PR 20,30,31,32,33,35,50,61,62,72,110,150,170, and 171
(71FR42952)

HEALTH PHYSICS SOCIETY

(13)

"Specialists in Radiation Safety"

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September 8, 2006

Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
Attn: Rulemakings and Adjudications Staff

Subject: RIN 3150-AH84; Requirements for Expanded Definition of Byproduct Material

Dear Sir or Madam:

As President of the Health Physics Society (HPS), it is my pleasure to provide you, on behalf of the HPS, comments on the Nuclear Regulatory Commission's (NRC) Proposed Rule for Requirements for Expanded Definition of Byproduct Material. These comments are provided in accordance with the Federal Register Notice Volume 71, No. 145, Friday, July 28, 2006.

The HPS is an independent non-profit scientific organization of professionals in the science and practice of radiation safety. The HPS has a relatively long history of advocating for a more uniform and compatible regulatory framework for the responsible regulation of radiation and radioactive materials. Over fourteen years ago, in January 1992, the HPS issued a position statement "Compatibility in Radiation Protection Regulations." In August 2000, the HPS revised its "Compatibility" position, now titled "Compatibility in Radiation-Safety Regulations," (http://hps.org/documents/regulations.pdf) to call for a single, independent federal agency to have the responsibility and authority to establish all ionizing radiation-safety standards for all controllable sources of occupational and public exposures. These statements calling for compatibility and single regulatory authority for all radioactive materials and sources of radiation are based on the need for a uniform and centralized regulation of radiation and radioactive materials for the protection of public health and safety.

The requirement for the current proposed rule to expand the definition of byproduct material to include certain radioactive materials not previously covered under the Atomic Energy Act, and thus not regulated by the NRC, has been legislated by the Energy Policy Act of 2005 (EPAct). Although the

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impetus for this legislation was a concern for increased security and control over these materials for reasons of common defense and security following the events of September 2001, the EPAct included reasons of public health and security in the legislative basis for the requirement.

When it became clear that there would be legislation addressing this issue, the HPS formed a working group with the Organization of Agreement States (OAS) to study the draft legislation. In January, 2005, the HPS and OAS issued the joint position statement "Congressional Action is Needed to Ensure Uniform Safety and Security Regulations for Certain Radioactive Materials," (http://hps.org/documents/MaterialControl.pdf) which contained seven specific principles that should be accomplished by the legislation. Subsequently, the EPAct enacted all seven principles of the HPS-OAS position statement, although it did not support the position that all radioactive materials subject to the expanded definition needed to be included.

Based on this active involvement of the HPS in the issue of centralizing authority and control over the radioactive materials covered by this rule, I presented preliminary comments at the public meeting on August 22, 2006, in Las Vegas, Nevada. I am now pleased to forward the final written comments from the HPS that (1) congratulate the NRC on its rule making process and proposed rule, (2) cite the need to continue to consider public health and safety in the justification and implementation of the rule, and (3) recommend specific DAC values for nitrogen-13 and oxygen-15.

Sincerely,

Brian Dodd, Ph.D.

Enclosure

HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

HEALTH PHYSICS SOCIETY COMMENTS

on the

NUCLEAR REGULATORY COMMISSION'S

PROPOSED RULEMAKING ON REQUIREMENTS FOR EXPANDED DEFINITION OF BYPRODUCT MATERIAL

Offices of the Executive Secretary, 1313 Dolley Madison Blvd., Suite 402, McLean, VA, 22101

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Comment 1: The HPS congratulates the Nuclear Regulatory Commission and its staff and the staffs of the State Radiation Control Agencies for engaging in a cooperative rule making process that has resulted in an outstanding proposed rule. The proposed rule adequately and appropriately implements the seven principles contained in the HPS-OAS joint position statement "Congressional Action is Needed to Ensure Uniform Safety and Security Regulations for Certain Radioactive Materials" (http://hps.org/documents/MaterialControl.pdf) to the extent required by the Energy Policy Act. Our review has not identified any fundamental radiation safety concerns. We recognize that many details of implementing the proposed rule may be subject to comment, input, and criticism by those responsible for their implementation. Our finding of no fundamental radiation safety concerns does not imply there are not valid comments, criticisms, or concerns about some details regarding the implementation of the rule.

Comment 2: While we find that the NRC has adequately met the requirements of the Energy Policy Act in regards to the extent of what materials must be included in the expanded definition of by-product materials, we point out that the Act does require considerations of **both** public health and safety and common defense and security. The Act restricts the extent to which the subject materials need to be included in the expanded definition by restricting its intended use, but not by restricting the activity or quantity of the material. However, the background discussion in the section "Other Naturally Occurring Radioactive Material With Similar Risk as Radium-226" offers three reasons not to include polonium-210 in the expanded definition. One of those reasons is "polonium-210 is very unlikely to be commercially used in individual radioactive sources with activity levels that would place them within IAEA Code of Conduct Category 1 or 2." Within the USA, IAEA categories 1 and 2 have been associated with 'high-risk' sources and activities of concern to common defense and security. The requirement to evaluate other naturally occurring radioactive materials for inclusion in the expanded definition is to evaluate those that pose a similar risk as radium-226 to the public health and safety as well as the common defense and security. Using IAEA category 1 and 2 as the benchmark for the risk of radium-226 does not meet the requirement to include risk to public health and safety. In fact, since the IAEA regards uncontrolled category 1, 2 and 3 sources as potentially 'dangerous' to human health, the HPS would argue that IAEA category 3 is also a threat and the analysis is deficient by at least not including category 3.

Having made this comment, the HPS does not disagree with the NRC conclusion that polonium-210 does not need to be included in the expanded definition under the category of naturally occurring radioactive materials posing a similar risk as radium because of the more persuasive argument that the production of polonium-210 discrete sources for commercial, medical, or research use is by activation in a reactor so it is already regulated as by-product material.

Comment 3: In Section G of the proposed rulemaking, the NRC requested comments on a number of specific issues including (G.(4)) "The adequacy of the applicable default ALIs and DACs in Appendix B to 10 CFR 20 for oxygen-15 and nitrogen-13, and whether staff should develop larger specific values for these radionuclides." In the discussion of this issue, the NRC stated their reason for proposing to use default values is "[b]ecause the approach used [by the NRC staff] in calculating values for nitrogen-13 and oxygen-15 is different from that used for other radionuclides included in 10CFR Part 20, Appendix B."

The HPS believes it is appropriate for the NRC to use specific values for these radionuclides since unnecessarily restrictive default values can result in unjustified cost for unnecessary radiological monitoring and controls.

In regards to the approach to calculate the specific values, the HPS endorses the approach presented by Dr. Michael G. Stabin, CHP, in the document attached to this enclosure. Dr. Stabin uses dose equivalent conversion factors for submersion in a semi-infinite cloud from Federal Guidance Report 12 (FGR-12), *External Exposure To Radionuclides In Air, Water, And Soil*, in conjunction with exposure limits and times used by the NRC in all other calculated values in 10CFR Part 20, Appendix B. FGR-12 dose conversion values are currently endorsed and used by the NRC in 10CFR Part 20, Appendix B for Hydrogen-3 and Argon-37. In addition, FGR-12 dose conversion values are endorsed and used by the NRC in other applications, such as dose modeling in support of the License Termination Rule. Therefore, Dr. Stabin's approach appears to be the same as other radionuclides in the appendix.

The HPS believes the values for the DACs calculated by Dr. Stabin should be rounded to one significant number as is done with the other radionuclides in 10CFR Part 20, Appendix B. This would result in specific DACs for occupational exposure and effluent concentrations as follows:

			Table 1 Occupational Values			Table 2 Effluent Concentrations		Table 3 Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				Monthly Average
Atomic No.	Radionuclide	Class	ALI (μCi)	ALI (μCi/ml)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
7	Nitrogen-13	Submersion[1]	-	-	4E-6	2E-8	-	-
8	Oxygen-15	Submersion[1]	-	-	4E-6	2E-8	-	-

Attachment (1): DAC Values for Occupational Exposure to Airborne N-13 and O-15

<u>DAC Values for Occupational Exposure to Airborne N-13 and O-15</u>

Michael G. Stabin, PhD, CHP
Vanderbilt University, Nashville, TN

July 11, 2006

Introduction

Nitrogen-13 (N-13) and oxygen-15 (O-15) are produced in radiochemical procedures related to the manufacture of various radionuclides for use in Positron Emission Tomography (PET). These nuclides are themselves used directly in such procedures: mostly N-13 as ammonia (NH_3) and O-15 as O_2 or H_2O. Workers in PET facilities may be exposed to airborne levels of N-13 or O-15 by immersion. The principal mode of exposure will be external irradiation of the body tissues, including the lungs, during inhalation. The U.S. Nuclear Regulatory Commission (NRC) has developed Derived Air Concentrations (DACs) for a number of radionuclides classified as Naturally Occurring and Accelerator-Produced Radioactive Material (NARM). Several DAC values for N-13 and O-15 have been proposed by various investigators. As resolution of the different proposed values was difficult, the NRC has to this point accepted 'default' values for these two radionuclides. These default DACs are several times lower than might be expected, based on basic concepts and methodology developed by the International Commission on Radiological Protection (ICRP), which originally proposed the DAC concept[1]. The purpose of this document is to serve as the basis of a Petition for Rulemaking (PRM) to propose specific DAC values to the NRC for these two radionuclides.

Calculation

Federal Guidance Report No. 12 from the Environmental Protection Agency (EPA)[2] gives dose coefficients for immersion in air of many radionuclides, including N-13 and O-15. The dose conversion factors (DCFs) are given as Sv m^3 Bq^{-1} s^{-1}, which gives a dose rate in Sv/s given an airborne concentration in Bq/m^3. Given a permissible dose rate for radiation workers of 0.05 Sv/year (effective dose) and 0.5 Sv/year (dose to any organ) and an assumed working year of 2000 hours, one can directly derive a DAC for both radionuclides:

$$DF_{O\text{-}15}(\textit{effective dose}) = 4.91\times10^{-14}\ Sv\, m^3\ Bq^{-1}\ s^{-1}$$

$$DAC_{O\text{-}15}(\textit{stochastic}) = \frac{0.050\,\dfrac{Sv}{y}\,\dfrac{1\,y}{2000\,h}\,\dfrac{1\,h}{3600\,s}}{4.91\times10^{-14}\,\dfrac{Sv\,m^3}{Bq\,s}} = 1.41\times10^{5}\,\frac{Bq}{m^3}$$

$$DF_{N\text{-}13}(\textit{effective dose}) = 4.90 \times 10^{-14}\ Sv\ m^3\ Bq^{-1}\ s^{-1}$$

$$DAC_{N\text{-}13}(\textit{stochastic}) = \frac{0.050\,\frac{Sv}{y}\,\frac{1\,y}{2000\,h}\,\frac{1\,h}{3600\,s}}{4.90 \times 10^{-14}\,\frac{Sv\,m^3}{Bq\,s}} = 1.42 \times 10^5\,\frac{Bq}{m^3}$$

The DFs and DACs for the two nuclides are nearly identical, as the decay schemes of the nuclides are nearly identical (positron at nearly 100% abundance and no other significant emissions, except for the necessary accompanying annihilation photons). These DACs represent the limit based on *stochastic* effects (effective dose basis); one needs to also calculate the DAC based on the nonstochastic limit (highest dose organ):

$$DF_{O\text{-}15}(\textit{bone surfaces}) = 8.46 \times 10^{-14}\ Sv\ m^3\ Bq^{-1}\ s^{-1}$$

$$DAC_{O\text{-}15}(\textit{nonstochastic}) = \frac{0.50\,\frac{Sv}{y}\,\frac{1\,y}{2000\,h}\,\frac{1\,h}{3600\,s}}{8.46 \times 10^{-14}\,\frac{Sv\,m^3}{Bq\,s}} = 8.21 \times 10^5\,\frac{Bq}{m^3}$$

The stochastic DAC is lower than the nonstochastic DAC, so the stochastic DAC is limiting. The calculation of the nonstochastic DAC is again nearly identical for N-13.

Dose to skin must also be considered in the calculations. The dose limit for skin is also 0.5 Sv/year. The calculations for O-15 and N-13 are:

$$DF_{O\text{-}15}(\textit{skin}) = 1.04 \times 10^{-13}\ Sv\ m^3\ Bq^{-1}\ s^{-1}$$

$$DAC_{O\text{-}15}(\textit{skin}) = \frac{0.50\,\frac{Sv}{y}\,\frac{1\,y}{2000\,h}\,\frac{1\,h}{3600\,s}}{1.04 \times 10^{-13}\,\frac{Sv\,m^3}{Bq\,s}} = 6.68 \times 10^5\,\frac{Bq}{m^3}$$

$$DF_{N\text{-}13}(skin) = 8.68\times10^{-14}\ Sv\ m^3\ Bq^{-1}\ s^{-1}$$

$$DAC_{N\text{-}13}(skin) = \frac{0.50\,\frac{Sv}{y}\,\frac{1\,y}{2000\,h}\,\frac{1\,h}{3600\,s}}{8.68\times10^{-14}\,\frac{Sv\,m^3}{Bq\,s}} = 8.00\times10^{5}\,\frac{Bq}{m^3}$$

Again, the stochastic DAC is seen to be the limiting value.

In non-SI units, the limiting value is:

$$1.4\times10^{5}\,\frac{Bq}{m^3}\times\frac{1\,m^3}{1000\,L}\times\frac{1\,L}{1000\,mL}\times\frac{\mu Ci}{3.7\times10^{4}\,Bq} = 3.8\times10^{-6}\,\frac{\mu Ci}{mL}$$

Effluent Air Concentrations

One may also calculate values for public exposure based on a 1.0 mSv/year exposure limit and continuous exposure:

$$DAC_{O\text{-}15}(public) = \frac{0.0010\,\frac{Sv}{y}\,\frac{1\,y}{8760\,h}\,\frac{1\,h}{3600\,s}}{4.91\times10^{-14}\,\frac{Sv\,m^3}{Bq\,s}} = 6.46\times10^{2}\,\frac{Bq}{m^3}$$

$$DAC_{N\text{-}13}(public) = \frac{0.0010\,\frac{Sv}{y}\,\frac{1\,y}{8760\,h}\,\frac{1\,h}{3600\,s}}{4.90\times10^{-14}\,\frac{Sv\,m^3}{Bq\,s}} = 6.46\times10^{2}\,\frac{Bq}{m^3}$$

In non-SI units, the limiting value is:

$$6.5\times10^{2}\,\frac{Bq}{m^3}\times\frac{1\,m^3}{1000\,L}\times\frac{1\,L}{1000\,mL}\times\frac{\mu Ci}{3.7\times10^{4}\,Bq} = 1.8\times10^{-8}\,\frac{\mu Ci}{mL}$$

Discussion and Conclusion

The proposed DAC value for exposure to airborne O-15 or N-13 via immersion, based on the calculations above, is **1.4×10^{5} Bq/m^3 (3.8×10^{-6} µCi/ml)**. The proposed DAC for public exposure to airborne O-15 or N-13 via immersion is **6.5×10^{2} Bq/m^3 (1.8×10^{-8} µCi/ml)**. This limit considers the effective dose and dose to all internal organs and skin. It does not consider possible intakes of O-15 as liquid water (inhaled as water vapor and crossing the lung/blood barrier). If needed, this DAC must be calculated separately. The geometry for the immersion sources is a semi-infinite cloud containing the emitter and surrounding a human standing on an air-ground interface. Adjustments to these calculations can be made for work within rooms of finite volume, as shown by the ICRP. Basically, the value for the semi-infinite cloud may be modified by a term $[1 - \exp(-\mu_A \cdot \rho_A \cdot r)]$, where μ_A is the mass energy absorption coefficient in air for the energy of the principal photon, ρ_A is the density of air, and r is the "effective radius" of the room. In ICRP 30, correction factors were given for room volumes of 100 m^3 (r = 2.9 m), 500 m^3 (r=4.9 m) and 1000 m^3 (r=6.2 m). The general effect on the calculations is to allow for higher DAC values in smaller rooms.

References

[1] International Commission on Radiological Protection. Limits for Intakes of Radionuclides by Workers. ICRP Publication 30, Pergamon Press, New York, 1979.

[2] External Exposure to Radionuclides in Air, Water, and Soil. Federal Guidance Report No. 12, Environmental Protection Agency (EPA), Washington, DC, 1993.

From: "Keith Dinger" <govtliaison@hps.org>
To: <SECY@nrc.gov>
Date: Sat, Sep 9, 2006 10:54 AM
Subject: RIN 3150-AH84 - HPS Comments

Dear Sirs

On behalf Health Physics Society (HPS) President Dr. Brian Dodd, I am forwarding HPS comments on the proposed rulemaking "Requirements for Expanded Definition of Byproduct Material." This is being submitted in accordance with the Federal Register Notice Vol. 71, No. 145/Friday, July 28, 2006/Proposed Rules page 42952.

Sincerely,

Keith H. Dinger, CHP
Governmental Relations Liaison
Health Physics Society
govtliaison@hps.org

CC: "Brian Dodd" <BDC.mail@cox.net>

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