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General Comment

See attached file(s)

Attachments

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January 31, 2010

Ms. Cindy Bladey
Chief, Rules, Announcements and Directives Branch
Office of Administration
Mail Stop 5B01M
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Washington, DC 20555-0001

Subject: Comments on Potential Changes to Radiation Protection Regulations Considering ICRP 103 Recommendations.

Reference: Federal Register/Vol. 75, No. 186/Monday, September 27, 2010. Pages 59160-59167. Radiation Protection Regulations and Guidance; Public Meetings and Request for Comments.

These comments are being submitted by Lantheus Medical Imaging, Inc. (LMI), a major manufacturer of diagnostic nuclear medicine products, headquartered in Billerica, Massachusetts. LMI's predecessor, New England Nuclear, was founded in the 1950s and the company, under various owners, has been manufacturing nuclear medicine products and operating cyclotrons for radionuclide production since the 1970s. Our radioactive diagnostic products are used throughout the United States and abroad for nuclear cardiology studies as well as other diagnostic areas. We produce Tl-201 and Ga-67 on our cyclotrons, and we receive large quantities of Mo-99, Xe-133 and Sm-153 from outside suppliers. These radionuclides are used to manufacture radiopharmaceutical products including vial products and Tc-99m generators. We are one of only a handful of companies involved in the complex manufacture of these radioactive diagnostic drug products.

We appreciate the opportunity to provide early input to the NRC on the major issues discussed in the above referenced Recommendations. As a member of CORAR (The Council on Radionuclides and Radiopharmaceuticals), we have provided our input on the NRC's questions to CORAR and are in substantial agreement with the CORAR positions on the questions posed by the NRC.

Of particular interest to our company is Issue No. 2: Occupational Dose Limits. The current dose limit is 5 rem (50 mSv) per year. The ICRP recommends a dose limit of 10 rem (100 mSv) over 5 years, with a

maximum of 5 rem (50 mSv) in any one year. Certain countries have gone to a 2 rem (20 mSv) per year limit. The NRC is seeking input on which of the above three options to adopt.

Before we provide our specific input, we would like to provide a review of the trends in our occupational doses over the last five to ten years. Our company has made significant investments in our manufacturing facilities over the years, which have resulted in significantly improved radiation safety for our employees. Since 2002, collective dose has been reduced by over 50%, even as production has increased. Since 2005, our in-house administrative dose limits have been reduced from 3.6 rem/y for our highest dose groups, to 3.0 rem/y. These results are clear indications of our commitment to the ALARA philosophy, however there is a small group of LMI employees for whom a 2 rem/y limit would be difficult to achieve, at least for the foreseeable future. These individuals are primarily involved in the maintenance and repair of our manufacturing infrastructure. From 2006 through 2010, there have been 7, 11, 6, 9 and 6 employees of LMI who have exceeded 2 rem/y. Unlike the collective dose data, however, the trend in these figures is not as clearly downward. This variability in our highest occupational doses is due to a number of difficult to forecast factors including customer demand for key radionuclides, the work load of certain machines, and the need for major repairs or maintenance. Another unpredictable variable impacting our worker dose is the availability of an adequate Mo-99 supply from the handful of suppliers of this critical radionuclide. During the recent Mo-99 supply crisis, we observed that a shortage in the supply of Mo-99 shifted demand to Tl-201. This increased demand resulted in a corresponding increase in the workload of our cyclotron operations, and with it the worker dose involved in running, maintaining and repairing these machines.

We support the idea of harmonizing federal regulations for occupation dose limits with international regulations and recommendations to further reduce workers' exposure and simplify regulatory compliance. However, as many groups have indicated, we recognize that the NRC's existing regulatory limits are currently protective of workers and do not need to be immediately changed to provide more protection. If the NRC's occupational dose limits were changed in the near term to align with the current ICRP Publication 103: 10 rem over 5 years, with a maximum of 5 rem/y, or 2 rem/y (Options 2.b and 2.c, respectively), there would be an immediate and negative impact on our collective dose and operations, since we would have to utilize less experienced individuals to perform highly technical repair work in high dose rate environments within shielded process cells and cyclotron vaults. These individuals would take longer to accomplish the same work and, therefore, would get more dose for a given job and dramatically increase LMI's collective dose. This would also likely have a negative impact on the performance of our manufacturing facility and production capacity since the utilization of less experienced individuals is likely to result in less effective repairs and/or more frequent maintenance. For these reasons, we feel that the benefits of harmonization are outweighed by the negative effects that would result from a too-rapid drop in occupational dose limits.

It's also important to note a few of the operational issues associated with a significant drop in dose limits. For example, if dose limits are reduced to 2 rem/y, licensees will almost certainly feel compelled to adopt a more restrictive in-house limit in order to avoid exceeding the 2 rem limit. Given the high and variable

dose rates associated with working on radioactive manufacturing infrastructure, we would probably set that in-house limit at no more than 1.75 rem/y. Over the past five years, an average of 11 LMI employees per year have exceeded this 1.75 rem/y threshold.

In addition, given the small number of manufacturers of certain critical diagnostic nuclear medicines, there is the very real potential for one manufacturer to gain an advantage over another manufacturer because of differences in their manufacturing infrastructure and ability to comply with much-reduced dose limits. For example, a manufacturer with more modern external beam cyclotrons could have a significant advantage in terms of worker dose control over a manufacturer with somewhat older, internal beam cyclotrons. To upgrade these kinds of cyclotron facilities would cost tens of millions of dollars and take years to implement before providing a meaningful change in radiation protection programs. As we emerge from the recent global supply shortages of Mo-99, it would be difficult to ask manufacturers and other industry participants to absorb the increased costs and other burdens associated with these much-reduced dose limits.

Given the factors that we have discussed above, Lantheus Medical Imaging generally supports CORAR's recommendation regarding Issue No. 2: Occupational Dose Limits. Specifically, we support Option 2.a., which retains the 5 rem/y limit, but with a modification to provide a constraint on annual TED exceeding 2 rem. We feel this option both recognizes that the current dose limit is adequately protective, and also allows and encourages licensees to work toward 2 rem/y without the significant negative effects that the abrupt implementation of a hard limit of 2 rem would cause. We feel this is a reasonable and responsible approach toward harmonization with ICRP 103.

Regarding the accompanying questions associated with issue 2, we offer the following responses:

Q2-1: Are there any significant anticipated impacts in assessing and retaining dose histories for each individual in order to comply with a multi-year average? Answer: We would expect there would be non-trivial but manageable administrative burdens on licensees and dosimetry service providers to ensure compliance with a multi-year average dose limit.

Q2-2: Are there any anticipated implementation impacts expected if the dose limit is decreased? Answer: If the dose limit is decreased abruptly from 5 to 2 rem/y, or to 10 rem/5 years, there would be significant impact to our business. These impacts would likely include a significant increase in collective dose, lower productivity, higher costs, and an overall dose control program that is not optimal. Please see the main body of our letter for further details.

Q2-3: Is there any information about the actual dose distributions for industrial and medical licensees? What are the trends for this data? Are the data available to share with the NRC? Answer: We have provided a high level summary of collective dose trends and trends in dose for our high-dose workers.

Q2-4: For the medical industry, are there any potential impacts on patient care? Answer: As we described above, we believe that an abrupt drop in dose limit from 5 rem/y to 2 rem/y could result in higher costs and the increased risk of a shortage in one or more diagnostic nuclear medicine products. For example, if there is a shortage of Mo-99 or some other event which triggers a surge in demand for Tl-201, the industry might be unable to meet this increased demand if there is a limited number of qualified workers available to operate and maintain cyclotron facilities.

Again, we thank you for the opportunity to comment on this significant issue. If you have any questions, please do not hesitate to contact me.

Sincerely,

William C. Dawes, Jr.
Vice President, Manufacturing and Operations