Washington University in St. Louis

(30)

Environmental Health & Safety **Radiation Safety Office**

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

September 8, 2006

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTN: Rulemaking and Adjudications Staff

SUBJECT: 10 CFR Part 20, 30, 31 et al. Requirements for Expanded Definition of Byproduct Material; Proposed Rule (RIN 3150–AH84)

Dear Rulemaking and Adjudications Staff,

On behalf of Washington University in St. Louis, Dr. Susan M. Langhorst, Ms. Sally J. Schwarz, Dr. Barry A. Siegel, and Dr. J. Gilbert Jost respectively submit these comments on the Nuclear Regulatory Commission proposed rule concerning requirements for expanded definition of byproduct material (71 FR 42952, July 28, 2006). 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.

Particle Accelerators Operated to Only Produce Particle Beams

We agree with NRC's decision to exclude from the new definition of byproduct material incidental radioactive material produced by accelerators that are operated to produce only particle beams. Only small amounts of these incidental radioactive materials are produced in the process and are typically of short half life. **In response to NRC's request for comment in Section II.G.(2), Washington University and the affiliated organizations in the Washington University Medical Center do not operate any particle accelerator for the purpose of producing radioactive materials and producing particle beams for other uses.**

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Exemptions Regarding Broad Scope Type A Licenses

We agree with NRC including the addition or relocation of a PET production area or radionuclide delivery line from a PET production area as exemptions not requiring license amendment or NRC notification as allowed for Broad Scope Type A Licenses under 10 CFR 35.15. This allowance is consistent with the level of decision making authority NRC has historically granted under this list of exemptions.

Grandfathering of Individuals

We agree with NRC's decision to "grandfather" individuals who have used only NARM byproduct materials for medical use as authorized users, Radiation Safety Officers, authorized nuclear pharmacists and authorized medical physicists. We also agree with NRC's conclusion that individuals already authorized to use byproduct materials in 10 CFR Part 35 are also authorized to use the newly added byproduct materials for medical use.

NRC's conclusion is based on the following statement:

> "The radiation safety knowledge needed to safely use the newly added byproduct material radionuclides for medical uses is similar to that for the existing byproduct radionuclides used in medicine."

Based on NRC's statement and conclusion, we believe that the "grandfathered" individuals should also be authorized to use byproduct materials already in 10 CFR Part 35. It may not be clear that NRC shares this conclusion when reading the proposed language for 10 CFR 35.57(a)(3) and (b)(3). **Therefore, we request that NRC provide clearer statements on the extent of these "grandfathered" authorizations.**

Derived Air Concentration Values for Oxygen-15 and Nitrogen-13

In response to NRC's request for comment in Section II.G.(4), we request that NRC include specific entries for O-15 and N-13 in 10 CFR 20 Appendix B.

License Application and Annual Fees

In response to NRC's request for comment in Section II.G.(7), we do not agree that there is need to establish the new fee category, 3.S., for the production of accelerator-produced radioactive materials. We believe the existing fee categories, 3.A., 3.B., 3.C., 7.B. and 7.C. can cover these production activities. The possession, use, processing, manufacturing, distribution and redistribution of accelerator-produced byproduct material are similar to that of the existing byproduct material covered by these existing fee categories. The conclusion of using these existing fee categories is consistent with NRC's conclusion regarding the "grandfathering" of medical uses. The choice of existing fee categories should be based on the type of particle accelerator used, and on the types and quantities of radioactive materials being produced. We also believe that NRC's establishment of the new fee category, 3.S., is not consistent with NRC's

attempt to minimize impact on the noncommercial distribution of PET radionuclides, drugs, and biologics.

Commercial vs. Non-Commercial Distribution and Consortiums

In the stated effort to minimize impact on the noncommercial distribution of PET radionuclides, drugs, and biologics, NRC proposes to grant an authorization for the noncommercial transfer of these materials from a medical use licensee to other medical use licensees within a "consortium". We find it difficult to comment on this plan. NRC's definitions of commercial distribution and noncommercial distribution are not clear. NRC's discussion of consortiums appears to only address the medical use of NARM, but does not recognize the need for similar consortiums allowing the noncommercial distribution of NARM in support of research and development.

Washington University and the Mallinckrodt Institute of Radiology have a long history of leadership in the research and development of uses of PET radionuclides, drugs, and biologics. We are currently being funded by the National Institutes of Health (NIH) to research non-standard PET radionuclides (Cu-64, Br-76, Y-86 and I-124) and make the results of that research available to the research community and beyond. Washington University has licensed the patented technology arising from this research to a private company for commercial marketing and distribution in order to further its transition to practical applications for the public good. Given our unique cyclotron facilities and knowledge of the patented methods, we are manufacturing the non-standard radionuclides for our patent licensee for a limited time until suitable alternative accelerator production facilities can be found. This model of transition follows the NRC's definition of "research and development". NRC has approved similar models for developing use of non-standard radionuclides produced at university production facilities and for supplying radionuclides that are not otherwise readily available in the U.S. from commercial production facilities

We request that NRC expand its new regulatory framework also to include authorization for licensees producing PET radionuclides, drugs, and biologics to allow noncommercial transfer to any licensee approved for research and development uses of these materials. We also request that NRC provide specific guidance on what is considered commercial transfer and noncommercial transfer well in advance of requiring submittal of license applications and amendments approving the production of accelerator-produced radionuclides.

Washington University has two cyclotron facilities. One facility is registered with the State of Missouri as a nuclear pharmacy. In this facility we prepare radiopharmaceuticals for routine medical use, as well as for research use. Our second cyclotron facility is not registered as a nuclear pharmacy with the State of Missouri. Instead, human use radiopharmaceuticals prepared in this facility are used in research protocols approved by the Washington University Radioactive Drug Research Committee (RDRC), which operates as an arm of the FDA in accordance with 21 CFR 361.1. Additionally, a few PET drugs prepared at this facility are used in research under the aegis of Investigational New Drug exemptions (INDs) filed with FDA. Accordingly, we consider this

facility "registered" with the FDA. **We request that the NRC clarify its position regarding facilities that prepare PET drugs for use in research under IND or with RDRC approval.**

Decommissioning Issues

The decommissioning of particle accelerators and facilities can range from the return of a simple self-shielded cyclotron unit to the unit's manufacturer to the major clean up of an older and more complex cyclotron used to produce radioactive materials in a 30 year old or older facility. Decommissioning costs will be significantly impacted by the time frame allowed for decommissioning. Under the current 10 CFR 30.36 regulations, completion of decommissioning for an accelerator production facility could be required in as little as 48 months following cessation of operation. However under 10 CFR 50.82, decommissioning of a power reactor is required to be completed within 60 years following cessation of operation. **We request that NRC modify its regulations in 10 CFR 30.36 to allow a longer time frame of at least 10 years for completion of decommissioning for accelerator production facilities.**

Implementation and Transition Plan

NRC granted waivers to allow States to continue their regulatory programs over activities involving NARM while NRC established its regulatory authority for use of these materials. Our understanding is that NRC plans to terminate these waivers in a yet to be disclosed step by step plan for States and/or for specific users. Based on review of the proposed rulemaking, we do not believe the proposed rules have been structured to allow transfer of PET radionuclides, drugs, and biologics to an NRC licensee from an accelerator-production facility that has not yet had the NRC waiver terminated.

Development of NRC guidance for licensing the production of accelerator-produced radioactive materials and requesting authorization for noncommercial transfer of these materials is expected to be complex and will require individuals responsible for accelerator production facilities in NRC-regulated States significant time for review and comment. Accelerator-production facilities designed and built to meet less restrictive State regulations may require significant time to be modified to meet NRC regulations and older facilities may require special approvals from NRC such as the authorization granted under 10 CFR 20.1301(d).

Based on these considerations, we request that the NRC allow as much time as possible for users to prepare for this significant regulatory change and not chance the supply disruption of PET radionuclides, drugs, and biologics. Therefore, we request that NRC terminate all waivers at the same time and effective August 7, 2009.

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

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Thank you for your consideration of these comments.

Sincerely,

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