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Five Years of Incorporation Monitoring on an ^{131}I Therapy Ward – Is Incorporation Monitoring Required for Routine?

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Abstract

Aim: Aim of this study was to evaluate five years of incorporation monitoring of the nursing staff of an ^{131}I therapy ward. The annual effective dose caused by incorporation of ^{131}I of this profession was compared to the dose limits defined in the German incorporation guideline. Furthermore, the ^{131}I incorporation factor stated in the incorporation guideline was verified using the obtained data.

Methods: The mandatory calculation of the potential possible annual effective dose due to incorporated ^{131}I provides values considerably exceeding the dose limit of 1 mSv/a to the staff of the observed ^{131}I therapy ward. To determine the actual work related incorporation, the ^{131}I activity concentration in 143 urine samples (collection over 24 h) of 14 employees of the nursing staff (subdivided into 1st shift: 07:00–15:00; 2nd shift: 15:00–21:00 and 3rd shift: 21:00–07:00) were examined over a period of five years. The median time of exposure prior to sampling was 5.1 days. ^{131}I was administered to patients mainly as capsules. Preparation was done in a fume hood.

Results: The measured activity concentration in urine samples was related to the individual time of exposure. A constant activity supply for at least three days was assumed. The mean annual effective doses were 0.16 mSv/a for the 1st shift (n=55), 0.12 mSv/a for the 2nd shift (n=48) and 0.02 mSv/a for the 3rd shift (n=40). Therefore all determined annual effective doses were well below the dose limits of the German incorporation guideline. In line with a theoretic "worst case" calculation based on the highest measured individual value of each subgroup a maximum annual effective dose was calculated (1.14 mSv/a for the 1st shift, 1.10 mSv/a for the 2nd shift and 0.23 mSv/a for the 3rd shift). The calculated mean incorporation factors ranged from 1.9×10^{-8} for the 2nd shift to 2.5×10^{-9} for the 3rd shift related to the whole activity administered to the patients during the observation time, and was therefore well below the ^{131}I incorporation factor assumed in the guideline.

Conclusions: The ^{131}I incorporation factor stated in the German incorporation guideline of 10^{-6} is disproportionally high. Following the evaluated urine samples, the ^{131}I incorporation factor can be reduced by a factor of 10 to 10^{-7} for employees working on an ^{131}I therapy ward independent of their profession. This will in most cases lead to more accurate calculations and may avoid time and cost intensive incorporation monitoring by the radiation protection authorities.

Keywords: Incorporation monitoring; ^{131}I therapy; Radiation exposure; Radiation protection

Introduction

For decades ^{131}I therapy (RIT) has been a well-established and accepted treatment for patients suffering from benign and malignant thyroid diseases worldwide [1-3]. Although the number of patients suffering from thyroid diseases is declining due to the improved alimentary iodine supply over the past decades [4,5] the rate of surgical interventions on the thyroid in Germany is still relatively high (>100,000 in 2008) [6]. On the other hand new approaches of combining local thermo-ablative treatments and ^{131}I therapy are increasingly shifting into the centre of public attention and may have the potential to gain new collectives of patients for ^{131}I therapy [7-9]. Currently, approximately 50,000 ^{131}I treatments are performed annually in over 100 nuclear medicine inpatient units in Germany [10].

The total radiation exposure to the staff of a ^{131}I therapy ward consists of external and internal radiation exposure. Direct handling of open and enclosed radioactive substances during preparation, labeling and administration as well as the contact with the administered patients themselves are responsible for external radiation exposure. Threshold values of annual effective radiation doses are given in the German radiation protection regulation [11]. Several studies describe radiation exposure caused by patients who incorporated ^{131}I to the population [12], family members [13-17] and the environment [18,19] as well as reservations of the population against the administration of radioactive substances [20-22]. Furthermore, there are several publications concerning external radiation exposure to employees in diagnostic and therapeutic nuclear medicine [23,24]. In contrast, data concerning radiation exposure of the staff caused by incorporation are still rare. The three potential pathways of incorporation are penetration, ingestion and inhalation. Penetration and ingestion can be excluded by the compliance with general radiation protection regulations such as appropriate protective clothing and prohibition of food intake inside radiation protection areas [11]. Therefore, the relevant path of incorporation in nuclear medicine diagnostic and therapy is inhalation. The reasonable arithmetical fundament of radiation dose caused by inhalation of radioactive substances is dose determination in the patients breathing air [25-30].

Since 2007 the determination of radiation exposure caused by incorporated radionuclides is regulated in German radiation protection regulation [1]. According to this regulation the radiation protection representative of a hospital is obligated to calculate the potential radiation dose caused by incorporation for every employee working in a radiation protection area and to evaluate the need for frequent incorporation monitoring. A frequent incorporation monitoring by the radiation protection authorities is necessary in all cases of potential effective radiation doses caused by incorporation beyond 1 mSv/a. Monitoring has to be performed by *in-vivo* or *in-vitro* procedures. Between 0.5 and 1 mSv monitoring can be performed in house by the internal radiation protection representative himself, which of course comes with financial and logistical advantages. For potential effective radiation doses below 0.5 mSv/a, an incorporation monitoring is not required.

Incorporated activity of ^{131}I has to be calculated based on an incorporation factor of 10^{-4} of the used activity which can be reduced to 10^{-6} for preparation in a fume hood [1]. Meanwhile an incorporation factor of 10^{-7} is accepted for ^{99m}Tc und ^{18}F [31]. A recent study evaluating the radiation dose caused by incorporation of ^{131}I by the measurement of urine samples of physicians, physicists, nursing and cleaning staff over 2 years suggested to decrease the incorporation factor for ^{131}I therapy wards (exclusive handling of ^{131}I) to 10^{-7} as well [32]. The highest incorporation factor in this study (5.1×10^{-7}) was determined for the nursing staff due to longest direct contact with the patient [32]. High single values and the absence of discrimination between the different working periods (samples of the night shift potentially decrease the mean values significantly due to reduced retention time in the patient's room) for these employees required a working time specific long term evaluation of this subgroup.

Therefore the results of five years of incorporation monitoring of a ^{131}I therapy ward's nursing staff are presented in this study to confirm the formerly obtained results and therefore verify that the incorporation factor should be reduced to 10^{-7} for all employees of a ^{131}I therapy ward, which will (in most cases) redundantize time, financially and personnel intensive incorporation monitoring by radiation protection authorities.

Material and Methods

The evaluated ^{131}I therapy ward has 12 beds. In the observed period of 5 years (2011-2016) a total activity of 4.3 TBq was administered to patients mainly orally *via* capsules. The ^{131}I therapy ward is equipped with a filtered ventilation system (15 air volume exchanges per hour).

Working place and job description of the nursing staff on the ^{131}I therapy ward

In a former study it could be shown that, compared to all the other occupational groups, the nursing staff is exposed most to the hazard of incorporation due to their comparatively long retention time in the patients' room and near the patient respectively [32]. The field of activity of these employees covers continuous comprehensive care of the patient over the complete period of stay and reaches from short timed medical manipulations such as measuring of blood pressure or administration of drugs to anxiolytic conversations. Furthermore, the performance of intra-therapeutic dosimetrical measurements of the patients` remaining whole-body and thyroid activity as well as the determination of the dose-rate prior to discharge is part of the nurses' duty.

Due to the high concentration of ^{131}I in the air of the patient room caused by exhalation by the patient, retention time is decisive for incorporation through inhalation. Extent of performed working activities inside the patient room should be adapted to the present remaining activity in the patients. A system of gamma-probes above the patient beds displays the current radiation dose rate of every patient on a computer in the nurse's station and directly on a display at the entrance to the patient room. This system ensures that only short lasting, necessary manipulations are performed in rooms with increased radiation dose rate. The radiation dose rate is a direct measure for the ^{131}I activity in the room and therefore for external radiation exposure. Despite these precautions the risk of incorporation through inhalation of ^{131}I is increased due to the contact time of the nursing staff inside the radiation area of the therapy ward which is mostly the whole working period excluding breaks in the 1st (07:00–15:00) and the 2nd (15:00–21:00) shift. In the 3rd shift (21:00–07:00) the contact time near the patients is of course significantly lower.

Calculation of the potential annual effective dose caused by incorporation of ^{131}I

For each radiation exposed employee the potential risk of incorporation has to be determined [1]. If only ^{131}I is considered formula 1 has to be used.

$A_{I-131} * e_{I-131} \geq 1\, mSv$ Equation 1

with:

AI-131: highest possible incorporable activity of ^{131}I per year in Bq

eI-131: Dose-coefficient of ^{131}I for inhalation (effective dose: 1.1×10^{-8} Sv/Bq [26])

AI-131 is the product of the handled activity of ^{131}I "A" specified in Bq per year and an unit-less nuclide-specific incorporation factor "a".

$A_{I-131} = a * A$ Equation 2

For less volatile radioactive substances "a" used to be 10^{-4} and for volatile radioactive substances 10^{-3}. If special protections such as a fume hood box or a glove box are used "a" can be reduced to 10^{-5} or 10^{-6} respectively. For the preparation of ^{131}I capsules in a fume hood an incorporation factor of 10^{-6} is considered reliable and representative [1]. In the presented study with a maximum allowed handling activity of 1.3 TBq per year and 10^{-6} as incorporation factor the maximum possible incorporable activity of ^{131}I in one year is

$A_{I-131} = 10^{-6} * 1.3 * 10^{12} \frac{Bq}{a} = 1.3 * 10^{6} \frac{Bq}{a}$ Equation 3

Possible absence of the employees due to vacation, illness or temporary closing of the therapy ward was not considered in this conservative scenario.

The resulting effective radiation dose according to equation one is 14 mSv/a and therefore obviously beyond the cut-off value of 1 mSv/a.

$$D = 1.3 * 10^6 \frac{Bq}{a} * 1.1 * 10^{-8} \frac{Sv}{Bq} = 14.3 * 10^{-3} \frac{Sv}{a} \sim 14 \frac{mSv}{a}$$

Equation 4

As a consequence of these calculations a total of 143 urine samples (24 h collection) of 14 employees were collected in irregular intervals over a period of five years. Analysis of the samples was performed by the Bavarian Environment Agency. Measured activity-concentrations were related to the intervals of exposition. The intervals of exposition prior to sample collection varied between 3 and 15 d (average 5.1 d). Considering the interval of exposure and the time between sample collection and measuring, one can calculate activity concentration in urine and therefore the incorporated activity. For calculation a constant incorporation in the period of observation by inhalation of Iodine aerosols with a particle size (AMAD) of 5 µm was assumed. Moreover, for calculation of the daily incorporation of Iodine a constant incorporation for at least three days was assumed. This was assumed because after three days the excretion rate *via* urine is already at its maximum at 0.32 Bq per Bq daily intake. The assumption of a singular intake in the middle of the observation interval is not reasonable for incorporation monitoring of the employees of a ^{131}I therapy ward by urine samples. Due to differing background radiation and sample volume, the activity detection limit was individually evaluated for each sample.

The mean effective dose per day was individually calculated by the ratio of the sum of the single effective doses and the whole observed period of exposition. For calculation of the annual effective dose, this mean effective dose (standardized to the period of exposition) was multiplied by 250 working days per year. Values were set to zero in cases where the results lay below the detection limit (according to [33]). With the obtained results for activity intake one can calculate the dose to the thyroid as well as the effective dose. In order to calculate the real incorporation factors, the results of the mean effective dose were related to the annual handled activity of ^{131}I and the dose coefficient for ^{131}I for inhalation for effective dose (1.1×10^{-8} Sv/Bq; [26]).

$$a = \frac{D_{eff}}{A * e_{I-131}} \text{ Equation 5}$$

with:

a: incorporation factor

Deff: average annual effective radiation dose [Sv/a]

A: handled activity of ^{131}I [Bq/a]

eI-131: Dose-coefficient of ^{131}I for inhalation [Sv/Bq] (1.1×10^{-8} Sv/Bq)

Results

In a period of five years, a total of 143 urine samples (24 h collection) of 14 employees of the nursing staff were analyzed by the radiation protection authority (Bavarian Environment Agency) for ^{131}I activity concentration. During this period of time a total of 4.3 TBq (8.77×10^{11} Bq/a, 2.4×10^9 Bq/d for 365.25 working days, 6×10^{11} Bq/a for 250 working days) ^{131}I was administered to 2,349 patients. The results of the analysis of the collected urine samples subdivided into three groups for 1st, 2nd and 3rd shift are presented in (Figure 1). The annual effective dose is determined by multiplication of the mean effective dose related to the time of exposition and 250 working days per year. Possible absences of the staff due to vacation, illness or temporary closing of the therapy ward were again not considered. The highest mean ^{131}I intake per day (58 Bq/d) and therefore the highest mean effective dose per day (6.38×10^{-4} mSv/d) and per year (1.60×10^{-1} mSv/a) was found for the subgroup of the 1st shift as expected, followed by the subgroup of the 2nd shift with a mean intake of ^{131}I of 44 Bq/d and a resulting mean effective annual dose of 1.22×10^{-1} mSv/a. The mean ^{131}I intake (6.1 Bq/d), and therefore the mean effective radiation dose (1.68×10^{-2} mSv/a) for the 3rd shift were lower (Figure 1).

The highest single value of the effective dose (mSv/d) and the resulting theoretically annual effective dose (extrapolated to 250 working days) is presented in Figure 1as well. This scenario has to be seen as a worst case calculation assuming that the employees of the appropriate shift were exposed to the highest measured ^{131}I intake on each working day of the observed period. Similar to the mean values, the highest annual effective dose was again detected for the subgroup of the 1st shift (1.14 mSv/a) followed by the subgroup of the 2nd shift with an annual effective dose of 1.10 mSv/a. Again, the subgroup of the 3rd shift showed the lowest value with an annual effective dose of 2.27 $\times 10^{-1}$ mSv/a (Figure 1).

Based on the mean dose and the mean incorporated activity for the subgroup of the 1st shift the mean incorporation factor was calculated using the determined data for the different subgroups according to equation 5, equation 6 shows an example for this calculation.

$$a = \frac{1.60 * 10^{-4} \frac{Sv}{a}}{6 * 10^{11} \frac{Bq}{a} * 1.1 * 10^{-8} \frac{Sv}{Bq}} = 2.4 * 10^{-8} \text{ Equation 6}$$

The calculated mean incorporation factors were between 2.54×10^{-9} for the subgroup of the 3rd shift and 2.42×10^{-8} for the subgroup of the 1st shift. The subgroup of the 2nd shift was in between (1.85×10^{-8}) (Figure 2). A theoretical worst case calculation was performed for the incorporation factor as well. The results of the maximum annual effective dose for all subgroups was related to the annual handled activity in the complete observed period and to the dose coefficients of ^{131}I for inhalation for the effective dose in Sv/Bq. The resulting theoretically possible incorporation factors ranged between 1.72×10^{-7} for the subgroup of the 1st shift and 3.44×10^{-8} for the subgroup of the 3rd shift (2nd: 1.66×10^{-7}). All calculated incorporation factors (even those of the worst case calculation) were well below the incorporation factor for ^{131}I of 10^{-6} for preparation in a fume hood defined in the German radiation protection regulation (Figure 2).

Discussion

Data concerning annual effective dose of employees of a nuclear medicine therapy ward caused by incorporation of ^{131}I is still rare in current literature.

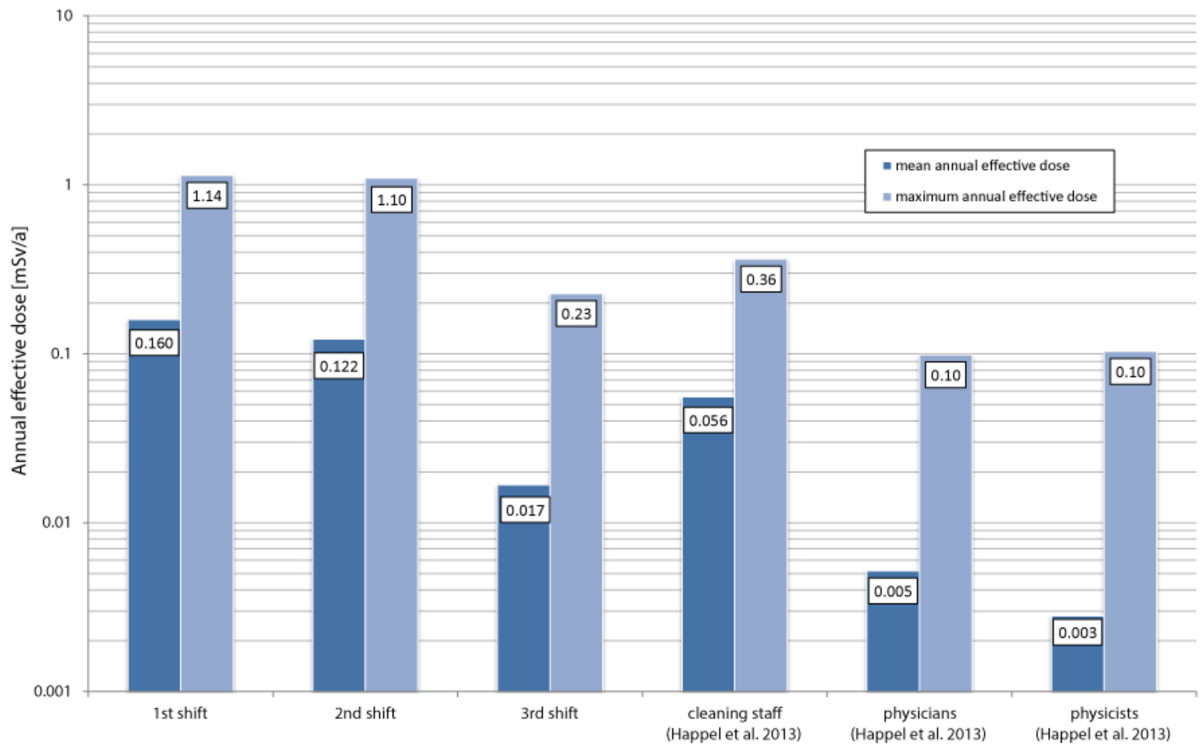

Figure 1: Mean and maximum annual effective dose of the employees.

D'Halluin et al. [23] investigated external radiation exposure of employees of five nuclear medicine departments (diagnostic and therapy) in Belgium. ^{131}I therapy can partly be performed as an outpatient treatment in Belgium, leading to a non-comparable radiation exposure of the employees compared to Germany. The lowest exposition was measured for the cleaning staff and the medical physicists (0-0.76 mSv/a) followed by the occupational group of the physicians (0-0.28 mSv/a). The highest exposition was measured for the technologists as expected (0.3-20.13 mSv/a). Dolezal et al. [24] obtained similar results. Effective doses of the physicians, technologists and pharmaceutical employees of a nuclear medicine department caused by external radiation exposure were evaluated over a period of six years. Again the effective doses of the physicians were considerably below the effective doses of the technologists. In 2003 Hänscheid et al. [33,34] described a method of incorporation monitoring of the employees by daily measurement of accumulated ^{131}I in the thyroid. The result was a mean organ dose to the thyroid of 0.35 mSv per month caused by incorporated ^{131}I. Unfortunately, a subgroup analysis of the different professional groups was not performed in this study. Laßmann et al. [35] reported in 2000 five years of incorporation monitoring of employees of a nuclear medicine therapy ward, but again only the incorporated ^{131}I in the thyroid was determined by use of a calibrated gamma probe. At least an estimation of the effective dose was performed using the proportional connection of organ and effective dose. The result was an effective dose of approximately 0.1 mSv per year. Although the dose to the thyroid seems to be of greater interest for employees of a ^{131}I therapy ward due to the selective accumulation of incorporated ^{131}I in this organ, only the effective dose was analyzed and discussed in this study because only threshold values for the effective dose are defined in the German incorporation guideline [1], not for thyroid organ doses. Apart from that there are already some publications concerning thyroid doses of employees of ^{131}I therapy wards in current literature [34,35]. In contrast to that, data concerning the effective dose caused by incorporation are still rare.

In a former study the annual effective dose caused by incorporation was investigated for different professional groups on a ^{131}I therapy ward [32]. In this study annual effective doses were 2.4×10^{-1} mSv/a for the nursing staff (n=3), 5.6×10^{-2} mSv/a for the cleaning staff (n=2), 2.8×10^{-3} mSv/a for the technical staff (n=2) and 5.2×10^{-3} mSv/a for the physicians (n=7). Therefore, the annual effective dose for every professional group and for every individual was below the dose limits of the German incorporation guideline. In line with a theoretic "worst case" calculation based on the highest measured individual value of each professional group a maximum annual effective dose was calculated (4 mSv/a for the nursing staff, 0.36 mSv/a for the cleaning staff, 0.1 mSv/a for the technical staff and the physicians). The calculated mean incorporation factors ranged from 3.0×10^{-8} for the nursing staff to 3.6×10^{-10} for the technical staff (cleaning staff: 7.0×10^{-9}; physicians: 6.5×10^{-10}) and were therefore well below the ^{131}I incorporation factor defined by the guideline. Only the theoretic "worst case" calculation of the nursing and the cleaning staff showed potential effective doses of beyond 1 mSv per year. The conclusion of this study was to reduce the incorporation factor by a factor of 10 to obtain effective annual doses corresponding to the actual effective annual dose caused by incorporation.

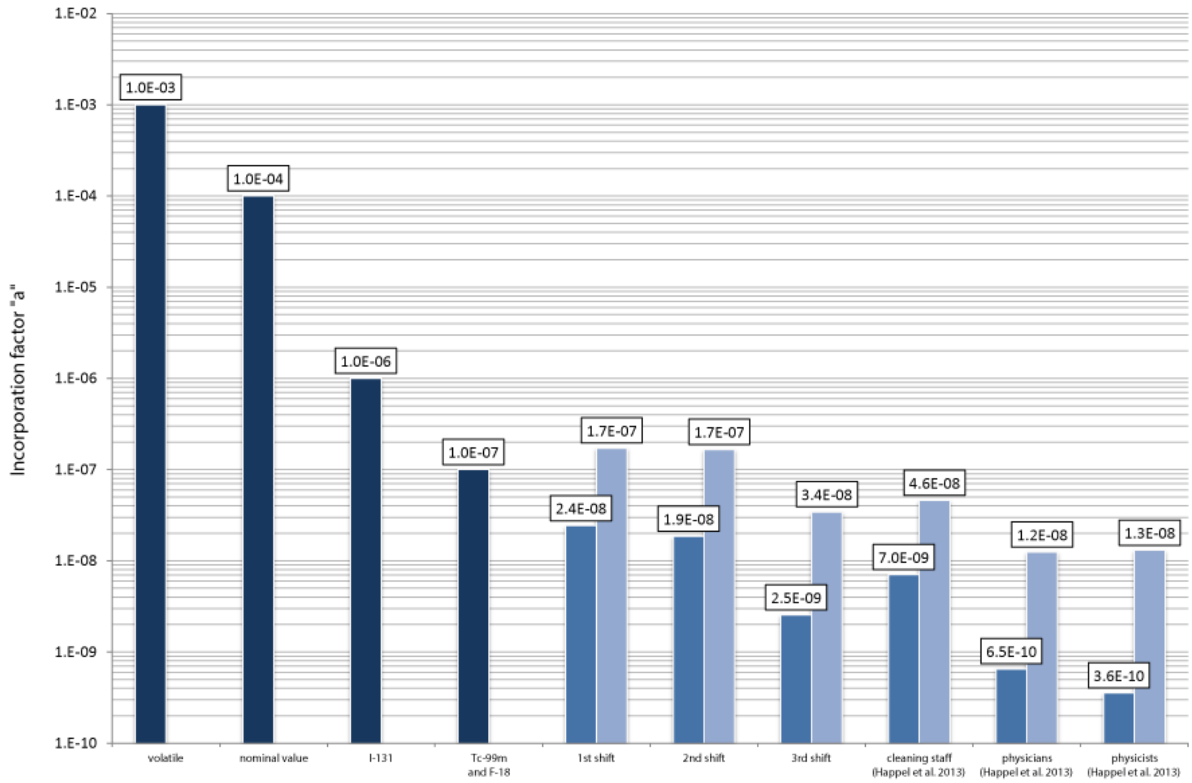

Figure 2: Mean and maximum incorporation factors "a" of the employees and regulative values.

For calculation of the incorporation factor it has to be considered to what extend the remaining activity in the patient equals the applied activity. The remaining activity in the patient is present on each day and therefore potentially higher compared to the applied activity which has to be used for calculation of the potential incorporable activity. An accurate description of the actual handled activity is therefore difficult. This concerns not only the physicians but also the nursing as well as the cleaning staff. Taking this into account, a considerably lower incorporation factor would result for these professional groups. The incorporation factor is therefore dependent on the collective of treated patients (malignant or benign diseases). However, for a conservative estimation an equalization of the administered activity and the handled activity is reasonable.

Our results show that the ^{131}I incorporation factor of 10^{-6} can be reduced to 10^{-7} to obtain a more realistic estimation of the incorporation risk especially for ^{131}I therapy wards where ^{131}I is administered exclusively as capsules, a fume hood for the measurement of the capsules is at hand, and the patient rooms are ventilated artificially. Also the collective of patients assumes an important role. In the evaluated therapy ward there were only a few patients with limited general condition who required an intensive medical care. If the amount of those patients is predominant, a re-evaluation of the incorporation factors has to be performed. On the other hand we did not consider in our conservative estimation that the staff is repeatedly exposed to the same activity, for example several ward rounds of the same patient or measurement of the capsules and handling of contaminated waste or wastewater by the same person. Considering this the handled activity would have been increased which would even lead to a significantly reduced incorporation factor. For ^{99m}Tc and ^{18}F an incorporation factor of 10^{-7} has been accepted since 2009 [31]. In the case of our ^{131}I therapy ward a reduction of the incorporation factor from 10^{-6} to 10^{-7} would have led to a potential effective dose caused by incorporation of 1.4 mSv/a. This result would have fit the real conditions much better than the effective dose of 14 mSv/a calculated by the use of an incorporation factor of 10^{-6}. Only in a worst case scenario, if the highest measured single values of the 1st shift and the 2nd shift were taken as basis, the cut off value of 1 mSv per year can be exceeded. For the night shift incorporation monitoring is definitely not necessary according to the submitted data. For the 1st and the 2nd shift, the annual effective dose caused by incorporation (1st shift: mean: 0.16 mSv/a; theoretical worst case: 1.1 mSv/a; 2nd shift: mean: 0.12 mSv/a; theoretical worst case: 1.1 mSv/a) is in a similar dimension as the effective dose caused by external exposition (1-2 mSv/a). It has to be considered that both values have to be added in order to obtain the real annual effective dose. An incorporation monitoring for the 1st and the 2nd shift can therefore be expedient in single cases. However, measurement of 24 h urine samples is not suitable as a continuous incorporation monitoring. Egestive measurements are suitable for long term continuous incorporation, but the more discontinuous the incorporation is, the greater are the errors of this approach due to the fast secretion kinetic. For individual persons and especially for single measurements an evidence of the detection threshold is not given. For a discontinuous activity accumulation a direct measurement of the thyroid is certainly more suitable.

Conclusion

The expense for an incorporation monitoring by investigation of the incorporated ^{131}I activity in 24 h urine samples by the radiation protection authorities considerably exceeds the costs of a frequent (for example weekly) incorporation monitoring by measurement of the ^{131}I in the thyroid performed by the on-site radiation protection physicist. Furthermore, there is only minor acceptance of the personal for this kind of incorporation monitoring.

For the 1st time the presented data clearly demonstrate in a long term investigation of a large study collective that the incorporation factor for ^{131}I that is stated in the German guideline [1] is disproportionally high and should be reduced to 10^{-7} for employees working on a ^{131}I therapy ward independent of their profession. This will in general lead to more accurate calculations and may avoid time and cost intensive incorporation monitoring by the radiation protection authorities.

Compliance with Ethical Standards

Conflict of interest

Ulrich Kratzel PhD is deputy of the Radiotoxicological Monitoring and Radiation Protection Laboratory Northern Bavaria; Kulmbach, Germany. The other authors declare that there is no competitive financial conflict of interest.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

This article does not contain any studies with animals performed by any of the authors.

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