

SSI FS 2000:4

The Swedish Radiation Protection Institute's Regulations on Radiation Therapy;

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.^{1, 2}

§ 1 These regulations are applicable to external radiation therapy, including grenz ray therapy, and brachytherapy.

However, in the case of grenz ray therapy, only §§ 2-4, § 6, § 7, § 8 clauses 1-2 and 6, § 9,

§ 12, § 22 clause 1 and the second and third paragraphs, as well as § 26 and § 29 are applicable.

These regulations are not applicable to nuclear medicine.

§ 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:

brachytherapy: treatment with ionising radiation using radiation sources located inside or on the patients body,

grenz ray therapy: external radiation therapy using x-rays with a tube voltage not exceeding 10 kilovolts (kV),

external radiation therapy: treatment of patients using ionising radiation with radiation sources located outside the patient,

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).

² Notification has been made in accordance with the European Parliament and Council Directive 98/34/EC of June 22, 1998 concerning an information procedure for technical standards and regulations OJ L204, 21.7.1998, p. 37, (Celex 398L0034), changed by the European Parliament and Council Directive 98/48/EG, OJ L217, 5.8.1998 p. 18 (Celex 398L0048).

interlock: a device that prevents emission of radiation in order to prevent unintentional exposure,

target volume: the volume that during treatment is intended to be affected by the planned radiation dose.

Competence

§ 4 Practice on radiation therapy shall be performed under the leadership of a registered physician with specialist competence in oncology or, in the case of gynaecological diseases, by a registered physician with specialist competence in gynaecological oncology. However, Grenz ray therapy may be performed under the leadership by a registered physician with specialist competence in dermatology.

§ 5 The practice shall be conducted in close co-operation with a medical physicist. She/he shall be the leader of those parts of the practice which concern the physical- and measurement-related stages. The medical physicist shall actively participate in the process of optimisation of the dose for each patient and ensure that the absorbed dose to the patient in connection with the treatment is correctly checked and administrated.

In addition to the stipulations of the first paragraph, the medical physics shall be the licence-holder's expert on further issues related to radiation protection. The medical physicist shall coordinate the work on radiation protection by which is meant that she/he shall

1. have a clear insight into the licence-holder's radiological practice,
2. in co-operation with the person who holds the radiological leadership, formulate procedures for taking care of patients undergoing such treatments where radioactive sources are retained in the body,
3. participate in the establishment and conduct of quality assurance programmes for equipment and procedures,
4. ensure that new treatment methods are evaluated from a radiation protection point of view,
5. participate in investigations of unplanned events that are of importance from a radiation protection point of view,
6. participate in the purchasing process of equipment,
7. plan for and check the physical radiation protection when premises are new- or rebuild,
8. in consultation with the superiors of the personnel concerned and the person holding the radiological leadership, participate in education of importance from a radiation protection point of view,
9. have a leading position in the design of routines for individual dose monitoring of the personnel and
10. participate in developing procedures for the transport of radioactive substances and the handling of radioactive waste.

§ 6 All personnel in the practice shall have the theoretical and practical education required to ensure that the work can be conducted in a manner that is satisfactory from the of radiation protection point of view.

Procedures for the education of personnel shall be documented in writing in the quality manual referred to in the sections 7 and 8. The document shall show which education elements different categories of personnel must have gone through in order to be entitled to perform a certain work.

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

Quality Assurance³

§ 7 The licence-holder shall have an established quality assurance programme which comprises checks of the equipment as well as of the working methods. A quality manual within the programme shall describe procedures that make sure that the absorbed dose in the target volume corresponds to the planned dose for each patient.

§ 8 The quality manual shall at least contain descriptions, and plans for measures in case of deviations, concerning

1. procedures for checking the correct performance of equipment used for planning, exposure, information transfer, verification, calibration and control,
2. procedures for determining and checking the doses in the radiation field,
3. procedures for regular calibration and check of measurement instruments,
4. safety systems and procedures for the inspection and service of these systems,
5. procedures for contamination checks and
6. programmes for the education and training of the personnel concerned.

§ 9 In addition to regular checks, the equipment shall be inspected after technical measures which may have affected the function of the equipment, after recharging as well as whenever it otherwise is considered to be necessary. The outcome of inspections and servicing shall be documented. Faults which have been detected shall be corrected.

§ 10 The quality manual shall contain descriptions of procedures preventing foreseeable faults which would result in unintentional or incorrect exposures.

§ 11 The quality manual shall contain a plan for external, independent, monitoring of the dose in the radiation field. Such monitoring shall always be done before new equipment is taken into clinical operation as well as when it otherwise is considered to be necessary.

Procedures

§ 12 Written method descriptions shall exist for all treatment methods. These descriptions shall specify which employee is performing the various steps in the treatment.

§ 13 Each treatment shall be preceded by an optimised individual dose planning which shall be conducted in close co-operation between the physician and the medical physicist. The established dose plan shall be signed by the physician and the medical physicist in an individual patient-specific medical treatment record.

All other parameters of importance for the treatment shall be recorded in the medical treatment record.

In the case of external radiation therapy, the individual patient dose shall always be monitored the first time when a new radiation field is administered and subsequently when it is considered to be necessary. In the case of intra-cavitary and interstitial treatment, the patient dose shall be measured to the extent that is possible.

³ 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.

§ 14 Parameters which are of importance for the treatment shall be checked, if possible by two mutually independent methods and signed by two persons. In any circumstances the parameters shall be checked by two persons independently. A reasonableness check shall always be conducted.

§ 15 When planning the treatment of a woman in childbearing age, it shall be taken into account whether she is pregnant or not. If pregnancy is confirmed or cannot be excluded, the justification of the exposure, whether it is urgent or whether alternative treatments are available, shall be scrutinised.

§ 16 Procedures shall exist for recording and correcting deviations. Detected deviations shall be entered into the treatment record.

There shall also be a system for compiling and analysing deviations.

§ 17 In the case of brachytherapy, care shall be taken to ensure that no radiation source remains inside the patient after treatment. This shall be monitored by two procedures, independently of each other, so that

1. a detector-monitoring system, or corresponding, indicates when all radiation sources are back in a protected position and
2. measurements are conducted over the treated area on the patient's body.

The fact that control monitoring of the patient has been carried out after treatment is concluded shall be confirmed by signature in the treatment record.

Equipment

§ 18 Equipment used for radiation therapy shall be suitable for the purpose. Where applicable, the equipment shall feature duplicate, independent safety systems which prevent malfunctions.⁴ The safety system shall comprise interlocks of the treatment room and readily accessible emergency breakers.

§ 19 In the case of the purchase of radioactive sources or equipment which contains such sources, a plan shall be drawn up for the future handling of radioactive waste.

§ 20 Equipment containing radioactive sources shall be marked with a warning symbol for ionising radiation⁵ and information about the nuclide and its activity.

§ 21 Suitable reference instruments shall be available for dose monitoring and checks. These instruments shall be calibrated at the National Standards Laboratory, or the equivalent, at least once every second year as well as when it is considered to be necessary. The function and stability of the reference instruments shall regularly be checked.

⁴ Equipment that is CE-marked is presumed to fulfil these requirements and in applicable Directives where the principles of CE-marking are established.

⁵ 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).

§ 22 Once a year, the licence-holder shall make an inventory of equipment and radioactive sources in his possession. During this process, a list shall be compiled specifying:

1. equipment and radioactive sources used for radiation therapy,
2. radiation sources used for planning and follow-up and
3. radiation sources for calibration.

The list shall contain information on type, manufacturer, type of radiation, energy, nuclides and their activities, year of purchase and location

Before the end of the month of March each year, the list shall be submitted to the Swedish Radiation Protection Institute. However, radioactive sources with activity levels less than 500 megabecquerels may be omitted in this report.

Premises

§ 23 Before new premises or premises which are altered in such a way that the radiation protection is affected are used for radiation therapy, the Swedish Radiation Protection Institute shall be consulted. This consultation relates to issues such as construction material, radiation shielding and safety systems. Consultation shall also be done if surrounding premises or buildings are changed in such a way that the requirement in section 24 is no longer met.

§ 24 The radiation shielding of a therapy room shall be such that it is not likely that any member of the general public will receive an effective radiation dose exceeding 0.1 millisievert per year.

§ 25 Each premises used for radiation therapy shall be documented with respect to:

1. the type, location and radiation field of the existing equipment in the premises,
2. the type, thickness and radiation shielding capability of the construction material,
3. labyrinth and safety systems and,
4. results of radiation monitoring outside the premises.

§ 26 There shall be a safety system which includes locks for premises and equipment which prevents unauthorised access and unauthorised use.

§ 27 In therapy rooms or premises where no other individuals, apart from the patient, may be present during exposure, there shall be a procedure for inspection of the room. A system of switches or other control devices which, when manoeuvred, confirm that inspection has been carried out shall exist. It shall not be possible to initiate exposure without such a confirmation.

Acoustic or optical signals shall be provided outside therapy rooms to indicate that irradiation is in progress.

§ 28 The handling and storage of radioactive sources for brachytherapy shall be conducted in a separate premises which is specifically adapted for the purpose.

Statistical information

§ 29 The licence-holder shall, on request, submit to the Swedish Radiation Protection Institute information concerning number and type of radiation therapy sessions and of the radiation doses given to the target volumes during those sessions as well as a report on deviations observed, in accordance with section 16.

Exceptions

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

These regulations enter into force on July 1, 2000.

On behalf of the Board of the Radiation Protection Institute

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