Statens strålskyddsinstitut
Swedish Radiation Protection Authority

SSI FS 2002:2 **Unofficial translation**

The Swedish Radiation Protection Authority's Regulations and General Advice on Diagnostic Standard Doses and Reference Levels within Medical X-ray Diagnostics;

issued on August 7, 2002.

On the basis of § 7 of the Radiation Protection Ordinance (1988:293) the Swedish Radiation Protection Authority has issued the following regulations and general advice.[1]

Scope
§ 1 These regulations are applicable to practices with medical x-ray diagnostics.

Definitions
§ 2 Terms and concepts used in these regulations have the same meaning as in the Swedish Radiation Protection Authority's regulations (SSI FS: 2000:2) on x-ray diagnostics.

Diagnostic reference level has the meaning of a dose level established by the Swedish Radiation Protection Authority for a certain type of examination, which, if exceeded, shall lead to an action.

Diagnostic standard dose has the meaning of 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.

Diagnostic standard doses and reference levels
§ 3 For the x-ray examinations given in *annex 1* to these regulations shall the diagnostic reference levels apply that are given in the same annex. The diagnostic standard dose for the examinations is calculated as the mean value for a group of normal-sized adult patients.

General advice
As to avoid a too large statistical uncertainty for the diagnostic standard dose the measurements should comprise at least 20 patients. They should weigh between 60 and 80 kg with a mean value of 70±3 kg, with the exemption of computed tomography of the skull. For mammography the thickness of the compressed breast should be between 40 and 60 mm with a mean value of 50±5 mm. If the number of patients is such that these

[1] 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).

limitations concerning the patient's anatomy would make the establishment of the diagnostic standard dose unduly difficult, deviations from these figures can be made and the diagnostic standard dose for a body weight of 70 kg respectively for 50 mm breast thickness can be determined by interpolation.

Guidance on how measurements and calculations should be performed is given in *annex 2, chapter 1*

Exceeding the diagnostic reference level

§ 4 The 12 § of the Swedish Radiation Protection Authority's regulations (SSI FS 2000:2) on x-ray diagnostics is containing requirements demanding that when the diagnostic standard dose is exceeding the diagnostic reference level the cause for that shall be investigated and measures taken in order to reduce the dose.

General advice
In *annex 2, chapter 3* is laid down what should be taken into consideration in the investigation. Examples of good radiological technique are given in *annex 2, chapter 4*.

Documentation

§ 5 A measuring protocol for the determination of the diagnostic standard dose shall be established and kept for at least three years.

The same applies for results from such investigations that are referred to in 4 § on exceeding diagnostic reference levels and information about measures taken.

General advice
What a measuring protocol should comprise is given in *annex 2 chapter 2*.

Measuring frequency

§ 6 The diagnostic standard dose shall be determined for all examinations according to *annex 1* within two years from the date when these regulations are entered into force and then again at least each third year.

When changes of equipment or examination methodology are planned the expected effect on the diagnostic standard dose shall be analysed. Measurements of the diagnostic standard dose shall be performed in connection with the changes, and when the changes have not been planned at the latest within three months.

For equipment used for screening with mammography the diagnostic standard dose shall be determined annually.

§ 7 The instructions in 6 § apply for all x-ray examinations according to *annex 1* that are performed with a specific x-ray equipment on more than 100 occasions a year.

Exceptions

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

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These regulations enter into force on October 1, 2002, when also the directions in 12 § in the Swedish Radiation Protection Authority's regulations (SSI FS 2000:2) on x-ray diagnostics shall enter into force.

On behalf of the Board of the Swedish Radiation Protection Authority

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Table 1 a: Diagnostic reference levels for conventional x-ray examinations

Examination	SoS code [1)]	Diagnostic reference level [2)] ($Gy \times cm^2$)
Heart and chest, chest health check-up [3)]	320, 322	0,6
Coronary angiography (one or several vessels) [4)]	373	80
Barium enema with double contrast	441	50
Urography with urethra compression	510	20
Lumbar spine and SI-joints	623	10
Pelvis, hip joints (only PA/AP view) [3)]	626, 639	4

[1)] Classification of radiological procedures 1991, ISBN 91-38-11235-3, Socialstyrelsen
[2)] Quantity: dose-area-product in the unit gray square centimetre ($Gy \times cm^2$)
[3)] Examinations with different codes may be mixed for the determination of the diagnostic standard dose
[4)] If combined with PTCA the dose values shall only comprise those from the angiography

Table 1b: Diagnostic reference levels for computed tomography examinations. When two diagnostic reference levels are given each apply individually.

Examination	SoS code	Diagnostic reference level	
		$CTDI_{vol}$ [1)] (mGy)	DLP [2)] ($mGy \times cm$)
Brain [3)]	810, 811	75	1200
Lumbar spine [3)]	824, 825	55	600
Thorax/Lungs [4)]			
”Embolism”	830	20	600
”Tumour”	832		
Abdomen [3)]	840–858	25	[5)]

[1)] Quantity: average dose in the irradiated volume ($CTDI_{vol}$) in the unit milligray (mGy). When an examination is consisting of several series (scan sequences) this is referring to the value from the series with the highest value for $CTDI_{vol}$.
[2)] Quantity: dose-length-product (DLP) in the unit milligray centimetre ($mGy \times cm$). Is referring to the complete examination, i.e. the sum of the DLP-values from all series.
[3)] When determining the diagnostic standard dose, examinations with different codes may be mixed.
[4)] Is recorded separately for the questions embolism and tumour, respectively, but may be merged together for the diagnostic standard dose. Is not applicable for high-resolution technique, the so-called HRCT-technique.
[5)] These examinations comprise a number of clinical questions that are connected with anatomical regions of different sizes. Therefore no diagnostic reference level has been established for DLP. However, the diagnostic standard dose for DLP shall be determined and recorded together with information about the diagnostic question.

Table 1c: Diagnostic reference levels for examinations with mammography. The diagnostic reference levels apply each on its own.

Examination	SoS code	Diagnostic reference levels [1]			
		Phantom measurements		Patient examinations	
		AGD_{F0} [2] (mGy)	AGD_{FK} [3] (mGy)	AGD per exposure (mGy)	AGD per examination [4] (mGy)
Mammography, complete examination	660	1,0	1,5	1,3	4,0
Mammography, screening, one- or two-views examination [5]	661, 662	1,0	1,5	1,3	2,5

[1] Quantity: Average glandular dose, AGD, in the unit mGy.
[2] Average glandular dose for a standard breast determined with a standard phantom with net film density 1,0. Is not applicable for digital technique.
[3] Average glandular dose for a standard breast determined with a standard phantom with the film density used clinically.
[4] AGD per examination is calculated as the sum of all AGD-values per exposure divided by two.
[5] For the determination of the diagnostic standard dose examinations with different codes may be mixed.

General advice

1 Measurement and calculations

1.1 Conventional examinations

Measurements are commonly performed with a transmission chamber attached to the x-ray tube, alternatively with a built-in transmission chamber or by means of an into the x-ray equipment integrated calculation function. Be aware that the measuring equipment must be accepted for use close to the patient according to the regulations for medical products of the Medical Products Agency. The measuring quantity is the dose-area-product[1] with the unit $Gy^{x}cm^{2}$.

Transmission chambers should be calibrated according to common practice[2]. In case the dose-area-product is calculated with an into the x-ray equipment integrated function calibrations/checks should be performed. Calibrations/checks should be repeated in regular time intervals, three years could be adequate. An estimation of the uncertainties for the measurement of the individual patient should be performed and documented. This comprises among other things the calibration factor under standard conditions, the dependency of the chamber on radiation quality including the uncertainty concerning the actual radiation quality and how account is taken to the attenuation of the table top for stands with under couch x-ray tubes.

1.2 Computed tomography examinations

The diagnostic standard dose (DSD) and the diagnostic reference level (DRL) are described with the quantities average absorbed dose in the irradiated volume ($CTDI_{vol}$) and the dose-length-product (DLP). Both are directly connected with the weighted CTDI-value $CTDI_W$, which according to the regulations of the Swedish Radiation Protection Authority (SSI FS 2000:2) on x-ray diagnostics, *annex 1 table 1*, shall be determined annually. $CTDI_W$ is determined by measurements with a pencil-shaped ionisation chamber in a PMMA standard phantom[3]. Alternatively values listed in literature for the respective type of computed tomography equipment may be used, but it should be ensured by measurements of the radiation output, that the individual computed tomography equipment is not differing significantly from that of the same type referred to in the literature.

DSD and DRL for DLP are referring to the value for the total examination. If the examination is consisting of several series DLP for the complete examination (DLP_{TOT}) will be the sum of the values for DLP for the different series. However, DSD for $CTDI_{vol}$ is referring to the value from the series with the highest value.

1.3 Mammographic examinations

DSD and also DRL for mammography are expressed in the quantity average glandular dose (AGD), in the unit mGy. AGD is determined indirectly with calculations based on a number of measured or recorded parameters. The method is described comprehensively in the European protocol on dosimetry in mammography. European Commission (1996) EUR 16263.

[1] The exact denomination is kerma-area-product. Notwithstanding this fact, following IEC standards and what is written in certain calibration certificates abroad, the quantity is called dose-area-product.

[2] Transmission chambers are calibrated in the unit kerma-area-product, that is traceable to international normals.

[3] The ionisation chamber is calibrated in the unit air kerma. As mentioned above despite this the unit is called dose.

For the calculation of DSD referring to AGD per exposure for each patient the average AGD from all exposures is calculated. For the calculation of DSD referring to AGD per examination the AGD values from all exposures for each patient are added and the sum is divided by two (both breasts together are seen as one organ).

2 Examples of what should be registered in connection with the determination of the diagnostic standard dose

Table 2a: Items that should be registered when determining the diagnostic standard dose for conventional x-ray examinations.

Per type of examination and equipment	Identification of the examination room Manufacturer and type of the x-ray equipment Time period for the collection of data Responsible for data collection Responsible for the measuring procedure and for the calibration of the measuring instruments Identification of the dose measuring equipment Total filtration Image receptor – type Image receptor – nominal sensitivity alternatively the average of the exposure index or normally applied radiation dose to the image receptor Diagnostic standard dose with standard deviation and, when applicable, the percentage from fluoroscopy Average value for the patient's age, weight and length, for the number of views and, when applicable, for the fluoroscopy time
In addition for each patient	Gender, age, weight and length Tube voltage used Use of automatic exposure control Use of compression Use of gonad shielding Number of views Total value of the dose-area-product When applicable fluoroscopy time and dose-area-product for fluoroscopy

Table 2b: Items that should be registered when determining the diagnostic standard doses for computed tomography examinations

Per examination type and equipment	Identification of the examination room Manufacturer and type of the x-ray equipment Time period for the collection of data Responsible for data collection Responsible for the measuring procedure and for the calibration of the measuring instruments Measuring protocol or other source for determination of the dose Diagnostic standard dose with standard deviation Average value for the patient's age, weight and length (weight and length not necessary for brain examinations)

In addition for every patient	Gender, age, weight and length (weight and length not necessary for brain examinations) Total DLP-value DLP_{TOT} Maximum value for $CTDI_{vol}$
In addition for every series	Tube voltage Tube loading per revolution of the x-ray tube Number of revolutions of the x-ray tube Nominal slice thickness Pitch factor $CTDI_{vol}$ –values

Table 2c: Items that should be registered when determining the diagnostic standard doses for mammographic examinations

For every equipment	Identification of the examination room Manufacturer and type of the x-ray equipment Time period for the collection of data Responsible for data collection Responsible for the measuring procedure and for the calibration of the measuring instruments Protocol from the measurements of the half-value-layer and the radiation output Type of anti-scatter grid Image receptor –brand and manufacturer Film processor: processing time and development time Diagnostic standard dose with standard deviation for the patients Average age of the patients Average breast thickness for all patients Average number of exposures per patients
In addition for every patient	Age and average breast thickness Number of exposures The sum of all AGD-values divided by two Average AGD per exposure
In addition for every exposure	Tube voltage Anode material Tube loading Filtration Breast thickness AGD per exposure
In addition for phantom measurements	Tube voltage Tube loading Anode material Filtration ADG_{FK} and for film-screen-systems also ADG_{F0} and the net and gross film density

3 Investigation

The diagnostic standard dose is compared with the corresponding diagnostic reference level. If the standard dose is higher than the diagnostic reference level and if the selection of the patients has been in accordance with what is recommended in the general advice 3 §, a first step in the investigation could be a comparison of the radiological technique used with what is given in chapter 4 as example for good radiological technique. Deviations from the recommended technique might be the cause for the high dose. Performance and radiological technique might also be compared between similar equipments. Checks should be performed both before and after measures are taken whether the diagnostic safety is good, i.e. that the image quality is not inferior and that all images are taken that are necessary for the diagnosis.

Another important factor is the selection of the patients. DRL are established on the basis of dose measurements comprising a mixture of all kind of patients. A certain patient group may require a more extensive examination and so receive a higher dose. Especially in teaching hospitals such patients may be over-represented and DSD-values higher than DRL might be justified.

4 Examples for good radiological technique

These examples describe how x-ray examinations can be performed according to recognised well-tried experience. The examples are referring to a normal patient with respect both to the anatomical dimensions and to the clinical indication for the x-ray examination in question.

Chest **(SoS-code 320, 322)**

Not applicable for bedside examinations of the chest

X-ray equipment:	dedicated chest stand with horizontal beam
Filtration:	> 6 mm Al equ. (3 mm Al + 0,1-0,2 mm Cu)
Screen-film-system:	sensitivity index 400; correspondingly for digital systems
Tube voltage:	120–150 kV
Number of views:	
Health check:	frontal PA, ev. plus lateral
Normal indications:	frontal PA plus lateral
Special indications:	frontal PA / lateral / side position/ oblique views

Coronary angiography **(SoS-code 373)**

X-ray equipment:	dedicated angiography equipment
Filtration:	$\underline{\geq}$ 8 mm Al equ. (3 mm Al + 0,2 mm Cu)
Tube voltage:	> 70 kV
Image frequency:	12,5 images per second
Number of views:	< 10 series normally
Dose per image:	0,08 – 0,12 µGy (entrance dose to the image intensifier, behind the anti-scatter grid)

Barium enema **(SoS-code 441)**

Only barium enema with double contrast is applicable.

X-ray equipment:	direct or remote controlled fluoroscopic stand
Filtration:	≥ 4 mm Al equ.
Screen-film-system:	sensitivity index 400, correspondingly for digital systems

Tube voltage (radiography):	100-140 kV, when taking radiograms with an image intensifier eventually somewhat lower
Number of views:	≤ 16 normally
Miscellaneous:	fluoroscopy time ≤ 5 minutes

Urography **(SoS-code 510)**

Only urography with urethra compression is applicable

X-ray equipment:	common purpose (x-y)-table
Filtration:	≥ 4 mm Al equ.
Screen-film-system:	sensitivity index 400, correspondingly for digital systems
Tube voltage:	70–80 kV
Number of views:	≤ 12 normally
Miscellaneous:	use of gonad shielding for male patients, if appropriate.

Lumbar spine **(SoS-code 623)**

X-ray equipment:	common purpose (x-y)-table
Filtration:	≥ 4 mm Al equ.
Screen-film-system:	sensitivity index 400, for lateral views up to 800; correspondingly for digital systems
Tube voltage:	
Frontal views:	70–80 kV
LS lateral:	80–90 kV
Sacrum, L5 lateral:	90–100 kV
Number of views:	2, lumbar spine frontal and lateral, eventually complement with sacrum or L5 frontal and/or lateral
Miscellaneous:	use of gonad shielding for male patients, if appropriate. Compression should be used; for the frontal view PA could be an alternative (abdomen on the table).

Pelvis **(SoS-code 626, part of 639)**

This examination is frequently part of an examination of the hip. Here the frontal overview projection alone is applicable.

X-ray equipment:	common purpose (x-y)-table
Filtration:	≥ 4 mm Al equ.
Screen-film-system:	sensitivity index 400; correspondingly for digital systems
Tube voltage:	70–80 kV
Övrigt:	use of gonad shielding for male patients, if appropriate.

Computed tomography brain **(SoS-code 810, 811)**

Imaged volume:	from foramen magnum to skull vertex
Nominal slice thickness:	2–5 mm posterior fossa; 5–10 mm in hemispheres
Pitch:	1,0 –normally axial technique is used
FOV:	adapted to the dimensions of the skull
Gantry angle:	0^{o}
Reconstruction algorithm:	soft tissue

Computed tomography lumbar spine **(SoS-code 824, 825)**

Imaged volume:	from pedicle of the vertebra above the suspected diseased disc to the pedicle of the vertebra below

Nominal slice thickness:	2–5 mm
Pitch:	1,0
FOV:	adapted to the dimensions of the spine
Gantry angle:	parallel with the discs between the vertebrae; different gantry angles may be required for the individual discs
Reconstruction algorithm:	soft tissue/standard or high resolution

Computed tomography thorax/lungs **(SoS-code: 830, 832)**

Imaged volume:	for the indication ”embolism”: From lung apex to the base of the lungs for the indication ”tumour”: From lung apex to the liver
Nominal slice thickness:	7–10 mm, thinner for “embolism”
Pitch:	1,5; 1,0 in certain circumstances
FOV:	adapted to the size of the thorax within the examined volume
Gantry angle:	0^o
Reconstruction algorithm:	standard or soft tissue

Computed tomography abdomen **(SoS-code 840-858)**

Imaged volume:	from the diaphragm arch to the symphysis
Nominal slice thickness:	7–10 mm; 4-5 mm when small lesions are suspected
Pitch:	1,0; when traumatic lesions are suspected 1,2–2,0
FOV:	adapted to the maximum size of the trunk
Gantry angle:	0^o
Reconstruction algorithm:	standard or soft tissue
Gonad protection:	gonad protection should be used for men if the examined volume is closer than 10 cm to the gonads

Mammography **(SoS-code 660, 661, 662)**

X-ray equipment:	dedicated mammographic x-ray equipment
Focal spot size:	≤ 0,4
Tube voltage:	25–35 kV for film-screen-systems, up to 40-50 kV for digital image receptors, also depending on the material of the anode and the filter as well as on the breast thickness
Anti-scatter grid:	movable, coal fibre, ratio 5:1
Focal spot to image receptor distance:	55–65 cm
Automatic exposure control:	yes
Measuring device for tube loading:	yes
Exposure time:	≤ 500 ms for normal-sized breast. For scanning systems the total exposure time ≤ 10 s and the local exposure time ≤ 100 ms
Number of views per breast:	
Screening:	2 (cranio caudal and oblique) for prevalence screening and for ”difficult” breasts, 1 (oblique) otherwise
Clinical mammography:	3 (cranio caudal, lateral and oblique). When appropriate, completions with e.g. cone images, amplification images or stereo tactic examinations, these are, however, not part of the basis for the diagnostic standard dose.