

#### **Instructions for Radiation Protection**

of the **University of Heidelberg** and of the **Heidelberg University Medical Centre** 

for the execution of the radiation protection regulation (*Strahlenschutzverordnung* StrlSchV), proclaimed on July 20<sup>th</sup> 2001 (BGBI. I Nr. 38, S. 1714) and the x-ray regulation (*Röntgenschutzverordnung* RöV), proclaimed on June 21<sup>st</sup> 2002 (BGBI. I Nr. 36, S. 1869).

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## § 1 Persons responsible for radiation protection

(1) Responsible for the radiation protection according to § 31 StrlSchV and § 13 RöV inside the University Heidelberg is the rectorship, especially the vice-chancellor (Kanzler, § 12 Abs. 2 UG). Within the university clinic the commercial director is responsible for radiation protection. Authorized representatives for radiation protection are appointed for the following areas:

#### I UNIVERSITY CLINIC

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except the departments situated in the THEORETIKUM.

#### **II UNIVERSITY**

including all departments situated in the THEORETIKUM.

(2) The persons responsible for radiation protection nominate the authorized representatives for radiation protection for the different institutions.

#### § 2

### The distribution of tasks and duties in the area of radiation protection between the University and the University Clinic

- (1) The tasks and duties in the area of radiation protection of the university are separated from those of the university clinic. This division arranges the radiation protection of persons and facilities with special consideration for the THEORETIKUM.
- (2) Employees of the university clinic who work in facilities of the university and/or in the THE-ORETIKUM have to follow the directives of the persons of the university who are responsible for the radiation protection and their representatives. The university clinic is responsible for the radiation protection of these employees but not for the facilities. The university is responsible for the radiation protection of the facilities but not for the employees.
- (3) Employees of the university clinic who work in facilities of the university clinic outside the THEORETIKUM have to follow the directives of the persons of the university clinic who are responsible for the radiation protection and their representatives. The university is responsible for the radiation protection of these employees but not for the facilities. The university clinic is responsible for the radiation protection of the facilities but not for the employees.

#### duties of radiation protection for employees are:

- to give Instructions about general precautionary measures and about radiation protection including the advice that specific instructions about the facility and working place are necessary
- to report the exceeding of the dose limit values in case of internal or external radiation exposition according to § 15 StrlSchV
- to report the removal of an employee exposed to radiation out of the radiation protection monitoring
- to report any bans from work according to § 14 of this radiation protection instruction
- to carry out medical check-ups in occupational medicine (registration, storage and administration of the results)
- to check the reliability of persons according to § 31 Abs. 3 StrlSchV
- (4) duties of radiation protection for facilities are:
  - to check the requirements given in section 4 for working in radiation protection areas
  - to give specific instructions for the working place
  - to monitor the radiation in the radiation protection areas
  - to report any overdose of internal or external radiation exposition, to report any bans from work according to § 14 of this radiation protection instruction, to report the monitoring of incorporation on special occasions, to report any offences against this instruction for radiation protection or against the orders of the persons responsible for radiation protection or the radiation protection agents.

### Authorized representatives for radiation protection (Strahlenschutzbevollmächtigte)

- (1) The authorized representatives for radiation protection are appointed in writing and for an unlimited time until revoked. The authorized representatives for radiation protection may appoint persons who act as their deputies. If the authorized representative for radiation protection and his deputy/deputies are unable to perform their duties then the authorized representative for radiation protection has to deliver a continuing regulation for any case in written form
- (2) The authorized representatives for radiation protection perform their tasks and duties (given on the behalf of the persons responsible for radiation protection) on their own responsibility according to the radiation protection regulation (§§ 31, 33 StrlSchV) and the X-ray regulation (§ 13 Abs. 1-2, § 14 Abs. 1-4, § 15 Abs. 1, § 15a RöV).
- (3) In order to implement the radiation protection regulation and the X-ray regulation the authorized representative for radiation protection have (besides the radiation protection agents) the authority to issue directives.
- (4) The authority to issue directives includes the right to inspections and supervisions and to take a look at the records, documents and plans according to the radiation protection regulation and the X-ray regulation. A report about all important events must be given to the persons responsible for radiation protection. A report about the results of the inspections and supervision must be given to the head of the department immediately.
- (5) The names of the authorized representatives for radiation protection must be forwarded to the supervisory authority and to the appropriate council for civil servants.

# § 4 <u>Tasks</u> and duties of the authorized representatives for radiation protection

- (1) The authorized representatives for radiation protection are obliged to take care that the principles of radiation protection (Kapitel 1, §§ 4, 5, 6 StrlSchV und § 15 RöV) are being observed in order to protect individuals and the general public against radiation damage (life, health and objects) in compliance with the state of science and technology.
- (2) The authorized representatives for radiation protection have to inform the persons responsible for radiation protection to what extend safety devices, personal protective kits and qualified personnel have to be provided to achieve the goals of chapter 1
- (3) The authorized representatives for radiation protection take care, that the work in the areas they are responsible for is performed according to the radiation protection instructions. For this purpose they may check the areas where ionising radiation occurs (radiation protection areas).
- (4) The authorized representatives for radiation protection have to advise the departments of the University and of the University clinic about radiation protection according to the latest developments in science and technology.
- (5) In case of new buildings and rebuildings the authorized representatives for radiation protection work together with the users and the safety department (Abteilung Sicherheitswesen) to include the necessary legal conditions.

- (6) The authorized representatives for radiation protection have to take care that the radiation protection agents and the personnel observe the radiation protection regulation and the X-ray regulation.
- (7) The authorized representatives for radiation protection have to check the regular inspection of function and maintenance of equipment and devices in the area of radiation protection. They also have to check the reports of the radiation protection agents within their responsibility.
- (8) The authorized representatives for radiation protection must provide a written report about their business in the field of radiation protection. They have to report about complained faults and their remedies. If they reject proposals from the radiation protection agents they have to give an explanation in written form to the persons responsible for radiation protection.
- (9) The authorized representatives for radiation protection give a written report about their activities each year at the 31<sup>st</sup> of March to the appropriate persons responsible for radiation protection.
- (10) The authorized representatives for radiation protection inform the radiation protection agents about the recent state of law in the field of radiation protection and about new developments concerning radiation damage
- (11) The authorized representative for radiation protection may call the radiation protection agents of their area of responsibility and the experts for occupational safety (Fachkräfte für Arbeitssicherheit) for a meeting if necessary. The responsible council for civil servants is allowed to take part at the meeting.
- (12) The authorized representative for radiation protection informs the supervisory authority twice a year about the purchase and the distribution of radioactive material in their area of responsibility (Befreiung von § 70 Abs. 1 StrlSchV), if the handling license does not imply something else.
- (13) The heads of the departments are obliged to support the authorized representative for radiation protection in any way.

#### § 5 Radiation protection agents

- (1) The radiation protection agents (with the appropriate knowledge) are appointed in written form according to § 31 Abs. 2 StrlSchV and § 13 Abs. 2 RöV. They have to supervise the personnel of the University and of the University clinic who work with radioactive materials, with x-ray devices and with disturbing radiation. The appointed persons must fulfil the requirements of §§ 30, 31 Abs. 3 StrlSchV and § 13 Abs. 3 RöV respectively.
- (2) The persons responsible for radiation protection of the University or of the University clinic appoint the radiation protection agents according to a proposal by the head of a department in agreement with the authorized representatives for radiation protection. The appointments are timewise unlimited but may be revoked. These proposals must be forwarded to the persons responsible for radiation protection via representatives for radiation protection. The retirement of radiation protection agents must be reported the same way in time. The person responsible for radiation protection of the University appoints also the radiation protection agents for the clinical facilities in the THEORETIKUM.
- (3) The radiation protection agents receives his certificate of appointment or discharge from the authorized representative for radiation protection. The certificate has to name the area for

- which the radiation protection agents and their deputies are responsible (the numbers of the buildings and rooms).
- (4) The appointment or discharge of radiation protection agents must be forwarded immediately to the supervisory authority by the persons responsible for radiation protection. Changes in the area of responsibility of the radiation protection agents must be handled the same way.
- (5) A sufficient number of radiation protection agents (usually at least one deputy) must be appointed to ensure an orderly and trouble-free work.
- (6) The tasks and duties of the radiation protection agents follow the radiation protection- and the X-ray regulation, these instructions for radiation protection and further rules given by the authorized representatives for radiation protection.
- (7) When fulfilling their duties, the radiation protection agents may not be hindered and they may not be discriminated because of their work (§ 32 Abs. 5 StrlSchV, § 14 Abs. 5 RöV). The person responsible for radiation protection must be informed when discrimination is suspected.
- (8) The heads of the department must support the radiation protection agents.

#### § 6 Tasks and duties of radiation protection agents

- (1) The radiation protection agents ensure for their area of radiation protection that the radiation protection- and X-ray regulations, the instructions for radiation protection and further rules are followed. All measures must be documented in written form. This documentation must be posted in the area of radiation protection.
- (2) The radiation protection agents have to inform the authorized representatives for radiation protection immediately about all faults in their area of radiation protection.
- (3) The radiation protection agents are obliged to inform the authorized representatives for radiation in time and without being asked about any change in where to find them.
- (4) The radiation protection agents must give a written report about their activities once a year to the authorized representative for radiation protection. These reports must contain all considerable incidents and data.
- (5) The radiation protection agents are obliged to give a written report (and in form of a chart on a data carrier) about the stock of radioactive material (with a half life longer than 100 days) at the end of each year to the authorized representatives for radiation protection within a month (§ 70 Abs. 3 StrlSchV).
- (6) In all radiation protection areas a notice has to be put up about the places where to find the radiation protection regulation, the X-ray regulation, this instructions for radiation protection and further regulations.

## § 7 Cooperation with the staff council for civil servants (Personalrat) and the safety department

(1) The authorized representatives for radiation protection and the radiation protection agents are obliged to co-operate with the council for civil servants and the safety department (Abteilung Sicherheitswesen) in all cases required by law (Personalvertretungsgesetz, §§ 68 (2), 79, 80, 83 Arbeitsstättenverordnung, Arbeitsschutzgesetz, § 32 Abs. 4 StrlSchV). They also have to inform and advise them about important matters of radiation protection.

#### § 8 Correspondence with authorities

(1) The authorized representatives for radiation protection and the persons responsible for radiation protection correspond with the supervisory authority (except for other regulations in this instructions for radiation protection).

### § 9 Authorization for the work with ionising radiation

- (1) An authorization from the supervisory authority (§ 7 StrlSchV and §§ 3, 4, 5 RöV) is required for the following activities: working with accelerators, working (generation, storage, processing, transport, disposal etc.) with open and shielded radioactive sources with activities higher than the exemption limit (according to Anlage III, Tabelle 1, Spalten 2, 3 StrlSchV) and working with X-ray devices (and disturbing radiation sources) which are not generally licensed. An authorization from the federal ministry for radiation protection (Bundesamt für Strahlenschutz) is required if X-rays are applied on humans (§ 28a RöV) for medical research.
- (2) The authorization from the authorized representative for radiation protection ist required for the following activities: working in any rooms with open and shielded radioactive sources with activities lower than the exemption limit (according to Anlage III, Tabelle 1, Spalten 2, 3 StrlSchV), the use of X-ray devices and disturbing radiation sources that don't require official approval or which are generally licensed.
- (3) The applications for approval (according to par. 1) or for agreement (according to par. 2) must be addressed to the authorized representative for radiation protection.
- (4) The authorized representatives for radiation protection examine if the applications are in accordance with the radiation protection regulation / instructions for radiation protection / X-ray regulation, especially whether the rooms and the employees are suitable and whether the measuring instruments and the other devices needed for radiation protection are present.
- (5) Applications for approvals to work with ionising radiation (according to par. 1) or for agreement (according to par. 2) which are connected with building projects or which change the existing constructions must be worked out by the authorized representative for radiation protection in accordance with the responsible administration.
- (6) The authorized representative for radiation protection together with the safety department and the fire brigade plan the measurements for fire protection and fire fighting in the area of radiation protection.
- (7) The authorized representatives for radiation protection give the examined applications (according to par.1) to the person responsible for radiation protection to forward it to the responsible supervisory authority.
- (8) The work with radioactive material may only be approved when at least one radiation protection agent is always present or reachable within the time given by the approval.

#### § 10 Safety regulations, accidents and failures

- (1) The authorized representative for radiation protection have to care, that the radiation protection agents keep radioactive substances locked. Unlocked radioactive substances may only be present at the working places as long as necessary for the procedure (§ 43 Abs. 3 StrlSchV). The loss of substances must be reported immediately to the authorized representative for radiation protection and to the responsible supervisory authority.
- (2) The radiation protection agents have to take care that when working with radioactive substances (e. g. uranyl acetate as contrast medium in the field of electron microscopy) the effective dose does not exceed 6 mSv per annum (§ 95 Abs. 1 and 2 and Anlage XI StrlSchV). Higher doses must be reported to the authorized representative for radiation protection.
- (3) In case of accidents or malfunctions measures have to be taken immediately to minimise danger for life, health and equipment.
- (4) In case of a contamination of persons, clothing, workplaces or traffic areas measures have to be taken immediately to prevent spreading or uptake of the radioactive substances. Next the radiation protection area must be closed and the authorized representative for radiation protection must be informed. There are special regulations for the diagnostic and therapeutic use of radioactive substances with humans.
  - (5) The radiation protection agents have to report accidents and malfunctions at once (by telephone or telefax) and later in written form to:
    - the responsible supervisory authority
    - the responsible authorized representative for radiation protection
    - the persons responsible for radiation protection
    - the safety department (Abteilung Sicherheitswesen)
    - the council for civil servants

#### § 11 Instructions

- (1) Persons who work in radiation protection areas with radioactive substances (packing, loading, transporting, processing etc.) must be informed and instructed by the responsible radiation protection agents about all the facts concerning the safety (according to § 38 StrlSchV). Persons who work with X-ray devices and disturbing radiation sources which require official approval must be informed and instructed by the responsible radiation protection agents about all the facts concerning the safety (according to § 36 RöV).
- (2) The following members of staff must also be instructed:
  - Persons who carry out maintenance and repair works.
  - Janitors, workmen, technicians etc. employed by the University or by the University Clinic who carry out maintenance and repair works.
  - Patients, experimentees or helpers, who have to stay in the radiation protection areas (§ 37 Abs. 1, § 81 Abs. 5 StrlSchV).
  - Visitors who are allowed to enter the radiation protection areas (the allowance is given by the authorized representative for radiation protection or by the responsible radiation

- protection agent in agreement with the supervisory authority). This is valid even then when the visitor is accompanied by an expert (§ 37 Abs. 1, § 38 Abs. 2 StrlSchV).
- Trainees and students who need to stay in the radiation protection areas to reach their aims of education (§ 37 Abs. 1, § 38 Abs. 1 StrlSchV).
- (3) The instructions according to the radiation protection regulation and the X-ray regulation must be given by the radiation protection agents and they must include the following subjects:
  - Persons involved in maintenance and repair services.
  - Methods of working
  - Possible risks
  - Safety and protective measures
  - Risks of radiation exposition during pregnancy
  - Relevant parts (for the stay) of the radiation protection- and X-ray regulation.
  - Instructions for radiation protection
  - More regulations given by the authorized representative for radiation protection.
- (4) The instructions according to StrlSchV and RöV must be repeated at least once a year if not otherwise regulated.
- (5) The contents and the date of the instructions must be recorded and the participants must sign the record. These rcords must be stored for 5 years (§§ 36 Abs. 4 RöV, § 38 Abs. 4 StrlSchV) and a copy must be given to the authorized representative for radiation protection.
- (6) The obligations for registration, recording and explanation in case of examination and treatment with ionizing radiation are given in §§ 27, 28, 28c, 28e RöV and in chapter 4 §§ 85, 87, 88, 89 StrlSchV.

#### § 12 Dosimetry

- (1) The radiation protection agents are responsible for the implementation of the official dosimetry of persons (ordering and distribution of dosimeters, recording the events etc.) in their own radiation protection areas. The body dose must be determined according to §§ 41 and 67 of the StrlSchV and in arrangement with the authorized representatives for radiation protection.
- (2) The relevant authorized representative for radiation protection administers the results of the official dosimetry of the employees of the University and the University clinic who are exposed to radiation.
- (3) Dosis above the critical value (officially or non officially registered) must be reported to the responsible authorized representative for radiation protection.
- (4) An employee who was exposed to radiation during his work and who is leaving the University or the University clinic must get (on demand) a written confirmation about the accumulated internal and external radiation dose during his employment from the relevant authorized representative for radiation protection.

(5) The authorized representative for radiation protection of the University or of the University clinic is responsible for the dosimetry of employees of foreign companies without permission according to § 15 StrlSchV.

### § 13 Medical precaution

- (1) Persons exposed to radiation may only be allowed to stay in radiation protection areas (according to § 60 StrlSchV and § 37 RöV) and they may only be allowed to work with open radioactive substances, if the authorized representative for radiation protection has received a written confirmation from the authorized physician within one year, which confirms that no health risks will occur whilst working with ionizing radiation (§§ 60 Abs. 2, 61 Abs. 1 4 StrlSchV and §§ 37, 38 RöV).
- (2) Only physicians with a permission of the relevant supervisory authority may carry out the medical control. (§ 41 RöV).
- (3) The person responsible for radiation protection must ensure the medical control by authorized physicians.
- (4) The entrance physical examinations of persons exposed to radiation (of Kategorie A or B, § 54 and § 60 Abs. 1 StrlSchV, § 37 Abs. 1 RöV) must be applied by the radiation protection agents. These applications must be addressed to the authorized representatives for radiation protection.
- (5) Necessary follow up examinations (according to § 60 Abs. 2 StrlSchV and § 37 Abs. 2, 3, 4 RöV) are carried out by the company doctor (*Betriebsärztlicher Dienst*)
- (6) The radiation protection agents apply the final physical examination. These applications must be addressed to the authorized representatives for radiation protection.
- (7) The result of the last medical check up must be added to the written confirmation mentioned in § 12 Abs. 4 of this instruction for radiation protection.

### § 14 Prohibitions and limitations of work

- (1) Conventional experiments (without radioactive substances) may not be carried out in the radiation protection areas as a routine matter (§ 6 StrlSchV).
- (2) Pregnant and nursing employees may not work with open or packed radioactive substances. Concerned employees must be exempted immediately from work in the radiation protection areas. Female employees must report their pregnancy to the radiation protection agent immediately (according to § 38 StrlSchV). Female employees who are exposed to radiation during work must be informed about this obligation to report their pregnancy. The radiation protection agent reports the pregnancy of an employee exposed to radiation during work to the authorized representative for radiation protection, to the company doctor and to the Council for civil servants in written form.
- (3) Persons under 18 years may not stay in the radiation protection areas. The supervisory authority may allow persons between 16 and 18 years to work with radioactive substances (if needed for their education) if permanent supervision and instruction by a competent employee is ensured. A written application by the den authorized representative for radiation protection is needed for this.

#### § 15 Proficiency in radiation protection

- (1) Proficiency is acquired not only by education and practical experience but also by attending officially accepted courses (§ 30 Abs. 1 StrlSchV, § 18a Abs. 1, 3, 4 RöV).
- (2) In case of an appointment as radiation protection agent by the person responsible for radiation protection according to § 1 Abs. 1 of this instruction for radiation protection, the proficiency will be checked and confirmed by the supervisory authority after a written application of the University or the University clinic (§ 30 Abs. 1 StrlSchV).
- (3) The appointment and official acceptance of radiation protection agents requires that the course needed to obtain proficiency in radiation protection took place not longer than 5 years ago (§ 30 Abs. 1 StrlSchV, § 18a Abs. 1 RöV).
- (4) To sustain proficiency it is necessary to take part in a course which is accepted by the supervisory authority every 5 Years (§ 30 Abs. 2 StrlSchV, § 18a Abs. 2 RöV).
- (5) The authorized representatives for radiation protection administer the data about proficiency and inform the radiation protection agents about the necessary training courses.

#### § 16 Foreign workers

- (1) Employees of foreign companies who do not posses radiation exposure record books or a authorization according to § 15 StrlSchV may only work in the radiation protection areas of the University and the University clinic when it is ensured that the effective dose limit per year (according to § 15 Abs. 1 StrlSchV) will not be exceeded and that they were instructed by radiation protection department of the University or the University clinic. When this dose limit is exceeded the authorized representative for radiation protection and the radiation protection agent must stop the work of these employees in the radiation protection areas of the University and the University clinic.
- (2) Employees of foreign companies who posses radiation exposure record books and authorization according to § 15 StrlSchV may only work in the radiation protection areas of the University and the University clinic if the University or the University clinic has concluded a contract with the company which exactly lays down the duties of the concerned persons.
- (3) The authorized representatives for radiation protection communicate before the start of work with the radiation protection agents of the foreign companies about the conditions of radiation protection and they exchange information about the expected exposition to radiation and about the sort, volume and the frequency of the employment.

## § 17 Purchase of radioactive substances and protective equipment against radiation

(1) The order form for radioactive material may only be subscribed by the radiation protection agent of the department or by his deputy. Written orders are necessary. Orders by telephone are not allowed.

- (2) The relevant authorized representative for radiation protection is responsible for the purchase of radioactive substances. The authorized representative for radiation protection must be informed immediately when an ordered substance has arrived. The bills and the pay off orders must be forwarded to the authorized representative for radiation protection. The cashier's offices of the University and the University clinic may only transfer this bills when they wear a safety remark of the authorized representative for radiation protection.
- (3) Radioactive substances may only be delivered to the radiation protection agent of the department or to his deputy.
- (4) The radiation protection agents must take special care that the order form is compatible to the relevant approval and that the approved total activity (including the existing stock) will not be exceeded.
- (5) The purchase of radiation measuring instruments and other radiation protection equipment should be performed just as in case of radioactive substances. The orders may not be directed to the vendors directly but must be given to the authorized representative for radiation protection. After a proficient check the authorized representative for radiation protection orders the purchase.

#### § 18 Payment

- (1) The relevant department pays the costs for the radiation protection which is needed for research and teaching.
- (2) The administration of the University or the University clinic pays the costs for acquiring and sustaining the expert knowledge of the authorized representatives for radiation protection, the radiation protection agents and their deputies.
- (3) The administration of the University ("Zentrale Universitätsverwaltung") or the administration of the University clinic gives monetary means to the authorized representative for radiation protection for central tasks of the radiation protection.

### § 19 Radioactive waste

- (1) Solid and liquid radioactive waste must be disposed by the department of radiation protection of the "Zentralbereich Neuenheimer Feld".
- (2) The conditions for the acceptance of radioactive waste ("Bedingungen für die Annahme radioaktiver Abfälle") of the department for radiation protection of the "Zentralbereich Neuenheimer Feld" are valid for the packaging and acceptance of radioactive waste.
- (3) The radiation protection agents of the relevant departments are responsible for separating and packing and for complete details on the forms for acceptance and transport ("Übernahme- und Transportbegleitscheine").
- (4) The department for radiation protection of the "Zentralbereich Neuenheimer Feld" may return wrongly packed and wrongly declared waste and waste that is not conformable with the conditions for the acceptance of radioactive waste ("Bedingungen für die Annahme radioaktiver Abfälle") to the sender.

(5) The producer pays the overhead expenses and measuring instruments needed for the disposal of waste.

### § 20 Coming into force

These instructions for radiation protection become valid after their publication. They are published by the vice chancellor (*Rektor*) of the University.

Heidelberg, September 22<sup>nd</sup> 2003

signed: Senni Hundt (Kommisarische Kanzlerin)

signed: Irmtraut Gürkan (Kaufmännische Direktorin des Universitätsklinikums)