Calculation and Prevention of Radionuclide Intake in Nuclear Medicine from Gases and Volatile Solutions

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The revision of the Nuclear Regulatory Commission's Rules and Regulations, Part 20 brought with it a new methodology for the determination of internal radiation dose and a change in the manner by which this dose is described. These regulatory revisions necessitate changes in radiation safety program activities. In this paper the authors describe these changes, propose a rationale for the determination of compliance with annual limit on intake (ALI) and derived air concentration (DAC) limits and reveal an apparent unwarranted and arbitrary conflict between the requirements of Part 20 and Part 35.

Key Words: bioassay; Part 20; radionuclide intake

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The potential for radionuclide intake by nuclear medicine technologists is a hazard that has been long appreciated and monitored. Previous to the 1994 revision of the Nuclear Regulatory Commission's (NRC) Title 10, Code of Federal Regulations, Part 20 (1) the usual evaluation of radionuclide intake in nuclear medicine was the determination of the thyroid uptake at various time periods following a potential exposure. There are many reasons to perform a bioassay. These reasons include: to confirm the containment of radioactive materials; to demonstrate compliance with existing regulations; and to assure radiation workers that they are receiving adequate protection.

Earlier regulations did not directly address the dosimetric consequences of radionuclide intake, nor did it adjust the individual's exposure to reflect the intake and retention of the radionuclide. Actions were based on singular uptakes. The accumulation of radionuclide in the individual was not considered. Consequently, the results of the bioassay were not included in an individual's dosimetric record. These results were more a measure of the radiation safety program than an individual's dosimetric evaluation. Performance of bioassays did not weigh the risk of stochastic or nonstochastic effects.

Stochastic and nonstochastic are descriptive radiobiologic terms recently included in Part 20. Briefly, stochastic effects are health effects that can occur randomly, such as leukemia or cancer. It is the *probability* of the effect occurring, rather than the severity of the effect that is increased with radiation exposure. These effects, when and if they occur, are not distinguishable pathologically from randomly occurring disease. These effects can be distinguished statistically by an increase in the incidence of a disease in a selected population. Conversely, nonstochastic effects are health effects that do not occur randomly. The severity of this effect does vary with dose. As the dose increases, the severity of the effect (rather than the probability) increases. In addition, nonstochastic effects are presumed to have a dose threshold. An example of a nonstochastic effect would be the effect that radiation exposure can have on skin. The greater the exposure to radiation, the more pronounced the effect this exposure has on skin.

Changes in the regulations and contemporary health physics philosophy require that the *uptake* (or excretion) derived as a result of a bioassay be translated to a radionuclide *intake*. The determination of the radionuclide intake is a more reliable dosimetric methodology for the evaluation of radiation exposures in that it more accurately reflects the effective dose equivalent (EDE) to various organs and organ systems as well as to the whole body. A summary of various dose equivalents is in Table 1.

REGULATORY BASIS

Part 20 requires that licensees limit the occupational dose to individuals to a total effective dose equivalent (TEDE) of 5 rems (0.05 Sv) and a limit the sum of the deep dose equivalent (DDE) plus committed dose equivalent (CDE) limit to any organ or tissues (except the skin, lens of eye and extremities) of 50 rems (0.5 Sv) (1).

Under conditions that it is likely an individual would receive 10% of the radiation dose limit for minors (1), declared pregnant women (1) or adult radiation workers (1), licensees are required to supply and radiation workers compelled to use individual monitoring devices (film badges or TLDs) (1). Also, licensees must monitor the radionuclide intake of individuals

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TABLE 1Selected Dose Equivalents

Dose equivalent	Abbreviation	Formula	Description
Deep dose equivalent	DDE	None	External dose at 1 cm
Committed dose equivalent	CDE	DE Calculated over 50 yr	Describes an internal dose
Super-effective dose equivalent	EDE	$DDE \times W_T^1$	Sum of DE to all organs
Committed effective dose equivalent	CEDE	$CDE \times W_{T}$	Sum of CDE
Total effective dose equivalent	TEDE	DDE + CEDE	Stochastic dose
Total organ dose equivalent	TODE ²	DDE + CDE	Nonstochastic dose

 $^{1}W_{T}$ (weighting factor) is a multiplier used to distribute the risk of stochastic effects from the uniform exposure of the whole body to the proportional risk of stochastic effects to a given organ or tissue. A table of W_T factors is in 10 CFR 20.1003.

²TODE is a term that is useful in describing the nonstochastic dose equivalent to an organ or tissue. It is described in ICRP Report 26 and is not, as are the other terms of this table, a term defined in 10 CFR 20.

who are likely to receive in one year an intake in excess of 10% of the annual limit on intake (ALI) (1).

In cases where a licensee is required to monitor both the external radiation exposure and radionuclide intake of occupational workers, the resulting doses may need to be summed (1) to demonstrate compliance. The summation of doses is required if 10% of the ALI is observed in the radiation worker. The NRC provides a form, NRC Form 5, to demonstrate compliance with Part 20 directives regarding the summation of internal and external doses.

The above requirements incorporate a risk-based methodology as described predominately by the International Commission on Radiological Protection in Reports 26 and 30 (2,3). These regulations describe radiation doses in terms of various equivalent doses. This concept attempts to inhibit the stocastic effects of exposure to ionizing radiation. Nonstochastic effects to organs and tissues are mitigated by considering and limiting doses to various organs and tissues separately.

In addition to the general requirements of Part 20, medical licensees are also subject to the requirements of Title 10, Part 35, Medical Use of Byproduct Material (4). This part provides guidance specific to the medical use of radionuclides. Section 35.315 of this part, which supersedes Part 20 for medical licensees, requires that bioassays must be performed within 72 hr of dose administration. A bioassay is required on any individual who helped prepare or administer ¹³¹I to a patient hospitalized as a matter of radiation safety. In essence, this requirement mandates the performance of a bioassay following the administration of greater than 1110 MBq (30 mCi) of ¹³¹I.

Substantially similar requirements can be found in most Agreement State regulations, with occasional variation. As an example, the state of Illinois requires that a bioassay be performed following the therapeutic administration of any amount of ¹³¹I to a patient who is hospitalized without regard to the reason the patient is hospitalized (5).

The apparent conflict between Part 35 and Part 20 with regard to the performance of bioassays is indeed a curious one. On one hand, Part 20 stipulates a plausible position mandating the performance of bioassays when it is likely that an individual would receive an intake of 0.1 ALI. This is consistent with NRC requirements pertaining to the use of film badges, which can be considered from a dosimetric perspective a parallel regulation. The conflict is that Part 35 mandates the performance of bioassays following the administration of greater than 1110 MBq (30 mCi) of ¹³¹I. This is without any regard to the potential intake. The rationale for this regulation is uncertain and a unity of regulatory requirements should be pursued in this area. Only medical licensees have the performance of bioassays determined by the activity handled as a matter of regulation.

ANNUAL LIMIT ON INTAKE (ALI)

Part 20 introduced a new concept in 1994 regarding the intake of radioactive materials. This concept, annual limit on intake (ALI) is a derived activity the intake of which results in a CEDE of 0.05 Sv (5 rem) or a committed dose equivalent to an organ or tissue of 0.5 Sv (50 rem) (1). In other words, the intake of one ALI will result in the absorbed dose to an individual, organ or tissue at the maximum annual limits of Part 20. It can be expressed in this fashion:

1 ALI = CEDE of 0.05 Sv (5 rem) to an individual

or

CDE of 0.5 Sv (50 rem) to any organ or tissue.

Appendix B, Table 1 of Part 20 lists 767 ALI values. There are separate ALI values for inhalation and ingestion. It should be noted that the ALI value for a given radionuclide can differ dramatically based on the chemical form or route of intake. The ALI value for ¹³¹I for instance, differs by a factor of four between intake via ingestion and inhalation. Depending on the isotope, ALI values can be stochastic only, stochastic and nonstochastic, or undefined.

A stochastic ALI value is the amount of radionuclide intake that will result in a CEDE of 0.05 Sv (5 rem). A nonstochastic ALI value is the amount of intake that will result in a CDE to an organ or tissue of 0.5 Sv (50 rem). If an ALI value is defined by the stochastic dose limit alone, then a solitary activity is defined.

Some radionuclides have more than one ALI value. In these cases, the nonstochastic ALI is listed with the most affected

(and therefore most limiting) organ identified below the nonstocastic value. If two ALIs are identified, the first value reached is the limiting activity value.

Iodine-131, for example, has two activities listed for inhalation ALI values. Column 1 of Table 1 reveals a thyroid ALI of 50 μ Ci. This indicates that in an euthyroid individual, intake via inhalation of 50 μ Ci (1.85 MBq) of ¹³¹I would result in a CDE to the thyroid of 0.5 Sv (50 rem). Parenthetically, the same column demonstrates that it would take an inhalation of 200 μ Ci (7.4 MBq) to realize a CEDE of 0.05 Sv (5 rem). Since the lower (50 μ Ci) intake of ¹³¹I would result in a CDE of 0.5 Sv, which is the limit proscribed by Part 20 (1), before the CEDE limit is reached, the *lower* value is the regulating value.

An ALI can also be unspecified as is the case for ¹³³Xe and other noble gases. In the case where an ALI is not specified then the internal dose as a result of radionuclide intake is negligible. The external dose, as a result of submersion in a semi-infinite cloud of gas is the limiting factor. In this case, the derived air concentration (DAC) value is the limiting factor.

DERIVED AIR CONCENTRATION (DAC)

DAC values are listed in Appendix B, Table 1, of Part 20. The DAC is the concentration of radionuclides in air that, if breathed by reference man for 2000 hr under conditions of light work, would result in an intake of one ALI (1) or an external exposure of 0.05 Sv (5 rem). DAC is related to two modes of occupational radiation exposure—intake via inhalation of a concentration of radioactive materials over time or submersion in a cloud of radioactive materials of uniform concentration.

As stated earlier, the radioactive form of noble gases do not have ALI values. By their nature, there is little biological retention of noble gases. Hence, the limiting factor for gases such as ¹³³Xe is the concentration of radioactive materials in a semi-infinite cloud that, if a worker is submerged in this cloud for 2000 hr that individual would receive a CDE of 0.05 Sv (5 rem). The objective of DAC limits is to control chronic occupational exposures.

DAC AND ALI RELATIONSHIPS

Both DAC and ALI values need to be managed by the licensee to reflect local practices and ALARA concerns. It is important to remember that 2000 hr of light work in an area whose air is at the DAC limit would result in a CEDE of 0.05 Sv (5 rem) or a CDE of 0.5 Sv (50 rem) to an organ or tissue. Accordingly, the DAC value used to determine minimum ventilation rates should be adjusted to account for doses received to ensure that the total exposure to nuclear medicine personnel are within dose limits. A model example of this adjustment is described in Appendix X of Regulatory Guide 10.8 (6).

The formula to adjust DAC values from Appendix X is:

$$\frac{(5 \text{ rem}) - (\text{Average external dose (in rem)})}{5 \text{ rem}} \times \text{DAC}.$$

Licensees are encouraged to determine a realistic DAC value based on their external dose rates when necessary. In this

fashion, maximal DAC values are locally realistic to the licensee's actual situation and provides for realistic ventilation rates specific to the facility at hand.

Naturally, ventilation rates should be adjusted to minimize the DAC as part of an ongoing ALARA program. The increase in ventilation rates can be an ALARA action in that individual absorbed doses would be decreased if the relative concentration of radioactive materials in the ambient air is decreased.

DAC and ALI values are mathematically related. The relationship can be determined by dividing the limiting ALI (in μ Ci) by 2.4 × 10°. The divisor was derived by multiplying together 2000 working hr per year × 60 min per hr × 2.0 × 10⁴ ml of air breathed per hr by reference man under light work conditions (1). As in:

$$DAC = \frac{ALI}{(2000 \text{ hr})(60 \text{ min/hr})(2 \times 10^4 \text{ml/hr})}$$

This demonstrates that the breathing of a radionuclide at the DAC limit for 2000 hr (2000 DAC-hr) for one yr results in an intake of one ALI. The consequence of an intake of one ALI is either a CDE of 0.5 Sv (50 rem) to an organ or tissue or a CEDE of 0.05 Sv (5 rem).

THE VOLATILITY OF IODINE

In nuclear medicine, the most common route of radioiodine intake is inhalation or ingestion. Numerous regulations and regulatory guides have been developed to mitigate or reduce the potential intake (7) via ingestion. These guides are routinely incorporated into the radioactive materials license as component of the application. The disciplined practice of universal precautions and the long required use of latex gloves and laboratory coats do much to reduce the potential intake via ingestion.

Intake via inhalation is controlled by the use of air exhaust systems. In small programs simple ventilation rates showing that the average concentration is below 10% of the DAC is sufficient. Larger programs may require fume hoods, air cleaning/filtration systems or glove boxes to contain the radioactive materials, especially ¹³¹I capsules and solutions.

Many authors have previously reported on the volatility of radioiodine and the resulting observed or potential radioiodine intakes (8-13). These authors report that both capsule and liquid forms of ¹³¹I are volatile. The volatility is affected by the temperature (14), pH (15) and the use of tap water for dilution (11).

Despite the occasional reporting of a radioiodine intake, we find it to be a relatively uncommon occurrence. A survey of more than 200 clients currently served by our firm covering all NRC regions and many Agreement States reveals that only four bioassays were noted to be in excess of background. The highest intake recorded was 6.29 Bq (0.17 μ Ci) representing 0.34% ALI. In every instance where an uptake was recorded, a breakdown in established radiation safety protocols was determined. These breakdowns include a failure to observe a posting on a patient's room door (two occurrences), lack of patient cooperation and a failure to use gloves consistently.

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 TABLE 2

 Published Methods to Reduce Iodine Volatility or Intake

Method	Action	Reference
Dilute with distilled water	Eliminates chlorine as an oxidizing agent	19
Use of gloves	Reduces hand contamination	20
Chilling to approximately 0°C	Reduces vapor pressure	22
Ventilate ¹³¹ I in hood for 10-15 min	Removes ¹³¹ I from staff breathing zone	24
Storage of ¹³¹ I containers in fume hood	Removes ¹³¹ I from staff breathing zone	24

PREVENTION OF RADIOIODINE INTAKE

Many authors have suggested simple and easy to perform radiation safety activities that can be effective in the reduction or elimination of radioiodine intake (8-10, 12, 14, 16). Published measures are summarized in Table 2. In addition to these measures to prevent radioiodine intake, we offer these additional contamination controls:

- Do not use chlorine-based household chemicals such as bleach to decontaminate ¹³¹I patient rooms or ¹³¹I spills. The use of chlorine can oxidize the elemental iodide to the volatile iodine and release it as a gas.
- 2. Cover the toilet bowl and seat with plastic wrap and drape the wrap into the water of the bowl. This prevents the iodine from contacting the porcelain and binding to it above the water line.
- 3. Careful education of the patient with respect to dose administration and toilet habits.
- 4. Consider saturation of the iodine binding sites in toilets and traps with a cold solution of potassium iodine such as Lugol's or SSKI solution.

Any effort that controls contamination will be effective to a certain extent in reducing the potential for radioiodine intake.

PERFORMANCE OF BIOASSAYS

Although the results of internal and external radiation exposure are recorded essentially in the same fashion, employee perceptions of external and internal radiation dose vary greatly. The main difference in this perception is probably related to the intake, deposition and retention of radioactive material(s) in the individual. This perception often causes undue anxiety and concern in the exposed individual. Most often, a worker's concern in not rationalized by the risk associated with the intake and resulting exposure. The summation of CDE and deep dose equivalent (DDE) to calculate the TEDE value received does, in part, account for the actual dose received by the individual and hopefully will put the resulting organ or tissue CDE exposure in perspective.

Bioassay data must continue to be collected, when necessary, in the same fashion as has been approved by the licensing agency having jurisdiction. Radiation workers whose activities necessitate the performance of bioassays will continue to have their thyroids counted in the usual fashion but an additional step is required to convert the microcuries observed in the thyroid to a radionuclide intake value.

A normal 24-hr thyroid uptake in the range of 7% to 30% is generally accepted (17). The calculation of the radionuclide *intake* accounts for the dosimetry of the previously unaccounted for ingested or inhaled iodine that was not observed in the thyroid.

Since 100% of any intake is not absorbed by the critical organ, a factor must be applied to the observed thyroid uptake (in microcurie units) to derive the intake. This factor is referred to as the intake retention factor (IRF). The NRC has developed a NUREG (18) to define various IRF values for many radionuclides and chemical forms. This NUREG provides IRF values for a majority of radionuclides. For ¹³¹I, thyroid IRF values are provided for time periods of 2.4 hr to 100 days. Also provided are 24-hr urine, accumulated urine and accumulated fecal IRF values. An abbreviated list of thyroid IRF values is in Table 3. Incorporating an IRF value into a classic thyroid bioassay formula is shown below:

Radioiodine intake (μ Ci) =

$$\frac{\text{Activity of }^{131}\text{I standard} \times \text{CPM}_{\text{Neck}} - \text{CPM}_{\text{Thigh}}}{\text{CPM}_{\text{Standard}} - \text{CPM}_{\text{Phantom}}} \div \text{IRF.}$$

As an example of the use of IRF values in the determination of radioiodine intake consider the following scenario. A nuclear medicine technologist administers 3700 MBq (100 mCi) of ¹³¹I-NaI solution to a patient. Current regulations (4) require the performance of a bioassay within 72 hr following the dose administration. Accordingly, the thyroid was counted

 TABLE 3

 Selected lodine-131 Intake Retention Factors*

Time after intake (days)	Fraction of initial intake in thyroid
0.5	9.59 × 10 ⁻²
1.0	1.33 × 10⁻ ¹
2.0	1.49 × 10 ^{°1}
3.0	$1.42 imes 10^{-1}$
4.0	1.31 × 10 ⁻¹
5.0	1.20 × 10⁻¹
6.0	1.09 × 10 ^{−1}
7.0	9.95 × 10 ^{⊶2}

using an uptake probe and following values were obtained at 48 hr:

CPM in the thyroid = 110 cpm

CPM 1.12 μ Ci ¹³¹I standard = 3729 cpm

CPM thigh = 28 cpm

Radioiodine intake = $1.12 \,\mu \text{Ci} \times$

 $\frac{110 \text{ CPM}_{\text{Neck}} - 28 \text{ CPM}_{\text{Thigh}}}{3729 \text{ CPM}_{\text{Standard}} - 16 \text{ CPM}_{\text{Phantom}}} \div 1.49 \times 10^{-1} = 0.17 \ \mu\text{Ci} \ (6.29 \text{ Bq})$

This value is below the evaluation threshold as described in Regulatory Guide 8.9 and, therefore, the result should be recorded for tabulation at the end of the year for possible inclusion on NRC Form 5 should the total intake exceed 5 μ Ci.

A new pattern of thinking related to the intake and bioassay results is also necessary. An ALI value of $50 \ \mu Ci \ (^{131}I)$ does not reflect an uptake of $50 \ \mu Ci$ in the thyroid. Rather, a 24-hr uptake of 6.65 μCi reflects an intake of $50 \ \mu Ci$. Calculations related to the determination of the radionuclide intake need to be adjusted by the time interval between the assumed intake and bioassay, route of intake and chemical form of the isotope.

One cannot show compliance by demonstrating that the uptake of a radionuclide is at or below a certain value other than background. The calculation must be extended to include the determination of radionuclide intake through the use of the IRF values of NUREG/CR-4884. The results of serial intakes need to be tallied over the year to assist in the completion of NRC Form 5 or to show that the total intake is below 0.1 ALI or 5 μ Ci for ¹³¹I.

Regulatory Guide 8.20 (19) has been generally incorporated into the NRC license application process since December 1979 and has not yet been revised or superseded. This guide suggests action levels (which are converted to license conditions) of 1.48 Bq (0.04 μ Ci) (investigation) and 5.18 Bq (0.14 μ Ci) (investigation and medical consultation) for ¹³¹I uptake in the thyroid. Licensees that administer 37 mBq (1 mCi) ¹³¹I and above may need to perform bioassays to maintain compliance if commitment to this guide has been included in the licensing process.

There can be a relaxation of the above thresholds if the license is coupled with the more current Regulatory Guide 8.9 Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program (20). These thresholds for evaluation or investigation do not imply new dose limits but rather standardize evaluation and investigational levels for all bioassays. The evaluation level is 2% of the ALI limit and the investigational level is 10% of the ALI limit. These levels correspond to 4.9 Bq (0.133 μ Ci) and 24.61 Bq (0.665 μ Ci) of ¹³¹I uptake in the thyroid gland at 24 hr following an intake via inhalation. These *uptake* values for radioiodine reflect actual inhalation intakes of 1.0 μ Ci (2%) and 5 μ Ci (10%), respectively.

These activity levels of 4.9 Bq (0.133 μ Ci) and 24.61 Bq (0.665 μ Ci) were derived from the following calculation based on a 24-hr bioassay (21).

Evaluation level:

50 μ Ci (ALI)×0.133 (IRF)×0.02=0.133 μ Ci uptake Investigation level:

50 μ Ci (ALI)×0.133 (IRF)×0.1=0.665 μ Ci uptake

If any single measurement exceeds 4.9 Bq (0.133 μ Ci) at 24 hr following a potential intake, the RSO should first evaluate the methods, techniques and calculations made to determine this value. Repeat bioassays are indicated to verify measurements and obtain a better measure of intake. Single measurements that exceed 24.61 Bq (0.665 μ Ci) at 24 hr should prompt the RSO to initiate a thorough investigation at once, perform serial measurements to better assess the intake, and perform detailed area surveys and air sample evaluations. If additional measurements and investigation confirm the intake, action should be taken to prevent additional intake and more effectively contain the radioiodine.

With a single or total 24-hr intake of 24.61 Bq (0.665 μ Ci) in any individual, the dose resulting from the intake must be summed with the external dose recorded on the film badge and recorded on NRC Form 5 or equivalent (1).

CONCLUSION

The revision of Part 20 incorporated a number of concepts new to the U.S. Terms such as ALI, DAC and the numerous dose equivalents challenge all licensees to reconsider the entire concept of internal dose and the relative concentration of radionuclides in air. The unification of ALI and DAC values, the summation of internal and external dose, a universal criteria to determine radionuclide intake and the necessity for bioassays are welcome.

Licensees need to readdress calculations related to ventilation rates and relative air concentrations of radioactive materials in air. In most instances, no changes will be necessary because realistic, as opposed to worst case, radionuclide values can be considered.

It would appear that the volatility of radioiodine in both capsule and liquid form continues to be observed. This volatility is best managed by first acknowledging its presence and appropriately venting the prepared dose. The effluent concentration of ¹³¹I in the stack should be considered at facilities that use large amounts of ¹³¹I, without regard to the physical form (capsule or liquid) of the material.

The minimization of radioiodine intake can be achieved by instituting relatively simple measures. Technically, the performance of bioassays is unchanged but an extra step to calculate the radionuclide intake is necessary.

Parts 20 and 35 should be reviewed by the licensing authorities and unified by the elimination of the redundant and, in our view, excessive requirement of 10 CFR 35.315 to perform bioassays for doses of ¹³¹I that require hospitalization as a matter of radiation safety. This regulation has been replicated in one form or another by numerous Agreement States. This requirement, which is based on an activity level of 1110 MBq (30 mCi), is completely arbitrary and should be removed from Part 35. If the complete extent of radioactive and byproduct materials licensing (except medical) does not require the performance of a bioassay in the absence of a potential intake of 0.1 ALI, why then is the medical community singled out for more restrictive regulatory control and oversight? Our experience indicates that any measurable intake under a variety of circumstance is a rare occurrence. An intake in excess of 1% of the ALI has not been observed in more than 200 client sites coast to coast.

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