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.

STUK
SÄTEILYTURVAKESKUS
STRÅLSÄKERHETSCENTRALEN
RADIATION AND NUCLEAR SAFETY AUTHORITY

Osoite / Address | Laippatie 4, 00880 Helsinki
Postiosoite / Postal address | PL / P.O. Box 14, FI-00811 Helsinki, FINLAND
Puh. / Tel. (09) 759 881, +358 9 759 881 | Fax (09) 759 88 500, +358 9 759 88 500 |
www.stuk.fi

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.

STUK
SÄTEILYTURVAKESKUS
STRÅLSÄKERHETSCENTRALEN
RADIATION AND NUCLEAR SAFETY AUTHORITY

Osoite / Address | Laippatie 4, 00880 Helsinki
Postiosoite / Postal address | PL / P.O. Box 14, FI-00811 Helsinki, FINLAND
Puh. / Tel. (09) 759 881, +358 9 759 881 | Fax (09) 759 88 500, +358 9 759 88 500 |
www.stuk.fi

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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Postiosoite / Postal address | PL / P.O. Box 14, FI-00811 Helsinki, FINLAND
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www.stuk.fi

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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