

## SAFETY IN RADIOTHERAPY

1	GENERAL	3
2	DEFINITIONS	3
3	SAFETY OF RADIOTHERAPY SHALL BE ENSURED	3
4	SAFETY LICENCE IS REQUIRED FOR RADIATION THERAPY	3
4.1	The responsible party shall be responsible for safety	3
4.2	Number of staff shall be sufficient	4
5	RADIOTHERAPY EQUIPMENT SHALL COMPLY WITH REQUIREMENTS	4
5.1	Equipment shall comply with the general requirements	4
5.2	Equipment shall comply with the acceptability criteria	4
6	QUALITY IS MANAGED IN ORDER TO ENSURE SAFETY	6
6.1	The management system is applied to implement requirements	6
6.2	Quality assurance is required for radiotherapy	6
6.2.1	Technical quality assurance includes measurements and related instructions	6
6.2.1.1	The acceptance test ensures the appropriateness and safety of the device	6
6.2.1.2	Commissioning measurements produce and verify planning data for patients' treatment	7
6.2.1.3	The technical quality shall be monitored	7
6.2.2	Quality assurance shall cover all of the radiation therapy chain	8
6.2.2.1	Abnormal events shall be prevented in advance	8
6.2.2.2	Radiotherapy records shall be monitored	8
6.2.2.3	Operations shall be assessed regularly	8

This Guide is valid as of 1 June 2011 until further notice.

It replaces Guide ST 2.1, Quality Assurance in Radiotherapy, issued on 22 May 2003.

Helsinki 2011

ISBN 978-952-478-624-9 (pdf)

ISSN 0789-4414

ISBN 978-952-478-625-6 (html)

7	EXPOSURE TO RADIATION DUE TO SCIENTIFIC RESEARCH SHALL BE JUSTIFIED	9
8	ABNORMAL EVENTS IN RADIOTHERAPY SHALL BE ANTICIPATED	9
8.1	Abnormal events shall be dealt with according to their significance	9
8.2	STUK shall be notified of all significant abnormal events	10
9	WORKERS SHALL BE TRAINED AND INTRODUCED TO THEIR TASKS	10

APPENDIX      DOSE CALIBRATION OF THERAPY EQUIPMENT

## Authorization

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.

Under section 70, paragraph 2, of the Radiation Act (592/1991), STUK – Radiation and Nuclear Safety Authority (Finland) issues general instructions, known as Radiation Safety Guides (ST Guides), concerning the use of radiation and operations involving radiation.

Translation. In the event of any differences in interpretation of this guide, the Finnish and Swedish versions shall take precedence over this translation.

# 1 General

This Guide sets out the duties of the parties running a radiation practice (hereafter the responsible parties) in respect of ensuring the safety of radiotherapy. The principles in Guide ST 6.3 and in this Guide shall apply to radionuclide therapy except for the accuracy of the dose received by the target volume, as defined in chapter 3.

*The general requirements for the supervision and quality assurance of medical radiation equipment are laid down in section 40 of the Radiation Act (592/1991), and in sections 18 and 32 of the Decree of the Ministry of Social Affairs and Health on the medical use of radiation (423/2000), hereinafter referred to as the MSAH Decree. Guide ST 1.10 imposes requirements on structural radiation shielding of radiotherapy equipment and the premises in which it is used, and on arrangements concerning warnings, security and safety. Guides ST 1.1 and ST 1.6 impose general safety principles for radiation practices, radiation safety procedures, and general principles concerning safety arrangements. Guide ST 1.9 presents the accuracy requirements for radiation measurements.*

## 2 Definitions

In this Guide

**management system** refers to the steering and control system of an organization, consisting of the rules and operation modes in common and shared in the organization. The management system contains, for example, the organization's business idea, its visions, values, strategy, operating processes, performance measurement principles, human resource policy principles and a description of how the operation is enhanced. The management system is manifested in various documents (guides, models, forms).

**quality assurance** refers to a set of planned and systematic functions in the management system, the operation of which is demonstrable when required, used for reaching a sufficient level of trust in that the object of quality assurance activities meets the quality criteria.

**quality control** refers to a set of techniques and activities in use so that the set quality criteria can be met.

**quality control programme** refers to the quality control document which describes the tests used in quality control, their purposes, methods, the equipment and devices required, the performers of the tests, the action levels related to the acceptability of results, and the actions in the case that the levels are exceeded.

## 3 Safety of radiotherapy shall be ensured

Good radiotherapy results and safety of treatment require radiation to be optimally applied to a specified target area. According to international recommendations, the average uncertainty in therapeutic doses should not exceed 5% [10, 25 and 26]. The need for high precision in therapeutic doses requires quality assurance to cover the entire radiotherapy process. Besides the physical and technical characteristics of the therapy equipment, quality assurance shall include all radiotherapy equipment and procedures that are significant for the correct magnitude and precision of application of the therapeutic dose, as well as for the radiation safety of the staff and external persons. The duties and responsibilities pertaining to various stages of treatment shall be precisely defined. Practices instituted for patient safety shall be described. The procedures shall be explained in writing in the management system. Safety shall be promoted through a good safety culture and systematic quality management.

## 4 Safety licence is required for radiation therapy

### 4.1 The responsible party shall be responsible for safety

The party operating the radiation practice, the responsible party, shall be responsible for the safety of the radiation practice and be obligated to take all actions required to maintain and promote radiation safety. The responsible party shall be responsible for ensuring that the radiation practice fulfils all requirements

and regulations under the Radiation Act and any statutes under it. To conduct radiotherapy operations, the responsible party is required to hold a safety licence (for further details see Guide ST 1.1). The safety licence application shall introduce the intended radiation user's organization.

The Radiation and Nuclear Safety Authority (STUK) shall grant the safety licence upon application if the use of radiation fulfils the general provisions laid down in the law and if the application demonstrates in a sufficiently reliable manner that, for example:

- the purpose and the place of use of radiation, radiation sources, and the equipment related to the use of radiation
  - radiation user's organization, and
  - the arrangements for handling the radioactive waste possibly produced by the operations
- are such that radiation can be used safely.

Unless otherwise specified in the licence, it is a condition of a safety licence that no new radiotherapy equipment may be commissioned before an inspection has been performed by STUK. Commissioning of new appliances and decommissioning of old appliances require an amendment to the safety licence.

The responsible party shall ensure that the radiation safety of any radiotherapy equipment and the premises on which it is used is at the level required in radiation legislation, described in more detail in this Guide and in Guide ST 1.10.

#### **4.2 Number of staff shall be sufficient**

The required and recommended minimum numbers of radiation therapy staff, based on international recommendations [18, 19], are presented in Table 1.

*Section 14 of the Radiation Act lays down provisions concerning the obligations of the responsible party, and section 16, the safety licence. More details are set out in Guide ST 1.1. Provisions concerning the general principles of radiation safety are laid down in section 2 of the Radiation Act. Guides ST 1.4 and ST 1.8 give more precise requirements concerning radiation users' organizations.*

## **5 Radiotherapy equipment shall comply with requirements**

### **5.1 Equipment shall comply with the general requirements**

The statutes on medical devices also apply to radiotherapy equipment. Equipment launched on the market after 13 June 1998 must have a CE marking compliant with the decree mentioned below. The CE marking is the manufacturer's warranty that the apparatus meets the essential equipment safety requirements imposed by European Community Directives.

Radiotherapy treatment planning must be conducted with a computer-based treatment planning system for treatments other than radionuclide therapy and treatments for which a superficial X-ray therapy unit is used.

The radiation shielding plans concerning the places in which radiation is used should be sent to STUK before implementation. Regardless of any shielding calculations, the final assurance of the adequacy of radiation shielding may only be obtained by measurements.

*Medical devices are covered by a law (629/2010) and a decree (1506/1994). Requests for advance statements and advance inspections by STUK are dealt with in more detail in Guides ST 1.1, ST 1.6 and ST 1.10.*

### **5.2 Equipment shall comply with the acceptability criteria**

Radiation equipment and the related auxiliaries and other devices shall comply with all in-service acceptability criteria given in STUK's decisions.

Acceptability criteria refer to the minimum requirements and tolerance limits imposed on the performance capacity of the equipment. If the acceptability criteria are not met, then one of the following actions must be taken:

- The device must be repaired and its performance capacity restored to an acceptable level.

- The use of the device must be restricted so that the characteristic exceeding the tolerance level does not affect treatment.
- The device must be decommissioned.

Acceptability criteria are not limiting values for the optimal performance of the apparatus. When procuring new apparatus, at acceptance tests and in the course of monitoring in-service

performance, responsible parties should apply stricter requirements, which may be based, for example, on the apparatus specifications or performance tolerance values proposed in apparatus standards.

*Acceptability criteria are laid down in section 30 of the MSAH Decree. Acceptability criteria are given through STUK's decisions.*

**Table 1.** Required and recommended minimum numbers for radiation therapy staff.

Professional group or duties	Minimum number	
	Requirement	Recommendation
Radiation Oncologist or other specialist competent in radiation therapy within the specialty (section 24 of the MSAH Decree)	1/(250 patients/year)	1/(25–30 patients/day)
Radiation physicist (medical physics expert)	1/(400 patients/year)	1–2 additional physicists where specialized treatment techniques are used (such as intensity modulated radiotherapy, stereotactic radiotherapy) 1–2 additional physicists where brachytherapy or radionuclide therapy are used
Treatment planning staff		1/(700 patients/year)
Mould room worker		1/(600 patients/year)
Radiographer	2/therapy unit <sup>*)</sup> during treatment	3/therapy unit when no more than 25 treatments per day 4/therapy unit when no more than 50 treatments per day 2/500 treatment simulations/year Additional need for brachytherapy
Service engineer or technician		1/(2 therapy units) or 1/(therapy unit + simulator), when maintained by own hospital

<sup>\*)</sup> linear accelerator for radiation therapy

## 6 Quality is managed in order to ensure safety

Quality management comprises the management, planning and direction of operations, their monitoring and evaluation, and the development of operations with a view to achieving targets. The organization's managers shall be in charge of quality management, but other members of the organization shall take part in its planning, development and implementation. The means of quality management include quality assurance and quality control.

### 6.1 The management system is applied to implement requirements

The best way to implement the requirements set for responsible parties in radiation legislation is to impose a management system to cover all operations. A management system can also be called a quality system. It refers to the system comprised of the organizational structures, procedures, processes and resources required for managing quality (see also Guide ST 1.1). The management system shall be documented, and the respective documents shall be arranged to form a unified, continuously updated totality (the procedures manual, the quality manual or similar).

### 6.2 Quality assurance is required for radiotherapy

The responsible party shall arrange quality assurance procedures for radiotherapy. Therefore, a quality assurance programme is required. The programme shall define the necessary quality assurance functions, and must also include the principles for preventing in advance errors and mishaps from which radiation doses may arise unintentionally. Quality assurance practices shall be assessed regularly and, when appropriate, changed. Quality assurance can be seen as assurance of the technical quality and the operational quality.

*The obligation of the responsible party to arrange quality assurance is laid down in section 40 of the Radiation Act and in section 18 of the MSAH Decree.*

### 6.2.1 Technical quality assurance includes measurements and related instructions

Quality assurance measurements of radiotherapy equipment and the instructions related to the measurement methods belong to technical quality assurance. Technical quality assurance consists of acceptance tests, commissioning measurements, and technical quality control.

The quality assurance requirements presented in this Guide shall apply to the following devices:

- radiotherapy accelerator
- X-ray therapy equipment
- brachytherapy equipment (afterloading therapy equipment or a radiation source used for brachytherapy)
- boron neutron capture (BNC) therapy equipment
- radiotherapy simulator
- imaging devices (e.g. devices for radiography, computed tomography, cone beam computed tomography, positron emission tomography, magnetic resonance imaging, and ultrasound), when used in radiotherapy treatment planning or verification.
- devices used for alignment and verification of therapy (such as lasers, cameras)
- treatment planning system.

#### 6.2.1.1 The acceptance test ensures the appropriateness and safety of the device

The responsible party shall ensure that any device about to be commissioned has undergone an acceptance test before the device is used for treating or examining patients. The purpose of the acceptance test is to verify that the device functions appropriately and safely after transportation, installation and connection of all parts. The equipment must comply with the requirements imposed by legislation, with the key performance characteristics given by the manufacturer, and with the in-service acceptability criteria given in STUK's decision. During the acceptance test, it is expedient to define the reference performance values which are needed for monitoring the operating condition and performance characteristics of the equipment.

An acceptance test may be carried out

by a representative of the user organization (purchaser), a representative of the supplier, or a third party. If the acceptance test is carried out by a party other than the user organization's representative, the person in charge in the user organization shall ensure that the test is appropriately supervised.

*Acceptance test requirements are laid down in section 32 of the MSAH Decree.*

### **6.2.1.2 Commissioning measurements produce and verify planning data for patients' treatment**

Before commissioning therapy equipment, the responsible party shall measure or verify the characteristics of the therapy equipment that are required as input data for the treatment planning system.

Unless specified otherwise in the licence, licensed therapy equipment (see chapter 3) may be commissioned after the acceptance test, commissioning measurements and an inspection by STUK. Other radiotherapy equipment that requires an inspection by STUK may be commissioned after the acceptance test, unless specified otherwise in the licence. STUK will inspect the equipment separately as indicated in the conditions of the safety licence.

### **6.2.1.3 The technical quality shall be monitored**

In addition to periodic inspections, the operation of the equipment must be checked after any repair, service or update performed on the equipment. The quality assurance requirements also apply to the treatment planning system.

Quality assurance measures for radiotherapy equipment must be applied from the time the equipment is commissioned, as stipulated in the safety licence and defined at the time of the commissioning inspection. A detailed quality control programme must be submitted in writing to STUK for approval within one year of the date when the device was commissioned. In all cases, the quality control programme for therapy equipment shall include dose calibration performed by the responsible party (see Appendix), which forms the basis for using the therapy equipment.

The quality control programme of any radiotherapy equipment shall set out the principal tasks involved in supervising the operating condition and performance characteristics of the equipment. The instructions and responsibilities pertaining to the supervision of the equipment shall be specified per appliance. A quality control programme for radiotherapy equipment shall specify:

- the inspections and measurements to be performed and the purposes thereof
- the inspection and measurement methods
- the devices and instruments to be used in inspections and measurements
- the intervals between inspections and measurements
- the approval criteria (action levels) for inspection and measurement results
- the measures to be taken when the approval criteria are exceeded.

The persons performing inspections and measurements and the persons in charge of them (professional groups) shall be specified. The inspection and measurement methods shall be described in sufficient detail for the inspections and measurements to be repeated on the basis of the quality control programme in the manner intended by the person who prepared the programme.

A party responsible for radiotherapy practice shall notify STUK of the following in particular:

- any significant changes in equipment, in the manner of using the equipment and in the approved quality control programmes
- any significant device faults and repairs performed.

To ensure the quality of the *treatment planning system*, the system must be tested before any new system or modification is introduced and at regular intervals in order to detect any unintended or random changes in the apparatus or software. The purpose of commissioning testing is to ensure that the system calculates the dose and the dose distribution correctly in relation to the criteria set by the user. This is done by comparing the dose calculation result from the system to the best measurement and calculation data available. The appropriateness

of the calculation of therapy plans, which are selected as a representative set with respect to use of the appliance, shall be ensured in addition to single open fields. Tests and limiting values defined in international publications can be used as criteria [22, 23 and 24]. The quality assurance of treatment planning shall include the inspection of each individual treatment plan using a procedure optimally independent of the treatment planning system. In addition, each whole body therapy must include an in vivo dose measurement. The use of in vivo dose measurement is recommended in other therapies as well. The correct targeting of therapy shall be ensured for every patient.

The responsible party shall procure and maintain measuring devices suitable for quality assurance measurements of radiotherapy equipment. The accuracy requirements for measurements are set out in Guide ST 1.9. The operating condition of measuring equipment shall be monitored according to a written quality assurance programme. A dosimeter used for dose calibration of therapy equipment shall be calibrated against a national standard or in an accredited calibration laboratory using standards that are traceable to primary standards. A dosimeter must be recalibrated at intervals no longer than three years.

Records must be kept of the inspections and measurements involved in quality assurance, detailing which inspections and measurements have been made, by whom, the results thereof, and the measures taken on account of those results. Records must also be kept of any equipment faults, functional errors and other incidents that occur during the use of the equipment and disrupt the normal use or endanger safety (see chapter 7).

*The quality control requirements for equipment are laid down in section 32 of the MSAH Decree.*

### **6.2.2 Quality assurance shall cover all of the radiation therapy chain**

Written instructions for the most common procedures in radiotherapy shall cover all stages of the radiotherapy process, as the planning and implementation of treatment requires many kinds of technically demanding apparatus and

procedures, and effective collaboration by several professional groups. The written instructions must also include practical directions for responding to and preventing accidents.

#### **6.2.2.1. Abnormal events shall be prevented in advance**

A quality assurance programme shall include the principles for preventing errors and mishaps which may cause unintended radiation doses. Therapy equipment quality assurance programmes shall therefore include the inspection of the operating conditions of the warning and safety devices that are associated with the therapy equipment and the related premises.

*Quality assurance programme requirements are laid down in section 18 of the MSAH Decree.*

#### **6.2.2.2 Radiotherapy records shall be monitored**

The responsible party shall arrange the recording of radiotherapy data so that sufficient data are available for statistical processing of treatments, the monitoring and comparison of the results of therapy, and the evaluation of the quality of treatments, for example, for the purpose of randomized patient studies. When recording data and treatment summaries, a written practice shall apply that is based on international recommendations [1, 2, 3, 4, 5 and 7]. Summaries of numbers of treatments shall be prepared according to separately issued instructions; the summaries will form the basis for national appraisals of radiation doses and their trends.

#### **6.2.2.3 Operations shall be assessed regularly**

Clinical audits must be arranged so that they complement the self-assessment of activities in an expedient manner. Radiotherapy practices shall, in all essential parts, be audited at intervals of no more than five years. An expedient audit respects the recommendations of the National advisory committee of clinical audit [8].

*Provisions concerning clinical audits are laid down in section 39 c of the Radiation Act and chapter 4 of the MSAH Decree.*

## 7 Exposure to radiation due to scientific research shall be justified

The plan of research for a scientific study shall assess the radiation exposure caused to the subjects of the study and shall show justification for it. All scientific studies of radiotherapy shall respect the guidelines and recommendations issued by the ICRP and the European Commission [15 and 16].

*The Medical Research Act 488 / 1999 deals with medical research. In addition, scientific research is discussed in section 6 of the MSAH Decree.*

## 8 Abnormal events in radiotherapy shall be anticipated

The responsible party shall protect all equipment containing radioactive substances against unlawful actions, loss and damage. In the case of an abnormal event, one shall proceed as instructed for the particular workplace

Abnormal events in the use of radiation must be reported to STUK. Professional users of medical devices must report all adverse incidents in the use of these devices to the National Supervisory Authority of Welfare and Health (Valvira). The reporting obligation concerns adverse incidents such as, for example, the deterioration of a characteristic or operation of a device, or the imprecision of a user instruction. The patient, or if the patient is legally incompetent, the patient's lawful representative, the patient's family member or some other near relative as well as the physician in charge of the patient shall be informed of an abnormal event which concerns the patient in the case that it is adverse to the patient.

This Guide classifies abnormal radiotherapy events and provides instructions on recording and reporting such events to STUK. Abnormal events do not include incidents in which an unexpected consequence for the patient arose solely on account of a medical decision made by

a physician, and the matter does not concern a deficiency in the radiotherapy activities quality system or a failure to comply with the system.

*Guide ST 1.6 provides more detailed information concerning the anticipation of abnormal events and actions upon the occurrence of such. Requirements for the anticipation of abnormal events concerning high-activity sources are presented in Guide 5.1. Provisions concerning the obligation to notify STUK are laid down in section 17 (1512/1991) of the Radiation Decree. Provisions concerning the obligation to notify Valvira are laid down in the Medical Devices Act (629/2010) [9].*

### 8.1 Abnormal events shall be dealt with according to their significance

An abnormal event is an adverse incident such as an equipment fault, human error or combination thereof that *caused* (harmful event) or *could have caused* (nearmiss incident) hazard to the health of a patient, a member of staff or an outsider. Harmful effects were avoided either by chance or because the abnormality or hazard was noticed and the harmful effects were prevented in time. The reason for a harmful event may be either a systematic or incidental fault.

*An equipment fault* is defined very generally to mean faulty equipment operation, a programme error, or an error or deficiency in user instructions or procedural instructions (quality system instructions). A *systematic fault* generally concerns more than one patient or person, while an *incidental fault* generally affects only one patient or person. Even a minor systematic fault may be significant when assessing factors that jeopardize safety and when collecting information with a view to preventing new errors.

Abnormal events are also classified according to whether the hazard affected the staff, external persons, or a patient. When the victim is a patient, hazards are classified according to the size of the real or possible accidental dose and the magnitude of the harm caused to the individual patient. A *faulty dose* is an abnormal dose which deviates significantly from the total dose as given in the appropriate radiotherapy plan, approved by a physician (Table 2).

Table 2 identifies four classes of abnormal events.

## 8.2 STUK shall be notified of all significant abnormal events

A party responsible for radiotherapy practice shall notify STUK of the following in particular:

- dose calibration deviations, if the result, allowing for any calibration adjustments of the equipment, differs by more than 5% from the value last ascertained in comparison measurements by STUK.
- any accidents in the use of radiation and incidents endangering radiation safety.

In addition, the events shall be reported that Guide ST 1.6 requires to be reported.

The initial report of an abnormal event must specify:

- the responsible party (holder of the safety licence) and the radiation safety officer
- the name and contact information of the person giving the notification
- time and place of the event
- radiation source
- description of the event
- information of the endangered persons and the radiation exposure to which they may have been subjected
- immediate measures
- initial evaluations of the reasons for the event.

All of the abnormal events presented in table 2 must be recorded. These records must be submitted to STUK upon request.

Table 2 specifies which abnormal events in radiotherapy must be reported to STUK. The

report must be submitted in writing immediately when the event has come to light. The initial report may also be submitted by telephone, but must later be confirmed in writing.

The responsible party shall report in writing any abnormal event or observation significant for safety, detailing the event or observation, and in addition to the information listed above, include more precise reasons for the event and the consequences of the event, such as the names of exposed workers (if possible), the doses received by them and the measures taken. In addition, the report shall present measures for the prevention of similar events in the future. The report must be sent to STUK without delay.

## 9 Workers shall be trained and introduced to their tasks

The responsible party shall train the staff to use the radiotherapy equipment in a safe and correct manner. Users and maintenance personnel shall have clear instructions for reporting abnormal events and for taking other measures. All staff using the equipment must be aware of the respective inspection reports issued by STUK.

*Requirements concerning the radiation protection training of staff involved in the use of radiation are presented in the MSAH Decree. More detailed requirements are given in Guide ST 1.7.*

**Table 2.** Classification of abnormal events and duty to report.

<b>Class</b>	<b>Event affected</b>	<b>Description of event</b>	<b>STUK to be notified</b>
A	Staff or an external person	A person has, due to an equipment fault or human error, received an abnormal radiation dose or one that exceeds the dose limit. When the matter concerns an equipment fault in a radiotherapy appliance or safety system, this class also includes all cases that could have resulted in such a situation without exceptionally great caution or good fortune.	All events
B1	Patient	<p><b>Seriously harmful effect</b></p> <p>The patient received (harmful event) or could have received (nearmiss incident) an incorrect radiation dose that causes objective medical adversity to the patient in comparison with normal treatment, or may seriously compromise the success prospects of the treatment.</p> <p>When assessing the error attention must be paid to the overdose applied to the target area or risk organ, on account of which the patient could suffer serious complications.</p> <p>The incorrect dose may also be an underdose seriously compromising the success prospects of the treatment.</p> <p>The deviation from the planned total dose is more than 25%. This limit applies both to overdoses and underdoses, even though underdoses are often easier to correct.</p> <p>The limit should not be applied as an absolute, but as typical when considering the consequences of the incorrect dose. If an overdose of less than 25% can cause serious complications, then the abnormal event belongs to this class.</p>	All harmful events All nearmiss incidents caused by a systematic error (an equipment fault or human error) or an incidental equipment fault
B2	Patient	<p><b>Mildly harmful effect</b></p> <p>The patient received (harmful event) or could have received (a nearmiss incident) a radiation dose on some area deviating 5–25% from the planned dose. These limits apply to both overdoses and underdoses. An overdose must not cause an increase in the risk of serious complications for the patient which differs clearly from general practice.</p>	All harmful events caused by a systematic error (an equipment fault or human error) Nearmiss incidents caused by a systematic equipment fault
C	Patient	Abnormal events not pertaining to radiation safety, such as hazards arising from the mechanical characteristics or electrical safety of equipment.	No notification to STUK required

## Bibliography

1. International Commission on Radiation Units and Measurements. Dose and volume specification for reporting intracavitary therapy in gynecology. ICRU Report 38. Bethesda, MD: ICRU; 1985.
2. International Commission on Radiation Units and Measurements. Prescribing, recording, and reporting photon beam therapy. ICRU Report 50. Bethesda, MD: ICRU; 1993.
3. International Commission on Radiation Units and Measurements. Dose and volume specification for reporting interstitial therapy. ICRU Report 58. Bethesda, MD: ICRU; 1997.
4. International Commission on Radiation Units and Measurements. Prescribing, recording, and reporting photon beam therapy. ICRU Report 62. Bethesda, MD: ICRU; 1962.
5. International Commission on Radiation Units and Measurements. Prescribing, recording, and reporting electron beam therapy. Report 71. *Journal of the ICRU* 2004; Vol 4, No 1.
6. International Commission on Radiation Units and Measurements. Dosimetry of beta rays and low-energy photons for brachytherapy with sealed sources. Report 72. *Journal of the ICRU* 2004; Vol 4, No 2.
7. Aaltonen P, Brahme A, Lax I, Levernes S, Näslund I, Reitan JB, Turesson I. Specification of dose delivery in radiation therapy. Recommendations by the Nordic Association of Clinical Physics (NACP). *Acta Oncologica* 1997; 36, Supplementum 10.
8. [www.clinicalaudit.net](http://www.clinicalaudit.net)
9. [www.valvira.fi](http://www.valvira.fi)
10. Brahme A (ed). Accuracy requirements and quality assurance of external beam therapy with photons and electrons. *Acta Oncologica* 1988; Vol 1, Suppl 1.
11. Bäuml A (ed). Quality assurance in radiation therapy. BGA Schriften 5/86. München; World Health Organization: 1986.
12. International Commission on Radiological Protection (ICRP). Protection of the patient in radiation therapy. ICRP Publication 43. Oxford: Pergamon Press; 1984.
13. International Atomic Energy Agency (IAEA). International basic safety standards for protection against ionizing radiation and for the safety of radiation sources. Safety series nro 115. Vienna: IAEA; 1996.
14. European Commission. Criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations. Radiation Protection 91. Luxembourg: Office for Official Publications of the European Communities; 1997.
15. International Commission on Radiological Protection. Radiological protection in biomedical research and Addendum 1 to publication 53 – Radiation dose to patients from radiopharmaceuticals. ICRP Publication 62. Oxford; Pergamon Press: 1993.
16. European Commission. Guidance on medical exposures in medical and biomedical research. Radiation Protection 99. Luxembourg: Office for Official Publications of the European Communities; 1998.
17. Säteilyturvakeskus. Sädehoidon laatu- ja järjestelmän perustaminen. Käytännön opas sädehoito-osastoille. (Establishing a radiotherapy system. A practical guide for radiotherapy units. Helsinki: Radiation and Nuclear Safety Authority; 2000.
18. International Atomic Energy Agency. Design and implementation of a radiotherapy programme: Clinical, medical physics, radiation protection and safety aspects. IAEA-TECDOC-1040. Vienna: IAEA; 1998.
19. International Atomic Energy Agency. Setting up a radiotherapy programme: clinical, medical physics, radiation protection and safety aspects. STI/PUB/1296. Vienna: IAEA; 2008.
20. Knuutila J. (ed.). Terveysturvallisuuden laadunhallinta. Radiologisen laitteen vastaanotto- ja tarkastus. (Quality management in health care. Acceptance test of radiological equipment). Publications of the National Agency for Medicines no. 2/2001. Helsinki: National Agency for Medicines; 2001.

21. International Commission on Radiation Units and Measurements. Prescribing, recording, and reporting photon-beam intensity-modulated radiation therapy (IMRT). Report 83. *Journal of the ICRU* 2010; Vol. 11, No. 1.
22. International Atomic Energy Agency. Commissioning and Quality Assurance of Computerized Planning Systems for Radiation Treatment of Cancer. IAEA-TECDOC-430. Vienna: IAEA; 2004.
23. International Atomic Energy Agency. Specification and acceptance testing of radiotherapy treatment planning systems. IAEA-TECDOC-1540. Vienna: IAEA; 2007.
24. International Atomic Energy Agency. Commissioning of radiotherapy treatment planning systems: testing for typical external beam treatment techniques. IAEA-TECDOC-1583. Vienna: IAEA; 2008.
25. Mijnheer BJ, Battermann JJ, Wambersio A. What degree of accuracy is required and can be achieved in photon and neutron therapy? *Radiotherapy and Oncology* 1987, 8 (3): 237–52.
26. Dische S, Saunders MI, Williams C, Hopkins A, Aird E. Precision in reporting the dose given in a course of radiotherapy. *Radiother. Oncol.* 1993; 29 (3): 287–293.

## APPENDIX

### Dose calibration of therapy equipment

This appendix specifies the meaning of dose calibration of therapy equipment in various cases.

#### Accelerator

The dose calibration of an accelerator is a matter of determining the correspondence between the dose produced by the therapy equipment and the appliance monitor unit setting. Dose refers to the absorbed dose to water along the central axis of the radiation beam, for example at a reference depth in a water phantom, when the surface of the phantom is at the reference distance. Dose calibration determines this correspondence for an open field and for all wedges, using a reference field size. It also determines the dependence of this correspondence upon selected field sizes for open and wedge fields. Dose calibration always requires an inspection of the uniformity of the radiation field. Dose calibration can be performed according to STUK's technical report [1].

The results of dose calibration are entered into the treatment planning system. If necessary, a separate dose table may be made, in which the monitor unit setting corresponding to a certain absorbed dose to water is given as a field size function.

#### X-ray therapy equipment, tube voltage 10 kV

The dose calibration of a superficial X-ray therapy unit denotes the determination of the dose rate produced by the therapy equipment. Dose rate refers to the absorbed dose rate to water at the surface of a water phantom. The dose rate is measured separately for each radiation beam cone.

The result of the dose calibration of a superficial X-ray therapy unit entered in a dose table is expressed either as a measured dose rate for each radiation beam cone or as an imputed dose rate as a function of field size.

#### Boron Neutron Capture (BNC)

##### therapy equipment

The dose calibration of boron neutron capture (BNC) therapy equipment

- determines the correspondence between the thermal neutron flux produced by the therapy equipment and the neutron radiation monitor reading
- determines or verifies the relationships between the thermal neutron flux, the simultaneous photon radiation and the fast neutron dose.

The thermal neutron flux refers to the value derived in a water phantom at the thermal neutron reference point on the central axis of the radiation beam when the phantom is attached to the irradiation aperture of the reactor. The dose of photon radiation and fast neutrons refers to the absorbed dose to tissue obtained on the central axis of the radiation beam in a water phantom with the same measurement geometry at the reference depth of photon radiation and fast neutrons.

#### Brachytherapy unit

Dose calibration of brachytherapy equipment refers to determination of the reference air kerma rate (photon sources) produced by the radiation sources of the equipment.

The reference air kerma rate refers to the air kerma rate at a distance of one metre from the source. In the case of low-energy photon sources, (e.g.  $^{125}\text{I}$  seed), the air kerma rate is determined on a plane perpendicular to longitudinal axis of the source passing through the source centre.

#### Bibliography

1. Kosunen A, Sipilä P, Parkkinen R, Jokelainen I, Järvinen H. Säteihoidon annosmittaukset. Ulkoisen säteihoidon suurenergisten fotonija elektronisäteilykeilojen kalibrointi. (Determination of absorbed dose to water in radiotherapy Calibration of high energy photon and electron radiation beams in external