

Operational Topic

A comparison of the survey requirement of old 10CFR35 with new 10CFR35 leaves some unanswered questions.

Nuclear Medicine Survey Recommendations for a Changing Regulatory Environment

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Abstract: The revision of 10 CFR 35 approved on 23 September 2000 and due for implementation in 2001, reduces the number of required radiation and contamination surveys to one ambient radiation survey each day when an administration requiring a written directive is used. This paper compares the current requirements in 10 CFR 35; the single, remaining, specific requirement in the revised part 35; the Nuclear Regulatory Commission's guidance in the proposed NUREG SR1556 and the general requirement for surveys to demonstrate compliance with 10 CFR 20. We also make recommendations on what periodic surveys are prudent. *Health Phys.* 81(Supplement 2):S70-S74; 2001

Key words: operational topic; radiopharmaceuticals; surveys; regulations

INTRODUCTION

On 14 August 1998, the Nuclear Regulatory Commission (NRC) published a proposed revision to 10 CFR 35, "Medical Uses of Byproduct Material," in the Federal Register (1998). The NRC Commissioners approved the fi-

nal version on 23 September 2000. The NRC replaced all of the specifically required radiation and contamination surveys in various parts of 10 CFR 35 with one required survey in 10 CFR 35.70. This is a survey at the end of each day where radiopharmaceuticals requiring a written directive are administered. With the removal of most of the specific requirements for nuclear medicine, the more general requirements of 10 CFR 20.1501 apply. This states that a licensee will make or cause to be made surveys necessary to demonstrate compliance with the regulations in that part and that are reasonable under the circumstances to evaluate the extent of radiation and radioactive material concentration or amounts. The NRC published proposed guidance in NUREG-1556, volume 9, appendix R. Most of the requirements removed in the Part 35 revision are reinstated as proposed Appen-

dix R recommendations. Although the comment period for NUREG-SR1556 (1998) ended in late 1998, we will not know which comments or recommendations the NRC staff incorporates until the final version is published. In any case, we feel that if it was appropriate to remove the requirements, then it is hard to justify "recommending" the same thing elsewhere.

DISCUSSION

The current Part 35 requirements are summarized in Table 1 below.

The revised 35.70 requires only an ambient radiation survey at the end of each day where a radiopharmaceutical that requires a written directive is administered.

The requirements in 35.59, 35.315 (a) (4) and (7) and 35.415(a) (4) are dropped from the revised regulation.

Area survey requirements, other than the one specific requirement on 10 CFR 35.70 will now be under 10 CFR 20 subpart F, Surveys, 20.1501 (a) and (b). These are more general requirements.

Basically, 10 CFR 20.1501(a) specifies conducting surveys sufficient to show Part 20 compliance. Area surveys might be needed to demonstrate compliance with subpart D, which re-

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Table 1. Summary of current Part 35 area survey requirements.

Section	Instrument or type of survey	Frequency	Where to survey
35.59	Ambient radiation	Quarterly	Where sealed sources or brachytherapy sources are stored.
35.76	Ambient radiation w/detection survey instrument	End of each day of use.	Where radiopharmaceuticals are routinely prepared or administered.
b.	Ambient radiation w/detection survey instrument	At least once/week.	Where radiopharmaceuticals or their waste is stored.
c.	Minimum Detection Limit for a. and b. at least 0.1 mrem.		
d.	Establish trigger levels for a and b.		
e.	Removable contamination	Once each week.	Where routinely prepared for use, administered or stored.
f.	Minimum detection limit for e at least 2,000 dpm.		
g.	Keep records of surveys for at least 3 y.		
35.315 (a) (4)	Ambient radiation w/measurement survey instrument	Promptly after administration.	Contiguous restricted and unrestricted areas.
(7)	Removable contamination	Before assigning another patient to the room	Patient's room where patient isolated under 35.75.
35.415 (a) (4)	Ambient radiation w/measurement survey instrument	Promptly after administration.	Contiguous restricted and unrestricted areas.

stricts dose to public to 100 mrem y^{-1} . The current provision of 10 CFR 20.1301 allows the request to allow a dose to the public of up to 500 mrem y^{-1} , while a new provision to be enacted with the new Part 35 allows a dose up to 500 mrem y^{-1} from patients who are isolated in accordance with (IAW) 10 CFR 35.75. The current provision of 35.75, "Release of patients containing radiopharmaceuticals," also allows a dose to the public from released patients up to 500 mrem y^{-1} .

Section 20.1501(b) also requires surveys that are "reasonable under the circumstances to evaluate, the extent of radiation levels, concentrations and quantities of RAM, and the potential radiological hazards that could be present." Table 2 below summarizes the area survey require-

ments under the revised 10 CFR 35 and the general requirement of 10 CFR 20.1501.

If one presumes that areas of radiopharmaceutical preparation and administration and camera rooms are "restricted areas," then one might assume that the dose to the public does not apply. However, one should consider whether all members of the public are excluded at all times. "Members of the public" should not include patients. It should also not include staff members. But, if a staff member is not a member of the public, then they must be provided dosimetry if they are likely to exceed 10% of an occupational exposure limit. For the whole body, this is 500 mrem y^{-1} of penetrating radiation. This is the same dose that

members of the public may receive from patients.

So, what surveys would be required, other than one at the end of the day when a pharmaceutical requiring a written directive is used? It is necessary only to show that the dose to those members of the public, who may be allowed to enter restricted areas, and those staff members who do not have dosimetry, is not more than 500 mrem y^{-1} . Since nuclear medicine technologists are usually assigned personnel dosimetry, and have the highest restricted area occupancy within nuclear medicine, one may use their exposures to calculate the maximum probable dose to unmonitored staff members and patients' families.

What surveys then would be reasonable under the circum-

Table 2. Area survey requirements under the revised 10 CFR 35 and current 10 CFR 20.1501.

Section	Instrument or type of survey	Frequency	Where to survey
35.70	Ambient radiation w/detection survey instrument	End of each day of use where an administration requiring a written directive was used.	Where radiopharmaceutical was prepared or administered.
20.1501	Surveys to show compliance with part 20 and that are "reasonable under the circumstances to evaluate, the extent of radiation levels, concentrations and quantities of RAM, and the potential radiological hazards that could be present."	As needed.	Where needed.

stances, in a nuclear medicine unit, to evaluate the radiation levels, the concentration or quantities of radioactive materials, and the potential radiological hazards? The recommendations of NUREG-SR1556, Vol. 9, Appendix R. "Model Procedures for Area Surveys" are summarized and critiqued below. The critique is in *italics*.

A. Appendix R recommends ambient radiation surveys when:

1. Exposure may exceed 10% of occupational limits. *This would probably only apply to a "hot lab" area where generators are eluted or bulk ^{99m}Tc is received and prepared for administration.*
2. Where an individual is working where dose rate $>2.5 \text{ mR h}^{-1}$ ($5,000 \text{ mrem y}^{-1}$ per 2,000 h per y). *This may occur in some Nuclear Medicine units.*
3. To show members of the public will not exceed 100 mrem y^{-1} in accordance with 10 CFR 20.1301. *Ambient radiation surveys are not normally very useful in this context unless a micro R meter of some kind is used. Long-term dosimeters are also frequently used.*
4. Survey monthly all labs where small ($<200 \mu\text{Ci}$) amounts of radioactive materials are used. *It is hard to imagine a Nuclear Medicine section using this little material. The only possibility the authors see is a lab room devoted to radioimmunoassay (RIA). RIA kits are generally licensed and as such, if kept separate from specifically licensed materials, are exempt from 10 CFR, parts 19, 20, and 21 (10 CFR 31.11) The authors see no reason to alter that exemption.*
5. Survey weekly all areas where radionuclides are used or stored and waste storage areas. *This is essentially putting back as a recommendation, a requirement that was removed in the revision of 10 CFR 35.*

6. Survey quarterly all areas where sealed sources or brachytherapy sources are stored. *This is essentially putting back as a recommendation, a requirement that was removed in the revision of 10 CFR 35. It would seem prudent to survey a source storage area and adjacent unrestricted areas initially with all possible sources present. It would then seem sufficient to do additional surveys only when the permanent source inventory is increased or the configuration of the storage area is changed.*

B. Appendix R recommends contamination surveys (normally contamination surveys are "wipe" surveys):

1. To identify areas of contamination that might result in doses to workers or the Public. *Ambient radiation surveys would identify areas of external dose. Assuming that dose from ingestion or inhalation is meant, it is necessary to know the "dose" threshold. One may define dose as an uptake of $1/5,000$ of an annual limit on intake (ALI), since 1 millirem is $1/5,000$ of the Occupational EDE of 5,000 and, according to ICRP (1989), is a "negligible dose to the public." Based on the "ingestion fraction" of 10^{-5} , such an uptake seems unlikely for most radionuclides found in a nuclear medicine environment.*
2. To evaluate radioactive contamination that could be present. . . *This is pretty all encompassing. Considering the other survey recommendations, this seems a little excessive.*
3. After any spill or contamination event. *This seems reasonable, although one might want to exempt spills known to involve only generally licensed materials or exempt quantities.*
4. When procedures or processes have changed. *With some qualification, this seems reasonable. Qualification being,*

that processes or procedural changes involve handling of radioactive material would be those requiring a survey.

5. To evaluate contamination of users and immediate work area, at the end of the day. . . *This is reasonable and should be normal practice. It is hoped that a quick informal survey would always be conducted when leaving the restricted work areas. We feel that requiring any recording of these surveys might be counterproductive.*
6. In unrestricted areas consistent with the type of use but not less than monthly. *This recommendation is not fully understood. Normally speaking, use of radioactive materials occurs within restricted areas. There is an exemption to surveying for infrequent administrations in a patient's room.*
7. In areas adjacent to restricted areas. *In the authors' opinion, surveys of adjacent unrestricted areas should always accompany restricted area surveys.*
8. Where personnel are working with 10% of an ALI. *The authors feel this is unrealistic. This is apparently based on 10% of an ALI being the level where bioassay is generally required, and that internal dose must be summed with external dose. But to ingest 10% of an ALI the worker would need to ingest the entire amount he or she was working with, just over the threshold. The NRC has used 10^{-5} as a conservative ingestion fraction in NUREG-1492 (1997a) and RG 8.39 (1997b), so it is overly conservative to assume that a worker is likely to ingest 100% of handled material. Brodsky (1980) developed the concept of the ingestion fraction.*
9. Removable contamination survey, weekly where radiopharmaceutical elution, preparation, assay, and ad-

ministration are done. *This is essentially putting back as a recommendation, a requirement that was removed in the revision of 10 CFR 35.*

10. Removable contamination survey of areas where small amounts (<200 μ Ci) are used monthly. *It is hard to imagine a Nuclear Medicine section using this little material. See comments under A.4.*

11. Removable contamination survey of areas of radiopharmaceutical storage and radiopharmaceutical waste storage. *This is essentially putting back as a recommendation, a requirement that was removed in the revision of 10 CFR 35.*

CONCLUSION

We reject A.5., A.6., B.9., and B.10. because we feel that if it was reasonable to dispense with them as requirements, then it does not make sense to recommend them elsewhere as guidance.

Recommendations A.4. and B.10 for monthly surveys of areas using less than 200 μ Ci are not being included, since it is unlikely to find a Nuclear Medicine unit with an inventory that low.

Recommendation B.2. for surveys to evaluate contamination that could be present is eliminated as too all-encompassing. We feel that it is sufficient to evaluate contamination that may result in a dose to workers or the public, which is recommendation B.1.

Recommendations B.6. and B.7. for surveys in unrestricted areas and adjacent to restricted areas are being eliminated because radionuclides are generally handled in restricted areas; areas adjacent to restricted areas should be surveyed as part of the usual restricted area survey.

Recommendation B.8. is being eliminated because it is unrealistic and inconsistent with the

NRC's use of the ingestion fraction in NUREG-1492 and Regulatory Guide 8.39.

Table 3 below contains what the authors feel are surveys needed to meet the specific requirement in the revised 10 CFR 35. It also lists those recommendations made in NUREG-SR1556, Volume 9, that we feel are prudent to meet the general requirements of 10 CFR 20.1501 and which constitute good health physics practice. Note that the recommendation B.1. greatly extends beyond the sole survey requirement of 10 CFR 35.70.

The problem is that the requirement is for surveys of ambient radiation. This implies the measurement and recording of dose or dose equivalent rate. The authors feel that rooms containing nuclear medicine cameras have no need to measure ambient radiation levels. As long before there is a concern over dose, the cameras would indicate a

Table 3. Requirements for surveys under 10 CFR 20 and revised 10 CFR 35 and authors' recommendations with specific requirements italicized.

Reg. section or NUREG Rec.	Instrument and or type of survey	Frequency	Where to survey
10 CFR 20.1501 10 CFR 20.1301 & Recommendation A.3.	Ambient radiation survey, using a micro-r meter or long-term dosimetry.	Initially, when conditions change and about every three years if not done for changes.	Unrestricted areas in Nuclear Medicine and immediately adjacent areas in other services.
A.6.	Ambient radiation using a measurement survey meter.	Initially and when inventory or configuration changes.	Sealed source and brachytherapy source storage areas.
10 CFR 35.70	<i>Ambient radiation is required to be surveyed for with a detection survey meter.</i>	<i>Whenever an administration requiring a written directive is done and at least weekly.</i>	<i>Where material was prepared for use or administered.</i>
NUREG Recommendation A.1. & 2.	Ambient radiation with a measurement survey meter.	Weekly	Hot lab or where radioisotopes are prepared and administered but not camera rooms.
B.1.	Radiation detection survey instrument for gross contamination.*	Weekly	Hot lab or where radioisotopes are prepared and administered.
B.3.	Depending on the isotope, survey with detection meter or take wipe samples.	After any spill that is not known to consist of less than exempt quantities or generally licensed materials.	Area of the spill and immediately adjacent areas.
B.4	The appropriate means of survey depend on the circumstances.	When procedures involving radioactive materials change.	Area the procedure is conducted in and immediately adjacent areas.
B.5.	Radiation detection survey instrument.	Whenever leaving the hotlab.	The users person and at the end of the day immediate areas of use.
	Removable contamination survey.	Before reassigning a room used to isolate a radioisotope therapy patient IAW 35.75.	Patient's room.

problem due to increased background. Thus, we feel that in the camera rooms it is appropriate to survey for gross contamination only. In areas where the radiopharmaceuticals are prepared and stored [hot labs] and where waste is stored, one should *quantify* ambient radiation exposure rates with an appropriate exposure rate meter, not with a radiation *detection* meter as specified in the revised 10 CFR 35. The meter used should be one that can be expected to give an accurate exposure rate measurement in a Nuclear Medicine unit and should measure radiation down to about half a milliroentgen per hour (mR h⁻¹).

One requirement in the current Part 35, that of doing a removable contamination survey in a room used to isolate a patient receiving radioisotope therapy prior to use with another patient, is not specifically recommended in Appendix R of NUREG-SR1556. A recommendation to do that survey could be inferred from Appendix R recommendations B.1, 2, and 6. We feel that a removable contamination survey is entirely appropriate when a room is being released after isolation of a radioisotope therapy patient. We are not in agreement with the action level recommended in NUREG-SR1556, Appendix R, Table R.3., "Acceptable Surface Contamination Levels in Unrestricted Areas in dpm/100 cm²" (Vernig and Miron 2000).

NOTE: The authors believe that detection of gross contamination is the real need that the revised 10 CFR 35.70 attempts to address, though not very well. Ambient radiation measurement is that for which one is required to survey. The most common instrument used for a radiation detection survey instrument is a GM count rate meter that does not measure *exposure rate* well unless calibrated

with very similar energy radiation. Since most calibrations do not use photon energies close to diagnostic nuclear medicine isotopes, GM count rate meters inaccurately quantify exposure rates. If ambient radiation is what is really desired, an air or pressurized air ion chamber, or tissue equivalent meter, should be used. Since radiation detection or measurement instruments are no longer defined in 10 CFR 35, the situation is further muddled. The use of a detection instrument for gross contamination makes more sense.

DEFINITIONS

Ambient radiation survey—A survey to determine the dose rate in an area.

Contamination survey—A survey to determine surface contamination, primarily on floors and horizontal work surfaces.

Gross contamination survey—A survey, using a portable instrument, for contamination of surfaces, which is not as sensitive as a wipe, or swipe survey for removable contamination.

Hot lab—Room or area where radiopharmaceuticals are received, processed, assayed, and stored prior to administration. This is where generators are eluted if used and frequently where most of the administrations are done. Some procedures require administrations be done while in the camera or imaging rooms.

Radiation detection survey instrument—Under current 10 CFR 35.2 a survey instrument, which can detect radiation at least from 0.1 mR h⁻¹ to 100 mR h⁻¹. In practice, this is frequently a GM count rate meter. *For ease of use and to conserve space, "detection meter" or "instrument" will be used for this term.*

Radiation measurement survey instrument—Under

current 10 CFR 35.2 a survey instrument that can measure radiation at least from 1 mR h⁻¹ to 1,000 mR h⁻¹. An air ion chamber is probably the most economical instrument that meets this definition. *For ease of use and to conserve space, "measurement meter" or "instrument" will be used for this term.*

Removable contamination survey—A survey of surface contamination that can be readily removed by use of a wipe. This survey does not address contamination that is not easily removed.

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In Search of Reasonable Room Decontamination Guidance

by Peter Vernig and Daniel J. Miron

Abstract

The current requirement (10 CFR 35.315 [a] [7]) for decontamination of a room assigned to a radioisotope therapy patient is for removable contamination to be equal or less than 200 dpm per 100 cm². The current patient release criteria (10 CFR 35.75) for radioisotope therapy allows release of the patient if the anticipated dose to the public is less than 500 millirem per year. Based on experience decontaminating I-131 therapy patient's rooms, localized levels of contamination prior to clean up are frequently in the range of 10⁴ to 10⁵ dpm. Iodine-131 currently comprises the vast majority of radioisotope therapy where a patient may be isolated. The proposed revision of 10 CFR 35 [FR 98] changes the provisions of Section 315, dropping the requirement to decontaminate to the 200 dpm per 100 cm² removable contamination level. The NRC has given the same limit of 200 dpm/cm² removable contamination for a group of isotopes—including I-131—in their medical use guidance document, NU-REG-1556V9, (Table R.3), published as a "Draft – for Comment Document" in August, 1998. The release criteria in 10 CFR 35.75 and room decontamination guidance in NUREG-1556 are inconsistent. This article reviews other room decontamination guidance and develops a method for independently establishing possible decontamination action levels for removable contamination based on the "dose-to-public" concept that is somewhat consistent with the patient-release criteria.

Dose to the public is estimated using the annual limit on intake [ALI] and ingestion fraction. Iodine-131 is the focus of concern for this article, but the method should be applicable to other isotopes.

Introduction

For years, the NRC has required (in 10 CFR 35.315) that licensees decontaminate rooms used for inpatient I-131 therapies down to 200 dpm/100 cm² for removable contamination before the room is released for unrestricted use. Limits ranging from 200 dpm /100 cm² to 2,000 dpm/100 cm² have been applied, depending on the isotopes used, for unrestricted areas (See [RG 10.8] Appendix N). The proposed revision to 10 CFR 35 removes the limits on removable contamination levels in 35.315. This should be a welcome change for licensees, since decontaminating areas to below 200 dpm/100 cm² can be a challenge. Although it is proposed that this requirement is removed from the regulations, the NRC has apparently chosen to retain this decontamination level for I-131 and other isotopes as guidance in draft NUREG-1556V9 table R3. Licensees that commit to NUREG-1556, Volume 9—in its entirety or in part—may be required to decontaminate to levels that are much lower than necessary when compared to other published limits. The current patient-release criteria (10 CFR 35.75) for radioisotope therapy allows release of the patient if the anticipated dose to the public is less than 500 millirem per year. The repetitive limit on dose to the

public is 100 millirem per year, but allowance is made for non-repetitive doses up to 500 millirem per year. The patient-release rules, which became effective in December 1994, were based on limiting the exposure to members of the public; in the case of patients, that would be family members or people living in the same residence. Guidance and support for the new rule was published prior to the effective date as Regulatory Guide 8.39 [RG8.39] and NUREG-1492. The primary units used in this article are disintegrations per 100 square centimeters [dpm/100 cm²]. Each of the guidance documents used *different* units and the primary units *they* used are given first, then dpm/100 cm². In the tables comparing guidance, dpm/100 cm² and SI units of Becquerel per square centimeter are given. This was done because it was felt operational radiation safety specialists in the United States, deal in dpm/100cm² and it would be cumbersome and confusing to have a string of different units in parenthesis. It was also felt that the SI units should be given, even though the work is primarily of interest to radiation safety personnel in this country.

Two other volumes—7 and 11—of NUREG-1556, issued in Final Report form, have fairly consistent use of the same 200 dpm/100 cm² level for removable contamination with levels of fixed contamination of 1000 dpm/100 cm² [0.17 Bq/cm²], for average and 3000 dpm/100 cm² [0.50 Bq/cm²], and for maximum fixed contamination for release of equipment from restricted areas. Volume 7, "...Academic, Research

and Development, and Other Licenses of Limited Scope," however, has a table—Q.3—which gives somewhat more reasonable levels of fixed surface contamination for rooms and areas. Iodine-131 is not listed in the table, but the level for strontium-90, which is in the same hazard class as I-131 is 8.7×10^3 dpm/100 cm². Volume 11 of NUREG-1556, on Broad Scope Licenses, has the same room and area clearance guidance—200 dpm/100 cm² removable, 1000 dpm/100 cm² average fixed, and 3000 dpm/100cm² maximum fixed contamination for I-131 as specified in Volume 9. A footnote indicates that the removable fraction is presumed to be 0.1, so that this relates to a level of removable contamination of 870 dpm/100 cm². It is not known why academic, research and development, limited scope licensees should have more liberal guidance than medical and broad scope licensees. It is also a mystery why the groups writing the various volumes of NUREG-1556 have ignored the dose-to-the-public approach used to justify release of patients receiving 100 to 200 millicuries [3.7 to 7.4 gigabecquerels] in NUREG 1492.

While it is commendable that NRC is finally removing the requirement to decontaminate to unreasonable levels, they are doing a disservice to many radiation safety personnel, by retaining the unreasonable levels as guidance. In the field of medical health physics, particularly, many of the people with radiation safety duties are neither devoted full time to those duties, nor are they health physicists. Faced with the choice of writing a procedure or accepting official NRC guidance, many of them will accept the guidance, which in this case is unreasonably restrictive. This is particularly hard to defend, as the NRC is reportedly moving to risk-based regulation and relying on consensus standards in its regulations.

Discussion

Most of the regulations that NRC publishes are based on recommendations of the National Commission on Radiation Protection and Measurement [NCRP]. The only guidance the authors could find in NCRP reports was in [NCRP 1964], published as NCRP Report Number 30 and National Bureau of Standards [NBS] Handbook 92 in 1964. Table 6, "Suggested Levels of Significant Contamination" gives 100 cpm as the level for a Geiger counter that is considered significant. The recommendation of NCRP 30 is that all significant radioactive contamination should be decontaminated. It seems likely that the 200 dpm/100 cm² is based on that guidance.

ICRP Publication 57 recommends decontamination to levels of 3 to 300 Bq/cm² [1.8×10^4 to 1.8×10^6 dpm/100 cm²] depending on the classification of the isotope. The limit of 3 Bq/cm² or 1.8×10^2 dpm/cm² applies to I-131. Twenty commonly used medical isotopes are listed in three categories. Not included in ICRP's table are P-32, Ga-67, or Sm-153. The limits appear to be applicable for areas but it is not clear whether they would apply to restricted or unrestricted areas. "(288) A routine monitoring survey for contamination of *accessible* areas shall be performed at regular intervals in all areas where work with unsealed radionuclides is undertaken. Any areas or items found to be significantly contaminated should be decontaminated to a level below that specified in Table 11." (Italics added.) It is inferred from the use of the word "accessible" and another section that refers to "articles removed from restricted areas" that the levels apply to unrestricted areas. The major problem with this guideline is the limited number of isotopes classified.

The International Atomic Energy Agency [IAEA] has recommended surface contamination limits for beta emitters of $10^{-3} \mu\text{Ci}/\text{cm}^2$ [2.22×10^4 dpm/100 cm²] for unrestricted or inactive areas. This information is from the Canadian "Advisory Committee on Radiological Protection" [ACRP-7] which cited IAEA references IA70, IA73, IA79, IA82B, IA83 as the source. The IAEA recommendations for inactive areas, as re-reported by the ACRP of Canada are similar to the ICRP 57 recommendations, discussed above. The recommendations appear to be for total contamination, as are the ICRP recommendations, instead of removable contamination, as specified in the current NRC regulations.

ANSI N13.12-1999 recommends a screening level of 60,000 dpm/cm² [10 Bq/cm²] for a group of isotopes that includes I-131. The list of isotopes in Table 1 of the ANSI standard includes 51 individual isotopes. Missing are TI-201, GA-67, Sm-153, and In-111—all isotopes which are of interest to medical health physicists. ANSI N13.12 does have a procedure to determine the hazard group of unlisted isotopes; unfortunately, it requires another standard, [NCRP1996]. The other issue which must be addressed with ANSI N-13.12 is applicability. At first glance, one might conclude it is not applicable to room clearance. Its scope statement [paragraph 1.2] says, "The following are not included in the scope of this standard:...3. Release of a licensed or regulated site or facility for unrestricted use." Both the purpose and scope paragraphs refer to items and equipment. However, Annex B, "Derivation of Screening Levels, Section B.1.2." includes a discussion of room clearance as follows: "...Clearance of rooms within an operating facility could result in scenarios associated with the reuse of portions of a building as a factory, office, or residence..." One of the authors contacted the

chair-person, Mr. William E. Kennedy, Jr., Chairman of the Health Physics Society working group that produced the standard. It was Mr. Kennedy's opinion that the standard could apply to release for unrestricted use of rooms or areas within a licensed facility. What the scope statement apparently intended to exclude was "decommissioning" of entire facilities and remediation. Since ANSI N13.12-1999 is a recent publication, produced and supported [HPS 99 & HPS 00] by the Health Physics Society under the auspices of the American National Standards Institute, it deserves careful consideration for use in clearance of hospital isotope therapy rooms and laboratories.

Table 1 summarizes the current regulations and recommendations of the previously mentioned organizations. The recommendations for I-131 area identified with an asterisk (*).

Prior to the receipt of ANSI N13.12, the authors developed a methodology to determine a decontamination action level based on the same dose to the public concept that supports the patient-release criteria that the NRC adopted in 10 CFR 35.75 and Regulatory Guide 8.39 [RG8.39]. This involved use of the concept of an ingestion or resuspension fraction, a negligible individual dose [NID], to the public and the annual limit on intake. [NCRP 1993] gives 0.01 mSv [1 mrem] as a negligible individual dose. The ingestion fraction or resuspension fraction deserves some comment. The concept was developed by Brodsky, [Brodsky 1980] and was given as less than 10^{-6} . The NRC used 10^{-5} in NUREG-1492 and prior to that in Reg. Guide 8.39. In this discussion, 10^{-3} to 10^{-4} is used. The reason is two-fold. First, the Brodsky work was intended for application to radioactive materials in work settings or accident situations. In a radioactive materials work setting,

personnel are presumably trained to handle and minimize ingestion of radioactive materials, and of course, they consent to work with them. Second, accidents are—by their nature—unavoidable by those encountering them. Personnel encountering contamination in a hospital room are encountering it involuntarily, as in an accident, but not unavoidably. Personnel entering a hospital room presume it has been cleaned or decontaminated but many, generally view that as an all-or-nothing situation—cleaned or dirty. Also this method accounts only for the internal dose; the external dose from contamination is not considered.

These are also the reasons that a negligible dose (1 mrem [.01 mSv]) to the public was selected instead of the 500-mrem [5 mSv] non-repetitive limit or 100 mrem [1 mSv] repetitive limit. (See [NCRP 1993]). Secondly and somewhat arbitrarily, the levels calculated using even the negligible dose and a resuspension

Table 1. Summary of current regulation and guidance

Organization	Bq/cm ²	dpm/100cm ²	Comments
NRC Regulation and guidance in NUREGS excluding volume 7.	Removable/Av. Fixed	Removable/Av. Fixed	From high risk isotopes in unrestricted areas* to low risk in restricted areas.
	0.0033/0.083	20/100	
	0.033/0.17*	200/1000*	
ICRP	0.17/0.83	1000/5000	
	3*	18,000*	High risk isotopes.*
	30	180,000	Medium risk isotopes.
IAEA	300	1,800,000	Low risk isotopes.
	3.7*	22,000*	Unrestricted areas*
	37	220,000	Unrestricted areas having low energy beta emitters.
ANSI 13.12	0.1	600	Group 1
	1	6,000	Group 2
	10*	60,000*	Group 3*
	100	600,000	Group 4

or ingestion fraction of 10^{-5} give levels of acceptable iodine-131 contamination that are relatively high—high enough that instrument dead time can be a problem. It may also be considered an application of the ALARA concept. We certainly can, without too much effort, reduce removable contamination to the levels below those calculated using an ingestion factor of 10^{-3} .

In 10 CFR Part 20 Appendix B, there are two applicable ALIs for ingestion. The stochastic ALI (S-ALI) represents a committed effective dose equivalent (CEDE/whole body) of 50 mSv (5 rem), whereas the non-stochastic ALI (N-ALI) represents a committed dose equivalent (CDE)/organ of 500 mSv (50 rem) to the maximally exposed organ. For limiting the dose in an occupational setting, the more restrictive of these two ALIs is used, but for our purposes, we will use the S-ALI. We chose the S-ALI because the N-ALI is derived to prevent acute effects to an organ and there is a demonstrable threshold for such acute effects. The NID of 0.01 mSv (1 mrem) is several orders of magnitude below the CDE of 500 mSv (50 rem); therefore, the N-ALI seems inappropriate for this problem.

The stochastic annual limit on intake, published in 10 CFR 20, is $90 \mu\text{Ci}$ [$1.11 \times 10^6 \text{ Bq}$] by ingestion. For purposes of demonstration, a room area of 10 square meters is used. This value would of course require adjustment for actual room dimensions.

$$DAL = \frac{PIL_{ND}}{IF \times AREA}$$

where:

DAL = Decontamination Action Level;

IF = Ingestion fraction;

Area = Room area in square centimeters; and

PIL_{ND} = Public Ingestion Limit, Negligible dose.

$$PIL_{ND} = \frac{S - ALI}{5000}$$

S-ALI = Stochastic Annual Limit on Intake, for I-131 = $90 \mu\text{Ci}$

Solving for IF = 10^{-4}

$$DAL = \frac{\left(\frac{90 \mu\text{Ci}}{5000} \right)}{10^5 \text{ cm}^2} = 1.8 \times \frac{10^{-3} \mu\text{Ci}}{\text{cm}^2}$$

or $\left[\frac{6.7 \times 10 \text{ Bq}}{\text{cm}^2} \right]$

Solving for IF = 10^{-3}

$$DAL = \frac{1.8 \times 10^{-4} \mu\text{Ci}}{\text{cm}^2} \text{ or } \left[\frac{6.7 \text{ Bq}}{\text{cm}^2} \right]$$

The values for a 100-cm² wipe are simply 100 times those above or

For IF = 10^{-4} ,

$$DAL = 1.8 \times \frac{10^{-1} \mu\text{Ci}}{100 \text{ cm}^2}$$

or $\left[\frac{6.7 \times 10^3 \text{ Bq}}{100 \text{ cm}^2} \right]$

For IF = 10^{-3} ,

$$DAL = 1.8 \times \frac{10^{-2} \mu\text{Ci}}{100 \text{ cm}^2}$$

or $\left[\frac{6.7 \times 10^2 \text{ Bq}}{100 \text{ cm}^2} \right]$

The range given in dpm/100 cm² would be 4.0×10^4 to 4.0×10^5 .

The size of room would scale the factor either up or down. The decontamination action level [DAL] is for uniform contamination over the entire room. This would rarely, if ever, be the case. In practice, there are "hot spots" which may exceed even a DAL based on an ingestion fraction of 10^{-5} or 1.33×10^6 dpm/100 cm² with much of the room at approximately background. While this approach would allow contamination averaging, the complications of doing such averaging may not be worth the effort. A slight or moderate attempt to decontaminate a spot of contamination is likely to yield results below 10^4 dpm/100 cm² and take less time than establishing the area of the

spot and average **removable** contamination.

This procedure was primarily intended for floor surfaces. However, two other surfaces should be considered—the bed mattress and the toilet seat. Mattresses are covered with sheets that are changed between patients so it seems reasonable to not adjust or change the limits from those used for the floor. The toilet seat however, comes into contact with the user whenever the user sits. Female users of course, sit habitually, male users much less frequently. Male radiotherapy patients are typically instructed to sit whenever using the toilet to minimize the possibility of urine-borne contamination. Additionally the contact is generally not completely dry due to perspiration, so transfer of material may be facilitated. It would seem a higher level of protection or assurance would be warranted for the toilet seat. Either the acceptable ingestion fraction could be again lowered to 10^{-2} or the 200 dpm/100 cm² could be used for that case. Since in practice, many seats are wrapped in plastic wrap or replaced and placed in storage rather than cleaned, it may not be necessary to decide an appropriate decontamination level.

To apply this procedure the steps would be:

1. Determine the area of the room in square centimeters.
2. Choose the ingestion fraction between 10^{-3} and 10^{-4} .
3. Calculate DAL for each room (= [PIL_{ND} / IF] / Area)

The resultant action level will be in units of $\mu\text{Ci}/\text{cm}^2$ if the ALI is taken from 10 CFR 20 in μCi . This can then be converted to dpm/100 cm² or Bq/100 cm² for the limit for a 100-cm² wipe.

The trigger levels obtained by this procedure may seem uncomfortably high. They are certainly higher than the current require-

Table 2. Comparison of current regulation and guidance with negligible dose to public approach

Organization	Bq/cm ²	dpm/100 cm ²	Comments
NRC Regulation and guidance in NUREGS excluding Volume 7.	Removable/Av. Fixed 0.0033/0.083 0.033/0.17* 0.17/0.83	Removable/Av. Fixed 20/100 200/1000* 1000/5000	From high risk isotopes in unrestricted areas* to low risk in restricted areas.
ICRP	3* 30 300	18,000* 180,000 1,800,000	High risk isotopes.* Medium risk isotopes. Low risk isotopes.
IAEA	3.7* 37	22,000* 220,000	Unrestricted areas* Unrestricted areas having low energy beta emitters.
ANSI 13.12	0.1 1 10* 100	600 6,000 60,000* 600,000	Group 1 Group 2 Group 3* Group 4
Negligible Dose to Public	6.7* 67*	40,000* 400,000*	For IF = 10 ⁻³ * For IF = 10 ⁻⁴ *

* Guidance or regulation applying to I-131.

ments and practice by two or three orders of magnitude. But using the very conservative ingestion fraction of 10⁻³, they are right in line with the levels recommended by the ICRP, IAEA, and ANSI.

Conclusion

With three published standards recommending values in the range of 10⁴ dpm/100 cm² for iodine-131 for total activity, it would seem that a level in that range should find ready acceptance. ICRP-57 is an applicable current standard. Its chief drawback is the limited list of

isotopes it includes. Of the IAEA documents cited in the ACRP of Canada document, only IA70—“Monitoring of Radioactive Contamination on Surfaces”—remains in print, and it must be obtained from Vienna. The best existing document is obviously ANSI N13.12-1999. It is unfortunate that it is vague about applicability to room clearance and requires the use of another document to establish which group an unlisted isotope belongs in.

The National Institutes of Health recently received an amendment to their NRC license to use ANSI 13.12 as the release criteria. So at least one NRC region apparently recognizes that higher release levels are than 200 dpm/100 cm² are appropriate. Use of the methodology

described above for establishing trigger levels of removable contamination provides another alternative. One that is consistent with the dose to public criteria that the NRC used for patient release, but is more conservative in using negligible dose to the public of 1 mrem/y, instead of the standard 100 mrem/y repeatable or 500 mrem/y single exposure criteria. This methodology easily allows any isotope to be evaluated that is listed in Appendix B to 10 CFR 20.

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