# PROCEDURE V.3 AUG. 2020

# REGULATIONS FOR DEVICES THAT GENERATE IONISING RADIATION

## INTRODUCTION

This procedure is meant for employees of the institutions that participate in the complex license Randwyck, who are involved in the acquisition, handling and management of devices that generate ionising radiation. The applicable legal requirements are presented and formalised in this procedure, in accordance with the prevailing law and the internal policies as described in the 'Regulations Randwyck'.

## DEVICES

Under the terms of the complex license Randwyck, devices that generate ionising radiation are used for the following purposes, which are listed including their ground of justification :

- medical diagnostics (II.A.2), including simulation (preceding medical therapy)
- medical therapy (II.A.1)
- medical research (II.A.3)
- prevention or early diagnostics among populations and individuals (II.A.4)
- medical legal investigations (II.A.5)
- veterinary diagnostics (II.B.1)
- therapeutic treatment of small laboratory animals (II.B.2)
- analysis and research by means of X-ray radiation (I.C.1)
- radiographic examination of objects (I.C.2)
- education (I.D.1) and drills/practices (I.D.3)
- research (I.C.4)

The Dutch Act '*Besluit basisveiligheidsnormen stralingsbescherming'* (*Bbs*) and further details as stated in the complex license and the 'Regulations Randwyck', present some subjects that must be considered during the acquisition and maintenance of devices, as well as putting them into operation. These subjects are further explained in this procedure.

## RESPONSIBILITIES OF DIVERSE FUNCTIONARIES

Every handling and manipulation of radioactive sources and X-ray devices fall under the responsibility of the coordinating radiation protection expert(s) (RPE; Dutch: 'stralingsbeschermingsdeskundige' or SBD, or alternatively 'coördinerend deskundige' or CD). The SBD/CD has been appointed by the licensee, and has been given a written mandate describing his authority (in compliance with the *Bbs, art. 7*). In the medical setting, this role is held by a clinical physicist.

For day to day surveillance of actions with radioactive sources or ionising radiation generating devices per division, cluster or work location, a supervising radiation protection officer (RPO; Dutch: 'toezichthoudend medewerker stralingsbescherming' or TMS) has been appointed by the licensee. The authority that comes with this position has also been formalised in a written mandate (*Bbs, art. 9*).

For the medical application of devices, a clinical physicist bears responsibility for, amongst others, dosimetry for patients and employees involved, optimisation of the application and quality control of the devices (a full listing of responsibilities is listed in the *Bbs, art. 8.8*). This implies that the clinical physicist has an important role in the acquisition of ionising radiation generating devices, and the criteria and requirements new devices must meet.

## ACQUISITION OF NEW DEVICES

When acquiring a new device, there are two possible scenarios:

1. the device and its application are under the terms of the granted internal permit (Dutch: 'schriftelijk interne toestemming' or SIT) and the accompanying risk analysis. In case that acquisition or exchange of devices will not result in any significant change to exposure of persons and the environment, a notification to the general coordinating expert (Dutch: 'algemeen coördinerend deskundige' or ACD) after the fact is sufficient, as stated in the paragraph 'Maintenance and reportage for all devices' on page 3 of this procedure;
2. the specification of the device or its applications are not under the terms of the granted internal permit. In this case, either a request for an amendment on the existing permit, or an application for a new permit must be submitted to the radiation protection unit (RPU; Dutch: 'stralingsbeschermingseenheid' or SBE), prior to purchasing the device.

The SBD/CD of the department that has ownership of the device is responsible for determining which scenario applies, as well as for the execution of the corresponding actions. As mentioned in §3, a clinical physicist must be involved in the acquisition of devices that are intended for medical use.

## REQUIREMENTS FOR IONISING RADIATION GENERATING DEVICES

It is the responsibility of the licensee to see to it that:

### Basic requirements for inherently safe devices (X-ray and linear accelerators)

1. the device is constructed in a way that it cannot be or come into operation when the device is open. The housing of the device is there for secured (if possible) with switches, that mechanically force the disconnection;
2. the device is only used when the safety devices, that have been attached to the device in order to reduce the radiation levels on the outside, are in good and working condition;
3. at no point, distanced 0.1 meters from an accessible position on the outside of the device, a dose rate can be measured that exceed 1 microsievert per hour
4. the device is equipped with a warning sign (see 'Procedure zoning and warning signs')

### Basic requirements for all other devices (X-ray and linear accelerators)

1. the device is shielded in such way, that the ionising radiation that is emitted, with the exception of the opening designed for the emission of the useful radiation beam, can cause the lowest reasonably possible damage;
2. a device is used to control the circumference of the useful radiation beam, which ensures at least the same level of protection against radiation as the shielding around the device does;
3. the device and its help- and safety measures are positioned and shielded in such way that individuals do not have to expose themselves to the primary beam, unless they are subject to medical exposure or non-medical imaging;
4. measures are being taken with regards to the set up and operation of the device to prevent people to be exposed to scattered radiation as much as reasonably possible;
5. a device cannot be put into operation by non-authorised persons;
6. measures have been taken to prevent non-authorised people from entering the room or area where the device is located, while the device is in operation;
7. the device has been equipped with a warning sign (see 'Procedure zoning and warning signs');
8. in case the device is not in operation, it should be stored properly closed off or in a closed room, which may only be opened by the licensee and those employees that have been authorised to do so.

Rule 1 does not apply in case the device is tested or under maintenance, repair or investigation, under the condition that measures have been taken to prevent exposure to external irradiation of individuals as much as reasonably possible.

### Safety requirements for all devices

1. the room and application/use of the device are tailored to one another regarding radiation protection aspects;
2. the effective dose will not exceed 1 mSv per year at the position where the device is being operated, nor on the outside of the room or area where the device is in use; the exception is the use of devices for interventional radiology;
3. the room is equipped in a way that the exposure of employees is reduced to a level that is as low as reasonably achievable;
4. additional organisational measures are taken in case the dose reduction cannot be realized by constructional measures;

### Control mechanisms for all devices

1. all devices and their safety mechanisms are checked for working properly at least once in a twelve month period;
2. the shielding and level of radiation leakage outside of the device or the housing it has been built into is checked at least once every year;
3. after each disassembly or reparation of a device, a check on proper functionality of the device, as referred to in point 1 and 2 of this paragraph, is carried out.

### Maintenance and reportage for all devices

All devices must be subsumed under a management system in which:

1. all devices are specified to their:
    a. brand, type and date of manufacture;
    b. place and nature of the application;
    c. in case of an X-ray device: maximum high tension of the X-ray tube and the voltage that the generator can produce;
    d. in case of a linear accelerator: the maximum acceleration voltage, the emitted type of radiation and the corresponding maximum energy thereof.
2. results of check-ups (as described in the previous paragraph, 'Control mechanisms for all devices') must be noted, including the following data:
    a. date of the check-up;
    b. name of the person that performed the check-up;
    c. possible shortcomings/malfunctions and subsequent repairs;
    d. radiation leakage levels outside of the device.
3. results of disassembly or repairs of the device are noted, including the following data:
    a. date and time of starting and ending of each disassembly and or reparation of devices;
    b. name of the person that performed the disassembly or reparation;
    c. eventual shortcomings/malfunctions and the nature of their repair;
    d. results of the check of proper functionality of the device; the safety measures and shielding, after the disassembly and/or repair has been carried out.

## ADDITIONAL REQUIREMENTS FOR DEVICES USED FOR MEDICAL APPLICATIONS

In addition to the requirements as listed in §5 of this document, there are specific requirements for devices used in the medical setting. The licensee must see to it that:

1. in the case a new device is taken into use, it is equipped with , if feasible, a provision that shows the radiation dose during a radiological procedure;
2. a filter is used to reduce the exposure of patients in each device that is used for radio diagnostic applications;
3. a device is equipped with a fixed or automatic diaphragm setting to make the contours of the X-ray beam visible, unless it concerns mammographic or dental procedures;
4. a device that is used for radio diagnostic application is equipped with a diaphragm, in order to restrict the X-ray beam to the right area;
5. the diaphragm is integrated in such way that it is possible to point out the dimensions of the X-ray beam in advance;
6. a device, suitable for continuous X-ray examination, will frequently release an acoustic signal when being in use cumulatively.

## TERMINATION OF APPLICATION / REMOVAL OF DEVICES

In case devices are no longer in use, or an application is terminated, this must be reported to the SBE, so granted internal permits (SIT) can be adjusted accordingly.

For removal of devices, specific legal directions apply, as formulated in *Bbs, §10.3, art. 10.8*.

In case the use of the device has been terminated permanently, the owner must dispose of the device within a period of two years, by handing the device over to:

- the party that has manufactured or sold the device;
- a party that is authorised to receive the device in consideration of use, reuse of the product or materials, or collection thereof;
- an accredited institution or authorised collection service that is qualified to receive the device.

Another possibility is to have the device turned into scrap, again within a period of two years after termination of the use or application. In this case, parts of an accelerator that contain radioactive substances as a consequence of activation, may not be included.

## LIST OF ABBREVIATIONS

| **Dutch** | | **English** | |
|---|---|---|---|
| ACD | algemeen coördinerend deskundige | - | general coordinating expert |
| Bbs | Besluit basisveiligheidsnormen stralingsbescherming | - | - |
| CD | coördinerend deskundige | - | coordinating expert |
| SBD | stralingsbeschermingsdeskundige | RPE | radiation protection expert |
| SBE | stralingsbeschermingseenheid | RPU | radiation protection unit |
| SIT | schriftelijke interne toestemming | - | written internal permit |
| TMS | toezichthoudend medewerker stralingsbescherming | RPO | radiation protection officer |

## REFERENCES


- Besluit basisveiligheidsnormen stralingsbescherming: https://wetten.overheid.nl/BWBR0040179/2018-07-01
- Complex license Randwyck
- Procedure ‘zoning and warning signs’
- ‘Regulations Randwyck’