PROCEDURE V3 MAY 2023

GUIDELINES FOR SEALED SOURCES

INTRODUCTION

This procedure is intended for employees who are currently employed in the institutions that are part of the complex license Randwyck, who are involved in the purchase, management and use of sealed sources. Conditions to the purchase, management and use of sealed sources are written down in this procedure and follow prevailing legislation and the local Regulations Randwyck.

SEALED SOURCE

A sealed source is a radioactive substance, which is encapsulated or sealed in a carrier material. The carrier material or casing is designed in such a way, that it is strong enough to prevent spreading of radioactive substances under normal operational use.

Within the complex license Randwyck, sealed sources are used for the following purposes (justifications[1] between brackets):

- Calibration (I.A.2)
- Analysis (I.A.3)
- Education (I.D.1)
- Exercises (I.D.3)
- Medical therapy (II.A.1)
- Clinical research based on medical indication (II.A.2)
- (Bio)medical research on volunteers (II.A.3)

Based on the risk a sealed source poses, it will be categorized. Following IAEA guidelines, this categorization is based on an A/D-value. The A/D-value is the ratio of the activity of the radioactive substance divided by a D-value for that particular radioactive substance, and is an indicator for the risk of possible detrimental tissue effects caused by the use of that radioactive substance when the source has not been managed correctly. This D-value can be found in IAEA publication EPR-D-Values[2]. The calculated value of A/D determines if a source should be classified as a HASS-source, which hold specific security requirements.

The decree on basic safety standards for radiation protection (Besluit basisveiligheidsnormen stralingsbescherming (Bbs)) and specific directions in the complex license and the Regulation Randwyck offer certain require attention when putting sealed sources in operation and performing maintenance on sealed sources. Additional requirements are put in place for so-called High Activity Sealed Sources (HASS). These requirements can be found at the end of this procedure.

RESPONSIBILITIES

For a complete description of tasks and responsibilities of all personnel involved in the radiation protection organization, we refer to the Regulations Randwyck. This procedure focuses on the responsibilities with regards to sealed sources.

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[1] *Regeling basisveiligheidsnormen stralingsbescherming, attachment 2.1 sub section A (Dutch only)*

[2] *Dangerous quantities of radioactive materials; EPR-D-values 2006; IAEA*

General coordinating expert (Algemeen Coördinerend Deskundige (ACD)):

- supervises, on behold of the licensee, compliance to the complex license;
- supervises the actuality and validity of the complex license and files changes to this license with the government on behalf of the licensee;
- supervises the correct administration of the presence of all sealed sources within the complex license;
- supervises the compliance of conditions formulated in the written internal approval (SIT) with regards to the correct use of sealed sources;
- reports at least once a year to the licensee and the government concerning the presence, the application and the control of the use of sealed sources.

Radiation Protection Expert/RPE (Coördinerend deskundige (CD)):

- is responsible for the risk analyses in which the risks associated with the use of sealed sources are described and the potential exposure for people and environment is quantified;
- supervises the purchase of sealed sources within the frame of the requirements described in this procedure;
- supervises the registration and management of sealed sources;
- supervises the execution of leak tests and assesses the results thereof[3];
- is responsible for the quality of the data that are documented and shared with the Radiation Protection Unit.

Radiation Protection Officer/RPO (Toezichthoudend Medewerkers Stralingshygiëne (TMS)):

- supervises the correct reception and handling of sealed sources as described in this procedure;
- executes a visual check and a leak test on received sealed sources;
- supervises the correct use of sealed sources within the framework of the written internal permission and the conditions as stated in this procedure;
- supervises the registration of the sealed source at the storage location;
- supervises the compliance of transport procedures when moving sealed sources between different locations;
- instructs when necessary about the correct use of the sealed source;
- manages the correct registration of sealed sources present at the location (for the Randwyck complex the digital management system NRG ReGuard is used, which also calculates the A/D-value for individual sealed sources as well as a cumulative value for all sealed sources in a storage location);
- provides an up-to-date list of sealed sources to the Radiation Protection Unit each year, for purposes of the annual report on radiation safety within the complex, in which changes compared to the previous year(s) are clearly marked.

CONDITIONS ON THE USE OF SEALED SOURCES

For the purchase, use and storage of sealed sources, specific legal requirements are in place to ensure safety. The purchase and application of sealed sources must always be within the bounds of the complex license, the written internal permission and under the supervision of the RPE/CD and the RPO/TMS.

[3] *art 4.35 e, verordening basisveiligheidsnormen stralingsbescherming (Dutch only)*

Practical conditions for purchase and use are[4]:

a a received shipment of sealed sources is unpacked and checked in a designated location, appointed by the RPO/TMS;
b when a package is damaged or in case a radiation incident has occurred during shipment, the RPO/TMS needs to be informed and needs to perform a contamination check prior to unpacking;
c when a shipment containing a sealed source is delivered outside working hours, the sealed source is immediately safely and securely stored in a storage location, and as soon as possible handed over to the RPO/TMS;
d the RPO/TMS must ensure that the empty packaging of a sealed source is cleared of any radioactive contamination on the inside and the outside before leaving the location, as well as all labels or indications that the packaging used to contain radioactive substances are removed;
e the sealed source is constructed in such a way that it complies to the ISO 2919:2012 (or newer) standard. If the sealed source does not comply to this ISO standard, one should consult the Radiation Protection Unit before purchasing such source.
f the sealed source is accompanied by a source certificate on which all relevant details about the source are given. For sources produced prior to 1995, all relevant details must be recorded in a file as far as all details are available or can be tracked down.
g Circumstances under which the source is used, cannot exceed the circumstances the source was designed for;
h prior to the use of the sealed source, a leak test has to be performed by or under supervision of the RPO/TMS to ensure the source is not leaking. Only after the results of this leak test have been assessed by the RPE/CD, the sealed source can be used;
i all relevant source data are known and the source is marked with a serial number, if this is possible;
j the sealed source or the source holder are marked with a radioactivity sign if possible;
k the sealed source will be stored in a storage room or facility after use, if technically possible;
l in the direct vicinity of the storage room, a list is present which shows all sealed sources that are present in that storage room.

MEASURES TO PREVENT IMPROPER USE OF SEALED SOURCES[5]

Improper use and unintentional exposure need to be prevented when storing and handling sealed sources. The following legal requirements apply (a-c concerning sealed sources integrated in a device):

a actions need to be taken to prevent the sealed source being brought into the irradiating position, either by unauthorized persons or unintentionally;
b a sealed source can only be in the irradiating position when the equipment or device containing the sealed source is used. On the outside of the source container, it should at all times be clear whether the sealed source is in their irradiating position, if necessary using measuring devices.
c The location itself cannot be freely accessible (or at least not without proper warnings) for people who are not directly involved in the procedure taking place;
d no flammable, fire promoting or explosive substances are present in close proximity to the sealed source(s), unless absolutely necessary for business operations;
e a sealed source should be stored in a storage facility after use;
f or, divergent of e, a sealed source which is part of a fixed setup should be stored in a storage facility when:

[4] *Verordening basisveiligheidsnormen stralingsbescherming art. 4.9 (Dutch only)*

[5] *Verordening basisveiligheidsnormen stralingsbescherming art. 4.10 (Dutch only)*

- the fixed setup is definitively out of use, or
- this is necessary from of radiation protection view.

INSPECTION OF SEALED SOURCES[6]

To ensure the safe use of sealed sources, inspections need to be performed periodically.
Specifically, these are:

- a visual check of the sealed source or source holder, at least once a year;
- a check of the sealed source following a written procedure, in which at least once a year:
  - the sealed source is tested for leakage;
  - the source holder or measurement setup is checked for radioactive contamination;
  - the dose rate on the outside of the source holder or measurement setup is checked.
- when executing these inspections, damage to the sealed source must be prevented and the following data must be written down:
  - date of inspection;
  - serial number of the sealed source;
  - means of execution of the inspection;
  - name of person performing the inspection;
  - inspection results;
  - follow-up of deviant results.

The leak test and check for contamination are not obligatory when the sealed source contains a gaseous radioactive substance or contains less than 0,02 Re_{inh} or 1 megabecquerel. It needs to be proven though, that the source is not leaking radioactivity, as described in the procedure 'leak test sealed sources'.

The leak test is obligatory for each sealed source from the age of 15 years, despite of its activity, because of the risk of leakage due to porosity or degradation of the carrier material.

If a sealed source is out of use, prior to returning it to the manufacturer or disposing of or storage in a storage facility, a leak test should be executed following the written procedure.

DISPOSING OF A SEALED SOURCE

When a sealed source is definitively put out of use, it should be stored in a storage facility prior to its disposal or return to the manufacturer. Prior to this, a leak test should be executed (see Inspection of sealed sources).

Actions necessary when disposing of sealed sources are written down in the procedure Collection, storage and transference of radioactive waste.

When disposing of a sealed source, this should be administrated in the local management system, as well as in the digital management system (NRG ReGuard).

[6] *Verordening basisveiligheidsnormen stralingsbescherming art. 4.11 (Dutch only)*

ADDITIONAL REQUIREMENTS FOR HASS-SOURCES

A Highly Active Sealed Source, also known as a HASS-source, is a sealed source containing a radionuclide with an activity that exceeds the A/D-value[7]. For these sources, besides all requirements for sealed sources as written down in this procedure, additional requirements apply[8].

These additional requirements are, among others, a supplementary permit requirement, a specific HASS-source dossier, financial security and conditions regarding security. Because of the specific character of these additional requirements and the fact that this is tailor-made for each HASS-source, these requirements will not be elucidated in this procedure. If a HASS-source needs to be purchased or taken into use, necessary measures need to be taken in consultation with the Radiation protection unit.

ABBREVIATIONS

ACD	General Coordinating Expert
Bbs	Besluit basisveiligheidsnormen stralingsbescherming
RPE/CD	Coordinating Expert
HASS	Highly Active Sealed Source
IAEA	International Atomic Energy Agency
RPO/TMS	Radiation Protection Officer

REFERENCES

- Besluit basisveiligheidsnormen stralingsbescherming https://wetten.overheid.nl/BWBR0040179/2021-07-01
- Regeling basisveiligheidsnormen stralingsbescherming https://wetten.overheid.nl/BWBR0040509/2022-08-24
- ANVS Verordening basisveiligheidsnormen stralingsbescherming https://wetten.overheid.nl/BWBR0040581/2023-02-24
- Dangerous quantities of radioactive materials; EPR-D-values 2006; IAEA https://www-pub.iaea.org/MTCD/Publications/PDF/EPR_D_web.pdf

[7] *Besluit basisveiligheidsnormen stralingsbescherming, attachment 4 (Dutch only)*

[8] *A.o. Besluit basisveiligheidsnormen stralingsbescherming §4.3.3 (art. 4.9 to 4.19), Regeling basisveiligheidsnormen art. 4.2 and Verordening basisveiligheidsnormen stralingsbescherming art. 3.8, 4.2 and 4.3) (Dutch only)*