

## SSI FS 2000:1

### **The Swedish Radiation Protection Institute's Regulations on General Obligations in Medical and Dental Practices using Ionising Radiation;**

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 medical and dental practices with ionising radiation used for medical exposures. The regulations are also applicable to exposures of persons who knowingly and willingly, other than as part of their occupation, support and comfort patients undergoing medical exposure.

In dental practices others than specialised x-ray examinations in dental radiology the section 11, clauses 3-5, as well as the sections 12-16 shall not apply.

**§ 2** In these regulations the following concepts are used with the meanings specified here.

- Justification:*
- a) a judgement according to which a medical exposure gives a benefit to the patient that, with respect to the diagnostic information or the therapeutic result, exceeds the detriment caused by the exposure, also taking into account the efficiency, the benefits and the risks of other methods implying less radiation dose, or not using ionising radiation at all, or
  - b) a judgement according to which medical exposure of volunteers gives a benefit to medical or biomedical research exceeding the detriment the exposure is estimated to cause or
  - c) a judgement according to which exposure of a person alive for an insurance or legal purpose gives a benefit for the individual or the society exceeding the detriment caused by the exposure or
  - d) a judgement according to which exposure of a relative or other person who supports and comforts a patient during the exposure gives a total benefit to the supporting person and the patient that exceeds the detriment caused by the exposure,

*constraint:* a restriction of the prospective doses to individuals which may result from a defined source, for use at the planning stage in radiation protection whenever optimisation is involved,

<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, p. 22 (Celex 398L0043).

<i>medical exposure:</i>	<p>exposure with ionising radiation of</p> <ul style="list-style-type: none"> <li>a) patients undergoing examinations or treatments,</li> <li>b) individuals as part of occupational health surveillance,</li> <li>c) individuals as part of health screening programmes,</li> <li>d) individuals in medical or biomedical research programs,</li> <li>e) living individuals in legal investigations or</li> <li>f) individuals for insurance purposes,</li> </ul>
<i>radiological leadership:</i>	<p>the tasks performed by a person<sup>2</sup> with prescribed competence and who, within his/her field of work, has an overall impact on the judgement on justification, optimisation, methods, competence of the staff, co-operation with other specialists and the clinical evaluation of the results,</p>
<i>optimisation:</i>	<p>the process, taking into account economical and social factors, of</p> <ul style="list-style-type: none"> <li>a) adapting the extent of the examination and the radiation dose to a patient in a diagnostic examination in such a way that the radiation dose is as small as reasonably achievable, but in the same time ensuring that the needed diagnostic information is obtained or</li> <li>b) adapting the radiation dose to a therapy patient in such a way that the intended therapeutic result is achieved whilst the radiation dose to non-target tissues is as small as reasonably achievable or</li> <li>c) taking into account the radiation dose to a foetus when planning and conducting the examination or treatment of the mother-to-be as low as reasonably achievable and</li> <li>d) at the same time perform such procedures that give radiation doses to the staff and members of the general public which are as low as reasonably achievable,</li> </ul>
<i>audit:</i>	<p>a systematic evaluation of the clinical procedures and routines with respect to established methods for good health care and, if needed, implies modifications of existing methods or introduction of new methods in order to increase the quality of the practice.</p>
<i>screening:</i>	<p>investigation of a large group of individuals in order to determine their health condition in a certain respect,</p>
<i>licence-holder:</i>	<p>the physical or juridical person who is running the practice, licensed according to the Radiation Protection Act for the particular practice.</p>

<sup>2</sup> In these regulations, the person holding the radiological leadership does not necessarily refers to the head of the practice according to the line organisation. It may be, but does not need to be, the same person.

## **Justification and optimisation**

§ 3 The licence-holder shall ensure that all exposures are justified and optimised.

§ 4 When judging whether exposures of relatives or other persons supporting and comforting patients undergoing medical exposures are justified or not, the need of the patients and other human considerations shall be taken into account, in particular if the patient is a child.

Persons who, outside their occupation, volunteer to support or comfort patients shall be informed about the examination or treatment. Written instructions on suitable measures to minimise their exposures shall be available. Those instructions shall be adjusted to the circumstances of the patients exposures and include foreseeable situations where the supporting persons might be exposed.

The radiation doses to the supporting persons shall be as small as reasonably achievable with respect to the circumstances.

§ 5 All exposures shall be judged to be justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved. An exposure may be justified in an individual case even if it is not generally justified.

All new methods or applications shall have been judged to be justified prior to their general use.

§ 6 The prescribing<sup>3</sup> physician or dentist and the physician or dentist who decides on the exposure shall seek, whenever possible, previous diagnostic information or journals in order to avoid unnecessary exposures.

§ 7 The use of any method or application shall be reconsidered if there are new findings on their effects or risks.

§ 8 The optimisation procedures shall include the selection of equipment, the ensuring of the diagnostic information or treatment results, the practical aspects of the performance and the evaluation of the methods with respect to the radiation doses given to patients.

§ 9 All new screening projects shall be reported to the Swedish Radiation Protection Institute, for judgement, before they are started.

## **Competence**

§ 10 The licence-holder shall ensure that all personnel that is taking part in the practice with medical exposures has the theoretical and practical skill that is needed to ensure the practice to be run under good radiation protection conditions. All personnel taking part in the practice shall have good knowledge of the radiation protection regulations that apply to their work.

All personnel involved shall receive education whenever new equipment or new methods are introduced.

§ 11 At any practice there shall be a person who holds the radiological leadership. This person shall have such a competence that is required by the Swedish Radiation Protection Institute for the respective practice. The radiological leadership may be held by several persons working at different medical units.

<sup>3</sup> Referral criteria are given in the European Commission report no 118: "Referral Criteria for Imaging" Office for Official Publications of the European Communities, L-2985 Luxembourg.

The person who holds the radiological leadership shall

1. have an overriding influence on the practice within her/his area,
2. ensure that evaluations of justification are conducted,
3. have knowledge of and, in co-operation with the medical physicist, influence actively and optimise the working methods,
4. in consultation with the medical physicist and the superiors of the personnel concerned, work towards that the personnel has the required competence and receives continuing education,
5. in consultation with the medical physicist, ensure that suitable equipment is used in the practice.

§ 12 In all practices a medical physicist shall be a member of the staff. The medical physicist shall serve as the licence-holder's qualified expert in matters related to radiation protection. By the licence holder the medical physicist shall be granted the mandate and resources that are needed for the radiation protection to be managed in a sound way.

### **Radiation protection organisation**

§ 13 The licence-holder shall establish a radiation protection organisation that is adapted to the nature and extent of the practice. The radiation protection organisation shall be documented in an organisation scheme by which is shown

1. how the different tasks on radiation protection are assigned,
2. the principles of collaboration, with respect to radiation protection, between the licence holder, the management of the hospital, the head of the clinic, the person or persons who hold the radiological leadership, the medical physicist and other persons involved,
3. how the education on radiation protection, methods and handling of the equipment is organised for the personnel concerned,
4. the name of a contact person towards the Swedish Radiation Protection Institute.

The organisation scheme shall be kept up to date. A copy shall be sent to the Swedish Radiation Protection Institute. The authority shall be informed about the name of the contact person and how this person normally can be reached. In medical practice the contact person shall be a medical physicist.

### *Local radiation protection committee*

§ 14 If the licence-holder's practice comprises more than one clinic, a radiation protection committee shall be part of the radiation protection organisation. The committee shall supervise the practice, mainly from the point of view of the protection of the patient.

Licence-holders may subdivide the committee into separate groups dealing with x-ray diagnostic, nuclear medicine and radiation therapy, respectively, or into groups working at different medical units.

§ 15 The radiation protection committee shall consist of the medical physicist, the person or persons who are holding the radiological leadership and representatives for further practices at the licence holder's decision.

§ 16 The tasks of the radiation protection committee is to

1. promote the practice to be carried out in accordance with applicable regulations on radiation protection,
2. be the licence holder's advisory expert body in matters of radiation protection, in the first place for protection of the patients,

3. give advice in matters concerning new methods and the use of new equipment, taken particularly into account the safety of the patient,
4. judge research programs in which volunteers are exposed to radiation and assist the ethic committee in its judgement,
5. moreover promote good radiation protection conditions.

Records shall be kept from the meetings of the radiation protection committee.

### **Quality assurance<sup>4</sup>**

§ 17 The licence holder shall ensure that a quality manual on radiation protection is established. The quality assurance program on radiation protection shall comprise at least what is mentioned in the sections 18 - 21.

§ 18 At each equipment, written manuals shall be available for all examinations or treatments that are routinely performed there.

§ 19 Before the first clinical use an acceptance test of new equipment shall be carried out. This test shall at least comprise all parameters and elements that may influence the radiation dose and the intended function. Checks of the functions shall thereafter be performed regularly as well as after service that may influence the characteristics of the equipment from a radiation protection point of view.

The quality manual shall contain information on which characteristics of the equipment are acceptable<sup>5</sup> and also contain action plans for measures to be taken if deviations are found.

If a check shows that the equipment deviates in such a way that is not acceptable from a radiation protection point of view, the defect shall be corrected.

§ 20 Potential exposure shall be taken into account. The likelihood of, and the consequence of unintentional or incorrect exposure shall, as far as possible, be minimised by adequate selection of equipment and adequate design of quality controls, working methods and education.

If an error occurs, that implies a risk of unintentional exposure of persons or incorrect exposure of patients, the equipment shall immediately be taken out of service until it is corrected.

§ 21 Audits of the practice shall be performed regularly.

### **Research**

§ 22 Anyone who conducts a medical, dental or biomedical research project where test subjects are exposed shall ensure that

1. the project is approved by the radiation protection committee and the ethic committee,
2. all persons involved are participating on a voluntary basis or, if the test subject is a child, that its legal guardian's approval is obtained,

<sup>4</sup> General regulations for quality systems are provided in the National Board of Health and Welfare's regulations and general recommendations (SOSFS 1996:24) concerning quality systems in the health and medical services.

<sup>5</sup> Recommendations on minimum requirements are given in the European Commission's report Radiation protection 91: Criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations. Office for Official Publications of the European Communities, L-2985 Luxembourg. ISBN 92-828-1140-9.

3. all persons involved have got information on the risks that the exposure may entail,
4. dose constraints have been established and are met concerning persons not having a direct medical benefit from the exposure,
5. that for the experimental exposure of patients who are expected to receive a medical benefit from the exposure, the same principles on optimisation are observed as for established procedures.

§ 23 A licence holder running a practice of minor extent, without a radiation protection committee, shall for the judging of research programmes consult the nearest local radiation protection committee or the competent authority.<sup>6</sup>

### **Pregnant women**

§ 24 The prescribing physician and the physician who decides on the exposure shall ask women of child bearing age if they are pregnant. If the woman is pregnant, or if pregnancy can not be excluded, particular attention shall be paid in order to protect the unborn child. When judging whether exposure is justified, the expected dose to the foetus, the degree of urgency and the existence of alternative methods for diagnostic or treatment without ionising radiation shall be taken into account.

### **Exposure for legal or insurance purposes**

§ 25 When examining persons who are not regarded to gain any medical benefit from the exposure, the method giving the smallest possible radiation dose, sufficient to answer the question at issue, shall be selected.

§ 26 An x-ray examination with the purpose of finding foreign objects within the body may be performed if

1. there are reasons to suspect a crime and
2. if a body examination is allowed according to Chapter 28 of the Code of Procedure and
3. if moreover the general principles in these regulations are met.

§ 27 Radiological examinations with the purpose of verifying injuries after a suspected assault may be performed if a physician is judging that the examination may be of benefit for the person exposed and if moreover the general principles in these regulations are met.

§ 28 Radiological examinations on insurance grounds may be performed if the person involved participates on a voluntary basis and if moreover the general principles in these regulations are met.

### **Reporting and statistics**

§ 29 Unplanned events that are of significance from a radiation protection point of view shall be reported to the Swedish Radiation Protection Institute through the contact person as soon as possible, but at the latest within one week. Such a report shall include a description of the event and what measures have been taken to prevent recurrence of the event.

<sup>6</sup> The competent authorities are for research with radioactive pharmaceuticals the Medical Products Agency according to the Medicinal Products Act (1992:859) and ordinance (1992:1752), and for other research the Swedish Radiation Protection Institute.

§ 30 The licence holder shall provide statistic information to the extent required by the Swedish Radiation Protection Institute.

**Exceptions**

§ 31 If special 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 Protections Institute's Regulations (SSI FS 1994:6) on Radiation Protection Organisation and Committee shall cease to apply.

On behalf of the Board of the Swedish Radiation Protection Institute

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