Unofficial translation from Finnish.
Legally binding only in Finnish and Swedish.

REGULATION STUK S/5/2019

Radiation and Nuclear Safety Authority Regulation on the In-service Radiation Safety of Radiation Sources and the Decommissioning of Radiation Sources and Places of Use

Adopted in Helsinki on 2 July 2019

In accordance with a decision of the Radiation and Nuclear Safety Authority, the following provisions are issued by virtue of the Radiation Act (859/2018):

Chapter 1

General regulations

Section 1

Scope of application

This regulation shall apply to the use of radiation requiring a safety licence.

Section 2

Definitions

For the purposes of this regulation:

1) *open beam analyser* shall refer to an X-ray analyser according to IEC 62495, with the radiation beam is directed outside the appliance;
2) *accelerator* shall refer to a radiation appliance in which ionizing radiation with energy higher than 1 mega electronvolt is generated by means of particle acceleration;
3) *in-service acceptability criteria of the appliance* shall refer to the minimum requirements set for the performance of the appliance, the acceptability limits;
4) *radiometric measuring device* means a measuring device consisting of a sealed source in a radiation shield, a radiation detector and measurement electronics;
5) *X-ray appliance* shall refer to a device which produces ionizing radiation electrically, which is not an accelerator;
6) *closed beam analyser* shall refer to an X-ray analyser according to IEC 62495, with the radiation beam is directed inside the device;
7) *shielded fluoroscopic device* shall refer to an X-ray device according to IEC 61010-2-091, where the X-ray tube and the radiation beam are protected by structural shields and the object to be examined or analysed is contained within the shield in a space accessible when the equipment is producing radiation.

Section 3

Activity values of high-activity sealed sources

Activity values of high-activity sealed sources are specified in Appendix 1.

Council Directive 2013/59/Euratom (32013L0059); OJEU L 13, 17.1.2014, p. 1
Reported to the Commission in accordance with Article 33 of the Treaty establishing the European Atomic Energy Community.

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Chapter 2

Premises where radiation sources are used and stored

Section 4

Radiation shielding of premises where radiation sources are used and stored

Premises where radiation sources are used and stored shall be planned and implemented in such a way that the exposure caused to employees and the public is as low as reasonably achievable, and that the dose caused does not exceed the dose constraint applicable to the facility and place where the radiation source is used and stored.

The type of use of the radiation source and the use of premises surrounding the place where the source is used and stored shall be considered in radiation shielding.

The adequacy of radiation shielding shall be re-evaluated if:

1) the radiation source is changed to another type or additional sources are added;
2) the type of use of the radiation source changes;
3) the use of premises surrounding the place where the source is used and stored changes in a way that might increase occupational or public exposure.

The adequacy of radiation shielding shall be ensured by means of radiation measurements or other reliable methods after the shielding has been constructed or changed.

Section 5

Activation

The design and implementation of places of use of neutron sources and accelerators must take into account possible activation of structures, systems and other materials regarding:

1) occupational and public exposure;
2) the nature, quantity and rendering harmless of radioactive waste arising from the decommissioning of the facility.

Section 6

Structural solutions contributing to the management of the radiation safety deviations

In facilities and places where radiation sources are used and stored, structural solutions shall be used which allow the organization of activities in such a way that:

1) potential exposure and its likelihood are as low as practicably achievable and the exposure does not exceed the constraint for potential exposure;
2) the radiation safety deviation can be managed;
3) after the radiation safety deviation:
    a) sources can be be made safe for workers and the public;
    b) radiation sources and the places of use can be brought into a safe situation allowing further use or treatment;
    c) the places of use can be cleaned of any radioactive substances that have spread in them.

Priority must be given to exploiting inherent safety features and systems and equipment which, in the event of a failure, are placed in a safety-favorable condition.

Section 7

Safety and alarm systems

Safety and alarm systems appropriate to the safety of the practice shall be placed in the place where radiation is used, in the space outside it, the control room, the control panel and the control device, such as:

1) emergency buttons which end the generation of radiation when pressed;
2) safety switches which prevent the generation of radiation if the door or similar to the place of use is used or someone enters a specific area when the appliance is on;
3) acknowledging switches used to ensure that no one stays in the space where radiation is used before the radiation appliance is started;
4) alarm lights or some other method of detecting when the radiation appliance is in operation and when it is generating radiation.

In addition, the use of particle accelerators for isotope production and research shall have safety, warning and measurement systems for releases, dose rate and pressure in the place of use and in order to ensure the safe status of the target of the accelerator, transmission line and hot cell.

In the use of a radiation appliance which result to occupational exposure category 1 due to potential exposure, the place of use shall be equipped with a warning light or other method referred to section 1, subsection 4, which is independent of the control system of the radiation appliance.

When the safety system referred to in subsection 1 has prevented the generation of radiation, operation may only be continued from the control unit or operating unit.

Section 8

Other safety and functionality

One of the doors leading to the place where the radiation source is used or stored shall be such that it can always be opened from inside the room. It shall also be possible to open the door in case of malfunction.

When using radiation in healthcare, the control room must have a visual and speech connection to the patient in the treatment or examination room, as appropriate for the safety of the operation. Also, the doors leading to the treatment or examination room shall be visible from the control room if the doors are not locked.

When radiation is used in industry and research whereby the occupational exposure category is 1 or 2, the room where the appliance is used or the door to this room shall be visible from the control or operating unit of the radiation appliance.

Section 9

Radiation safety solutions as a whole

If the occupational exposure category is 1 or 2 due to potential exposure, the structural solutions of the places where radiation sources are used, and the safety systems referred to in section 7 shall be such that:

1) an individual technical failure, human error or acting in violation of the instructions does not cause the realization of the potential occupational or public exposure;
2) radiation sources can be made safe for the exposure in question even if an individual safety device is out of use or not operating.

Section 10

Marking of places of use

The marking warning of radiation hazard referred to in section 66, subsection 2, of the Radiation Act, shall be placed at the doors of places where radiation is used and stored if the door is at the border of the controlled or supervised area. The marking shall be done in accordance with standard SFS-EN ISO 361. The marking may also be a marking of the intended use of the room, if the related radiation hazard is shown clearly in the marking.

Places of use and storage of radiation sources in which the design of radiation shielding is based on the estimate that no one stays in the room permanently shall be marked with a sign prohibiting people from staying in such rooms. However, marking is not necessary if the purpose of the place or other considerations do not allow for continuous occupation.

Section 11

Specific requirements for contamination

When unsealed sources are used and in other activities involving the risk of contamination, solutions shall be implemented in the places where radiation sources are used and stored which allow the organization of activities in such a way that during normal operation and in case of a radiation safety deviation:

1) contamination can be removed from surfaces as easily as possible;
2) spreading of radioactive substances to indoor air in the place of use and to the other places of the building can be restricted effectively;
3) releases of radioactive substances to the environment can be restricted effectively;
4) transfer of contamination outside the place of use with the employees can be restricted effectively;
5) waste generated in the operations can be processed safely.

Section 12

Specific requirements for the patient room

A patient who is hospitalized as a result of exposure to radiation following isotope treatment must have a separate patient room with its own washroom and toilet. Entry to the patient room shall be marked with a sign warning of a radiation hazard.

Section 13

Specific requirements for the storge of a radiation source

Radiation sources containing radioactive substance must be stored separately from goods and materials not related to their use.

Section 14

Specific requirements for places surrounding the place for radiotherapy

If the places surrounding the place intended for radiotherapy include areas where the dose rate of radiation is higher than 20 µSv/h, working and staying in these areas shall be restricted.

Chapter 3

In-service acceptability criteria of radiation sources

Section 15

General requirements

The radiation source and the equipment related to its use shall be suitable for the intended use.

An appliance generating radiation electrically shall not be used at operating values higher than necessary for its intended purpose.

The sealed source shall comply with the requirements of SFS-EN ISO 2919.

The marking of the sealed source referred to in section 66, subsection 2, shall be the word "Radioactive", or, if this is not possible, the symbol for ionizing radiation in accordance with SFS-EN ISO 361:2015.

Section 16

In-service acceptability criteria for a heath care radiation appliance

In addition to what is specified section 15, a heath care radiation appliance shall meet the in-service acceptability criteria specified in this section.

During use, the appliance shall meet the essential performance and safety characteristics declared by the manufacturer.

Information shall be available at the place of operation of the appliance, indicating the in-service acceptability criteria and their fulfilment.

Further provisions on the in-service acceptability criteria for health care and veterinary radiation appliances are given in Appendices 2 – 5.

Section 17

In-service acceptability criteria for a radiation appliance for industrial and research purposes

In addition to what is specified section 15, a radiation appliance for industrial and research purposes shall meet the in-service acceptability criteria specified in this section.

During use, the radiation appliance shall meet the radiation and safety characteristics declared by the manufacture and specified in the application for a safety license or in the notification.

Further provisions on the in-service acceptability criteria for a radiation appliance for industrial and research purposes are given in Appendices 6 – 8.

Chapter 4

Information and notifications on radiation sources and records of radiation sources

Section 18

Information about the radioactive substance

The shield or storage container or cover of a radiation source containing radioactive substance shall be marked with the radionuclide, activity and the activity's determination date.

In case of unsealed sources, the total volume or activity concentration shall be marked.

Section 19

Identification of sealed source and information concerning the identification of the source

The serial number of sealed source or other identifier of the source shall be presented in the certificate of compliance referred to in section 73, subsection 1, of the Radiation Act.

A high-activity sealed source shall be identified by means of a serial number assigned by the manufacturer.

Section 20

Records of high-activity sealed sources

Information to be included in the records of high-activity sealed sources is set out in Appendix 9.

Section 21

Information provided with the radiation source

A sealed source shall be accompanied with the manufacturer's written commitment referred to in section 76, subsection 1 of the Radiation Act, to receive the sealed source after the end of use, unless the source can be safely aged in the manner referred to in the same section as well as the results of the latest leak test.

A high-activity sealed source shall be accompanied with written documentation indicating that the sealed source is marked and identified in accordance with section 15, subsection 4, and section 19. The documentation shall also include pictures of the sealed source and its transport packaging as well as the structure of its shielding and the appliance in which it is used.

Section 22

Annual notifications of radiation sources

The annual notification on the manufacture, storage, trade, export and import of radiation sources referred to in section 71, subsection 2, of the Radiation Act, shall detail the information specified in Appendix 10. The notification shall be made even if no receipts or transfers have taken place and no radiation sources are possessed.

The notification on the use and possession of high-activity sealed sources referred to in section 71, subsection 3, of the Radiation Act, shall detail the information of the records of high-activity sealed sources referred to in section 20.

The notifications shall be submitted to the Radiation and Nuclear Safety Authority by the end of January of the year following the calendar year.

Section 23

Notification on transport requiring a safety licence

The notification referred to in section 72, subsection 3 of the Radiation Act, shall include the information specified in Appendix 10.

Chapter 5

Quality assurance measures related to radiation sources

Section 24

Ensuring the operation of a radiation appliance

The safe operation of a radiation appliance shall be ensured following a substantial repair, maintenance or software update as well as always when there is reason to suspect that there are disturbances or changes in the operation of the appliance. Faults and deficiencies affecting radiation safety must be repaired before using the appliance.

Section 25

Documentation of events related to a radiation appliance

Records shall be kept of defects, malfunctions or other adverse events that have occurred during the use of the appliance as well as events affecting the use or safety of the appliance. The records shall be kept throughout the life cycle of the appliance.

Section 26

Acceptance inspection of a radiation appliance in health care and veterinary medicine

The quality assurance programme of the use of radiation in health care and veterinary medicine shall include an acceptance inspection in which compliance with the in-use acceptability requirements of the radiation appliance is ensured before its commissioning. The acceptance inspection shall also establish reference performance values which shall be used for monitoring of the appliance's operational capacity and performance characteristics.

Section 27

Quality assurance measures in the use of radiation in health care and veterinary medicine

The quality assurance programme of the use of radiation in health care and veterinary medicine shall include measures to ensure:

1) before commissioning a medical radiation appliance, that adequate information on the risk assessment of the patients and the available clinical operation results of the appliance are available;
2) the targeting of the treatment dose to the specified target area in the designed magnitude as accurately as possible;
3) an imaging quality adequate for obtaining the examination result;
4) the accuracy of the assessment radiation exposure caused to the patient and the verification of activity administered to the patient.

The radiotherapy quality assurance programme shall include the risk assessment of exposure due to a radiation safety deviation or unplanned exposure based on the safety assessment referred to in section 26 of the Radiation Act.

The intervals of quality assurance measures in X-ray practices, nuclear medicine and veterinary medicine may not be longer than what is specified in Appendix 12.

Section 28

Commissioning and regular dose calibration of radiotherapy appliance

Before commissioning a radiotherapy appliance, the operator shall measure or verify the characteristics of the appliance that are needed for the input information of the radiotherapy treatment planning system used.

Quality assurance in radiotherapy must, before introducing new techniques for dose calculation and use of radiation, compare calculated and measured dose distributions using tests corresponding to a range of different treatment scenarios and, where appropriate, tests based on dose measurements of actual treatment plans. The radiotherapy appliance shall undergo regular dose calibrations.

Dose calibration shall be verified before the radiotherapy appliance is taken into use to treat patients in such a way that:

1) the verification is conducted by a person other than the one conducting the dose calibration;
2) the dosemeter and the equipment used with it during the measurement are others than those used in the dose calibration.

Furthermore, an independent verification of dose calibration shall be conducted before taking a radiotherapy beam with a different nominal energy or other characteristics into use to treat patients.

Section 29

Other quality assurance measures in radiotherapy

Quality assurance of radiotherapy shall include the verification of each individual treatment plan when taking a new method into use.

In addition, every whole-body treatment must include in vivo dose measurement if the treatment is not based on a sliced tomography. The targeting of treatment shall be individually verified.

Section 30

Leakage tests of sealed sources

The operator shall ensure that a sealed source requiring a safety licence is subjected to leakage testing in accordance with ISO 9978:

1) if the environmental conditions of the sealed source or other reasons may have impaired the tightness of the sealed source;
2) if it is possible that the sealed source has suffered damage as a result of an incident or handling;
3) if the place of use or storage of a radiometric measurement device or other fixed sealed source is changed and more than one year has passed since the last leakage test;
4) when a sealed source is removed from the shield or installed in a shield;
5) when more than 15 years or more than the recommended service life specified by the manufacturer has passed since the last demonstration of compliance, and at regular intervals after that, at least every three years, taking into account the design of the sealed source, the type of use and the environment and other factors affecting the tightness of the sealed source;
6) when a sealed source removed from use is handed over for transport.

A leakage test in accordance with ISO 9978 shall, however, be performed on high activity sealed sources at least once per year.

The leakage test does not need to be performed on a sealed source where the radioactive substance is in gaseous form and in the situations referred to in paragraphs 3, 4 and 6 of subsection 1, if the half-life of the radioactive material is is less than 150 days and no more than three years have elapsed since the last leakage test.

An operator who receives sealed sources for processing as radioactive waste shall perform the leakage test referred to in subsection 1 upon receipt of the sealed source.

If grounds exist to suspect that the tightness of the sealed source may have been compromised, the conformity of the source shall be redemonstrated before continuing its use.

Section 31

Quality assurance measures of radiation sources used in industry and research

The quality assurance measure applicable to use of radiation in industry and research are specified in Appendix 13.

Chapter 6

Decommissioning of radiation sources and facilities

Section 32

Ageing of radioactive substance

The following procedures shall be followed in the ageing of a radiation source containing radioactive substance by means of storage referred to in section 83, subsection 2, of the Radiation Act:

1) the objective, duration and target activity of ageing shall be determined in advance;
2) the objective of ageing shall be that:
    a) the waste ceases to be considered as radioactive waste;
    b) the waste can be reused, recycled, utilized or disposed of in accordance with section 84 of the Radiation Act; or
    c) the waste can be released to the environment or to the sewer in accordance with section 127 of the Radiation Act; or
    d) the ageing will result in some other pre-identified benefit for the safety, technical solutions or economy of rendering the waste harmless;
3) the maximum duration of storage shall be:
    a) three years, when the objective of the ageing is in accordance with subsection 2, section a–c;
    b) one year, when the objective of the ageing is in accordance with subsection 2, section d.

However, the duration of ageing may be longer than that referred to in section 1, subsection 1, if the safety assessment shows that ageing is the best option from the radiation safety point of view.

Section 33

Transferring a sealed source to another undertaking

When a sealed source removed from use is transferred to another licence-holder for use, the transferor shall ensure that:

1) the sealed source and its shielding as well as the information and documentation supplied with the source meet the applicable requirements;

2) the leakage tests referred to in section 30 have been conducted for the sealed source;
3) the sealed source has a transport packaging which meets the applicable legal requirements if the transfer requires transportation.

Section 34

Decommissioning of contaminated premises and activated structures and materials

Cleaning for which a safety licence is required in accordance with section 83, section 4, of the Radiation Act shall be planned in advance;

1) by identifying the type and level of contamination and activated structures and materials at the site;
2) by identifying the available cleaning methods and practices;
3) by assessing the volumes and types of waste generated in the cleaning and determining the possible waste management routes for the waste;
4) by identifying the possible methods of implementation, taking into account the results of studies referred to in subsections 1–3.

The cleaning method shall be selected in such a way that the best possible overall solution can be reached, considering the safety of cleaning as well as the hazards caused by handling, storage and management of the waste.

A cleaning plan shall be prepared, detailing in particular:

1) the desired end state and procedures used for the demonstration of its fulfilment after cleaning;
2) phases and schedule of measures;
3) work methods to be used;
4) arrangements for the radiation protection of workers and the members of the public, including arrangements for preventing the spread of contamination;
5) waste disposal arrangements;
6) arrangements for quality assurance and documentation of measures.

After the cleaning, the undertaking shall demonstrate that the desired end state has been reached.

Section 35

Entry into force

This regulation enters into force on 3 July 2019 and is valid until further notice.

This regulation applies to any matters pending on the date of its entry into force.

This regulation repeals the Radiation and Nuclear Safety Authority's Regulation on activity values for high-activity sealed sources (STUK S/1/2019).

In Helsinki on 2 July 2019

Director General Petteri Tiippana

Director Tommi Toivonen

APPENDICES:

1) Activity values of high-activity sealed sources;
2) In-service acceptability criteria for X-ray imaging and fluoroscopic appliances, computed tomography appliances and bone mineral density measurement appliances based on the attenuation of X-radiation used in health care;
3) In-service acceptability criteria for X-ray imaging and fluoroscopic appliance and the related auxiliary devices and equipment used in veterinary medicine;
4) In-service acceptability criteria for radiotherapy appliance and the related auxiliary devices and equipment;
5) In-service acceptability criteria for equipment used in nuclear medicine;
6) In-service acceptability criteria for radiometric measurement devices in industrial use;
7) In-service acceptability criteria for imaging equipment in industrial use;
8) In-service acceptablity criteria for X-ray appliances used in industry and research;
9) Information to be presented in the records for high-activity sealed sources;
10) Information to be presented in the notification on the receipt, transfer and possession of radiation sources;
11) Information to be presented in the notification on transport requiring a safety licence;
12) Intervals of quality assurance measures in radiography practices, nuclear medicine and veterinary medicine;
13) Quality assurance measures of radiation sources used in industry.

Availability of the regulation, guidance and advice

This regulation has been published as part of the regulations issued by the Radiation and Nuclear Safety Authority (STUK) and it is available
from the Radiation and Nuclear Safety Authority.

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APPENDIX 1

Activity values of high-activity sealed sources

Table 1. Activity values of high-activity sealed sources.

Radionuclide	**Activity (Bq)**
Co-60	3×10^{10}
Se-75	2×10^{11}
Sr-90 (Y-90)	1×10^{12}
Cs-137	1×10^{11}
Pm-147	4×10^{13}
Gd-153	1×10^{12}
Yb-169	3×10^{11}
Tm-170	2×10^{13}
Ir-192	8×10^{10}
Ra-226	4×10^{10}
Pu-238	6×10^{10}
Pu-239/Be-9[1)]	6×10^{10}
Am-241	6×10^{10}
Am-241/Be-9[1)]	6×10^{10}
Cm-244	5×10^{10}
Cf-252	2×10^{10}
[1)] The activity indicated concerns the radionuclide emitting alpha radiation.	

For other radionuclides, the Radiation and Nuclear Safety Authority determines the value of the high-activity sealed source based on international recommendations.

ANNEX 2

In-service acceptability criteria for X-ray imaging and fluoroscopic appliances, computed tomography appliances and bone mineral density measurement appliances based on the attenuation of X-radiation used in health care

Suitability and operation of an X-ray appliance

1. The appliance and the equipment and safety equipment related to it or its operation shall be intact and operate as intended.

2. The appliance shall allow the use of aids to protect the persons assisting the patient from radiation and to keep the patient immobile. If the device is also used for the examination of children, its operation and performance characteristics shall be suitable for the examination of children as well.

Distance between the focal point and skin

3. In intraoral dental X-ray devices, the distance between the focal point of the X-ray tube and the skin of the person under examination shall be at least 20 cm when the voltage of the X-ray tube is higher than 60 kV, and at least 10 cm when the voltage is 60 kV or less.

Dose display

4. X-ray appliances taken into use after 1 April 2006 shall contain a display indicating the radiation exposure of the patient (hereinafter referred to as the dose display), based either on dose measurement or a calculated estimate. The dose display shall indicate the value of the quantity given in Table 1. In X-ray imaging appliances, with the exception of fluoroscopic appliance, the deviation of the dose display from the actual value of the quantity shall not exceed 25%. In fluoroscopic equipment, the deviation of the dose display from the actual value shall not exceed 35%. The requirement of the maximum deviation of the dose display applies to the entire normal operating range of the appliance.

5. The dose display of a appliance used for interventional radiology shall be able to indicate the cumulative radiation exposure caused to the patient during the procedure. Appliances used for interventional radiology and computed tomography shall include a function for transferring the dose display data to the examination file. X-ray devices other than those used for interventional radiology and computed tomography shall, if necessary, include a function for transferring the dose display data to the examination file.

Table 1. Quantity used in dose display.

<table>
<tr><th colspan="2" rowspan="2">Appliance type</th><th colspan="2">Commissioning date of appliance</th></tr>
<tr><th>Before 1 June 2014</th><th>After 1 June 2014</th></tr>
<tr><td rowspan="2">Normal
x-ray imaging appliance</td><td>Appliance mainly used for x-ray examinations of children</td><td colspan="2">The air kerma -area product (KAP) or other suitable dose quantity[1)]</td></tr>
<tr><td>Other appliance</td><td>Imaging values that allow the estimation of the patient's radiation exposure.</td><td>The air kerma-area product (KAP) or other suitable dose quantity[1)]</td></tr>
<tr><td colspan="2">Bone mineral density measurement appliance</td><td colspan="2">Imaging values that allow the estimation of the patient's radiation exposure.</td></tr>
<tr><td rowspan="2">Dental X-ray appliance</td><td>Intra oral X-ray appliance</td><td colspan="2">Imaging values that allow the estimation of the patient's radiation exposure.</td></tr>
<tr><td>Other X-ray appliance</td><td colspan="2">The air kerma-area product (KAP) [1)] or other suitable dose quantity in appliances commissioned after 1.1.2020.</td></tr>
<tr><td rowspan="2">Fluoroscopy appliance</td><td>Appliance, which is only used for the fluoroscopy of limbs</td><td>Imaging values that allow the estimation of the patient's radiation exposure.</td><td>The air kerma-area product (KAP) or other suitable dose quantity[1)]</td></tr>
<tr><td>Other fluoroscopy appliance</td><td colspan="2">The air kerma-area product (KAP) or other suitable dose quantity[1)]</td></tr>
<tr><td colspan="2">Mammography appliance</td><td>Imaging values that allow the estimation of the patient's radiation exposure.</td><td>Mean glandular tissue dose (MGD)</td></tr>
<tr><td colspan="2">CT appliance</td><td colspan="2">Weighted air kerma-length product (KLP)[2)] and volume CT air kerma index ($CTKI_{vol}$)[3)]
NOTE! The phantom size used in the determination shall be specified.</td></tr>
<tr><td colspan="4">[1)] This quantity is also referred to as the dose-area product (DAP).
[2)] This quantity is also referred to as the dose-length product (DLP).
[3)] This quantity is also referred to as the CT dose volume index (($CTDI_{vol}$).</td></tr>
</table>

Filtration of primary radiation

6. The undertaking shall have information about the total radiation filtration of each X-ray appliance. If changing the filtration is possible, it must be possible to detect the selected additional filtration.

7. In dental x-ray appliances, the total filtration of primary radiation shall correspond to at least 1.5 mm Al when the imaging voltage is not higher than 70 kV, and at least 2.5 mm Al when the imaging voltage is higher than 70 kV.

8. In X-ray appliances other than those used for mammography or dental imaging, the total filtration of primary radiation shall correspond to at least 2.5 mm Al. This requirement is deemed met also if the half-value thickness (HVT) of primary radiation corresponds at least to the minimum value shown in Table 2.

Table 2. The minimum acceptable half-value thickness for the primary radiation of appliances other mammography appliances or dental X-ray appliances (IEC 60601-1-3:2008).

X-ray tube voltage (kV)	**Minimum half-value thickness (mm Al)**
50	1.8
60	2.2
70	2.5
80	2.9
90	3.2
100	3.6
110	3.9
120	4.3
130	4.7
140	5.0
150	5.4

9. The total filtration of primary radiation of mammography appliances shall correspond at least to the values shown in Table 3. The total filtration of anode/filtration material combinations not shown in Table 3 shall be such that the condition for the half-value thickness, HVT ≥ U·(0.01 mmAl/kV), is fulfilled. In the formula, U is the voltage of the X-ray tube.

Table 3. The minimum total filtration values for the most commonly used combinations of X-ray tube anode/filtration material in mammography.

Anode material/ filter material	**Mo/Mo**	**Mo/Rh**	**W/Mo**	**W/Rh**	**Rh/Rh**	**W/Ag**
Minimum total filtration	30 µm Mo	25 µm Rh	60 µm Mo	50 µm Rh	25 µm Rh	50 µm Ag

X-ray tube voltage

10. The deviation of the X-ray tube voltage from the set or indicated value shall not exceed 10%. Furthermore, when the voltage value is changed, the actual voltage change must be at least 0.5 times and not exceed 1.5 times the difference of the set voltages.

11. The deviation of the X-ray tube voltage in a mammography appliance from the set or indicated value shall not exceed 2%.

12. The voltage of an intraoral X-ray appliance shall not exceed 75 kV. An intraoral X-ray appliance with a nominal voltage of less than 50 kV may not be taken into use.

Electric charge

13. The deviation of electric charge, i.e. the product of the X-ray tube current and the exposure time, from the set value shall not exceed 20% + 0.2 mAs. [1]

X-ray tube current

14. The deviation of X-ray tube current from the set value shall not exceed 20%.

Exposure time

15. The deviation of the exposure time from the set value shall not exceed 20%.

16. When exposure is repeated five times, the deviation of the set exposure time from average of the measured exposure times shall not exceed 10%.

17. When a 45 mm thick breast is imaged with a mammography appliance using traditional projection imaging and automatic exposure control unit, the exposure time shall be shorter than 2 s.

X-ray tube radiation output

18. When imaging is repeated using the fixed imaging values corresponding to the clinical use of the appliance (manually set values) five consecutive times, deviating the set values between the scans, thedeviation of the radiation output shall not exceed 20% of the average measurement value.

19. When using manually set values, the dose measured in the radiation beam of the X-ray appliance shall correspond to the electric charge set in such a way that

$$\left|\frac{\bar{K}_1}{Q_1} - \frac{\bar{K}_2}{Q_2}\right| \leq 0,2 \cdot \frac{\frac{\bar{K}_1}{Q_1} + \frac{\bar{K}_2}{Q_2}}{2}$$

where K_1 is the dose corresponding to electric charge Q_1, K_2 is the corresponding to electric charge Q_2 and

$Q_1 < Q_2 < 2 \cdot Q_1$.

Radiation beam indicators and alignment

20. The guide lights and the light fields must be clearly visible in normal working lighting conditions.

21. The guide lights or other radiation beam indicators and the edges of the radiation field shall not deviate from each other on the image receptor by more than 1% of the distance between the focal point of the X-ray tube and the image receptor on any side of the radiation field. In mammography appliance, this requirement is 2%.

22. The radiation beam shall fit the image receptor appropriately and as intended by the appliance manufacturer. In traditional X-ray imaging devices and fluoroscopic equipment, the deviation of the radiation beam from the intended point of the image receptor may not exceed 2% of the distance between the focal point and the image receptor.

23. If the X-ray imaging or fluoroscopic appilance is equipped with so-called automatic collimator which automatically limits the radiation beam to the size of the image receptor, the operator of the equipment must be able to change the image field size to a smaller size than that set by the automation.

24. In fluoroscopy, the ratio between the radiation field size and the active surface area of the image receptor may not exceed 1.25. The radiation field may not exceed the primary radiation shield of the device.

25. In an intraoral X-ray device, the central axes of the cross sections of the radiation beam and the orientation tube (distance limiter) may not deviate from each other by more than 2 mm. The diameter of the field size at the end of the orientation tube may not exceed 6 cm.

26. In mammography devices, the radiation beam may not exceed more than 5 mm over the edge of the treatment table outside the patient's chest. In other directions, the beam may not reach outside the equipment's primary radiation shield.

27. When the treatment table of a CT appliance moves a 30-cm distance, the actual movement of the table may not deviate from the value indicated in the table's movement display by more than 3 mm. The indicated starting point of CT scanning may not deviate from the actual starting point by more than 3 mm.

Compression force of mammography equipment

28. A mammograpy device shall be equipped with a device intended for the compression of the breast. When the breast is compressed mechanically, the maximum compression force shall be 130–200 N. When the breast is compressed manually, the compression force shall not be more than 300 N.

Image monitors

29. The operation of the image monitor may not restrict the quality of the image being displayed in such a way that it significantly decreases the certainty of diagnosis. Ambient lighting may not be strong enough to prevent the detection of contrast differences. Disturbing glares of light sources may not be reflected on the dark screen.

Image quality and digital imaging receptors

30. The image quality shall meet the clinical requirements set by X-ray examinations.

31. Clinical images may not show signs of previous images.

32. An image of a homogenic area may not show any image errors that might hinder the setting of diagnosis based on the patient images.

33. The reproducibility of the exposure index of a digital image shall be such that the deviation of dose determined from the exposure index of a specific image does not exceed 20% of the average of repeated measurements.

Operation of automatic exposure control unit

34. An automatic exposure control unit shall operate as intended by the device manufacturer.

35. An automatic exposure control unit shall be equipped with a display showing the electrical charge or exposure time after the scanning.

36. When an automatic exposure control unit is used, the maximum electric charge of the X-ray imaging device shall not exceed 600 mAs or correspond to an energy higher than 60 kWs. In mammography devices, this maximum electric charge is 800 mAs.

37. When the imaging of the same, suitable target is repeated five consecutive times, the automatic exposure control unit shall reproduce the exposure in such a way that the deviation of measured values of dose or a corresponding quantity from the average is less than 10%.

Fluoroscopy equipment

38. In the normal operational mode of the device, the air kerma rate of the reference point [1] shall not exceed 88 mGy/min. For transportable X-ray appliance, this requirement concerns the 30 cm distance from the outer surface of the imaging receptor shield instead of the reference point.

39. If the appliance has an operational mode allowing a dose rate higher than above, it may be approved under the following conditions:
    - The air kerma rate of the reference point shall not exceed 176 mGy/min. For transportable X-ray appliance this requirement concerns the 30 cm distance from the outer surface of the imaging receptor shield instead of the reference point.
    - The device is equipped with a switch which the operator must activate continuously in order to use a dose rate higher than the one used in the normal operational mode.
    - An uninterrupted audio signal informs the operator of the use of dose rate higher than the one used in the normal operational mode.

40. In the normal operational mode of the device, the level of dose rate automation[1)] shall not exceed 0.8 mGy/min.

[1)] The level of dose rate automation refers to the air kerma rate measured on the surface of the image receptor shield adjusted by the automation system. In the measurement, a 2-mm copper plate or a 20-mm aluminium plate attached to the X-ray tube curtains is used as a test phantom. If the stray radiation lattice cannot be removed, the measurement shall be corrected so that the air kerma rate measured corresponds to the situation behind the stray radiation lattice.

41. If the person performing the examination has to work near the patient, the adequate radiation protection must be provided for the operator in the equipment or as auxiliary equipment to attenuate the radiation scattered from the patient.

42. Fluoroscopy appliances shall have a display of the latest fluoroscopic image.

43. Using an X-ray fluoroscopy device in health care without an automatic dose rate control unit or an image intensifier or a corresponding device is prohibited.

Reference:

[1] EN (IEC) 60601-2-43:2010. Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures.

APPENDIX 3

In-service acceptability criteria for X-ray imaging and fluoroscopic appliance and the related auxiliary devices and equipment used in veterinary medicine

Table 1. Performance measurement results depend on the measurement conditions and the method of measurement used.

Test	**Requirement**
X-ray tube voltage	The deviation of the measured X-ray imaging voltage shall not be more than 10% from the nominal value.
Total filtration	The total filtration of primary radiation shall be at least 1.5 mm Al when the imaging voltage is no more than 70 kV, and at least 2.5 mm Al when the imaging voltage is greater than 70 kV. The operator shall have information about the total radiation filtration of each X-ray appliance. If changing the filtration is possible, it must be possible to detect the selected additional filtration.
Radiation output of the X-ray tube	When imaging is repeated five consecutive times, deviating the set values between the scans, the deviation of the radiation output shall not be more than 20% of the average measurement value. If the imaging current or exposure time can be adjusted in the device, the air kerma shall correspond to the electric charge Q in such a way that $\left\lvert \frac{\bar{K}_1}{Q_1} - \frac{\bar{K}_2}{Q_2} \right\rvert \leq 0,2 \cdot \frac{\frac{\bar{K}_1}{Q_1} + \frac{\bar{K}_2}{Q_2}}{2}$, where $\bar{K}_1$, $\bar{K}_2$ are the measured air kermas and Q_1, Q_2 are the products of imaging current and exposure time. Q_1, Q_2 differ from each other by a factor which is as close as possible to factor 2 without exceeding it.
Radiation and light field	The edges of the radiation and light fields may not deviate from each other by more than 1 cm at the imaging distance used. The edge of the light field must be clearly visible under normal working lighting conditions.

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APPENDIX 4

In-service acceptability criteria for radiotherapy appliance and the related auxiliary devices and equipment

1. The following table summarizes the acceptability criteria for accelerators, brachytherapy appliances (afterloading appliance) and treatment focusing devices used in radiotherapy. Performance measurement results depend on the measurement conditions and may also depend on the method of measurement used. The acceptability criteria specified in the table are for the measurement conditions specified in reference [1], unless another reference is given for a specific requirement.

Table 1. Acceptability criteria for accelerators, brachytherapy appliance (afterloading appliance) and treatment focusing devices used in radiotherapy.

Appliance	**Test**	**Maximum allowable deviation**
Radiotherapy appliance[1)]	Dose accuracy in the reference geometry [2]	3%
	Dose accuracy in the GTV[2)] of the treatment field in a water-equivalent material phantom [3]	5%
	Reproducibility in the phantom in the reference geometry	0.5%
Treatment focusing devices	Precision of focusing devices	4 mm
Brachytherapy equipment	Positional accuracy of the source[3)]	2 mm
	Timer error	3% of treatment time or maximum 1 s
[1)] Appliance producing the photon and electron treatment does. [2)] GTV (gross tumor volume) [3)] When measured using a straight applicator.		

2. A computerized radiotherapy treatment planning system shall be used in the dose planning of radiotherapy with the exception of radionuclide therapy and treatment given with an X-ray surface radiotherapy device. A dose planning system must be available for use in the dose planning of radionuclide treatment where it may be of use for obtaining the objective referred to in section 9, subsections 1 and 3 of regulation S/4/2019.

3. A treatment verification system must always be available for use with an external radiotherapy accelerator. A system or other function indicating the appropriate parameters to be used for the definition of dose incurred to the patient when using a radiotherapy appliance generating ionizing radiation other than an accelerator used for external radiotherapy. If necessary, the equipment must be equipped with a function for transferring this data to the examination file.

4. An afterloading device shall be equipped with an installation allowing the manual returning of radioactive substances to the exposure container.

References:

[1] International Electrotechnical Commission (IEC): Medical electrical equipment. Medical electron accelerators – Functional performance characteristics, International standard IEC 976.

[2] Säteilyturvakeskus: Sädehoidon annosmittaukset. Ulkoisen sädehoidon suurenergisten fotoni- ja elektronisäteilykeilojen kalibrointi. STUK-STO-TR 1. STUK, Helsinki 2005.

[3] Commissioning and Quality Assurance of Computerized Planning Systems for Radiation Treatment of Cancer. IAEA-TECDOC-430, IAEA 2004.

APPENDIX 5

In-service acceptability criteria for equipment used in nuclear medicine

Table 1. In-service acceptability criteria for equipment used in nuclear medicine.

Appliance	**Characteristic**	**Maximum allowable deviation or result**
Gamma camera	Uniformity • integral irregularity of the useful field of view (UFOV) [1]	7%
	Centre of rotation [1]	1 pixel
	Sensitivity • difference of sensitivity between different detectors [1]	10%
	Spatial resolution • full width at half maximum (FWHM) [1]	≤ 6 mm
	Spatial resolution of full body imaging • full width at half maximum (FWHM) [2]	≤ 12 mm
Activity meter (dose calibrator)	Linearity [1]	± 5%
	Stability (reproducibility, constancy) [2]	± 5%
	Accuracy • for over 100 keV gamma energies [1] • for under 100 keV gamma energies [3]	±5% ±10%
PET camera	Quantitativity of PET images (SUV measurement)[4]	10%
	Uniformity • Variation of background regions of interest in the NEMA image quality test; standard deviation/average [2]	10%
	Spatial resolution • full width at half maximum (FWHM) [2]	≤ 8 mm
SPECT-CT and PET-CT	Geometrical position of a radionuclide imaging device and a CT device[1)] with regard to each other [1]	1 Pixel (of PET or SPECT scan)
Gamma detectors used in surgery	Constancy of sensitivity [2]	20%
Gamma counter (well crystal)	Constancy [2]	5%

[1)] In addition to this regulation, computed tomography appliance is subject, where applicable, to the in-service acceptability requirements for X-ray appliances.

References:

[1] Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy. Radiation Protection No 162, European Union 2012.

[2] Recommendation of the expert group that prepared STUK's Decision 9/3020/2013

[3] National Physics Laboratory. A National Measurement Good Practice Guide No 93.

[4] Quality control guidance for nuclear medicine equipment. Advice from STUK 1/2010.

APPENDIX 6

In-service acceptability criteria for radiometric measurement devices in industrial use

Using a radiometric measurement device containing a sealed source requires that the following conditions are met:

1) The device can withstand the operational conditions and the effects of radiation;
2) The device must be designed in such a way that the sealed source stays shielded also in case of fire. The shielding capacity of the shield may not deteriorate substantially in case of fire;
3) The attachment of the sealed source in the device is secured by means of a seal or a lock or, if this is not possible, using some other reliable method;
4) The radiation shield of the device shall be such that the size of the radiation beam is as small as possible;
5) If necessary, shields must be installed around the device that prevent entry to the primary beam of the radiation source;
6) The shutter of the device must operate reliably under all operational conditions;
7) The surface layer of the shutter and the adjoining parts may not consist of lead;
8) The shutter shall be so constructed that it cannot be opened accidentally and can be closed without tools;
9) The radiation shield shall be fitted with a latch to lock the shutter in the closed position. The lock shall not be openable by means of a key substitute. The shutter shall not be lockable in the open position but shall be capable of being in locked in closed position without the use of a key;
10) The radiation device must be equipped with texts or other clear indicators of the shutter positions;
11) Electrically or pneumatically operated shutters shall close automatically in the event of loss of electrical power or compressed air supply. In this case, the shutter itself does not require a separate lock;
12) If the device has a remote shutter, it has indicator lights to show the position of the shutter. The indicator lights are controlled directly by shutter movements. Indication of shutter closing indicator light is lit only when the shutter is fully closed. If the shutter is partially open, the the shutter open indicator light must be illuminated;
13) If access to the radiation beam is possible through a service hatch or similar, a sign shall be placed on the access route to the source, advising to close the radiation source shutter before entering the space;

Mobile radiometric measuring devices and other radiation appliances containing sealed sources shall meet the above requirements, where applicable.

The dose rate in the vicinity of a radiometric measuring device containing a sealed source outside the radiation beam shall be as low as is practicable for the intended use of the device and shall not exceed the following values:

1) 500 μSv/h at 5-cm distance from the touchable surface of the device;
2) 7.5 μSv/h at 1-m distance from the touchable surface of the device.

Where necessary, permanent shields must be installed around the device to ensure that the dose rates are lower than those mentioned above.

APPENDIX 7

In-service acceptability criteria for imaging equipment in industrial use

1. Collimators must be used in imaging equipment in industrial use to limit the radiation beam to a size as small as necessary for the safety of imaging.

In-service acceptability criteria for customary X-ray imaging devices

2. The protective shield of the tube unit must be such that leakage radiation is minimized and does not exceed the following values at 1-metre distance from the tube:

Tube voltage	Leakage radiation
under 150 kV	1 mSv/h
150–200 kV	2.5 mSv/h
over 200 kV	5 mSv/h

3. The total filtration of primary radiation must correspond at least to the following values:

Tube voltage	Total filtration
under 50 kV	no requirements
50–100 kV	2 mm aluminium
100–200 kV	3 mm aluminium
200–300 kV	4 mm aluminium
over 300 kV	0.5 mm copper

4. The device must be equipped with an additional filter unless the imaging technology requires a filtration lower than customary and the tube unit's own filtration is lower than the values above. In such case, the total filtration shall correspond to the total filtration values stated above.

5. For the preheating of the X-ray tube, a shutter must be available for attenuating the primary radiation in such a way that leakage radiation does not exceed the values stated above.

In-service acceptability criteria for gamma imaging devices

6. It must be possible to lock the exposure container of the gamma imaging device when the device is not used.

7. The protection capacity of the collimator shall be at least two tenth-value thicknesses.

8. The gamma imaging device shall comply with the requirements of ISO 3999. Conformity shall be evidenced by a certificate to that effect.

9. The sealed source used in the gamma imaging device shall meet at least the requirements of the class C 43515 of standard SFS- EN ISO 2919.

APPENDIX 8

In-service acceptance criteria for industrial and research X-ray appliances other than industrial imaging appliances

The control unit or operating panel of the X-ray appliances shall be located in such a way that the use of the equipment can be monitored.

1. The X-ray appliance or its immediate vicinity shall be equipped with an indicator light or lights to indicate when the appliance is emitting radiation. At least one light shall be visible around the appliance at each door, panel and hatch or the like.

2. The shielding of the X-ray appliance shall be such that the dose rate from any touchable surface of the appliance and outside the radiation beam is as small as possible and does not exceed:
   a) 1 µSv/h at a distance of 10 cm for a closed beam analyser;
   b) 25 µSv/h at a distance of 5 cm for a open beam analyser;
   c) 5 µSv/h at a distance of 5 cm for a shielded fluoroscopic device.

3. The X-ray device must also be equipped with the following safety and alarm systems, as appropriate to the safety of the equipment:
   a) safety switches to prevent the generation of radiation if the doors, panels and hatches or similar acting as integral shielding of the appliance are opened and, once the safety system has cut off the radiation generation, the appliance must not be switched on without action by the user;
   b) emergency buttons and other switches which, when actuated, stop the radiation generation;
   c) if the radiation beam is directed outside the appliance or the design of the appliance is such that access to the radiation beam is possible, the activating of the appliance shall be only by means of a key, code or similar switch. The switch shall be such that the radiation cannot be produced without it;
   d) electrical safety and warning systems shall be provided with a protective circuit to prevent operation of the equipment in the event of failure or shall be duplicated and independent of each other.

4. Once the safety system referred to in section 1, subsection a) (see list above) has prevented the generation of radiation, it must not be possible to resume it without the intervention of the user of the equipment.

5. A mobile open beam anayser shall be equipped with a safety switch to prevent operation of the instrument without the object to be analyzed or examined.

6. The specimen to be examined or analyzed shall be placed inside the shield of the shielded fluoroscopic device before radiation exposure is initiated, or the sample transfer mechanism shall be automatic.

7. Shielded scanning devices used for the inspection of products and goods shall be fitted with additional shields which attenuate the radiation in the vicinity of the inlet and outlet openings.

8. Where shielded scanning devices are used in public places and the inlets and outlets have access to the radiation beam, access barriers shall be provided around the openings.

APPENDIX 9

Information to be presented in the records for high-activity sealed sources

Table 1. Record sheet for a high-activity sealed source.

Main category	Detailed information	
1. Sealed source identifier	Serial number of the source capsule	
2. Licence-holder information	Holder of the safety licence	
	Address	
	User type (manufacturer, supplier or user)	
3. Location of appliance/sealed source	Location of the appliance. Storage or warehousing location of a portable appliance.	
	Address of the location of appliance (if other than the one in section 2). Address of the storage or warehousing location of a portable device.	
	Installation method (fixed or portable)	
4. Records	Record-keeping concerning this sealed source was started on	
	Date of last entry (date when the sealed source has been transferred and active record-keeping has ended)	
5. Safety licence	Safety licence number	
	Issue date of licence	
	Period of validity of licence	
6. Holder's own supervision	Dates of appliance/source inventory	
	Dates of wipe tests	
7. Information of the radiation appliance/ sealed source	Purpose of use of the appliance	
	Appliance manufacturer	
	Shield type	
	In use or in storage	
	Radionuclide	
	Activity on the date of manufacture [1)]	
	Date of manufacture [2)]	
	Manufacturer name [3)]	
	Manufacturer address [3)]	
	Chemical form of radioactive substance in the sealed source	
	Physical properties of the source capsule	
	Issuer of certificate for the sealed source and date of issue	
8. Information on the receipt of sealed source	Date of receipt	
	Received from	
	Address for the above	
9. Information on the transfer of sealed source	Date of transfer	
	Transferred to	
	Address for the above	
10. Further information	Information concerning abnormal events	
	Other information	

[1)] If the date of manufacture is not known, record the activity on the date of placing the source on the market.

[2)] If the date of manufacture is not known, record the date of placing the source on the market.

[3)] If the manufacturer of the sealed source is located outside the European Union, the name and address of the importer may be recorded here.

APPENDIX 10

Information to be presented in the notification on the receipt, transfer and possession of radiation sources

General information of the notification

1. Name of the holder of the safety license and the number of the safety license;
2. Name and contact details of the contact person.

Information of notification concerning sealed sources

3. For sealed sources, the sealed sources transferred and received during the calendar year and held in the undertakings's storage at the end of year are reported. The following information must be provided for each sealed source:
   a) radionuclide;
   b) activity and the activity's determination date;
   c) unique manufacure number;
   d) name of transferor or consignee and, for Finnish parties, the licence number; for foreign parties, the country;
   e) transferor of sealed sources in storage and the plan to whom the sealed source will be transferred to;
   f) whether the transferred sealed sources have been sold or leased and, in the case of those leased, the period of lease.

Information of notification concerning unsealed sources

4. For unsealed sources, the following information must be provided for each radionuclide:
   a) total activity imported;
   b) total activity exported;
   c) total activity manufactured.

Information concerning appliances generating ionizing radiation electrically

5. For X-ray appliances and other appliances generating ionizing radiation electrically, the numbers of applainces imported during the calendar year, transferred to Finnish undertakings and held in the undertakings's storage at the end of year. The following information must be provided for each appliance:
   a) unique serial number;
   b) the manufacturer of the appliance and the name of the model;
   c) for transferred appliances, the name of transferee and licence number;
   d) for imported appliances, the country from which the appliance is imported;
   e) whether the transferred appliances have been sold or leased and, in the case of those leased, the period of lease.

APPENDIX 11

Information to be presented in the notification on transport requiring a safety licence

1. In the notification concerning a transport requiring a safety licence, the information of the undertaking, description of transport, information of the high-activity sealed source and other approvals of the authorities related to the transport must be spesified. The notification must include the following details:

2. Information of the undertaking
   - holder of the safety licence
   - safety licence number
   - contact information in case of radiation safety deviations
   - maker of notification and notification date.
3. Description of transport
   - mode of transport (road/rail/combination)
   - departure point
   - planned departure date/date of entry into Finland
   - destination
   - planned date at destination
   - route
   - consignor information
   - transferee information.
4. Information of high-activity sealed sources
   - radionuclide(s)
   - total activity during transport
   - UN number and name
   - package type.
5. Other approvals of the authorities related to the transport
   - identifiers of the package approval certificate and special format certificate.

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APPENDIX 12

Intervals of quality assurance measure in radiography, nuclear medicine and veterinary medicine

Table 1. Quality control intervals (safety tests and image viewing monitors).

Test or characteristic	**Maximum interval**	
Safety tests Condition of device, mechanical operation and safety switches Operation of warning lights Condition of protective devices	12 months 12 months 12 months	
Image monitor tests (not applicable to veterinary medicine)	Diagnostic monitors (so called primary monitors)	Secondary monitors
Operation of image monitor using the test image Luminance of image monitor	1 month 12 months	6 months

Table 2. Quality control intervals (X-ray applinaces used in health care and veterinary medicine).

Test or characteristic	**Maximum interval**
Verification of compliance with in-service acceptability criteria (excluding intraoral X-ray appliances) Exceptions**:** CT scanners, fixed fluoroscopic applaince used in interventional radiology Radiation appliances used in veterinary medicine (excluding intraoral X-ray appliances)	24 months 12 months 36 months
Imaging of test piece/image quality (not applicable to veterinary medicine appliance) Intraoral appliance Panoramic radiograph appliance Mammography appliance Fluoroscopy appliance, fixed CT appliance Conventional X-ray appliance Fluoroscopy appliance, portable	12 months 6 months 6 months 6 months 6 months 12 months 12 months

Table 3. Quality control intervals (nuclear medicine).

Appliance	**Test or characteristic**	**Maximum interval**
Activity meter (dose calibrator)	Accuracy	1 month
	Linearity	6 months
Gamma camera	Spatial resolution	12 months
	Sensitivity	12 months
	Uniformity of image field	1 month
PET camera	Image quality	12 months
	Quantitativity of PET images	3 months
Combination imaging appliances (SPECT-CT, PET-CT and PET-MRI)	Geometrical position of a radionuclide imaging device and a CT appliance or an MRI device with regard to each other	6 months
Gamma detector (gamma detectors used in surgery)	Constancy of sensitivity	12 months
Gamma counter (well crystal)	Constancy	3 months

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APPENDIX 13

Quality assurance actions of radiation sources in industrial use

1. The operating condition of industrial and research radiation sources and equipment and other equipment, software and peripheral devices affecting safety shall be checked at least once every calendar year.

2. If the manner of use of the radiation appliance or the conditions at the place of use are such that it is necessary to ensure compliance with its in-use acceptance requirements, more frequent inspections to this effect shall be carried out.

3. The operating condition of a radiation source and appliance which is associated with occupational exposure category 1 or 2 and other safety relevant equipment and accessories shall be checked every time before the appliance is used.

4. The inspection of a gamma radiograph appliance according to the quality assurance programme must include at least the control tube, transfer wire, fixing joint, remote control and exposure container. Inspection entries of a gamma radiograph appliance shall be made on the exposure container.

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