

**D e c r e e**  
**of the State Institute for Nuclear Safety**  
**of July 24, 1997**  
**on requirements for security of radiation protection**

**Catch III**

**Art. 34**

***Details concerning the conditions of medical irradiation***

- 1/ For the medical irradiation sources of ionising radiation exclusively on medical indication is used. Following adequate training in the technique used in such irradiation procedures the medical irradiation treatment can be performed only by:
  - a/ physicians specialised in radio-diagnostics, radiotherapy or nuclear medicine,
  - b/ physicians with specialisation in stomatology when stomatological X-ray examinations are indicated,
  - c/ other physicians performing medical irradiation provided the physician is competent by the accomplished education in the respective specialisation,
  - d/ radiological technical assistants or paramedicals adhering to physician's prescription and in possession of qualification ad a/ - c/
  - e/ nurses in nuclear medicine wards, according to advice of physician with specialisation in the particular discipline.
  
- 2/ In order to comply with the approved quality safeguarding /art.17, par. 1 d, of the Law/, specialised radio-therapeutic wards and dept. of nuclear medicine the presence of a College-educated specialist is required. This specialist must additionally be approved by the Institute for work in departments with nuclear sources. The specialist must be trained for technological co-operation with dept. of nuclear medicine, radio-diagnostics or radiotherapy according to a separate rule /Regul. Min. of Health, art. 77/81, on medical personnel/. The requirement for specific ability of persons engaged in the procedures with medical irradiation is given in a separate regulation /see Decree 146/97/.
  
- 3/ The medical irradiation of individuals is justified /art.4, par.2, Law/ by the expected individual health benefit of the patient under possible choice of other examination procedures or visual methods or different therapeutically interventions. The irradiation-based monitoring applicable in secondary prevention in population groups is justified by the expected improvement for the patient whose disease is disclosed, along with possible therapeutically influencing of his disease. In some cases the reason for monitoring may be protection of the population groups. Monitoring and other irradiation-based examinations without clinical indication can be performed only when approved by the Ministry of Health.
  
- 4/ The guiding criteria for medical irradiation are given ad 9/. These criteria relate to examination of a standard adult patient of 70-kg mass, for other persons their body mass and physical constitution will be taken in consideration.
  
- 5/ Optimisation of radiation safety during medical irradiation is achieved by the choice of an adequate radio-diagnostic or radio-therapeutic procedure, whereby:
  - a/ during radio-diagnostics using external irradiation it is necessary to use the recommended working parameters of the irradiation appliances considering the requirements for the correct visualisation and using the correct visualisation techniques so that the doses in the tissues in the examined body parts are as low as possible without any risk of not-receiving the necessary radio-diagnostic information,
  - b/ when using radionuclides it is essential to apply the indispensable amount of a radioactive substance of required parity and activity, which enables the sufficient diagnostic information at the lowest possible load of the patient,
  - c/ in radio-therapeutic procedures the irradiation of the target volume being the object of radiotherapy is

done within a range necessary for obtaining the expected effect; the irradiation of other tissues must be as low as reasonably practical without impairment of the treatment.

- 6/ The health centre performing medical irradiation must be equipped with personal protective tools and aids also for radiation protection of the patients and health care volunteers. These protective tools must be used according to the character of examination. The technological devices used for diagnostics or therapeutic procedures in medical irradiation are liable to approval by special regulations.
- 7/ Before every application of ionising radiation for patients' examination or treatment it is necessary to search for previous significant radionuclide or ionising radiation treatments, which *might* be of importance for the planned examination or therapy. Examined is taking, if any, of a pacemaker, joint prostheses and possible pregnancy in women of fertile age. Such anamnestic data are included in health care documentation.
- 8/ All medical interventions using ionising radiation are recorded thus enabling the assessment of irradiation doses in the examined or treated person. For radio-diagnostic procedures input doses are recorded /persons of average constitution, volume or mass/ or data for estimation /in case of radio-therapeutically irradiation/of the dose in the target volume surface dose and time sequence of irradiation; in nuclear medicine mostly the specification of the radio-nuclide applied the form of application and activity are evidenced.
- 9/ In pregnant women it is possible to apply irradiation-based procedures only in emergency or when indicated by an obstetrician. Here invariably should carefully be considered the necessity to obtain the required information by means of radiation sources whereby foetus-sparing methods are indicated.
- 10/ The patient's discharge in home care following radionuclide therapy should be done so as to never exceed the special limits ad art.12, par. 1. The said limits also relate to the irradiation control by patients and visitors after radionuclide therapy, or brachy-therapeutic sources of ionising radiation. The data are included in the health files of the patient.
- 11/ Radionuclide therapy is done only in in-patient wards specially equipped and arranged as to meet the requirements for workplaces with open radionuclide emitters. Measures must be taken to prevent the patients from using their own clothing, and on discharge all objects used by the patients are to be checked for potential radionuclide contamination, and, if necessary, decontaminated or discarded as radio-nuclide-contaminated objects or radioactive wastes.  
The out-patient radio-nuclide therapy may be applied only when the Institute-in justifiable cases, e.g. palliative treatment-stipulates the particular conditions of the permission, provided this policy is not used in incontinent patients or persons unable to adopt the basic hygienic habits.

#### **Catch IV**

##### **Art. 35**

##### ***Details for delimitation of the zone under control***

- 1/ The zone under control in workplaces using ionising radiation is defined so as to guarantee, by means of barriers, construction shape, work regimen, monitoring and security measures normal in source applications, the sources will be handled by persons physically healthy and expertly skilled and equipped adequately, informed about the potential hazards, and the effects of radiation accidents, if any, will be minimised.
- 2/ The zone under control is defined anyplace if the irradiation under normal operation or foreseeable irregularity might rise in the personnel by three tenth exceeding the basic limit. Unless any special handling of irradiation sources is justified /e.g. in time-limited applications/ it is advisable to delimit the controlled zone in places if:
  - a/ the effective input dose of external irradiation on the site is higher than 2.5  $\mu\text{Sv/h}$ ,
  - b/ the sum of volume activity products of individual radio-nuclides in the occupational atmosphere and those of conversion factors for intake by aspiration of the source attendant according to encl. 3 Table

exceeds 2.5  $\mu\text{Sv/h}$ , in suppl. 2 Table 1.

c/ surface contamination of workplaces is higher than the target values for surface contamination by radionuclides as given in suppl. 2 Table

- 3/ The controlled zone is defined as integrated, explicit ionising radiation source workplace usually detached, which has to be safe against access of unauthorised persons. For temporary field stations /e.g. defectoscopic/ the controlled zone is defined by dose input zones with non-access of unauthorised persons. The controlled zone on entrance or borders is marked with signs of radiation hazard CSN 01 5015.
- 4/ The proposal for controlled zone delimitation is part of the documentation approved by the Institute as pertinent to the application for authorised handling of ionising radiation source. This proposal includes:
  - a/ the range of the controlled zone, usually in terms of numbers of rooms and layout thereof, or in case of temporary facilities the particular dose input limits are given,
  - b/ justification of the proposed range or extent of the zone mostly calculations and other data substantiating the fulfilment of par. 2,
  - c/ description of the constructional and technological safety of the controlled zone against access of unauthorised persons,
  - d/ planned number of workers in the controlled zone, informative instruction for the personnel about occupational risks in the zone, e.g. instructions for entering and work in the zone under control.

#### **Art. 36**

##### ***Technological and organisational conditions for work in the controlled zone***

- 1/ The controlled zone is accessible only to persons instructed about behaviour preventing health damage to themselves and others. The workers of A and B category undergo instruction courses at least once a year, with an attest in writing.
- 2/ Access to ionising radiation control zone is prohibited to pregnant women and persons under 18 years of age, except to patients summoned to a medical irradiation therapy /art.18, par 1, ad 1/ / and persons working in such facilities or training for professional activity using of ionising radiation sources.
- 3/ On entering the controlled zone every worker must have a personal dosimeter complying with the monitoring program as well as aids adequate to the methods handling the ionising radiation sources, and in case the equivalent dose input exceeds 1 mSv/h also the direct reading signalling personal dosimeter. For important sources these rules relate to all entering persons except those visiting the controlled zone of a health care centre using ionising radiation sources in order to undergo a treatment or examination applying ionising radiation.
- 4/ In the controlled zone, the sources of ionising radiation can be handled by workers of A category only, under their supervision also pupils, students and trainees for the period of their specialised preparation for jobs using ionising radiation sources.
- 5/ The controlled zone of a workplace with powerful sources and work places handling open radionuclide emitters of Cat. III and also II, /unless stated otherwise, by the permission/ are operated following the change of clothing, and on exit the persons are checked for radioactive contamination, or body recontamination is done.

#### **Art. 37**

##### ***Basic conditions for the safe operation in workplaces with ionising radiation sources***

- 1/ For the safe operation on every workplace using ionising radiation sources /except for less powerful or minor ones/, before the start of actual manipulation with these sources, it is necessary to provide:
  - a/ constant supervision of compliance to radiation protection rules /art. 18, par.1 ad 1/- Law/ by at least one person having expert knowledge in radiation protection
  - b/ delimitation and marking of the controlled zone according to art. 35, providing for means to control the

- movement of persons in the zone according to art.36,
- c/ the equipment of the workplace with apparatus, facilities or aids of quality and number sufficient to safeguard all measurements of the monitoring program, internal accident emergency regulations, take-over protocol as defined by the Institute in the permission to handle and maintain the above said aids in proper technical condition,
  - d/ the outfit of personnel working with sources with personal protective tools /overalls, aprons, goggles, gloves with adequate shielding effect/ and other protective instruments /tweezers, pincers, safety wraps, containers, etc./
- 2/ The specific health faculty of cat. A worker has to be checked, at least once in 2 years by an Institute-charged health centre, which performs preventive examinations analogical to those usual on hazard workplaces. The health records at the authorised health care centres are kept for 30 years following the end of the job in the controlled zone, and minimally up to 90 years of age or 10 years after the worker's death. The worker is informed about the outcome of the health checks, and upon request these data are sent to the respective owners of permission to handle the ionising radiation sources.
- 3/ For A category- workers it is necessary to provide:
- a/ regular replacement and evaluation of personal dosimeters,
  - b/ instant replacement and dosimeter evaluation in suspect or actual radiation accident
  - c/ information of the workers about the results of personal dosimeter evaluations
- 4/ Radionuclide contamination of body surface, clothing, facilities or construction parts in the workplace with ionising radiation sources is to be kept below the values for surface radionuclide contamination as given in Table 1, suppl. 2. If radionuclide contamination exceeds these values, effective decontamination must be done whereby for the controlled zone-surface contamination occurring as the result of foreseeable methods of handling ionising radiation the given values relate only to the take-off parts of the surface contamination by radionuclides.
- 5/ A prerequisite for the source-using workplace operation to be considered safe is:
- a/ the average effective doses, due to discharge in the air for the particular critical population group never exceed 200  $\mu\text{Sv}$  yearly, or 50  $\mu\text{Sv}$  due to discharge in water-flows or 250  $\mu\text{Sv}$  in total from all discharges of the said workplace,
  - b/ in rooms adjacent to radiotherapeutic wards the annual effective doses never exceed 250  $\mu\text{Sv}$ ,
  - c/ in rooms adjacent to radiodiagnostic laboratories the annual effective doses never exceed 100  $\mu\text{Sv}$ .

### **Art. 38**

#### ***Special requirements for the safe operation in workplaces using radiation generators***

- 1/ The radiation generator can be On and used for the necessary time only
- 2/ When entering the delimited or shielded irradiation space during irradiation and radiography with a generator as well as after finishing the operation checks by signalling or measurement must be made to make sure the generator was Off.
- 3/ Stationary X-ray facilities and other stationary radiation generators are installed in separate irradiation rooms or examining cubicles, and are operated from shielded service booths, except for X-ray apparatus whose construction or application prevents the excess of irradiation limit values. As to X-ray facilities for radiodiagnostics, which has to be operated directly from the examining cubicle, rigid or sliding protective screens preventing exceeding of irradiation limits are used.
- 4/ Workplaces using radiation generators being components of another facility or apparatus whose protective screening is required, must, during the operation, provide for:
  - a/ a protective screening installed in a space accessible only by attendant's hands and capable of keeping the dose equivalent below 250  $\mu\text{Sv/h}$ , and on any other accessible place at a distance of 0.1 m from the surface, the dose equivalent is less than 1  $\mu\text{Sv/h}$ .
  - b/ means how to prevent putting the apparatus or facility in operation in case the protective screen is absent, and the facility will automatically be shut off when the protective screen is open. The radiation

generator must not be used before passing a take-over test /art.43/ or if the time period for a long-term stability test for periodical checks is over, or when some other reasons for performing this test occurred.

#### **Art. 39**

##### ***Special conditions for a safe operation in workplaces with closed radionuclide emitters***

- 1/ The closed radio nuclide emitter can be in use only for the time this necessary, and beyond this time it will not be kept in On-position but inserted in a screening casing or shielded in any other way. The closed radionuclide emitters must be stored in such a way so as the input dose equivalent inside the storing rooms and space never exceeds 1 µSv/h.
- 2/ During irradiation and radiographic operations with a closed radio nuclide emitter it is necessary to check, after finishing work or before entering the delimited or screened irradiation space, using signalling or measurement, the emitter was properly screened or inserted in the protective casing. During handling the closed radionuclide emitter likely to get loosened, or its loss from the irradiation kit cannot be excluded, a measuring device is used which enables to fix under all conditions, the emitter's position.
- 3/ The closed radionuclide emitter must not be used until passing the take-over test /art.45/ or time period for regular long term testing was over, /art.44/ or other reasons for performing the test occurred. Under suspect radionuclide leakage or untightness the closed emitter has to be put out of operation immediately.

#### **Catch V**

#### **Art. 49**

##### ***Monitoring of a workplace with ionising radiation sources***

- 1/ Workplace monitoring is done by measurement, follow-up, evaluation and recording of parameters characteristic for the ionising radiation field and occurrence of radio nuclide in a workplace with ionising radiation sources, particularly input equivalent dose, volume activities in the indoor air and surface activities of the workplace. Except for unimportant minor sources monitoring is introduced in every workplace using ionising radiation sources.
- 2/ With the start and change of working procedures or changed system of radiation protection the effectiveness of radiation protection against external and internal irradiation is checked by detailed measuring of input equivalent dose, volume activity and other values of ionising radiation sources, on the processing sites and sites of probable workers' stay.
- 3/ Monitoring of radionuclide surface contamination is done on work sites with open emitters to enable signalling of operational abnormality against the usual run, incorrect function or failure of barriers preventing scattering of radioactive substances. With permanent high surface contamination monitoring of surface volume activities and regular personal monitoring for radionuclide intake is done.
- 4/ The regular ambient monitoring done by consistent measurements of radionuclide volume activities in the air is always introduced in workplaces with open radionuclide emitters being very important sources of ionising radiation.

#### **Art. 50**

##### **Monitoring of persons**

- 1/ Monitoring of persons determines the personal doses by follow-up, measurement and evaluation of individual external and internal irradiation of persons
- 2/ Monitoring with personal dosimeters is done for all A category workers and persons who on workplaces with ionising radiation sources are involved in radiation accidents or catastrophes, unless otherwise stated in the conditions for approval of the monitoring program.
- 3/ The personal dosimeter is worn on a body part exposed to the highest irradiation, normally on front left side of the chest /further-reference place/. If protective screening apron is used the dosimeter is attached to the

outer side of the apron and personal dose equivalent found outside the apron is reduced by the value equal to attenuation inside the apron. Should the dosimeter in the reference place prevent the estimation of equivalent and effective doses subject to strict limits the worker is in possession of another dosimeter, which due to its characteristics or location enables the estimation.

- 4/ The personal dosimeter must measure all types of radiation active in external irradiation of the source-handling individual, If one dosimeter fails to meet this requirement the worker receives more dosimeters so as to meet this provision provided no other monitoring method was approved by the Institute for the monitoring program.
- 5/ On work site where the loss of control over the ionising radiation source is likely to cause radiation accident due to a single external irradiation, the workers using sources have operative dosimeters capable of direct signalling the excess of the set limits. If the radiation source is capable by a single irradiation of exceeding the five-fold of the basic limit for workers using sources, monitoring must enable to fix the doses and their distribution in the worker's body as well reconstruction of the accident.
- 6/ In workplaces with likely internal irradiation of the personnel the radio nuclide intake or effective dose load from internal irradiation of individual workers is established by measuring of radio nuclides in the body or excretions and is calculated for intake values using models of respiratory tract, GIT and kinetics of the respective elements. If handling open radiation emitters being simple sources of ionising radiation the measurement of radionuclide activity in the worker's body or excrements is not required.
- 7/ Under suspicion of a random single irradiation of the worker immediate evaluation of personal dosimeters and dosimetric rating of the actual accident must be done.