

PR 30,40,70,170 and 171  
(75FR43425)

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February 10, 2011 (11:30 am)

February 10, 2011

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

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

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)

To Whom It May Concern:

Global Tungsten & Powders Corp. (GTP) currently holds Pennsylvania Department of Environmental Protection (PADEP) License Number STB-281 for the manufacture and distribution of thorium-bearing products to persons that use source material under exemptions from licensing. We have reviewed 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 and we have a number of questions and comments.<sup>1,2</sup> The purpose of this letter is to provide comments (delineated below) on those aspects of the proposed rule that are of the greatest concern to us.

1. Licensee responsibility for the end use of exempted or generally-licensed items - Currently, GTP manufactures and distributes products exempted under the provisions of 10 CFR 40.13(c)(1) and 40.13(c)(4). Under the first category, the products in question are thoriated tungsten rods used for welding. Under the second category, products include high-intensity lighting electrodes, electron grid tube wire, incandescent lamp coils, customer-machined spray metalizing nozzles, and other items where the end use is not known. Customers using thoriated tungsten alloys under 40.13(c)(4) may very well perform some sort of physical operation in the piece (e.g., machining, heat treatment, welding, etc.), which would appear to invalidate the 40.13(c)(4) exemption. However, the amount of thorium sold to those end users typically meets the current definition of small quantities in 10 CFR 40.22, thus they do not require a specific license. If the proposed rule is finalized as written, many of these customers will not be able to limit their usage to the reduced quantity limits proposed in 40.22 (a)(1). Many may perform some alteration of the physical form of the product (e.g., bending, shaping, etc.) and thus they would not qualify for a 40.22(a)(2) general license. In summary, many current users of thoriated tungsten alloys under the current version of 40.13 or 40.22 will be required to obtain a specific license in order to purchase our products.

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As stated above, "chemical, physical or metallurgical treatment or processing" is not authorized under the current 40.13(c) (4) exemption. Likewise the proposed 40.22 (a)(1) persons may not "alter the chemical or physical form" of the source material. However it is not clear what activities the USNRC believes would alter the chemical or physical form or what would constitute chemical, physical or metallurgical treatment or processing. *Recommendation: In order for users of source materials under 40.13 (c)(4) or 40.22 (a)(2) to better understand the limitations on the use of source material under these paragraphs and possible need for specific licensing, clear definitions of "altering chemical or physical form" and "chemical, physical or metallurgical treatment or processing" should be provided in a revision to 10 CFR 40.4.*

It is not clear in the proposed rule language what the obligations of the initial distributor are with respect to the licensing status of recipients. Under current 40.51(c), before transferring source material to a specific or general licensee, the transferor must verify that the transferee's license authorizes receipt of the material in question. There is no similar requirement related to transfer of source material under a 40.13 exemption. For example there is no requirement to confirm that the person receiving source material under 40.13(c)(4) does not perform "chemical, physical or metallurgical treatment or processing" of the product. Thus, a licensee distributing an exempted article under 40.13 may not know if the person receiving the article requires a general or specific license for its subsequent use (treatment or processing). Under these circumstances, would the initial distributor be subject to enforcement action for failing to fully understand what customers are doing with their products and thus failing to comply with the applicable distribution requirements or securing evidence of the end user's licensing status? The additional level of effort that appears to be required to ensure initial distributors do not distribute source material to unauthorized persons, in light of the understandable reticence customers may have with sharing information about their products and operations, poses an undue burden on the initial distributor. *Recommendation: The rule or the Draft Implementation Guidance should clearly absolve the initial distributor of exempted articles under 40.13 of responsibility for the licensing status of the end user of their products.*

2. License Specificity - Section 40.52(b) requires licensees to submit detailed construction/design information for products distributed under 40.13(c) as part of the license application. This requirement is straight-forward for products like welding rods, certain electrodes and related items. However, GTP also manufactures a variety of miscellaneous items where the design, size and dimensions are dictated by the customer. Furthermore, many of these miscellaneous items are infrequent or one-time orders. The need to provide detailed construction/design information for each of these products prior to their distribution would likely require frequent license amendments (i.e., with each new product order) and would challenge a company's ability to meet shipment schedules while awaiting regulatory action on each application. *Recommendation: The USNRC should publish a regulatory guide for the preparation of a distribution license, and ensure the guidance requests generic construction/design information rather than detailed.*

3. Transfer of Regulatory and Safety Information Prior to Product Transfer - Proposed section 40.55 requires the initial distributor to forward a copy of 10 CFR 40.22 and 40.51 (or Agreement State equivalents) to customers who possess source material under a general license prior to the transfer of products. As stated in Comment 1 above, there may be situations where the distributor does not know if the customer is using the material under a 40.22 general license as opposed to a 40.13 exemption. This again raises the question of how much responsibility the initial distributor must assume for determining license status prior to shipment of products. Without a provision in

the proposed rule that absolves the initial distributor of the need to confirm license status prior to shipment, the rule poses an undue burden and presents increased enforcement risk. *Recommendation: The rule or the Draft Implementation Guidance should clearly absolve the initial distributor of responsibility for the licensing status of the end user of their products.*

4. Basis for the 50 gram reporting limit - Sections 40.55(d)(1) and (2) require the filing of an annual report for each distribution of "greater than 50 grams" of source material to a 40.22 general licensee in a 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 the threshold is only 50 grams. *Recommendation: Modify the annual reporting threshold to the limits given in 40.22(a)?*

5. Submission of Annual Reports to Agreement States - Proposed section 40.55(d)(1) requires licensees to submit annual distribution reports to the USNRC and 40.55 (d)(2) requires a report be sent to "the responsible Agreement State agency". However, 40.44(d)(2) also requires the report to include "the following information specific to those transfers made to the Agreement State being reported to . . . [information follows]". It is not clear if the Agreement State report goes to the specific licensee's Agreement State agency or to the Agreement State agencies where distributions were made. The latter interpretation would require 38 reports per year be prepared since reports must be sent even if no distributions take place. *Recommendation: Kindly clarify which Agreement State agencies are to receive the required annual reports.*

6. Annual Reporting of Quantities/Concentrations - Section 40.53 of the proposed rule requires distribution licensees to assess the total quantity of source material in each 40.13 product to ensure they remain below the applicable quantity or concentration limit for that product and for the preparation of the annual reports to the USNRC. However the required precision in these assessments is not clear. A determination of actual thorium concentrations or quantities in the finished product would require some sort of a measurement method (i.e., sample collection/analysis) on a "per batch" basis. To mount such a campaign would increase the contamination potential of our operations, product cost, delivery times and personnel exposures, all of which would be burdensome. *Recommendation: The rule should state the level of precision expected in the annual reporting of quantities, or simply allow confirmation that each distributed item contained less than the limiting quantities.*

7. Annual Reporting of Confidential Information - Information about a GTP's customers, who they are, what they purchase and how much is proprietary marketing and business information. Including these specifics in the annual reports required in 40.53 and 40.55 would require GTP and most companies to designate each submission as needing to be withheld from public inspection pursuant to 10 CFR 2.390, which would be burdensome.

8. Regulatory Jurisdiction - Section 40.52 of the proposed rule appears to require us to secure a USNRC license to initially distribute unimportant quantities of source material (i.e., 40.13 items), even though our existing Agreement State license already authorizes distribution of these items. This is further confirmed on Page 15, Question 5 of the Draft Implementation Guidance. On the other hand, Section 40.54 and Page 21, Question 5 of the Draft Implementation Guidance confirm that our existing Agreement State license will continue to authorize the distribution of small quantities of source material (i.e., 40.22 items). Because annual reports to the State are required in both cases, who would presumably share that information with the USNRC, the need to secure and maintain a separate distribution license for unimportant quantities is unnecessarily costly (see

below) and burdensome. *Recommendation: Licenses for the distribution of both 40.13 and 40.22 materials by Agreement State licensees should continue to be issued by the Agreement State. Agreement States should be required to report to the USNRC under their Agreement State Program obligations.*

9. Cost Considerations - The proposed rule, if finalized as written, would impose significant cost penalties on the manufacture and sale of our products. Because we are an existing Agreement State licensee, the cost of preparing an application for a USNRC distribution license, along with the application fee, the additional annual licensing fees and the cost of the additional resources that would be necessary in order to comply with another set of rules and license requirements would add more than \$37,000 per year to our current annual regulatory costs.<sup>3</sup> The cost of developing and implementing a quality control program pursuant to 10 CFR 40.52 and 40.55 would add more than \$30,000 to our existing product quality control program.<sup>4</sup> The resources necessary to provide a copy of applicable regulations and safety instructions/precautions to each recipient of our products once each year, including the cost of developing and managing the program, is likely to exceed \$10,000 per year. This would result in a cost ramification of \$75,000 or more in the first year, excluding the cost of designing new packaging in order to meet the labeling requirements of 10 CFR 40.52 and 40.55. It is difficult to estimate packaging costs in light of the fact that many of our products are small, infrequent and/or "one time only" orders. In any case, these additional costs will impact the competitive nature of our products on the national and international marketplace.

GTP will monitor the Federal rulemaking web site at <http://www.regulations.gov> for further action on our comments, the comments of others and the USNRC's responses. We are concerned about the content, implementation and cost of the rule as written and thus look forward to hearing how these concerns will be addressed before the rule is finalized.

Sincerely,



Carmen Venezia, CIH,  
Radiation Safety Officer

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<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> For the first year, this amount is based upon an estimated \$5,000 to prepare the application, \$7,000 for the application fee, and at least \$25,000 to modify existing procedures to incorporate both USNRC and PADEP license/regulatory requirements and train personnel accordingly.

<sup>4</sup> This amount is based upon an estimated \$10,000 per year in sample analysis costs, \$10,000 for program development/management and \$10,000 for data management, verification and reporting.

## Rulemaking Comments

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**From:** Venezia Carmen F. [Carmen.Venezia@globaltungsten.com]  
**Sent:** Thursday, February 10, 2011 10:36 AM  
**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:** GTP Comments(RIN 3150-AW15;Docket ID NRC-2009-0084).pdf

To Whom It May Concern:

Please find attached comments from Global Tungsten & Powders Corp. (GTP) 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,

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**Global Tungsten & Powders Corp.**

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Feb 2011 10:36:26 -0500

From: Venezia Carmen F. <Carmen.Venezia@globaltungsten.com>

To: "Rulemaking.Comments@nrc.gov" <Rulemaking.Comments@nrc.gov>

Subject:

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