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Radiation Protection Principles for Radioiodine Therapy

Recommendation by the German Commission on Radiological Protection

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In the event of any doubts about the meaning, the German original as published shall prevail.

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1 Introduction

The use of radioiodine therapy to treat diseases of the thyroid is considered world-wide to be an effective, economical method of treatment with minimal side effects. For most patients with a thyroid carcinoma, repeated radioiodine therapy is necessary at times. For benign diseases of the thyroid (e.g. hyperthyroidism, autonomous goitre), radioiodine therapy can often replace an operation. Especially with high-risk patients, radioiodine therapy is considered a good alternative to operations in terms of cost-effectiveness and risk-benefit ratios. Currently in Germany, approximately 90,000 thyroid operations and 35,000 radioiodine treatments are performed each year.

While the majority of European countries, the USA, Canada and Australia permit radioiodine therapy to be conducted on an outpatient basis up to certain level of applied activity, the Federal Republic of Germany is one of the few countries where a patient must be admitted into hospital, and this for good reason. On the one hand, this permits the therapy itself to be conducted under optimal conditions (quality assurance by means of dosimetry under inpatient conditions), and on the other hand, ensures that the general public is protected from radiation. In Germany, the prerequisites for a radioiodine therapy include the presence of qualified personnel (expert knowledge) and an appropriate facility (radiation protection equipment, waste water storage). The patient must remain in hospital until the level of activity permissible on release is reached (discharge level), yet at least for 48 hours.

Especially in Germany, a low-iodine area, it is particularly important that the optimal requirements for radioiodine therapy be met, including optimal quality of treatment, while ensuring that the general public and the environment are protected from radiation. The long waiting periods for radioiodine therapy (currently more than one to two years) resulting from long hospital stays and limited number of hospital beds in nuclear medicine in the Federal Republic of Germany have led to a phenomenon known as “radioiodine tourism”. This leads to situations where a single patient treated abroad can release upon his return to Germany more I-131 into the sewage system in one day than most nuclear medicine wards are permitted to release in an entire year.

It would be easy to shorten hospital stays and thereby increase treatment capacity and shorten waiting periods simply by raising the level of radioactivity which must be reached before release from hospital. This would not result in any change in the quality of the radioiodine therapy. It would increase the quality of medical care in Germany, lower costs, and at the same time decrease the amount of radiation exposure for the general public, as it would practically eliminate the reasons for “radioiodine tourism”.

2 Conditions for radioiodine therapy related to radiation protection

Radioiodine therapy is conducted on patients with both benign and malignant diseases of the thyroid. For patients with benign diseases of the thyroid, generally between 200 and 2,000 MBq (5-50 mCi) of I-131 are administered, of which 40-80% are stored in the thyroid. The remaining radioactivity is excreted with urine: more than 90% within the first 2 days after

administration. The radioactivity stored in the thyroid decreases with an effective half-life of 4 to 7.7 days.

For malignant diseases of the thyroid, usually the thyroid is removed in an operation, after which generally between 1,000 and 8,000 MBq (30-200 mCi) of I-131 are administered. The percentage storage in residual thyroid tissue and metastases is considerably lower than in the intact thyroid (less than 1-20% of the radioactivity administered). Of the radioactivity not stored, considerably more than 90% is excreted within 2 days of administration, too.

3 Current radiation protection regulations for radioiodine therapy

According to the “Guidelines for radiation protection in medicine” [1], the following regulations govern therapy with open radioactive substances:

- Approval in accordance with § 3 of the Radiation Protection Ordinance
- Presence of sufficient personnel qualified in radiation protection for treatment with open radioactive substances
- Presence of a physician as radiation protection officer, and if requested by the authority, availability of a further radiation protection officer qualified in the physical-technical field
- Hospitalisation for at least 48 hours in control area after treatment with open radioactive substances
- Presence of radiation protection equipment (construction measures, means of storage for waste water and, if required, waste air, measuring instruments and other radiation protection equipment)
- Conducting of a dose estimate before treatment with open radioactive substances
- Observation of decrease of radioactivity over time after administration of the open radioactive drug (“dosimetry under therapy”)
- Release of patient from the control area of the radiotherapy facility when the radiation exposure for people in the vicinity of the patient (so-called “other people”) will not exceed 1.5 mSv per year. Using a conservative estimate of 7.7 days for the effective half-life of radioiodine, a radioactivity of 95 MBq for I-131 causes an equivalent dose of 1.5 mSv in a person remaining at a proximity of one meter from the treated patient for an extended period of time.

4 Raising the level of radioactivity permissible on release from hospital while adhering to the concept of inpatient treatment

In some European countries, outpatient radioiodine therapy is conducted with activities of 550 MBq of I-131 and more. For outpatient treatment outside of control areas equipped with suitable waste storage equipment, 20-60% of the radioactivity used for treatment of benign diseases of the thyroid and 80-90% of that of malignant diseases of the thyroid is released into the public sewage system. In addition, people in the vicinity of the treated patient are exposed to relatively high radiation levels, especially in the first days following treatment. These facts speak clearly for radioiodine therapy in hospital, in the control area of a radiotherapy facility. In addition, dosimetry under therapy conditions prescribed in the guideline also require hospitalisation for at least 2-3 days. Outpatient treatment with repeated administration of low activities (so-called fractionated radioiodine therapy) is not considered acceptable by the Commission on Radiological Protection for radiohygienic and medical reasons (see Recommendation of the Commission on Radiological Protection on „Fractionated radioiodine therapy in outpatients“[2]).

More realistic assumptions when specifying values for release from hospital would result in fewer bottlenecks in the field of medical care. To this end, the new limits for effective dose according to ICRP 60 [3] for “other people” (1 mSv/a) and for people caring for the patients at home after they have been received radioiodine therapy (5 mSv/a) could be retained. For previous calculations, it was assumed that the “other person” remained constantly within one meter of the patient after his/her release from the control area. This assumption is extremely conservative and leads to a severe overestimation of actual exposure levels. If a distance of about two meters is assumed instead of one, a residual radioactivity of 250 MBq of I-131 on the day of release from hospital will lead to an equivalent dose of 1 mSv due to external exposure. The inhalation of exhaled I-131 also contributes, though to a lesser degree, to the radiation exposure of people in the vicinity of the patient.

If the instructions given to a patient upon release from hospital are observed, it can be expected that at an activity level of 250 MBq upon release, a dose of 1 mSv will not be exceeded, taking into consideration all methods of exposure.

5 Release of radioiodine with waste water and air

The Commission on Radiological Protection recommends a uniform procedure for the calculation of radiation exposure due to the release of radionuclides from nuclear medicine.

5.1 Waste water

§ 46 para. 4 of the Radiation Protection Ordinance [4] states: “If the responsible authority does not specify the maximum permissible release of radioactivity with water per year, then water from control areas or monitored areas can only be released into sewage systems or surface bodies of water if the mean annual quantity of radioactivity due to activities as described in paragraph 1 in one cubic meter of waste water does not exceed 10^{-2} times the values found in Appendix IV, Table IV 1 and IV 3, column 6”. For I-131 this limit is an annual mean of 7 Bq/l.

The Commission on Radiological Protection recommends that the concentration of radionuclides released with waste water into sewage systems be calculated where the drainage system first opens into the accessible or open part of the sewage system. If there are no accessible sewage channels before the water reaches the sewage treatment plant, samples are to be taken where the water enters the plant.

Alternatively, according to § 46 para. 5 of the Radiation Protection Ordinance, the authority can permit higher activity concentrations and higher releases of activity if radioecological observations can prove that the stipulations of § 45 of the Radiation Protection Ordinance are being met.

If the sewage system in the area in question is accessible, the sewage workers are to be considered the critical group for which the exposure pathways direct radiation from waste water and inhalation of radionuclides are relevant. The use of waste water as drinking water is forbidden for hygienic reasons. Exposure to radiation is to be calculated at the point at which the waste water leaves the nuclear medicine facility and enters the accessible or open part of the sewage system. For the calculation of radiation exposure, the quantity of radionuclides released annually and the mean dilution factor (different for each location) must be taken into consideration. If this is unknown, it should be assumed that the dilution ratio of waste water from the nuclear area is 1:10. The assumption that the waste water is retained in this area for 1,000 hours is considered to be sufficiently conservative.

If no sewage channels are accessible before the water enters the sewage treatment plant, the workers in the sewage treatment plant are to be considered the critical group, for which a stay of 2,000 hours per year and the same exposure pathways are to be assumed.

5.2 Waste air

§ 46 para. 3 of the Radiation Protection Ordinance [4] states: “If the responsible authority does not set the maximum permissible release of radioactivity with air per year, then air from control areas or monitored areas must not contain (annual mean per cubic meter of waste air) a level of radioactivity due to activities as described in para. 1 which is higher than

- in the case of radionuclides and radionuclide mixtures for which incorporation determines the limits, 10^{-6} times the values in Appendix IV, Table IV 1 and IV 2, column 5
- in the case of radionuclides and radionuclide mixtures for which submersion determines the limits, 1/500th of the values in Appendix IV, Table IV 4, column 5.”

Since incorporation determines the limit for I-131, the annual mean is 1 Bq/m^3 for I-131. The Commission on Radiological Protection recommends that activity concentrations of radionuclides be calculated where the waste air is released into the atmosphere.

No control measurements need to be made if it can be proved by means of calculation that the annual mean of 1 Bq/m^3 for I-131 is not exceeded due to the limitation of the total radioactivity used in the control area, bearing in mind the air exchange and annual waste air volume.

According to § 46 para. 5 of the Radiation Protection Ordinance, the authority can permit higher activity concentrations and higher releases of activity if radioecological observations can prove that the stipulations of § 45 of the Radiation Protection Ordinance are being met.

6 Recommendations

The Commission on Radiological Protection therefore recommends that:

1. Radioiodine therapy should continue to be performed in hospital, with a minimum stay of 48 hours, regardless of the I-131 radioactivity administered.
2. Patients can be released if the effective dose for persons in the vicinity of the patient is not expected to exceed 1 mSv per year. The radioactivity level upon release should therefore be no higher than 250 MBq. This is equivalent to a dose of 3.5 $\mu\text{Sv/h}$ at a distance of approx. 2 m. Preventive radiation protection measures in the patient's vicinity are to be explained to the patient both verbally and in written form.
3. The exceptions outlined in the "Guideline for radiation protection in medicine" governing the release of patients should be retained (must be reported up to 5 mSv, must be approved > 5 mSv).
4. When releasing radioiodine from a nuclear medicine facility with waste water, an annual mean of radioiodine activity of 7 Bq/l should not be exceeded. The concentration is to be calculated where the drainage system first opens into the accessible or open part of the sewage system, or, if there are no accessible sewage channels before the water reaches the sewage treatment plant, where the water enters the plant.
5. The mean annual radioiodine radioactivity in waste air released from a nuclear medicine facility should not exceed 1 Bq/m³ at the point of release into the atmosphere.
6. According to § 46 para. 5 of the Radiation Protection Ordinance, the authority can permit higher activity concentrations and higher releases of activity for radioiodine with waste water and air if radioecological observations can prove that the stipulations of § 45 of the Radiation Protection Ordinance are being met.

7 Literature

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- [2] Strahlenschutzkommission SSK:
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- [3] International Commission on Radiological Protection ICRP:
Empfehlungen der Internationalen Strahlenschutzkommission (ICRP) 1990.
ICRP Veröffentlichung 60, Gustav Fischer Verlag, Stuttgart, 1993
- [4] Verordnung über den Schutz vor Schäden durch ionisierende Strahlen (Strahlenschutzverordnung – StrlSchV) in der Fassung der Bekanntmachung vom 30. Juni 1989 (BGBl. I S. 1321, 1926), zuletzt geändert durch Artikel 1 der Verordnung vom 25. Juli 1996 (BGBl. I S. 1172)