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Use and Regulatory Control of Dental X-ray Installations

STUK • SÄTEILYTURVAKESKUS • STRÅLSÄKERHETSCENTRALEN
RADIATION AND NUCLEAR SAFETY AUTHORITY

STUK

GUIDE
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Use and Regulatory Control of Dental X-ray Installations

This Guide is valid as of 1 January 2000 until further notice. It replaces SS Guide 3.1 "Dental X-ray Equipment: Type Inspection and Technical Requirements", issued on 25 February 1987.

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Authorisation

Under section 70, paragraph 2, of the Radiation Act (592/1991), STUK – Radiation and Nuclear Safety Authority (Finland) issues general instructions, known as Radiation Safety Guides (ST Guides), concerning the use of radiation and operations involving radiation.

The Radiation Act stipulates that the party running a radiation practice is responsible for the safety of the operations. The responsible party is obliged to ensure that the level of safety specified in the ST Guides is attained and maintained.

Translation. Original text in Finnish.

This Guide includes the requirements relating to the implementation of Council Directive 96/29/Euratom; OJ No. L 159, 29.6.1996, p. 1 and 97/43/Euratom; OJ No. L 180, 9.7.1997, p. 22.

1 Introduction

The fundamentals of safe dental X-ray practice are the use of working premises that are in accordance with the regulations, installations which meet the constructional and technical requirements and which function reliably, and the correct use of these installations. The X-ray equipment must be suitable for the dental imaging of both adults and children when using fast and slow films or other sensitive image receptors. The photographer must know the various factors which affect radiation exposure, and the means of shielding from unnecessary radiation. The X-ray images must be of a high technical standard of reproduction, and the films must be developed to a state allowing reliable diagnosis to be made.

In this Guide the safety requirements concerning dental X-ray installations and their use, prerequisites for exemption from a safety licence, and regulatory control are presented. The Guide applies to conventional dental X-ray installations, by which an image is created on an X-ray film or other image receptor placed inside the mouth, and panorama tomography installations for dentition and the cephalostats associated with these. The Guide does not apply to multitechnique tomography installations intended for the special imaging of the skull or jaws.

2 General Principles of Radiation Protection

In order to be acceptable, the use of radiation must fulfil the following requirements as laid down in the Radiation Act (592/1991):

1. The benefit accruing from the practice shall exceed the detriment it causes (principle of justification).
2. The practice shall be organised in such a way that exposure to radiation hazardous to health is kept as low as possible, taking into consideration practical and economic factors (the optimisation principle).
3. The exposure of workers to radiation must not exceed the dose limits laid down in the Radiation Decree.

Radiation may, in general, be deliberately targeted on a person only on medical grounds, for the examination or treatment of illness. The need for a dental X-ray examination must always be considered on a patient-specific basis, and this must be of benefit to the patient. There will be adequate grounds for X-ray examination if the information to be obtained by X-ray imaging is necessary for correct diagnosis or treatment, and if the necessary information cannot be obtained in any other way.

3 Exemption from a Safety Licence

3.1 New Installations

A Safety licence as referred to in section 16 of the Radiation Act is not required for the use of the following dental X-ray installations:

- an apparatus which is used with an image on an image receptor inside the mouth
- a panorama tomography apparatus
- a cephalostat.

Exemption from the safety licence in accordance with Decision 202/310/99 of STUK requires that

1. the apparatus has a CE marking (Directive 93/42/EEC) in accordance with the Medical Devices Act (1505/1994)
2. the shielding at the place of use of the apparatus is in accordance with this Guide
3. an authorised dentist or doctor directs the use of the equipment and takes responsibility for safety in such use.

An apparatus which is exempted from the safety licence must be notified to the Radiation and Nuclear Safety Authority (STUK) for registration in accordance with chapter 7.

3.2 Old Installations

Dental X-ray equipment manufactured prior to 14.6.1998 may be transferred for use in a new place or to a new owner, if the equipment and the activity fulfil the requirements set out in this Guide or in SS Guide 3.1 (25.2.1987) (Decision 77/310/92 of STUK).

Dental X-ray installations where the imaging voltage is less than 50 kV may continue to be used in the place and under the supervision of the dentist to whom the apparatus is registered when this Guide comes into force. However, such an apparatus can no longer be approved for use by a new responsible party.

3.3 Registration

Dental X-ray installations which are exempted from the safety licence must be notified to STUK for registration in the manner set out in chapter 7.

4 Situations Requiring a Safety Licence

Where dental X-ray apparatus or its use does not fulfil the preconditions for exemption from the safety licence laid down in chapter 3, a safety licence as referred to in section 16 of the Radiation Act must be obtained for the use of the apparatus. The terms concerning use of the apparatus will be specified in the safety licence.

Exemption from a safety licence applies only to the use of dental X-ray installations for the examination of a patient in connection with the ordinary activities of a dentist. For scientific research work or screening examinations which are to be carried out on dental X-ray installations, a safety licence must be obtained from STUK. In this case the licence application must be accompanied by a supporting statement of the Ethical Committee concerning the justification of the activity. More precise directions are given in ST Guide 1.1. In addition, the use of radiation in connection with training and product development and clinical trials of installations is activity that is subject to licence.

A notification to the National Agency for Medicines on the basis of the Medical Devices Act (1505/94) must be made concerning clinical research which is carried out in order to demonstrate compliance with the demands concerning a health care installation or item of apparatus, before the installation or item of appliance is placed on the market or brought into use.

5 Requirements Concerning Use of Installations

Apparatus

The requirements set out in Appendix A shall be applied to the use of dental X-ray installations. For dental X-ray installations manufactured before 14.6.1998, instead of these requirements the requirements set out in SS Guide 3.1 (25.2.1987) can be applied.

Use of Installations

Regardless of exemption from the safety licence, the provisions of the Radiation Act and STUK Guides issued on the basis of the Act must be complied with in the use of dental X-ray installations. Special attention must be paid to the requirements for the medical use of radiation as set out in chapter 10 of the Radiation Act.

The dental X-ray imaging must be made in such a way that the objective set for the examination is attained while, at the same time, minimising the exposure to radiation of the patient, staff and other persons. When imaging onto conventional X-ray film (speed category U) placed inside the mouth, the absorbed dose on the patient's skin (the Entrance Surface Dose) should not be greater than 7 mGy per image (reference level). If the speed of the X-ray film (speed category E) is twice the speed of a conventional film, the patient dose comparison value will be 3.5 mGy. This value may also be regarded as the upper limit in digital imaging.

In medical practices, the responsible party must arrange quality assurance for the radiation sources to be used, the installations and accessories and their use (Radiation Act, section 40). More precise instructions on the arrangement of quality assurance can be obtained from STUK.

Radiation installations may be installed, repaired and maintained only by a person who has the necessary occupational skills and expertise. The performer of the work is under the obligation, after the work has been carried out, of ensuring that the equipment functions flawlessly (Radiation Act, section 25).

The holder of dental X-ray equipment must ensure that, apart from a dentist or phycician, X-ray imaging is made only by a person who has received occupational training in X-ray imaging (e.g. a dental assistant, dental hygienist or X-ray technician), under the supervision of a dentist or phycician. Such a person must have adequate radiation safety training and guidance in the use of the apparatus, in shielding from radiation and in the development of the films.

It is the duty of the dentist or phycician in charge of the dental X-ray activity to maintain their knowledge and professional skill concerning radiation safety. In addition, they must ensure that other members of staff who use radiation also have user instructions and up-to-date and adequate information on radiation safety and factors affecting it.

The examination results and X-ray images must be recorded in such a way that they are available for the future treatment of the person being examined.

6 Radiation Shieldings at the Premises of Use

The need for radiation shielding of the exposure room depends on how much the X-ray equipment is used, on the imaging voltage and the product of the imaging current and time (mAs), on the location of the X-ray equipment in the exposure room and on the use of the surrounding areas. If persons remain in the immediate vicinity of the exposure room continually during the exposure, the shielding requirements for an area in the direction of the radiation beam will be in accordance with Table *I* of Appendix B. Table *III* sets out the shielding requirement for areas to which only scattered radiation is directed. In the calculations the weekly dose limit of 0.02 mSv is used, as derived from the dose limit for the general public (1 mSv per annum). Places which are regarded as being continuously occupied include the dentist's or other person's workroom or consulting room and the waiting room.

In the shielding calculations for toilets, corridors or other areas in temporary use that are located adjacent to the exposure room, the weekly dose limit value of 0.1 mSv is used. The shielding requirement for areas located in the direction of the radiation beam are presented in Table *II* of Appendix B. If scattered radiation only is directed to an area which is in temporary use, and which is situated at a distance of at least 1 m from the X-ray equipment, and the product of the imaging current and time is no greater than the value of 600 mAs per week, no additional shielding will be needed.

7 Reporting Obligation and Registration

7.1. Holder of X-ray Equipment

The holder of the equipment (the organisation or dentist who uses the equipment) must give notification of dental X-ray equipment which is exempted from a safety licence for registration to STUK in accordance with section 20 of the Radiation Decree. In this notification, information must be presented which STUK can use (in connection with the registration of the equipment) in ascertaining whether the preconditions for exemption from the safety licence are being met (see chapter 3). The equipment may be taken into use when the holder of the equipment has received notification that registration has been approved.

If the holder or place of use of the equipment (to whom or in which the use of the dental X-ray equipment is registered) changes, or if the apparatus is withdrawn from use, notification of the change must be made to STUK without delay.

The holder of the apparatus is responsible for the authenticity of the information notified to the register.

7.2 Supplier of X-ray Equipment

The seller or other transferor of dental X-ray equipment must, on the basis of section 21 of the Radiation Act, provide the following information to STUK concerning the dental X-ray equipment transferred by them:

- the owner of the equipment
- the address to which the equipment is delivered or installed
- the type and serial number of the equipment
- the date of sale or consignment of the equipment.

The information pertaining to a specific year must be delivered during January the following year.

8 Notifications of Radiation Hazard Situations

STUK must be notified, without delay, of an exceptional event connected to the use of radiation and of other exceptional observations and information which are of essential importance from the point of view of the radiation safety of workers or the environment (Radiation Decree, section 17).

The Medical Devices Act (1505/1994) lays down the obligation of those engaged in the professional use of health care installations and equipment to give notification to the National Agency for Medicines of all proven or suspected serious danger situations in connection with the use of the installation and equipment, and of such inadequate or erroneous labelling or user instructions which could cause such a situation.

9 Regulatory Control

STUK oversees the radiation safety of dental X-ray installations and the use of these on the basis of the Radiation Act.

In order to ensure the radiation safety of dental X-ray practices, STUK carries out control measurements and inspections on X-ray installations that are in use. Furthermore, installations which are exempted from the safety licence are inspected in order to ensure that the installations and their use are in accordance with the conditions set for exemption. Regulatory control of the quality of X-ray practices, the condition of the X-ray equipment and patient doses are carried out by means of measurements and inspections. The reasons for doses that are greater than normal will be investigated. Where necessary, demands for the reduction of doses or improvement of the quality of X-ray activity will be presented.

10 Bibliography

1 Criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations. European Commission, Radiation Protection 91, Luxemburg: Office for Official Publications of the European Communities, 1997.

2 Council Directive 93/42/EEC, issued 14 June 1993, concerning medical devices. European Communities Official Journal No. L 169/1, 12.7.1993, p 1.

APPENDIX A

REQUIREMENTS CONCERNING THE USE OF CONVENTIONAL DENTAL X-RAY EQUIPMENT, PANORAMIC TOMOGRAPHY EQUIPMENT AND CEPHALOSTAT

Voltage of X-ray Tube

The voltage of the X-ray tube may deviate from the set value by no more than 10%.

When repeating the measurement of the voltage of the X-ray tube, the coefficient of variation* must be smaller than 5%.

Total Filtering

Total filtering of primary radiation must be equivalent to at least 1.5 mm Al when the imaging voltage is up to 70 kV, and to at least 2.5 mm Al when the imaging voltage is greater than 70 kV.

Focus to Skin Distance

The distance between the focus of conventional dental X-ray equipment and the skin of the person being examined must be at least 20 cm when the voltage is greater than 60 kV, and at least 10 cm when the voltage is 60 kV or less.

Size of Radiation Beam

The field size diameter of conventional dental X-ray equipment at the end of the collimation tube may not be greater than 6 cm.

Exposure Time

The actual exposure time may deviate from the set value by no more than 20% if the time indicated is greater than 100 ms. The coefficient of variation of the measured exposure time must be less than 10%.

* Coefficient of variation (relative standard deviation) = Standard deviation divided by mean value of the measurement results.
Standard deviation = The positive square root of the arithmetic mean of the squares of differences of the measurement results and their mean value.

APPENDIX A

Radiation Output of X-ray Tube

When repeating the imaging, the radiation output must be within ± 20% of the mean value of the measurement results. If the equipment contains an imaging current or exposure time control, the air kerma must be proportional to the indicated current time product Q in such a way that:

$$\left|\frac{\overline{K_1}}{Q_1} - \frac{\overline{K_2}}{Q_2}\right| \leq 0.2 \cdot \frac{\frac{\overline{K_1}}{Q_1} + \frac{\overline{K_2}}{Q_2}}{2}, \text{ where}$$

$\overline{K_1}$, $\overline{K_2}$ are the measured air kerma values and

Q_1, Q_2 are the products of the X-ray tube current and exposure time.

Q_1, Q_2 differ from one another by a factor which is as close as possible to factor 2 without, however, exceeding it.

Centralization and Collimation of the Radiation Beam

In conventional dental X-ray equipment, the central axes of the cross sections of the radiation beam and the collimation tube must not differ from one another by more than ± 1% of the focus distance.

When using panoramic tomography equipment and a cephalostat, the radiation beam must fall entirely on the image receptor.

APPENDIX B

RADIATION SHIELDINGS OF DENTAL X-RAY PREMISES

Table I. *Need for radiation shielding in the direction of the primary beam; for continuous occupation. Dose limit 0.02 mSv / week.*

Voltage of X-ray tube	Amount of use	Distance from focus of X-ray tube		
		1 m	2 m	4 m
kV	mAs/week	Shielding at least (mm Pb)		
50	60	0.2	0.1	0.1
50	180	0.3	0.2	0.1
50	600	0.4	0.3	0.2
50	1800	0.5	0.4	0.3
70	60	0.5	0.3	0.2
70	180	0.6	0.4	0.3
70	600	0.8	0.6	0.4
70	1800	1.0	0.8	0.6

Table II. *Need for radiation shielding in the direction of the primary beam; for temporary occupation. Dose limit 0.1 mSv / week.*

Voltage of X-ray tube	Amount of use	Distance from focus of X-ray tube		
		1 m	2 m	4 m
kV	mAs/week	Shielding at least (mm Pb)		
50	60	0.1	0.1	0
50	180	0.2	0.1	0.1
50	600	0.3	0.2	0.1
50	1800	0.3	0.2	0.2
70	60	0.3	0.1	0.1
70	180	0.4	0.2	0.1
70	600	0.6	0.4	0.2
70	1800	0.8	0.5	0.3

Appendix B

Table III. *Need for radiation shielding in directions other than that of the primary beam; for continuous occupation. Dose limit 0.02 mSv / week.*

Voltage of X-ray tube	**Amount of use**	**Distance from focus of X-ray tube**		
		1 m	**2 m**	**4 m**
kV	**mAs/week**	**Shielding at least (mm Pb)**		
50	60	0		
50	180	0		
50	600	0.1	0	
50	1800	0.2	0.1	0
70	60	0		
70	180	0.1	0	
70	600	0.2	0.1	0
70	1800	0.4	0.2	0

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