Washington University in St. Louis

Environmental Health & Safety **Radiation Safety Office**

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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SUBJECT: Draft Guidance NUREG-1556, Volume 9, Rev. 2: "Consolidated Guidance About Materials Licenses Program-Specific Guidance About Medical Use Licenses"

Dear Rulemakings, Directives, and Editing Branch Chief:

On behalf of Washington University in St. Louis (WU), Dr. Susan M. Langhorst, Ms. Sally Schwarz, Dr. Barry A. Siegel, and Dr. R. Gilbert Jost respectfully submit these comments on the Nuclear Regulatory Commission draft guidance, NUREG-1556, Volume 9, Rev. 2 (72 FR 42442, August 2, 2007).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 of all byproduct materials for medical use.

Sealed Source Registry for New Byproduct Materials

NRC's guidance is inconsistent in this draft on how a licensee should add a Ra-226 or NARM sealed source or device to their NRC license when that source or device does not have SSDR certificates. We consider the following statements to be reasonable guidance:

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SUNSI Review Complete

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Page 8-11: "Applicants requesting authorization for the medical use of a discrete source of Ra-226 (which includes a sealed source of Ra-226) or other NARM sources or devices containing NARM sources that do not have the information described above, or the information required in 10 CFR 30.32(g)(3) (e.g., manufacturer and model number from a SSDR certificate) should consult with the appropriate NRC Regional Office to discuss the contents of their application."

Page 8-12: "Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that NRC can verify that they have been evaluated in an SSDR certificate or specifically approved on a license."

We also feel that the following statements are inconsistent with the previous two statements, confusing, and may result in NRC receiving many requests to register the same source or device:

Page 8-13: "If the sealed source or device that has not been reviewed contains NARM material and was produced before the effective date of the rule, TBD, the information required by 10 CFR 32.210 may not be available. If this is the case, the applicant must provide the information required in 10 CFR 30.32(g)(3)."

Page 8-76: "***Note:*** There may be sources and devices containing the newly defined byproduct material that do not have SSDR certificates. If these legacy sources or devices have manufacturers' recommendations or instructions, they should be followed. If not, contact the appropriate NRC Regional Office for licensing guidance."

Comment & Recommendation (repeated from WU comment letter for Vol. 13, Rev. 1, dated August 1, 2007) – The information NRC requests may not be readily available to the applicant if they purchased the source from someone else. If NRC asks for this information from every applicant possessing the sealed source, then it appears that NRC will be receiving multiple requests to do a safety evaluation for the same sealed source model. We **recommend** that NRC work directly with the sealed source manufacturers to begin conducting safety evaluations and issuing SSDR certificates. Guidance for applicants who only possess these sealed sources should be to provide NRC with the manufacturer name, source model number and general physical description, e.g., Ge-68 rod source 1/4" diameter & 8" long.

Section 8.42 "Sealed Source Inventory" (**Page 8-80**) was not updated in this draft guidance, but we **recommend** that NRC update this section in Rev. 2 to reflect the guidance needed by medical use licensees to meet the new National Source Tracking regulations (71 FR 65686, November 8, 2006).

Broad Scope Type A Medical License also Incorporating a License for Radioactive Material Produced Using an Accelerator

With regard to production of new byproduct material, we repeat the following questions:

Question (repeated from WU comment letter for Vol. 21, dated July 3, 2007) – 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?

Question (repeated from WU comment letter for Vol. 13, Rev. 1, dated August 1, 2007) – What guidance does NRC give license applicants for 10 CFR 32.72 distribution of radionuclides that may contain other radionuclide contaminants? Should not guidance on how to describe these potential contaminants be included in this document? Examples of these types of radiopharmaceuticals that are widely used include:

Sm-153 Quadramet which can include Eu-154 and Eu-155

Tl-201 Thallous Chloride which can include Tl-200, Tl-202 and Pb-203

In-111 Indium Chloride which can include In-114m and Zn-65

10 CFR 35 Training and Experience Requirements

With regard to "grandfathering" individuals, we repeat our recommendations made in WU comment letter for Vol. 13, Rev. 1, dated August 1, 2007.

Recommendation 1 – As NRC is preparing to "grandfather" individuals who have used accelerator-produced radionuclides to be an ANP (or an AU, AMP or RSO), there is an opportunity to bring the training and experience criteria for ANPs (AUs, AMPs and RSOs) more in line with the preceptor definition. We agree that a preceptor statement from a current ANP is appropriate for those individuals seeking to become an ANP by the alternative pathway. WU strongly **recommends** that the NRC Staff and, in particular, the Nuclear Regulatory Commissioners reconsider the need for an ANP preceptor statement for those individuals who are board-certified by an NRC-recognized specialty board. Each of the specialty boards recognized by the NRC have proven to the NRC that their board-eligible candidates meet the training and experience requirements for the type(s) of medical use for which they are recognized. In order to sit for a board exam, an individual requires the recommendation of a sponsor who verifies the individual has met all of the requirements to become board-certified. While this sponsor may not be an ANP, the sponsor is responsible to the board for recommending only individuals who meet the board's, and therefore the NRC's, requirements. Successful completion of the board exam by the individual gives further verification of the individual's training and experience. WU believes the current regulations imposing the additional requirement of an ANP preceptor statement is an unnecessary redundancy that has greatly complicated the process of approving an individual as an ANP, and has led to the trivialization of long-established radiopharmacy board-certification.

Recommendation 2 – We appreciate that NRC has taken care to ensure the continuing access of PET imaging techniques by allowing the "grandfathering" of individuals who have used accelerator-produced radionuclides to become ANPs (or AUs, AMPs or RSOs). We believe that NRC also "grandfathering" individuals who have received board-certification prior to NRC's recognition of a specialty board would be in line with the grandfathering for medical use of the new byproduct materials. In certain cases, such as those individuals who have been board certified by the American Board of Health Physics (ABHP) prior to January 1, 2005 and never named as RSO on a NRC or Agreement State license, an individual could not currently be named as an RSO based on their board-certification even though the ABHP made no changes in its certification process to receive NRC-recognition. WU also strongly **recommends** that NRC allow grandfathering of all individuals who were board-certified prior to NRC-recognition for any specialty boards which receive NRC-recognition prior to the required implementation date, August 9, 2009, for the new byproduct definition.

As stated in this draft guidance, NRC is committed to risk-informed, performance-based regulation, guidance, inspection and enforcement. We believe the latest revision of NRC 313A forms documenting training and experience, plus the preceptor statement, indicate that NRC is moving towards prescriptive "requirements" in the name of "guidance" which has the effect of impeding individuals from being approved as an RSO, an authorized user, an authorized nuclear, pharmacists, or an authorized medical physicist. We also see further indication of NRC's tendency to "regulate via guidance" as it appears in the recent NRC guidance on licensing the Leksell Gamma Knife® Perfexion™ (guidance document not dated, but medical generic communications sent notice of availability on August 8, 2007). This new gamma knife guidance states that this new device must be licensed under 35.1000 rather than 35.600, but does not justify why the existing 35.600 regulations do not adequately cover the radiation safety considerations for the new gamma knife device. We agree that specific training for a new gamma knife device that has expanded treatment capabilities is required, but we do not agree this change in device capability warrants a change in the type of medical use. By telling licensees to consider the use of this new gamma knife device as 35.1000, NRC will be imposing unnecessary training and experience documentation of individuals who are currently approved for another gamma knife, and vice versa.

Recommendation – We ask that NRC evaluate the current NRC 313A forms, and the current guidance on licensing the Leksell Gamma Knife® Perfexion™, with regard to NRC's policy promoting risk-informed, performance-based regulation, guidance, inspection and enforcement. We note that NRC did not ask for public comment on these documents, nor has NRC taken full advantage of the expert review that NRC's Advisory Committee on the Medical Use of Isotopes could provide NRC if given the time to really partner with the NRC Staff in developing these documents. We are concerned that NRC is moving away from these valuable review processes. As medical use of PET and other accelerator-produced radionuclides come under NRC authority, the problems we are experiencing with training and experience documentation, and with NRC issuing minimally reviewed prescriptive guidance, will be compounded.

Comments, Suggestions and Questions on Specific Items in NUREG-1556, Vol. 9, Rev. 2 Draft

Page 3-1 – Definition of "Management" should be similar to that found in Vol. 11 (Broad Scope). We suggest it should be the same for all NUREG 1556 volumes, and thus be modified to read:

> "'Management' refers to the processes for conduct and control of a Radiation Safety Program and to the individuals who are responsible for those processes and have *authority to provide necessary resources* to ensure safety and to achieve regulatory compliance."

Page 8-8 – The word, cyclotron, is misspelled in the footnote.

Page 8-40 – We suggest that the references should be updated: replace NCRP Report 49 with NCRP Report 147; replace NCRP Report 102 with NCRP Report 151; and add NCRP Report 144 "Radiation Protection for Particle Accelerator Facilities" to the list.

Appendix B – Will this appendix have the current NRC 313A forms in the final version, or will you just point to the NRC website for the current forms?

Appendix AA – This appendix appears to be the same kind of guidance as in NUREG 1556 Vol. 21 draft Appendix P, but is not word for word the same. Will these two appendices be made identical in the final publications of these two NUREG 1556 volumes?

NUREG 1556 Update and Review

In reviewing the draft of Volume 21 and updates for Volumes 13 and 9 of the NUREG 1556 guidance documents, we noted that only NRC Staff plus one former state regulator were involved in the drafting of these documents. We appreciate that the NRC Staff have been under a tight time schedule to provide these much needed guidance documents in advance of the final rule being published. We have also faced this time pressure in being allowed only 30 days to review and comment on these guidance documents. Because of the limited involvement by people who have safely produced and worked with cyclotron-produced radioactive materials for many years, we hope that the NRC Staff accepts the recommendations made by this community. In the May 14, 2007 NRC memo announcing that the Commission had approved implementation of the final rule, they made this recommendation:

> "The staff should conduct a review of the effectiveness of this rulemaking after it has gained some experience with implementing the new regulations. This review should occur no sooner than 18 months after the effective date of the rule and include recommendations for studies or rule changes that may be needed to more effectively implement the EPAct."

We support and suggest that the NRC more fully include the newly regulated community in this effort.

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:

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

Sincerely,

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