

SSI FS 2000:5

The Swedish Radiation Protection Institute's Regulations and General Advice on Practice with X-rays in Veterinary Medicine;

issued on May 26, 2000.

On the basis of § 7 of the Radiation Protection Ordinance (1988:293), the Swedish Radiation Protection Institute has issued the following regulations.^{1, 2}

§ 1 These regulations apply to work with x-ray equipment with a tube voltage maximum of 150 kilovolts (kV), used for x-ray examinations or radiology of living animals.

For x-ray examinations of teeth, using an x-ray equipment intended for exposure of intra orally placed film, the sections 14 and 15 shall not apply.

§ 2 In these regulations and general advice the following concepts are used with the meanings specified here.

Lead equivalence: the thickness of a layer of lead corresponding to the thickness of a certain material, with respect to the attenuation of radiation that is obtained at a certain nominal voltage,

filter: a device that attenuates the part of the radiation spectrum that does not contribute to the information,

primary radiation direct radiation from an x-ray tube.

field:

REGULATIONS

Organisation

§ 3 The licence holder shall have established a radiation protection organisation which is described in an organisation chart. The chart shall show how the different tasks, from a radiation protection point of view, are delegated to the veterinarian who conducts the practice, the contact person with the Swedish Radiation Protection Institute and other persons who take part in the practice. These persons shall be named. The organisation chart shall be kept up to date.

¹ Cf. Council Directive 96/29/Euratom of May 13, 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. OJ L 159, 29.6.1996, p. 1, (Celex 396L0029).

² Notification has been made according to the Parliament and Council directive 98/34/EG, June 22 1998, on information on technical standards and regulations, OJ L 204, 21.7.1998, p.37 (Celex 398L0034), amended by the Parliament and Council directive 98/48/EG, OJ L 217, 5.8.1998, p.18, (Celex 398L0048).

Competence

§ 4 The practice shall be conducted by an authorised veterinarian, who has a basic knowledge of radiation protection and x-ray technique. This leader shall be familiar with the handling of the equipment, function checks, working methods used, applicable radiation protection regulations and such measures on radiation protection that are needed due to the kind of the practice.

The person conducting the practice shall be granted the necessary authority and resources that is needed to afford sound radiation protection.

§ 5 The licence holder shall ensure that all individuals participating in the practice have the theoretical and practical knowledge needed to handle the equipment correctly and be able to perform the work in a sound way from a radiation protection point of view. The personnel shall have good knowledge of the applicable regulations and on the measures to be taken in order to keep the personal doses as low as reasonable achievable.

The personnel shall get education whenever new equipment or working methods are introduced.

§ 6 The licence holder shall appoint somebody a contact person with the Swedish Radiation Protection Institute. The contact person shall have the same degree of competence as the veterinarian who conducts the practice. Nothing prevents that it is the same person.

The Swedish Radiation Protection Institute shall be notified of the contact person's name.

Quality assurance

§ 7 The licence holder shall ensure that a quality assurance program on radiation protection is established. The program shall at least include what is laid down in the sections 8-11.

§ 8 A quality manual shall include

1. a copy of the licence, special conditions if any and applicable regulations,
2. the organisation chart,
3. manuals in Swedish on equipment used,
4. routines for education of the personnel,
5. locally adjusted working instructions,
6. a process chart for function checks and
7. routines for the reporting of unintended events of significance from a radiation protection point of view.

The quality manual shall be known by, and available to all personnel.

§ 9 Routines for the work that imply that the personnel can be situated within a shielded manoeuvre area or behind an equivalent radiation shield when exposure is in progress shall be aimed at. It shall be possible to observe the animal from the shielded area with the aid of a lead window, mirror, TV-set or equivalent. If a person have to be in the x-ray room while exposure is in progress, he or she shall be as far from the primary radiation field as possible and use personal protection devices or a radiation shield.

If mobile equipment is used outside the x-ray room³, for instance in stables or similar, mobile shielding that limits the direct radiation field shall be used to protect the personnel and other persons. The shielding shall have at least such lead equivalence as stated in the Swedish Radiation Protection Institute's regulations (SSI FS 1991:3) on Radiation Shielding of X-ray Installations for Veterinary Diagnostics.

§ 10 At all equipment there shall be written descriptions on all standard examinations that are performed by the equipment. Among others, the descriptions shall include instructions on optimisation, by which is meant methods that give sufficient information with as small personal doses as possible.

§ 11 A delivery check of the equipment shall be made before it is clinically used after having been installed in a new premise. Function checks shall thereafter be made at least once a year and after service that might have affected the radiation protection properties.

Delivery checks and function checks shall comprise what is said in annex 1. The results of the function checks shall be kept so that long term deviations may be traced.

If a check shows that the equipment has faults of significance of radiation protection, it shall be taken out of service until rectified.

Equipment⁴

§ 12 If the licence does not comprise radioscopy⁵, the mode for radioscopy shall be locked in such a way that tools are required to activate this mode. The mode for radioscopy may only be activated in connection with service.

§ 13 The function of the controls shall be made clear by texts or symbols. The settings of the x-ray tube voltage and the loading (mAs), or the x-ray tube current and the exposure time, shall be displayed at the operator's panel.

The x-ray tube housing shall be marked with information about the highest permitted voltage and the position of the focus.

§ 14 The x-ray tube voltage shall be variable.

§ 15 Equipment that is used for radiography only shall be provided with a light field indicator with adjustable edges. The edges shall be clearly visible.

The light field indicator shall be adjusted to correspond with the x-ray field within the tolerances shown in annex 2.

§ 16 The total filtering between the x-ray tube focus and the animal shall be at least

1. 1.5 mm Al for x-ray tube voltages up to 70 kV or
2. 2.5 mm Al for x-ray tube voltages up to 150 kV.

³ For a practice with mobile x-ray equipment a special licence from the Swedish Radiation Protection Institute, according to § 20 of the Radiation Protection Law, is required.

⁴ Equipment that is CE-marked is presumed to fulfil these requirements as well as other requirements laid down for CE-marking.

⁵ To perform radioscopy a special licence from the Swedish Radiation Protection Institute, according to § 20 of the Radiation Protection Act, is required.

§ 17 If the equipment is provided with a stationary image receptor, the x-ray field shall be adjusted to the centre of the image receptor or, with the aid of clearly visible markings, be able to adjust in such a way.

§ 18 Exposure shall be automatically indicated, visually or audible, during exposure.

§ 19 The exposure shall be automatically cut off after an exposure time, loading or exposure that is preset, even if the trigger for exposure is activated.

It shall not be possible to get another exposure until the trigger is reset. Delayed exposure must not be possible.

§ 20 It shall be possible to release the exposure at least at a distance of 2 metres from the x-ray tube, if the trigger is not situated behind a wall, or equivalent, with shielding properties in compliance with the regulations of the Swedish Radiation Protection Institute⁶.

§ 21 The leakage radiation must not, in any accessible point at a distance of 1 metre from the focus, give an effective dose per unit time that exceeds 1 millisievert per hour. For the purpose of checking, the light field indicator shall be shut and the loading at its maximum value.

Checks of the leakage radiation shall be part of the delivery check, and also be performed if an event has given reasons to suspect increased leakage.

Radioscopy

§ 22 Equipment used for radioscopy shall be provided with an intensifying screen and a TV-monitor. The x-ray tube and the intensifying screen shall be mechanically coupled to each other, or be able to be centred with respect to each other without using x-ray radiation.

Radioscopy without the use of an intensifying screen, or equivalent, must not be performed.

§ 23 X-ray radiation may be emitted only when the radioscopy switch is activated. It must not be possible to lock the switch in a mode where x-ray radiation is emitted.

§ 24 The equipment shall be adjusted so that the x-ray field, when at its largest, falls within the intensifying screen.

§ 25 An equipment used for radioscopy shall be provided with a timer that gives an audible signal after 5 minutes accumulated time of operation.

⁶ Regulations are given in the Swedish Radiation Protection Institute's regulations (SSI FS 1991:3) on Radiation Shielding of X-ray Installations for Veterinary Diagnostics. (Concern the construction materials of walls, ceilings and floors)

Service

§ 26 A service journal shall be kept up to date and contain information on what measures have been taken and who did them⁷. Function checks according to the section 11 are not considered as service.

Changes of the practice

§ 27 The licence holder shall notify purchase or transfer of equipment as well as scrapped equipment to the Swedish Radiation Protection Institute not later than a month after the change.

Transfer of x-ray equipment must only be addressed to somebody who has a licence from the Swedish Radiation Protection Institute for the possession and use such equipment.

Exception

§ 28 If there are special reasons the Swedish Radiation Protection Institute may grant exception from these regulations.

GENERAL ADVICE

Work

General

1. The animals should be anaesthetised or be given sedative before an x-ray examination, if there are no medical reasons to prevent this or if the examination would be impossible for other reasons.

Generally there is no need for persons to be in the x-ray room during exposure if the animal is asleep.

2. X-ray examinations should be done using as small exposure parameters as the most sensitive image receptors can afford.

3. A person who has to be in the x-ray room, to hold the animal or for another reason, should during exposure or radioscopy use a radiation shield or a lead apron having a lead equivalent of at least 0.25 mm.

If the hands are closer to the primary radiation field than 0.4 metres, radiation protection gloves should be worn. The lead equivalence should be at least 0.25 mm at exposure of small animals, and 0.5 mm at exposure of big animals.

Photographic imaging

4. The table should be placed so that there is free space of 1x1 metre by the short sides. A person that must be in the room to hold the animal while exposure can by standing at one of the short sides keep a certain distance to the primary radiation field.

⁷ To perform service of x-ray equipment, a special licence from the Swedish Radiation Protection Institute, according to § 20 of the Radiation Protection Act, is required.

It is advantageous if the animal owner, provided he or she is more than 18 years old and is not pregnant, can be of help, rather than somebody from the personnel routinely assists in the x-ray room during exposure.

5. The primary radiation field should be limited so it only hits the part of the animal of interest for the examination. The field should completely fall within the border lines of the film. The borders of the light field indicator should be visible on the developed film.

6. At exposure of big animals such methods that imply that the image receptor can be positioned by a flexible stand should be used. Holding the film holder by hand must be regarded as the last way out and should only occur in exceptional cases.

7. At exposure of small animals there should be a radiation shield behind the film holder, as seen from the x-ray tube, that absorbs the primary radiation. The shield should have at least a lead equivalence of 1 mm.

8. Film should be developed according to the instructions given by the manufacturer regarding develop time, temperature, dark room lights etc.

If an automatic developing system is used, the constancy of the developing process should be checked at least once a week.

Radioscopy

9. Routines that imply that as few persons as possible must be by the radioscopy table should be aimed at. Automatic dose control should be used.

10. The surgeon should avoid having the hands in the primary radiation field.

11. After each event of radioscopy, the type of investigation or operation, the duration time of radioscopy and the veterinarian's name should be recorded in a journal.

These statutes enter into force on October 1, 2000 when the Swedish Radiation Protection Institute's Regulations (SSI FS 1985:1) on X-ray Equipment for Veterinary Diagnostics shall cease to apply.

The regulations replace earlier issued conditions for practices.

On behalf of the Board of the Swedish Radiation Protection Institute

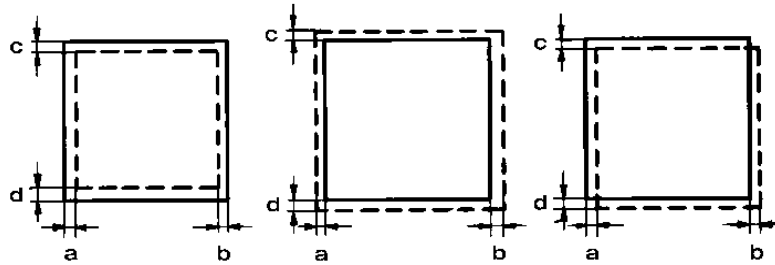
LARS-ERIK HOLM

Sten Lyckefält

Extent of delivery check and function check according to § 11

Moment	delivery check	function check
Manual in Swedish: existence	x	x
Lock for radiology (§ 12)	x	x
Marking of the controls (§ 13)	x	x
Marking of the x-ray tube housing (§ 13)	x	x
Agreement between preset and real exposure parameters (§§ 13,14)	x	
Light field indicator: agreement with the x-ray field (§ 15)	x	x
Filtering (§ 16)	x	
Agreement between the centres of the x-ray field and the image receptor (§ 17)	x	x
Visible or audible signal during exposure (§ 18)	x	x
Exposure timer or equivalent (§ 19)	x	x
Remote control: possibility (§ 20)	x	
Leakage of x-ray radiation (§ 21)	x	
Agreement between the centres of the x-ray field and the intensifying screen at radiology (§ 22)	x	x
Switch for radiology (§ 23)	x	x
The size of the x-ray field compared to the size of the intensifying screen (§ 24)	x	x
Radiology timer (§ 25)	x	x

Tolerances according to § 15 for agreement between the extension of the x-ray field and the light field indicator



Example on x-ray field - - - - and light field indicator —

With notations as above the following apply:

$a + b < 2$ percent of the distance between the focal point and the image receptor.

$c + d < 2$ percent of the distance between the focal point and the image receptor.