

SSI FS 2000:2

## The Swedish Radiation Protection Institute's Regulations on X-ray Diagnostics;

issued on April 28, 2000.

On the basis of § 7 of the Radiation Protection Ordinance (1988:293) and after consultation with the National Board of Health and Welfare, the Swedish Radiation Protection Institute has issued the following regulations.<sup>1</sup>

**§ 1** These regulations are applicable to practices with ionising radiation with respect to medical and dental diagnostics by means of external radiation sources like x-rays or radioactive substances. The regulations are also applicable to medical or dental use of such radiation sources for planning and guidance, for research and for legal and insurance related examinations.

For dental practices with panoramic x-ray equipment and with x-ray equipment with a maximum tube voltage not exceeding 75 kilovolts (kV) intended for intra-oral image receptors, § 7 is not applicable.

**§ 2** Terms and concepts used in the Swedish Radiation Protection Institute's regulations (SSI FS: 2000:1) on general obligations in medical and dental practices using ionising radiation have the same meaning in these regulations.

**§ 3** In these regulations the following concepts are used with the meanings specified here:  
*diagnostic reference level:* a dose level established by the Swedish Radiation Protection Institute for a certain type of examination which, if exceeded, shall lead to a measure,

*diagnostic standard dose:* a radiation dose for a certain type of examination, confirmed by the licence holder and determined in the same way as applicable for the corresponding diagnostic reference level,

*technical measuring protocol:* a protocol that is set up during acceptance tests or other mandatory checks,

*specialised examinations in dental radiology:* all practices within dental diagnostic radiology except panorama radiography of the set of teeth, cephalography for dental purpose and intra-oral x-ray diagnostics.

<sup>1</sup> Cf. Council Directive 97/43/Euratom of June 30, 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure, and repealing Directive 84/466/Euratom, OJ L180, July 9, 1997, p.22 (CELEX 397L0043).

## **Competence**

§ 4 The radiological leadership for medical practices with x-rays shall be held by a registered physician with specialist competence in one of the disciplines medical radiology, neuroradiology or paediatric and adolescence radiology.

The radiological leadership for medical practices with x-rays that are used for guidance or dose planning for medical radiotherapy may be held by a registered physician with specialist competence in either radiology or oncology.

The radiological leadership for practices concerning bone densitometry or other diagnostics using external radioactive sources may, alternatively, be held by a registered physician with specialist competence in a field that is relevant for the practice.

§ 5 The radiological leadership for practices with specialised examinations in dental x-ray diagnostics shall be held by a registered dentist with specialist competence in dental x-ray diagnostics.

The radiological leadership for practices with dental panorama examinations shall be held by a registered dentist with special training for panorama examinations.

The radiological leadership for practices with dental x-ray diagnostics using equipment with a maximum tube voltage not exceeding 75 kV and intended for use of intra-oral image receptors shall be held by a registered dentist.

§ 6 The physician who holds the radiological leadership for medical x-ray diagnostics shall have participated in a specialist's competence course or an equivalent course comprising x-ray technique and radiation protection, or shall have acquired the corresponding knowledge by other means.

§ 7 The medical physicist and the person who holds the radiological leadership shall together ensure that the radiation is used in an optimised way taking into account the medical objectives and the radiation dose to the patient.

The medical physicist shall be the licence-holder's expert on issues concerning radiation physics and radiation protection. The medical physicist shall co-ordinate the radiation protection activities by which is meant that she/he shall

- 1 have a clear insight into the radiological practices of the licence holder,
- 2 participate in the establishment and conduct of quality assurance programmes for both equipment and procedures,
3. ensure that new examination methods are evaluated from a radiation protection point of view,
4. have a leading position in patient dose measurements and calculations,
5. have a leading position in how mandatory checks of equipment are performed,
6. participate in investigations of unplanned events that are of importance from a radiation protection point of view,
7. participate in the purchasing process of equipment for radiological practices,
8. plan for and check the physical radiation protection when premises are new or re-built,
9. in consultation with the superiors of the personnel concerned and the person holding the radiological leadership, participate in the education the personnel in matters of importance from a radiation protection point of view,
10. have a leading position in the design of routines for individual dose monitoring of the personnel.

§ 8 All personnel in the practice shall have adequate education needed to perform the practice in a sound way from a radiation protection point of view.<sup>2</sup>

Routines for such education shall be documented in writing in the quality manual. The document shall show which education elements different categories of personnel have to go through in order to be entitled to perform a certain work. For personnel working routinely with x-ray examinations of children, with screening or with large dose procedures like computed tomography or interventional radiology, particular high demands shall be required for education.

The personnel shall certify by signature that safety routines and other education elements have been gone through.

### **Quality assurance<sup>3</sup>**

§ 9 The licence-holder shall have an established quality assurance programme which comprises checks of the equipment as well as of the working methods.

All equipment shall be provided with written method descriptions covering the examinations that are conducted there. The descriptions shall comprise *inter alia* exposure tables and information about adequate dose reduction methods like compression and use of devices for protection of the gonads or the thyroid. When applicable, the method descriptions shall content alternative procedures or methods for the examination of pregnant women.

§ 10 Fluoroscopy times for interventional procedures and for x-ray equipment used outside the x-ray department shall be recorded in a logbook.

§ 11 The person who holds the radiological leadership shall ensure that women in child bearing age are asked whether they are pregnant or not before examinations where the lower abdomen is in the primary beam are performed. If the woman is pregnant, or if pregnancy cannot be excluded, the justification of the examination and the urgency shall be scrutinised particularly.

Pregnant women shall be examined with such equipment and methods that give a radiation dose to the foetus as low as reasonably achievable. The selection shall, however, be made such that the necessary diagnostic information is obtained or other medical purposes are achieved.

### **Diagnostic reference levels**

§ 12 The diagnostic standard dose shall be determined for those examinations for which the Swedish Radiation Protection Institute has established diagnostic reference levels. If the diagnostic standard dose is exceeding the diagnostic reference level, the reason for that shall be investigated and measures shall be taken as to reduce the dose.

The results from the dose measurements according to the first paragraph shall be documented and, on request, be sent to the Swedish Radiation Protection Institute.

<sup>2</sup> Example for the design of the content of the education and training is given in the SSI report 95-12 (1995).

<sup>3</sup> General regulations for quality systems are provided in the National Board of Health and Welfare's regulations and general advice (SOSFS 1996:24) on quality systems in the health and medical services.

## **Equipment**

§ 13 Fluoroscopy without image intensifier or equivalent technique must not be used.

§ 14 New purchased x-ray equipment for fluoroscopy shall be provided with automatic brightness control with at least two dose levels.

New purchased x-ray equipment shall be provided with means showing the amount of radiation that the equipment is emitting during the examination, if the equipment is intended for computed tomography, interventional radiology, angiography of the trunk, examination of the digestive organs or is to be used especially for the examination of children.

§ 15 The equipment shall be well adapted to the intended use. Equipment that is intended to be used mainly for screening, examination of children and for high dose procedures such as computed tomography or interventional radiology should be specially designed for the respective application.

§ 16 Equipment for diagnostics containing radioactive substances shall be marked with a warning symbol for ionising radiation<sup>4</sup> and with information about nuclide and activity.

## **Check of equipment**

§ 17 An acceptance test shall be performed before the first clinical use of the equipment. The acceptance test shall at least comprise all parameters and functions that influence image quality and radiation dose.

§ 18 Base line values aimed to be used for comparison for the checks according to § 19 shall be established in connection with the acceptance test of the equipment or when the equipment after delivery is regarded to have been tested and is free for clinical use.

After equipment or its accessories have been subjected to changes that may influence the base line values new base line values shall be established.

§ 19 Equipment and its accessories shall be checked from a radiation protection point of view to at least the extent and with the frequency that is indicated in Annex 1. The following is applicable:

1. Table 1 for check of medical and dental x-ray equipment except equipment for dental panorama x-ray examinations or equipment for dental x-ray diagnostics with a maximum tube voltage not exceeding 75 kV intended for intra-oral image receptors,
2. Table 2 for check of equipment for dental panorama x-ray diagnostics,
3. Table 3 for check of equipment for dental x-ray diagnostics with a maximum tube voltage not exceeding 75 kV intended for intra oral image receptors, and
4. Table 4 for check of equipment containing radioactive substances.

In addition, checks shall be performed of those parts or functions that might be influenced by a performed service measure, before the equipment or its accessories are brought again into clinical use.

<sup>4</sup> The warning symbol for ionising radiation is provided in Svensk Standard SIS 031210 "Bildsymboler för märkning". The symbol is identical to the symbol provided in Council Directive 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work (OJ L 245, 26.8.29, p. 23, Celex 392L0058).

§ 20 A technical measuring protocol shall be drawn up and signed for each check, and be kept for so long time that long term trends of deviations can be revealed.

§ 21 Confirmed faults shall be attended to. If faults, not implying an acute radiation hazard, are not corrected immediately, an action plan for rectification shall be drawn up including a time schedule, in which due attention is given to the real and potential consequences from a radiation protection point of view to which the fault could lead to.

#### **Other obligations for the licence holder**

§ 22 Holders of collective licences shall every year, during the period October-November, provide the Swedish Radiation Protection Institute with an updated list of equipment covered by the licence. The list shall contain those specifications that the Swedish Radiation Protection Institute is stating.

§ 23 If the licence comprises manufacturing, the manufacturing is restricted to the licence-holder's field of responsibility. Manufacturing implies modification, production of components that lead to improvements and putting together parts from different equipment.

§ 24 Transfer or lease of equipment within the country may only be done to those who have a valid licence for possession and use of such equipment.

#### **Statistical information**

§ 25 The licence holder shall, on request, submit to the Swedish Radiation Protection Institute information concerning number and type of x-ray examinations as well as radiation doses to patients that have undergone different types of examinations.

#### **Exceptions**

§ 26 If particular grounds exist, the Swedish Radiation Protection Institute may grant exceptions from these regulations.

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These regulations enter into force on July 1, 2000, when the Swedish Radiation Protection Institute's regulations (SSI FS 1981:4) on check of equipment for x-ray diagnosis shall cease to apply. However, the section 12 shall not apply until the Swedish Radiation Protection Institute has issued regulations on diagnostic reference levels in its code of statutes.

On behalf of the Board of the Swedish Radiation Protection Institute

LARS-ERIK HOLM

Wolfram Leitz

**Table 1**

**Checks with respect to medical and dental x-ray equipment with the exception of dental panorama x-ray equipment and dental equipment with a maximum tube voltage not exceeding 75 kV intended for intra-oral image receptors**

			Frequency of checks		
			annual	weekly	daily
1 X-ray system	a	Function of the exposure switch and function of the radiation indicator and the fluoroscopy timer	x		
	b	Agreement between indicated and real tube voltage	x		
	c	Relationship between dose (mGy) and indicated tube loading (mAs)	x		
	d	The pre-selected dose of the automatic exposure system and its reproducibility	x		
	e	Filtration of the radiation beam in front of the patient	x		
	f	Agreement in size and position between intended and real radiation field	x		
	g	Function of the compression device	x		
2 Image receptor system	a	Spatial resolution	x		
	b	Sensitivity	x		
	c	Conformity of sensitivity of imaging systems of the same type	x		
	d	Homogeneity and absence of artefacts	x		
	e	Mechanical function of the x-ray cassettes	x		
	f	Centring, function and condition of the anti-scatter grid	x		
	g	Contrast and resolution of monitors	x		
3 X-ray stands	a	Mechanical stability of the stand	x		
	b	Condition of radiation shields including the fastening devices	x		
4 Additional for CT-scanners	a	Adjustment of the radiation field to the selected slice thickness, detector aperture and indicated slice position	x		
	b	Noise level as a function of tube loading (mAs) for some clinical relevant settings	x		
	c	Agreement between selected and real movement of the patient table	x		
	d	Weighted CTDI-value <sup>5)</sup> for commonly used clinical settings.	x		
	e	Homogeneity	x		

to be continued

<sup>5)</sup> Definition of the weighted CTDI-value is given e.g. in the Swedish standard SS-EN 60601-2-44.

**Table 1 (continuation)**

5 Further checks	a	The content and accessibility of the instruction for use	x		
	b	Marking and function of the controls	x		
	c	Gonad protection devices - accessibility and function	x		
	d	Personal and fixed protection devices - accessibility and function	x		
	e	Film processing - constancy		x	
6 In addition for equipment for mammography	a	Reference dose with standard phantom	x		
	b	Low contrast resolution	x		
	c	Film processing - constancy			x
	d	Automatic exposure control - Constancy with respect to tube loading and film density			x

**Table 2  
Dental panorama x-ray equipment**

			Frequency of checks		
			annual	weekly	daily
1 X-ray system	a	Function of the exposure control	x		
	b	Agreement between real and indicated tube voltage	x		
	c	Filtration of the radiation beam in front of the patient	x		
	d	Agreement between the real and intended values of the position and the size of the radiation beam.	x		
	e	The intensity of the radiation beam as a function of the position during the tomographic movement.	x		
2 Image receptor system	a	Geometrical resolution	x		
	b	Conformity of the sensitivity of imaging systems of the same type	x		
	c	Homogeneity and absence of artefacts	x		
	d	Mechanical function of film cassettes	x		
	e	Monitors - contrast and resolution	x		
3 X-ray stand		Mechanical stability of the stand	x		
4 Further checks	a	Accessibility of the instruction for use	x		
	b	Marking and function of the controls	x		
	c	Film processing - constancy		x	

**Table 3**

**Dental x-ray equipment with a maximum tube voltage not exceeding 75 kV intended for intra-oral image receptors**

		Frequency of checks		
		annual	weekly	daily
1 X-ray system	a	Presence of the filter in the primary beam	x	
	b	Marking and function of the controls	x	
	c	Function of the exposure indication	x	
	d	Agreement of position and size between the radiation field and the aperture of the positioning device	x	
2 Further checks	a	Radiation protection devices for patients (such as thyroid shields) – presence and condition	x	
	b	Accessibility of the instructions for use	x	
	c	Review of the film processing procedure	x	
	d	Film processing		x

**Table 4**

**Equipment for diagnostic with external radiation sources consisting of radioactive substances**

	Frequency of checks
Functioning of the shutter Leakage check of the radiation source Check of the markings Detector system	Annually and after changing the radiation source