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12

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USNRC

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Rulemakings and Adjudications Staff
U. S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Re: Comments on "Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions" (RIN 3150-AH15; Docket ID NRC-2009-0084)

Dear Sirs:

II-VI Incorporated (II-VI) currently holds Pennsylvania Department of Environmental Protection (PADEP) License No. PA-0760 for the manufacture and distribution of thorium-bearing optics and other products to persons who use them under exemptions from licensing or under a general license. As an Agreement State licensee and the largest distributor of thorium-coated optics in the country, the impacts of the provisions of the U. S. Nuclear Regulatory Commission's (USNRC's) proposed amendments to Title 10, Code of Federal Regulations, Part 40 (10 CFR 40) and Draft Implementation Guidance on our operations will be significant.^{1,2} Therefore, we respectfully submit the following comments, questions and concerns:

Comment 1: Licensee responsibility for the end use of exempted or generally-licensed items

Currently, II-VI manufactures and distributes optical lenses and mirrors exempted under the provisions of 10 CFR 40.13(c)(7). Users of these products could perform some sort of physical operation on the article (e.g., machining, heat treatment, grinding, etc.), which would appear to invalidate the 40.13(c)(7) exemption. It is not clear in the proposed rule language what our obligations are with respect to the licensing status of recipients. Would a specific licensee be in regulatory jeopardy if the end user's intent for the products is not determined before those products are delivered? We suggest the rule or the Draft Implementation Guidance be modified to clearly state the limits of licensee liability for determining end user licensing status.

Comment 2: Submitting detailed information with a distribution license application

Section 40.52(b) of the proposed rule would require us to submit to the USNRC detailed construction/design information for products distributed under 40.13(c) as part of our license application. This may not be possible because II-VI manufactures thousands of product designs that are often

¹ Proposed Rule, U. S. Nuclear Regulatory Commission, "Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions", Federal Register, Vol. 75, No. 142, July 26, 2010.

² U. S. Nuclear Regulatory Commission, "Draft Guidance for Implementation of the Proposed Rule, 'Distribution of Source Material to Exempt Persons and to General Licensees and Revisions of General License and Exemptions,' in 10 CFR Parts 30, 40, 70, 170, and 171", September 2010, Draft for Comment.

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produced on an infrequent or even a one-time basis. Furthermore, product specifications are often dictated by the customer and subject to change during the production process. Would the USNRC consider publishing additional regulatory guidance on the acceptable level of detail on product construction and design submissions with license applications? Would the USNRC consider generic information about products in general, rather than model-specific, to be acceptable as a means of avoiding multiple license amendments to accommodate one-time or limited edition designs and in-process design modifications?

Comment 3 - Submitting Annual Reports to both the USNRC and Agreement States

Proposed section 40.55(d)(2) requires licensees to submit annual distribution reports to "the responsible Agreement State agency". However, it is not clear if the Agreement State report goes to the licensee's own Agreement State agency or to the Agreement State agencies in States where distributions were made. The proposed rule also requires reports be sent even if no distributions are made to a particular state, thus it appears licensees will need to prepare 38 reports each year. Would the USNRC provide clarification of its intent for the 40.55(d)(2) requirement?

Comment 4 - Basis for the 50 gram reporting limit

Sections 40.55(d)(1) and (2) require the filing of an annual report for each source material distribution of "greater than 50 grams" to a 40.22 general licensee in any single quarter. However, Section 40.53 has no threshold for reporting distributions of 40.13 unimportant quantities. It is not clear why there is a difference between the two categories or why a threshold of 50 grams was selected. Would the USNRC consider modifying the 40.55 threshold to the limits given in 40.22(a) for consistency with 40.53?

Comment 5 - Determination of Quantities/Concentrations Distributed

Section 40.53 of the proposed rule would require us to report the total quantity of source material in each 40.13 product we distribute in our annual report. It is not clear if the USNRC simply wishes us to confirm whether each item contains less than the 40.13(c)(7) exemption limit of 10% by weight, or if measured concentrations/quantities on a "per optic" basis are required. Would the USNRC consider inserting clarification on this requirement either in the proposed rule or in the Draft Implementation Guidance? In addition, in order to avoid what is likely to be significant measurement and analytical costs for assessing "per optic" concentrations/quantities on the thousands of optics we manufacture, would the USNRC consider reports of nominal quantities (i.e., less than 10%) rather than optic-specific quantities in the annual report?

Comment 6 - Annual Reporting of Confidential Information

II-VI's customer list, the items sold to each customer, and sale frequencies are confidential and proprietary business information. It is not clear how or if this information, which is required to be submitted to the USNRC as part of each 40.53 or 40.55 annual report, will be protected from public disclosure. For II-VI to request protection of our confidential information pursuant to 10 CFR 2.390 with each report would be burdensome. Would the USNRC consider eliminating customer-specific information from the annual reporting requirements and instead simply require licensees to maintain customer-specific information and make it available for USNRC review during regulatory inspections?

Comment 7 - Tracking, compiling and reporting distributions on an annual basis

The information required in the 40.52 and 40.55 annual reports, contrary to the statement on 75 FR 4340,

will not be a minimal burden on II-VI because the information requested is *not* part of our existing business recordkeeping practices. In order to comply with the requirements as stated, II-VI must develop, implement and staff a data acquisition/management system that does not currently exist and for which we have no other need. The result will be the expenditure of significant additional resources that will adversely affect our worldwide competitiveness.

Comment 8 - Securing a USNRC distribution license for 40.13-exempted items

It is not clear why the USNRC does not defer jurisdiction over the distribution of 40.13-exempted items to the States under the Agreement State program. As an Agreement State licensee with program documents, procedures and personnel training specific to PADEP requirements, the resources required to secure and maintain a USNRC distribution license plus our PADEP possession and distribution license, and modify all of our procedures to reflect joint jurisdiction, will be significant. Would the USNRC consider handling 40.13 distributions the same way as the 40.22 distributions (i.e., either by the applicable Agreement State or the USNRC if a USNRC possession license is held)?

Comment 9 - Providing safety precautions and instructions with each product

II-VI makes available Material Safety Data Sheets (MSDSs) for its products. These contain applicable precautions and instructions for handling, storage and use. It is not clear in either the proposed rule or the Draft Implementation Guidance if an MSDS that contains the safety information required in 40.52(b)(5) must be placed inside of each inner container (box) of lenses, whether it can be provided to the purchaser as part of other purchase documentation, or if can be simply referenced as being available, with instructions as to how to secure one, on either the inner package or on purchase documents. It is likewise unclear if the MSDS needs to be distributed to the customer before or after the purchase takes place. Would the USNRC provide additional guidance on the acceptable methods of forwarding safety information to customers? Would USNRC consider requiring an annual submission (as USEPA requires of Toxic Chemical shipments in 40 CFR 372.45(c)(1)) of the MSDS to each customer instead of including them with each shipment?

Comment 10 - Product labeling

Section 4052(b)(4) requires each unit and/or its container bear a label that identifies the manufacturer (or initial transferor) and the source material in the product. It is not clear if this requirement means the label should simply state "this product contains source material", or if the specific source material type (e.g., thorium) should be identified on the label by stating "this product contains thorium". The use of "thorium" or "<10% thorium" alone in the label also could unnecessarily alarm users who may not understand the weight designation or be able to relate that information to the trivial activity that is actually in the product. Would the USNRC modify the Draft Implementation Guidance to address this concern and further confirm whether the source material activity or concentration of each item must be included on the label as well?

Comment 11 - Cost benefit of the proposed rule

It is important for the USNRC to understand that the implementation of the proposed rule, if finalized as written, would impose significant costs on II-VI and severely limit our ability to remain competitive on the international market. For example, because we are an existing Agreement State licensee, we already bear the cost of maintaining our PADEP possession/distribution license (i.e., annual fees). However, the rule will add the cost of preparing an application for a USNRC distribution license, plus the application fee, additional annual fees and the cost of modifying our existing PADEP-focused compliance program in

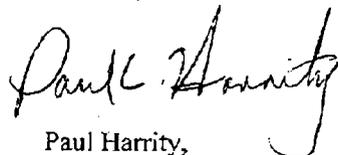
order to accommodate another set of rules and license requirements. Other costs we envision incurring when the rule is finalized are associated with developing and implementing a quality control program as required in 10 CFR 40.52 and 40.55, a program to track and distribute applicable regulations and safety instructions/precautions to our customers, designing new packaging that meets the new labeling requirements in §40.52 and §40.55, developing and managing a database for tracking where 40.13 and 40.22 items are distributed, and more. We are not convinced the maximum radiation dose potential of 20 millirem TD50 associated with the use of thorium in finished optics, as described in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials" (June, 2001), justifies the significant cost associated with implementing the proposed rule requirements, since this value is well-within the range of normal background radiation exposures incurred by the US population.

In closing, please let me re-iterate that II-VI is the largest US supplier of thorium-coated optics and thus stands to incur most of the negative ramifications of the proposed rule. In 2008, we gladly forwarded information about our products and our operations to the USNRC's contractor tasked with updating NUREG-1717 to help them understand and evaluate potential risks. In return, we explicitly asked for an opportunity to review the findings of the study before they triggered any rulemaking activity. We heard nothing from either the USNRC or its contractor in response to our request, thus we are troubled by how far the rulemaking has progressed without our having been queried for input.

To that end, we would very much like an opportunity to meet with the USNRC, face to face, to further discuss the significant negative impacts the proposed rule will have on II-VI's operations, our ability to compete for business, and on our customers. We would be pleased to host representatives of the USNRC and/or Staff at our Saxonburg, Pennsylvania facility so you can see for yourself what is involved in the production and distribution of our optics and how that will be impacted by implementation of the rule. Alternatively, we would be pleased to travel to the USNRC's Rockville, Maryland facility if that presents a more convenient meeting opportunity.

II-VI appreciates this opportunity to comment on the proposed revisions to 10 CFR 40 and we look forward to hearing how our concerns, and those of others, are addressed. We believe the negative impacts of finalizing the proposed rule as written will be significant and more widespread than the USNRC envisions, thus we look forward to an opportunity of meeting with you *before* the rule is finalized. Please contact me at (724) 352-5740 if you have any questions and to schedule a meeting.

Sincerely,



Paul Harrity,
Radiation Safety Director

cc: R. Leonard
L. Nitoski
David Allard (PADEP)