From: "Ralph Lieto" <LietoR@trinity-health.org>
To: <SchwarzS@mir.wustl.edu>, <LWC1@nrc.gov>
Date: Fri, Feb 3, 2006 9:51 AM
Subject: Re: ACMUI Comments Due Date on the Draft Proposed Rule on NARM

Lydia,
I should have caught this the first time, but there were a few typos & the numbering of items that I corrected in the attached. I think they were missed in rush to meet our deadline.
Sorry for any inconvenience.

Ralph

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>>> <SchwarzS@mir.wustl.edu> 2/3/2006 9:39 AM >>>
Lydia,

I had made a correction to the original submission, which I had forgotten
to save. Ralph Leito mentioned that I had emailed the uncorrected document. I am now sending the Revised ACMUI summary.

(See attached file: Revised ACMUI Summary NARM 2-3-06.doc)

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Advisory Committee on Medical Use of Isotopes

Response to Predecisional Information on

Nuclear Regulatory Commission

10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, and 150

RIN: 3150-AH84

Requirements for Expanded Definition of Byproduct Material

Charge to the ACMUI

On January 5, 2006, Mohammad Saba, NMSS, sent a request to ACMUI members stating:

The attached draft proposed rule on Naturally Occurring and Accelerator-Produced Radioactive Material (NARM) is being provided for the ACMUI review and comment requested by January 31, 2006. This rulemaking contains revisions to Part 35 and will impact the medical licensees that possess NARM.

He has now allowed the final response to be delivered at the latest the morning of 2/3/06. He requested that comments be sent to Sally Schwarz, R.Ph., M.S., who volunteered to provide the ACMUI summary of comments by February 3, 2006. Five ACMUI members, Richard Vetter, David Diamond, William Van Decker, Ralph Lieto and Sally Schwarz, have provided comments which are summarized below.

Summary Comments:

1. The Commission plans to allow continued medical use of NARM until they codify new regulations. It is critical that the regulatory burden does not limit access to good patient care by adding excessive cost or by limiting qualified individuals from practicing the full extent of their field in a variety of patient care venues.

2. The NRC has involved the OAS and CRCPD in development of these draft rules. It is very important that the final rules incorporate the positions of these two organizations to the extent possible. On the other hand, it is important that the final rules of NRC and Agreement States be as compatible as possible. It seems some of the proposed levels of compatibility are low (Level D = Level H & S applies to most changes in Part 35, definition of cyclotron, and activities requiring license.) Unless there is a high level of compatibility there will be a wide variation among agreement states which is the essence of the complaint raised by the CORAR group at the round table discussion.

3. "The NRC does not propose to regulate the incidental radioactive material produced by accelerators that are operated to produce only particle beams and not radioactive materials for...use for a commercial, medical or research activity." This is a very important provision (particularly accelerators used in Clinical Radiation Oncology) that prevents this rule from becoming burdensome.

Strongly support the NRC grouping of accelerators into three classes and intention to regulate only accelerators that are intentionally operated to produce a radioactive material for its radioactive properties. However, a question or concern may be raised by the public as to level of hazard from radionuclides produced incidental to the particle beam being used for commercial, medical, research, or other uses. Will this fall to the States as NARM did for non-Agreement States before the EP Act? Will this be considered, or develop into, an "orphan" radiation source? Can it be classified as a trivial ("de minimus") source from a regulatory concern?

4. Discrete Sources: Recommend a stronger regulatory strategy than General Licensing for discrete radium sources. Because it is not specified in the document, an assumption is that this spectrum of old sources can range from household items to milligram "sealed" sources. ACMUI would discourage an exemption strategy over a broad range of radium sources. One suggestion for NRD would be to approach the Health Physics Society to address this issue to provide scientific input on the radiation risks from the radium sources of interest.

5. Radioactive Waste: All changes made for disposal of NARM appear to deal with regulatory definitions and have little impact on changing how we dispose of these materials. It is not clear what impacts these changes will have on radioactive waste disposal licensees, brokers, and disposal costs.

6. Decommissioning Costs: The NRC is proposing changes in the rules for financial assurance for decommissioning. They are exempting short lived used in medicine, but radionuclides with a half-life of more than 120 days, which are present in sufficient quantities to cause a public health and safety concern, need to be addressed for the purposes of establishing adequate financial assurances for decommissioning. These regulatory changes will likely require us to include decommissioning costs in our NRC decommissioning funding plan, and will have to meet NRC facility decommissioning requirements and documentation. This has the potential for increased burden for licensees, and potentially could affect the availability of PET radiopharmaceuticals.

7. Availability of radioactive drugs: The EP Act requires NRC to consider the impact of its regulations on availability of all NARM, including PET and traditional cyclotron produced isotopes such as Tl-201 and I-123. As recently demonstrated by the Mallinckrodt generator issue, it doesn't take much to disrupt supply. The NRC believes that their proposed framework will minimize the impact of its regulations on availability of radioactive drugs, but ACMUI suggests they should specifically request comments on the impact of these proposed regulations on availability of radioactive drugs. For example, when the cyclotron at a medical facility suddenly fails, the medical facility

should be able to obtain F-18 (and potentially other PET radionuclides/radiopharmaceuticals) on an emergency basis from another facility whether gratis or purchased (i.e. not from a commercial operation, but from another non-commercial facility on an emergency basis). In other words, a medical facility should be permitted to sell F-18 on an emergency and temporary basis to help out another medical facility, i.e. to provide the F-18 that is necessary for patient-care.

8. Use of NARM, Including PET, Materials and Drugs: When NRC refers to "PET radionuclides", is this limited to medical or human use imaging uses, or does it also extend to any handling of cyclotron-produced radionuclides used in research and development? If the proposed regulations include research and development, there will be impact on broad scope license authorization and inspection of end uses of NARM (including PET) materials used in medical use and human research. Significant impact is expected in production and delivery of NARM (including PET) materials and drugs, and in the RDRC review and approval of PET drug production and use in humans. Additional significant impact is expected from increased inspection scrutiny by NRC of all of these activities.

9. Incidentally activated radioactive material:

> "The NRC proposes to regulate the radioactive material produced by all accelerators that are intentionally operated to produce a radioactive material for its radioactive properties." "... the NRC proposes to regulate both the radionuclides produced in these accelerators as well as the incidentally activated radioactive material."

These statements make clear that NRC regulations will start at any radioactive material produced, whether intentionally or incidentally. What will be NRC's expectation on ability to specifically identify and quantify the amounts of radioactive materials produced, in particular for incidentally produced radionuclides? This will also directly relate to waste disposal and decommissioning issues.

10. Qualification of person maintaining or operating a particle accelerator: Since the NRC says that it does not propose to adopt any rule regarding the operation of a particle accelerator, or the qualification of any person maintaining or operating a particle accelerator." What is meant by the "...individuals with training and experience in the production of PET radionuclides ...such that the requirements in 10 CFR 30.33 (a)(3) are met...Individuals such as radiochemists, physicists, engineers and others...will be recognized as authorized users...and will...be evaluated on a case-by case basis."? What criterion will be used for qualification?

> "To ensure availability of PET drugs from commercial nuclear pharmacies that are not registered with the FDA or a State as a PET cyclotron facility, these pharmacies will be authorized for PET radionuclide production if there are individuals with training and experience in the production of PET radionuclides, i.e., the processed from insertion of targets in the accelerator/cyclotron beam to

> radiochemical isolation, purification, and testing, such that the requirements in 10 CFR 30.33(a)(3) are met. Individuals, such as radiochemists, physicists, engineers, and others with appropriate training and experience, will be recognized as authorized users under the pharmacy's 10 CFR Part 30 authorization for the production of PET radionuclides and other radionuclides using cyclotrons and other types of accelerators. This training and experience will be evaluated by the NRC through reviewing and processing of a license application on a case-by-case basis."

While these statements refer to "commercial nuclear pharmacies that are not registered", it lays the groundwork of what NRC will be regulating and inspecting with regard to individuals working in broad scope on-site cyclotron facilities. Will this NRC review be limited to only "commercial nuclear pharmacies that are not registered" as stated?

11. Distribution of Cyclotron-Produced Radionuclides:

> "... if the medical use facility does not intend to commercially distribute the PET radionuclides, drugs, or biologics, but intends to transfer them to other medical facilities in its consortium, a medical distribution license is not needed, but an authorization for the noncommercial transfer of the radionuclides, drugs, and biologics to other medical use licensees is needed. With minor revisions to 10 CFR Part 35, the consortium medical use facilities would be authorized by regulation to receive theses PET drugs."

What are the definitions for "noncommercial distribution" and "consortium"? What will be needed to obtain authorization for noncommercial or consortium distribution? NRC's draft document has no discussion of licensing requirements for distribution of NARM (including PET) for research and development purposes, such as distribution of PET radionuclides to other institutions for research licensees/registrations. It is not clear if a specific NRC license (plus license fee) would be needed for this kind of radionuclide distribution.

How does this apply to distribution of cyclotron-produced radionuclides used in research and development, rather than medical use or human research? Can these radionuclides be distributed to non-medical use licensees?

12. Definitions are needed: What does "PET cyclotron facility" mean? What does a FDA registration as a "PET cyclotron facility" mean? What is a "direct output port"? Does it include pneumatic-tube transfer lines and or radioactive gas-line delivery system? Is the cyclotron "port" a radionuclide delivery line from the cyclotron.

It was sometimes confusing in reading this document because the term "medical accelerators" meant medical production accelerator (e.g., PET). However, in the radiological community, this is generally considered to mean a radiation therapy linac. The NRC is encouraged to use the term "production accelerator" as the category of accelerator, whether medical or industrial, that they intend to regulate.

13. Part 35 Issues: Many sections of the document discuss "grandfathering" individuals using NARM currently. Does this imply new regulatory standards beyond current industry standards for users/producers in the future? It is anticipated that the radiation safety knowledge required for PET radionuclides and radiopharmaceuticals is similar to traditional gamma radionuclides and radioharmaceuticals, and training requirements will not need to be altered. Additionally it is anticipated that ALARA programs will be able to use flexible rule guidance to maintain radiation safety under EP Act.

14. Implementation Period: The NRC should plan to issue licensing guidance at the time the Federal Register publication so licensees will have the full 6 months to develop their license and license amendment requests. The NRC should consider that it will take significant time to review all of these new license applications and amendment requests. It does seem that the NRC will need to use "enforcement discretion" after the period of the effective date. The implementation period for non-Agreement States may be problematic—one year may not be enough. Every hospital with a specific license may employ mobile PET service. These are imaging vans docked to the facility for 1 day/week. Each of these licenses will need to amend their license for the added location of use. In addition, there will be a significant increase in mobile Nuclear Medicine licensing action, which will include receipt & assay functions. This will result in a significant burden on NRC Regional licensing staff.

15. Consideration of SSRs:
There is a major omission in neglecting to update Part 20 - specifically Appendix B (DACs and ALIs) and Appendix C (Quantities of Licensed Material Requiring Labeling) - to include isotopes of NARM. This must be done. ACMUI endorses the NRC regulatory approach to treat NARM as it did reactor-produced radionuclides, which is reflected in the CRCPD SSRs.

16. Exempt Quantities:
The NRC indicates that there are only 13 radionuclides, based on the SSRs, to update the regulations for accelerator-produced radionuclides. This does not address all the accelerator-produced medical radionuclides

17. Editorial Comments:
   a. On page 12, Palladium-203 should be Palladium 103.
   b. Page 8, 3rd paragraph, last line: "my" should be "may"
   c. The abbreviation "EPAct" is confusing. It gives the impression that we are dealing with the Environmental Protection Agency. Possibly consider "EP Act" or "EP2005" or some other alternative.