April 29, 2008

PAJ, Inc.
Attn: Joseph A. Corso
18325 Waterview Parkway
Dallas, TX 75080

Mail Control No. 022628

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Corso:

This refers to your Application for Material License, NRC Form 313, dated September 4, 2007, as revised, and the Technical Basis Document dated January 8, 2008, applying for a Nuclear Regulatory Commission exempt distribution license to distribute irradiated gemstones under the provisions of 10 CFR 32.11. We do not have sufficient information to complete the review of your application. In order to continue our review we ask that you provide the additional information discussed in subsequent paragraphs. The delay in issuing this request was caused by the need for our Office of Federal and State Materials and Environmental Management Programs (FSME) to request advice from the legal staff in the Office of General Counsel.

The following questions refer to the Technical Basis Document.

1. Comparison of irradiated gemstones with irradiated foods

   In the Introduction to your Technical Basis Document (TBD), you state "The Food and Drug Administration (FDA) has declared that foods irradiated with electron or gamma radiation is suitable for human consumption provided the energy of the incident gamma ray or electron radiation does not exceed 7.5 MeV, because food materials do not become activated when irradiated with lower-energy radiation." A review of the FDA's methodology and conclusions does not necessarily appear to allow an extrapolation to applicability to gemstones. The FDA concluded that these doses were sufficiently low to allow the statement to be made that irradiated foods are safe for human consumption. As indicated in our December 11, 2007, Request for Additional Information, the intensity of irradiation (total dose) for food is in the range of 3 to 4 orders of magnitude lower than that for gemstones, and the mechanisms of radiation interaction differ for food and gemstones. Activation is dependent upon fluence, once an activation threshold is exceeded. You indicated in the TBD that "virtually every element found in gemstones is also present in foods" . . . and "as such, it is reasonable to assume that food materials offer the same activation targets as do gemstones."

While this may be so, it is also possible that some elements found in gemstones may not normally be found in foods, and that the much larger doses delivered to gemstones may activate some elements to a degree sufficient to produce concentrations above the exempt concentration levels listed in 10 CFR 30.70, a situation that would not be evident without being subjected to an analytical process by a licensed distributor.

Given the lack of documented data on gemstones similar to the FDA's food irradiation studies, we are currently not confident that the results and conclusions of the FDA's studies can be applied directly to irradiated gemstones.

Please indicate whether empirical data are available to support your assumption "that food materials offer the same activation targets as do gemstones," and that the much larger doses to gemstones do not activate contaminants to the concentration levels above those of 10 CFR 30.70. Please provide any additional information you may have in support of this comparison, or indicate whether you wish to continue the application process without reference to this information.

2. Absolute vs intrinsic efficiency:

The table on pages 6 - 7 of the TBD lists detection efficiencies for a GM detector and a NaI(Tl) detector. This table indicates that the efficiency for all but two of the photon emissions is 5%. It is not clear how these values were determined, or whether the listed values refer to intrinsic efficiency or absolute efficiency.

- Various references indicate that intrinsic efficiencies for photons in the range of 0.32 to 1.69 MeV (those shown in the table) are in the range of about 50% down to about 25% for a source 1 cm from the center of the detector.

- The absolute efficiency is dependent upon the solid angle of the detector seen from the actual source position, and thus the distance of the source from the detector. In the footnote to this table the term "absolute counting efficiency" is defined as the product of the emission probability and the detection efficiency for a given photon. This does not appear to correspond to the accepted definition of absolute efficiency.

The absolute efficiency is defined as the ratio of the number of particles or photons detected to the number of similar particles or photons which have struck the sensitive volume:

$$\epsilon_{abs} = \frac{\text{number of pulses recorded}}{\text{number of quanta emitted by source}},$$

while the intrinsic efficiency refers to the ratio of the number of events recorded to the number striking the detector, and is determined by the energy of the photons and the atomic number, density, and thickness of the detector:

$$\epsilon_{int} = \frac{\text{number of pulses recorded}}{\text{number of quanta incident on detector}}.$$

For isotropic sources,

$$\epsilon_{int} = \epsilon_{abs} (4\pi / \theta)$$

where θ is the solid angle of the detector seen from the actual source position.

Per Knoll, "Radiation Detection and Measurement," second edition (1989), pp. 117-118: "A slight dependence on distance between the source and the detector does remain, however, because the average path length of the radiation through the detector will change somewhat with this spacing."

Please clarify how the efficiency values were determined, and whether the listed values refer to intrinsic efficiency or absolute efficiency. If you maintain that the term "absolute counting efficiency" is used correctly in the TBD, please cite a reference for this definition.

3. Methods for achieving minimum detectable activities (MDAs)

Background: The details of the survey procedure must be known before the required probabilities and detection limits can be calculated. A determination of the minimum detectable activity requires that the counting setup first be specified; i.e., it is necessary to establish the background count rate for the measurement geometry used, which in turn requires specification of the detector type, shielding, the time over which the background rate was determined, and the counting time for the sample. It is then necessary to specify the method of determination, for a specific count, whether activity above background was detected.

a. Please indicate what type of instrument is to be used for measuring the gemstones, namely is it a rate meter or a counting instrument.

b. Indicate the type and configuration of shielding to be used.

c. Indicate how the gems are to be scanned, whether a conveyor belt will be used, and if so, how its speed may affect the measurement process.

d. If a rate meter is to be used, please indicate how the MDA for this system is to be determined, based on the response time of the rate indicating circuits.

e. Indicate how the efficiency of the instrument(s) will be determined for the different types of radiation expected to be measured, how the background count rate will be determined, how long the sample will be counted, and any other details relevant to the remaining questions.

f. Based on the characteristics of your specific system, including efficiencies, counting times for background and sample, etc., describe the method to be used to decide whether or not a batch shows activity that is above background, and indicate the MDA that you expect to obtain and show that it meets regulatory requirements.

g. If a counting instrument is to be used, please provide details on the counting set-up, including: how is the background to be determined (how long a count is to be used), what is the counting time for the gemstones, and what net count is to be used to determine whether the indication of the instrument shows the presence or otherwise of radioactivity that differs from background.

h. Indicate any tests that will be performed on a regular basis to ensure that the detection system and its associated electronics continue to function properly without any changes over time that might affect the ability of the system to perform its intended function.

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).

If you have any questions, please contact me at (301)415-5477 or electronic mail: richard.struckmeyer@nrc.gov.

Sincerely,

/RA/

Richard K. Struckmeyer
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. 030-37542
Mail Control No. 022628

g. If a counting instrument is to be used, please provide details on the counting set-up, including: how is the background to be determined (how long a count is to be used), what is the counting time for the gemstones, and what net count is to be used to determine whether the indication of the instrument shows the presence or otherwise of radioactivity that differs from background.

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If you have any questions, please contact me at (301)415-5477 or electronic mail: richard.struckmeyer@nrc.gov.

Sincerely,

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Richard K. Struckmeyer
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