FINNISH CENTRE FOR RADIATION
AND NUCLEAR SAFETY
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Radiation Practices and Regulatory Control

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Authorisation

Under section 70, paragraph 2, of the Radiation Act (592/91), the Finnish Centre for Radiation and Nuclear Safety issues general instructions, known as Radiation Safety Guides (ST Guides), concerning the use of radiation and operations involving radiation.

The Radiation Act stipulates that the party running a radiation practice is responsible for the safety of the operations. The responsible party is obliged to ensure that the level of safety specified in the ST Guides is attained and maintained.

Translation. Original text in Finnish.
Translated by R. Milton

1 General

The Radiation Act (592/91) lays down the bases for the safety and acceptability of radiation use and other practices.

Use of radiation means the use of radiation sources in medicine, industry, research and teaching, *and manufacture of and trade in radiation sources, and related activities or circumstances such as possession, safekeeping, servicing, repairs, installation, import, export, storage, transport and rendering radioactive wastes harmless.** Other practices include activities or involve circumstances under which exposure to natural radiation causes, or may cause, health risks.

The organization or person responsible for radiation safety is referred to below as the responsible party. Its, his or her** responsibility covers all measures to maintain and promote radiation safety regardless of the way in which, or the extent to which, the safety is supervised. Regulatory control of compliance with the Radiation Act and subordinate regulations in Finland is handled by the Finnish Centre for Radiation and Nuclear Safety (STUK). STUK's supervision and inspection rights and entitlement to receive information are laid down in the Radiation Act. STUK also issues information and guidance on matters related to radiation safety.

This ST Guide lays down the general principles to be observed in the regulatory control of ionizing radiation use and practices. It also takes account of additions and alterations needed for compliance with European Union (EU) directives that have not been mentioned in other ST Guides.

Extra information on matters dealt with in this ST Guide can be obtained from the References at the end.

* Italics denote direct quotations from the Radiation Act or Decree throughout this ST Guide.

** From here on referred to as 'it.' Nearly all responsible parties are corporative.

2 Principles of Safety in Radiation Practice

The purpose of radiation protection is to protect human beings and their descendents from the hazards of radiation without unnecessarily restricting the use of radiation or activities involving exposure to radiation that are considered useful by society.

For acceptability, a radiation practice must comply with the following principles mentioned in the Radiation Act: The benefits of the practice must be greater than the detriment it causes *(principle of justification).* Exposure to radiation due to the practices must be *kept as low as is reasonably achievable (principle of optimization).* Radiation exposure of workers and the general public may not exceed the prescribed maximum values *(principle of limitation).*

Before starting a new practice, the responsible party must consider whether it is justified. It can only be started if its benefit to the persons or community exposed is greater than its detriment. ('Detriment' includes other defects, disadvantages and costs besides exposure to radiation). If no safety licence has earlier been granted for such a practice, the application for a licence must include enough detail for STUK to decide whether it is justified. Justification of an existing practice must be reconsidered when new data on its efficiency or consequences are obtained. If its benefit-detriment ratio is no longer high enough, it is no longer justified and must be discontinued.

Once a practice is found to be justified, the responsible party must take all measures to improve its radiation safety that are feasible in view of their nature and their costs in ratio to their beneficial effects on radiation safety. The object is to ensure that individual doses, the number of persons exposed and the probability of exposure are kept as small as possible taking economic and social factors into account.

A practice that complies with the principles of justification and optimization seldom needs to be limited. The purpose of dose limits is to ensure that not even the total exposure due to different practices will cause unacceptable detriment to workers. Even if the exposure is below the prescribed upper limits, it must still be minimized by applying the principle of optimization.

3 Regulations

The Radiation Act (592/91) and its amendments (1102/92, 1334/94, 594/95) concern both ionizing and non-ionizing radiation. Based on the act are a Radiation Decree* (1512/91) and amendment (1598/94), which concern natural radiation as well as the use of ionizing radiation, and a Supervision of Non-Ionizing Radiation Decree (1306/93). The Ministry of Social Affairs and Health has issued an Order on the Upper Limits for Radon Concentration in Places of Residence (944/92) and an Order on Limits of Exposure to Non-Ionizing Radiation (1474/91), both in accordance with the Radiation Act.

In accordance with section 70, paragraph 2 of the Radiation Act, STUK issues ST Guides containing *general instructions on how to attain the level of safety defined in this Act* with regard to radiation use and practices.

The Nuclear Energy Act (990/87) prescribes the use of nuclear energy and the utilization of nuclear materials, equipment and waste. Nuclear materials whose use is controlled under this law include uranium, thorium and plutonium. If they are exempt from regulatory control due to their small amounts or contents, they are also exempt from control under the Radiation Act. The principles of justification, optimization and limitation according to the Radiation Act, together with the provisions concerning dose monitoring and medical surveillance for workers, apply similarly to nuclear energy.

The requirements concerning ionizing and non-ionizing radiation in the Labour Protection Act (299/58), Supervision of Labour Protection Act (131/73), Occupational Health Care Act (743/78) and their subordinate regulations likewise apply to radiation use and practices.

Legislation of the European Communities (EU) on radiation safety includes Regulations, Directives and Decisions. Regulations are binding on all Member States of the EU. For example, Council Regulation No. 1493/93/ Euratom concerning shipments of radioactive substances became binding on Finland when Finland joined the EU [1]. Directives apply to all Member States, and their provisions must be included in national regulations within specified periods. Decisions apply to specific Member States, organizations or persons. The European Council and Commission can also issue Resolutions, Recommendations, Opinions and Communications that are not binding.

EU legislation and European Standards are taken into account in STUK's ST Guides.

A responsible party must ensure that its safety level complies both with the Finnish regulations on radiation and with the ST Guides. The safety-level instructions in ST Guides are not absolutely binding. A responsible party can also plan a system or safety measures not specified in an ST Guide, but in that case it must prove to STUK's satisfaction that its solution to the problem complies with the regulations and the safety levels specified in ST Guides. Any such solution that involves a practice requiring a safety licence but deviates from ST Guide instructions must be submitted to STUK for approval before it is applied.

* Executive order issued by the President of Finland by virtue of an Act of Parliament.

4 Product Control of Radiation Sources

4.1 Effects of the EU and the European Internal Market

Goods, services, capital and persons can move freely within the European Internal Market in compliance with common rules and principles. For goods, freedom of movement is regulated by the Treaty establishing the European Economic Community (EEC) and by 'new approach' product directives.

Radiation-emitting equipment and radioactive substances are also subject to the Treaty establishing the European Atomic Energy Community (Euratom),* basing on which the Radiological Safety Directives [2—5] have been issued. The most important of these is Council Directive 96/29/Euratom of 13 May 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.** This directive also specifies the procedures for prior authorization and supervision of radiation equipment and radioactive substances. Subject to certain conditions and under given circumstances, the use of radioactive substances and of sources that cause ionizing radiation can be exempt from supervision with the approval of the competent authority. Under the Radiation Decree (section 2a, amendment 1598/94), the regulatory authority in Finland referred to in the Euratom Treaty is STUK.

4.2 Assessment of Conformity and Market Control

Product control ensures that products meet the requirements. It takes the form of preliminary control of products coming on to the market, followed by market control. If a product meets the requirements in one EU Member State, it can be sold on the whole of the European Internal Market. Products shall meet the requirements of harmonized EU legislation, or at least satisfy those of one Internal Market country. In a case where EU legislation has not yet been harmonized, the product can come on to the Internal Market via any Member State provided it satisfies that country's national requirements. The transitional period for harmonized EC legislation to take effect can be several years.*

When a product meets the requirements, the manufacturer or his representative on the European Internal Market must issue a declaration of conformity and affix a CE marking to the products.

Regulatory control of a product already on the market is called 'market control.' Its purpose is to ensure that the preliminary control has been carried out satisfactorily. If the product does not meet the requirements, it must be taken off the market.

In Finland, the acceptability of medical devices and accessories bearing the CE marking is supervised by the National Agency for Medicines in accordance with the relevant act (1505/94). Personal protective equipment bearing the CE marking and used by workers is supervised by the labour protection authorities.

4.3 Obligations of Suppliers

The manufacturer or dealer (importer, seller or other transferor) is responsible for assuring the conformity of a product. A dealer in radiation equipment, radioactive substances, material containing radioactive substances, or other products affecting radiation safety, is obliged to prove that the product meets the relevant safety requirements. To do this, the dealer must either have it inspected by the

* Article 232 of the Treaty establishing the European Economic Community (EEC).

** Due to take effect on 13 May 2000.

* For example, the transitional period for medical devices lasts until 13 June 1998. Till then, such products can be put on the European Internal Market provided they meet the national requirements that were valid in 1994.

notified body (approved organization), or present a declaration of conformity issued by the manufacturer.

STUK's market control covers products on the market that are subject to Finnish regulations on radiation, except those which are subject to on-site surveillance as specified below, in point 4.4. Such product marketing applies especially to consumer goods that emit radiation or contain radioactive substances (e.g. smoke detectors and compasses).

4.4 On-site Surveillance

On-site surveillance applies to the operations of the responsible party, the use of products, their servicing, the safety of equipment and premises, and to other factors relating to labour protection, the working environment and environmental conditions in general. The inspections are made by STUK, as stipulated by the Radiation Act.

5 Regulatory Control of Radiation Practices

5.1 Safety Licence Procedures

Under the Radiation Act, the use of ionizing radiation requires a safety licence unless the practice is exempted from licencing. Application for a licence must be made in writing to STUK, which will provide the application forms and instructions.

The conditions for granting a safety licence are laid down in the Radiation Act (section 16). If the intended use of radiation is completely new in kind, the application must be accompanied by detailed reasons for its justification.

It is particularly important to prove that the practice complies with the principle of justification if it is intended to target the radiation at human beings for reasons other than medical diagnosis, screening or treatment. In the case of medical research, the application must be accompanied by an opinion from the ethical committee of the organization (hospital, university, etc.) supervising the research. An ethical committee opinion is also required when it is planned to adopt a new method of medical examination or treatment. Greater detail on justification of medical procedures is given in Chapter 7.

In considering an application, STUK will investigate to make sure that the intended use, the place of use, the radiation sources, equipment and accessories, and the user's organization meet the safety requirements specified in the regulations and in the relevant ST Guides. Radiation shieldings for the premises and equipment, and their adequacy, will be checked from the drawings and construction specifications, basing on the planned use of the radiation sources. STUK will also make sure that an adequate plan has been made for the disposal of radioactive wastes, if any.

The licence itself will specify the safety conditions.

The Radiation Act deals with the installation, repair and servicing of radiation equipment, and specifies the cases in which these operations require safety licences. Installation, repair and servicing of equipment can affect the safety of patients and staff particularly in the medical use of radiation. The Electricity Safety Act (410/96) specifies the staff qualifications required in electrical work.

In most cases, the application for a safety licence must be accompanied by the applicant's safety instructions to employees in addition to the documents mentioned in the Radiation Act and Decree.

If a fundamental change in a practice is planned, the responsible party must apply for an amendment to the safety licence (Radiation Decree, section 16). Examples include: changing the place of use of a radiation source, start-up of a new radiation source,

use of higher energy or change in the beam direction of radiotherapy equipment, a change of the responsible party or its name, a change of the radiation safety officer, or any other alteration or change that calls for a re-evaluation of radiation safety or the conditions for granting a licence.

5.1.1 User's Organization

Under the Radiation Act (section 18), an application for a safety licence must be accompanied by a *description of the user's organization,* including *the name of the radiation safety officer,* the qualifications and duties of the relevant staff members and the division of responsibilities between them, and the safety organization of the place of use. Detailed instructions on describing a user's organization are given in ST Guide 1.4.

The qualification requirements for the radiation safety officer and other staff included in the user's organization are presented below. If the qualifications required of a radiation safety officer and relevant staff are not specified adequately for the case in point in any ST Guide or other document, STUK will specify them separately upon approving the description of the user's organization.

Before accepting the description of a user's organization, STUK will check that the organization is adequate for safety, and that the qualifications of the responsible workers in the organization are satisfactory. The same procedure is followed in on-site inspections.

If radiation sources are used at several locations in an organization, every such place must generally have a staff member responsible for radiation safety, in addition to the radiation safety officer. The responsibilities and duties of these staff members must be specified in the description of the user's organization.

In a hospital with separate X-ray, radiotherapy and nuclear-medicine units, for example, every such unit needs an expert to take responsibility for radiation safety. In this case, it is necessary for the whole hospital to have a radiation safety committee (or the like) in addition to the radiation safety officer. The committee members represent the various groups involved in the use of radiation.

Radiation Safety Officer

Appendix A lists the qualifications required of radiation safety officers in the most important branches and types of radiation use. In general they must be knowledgeable and experienced in the kinds of radiation involved and the branches in which it is used (Radiation Act, section 18, paragraph 3).

Certain professionals — hospital physicists and radiologists, for example — are qualified as such to act as radiation safety officers. In other cases candidates for the post must undergo radiation safety courses or pass qualifying examinations acceptable to STUK. The training programmes and curricula are subject to approval (upon application) by STUK, which keeps a Register of Training Establishments.

A certificate issued by the Radiation Officer Examination Board in accordance with the former Radiation Protection Act (174/57) can be accepted as qualifying a candidate for the post of radiation safety officer, provided he or she is found to have had sufficient experience in the branch since he was awarded this certificate.

If a practice is very demanding (e.g. large-scale use or manufacture of radioactive substances), the qualification requirements of the radiation safety officer and the need for a deputy safety officer will be considered separately for the case in point. If necessary, STUK will subject the candidate(s) to a special qualifying examination.

Apart from being suitable for the post, a radiation safety officer must have adequate status and authority in the user's organization. He or she must be fully aware of his future obligations, and he must sign a document

consenting to be the safety officer. No one can be obliged against his or her will to become a permanent safety officer.

Other Staff

The operational staff must receive guidance on the use of radiation sources and training on radiation safety, including information on the safety regulations and on the health risks and protective measures involved in the work. Such guidance and training must be given to all new employees. Whenever needed, existing employees must receive complementary training.

The radiation safety officer has to make sure that the employees understand the dangers involved in radiation use, that the guidance on the use of radiation sources and methods of protection has been adequate, and that employees are using their protective devices and equipment correctly. A good way of doing this is to hold radiation safety courses and examinations for which employees receive certificates.

Before starting radiation work, every employee must undergo a health examination followed by periodical reviews of health, as specified in ST Guide 1.7.

As part of their training, female employees must told about the special risks of radiation use during pregnancy and breast feeding. They must be advised to notify the employer of pregnancy as early as possible. After that, the radiation safety officer must ensure that the employee knows the practical measures she must take to protect her fetus.

Any person who uses or participates in the use of radiation for medical purposes, or physician who refers patients to radiological examination and therapy, must receive supplementary on-the-job training if his, or her, medical training has not included a separate course on radiation safety.

A responsible user must be named for every mobile device used for industrial radiography. His or her responsibilities include radiation safety at the place of use and its surroundings during radiography. He or she requires a certificate of competence following a course or examination that has been approved by STUK.

5.1.2 Equipment and Practice

The application for a safety licence must contain whatever data on the radiation sources are relevant to evaluation of their safety. The construction and functioning of radiation sources and their equipment and accessories must be designed so as to ensure that they will not jeopardize the safety of the operator or others. The application must be accompanied by documents proving that the radiation equipment and accessories meet their technical and safety requirements. Their functioning and condition must be monitored regularly during use, and any defects affecting their safety must be eliminated without delay.

Requirements concerning equipment and its operation are presented in ST/SS Guides 2.1, 2.8—2.10, 3.1—3.4, 5.1, 5.3 and 5.6. Bases for the design of radiation shieldings on premises where radiotherapy and X-ray equipment are used will be found in ST/SS Guides 2.8—2.10, 3.6 and 5.6. Safety requirements to be taken into account in the planning of laboratories and other premises in which radionuclides will be used are given in ST Guide 6.1.

If a planned practice calls for the construction of radiation shieldings that differ from the usual, and if specific requirements on the type of premises involved are not given in any ST Guide, a prior opinion should be sought from STUK on the adequacy of the radiation protection and on special requirements in its construction, if any. It is also recommended that prior opinions be requested from STUK on plans for Type A radionuclide laboratories, radiotherapy premises, particle acceleration plants and radiation sterilizing plants.

5.2 Safety-licence Exemptions and Notification Procedures

Licence-free operations are mentioned in the Radiation Act (592/91, section 17, amendment 1334/94). STUK can also exempt other uses of radiation from a safety licence if it can be verified with adequate certainty that they will cause no detriment or pose no danger to health.

In a decision on safety-licence exemption, STUK can order users to notify it of licence-free radiation use. It can also order that licence-exempted equipment (e.g. dental X-ray devices and physics and chemistry teaching equipment containing radiation sources) be notified to it for registration.

In the case of radiation uses and sources subject to such notification, a notification of change is required if the holder of a radiation source or the location of a practice changes, or if a radiation source is altered, exchanged or taken out of use. The holder is responsible for the correctness of the information notified. Notification forms concerning dental radiology can be had from STUK.

Use of dental X-ray equipment is exempted from a safety licence: 1) if the radiation shielding at its place of use complies with the requirements stated in ST Guide 3.6; 2) if a dentist or physician is responsible for the use and safety of the equipment; 3) if the equipment meets the radiation safety conditions for licence exemption (SS Guide 3.1). A safety licence is required unless all these conditions are met. Entitlement to licence exemption will be checked when the equipment is registered.

This exemption applies only to X-ray equipment for patient examination in ordinary dentistry. Dental X-ray equipment for screening or research requires safety licences.

The responsible party must also arrange quality assurance of its dental X-ray equipment (Radiation Act, section 40, amendment 1334/94). STUK checks on the supervision of patient doses and on the working condition of licence-free equipment by means of measurements and inspections.

Other details on exemption from safety licences in general, and on applications for such exemption are given in ST Guide 5.4.

5.3 Inspections and Other Regulatory Control During Use

STUK oversees radiation safety with inspections at places where radiation is used, among other things. The purpose of the inspections is to ensure that the regulations, STUK's instructions and the conditions for granting the licence are being observed. The main objects of inspection are that the equipment and practice meet the provisions, that the radiation shielding and safety arrangements are adequate, that dose limits and constraints are not being exceeded, and that the monitoring and medical surveillance of exposed workers comply with the regulations. It is also checked to see that radioactive substances and wastes are being handled properly, and that users have been given adequate instructions on the use of the radiation sources and action to be taken in the event of accidents.

The first inspection of radiation equipment and its use is generally made at start-up. If necessary, the start-up inspection will be mentioned in the safety licence. After that, periodical inspections will be made to ensure that no practice has been altered in such a way as to necessitate a re-evaluation of the licence conditions or safety measures.

If necessary, inspections will also be made at other times — say, in the event of a major expansion or alteration of a practice. Defects and deficiencies in practices, or in radiation sources, their equipment or shieldings will be noted in the minutes of the inspection, together with the deadlines for their repair or remedy. Defective or deficient radiation sources may not be used until the fault has been eliminated. The licensee must inform

STUK in writing of the repairs made or other measures taken, after which a new inspection will be made, if necessary, to ensure safety.

STUK monitors the condition and use of dental X-ray equipment mainly by means of test films and dosimeter measurements sent by mail. Exposure to radiation due to X-raying is estimated from the measurement results. The object of the measurements is to reveal excessive patient doses and faulty equipment that needs repairing. From the test results it can also be seen whether there is any reason to inspect the dental X-ray equipment at its place of use.

6 Obligations of the Responsible Party

6.1 Radiation Exposure Monitoring and Medical Surveillance

The responsible party must organize monitoring of radiation exposure and related working conditions at the place of work to whatever extent is required by the nature and scope of the practice (Radiation Act, section 32). It must ensure that exposure monitoring and medical surveillance are extended to all radiation workers, including outside workers *who are not employees of* the licensee, *but are taking part in* radiation work within the controlled area (Radiation Act, section 32, amendment 1334/94). Exposure monitoring and medical surveillance must be organized for outside workers according to the same principles as for the licensee's own employees, unless this is already being done.

Exposure to radiation must also be monitored in the same way in cases where work involving natural radiation has been classified as radiation work.

Monitoring of radiation exposure and medical surveillance of workers are dealt with in ST Guides 1.6 and 1.7.

STUK keeps a Dose Register containing information on all workers engaged in radiation work, and their exposure to ionizing radiation (Radiation Act, section 34). These data enable the total radiation exposure of every such worker to be determined. All information required for monitoring in accordance with section 32 of the Radiation Act can be obtained from the Dose Register upon request. STUK's Dose Register is the national register referred to in Article 4 of Directive 90/641/Euratom.

Every Category A worker going abroad to do radiation work will be supplied by STUK with an individual radiological monitoring document.* This document is an extract from the Dose Register. It must be presented to the responsible party in the country of arrival, who will enter monitoring data in it, such as duration of radiation work, radiation exposure during the work, and data from medical surveillance, if any. When the work abroad ends, the document must be returned to STUK for entry of its data in the Dose Register.

Individual dosimeters are generally used for monitoring workers' exposure to external radiation. The system of measurement for individual dose monitoring is subject to inspection and approval by STUK, for which the licensee must apply (for accuracy requirements, see Appendix C). The measurement system calls for adequate quality control, and it must be calibrated periodically. For approval of the system, STUK requires data on the methods of dose measurement, assignment of responsibilities, quality control programme and documentation of results, as well as reports to the Dose Register. The functioning and reliability of the system has to be monitored by means of comparison tests. Approved systems of measurement are in use at nuclear power plants, for example.

* Directive 90/641/Euratom, Article 2 [5].

6.2 Quality Assurance

Radiation safety calls for quality awareness. The Radiation Act (amendment 1334/94, section 40) emphasizes the importance of quality assurance in medical use of radiation, in which examination and treatment goals have to be achieved simultaneously with radiation safety: . . . . *the responsible party is required to organize quality assurance of radiation sources, related facilities and their use,* . . . .

'Quality assurance' comprises all systematic measures needed to create sufficient confidence that radiation sources and their equipment and accessories meet their quality requirements. This also applies to the way in which they are used.

'Quality control' refers to the procedures and techniques used to satisfy quality requirements.* The terms 'quality assurance' and 'quality control' are defined in SFS-ISO Standard 8402 [6].

The quality control system needed for medical X-ray and radiotherapy equipment is described in ST Guides 3.4, 3.5 and 2.1. Constancy tests and criteria to be applied to certain diagnostic X-ray devices and accessories are presented in IEC Standards.** These can be used in quality control.

References [7—11] deal with principles and methods of quality assurance in nuclear-medicine. Wherever appropriate, they must be applied to the quality assurance of radiopharmaceuticals, and of imaging devices and their accessories. Quality assurance is also required in dental radiology. References [12—14] contain recommendations on quality criteria for X-ray examinations and on patient doses. They also give examples of good radiographic techniques.

Methods of quality assurance and their adequacy are monitored by means of on-site inspections.

6.3 Trade and Transport of Radiation Sources and Management of Radioactive Wastes

The safety requirements for trade and transport of radiation sources are given in ST Guide 5.4. Transport of nuclear materials is dealt with in YVL Guide 6.5.

The responsible party is also responsible for managing the radioactive wastes caused by its operations, and it must bear any costs of measures to clean up the environment, including decontamination. If the estimated costs incurred in environmental cleaning or rendering radioactive waste harmless are substantial, the licensee must *furnish security* (Radiation Act, section 19).

Regulations on the export and import of radioactive wastes are detailed in ST Guide 5.4. Instructions on waste management by radionuclide laboratories are given in ST Guide 6.2. Sealed sources with activities higher than 100 kBq may not be treated as laboratory wastes; their disposal is subject to approval by STUK.

7 Protection of Patients in Medical Practices*

The principles of justification and optimization are particularly important in medical examination and treatment. Physicians who give examination or treatment and those who refer patients to it must in every case make sure the exposure to radiation is justified.

* The term 'quality control' was used in the previous version of section 40 in the Radiation Act (592/91). In Amendment 1334/94 of the act, it has been replaced by the term 'quality assurance,' which has a broader meaning. Quality control is the part of quality assurance in which the user makes sure that the equipment and practices meet the quality requirements. It does not mean inspections and measures taken by the authorities.

** Standard Series 1223—Evaluation and routine testing in medical imaging departments.

* Directive 84/466/Euratom [3] lays down the measures to be taken by Member States of the EU for the protection of patients.

Before referring a patient for examination, a physician should consider whether medical exposure is necessary for the treatment of his or her health problem. In other words, will the examination results affect the diagnosis or treatment? No referral to X-ray examination may be made purely as a routine, without clinical indications. With certain exceptions, radiological examination and radiotherapy must be based on a physician's preliminary examination and referral. Such exceptions include examination following an injury, and examinations and screening under the Occupational Health Care Act or the Public Health Act.

If two alternative methods of diagnosis or treatment are equally effective, the method that is less dangerous to health should be used.

International recommendations on radiation protection [15—18] must be followed when considering the justification of examinations not directly associated with illness — such as those performed in medical research, health assessments of prospective employees, screening, and examinations for medico-legal or insurance purposes.

Radiation exposure of test subjects in research is justified only for very special reasons. It requires a positive opinion from an ethical committee, and dose constraints for each research project [19]. If no ethical committee is available, instructions on obtaining an expert opinion can be had from STUK.

In cases where patients voluntarily undergo experimental examination or treatment, the licensee must fixed optimum dose levels for each volunteer separately.

It is unacceptable to expose people to radiation in order to demonstrate or check on the functioning of equipment — i.e. for purposes other than diagnosis or treatment.

A person giving an X-ray examination must ensure that the patient's protection is optimized [15, 16]. Optimization in diagnosis entails minimizing the radiation dose needed to get sufficient information from the examination results (e.g. an image adequate for diagnostic purposes).

Radiotherapy must be based on a reliable diagnosis. The radiotherapy dose and target area must be optimized for precision of dose delivery so as to ensure the best possible treatment result with a minimum of side effects.

Persons using radiation in medical examination and treatment must possess the skills and specialist training or diploma needed for the purpose. X-ray and nuclear medicine examination results should be interpreted by a specialist. In other cases the physician should, if necessary, consult such a specialist for the interpretation of the images.

X-ray and nuclear-medicine examination results and recordings, accompanied by earlier results if necessary, must be available to physicians who give examinations and treatment or refer patients to them. If necessary, they should be delivered to him or her together with the patient. To avoid unnecessary exposure it must be checked, before starting the examination, to see whether the data required can be obtained from earlier results on the patient. This applies particularly to examinations for medico-legal and insurance purposes.

Exposure to radiation in X-ray and nuclear-medicine examinations must be kept as small as possible without jeopardizing the results. Examples of reference levels for patient doses in certain conventional projections used in X-ray examinations are given in ST Guide 3.5. In nuclear-medicine examination and treatment, exposure affecting other persons via the patient must also be taken into account.

On being discharged, a patient who has received nuclear-medicine treatment must, when needed, be given instructions aimed at avoiding unnecessary radiation exposure for those who come into contact with him or her. The exposure must be limited, taking into account the maximum values specified in section 5 of the Radiation Decree (1512/91) for persons not engaged in radiation work.

A physician in charge of a radiotherapy department must be a qualified specialist in oncology. Qualified experts in radiation physics must be available to radiotherapy and nuclear-medicine departments [3]. For a radiotherapy department, such an expert must be a qualified hospital physicist. If necessary, expertise in radiation physics should also be available to an X-ray unit.

The uncertainty of a patient dose in radiotherapy should not exceed 5% on the average (ST Guide 2.1, basing on a WHO recommendation [20]). A treatment plan that includes dose calculations must be drawn up for each patient. Radiotherapy requires accurate targeting on a patient's body. The principal method of ensuring such accuracy is treatment simulation. A record must be kept of the radiotherapy given, including the doses and technique as well as the results of the treatment. Accurate targeting and dosage per treatment must be checked — if necessary, with *in vivo* measurements. Uniform terminology according to international recommendations should be used in dose planning and determination and in reporting.

8 Natural Radiation

Under section 45 of the Radiation Act, a responsible party *is required to investigate* exposure to natural radiation if a practice involves such radiation, or if there is reason to suspect that it does.

The investigation must be made by methods acceptable to STUK. ST Guides 1.2 and 12.1—12.3 mention practices and conditions under which exposure to natural radiation may be so great that measures are necessary to reduce it. Appendix B gives maximum values, below which measures to limit exposure are not usually necessary. The ST Guides just listed also specify practices that must be notified to STUK. Basing on these notifications, STUK will decide whether exposure investigations, inspections or other measures are necessary.

Cosmic radiation sometimes causes such high doses for air crews that measures may be needed to reduce their exposure. The dose rate varies according to the altitude, latitude and sunspot activity. If an air crew works regularly at altitudes above 8,000 metres, its annual dose may rise above 1 mSv. In that case the responsible party must investigate the exposure as stipulated by the Radiation Act (section 45). In particular, the flying hours of a pregnant female employee must be monitored and, if necessary, limited so that the total dose to the fetus does not exceed 1 mSv.

STUK will decide on the need for measures to limit exposure to natural radiation, basing on the reponsible party's investigation. If the investigation shows that the effective dose after the responsible party's measures have been taken is still liable to exceed 5 mSv annually, the practice must be classified as radiation work. In that case the responsible party must organize exposure monitoring and medical surveillance for his workers, and comply with the dose limits specified in section 3 of the Radiation Decree.

9 Radiation Meters

Methods and equipment used for monitoring radiation exposure the relevant working conditions are subject to approval by STUK (Radiation Decree, section 12). Such approval is needed, among other things, for systems of monitoring individual doses and of measuring radon concentrations.

Radiation meters used for evaluating the acceptability of working conditions, for monitoring individual doses, or to ensure safety must be properly calibrated.* Radiation meters used for monitoring medical radiation equipment (e.g. for measuring patient doses and for quality assurance) must be calibrated within the energy range of the radiation produced by the radiation equipment. Radiation meters used for measuring doses from radiotherapy equipment must be calibrated as specified in ST Guide 2.1. A responsible expert must be named for such meters, and also for meters used for measuring radiation doses and checking on radiation shieldings.

STUK approves a radiation meter for its stated use at the same time as it grants the safety licence or during inspections of the practice. The acceptability of meters is assessed from type inspection data, test results and other reliable data on their properties.

The responsible party must ensure that its radiation meters are calibrated in a laboratory whose calibration traceability to national or international standards has been assured. The meters must be calibrated before they are put to use, and then at intervals of not more than five years, unless STUK instructions upon approval of the method or practice, or in some other connection, state otherwise.

Manufacturer's calibration often suffices for the acceptability of a new radiation meter, but not if the meter is to be used for monitoring exposure to radiation and working conditions affecting such exposure. For example, meters for individual monitoring or measurement of exposure to radon must be calibrated before they are put to use. The proper functioning of meters must be checked at regular intervals between calibrations. Apart from checking the general condition of the meters, this includes testing them in operation, using suitable radiation sources.

STUK gives detailed instructions on calibrating individual dosimeters for monitoring exposure to radiation when it accepts them for use. For example, they can be calibrated in accordance with Technical Recommendations EUR 14852 [21].

Accuracy requirements for radiation measurements are presented in Appendix C.

10 Notifications to STUK

Several provisions of the Radiation Act and Decree specify matters to be notified to STUK by responsible parties. Appendix D gives a list of such matters. Other matters to be notified are mentioned in ST Guides and STUK decisions.

11 References

1 Council regulation (Euratom) No 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States. Official Journal of the European Communities No L 148, June 19,1993. p. 1.

2 Council Directive 96/29/Euratom of 13 May 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. Official Journal of the European Communities No L 159, June 29,1996, p. 1.

3 Council Directive of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment (84/466/Euratom). Official Journal of the European Communities No L 265, October 5, 1984, p. 1.

* Calibration means determining the ratio between the true values of a quantity and the values shown by a meter.

4 Council Directive of 14 June 1993, concerning medical devices (93/42/EEC). Official Journal of the European Communities No L 169, July 12, 1993, p. 1.

5 Council Directive of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas (90/641/Euratom). Official Journal of the European Communities No L 349, December 13, 1990, p. 21.

6 SFS-ISO 8402. Quality management and quality assurance. Vocabulary.

7 Radiopharmacy. Preparation and Control of Radiopharmaceuticals in Hospitals. Nordic Guidelines. NLN Publication No 26. Nordic Council on Medicines, Uppsala 1989.

8 Quality Assurance in Nuclear Medicine. World Health Organization, Geneva, 1982.

9 Quality Control of Nuclear Medicine Instruments. IAEA-TECDOC-317. International Atomic Energy Agency, Vienna 1991.

10 IEC 789. Characteristics and test conditions of radionuclide imaging devices; Anger type gamma cameras.

11 Quality Assurance Project in Nuclear Medicine, Final Report 1992 - 1993, Kuopio University Hospital, Department of Clinical Physiology and Nuclear Medicine, Kuopio 1993 (in Finnish).

12 Quality Criteria for Diagnostic Radiographic Images. Doc XII/173/90, 2nd edition, Commission of the European Communities, 1990.

13 Quality Criteria for Diagnostic Radiographic Images in Paediatrics. Doc XII/307/91, Commission of the European Communities, 1992.

14 European guidelines for quality assurance in mammography screening. EUR 14821 EN, Commission of the European Communities, 1993.

15 Summary of the Current ICRP Principles for Protection of the Patient in Diagnostic Radiology, Pergamon Press, Oxford 1993.

16 Summary of the Current ICRP Principles for Protection of the Patient in Nuclear Medicine. Pergamon Press, Oxford 1993.

17 Declaration of Helsinki. Adopted by the 18th World Medical Assembly, Helsinki, 1964, and as amended by the 29th World Medical Assembly, Tokyo, 1975, the 35th World Medical Assembly, Venice, 1983, and the 41st World Medical Assembly, Hong Kong, 1989; available from the World Medical Association, F-01210 Ferney-Voltaire, France.

18 International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources. Safety series No. 115. International Atomic Energy Agency (IAEA), Vienna 1996.

19 The International Commission on Radiological Protection. 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. Oxford: Pergamon Press, 1991, p. 74.

20 Quality Assurance in Radiation Therapy. World Health Organization, Geneva 1988.

21 Technical recommendations for monitoring individuals occupationally exposed to external radiation. EUR 14852, Commission of the European Communities, 1994

APPENDIX A

QUALIFICATIONS REQUIRED OF RADIATION SAFETY OFFICERS

Medical radiology
- Radiologist (physician specializing in radiology)*
- Physician who has undergone a radiation safety course or passed an examination acceptable to STUK
- Hospital physicist

Use of radioactive materials in medicine
- Hospital physicist
- Hospital chemist*
- Nuclear-medicine physician*
- Chemist, physicist or physician who has undergone a radiation safety course or passed an examination acceptable to STUK

Radiotherapy
- Hospital physicist
- Specialist in oncology who has undergone a radiation safety course or passed an examination acceptable to STUK

Dental radiology (if a safety licence is required)**
- Dentist or physician who has undergone a radiation safety course or passed an examination acceptable to STUK
- Radiologist*
- Hospital physicist

Veterinary roentgenology
- Veterinarian or other person who has undergone a radiation safety course or passed an examination acceptable to STUK

Installation, servicing and repair of radiation equipment
- A person who has undergone a radiation safety course or passed an examination acceptable to STUK

In addition, the responsible party must have a staff member who is qualified under the regulations on electricity safety to direct and supervise the installation, servicing and repair of such equipment.

Trade in radioactive sources
- A person who has undergone a radiation safety course or passed an examination acceptable to STUK

In exceptional cases, other persons with adequate expertise in such trade are acceptable as radiation safety officers.

Use of radiation in industry, research and teaching
- A person who has undergone a radiation safety course or passed an examination acceptable to STUK

In exceptional cases, other persons with adequate basic training and experience in the use of radiation for such purposes are acceptable as radiation safety officers.

In all other cases, the qualifications required of radiation safety officers will be specified separately.

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* A candidate for the post whose training has not been followed by a radiation safety officer's examination must undergo a separate radiation safety course or pass an examination acceptable to STUK.

** In most cases dental radiology is exempt from a safety licence (see point 5.2 above).

APPENDIX B

EXPOSURE TO NATURAL RADIATION: MAXIMUM VALUES

If the exposure is below the values listed in the following two tables, limiting measures (Radiation Act, section 46) are not needed.

WORKERS

Cause of exposure	Effective dose per annum mSv
Mining or underground excavation*	2.5
Radon at place-of-work*	2.5
Handling of materials containing natural radioactive substances**	1
Handling of fuel peat or peat ash	1
Cosmic radiation at high altitudes (air crew)	1

* According to ICRP Report 65 (Protection against Radon-222 at Home and at Work, Pergamon Press, Oxford 1994), the conversion coefficient between exposure to radon and effective dose is as follows: the effective dose corresponding to a radon exposure of 100 Bq h m^{-3} is 0.8 μSv, when the equilibrium ratio is 1. When the equilibrium ratio is 0.5, the effective dose corresponding to a radon exposure of 100 Bq h m^{-3} is 0.4 μSv.

** Does not apply to exposure due to radon. Radon exposure is taken into account in workplace and indoor-air radon concentration.

GENERAL PUBLIC

Cause of exposure	Effective dose per annum mSv
Building materials*	1
Peat ash added to building materials*	0.1
Materials used in earthworks (street, road, courtyard, etc.)*	0.1
Household water	0.5
Waste area containing natural radioactive substance	0.5

* Dose constraints imposed on materials containing radioactive substances according to the optimization principle — i.e. at reasonable cost taking into account the radioactivity of the materials and times spent in such places. Dose constraints apply to the extra effective dose per annum due to the use of the material; their values depend mainly on times spent in the areas. They are justified because low-activity materials are easily available (see ST Guide 12.2).

APPENDIX C

ACCURACY OF RADIATION AND DOSE MEASUREMENTS

The following requirements imposed on uncertainties in measurement results are based on the standards and reports listed in the References at the end of this Appendix.

1. Individual dose measurements are based on EUR 14852 [1] unless other requirements are imposed in specific cases. In these measurements, the uncertainty,* at a confidence level* of 95%, of an annual dose (personal dose equivalent $H_p(0.07)$ or $H_p(10)$) near the annual dose limit may not be greater than -33% or +50%.

2. The uncertainty of a measurement result in radiation protection measurements at a confidence level of 68% may not be greater than ±30% [2].

   The intrinsic error* of a portable dose rate meter may not be greater than ±15% and the error* may not be greater than ±35% when the radiation is measured within an energy range of 30—200 keV [3].

3. The accuracy of meters used in measurements for the quality control of radiation devices and of their performance and safety properties, must be such that the meters can be used for a reliable determination of whether the devices meet their requirements. The uncertainty of absorbed doses in radiotherapy dose measurements may not be greater than ±2% at a confidence level of 68%. The requirements for such meters are laid down in IEC Standard 731 [4].

   The uncertainties permitted in measurement results on X-ray diagnostic devices at a confidence level of 68% are as follows: ±3.5% in measurements of their performance, and ±10% in measurements of their leakage and scatter radiation [5].

4. The intrinsic error of a dose calibrator used for measuring the activity of radiopharmaceuticals in nuclear medicine may not be greater than ±10% when measuring activities higher than 3.7 MBq. When the measurements are repeated in the same measurement geometry and with the same source, the error of a single measurement in a series of ten measurements may not be greater than ±5%. If the activity is below 3.7 MBq, the intrinsic error of each calibrator must be determined separately. In this case the intrinsic error can be higher than ±10% [6].

5. The intrinsic error of meters used for measuring radon concentration may not be greater than ±25%, the *standard deviation** of the measurement results may not be greater than ±10%, and the error due to environmental effects like humidity, temperature and the background dose rate may not be greater than ±10%.

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* Definitions:

confidence level:	probability that the correct value of the measured quantity lies within the error limits. (Confidence level can also be expressed by a so-called coverage factor).
error:	difference between a measurement result and the correct value of the measured quantity.
intrinsic error:	error determined in the reference conditions.
standard deviation:	positive square root of the arithmetic mean of the squares of the differences between measurement results and their mean value.
uncertainty:	error limits within which the correct value of the measured quantity most probably lies. (Here, 'uncertainty' means 'expanded uncertainty').

All the concepts defined above are expressed as relative values — i.e. the value of the concept is expressed in per cent of the measurement results (probability of 1 in the case of confidence level, mean of the measurement results in the case of standard deviation).

(to be continued)

APPENDIX C *(continued)*

6. For other determinations of activity, methods of measurement suitable for the purpose must be used. No special requirements are imposed on the measurement devices. The acceptability of their results will be checked with comparative measurements or some other reliable method.

References

1 Technical recommendations for monitoring individuals occupationally exposed to external radiation. EUR 14852, Commission of the European Communities, 1994.

2 ICRU Report 47, Measurements of Dose Equivalents from External Photon and Electron Radiation, 1992.

3 IEC 846. Beta, X and Gamma Radiation Dose Equivalent and Dose Equivalent Rate Meters for Use in Radiation Protection.

4 IEC 731. Medical Electric Equipment. Dosimeters with Ionization Chambers as Used in Radiotherapy.

5 AAPM Report No. 35. Recommendations on Performance Characteristics of Diagnostic Exposure Meters, March 1992.

6 IEC 1145. Calibration and Usage of Ionization Chamber Systems for Assay of Radionuclides.

APPENDIX D

MATTERS TO BE NOTIFIED TO STUK ACCORDING TO THE REGULATIONS

To be notified	Radiation Act/Decree and section No.
Radiation use (authorization)	RA 16
Radiation use exempted from safety licence if STUK requires notification	RA 17 (amendment 1334/94)
Changes in radiation practice	RD 16
Abnormal occurrence in the use of radiation	RD 17
Licence-free radiation appliance, for entry in STUK Register	RD 20
Cessation of a use of radiation	RA 20
Licensee's death, loss of legal capacity or (in the case of a physician, dentist, veterinary surgeon or other practitioner) loss of right to practise profession*	RA 20
Data on products marketed, if required for regulatory control of radiation safety	RA 21 (amendment 1334/94)
Transport of radioactive substances: - if special arrangements are to be used - if a type B(M) package is to be used - if the activity in a type B(U) package, or that in a package containing fissile material, exceeds $3 \cdot 10^3 A_1$, $3 \cdot 10^3 A_2$, or 1,000 TBq - before a type B(U) package arrives in Finland for the first time**	RA 29
Shipments of radioactive waste if Finland is the first country to receive the waste, and if its final destination is outside the EU	RA 52a (amendment 1334/94)
Data on workers engaged in radiation work, for entry in the Dose Register	RA 34
Data on exposure of workers doing radiation work abroad, for entry in the Dose Register	RA 35
Data on workers doing radiation work and on their exposure monitoring results, for the Dose Register. Indications or reason to suspect that dose limits or constraints have been exceeded	RD 10
Medical surveillance findings on any worker doing radiation work that indicate a need to investigate whether he or she has suffered abnormal exposure to radiation	RD 13
Any report containing measurement results referred to in RA 45	RD 26
Notification, before start-up of mining, quarrying, excavation, or utilization of natural resources containing uranium	RD 29

* Notification to be made by the *negotiorum gestor*.

** Before despatching the goods, the sender must make sure a copy of the certificate of approval for each package has been sent to STUK.

ST (SS) GUIDES (3.2.1997)

General Guides

ST 1.1 Radiation Practices and Regulatory Control, 20.6.1996 (in English, Finnish and Swedish)
ST 1.2 Application of Maximum Radiation Exposure Values and Monitoring of Radiation Exposure, 10 October 1995 (in English and Finnish)
ST 1.3 Safety Signs Denoting Radiation Sources, 9 April 1992 (in Finnish and Swedish)
ST 1.4 Organization for the Use of Radiation, 24 October 1991 (in English, Finnish and Swedish)
ST 1.5 Maximum Values and Classifications of Radionuclides, 26 November 1991 (in English, Finnish and Swedish)
ST 1.6 Monitoring of Radiation Exposure and Registration of Doses, 10 October 1995 (in English, Finnish and Swedish)
ST 1.7 Health Surveillance of Persons Engaged in Radiation Work, 19 December 1991 (in English, Finnish and Swedish)

Radiation Therapy

ST 2.1 Quality Assurance for Radiotherapy Equipment, 13 January 1993 (in English, Finnish and Swedish)
SS 2.8 Radiation Protection Requirements for Radiotherapy Equipment and Treatment Rooms. High-Energy Radiotherapy Equipment, 21 December 1989 (in English, Finnish and Swedish)
SS 2.9 Radiation Protection Requirements for Radiotherapy Equipment and Rooms. X-ray Therapy Equipment (25 kV ... 400 kV), 21 December 1989 (in Finnish and Swedish)
SS 2.10 Radiation Protection Requirements for Radiotherapy Equipment and Rooms. Afterloading Therapy Equipment, 21 December 1989 (in Finnish and Swedish)

Diagnostic Radiology

SS 3.1 Dental X-ray Equipment: Type Inspection and Technical Requirements, 25 February 1987 (in English, Finnish and Swedish)
SS 3.2 Radiation Safety Requirements for Mammographic Equipment, 17 February 1987 (in English, Finnish and Swedish)
ST 3.3 Diagnostic X-ray Equipment and Its Use, 27 August 1992 (in English, Finnish and Swedish)
ST 3.4 Quality Control of Image Intensifier - Television Chains, 24 October 1991 (in English, Finnish and Swedish)
ST 3.5 Quality Control of Diagnostic X-ray Equipment and Film Processing, 3 December 1991 (in English, Finnish and Swedish)
ST 3.6 Radiation Shielding of X-ray Examination Rooms, 20 December 1991 (in English, Finnish and Swedish)

Measurement of Radiation

ST 4.2 Radiation Meters for Civil Defence, 6 June 1991 (in English and Finnish)

Industry, Research, Education and Commerce

ST 5.1 Radiation Safety of Sealed Sources and Equipment Containing Them, 27 August 1992 (in English, Finnish and Swedish)
ST 5.3 Use of Ionizing Radiation in the Teaching of Physics and Chemistry, 14 December 1992 (in English, Finnish and Swedish)
ST 5.4 Trade in and Transport of Radiation Sources, 9 June 1995 (in English, Finnish and Swedish)
SS 5.6 Radiation Safety in Industrial Radiography, 6 January 1989 (in English, Finnish and Swedish)

SS 5.8 Installation, Repair and Maintenance of Radiological Equipment Used for Medical Purposes, 28 March 1988 (in English, Finnish and Swedish)

Unsealed Sources and Radioactive Wastes

ST 6.1 Radiation Safety Requirements for Radionuclide Laboratories, 30 May 1991 (in English, Finnish and Swedish)

ST 6.2 Radioactive Wastes and Discharges, 20 December 1991 (in English, Finnish and Swedish)

Non-Ionizing Radiation

SS 9.1 Radiation Safety Requirements and Type Inspection of Solarium Equipment and Sun Lamps, 1 September 1989 (in Finnish and Swedish)

ST 9.2 Radiation Safety of Pulsed Radars, 11 December 1991 (in Finnish)

ST 9.3 Radiation Safety During Work on Masts at FM and TV Stations, 7 April 1992 (in Finnish)

ST 9.4 Radiation Safety of High Power Display Lasers, 8 October 1993 (in Finnish)

Natural Radiation

ST 12.1 Radiation Safety in Mining and Excavation Work, 27 August 1992 (in English, Finnish and Swedish)

ST 12.2 Radioactivity of Construction Materials, Fuel Peat and Peat Ash, 2 February 1993 (in English, Finnish and Swedish)

ST 12.3 Radioactivity of Household Water, 9 August 1993 (in English, Finnish and Swedish)

SS Guides will be replaced by ST Guides when necessary.

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