1}{\dot{D}_2}}$
<p>Transmission factor</p> <p><i>Transmission factor <math>T</math> is determined from the dose rate with shielding, <math>\dot{D}_m</math> and the dose rate without shielding, <math>\dot{D}_u</math> (measured at the same distance from the source).</i></p>	$T = \frac{\dot{D}_m}{\dot{D}_u}$

\* where the radiation source can be considered a point source.

Symbol	Description	Unit
$\dot{D}$	Dose rate <i>Dose per unit time</i>	[Sv/h, sieverts/hour] <i>In practice typically units of <math>\mu\text{Sv/h}</math></i>
$I$	Current <i>Charge per unit time</i>	[A, amperes] <i>In practice typically units of mA</i>
$T$	Transmission factor <i>The ratio of the amount of radiation transmitted through a material to the amount of radiation incident on that material.</i>	Dimensionless
$x$	Distance	[m, metres]

Conversion factors
<p><b>Absorbed dose</b></p> <ul style="list-style-type: none"> <li>• gray [Gy] = <math>\text{J kg}^{-1}</math></li> <li>• 1 Gy = 100 rad</li> <li>• 1 rad = 10 mGy</li> </ul> <p>Note: The SI unit for absorbed dose is the gray<sup>62</sup>, rad being an obsolete unit.</p>
<p><b>Equivalent and effective dose</b></p> <ul style="list-style-type: none"> <li>• sievert [Sv] = <math>\text{J kg}^{-1}</math></li> <li>• 1 Sv = 100 rem</li> <li>• 1 rem = 10 mSv</li> </ul> <p>NB. The SI unit for equivalent dose is the sievert<sup>63</sup>, rem being an obsolete unit.</p>

<sup>62</sup> Annex 1, Executive Order No. 1229/2009.

<sup>63</sup> Annex 1, Executive Order No. 1229/2009.

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



### **Radiation protection advice**

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### **Questions concerning personal dosimetry**

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