



Washington University in St. Louis

Environmental Health & Safety

Radiation Safety Office

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72 FR 29555

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RULES AND DIRECTIVES
BRANCH
USNRC

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

SUBJECT: Draft Guidance NUREG-1556, Volume 21: "Consolidated Guidance About Materials Licenses Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator"

Dear Rulemakings, Directives, and Editing Branch Chief:

On behalf of Washington University in St. Louis, Dr. Susan M. Langhorst, Ms. Sally J. Schwarz, Dr. Barry A. Siegel, and Dr. R. Gilbert Jost respectively submit these comments on the Nuclear Regulatory Commission draft guidance, NUREG-1556, Volume 21 (72 FR 29555, May 29, 2007). We appreciate NRC's efforts to enact the Energy Policy Act of 2005 expansion of definition for byproduct materials, especially as related to your attempt to minimize the impact these regulatory changes will have on the availability of radioactive drugs containing accelerator-produced radionuclides. We offer our comments in support of the continued availability of accelerator-produced radionuclides for research and development, as well as for medical use.

Medical License Incorporation of Radioactive Material Produced Using an Accelerator

We recommend NRC allow a Medical license to include possession for production of radioactive materials using an accelerator.

Question – Does the "Note" listed in Appendix P referring the reader to Appendix AA of the current version of NUREG-1556, Vol. 9 indicate that the new draft Vol. 9 Appendix AA will be similar to Vol. 21 Appendix P, indicating that NRC will allow inclusion of this "production" license as part of another license type?

SONSI Review Complete
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E-REDS = ADM-013
Add = J. White (DEW2)
J. Tobin (JCT1)
T. TAYLOR (TMT)

Washington University in St. Louis, Campus Box 8053, 660 S. Euclid Avenue, St. Louis, MO 63110-1093

(314) 362-3476, Fax: (314) 362-4776, rad safety@wustl.edu, <http://rad safety.wustl.edu>



Request for Unsealed Byproduct Material Produced by an Accelerator

The activity of radioactive materials intentionally produced in an accelerator is limited by the characteristics of the particle beam and the target materials. The incidental activation of other radioactive materials is limited, either by the materials not being in the direct beam or by the design of the target materials to minimize the production of long-lived radioactive materials. The incidental activation of short-lived radioactive materials may result in high activities being produced, but which quickly decay away.

Question – Instead of listing Co-60, Mg-54 and Cd-109 separately, as indicated in Table 8.1, should not the radioisotope request be any byproduct material with atomic numbers 1 through 83, target foil or body, not to exceed 20 millicuries per radionuclide and 1 curie total, except as noted – Co-60 not to exceed 50 millicuries; Mg-54 not to exceed 100 millicuries; and Cd-109 not to exceed 100 millicuries?

Questions – How will NRC deal with very short-lived radioactive materials (e.g., half-life less than 2 minutes) that may be activated to activities exceeding the requested limits? Should the license application state that possession limits apply to incidentally activated radioactive materials with half-lives greater than or equal to 2 minutes?

Comments, Suggestions and Questions on Specific Items in NUREG-1556, Vol. 21 Draft

Page 3-1 – The definition of “Management” should be identical to the definition in Vol. 9 by adding “... ensure safety and to...” between “to” and “achieve”.

Page 8-3, Second paragraph under 8.3 – Is this paragraph needed here, because it is covered in 8.9 describing what information is required for “Item 9: Facilities and Equipment”?

Page 8-10, First paragraph under 8.6 – Does the statement, “Once material is produced, it will be transferred internally to another license...” mean that the NRC recognizes that an accelerator production license can be combined with any of the license types listed in this section?

Page 8-14, Paragraph continued from previous page under 8.7 – The first complete sentence starts, “As discussed later in this guide, senior management will delegate to the RSO sufficient authority....” Does NRC consider “senior management” to be the same as “executive management”? Where is the discussion in this guide of senior management’s responsibilities?

Page 8-21, Figure 8.5 – This figure is labeled as “Security-Related Information”, but a disclaimer statement is also listed. Should applicants only use this labeling for byproduct materials subject to Increased Controls? Will applicants be able to consider information on their facilities and procedures as privileged and confidential under 10 CFR 2.390(a)(4)?

We believe that NRC needs to have information on the facilities involved in the production and use of accelerator-produced radioactive materials, but we would prefer not to provide this detailed information in a public forum.

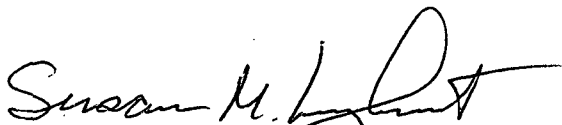
Page 8-29, First bullet after Table 8.2 – Not all activities produced in an accelerator will be measured, but instead may be estimated by calculation or by dose rate measurements. We recommend the statement end with "... and activity date of the byproduct material".

Please contact the following individuals if you have any questions or concerns on the comments we have submitted on behalf of Washington University in St. Louis:

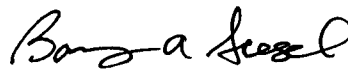
Susan M. Langhorst at (314) 362-2988 or langhors@msnotes.wustl.edu
Sally J. Schwarz at (314) 362-8426 or schwarzs@wustl.edu

Thank you for your consideration of our comments, suggestions and questions.

Sincerely,



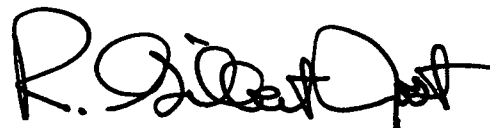
Susan M. Langhorst, Ph.D., CHP
Radiation Safety Officer



Barry A. Siegel, M.D.
Professor of Radiology and Medicine
Director, Division of Nuclear Medicine
Chair, Radiation Safety Committee
Chair, Radioactive Drug Research Committee



Sally J. Schwarz, R.Ph., M.S., BCNP
Associate Professor of Radiology
PET Production Radiopharmacist
Authorized Nuclear Pharmacist



R. Gilbert Jost, M.D.
Professor and Chair, Department of Radiology
Director, Mallinckrodt Institute of Radiology