

From: "Yelon, William B." <yelonw@umr.edu>
To: "Anthony Kirkwood" <ASK@nrc.gov>
Date: 09/29/2007 1:07:33 PM
Subject: RE: Action: E-mail Request For Additional Information From IdealSource,MC#022617

Dear Mr. Kirkwood,

Attached are the answers to the questions you presented in this email. We will send the affidavit regarding the proprietary information and the letter authorizing me to represent Ideal Source on License questions, as soon as I return from Bangladesh, late this week.

I'm always happy to answer any additional questions, etc.

Thanks,
Bill Yelon

From: Anthony Kirkwood [mailto:ASK@nrc.gov]
Sent: Thu 9/27/2007 9:29 AM
To: Yelon, William B.
Cc: Duncan White; J Bruce Carrico; Joseph DeCicco; Richard Struckmeyer
Subject: Action: E-mail Request For Additional Information From IdealSource,MC#022617

Dear Dr. Yelon,

Below please find a summary of the new additional information I requested during our meeting on Tuesday, September 25, 2007. At the meeting you indicated that your response to our September 12, 2007, Request For Additional Information, question number 4, in regards to the need for withholding of certain proprietary information from public disclosure, would be forthcoming.

At the meeting on Tuesday, September 25, 2007, I requested the following additional information:

- 1) I requested you provide the frequency and scope of audits performed at the irradiation facility in Poland. I referenced NRC Reg Guide 6.9 and 10 CFR 32.110 (LTPD 5%, etc., tables) as a guide for this response.
- 2) I asked that you provide a definition of small, medium, and large stones.
- 3) I asked that you provide the square centimeter area of skin exposed in your dose calculations.
- 4) I asked that you confirm that the sampling mass restricted amounts mentioned in your application, ranging from 200 to 2,000 grams, match the volumes associated with your measurement systems calibration standards.
- 5) Finally, I asked for a letter from an Ideal Source company officer, which states that you have authority to make licensing decisions for Ideal Source as indicated in our guidance document, NUREG-1556, Vol. 8, Section 8.8.

In addition, I informed you that your proposal to only ship samples of

Information in this record was deleted in
accordance with the Freedom of Information Act.
Exemptions 4
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entire lots to the U.S. licensee and have the bulk of the shipment be sent from your overseas storage facility to the overseas topaz stone mounting firms, without physically going through the U.S. licensee may have to be considered by NRC management as a previously unreviewed distribution method. This would add additional review time before the license could be issued. I indicated that NRC could consider this in a future amendment.

Sincerely . . . Anthony Kirkwood

Anthony S. Kirkwood, Health Physicist
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Mail Envelope Properties (46FE8647.416 : 20 : 21526)

Subject: RE: Action: E-mail Request For Additional Information From
IdealSource,MC#022617
Creation Date 09/29/2007 1:06:57 PM
From: "Yelon, William B." <yelonw@umr.edu>
Created By: yelonw@umr.edu

Recipients

nrc.gov
OWGWPO04.HQGWDO01
ASK (Anthony Kirkwood)

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Files	Size	Date & Time
MESSAGE	2680	09/29/2007 1:06:57 PM
Response to kirkwood email-9-27-07.doc		34816
Mime.822	53301	

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

**Response to e-mail request for additional information
From Anthony Kirkwood
Dated 9/27/07**

**William B. Yelon
Ideal Source Quality Assurance**

1) Frequency and scope of audits of the irradiation facility in Poland

I will personally conduct an annual audit of the neutron irradiation facility in Poland.

The scope of the work will include, but may not be limited to:

- a. Verification that changes to the irradiation facility will not increase the concentration of by-product material in the gemstones or the ratios of activities of the respective isotopes. Any improvements (while unlikely, based on the extensive studies carried out to date) will be followed by re-evaluation of the estimated release dates based on the concentration and ratios of the isotopes present as by-product material.
- b. Verification that irradiations continue to be conducted in such a manner that stones of a given size, shape and geological origin are irradiated in separate, well defined packets, so that the products are homogeneous to the extent of the homogeneity of the impurities for material from that particular origin.
- c. Verification that the sorting of stones for outliers (those exceeding twice the exempt limits based on the sum-of-ratios) is conducted in accordance with the procedures described in the application of the license. The methods will be tested by re-sorting, under my supervision, of one or more previously sorted packets, to confirm that no outliers are present. The packets to be tested will contain stones with masses in the range of 1-2 cts (0.2-0.4 gm) to be sure that the testing is done

on stones which are difficult to test using conventional, single stone counting at the time of release.

- d. Verification that calibration of the NaI(Tl) system is carried out with the frequency described in the application for license, based on the records of calibration and observation of the daily system tests.
- e. Verification that the stones are reliably measured using the high resolution Ge detector to determine the ratio of isotopes in the packet. The calibration of the Ge detector will be tested using the procedures described in the application, using unirradiated topaz and ^{152}Eu beads. Calibration of several packets with masses between 200 and 2000 gms will be conducted and the results compared with stored calibration files.
- f. Verification that the stones are properly labeled and stored according to the estimated dates of release, and that the identity of the stones, with regard to size, shape, mass and irradiation history is maintained.
- g. Verification of the completeness and accuracy of shipping records.

With regard to irradiations carried out at electron beam facilities:

I will conduct an annual audit to assure that previously neutron irradiated stones are handled in such a way that their unique identity is preserved and that on completion of irradiation the stones are returned to their original packages so that their unique histories are preserved. It is our intention to send stones to the electron facilities only after they have been sorted for outliers, but prior to their estimated release date. Material from the electron facility will be tested to assure that additional activity induced by the irradiation

does not cause the sum-of-ratios to exceed 1 at the release date, or to adjust that date accordingly. Experience has shown that, even in the worst case, the additional activity contributes only a minor part to the sum-of-ratios.

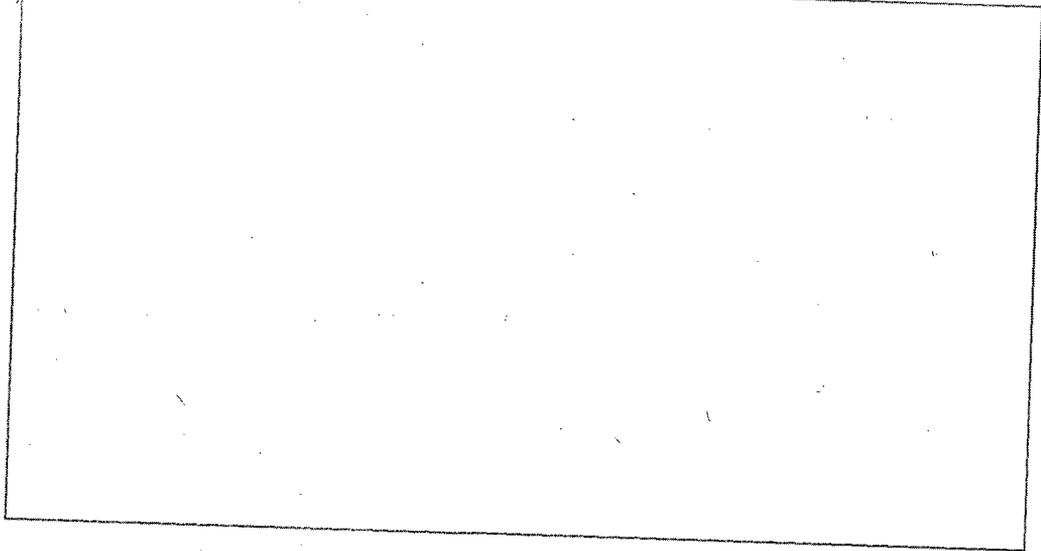
1a) Lot Tolerance Percent Defective

The tables for Lot Tolerance Percent Defective (LTPD) in title 10 appear to be based on a lot consisting of a large number of identical units. For large lots (more than 5,000 pieces) the sample to be tested is less than 5% of the total. For irradiated topaz, the lot (shipment) contains a variety of sizes, shapes, geological origins and irradiation histories. Thus, direct utilization of the data in LTPD 0.5 is problematic. The typical lot, however, will rarely, if ever, contain less than 20 Kg of irradiated material.

Assuming an average stone mass equal to 1 ct (0.2 g), such a shipment will contain 100,000 or more pieces. We have committed to testing 5% of the individual parcels in the lot (and have agreed to test a larger fraction of smaller lots, should they be prepared for shipment).

(b)(4)

(b)(4)



Ex 4

stringent rejection than is required under title 10.

In addition, if the NRC requests, we are prepared to conduct single stone counting on one parcel containing large enough stones (> 5 ct) to allow a direct determination of the distribution of activities, and confirmation that the one in one thousand criterion is not violated. Inasmuch as the sorting in Poland does not utilize single stone counting, this constitutes a non-redundant testing of the procedures and results.

2) Definition of small, medium and large sizes for topaz gemstones.

The distinction between small topaz sizes and the remainder of the topaz material is based on the fact that "small" stones cannot be sorted for the one in one thousand test in a reasonable time, based both on the number of pieces to be tested in a typical 500 gm parcel, and the required counting time to identify outliers. Based on the re-analysis of the isotope distribution presented in the response to the earlier questions from A. Kirkwood, and the maximum plausible dose from an outlier in this group, we define "small" as stones having mass less than 1 ct (0.2 g). Medium stones are (arbitrarily) defined as having mass between 1 and 10 ct, while large stones exceed that mass.

3) Area of skin exposed in the dose calculations

The area of skin exposed for the minimal distance described in the dose calculations is equal to the area of the disk used to simulate a topaz with 5 g mass, and is 0.78 cm². For the 10 cm distance, the exposure is maximal directly below the stone (perpendicular to the disk surface) and is equal to the tabulated value. To first order, any point 10 cm from the disk receives this dose, while for points further away the dose drops off approximately as the ratio of the distance squared, i.e. $D_r = 100/r^2$, where r is the distance from the disk

in cm. Thus, a point on the skin or inside the body (neglecting attenuation) 20 cm from the disk would receive approximately 25% of the calculated dose.

4) The sampling mass from 200 to 2000 g corresponds to the measurement system calibration.

I expect that there has been a misinterpretation of the information presented in the application, or lack of clarity on my part. The masses quoted above refer to the measurements of the full parcels using the high resolution Ge detection system for which self-shielding corrections are required. No parcels greater than 2000 g are permitted, and the correction for parcels lighter than 200 g is small and uses the values extrapolated from heavier masses. The calibration of the system is, therefore, adjusted according to the procedure described in the application. In this procedure unirradiated (and therefore non-radioactive) topaz is mixed with a known quantity of radioactive beads, each containing 30 Bq of ^{152}Eu . The measured activity provides an accurate assessment of the average attenuation of the ^{152}Eu gamma rays and thus, of the self shielding for radioactive topaz of the same mass. By making this measurement with the range of masses referenced, the self-shielding correction for any arbitrary mass in this range is established by interpolation or extrapolation.

5) Re: letter from Ideal Source International granting authority to William Yelon to make licensing decisions.

This letter will be drafted and sent to the NRC under separate cover during the week of Oct. 8, 2007.

With regard to my inquiry regarding the possibility of delivering to customers directly from the overseas location, after completion of tests on the selected samples, we agree to defer a request for such permission during the first six months of operation under the Import and Distribution License. During that period we would like to discuss this matter further with your office, to establish the conditions that might permit this practice, and, if appropriate, would prepare an amendment to our license. At this time, however, we do not wish to delay issuance of the license while matters of NRC policy are uncertain.