POINT/COUNTERPOINT

Suggestions for topics suitable for these Point/Counterpoint debates should be addressed to the Moderator: William R. Hendee, Medical College of Wisconsin, Milwaukee: whendee@mcw.edu. Persons participating in Point/Counterpoint discussions are selected for their knowledge and communicative skill. Their positions for or against a proposition may or may not reflect their personal opinions or the positions of their employers.

NRC restrictions on the packaging of radioactive material should be expressed more explicitly than simply in terms of "activity"

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(Received 15 July 2004; accepted for publication 15 July 2004)

[DOI: 10.1118/1.1830041]

OVERVIEW

As promulgated by the Nuclear Regulatory Commission, packaging regulations for radioactive material are confusing (e.g., "activity" vs "contained" activity vs "total" activity). As a consequence, medical physicists are forced to second-guess the intent of the regulations. This dilemma is the subject of this month's Point/Counterpoint. These authors wish to remind the readers of Point/Counterpoint that the views presented here do not reflect the views of any regulatory body mentioned.

Arguing for the proposition is Michael S. Gossman, M.S. Beginning academically at Indiana University, he furthered his education by attaining a Master's Degree at the University of Louisville. Pioneering in atomic physics, he eventually published a book on scanning tunneling microscopy in 1997. Mr. Gossman attended Vanderbilt University, where he studied medical physics and worked as a health physicist. His current focus is research and planning for special procedures in the area of high dose-rate brachytherapy. Mr. Gossman is certified in therapeutic radiologic physics by the American Board of Radiology (ABR) and is a clinical medical physicist at Erlanger Medical Center in Chattanooga, TN.

Arguing against the Proposition is Beth Felinski-Semler, M.Sc. She received her B.A. in Physics from LaSalle College (University) in 1976, and her M.Sc. from Temple University in 1977. She began working in medical physics in 1977 at Cooper Hospital/University Medical Center in Camden, New Jersey, first in nuclear medicine and later in radiation therapy. She has instructed both radiation oncology residents and therapists in physics and dosimetry. She is certified in radiation therapy physics by the ABR. Beth is presently the senior clinical radiation therapy physicist at the Department of Radiation Oncology, South Jersey RMC in Vineland, New Jersey.

FOR THE PROPOSITION: Michael S. Gossman, MS, DABR

Opening Statement

There are troubling inconsistencies in the practice of transporting sealed radioactive sources in the United States. There are currently no uniform guidelines governing the proper disclosure of radioactive sources in transit. The purpose of such disclosure is to enable both receivers and response teams to properly assess situations involving damage to packages containing radioactive material. Unfortunately, physicists are left to use their own interpretations as to the method for labeling such packages and determining which values to disclose. Without specific guidelines, many ques-

 0094-2405/2005/32(1)/1/0/$22.00

tions remain unanswered. Notably, which activity level should be used for labeling packages—the apparent activity or the contained activity? In many instances there is a great disparity between the two. Currently, a survey including twenty brachytherapy source manufacturers revealed half are labeling according to the apparent activity rather than the contained activity.[1] My discussions with some of our collegial society members on how they transport radioactive materials validate the breadth of the problem.

Consider, for example, the inconsistencies in the shipment of prostate seeds. The (contained activity to apparent activity) conversion factors for all prostate seed manufacturers range from 1.30 to 1.78 for iodine-125 and from 1.80 to 2.20 for palladium-103. Depending on which activity the physicist chooses for labeling, the value could differ from what another might label by as much as 78% for iodine-125 and 220% for palladium-103. There is a potential for a source encapsulation to break open and leave a bare source with a higher exposure rate than that which would occur if the encapsulation did not break. Currently, response personnel are not equipped with enough information to know the worst-case scenario when radioactive materials are damaged. This deficit could have devastating results.

Clearly we need uniformity to ensure all avenues of safety. Regulations governing the shipment of radioactive material, however, do not specifically address this troubling issue. No guidance regarding proper labeling criteria is available from the Nuclear Regulatory Commission, the U.S. Department of Transportation, the U.S. Department of Energy, the International Atomic Energy Agency or the International Air Transport Association.[2–5] Explicit guidelines need to be promulgated and followed to govern the process for labeling radioactive material. To do so, the conversion factors for apparent to contained activity need to be determined and published for all sealed sources. Using this information, a guideline should be produced by the Nuclear Regulatory Commission to indicate what the explicit labeling standard will be. Furthermore, it should be uniformly recognized by the other supervisory agencies and departments.

Rebuttal

Modern treatment planning systems use air-kerma strength and other appropriate factors inclusive of apparent activity for source specification.[6,7] For older models, source specifications come from the activity and gamma factor stated by the vendor. As my worthy antagonist affirms, some vendors maintain they do not indicate whether the activity is "contained" or "apparent," and some do not even provide the conversion factor.

The FDA requires that manufacturers of radiological devices specify how the source encapsulation (and substrate) influences the output.[8] The physical quantity of activity is also to be listed as "apparent" or "contained."[8] These data were not required for sources made long ago. Still, conversion factors can be determined experimentally. The method has been published, and results were provided for sources currently used in intravascular brachytherapy treatments.[9,10] The method involves assaying the output of the encapsulated source and then assaying the material again when the encasement has been chemically digested with an acid.

Guidelines from no regulatory body specify to label radioactive material shipments according to apparent or contained activity. This implicit wording is nothing short of permission to do either. It is my suggestion to have regulations explicitly state "apparent activity" when the activity rating in shipments is used. Furthermore, it is my suggestion that the shipper make the conversion factor for that source model readily available by presenting it in the clear pouch external to the package.

To attain uniformity, the NRC should first require manufacturers to provide the conversion factor for each source model. This information should be available, since it was originally requested by the FDA for medical use approval. For sources that are no longer available, documentation may be obtained from the FDA or in the files of the applicable former manufacturer. If factors are not available, they can be identified using the method discussed previously. Moreover, the factors must be made available before these proposed regulation changes are introduced.

I agree that such a change in shipping regulations will affect the wording in other regulations. It will affect and should affect regulations like those from the IATA internationally. Regardless of the inconvenience associated with change, we need to endorse strictness and uniformity. Only by establishing a standardized method for classifying and monitoring radioactive material, can we appropriately account for what is transported.

AGAINST THE PROPOSITION: Beth Felinski-Semler, MSc, DABR

Opening Statement

In the field of medical physics, definition and consistency of procedures have always been important. These are the foundation for our field today. We improve and make things better and clearer, but are always able to trace back to the foundation. We now have an inconsistency in the shipping and receiving of brachytherapy "sealed sources." The confusion occurs because of the specification of source strength. Source strength has been defined in one of four ways: the contained activity, the apparent activity, the equivalent mass of radium, and the exposure rate at a specified distance.[11] Three of these methods depend on the inherent filtration associated with source construction. It is this filtration that gives rise to the term "apparent activity" for clinical use, because the apparent activity is less than the contained (actual) activity due to source filtration. The exposure to persons handling the sources, and the dose to the patient, are not dependent on the actual (contained) isotope activity, but instead on the "filtered" activity outside of the source walls. Hence the problem: which activity, apparent or contained, should be used when describing sealed sources in transit.

The NRC (Part 20 appendix A) establishes activity levels and their shipping requirements for specific sources. In Part 71 the NRC defines and establishes shipping container re-

quirements. Then the DOT and IAEA take over and establish labeling requirements based on the exposure level at the surface of the package and at one (1) meter. The purpose of all these regulations is to set universally known safety standards. Are any of these regulations affected if the apparent activity or the contained activity is used, even if in some cases such as palladium-103 the difference could be as much as 200%? I think not. The difference in activity only comes into consideration if a source is ruptured in some type of accident. In this situation, one would hope the outer shipping container that the sources are housed in will still be adequate to contain the activity at the required level. If contamination is the concern, first and foremost to the emergency response personnel is the qualitative knowledge of what the exposure rate in the area is, then what the specific isotope is, what type of radiation is involved, and what the physical form is. What the labeled activity states is not the primary concern in this situation.

So, should the use of apparent or actual activity be causing so much concern? No! Is there a problem with not establishing which of the two should be used? Yes! As stated previously, consistency has always been a mainstay for our field. Therefore the answer is simple: we should use apparent activity. The source has inherent filtration which is an intrinsic part of the source itself. The filtration is not removed when the source is used clinically. All clinical documentation, such as the written directive, describes the source in terms of apparent activity. All computational systems use apparent activity.

In closing I have one last thought. If it were to be decided that contained activity should be the standard for shipping, then it will be necessary to alter the departmental paperwork to state this activity. Who will supply the factors to convert all of the available sources? What about long-term existing sources whose manufacturer no longer exists? I have called several of the companies who supply seed sources. Several of them do not supply this information.

Rebuttal

I agree with my colleague's desire for uniformity, as evidenced in my opening statement—definition and consistency are a foundation for our field. But I do not believe that if actual activity is not used, we are putting ourselves and emergency response personnel at risk. Have there been hospital incidents where seeds have ruptured? Yes, mostly due to errors in judgment. With proper handling, these incidents would not create dangerous exposure levels. "Time, distance, shielding and containment" are the keys to radiation safety. Policies and procedures are in place in all institutions using radioactive material; we just have to read them!

What about the public arena? There are policies and procedures there also. The federal government and individual states have emergency response policies, a section of which covers radiation emergencies. In my home state of New Jersey, the state[12] has a radiation response team under the jurisdiction of the State Police. There are two levels of response: an awareness group and the HAZMAT technicians. The awareness group is the first responder to a site. They know how to evaluate and recognize a hazardous situation, and they have responsibility for defensive measures—the protection of life and property including evacuation of an area and its security when called for. They also are responsible for notifying the HAZMAT team when warranted. HAZMAT is responsible for measuring, containing, and removing dangerous materials. In case of an accident involving radioactivity, the exposure level at the site is the controlling factor.

My knowledgeable opponent states that if actual activity is to be used, the conversion factors from apparent to actual activity need to be supplied. We are of like minds here: I just posed the question "Who" should supply the information. This is no trivial matter. The easy answer would be the NRC. They have written the guidelines for activity levels and shipping requirements, and they license the manufacturing of sources and their use in institutions. But this is true only for reactor-made products. What about accelerator-produced isotopes? For these materials the States are in control. In addition we must not leave out the DOT. This agency has definitions and areas of control of their own, which may agree with the NRC and States, but are not limited by them. These are only three of the multiple groups who are responsible for defining activity. All of these groups will have to be involved. So perhaps my simple question "Who should supply the information we need?" should be rephrased to, "When will this issue be resolved?"

I agree that a guideline is needed for all to follow, when describing the activity of a sealed source. We simply cannot continue to use both actual and apparent activity. I doubt that much will happen soon. In the meantime, the use of apparent activity is the best way to proceed when dealing with sealed sources. In the event of an accident, we can put our minds at ease by knowing that the exposure level is the controlling factor in how the event is dealt with, not a number written on a slip of paper.

I wish to thank Daniel Januseske, M.S. for the information and time he shared with me during the past month.

[1]M. S. Gossman, Survey-Shipping methodology of current brachytherapy source manufacturers (2004).
[2]US Code of Federal Regulations, Title 10, Energy, Nuclear Regulatory Commission (NRC) and U.S. Department of Energy (DOE), cur. ed.
[3]US Code of Federal Regulations, Title 49, Transportation, U.S. Department of Transportation (DOT), cur. ed.
[4]International Atomic Energy Agency (IAEA), Safety Standards, Regulations for the Safe Transport of Radioactive Materials, Safety Series 6, 7, 37, and 80, cur. ed.
[5]International Air Transport Association (IATA), Dangerous Goods Regulations, 44th ed. (2003).
[6]Recommendations of the AAPM Radiation Therapy Committee Task Group No. 43, "Dosimetry of interstitial brachytherapy sources," Med. Phys. **22**, 209–234 (1995).
[7]Update of AAPM Task Group No. 43. Report, "A revised AAPM protocol for brachytherapy dose calculations," Med. Phys. **31**, 633–674 (2004).
[8]US Food and Drug Administration (US FDA), Department of Health and Human Services, Center for Devices and Radiological Health, Device Evaluation Information, *Guidance for the Submission of Premarket Notifications for Photon-Emitting Brachytherapy Sources* (2002).
[9]R. Colle, "Chemical digestion and radionuclide assay of TiNi-encapsulated 32P intravascular brachytherapy sources," Appl. Radiat. Isot. **50**, 811–833 (1999).

[10]R. Colle, "Activity characterization of pure beta-emitting brachytherapy sources," Appl. Radiat. Isot. **56**, 331–336 (2002).
[11]F. M. Khan, *The Physics of Radiation Therapy* (Williams & Wilkins, 1984).
[12]New Jersey State Emergency Response Plan, http://www.nj.gov/dep/infofinder/topics/emergency.htm (accessed 5/2004).