Federal Ministry for
The Environment, Nature Conservation and Nuclear Safety

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RADIATION PROTECTION IN MEDICINE

Directive
on the
Ordinance on the Protection against Damage and Injuries Caused by Ionizing Radiation

(Radiation Protection Ordinance, StrlSchV)

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In case of discrepancies the German text shall prevail.

The reference list in Appendix B equates to the style used in the German administration; it might not be in accordance with the international style of citation.

TABLE OF CONTENTS

INDEX OF APPENDICES

PRELIMINARY OBSERVATIONS

Firstly the directive is addressed to the competent regulatory and supervisory authorities, secondly it is intended to set out the licensing process in clear form for both applicants and radiation protection supervisors; moreover, it provides a guide to the rights and obligations of persons as stipulated in the Radiation Protection Ordinance (StrlSchV), while supplying staff operating in the relevant medical fields with advice on how to implement the principles of radiation protection.

In and of itself the directive is not legally binding. If, however, the directive is included as an integral element in the official licence, its content becomes binding, by virtue of the fact that it substantiates the relevant requirements as stipulated in the StrlSchV. The requirements featured in this directive are therefore to be read in conjunction with the provisions set out in the StrlSchV. Should the directive contain statements that conflict with the relevant technical standards, e.g. DIN, priority shall be given to the version presented in the directive.

Reference to legal principles, other legislation (such as standards), or recommendations is only made at those points within the directive where it is deemed necessary for immediate comprehension. The comprehensive bibliography included in Appendix B serves as a general reference.

For the sake of readability, gender-specific differentiations such as job titles have been omitted. The directive naturally applies to both sexes.

1 SCOPE OF APPLICATION

This directive explains how the Ordinance on the Protection against Damage and Injuries Caused by Ionizing Radiation (Radiation Protection Ordinance, StrlSchV) passed on 20th July 2001, and most recently amended by the Ordinance amending the Ordinances on Protection against Damage and Injuries Caused by Ionizing Radiation dating from 4th October 2011 (Appendix B number 3.1), shall be fulfilled while taking account of advances in science and technology.

This directive addresses radiation protection in the medical field and specifically how it relates to patient applications. Its aim is to uphold the radiation protection principles of justification (§ 4 StrlSchV), avoidance of unnecessary radiation exposure (§ 6 StrlSchV), and dose limitation (§ 5 StrlSchV).

Every single application of radioactive substances or ionizing radiation must be justified. This applies to new forms of application in particular. The justification of existing forms of application may be reviewed as soon as new information is available concerning the relevant risks and benefits. Activities pursuant to Appendix XVI of the StrlSchV are not justified.

§ 80 para. (1) of the StrlSchV standardises the principal of individual justification in the medical application of radioactive substances or ionizing radiation to patients. It states

that radioactive substances or ionizing radiation may only be used directly on patients within the scope of medical or dental practice if a justifying indication has been established by a physician or dentist with the requisite expertise in radiation protection. For an indication to be justified, the health benefits of direct application must outweigh the risks posed to the patient by radiation. Such an assessment should also take procedures into account that offer comparable health benefits without or with negligible radiation exposure.

This directive applies to the following areas:

Nuclear medicine

- handling unsealed radioactive substances for direct human application, either during examinations or treatment, also in connection with computer tomography (CT), e.g. PET/CT and SPECT/CT.

Teletherapy

- radiotherapy applications with a considerable distance between the radiation source and the tissue being irradiated. Teletherapy is conducted using
  - installations for generating ionizing radiation, e.g. electron and ion accelerators, neutron irradiation units and
  - irradiation units with sealed radioactive substances, e.g. gamma irradiation systems with multiple radiation sources (known as gamma irradiation units).

Brachytherapy

- radiotherapy applications with a negligible distance between the radiation source and the tissue being irradiated

  Brachytherapy, for instance, is conducted using remote-controlled, automatic afterloading devices, including interstitial, endovascular and intracavitery treatment, as well as contact radiotherapy. Brachytherapy with unsealed radioactive substances is subject to the regulations governing nuclear medicine treatments.

This directive also applies to

- the planning of facilities (e.g. including waste water treatment installations) intended for handling or operations as described above.
- the application of radioactive substances or ionizing radiation on patients within the scope of medical research and subject to licensing by the Federal Office for Radiation Protection pursuant to § 23 of the StrlSchV.

The following regulations and applications respectively remain unaffected:

- the production of radiopharmaceuticals pursuant to §§ 13 to 20a of the German Pharmaceuticals Act (AMG, Appendix B number 2.2); special attention should be paid to the AMG and particularly to the provisions specified in § 7.
- the production and first market placing of pharmaceuticals reliant on the use of radioactive substances or ionizing radiation. Particular attention should be paid to the German Medical Devices Act (MPG, Appendix B number 2.3) and the regulations arising from it.
- the operation of both X-ray facilities for application in medical and dental settings and of stray radiation sources in compliance with the German X-ray Ordinance (RöV, Appendix B number 3.2).

The directive does not apply to

- employment requiring a licence (§ 15 StrlSchV) at third-party facilities or installations.
- the addition and activation of radioactive substances that require a licence (§ 106 StrlSchV).
- laboratory tests (in-vitro diagnostics using radioactive substances).

2 LICENSING REQUIREMENTS

Pursuant to the Radiation Protection Ordinance, this directive addresses the following licences which are required in the medical sector:

- licence to handle unsealed radioactive substances (§ 7 StrlSchV)
    - for examinations
    - for treatment
- licence to handle sealed radioactive substances, including highly radioactive radiation sources (§ 7 StrlSchV)
    - during interstitial, endovascular, and intracavitery treatment or contact radiotherapy
    - for irradiation units with sealed radioactive substances (radiation sources) used in treatment
    - for examinations, e.g. PET transmission sources
- licence to operate ionizing radiation installations (§ 11 para. (2) StrlSchV)

Pursuant to § 31 para. (1) of the StrlSchV (see Ch. 2.1.1), the radiation protection supervisor needs to submit an application for the required licence to the competent authority.§ 9 of the StrlSchV lists the licensing requirements for handling radioactive substances and § 14 of the StrlSchV the licensing requirements for the operation of ionizing radiation installations. A few of the requirements which can or may play a role in the licensing process will now be addressed in more detail, including

- staffing requirements,

- possession of the requisite expertise in radiation protection by the applicant and/or radiation protection expert
- the technical requirements as laid down in § 9 para. (1) number 5 of the StrlSchV and § 14 para. (1) number 5 of the StrlSchV.

Should new areas of medical application emerge that have yet to be included in this directive, the competent authority shall stipulate the specific radiation protection requirements.

2.1 Staffing requirements

In order to ensure adherence to the protection regulations, the activities requiring licensing listed above necessitate the existence of sufficiently and suitably trained medical and non-medical personnel.

An appropriate number of radiation protection experts shall be appointed pursuant to § 31 para. (2) of the StrlSchV for the activity in question. These shall, for instance, include physicians and medical physics experts respectively.

Furthermore sufficient staff shall be allocated for the fulfilment of medical and non-medical duties respectively, who, depending on the field of activity, have either acquired the requisite expertise in radiation protection (see Appendix A 1 to A 3 of this directive) or possess the requisite know-how in radiation protection, see also § 82 of the StrlSchV. These include physicians with the requisite expertise in radiation protection, physicians without the requisite expertise in radiation protection, technical medical assistants (medical technical radiology assistants MTRAs) and assisting persons with the requisite know-how in radiation protection. Chapter 3 features detailed descriptions of the requisite expertise and requisite know-how in radiation protection respectively.

2.1.1 Radiation protection supervisors and radiation protection experts

A radiation protection supervisor is subject to licensing under the terms of §§ 7 or 11 of the StrlSchV.

The radiation protection supervisor to whom the legal standards contained in § 31 para. (1) sentence 1 and § 33 of the StrlSchV are addressed, may either be a natural person (e.g. a physician with his own practice) or several natural persons (e.g. partners in a private company) or a legal entity governed by private law (e.g. a public or private limited company) or a statutory body under public law (e.g. the German Federation, Federal state, public authority). In the case of legal entities or companies where legal responsibility is shared (e.g. a joint practice, registered partnership), the duties of the radiation protection supervisor are assumed by a person authorised to represent the company or to manage its business. This may, for instance, be the managing director, company chairman, the medical director of a clinic, or the head of a public company. If the representative body consists of several members or if, in the case of companies with no single legal entity, more than one person holds powers of representation, the company must inform the competent authority as to which person shall assume the duties of radiation protection supervisor.

The authorised representative and the person nominated to assume the duties of radiation protection supervisor respectively shall be entered in the official licence.

The radiation protection supervisor shall appoint, pursuant to requirements, the number of radiation protection experts necessary for the safe execution of the licensed activity. Those appointed must be absolutely reliable and in possession of the requisite expertise in radiation protection, pursuant to Appendix A 1 or A 2, required for the activity in question. A written record shall be made of their duties, their internal decision-making scope, and their powers as radiation protection experts. The competent authority shall be informed immediately of any appointment, giving details of the individual duties, the relevant scope of internal decision-making, and any attendant powers. A certificate verifying possession of the requisite expertise in compliance with Appendix A 6 shall be submitted. The authority shall be informed of any changes to the decision-making scope and any removal of radiation protection experts. See below for details on providing cover occasioned by the absence of radiation protection supervisors with the requisite expertise in radiation protection and radiation protection experts.

Radiation protection supervisors may delegate their supervisory duties to an authorised representative; the latter does not need to be a radiation protection expert and is merely required to function in duty of a radiation protection supervisor without limiting the responsibility of the former.

The appointment of radiation protection experts or the naming of authorised representatives by radiation protection supervisors does not release the latter from the fulfilment of their tasks and responsibilities.

It is recommended that radiation protection supervisors (without the requisite expertise in radiation protection) and their authorised representatives, if any, attend training on the legal aspects of radiation protection; this should provide them with sufficient knowledge to perform their duties, and put them in a better position to assess the issues associated with implementing radiation protection measures.

For the sake of clarity, an organizational chart displaying company radiation protection hierarchies shall be produced (§ 34 StrlSchV).

Any radiation protection supervisor or radiation protection expert who is personally involved in the application of radioactive substances or ionizing radiation on patients, or who directs or supervises such activities, including any technical assistance, must hold a physician's licence. He assumes medical responsibility for the application of radioactive substances or ionizing radiation to patients.

Cover for radiation protection experts, guaranteeing the fulfilment of their tasks and responsibilities shall be ensured by appointing a sufficient number of radiation protection experts.

Radiation protection supervisors with the requisite expertise in radiation protection, who are themselves required to fulfil a licensed function, must - if said function is to continue during their absence - appoint a medical radiation protection expert in possession of the requisite expertise in radiation protection. If no substitute radiation

protection expert can be provided, the application of radioactive substances or ionizing radiation in a medical context must cease.

For details on the availability of radiation protection experts see Chapter 4.3.

2.1.2 Staffing levels

If there is no reason to suspect that insufficient staffing might jeopardize the safety of handling and operations respectively, the competent authority may issue a licence pursuant to § 9 para. (1) number 6 and § 14 para. (1) number 6 of the StrlSchV.

In general it is the responsibility of the applicant himself to determine staffing levels. Tables 1 and 2 shown below provide sample figures to give assistance in the calculation of staffing levels necessary for safe handling and operations. Among other things, the number of staff required is calculated according to patient numbers, the technique being used, and the technical equipment and devices in question, while taking into account the 40-hour standard working week for single-shift operations (see Appendix A 23 for examples). Staffing levels in the case of proton, ion, and neutron radiation installations used in radiotherapy (particle therapy) are calculated according to the type and scope of application (Appendix B number 5.38;). Additional staffing level recommendations, e.g. issued by professional associations, may be referred to if there is an increase in the number of patients, or in the case of special procedures.

If, during the licensing process, the authority becomes concerned that the necessary staffing is not available, it must assess whether the licence may still be granted and whether operations that are radiation protection-safe can still be achieved by applying additional constraints or conditions, respectively. Tables 1 and 2 shall provide the necessary orientation in such instances.

The radiation protection supervisor may also use tables 1 and 2 as a guide when fulfilling the existing and on-going requirement of § 33 first half of para. (1) of the Radiation Protection Ordinance, according to which the radiation protection supervisor must ensure, by means of suitable measures, including the "provision of adequate and suitable staff", that the protection regulations in Part 2 of the Radiation Protection Ordinance are observed.

In certain cases, provided that a sufficient number of radiation protection experts exists (§ 9 para. (1) number 3 of the StrlSchV and § 14 para. (1) number 3 of the StrlSchV), persons in the process of acquiring their practical experience may be considered with a factor of 0.5.

There may also be other reasons pertaining to individual cases which allow a deviation from the prescribed numbers.

A requirement may also be included in the licence that foresees the annual communication of staff numbers, type, and qualifications of those involved in handling and operations respectively by the licence holder to the competent authority.

If it becomes apparent, whether through a related report, or monitoring carried out by the medical authority or other official bodies that handling or operative safety can no longer be guaranteed, or that safeguards are being flouted, the competent authority may take appropriate action. It may, for instance, order that sufficient and suitable staff are deployed, pursuant to § 113 para. (1) first sentence of the StrlSchV, to ensure adherence to Radiation Protection Ordinance safeguards.

In the event that more than one facility is involved in either the operation of devices or the handling of radioactive substances, every single location shall be taken into account when calculating the necessary levels of adequately trained, suitable staff.

The information on necessary staffing levels featured in tables 1 and 2 is not comparable with the number of posts (staffing ratio) of the institutes/practices, since additional external staff and staff made available by other departments, for instance, may also be deployed. In the case of unforeseen staffing shortages, external staff with the requisite expertise in radiation protection or know-how in radiation protection, and experience in the relevant procedures and medical technology, may be brought in (see Chapter 5.2.2 and Chapter 5.3).

Tables 1 and 2 do not take into account potential staffing requirements arising from the additional duties of the physicians, medical physics experts, and technical assistants involved. As far as physicians are concerned, the tables specifically omit to take those positions into account which are required solely for the medical care of in- and outpatients and radiotherapy aftercare. Furthermore, additional staffing requirements may arise among all occupations as a result of the implementation of methods and procedures not mentioned here (e.g. intravascular irradiation, SIRT, etc.).

All physicians and medical physics experts must possess the knowledge in radiation protection requisite for the relevant area of application. Not all persons with the requisite expertise in radiation protection need be appointed radiation protection experts, as long as at least one radiation protection expert per field of activity is available during operating hours.

Table 1: Sample figures for calculating staffing levels with the requisite expertise or know-how in radiation protection in the various fields of activity

* = dependent on organisational factors
** = the organisation of substitute cover shall be given
*** = if more than 10% of radiotherapy courses use these techniques
**** = "diagnostic devices" refer to gamma cameras, incl. SPECT, and PET units

Staff / **Fields of activity**	Physicians with requisite expertise in radiation protection	Medical physics experts (MPE)	Technical assistance staff
Teletherapy ionizing radiation installations & gamma irradiation units - for additional applications e.g. of the following methods*: - brachytherapy - IMRT*** - IORT*** - stereotactic surgery***	n units: n plus 1 2 or more methods: plus 1*	n units: n plus 1 2 or more methods: plus 1*	2 MTRAs** per unit 3 or more methods: plus 1 MTRA*
Brachytherapy on its own (afterloading, seeds, eye therapy)	at least 1 **	at least 1 **	
Nuclear medicine (with therapy station)	at least 2	at least 2	depends on the number of diagnostic units**** n gamma cameras, SPECT, SPECT/CT: n plus 1, n PET, PET/CT: n plus 2
Nuclear medicine diagnostics (with or without standard therapy)	at least 1 **	at least 1 available MPE	depends on the number of diagnostic units**** n gamma cameras, SPECT, SPECT/CT: n plus 1, n PET, PET/CT: n plus 2

Table 2: Sample figures for calculating additional staffing requirements made necessary by an increase in patient numbers (Appendix B nos. 7.13, 7.14, 7.15, 8.1, 8.2)

* = at least 2 MTRAs per unit and per shift shall be calculated for two-shift operations
** = total of gamma camera systems, PET, PET/CT, SPECT, SPECT/CT
*** = overall annual total of radiotherapy courses divided by the number of units

Staff / **Fields of activity**	Physicians with requisite expertise in radiation protection	Medical physics experts (MPE)	Technical assistance staff
Teletherapy ionizing radiation installations and gamma irradiation units	average of more than 350 radiotherapy courses per year spread across all units ***: total plus 1	average of more than 350 radiotherapy courses per year spread across all units ***: total plus 1	
	plus 1 for every 2 units	plus 1 for every 2 units	plus 2 MTRAs* per unit
Nuclear medicine (with therapy station)	more than 3 diagnostic units**: plus 1 for every 2 additional units more than 10 treatment beds: plus 1	more than 4 diagnostic units**: plus 1 more than 10 treatment beds: plus 1	more than 4 gamma cameras, SPECT, SPECT/CT: plus 1 for every two additional units more than 2 PET, PET/CT: plus 2 for every two additional units
Nuclear medicine diagnostics (with or without standard therapy)	more than 3 diagnostic units**: plus 1 for every 2 additional gamma cameras	more than 4 gamma cameras and two or more PET, PET/CT: plus 1 available MPE	more than 4 gamma cameras, SPECT, SPECT/CT: plus 1 for every two additional units more than 2 PET, PET/CT: plus 2 for every 2 additional units

2.1.3 Availability of medical physics experts (MPE)

When treating patients with radioactive substances or ionizing radiation, the requisite number of medical physics experts with the requisite know-how in radiation protection shall be appointed as radiation protection experts (§ 9 para. (3) number 1 and § 14 para. (2) number 2 StrlSchV) to the areas of patient dosimetry, development and application of complicated procedures, and equipment, optimization, and quality assurance, including quality control, and any other issues associated with radiation protection. The number of medical physics experts shall be commensurate with the organisation of the facility, the procedures applied there, and the responsibilities allocated.

In the case of nuclear medicine examinations or standard treatment involving radioactive substances, which neither require nor permit individual dose calculations, the availability of a medical physics expert with the requisite expertise in radiation protection must be guaranteed (§ 9 para. (3) number 2 StrlSchV). This may be specified by written agreement, in which on-site working times are regulated (e.g. 50 hours per year in the case of a medium-sized facility, of these approx. 50% on site). If requested, the medical physics expert must make himself available promptly - generally within 24 hours - at the venue of application. If appointed to act as a radiation protection expert, the medical physics expert shall be on site as per the terms of the licence.

2.1.4 Other persons involved

Pursuant to § 9 para. (1) number 4 of the StrlSchV and § 14 para. (1) number 4 of the StrlSchV, it must be ensured that all other persons involved in handling and operations respectively possess the requisite know-how concerning the possible hazards of radiation and the protective measures requiring application. “Other persons involved” may, for instance, include physicians without the requisite expertise in radiation protection, nurses, and orderlies.

2.2. Requisite expertise in radiation protection for physicians and medical physics experts

For licences associated with human application, it is a condition of the licence that either the applicant or the radiation protection expert appointed by him is a qualified physician, or is temporarily permitted to practice medicine or dentistry, and is in possession of the requisite expertise in radiation protection (§ 9 para. (3) in conj. with para. (1) number 1 StrlSchV and § 14 para. (2) number 1 in conj. with para. (1) number 1 StrlSchV). The requisite expertise in radiation protection (see Chapter 3) is intended to ensure that, in the human application of radioactive substances or ionizing radiation, sufficient consideration is given to the fundamental principles of radiation protection (justification, optimization, radiation exposure limitation). Both physicians and medical physics experts are required to submit certification pursuant to Appendix A 6 proving they possess the requisite expertise in radiation protection.

2.3 Technical requirements

Pursuant to § 9 para. (1) number 5 of the StrlSchV and § 14 para. (1) number 5 of the StrlSchV, it must be ensured for the purpose of safeguard compliance that the necessary

equipment and measures are applied, commensurate with the latest advances in science and technology, during handling and operations respectively. To this end the following aspects, among others, must be considered:

2.3.1 Discharge of radioactive substances via exhaust air or waste water

Pursuant to § 6 para. (2) of the StrlSchV (principle of dose reduction), commensurate with the latest advances in science and technology, and as far as individual circumstances allow, every exposure of humans or the environment to radiation or radioactive contamination shall be kept to a minimum. Taking into account the principle of dose reduction, this means that as far as the discharge of radioactive exhaust air and radioactive waste water is concerned, the level of activity released shall be kept to a minimum.

The protection concept pursuant to § 46 of the StrlSchV specifies general public radiation exposure limits, direct radiation limits, and limits concerning the discharge of radioactive material via air and water.

§ 47 of the StrlSchV regulates the discharge of radioactive materials via air and water. Paragraph 1 of the section specifies the radiation exposure limits for individual members of the public resulting from the discharge of radioactive materials from units or facilities via air or water.

The monitoring of discharge is subject to § 48 of the StrlSchV.

2.3.1.1 Discharge of radioactive substances via exhaust air

The use of unsealed radioactive substances in examinations and treatment can result in the release of radioactive substances into the surrounding air. This also applies to the operation of ionizing radiation installations, electron accelerators (charges > 10 MeV), and in particular, moreover, to the operation of both proton and heavy ion accelerators, as well as neutron irradiation units, owing to the associated degree of air activation.

It may also be necessary to use appropriate retention apertures for the air extracted from wards and examination rooms, as well as from waste water treatment installations and waste storage rooms (Appendix B number 5.5).

2.3.1.2 Discharge of radioactive substances via waste water

Waste water with a higher amount of activity, which occurs particularly in nuclear medicine treatment stations, shall be conveyed separately to a dedicated decay plant. There must be no intentional and separate dilution of the waste water in question to achieve a reduction in the level of activity. To comply with the values stipulated in § 47 para. (4) of the StrlSchV, waste water with a higher amount of activity originating, for instance, from treatment stations, may only be discharged following decay in a containment chamber. The competent authority may specify suitable points for the discharge of this waste water (e.g. final discharge points into the public sewage system) at which no more than the annual average for maximum permitted concentrations of activity may be released. This allows the entire waste water of the relevant institution to

be monitored at the point of final discharge. Details are regulated in the licence pursuant to § 7 of the StrlSchV.

Equally, when dealing with the discharge of waste water which, following examinations using short-lived unsealed radioactive substances - especially Tc-99m and F-18 - and as a result of patient excretions, flows directly into the public sewage system, the competent authority may specify suitable points for the discharge of this waste water (e.g. final discharge points into the public sewage system) at which no more than the annual average for maximum permitted concentrations of activity may be released. The authority is able to monitor adherence to said limits, pursuant to § 47 para. (1) of the StrlSchV (§ 47 para. (4) sentence 3), by using the activities applied and recorded, pursuant to § 70 para. (3) of the StrlSchV, as a basis for discharges occurring in the relevant area.

2.3.2 Aspects requiring particular consideration

When planning and installing ionizing radiation installations or units for handling radioactive substances within the scope of this directive, the maximum annual body dose for occupationally exposed staff in charge of the control units may not exceed 1 mSv.

The condition of rooms allocated for activities requiring licensing and the equipment therein depends on the application in question. The following areas are classified as controlled areas pursuant to § 36 para. (1) number 2 of the StrlSchV:

- irradiation rooms (§ 84 StrlSchV)
- rooms generally used for the preparation or storage of radioactive substances
- rooms generally used for the application of radioactive substances
- wards generally used to accommodate patients treated with unsealed or sealed radioactive substances, as well as the adjoining sanitary facilities and hallways
- waiting rooms, if relevant, for patients to whom radioactive substances have already been applied

Taking the length of patient stay into account, wards accommodating patients to whom radioactive substances have been applied, are only classified as controlled areas with regard to said radioactive substances, and not as a result of any influence from adjacent controlled or exclusion areas. Wall thicknesses within the controlled area shall be designed to ensure that any rooms outside the controlled area belonging to the same department are classified as supervised areas (§ 37 StrlSchV) at the most. The effective annual dose of 1 mSv may not be exceeded for persons free to circulate in rooms outside the department and outside the medical practice in question.

It must be guaranteed, especially when switching on ionizing radiation installations or irradiation units, that no unauthorised persons are present in the irradiation room. The use of suitable technical personnel protection systems, for instance, can ensure this.

Irradiation rooms shall be suitably protected against unauthorised access during irradiation sessions. Even if there is a malfunction, it must be possible to open

irradiation rooms at all times. This shall be guaranteed by appropriate measures and considered during the planning of installations, e.g. sliding doors must be mounted in such a way as to ensure permanent access to the mechanical and electrical control and guidance systems.

As long as no other provisions have been entered in the licence, leakage tests shall be conducted on all sealed radioactive substances pursuant to the leakage test directive (Appendix B number 4.3).

Compliance with the DIN 25422 terms of fire and theft protection is mandatory.

Pursuant to § 36 para. (3) of the StrlSchV, the competent authority may, upon request, approve that the rooms in which

- gamma irradiation units and irradiation facilities used in brachytherapy are operated, are not categorised as exclusion areas outside beam times, and
- ionizing radiation installations are operated, pursuant to § 11 para. (2) in the StrlSchV, are only classified as exclusion or controlled areas only when the equipment is switched on.

The relevant technical standards (Appendix B number 6) detail the radiation protection requirements, to which the facilities are subject, radiation protection rules relating to unit installation, rules for monitoring radiation protection, and the radio-labelling methods to be used.

Pursuant to § 36 para. (3) of the StrlSchV, the competent authority may exclude

- rooms in which radiation sources are used,
- rooms in which radiation protection safes are located,
- wards for the accommodation of patients to whom radiation sources have been applied,

from the regulations governing controlled areas, if the radiation sources are not located in the rooms in question, or if radiation sources are stored in shielded radiation protection safes, or if no patients to whom radiation sources have been applied are located in these rooms. Thanks to these measures staff not occupationally exposed to radiation, other persons, or visitors may also be granted access to these rooms without special monitoring.

Rooms which are intended for the use of unsealed radioactive substances and wards for the accommodation of patients who have been treated with unsealed radioactive substances may only be allocated for re-use or subsequent use once they have been tested for contamination and decontaminated if necessary.

2.3.3 Radiation protection measuring devices

Pursuant to § 67 of the StrlSchV, a sufficient number of the required measuring devices suited to the application in question shall be available (Appendix A 12) for taking radiation protection monitoring readings. The radiation protection supervisor or the radiation protection expert is responsible for the procurement, operational readiness, and regular monitoring of device display accuracy in line with manufacturer specifications. The devices must conform to the latest technological standards; suitable test emitters must be available for conducting function tests. In the case of certain measuring activities, area dosimeters and photon radiation personal dosimeters are subject to the German Federal Weights and Measures Regulations (cf. § 2 Weights and Measures). A summary of the requirements governing the contamination monitoring of persons leaving a controlled area has been produced, for instance, in the form of a recommendation issued by the Radiation Protection Commission (SSK) (Appendix B number 5.16). The appropriate measuring devices shall be specified in the radiation protection instructions (Appendix A 21). Personal dosimeters shall be requested from the designated measuring office (§ 41 para. (3) StrlSchV).

2.3.4 Outage concepts for the operation of ionizing radiation installations and irradiation facilities

Concepts designed to cope with the technical malfunction of irradiation facilities or ionizing radiation installations must include the appropriate ongoing treatment of patients within the scope of radiobiological necessity; agreements with neighbouring facilities are one effective option.

2.3.5 Requisite licensing documents

The licence application pursuant to

- § 7 StrlSchV must feature the information and certificates detailed in Appendix II Part A of the Radiation Protection Ordinance to enable effective verification of the licensing prerequisites pursuant to § 9 StrlSchV;
- § 11 para. (2) of the StrlSchV must feature the information and certificates detailed in Appendix II Part B of the Radiation Protection Ordinance to enable effective verification of the licensing prerequisites pursuant to § 14 StrlSchV.

Use of the *Application Documentation Annotations* (Appendix B number 4.5) is specifically recommended when submitting ionizing radiation installation applications (§ 11 StrlSchV), in order to ensure the standardised inspection and evaluation of all applications.

2.3.6 Registering with the medical authority

The radiation protection supervisor must register any position requiring special licensing with the medical authority designated by the competent authority (§ 83 para. (4) StrlSchV). A copy of the registration shall be sent to the competent authority. Appendix A 22 features the relevant form for medical authority registrations. For more

information on medical authority inspection content and procedures, see Appendix B, nos. 4.6 and 4.7.

2.4 Significant changes in activity

Significant changes to or new inclusions of procedures involving radioactive substances or ionizing radiation that either go beyond the scope of the licence issued in accordance with the Radiation Protection Ordinance or the application documents on which it is based, require special prior licensing (e.g. IMRT, stereotaxy, gating, SLN, PET etc.). This may also apply to changes in equipment or control systems (e.g. microprocessors or software) responsible for monitoring security-related functions (Appendix A 13).

3 REQUISITE EXPERTISE AND REQUISITE KNOW-HOW IN RADIATION PROTECTION

3.1 Requisite expertise in radiation protection

3.1.1 General

The knowledge in radiation protection required for the various positions comprises theoretical knowledge acquired during vocational training, hands-on experience (practical experience), and successful participation in radiation protection courses (§ 30 para. (1) StrlSchV). The competent authority shall verify and certify the acquisition of the requisite expertise in radiation protection (§ 30 para. (1) sentence 3 StrlSchV). The vocational training scheme shall be documented by reports, hands-on experience by supporting documents, and successful course participation by certificates (§ 30 para. (1) sentence 2 StrlSchV). When applying for a knowledge licence, the applicant must have attended a course in radiation protection during the last five years (§ 30 para. (1) sentence 4 StrlSchV).

The following groups of persons require the requisite expertise in radiation protection to fulfil their designated functions:

a) the radiation protection supervisor, in the absence of an appointed radiation protection expert (licensing requirement pursuant to § 9 para. (1) number 1 and § 14 para. (1) number 1 StrlSchV);
b) radiation protection experts (§ 9 para. (1) number 2 and § 14 para. (1) number 2 StrlSchV);
c) physicians who are themselves licensed to use radioactive substances or ionizing radiation on patients (§ 82 para. (1) number 1 StrlSchV);
d) physicians who diagnose the justifying indication (§ 80 para. (1) sentence 1 StrlSchV);
e) physicians responsible in a supervisory capacity for the application of radioactive substances or ionizing radiation pursuant to § 82 para. (1) number 2 and the technical execution pursuant to § 82 para. (2) nos. 3 and 4 of the StrlSchV;

f) physicians who direct the application of radioactive substances or ionizing radiation on patients within the scope of medical research (§ 24 para. (1) number 3 StrlSchV);

g) medical physics experts (§ 3 para. (2) number 21 StrlSchV);

h) persons not subject to permanent supervision who provide technical assistance during examinations and treatment involving radioactive substances or ionizing radiation (§ 82 para. (2) nos. 1 and 2 StrlSchV).

The acquisition of this knowledge may be divided into the following areas:

3.1.1.1 Appropriate training

One prerequisite for acquiring the requisite expertise as stipulated in § 30 para. (1) StrlSchV is vocational training commensurate with the respective medical and/or medical physical functions.

3.1.1.2 Hands-on experience (practical experience)

Prior to acquiring any practical experience in radiation protection, persons must have been given the necessary -, induction in the workplace, and received clear instructions on working in radiation protection areas (see Appendix A 8).

Practical experience may only be gained under the permanent supervision of someone with the requisite expertise in radiation protection. Practical experience shall be acquired in a facility with the requisite technology and staff, which is thus able to demonstrate the practical application of radiation under radiation protection conditions. This can be confirmed by the competent authority prior to a candidate starting the acquisition of practical experience. Any certification of practical experience shall take account of the aspects listed in Appendices A 4 and A 5 respectively.

Practical experience comprises theoretical knowledge and hands-on experience in the use or application of radioactive substances or ionizing radiation in the respective field of application. Physicians and medical physics experts acquire practical experience with a specific focus on radiation protection under the guidance of persons with an appropriate work profile and specialist experience that possess the requisite expertise in radiation protection within the relevant field. The acquisition of practical experience is subject to prior instruction relating to the relevant functions. Details of the content and duration of practical experience, as well as the required number of practical application repetitions, can be found in Appendices A 1 and A 2 of this directive.

The process of acquiring practical experience is generally continuous; in the case of full-time positions, it should take no longer than double the designated practical experience timeframe.

3.1.1.3 Radiation protection courses

Radiation protection courses supply specialist theoretical and legal knowledge. More information on the types of prescribed courses and the mechanisms used for monitoring their success can be found in Appendices A 1 number 2 and A 2 number 1.3,

with details of course syllabuses appearing in Appendix A 3 of this directive. The numbers of hours given in the appendices stand for 45-minute tuition periods; in the case of events lasting several days, no more than 10 periods may be taught on any one day (see also Appendix A 3 number 7).

Approval of courses and further training measures

Upon written application by the course organisers, the competent authority shall approve courses intended to supply and update the requisite expertise in radiation protection pursuant to the provisions laid down in § 30 para. (3) of the StrlSchV. Once the courses have been approved (see Appendix A 3 number 6 for the relevant criteria) by the competent authority, the training centre may issue an attendance certificate pursuant to Appendix A 7.1.

The competent authority may approve distance learning courses in the requisite radiation protection knowledge, if the approval conditions specified for attendance-based courses in Appendix A 3 number 6 are fulfilled where relevant, and if, in addition to monitoring success, practical repetitions are scheduled to take place during attendance phases. Distance learning courses must also comply with the provisions of the Distance Learning Protection Act (FernUSG).

3.1.2 Acquiring the requisite expertise in radiation protection (physicians)

Proof of the requisite expertise in radiation protection shall be confirmed by certificate pursuant to Appendix A 6. The competent authority shall verify and certify the acquisition of the requisite expertise in radiation protection, as set out in Appendix A 1. This is generally in the form of a viva voce examination organised by the competent authority. The viva is conducted by at least two physicians, each with many years experience in the relevant field of application as well as the requisite expertise in radiation protection; if necessary, and at the specific request of the competent authority, a medical physics expert may also sit on the panel. The viva voce examination may not be repeated within a three month period. This viva is staged separately from examinations subject to the relevant medical CPE requirements (medical specialist examinations) and deals with all aspects associated with radiation protection (in particular justifying indications, medical aspects requiring special consideration during application, staff and environmental protection, etc.).

The competent authority may impose additional requirements if a candidate is seeking to expand his existing requisite expertise in radiation protection to include another field of application. In such cases a viva voce examination may also be held if necessary.

3.1.3 Acquiring the requisite expertise in radiation protection (medical physics experts)

Pursuant to § 3 number 21 of the StrlSchV, a medical physics expert is a specially trained physicist with a degree in medical physics and the requisite expertise in radiation protection, or any other trained person with a college or university degree of equivalent content, and with the requisite expertise in radiation protection.

The prerequisite for qualifying as a medical physics expert is a degree (diploma, master's or bachelor's qualification from a college or university) in the field of science and technology. A medical physics qualification may be acquired within the context of university studies or by any other appropriate means. At the latest, the level of qualification specified in Appendix A 2 number 3 must have been achieved by the time a person receives certification of the requisite expertise in radiation protection.

Proof of the requisite expertise in radiation protection shall be confirmed by certificate pursuant to Appendix A 6. Acquisition of the requisite expertise in radiation protection, as set out in Appendix A 2 no 1, is verified and certified by the competent authority.

Proof of education, including a certificate confirming the study of radiation protection theory and medical physics, of additional merits required for qualification as a medical physics expert, and of the requisite practical experience and attendance at courses in radiation protection, shall be submitted to the competent authority (Appendices A 2, A 3).

The competent authority shall organise a viva voce examination if necessary. If the level of qualification specified can be confirmed by a master's degree or diploma in medical physics, a viva voce examination generally deemed unnecessary. The viva is conducted by at least two medical physics experts, each with many years experience in the relevant field of application as well as the requisite expertise in radiation protection; if necessary, and at the specific request of the competent authority, a physician may also sit on the panel. The viva voce examination may not be repeated within a three month period. Candidates are examined on all aspects relating to radiation protection. The competent authority may impose additional requirements if a candidate is seeking to expand his existing requisite expertise in radiation protection to include another field of application. In such cases a viva voce examination may also be held if necessary.

3.1.4 Acquiring the requisite expertise in radiation protection (medical technical assistants)

Persons who, pursuant to § 1 number 2 of the MTA Act, are authorised to pursue the occupation of MTRA and have acquired during their studies the requisite expertise in radiation protection to be able to provide technical assistance during the application of radioactive substances and ionizing radiation to patients (cf. Training and Examination Regulations for Medical Technical Assistants MTA-AprV dated 24th April 1994 (Federal Law Gazette/BGBl. I p. 922), last amendment: Art. 24 G dated 2.12.2007 (Federal Law Gazette/BGBl. I p. 2686)).

3.1.5 Acquisition of the requisite expertise in radiation protection for persons who have successfully completed state-regulated, state-approved, or state-supervised training, in which technical assistance formed part of the coursework and final examination

Persons authorised to provide technical assistance pursuant to § 82 para. (2) number 2 of the StrlSchV must possess the requisite expertise in radiation protection. This applies to persons, for instance, who have completed their training abroad, and whose qualifications have been approved by the competent authority in Germany as being

equivalent to an MTRA qualification. Pursuant to § 30 para. (1) of the StrlSchV, knowledge in radiation protection shall be confirmed by a certificate issued by the authority competent under national law.

3.1.6 Updating the requisite expertise in radiation protection

Pursuant to § 30 para. (2) of the StrlSchV, the requisite expertise in radiation protection shall be updated at least every five years by successful participation in a course approved by the competent authority, or by any other updating measures deemed suitable by the competent authority (see Appendices A 3 number 1.5, number 2.3 and number 3).

Pursuant to § 30 para. (2) sentence 4 of the StrlSchV the competent authority may, upon failure to submit documentation of further education measures, or if said documentation should prove incomplete, suspend the knowledge licence or impose conditions upon its continuance. In the case of well-founded doubts as to the existence of the requisite expertise in radiation protection, the competent authority may, pursuant to § 30 para. (2) sentence 5 of the StrlSchV, request an examination of said knowledge; consequentially the knowledge licence may be suspended or subject to conditions upon its continuance.

3.1.7 Other further education measures

The competent authority may recognise seminars, workshops and conferences as further education measures aimed at updating the requisite expertise in radiation protection, if the programme of events clearly states which subjects essential to an update are covered and if the conditions set out in Chapter 3.1.1.3. are fulfilled.

3.1.8 Approval of courses and practical experience acquired outside Germany

The competent authority may recognise courses completed outside Germany, if the subject matter as specified in Appendix A 3 of this directive pertaining to the field of application is covered, and additional proof is provided that the candidate has sufficient knowledge of German radiation protection legislation. The latter may be achieved by successfully completing the *Legislation* section of a radiation protection course, pursuant to Appendix A 3, or by passing an examination set by the competent authority. The competent authority may recognise periods of practical experience certified outside Germany, as long as the certificate contents comply with the provisions laid out in Appendix A 5.

3.1.9 Validity: requisite expertise in radiation protection

Regardless of the federal state of issue, a certificate confirming the requisite expertise in radiation protection is valid throughout the Federal Republic of Germany.

3.1.10 Transitional regulations

Those who began acquiring practical experience in a specific field of application prior to an amendment in the knowledge acquisition guidelines may conclude said acquisition under the regulations valid at the time of commencement.

3.2 Requisite know-how in radiation protection

3.2.1 General

Persons who

a) as physicians use radioactive substances or ionizing radiation on patients (§ 82 para. (1) number 2 StrlSchV),
b) technically assist in the use of radioactive substances or ionizing radiation on patients in the medical field as part of their vocational training (§ 82 para. (2) number 3 StrlSchV) or
c) technically assist in the application of radioactive substances or ionizing radiation having successfully completed other medical education (§ 82 para. (2) number 4 StrlSchV),

and yet do not possess the requisite expertise in radiation protection, must nevertheless demonstrate the requisite know-how in radiation protection for the respective occupation or training mentioned. The persons named in sentence 1 may only be involved in the use of radioactive substances or ionizing radiation on patients under the permanent supervision and responsibility of a physician with the requisite expertise in radiation protection.

Pursuant to § 30 para. (4) sentence 1 of the StrlSchV, the requisite know-how in radiation protection is generally acquired through instruction and practical experience in the respective field of application. § 30 para. (4) sentence 2 of the StrlSchV prescribes that persons classified in groups a) and c) above shall be subject to § 30 para. (1) sentences 2 to 4, and para. (2). These groups of persons are to acquire their know-how in radiation protection under conditions comparable to those set for the acquisition of requisite expertise, i.e. they too are required submit proof of said know-how to the competent authority.

The competent authority verifies and certifies the acquisition of the requisite know-how in radiation protection pursuant to § 30 para. (4) sentence 2 in conjunction with § 30 para. (1) sentence 3.

3.2.2 Acquiring the requisite radiation protection know-how (physicians)

As specified above, physicians without the requisite expertise in radiation protection may only apply radioactive substances or ionizing radiation to patients if under the permanent supervision and responsibility of a physician with the requisite expertise in radiation protection, and if they themselves possess the requisite radiation protection know-how needed for handling and operations within their own particular field. The requirements are listed in Appendix A 3 number 4.1. Where appropriate, the duration of such activity within the context of acquiring the requisite expertise in radiation protection may be approved as the acquisition of radiation protection know-how (Chapter 3.1.1.2). A physician who is merely certified in radiation protection know-how

may not diagnose a justifying indication. This remains the prerogative of physicians with the requisite expertise in radiation protection.

3.2.3 Acquiring the requisite radiation protection know-how (persons in training) § 82 para. (2) number 3 StrlSchV

Persons attending a course which includes tuition in the requisite expertise or requisite know-how for providing technical assistance in the application of radioactive substances or ionizing radiation to medical patients, shall acquire the requisite know-how in radiation protection by means of suitable instruction and practical experience in the respective field of application (§ 30 para. (4) StrlSchV).

3.2.4 Acquiring the requisite radiation protection know-how (persons who have successfully completed other medical education)

Persons who have successfully completed other medical education, e.g. as medical assistants or nurses, must submit proof of their acquisition of the requisite know-how in radiation protection to the competent authority. The requirements are listed in Appendix A 3 number 5.

3.2.5 Approval of courses and further education measures

Upon written application by the course organisers, the competent authority shall approve courses intended to supply and update radiation protection know-how pursuant to the provisions laid down in § 30 para. (3) of the StrlSchV. Once the courses have been approved (see Appendix A 3 number 7 for the relevant criteria) by the competent authority, the training centre may issue an attendance certificate in compliance with Appendix A 7.1.

The competent authority may approve distance learning courses in radiation protection know-how, if the approval conditions specified for attendance-based courses in Appendix A 3 number 6, where relevant, are fulfilled, and if, in addition to monitoring for success, practical repetitions are scheduled to take place during attendance phases. Distance learning courses must also comply with the provisions of the Distance Learning Protection Act (FernUSG).

3.2.6 Requisite radiation protection know-how updates

Pursuant to § 30 para. (4) sentence 2 in conjunction with § 30 para. (2) sentence 1 of the StrlSchV, persons belonging to groups a) and c), as specified in Chapter 3.2.1, are obliged to update their requisite know-how in radiation protection every five years by successfully attending a course approved by the competent authority, or to submit proof of updating by any other appropriate means (see Appendices A 3 number 1.5, number 2.3, number 3 and number 6).

Pursuant to § 30 para. (4) in conjunction with § 30 para. (2) sentence 4 of the StrlSchV, the competent authority may, upon failure to submit documentation of further education measures, or if said documentation should prove incomplete, suspend the know-how licence or impose conditions upon its continuance.

3.2.7 Other further training measures

The competent authority may recognise seminars, workshops and conferences as further training measures aimed at updating the requisite know-how in radiation protection, if the programme of events clearly states which subjects essential to an update are covered, and if the conditions set out in Chapter 3.1.1.3. are fulfilled.

3.2.8 Approval of courses completed outside Germany

The competent authority may recognise courses completed outside Germany, if the subject matter appropriate to the field of application is covered as specified in Appendix A 3 of this directive.

3.2.9 Validity: requisite know-how in radiation protection

Regardless of the federal state of issue, a certificate confirming the requisite know-how in radiation protection is valid throughout the Federal Republic of Germany.

3.2.10 Transitional regulations

Those who began acquiring the requisite know-how in radiation protection prior to an amendment in the know-how acquisition guidelines may conclude said acquisition under the regulations valid at the time of commencement.

4 ORGANISATIONAL RADIATION PROTECTION REQUIREMENTS

4.1 Physical radiation protection monitoring and radiation exposure limits

Physical radiation protection monitoring (§§ 39 and 41 StrlSchV) is conducted pursuant to the directive on 'Physical Radiation Protection Monitoring for Determining Body Doses,Parts 1 and 2' (Appendices B number 4.1 and number 4.2a), as well as to the recommendation 'Concerning the Application of the Incorporation Monitoring Guideline in the Field of Nuclear Medicine' (Appendix B number 4.2b).

Ascertaining whether, pursuant to § 54 of the StrlSchV, a person occupationally exposed to radiation belongs in category A or category B is a decision for the radiation protection supervisor or expert, based on the person's field of operation and potential body dose. Organisational aspects, such as substitute cover in the event of holidays or sick leave must also be taken into account.

4.2 Records

Personal records pursuant to § 42 of the StrlSchV and §§ 60 to 64 of the StrlSchV (e.g. medical certificates, physical radiation protection monitoring results) should be compiled by name, to allow ease of forwarding to the licensed physician pursuant to § 64 of the StrlSchV and the competent authority or any other employer.

The data retention periods set out in § 42 para. (1) of the StrlSchV must be observed.

For the duration of operations and handling respectively, all paperwork concerning the delimitation of radiation protection areas shall be retained together with the radiation protection construction plans; they shall be held either by the radiation protection supervisor or the radiation protection expert responsible.

4.3 Radiation protection instructions

The mandatory radiation protection instructions pursuant to § 34 of the StrlSchV (see also DIN 6843) must feature details of the various different operative stages, the allocation of tasks among those involved, and the protective measures requiring observance - both during daily operations and in a safety-related emergency. The radiation protection instructions should also regulate the respective presence and availability of the radiation protection expert. The radiation protection supervisor - if he himself possesses the requisite expertise in radiation protection - or a radiation protection expert must be able to be present on site within approx. 15 minutes of a call-up (*permanent supervision*), unless the competent authority has prescribed *direct supervision* (i.e.: always physically present; exercising direct control). In terms of definition, the umbrella term *supervision* is understood to mean monitoring that does not always entail a supervisor's actual physical presence and which may be conducted via spot check. The provisions agreed shall be included in the radiation protection instructions (Appendix A 21) pursuant to § 34 of the StrlSchV.

The instructions must specify what protective and measuring devices shall be kept available and the means of monitoring their functions and operative state. Fire safety measures pursuant to § 52 of the StrlSchV also need to be included among those provisions requiring regulation. Moreover, measures also need to be included which, in the event of an uncontrolled radiation leak or incidents at odds with normal operations, enable the safe rescue of the patient; reference to manufacturer or supplier instructions should be made as appropriate.

Notes on drafting radiation protection instructions are included in Appendix A 21.

4.4 Instruction prior to beginning and during an activity

4.4.1 Professional activity

Prior to gaining access to controlled areas to conduct or maintain the operations planned therein or, in the case of trainees or students, to attain the level of training stipulated in § 38 para. (1) sentence 1, in conjunction with § 37 para. (1) sentence 1 number 2 letters a or c of the StrlSchV, every person is subject - before beginning work - to instruction in

- working procedures,
- possible hazards,
- safety and protection measures to be taken,
- the sections of the Radiation Protection Ordinance, the licence and the radiation protection instructions relating to their duties or their presence,

- and the ensuing processing and use of personal data for the purpose of monitoring dose limits and observing radiation protection principles.

Pursuant to § 38 para. (1) sentence 1 in conjunction with § 37 para. (1) sentence 1 number 3 letter a of the StrlSchV, the same applies to access to exclusion areas, if a person is required to carry out scheduled operational processes in the exclusion area, or has to work there for urgent operational reasons, and is under the supervision of a radiation protection expert or deputy, authorised by the former, with the requisite expertise in radiation protection. Instruction pursuant to § 38 para. (1) sentence 2 of the StrlSchV shall also be provided for persons required to handle radioactive substances or use ionizing radiation outside controlled areas, insofar as the activities in question require licensing.

The instruction provided is verbal and if necessary is provided in the workplace. Appendix 8 contains examples of specific instruction topics.
Further instruction, in line with the latest advances in science and technology, is provided at least once a year with the aim of refreshing and updating the content of the initial induction. Any amendments to radiation protection regulations shall be included in this instruction. A record shall be made of the content covered and the date of instruction. Those receiving instruction must sign to confirm their participation in the instruction session.

Pursuant to § 38 para. (4) of the StrlSchV the relevant paperwork shall be stored for at least five years. The competent authority may stipulate an increase in the frequency of instruction.

4.4.2 Other persons in the controlled area

Other persons to whom access to controlled areas is granted shall be instructed in advance as to any possible hazards and their prevention. These are either such persons mentioned in § 37 para. (1) sentence 1 number 2 letters b and d, and number 3 letter b of the StrlSchV, or persons to whom access is granted pursuant to § 37 para. (1) sentence 2 of the StrlSchV. A record shall be made of the content covered and the date of instruction. Those receiving instruction must sign to confirm their participation in the instruction session.

4.4.3 Pregnant and nursing women

During such instruction women shall be advised that, in view of the risks of radiation exposure, it is imperative they disclose the existence of a pregnancy as early as possible (§ 38 para. (3) sentence 1 StrlSchV). In the case of contamination of the mother, it shall be pointed out that the infant could absorb radioactive substances while being nursed (§ 38 para. (3) sentence 2 StrlSchV).

As soon as a woman informs her employer that she is either pregnant or nursing, her working conditions shall be modified to ensure that any internal radiation exposure occurring occupationally can be ruled out (§ 43 para. (2) StrlSchV; see also Appendix B number 5.44). Such women shall neither be allowed to handle unsealed radioactive substances nor, unless a workplace-related incorporation risk estimate demonstrates the

dose in this particular instance to be within the limit specified in § 55 para. (4) sentence 2 of the StrlSchV, remain in rooms in which licensed operations involving unsealed radioactive substances are taking place.

The employment of pregnant and nursing women in irradiation rooms equipped with ionizing radiation installations is

- not permitted in instances where photon energies exceed the nuclear photo-effect activation threshold for air (10 MeV bremsstrahlung), owing to § 43 of the StrlSchV.
- generally permitted in radiation protection terms in instances where photon energies are within the nuclear photo-effect activation threshold and irradiation room ventilation systems are working properly.

Pregnant women should not be assigned to any potentially necessary rescue procedures involving gamma irradiation and afterloading units, e.g. in the case of radiation source recirculation malfunctions. Staffing plans should take this into account.

4.5 Interdisciplinary cooperation

An example of interdisciplinary cooperation in the case of sentinel lymph node (SLN) scintigraphy is given in Chapter 6.9.

4.6 Occupational medical prevention

Occupational medical prevention shall take place pursuant to §§ 60 to 64 of the StrlSchV and the *Occupational Medical Prevention for Occupationally Exposed Persons by Authorised Physicians* directive (Appendix B number 4.8).

5 APPLICATION-RELATED RADIATION PROTECTION REQUIREMENTS

When using radioactive substances or ionizing radiation on patients, it is essential that a clear identification of the patient takes place. The methods used in the process shall be submitted to the competent authority as part of the licensing and supervision procedures.

In addition to the provisions laid out in §§ 23 and 24 and §§ 87 to 92 of the StrlSchV, compliance with the principles set out in this chapter is mandatory, even in cases where radioactive substances or ionizing radiation are being used on patients for purposes of medical research.

5.1. Diagnosis - justifying indication

Within the scope of medical practice and pursuant to § 80 of the StrlSchV, a physician with the requisite expertise in radiation protection must lay down a justifying indication prior to every use of radioactive substances or ionizing radiation on patients.

With the aim of avoiding unnecessary radiation exposure in a medical context, it shall be decided whether the health benefits of such an application outweigh the risks posed to the patient by radiation. In the process, it shall be ascertained whether the same medical purpose might instead be fulfilled by a procedure that does not involve the application of radioactive substances or ionizing radiation, thus constituting a lower overall risk. If in doubt, such an assessment should be made in close consultation with the referring physician, who will not generally possess the requisite expertise in radiation protection.

Prior to every examination and treatment, and according to the physician's legal obligation to provide information, the patient shall be suitably briefed on the specific risks of the planned application of radiation. In the case of treatment, the patient shall sign a form to confirm that such a briefing has taken place.

The patient shall be asked about any previous applications of radiation; any usable results, as well as any information provided by the referring doctor shall be taken in account (§ 80 para. (2) StrlSchV). The analysis of results supplied by previous examinations helps prevent the unnecessary repetition of examinations.

Pursuant to § 80 para. (3) off the StrlSchV, the physician charged with the application, where appropriate in cooperation with the referring physician, must ask women of child-bearing age whether they are or might be pregnant, and whether they are nursing. If, despite the existence or possible existence of a pregnancy, the application of radioactive substances or ionizing radiation remains necessary for medical reasons, every last effort shall be made to reduce the radiation exposure of the pregnant woman and her unborn child to a minimum. If nursing, women are recommended to take a break from breastfeeding.

The referring physician is responsible for formulating the question, which it is hoped will be answered by the examination, and for supplying any relevant clinical information. The *Guidance on Diagnostic Imaging in Medicine* (Appendix B number 5.31) may prove a useful source of reference. The physician charged with the application is responsible for and decides on the type and method of radiation application selected. A justifying indication can only be laid down, if the physician responsible for diagnosing the justifying indication is able to interview and examine the patient at the facility and in person.

Records of the interview and examination and/or treatment shall be kept in accordance with § 85 para. (1) of the StrlSchV. The patient may request a copy of these records. Appendices A 14 to A 19 feature templates which may be used for this purpose.

5.2 Radiation applications and technical assistance

The term application shall be understood as the technical assistance and

a) diagnostics of an examination or

b) the analysis of results arising from treatment

with radioactive substances or ionizing radiation, once a person with the requisite expertise in radiation protection has laid down the justifying indication for the case in question.

Persons applying radioactive substances or ionizing radiation to patients must possess the requisite expertise in radiation protection. With the exception of those persons mentioned in Chapter 5.2.2 letter a), proof of the requisite expertise in radiation protection shall take the form of a certificate issued by the authority competent under national law.

5.2.1 Radiation applications

5.2.1.1 Authorised persons

Taking the justifying indication as a basis, physicians with the requisite expertise in radiation protection (see Chapter 3.1.1) may use radioactive substances or ionizing radiation on patients (§ 82 para. (1) number 1 StrlSchV).

Based on the justifying indication laid down by a physician with the requisite expertise in radiation protection, physicians who do not possess the requisite expertise in radiation protection may use radioactive substances or ionizing radiation on patients, if they possess the requisite know-how in radiation protection pursuant to Appendix A 3 number 4.1, and if they work under the permanent supervision and responsibility of a physician with the requisite expertise in radiation protection (§ 82 para. (1) number 2 StrlSchV).

5.2.1.2 Examinations involving unsealed radioactive substances

When using unsealed radioactive substances in an examination context, the level of radiation exposure shall be kept to a minimum taking into account all the circumstances of the case in question and the requirements of medical science. If the physician is faced with a choice of methods - each of comparable validity - he shall select the one associated with the lowest level of radiation exposure.

This is achieved by

- selecting a suitable radiopharmaceutical on the basis of its chemical form, metabolic behaviour, as well as the type of radiation, radiation energy and effective half-life.
- patient preparation.
- taking the diagnostic reference levels for standard examination methods (Appendices B nos. 4.14 and 4.14a) published by the Federal Office for Radiation Protection into account when selecting the radioactivity to be applied.
- using suitable devices and equipment commensurate with standard levels of up-to-date technology, and the appropriate quality assurance methods (§ 83 paras. 5 and 6 StrlSchV) for the devices to ensure that low levels of radioactivity can be used.

Pursuant to § 82 para. (3) of the StrlSchV, written work instructions for frequently conducted examinations shall be permanently available at every workplace for the perusal of those persons there employed. In particular instances, work instructions may also be produced for complicated procedures. Such work instructions provide specific, workplace-related procedural information and include details about

- any organisational preparation prior to the application, including any diagnostic evaluation paperwork and staff instructions.
- patient preparation.
- technical procedure.
- analysing and recording results, compiling medical reports.

5.2.1.3 Treatment involving unsealed radioactive substances

Prior to beginning treatment with unsealed radioactive substances and in implementation of § 81 para. (3) of the StrlSchV, a physician with the requisite expertise in radiation protection and a medical physics expert are to produce a written therapy plan in close cooperation tailored to the needs of the individual patient (Chapter 7.3.2). The target volume (target tissue or target organ) dose intended by the physician shall be individually determined according to the requirements of medical science. In the process the dose affecting the remaining organs and parts of the body shall be kept as low as possible given the purpose of treatment.

This is achieved by

- selecting a suitable radiopharmaceutical on the basis of its chemical form, metabolic behaviour, as well as the type of radiation, radiation energy and effective half-life.
- taking patient-specific parameters into account when calculating the level of radioactivity to be applied (target volume, degree of radioactive incorporation, biological half-life).
- taking steps to reduce the dose to which the rest of the body is exposed.

For standard treatments which do not require individual therapy planning (i.e. the palliative treatment of bone metastases, RSO), the competent authority must receive proof of the availability of a medical physics expert. This may, for instance, form part of a contractual agreement.

5.2.1.4 Radiation applications for the purpose of attenuation compensation and/or morphology specification

If radioactive substances or ionizing radiation are to be used in the measurement of attenuation compensation or the specification of morphology (i.e. transmission images

or CT in the case of PET/CT), the dose shall be kept as low as possible given the requirements of medical science.

This is achieved by

- limiting the area under examination (e.g. CT scan length).
- suitable positioning aids.
- restricting the radiation exposure of other areas of the body.
- restricting exposure by setting appropriate examination parameters (duration of transmission measurement, special imaging reports).
- using attenuation compensation measurements only if these are expected to improve the quality of information provided by the examination.

5.2.1.5 Radiotherapy (Teletherapy, Brachytherapy)

In cases of radiotherapy, and pursuant to § 81 para. (3) of the StrlSchV, a physician with the requisite expertise in radiation protection and a medical physics expert are to produce a written therapy plan in close cooperation tailored to the needs of the individual patient (Chapter 7.3.2). The dosage and dose distribution planned by the physician must conform with the requirements of medical science while at the same time ensuring that exposure of the remaining body parts and organs is kept to a minimum.

This is achieved by

- using suitable localisation methods (e.g. CT, scintigraphy, PET/CT, sonography, MR tomography, simulators, or similar imaging procedures depending on the details of the case) to determine the planning target volume (PTV).
- selecting radiation sources according to radiation type and energy.
- using high-tech methods of computer-assisted therapy planning to predict dose distribution.
- using phantoms to verify patient plans.
- using suitable application devices, programming and positioning aids.
- restricting radiation exposure, as far as is practical, of remaining areas of the body.
- employing special shielding measures for areas of the body requiring protection.
- taking into account possible movements of the PTV and/or other organs at risk that require protection.
- ensuring correct data exchange between radiotherapy system components.

5.2.2 Technical assistance

Based on the identification of a justifying indication and under the responsibility of a physician with the requisite expertise in radiation protection, the following persons

may technically assist in the fields of nuclear medicine and radiotherapy (teletherapy and brachytherapy):

a) medical technical radiology assistants pursuant to MTA legislation (MTAG: Act on Technical Assistants in Medicine, Appendix B number 2.4; § 82 para. (2) number 1 StrlSchV).

b) persons who have successfully completed state-regulated, state-approved or state-supervised training, in which technical assistance (§ 9 para. (1) number 2 MTAG) formed part of the coursework and final examination (§ 82 para. (2) number 2 StrlSchV), and who possess the requisite expertise in radiation protection.

c) medical physics experts if operating under the permanent supervision and responsibility of a physician with the requisite expertise in radiation protection (§ 82 para. (2) number 5 StrlSchV).

d) persons undergoing vocational training that provides the required qualifications for technical assistance, following a radiation protection instruction session - provided they work under the permanent supervision and responsibility of a physician with the requisite expertise in radiation protection. This regulation only applies to occupational groups for which technical assistance is a stated component of the training and examination syllabus, i.e. within the context of MTA legislation (§ 82 para. (2) number 3 StrlSchV).

e) persons who have successfully completed other medical education, if under the permanent supervision and responsibility of a physician with the requisite expertise in radiation protection, and if they themselves possess the requisite know-how in radiation protection (Appendix A 3 number 5) (§ 82 para. (2) number 4 StrlSchV).

To provide the *technical assistance* associated with operating irradiation facilities and ionizing radiation installations for the treatment of patients, special knowledge of anatomy and positioning techniques, for instance, is required which can only be acquired through a period of mandatory intensive training (§ 82 para. (2) sentence 1 nos. 1 and 2 StrlSchV: MTRA, MTA); such training also supplies the requisite expertise in radiation protection necessary for providing technical assistance. For reasons of patient safety and quality assurance, especially in view of the potential for serious radiation damage, only persons with the requisite expertise in radiation protection are permitted to operate such devices and position the patient appropriately. Those persons pursuant to § 82 para. (2) number 4 with radiation protection know-how (Appendix A 3 number 5) are only permitted to act in a supporting function.

5.3 Other persons involved

Other supporting activities associated with the application of radioactive substances, ionizing radiation and radiation sources, or the operation of equipment used in human radiotherapy may be undertaken by other persons involved with the necessary know-how about radiation hazards and protective measures to be taken (§ 9 para. (1) number 4 or § 14 para. (1) number 4 StrlSchV).

As a result of the new academic bachelor's and master's university degree courses, the competent agencies need to be advised on how bachelor qualifications in medical physics shall be rated with regard to radiation protection functions as regulated by the Radiation Protection Ordinance. Subject to permanent supervision by a medical physics expert, a graduate with a bachelor's degree in science or physics and technology may work in a radiation protection-related medical physics context, e.g. measuring doses, measuring contamination and incorporation levels, quality assurance activities, or providing technical assistance during the therapy planning process, as long as the performance of such tasks is not restricted, pursuant to the MTA Act, to medical technical radiology assistants.

5.4 Supporting persons

Pursuant to § 81 para. (5) of the StrlSchV, the Radiation Protection Ordinance dose limits do not apply to persons capable of consent, or those acting with the consent of their legal representative, who voluntarily engage outside the scope of their work in the support and nursing of patients who are currently undergoing, or have undergone, applications of radiation e.g. within the context of inpatient or home care.

The radiation protection expert is responsible for ascertaining and recording the body dose for said persons (§ 81 para. (5) in conjunction with § 42 para. (1) and § 40 para. (1) sentence 1 StrlSchV). The Physical Radiation Protection Monitoring Directive for Determining Body Doses, Part 1: Calculating External Radiation Body Doses (§§ 40, 41, 42 StrlSchV; § 35 RöV) (Appendix B number 4.1) provides details on the calculation procedure. Irrespective of this, a supporting person should not be exposed to more than a few millisieverts as a result of the treatment or examination of a patient. This reference level of a few millisieverts for a supporting person may only be reached in special instances (e.g. parents with seriously ill offspring).

The access of supporting persons to controlled areas is only permitted, pursuant to § 37 para. (1) number 2 letter b of the StrlSchV, if granted by a physician with the requisite expertise in radiation protection. Pursuant to § 38 para. (2) of the StrlSchV, supporting persons shall be informed of the possible hazards prior to entering radiation protection areas and instructed by means of an information sheet (e.g. contents pursuant to Appendices A 16 and A 17 respectively) on behaviour designed to keep radiation exposure to a minimum.

If residential accommodation for supporting persons as defined by § 3 number 24 of the StrlSchV shall be provided within the radiation protection area, the regulations concerning access to radiation protection areas (§ 37 StrlSchV) and restricting radiation exposure (§ 81 para. (6) StrlSchV) shall apply.

5.5 Record-keeping

Operational records book

In addition to patient-related records (irradiation reports, irradiation lists etc.), an operational records book (service book) shall be kept pursuant to § 34 sentence 2 number 4 of the StrlSchV, in which the main operational procedures associated with radiation protection are entered. In addition to the date, time, and name of the operator

responsible, all observations concerning malfunctions and any steps taken to correct them, as well as quality controls and leakage tests shall be entered. The record book may be combined with records required by the German Medical Devices Act (Appendix B number 2.3).

The operational records book must feature the following details in particular:

- observations concerning operational malfunctions and irregularities associated with the entire technical apparatus,
- records of maintenance, software modifications, repairs, as well as the companies and persons conducting the repairs and any parts replaced.

Theoperational records book must also include an inventory of radiation sources being used for therapeutic purposes, their removal from the safe and their return following application. In addition to the date, time, and name of the operator, entries must show which radiation sources have been used according to their type and level of radioactivity. Observations concerning visible damage, jammed radiation sources and similar malfunctions, as well as any steps taken to correct them, shall be entered.

Radiation source inventory

An inventory list of radiation sources with a half-life in excess of 100 days shall be prepared for the last day of every calendar year and forwarded to the competent authority by the date stipulated in the licence and/or by the end of January of the following year respectively, giving details of activity levels (§ 70 para. (1) number 3 StrlSchV).

Special inventory duties, as defined in § 70 para. (1) sentence 3 of the StrlSchV, apply to high activity radiation sources.

Irradiation records

Pursuant to § 85 para. (1) of the StrlSchV, irradiation records shall be maintained detailing patient irradiation. Treatment with electron accelerators and gamma irradiation units shall be documented pursuant to DIN 6827-1, diagnosis and treatment with unsealed radioactive substances pursuant to DIN 6827-2, and brachytherapy involving sealed radioactive radiation sources pursuant to DIN 6827-3. All radiation exposure calculation data arising from imaging used during the therapy planning process, simulations, and pre-irradiation patient positioning checks are also to be documented. Pursuant to § 85 para. (1) of the StrlSchV, these records shall be kept for 30 years and presented upon request to the competent authority (§ 85 para. (3) sentence 1 StrlSchV).

To enable the prompt detection of errors in or deviations from the therapy plan, the physician with the requisite expertise in radiation protection shall review the irradiation record on the day of application, while the medical physics expert shall sign the record book regularly in confirmation of its contents. Such signatures may be replaced by an electronic record protected by personal password, e.g. also accepted in

the form of a digitally signed error/differences log. Irradiation records shall be kept for 30 years and presented to the competent authority upon request.

For the adequate documentation of the examination or treatment consultations and records, as required by § 85 of the StrlSchV for the purpose of radiation protection, patient files shall include the type and aim of the examination or treatment, the date of application, and any information arising from consultation with the patient concerning previous applications of radioactive substances or ionizing radiation and, if relevant, details of an existing or possible pregnancy. Records shall also comply with the specifications of DIN 6827-1 to -5.

Personal medical data is subject to the general rules governing data protection and specific provisions pertaining to physician-patient confidentiality. Within a clinical setting, state hospital legislation on the processing and use of patient data shall also apply. Electronic storage media may be used for record-keeping, as long as the requirements of the relevant data protection legislation (Federal Data Protection Act, data protection laws of the individual state) are met. It shall be guaranteed that, for the duration of the storage period (treatment: 30 years; diagnostics: 10 years, c.f. § 85 para. (3) StrlSchV), the data remains readable at all times and in unchanged form. Digital records shall be made available in suitable form to physicians involved in the current and/or further treatment of the patient, as well as to the medical authority (Appendix B number 4.6). Such records must feature the same visual and written material as the original data sets and provide a suitable diagnostic basis. The clear designation of data by means of personal login and password, as well as the inclusion of an audit trail (maintains an independent record of every data modification in a separate file), is sufficient to ensure integrity after saving. Electronic radiotherapy medical files must feature all the above-mentioned records, including any documents submitted to assist in the decision-making process and all documents in their entirety issued during and as a result of the radiotherapy given. The data retention periods set out in the StrlSchV must be observed.

6 EXAMINATIONS AND TREATMENT INVOLVING UNSEALED RADIOACTIVE SUBSTANCES

6.1 Quality assurance of examinations involving unsealed radioactive substances

6.1.1 Preliminary observations

The aim of quality assurance during a nuclear medicine examination is to ensure that the utmost diagnostic accuracy is achieved while keeping patient radiation exposure to a minimum.

The main factors contributing to a reduction in patient radiation exposure are

- an appropriate indication.
- a technically perfect execution of the examination.
- a correct interpretation of any examination findings.

The expertise and experience of the examining physician with the requisite expertise in radiation protection exerts a major influence on the quality of diagnosis, technical execution, and subsequent analysis. In the process, the physician has to rely on sufficient information being provided by the referring physician concerning any previous radiation applications, findings established to date, the precise nature of the clinical problem and, if relevant, details of pregnancy and nursing. Quality assurance measures are used to monitor the execution of nuclear medicine examinations. Approved guidelines and recommendations (e.g. issued by the SSK, EU) shall be taken into account as appropriate. Among others, these are available from the various medical councils, medical agencies and scientific medical associations (see also Appendix B 9).

6.1.2 Indication, justifying indication and execution of nuclear medicine examinations

When laying down an indication particular reference should be made to the following:

- anamnesis to determine the clinical problem.
- inclusion of results from previous examinations (if relevant, those conducted by the referring physician) to avoid unnecessary repetition.
- selection of a radiopharmaceutical and a method of examination suited to solving the clinical problem while keeping patient radiation exposure to a minimum (Chapter 5.1).
- establish existence/potential existence of a pregnancy prior to any examination; nuclear medicine examinations should only be executed in the knowledge of an existing or potential pregnancy following an especially careful assessment of the risks involved.
- when executing necessary nuclear medicine examinations on a nursing mother, the use of technetium-99m or radiopharmaceuticals marked with shorter half-life isotopes to allow adherence to an appropriate interruption in the nursing cycle (e.g. 12 hours, or the number of meals for which the infant receives breast milk substitute).

When performing examinations, the following shall be observed:

- ascertain patient identity.
- brief patient on the examination procedure.
- before applying the radiopharmaceutical, ensure the patient is correctly positioned and willing to cooperate during the examination.
- block the thyroid and/or other organs, as appropriate.
- measure activity levels, observing the principle of dose minimisation.
- select imaging parameters which ensure, in the event of sufficient counting statistics, that the necessary information is obtained.
- check medication radioactivity prior to application.

- ensure and monitor that medication is applied correctly.
- in the case of children observe the particular anatomical, pharmakokinetic and other peculiarities.
- perform examinations at the optimum post-applicational interval.
- fluid intake and frequent urination following application of rapidly excreted radiopharmaceuticals.

The proper function and properties of examination and measuring devices respectively, as well as of the radiopharmaceuticals used, shall be established within the scope of mandatory quality assurance measures described below.

When conducting examinations with unsealed radioactive substances, the diagnostic reference levels published by the Federal Office for Radiation Protection (§ 81 para. (2) StrlSchV) shall apply. These are levels of activity recommended for frequently conducted nuclear medicine diagnostic examinations. The clinical auditing commissions are responsible for ensuring said levels are adhered to and issuing recommendations concerning the optimization of procedures and the reduction of radiation exposure. If the diagnostic reference levels are consistently exceeded without justification and recommendations pursuant to § 83 para. (1) of the StrlSchV are repeatedly ignored, the clinical auditing commissions must inform the competent authority.

It is not usually necessary to admit a patient to hospital for reasons of radiation protection following an examination involving unsealed radioactive substances, since, especially in terms of adhering to the diagnostic reference levels specified in § 81 para. (2) of the StrlSchV (Appendix B number 4.14 a), the effective dose for the patient's direct environment is never likely to exceed 1 mSv per calendar year. Exceptions may include examinations using iodine-131 in iodide form conducted as part of therapy planning and aftercare programmes for patients with thyroid carcinoma (Appendix B number 5.27; see also Chapter 6.7.2 and Chapter 9.1).

6.1.3 Interpretation, documentation and recording of nuclear medicine examinations

The following factors shall be observed during evaluation and interpretation:

- the evaluation of findings shall entail regular validation of the methods used.
- the interpretation of examination results shall take patient medical history, clinical findings and the results of other or previous examinations into account.
- the possibility of pitfalls shall be considered.

All findings shall be documented and recorded in such a way as to enable examination results to be reconstructed at any time during the prescribed period of data storage.

In addition to patient-related data, a record shall also be made of all anamnesis data used to determine the justifying indication. This data must form part of the radiological report (DIN 6827-5).

The records on technical execution and interpretation must include

- the radiopharmaceutical,
- the activity administered,
- the date and time of application,
- the type of examination,
- the variable settings of the devices used,
- the software used to analyse findings (where appropriate) and
- the image documentation (where appropriate)

(see DIN 6827-2). If the activity reference level is exceeded, the reason shall be recorded.

A written radiological report (DIN 6827-5) is a mandatory element of the documentation process as specified by § 85 of the StrlSchV.

Image documentation systems used to produce images (e.g. laser imagers or printers) intended for analysis, archiving, forwarding to clinical auditing, or establishing justifying indications in the case of additional radiation applications, shall be checked for image quality at least every six months, in cases of apparent malfunction, and following any repair work respectively. This entails the use of appropriate test patterns (e.g. SMPTE test pattern). The settings of diagnostic monitors shall also be subject to routine image quality checks using such test patterns. These checks may be modelled on the corresponding stipulations found in the X-Ray Ordinance Quality Assurance Directive (see Appendix B number 4.11).

6.1.4 Quality assurance of diagnostic apparatus and measuring devices

Pursuant to § 83 para. (5) of the StrlSchV, the starting point for assuring the quality of nuclear medicine devices is an acceptance test; that has to be performed upon commissioning of the apparatus, or following major repairs and other interventions in the system, and the results recorded. These records shall be kept for the entire service life of the device, and at least for two years, starting from the completion of the last complete acceptance test (§ 83 para. (7) StrlSchV). The acceptance test ensures that manufacturer specifications pertaining to unit performance are fulfilled, while also serving to pinpoint errors. Once the device is operating properly and without error, the reference values shall be recorded for future constancy tests. This is done by either the manufacturer, the supplier or a medical physics expert. In the process, it is important to bear in mind the latest technological standards and the requirements of the medical applications to be performed.

Action thresholds and tolerance limits both need to be specified. If the former are breached, quality-improving measures must be initiated; if the latter are breached the device may no longer be used on patients. Constancy tests shall be conducted at regular intervals; following repairs, and if there is a suspected malfunction with the aim of establishing whether the condition of the device still meets the required standard. If results are documented and the proper function of the device is confirmed, the constancy testing of individual parameters may be replaced by calibration and optimization routines prescribed by the manufacturer. Constancy test results shall be recorded; all records shall be kept for ten years (§ 83 para. (7) StrlSchV). If the device is no longer operating to the required standard, the cause shall be established and rectified immediately (Appendix B 5.40).

The clinical auditing commissions responsible with monitoring the results of quality control tests may also advise the operator when it comes to determining the necessary scope and frequency of constancy tests. The fixing of deadlines for the relevant tests shall be subject to the respective standards (Appendix B 6). Malfunctions and actions taken as a result shall be documented in the record book in accordance with § 34 of the StrlSchV.

6.1.4.1 Gamma cameras

All the system parameters relevant to camera operation (heterogeneity, spatial resolution and linearity, energy window setting, background count rate, correct function of the whole body imaging process, angle displays etc.) must be included in the constancy test. Prior to beginning an examination, the operator must check that all devices are functioning properly. As far as is possible, homogeneity and yield shall be monitored pursuant to technical standards (DIN 6855-2 and -4, DIN EN 61675-2) or other appropriate quality standards (e.g. National Electrical Manufacturers Association NEMA). Furthermore, constancy tests shall be carried out whenever a gamma camera appears to be malfunctioning; moreover all imaging parameters which are likely to have an impact on the imaging properties of the device (e.g. the usability of homogeneity correction matrices) shall be checked following new installation or calibration.

Gamma camera final inspections and constancy tests shall be performed under reproducible conditions; this applies for instance to the activity used, the measuring geometry, as well as the use, if relevant, of a collimator. Constancy test parameters must comply with the technical requirements governing the quality of examinations conducted. Appropriate reaction thresholds and tolerance limits shall be specified in consultation with a medical physics expert. The reaction thresholds should be related to the reference figures (optimum values) reached during the acceptance test and/or routine constancy tests respectively.

When using gamma cameras for tomographic examinations, quality assurance standards need to be particularly high:

- correction matrices of sufficient statistical reliability shall be used to correct heterogeneity.
- the calculation of centre-of-rotation correction values shall take overall system stability into account.
- suitable phantom volumes, as well as reproducible imaging and reconstruction parameters shall be used to check the quality of tomographic images.
- the action thresholds for acceptable planar constancy test parameter deviations shall be modified to the particular requirements of SPECT operations. This specifically applies to image homogeneity.

6.1.4.2 Positron emission tomography (PET) and hybrid systems

Positron Emission Tomography(PET)

To ensure the quality of positron emission tomography scans, it is essential that

- the tomograph is regularly checked, either by means of a phantom or integrated transmission sources, for proper function, and
- the image properties and calibration are checked.

In such instances, official standards (e.g. DIN 6855-4) or automated testing programs and procedures prescribed by the manufacturer usually provide the point of reference. The test results, including any image data, shall be documented appropriately.

PET/CT and SPECT/CT

In the case of combined systems, such as PET/CT and SPECT/CT, those quality assurance measures prescribed for the individual systems in question shall be used. In addition the congruency of the different imaging levels which combine to produce the fusion images must also be tested.

6.1.4.3 Probe measurement systems

The background count rate and the energy window shall be checked every working day; the settings and yield for reproducible geometries shall be tested pursuant to the DIN standard (DIN 6855-1) using a suitable test emitter, e.g. caesium-137. Geometric factors (known as "borehole factors"), which are used in the quantitative analyses of patient examinations, shall be checked and/or redefined respectively at least every six months.

Depending on the probe system´s field of application, other suitable quality control procedures may be used.

6.1.4.4 Dose calibrators

A suitable test emitter shall be used for dose calibrator constancy tests. Reference figures for all nuclide settings used must be available for this test emitter. These are

usually determined by the dose calibrator manufacturer or supplier during a technical safety inspection. The use of certified activity standards is recommended when specifying and monitoring nuclide- and geometry-specific factors.

Constancy tests shall be performed pursuant to DIN 6855-11.

For every dose calibrator used in the measurement of technetium-99m, an accessory device shall be on hand to test for molybdenium-99 penetration (DIN 6854).

6.2 Quality assurance of transmission measurements

Device quality assurance (i.e. PET and SPECT transmission measurements) is subject to manufacturer specifications and the relevant technical standards currently in force.

6.3 Quality assurance of treatment involving unsealed radioactive substances

When performing treatment with unsealed radioactive substances, the aim of quality assurance is to ensure treatment effectiveness, while at the same time avoiding any unnecessary radiation exposure of the patient, staff and the environment.

For information on follow up cooperation involving other medical departments see Chapter 7.3.3.

6.3.1 Planning and performing treatment

The physician with the requisite expertise in radiation protection is responsible for nuclear medicine treatment.

When planning nuclear medicine treatment, the dose for the organs or tissue receiving treatment, as well as for any particularly radiosensitive organs, shall be calculated in advance - as far as is necessary and technically possible - and the activity appropriate for administration assessed. Customised calculations and data shall be consulted in cases where patient-specific parameters are required.

The nuclear medicine treatment of patients shall be performed pursuant to the principles of radiation protection set out in Chapter 6.7. The identity of the patient shall be verified prior to beginning treatment. The patient may request a copy of any records arising (§ 85 para. (2) StrlSchV). If technical implementation falls to a person with know-how in radiation protection (e.g. physician acquiring practical experience, medical assistant), a physician or MPE with the requisite expertise in radiation protection must provide direct supervision.

Appropriate steps shall be taken to reduce patient side-effects or to reduce the dose in especially radiosensitive organs not included in the target volume. Treatment with unsealed radioactive substances is subject to the aims laid down in Chapter 6.1.

6.3.2 Monitoring treatment

If possible from a metrological perspective, treatments involving patient-specific dose-planning parameters should be monitored with regard to chronological development of activity and an adequate degree of correlation, where relevant, between the target

volume dose and the original planned dose. If medically expedient and metrologically possible, scintigraphic examinations shall be used to record the local distribution of the radiopharmaceutical. Upon request the patient shall be issued with a duplicate or copy of these records.

6.3.3 Quality assurance by monitoring treatment success

The quality assurance of nuclear medicine treatments foresees that the data of all patients is monitored for results by the treating physician. Insights are gained, individual patients receive the optimum benefit from their treatment, and general comparisons can be made. It is therefore crucial that the physician with the requisite expertise in radiation protection responsible for performing treatment register and document any effects and side-effects of the nuclear medicine treatment by conducting suitable follow-up examinations at regular intervals. The physician with the requisite expertise in radiation protection may confer elements of these follow-up examinations on another physician of suitable specialism, who shall then inform the former of the results.

6.4 Quality assurance when using radiopharmaceuticals

The degree of quality assurance required depends on the type of radiopharmaceutical being applied. A distinction shall be drawn between

- ready-to-use radiopharmaceuticals,
- radioactive pharmaceuticals, which are produced on site by the operator using a radio-labelling kit licensed in accordance with the German Medicines Act, and
- other radiopharmaceuticals produced by the operator himself, including radio-labelled bodily substances.

Particular attention shall be paid to the German Medicines Act (Appendix B number 2.2) and the German Medical Devices Act (Appendix B number 2.3), and the resulting regulations.

The operator shall compare the exact specifications of ready-to-use radiopharmaceuticals supplied with the information contained in the consignment note and on the packaging label. The activity of ready-to-use radiopharmaceuticals must always be measured before any application.

The quality assurance of the technetium-99m generator is especially important. When commissioning a technetium-99m generator, or if such a generator is in operation for more than 14 days, the operator shall, pursuant to DIN 6854, conduct tests for molybdenum-99 break through.

Radiopharmaceuticals which are produced by the operator using a radio-labelling kit shall be checked for radiochemical purity according to manufacturer specifications; if necessary, the relevant up-to-date information shall be requested from the manufacturer. Tests conducted at a suitable frequency ensure that adequate radio-

labelling efficiency is reliably achieved. Such testing is particularly important if new or modified radio-labelling kits or radionuclide generators are introduced by the operator, or when problems occur. Such tests shall be conducted in such a way as to allow the assessment of the maximum time period between preparation and application to the patient, and extended nuclide generator operating times with relation to the impact on radio-labelling efficiency. Written instructions on how to conduct radiopharmaceutical quality controls shall be provided and all results documented. The following quality assurance measures shall be applied to kit radiopharmaceuticals:

- quality controls of licensed kit radiopharmaceuticals shall be conducted for every newly opened kit batch, with subsequent checks being held at a suitable frequency.
- quality controls shall be conducted immediately if clinical examination results would appear to indicate a quality issue.
- in general the quality control methods recommended by the manufacturer should be adhered to. Should another method be chosen for application, said method shall be validated against the method recommended by the manufacturer. Any documentation concerning this "validation by juxtaposition" shall be kept.
- standard instructions shall be produced for the radio-labelling and quality control of these products.
- quality control results shall be documented and archived.

The operator shall be responsible for the entire quality control process pertaining to other radiopharmaceuticals, including radio-labelled bodily substances, whether produced or radio-labelled on site. This also applies to testing for radionuclide purity in instances where short-lived radionuclides are produced (e.g. using a cyclotron) for radio-labelling purposes by the operator (PET positron emitters). There is no need to perform additional quality assurance measures, particularly with regard to pharmaceuticals marked with short-lived radionuclides, if

- the radiopharmaceuticals carry no risk of pharmacological or toxic impact,
- production and application takes place within a monitored system of patient allocation, and said production is either conducted accordingly by radiopharmacists or radiochemists, or in compliance with a controlled and scientifically accepted formula and
- the whereabouts of the radiopharmaceutical within a controlled area belonging to the licence holder is guaranteed by a physician with the requisite expertise in radiation protection.

6.5 Technical assistance

Within the field of nuclear medicine diagnostics, technical assistance (Chapters 6.1.4, 6.2 and 6.4) applies to the following areas:

- elution of radionuclide generators

- testing generator eluate for molybdenum break through
- monitoring ready-to-use supplies of radiopharmaceuticals (acc. to consignment note)
- producing radiopharmaceuticals, which are produced by the operator using a commercial radio-labelling kit, including quality control tests pertaining to radiochemical purity as necessary (according to manufacturer specifications)
- technical quality assurance of diagnostic devices
- technical performance of examinations (e.g. gamma camera, PET, SPECT)
- documentation pursuant to § 85 StrlSchV

Within the remit of technical assistance, the administration of a radiopharmaceutical may be delegated in compliance with the Radiation Protection Ordinance, this directive, MTA legislation, and the unique properties associated with nuclear medicine, if

- the technique of administration is straightforward,
- the substance in question is not likely to induce allergic reactions or side-effects,
- the procedure in question is standard nuclear medicine practice and
- the person in question is licensed, in line with occupational regulations, to administer.

The following procedures serve as examples:

- thyroid scintigraphy with intravenous administration of Tc-99m-pertechnetate
- skeleton scintigraphy with intravenous administration of Tc-99m MDP/HDP/DPD
- renal scintigraphy with intravenous administration of Tc-99m MAG3
- rest myocardial scintigraphy with intravenous administration of Tc-99m isonitriles
- ventilation scintigraphy with inhalation of Tc-99m particles or aerosols
- gastrointestinal diagnostics (oesophageal transit, gastric emptying) with oral radiopharmaceutical administration
- radioactive iodine uptake test with oral administration of iodine-131
- C-14 urea breath test to identify helicobacter pylori

6.6 Safety requirements when using unsealed radioactive substances

Unsealed radioactive substances must be stored securely and protected against unauthorised access (DIN 25422). Such substances may only be stored in locked rooms or locked radiation protection safes.

Examinations and inpatient treatment involving unsealed radioactive substances must take place in separate rooms. A nuclear medicine treatment ward is a self-contained spatial and functional unit (DIN 6844-1 and -2). This means, among other things, that a sufficient number of care staff instructed in radiation protection must be available and that such personnel may not generally be simultaneously allocated care tasks outside the nuclear medicine treatment ward. A spread of contamination from the controlled area by staff members must be avoided (e.g. by means of suitable airlock entrances).

Necessary decontamination measures may also be facilitated by structural measures (DIN 6844-1 and -2).

If the competent authority prescribes waste water treatment installations for the collection of contaminated waste water (e.g. so-called decay plants), it must be ensured that there is no way in which contaminated waste water can circumvent said systems for direct release into the general sewage system.

If foreseen by the recommendations concerning the application of the Incorporation Monitoring Guideline (Appendix B number 4.2b), an exhaust system shall be used during pulmonary ventilation examinations to prevent or reduce staff contamination and incorporation.

If the competent authority prescribes the use of filter systems to contain radioactive substances present in gaseous or aerosol form, it must be ensured that extracted air may only be released into the atmosphere via said systems.

6.7 Organisational radiation protection measures when using unsealed radioactive substances

6.7.1 General measures

Prior to examination or treatment with unsealed radioactive substances, patients shall be instructed on the possibility of contamination, to enable them to assist in preventing the spread of radioactive contamination. This particularly applies to hygiene in the homes. Leaflets pursuant to A 16 or A 17 may be handed out for this purpose.

In general both the preparation and the administration of unsealed radioactive substances must take place in rooms equipped especially for the purpose. The surfaces in rooms (see DIN 6844-1), in which preparation and application takes place, must be designed with possible decontamination measures in mind.

Only the amount of unsealed radioactive substances necessary for the application shall be held ready. Substances not intended for immediate use are to be stored securely in the radiation protection safes or other installations designed for permanent storage and protected from unauthorised access.

If necessary for reasons of radiation protection, shields, grip tools, and filling systems (if possible) shall be used as appropriate during the application of unsealed radioactive substances. It is also important to ensure staff members are adequately protected against external exposure when using unsealed radioactive substances.

In the case of beta radiation applications, for example during radiosynoviorthesis (RSO) or selective internal radiotherapy (SIRT), both procedures associated with high levels of staff radiation exposure, particular care shall be taken to observe the above-mentioned radiation protection measures. Personal dosimeters calibrated for beta radiation shall be used and worn in a suitable manner (see also Appendix B number 4.13). If drainage dressings are used, these must be replaced using suitable protective gloves. Tubes may only be disposed of using appropriate gripping tools (e.g. tongs). Tasks shall be conducted in such a way as to prevent contamination and especially incorporation (DIN 6843). These protective measures shall be brought to the attention of the nursing team in particular. Based on manufacturer specifications, special SIRT and Re-188 PTCA work instructions shall be produced for the preparation and administration of substances (see Appendix B number 5.39).

When not in use, unsealed radioactive substances must be stored in tightly sealed vessels within protective containers with sufficient 360° shielding (DIN 6850).

Suitably shielded transport containers must be used for transfers within the facility. These containers must be designed so as to ensure their contents are protected against damage.

6.7.2 Examinations and treatment involving admission of the patient to hospital

Examinations and treatment involving unsealed radioactive substances shall be conducted in such a way as to ensure that neither patients, their fellow human beings, nor the environment are subject to undue risk as a result of the radiation originating from the patient and any excreted radionuclides. This is guaranteed if treatment is conducted under inpatient conditions on a ward designed to comply with radiation protection requirements (structural features, waste water treatment installation, specially trained staff etc.).

Patients who have been treated with unsealed radioactive substances shall remain as inpatients within the controlled area of the treatment ward for at least 48 hours following administration, except in instances of outpatient treatment specified in Chapter 6.7.3 (see Appendix B number 5.5). The conditions of discharge can be found in Chapter 9.

Since more than 90% of radioactive excretions occur during this period, patients shall be admitted to a suitable nuclear medicine ward for at least 48 hours following either the administration of iodine-131 during thyroid carcinoma aftercare, or when necessary as part of the therapy planning process for suspected metastases. The ward must be equipped with a waste water treatment installation (Appendix B number 5.27). Patients must also be admitted to hospital for other examinations which might lead to persons without supporting person status being exposed to radiation levels in excess of the limits set for the general public, and where hospital admittance could help to reduce radiation exposure considerably.

6.7.3 Treatment without admission of the patient to hospital

If the levels of activity applied are commensurate with conventional practice, patients do not need to be admitted to hospital on the grounds of protecting the general public from radiation in the case of intraarticular treatment, e.g. radiosynoviorthesis (RSO) with yttrium-90, rhenium-186 or erbium-169, or the palliative treatment of bone metastases, e.g. with strontium-89, yttrium-90, samarium-153 or rhenium-186. No radioactive contamination of the environment need be expected nor shall the annual dose of 1 mSv for persons at a distance of two metres be exceeded as a result. For reasons of radiation protection and quality assurance, only those facilities which fulfil the requirements for conducting treatments with unsealed radioactive substances (Chapters 6.6 and 6.7) and which field sufficient staff shall be granted a licence to conduct these treatments.

In the case of outpatient treatment, proof of adherence to the following criteria shall be submitted for all other treatments not listed here:

- external exposure and exposure through incorporation does not exceed the limits set for the general public (§ 46 StrlSchV) and
- if necessary, the proper disposal of radioactive bodily fluids shall be guaranteed following intracavitary treatment.

For radioimmunotherapy with Y-90 ibritumomab tiuxetan see Appendix B number 5.30.

6.8 Monitoring and protective measures in the use of unsealed radioactive substances

In controlled and monitoring areas, in which unsealed radioactive substances are handled, workplaces shall be monitored for contamination, depending on the type of workplace and nature of work, at least once every working day. Additional monitoring shall take place immediately if contamination is suspected. If items display a level of contamination in excess of the limits listed in Appendix III Table 1 Column 4 of the StrlSchV, decontamination measures shall be initiated. If compliance with the limits cannot be achieved, steps must be taken immediately to prevent staff members working in these areas from being at risk from external exposure, contamination, and incorporation. The spread of contamination shall be prevented (barriers, sealing and labelling affected rooms or areas if necessary, leaving behind work clothes and shoes; see also DIN 6843).When it comes to handling unsealed radioactive substances, specific decontamination instructions shall be produced for the facility in question and also, as necessary, for individual workplaces. Specific protective measures, such as suitable shields in the case of syringes, shall be used during preparation and application.

Persons leaving controlled areas in which unsealed radioactive substances are used shall be monitored for skin or clothing contamination (Appendix B number 5.16). Procedures that comply with the Radiation Protection Commission's *Measures to be Taken in Cases of Radioactive Contamination of the Skin* (Appendix B number 5.1), shall be

initiated if skin contamination is established; the dose rate factors listed therein provide assistance in calculating equivalent skin doses.

Movable items used in controlled areas shall only be handed over or transferred to other areas if tests have shown that levels of contamination do not exceed the relevant limits listed in Appendix III Table 1 Column 4 of the StrlSchV (§ 44 para. (3) StrlSchV). In order to prevent contamination via radioactive substances or any risk to individuals, this also applies to items, such as bedding, towels, tools, waste, etc. from hospital wards where patients are treated with open radioactive substances.

The necessary radiation protection measures associated with the transfer of patients from controlled areas, such as treatment wards, shall be specified. The corresponding arrangements shall be displayed.

6.9 Quality assurance of interdisciplinary cooperation

The following presents interdisciplinary cooperation using an example of radiation protection in the case of sentinel lymph node scintigraphy (SLN scintigraphy, Appendix B number 5.19).

The level of radiation exposure associated with the scintigraphic examination of lymphatic vessels or lymph nodes, owing to the latter's lower degree of activity compared with other nuclear medicine examinations, is at the bottom end of the scale of possible exposure. The diagnosis, application of the activity, the lymph scintigraphy itself, the intraoperative search and removal process, as well as the histopathological examination of the SLNs, all involve experts from a range of different medical disciplines.

When it comes to SLN diagnostics, the physician with the requisite expertise in radiation protection shall take the following requirements into account prior to pronouncing the justifying diagnosis:

- written instructions pursuant to § 82 para. (3) of the StrlSchV shall be issued on intraoperative probe readings; these are to be signed and followed by the operator in question (Appendix A 20).
- intraoperative diagnostics shall be conducted using quality-assured probes in line with the latest technological standards.
- if the physician responsible for conducting the SLN diagnostic procedure does not personally hold a radiation protection licence, the existing contractual relations between the licence holder and external partners are to be used to pinpoint specific radiation protection issues within the context of any SLN diagnostics agreement (e.g. pursuant to Appendix A 20) - with the aim of optimising radiation protection provision and confirming the responsibility of the physician with the requisite expertise in radiation protection.

Within the scope of SLN diagnostics, overall responsibility for radiation protection pertaining to the handling of radioactive substances during the diagnostic process shall reside with the physician with the requisite expertise in radiation protection, i.e. even with reference to other physicians and pathologists involved in the process.

If the intraoperative measurements are not conducted by suitably qualified staff, with the requisite expertise or know-how in radiation protection, within the context of a licence issued in accordance with § 7 of the StrlSchV, the competent authority must stipulate within the licence the need for a formal agreement (Appendix A 20) and instructions (Appendix A 21) to regulate cooperation between the physician with the requisite expertise in radiation protection, and both the operating physician and pathologist in question. The aim thereby is to ensure adherence to the principles of radiation protection and secure the necessary supervision and responsibility of a physician with the requisite expertise in radiation protection (nuclear medicine specialist). This agreement must for instance demonstrate that the operating physician has experience in handling probes, while also determining who shall be responsible for performing quality assurance measures (Chapter 6.1.4.3) and to what extent.

Moreover the physician with the requisite expertise in radiation protection shall also present the operating physician and the pathologist with mandatory written instructions pursuant to § 82 para. (3) of the StrlSchV. Insofar as the procedure is linked to nuclear medicine diagnostics, the operating physician charged with the intraoperative application of probes must demonstrate the requisite know-how in radiation protection, as required by the licensing procedure pursuant to § 9 para. (1) number 4 of the StrlSchV. In order to acquire this know-how, the physician must attend a special training course pursuant to Appendix A 3 number 4.2. This may form part of a further training event on the topic or an in-house event featuring speakers with experience in conducting such examinations. In this instance official approval of the event pursuant to § 30 para. (3) of the StrlSchV (course approval) is not necessary.

When it comes to the handling and disposal of radioactive tissue and/or its return to the nuclear medicine department by the physicians performing surgery or pathologists, an “on-site” instruction session of those involved is sufficient.

The performance of sentinel lymph node scintigraphy in a location other than a nuclear medicine clinic can lead to members of the operating and pathology team being exposed to radiation. In both instances, external exposure is possible via the patient or the tissue removed. At the same time there is also the theoretical possibility of the incorporation of radioactive substances. Adherence to standard hygiene practices is however sufficient to rule out the latter. Owing to the way in which the radioactive substances are handled, the monitoring of staff as being occupationally exposed to radiation is inappropriate. Intraoperative probe readings do not require the direct supervision of a radiation protection expert.

The model agreement reached with operating physicians in other specialist fields (Appendix A 20) must be supplemented by written instructions, pursuant to § 82 para. (3) of the StrlSchV (Appendix A 20 final paragraph) and supplied by the radiation protection expert, which address aspects specifically associated with the application in question, and which the staff involved (operator, pathologist, other persons involved) are required to follow.

Any similar radiation applications arising in the future shall be subject to the provisions specified above.

7 RADIOTHERAPY (TELETHERAPY, BRACHYTHERAPY)

7.1 Aim of radiotherapy

The aim of using ionizing radiation in medical treatment is to apply a specific dose to a defined area of the human body (target volume), while largely protecting the remaining areas. The target volume dose and its temporal distribution shall be determined for each individual patient in accordance with the requirements of medical science. The dose affecting the rest of the body shall be kept as low as possible given the purpose of treatment (§ 81 para. (3) StrlSchV).

7.2 Justifying indication - further requirements

Prior to using ionizing radiation on patients, the physician responsible with the requisite expertise in radiation protection shall diagnose the justifying indication (see Chapter 5.1) and a written therapy plan (Chapter 7.3.2) tailored to the requirements of the individual patient shall be produced; the physician with the requisite expertise in radiation protection who has been assigned to the course in radiotherapy bears sole responsibility for the implementation of the latter on the patient.

Prior to diagnosing the justifying indication, it is necessary to ensure that

- the patient receives the treatment which offers the best chances of success (curative or palliative) combined with a minimum of side-effects,
- a medical physics expert (Chapter 2.1.3) in closely involved in producing the therapy plan and bears responsibility for its physical content, and that
- interdisciplinary cooperation has been secured for the examination, treatment and follow-up of the patient.

All documentation relating to the official diagnosis and subsequent radiotherapy must be filed to provide a decision-making basis for further examinations and treatment and archived for 30 years. From these records it must be possible at any time to follow the reasoning behind the radiotherapy and understand the decisions made.

If a combination of different treatments is used, the physician with the requisite expertise in radiation protection responsible for laying down the justifying indication must take into account any possible effects and side-effects arising from the various types of treatment. In such circumstances it is crucial to factor in any potential radiation-related combination effects arising from previous or other on-going treatment. To this end the physician with the requisite expertise in radiation protection shall apply for the necessary information from the other physicians involved in treating the patient and obtain their prior agreement to any changes in the therapy plan.

7.3 Quality assurance

The radiation protection supervisor or expert must introduce quality assurance measures (e.g. a quality management system, see DIN 6870-1) that suit the system hierarchy and which foresee the interaction of all system components. Any procedures that are newly introduced shall be subject to systematic and targeted testing. It is particularly important to check for the consistency of and adherence to specific, safety-related and functional requirements. These requirements must comply with national and international recommendations.

When taking delivery of apparatus, the radiation protection supervisor or expert must obtain from the manufacturer or supplier documents (in German) featuring the information necessary for the safe operation of said apparatus and the provision of appropriate radiation protection.

For the sake of patient safety and staff radiation protection, the radiation protection supervisor or expert shall inform the competent authority immediately of any relevant device faults or malfunctions pertaining to ionizing radiation generators or irradiation units - in line, where appropriate, with medical device legislation.

7.3.1 Final inspection and constancy test

During radiotherapy, irradiation zones – being subject to strict tolerance limits - may only vary slightly: radiobiological research has revealed that even minimal dose variations can lead to significantly different treatment outcomes. As a result, it is crucial that all devices used are monitored constantly for technical quality.

The definition of test parameters and the measuring techniques applied must comply with the latest technological standards. Pursuant to § 83 para. (5) of the StrlSchV, test parameter values are specified during the full and/or partial final inspection respectively; the on-going monitoring of variations is known as the constancy test (see also Appendix B 10) and forms part of the in-house quality assurance system pursuant to § 83 para. (6) of the StrlSchV. Full final and partial inspections must always be carried out following new purchases of irradiation equipment, as well as in the event of any potential or suspected deviations from the tested status, e.g. following repairs or observed malfunctions. The final inspection ensures that the manufacturer specifications relating to unit performance are fulfilled, and serves to pinpoint errors. Once a device is operating properly and without error, its reference values shall be recorded for future constancy tests. These records shall be kept for the entire service life of the device, and at least for two years, starting from the date of the last full final inspection (§ 83 para. (7) StrlSchV). It must be ensured that the test conditions correspond as closely as possible to the intended clinical application. If the constancy test requires dose measurements, these must be conducted using a suitable dosimetry technique. If deviations from the set values are recorded, the cause of the deviations must be eliminated and the test in question repeated. If in the case of older devices it proves impossible to reinstate the original values, those reached are to be recorded as the new, revised set of reference values, assuming these values still comply with the licensing criteria.

As radiation protection expert, the MPE must ensure that the data sets used within the entire system are compatible with each other. Within the licensing or monitoring process, the competent authority requires proof that an integrated technical inspection, relating especially to the dosimetry of the overall system, has been performed. A comparison shall also be made between the dose calculated and the dose measured. Moreover standards for the transfer of data between the therapy planning system and the irradiation devices need to be set and their observance monitored.

The adherence to and validity of all reference figures shall be confirmed at least once a year by extensive constancy tests conducted by the MPE, in his capacity as radiation protection expert. A selection of functions shall be monitored by means of additional less comprehensive constancy tests held at regular intervals (cf. also DIN 6873-5, DIN 6846-5, DIN 6847-5, DIN 6875-2, DIN 6853-5). If a constancy test reveals that a specified tolerance limit is being exceeded, the check shall be repeated using the final inspection procedure, and measures initiated to restore the function in question to its original state. Constancy test results must be recorded; all records are to be kept for ten years (§ 83 para. (7) of the StrlSchV).

Sufficient time shall be allocated within daily planning and organisation operations for the implementation of acceptance tests, partial acceptance tests, and routine constancy tests.

7.3.2 Therapy planning

Therapy planning refers to the preparation of radiotherapy for the needs of a specific patient. It entails the planning of both medical and physical aspects.

7.3.2.1 Medical aspects

The medical aspects of therapy planning specifically include:

- localisation and simulation.
- determining target volumes and organs at risk in line with ICRU specifications relating to position, shape, size and appropriate dosage, as well as taking the movement of target volumes into account.
- the timeframe and temporal distribution during which the dose shall be applied.

The target volume is localised and specified with the aid of imaging techniques. This generally involves the use of a treatment simulator or other appropriate imaging system. When creating computer tomograms or simulations to assist in therapy planning, the position of the patient must be identical with the patient's position during localisation and irradiation. The same positioning aids must be used or appropriate account taken of any modifications.

7.3.2.2 Physical aspects

The physical aspects of therapy planning include selecting an irradiation technique, supplying the necessary physical data, and determining the irradiation parameters

required to realise the treatment aim on the basis of the physician's instructions. In the process possible organ movement and positioning uncertainties also need to be taken into account. Adequate note shall be taken of other uncertainties e.g. resulting from algorithms or approximations used in the therapy planning system; for instance, it shall be tested whether, when calculating the photon dose for areas of pronounced tissue heterogeneity and using small fields (e.g. stereotactic radiotherapy and thoracic IMRT), correct results can be achieved with a pencil beam algorithm.

Mechanical fixation aids (e.g. masks, vacuum mattresses) must be used when applying radiotherapy to critical areas of the body. Preference shall be given to isocentric irradiation techniques.

Conformal radiotherapy techniques require irregular field configurations which are realised using customised multi-leaf collimators, made-to-measure satellite apertures or scanning techniques. In the case of the last two, technical monitoring systems need to ensure the field configuration remains the same for each radiotherapy session. Radiation field settings shall be documented in the imaging position (IGRT) at medically indicated intervals by taking reference images of the field using portal imaging systems involving the treatment radiation source, or suitable X-ray systems (Appendix B number 5.41).

7.3.2.3 Localisation

Imaging techniques are used to record the anatomical and topographical status of the target volume to be irradiated. In teletherapy and brachytherapy, treatment simulators, various X-ray facilities, or other imaging techniques are used in the localisation, simulation and documentation of the radiation fields. The use of computer tomography and/or MRT units respectively is necessary in order to calculate dose distribution from the resulting data sets using therapy planning software. This also facilitates virtual simulation. The radiation protection principle of minimisation shall also apply to the use of imaging techniques involving radioactive substances or ionizing radiation for the purpose of localisation and documentation during radiotherapy.

Not only must quality assurance (DIN 6873-5) take geometric test parameters into account, but also the correct assessment of tissue characteristics. Localisation aids shall be tested at least every six months. In the case of localisation equipment (including CTs) which are subject to the German X-ray Ordinance, quality assurance measures must be applied appropriately in accordance with the above-mentioned legislation.

The type and minimum scope of tests conducted on localisation and imaging systems, as well as simulation units are as follows:

- measures to test the quality of geometric imaging, including guaranteed artefact-free imaging and properly functioning distortion correction software.
- testing of radiophysics parameters of relevance to radiation protection and/or image quality respectively.
- measures to ensure the consistency and integrity of all image data transferred.
- measures to ensure the constancy of all mechanical and geometric parameters.

- testing of positioning aids and supports (laser systems etc.).

7.3.2.4 Therapy planning, verification and patient data administration

Therapy planning systems (therapy planning software) shall be included in quality assurance measures (cf. also DIN 6873-5). Detailed documentation provided by the manufacturer on the therapy planning system must be made available to the operator. This should specifically include an overview of any device-related data to be saved in the therapy planning system, a comprehensive description of the physical model used to calculate dosage and instructions on how to enter calculation parameters.

Before the system can be used in a clinical setting, its various functions and the achievable degree of precision must be tested using a representative set of calculation parameters which effectively covers the range of radiotherapy techniques and methods offered by the institution.

Readings shall be taken to verify predetermined standard therapy plans or the monitor preselected for a certain dose in a specific reference location. Such readings shall also include doses received by points outside the central beam, in particular if the useful beam bundle falls at an oblique angle, as well as the influence of heterogeneities and wedge filters (DIN 6875-3).

The therapy planning system must be tested prior to clinical commissioning and at routine intervals thereafter pursuant to DIN 6873-5. In the process the repeated calculation may serve for a set of selected examples. Results arising from these routine tests must be compared with the initial test at commissioning. Such tests should always be conducted if modifications are made to the device-related data entered in the system, the software, or the hardware.

In the case of straightforward plans, suitable methods (such as tables) must be available with which the therapy planning system can be checked for plausibility; these may also be temporarily referred to, as appropriate, in the event of a therapy planning system failure.

7.3.3. Quality assurance by monitoring treatment success

Radiotherapy quality assurance requires that the data of all patients is monitored for treatment results by the physician conducting treatment. In the process knowledge is gained that individual patients receive the optimum benefit from their treatment, and general comparisons can be drawn. It is therefore crucial that the physician with the requisite expertise in radiation protection responsible for performing the treatment register and document any effects and side-effects of the radiotherapy in question by conducting suitable follow-up examinations at regular intervals. The physician with the requisite expertise in radiation protection may transfer elements of these follow-up examinations to other medical specialists who are then obliged to inform the former of the results.

7.4 Spatial requirements

A radiotherapy department must feature the following areas:

- rooms in which the irradiation facilities or ionizing radiation installations are installed, including side rooms (control rooms, machine rooms, rooms used for producing and storing radiotherapy aids, and rooms for measuring equipment).
- rooms for the medical and physical planning of radiotherapy.
- rooms for conducting localisation, simulation, and CT scans, etc. as appropriate.
- rooms for treatment with radiation sources and rooms for patient examinations.

7.5 Teletherapy

Pursuant to Chapter 1, the following regulations apply to the operation of

- ionizing radiation installations (DIN EN 60601-2-1)
  including such units intended for intraoperative, external radiotherapy,
- irradiation facilities (DIN EN 60601-2-11), including those for radiotherapy involving multiple radiation sources and
- other types of particle sources (e.g. particle radiation).

7.5.1 Organisational aspects

The radiation protection supervisor, the physician with the requisite expertise in radiation protection and the medical physics expert, the latter in his capacity as radiation protection expert, are obliged to ensure that the radiation protection safeguards integrated in ionizing radiation installations and gamma irradiation units remain intact by means of correct use and maintenance, and that they are modified to comply with the latest technological standards.

Deviations from prescribed fractionation schemes shall be avoided. Irradiation continuity must be guaranteed even if a unit malfunctions. If the institution in question does not own two comparable irradiation units, continuance of radiotherapy in another suitable facility must be assured (see Chapter 2.3.4).

During the treatment of patients, ionizing radiation installations or gamma irradiation units may only pursuant to § 82 para. (1) of the StrlSchV be operated by a physician with the requisite expertise in radiation protection, or by a physician without the requisite expertise in radiation protection, if the latter possesses the requisite know-how in radiation protection and is under the permanent supervision and responsibility of the above-mentioned physician with the requisite expertise in radiation protection, or by other individuals licensed within the scope of technical assistance (Chapter 5.2.2) such as medical technical assistants, as per MTA legislation, or medical physics experts pursuant to § 82 para. (2) number 5 of the StrlSchV. Operating staff must have received instruction on a suitable ionizing radiation installation or gamma irradiation unit, and possess the specialist knowledge necessary for operations. Persons designated to assist in the positioning and care of patients, without actually operating the unit, need to possess the requisite know-how in radiation protection (training course pursuant to Appendix A 3 number 5), as well as having received initial instruction and follow-up instruction at regular intervals (§ 38 para. (1) StrlSchV).

The minimum requirement for medical staff during patient operations is that a physician with the requisite expertise in radiation protection provides permanent supervision.

The radiation protection supervisor shall ensure that every operational irregularity is immediately reported either to him or the radiation protection expert.

Technical malfunctions involving ionizing radiation installations or gamma irradiation units shall be entered in the record book. The medical physics expert appointed radiation protection expert shall decide on what measures need to be taken (interruption of patient operations if necessary, repairs etc.). If necessary, the safety concept for cases of operational failure shall be implemented in consultation with the physician with the requisite expertise in radiation protection.

The radiation protection supervisor shall ensure that ionizing radiation installations and gamma irradiation units are inspected prior to commissioning for patient operations and are subject to regular in-house monitoring thereafter (§ 83 paras. 5 and 6 StrlSchV, see also Chapter 7.3.1). Such measures shall be allotted sufficient time within the daily planning and organisation of operations. A list detailing inspection preliminaries, inspection scope and the applicable schedule shall be compiled and presented to the competent authority on request. Such monitoring is intended to supplement the maintenance and inspections specified in § 66 of the StrlSchV.

Radiation protection instructions are to be produced in accordance with § 34 of the StrlSchV (Appendix A 21).

7.5.2 Ionizing radiation installations

The dose administered, as specified in the therapy plan, must be checked by two independently operating monitoring systems (e.g. two dose monitors, or one dose monitor and one time monitor, etc.). Both systems must guarantee the independent termination of the irradiation process.

In addition to regular checks relating to technical safety, general safety and radiation protection pursuant to § 66 para. (2) of the StrlSchV, quality assurance monitoring must also take place. Appropriate organisation and the selection of suitable test conditions may enable technical safety inspections to be referred to for the purpose of quality assurance.

The minimum scope for quality assurance monitoring can be found in Appendix A 11.

Units generating particles other than electrons, such as particle radiation for instance (neutrons, protons or heavy ions), generally require additional quality assurance measures. The competent authority shall specify the requirements for each individual case.

7.5.3 Gamma irradiation units

A clearly noticeable, appropriate signal must be emitted by a radiation measuring device independent of the irradiation unit if someone enters the irradiation room when the seal is open. This device must always be switched on when the irradiation unit is in operation. If there is a power cut, device function and signal display must continue for at least another 30 minutes (cf. Appendix B number 4.4). For brachytherapy units see Chapter 7.6.

Instructions must be produced and kept next to the control panel for every relevant measure to be implemented should the seal closing mechanism malfunction. These measures shall be practiced every six months. Patient rescue in the case of a malfunction shall be planned to ensure that no member of staff is exposed to radiation exceeding the limits specified in § 55 of the StrlSchV. Should risk prevention measures for the protection of persons prove necessary, the aim should be to reach an effective dose of 100 mSv no more than once during a calendar year, and an effective dose of 250 mSv no more than once in a lifetime (§ 59 para. (1) StrlSchV).

Every significant safety-related incident, and in particular, every seal malfunction, shall be reported immediately to the competent authority by the radiation protection supervisor or radiation protection expert respectively.

Leakage tests shall be implemented in accordance with the Leakage Testing of Sealed Radioactive Substances directive (Appendix B number 4.3).

Following every change in radiation source, the useful beam dose rate or reference dose shall be redefined and all radiation-relevant parameters checked.

Inspecting a gamma irradiation unit or an electron accelerator with relation to geometric radiation parameters only differs insofar as the former allows additional movement of the emitter head. The minimum scope for quality assurance monitoring can be found in Appendix A 11.

7.5.4 Patient positioning

Owing to the significance of geometry when it comes to dose distribution during treatment, the geometric relationships need to be comparable, indeed - if possible – identical, for the gamma irradiation units, the simulator, the computer tomography unit and any other apparatus used to assist in localisation and positioning (e.g. incl. IGRT) within a single institution.

Any use of ionizing radiation imaging techniques during treatment to determine whether positioning is consistent with planning data shall be subject to the radiation protection principle of dose minimisation. The physician with the requisite expertise in radiation protection shall determine the frequency of monitoring and any necessary consequences (e.g. radiation table position modifications); any such modifications shall be documented.

The mechanical and optical patient field adjustment aids, which are either attached to the unit or the walls of the irradiation room, shall be checked according to the time periods specified in Appendix A 11 for geometric radiation parameters.

7.5.5 Technical requirements

It must not be possible for ionizing radiation installations and gamma irradiation units to be used or their settings changed without authorisation.

In the case of unforeseen interruptions in the radiotherapy process, it must be possible to ascertain the dose already applied, the dose still needing to be applied, and the necessary parameters for continuing radiotherapy respectively.

To ensure operational safety, all medical and technical-physical units must comply with Appendix A 9. In special circumstances, the competent authority may prescribe the provision of additional units or other accessories.

7.5.6 Maintenance, repair and inspections

The radiation protection supervisor shall organise servicing for the ionizing radiation installation and the gamma irradiation unit at least once a year, to be conducted either by the manufacturer or by a company specified by the manufacturer. Upon completion of the service, the radiation protection supervisor shall request a report from the maintenance company detailing the date, duration and scope of maintenance work, any adjustments made and parts replaced.

Following servicing or repairs, operations with the ionizing radiation installation or gamma irradiation unit in question may only resume if authorised by the medical physics expert upon receipt of information concerning the service or repairs and following a test run of relevant operational parameters.

Any repairs which have been carried out shall be documented by the service technician, specifying any parts replaced, any modifications, any alterations to electrical safety circuits and changes to process controls and software. The repair report shall be submitted to the medical physics expert appointed as radiation protection expert.

The holder of an ionizing radiation installation or gamma irradiation unit operating licence and the servicing and repair company are jointly responsible for ensuring that radiation protection is guaranteed during the entire servicing period and the responsibilities of the various radiation protection experts are clearly defined (cf. § 15 para. (3) StrlSchV).

As part of the licensing process and prior to commissioning for patient radiotherapy the radiation protection supervisor shall arrange an inspection by a professional expert focusing on the safe technical functionality of the unit and adherence to radiation protection requirements. The radiation protection supervisor or medical physics expert shall also conduct or organise an inspection of operations-related properties.

Once a year, and whenever major modifications have been made, or new radiotherapy techniques introduced - insofar as these necessitate technical change - the radiation protection supervisor or radiation protection expert shall arrange an inspection of the installation by a professional expert nominated by the competent authority pursuant to

§ 66 para. (1) of the StrlSchV, focusing on safety-related functions, safety and radiation protection (see Appendix B number 4.4).

In the case of treatment installations made up of several components, the flawless interaction of the individual components (Appendix B number 5.35) must be checked.

7.6 Brachytherapy

The following regulations apply to treatment methods, during which radiation sources are temporarily (temporary application) or permanently (permanent implants) applied, whether manually or with afterloading devices (DIN EN 60601-2-17), to the tissue, body cavities, vascular system, or skin of the patient. These regulations also apply to endovascular catheters and radioactive stents (Chapter 7.6.3).

The physician responsible for performing brachytherapy must possess the requisite expertise in radiation protection pursuant to Appendix A 1 number 2.2.1 or A 1 number 2.2.2. An additional radiation protection expert in the form of a medical physics expert must also be appointed. Regardless of the brachytherapy technique being used, the medical physics expert's scope of involvement during the application planning and implementation phase shall be precisely defined.

The treatment shall be monitored for success pursuant to Chapter 7.3.3.

In addition to a suitable control and application room, the following are required when performing brachytherapy (see also Appendix B number 4.4):

- access to localisation apparatus, as necessary,
- radiation protection safes and
- therapy planning rooms, as necessary.

7.6.1 Afterloading devices

These are devices used to remotely guide radioactive substances from the rest position (radiation-shielded position) into applicators located in cavities or areas of the body to be irradiated.

7.6.1.1 Medical aspects

By analogy, afterloading treatment is also subject to the principles of therapy planning as specified in Chapter 7.3.2.

Verification imaging techniques shall be used to check the position of applicators. These are generally conducted in the radiation application venue.

The position of the applicator must always be determined prior to performing radiotherapy.

7.6.1.2 Physical aspects

The afterloading device must comply with the latest technological standards (DIN EN 60601-2-17). At the very least, the following safety requirements shall apply:

- if the device demonstrates a technical malfunction which could lead to unintended irradiation of the patient, the radiation source must remain in the rest position or automatically return to the rest position respectively.
- if the radiation source is not in the rest position when someone enters the irradiation room, a clearly noticeable signal must be emitted by a radiation measuring device independent of the afterloading device. This radiation measuring device must remain switched on for the duration of afterloading operations. If there is a power cut, device function and signal display must continue for at least another 30 minutes (cf. Appendix B number 4.4).
- if the radiation source guide or applicator has not been connected, the radiation source must remain in the rest position; it must also return automatically to the rest position if one of the intended connections between applicator, radiation source guide and radiation source storage container becomes disconnected.
- the radiation source must automatically return to the rest position when the door of the irradiation room is opened, if an emergency switch is pressed, or in the case of a power cut.
- it must be guaranteed that the afterloading device cannot be used and its settings cannot be changed without authorisation.

When using low dose rate afterloading devices, which allow the use of several applicators in quick succession, the above-mentioned regulations shall be applied analogously; for staffing guidelines see Chapter 7.6.1.3.

Upon delivery of the device, the radiation protection supervisor or the radiation protection expert shall obtain from the manufacturer or supplier the documents (in German) necessary for the safe operation of said device and the provision of appropriate radiation protection, specifically with relation to

- the correct operation of the device,
- the storage and guidance of radiation sources,
- the measures to be taken if the radiation source fails to return automatically to the rest position, and
- the performance of leakage tests (e.g. replacement test zones).

The radiation protection instructions must include measures to be implemented should the radiation source fail to return automatically to the rest position. These instructions must be positioned next to the operating device. These measures shall be practiced at least every six months.

The radiation protection supervisor and, where appropriate, the radiation protection expert, shall ensure that the afterloading device is subject to servicing and routine

inspections. A routine inspection shall be conducted once a year. The competent authority can extend the time period to a maximum of three years, if pursuant to the licensing terms the device is inspected at least once a year by a medical physics expert and its activity is found not to exceed 10^{14} Becquerels (§ 66 para. (3) number 1 StrlSchV).

The minimum scope for quality assurance monitoring can be found in Appendix A 11.

Upon delivery and prior to their initial application, new radiation sources shall be checked by the medical physics expert for manufacturer specification accuracy relating to their characteristic dose rate or activity. Following this initial inspection, the characteristic dose rate must be checked at least once more for radionuclide purity within a subsequent interval suitably adapted to the radionuclide half-life. On days when operations take place, appropriate checks must be made to ensure that the body probes are functioning properly and the dose rate is corrected taking the radioactive decomposition of the radiation source into account.

The radionuclide used must be recorded in the irradiation report.

The competent authority shall prescribe routine leakage tests within the terms of handling in accordance with the Leakage Testing of Sealed Radioactive Substances directive (Appendix B number 4.3).

7.6.1.3 Organisational aspects

Routine inventory checks and record-keeping shall be used to determine precisely the type and number of radiation sources on site. Special inventory duties, as defined in § 70 para. (1) sentence 3 of the StrlSchV, apply to high activity radiation sources.

When not in use, the radiation sources must be stored in shielded rooms or protective containers and secured against loss of actual control and unauthorised access (§ 65 para. (1) StrlSchV). Mobile devices and radiation source storage containers must be secured in such a way as to prevent unauthorised persons from removing them from the zones prescribed and foreseen in the licence (see also DIN 25422).

Rooms and facilities that comply with structural radiation protection requirements must exist for the performance of treatment involving afterloading devices. The existence of device control, patient preparation, and therapy planning rooms must also be verified.

Afterloading devices with an activity of more than $5 \cdot 10^{10}$ Becquerels may only be operated in irradiation rooms that comply with § 84 of the StrlSchV.

Pursuant to § 82 para. (1) of the StrlSchV, afterloading devices used in the treatment of patients may only be operated by a physician with the requisite expertise in radiation protection, or by a physician without the requisite expertise in radiation protection, if the latter possesses the requisite know-how in radiation protection and is under the permanent supervision and responsibility of the above-mentioned physician with the requisite expertise in radiation protection, or by other individuals licensed within the

scope of technical assistance (Chapter 5.2.2) such as medical technical assistants, as per MTA legislation, or medical physics experts pursuant to § 82 para. (2) number 5 of the StrlSchV. Operating staff must have received instruction on the afterloading device and possess the practical experience necessary to operate it. Persons assigned to assist in the positioning and care of patients, without operating the unit, need to possess the requisite know-how in radiation protection (training course pursuant to Appendix A 3 number 5), as well as having received initial instruction and follow-up instruction at regular intervals (§ 38 para. (1) StrlSchV).

The minimum requirement for medical staff during patient operations is that permanent supervision is provided by a physician with the requisite expertise in radiation protection. If, in the case of low dose rate afterloading devices, several applicators are to be used in quick succession, the competent authority shall prescribe appropriate operating regulations concerning obligatory attendance and application monitoring.

The radiation protection expert responsible shall be informed at once of any suspected malfunctions, radiation source damage, or other incidents of safety-related relevance. If damage is suspected, a leakage test shall be carried out and any necessary steps taken to prevent contamination or incorporation. Only when the situation has been clarified may radiotherapy resume. Any loss of actual control (loss or theft) of radioactive substances must be reported immediately to the authority responsible for public safety and order or to the competent nuclear supervisory authority, as well as to the radiation protection expert. If a leak is suspected (§ 66 para. (6) StrlSchV), or if there has been a significant safety-related incident, the radiation protection supervisor or expert shall report this immediately to the competent authority. Special duties, as defined in § 71 para. (1) sentences 2 and 3 of the StrlSchV, apply to high activity radiation sources.

Radiation protection instructions are to be produced in accordance with § 34 of the StrlSchV (Appendix A 21).

7.6.2 Radiation sources for temporary or long-term use on patients

When handling radiation protection sources, protective measures particularly need to be taken against external radiation. The risk of incorporation or contamination only exists if the casing of the radioactive source has been damaged. Measures need to be in place to prevent such damage and to enable its swift detection respectively.

7.6.2.1 Medical aspects

Radiation source applications are subject to the principles of therapy planning specified in Chapter 7.3.2.

Verification techniques shall be used to check the position of radiation sources or applicators. These are generally conducted in the radiation application venue. In instances where the radiation source has been idle for an extended period, the position of said radiation source shall be subject to additional checks as necessary.

If necessary, and depending on the dose rate, patient rooms shall be equipped with staff radiation protection devices to enable appropriate patient care.

Following every patient application, any radiation sources used shall be checked for completeness and a visual inspection for damage conducted. The first step in the event of suspected loss or damage is to take patient readings. A record of these shall be kept, to be submitted to the competent authority upon request.

All waste containers are to be screened using an appropriate radiation measuring device prior to their removal in order to prevent the accidental disposal of radiation sources, e.g. with soiled bandages or other waste.

When treating patients with radiation sources the following regulations apply:

- patients must be informed about any required behaviour in an appropriate and suitable form, such as an information sheet (Appendix A 18).
- patients wishing to leave the controlled area may only do so with the permission of the radiation protection expert. see Chapter 9 of this directive for regulations governing patient discharge.
- precautions must be taken to prevent the loss of radiation sources via bodily excretions.

The competent authority may permit either the radiation protection supervisor with the requisite expertise in radiation protection or the radiation protection expert to grant other persons (visitors) access to the patient (§ 38 para. (1) sentence 2 StrlSchV). The individual dose received by visitors shall be determined and recorded. More detailed provisions are contained in the relevant StrlSchV directive (Appendix B number 4.1). Visitors shall be informed about appropriate measures aimed at minimising their own exposure to radiation.

7.6.2.2 Physical aspects

In cases where the design of the application device does not allow the type and number of radiation sources existing and applied to be determined, these must be ascertained by means of inventory checks and record-keeping. Special duties, as defined in § 71 para. (1) of the StrlSchV, apply to high activity radiation sources.

A certificate issued by the manufacturer or supplier shall accompany every radiation source; this must specify the leakproof of the radiation source, type and activity, as well as the characteristic dose rate of the source in question. The user may adopt this data, especially if the radiation sources have been supplied for application as medical products in sterile form and are intended for permanent application. The adoption of manufacturer specifications does not, however, absolve the user from subjecting the manufacturer specifications to random tests. The scheduling of such tests shall be agreed in consultation with the competent authority. These tests may be omitted if the manufacturer is able to include the results of appropriate quality control measures with radiation source consignments (e.g. autoradiographs). Special duties, as defined in § 69 para. (2) of the StrlSchV, apply to high activity radiation sources.

The accuracy of manufacturer specifications relating to radiation sources intended for multiple temporary applications must be checked upon delivery and prior to the first application. Each type of radiation source must, its form permitting, be furnished with identification marks by the manufacturer or supplier.

A schedule of routine leakage tests shall be determined within the licensing terms pursuant to § 7 of the StrlSchV, in accordance with the Leakage Testing of Sealed Radioactive Substances directive (Appendix B number 4.3). Special duties, as defined in § 66 para. (4) of the StrlSchV, apply to high activity radiation sources.

Radiation sources shall be stored in a protective container (safe), which depending on the total activity of the material stored therein shall be fireproof and adequately protected against theft (DIN 25422). These radiation protection safes shall only be used for the storage of radiation sources.

Radiation sources, representing the approximate requirements for a single day, and thus requiring only short-term storage, may be stored in an additional safe or storage container. For short-term storage prior to and following application, radiation sources are to be kept in a shielded environment that guarantees their safe transport, and is thus designed to ensure that, taking staff attendance conditions into account, the effective dose reference figure of 1 mSv per calendar year cannot be exceeded.

If it may be assumed - owing to the radiation source properties, the protective measures in place, and the type of application - that an effective staff dose of 1 mSv per calendar year cannot be exceeded, the radiation sources may be applied in those rooms, which owing to their equipment and the medical requirements associated with the case, offer the best means of application for the patient. In all other instances, rooms and facilities must exist for the performance of treatment that comply with structural radiation protection requirements.

Radiation sources must be transported between the safe, the venue of preparation, and the venue of application in suitable protective containers.

The handling of radiation sources in preparation for application shall take place in an appropriately shielded work area and involve the use of grip tools. If necessary, cleaning and sterilisation shall also take place in this or similarly protected work areas.

Depending on the radiation quality involved, application to patients may involve the use of protective mobile panels and protective chairs. Transferring patients to different beds should be avoided.

The inventory of radiation sources in regular use shall be checked once a week. Every six months at least a full inventory shall be made of all radiation sources, e.g. within the context of the leakage test. If radiation sources are not being used, they may be stored in a separate, sealed section of the safe. Weekly checks to ensure the seal is intact may thus replace the inventory check; immediate inventorizing is only necessary if the seal has been tampered with or is missing. Otherwise an inventory becomes mandatory; this must take place at least as often as – and in the context of - the leakage test.

7.6.2.3 Organisational aspects

Work area organisation has a considerable impact on the effectiveness of radiation protection measures. During applications, staff often needs to remain with the patient, meaning close proximity to radiation sources is frequently unavoidable. Radiation protection devices are of little use when caring for patients to whom radiation sources have been applied. The extent to which staff is exposed to radiation therefore depends on the speed and reliability of their working methods, familiarity with the expected patterns of behaviour, and the degree of cooperation within the team.

Any loss of actual control (loss or theft) of radioactive substances must be reported immediately to the authority responsible for public safety and order or to the competent nuclear supervisory authority, as well as to the radiation protection expert. If a leak is suspected (§ 66 para. (6) StrlSchV), or if there has been a significant safety-related incident, the radiation protection supervisor or expert shall report this immediately to the competent authority. Special duties, as defined in § 71 para. (1) sentences 2 and 3 of the StrlSchV, apply to high activity radiation sources.

Particularly if radiation sources have gone missing or a leak is suspected, the radiation protection supervisor or radiation protection expert must inform the competent authority immediately.

Radiation protection instructions are to be produced in accordance with § 34 of the StrlSchV (Appendix A 21).

7.6.3 Endovascular radiotherapy

Endovascular radiotherapy, e.g. to prevent or minimise coronary or peripheral vessel restenosis following interventional angiographic procedures, is not classified as standard treatment, since each application – analogous to Chapter 7.3.2 - requires a therapy plan tailored to the individual patient. Verification imaging (analogous to Chapter 7.3.2.4) is required to determine the site of radiation application.

The radiation exposure of staff hands involved either in the application or the preparation of the activity to be applied must be measured using suitable means (e.g. ring dosimeter). Moreover, the monitoring and protection measures for unsealed radioactive substances specified in Chapter 6.8 also apply.

Unsealed radioactive substances in balloon catheters

For reasons of radiation protection in the event of a balloon rupture or contamination and quality assurance associated with angiopathy treatment using balloon catheters (e.g. filled with rhenium-188), licences may only be issued to those institutions where persons in possession of the necessary experience in handling contamination and incorporation are appointed radiation protection experts, and where a ward or access to a ward exists for the treatment of patients with unsealed radioactive substances pursuant to Chapter 6.3.

The physician responsible for treatment must possess the requisite expertise in radiation protection pursuant to Appendix A 1 number 2.1.1 (Entire field of unsealed

radioactive substances diagnostics and treatment) or Appendix A 1 number 2.1.6 (endoluminal and endocavity radiotherapy). In the process he shall cooperate with the physician performing the operation. A medical physics expert with the requisite expertise in radiation protection relating to nuclear medicine and brachytherapy must also be appointed as an additional radiation protection expert. The scope of the latter's involvement in planning and implementing the application, as well as determining and dealing with contamination and malfunctions shall be specified. If technical implementation falls to a physician with the requisite know-how in radiation protection, direct supervision must be provided by a physician or MPE with the requisite expertise in radiation protection relating to nuclear medicine.

Metal-bound radioactive substances

This refers to the use of wire-bonded radiation sources (known as seeds, trains) or radionuclide-coated materials (such as radioactive stents). The leakage test regulations specified in Appendix B number 4.3 do not apply in this instance.

The physician responsible for treatment must possess the requisite expertise in radiation protection pursuant to Appendix A 1 number 2.2.1 (Entire field of radiotherapy teletherapy and brachytherapy), Appendix A 1 number 2.2.2 (brachytherapy) or Appendix A 1 number 2.2.4 (endovascular radiotherapy using sealed radioactive substances). In the process he shall cooperate with the physician performing the operation. A medical physics expert with the requisite expertise in radiation protection relating to brachytherapy must also be appointed as additional radiation protection expert. The scope of the latter's involvement in planning and implementing the application, as well as determining and dealing with contamination and malfunctions shall be specified.

When removing organs containing radioactive substances, operating staff are obliged to proceed in accordance with the "quality assurance of interdisciplinary cooperation" guidelines (see Chapter 6.9).

8 CLEARANCE, RETURN, TRANSFER, DELIVERY AND REMOVAL OF RADIOACTIVE SUBSTANCES

8.1 Clearance

Radioactive substances and activated or contaminated items respectively, originating from procedures (§ 29 para. (1) StrlSchV) and which have been handled within the scope of a licence pursuant to § 7 para. (1) of the StrlSchV, may under certain conditions regulated by the Radiation Protection Ordinance be granted clearance (clearance pursuant to § 29 StrlSchV). Following clearance they may, for instance, be disposed of as non-radioactive materials. Ionizing radiation installation units and unit components are also subject to StrlSchV regulations and must be granted clearance prior to other use or disposal. Clearance is also required for rooms in which no further handling of radioactive materials or operation of ionizing radiation installations is to take place (change in use), since such rooms could be either activated or contaminated.

Clearance pursuant to § 29 of the StrlSchV is granted by the competent authority in the form of a clearance notification. The competent authority may also determine (§ 29 para. (4) StrlSchV) via notification the procedure necessary to meet the requirements, particularly with reference to clearance measurements and documentation. Cleared substances, protective containers, storage containers, transport casings, units and unit components may no longer be marked as radioactive substances (§ 68 para. (4) StrlSchV).

It should be noted that during the operation of ionizing radiation installations, electron accelerators (for energies of more than 8 MeV), and in particular of proton and heavy ion accelerators, not to mention neutron irradiation units, parts of the accelerator and unit respectively can become activated. When replacing parts during maintenance work or dismantling units, it is particularly important either to obtain clearance pursuant to § 29 of the StrlSchV, or to ensure said parts and components - as long as they are not earmarked for disposal as radioactive waste (see Chapter 8.4) - are transferred pursuant to § 69 of the StrlSchV (see also Appendix B number 5.43) to others in possession of a licence pursuant to the StrlSchV.

8.2 Return

It is recommended that the user and manufacturer or supplier come to a contractual agreement concerning the return of devices containing radioactive substances, such as generators and marking, calibration, or testing sources at the time of purchase. The manufacturer or supplier is not under general obligation to take back any materials.

8.3 Transfer and delivery

Radioactive substances may only be transferred if the receiving party holds the requisite licence for handling the relevant substance (§ 69 para. (1) StrlSchV). When transferring sealed radioactive substances intended for subsequent use as such, the substance casings must be certified leak-proof and free of contamination pursuant to § 66 of the StrlSchV (§ 69 para. (2) StrlSchV). The certificate may not pre-date the date specified by the competent authority for the last routine leakage test. In the absence of any additional licensing provisions, only those persons with express authorisation to do so (§ 69 StrlSchV) may take delivery of radioactive substances.

8.4 Removal

Radioactive substances no longer intended for use that have not been

- cleared pursuant to § 29 of the StrlSchV (Chapter 8.1) or
- returned pursuant to § 27 of the StrlSchV as part of a type-approved device (Chapter 8.2) or
- transferred to another person pursuant to § 69 of the StrlSchV (Chapter 8.3),

must be delivered to state collecting facilities (§ 76 para. (4) StrlSchV) as radioactive waste, insofar as no other means of disposal or transfer pursuant to § 77 of the StrlSchV has been prescribed or licensed.

9 DISCHARGE OF PATIENTS FOLLOWING THE USE OF UNSEALED RADIOACTIVE SUBSTANCES OR OF PATIENTS BEARING SEALED RADIOACTIVE SUBSTANCES (RADIATION SOURCES) IN THEIR BODIES

Procedure-related radiation exposure is limited to protect the general public and the environment. For individual members of public, the effective dose limit for radiation exposure during procedures defined under § 2 para. (1) number1 of the StrlSchV is 1 mSv per calendar year.

Prior to being discharged, patients shall receive both instruction, as per treatment given and based on the patient information sheet, and additional recommendations (Appendices A 14 to A 19) on how to behave for the protection of others.

9.1 Unsealed radioactive substances

Radioiodine therapy is subject to the following regulations. The competent authority shall prescribe specific requirements for other applications involving unsealed radioactive substances.

Following inpatient treatment involving the application of unsealed radioactive substances, a patient may be discharged by a physician with the requisite expertise in radiation protection, if

- the patient has spent at least 48 hours on the ward following treatment,
- taking into account the expected level of social contact, the resulting radiation exposure for other persons is estimated to be such, that individual members of the general public would not be exposed to more than 1 mSv per calendar year. This occurs in the case of iodine-131 when the local dose rate is less than 3.5 µSv per hour at a distance of 2 metres from the patient, or the activity measured throughout the entire body is no more than 250 MBq (conservative assumptions: continuous presence and pinpoint source, free air). based on these conservative assumptions, actual exposure does not generally exceed 0.3 mSv (Appendix B number 5.14).

It is advisable to measure the equivalent dose rate, since residual activities vary from medical procedure to procedure and from patient to patient (Appendices B nos. 5.5 and 5.21).

If the patient is to undergo treatment more than once a year, this shall be taken into account accordingly. The regulations governing patient discharge also apply to transfers to other departments or other hospitals. Institutions charged with the

provision of further treatment must be informed in cases where further treatment is associated with a risk of contamination.

Following diagnostic procedures which require patient admission to hospital (e.g. whole body scintigraphy using iodine-131 as part of thyroid carcinoma aftercare or therapy planning), such patients may only be released 48 hours later at the earliest (Appendix B number 5.27).

The patient may also be discharged, for instance for social reasons, upon the following conditions:

- the patient has spent at least 48 hours on the ward following the application of unsealed radioactive substances,
- radiation exposure for individual members of the public may not exceed 1 mSv per calendar year; the option to discharge patients earlier nevertheless exists if the regulations relating to supporting persons within the patient's own home are adhered to pursuant to Chapter 5.4 and
- the competent authority is informed immediately of the discharge, with reasons given.

9.2 Sealed radioactive substances

In the case of radiation sources permanently installed in the patient's body, the patient may only be discharged when an individual member of the public, continuously present, cannot be exposed to more than 1 mSv per calendar year (see Chapter 9.1). The radiation protection expert (physician, MPE) is responsible for estimating radiation exposure levels for individual members of the public. These must be based on realistic exposure conditions (e.g. continuous presence at a distance of 2 m from the patient). The estimate shall be documented and submitted to the competent authority upon request.

10 REMOVAL OF IMPLANTED RADIATION SOURCES; POST-MORTEMS, TRANSPORTATION AND BURIAL OF CORPSES CONTAINING RADIOACTIVE SUBSTANCES

The radiation protection supervisor responsible for any prior treatment with radioactive substances or the radiation protection expert must ensure adherence to the requisite radiation protection measures and observance of the principle of dose minimisation (§ 6 StrlSchV) during the removal of implanted radiation sources, as well as the transportation, post-mortem and burial of corpses.

10.1 Removal of implanted radiation sources; post-mortems

If the radiation protection supervisor responsible for the treatment or the radiation protection expert appointed by him has arranged either for the removal of implanted radiation sources or for the post-mortem of a corpse containing unsealed or sealed

radioactive substances, the principles of radiation protection relating to handling sealed or unsealed radioactive substances shall apply.

The radiation protection supervisor responsible for treatment or the radiation protection expert shall ensure adherence to the following:

- the operation and post-mortem respectively shall be conducted, observing the requisite radiation protection measures, in a room marked as a controlled area; if necessary, this controlled area status may be temporary in nature and thus subject to concluding contamination tests,
- the operation and post-mortem respectively shall be monitored by a radiation protection expert who does not need to be a physician and
- the safeguards pursuant to Chapter 5 of this directive shall be adhered to.

Any tissue and organs removed respectively shall be handled pursuant to Chapter 8.

All waste containers are to be screened using an appropriate radiation measuring device prior to their removal in order to prevent the accidental disposal of radiation sources or unsealed radioactive substances, e.g. with soiled bandages or other waste.

10.2 Transportation and burial of corpses

The transportation of corpses containing radioactive substances is not subject to the terms of the Transport of Dangerous Goods Act (Appendix B number 2.7).

Special permission is not required for the burial of corpses containing radioactive substances.

To reduce the overall activity of a corpse containing radioactive substances, the radiation protection supervisor responsible for treatment or the radiation protection expert may, insofar as this is deemed necessary, arrange for the removal of organs demonstrating higher levels of activity (e.g. thyroid, prostate) to reduce radiation exposure (Chapter 10.1). The organs removed shall be handled pursuant to Chapter 8.

Cremation may only take place when the local dose H*(10) at a distance of 2 metres integrated over one year does not exceed the 1 mSv limit. The competent authority shall be informed immediately if this is not the case, or if the process would entail unwarranted expense. Pacemakers fitted with a radioactive energy source must always be removed prior to cremation.

The potential radiation exposure for any hospital staff involved, undertakers, and relatives shall be estimated and recorded on the basis of realistic assumptions. Should there be a chance that the annual limit of 1 mSv could be exceeded in individual cases, the provisions concerning supporting persons (Chapter 5.4) shall be taken into due consideration.

The hospital shall inform the firm of undertakers if a corpse contains radioactive substances and shall provide instruction on radiation protection measures for its staff.

10.3 Pacemakers with radionuclide batteries

Pacemakers fitted in Germany are subject to strict licensing criteria and must be officially registered and disposed of (BMI publication dated 31.10.1973: "Recommendation concerning the licensing and monitoring of radionuclide sources installed in pacemakers"; Joint Ministerial Gazette 1973, number 28 p. 509). This however does not apply to pacemakers implanted abroad. In the course of globalisation, it is increasingly likely that persons who have been fitted with such a device abroad may seek medical attention here in Germany.

Operations on patients with such pacemakers should comply with the following procedure:

1. In the case of planned interventions, these should take place in a clinic with both the requisite experience in medical radiation protection and the necessary technical equipment, such as measuring devices and storage facilities.
2. Provided that the operation cannot be postponed for reasons of urgent medical necessity, the clinic in which the intervention takes place shall undertake to inform the competent radiation protection authority (as with, where applicable, finds pursuant to § 71 StrlSchV).
3. The competent radiation protection authority shall also be informed whenever physicians become aware that a patient is fitted with such a pacemaker.

Even if, on the basis of current information, those pacemakers covered by the latest studies and equivalent models from abroad pose a minimal risk to humans and the environment in the case of burial, every pacemaker found must be registered with the competent radiation protection authority (finds pursuant to § 71 StrlSchV).

Appendix A

Specialist training and required certification

A 1 Radiation protection expertise required by physicians

When acquiring the requisite expertise in radiation protection for the application of radioactive substances or ionizing radiation on humans, and taking into account the factors set out in Chapter 3.1.2, the following conditions apply:

A 1 1 General

A 11.1. Practical experience in the application of radioactive substances or ionizing radiation to patients within the specific field of medical application (practical experience)

In the acquisition of practical experience, three aspects associated with the application of radioactive substances and ionizing radiation need to be given adequate weighting to achieve the quantity of documented examinations and treatment required by this directive (for examinations: diagnosis of the justifying indication, technical assistance, and reporting; for treatments: diagnosis of the justifying indication, technical assistance and success monitoring).

If the requisite expertise in radiation protection is acquired consecutively for a number of application fields, periods of practical experience may be carried forward; the relevant quantities specified must nevertheless be fully substantiated.

Upon request, and if in compliance with the principles of this directive, the acquisition of practical experience outside the scope of the Radiation Protection Ordinance may be either fully or partially approved.

The acquisition of practical experience shall be certified pursuant to the factors listed in Appendix 4.

A 11.2 Legal expertise, theoretical knowledge and practical exercises in radiation protection

A 1 1.2.1 Radiation protection courses

Successful completion of one or more courses covering the full scope of radiation protection and approved by the competent authority provides the expertise necessary for the requisite expertise in radiation protection. In terms of length and content, all courses in radiation protection must comply with Appendix A 3.

Participation in a radiation protection basic course pursuant to Appendix A 3 number 1.1 is prerequisite to attending specialist courses.

A 1 1.2.2 Examination

A certificate pursuant to Appendix A 7.1 shall be issued, if course attendance was regular and the candidate has passed the concluding examination.

A 11.3 Requisite expertise licence

Training shall be documented by reports, practical experience (practical experience) by reports pursuant to Appendix A 4, and successful course participation by certificates. The competent authority under national law - usually the relevant regional medical association - shall examine and certify the acquisition of the requisite expertise in radiation protection pursuant to § 30 para. (1) of the StrlSchV. (see Chapter 3.1.2).

A 1 1.4 Period of validity and renewal

Licences in the requisite expertise in radiation protection must be renewed at least every 5 years by successful participation in a suitable course approved by the competent authority pursuant to Appendix A 3 number 1.5, or other further training measures deemed appropriate by the competent authority (§ 30 para. (2) StrlSchV; see also Chapter 3.1.2).

A 1 2 Requisite expertise and the different areas of application

A 1 2.1 Unsealed radioactive substances

A 1 2.1.1 Entire field (diagnostics and treatment)

- At least 36 months of practical experience in the application of unsealed radioactive substances on humans, of these at least 24 months spent in diagnostics and 6 months in treating with unsealed radioactive substances.

  Should the requisite expertise also include endovascular radiotherapy with unsealed radioactive substances, proofs must also be submitted concerning the acquisition of practical experience in this area and the necessary number of documented applications; this practical experience may be acquired concurrently within the 36 month period. In the licence issued pursuant to Appendix A 6, separate mention shall be made of the requisite expertise in this area.

- Number of documented applications: 2,200
  (pursuant to Appendices A 1 number 2.1.2 and A 1 number 2.1.5)

- Special radiation protection course in the handling of unsealed radioactive materials in nuclear medicine pursuant to Appendix A 3 number 1.2

A 1 2.1.2 Diagnostics (including tomographic techniques (PET, SPECT)

- At least 30 months spent acquiring practical experience in the application of unsealed radioactive substances during patient examinations

- Number of documented examinations: 2,000
  (suitably weighted, of these at least 500 involving PET technique)

- Special radiation protection course on the handling of unsealed radioactive materials in nuclear medicine pursuant to Appendix A 3 number 1.2

A 1 2.1.3 Organ-based diagnostics

- At least 18 months acquisition of practical experience in diagnostics involving unsealed radioactive substances, of these at least 12 months spent on the organ area in question; if extending to include other organ areas, 6 months on each

- Number of documented examinations:

a) Central nervous system	150
b) Skeletal and joint system	800
c) Cardiovascular system	500
d) Respiratory system	200
e) Gastrointestinal tract	50
f) Urogenital system	250
g) Endocrine organs	800
h) Haematopoietic and lymphatic system (including oncology and inflammation diagnostics)	400

- Special radiation protection course on the handling of unsealed radioactive materials in nuclear medicine pursuant to Appendix A 3 number 1.2

A 1 2.1.4 Nuclear medicine imaging diagnostics (e.g. PET/CT; without thyroid and in-vitro diagnostics) for persons who have already acquired the requisite expertise in radiation protection for the entire field of diagnostic radiology pursuant to the X-Ray Ordinance

- At least 24 months of practical experience in diagnostics using combined PET/CT examination techniques

- Number of documented examinations: 1,600
  (of these at least 800 not with PET or SPECT technique)

- Special radiation protection course on the handling of unsealed radioactive materials in nuclear medicine pursuant to Appendix A 3 number 1.2

A 1 2.1.5 Treatment (only in conjunction with Appendix A 1 number 2.1.2)

- At least 6 months practical experience in nuclear medicine treatment
- Number of documented applications: 200

  of these at least

  - benign thyroid disorders 100
  - malignant thyroid disorders 25
  - other malignant solid or systemic tumours and/ or benign disorders (including Appendix A 1 number 2.1.6) 10

A 1 2.1.6 Endoluminal, endovascular and endocavitary irradiation treatment using unsealed radioactive substances (e.g. SIRT, RSO, right balloon catheter) (only in addition to Appendices A 1 number 2.1.1 and A 1 number 2.1.5 respectively; see also knowledge group N6 in Appendix B number 5.38)

- Number of documented applications: 10

A 1 2.2 Radiotherapy (teletherapy, brachytherapy)

A 1 2.2.1 Entire area of radiotherapy

- At least 36 months practical experience in the field of radiotherapy including
  - at least 12 months experience of diagnostics and image-assisted therapy planning,
  - at least 18 months experience of applications using teletherapy devices: linear accelerators (at least 12 months; Appendix A 1 number 2.2.5) and gamma irradiation units,
  - at least 12 months experience of treatment with afterloading devices and sealed radioactive substances.

  Should the requisite expertise also include endovascular radiotherapy with sealed radioactive substances, practical experience in this area must amount to at least 3 months; this practical experience may also be acquired concurrently during the overall 36 month period. In the licence issued pursuant to Appendix A 6, separate mention shall be made of the requisite expertise in this area.

- Number of documented applications:

  - Therapy planning 200
  - Treatment 200
  - Brachytherapy 60

  (only in appropriate relation to all applications)

- Special course in teletherapy radiation protection pursuant to Appendix A 3 number 1.3
- Special course in brachytherapy radiation protection pursuant to Appendix A 3 number 1.4
- Practical experience and courses in therapy planning pursuant to Appendix A 1 number 2.2.6

A 1 2.2.2 Brachytherapy

- At least 24 months practical experience in brachytherapy including at least 12 months experience of applications using afterloading devices. In this instance up to 6 months of applications involving sealed radioactive substances for temporary application may be recognised.

Up to 6 months may also be recognised from a pre-existing licence in radiation protection knowledge.

- Number of documented applications: 60 (only in appropriate relation to all applications)

- Special course in brachytherapy radiation protection pursuant to Appendix A 3 number 1.4

- Practical experience and courses in therapy planning pursuant to Appendix A 1 number 2.2.6

A 1 2.2.3 Application of sealed radioactive substances for permanent implantation

- For the first organ area at least 18 months practical experience, including at least 9 months of therapy planning, production of differential diagnoses and care of patients in a radiotherapy institution; if extending to include other organ areas, at least 25 applications for each organ area

- Number of documented applications: 40 each
  - e.g. eye, skin, brain, prostate

- Special course in brachytherapy radiation protection pursuant to Appendix A 3 number 1.4

A 1 2.2.4 Endovascular radiotherapy with sealed radioactive substances

- At least 6 months practical experience of endovascular radiotherapy (may be acquired within a period of general practical experience pursuant to Appendix A 1 number 2.2.1)
- Number of documented applications: 25

- Special course in brachytherapy radiation protection pursuant to Appendix A 3 number 1.4

A 1 2.2.5 Teletherapy (ionizing radiation installations and gamma irradiation units)

A 1 2.2.5.1 Entire field of teletherapy

- At least 36 months practical experience in radiotherapy, including at least 12 months of therapy planning, as well as at least 12 months operating a gamma irradiation unit or ionizing radiation installation; proofs must be submitted to confirm that at least 6 months of the latter have been spent on an ionizing radiation installation

- Number of documented applications:

  - Therapy planning 200
  - Treatments 200

- Special course in teletherapy radiation protection pursuant to Appendix A 3 number 1.3

- Practical experience and courses in therapy planning pursuant to Appendix A 1 number 2.2.6

A 1 2.2.5.2 Organ-specific applications (e.g. brain)

- At least 18 months practical experience in the field of radiotherapy including at least 9 months therapy planning in the specific organ application area

- Number of documented applications: 40

- Special course in teletherapy radiation protection pursuant to Appendix A 3 number 1.3

A 1 2.2.5.3 New applications (e.g. treatments involving particle radiation)

Approval of the requisite expertise in radiation protection is issued by the competent authority on a case-by-case basis.

A 1 2.2.6 Therapy planning using CT for image-guided radiotherapy (IGRT using X-ray facilities), as well as simulation and verification

These provisions governing requisite expertise are defined in the X-Ray Ordinance directive *Knowledge and Know-how in Radiation Protection for the Operation of X-ray Facilities in Medical or Dental Practice* (Appendix B number 4.10).

A 2

A 2 1 Radiation protection expertise required by medical physics experts

The requisite expertise in radiation protection may be acquired by medical physics experts for the entire field or for the application areas of teletherapy, brachytherapy or nuclear medicine.

A 2 1.1 Training

A degree (diploma, master's or bachelor's qualification) in the field of science and technology from a college or university, as well as proof that the level of medical physics qualification specified in Appendix A 2. 3 has been achieved.

A 2 1.2 Hands-on experience (practical experience)

Acquiring practical experience over a minimum period of 24 months in

- using ionizing radiation installations,
- using gamma irradiation units,
- the application of sealed radioactive substances,
- afterloading devices or
- nuclear medicine

for human application. This minimum duration also applies if the requisite expertise is being acquired for only some of the application areas.

For applications seeking the approval of practical experience periods for the entire field, proof of

- at least 6 months nuclear medicine,
- at least 6 months brachytherapy (sealed radioactive substances or afterloading devices),
- at least 6 months teletherapy (ionizing radiation installations, gamma irradiation units)

must be submitted in certificate form pursuant to Appendix A 5. A maximum of 6 months working in X-ray diagnostics may be credited. The acquisition of practical experience is a full-time activity. In the case of part-time employment, the time spent acquiring practical experience lengthens accordingly.

In addition thorough knowledge of therapy planning, imaging and/or nuclear medicine is required. For activities with a nuclear medicine focus, knowledge must exist of imaging, dosimetry and radiotherapy using unsealed radioactive substances.

Moreover in individual cases, practical experience, relevant to the candidate's future occupation as a medical physics expert, gained either during or after training may be credited - to a reasonable extent - to the specified period of practical experience. This may, for instance, include radiation protection and dosimetry activities associated with ionizing radiation installations used in the practice of medicine on humans, gamma irradiation units and sealed radioactive substances used in the practice of medicine on humans, or ionizing radiation installations used for non-medical purposes.

The necessary practical experience in the application of X-ray radiation to humans may be acquired concurrently with the acquisition of practical experience specified in this section.

The competent authority pursuant to § 30 para. (1) sentence 3 of the StrlSchV may recognise the acquisition of practical experience arising from successfully completed master's degree courses. The authority may recognise periods of practical experience for which proofs have been furnished, if all the following conditions are met, namely

- no more than 1/5 of weekly teaching is dedicated to theory,
- hands-on (practical) experience is acquired under the guidance of mentors with comprehensive, long-term experience within the relevant specialist field,
- hands-on (practical) experience remains mandatory during university vacations, and statutory holidays (no more than 6 weeks) form the basis for any free time,
- students are involved as closely as possible in the relevant hospital working routines,
- acquisition of hands-on (practical experience) is recorded by the mentors,
- the university syllabus is approved as a radiation protection course for medical physics experts by the competent authority,
- a bachelor's degree in science/physics/technology was completed prior to the master's qualification and
- a course in radiation protection pursuant to Appendix A 3 number 1.1 or A 3 number 2.1 was completed prior to beginning the acquisition of practical experience.

A 2 1.3 Radiation protection courses

These are radiation protection basic and specialist courses pursuant to A 3 number 2.2 which address the relevant application areas pursuant to Appendix A 3, unless already covered during training.

A 2 1.4 Requisite expertise licence

Proof of the requisite expertise in radiation protection shall be confirmed by a certificate pursuant to § 30 para. (1) of the StrlSchV. This certificate shall be issued pursuant to Appendix A 6 by the competent authority.

If the medical physics expert only possesses the requisite expertise for partial areas (nuclear medicine, brachytherapy, teletherapy), he may acquire the requisite expertise for a missing area during an additional six month period of practical experience.

The requisite expertise acquired in accordance with this directive also includes knowledge of the handling of unsealed and sealed radioactive substances used within the context of quality assurance and radiation protection measurements.

Proof of the requisite expertise in radiation protection according to the prior provisions, as well as proof of training and experience in the new area of application, must be submitted for every new application area.

A 2 2 Duties of a medical physics expert (MPE)

Within the MPE's field of activity, he is responsible, among other things, for

- optimizing radiation applications, including patient dosimetry,
- providing any physical data required for the application of radiation,
- optimizing and elaborating the physical content of the therapy plan, and being involved in its implementation on patients,
- specifying the activities necessary - according to dosages determined by the physician - for the planning and implementation of radiation applications,
- monitoring diagnostic and therapeutic systems regularly with regard to the interaction of individual components and the precision of data transfer,
- developing and implementing quality assurance and quality control measures for all the components used in diagnostics and treatment and their interactions,
- constancy tests and monitoring repair and maintenance work,
- providing advice on radiation protection in the context of medical exposure,
- contributing to the development, supply and implementation of new examination and treatment methods,
- helping specify general technical requirements, including producing specification terms, and providing advice on the clinical application of units and devices,
- radiation protection-related safety procedures, as well as any necessary structural radiation protection measures,
- where relevant, being involved in postgraduate and on-going training, in radiation protection courses pursuant to Appendix A 3, as well as holding annual instruction sessions (Appendix A 8) pursuant to § 38 of the StrlSchV for physicians, medical technical assistants, and any other persons involved,
- providing induction courses for medical technical assistants in the operation of ionizing radiation installations,
- radiation protection relating to waste, exhaust air, and waste water disposal,
- performing the duties and complying with the safety-related intention and the radiation protection requirements of the German Medical Devices Act (MPG),
- being involved in a responsible capacity in the planning, application and optimization of medical/physical and medical/technical examination and treatment methods,
- assisting in the design of information and archiving systems, as well as radiation protection planning for new hospital facilities.

A 2 3 Required qualifications for medical physics experts

The requisite level of qualification is reached when specialist knowledge can be proven to exist in all the areas listed below. In the process the depth of specialist knowledge achieved must be commensurate with the level taught in a master's degree course in medical physics.

A.) Basic knowledge

Anatomy
Biochemistry
Biophysics
Medical information technology, biomathematics
Physiology, including pathophysiology
Legal principles
X-ray diagnostics, other imaging methods used in medicine
Radiobiology
Radiophysics

B.) Specialist knowledge of the desired area requiring radiation protection knowledge and basic knowledge of the various other areas

- Application area: nuclear medicine

Biokinetic radio-labelled substances, determining organ doses
Biological effects of radiation and toxicity from radio-labelled substances
Data acquisition and processing in nuclear medicine
Emission tomography using gamma rays (SPECT)
Gamma camera systems
Basic principles of nuclear medicine applications (radiopharmaceuticals)
Production of radionuclides (cyclotrons, reactors, generators)
In vivo examination methods
Nuclear medicine treatment and intratherapeutic dosage measuring
Basic physics of nuclear medicine
Planning and equipping nuclear medicine departments
Positron emission tomography (PET)
Quality control and quality assurance
Patient and staff radiation protection
Radiation measuring techniques and dosimetry

- Application area: radiotherapy

Irradiation units for teletherapy and brachytherapy
Irradiation field verification techniques and treatment imaging techniques
Therapy planning and simulation
Irradiation techniques to achieve specific dose distributions within the body
Biological effects of radiation and toxicity associated with radiotherapy
Ionizing radiation dosimetry; measuring technique; clinical dosimetry
Optimization of dose distribution within the body, application of biological models

Basic physics of radiotherapy
Planning and equipping radiotherapy departments
Quality assurance including verification and logging systems
Patient and staff radiation protection
Tumour localization techniques
Dose and dosage distribution calculation techniques

C.) Knowledge of imaging and image processing in medicine

Image distortion, artefacts
Image analysis
Image presentation
Image transmission and networking technologies
Data acquisition and data protection
Digital filtering
Digitalization of image information
Grey value distribution, statistical parameters
Basic imaging method terminology
Image quality parameters, testing methods, quality assurance
Mathematical image processing methods
Reconstruction techniques and visualizations
Standard digital image communication protocols, data compressions
Digital image archiving systems

A 3 Courses for acquiring and updating requisite expertise and requisite know-how in radiation protection

All course durations given below in hours relate to tuition periods lasting 45 minutes. The following topics comprise the main syllabus elements of the various courses. Moreover, current topics or demonstrations related to the course syllabus that are not mentioned here may also be taken into account.

When combining courses, thematic overlap may enable the competent authority to recognise an appropriate reduction in the total number of required study hours.

A 3 1 Radiation protection courses for physicians seeking work pursuant to Appendix 1

A 3 1.1 Radiation protection basic course pursuant to the StrlSchV and RöV

- Aim: The basic course provides the basics in radiation protection for all medical applications of ionizing radiation and radioactive substances; the syllabuses of the specialist courses build on this basis.
- Duration (including exercises) at least 24 hours

A 3 1.1.1 Basics of radiophysics

(1) The genesis and characteristics of ionizing radiation
(2) The effect of radiation on matter
(3) Basic radioactivity terminology

A 3 1.1.2 Basics of radiobiology, including the effects of small radiation doses

(1) LET and RBE
(2) Effects of radiation on DNA, repair, cells, cell cycle,
cell survival curves
(3) Effects of radiation on tissue and organs; tumour tissue
(4) Radiation damage; stochastic, deterministic and teratogenic radiation damage

A 3 1.1.3 Dosage terminology and dosimetry

(1) Dose sizes and dose units
(2) Basic dosimetry terminology
(3) Dosage measuring techniques

A 3 1.1.4 Radiation protection basics and basic principles (staff, general public and patients)

A 3 1.1.5 Human radiation exposure derived from natural and civilisation-related sources

A 3 1.1.6 Legal provisions and recommendations relating to radiation protection, requisite expertise in radiation protection, technical regulations, regulations concerning accident situations and incidents

A 3 1.2 Specialist radiation protection course for the handling of unsealed radioactive materials in nuclear medicine

- Aim: To provide specialist radiation protection knowledge relating to the handling of unsealed radioactive substances in nuclear medicine; also addresses the need for a justifying indication and details the position of radiation protection expert
- Duration (including exercises) at least 24 hours

Course attendance depends on certified completion of the basic course pursuant to Appendix A 3 number 1.1.

A 3 1.2.1 Radioactive substances in medicine

A 3 1.2.2 Radiopharmaceuticals and their quality assurance

A 3 1.2.3 Dosimetry and dosage calculation

A 3 1.2.4 Radiation protection in the application of unsealed radioactive substances

(1) Supplying the justifying indication, alternative techniques
(2) Optimising the procedure

A 3 1.2.5 Radiation protection monitoring and records

A 3 1.2.6 Staff, patient and environmental radiation protection

A 3 1.2.7 Storage, transportation and disposal of radioactive substances

A 3 1.2.8 Quality assurance of methods and devices

A 3 1.2.9 Special legislation, guidelines, recommendations, technical code

A 3 1.2.10 Behaviour in the event of accidents and incidents, reporting requirements

A 3 1.2.11 Instruction of staff

A 3 1.3 Specialist teletherapy radiation protection course

- Aim: To provide specialist radiation protection knowledge relating to teletherapy; also addresses the need for a justifying indication and details the position of radiation protection expert
- Duration (including exercises) at least 28 hours

Course attendance depends on certified completion of the basic course pursuant to Appendix A 3 number 1.1.

A 3 1.3.1 Design and function of medical irradiation apparatus

A 3 1.3.2 Technical features of teletherapy units

(1) Operating and safety systems
(2) Essential equipment

A 3 1.3.3 Basic radiotherapy terminology

(1) Therapy plan as it relates to patient protection
(2) Therapy planning
(3) Irradiation simulation
(4) Recording and clarification
(5) Verification

A 3 1.3.4 Dosimetry and physical therapy planning

A 3 1.3.5 Radiation protection in teletherapy

(1) Staff protection
(2) Patient protection
(3) Structural and equipment-based radiation protection

A 3 1.3.6 Radiation protection monitoring and records

(1) Staff
(2) Patients
(3) Leakage test
(4) Technical monitoring measures

A 3 1.3.7 Effects and side effects of radiation in teletherapy

(1) Tolerance doses
(2) Personal sensitivity to radiation, including interactions with drugs
(3) Deterministic and stochastic consequences of radiation
(4) Monitoring treatment success

A 3 1.3.8 Instruction of staff

A 3 1.3.9 Medical treatment methods

(1) Supplying the justifying indication, alternative techniques
(2) Optimising the procedure

A 3 1.3.10 Quality assurance of methods and devices

A 3 1.3.11 Special legislation, guidelines, recommendations, technical code

A 3 1.3.12 Regulatory procedures and monitoring, reporting requirements

A 3 1.3.13 Behaviour in the event of accidents and incidents

A 3 1.4 Specialist brachytherapy radiation protection course (irradiation units, applications involving sealed radioactive substances, and endovascular radiotherapy)

- Aim: To provide specialist radiation protection knowledge relating to brachytherapy; also addresses the need for a justifying indication and details the position of radiation protection expert
- Duration (including exercises) at least 18 hours

Course attendance depends on certified completion of the basic course pursuant to Appendix A 3 number 1.1.

A 3 1.4.1 Treatment equipment and methods used

A 3 1.4.2 Basic principles of brachytherapy

(1) Therapy plan as it relates to patient protection
(2) Therapy plan
(3) Treatment simulation
(4) Recording and clarification
(5) Verification

A 3 1.4.3 Dosimetry

A 3 1.4.4 Radiation protection in brachytherapy

(1) Protective measures
(2) Patient radiation protection
(3) Structural and equipment-based radiation protection

A 3 1.4.5 Radiation protection in the application of sealed radioactive substances

(1) Protective handling measures
(2) Patient radiation protection
(3) Structural radiation protection
(4) Selection criteria for sealed radioactive substances used
(5) Special regulations concerning high-activity radiation sources (German HRQ register)

A 3 1.4.6 Radiation protection during endovascular radiotherapy

(1) Protective handling measures
(2) Patient radiation protection
(3) Structural and equipment-based radiation protection

A 3 1.4.7 Radiation protection monitoring and records

(1) Staff
(2) Patients
(3) Leakage test
(4) Technical monitoring measures

A 3 1.4.8 Radiation exposure and the risk to patients, staff and the environment

(1) Methods of determining radiation exposure
(2) Staff radiation exposure
(3) Patient radiation exposure
(4) Other persons and radiation exposure

A 3 1.4.9 Storage, transport, release, return, discharge or removal of radioactive substances

(1) Regulations
(2) Devices and equipment
(3) Records

A 3 1.4.10 Instruction of staff

A 3 1.4.11 Quality assurance of methods and devices

A 3 1.4.12 Special legislation, guidelines and technical code

A 3 1.4.13 Regulatory procedures and monitoring

A 3 1.4.14 Behaviour in the event of accidents and incidents

A 3 1.5 Radiation protection refresher course for physicians

- Pursuant to § 30 para. (2) of the StrlSchV, the requisite expertise must be updated at least every 5 years (see Chapter 3.1.6).

  - Aim: Update knowledge, learn about new radiation protection developments and regulations
  - Duration: 8 hours
  - Course content: Current course content pursuant to A 3 nos. 1.1 - 1.4, update basic knowledge

A 3 2 Radiation protection courses for medical physics experts

A 3 2.1 Radiation protection basic course

- Aim: To provide the basics in radiation protection for all medical applications of ionizing radiation and radioactive substances; the syllabuses of the specialist courses build on this basis.
- Duration (including exercises): at least 24 hours
- Course content: Pursuant to Appendix A 3 number 1.1

A 3 2.2 Specialist radiation protection course for medical physics experts covering all application areas pursuant to the StrlSchV

- Aim: To provide specialist radiation knowledge with a particular focus on the quality assurance of radiation medicine applications and the position of radiation protection expert
- Duration (including exercises): at least 48 hours
- Course content: Pursuant to Appendix A 3 nos. 1.2 - 1.4 while taking into account the requisite radiation protection know-how of this occupational group

Alternatively, successful attendance at all courses pursuant to Appendix A 3 nos. 1.1 - 1.4 may be approved.

A 3 2.3 Radiation protection requisite expertise refresher course for medical physics experts

Pursuant to § 30 para. (2) of the StrlSchV, the requisite expertise must be updated at least every 5 years (see Chapter 3.1.6).

- Aim: Update knowledge, learn about new radiation protection developments and regulations
- Duration: 8 hours
- Course content: Current course content pursuant to Appendices A 3 nos. 1.1 - 1.4 or A 3 nos. 2.1 – 2.2, update basic knowledge

A 3 3 Radiation protection requisite expertise refresher course for MTRAs pursuant to Chapter 3.1.7 of this directive

Pursuant to § 30 para. (2) of the StrlSchV, the requisite expertise must be updated at least every 5 years (see Chapter 3.1.6).

- Aim: Update knowledge, learn about new radiation protection developments and regulations
- Duration: 8 hours
- Course content: Current course content pursuant to Appendices A 1 and A 2, update basic knowledge

A 3 4 Other elements of radiation protection training

A 3 4.1 Requisite radiation know-how for physicians without the requisite expertise in radiation protection

Successful attendance at a radiation protection basic course pursuant to Appendix A 3 number 1.1 and the additional acquisition of practical experience (4 hours) in specialist application areas (e.g. assistant doctors acquiring practical experience pursuant to § 81 para. (1) number 2 StrlSchV, radiologists for selective internal radiotherapy (SIRT), urologists for prostate seeding). This know-how shall be taught with particular reference to the specific working conditions and associated technical equipment. This

may take the form of workplace instruction carried out by a radiation protection expert or a suitable person authorised to do so by the former.

A certificate pursuant to Appendices A 7 number 1 and A 7 number 2 shall be issued.

A 3 4.2 Teaching the requisite radiation protection know-how for the involvement of other persons in SLN diagnostics (physicians charged with conducting operations, e.g. surgeons, dermatologists, urologists, gynaecologists)

- Aim: Teaching the requisite know-how in radiation protection to enable involvement
- Duration (including exercises): at least 6 hours
- Content

(1) Introduction to the method
(2) Legal principles
(3) Basics of nuclear medicine
(4) Physics and radiation protection
(5) SLN gamma probes
- quality characteristics and requirements

- Exercises:
  - Implementation of quality assurance measures
  - Phantom readings

A 3 5 Requisite radiation protection know-how course for persons (Chapter 5.2.2.e) who have successfully completed other medical education

- Aim: To provide the requisite know-how in radiation protection to enable technical involvement
- Duration: at least 40 hours, of these at least 20 hours of practical exercises on site. Course attendance must be regular and the course completed successfully.
- Theory content: Teaching of radiation protection know-how for persons pursuant to Chapter 5.2.2 letter e of this directive

Basics of radiation physics

(1) The genesis and characteristics of ionizing radiation
(2) The effect of radiation on matter
(3) Basic radioactivity terminology

Dosage terminology and dosimetry

(1) Dose sizes and dose units
(2) Basic dosimetry terminology
(3) Dosage measuring techniques
(4) Activity including activity determination

(5) Measuring and verification procedures

Radiation protection in the application of radioactive substances

(1) Risk and risk assessment
(2) Staff radiation protection
(3) Structural and equipment-based radiation protection
(4) Contamination and decontamination
(5) Incorporation and decorporation
(6) Contamination and incorporation monitoring
(7) Determining patient and staff radiation exposure

Radiation exposure and the risk to patients, staff and the environment

Conduct and the prevention of accident situations

Special legislation, technical code, recommendations

Radiation protection and quality assurance exercises relating to the application of radioactive substances to patients in the medical field

A certificate pursuant to Appendix A 7 number 2 shall be issued.

A 3 6 Requisite radiation protection know-how refresher course for persons (Chapter 5.2.2.e) who have successfully completed other medical education

- Aim: To update the requisite know-how in radiation protection (Chapter 3.2.6.)
- Duration: 4 hours
- Course content: Current course content pursuant to Appendix A 3 number 5

A 3 7 Approval of courses/further training measures and organisers' duties

Upon written application by the organisers, the competent authority may recognise courses as contributing to the acquisition of the requisite expertise in radiation protection, and specific further training measures to its update. Once a course has been approved by the competent authority, its organisers may issue certificates of attendance pursuant to Appendix A 7. A minimum framework for the approval of courses can be found in the Requisite expertise in Radiation Protection: Approval of Courses circular issued by the Federal Ministry for the Environment (Appendix B number 4.15).

Attendance-based courses

Course organisers shall submit the following details to the competent authority:

a) A course syllabus featuring the content listed in Appendix A 3 and giving details of the course duration and the content of modules, as listed in Appendix A 3. Details of course content shall be submitted in the form of manuscripts, at the very least in the form of keywords. For events lasting several days, tuition per day shall not exceed ten hours. If the radiation protection courses cannot be scheduled successively, suitable provision should be made for refresher modules. Courses that are thus separated shall not exceed a total duration of more than 12 months.

   Refresher courses shall be held in a maximum of two tuition blocks, not more than three months apart. The requisite update must be completed within the 5 year period.

b) Courses shall be held in suitable venues featuring the necessary equipment.

c) Suitably up-to-date written teaching materials shall be provided. Teaching materials shall include lecture notes, source reference lists referring to regulations, technical standards and directives, and other documents containing illustrations, tables, diagrams and formulae that course participants will need in their future work.

d) The course shall be conducted by instructors with the requisite up-to-date specialist knowledge. Professional experience, time spent teaching to date, and membership of specialist committees are all taken into account.

e) Attendance on the course shall be recorded and success monitored by means of a final examination. The examination criteria shall be established in advance.

f) The course instructor shall be responsible for ensuring the course takes place, acting as contact person for course participants for the duration, and making sure that any questions posed are expertly answered.

Other further training measures

The competent authority may recognise seminars, workshops and conferences as further training measures aimed at updating the requisite expertise in radiation protection, if the programme of events clearly states which subjects essential to an update are covered and the conditions a.) to f.) listed above for attendance-based courses are fulfilled.

The organisers' on-going responsibilities

a) The quality of content and teaching shall be assessed by the course participants. The organisers shall analyse the assessments and ensure that any deficiencies are eliminated.

b) The organisers shall establish participant identities and use registers to record regular attendance. In duly justified, exceptional cases, a maximum absence of 10% shall be permitted.

c) The general level of prior knowledge to be expected from participants on the course in question shall determine how the course syllabus is to be taught.

A 4 Certification of practical experience (hands-on experience) in radiation protection for physicians

A complete record of approved periods of practical experience should be maintained, especially if said experience is acquired at a number of different institutions. The following certificates shall be submitted:

- Submission of the certificate of requisite expertise in radiation protection issued by the instructor for the appropriate application area.
- Submission of other certificates, if practical experience was acquired in a context other than residency

Although the design of the certificate is not regulated, it should nevertheless include the following aspects.

The certificate should be divided into three sections and feature the following details:

General information

- Proof of occupation and periods of employment in the different application areas pursuant to Appendix A 1.
- Proof that the requisite practical experience was acquired in the time and manner foreseen (clarifying statement made by course instructor: "Under my expert guidance and responsibility, xx has …").
- Information as to whether the practical experience was acquired in one or in a number of institutions. In the latter instance, a certificate corresponding to the guidelines set out here should be requested from each of the specialist departments involved.
- Details of any prior knowledge and training in the area of ionizing radiation within medicine.
- Details concerning the duration and type of activities which have contributed to the acquisition of practical experience in the relevant field of application and a description of the number of applications, type of examinations and technical equipment used with relation to the application of radioactive substances or ionizing radiation on humans.

Details of special activities

This section should only feature those activities directly related to the acquisition of practical experience. In the case of the first four application areas listed below, details shall be given of the frequency of examinations and treatment measures conducted independently:

- Acquisition of practical experience in the use of unsealed radioactive substances during human examinations, including details of the radioactive substances, examination procedures, and evaluation methods used.
- Acquisition of practical experience in the use of unsealed radioactive substances in human treatment, including details of the radioactive substances used, the types of treatment, and the dose calculations.
- Acquisition of practical experience in treatments involving the use of sealed radioactive substances, including details of the type of treatments conducted and the dose calculations.
- Acquisition of practical experience in the field of radiotherapy involving the use of ionizing radiation installations, gamma irradiation units, and afterloading devices, including details of the localization methods, type of treatments, and quality assurance programmes used.
- Know-how of the physical and radiobiological basics relating to the application of ionizing radiation in medicine.
- Any other details related to further training or the acquisition of practical experience, e.g. participation in tuition or lectures, attendance at further training courses and special events, publications etc.

Final assessment

Final assessment as to whether the candidate - in the opinion of the physician(s) responsible for monitoring the acquisition of practical experience in radiation protection - possesses the necessary know-how and experience that are prerequisite to being granted a licence in requisite expertise.

Certificate issuer's signature; date

A 5 Certification of practical experience (hands-on experience) in radiation protection: medical physics experts and other radiation protection experts

It is recommended that individuals maintain a complete record of approved periods of practical experience, especially if said experience is acquired at a number of different institutions.

Although the design of the certificate is not regulated, it should nevertheless take the following aspects into account.

The certificate should be divided into three sections and feature the following details:

General information

- The areas in which the instructor works where the training took place or practical experience was acquired.
- Details of activities during the candidate's vocational training or following its conclusion.
- Details of the duration and type of activity in the relevant application area, in which unsealed or sealed radioactive materials were handled, or which included the operation of ionizing radiation installations.
- Proof of employment in medical fields, e.g. in hospitals.
- Details as to whether training, further training, or the acquisition of practical experience took place at a single institute, a single department, or in a number of departments. In the latter instance, a certificate should be requested from each of the departments involved.

Details of special activities

This section should only feature those activities directly related to the acquisition of practical experience. In the case of the first three application areas listed below, details shall be given of the frequency of measurements, quality controls, scientific activities, technical examination and treatment assistance etc. conducted independently:

- Acquisition of practical experience in the application of sealed radioactive substances or in the operation of ionizing radiation installations, gamma irradiation units, and afterloading devices, giving details of the work areas and tasks completed, the type of irradiation technique applied, the dose calculation method, quality assurance techniques, or any other activities.
- Acquisition of practical experience in the production or application of unsealed radioactive substances in medicine, giving details of the tasks conducted and application areas involved.

- Relevant activities in other fields of medicine.
- Know-how of physical and radiobiological radiation protection basics.
- Other details relating to the handling of radioactive materials or ionizing radiation, such as any involvement in tuition or lectures, participation in further training courses and special events, scientific activities, publications, etc.

Final assessment

Final assessment as to whether the candidate - in the opinion of the instructor responsible for training and the acquisition of practical experience in radiation protection respectively - possesses the necessary know-how and experience that are prerequisite to being granted a licence in requisite expertise.

Certificate issuer's signature; date

A 6 Sample certificate for the requisite radiation protection knowledge or requisite radiation protection know-how in medicine

Competent authority including address

Implementation of the Radiation Protection Ordinance - StrlSchV
Certificate of the requisite expertise in radiation protection/know-how in radiation protection

Pursuant to § 30 para. (1) of the StrlSchV

Ms/Mr*)

first name, surname .....
occupation.....

.....

born on ....., in .....

has acquired the requisite expertise/know-how*) in the following application area/following application areas*) pursuant to Appendix A 1/Appendix A 2*) of the "Radiation Protection in Medicine" directive.

.....

.....

.....
If requested, this certificate shall be submitted to the competent authority.
Pursuant to § 30 para. (2) of the Radiation Protection Ordinance, the requisite expertise in radiation protection must be updated within 5 years of certification.

…….

(place, date, signature) *) delete as appropriate

A 7

A 7 1 Sample certificate verifying attendance at a course in medical radiation protection

Certificate

Mr/Ms .....

born on.....

in.....

has regularly attended the following course in medical radiation protection and passed the final examination:

.....

.....

(course description and duration)

at.....

.....

(institution)

Pursuant to the "Radiation Protection in Medicine" directive and § 30 para. (3) of the StrlSchV, the course was approved by the following competent authority

……. under the serial number : …….. .

(place).....

(date).....

.....

(signature of course instructor)

A 7 2 Sample certificate verifying attendance at a course to acquire the requisite know-how in radiation protection

for persons pursuant to Chapter 3.2.2 and 3.2.4 of this directive
(§ 30 para. (4) sentence 2 in conjunction with § 30 para. (1) StrlSchV)

Certificate
Mr/Ms .....

born on.....

in.....

has regularly attended a course at.....

.....
(institution)

with practical instruction as necessary, to acquire the requisite know-how in radiation protection.

……
(course description and duration; e.g. SIRT etc.)

……
Subject matter and content

(place).....

(date).....

.....

(signature of course instructor responsible)

A 8 Contents of instruction provided prior to beginning and during work in radiation protection areas

A 8 1 Instruction pursuant to § 38 of the StrlSchV

The persons named in Chapter 4.4.1 require instruction. This shall be provided by a radiation protection expert or by a person appointed by him to do so.
Oral instruction shall be given on the specific basis of the radiation protection instructions issued for the operation in question (§ 34 StrlSchV). The operating procedures and radiation protection requirements of major significance to the work in question must be addressed. Generally such instruction is supplemented by practical training at the workstation. If no other requirement has been issued by the competent authority, instruction shall be repeated on an annual basis. Participation shall be confirmed by signature; the nature of the instruction and the topics covered shall be recorded. The person conducting such instruction shall also be considered as instructed.

A 8 2 Sample topics for initial or repeat instruction on the basis of the individual location-specific situation

A 8 1 General

- Licence content
- Operative radiation protection organisation
- Supervisors and their fields of activity
- Radiation Protection Ordinance and instructions (notice)
- Medical monitoring, participation in instruction, existing methods for measuring personal doses
- Utilization and processing of personal data
- Record-keeping requirements

A 8 2.2 Induction in operative radiation protection for the activity in question

A 8 2.3 Applicable protective measures when handling unsealed radioactive substances and the application of ionizing radiation respectively

- Conduct and measures in the event of significant safety-related events
- Prohibited activities
- Protection of air, water and soil
- Radiation protection measuring devices, personal dosimetric monitoring
- Emergency rescue of patients

A 8 2.4 Special topics associated with the handling of radioactive substances

- Special working practices

- Radiation protection measuring devices and conducting measurements
- Quality controls
- Order, delivery, storage and inventorizing of radioactive substances
- Waste disposal and transfer
- Safeguards against loss of actual control (loss or theft) of unsealed and sealed radioactive substances

Facility features and quality assurance

A 9 Equipment required for the operation of ionizing radiation installations, gamma irradiation units and plant used for generating other types of radiation applied in medicine (e.g. heavy ions or protons)

The equipment listed should enable the radiation protection supervisor or radiation protection expert to conduct irradiation pursuant to the latest advances in medical science, to guarantee the requisite radiation protection, to carry out practical checks on operationally relevant specifications following maintenance and repairs, and to localise malfunctions quickly. Depending on the specific individual circumstances (type of ionizing radiator installation or gamma irradiation unit, irradiation methods, quantity of irradiated patients) the equipment may also be subject to additional requirements. The equipment listed here represents a minimum which may be adapted as necessary to the individual circumstances of the relevant location.

To maintain the quality assurance of X-ray facilities used in radiotherapy, access to the necessary measuring devices, aids and appliances must be ensured at all times.

A 9 1 Radiation protection

- Radiation measuring apparatus used to record the quantity of radiation protection-relevant radiation and their types that occur during the correct operation of ionizing radiation installations or gamma irradiation units
- Additional devices for neutron irradiation units designed to calculate the quantity of activated radioactive substances, and record contamination caused by beta and gamma-radiation emitting radionuclides

A 9 2 Dosimetry and therapy planning

- Two ionization dosimeters pursuant to DIN EN 60601-2-1 for dosimetric activities associated with ionizing radiation installations and to measure patient and phantom dosages and dose distribution
- Suitable measuring equipment designed to perform electron energy constancy tests on electron therapy units
- Two pairs of dosimeters for neutron irradiation units, each with one neutron-sensitive and one neutron-insensitive detector
- Devices for measuring and recording dosage distribution in a water phantom of sufficient expansion with remote-controlled detector motion (in three planes, paired vertically in stacks), suitable for measurements involving pulsed radiation and medium-dose intermittent radiation, with automatic isodose measuring and recording functions
- Access to tissue-equivalent phantoms for dosimetric purposes

- Film dosimetry equipment including densitometers
- Measuring equipment for conducting geometric beam parameter constancy tests
- Measuring equipment for assuring the quality of dynamic, fluence-modulating, ionizing radiation installation components
- Localisation devices for determining the topography of the body section to be irradiated
- Access to imaging systems for the production of cross-sectional images e.g. CT
- Imaging systems for monitoring the correct irradiation position and for scanning at treatment distance to produce measurements
- Therapy planning documents
- Access to a computer-assisted therapy planning system
- Access to a mechanical workshop for the production of customised patient-specific absorbers, positioning and securing aids, as well as an electrical workshop, including technical staff, customised to the demands of the technical equipment in question and the irradiation methods used
- Other suitable devices, respectively, which enable compliance with measuring and recording targets.

A 9 3 Written documents

- Operating instructions in German
- Device manuals
- Legal provisions and guidelines
- Technical code (standards, recommendations)

A 10 Equipment required for the operation of afterloading devices

The equipment listed should enable the radiation protection supervisor or radiation protection expert to guarantee the requisite radiation protection, to carry out practical checks on operationally relevant specifications following maintenance and repairs, and to localise malfunctions quickly. Depending on the specific individual circumstances (type of afterloading device, irradiation method, quantity of irradiated patients) the equipment may also be subject to additional requirements.

A 10 1 Radiation protection

- Portable dosimeter for measuring local dose rates
- Shielding device for radiation source storage in the event of a malfunction

A 10 2 Dosimetry and therapy planning

- Localisation device for determining the position of applicators in relation to critical organs and specific anatomical points
- Access to diagnostic X-ray equipment for applicator monitoring and positioning, with the possibility of reconstructing the position of the applicators and the body-specific points (orthogonal, semi-orthogonal, isocentric, semi-isocentric, or stereo-imaging)
- Computer-assisted therapy planning system or therapy planning documents, adequate for the relevant applicators and irradiation techniques
- These documents also need to include isodose plans for the relevant applicators and irradiation programmes, as well as specific instructions concerning the reconstruction of applicator positions.
- Dosimetry system for measuring dose rates, doses and patient dosage distributions
- Access to a dosimetry system for monitoring the reference dose rate or equivalent activity
- Device for monitoring the position of the radiation source within the applicator

A 10 3 Written documents

- Operating instructions in German
- Device manuals
- Legal provisions and guidelines
- Technical code (standards, recommendations)

A 11 Minimum scope of in-house technical quality assurance monitoring for ionizing radiation installations, gamma irradiation units, brachytherapy units, sealed radioactive substances, and plant used for generating other types of radiation used in medicine (e.g. heavy ions or protons)

A 11 1 General

The minimum scope compiled here is limited to general information. Depending on the individual circumstances associated with the ionizing radiation installation, gamma irradiation unit, or afterloading device, as well as the experience gained, it may be necessary to increase the frequency of monitoring. In the case of entire systems, it is necessary to check not only the entire system, but each component individually (Appendix B number 5.35). In addition attention must be paid to the transfer of data between the components and the software used.

DIN, DIN EN and DIN IEC standards specify the functions to be checked, the testing procedures and quality assurance requirements, thus providing a basis for all technical monitoring activities. New device components not yet included in DIN or IEC standard specifications shall be subject, by way of analogy, to correspondingly appropriate monitoring activities produced internally for the purpose.

A 11 1.1 Safety devices

Daily safety circuit checks, if accessible to operating staff:

- Monitoring functions which switch off the radiation
- Control functions, where relevant, for monitoring moving field radiotherapy

A 11 1.2 Therapy planning system

Performance testing of the entire system: the scope of the test is described in DIN 6873-5, as well as in other DIN EN and DIN IEC standards.

A 11 1.3 Localisation devices (X-ray imaging devices, treatment simulators, computer tomographs)

Monitoring of all parameters that have an impact on the precision of determination of topography. Tests should be based on DIN 6847-5, while referencing DIN EN 61168. They are described in the DEGRO “Constancy tests on treatment simulators” directive (Appendix B number 4.4).

A 11 1.4 Tomographic techniques used in therapy planning

- Constancy test pursuant to the German X-ray Ordinance
- Monitoring of image precision
- Hounsfield unit density allocation check
- Check for metric precision of the digital position sizes displayed
- Check for any deviation from positioning aids (e.g. laser systems)

A 11 2 Special provisions concerning ionizing radiation installations

The scope of testing is laid out in DIN 6847-5.

A 11 3 Special provisions for gamma irradiation units

The scope of testing is laid out in DIN 6846-5.

A 11 4 Special provisions for afterloading devices

The scope of testing is laid out in DIN 6853-5.

A 11 5 Special provisions for stereotactic radiotherapy using ionizing radiation installations

The scope of testing is laid out in DIN 6875-2.

A 11 6 Special provisions for stereotactic radiotherapy using gamma irradiation units

The appropriate tests shall be conducted in line with the manufacturer's specifications. At the same time, the relevant recommendations and guidelines (latest technological standards) shall be observed.

A 11 7 Special provisions for endovascular radiotherapy

The appropriate tests shall be conducted in line with the manufacturer's specifications. At the same time, the relevant recommendations and guidelines (latest technological standards) shall be observed.

A 12 Radiation protection measuring devices – selection criteria

a) Radiation protection measuring devices must
b) fulfil the measuring purpose requirements,
c) be available in sufficient quantity and
d) be checked and maintained at least every three months for display accuracy in accordance with manufacturer specifications - more often if a malfunction is suspected.

The date and the result of the performance test and any maintenance shall be recorded. These records shall be kept for 10 years and submitted to the competent authority upon request or stored in a location stipulated by the latter. Responsibility for the radiation protection measuring devices shall be stipulated in writing as part of the radiation protection instructions. With regard to the type of radiation being measured, the radiation protection measuring devices need to fulfil certain requirements.

Prior to their procurement, the following questions shall serve as selection criteria:

- What type of radiation is going to be measured? Should the measuring device be sensitive to alpha, beta, gamma, or neutron radiation, to combinations of several radiation types or to pulsed radiation?
- Will it be used to measures dose, (sieverts), dose rates (sieverts/h) or activitiy (Becquerels)?
- What form does the radioactive substance take (solid, liquid, gaseous, aerosol)?
- What is the level of radiation energy (keV or MeV)?
- What fluence* is going to be measured?
- What energy resolution is required of the radiation detector?
- What degree of measuring accuracy is required?
- How much time is available for measuring?
- Under what environmental conditions is the measuring device to be used?

* Number of particles or photons that intersect a unit area during a specified time interval.

A 13 Examples of significant changes relating to ionizing radiation installations requiring re-inspection by a professional expert, pursuant to § 66 of the StrlSchV

Pursuant to § 66 para. (1) of the StrlSchV, any major changes made to ionizing radiation installations generally require re-inspection by a professional expert nominated by the competent authority. Here are some examples:

• Beam guidance:	replacement of accelerator tubes
• Beam geometry:	upgrading of multileaf collimators
• Control program:	new version number (first digit)
• Program expansion:	virtual wedge (e.g. in the case of IMRT)
• Operating changes:	additional electron operations
• Structural radiation protection:	change in material composition, material thickness, structural re-design (e.g. removal of walls, replacement of doors, change in designated use of adjacent rooms)

A 14 Sample patient information sheet issued following examinations involving unsealed radioactive substances

Name of hospital/physician
Address

Medical application of unsealed radioactive substances

Ms/Mr ..... born on.....

in.....

current address .....

was, on ....., in .....
.....(hospital/practice)

subjected to an examination involving unsealed radioactive substances.

Type of examination: .....

Radiopharmaceutical applied:.....

Activity: ……..……..MBq

For queries please contact:

Attending physician: .....Phone number: .....

Date, signature .....

This information sheet may also be submitted prior to subsequent examinations.

Sanitary items (e.g. sanitary pads, tampons) must be amassed separately from normal household waste until …… . Only once this deadline has passed may sanitary items be disposed of along with the household waste.

A 15 Sample patient information sheet issued following treatment involving unsealed radioactive substances

Name of hospital/physician
Address

Medical application of unsealed radioactive substances

Ms/Mr ..... born on.....

in.....

current address .....

was, on ....., in .....
.....(hospital/practice)

subjected to treatment involving unsealed radioactive substances.

Type of treatment: .....

Radiopharmaceutical applied:.....

Activity: ……..……..MBq

Average dose at a distance of 2 metres from patient, presence continuous, mSv

Dose rate upon discharge, at 2 metres distance from patient: .....µSv/h

For queries please contact:

Attending physician: .....Phone number: .....

Date, signature .....

This information sheet may also be submitted prior to subsequent examinations.

Sanitary items (e.g. sanitary pads, tampons) must be amassed separately from normal household waste until …… . Only once this deadline has passed may sanitary items be disposed of along with the household waste.

A 16 Sample patient leaflet issued following treatment involving unsealed radioactive substances

(Hospital, department, address)

(Name and phone number of attending physician, nominated as radiation protection expert)

Dear patient,

Owing to the treatment you underwent in hospital, you still have radioactive substances in your body. These are emitting low levels of radiation. Over time these radioactive substances will either be excreted from your body or will lose their radioactivity. This process is generally concluded within a few days or weeks. Radiation which has been used to heal you, however, may endanger those around you. So, just in the way we don't give medicine to people who are healthy, it's important we avoid exposing these people to radiation, however minimal it may be. These individuals can be affected by direct radiation, yet they may also come into contact with radioactive substances excreted by your body.

To protect your relatives and those around you, we request that you

adhere to the following precautionary measures until this date …….:

- Avoid frequent and close physical contact, especially with those who are particularly sensitive to radiation. These include children and pregnant women.
- Since your excretions, especially your urine, may contain radioactive substances, please ensure the toilet flushes properly. Please seek our advice on the use and disposal of incontinence products.
- Avoid using appliances such as urine bottles and bed-pans. If this should prove necessary, care must be taken to ensure proper rinsing.
- And whatever else you do, please follow the instructions of your physician. He's there to answer any queries you may have.

Apart from the above, the radioactive substances should not prove any further hindrance or annoyance. You can go about your daily activities just as you always have done.

Should you have any queries, you'll find the name, address and phone number of the attending physician at the top of this leaflet.

A 17 Recommendations for patients being discharged early, having been treated with radioactive iodine, with the aim of reducing the radiation exposure of supporting persons

The following recommendations may be handed out to the patient, his legal representative, or his family.

You have been treated with radioactive iodine (I-131) on account of your thyroid disorder. Most of the iodine will be excreted from your body with your urine. Small traces of iodine, however, will remain in your body for weeks, in ever-decreasing quantities, so that others around you might be exposed to radiation. The following questions and answers are intended to inform you about simple modes of conduct suitable for reducing any radiation exposure.

These instructions should be followed until …….. (i.e. the point at which the limit of 1 mSv/year for persons in continuous presence of a patient at a distance of 2 metres is no longer exceeded).

What's the most important thing to remember?

Keep your distance from others; over extended periods (more than an hour) this distance should be approximately two metres.

What about contact with pregnant women?

Contact with pregnant women should be kept to a minimum. If a pregnant woman shares your home, you should maintain a distance of approximately two metres from her.

May I see and look after my children?

Please avoid close contact as much as you can with children under the age of ten (e.g. hugging or allowing them to sit on your lap), especially over extended periods.

May I receive visitors?

Short visits lasting less than two hours are no problem. Maintain an approximate distance of two metres and avoid close contact as much as possible. Visits by small children and pregnant women should not be permitted during the first few days following discharge from hospital.

May I return to work?

Most people may return to work. If for work reasons you are required to spend more than two hours a day at a distance of less than two metres from another individual, please consult your physician.

May I use public transport?

Until the date specified above, please restrict any travel on public transport to those trips that are absolutely necessary (e.g. medical check-ups). For international travel (concerning your destination/transit stop) the relevant immigration regulations should be taken into account.

May I use the same toilet as other people?

Yes, but you must ensure there are no urine splashes. Please sit down when urinating (men too). Always dry your genitals with toilet paper and make sure you flush. It is also important to always wash your hands after urinating. Please seek advice from your attending physician on the use and disposal of incontinence materials.

What about cutlery, crockery, bedding, towels, sanitary items, etc.?

Radioactive iodine is also excreted from the body through the patient's saliva and sweat. Do not therefore share cutlery, crockery, towels, bedding, etc. with others. Once these items have been washed, however, there is no longer any danger. There is no need to wash items separately. Used sanitary items (e.g. sanitary pads) should be packed in plastic bags, allowed to rest for several days, and then added to the household waste.

What if I need to go into hospital?

If you need to go into hospital unexpectedly, please inform the physician that you have recently been treated with radioactive iodine, even if you're returning to the same hospital.

Always ask the attending physician if unsure about anything!

A 18 Sample personal document following application of sealed radioactive substances (radiation sources)

You must carry this document with you at all times until …..……. !

Application of sealed radioactive substances

Patient name
Address

Attending physician/hospital
Address/phone number

The above-mentioned patient received treatment using sealed radioactive substances on ..... ; these substances remain in the body.

Radionuclide used: .....

Activity applied: …….MBq

Discharge dose rate at a distance of 2 metres from the body surface :

……. µSv/h

For more details please contact the above-mentioned hospital.

Owing to the low dose rate on the body's surface, first aiders and rescue services are not at risk from radiation.

A 19 Sample patient information sheet issued following treatment with ionizing radiation

Name of hospital/physician
Address

Treatment with an ionizing radiation installation, a gamma irradiation unit or an afterloading device

Ms/Mr ..... born on .....

in .....
current address .....

was, from ..... till ....., in.....
(hospital/practice)

subjected to radiotherapy with.....
(type of radiation)

using an ionizing radiation installation*/a gamma irradiation unit*/an afterloading device.
*) delete as appropriate

Type, purpose of treatment – if relevant; treated areas of the body:.....

.....

Target volume dose: …..... Gy

Number of radiotherapy sessions:.....

Radiotherapy timescale: .....

For queries please contact:

Attending physician: .....Phone number: .....

.....
(date, signature)

This information may also be presented to subsequently attending physicians.

A 20 Sample agreement concerning the use of sentinel lymph node (SLN) diagnostics

Sample agreement

This sample agreement regulates SLN diagnostics cooperation in circumstances where dynamic lymph scintigraphy, intraoperative detection measurements and further pathology examinations take place in different institutions (except for facilities to which the owner of the handling licence pursuant to § 7 para. (1) StrlSchV has direct access).

The following is agreed between

{the owner of the nuclear medicine handling licence}, hereinafter referred to as the {nuclear medicine department},

and
{the legal representatives of the operating institution and separate pathology department, where applicable}:

1. The technical implementation of intraoperative detection measurements associated with sentinel lymph node diagnostics shall be conducted on patients with {breast carcinomas, malignant melanomas, ENT tumours, etc.} in facilities belonging to the {legal representatives of the operating institution}.
2. These measurements are integral to the application of radioactive substances to humans for medical reasons, and as such are subject to the provisions of the Radiation Protection Ordinance (StrlSchV) in their currently valid version. The {nuclear medicine department} is licensed by the authority competent in radiation protection and shall supply physicians and medical physics experts with the requisite expertise in radiation protection. The physician with the requisite expertise in radiation protection shall decide on the justifying indication for the application of radioactive substances to humans, and bears the resultant legal responsibility pursuant to the StrlSchV until SLN diagnostics on the patient in the operating institution have been concluded, and the pathologists have finished any further examinations of the dissected tissue.
3. The persons from the {nuclear medicine department} mentioned in clause 2 with the requisite expertise in radiation protection shall either ensure that the applied activity is dosed in such a way that, by the time of the planned operation, patient activity does not exceed the exemption value of 10 MBq, or they shall specify the earliest date when an operation may take place.
4. All declarations and notifications required by the terms of the Radiation Protection Ordinance and the handling licence (e.g. annual notifications to the competent authority, declarations to the medical authority pursuant to § 83 para. (4) StrlSchV etc.) are the responsibility of the {nuclear medicine department}.
5. The {nuclear medicine department} is responsible for all cooperation associated with SLN diagnostics.

6. The {legal representatives of the operating institution and separate pathology department, where applicable} undertake, in consultation with the {nuclear medicine department}, to create the conditions necessary for adherence to the principles and provisions of radiation protection, and upon request to provide the {nuclear medicine department} with access to the necessary documents.
7. Those employed by the {legal representatives of the operating institution} with the necessary experience in using probes may only carry out intraoperative measurements within the context of sentinel lymph node ectomy (SLNE) and conduct probe quality controls, if they are certified holders of the requisite expertise in radiation and they have received instruction, based on operating instructions provided by the {nuclear medicine department}(see below), in the rules and working practices to be observed.
8. Prior to beginning SLN diagnostics, the staff involved (operating physicians, theatre staff, anaesthetists and pathologists) shall receive instruction from the {nuclear medicine department} – and thereafter at yearly intervals - on radiation protection and SLNE, new findings, and any revised working practices. Records shall be kept detailing the content and date of instruction sessions, to be signed by those persons under instruction.
9. Probe quality controls shall be conducted every working day and recorded pursuant to the requirements specified by the {nuclear medicine department}.
10. If the operating physician is not subject to dosimetric monitoring pursuant to the German X-ray Ordinance, the {nuclearmedicine department} must be informed - with the aim of ensuring adherence to the dose limit of 1 mSv/year –of the existence of any additional referring physicians.

{Place, date} {authorised signatory from the nuclear medicine department, legal representatives of the operating institution and separate pathology department, where applicable}

An appendix shall be created listing the persons responsible and other involved parties.

The operating instructions shall specify the following:

- technical implementation schedule and related requirements
- probe quality control provisions
- measures for dealing with malfunctions and measuring problems
- adherence to radiation protection provisions and principles
- handling sample material
- documentation

A 21 Notes on drafting radiation protection instructions

Radiation protection instructions (§ 34 StrlSchV) must, depending on the field of application (sealed or unsealed radioactive substances; gamma irradiation units and ionizing radiation installations), feature the following:

A 21 1 General

- the legal bases (Radiation Protection Ordinance, StrlSchV; Atomic Energy Act, AtG; associated directives), the latest official licence papers, the StrlSchV in notice or display form pursuant to § 35 of the StrlSchV
- radiation protection organisation:
  responsible persons (radiation protection experts and the radiation protection supervisor) pursuant to § 31 of the StrlSchV (contact details, professional and personal; holiday and illness cover), areas of responsibility, provisions outside working hours
- note about contacting the supervisory authority should there be a change in radiation protection expert
- medical physics experts appointed pursuant to § 82 para. (4) of the StrlSchV (contact details, professional and personal; holiday and illness cover), areas of responsibility, provisions outside working hours
- annual staff instruction session pursuant to § 38,para. (1) and (2) resp., of the StrlSchV and record-keeping pursuant to § 38 para. (4) of the StrlSchV
- occupation prohibitions and occupation restrictions
  (pursuant to §§ 37, 43 and 45 StrlSchV)
- medical examination of occupationally exposed persons
  (pursuant to § 60 StrlSchV)
- physical radiation protection monitoring of occupationally exposed persons and other individuals (pursuant to §§ 40, 41, 42 and 44 StrlSchV)
- function tests and maintenance of radiation measuring apparatus (pursuant to § 67 StrlSchV)
- required initial and further training in radiation protection
- supervisory authority reporting and immediate reporting requirements

A 21 2 Unsealed radioactive substances

- rooms in which radioactive substances may be handled
- controlled areas, supervised areas
  pursuant to § 36 para. (1) nos. 1 and 2 of the StrlSchV
- general rules for working with unsealed radioactive substances (e.g. protective clothing, preparing radioactive solutions, cleaning activities, conducting and recording contamination checks of work spaces and workstations every working

day, pursuant to § 44 of the StrlSchV, no eating or use of cosmetics, no smoking and suchlike.; cf. § 43 para. (3) StrlSchV)

- work instructions pursuant to § 82 para. (3) of the StrlSchV
- conduct in emergency situations (fire, contamination and similar), alert plan
- ordering, labelling, record-keeping, storage and transfer of radioactive substances (including a note on the annual reporting requirement pursuant to §§ 48 and 70 StrlSchV concerning the inventory, acquisition and transfer of radioactive substances)
- the transfer of waste from radiation protection areas shall be regulated by disposal instructions included in the radiation protection instructions. The disposal instructions shall, as applicable, contain information on and indications about:
  - the type of waste disposal:
    - transfer to the state collecting facility
      (also to central university collecting facilities, as applicable)
    - clearance procedure (clearance measurement, assessment) pursuant to § 29 of the StrlSchV taking any clearance notification conditions into account
    - conventional disposal of non-radioactive waste
  - waste type and composition
  - waste containers (size, weight, packaging)
  - which nuclides waste should be tested for
  - the measuring device and its specifications (decision and detection limits respectively)
  - measuring technique and the measuring venue
  - persons involved in disposal and their qualifications
  - disposal documents
  - measuring device quality control
  - sorting according to half-lives and nuclides, solid and liquid substances
  - removal of radioactive symbols
  - transfer of radioactive waste water and air, if applicable, pursuant to § 47 para. (4) of the StrlSchV
  - all changes require the issue of new disposal instructions
- patient records pursuant to § 80 para. (3) and § 85 of the StrlSchV (medical imaging and radiation dose history)
- quality assurance pursuant to Chapter 5 of this directive in its currently valid version, also pursuant to Appendix B number 4.11 where applicable
- transport of radioactive substances pursuant to §§ 16, 17 and 18 of the StrlSchV, as applicable, in conjunction with the Transport of Dangerous Goods by Road, Rail and Inland Waterways Ordinance (GGVSEB, Appendix B number 3.8) and, in the case of in-plant transports, with DIN 6843, section 6, respectively

- accepting (§ 69 para. (4) StrlSchV) and safeguarding radioactive substances (§ 65 para. (1) number 2 StrlSchV)
- information concerning the prevention of third-party intervention and the loss of actual control of radioactive substances pursuant to § 71 of the StrlSchV.

Furthermore comments should also be included, as applicable, concerning

- specifying responsibility for the supervision of waste water treatment installation operations
- measures relating to animal experiments involving radioactive substances
- application of radioactive substances to humans for research purposes pursuant to § 23 StrlSchV
- measures relating to the transfer of a patient treated with radioactive substances from the controlled area to another area of the hospital
- measures relating to the decease of a patient treated with radioactive substances

A 21 3 Sealed radioactive substances

- designation of supervised and controlled areas respectively pursuant to §§ 36, 37 of the StrlSchV
- provisions governing key radiation protection operations
- work instructions pursuant to § 82 para. (3) of the StrlSchV
- procedure when swapping radiation sources
- conduct when faced with a fire risk and other emergency situations respectively (alert plan)
- leakage test of sources pursuant to § 66 para. (4) of the StrlSchV
- quality assurance pursuant to Chapter 6 of this directive in its currently valid version, also pursuant to the X-Ray Ordinance QS-RL standard, where applicable
- information concerning the prevention of third-party intervention and the loss of actual control of radioactive substances pursuant to § 71 of the StrlSchV
- accepting (§ 69 para. (4) StrlSchV) and safeguarding radioactive substances (§ 65 para. (1) number 2 StrlSchV)

A 21 4 Gamma irradiation units and ionizing radiation installations

- designation of supervised and controlled areas respectively pursuant to §§ 36, 37 of the StrlSchV
- conduct in controlled areas (keep distance, short duration of stay, etc.)
- conduct when faced with a fire risk and other emergency situations respectively
- facility operations:
  - staff licensed to operate the facility
  - security keys, custody
  - operating instructions provided by the manufacturer
  - therapy plan and monitoring of settings by the physician responsible
  - irradiation record: entry of doses applied, the geometric irradiation parameters, and - if applicable - the energies used
  - operator's technical log book: entry of operating data checks, malfunctions and irregularities, maintenance, repairs, replacement of facility components
  - the door to the irradiation room may only be closed once the irradiation field has been set and all those present, with the exception of the patient, have left the irradiation room
  - it is forbidden to bypass any safety circuit switching elements (door contacts, etc.)
  - when entering the irradiation room (only applicable for facilities that use high activity radiation sources) staff habitually need to check that the radiation source indicator is in the "OFF" position (mechanical display)
  - defective warning lamps must be replaced immediately
- technical instructions:
  - facility checks and monitoring activities (daily, weekly, monthly, yearly)
  - conduct in the case of malfunctions:
    - malfunction of door contacts
    - switching on radiation
    - switching off radiation
    - power failure
- facility maintenance pursuant to § 66 para. (2) of the StrlSchV
- leakage test of sources pursuant to § 66 para. (4) of the StrlSchV
- quality assurance pursuant to Chapter 7 of this directive in its currently valid version, also pursuant to Appendix B number 4.11 where applicable
- information concerning the prevention of third-party intervention and the loss of actual control of radioactive substances pursuant to § 71 of the StrlSchV

A 21 5 Additional information

It has proved expedient to include the addresses of

- the supervisory authority
- the physicians licensed to conduct the requisite examinations pursuant to § 60 of the StrlSchV
- an officially approved individual dosimetry service
- an officially approved incorporation dosimetry service

in the radiation protection instructions.

A 22 Sample medical auditing commission registration form

Pursuant to § 83 para. (4) of the StrlSchV, the radiation protection supervisor must register any position requiring special licensing or declaration with the medical auditing commission nominated by the competent authority. This form may be used for the purpose:

Reply to:

(Name and address of the medical auditing commission)

Registering with the medical auditing commission

(§ 83 para. (4) of the Radiation Protection Ordinance - StrlSchV)

Radiation protection supervisor:

natural person, is charged with the duties of radiation protection supervisor (§ 31 StrlSchV):

Radiation protection expert (§ 31 StrlSchV):

Contact:	Name: ……..……
For queries:	Tel.: ……... Fax: …….
	Email: …….

Notifications issued by the competent authority:	date	ref. no.
……	…….	……..
……	…….	……..

Radiotherapy	**no/yes:**	**qty**
	Ionizing radiation installations	
	Cobalt-60 ……..	……
	Gamma knife ……...	……
	Afterloading …….	……
	X-ray therapy ……...	……

Other treatments …….. ……

Nuclear medicine	**no/yes:**	
Diagnostics:	Gamma cameras ……..	……
	of these with SPECT function……...……	……
	of these with full body function ……...……..	……
	PET scanners ……	……
	PET/CTs ……	……
	SPECT/CTs……	……
	Probe measuring station	
	Other	

Nuclear medicine	**no/yes:**		
Treatment.	Bone pain therapy	no	yes
	RSO	no	yes
	Other treatments ……..		
	……..		
	Iodine-131 treatment	no	yes, no. of beds: ……

……..

date, signed by the Radiation Protection Supervisor

A 23 Sample calculation of recommended staffing levels

For more details see Chapter 2.1.2.

A.) Nuclear medicine (2 gamma cameras) involving standard treatment:

Physicians: **1** (basic requirement acc. to table 1; cover assured)

MPE: **1** (basic requirement; MPE available)

Technicians: **3** (basic requirement)

B.) Nuclear medicine (4 gamma cameras) involving standard treatment:

Physicians: **1** (basic requirement acc. to table 1)
1 (additional requirement for more than 3 diagnostic devices acc. to table 2)
Total: **2** (persons acquiring practical experience do not count)

MPE: **1** (basic requirement; MPE available)

Technical staff: **5** (basic requirement)

C.) Nuclear medicine (4 gamma cameras, 1 PET/CT) with treatment station, 8 beds:

Physicians: 2 (basic requirement acc. to table 1)
1 (additional *diagnostic devices* requirement acc. to table 2)
Total: **3**

MPE: **2** (basic requirement acc. to table 1)

Technicians: **8** (basic requirement)

D.) 3 accelerators (with IMRT), 1 brachytherapy unit, 1 IORT, virtual simulation; average of 360 patients/year per system; single-shift operations:

Physicians: 4 (basic requirement acc. to table 1)
1(additional *other types of application* requirement acc. to table 1)
1 (additional requirement acc. to table 2)
Total: **6** (in addition to 4 physicians with the requisite expertise in radiation protection, up to 4 persons in the process of acquiring practical experience, for instance, may be counted to the value of 0.5)

MPE: 4 (basic requirement acc. to table 1)
1 (additional *other types of application* requirement acc. to table 1)
1 (additional requirement acc. to table 2)
Total: **6** (up to 4 persons in the process of acquiring practical experience may be counted to a value of 0.5)

Technicians: 6 MTRAs (basic requirement acc. to table 1)
1 MTRA (additional *other types of application* requirement acc. to table 1)
Total: **7 MTRAs**

APPENDIX B

Legislative index and related information

B1 European legislation and recommendations

Council Directive 96/29/EURATOM of 13thMay 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 number L 159/1, 39thissue, 29thJune 1996

B 1.2
Council Directive 97/43/EURATOM of 30thJune 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom. Official Journal of the European Communities number L 180, 40thissue, 9thJuly 1997

B 1.3
European Commission, Directorate General for the Environment, Nuclear Safety and Civil Protection: Criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations. Radiation Protection 91 (1997)

B 1.4
European Commission, Directorate General for the Environment, Nuclear Safety and Civil Protection: Radiation protection following iodine-131 therapy. Radiation Protection 97 (1998)

B 1.5
Expert Group ex art 31 EURATOM: Guidance for Radiation Protection Following Radioactive I-131-Therapy Concerning Doses due to Out-patients or Discharged Inpatients. Brussels 1997

B 1.6
The European Higher Education Area, Joint Declaration of the European Ministers of Education, 19thJune 1999, Bologna

B 2 Laws

B.2.1
Act on the Peaceful Utilization of Atomic Energy and the Protection against its Hazards (German Atomic Energy Act, AtG) of 23rd December 1959 (Federal Law Gazette I, p. 814), as amended and promulgated on 15th July 1985 (Federal Law Gazette I, p. 1565), last amendment by the Act of 8th December 2010 (Federal Law Gazette I, p. 1817)

B 2.2

Medicinal Products Act (German Drug Law, AMG) in the version published on 12th December 2005 (Federal Law Gazette I, p. 3394)

B 2.3
The Act on Medical Devices (Medical Devices Act) in the version promulgated on 7th August 2002 (Federal Law Gazette I, p. 3146), last amendment by Article 12 of the Act dated 24th July 2010 (Federal Law Gazette I, p. 983)

B 2.4
The Act on Technical Assistants in Medicine (German MTA Act – MTAG) of 2nd August 1993 (Federal Law Gazette I, p.1402), last amendment by Article 23 of the Act dated 2nd December 2007 (Federal Law Gazette I, p. 2686)

B 2.5
German Criminal Code (StGB) in the version promulgated on 13th November 1998 (Federal Law Gazette I, p. 3322), last amendment by Article 3 of the Law dated 2nd October 2009 (Federal Law Gazette I, p. 3214)

B 2.6
Act on the Further Development of Data Processing and Data Protection (German Federal Data Protection Act, BDSG) of 20th December 1990 (Federal Law Gazette I, p. 2954), last amendment by Article 2, Paragraph 5 of the Act of 17th December 1997 (Federal Law Gazette I, p. 3108)

B 2.7
Act on the Transport of Dangerous Goods (German Transport of Dangerous Goods Act, GGBefG). Version from 9th October 1998 (Federal Law Gazette I, p. 3114)

B 2.8
Act to Protect Participants in Distance Learning (German Distance Learning Protection Act, Fern-USG) in the version promulgated on 4th December 2000 (Federal Law Gazette I, p. 1670), last amendment by Article 8, Paragraph 1 of the Act of 29th July 2009 (Federal Law Gazette I, p. 2355)

B 3 Regulations

B 3.1
Ordinance on the Protection against Damage and Injuries Caused by Ionizing Radiation (Radiation Protection Ordinance, StrlSchV) of 20th July 2001 (Federal Law Gazette I, p. 1714), last amendment by the Ordinance amending the Ordinances on Protection against Damage and Injuries Caused by Ionizing Radiation of 4th October 2011 (Federal Law Gazette I, p. 2000)

B 3.2
Ordinance on the Protection against Dangers Arising from X-rays (German X-ray Ordinance, RöV) of 8th January 1987 (Federal Law Gazette I, p. 114) in the version promulgated on 30th April 2003 (Federal Law Gazette I, p. 604), last amendment by the Ordinance on Modifications to Radiation Protection Ordinances of 4th October 2011 (Federal Law Gazette I, p. 2000)

B 3.3
Ordinance Concerning the Financial Security Pursuant to the Atomic Energy Act (Nuclear Financial Security Ordinance, AtDeckV) of 25th January 1977 (Federal Law Gazette I, p. 220), last amendment by § 1 of the Transference of Federal Law to Berlin (West) Act (Sixth Law of Transference)

B 3.4
Ordinance on Radioactive Medicinal Products and Medicinal Products Treated with Ionizing Radiation (AMRadV) of 28th January 1987 (Federal Law Gazette I, p. 502), last amendment by § 1 of the Transference of Federal Law to Berlin (West) Act (Sixth Law of Transference)

B 3.5
Ordinance on Medical Devices (Medical Devices Ordinance, MPV) in the amended version of 20th December 2001 (Federal Law Gazette I, p. 3854)

B 3.6
Ordinance concerning the Creation, Operation and Application of Medical Devices (Medical Devices Operator Ordinance, MPBetreibV) of 29th June 1998 (Federal Law Gazette I, p. 762), last amendment by Article 11 of the Second Act Amending the Act on Medical Devices (2nd Medical Devices Act Amendment Act, MPG-ÄndG) of 13th December 2001

B 3.7
Ordinance concerning the Training and Examination of Technical Assistants in Medicine (Medical Technical Assistants Training and Examination Ordinance, MTA–APrV) of 25th April 1994 (Federal Law Gazette I, p. 922)

B 3.8
Ordinance on the National and International Transport of Dangerous Goods by Road, Rail and Inland Waterways (Dangerous Goods Ordinance – Road, Rail and Inland Waterways, GGVSEB) of 17th June 2009 (Federal Law Gazette I, p. 1389), last amendment by Article 1 of the Ordinance of 3rd August 2010 (Federal Law Gazette I, p. 1139)

B 4 National directives and other legislation

B 4.1
Physical Radiation Protection Monitoring Directive for Determining Body Doses, Part 1: Calculating External Radiation Body Doses (§§ 40, 41, 42 StrlSchV; § 35 RöV). Circular dated 8th December 2003 (Joint Ministerial Gazette 2004, p. 410)

B 4.2a
Physical Radiation Protection Monitoring Directive for Determining Body Doses, Part 2: Calculating Internal Radiation Body Doses (§§ 40, 41, 42 StrlSchV) of 12th January 2007 (Joint Ministerial Gazette, p. 623)

B 4.2b
Recommendation concerning the Application of the Incorporation Monitoring Guideline in the Field of Nuclear Medicine. Circular dated 5th January 2009 (Joint Ministerial Gazette 2009, p. 266)

B 4.3
Leakage Testing of Sealed Radioactive Substances. Directive of 4th February 2004 (Joint Ministerial Gazette 2004, p. 530)

B 4.4
a)Framework Monitoring Directive Pursuant to § 66 Paragraph 2 of the Radiation Protection Ordinance of 11thJune 2001 (Joint Ministerial Gazette 2002, p. 620)
b)Installation and Irradiation Facility Inspections Pursuant to § 66 Paragraph 2 of the StrlSchV in Accordance with Nos. 3.3 and 4.1 of the Framework Monitoring Directive Pursuant to § 66 Paragraph 2 of the StrlSchV of 11th June 2002. Circular dated 13th October 2004 (Joint Ministerial Gazette 2004, p. 1091)

B 4.5
Application Dossier Annotations Relating to the Approval Procedure for Ionizing Radiation Installations Pursuant to § 11 Paragraphs 1 and 2 of the StrlSchV (Joint Ministerial Gazette 2004, p. 9)

B 4.6
Medical and Dental Authorities. Directive on the Radiation Protection Ordinance and on the X-ray Ordinance. Circular dated 18th December 2003 (Joint Ministerial Gazette 2004, p. 258)

B 4.7
Uniform Medical Authority Evaluation System and Detailed Inspection Criteria. Letter from the Federal Ministry for the Environment to the Highest Competent Regional Authorities Responsible for Implementing the Radiation Protection Ordinance and the X-ray Ordinance, dated 13th January 2009 (for current publications see www.zaes.info)

B 4.8
Occupational Medical Prevention for Occupationally Exposed Persons by Authorised Physicians. Directive on the Radiation Protection Ordinance and on the X-ray Ordinance. Circular dated 18th December 2003 (Joint Ministerial Gazette 2004, p. 350)

B 4.9
Radiation Protection in Veterinary Science. Directive on the Radiation Protection Ordinance and on the X-ray Ordinance. (Joint Ministerial Gazette 2005, p. 666)

B 4.10
Knowledge and Know-how in Radiation Protection for the Operation of X-ray Facilities in Medical or Dental Practice. Directive on the X-ray Ordinance dated 22nd December 2005 (Joint Ministerial Gazette 2006, p. 414)

B 4.11
Directive on Quality Assurance Implementation for X-ray Facilities used in the Examination or Treatment of Persons pursuant to §§ 16 and 17 of the X-ray Ordinance Quality Assurance Directive (QS-RL) dated 20th November 2003 (Joint Ministerial Gazette 2004, p. 731), final amendment by circular of 15th July 2010, Joint Ministerial Gazette 2010, p. 1242)

B 4.12
Directive on the Requisite expertise in Radiation Protection (Requisite expertise Technology Directive pursuant to StrlSchV) dated 18th June 2004 (Joint Ministerial Gazette 2004 p. 799), amended by circular of 19th April 2006 (Joint Ministerial Gazette 2006, p. 735)

B 4.13
Implementation of the Radiation Protection Ordinance: Beta Dosimetry in RSO Workplaces. Circular dated 15th September 2009 (Joint Ministerial Gazette 2010, p. 710)

B 4.14
Publication of Diagnostic Reference Levels for Radiological and Nuclear Medicine Examinations. Federal Gazette number 143 of 3rd August 2003

B 4.14a
Publication of Updated Diagnostic Reference Levels for Diagnostic and Interventional X-ray Examinations. Federal Office for Radiation Protection. Federal Gazette number 111 of 28th July 2010, p. 2594

B 4.15
Requisite expertise in Radiation Protection: Approval of Courses. Circular of 20th October 2009 (Ref. RS II 3 15040/3)

B 5 Recommendations by the Commission on Radiological Protection (SSK)

All the following recommendations issued by the Commission on Radiological Protection can also be viewed online at www.ssk.de; since 3.11.2009 some have also been translated into English.

B 5.1
Measures to be Taken in Cases of Radioactive Contamination of the Skin. Recommendation by the Commission on Radiological Protection, adopted at the 92nd meeting on 22nd September 1989 (Federal Gazette number 45 of 6th March 1990)

B 5.2
State-Certified Additional Education and Training in Medical Physics. Recommendation by the Commission on Radiological Protection, adopted at the 101st meeting on 14th December 1990 (Federal Gazette number 55 of 20th March 1991)

B 5.3
Interventional Radiology. Recommendation by the Commission on Radiological Protection, adopted at the 217th meeting on 20th/21st September 2007. Reports of the Commission on Radiological Protection,
Issue 56. Stuttgart: Gustav Fischer Verlag, 2008

B 5.4
Application of Sr-89 in Radiation Therapy. Statement by the German Commission on Radiological Protection, adopted at the 136th meeting on 23rdFebruary 1996. Publications of the Commission on Radiological Protection, Volume 40, edited by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. Stuttgart: Gustav Fischer Verlag, 1998

B 5.5
Radiation Protection Principles in Radioiodine Therapy. Recommendation by the Commission on Radiological Protection, adopted at the 142nd meeting on 6th December 1996 (Federal Gazette number 68 of 11th April 1997)

B 5.6
Fractionated Radioiodine Therapy in Outpatients. Recommendation by the Commission on Radiological Protection, adopted at the 136th meeting on 23rdFebruary 1996 (Federal Gazette number 132 of 18th July 1997)

B 5.7
The Radiation Emergency. A Guideline on First Responses. Publications of the Commission on Radiological Protection, Volume 32, edited by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. Stuttgart: Gustav Fischer Verlag, 1996

B 5.8
The Radiation Emergency. A Guideline on First Responses (Abridged). Information from the Commission on Radiological Protection (SSK) number 1/1997, edited on behalf of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety by the Radiological Protection Commission Office at the Federal Office for Radiation Protection, Postfach 12 06 29, 53048 Bonn

B 5.9
Use of the Effective Dose in Medical Examinations. Recommendation by the Commission on Radiological Protection, adopted at the 147th meeting on 4thJuly 1997 (Federal Gazette number 213 of 4th November 1997)

B 5.10
Further Education and Vocational Training of Medical Physicists. Recommendation by the Commission on Radiological Protection, adopted at the 149th meeting on 17thNovember 1997 (Federal Gazette number 38 of 25th February 1998)

B 5.11
Use of Sr-89, Re-186, Y-90 and Sm-153 in Palliative Radiotherapy. Statement by the German Commission on Radiological Protection, adopted at the 147th meeting on 4thJuly 1997. Publications of the Commission on Radiological Protection, Volume 41, edited by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety.
Stuttgart: Gustav Fischer Verlag, 1998

B 5.12
Use of Short-lived Dose Reducing Radiopharmaceuticals in Nuclear Medicine Diagnostics. Statement by the German Commission on Radiological Protection, adopted at the 147th meeting on 4thJuly 1997. Publications of the Commission on Radiological Protection, Volume 41, edited by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. Stuttgart: Gustav Fischer Verlag, 1998

B 5.13
Follow-up of Patients after Radiotherapy Procedures. Recommendation by the Commission on Radiological Protection, adopted at the 151st meeting on 12thFebruary 1998 (Federal Gazette number 144 of 6th August 1998) (under revision)

B 5.14
Radiation exposure from nuclear medicine patients. Recommendation by the Commission on Radiological Protection, adopted at the 152nd meeting on 23rdApril 1998 (Federal Gazette number 208 of 5th November 1998)

B 5.15
Effects from the Introduction of New Dose Measurement Parameters in Radiation Protection. Statement by the German Commission on Radiological Protection. Reports of the Commission on Radiological Protection,
Issue 11. Stuttgart: Gustav Fischer Verlag, 1998

B 5.16
Requirements on Contamination Control Procedures after Leaving the Controlled Areas (§ 64 para. (2) StrlSchV). Recommendations by the Commission on Radiological Protection. Reports of the Commission on Radiological Protection, Issue 21. Stuttgart: Gustav Fischer Verlag. 1999

B 5.17
Diagnostic Reference Levels in Nuclear Medicine. Recommendation by the Commission on Radiological Protection, adopted at the 167th meeting on 7th July 2000 (Federal Gazette number 164 of 1st September 2001)

B 5.18
Endovascular Radiotherapy. Recommendation by the Commission on Radiological Protection, adopted at the 170th meeting on 8thDecember 2000 (Federal Gazette number 134 of 21st July 2001)

B 5.19
Detection of Sentinel Lymph Nodes in Nuclear Medicine. Recommendation by the Commission on Radiological Protection, adopted at the 175th meeting on 14thDecember 2001 (Federal Gazette number 115 of 26th June 2002)

B 5.20
Survey of Radioactivity from Nuclear Medicine Procedures Released into the Environment by Excretion. Recommendation by the Commission on Radiological Protection, adopted at the 179th meeting on 5thJuly 2002 (Federal Gazette number 207 of 7th November 2002)

B 5.21
Use of Iodine-131 in Nuclear Medicine. Statement by the German Commission on Radiological Protection, adopted at the 182nd meeting on 6thDecember 2002. Publications of the Commission on Radiological Protection, Volume 50, edited by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. Stuttgart: Gustav Fischer Verlag, 2003

B 5.22
Individual Justification according to § 80 StrlSchV ("Strahlenschutzverordnung", Radiation Protection Ordinance) of Bone Scintigraphy out of a "Referral Order". Statement by the German Commission on Radiological Protection, adopted at the 178th meeting on 12th April 2002. Publications of the Commission on Radiological Protection, Volume 50, edited by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. Stuttgart: Gustav Fischer Verlag, 2003

B 5.23
Radiation Protection in Brachytherapy, Radiosynoviorthesis and Radio Immune Therapy with Open Beta Emitters. Recommendation by the Commission on Radiological Protection, adopted at the 184th meeting on 1st April 2003 (Federal Gazette number 218 of 21st November 2003)

B 5.24
The Use of Positron Emission Tomography (PET) as an Efficient and Dose Sparing Procedure. Recommendation by the Commission on Radiological Protection, adopted at the 184th meeting on 1stApril 2003 (Federal Gazette number 218 of 21stNovember 2003)

B 5.25
Acquisition of Knowledge in Radiation Protection During a Medical Course of Study. Recommendation by the Commission on Radiological Protection, adopted at the 184th meeting on 1stApril 2003 (Federal Gazette number 218 of 21st November 2003)

B 5.26
Demand on Medical Physics Experts in Radiation Protection. Recommendation by the Commission on Radiological Protection, adopted at the 186th meeting on 12th September 2003 (Federal Gazette number 83 of 4th May 2004)

B 5.27
Necessity of Hospitalization of Patients with Thyroid Carcinoma Undergoing Whole Body Scintigraphy with Iodine 131 Recommendation by the Commission on Radiological Protection, adopted at the 190th meeting on 23rd April 2004 (Federal Gazette number 158 of 24th August 2004)

B 5.28
On the Use of Radioactive Substances in Medical Research: Licencing According to § 28a RöV ("Röntgenverordnung", X-ray Ordinance) and § 23 StrlSchV ("Strahlenschutzverordnung", Radiation Protection Ordinance). Recommendation by the Commission on Radiological Protection, adopted at the 190th meeting on 23rd April 2004 (Federal Gazette number 158 of 24th August 2004)

B 5.29
Determination of the Contribution to Radiation Exposure at a Nuclear Facility Site due to Radionuclides Excretion from Patients Following Nuclear Medical Treatments. Recommendation by the Commission on Radiological Protection, adopted at the 197th meeting on 17th December 2004 (Federal Gazette number 68 of 12th April 2005)

B 5.30
Radioimmunotherapy Using [90Y]-Ibritumomab-Tiuxetan (90Y-Zevalin). Recommendation by the Commission on Radiological Protection, adopted at the 198th meeting on 17th February 2005 (Federal Gazette number 12 of 18th January 2006)

B 5.31
Guidance on Diagnostic Imaging in Medicine. Recommendation by the Commission on Radiological Protection. Publications of the Commission on Radiological Protection, Issue 51, edited by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety.
H. Hoffmann Verlag Berlin, 2006, 2nd revised edition 2011

B 5.32
New Technologies in Diagnostic Radiology and Radiotherapy: Summary and Evaluation of the Results of the Closed SSK Session of 11th/12th November 2004 in Berlin. Statement by the German Commission on Radiological Protection, adopted at the 199th meeting on 22nd April 2005. Publications of the Commission on Radiological Protection, Volume 57, edited by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. H. Hoffmann Verlag Berlin, 2007

B 5.33
The Principle of Justification: Statement of the SSK for the ICRP. Statement by the German Commission on Radiological Protection, adopted at the 201st meeting on 23rd September 2005. Publications of the Commission on Radiological Protection, Volume 59, edited by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. H. Hoffmann Verlag Berlin, 2007

B 5.34
Radiation Protection in Positron Emission Tomography/Computer Tomography (PET/CT) Statement by the German Commission on Radiological Protection, adopted at the 204th meeting on 8th December 2005. Publications of the Commission on Radiological Protection, Volume 59, edited by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. H. Hoffmann Verlag Berlin, 2007

B 5.35
Physical-technical quality assurance in radiotherapy. Recommendation of the Commission on Radiological Protection. Proposals for the Testing of the Total Treatment System. Statement by the German Commission on Radiological Protection, adopted at the 241st meeting on 28th/29th April 2010 (www.ssk.de).

B 5.36
Standard Numbers for Nuclear Medicine Residencies of the Federal Chamber of Physicians (BÄK). Recommendation by the Commission on Radiological Protection, adopted at the 201st meeting on 22nd September 2005 (Federal Gazette number 11 of 17th January 2006)

B 5.37
Initial Qualifications and Acquisition of the Required Knowledge of and/or Skills in Radiation Protection within the Field of Medical Physics. Recommendation by the Commission on Radiological Protection, adopted at the 224th meeting on 3rd July 2008 (Federal Gazette number 32 of 27th February 2009)

B 5.38
Requirements for Obtaining a Qualification in Radiological Protection for Physicians: Explanatory Notes on the Practical Experience Required for the Licence. Recommendation by the Commission on Radiological Protection, adopted at the 246th meeting on 2nd/3rd December 2010

B 5.39
Radionuclide Therapy by Means of Selective Internal Radiation Therapy (SIRT) and Intravascular Irradiation with Open Radionuclides. Recommendation by the Commission on Radiological Protection. Adopted at the 236th meeting of the Commission on Radiological Protection on 18th September 2009

B 5.40
Quality Control of Nuclear Medicine Equipment: Definition of Action Levels and Tolerance Limits. Recommendation by the Commission on Radiological Protection. Adopted at the 243rd meeting of the Commission on Radiological Protection on 17th September 2010

B 5.41
Radiation hygiene requirements for IGRT (image guided radiotherapy). Recommendation by the Commission on Radiological Protection. Adopted at the 242nd meeting of the Commission on Radiological Protection on 1st/2nd July 2010

B 5.42
Radiation Hygiene Requirements for Highly Conformal Radiation Therapy. Recommendation by the Commission on Radiological Protection. Adopted at the 248th meeting of the Commission on Radiological Protection on 14th/15th April 2011

B 5.43
Clearance of Accelerators and the Removal of Accelerator Parts from Radiation Protection Areas. Statement by the Commission on Radiological Protection. Federal Gazette number 176, 20.11.2009, p. 3964

B 5.44
Radiological Protection of the Unborn Child. Recommendation and Scientific Reasoning. Recommendation by the Commission on Radiological Protection. Adopted at the 197th SSK meeting on 16th/17th December 2004

B 6 Technical standards

Where reference is made to technical standards in this directive, those versions thereof that are currently in force shall apply. The publication dates of the versions current at the time this directive was published are included in the following list for orientation purposes only.

DIN 6809 Clinical Dosimetry

-1 Clinical dosimetry; therapeutical application of X-ray, gamma-ray and electron beams (September 1976)
(new draft standard: Radiation Quality of Photon and Electron Radiation - April 2008)

-2 Brachytherapy with sealed gamma sources (November 1993)
-6 Application of high energy photon and electron radiation in percutaneous radiotherapy (February 2004)

DIN 6818 Radiation protection dosimeters

-1 General (August 2004)

DIN 6827 Recording in medical application of ionizing radiation

-1 Therapy with electron accelerators as well as X-ray and gamma-ray therapy systems (September 2000)
-2 Diagnosticsand treatment with unsealed radioactive substances (May 2003)
-3 Brachytherapy with enclosed radiation sources (December 2002)
-5 Radiological report (April 2004)

DIN 6834 Radiation protection doors

-1 Requirements (September 1973)
(new draft in preparation)
-2 Revolving folding-doors, single wing doors, dimensions (September 1973)
-3 Revolving folding-doors, double wing doors, dimensions (September 1973)
-4 Sliding doors, single wing doors, dimensions (September 1973)
-5 Sliding doors, double wing doors, dimensions (September 1973)

DIN 6843 Radiation protection rules for handling unsealed radioactive material in medicine (December 2006)

DIN 6844 Nuclear medicine departments
-1 Rules for the installation and equipment for diagnostic applications of unsealed radioactive sources (January 2005)
-2 Rules for the installation and equipment for therapeutic applications of unsealed radioactive sources (January 2005)
-3 Radiation protection calculations (December 2006)

DIN 6846 Medical teletherapy systems with gamma-emitting sources
-2 Radiation safety requirements for installation (June 2003)
-5 Constancy testing (March 1992)

DIN 6847 Medical electron accelerators
-2 Rules for construction of structural radiation protection (September 2008)
-5 Constancy test of functional performance characteristics (January 1998)

DIN 6850 Radiation protection containers, tables and safes for use in nuclear medicine - Requirements and classification (December 2006)

DIN 6853 Medical remote-controlled automatically-driven afterloading systems
-2 Radiation protection rules for installation (October 2005)
-3 Requirements of the radioactive sources (December 1992)
-5 Constancy testing (February 1992)

DIN 6854 Technetium generators - Requirements and operation (December 2006)

DIN 6855 Constancy testing of nuclear medical measuring systems
-1 Radiation counting systems for measurements in vivo and in vitro (July 2007)
-2 Constancy testing of single crystal gamma-cameras used in planar scintigraphy and in anger type gamma cameras with rotating detector heads used in single photon emission tomography (January 2005)
-4 Constancy testing of positron emission tomographs (PET) (November 2004)
-11 Radionuclide calibrators (May 2009)

DIN 6870 Quality management system in medical radiology
-1Radiotherapy (February 2009)

DIN 6873 Radiotherapy therapy planning systems
-5 Constancy testing (August 1993)

DIN 6875 Special radiotherapy equipment

-2 Percutaneous stereotactic radiotherapy - Constancy testing (November 2008)
-3 Intensity-modulated radiation therapy – Characteristics, test methods and rules for clinical application (March 2008)

DIN 6878 Digital archiving in medical radiology

-1 General requirements for the archiving of images (May 1998)
(new draft standard: March 2009)

DIN 25407 Shielding walls against ionizing radiation
Supplement 1: Recommendations for the construction of walls made of bricks (August 1994)

DIN 25415 Decontamination of radioactively contaminated surfaces
-1 Method for testing and assessing the ease of decontamination (August 1988)

DIN 25422 Storage and keeping of radioactive materials - Requirements on protection against radiation, fire and theft to be met by storage facilities (August 1994)

DIN 25425 Radioisotope laboratories
-1 Rules for design (September 1995)
-1 Supplement 1: Rules for design, examples (September 1995)
-2 Internal radiation protection rules (October 1997)
-2 Supplement 1: Principles for the establishment of internal radiation protection rules; guidance notes on shielding of gamma and beta radiation (June 1989)
-2 Supplement 2: Internal radiation protection rules; examples for application and comments (November 1999)
-3 Rules for preventive fire protection (October 1991)
-5 Rules for the decontamination of surfaces (August 1994)

DIN 25426 Sealed radioactive sources

-1 Requirements and classification (October 1988)
-2 Special form radioactive material, requirements (October 1992)
-4 Leakage test methods for recurrent inspections (April 1995)

DIN 25430 Safety marking in radiation protection (February 1991)

DIN EN 421 Protective gloves against ionizing radiation and radioactive contamination (June 1994)
(new draft standard: December 2007)

DIN EN 60731 Dosimeters with ionization chambers

DIN EN 60601 Medical electrical equipment
-2-1 Particular requirements for basic safety of electron accelerators in the range 1 MeV to 50 MeV (December 2003)
New draft standard July 2008: Medical electrical equipment Part 2-1: Particular requirements for basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV
-2-9 Dosimeters with ionization chambers; particular requirements for the safety of dosimeters used in radiotherapy with electrically-connected radiation detectors (January 2007)
-2-11 Particular requirements for the safety of gamma beam therapy equipment (January 2007)
New draft standard: June 2009: Particular requirements for the safety and essential performance of gamma beam therapy equipment
-2-17 Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment (December 2004)
-2-29 Particular requirements for the basic safety and essential performance of radiotherapy simulators (June 2009)

DIN EN 60789 Medical electrical equipment - Characteristics and test conditions of radionuclide imaging devices - Anger type gamma cameras (June 2008)

DIN EN 60976 Medical electrical equipment - Medical electron accelerators - Functional performance characteristics (November 2005)

DIN EN 61168 Radiotherapy simulators - Functional performance characteristics (January 2000)

DIN EN 61303 Medical electrical equipment – Radionuclide calibrators - Particular methods for describing performance (March 1996)

DIN EN 61217 Radiotherapy equipment – Coordinates, movements and scales (IEC 61217:1996 / A1:2000) (August 2003)
(new draft standard: DIN EN 61217/A2:2007-09)

DIN EN 61675 Radionuclide imaging devices - Characteristics and test conditions
-1 Positron emission tomographs (October 2000)
(new draft standard: DIN EN 61675-1/A1 March 2007)
Radionuclide imaging devices - Characteristics and test conditions - Part 1: Positron emission tomographs
-3 Gamma camera based whole-body imaging systems (Dec. 1999)

B 7 International recommendations and directives

B 7.1
International Commission on Radiological Protection (ICRP) Radiation Dose to Patients from Radiopharmaceuticals. ICRP-Publication number 53. Oxford: Pergamon Press, 1988

B 7.2
International Commission on Radiological Protection (ICRP): 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication number 60. Annals of the ICRP Vol. 21, number 1-3. Oxford: Pergamon Press, 1991

B 7.3
International Commission on Radiological Protection (ICRP): Radiological Protection in Biomedical Research; includes Addendum 1 to Publication 53. ICRP-Publication No. 62. Oxford: Pergamon Press, 1993

B 7.4
International Commission on Radiological Protection (ICRP): Radiological Protection and Safety in Medicine. ICRP Publication number 73. Annals of the ICRP Vol. 26, number 2.
Oxford: Pergamon Press, 1996

B 7.5
International Commission on Radiation Units and Measurements (ICRU): Determination of Dose Equivalents Resulting from External Radiation Sources. ICRU Report 39, Bethesda, 1985

B 7.6
International Commission on Radiation Units and Measurements (ICRU): Determination of Dose Equivalents Resulting from External Radiation Sources - Part 2. ICRU Re-port 43, Bethesda, 1988.

B 7.7
International Commission on Radiation Units and Measurements (ICRU): Measurement of Dose Equivalents from External Photon and Electron Radiations. ICRU Report 47, Bethesda, 1992

B 7.8
International Commission on Radiation Units and Measurements (ICRU): Quantities and Units in Radiation Protection. ICRU Report 51, Bethesda, 1993

B 7.9
United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) Sources, Effects and Risks of Ionizing Radiation. 1988 Report on the General Assembly. New York: United Nations, 1988

B 7.10
United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) Sources, Effects and Risks of Ionizing Radiation. 1993 Report on the General Assembly. New York: United Nations, 1993

B 7.11
Committee on the Biological Effects of Ionizing Radiation (BEIR V): Health Effects to Exposure of Low Levels of Ionizing Radiation. United States National Academy of Sciences, National Research Council. Washington: National Academy Press, 1990

B 7.12
International Atomic Energy Agency (IAEA): Lessons learned from accidents in radiotherapy. Safety Report. Vienna, Austria, 1998

B 7.13
International Atomic Energy Agency (IAEA): On- site Visits to Radiotherapy Centres Medical Physics Procedures Quality Assurance Ream for Ration Oncology, TECDOC 1543. Vienna, Austria, 2007

B 7.14
International Atomic Energy Agency (IAEA): Report of the Inter Society Council for Radiation Oncology, Radiation Oncology in Integrated Cancer Management, Site 26, Table VIII-1 Minimum Personnel Requirements for Clinical Radiation Therapy. Vienna, Austria, 1998

B 7.15
International Atomic Energy Agency (IAEA): Setting Up a Radiotherapy Programme Clinical, medical Physics Radiation Protection and Safety Aspects. Vienna, Austria, 2008

B 8 Further reading

B 8.1
The German Society for Medical Physics (DGMP): Medical physics staffing levels recommendations. Report number 8, 1994

B 8.2
The German Society for Medical Physics (DGMP): Medical physics staffing levels recommendations Part II: Supplementary information concerning specialist techniques and specialist tasks. Report number 10, 1998

B 8.3
German Radio-oncology Association (DEGRO): Quality assurance guideline "Constancy testing of therapy simulators" (German Association of Scientific Medical Societies, AWMF online)

B 9 Internet addresses

Several of the publications quoted may be viewed online at the following websites:

Federal Ministry for the Environment, Nature Conservation and Nuclear Safety	www.bmu.de
Federal Office of Radiation Protection	www.bfs.de
Commission on Radiological Protection (SSK)	www.ssk.de
International Commission on Radiological Protection (ICRP):	www.icrp.org
German Association of Scientific Medical Societies	www.uni-duesseldorf.de/AWMF

B 10 Glossary of terms and abbreviations

Final inspections and constancy tests
Final inspections and constancy tests are quality assurance procedures. The final inspection of ionizing radiation installations, irradiation facilities and other devices, including diagnostic devices by means of which radioactive substances or ionizing radiation are applied during the examination or treatment of patients, requires the manufacturer or supplier to prove that the quality standard specified by the application in question has been reached. Additional testing, which includes all integrated localization, therapy planning and positioning systems, must be carried out on ionizing radiation installations by the operator.

At regular intervals and particularly if malfunction is suspected, constancy checks are performed by the user - comparing reference values or images to ensure that the quality of device operations are still adequate to permit use. The constancy test reference figures are either established during final inspection using the operator's measuring equipment, or by a medical physicist on the basis of control readings. The specification of reference figures may only take place if the device is confirmed to be functioning correctly and in an optimum manner.

Afterloading devices
Equipment by means of which sealed radioactive substances are remotely guided from the rest position (radiation-shielded position) into applicators located in cavities or areas of the body to be irradiated.

Application
Diagnosis of the justifying indication, technical assistance, and reporting in the case of examinations; diagnosis of the justifying indication, technical assistance and success monitoring in the case of treatments.

Medical application areas
The directive uses this term collectively to refer to medical fields of operation which involve the application (diagnostic or therapeutic) of radiation (e.g. in nuclear medicine: organ-related examinations; in radiotherapy: brachytherapy; etc.).

Every working day
refers to those working days when the relevant procedure, application or activity in question is carried out. With reference to the acquisition of practical experience, the term "every working day" is limited to the actual number of days worked by the person in question.

Radiopharmaceuticals
Radiopharmaceuticals are medicines used in nuclear medicine. They may either be a single radioactive substance, or a carrier to which a radioactive substance has been

linked. Radiopharmaceuticals are particularly used for diagnosis (radiodiagnostics) in scintigraphy, positron emission tomographs (PET) and *single photon emission computed tomography* (SPECT); in contrast to other procedures, such as X-ray, these do not capture stationary states but rather metabolic processes. In addition radiopharmaceuticals may also be used to treat illness or physical states (radiotherapeutic agents).

Supervision (direct/permanent)
Direct supervision takes place in direct physical proximity to the person under supervision, allowing instant intervention should errors occur.
Permanent supervision must mean that the supervisor can be physically present within 15 minutes. Within the terms of permanent supervision, prior induction and instruction, spot checks, support and correction respectively shall be provided by a person with the requisite expertise in radiation protection for the application in question.

Radiotherapy course
Collective term for all radiotherapy sessions associated with the irradiation treatment of a target volume or several oncologically-related target volumes, regardless of whether the suspension of irradiation treatment was planned or not planned.

Requisite expertise (requisite expertise in radiation protection)
Requisite expertise in radiation protection comprises vocational training suited to the relevant application area, practical experience (practical experience of technical and medical radiation protection requirements to safeguard adherence to the basic principles of radiation protection during the application of radioactive substances or ionizing radiation on patients, justification, optimization, radiation exposure limitation), and successful participation in courses approved by the competent authority.

Gamma irradiation unit
Irradiation units with sealed radioactive substances, e.g. gamma irradiation systems featuring multiple radiation sources for use in teletherapy.

Gating
Monitoring irradiation progress or assigning images based on the registration of physiological patient parameters (e.g. breathing, heart beat).

IGRT (Image Guided Radiation Therapy)
Radiotherapy which ensures patient localization during treatment corresponds to that featured in the therapy plan; during a course of radiotherapy this is achieved by imaging systems that are linked directly to the irradiation unit.

IMRT (Intensity Modulated Radiation Therapy) radiotherapy that features a planned variation in dose distribution within the irradiation field
IMRT may be used as a synonym for “fluence-modulated radiotherapy”.

IORT (Intraoperative Radiation Therapy)
Radiotherapy conducted during surgery.

Constancy test
see Final inspections and constancy tests

Emergency diagnosis
An emergency diagnosis exists in the case of patients for whom, from a medical viewpoint, any delay in examination would lead to severe medical complications.

Particle radiation
Proton, neutron and ion radiation; does not include electron radiation.

Other persons involved
"Other persons involved" may, for instance, include physicians without the requisite expertise in radiation protection, nurses and orderlies, or persons with know-how in medical physics and radiation protection.

RSO (Radiosynoviorthesis)
Nuclear medicine technique used to treat inflammation, during which a beta-emitting radiopharmaceutical is applied to the gap of the relevant joint.

SIRT (Selective Internal Radiation Therapy)
Nuclear medicine treatment technique which involves injecting radioactively charged particles into a tumour via a catheter.

Standard treatment
Standard treatment is the treatment of patients for whom a customised therapy plan and dose estimation respectively is not required. For treatments with radiopharmaceuticals, this includes the palliative treatment of tumours (radiopharmaceuticals containing strontium 89, yttrium 90, samarium 153 and/or rhenium 186) and radiosynoviorthesis (radiopharmaceuticals containing yttrium 90, erbium 169 or rhenium 186). In most cases, however, such as when treating with iodine 131, individual dose estimations and follow-up examinations to monitor success are necessary. Radioimmunotherapy, SIRT and endovascular rhenium irradiation are not considered standard treatment.

Competent authority
The competent authority is assigned pursuant to the state government ordinance regulating the allocation of responsibilities or by decree of the supreme state authority responsible for radiation protection. It is subject to technical supervision by the same. Within this context the task of licensing the requisite expertise in radiation protection for physicians is usually assigned to the respective state medical council. Radiation protection courses are approved in part by the ministries in question or by the "competent authority" appointed.

Effects of radiation
Biological effects of irradiation.

Technical assistance
Technical assistance in the medical application of radioactive substances or ionizing radiation is every activity that has an influence on the medical radiation exposure and patient radiation readings required by an examination or treatment method, including all associated quality assurance measures.
Pursuant to the MTA Act (Appendix B number 2.4) the following activities shall only be conducted by MTRAs:

a) performance of any technical work and assessment of its quality associated with radiological diagnostics and other imaging techniques including quality assurance,
b)technical assistance during radiotherapy - producing the therapy plan and its realisation on the patient including quality assurance,
c)technical assistance in nuclear medicine diagnostics and treatment, including quality assurance,
d) performance of dosimetric and radiation protection measuring tasks in radiological diagnostics, radiotherapy, and in nuclear medicine.

Virtual simulation
Transfer of planning results to the patient using a CT, thereby allowing simulation **of** the actual irradiation and positioning parameters.