

Release of Patients Containing Therapeutic Dosages of Iodine-131 from Hospitals

James E. Carey, Thomas M. Kumpuris and Mark C. Wrobel

Division of Nuclear Medicine, University of Michigan Medical Center and Medical Physics Consultants, Inc., Ann Arbor, Michigan

This continuing education article presents an analysis of NCRP recommendations and the evolving NRC regulations, with emphasis on ^{131}I therapies. The literature on this topic is reviewed and incorporated into the analysis.

Key Words: NRC; NCRP; radionuclide therapy; ^{131}I therapy; patient release

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In the U.S., the safe use of radioactive materials in nuclear medicine is regulated by the Nuclear Regulatory Commission (NRC) or by state government. In addition, the National Council on Radiation Protection and Measurements (NCRP) provides recommendations on a variety of radiation safety issues. The release of patients from hospitals following the administration of large doses of radiopharmaceuticals is a topic that has recently been addressed by both the NRC and the NCRP. The NRC is proposing changes, to their patient release regulations, that represent an important deviation from their previous approach and that will have an impact on nuclear medicine.

RECOMMENDATIONS OF THE NCRP

NCRP Report Number 37

NCRP Report Number 37 (1) was "designed for the use of persons caring for or associating with patients who have received therapeutic doses of radionuclides." It contains recommendations on many of the radiation safety issues associated with these patients, including release from hospitals. Although dated and currently being revised, it serves as a useful handbook that is often quoted and that has established a blueprint for today's regulators and nuclear medicine community to follow.

For correspondence and reprints contact: James E. Carey, MS, Nuclear Medicine, University of Michigan Hospital, 1500 E. Medical Center Dr., Room B1G412, Ann Arbor, MI 48109.

The report provides a table of "small" therapeutic doses and patients who are administered these or smaller activities can be released from the hospital without restrictions. The activities listed are those that will result in a total accumulated exposure of 0.5 R at 1 m during complete decay. For the radiations considered in the report, it is assumed that an exposure of 1 R will result in an absorbed dose of 1 rad and a dose equivalent of 1 rem. This equivalence is also assumed throughout this review. When Report Number 37 was written (October 1970), the NCRP-recommended permissible level for nonoccupational exposure from external radiation was 0.5 rem in any one year. Exposure from internal contamination was not addressed.

It is important to understand how the total accumulated exposure was calculated and the simplifying assumptions that were used. The equation for total accumulated exposure is as follows:

$$D(\infty) = \frac{34.6\Gamma Q_0 T}{r^2}, \quad \text{Eq. 1}$$

where $D(\infty)$ is the accumulated exposure in roentgen for total decay, Γ is the specific gamma-ray constant in R/mCi-hr at 1 cm, Q_0 is the initial activity in mCi, T is the physical half-life in days, and r is the distance in cm from the activity to the point of interest.

The simplifying assumptions are as follows:

1. The source is a point source and exposure varies inversely with the square of distance from it (i.e., the source is not distributed in the patient).
2. The source is in air (i.e., there is no photon attenuation in the patient).
3. The removal of activity from the patient is by physical decay alone (i.e., there is no biological elimination of the radionuclide). However, if measured, the report notes that it may be accounted for in the calculations.
4. The exposure occurs at a distance of 1 m from the source for total decay (i.e., there is no allowance for occupancy factors).

The calculated initial activity and corresponding initial exposure rate for ^{131}I which result in a total integrated exposure of 0.5 R at 1 m for total decay is 8 mCi and 1.8 mR/hr, respectively. A physical half-life of 8.04 days and a specific gamma ray constant of 2.2 R/mCi-hr were used.

Thus patients may be released without restrictions when their ^{131}I activity is down to 8 mCi or 1.8 mR/hr at 1 m. However, in an often overlooked notation, the report does allow for a higher ^{131}I initial activity. The report notes that since "thyroidal uptake and urinary excretion are maximal before 24 hr . . . thyroidal radioactivity at 24 hr should be used in place of the initial activity for the determinations of integrated exposure rate" (1). A value of "approximately 1/3 of the administered activity" (1) is suggested.

Assuming a thyroid burden at 24 hr of 8 mCi and the 1/3 uptake factor, a patient could be released immediately after the administration of 24 mCi with a corresponding exposure rate of 5.3 mR/hr at 1 m. In the case of hyperthyroidism (for which this notation seems most relevant), Hilditch et al. (2) observed an average thyroid retention of $56.1 \pm 11.1\%$ at 24 hr in 77 patients. Using these values, one obtains a range of release activities from approximately 12 to 18 mCi without restrictions. However, although the use of the thyroidal activity at 24 hr may be appropriate for exposures involving persons in the patient's household, some restrictions may be required at these activities for travel from the hospital to the home.

NCRP Report Number 37 (1) allows further flexibility for "some relatively rare and unusual situations where it would be necessary, or highly desirable, to send a patient home in spite of his carrying a burden that could result in a dose to other persons in excess of 0.5 rem." These cases are allowed as exceptions, provided that no person under the age of 45 yr shall receive a dose in excess of 0.5 rem per year and no person over the age of 45 yr shall receive a dose in excess of 5 rem per year.

The five recommendations for discharge from the hospital are as follows.

1. A patient may be released without restrictions if his residual activity is 8 mCi or less.
2. A patient shall not be released if the total integrated exposure, at a distance of 1 m from the patient, for continuous exposure, exceeds 5 R in any one year. For ^{131}I , this represents a release activity of 80 mCi.
3. If all individuals in the household of the patient are over the age of 45 yr: the patient should remain at distances greater than 3 ft from other people, except for brief periods for necessary procedures, and people under the age of 45 yr should not visit the patient, but if they do, the visits should be brief and a distance of 9 ft from the patient should be maintained.
4. If a person under the age of 45 yr lives in the household of the patient: stricter precautions shall be observed; children and other individuals under 45 yr of age shall not be allowed in the same room, nor at a distance of

less than 9 ft, for more than a few minutes a day; and other restrictions may be specified by the treating physician.

5. All restrictions may be removed when the activity reaches 8 mCi.

Thus, the NCRP allows for release of patients with restrictions and the restrictions are based on the age of the individuals with whom the patient is likely to come into contact. The precautions introduce the use of specific distances and time limitations to reduce exposures (i.e., occupancy factors).

In order to provide more detailed data, for households with individuals under 45 yr of age, the NCRP provides a table (1) based upon three categories of contact at home: (1) no contact (greater than 2 m); (2) 1/2 hr per day at 1 m (3 ft) plus 2 hr per day at 2 m; and (3) 4 hr per day at 1 m.

For a patient burden at discharge of 50 mCi of ^{131}I , Category 1 is recommended for the first week following discharge, Category 2 is recommended for the second through the fourth weeks and Category 3 is recommended for the fifth through the eighth weeks.

NCRP Commentary Number 11

The estimates of the risks associated with exposure to ionizing radiation have been increased within the past few years (3). In response to these increased risk estimates, both the ICRP (4) and the NCRP (5) now recommend an annual effective dose limit of 1 mSv (0.1 rem) for members of the public. However, both allow for a maximum dose limit of 5 mSv (0.5 rem) for infrequent exposures.

NCRP Commentary Number 11 (6) concludes that "the dose limit of 1 mSv for individual members of the public" is appropriate. However, for members of the patient's family, a limit of 5 mSv (0.5 rem) is recommended. Furthermore (consistent with NCRP Report Number 37 (1)), the commentary recommends that a member of the patient's family "may be permitted to receive up to 50 mSv (5 rem) in a year." Table 1 lists the specific recommendations.

For a total accumulated exposure of 1 mSv (0.1 rem), the calculated initial ^{131}I activity (Eq. 1) for no restrictions is 1.6 mCi. As with NCRP Report Number 37 (1), exposure to members of the public from the intake of radioactive materials was not included and "a contamination accident that could lead to a significant intake of radioactive material" was considered to be very unlikely.

The NCRP commentary (6) also briefly addresses the issue of restrictions for patients who have received ^{131}I for the treatment of hyperthyroidism and thyroid carcinoma. Using the data of Culver and Dworkin (7,8) it was concluded that restrictions for 2 to 4 days may be necessary for thyroid cancer patients and for up to two weeks for hyperthyroid patients.

TABLE 1
Doses Limits for Release of Radionuclide
Therapy Patients from NCRP Commentary
Number 11 (6)

$$R/\text{hr} = \frac{n\Gamma}{r^2}, \quad \text{Eq. 2}$$

Category of exposed person	Recommended dose limit
Patient's family	
Adults	
In general	5 mSv (0.5 rem)
Maximum	50 mSv (5 rem)*
Children	1 mSv (0.1 rem)
Pregnant women	1 mSv (0.1 rem)
Co-workers	
In general	1 mSv (0.1 rem)
Maximum	5 mSv (0.5 rem)†
General public	1 mSv (0.1 rem)

*On the recommendation of the treating physician.

†A limited number under carefully controlled conditions.

REGULATIONS OF THE NRC

Title 10 CFR Part 20

Consistent with the recommendations of the NCRP and the ICRP, the NRC recently revised their regulations (9) to establish a dose limit for individual members of the public to 1 mSv (0.1 rem) per year. Specifically, the new regulations require that "the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year" and "the dose in any unrestricted area from external sources does not exceed 0.002 rem (0.02 mSv) in any one hour."

These limits were a cause of concern to the nuclear medicine community. If applied to the transient, external exposures associated with nuclear medicine patients, patient care would have been adversely affected. Prudently, the NRC determined that the 10 CFR 20 permissible doses for members of the public do not apply to patients who have been released in accordance with 10 CFR 35 regulations. A proposed rule for revision of 10 CFR 35 (10) on patient release criteria clarifies that 10 CFR 35 governs the release of patients containing residual radioactivity, not 10 CFR 20.

Title 10 CFR Part 35.75

Current Regulations. The current 10 CFR 35 regulations for release from confinement state that a licensee may not authorize release from confinement for medical care any patient or human research subject administered a radiopharmaceutical until either: (1) the measured dose rate from the patient or the human research subject is less than 5 mrem per hour at a distance of 1 m; or (2) the activity in the patient or the human research subject is less than 30 mCi.

Although these regulations apply to all radiopharmaceuticals, the 5 mrem per hour is the exposure rate the NRC associated with 30 mCi of ^{131}I distributed in a patient. The exposure rate from a point source of ^{131}I in air is given by the equation:

where n is the source activity in mCi, Γ is the specific gamma-ray constant in R/mCi/hr at 1 cm and r is the distance in cm from the source to the point of interest. For 30 mCi of ^{131}I and a specific gamma ray constant of 2.2 R/mCi-hr at 1 cm, the calculated exposure rate at 1 m is 6.6 mR/hr. With distribution and photon attenuation in the patient, the exposure rate is assumed to be reduced to 5 mR/hr. This represents an effective Γ of 1.7 R/mCi-hr at 1 cm.

Unpublished data (11) from the University of Michigan for ^{131}I -labeled MIBG following intravenous administration (10 patients) yields exposure rates that vary from 4.2 mR/hr to 6.3 mR/hr at 1 meter for a 30 mCi administration. The average of 5.3 ± 0.6 mR/hr at 1 m is in good agreement with the NRC assumed value.

Proposed Regulations. The NRC proposes to change from the use of activity or exposure rate at 1 m to a dose-based approach. The proposed regulations, cited in the Federal Register (volume 59, number 114; June 15, 1994), are as follows:

"A licensee may authorize release from licensee control any patient administered radiopharmaceuticals . . . containing radioactive material if the total effective dose equivalent to an individual from exposure to the released patient is not likely to exceed 5 mSv (0.5 rem) in any one year."

"If the total effective dose equivalent (TEDE) to any individual other than the patient is likely to exceed 1 mSv (0.01 rem) in a year from a single administration, upon release the licensee shall: (1) provide the patient with written instructions on how to maintain doses to other individuals as low as reasonably achievable; and (2) maintain, for three years, a record of the released patient and the calculated total effective dose equivalent to the individual likely to receive the highest dose."

Thus, the NRC is establishing 5 mSv (0.5 rem) as the maximum dose for release. However, with 1 mSv (0.1 rem), release can be without restriction. If it is likely that the 1 mSv dose will be exceeded, ALARA written instructions must be given and the dose to the individual likely to receive the highest dose must be calculated and recorded.

The TEDE is the sum of the committed effective dose equivalent (CEDE) and the deep dose equivalent (DDE). The CEDE is the dose from the uptake of radionuclides in the exposed individual and the DDE is the dose from external exposure to penetrating radiations. However, the transfer of ^{131}I activity from a therapy patient to a member of the public (including a family member) is insignificant (12-14) and, therefore, for ^{131}I therapies, the TEDE is assumed to be equivalent to the DDE.

TABLE 2
Calculated Activities and Corresponding Dose Rates for ¹³¹I Which Result in a Total Integrated Exposure of 0.1 rem and 0.5 rem at 1 m for Total Decay

	For 1 mSv (0.1 rem)		For 5 mSv (0.5 rem)	
	Activity (mCi)	Dose rate at 1 m (mrem/hr)	Activity at 1 m (mCi)	Dose rate (mrem/hr)
NRC*	6.5	1	33	7
NCRP	1.6	0.4	8	1.8

*The NRC values were rounded in the regulatory guide (15).

Draft Regulatory Guide DG-8015

The NRC is developing a regulatory guide (15) to “provide guidance on determining the potential doses to an individual likely to receive the highest dose from exposure to the patient” and “to establish appropriate activities and dose rates for release.” For ¹³¹I, the NRC calculates that 6.5 mCi and 33 mCi will deliver a total effective dose equivalent of 1 mSv (0.1 rem) and 5 mSv (0.5 rem), respectively. The guide lists these activities and their corresponding dose rates. Table 2 compares the NRC values with the recommended NCRP values.

If the activity of ¹³¹I in the patient is less than 6.5 mCi or the dose rate at 1 m is less than 1 mrem/hr the patient may be released without instruction. If above 6.5 mCi or 1 mrem/hr, written ALARA instructions must be provided to the patient, the TEDE to the individual likely to receive the highest dose must be calculated and records must be kept for inspection for three years. The patient must be below 33 mCi to be released from licensee control.

The guide uses the same equation (Eq. 1) and the same simplifying assumptions as the NCRP Report Number 37 (1). However, the guide introduces the concept of an exposure factor that, for ¹³¹I, is assumed to be 0.25. The exposure factor adjusts for the different times and distances that an instructed individual is actually around the patient. The 0.25 represents an intuitive judgment and is based, in some part, on the published literature.

The individual likely to receive the highest dose will most likely be a member of the patient’s family. Buchan and Brindle (13) found that the spouses of patients averaged approximately four times more radiation than other family members. Thomson et al. (16) identified that most of this dose is delivered during the night. Spouses of patients who were treated for hyperthyroidism received an average of 18 mrad/mCi (17). No instructions were given to minimize exposure. Wasserman and Klopper (18) modified this for total elimination of the activity and estimated an average of 20.7 ± 13.7 mrad/mCi. Thus, for a 33-mCi administration, the average dose is estimated to be between 230 and 1140 mrem. With instruction, the predicted maximum dose from this data is 285 mrem using the exposure factor of 0.25.

If a licensee wishes to release a patient with an activity of greater than 33 mCi ¹³¹I, the guide allows for the calculation of dose on a case-to-case basis to account for “certain factors specific to an individual” (15). The factors include attenuation, effective half-life and exposure factor. For an example for thyroid cancer, a Γ of 1.7 R/mCi-hr at 1 cm accounts for the attenuation in the patient’s body and a T_{eff} of 2 to 3 days is appropriate for a patient being treated for metastatic carcinoma.

Using Equation 1, a dose of 0.5 R and multiplying by the 0.25 exposure factor (E), we get:

$$D = \frac{34.6\Gamma Q_0 T_{eff} E}{(r)^2}$$

$$Q_0 = \frac{D(r)^2}{34.6\Gamma T_{eff} E}$$

$$Q_0 = \frac{(0.5R)(100 \text{ cm})^2}{(34.6)(1.7R\text{-cm}^2 \text{ per mCi-hr})(3d)(0.25)}$$

$$Q_0 = 113 \text{ mCi.} \quad \text{Eq. 3}$$

Thus, if the NRC accepts the above assumptions for attenuation and elimination, the patient could be released with an activity of 113 mCi and a set of written instructions on how to keep doses to exposed family members ALARA. In NUREG-1492 (19), the NRC calculates that a maximum likely dose of 0.5 rem will be obtained with 100 mCi.

PATIENT INSTRUCTIONS

The instructions given to patients after ¹³¹I therapy are fairly basic and are designed to minimize both the internal contamination and external exposure of other persons (20). They should be given to the patient both orally, with adequate time allowed for discussion, and in writing. Compliance will strongly depend on the type and duration of the restrictions imposed (21).

To minimize the transfer of the ¹³¹I, the instructions typically include:

1. Avoid mouth-to-mouth contact (e.g., kissing).
2. Don’t share items that contact the mouth (e.g., toothbrushes and eating utensils).
3. Use separate or disposable eating utensils and wash them separately.
4. Keep the toilet especially clean. Flush it two or three times after each use. Men should be encouraged to sit during urination.
5. Wash your hands thoroughly each time you go to the toilet.
6. Use separate towels and washcloths.

The question has been raised (17) whether there is any justification in giving special instructions regarding contamination precautions except where very young children are

TABLE 3
Times for Precautions Following ^{131}I NaI
Treatment for Hyperthyroidism

Advice	Administered activity (mCi)		
	5 mCi	10 mCi	20 mCi
Avoid nonessential contact with children	2 days	9 days	15 days
Avoid close contact with other people	0	0	2 days
Stay away from the workplace	0	0	2 days
Avoid public places of entertainment	0	0	2 days

involved. For small children, the only concern was for urinary contamination around the toilet and potential ingestion. Although accumulated experience has shown that internal contamination is a minor problem, the ALARA principle dictates that observing some precautions would be prudent. However, the duration for these precautions need not be prolonged and a few days seems appropriate.

To reduce external exposure, the instructions typically include:

1. Sleep in separate beds.
2. Avoid prolonged close contact with children and pregnant women.
3. Avoid close contact with other people in the home.
4. Delay return to work.
5. Avoid public transportation.
6. Limit time spent in public places.

The duration of these precautions depends upon the activity at discharge, the T_{eff} of the radiopharmaceutical in the patient, the individuals with whom the patient will have contact, and the dose limit that is being observed. For a 30-mCi discharge activity and a dose limit of 0.5 rem, the duration for precautions may vary from a few days to 1 or 2 weeks for thyroid carcinoma and hyperthyroidism, respectively. Table 3, adapted from Hilditch et al. (21), lists the recommended times for precautions following ^{131}I treatment for hyperthyroidism.

Breastfeeding Women

The administration of ^{131}I -labeled radiopharmaceuticals is contraindicated in lactating women who breastfeed their babies (22,23). For women receiving therapeutic dosages of ^{131}I , the dose from activity in the breast milk and exposure from activity in the mother's body can be substantial. Robinson et al. (24), after evaluating the breast milk secretion of ^{131}I following the administration of approximately 110 mCi of ^{131}I -iodide, estimated that breastfeeding would need to be discontinued for at least 52 days. They further recommend that breastfeeding be stopped several days prior to administration in order to reduce the dose to the mother's breasts.

The ICRP (25) recommends that breastfeeding stop for at least 3 weeks even for diagnostic dosages of most ^{131}I -labeled radiopharmaceuticals.

DISCUSSION

If the proposed NRC regulations are adopted, we will change from a system based on activity (30 mCi) or dose rate (0.005 rem at 1 m) to a dose-based system. The dose limit that the NRC considers acceptable is 0.5 rem (5 mSv) in a year. This is positive in that the 0.1 rem (1 mSv) dose limit to members of the public (9) is not being applied. In addition, apparently licensees will be allowed to release patients from confinement containing higher activities than in the past (15). However, under the proposed regulations, if the dose to any individual other than the patient is likely to exceed 0.1 rem (1 mSv) in a year from a single administration (estimated to be the dose associated with 6.5 mCi of ^{131}I), written instructions must be given, calculations must be performed and records must be kept. Thus, on the negative side, it appears that the regulatory burden for those who perform therapies is about to increase. The gain on the side of radiation safety has yet to be proven.

The NCRP, in two publications that address the topic of patient release (1,6), recommends that adult members of the patient's family be allowed to receive an annual dose limit of 5 rem (50 mSv) and when they might exceed 0.5 rem (5 mSv) "they should receive appropriate training and individual monitoring." Philosophically, one might argue that if an adult member of the patient's family is willing to accept the same risk allowed a radiation worker in order to care for a loved one, then it should be permitted. However, the regulatory problems associated with the implementation of this recommendation are probably insurmountable.

It seems that a reasonable compromise would be as follows:

1. Adult members of the patient's family shall be allowed a dose limit of 0.5 rem (5 mSv) per year.
2. The dose to children and pregnant women in the family should not exceed 0.1 rem (1 mSv) per year.
3. The dose to co-workers should not exceed 0.1 rem (1 mSv) per year.
4. The dose to members of the general public should not exceed 0.1 rem (1 mSv) per year.

For patients containing less than 30 mCi of ^{131}I or a dose rate of less than 5 mrem/hr at 1 m:

1. Provide the patient with ALARA instructions to help keep doses below the above dose limits.
2. Precautions may cease when the licensee estimates that residual activity is below 6.5 mCi or the dose rate is less than 1 mrem/hr at 1 m.

For patients containing greater than 30 mCi of ^{131}I or a dose rate greater than 5 mrem/hr at 1 m:

1. Release activity shall be below 100 mCi.
2. The licensee shall provide the patient written radiation safety instructions, demonstrate by calculation that the doses will be below the above dose limits, and keep the appropriate records for a period of three years.
3. Precautions may cease when the licensee estimates that residual activity is below 6.5 mCi or the dose rate is less than 1 mrem/hr at 1 m.

For any patient with residual activity above 6.5 mCi, confinement may be necessary if compliance with the ALARA instructions or with the written radiation safety instructions is in doubt. This should be the decision of the treating physician and the hospital radiation safety officer.

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Please see end of second continuing education article, by Glowniak, for CE tests questions, answer sheet and answers to the June 1995 CE test.