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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:

Exotic Electro-Optics (EEO) is licensed by the State of California Radiologic Health Branch (License No. 6438-33) to possess, use, ship and receive natural thorium for thin-film optical coating, the manufacture of coated optical lenses, the repair of optical equipment and the distribution of optical lenses and windows to persons exempt from licensing pursuant to Title 10, Code of Federal Regulations, Section 40.13. These operations are performed at our Murrieta, California facility.

Recently we took the opportunity to review the U. S. Nuclear Regulatory Commission's (USNRC's) proposed modifications to 10 CFR 40 and the Draft Implementation Guidance and we have determined that, if finalized, it will have a significant impact on our operations.^{1,2} Therefore, we respectfully submit the following comments, concerns and recommendations for USNRC consideration.

1. Regarding the applicability of the proposed revisions on EEO's operations - EEO manufactures optics that come in a wide variety of sizes and shapes. For example, we manufacture large windows with nominal dimensions of 18-in. by 12-in., as well as small lenses that are less than one inch in diameter, that contain less than 0.05% thorium, by weight. Section 40.13(a), which was not modified in the proposed rule, would appear to exempt EEO from the need for a distribution license as specified in proposed Section

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² U. S. Nuclear Regulatory Commission, "Draft Guidance for Implementation of the Proposed Rule, 'Distribution of Source Material to Exempt Persons and to General Licensees and Revisions of General License and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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40.52 because of the low weight percent of our mixture.³ However, proposed Sections 40.13(c)(7) and 40.52 clearly address exemptions and licensing for optics, thus there is confusion as to whether the proposed rule would require EEO to secure a 40.52 license for our lenses with less than 0.05% source material. We recommend the Draft Implementation Guidance be modified to include an example and determination for *optics* that contain less than 0.05% source material by weight.

2. Regarding annual reporting of quantities and concentrations distributed - It is not clear if the annual reports required in Section 40.53 of the proposed rule would require us to determine the quantity or concentration of source material for individual optics, or simply confirm that the weight percent of each optic is below the 40.13(a) or 40.13(c) limit. It is further unclear whether the reporting units should be weight percent (i.e., ppm) or activity (i.e., Ci or Bq). We recommend the Draft Implementation Guidance be modified to include clear instruction on how quantities and concentrations should be reported under Section 40.53.
3. Regarding product tracking and reporting - EEO's product line includes optics that do have thorium coatings and optics that do not. In order to prepare the annual reports required in Proposed Section 40.53, EEO would need to institute a separate tracking and reporting system for both types of optics. Such a two-tiered system does not currently exist, thus it is important that the USNRC understand that significant additional resources would be required in order to meet this requirement. (See Comment No. 10, below.)
4. Regarding the need for a USNRC distribution license - Proposed Section 40.52 would require EEO, a State of California Licensee, to apply for, secure and maintain a license from the USNRC to distribute products exempted under Section 40.13. EEO's existing license with the Radiologic Health Branch already authorizes us to distribute these products, thus we do not understand the need for dual jurisdiction over the process. Dual jurisdiction would require significant modification to EEO's existing procedures, and could lead to confusion as to which requirement (USNRC or State) is applicable for any given evolution. Furthermore, the cost of securing and maintaining *both* a USNRC and a California license is not only unnecessary, it could render our products non-competitive in our international marketplace (see Comment 10, below). We thus recommend proposed Section 40.52 be modified to eliminate the requirement for Agreement State licensees to secure a USNRC license in order to distribute.
5. Regarding the need to determine end-user's license status - End users of EEO's products could very well machine, heat treat, bend, or otherwise physically manipulate

³ Section 40.13(a) reads as follows: "Any person is exempt from the regulations in this part and from the requirements for a license set forth in section 62 of the Act to the extent that such person receives, possesses, uses, *transfers or delivers* source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than one-twentieth of 1 percent (0.05 percent) of the mixture, compound, solution or alloy [emphasis added]."

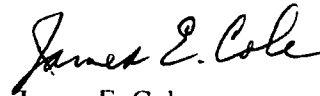
the product such that the proposed Section 40.13(c)(7) exemption would not apply. It is not clear whether EEO would need to evaluate our customers' activities or uses of our products in order to ensure we do not violate the proof of licensing requirements specified in Section 40.51(c) and (d). We recommend additional guidance on this issue be incorporated in the Draft Implementation Guidance, and that the proposed rule be modified to clearly specify the limits of a specific licensee's liability with respect to the requirements of Section 40.51(c) and (d).

6. Regarding the need to submit detailed product information in a license application - As described in Comment 1, above, our products come in a wide variety of shapes and sizes, and most are produced to customer specifications rather than being "off the shelf" items. However, Section 40.52(b) of the proposed rule would require EEO to submit detailed construction/design information for all products distributed under the Section 40.13(c) exemption in our application to the USNRC for a distribution license. If we must amend our license with each and every design change, this would place a significant burden on our ability to provide products to customers on a timely and cost-effective basis. We thus recommend Section 40.52(b) be modified to permit the submission of information about our products in general, rather than detailed designs and specifications for each product model.
7. Regarding the need to report source material distributions in excess of 50 grams - In the proposed rule, 10 CFR 40.55(d)(1) and (2) require an annual report be filed for each source material distribution of "greater than 50 grams" to general licensees in each quarter. However, 10 CFR 40.53 has no such threshold. We recommend the 40.55(d)(1) and (2) thresholds be harmonized with the threshold limits in 40.22(a)?
8. Regarding the transmittal of confidential information - EEO sells products to primarily military clients. These transactions are subject to security restrictions which may prohibit us from submitting the information required in the 10 CFR 40.53 or 40.55 annual report. We recommend eliminating customer-specific information from the annual reports and instead require the submission of generic information on amounts distributed on a "per state" basis, rather than a "per customer" basis.
9. Regarding product labeling - In the proposed rule, 10 CFR 40.52(b)(4) requires each unit (i.e., lens or window) and/or its container be labeled with the identity of the manufacturer and the fact that there is source material in the product. Regarding the latter requirement, is it sufficient to state "this product contains source material" or should the type of source material (i.e., thorium) also be identified in the label? We recommend the Draft Implementation Guidance be modified to include additional guidance on how to label lenses, windows and packages.
10. Regarding the cost of implementing the proposed rule as written - The proposed rule, if finalized as written, would significantly increase our production costs. For example, as an existing Agreement State licensee, we would incur the cost of preparing an application for a USNRC distribution license, submitting the application fee, paying

additional annual licensing fees, and revising/implementing all of our procedures to reflect dual regulation of what is essentially the same process. We would also be required to develop and implement a quality control program and a product tracking program, in a form that does not exist in our current operations. Other expenditures, including new packaging and product safety information sheets, would also be required. It is not clear to us that the benefits of the proposed rule in light of the trivial risk of using our products outweigh the significant increase in cost. It is also important to note that, depending on when the rule is finalized, EEO may not be able to recover the additional new costs from existing contracts, thus placing us in financial jeopardy until those contracts expire. We thus recommend the rule *be rejected* and that the requirements in the current version of 10 CFR 40 be maintained. In return, EEO would be pleased to track general information about the distribution of all products that contain source material, and make that information available to our State agency during routine inspections of our operations.

EEO is very interested in how the USNRC resolves our comments on the proposed rulemaking. We also want to express our concern about the content, practicality and cost of the rule as written in the hopes that the USNRC will consider significant modification or withdrawal. If you have any questions, I can be reached at (951) 926-7692. Thank you very much.

Sincerely,



James E. Cole,
Radiation Safety Officer

cc: Andrew Riser
General Manager
Exotic Electro-Optics

Lauren B. Labbe
Chief, Industrial and GLD Licensing
Radiologic Health Branch
California Department of Public Health

Rulemaking Comments

From: Janice Roewer [JRoewer@exotic-eo.com]
Sent: Tuesday, February 15, 2011 5:31 PM
To: Rulemaking Comments
Cc: Andrew Riser; Jim Cole
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: NRC Letter.pdf

Dear Sirs,

In response to your request regarding proposed modifications to 10 CFR Part 40, please accept our attached comments.

Should you have any questions or comments, please contact James Cole, Radiation Safety Officer, at 951-926-7692.

Best regards,

Janice Roewer
Inside Sales Administrator
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with mapi; Tue, 15 Feb 2011 14:31:10 -0800
From: Janice Roewer <JRoewer@exotic-eo.com>
To: "Rulemaking.Comments@nrc.gov" <Rulemaking.Comments@nrc.gov>
CC: Andrew Riser <ARiser@exotic-eo.com>, Jim Cole <jcole@exotic-eo.com>
Date: Tue, 15 Feb 2011 14:31:09 -0800
Subject: Comments on "Distribution of Source Material to Exempt Persons and
to General Licensees and Revision of General License and Exemptions" (RIN
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Thread-Topic: Comments on "Distribution of Source Material to Exempt Persons
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