

**NRCREP - Comments on NUREG-1556 Vol 21**

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**Date:** 07/11/2007 12:51 PM  
**Subject:** Comments on NUREG-1556 Vol 21

(H)

5/29/07  
72 FR 29555

Our comments are attached. If we can be of additional assistance, please contact me.

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STATE OF MICHIGAN  
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LANSING



STEVEN E. CHESTER  
DIRECTOR

July 11, 2007

Mr. Michael T. Lesar, Chief  
Rulemakings, Directives, and Editing Branch  
Division of Administrative Services  
Office of Administration  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Dear Mr. Lesar:

We appreciate the opportunity to review and comment on the draft NUREG-1556 Volume 21, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator."

General Comments

1. Accelerators that produce radionuclides used for positron emission tomography (PET) and the associated radiochemical synthesis units release radioactive material to the air during their normal processes. The integrity of the accelerator target can catastrophically fail. We strongly urge the Nuclear Regulatory Commission (NRC) to require PET accelerator facilities to submit an assessment of the potential doses to members of the public during routine use and during a catastrophic target failure.

The five accelerator facilities in Michigan used five different computer codes to model their public dose due to air emissions. Instead of our staff trying to learn the five different computer codes, we entered the input parameters in a standard methodology we use and compared our results with their results. Significant discrepancies were discussed with the applicants.

We do not believe that the average NRC or state agreement inspector can adequately evaluate the ventilation system design and the computer modeling of public doses during a routine inspection. The complexity of the ventilation systems, the inherent limitations of the different computer codes, and the breadth of input data for the computer codes would be difficult for an inspector to evaluate during an on-site inspection. With the dose assessment submitted during licensing of the facility, NRC staff can adequately evaluate the premises and conclusions of the dose assessment. Then the inspector knows before the inspection that an annual release to the atmosphere of "x" curies of a radionuclide means a dose of "y" millirems to a member of the public. The inspector would need to verify during the inspection that the other input parameters in the dose assessment had not changed.

2. All material made radioactive during operation of an accelerator is an activation product including the intended radioactive product and the other accelerator and shielding components incidentally made radioactive. To eliminate confusion, we recommend that the terms activation products, activation radionuclides, activation radioisotopes, activation materials, activated material, activated products, activated components, and activated

targets be replaced by incidental activation products, incidentally activated material, etc. when referring to the incidentally radioactive products.

3. The ANSI standards referenced in Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities" and Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," have been revised. These Regulatory Guides should be reviewed and revised.
  - ANSI N42.18 "Specification and Performance of On-Site Instrumentation for Continuously Monitoring Radioactivity in Effluents" was revised in 2004.
  - ANSI N13.1 "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities" was revised in 1999 and renamed "Sampling and Monitoring Releases of Airborne Radioactive Substances From the Stacks and Ducts of Nuclear Facilities."

Specific Comments

Pages xiii to xv - Abbreviations

- Add
 

|          |                                    |
|----------|------------------------------------|
| Nal      | Sodium Iodide                      |
| Nal (TI) | Sodium Iodide (thallium activated) |
| Rad      | Unit of Absorbed Dose              |
| RIS      | Regulatory Issue Summary           |
- Change "Sv sievert" to "Sv Sievert"
- Delete
 

|         |                       |
|---------|-----------------------|
| cm      | centimeter            |
| mCi     | millicurie            |
| mGy     | milliGray             |
| mR      | milliroentgen         |
| mrem    | millirem              |
| mrem/hr | millirem per hour     |
| mSv     | millisievert          |
| mSv/hr  | millisievert per hour |
| µCi     | microcurie            |

- Add
 

| SI Prefixes   |               |                   |                 |
|---------------|---------------|-------------------|-----------------|
| <u>Prefix</u> | <u>Symbol</u> | <u>Factor</u>     | <u>Examples</u> |
| micro         | µ             | 10 <sup>-6</sup>  | µR              |
| Milli         | m             | 10 <sup>-3</sup>  | mCi, mR         |
| Centi         | c             | 10 <sup>-2</sup>  | cm              |
| Kilo          | k             | 10 <sup>+3</sup>  | kg, kBq         |
| mega          | M             | 10 <sup>+6</sup>  | MBq             |
| Giga          | G             | 10 <sup>+9</sup>  | GBq             |
| Tera          | T             | 10 <sup>+12</sup> | TBq             |

Page 8-12. Table 8.1 "Sample Format for Providing Information About Requested Radioisotopes" should have an entry such as

| Radioisotope  | Chemical/ Physical Form       | Maximum Possession Limit | Proposed Use   |
|---|-------------------------------|--------------------------|----------------|
| Any byproduct material with atomic numbers 1 through 83 | Any chemical or physical form | 1 millicurie             | Basic Research |

Page 8-20, "Response from Applicant" regarding "Facilities and Equipment." This section states, "Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within the ALARA constraints for air emissions established under 10 CFR 20.1101(d)." What would be considered sufficient verification? Does a facility need to submit a computer model calculating the projected doses to members of the public at various nearby locations or will an unsupported statement that public doses are ALARA be considered sufficient?

Page 8-24. The Radiation Protection Program Audit program should include:

**Air Emissions.** Verify that the annual average concentrations of radioactive material released to the air at the boundary of the unrestricted area did not exceed the values specified in table 2 of appendix B to part 20 and, if a catastrophic release occurred, that an individual in an unrestricted area would not have received a dose in excess of 0.002 rem (0.02 mSv) in an hour.

Page 8-24. Under Radiation Surveys, add a section verifying that the radiation exhaust monitors have been calibrated with a known bolus of activity and/or periodically checked with a check source.

Page 8-43, "Maintenance." This section should specifically mention that a radiation survey and wipe tests should be conducted when the accelerator is opened for servicing.

Page 8-47, "Decay in Storage." It is a reality of accelerator operation that a mixture of radionuclides is produced within the same metal part. Some of these radionuclides have short half-lives and some have longer half-lives. This section on decay in storage should discuss whether the licensee can store activated components having both short and long half-lives. In Michigan, we had an incident where an activated component was partially vaporized during operation of a 50-MeV accelerator. When the accelerator was opened for servicing, contamination spread throughout the therapy suite. Laboratory analysis of a wipe of the contaminated area identified Sb-124 (14 d), Cr-51 (28 d), Fe-59 (45 d), Co-58 (71 d), Sn-113 (115 d), Zn-65 (244 d), Co-57 (271 d), Mn-54 (313 d), Sb-125 (1,023 d), and Co-60 (1,936 d). If adequate storage space is available, we support storing radioactive components to reduce ambient radiation levels.

Page 8-48, "Release into Air and Water." This section should have an extensive discussion on computer modeling and the input parameters needed for dose assessment due to atmospheric releases.

Page C-2, "Radioactive Material." The note states: "For activation radionuclides, the applicant could request authorization to possess and use any form of byproduct material with atomic numbers 1 through 83. However, the applicant should indicate the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides." The purpose of having an "activation products" designation is to allow the activated parts of the accelerator to be licensed without the licensee needing to determine exactly what will be the incidentally activated radionuclides and their individual activities. The second sentence should be amended to read "However, the applicant should indicate the maximum total activity for all these activation products to be possessed at any one time." If a specific activity limit is stipulated for a radionuclide, how will the licensee or an NRC inspector verify that the sum of that radionuclide's activity in all activated components is less than the stipulated quantity?

Page C-4, "Facilities and Equipment" states: "Provide verification that ventilation systems ensure that effluents are within the dose limits of 10 CFR 20.1301, and the ALARA constraints for air emissions established under 10 CFR 20.1101(d) are ALARA." What would be considered sufficient verification? Does a facility need to submit a computer model calculating the projected doses to members of the public at various nearby locations or will a statement that public doses are ALARA be considered sufficient?

APPENDIX H, "Radiation Monitoring Instrument Specifications and Model Survey Instrument and Air Sampler Calibration Program" should include a discussion on the calibration of radiation detection equipment installed to monitor and quantify the activity released to the atmosphere. For PET accelerators, stack exhaust monitors are typically sodium iodide detectors mounted adjacent to the exhaust system. They are calibrated by releasing a known millicurie quantity of radioactive material at installation. The number of counts above background can then be correlated with a known activity. This guidance document should state if the NRC will require subsequent periodic releases to annually (quarterly, monthly) "calibrate" these monitor or will the NRC accept a procedure using check sources to confirm that the response to the check source has not changed since the initial calibration.

APPENDIX I, "Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits" should mention that air intakes for the accelerator building and for adjacent buildings need to be considered in the evaluation of doses to members of the public.

Page L-1, "Ambient Radiation Level Surveys." For self-shielded cyclotrons, an ambient radiation survey should be performed whenever the cyclotron is opened for repair or other modifications.

Page L-2, "Contamination Surveys." For self-shielded cyclotrons, a contamination survey including wipe tests should be performed whenever the cyclotron is opened for repair or other modifications.

Page L-4. The term "FCi" should be clarified in the following paragraph: "The object is to determine how often to survey the laboratory or area of use. To do this, multiply the activity range under the LOW, MEDIUM, and HIGH survey frequency in Table L.2 by the appropriate Modifying Factor to construct a new set of FCi ranges for LOW, MEDIUM, and HIGH survey frequency."

Page L-8, "Airborne Effluent Release Monitoring." ANSI N13.1 "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities" was revised in 1999 and renamed "Sampling and Monitoring Releases of Airborne Radioactive Substances From the Stacks and Ducts of Nuclear Facilities."

Page L-10, "References."

- ANSI N13.1 "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities" was revised in 1999 and renamed "Sampling and Monitoring Releases of Airborne Radioactive Substances From the Stacks and Ducts of Nuclear Facilities."
- ANSI N42.18 "Specification and Performance of On-Site Instrumentation for Continuously Monitoring Radioactivity in Effluents" was revised in 2004.

Mr. Michael T. Lesar  
Page 5  
July 11, 2007

Spelling Errata

Page 8-12, "Maganese-54" to "Manganese-54"  
Page 11-1, "superceded" to "superseded"  
Page O-2, "Gbq" to "GBq"  
Page P-5, "Radioapharmacies" to "Radiopharmacies"

If we can be of additional assistance, please contact me.

Sincerely,



Robert D. Skowronek, Chief  
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RDS:JK