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DOCKETED
USNRC

February 15, 2011 (3:45 pm)

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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:

VLOC is a general licensee that manufactures and distributes thorium-bearing optics and other products to persons who use them under exemptions from licensing or under a general license. 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, VLOC 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 piece (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

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² U. S. Nuclear Regulatory Commission, "Draft Guidance for Implementation of the Proposed Rule, 'Distribution of Source Material to Exempt Persons and to General Licensees and Revisions of General License and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.

Template = SECY-067

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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. VLOC currently manufactures about 50 product designs. 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) requirements?

Comment 4 - 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 optics we manufacture, would the USNRC consider reports of nominal quantities (i.e., less than 10%) rather than optic-specific quantities?

Comment 5 - Annual Reporting of Confidential Information

VLOC'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 release. For VLOC 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? VLOC currently keeps these records for review for 7 years.

Comment 6 - 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 because the information requested *is not* part of our existing business recordkeeping practices. In order to comply with the requirements as stated, VLOC 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.

Comment 7 - Securing a USNRC distribution license for 40.13-exempted items

It is not clear why the USNRC does not wish to defer jurisdiction over the distribution of 40.13-exempted items to the States under the Agreement State program. As a potential future Agreement State licensee with program documents, procedures and personnel training specific to FDEP requirements, the resources required to secure and maintain a USNRC distribution license plus our purchase a future FDEP possession and distribution license, and modify all of our procedures to reflect joint jurisdiction would be a significant burden. 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 8 - Providing safety precautions and instructions with each product

VLOC makes available Material Safety Data Sheets (MSDSs) for its products which 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 required in 40.52(b)(5) safety information 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?

Comment 9 - 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". 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 10 - 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 VLOC and severely limit our ability to remain competitive on the international market. For example, because we are not an existing Agreement State licensee, we would stand to bear the cost of procuring and maintaining a future FDEP 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 purchasing a future FDEP-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 risks associated with the use of source material pursuant to the current version of 10 CFR 40, as described in NUREG-1757, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials" (June, 2001) justifies the significant cost associated with implementing the proposed rule requirements.

Comment 11 – Reduction in General License Thresholds

The proposed rule in 40.22(a)(1) reduces the source material inventory threshold for a general licensee from 15 lbs to 3.3 lbs and the annual usage threshold from 150 lbs to 15.4 lbs. The proposed inventory threshold reduction is thus 78% while the proposed annual usage threshold reduction is 90%. The reason for the greater percentage reduction in the annual usage threshold is not clear. Would the USNRC consider reducing the annual usage threshold by the same percentage as the inventory threshold? Such a reduction would result in a new proposed annual usage threshold of 33 lbs.

VLOC 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.

Sincerely,



Scott Rintz

VLOC Radiation Safety Officer

Rulemaking Comments

From: Steve Sacone [Ssacone@vloc.com]
Sent: Tuesday, February 15, 2011 3:24 PM
To: Rulemaking Comments
Subject: 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)
Attachments: 3577_001.pdf

Attention: Rulemakings and Adjudications Staff

Please see attached letter outlining our 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).

Regards

Steve Sacone
General Manager, VLOC

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Received: from mail1.nrc.gov (148.184.176.41) by TWMS01.nrc.gov
(148.184.200.145) with Microsoft SMTP Server id 8.2.247.2; Tue, 15 Feb 2011
15:24:46 -0500
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X-MID: 31686766
X-fn: 3577_001.pdf
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d="pdf?scan'208,217";a="31686766"
Received: from exprod7og105.obsmtip.com ([64.18.2.163]) by mail1.nrc.gov with
SMTP; 15 Feb 2011 15:24:20 -0500
Received: from source ([12.153.84.4]) by exprod7ob105.postini.com
([64.18.6.12]) with SMTP ID DSNKTVrg8y9RFJ3aqVJSI+/OgpU+oaFQO04u@postini.com;
Tue, 15 Feb 2011 12:24:20 PST
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NRC-2009-0084)
Date: Tue, 15 Feb 2011 15:24:16 -0500
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X-MS-TNEF-Correlator:
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General Licensees and Revision of General License and Exemptions" (RIN 3150-AH15; Docket
ID NRC-2009-0084)
Thread-Index: AcvNTIEecjfmYrrLRFOFKwRgGLe1Jw==
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