

SSI FS 2000:3

The Swedish Radiation Protection Institute's Regulations and General Advice on Nuclear Medicine;

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

§ 1 These regulations and general advice are applicable to nuclear medicine within human medical care. The regulations are also applicable to activities where radioactive substances are administered to individuals in connection to medical or biomedical research and medical examinations for insurance or legal purposes.

§ 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 meanings in these regulations.

§ 3 In these regulations and general advice 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 an action,

individual dose planning: planning of the activity which will be administered to the patient taking into account the general condition of the patient, previous treatments, laboratory test results, weight and other individual factors as well as the characteristics of the target tissue,

target tissue: the tissue or the organ which the therapy is intended to affect.
target volume:

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

REGULATIONS

Competence

§ 4 The radiological leadership of a practice involving nuclear medicine diagnostics shall be held by a registered physician with specialist competence in nuclear medicine.

The radiological leadership of a practice involving nuclear medicine treatments shall be held by a registered physician with specialist competence in oncology.

§ 5 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 in matters concerning radiation physics and radiation protection. She/he shall be the co-ordinator of the radiation protection activities by which is meant that the medical physicist shall

1. have a clear insight into the licence-holder's radiological practice,
2. participate in the establishment and conduct of quality assurance programmes for both equipment and procedures,
3. evaluate new methods for examination and treatment from a radiation protection point of view,
4. participate in establishing procedures for how patients are taken care of when radioactive substances have been administered to them,
5. have a leading position in developing measurement methodology in connection with the measurements of radioactivity administered to patients as well as for the management and control of measurement instruments.
6. participate in the investigation of unplanned events that are of importance from a radiation protection point of view,
7. participate in the purchasing process of equipment for nuclear medicine practice,
8. plan for and check the physical radiation protection when premises are new- or rebuild,
9. 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,
10. have a leading position in the design of routines for individual dose monitoring of the personnel and
11. participate in establishing procedures for transport of radioactive substances and 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 radiation protection point of view.

Procedures for such education shall be documented in writing in the quality manual referred to in section 7. 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 examinations of children, with screening practices or with examinations giving large radiation doses particularly high demands shall be required for the education.

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

Quality assurance²

§ 7 The licence-holder shall have an established quality assurance programme. A quality manual that is part of the programme shall contain at least the following:

1. a description of procedures which ensure that the right patient receives the correct radio pharmaceutical and the correct quantity of radioactivity,
2. descriptions of special procedures for adapting the activities for administration to children,
3. a preparedness plan, which includes measures aiming at mitigating the harmful effects if an incorrect dose should be administered, in spite of everything,
4. a description of measures to be taken if a patient with radioactivity remaining in the body dies,
5. a description of procedures for checking the performance of gamma cameras, uptake monitors and other equipment used in the practice,
6. a description of procedures for the acquisition, calibration, administration and maintenance of radiation protection instruments, instruments for the identification of radio nuclides as well as for activity measurements and
7. programmes for the education of the personnel concerned.

§ 8 Instruments for activity measurements shall be checked with respect to function and stability at least once a month. The results of the checks shall be documented.

Premises

§ 9 The preparation of radioactive preparations before administration to patients shall be conducted in a laboratory intended for the handling of open radioactive sources.

§ 10 The administration of radioactive preparations shall be conducted in an area which is easy to clean and suitable for the handling of open radioactive sources.

The transport distance between the laboratory where the radioactive preparations are prepared and the patient shall be as short as reasonably achievable.

§ 11 Patients to whom radioactive substances have been administered for treatment purposes and who remain in hospital shall be placed so that radiation doses to the personnel, other patients or visitors are as low as reasonably achievable.

Dose planning

§ 12 Each treatment shall be preceded by individual dose planning conducted in close co-operation between the physician and the medical physicist. Dose planning shall be conducted in such a way that the exposure of the target tissue is sufficient to achieve the intended effect, while the radiation dose to surrounding healthy tissues is as small as reasonably achievable.

Treatments may not be fractionated for any other but purely medical reasons.

² 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.

§ 13 The medical physicist shall ensure that the activity given to the patient is checked by measurements prior to each treatment. Performed checks shall be signed.

Diagnostic reference levels

§ 14 For the different types of examinations for which the Swedish Radiation Protection Institute has established diagnostic reference levels, the average values of radioactivity administered to a group of patients of normal size shall be determined. If the average values exceed the diagnostic reference levels, the reason for that shall be investigated and measures taken to optimise of the examination.

The results of the average values determined shall be documented and, on request, be sent to the Swedish Radiation Protection Institute.

Pregnant or breastfeeding women

§ 15 When planning an examination or treatment of a woman of childbearing age, special care shall be taken when she is pregnant or breastfeeding. If pregnancy is confirmed or cannot be excluded, the justification and the degree of urgency shall be scrutinised.

Breastfeeding women shall, before the examination or treatment starts, be provided with information concerning recommended breaks in breastfeeding, in accordance with the general advice, clause 1.

Dose constraints

§ 16 An assessment of the radiation doses which relatives and members of the general public can be exposed to shall provide guidance for when a patient can be discharged from hospital after treatment. When discharging the patient it shall be unlikely that the effective dose

1. to any member of the general public will exceed 0.3 millisievert (mSv),
2. to children related to the patient will exceed 1 mSv and
3. to adults related to the patient will exceed 3 mSv or, for relatives aged 60 or more, will exceed 15 mSv.

Some values indicating when a patient can be discharged from hospital are provided in the general advice, clause 2.

§ 17 Before a patient is discharged from hospital, the physician who has conducted the treatment shall ensure that the patient or the person accompanying the patient, receives the information as stipulated in section 15 and expressed in the general advice, clause 2 and 3 as appropriate. The information shall be provided in writing and formulated so that it can be understood by a layman.

Statistical information

§ 18 Before the end of the month of April, the licence-holder shall submit information to the Swedish Radiation Protection Institute concerning the practice during the preceding calendar year. For each type of examination or treatment, the information shall cover the number of examinations and treatments and the radioactive pharmaceuticals used as well as the average activities administered.

Exceptions

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

Provisional regulations

A registered physician with competence within a speciality that is related to nuclear medicine and who has experience of nuclear medicine-related practice before nuclear medicine was formally adopted by the National Board of Health and Welfare as a separate speciality, may be appointed a radiological leader.

GENERAL ADVICE

1. Recommended break for breastfeeding after administration of different radioactive pharmaceuticals

These recommendations are taken from a report by the European Commission, Radiation Protection 100: "Guidance for Protection of Unborn Children and Infants Irradiated due to Parental Medical Exposures". Office for Official Publications of the European Communities, L-2985 Luxembourg. ISBN 92-828-5175-3.

1.1 Normally, no break is required for the following radioactive pharmaceuticals:

^{51}Cr -EDTA	$^{99\text{m}}\text{Tc}$ -gluconate
$^{99\text{m}}\text{Tc}$ -DMSA	$^{99\text{m}}\text{Tc}$ -HMPAO
$^{99\text{m}}\text{Tc}$ -DTPA	$^{99\text{m}}\text{Tc}$ -MIBI
$^{99\text{m}}\text{Tc}$ -diphosphonate	$^{99\text{m}}\text{Tc}$ -colloids
$^{99\text{m}}\text{Tc}$ -glucoheptonate	

1.2 No break is required as long as the administered activity does not exceed the following levels:

$^{99\text{m}}\text{Tc}$ -MAG3	100 MBq
^{111}In -leucocytes	20 MBq
^{201}Tl -chloride	80 MBq

1.3 Break in breastfeeding when the following doses are administered:

$^{99\text{m}}\text{Tc}$ -MAA	100 MBq:	12 h
$^{99\text{m}}\text{Tc}$ -pertechnetate	80 MBq:	24 h
$^{99\text{m}}\text{Tc}$ -pertechnetate	800 MBq:	48 h

1.4 A break where the duration depends on the prognosis based on measurements of the specific activity in breast milk and the biological half life.

$^{99}\text{Tc}^{\text{m}}$ -RBC	$^{99}\text{Tc}^{\text{m}}$ -pyrophosphate
$^{99}\text{Tc}^{\text{m}}$ -technegas	^{123}I -iodide
$^{99}\text{Tc}^{\text{m}}$ -MAG3 (>100 MBq)	^{123}I -MIBG
$^{99}\text{Tc}^{\text{m}}$ -microspheres	^{123}I -hippuran

1.5 Normally, breastfeeding should be interrupted after treatment.

2. Recommendations concerning patients treated with radioactive pharmaceuticals

The patient should remain in hospital at least as long as the radioactivity in the body exceeds the values specified in the table below. The Swedish Radiation Protection Institute can specify values for radio nuclides not included in the table.

If the recommended dose constraints for surrounding individuals cannot be complied with, for example, due to long travel time or the presence of small children in the home, the patient should stay in hospital until the activity level has decreased further.

The medical physicist is making a judgement of when the patient can leave hospital and when radiation protection measures are not necessary any more. The patient should be informed about the times together with the submission of information, in accordance with section 17 and the general advice, clause 3.

2.1 Recommended highest activities (MBq) in patients in different situations.

	^{131}I	^{32}P	^{90}Y
Radiation protection measures necessary only with respect to pregnancy and breastfeeding	150	300	100
The patient may be discharged from hospital after having received radiation protection information	600	1200	1200
Post mortem without radiation protection measures	600	400	200
Cremation without radiation protection measures	1200	400	1200

2.2 Radiation protection measures are not necessary after treatment with ^{89}Sr if the administered activity does not exceed 150 MBq.

3 Suggested information to patients

3.1 Background

These examples are mainly taken from the report by the European Commission, Radiation Protection 97: "Radiation Protection following Iodine-131 Therapy (Exposure Due to Outpatients or Discharged Inpatients)", Office for Official Publications of the European Communities, L-2985 Luxembourg. ISBN 92-828-4194-4.

The report deals with patients who have been treated with I-131. However, the principles can also be applied after treatment with other radio nuclides when the patient is discharged from the hospital. Sections not applicable to the individual patient can be omitted. Further relevant advice can be added.

3.2 Information

You have been treated with to cure Most of the radioactive substance will leave your body through faeces and urine and some through saliva and sweat. The radioactivity is also decreasing through radioactive decay. However, for a period of, radioactivity will remain in your body and, therefore, people around you will be exposed to radiation. During that time, you should follow the advice given below. It is your responsibility to protect relatives, friends, colleagues and others.

- * The most important precaution is that you do not stay close to other people (less than 1 meter) for an extended period of time (more than one hour). For a longer period of time the distance should be at least two meter.
- * You should not stay close to a pregnant woman.
- * Do not plan to become pregnant or father children within the next months.
- * If your children are under ten years old, avoid close contact, such as hugging and holding, as far as possible. Children are more sensitive to radiation than adults.
- * Infants should be looked after by someone else.
- * Stop breastfeeding.
- * Close contact with your partner should be limited to half-an-hour a day. You should not sleep in the same bed and you should sleep no less than two meters from each other. This also applies if there is a wall between the beds. Normal inside walls do not provide any radiation shielding.
- * If your partner is pregnant, you should avoid contact with her.
- * For persons older than 60 years the risk of radiation detriment is small. For relatives or close friends in this age group, it is less important to exercise precautions.
- * You can receive short visits, up to a couple of hours. Keep distance, 2 meters or more. Do not encourage visits from children or pregnant women.
- * Most people can go to work if the work is not such that you are close to a colleague for a long period of time. Inform your employer.
- * Stay at home if you normally work in close contact with children, e.g. at day care centres.

- * Avoid visits to cinemas or theatres and other places where many people are sitting close.
- * You can travel by bus or train as long as the travel time is short – less than one hour. If the bus is not full, try to sit alone.
- * If you travel by taxi, sit in the back seat on the opposite side to the driver. Avoid trips that last longer than two hours with the same driver.
- * You can use the same toilet facilities as other people. However, you must be exceptional careful with your hygiene. Be careful not to spill or splash your urine.
- * Sweat and saliva can also be radioactive. Do not share clothing, towels or cutlery with anyone else. After normal washing up or cleaning these items can be used as usually.
- * If you have to be admitted to hospital, inform the personnel that you have been treated with radioactive substances.

These regulations and general advice enter into force on July 1st 2000. However, the section 14 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

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