

**From:** "Yelon, William B." <yelonw@umr.edu>  
**To:** "Anthony Kirkwood" <ASK@nrc.gov>  
**Date:** 09/18/2007 10:17:25 AM  
**Subject:** RE: Action:Request For Additional Information From Ideal Source,MC#022617

Dear Mr. Kirkwood,

Attached are our responses to items 1-3 of your e-mail. One section is proprietary and is attached as a separate file. Please let me know if you need an original by mail or if the email rponses are adequate.

We will see to the paperwork you identified in item 4 (protection of I.P.) as soon as possible and will send a notarized document.

I look forward to meeting you on the 27th.

Regards,  
Bill Yelon

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From: Anthony Kirkwood [mailto:ASK@nrc.gov]  
Sent: Wed 9/12/2007 12:25 PM  
To: Yelon, William B.  
Cc: Duncan White; J Bruce Carrico; Kevin Null; Linda Eusebio; Maureen Moriarty; Richard Struckmeyer  
Subject: Action:Request For Additional Information From Ideal Source,MC#022617

September 12, 2007

Mail Control No. 022617

Ideal Source International, LLC

ATTN: Dr. William B. Yelon,

QA Manager

55 W 39th Street, 17th Floor

New York, NY 10018

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION ON APPLICATION FOR NEW EXEMPT DISTRIBUTION LICENSE

Dear Dr. Yelon:

Information in this record was deleted in  
accordance with the Freedom of Information Act.  
Exemptions 4  
FOIA/PA 2007-0061

~~CONFIDENTIAL~~ 6/3

This refers to your Application for Material License, NRC Form 313, dated July 13, 2007. We do not have sufficient information to complete the review of your application. Please respond to the following questions:

1) Title 10, Code of Federal Regulations, Section 30.33 (10 CFR 30.33), requires you to apply for and obtain a specific license authorizing possession and use of radioactive material (induced radioactivity in gemstones) from the NRC. Prior to issuing a Nuclear Regulatory Commission (NRC) exempt distribution license, you must first satisfy the general requirements of 10 CFR 30.33. Please alert us when you receive your possession license from NRC Region III.

2) Title 10, Code of Federal Regulations, Section 32.11(b) [10 CFR 32.11(b)] requires that you provide a description of the control methods to assure that no more than the specified concentration is introduced into the product or material during treatment. Please submit your description of the above. In addition, 10 CFR 32.11(b) also requires an estimate of the concentration of the radioisotopes in the product at the time of transfer of the product. However your dose estimates appear to be much higher than those also based on the exempt concentrations, found in NUREG-1717, Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials, June 2001 (<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1717/>), Section 2.2. Explain why your dose calculations on page 12 of your application, Section E. 2., are significantly higher than those in NUREG-1717, Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials, June 2001, and why the public dose limits in 10 CFR 20.1301, will not be exceeded when the irradiated gemstones are transferred to the public.

3) Title 10, Code of Federal Regulations, Section 10 CFR 32.11(c) requires that you provide reasonable assurance that the concentrations of byproduct material at the time of transfer will not exceed the concentrations in 10 CFR 30.70. Submit calculations that demonstrate 0.2 gram stones, that exceed twice the exempt concentration limit, can be excluded from the one in one thousand screening criteria and why the public dose limits in 10 CFR 20.1301, will not be exceeded when the 0.2 gram irradiated gemstones are transferred to the public.

4) The application includes sections that are marked as proprietary. Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

In order to request that NRC withhold information contained in an application from public

disclosure, the applicant must submit the information and application, including an affidavit, in accordance with 10 CFR 2.390. The applicant should submit all of the following:

A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.

A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the non-proprietary portions intact. This copy should not be marked as proprietary.

An affidavit that:

Is notarized.

Clearly identifies (such as by name or title and date) the document to be withheld.

Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information sought to be withheld and who has been authorized to apply for withholding on behalf of the company.

States that the company submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.

Provides a rational basis for holding the information in confidence.

Fully addresses the following issues:

Is the information submitted to and received by NRC in confidence? Provide details.

To the best of the applicant's knowledge, is the information currently available in public sources?

Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.

Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant? If so, explain why in detail. The explanation should include the value of the information to your company, the amount of effort or money expended in developing the information, and the ease or difficulty of others to acquire the information

In accordance with 10 CFR 2.390 of NRC's Rules of Practice, a copy of this letter will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room).

Please submit the requested information within thirty days of the date of this e-mail. If we have not received complete information within thirty days of the date of this e-mail, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete application.

If you have any questions, please feel free to contact me at (301) 415-6140 or electronic mail: [www.ask@nrc.gov](mailto:www.ask@nrc.gov) <<http://www.ask@nrc.gov/>>

Sincerely,

/RA/

Anthony S. Kirkwood

State Agreements and Industrial

Safety Branch

Division of Materials Safety and

State Agreements

Office of Federal and State Materials and

Environmental Management Programs

Docket No. 030-37534

Mail Control No. 022624

**Mail Envelope Properties** (46EFDDE7.2FF : 18 : 25343)

**Subject:** RE: Action:Request For Additional Information From Ideal  
Source,MC#022617  
**Creation Date** 09/18/2007 10:12:09 AM  
**From:** "Yelon, William B." <[yelonw@umr.edu](mailto:yelonw@umr.edu)>  
**Created By:** [yelonw@umr.edu](mailto:yelonw@umr.edu)

**Recipients**

nrc.gov  
OWGWPO04.HQGWDO01  
ASK (Anthony Kirkwood)

**Post Office**

OWGWPO04.HQGWDO01

**Route**

nrc.gov

Files	Size	Date & Time
MESSAGE	7544	09/18/2007 10:12:09 AM
Responses to Kirkwood email-9-12-07.doc	33280	
Proprietary information-calculation-1ct-sort.doc	30720	
Mime.822	98822	

**Options**

**Expiration Date:** None  
**Priority:** Standard  
**ReplyRequested:** No  
**Return Notification:** None

**Concealed Subject:** No  
**Security:** Standard

**Junk Mail Handling Evaluation Results**

Message is eligible for Junk Mail handling  
This message was not classified as Junk Mail

**Junk Mail settings when this message was delivered**

Junk Mail handling disabled by User  
Junk Mail handling disabled by Administrator  
Junk List is not enabled  
Junk Mail using personal address books is not enabled  
Block List is not enabled

**Responses to e-mail request for additional information on application for new  
exempt distribution license**

**Email from Anthony Kirkwood, Sept. 12, 2007**

**William B. Yelon**

**1. Notification regarding possession license:**

At this moment I believe that all questions have been answered. Kevin Null from Region III will be visiting the facility in Columbia, MO on Wed. Sept. 19. I hope the license will be issued shortly after his visit and will notify NRC H.Q. as soon as the license is received.

**2-a. Methods to assure that no more than the specified concentration is  
introduced into the product.**

Topaz is a natural mineral, subject to variability in the impurities, which affects the concentration of byproduct material introduced into the stones during a typical irradiation (which averages in the range of  $10^{17}$  /cm<sup>2</sup> (fast neutrons). At the time of irradiation the principle isotope <sup>54</sup>Mn will have a concentration of 1-3 times the exempt concentration (depending on the origin and dose), while the <sup>182</sup>Ta concentration will range from 0.5 to 100 times the exempt concentration. This variability is the principle reason behind the need to sort topaz for outliers. Our method assures that at release no more than 1 stone per thousand exceeds twice the exempt limits based on the sum-of ratios (SOR).

Note that the concentration of isotopes can be affected strongly by the nature and thickness of shielding used to eliminate thermal and some of the epithermal neutrons, as well as the effects of re-moderation of fast neutrons in the irradiation space. We have invested a great deal of time and effort in attempting to optimize the shielding, including investigation of the effect of Ta screens, and Hf foils to eliminate epithermal neutrons. We believe that there is little room to further reduce the concentrations of by-product material, at the time of irradiation.

It should be further noted that the by-product material in topaz is unwanted and is the inadvertent result of the fast neutron irradiation used to create the color centers that make the treatment valuable. Other cases of exempt distribution involve the deliberate production of known concentrations of radioactive isotopes used for their radioactive properties (e.g. in tritium dial watches or in smoke detectors). Thus, the control over production that is required in those cases cannot be maintained in the case of topaz, and, thus, the control must be exercised after production and before release.

**2-b. Dose estimates appear to be higher than in NUREG-1717.**

The apparent discrepancies between the doses calculated in our application and those given in NUREG-1717 are due to a number of factors, which when properly taken into account, actually show good agreement between the two results.

With regard to the whole body gamma dose, our result shows, e.g. for  $^{182}\text{Ta}$ , at a distance (d) of 4.0 cm, a dose of 2.3 mrem. The value in table 2.2.11 of NUREG-1717 is given as 0.1 mrem. However, the basis for that calculation is for a distance of 10.0 cm, and exposure 8 hours per day, versus the 24 hour exposure assumed in our application. The dose is proportional to  $1/d^2$ , leading to a factor of  $1/6.25$  in our reported doses for the 10 cm case, with an additional factor of 3 for the time, resulting in a net reduction by a factor of 18.75. This reduces our reported 2.3 mrem to 0.12 mrem, in complete agreement with the data of table 2.2.11. Likewise, by adjusting the  $^{54}\text{Mn}$  gamma dose by the same factor, we arrive at a dose of 0.37 mrem, in complete agreement with the value in table 2.2.11 (0.4 mrem).

With regard to the beta dose, we report 185 mrem for  $^{182}\text{Ta}$ , versus 30 mrem reported in table 2.2.11. Applying the same time correction (1/3) reduces our result to 60 mrem, within a factor of two of the 2.2.11 result. This is already within the error limits for calculating beta doses, but an additional factor actually brings these two results into better agreement. Our calculation uses a disk shaped reference stone, with a 1 cm diameter, whereas the data in table 2.2.11 is based on a spherical reference stone. It is obvious that the relative dose of the sphere will be lower than for a disk, as the area of the sphere in contact with the skin is small, while that for the disk is large. With this in mind, it is clear that our calculated doses are in good agreement with those tabulated in Table 2.2.11 of NUREG-1717.

Finally, we note that the application for license previous filed by Alnor/Studsvik (and issued) arrives at approximately the same results as we have found and reported in our application.

In summary, our results are in accord with NUREG1717!

**3-a. Submit calculations that demonstrate that 0.2 gram stones that exceed twice the exempt concentration limit can be excluded from the one in one thousand screening criteria.**

(submitted on a separate page-contains proprietary information)

**3-b. Public dose limits will not be exceeded when the 0.2 gm irradiated gemstones are transferred to the public.**

If one assumes that one stone per thousand is released at twice the exempt

concentration, the dose received by an individual wearing that stone will still be 1/15 of the doses calculated for a 30 ct (6 gm) stone in NUREG-1717, resulting in a negligible dose both to the whole body (photon) of less than 0.008 mrem, and to the skin (beta) of 2 mrem. The collective dose equivalent will be increased only by one part in 1/1000, from 1 mrem to 1.001 mrem. In both cases these represent no concern.

**4. Certain portions of the application are marked as proprietary.**

We will submit, under separate cover, the required affidavit. The proprietary information describes a method for identifying and eliminating outliers, which, to the best of our knowledge, has not previously been described or used. As such, it represents a significant improvement over others methods in use, and allows us to lower the cost of sorting and better insure that the one in one thousand criteria is met.

Pages 11 through 12 redacted for the following reasons:

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(b)(4)