June 22, 2008

Mr. Richard Struckmeyer
State Agreements & Industrial Safety Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials and Environmental Management Programs
U.S. Nuclear Regulatory Commission

Re: Request for additional information, letter dated June 11, 2008

Dear Mr. Struckmeyer:

PAJ received the letter referenced above and is pleased to submit the following information in answer to your questions. We hope that the information provided will suffice to address the concerns you raise.

PAJ also notes that it has been almost a year since beginning the licensing process, and that PAJ has lost a great deal of business during this time. This length of time is longer than is required for many organizations seeking licensing for much higher levels and concentrations of radioactivity, including irradiators with hundreds of curies of radioactivity. In addition, PAJ notes that the concentration of radioactivity induced in gemstones is far lower than those found in many exempt radioactive materials, as noted in 10 CFR 30. For example, a single timepiece may contain up to 200 μCi of Pm-147, and electron tubes may contain up to 1 μCi of Co-60 or μCi of Cs-137; among many other specific exemptions. The amounts of radioactivity contained in all of these exempt items are far in excess of the amounts of radioactivity contained in irradiated gemstones, and they have the potential to produce a much higher radiation exposure than what has been reported from irradiated gemstones in the scientific literature and in NRC reports. Given that the scientific literature and NRC documents both agree that the radiation dose from irradiated gemstones is extremely low and that irradiated gemstones do not pose a risk to public health, the length of time spent and the amount of detail requested on this license application is curious.

PAJ hopes that the information provided in this document will suffice to address the remainder of NRC's concerns with our license application. PAJ further hopes that it will be possible to grant this license expeditiously to prevent the further loss of revenue.

1. *Comparison of irradiated gemstones with irradiated foods*

   a. *Page 1, last paragraph. It does not appear that our question concerning the applicability of the data pertaining to food irradiation has been fully addressed. Can it be said with certainty that nuclides other than those highlighted in the table (on page 2) cannot be activated? Does your evaluation take into account (a) nuclides not listed in the table that may be present in gemstones; and (b) the effect of bremsstrahlung on any nuclides that may be present?*

   b. *Although you provide calculations related to the nuclides listed in the table on page 2, it does not appear that you directly responded to one item in our letter of April 23, 2008, wherein we asked you to indicate whether empirical data are available to support your assumption "that food materials offer the same activation targets as do gemstones." Please indicate whether such empirical data are available.*

Major elements that are present in gemstones include Al, Si, O, H, F, C, Be, and Ca, with impurities that include Fe, Mn, Ti, Cr, Mg. While this list of elements is non exhaustive, it does include the great majority of elements found in gemstones, where they are irradiated or not.

Elements present in food as essential "minerals" include H, Na, Mg, K, Ca, V, Cr, Mn, Fe, Co, Ni, Cu, Zn, Mo, B, C, N, O, F, Al, Si, P, S, Cl, As, Se, and I; some of these elements are basic to organic chemistry (e.g. C, H, O, N), others are macrominerals that are found in all living organisms (e.g. K, Cl, Na, Fe), and the rest are essential minerals that can be found listed as ingredients in vitamins. Manganese, for example, is an essential trace element that is found in all living organisms. Magnesium is used in nucleic acid chemistry and is found in all plants, as a component of chlorophyll. Titanium, while having no known purpose in human nutrition, is found in virtually all plants, in human tissue, and in the tissues of all plant-eating animals. The role of these and other elements in biology and their presence in foods can be found in many human nutrition or biochemistry textbooks . *All* of the elements listed above are found in food that is irradiated. People do not eat rocks; for these elements to be essential minerals, and for them to be a necessary part of our diets, they must be present in foods as well.

Foods also contain elements that are not essential minerals. Minor concentrations of non-nutrient metals found in food include Li, Rb, Sn, As, Ge, Br, and most of the rare earth elements. In fact, one reference (*Trace Element Analysis of Food and Diet*, Aras and Ataman, Royal Society of Chemistry, 2006) summarizes information on 71 trace elements found in food; these elements, in addition to the major nutritive elements, comprise every known naturally

occurring element. **This means that every element that might be present in irradiated gemstones is also present in food, and that this fact has been reported in the scientific literature.**

The IAEA has published a lengthy reference (cited in the revised TBD) listing the activation cross sections for 164 isotopes of 47 elements, the majority of stable nuclides found in nature. These elements include all of those that comprise topaz, diamond, beryl-group minerals, and other gemstones that are currently subjected to irradiation (for example, the chemical formula for topaz is $Al_2SiO_4(F.OH)_2$; all of these elements are included in the IAEA database. The most common color-inducing impurities found in gemstones include Fe, Mg, Mn, Cr, and Ti; all of which are represented in the IAEA reference. **The elements reported by the IAEA represent over 97% of the mass of the earth's crust and more than 99% of the atoms found in the crust of the Earth.** Thus, the nuclides listed in the table mentioned represent the overwhelming majority of possible activation targets, including all major and virtually all minor constituents found in irradiated gemstones. While it cannot be said with certainty that there are no nuclides present that cannot be activated, it can be said that there is a high probability that the nuclides listed in the IAEA report from which this table was derived represent all but a tiny fraction of the atoms likely to be present in any irradiated gemstones.

Based on the above, PAJ notes that the scientific literature makes it clear that irradiated food materials offer the same activation targets that are present in irradiated gemstones. In fact, given the relatively limited elemental composition of gemstones and the fact that all known natural elements are present in food materials, there are more activation targets in food than are expected in gemstones. The scientific literature, as well as the scientific and professional opinion of Dr. Donald Cossairt, agree that activation is not expected in materials exposed to electron energies of less than 7.5 MeV. The analysis presented in the most recent communication to the NRC make it clear that the majority of atoms produced by neutron capture following electron irradiation at energies of less than 7.5 MeV are either stable or are very short-lived. The IAEA Handbook on Photonuclear Data and other scientific papers cited in earlier communications on this matter are clear that the primary interactions that take place in materials irradiated with high-energy electrons are due to the bremsstrahlung; therefore bremsstrahlung interactions are accounted for in the above discussion for both foods and gemstones.

PAJ also notes that the request for absolute certainty is not found in any aspect of health physics, and it seems an unreasonable standard to require in this instance. There is no area of health physics in which absolute certainty is demanded, and to require for such certainty in this one area seems inconsistent with other aspects of radiation safety practice and regulation. **PAJ contends that the scientific and technical references cited, the calculations performed, and the discussion presented in the TBD and other documents offer a satisfactorily high degree of certainty to assure the NRC that the public health and safety will not be adversely affected by granting PAJ's radioactive materials license application, based on**

the scientific and technical discussions presented in the documents submitted to the NRC in support of this license application.

2. *Absolute vs intrinsic efficiency*

   a. *Note that in the footnote to the table on pages 4 - 5 of your TBD, you state that the absolute counting efficiency is the product of the detection efficiency and the emission fraction. Yet in your May 26, 2008, reply to question 2 in our letter of April 23, 2008, you state "Absolute counting efficiency is used in the TBD in the same manner mentioned in this letter - the intrinsic counting efficiency multiplied by the geometric counting efficiency." Please provide further clarification concerning the definitions related to counting efficiency.*

The absolute counting efficiency is as described by the NRC – the intrinsic counting efficiency multiplied by the geometric counting efficiency multiplied by the emission fraction for the radiation of interest. The intrinsic counting efficiency refers to the fraction of radiation entering the detector that is registered as a count. The geometric counting efficiency refers to the fraction of radiation emitted that is intercepted by the detector. Thus, a detector that has an intrinsic counting efficiency of 80% and a geometric counting efficiency of 50% will have an absolute counting efficiency of 40% (80% x 50% = 80%) because 40% of the radiation emitted by the nuclide being counted will be detected by the probe.

If the radiation of interest is emitted by the nuclide in question in less than 100% of decays, the efficiency calculated above must be multiplied by the emission fraction. In this case, to continue the hypothetical example given above, the absolute efficiency of a gamma radiation detector for a nuclide in which gamma radiation is emitted with an emission probability of 15% would be 6% ($\varepsilon_{abs}=\varepsilon_{int} \times \varepsilon_{geo} \times I_\gamma$, where ε refers to, respectively, the absolute, intrinsic, and geometric counting efficiencies, and I_γ is the intensity, or probability of a particular gamma emission). So, in this example, the absolute efficiency is equal to 80% x 50% x 15% = 6%.

We understand that earlier documents used imprecise terminology to explain this point, and we apologize that these earlier documents have given rise to this confusion.

   b. *You indicated that your procedure will involve counting a sample of 5 grams for a total of 5 minutes. Please indicate how the size(s) of the gemstones in a sample will affect the efficiency (for example, would a detector at one cm from a large gemstone result in a larger or smaller efficiency than several smaller gemstones?). Also, would the efficiency be significantly dependent upon the energies involved?*

Large gemstones will provide slightly more shielding than an equivalent weight of smaller gemstones because the greater thickness of the gemstone provides a higher degree of shielding for nuclides within the gemstone. This effect is most noticeable for low-energy beta emitters. The majority of irradiated gemstones are relatively small – a few mm to a cm in diameter and a few mm thick. A 1 gram (5 ct) blue topaz, for example, has a total volume of about 1/3 cm^3 which, as a sphere, would be about 0.7 cm in diameter, with a radius of 0.35 cm (3.5 mm). In reality, gemstones are not spheres, and a 5 ct blue topaz is more likely to be no more than about 3 mm (0.03 cm) thick. With a density of about 3.5 gm/cm^3, the density thickness of this gemstone would be about 0.15 gm/cm^2, meaning that the most material a beta would have to penetrate would be 0.15 gm/cm^2 and the majority of the beta particles would have less than about 0.1 gm/cm^2 of topaz. The majority of irradiated gemstones sold by PAJ are 5 ct in weight or less, and none exceed 10 ct. A 10 ct gemstone has a depth of about 6.2 mm (0.0062 cm), and, due to the way that gemstones are faceted, over 80% of the volume is within 3 mm of the surface of the gemstone. Accordingly, 80% of any induced radioactivity will be at a density thickness of less than 0.15 gm/cm^2 from the surface of the gemstone.

Among the nuclides reported in the scientific literature to be produced in irradiated gemstones(see the citations in the TBD), only P-32 is a pure beta emitter, and the range of these beta particles is about 0.8 gm/cm^2, which encompasses about the entire volume of a 10 ct gemstone. Thus, the counting efficiency of P-32 in a large (6.2 mm thick) gemstone will be about ½ that of a thinner gemstone. However, the counting efficiency for P-32 is quite high – typically between 35-40% with a GM "pancake" probe. Given the assumed counting efficiency of 8% used for calculations in the TBD, the counting methodology proposed in the TBD is adequate to detect P-32 at or below the exempt concentration limits. The other major nuclides noted in the TBD emit both beta and gamma radiation; the gamma radiation will not be substantially attenuated by passing through the density thickness of a 10 ct gemstone. Thus, it is reasonable to assume that induced radioactivities can be detected in large gemstones at concentrations equal to or greater than exempt concentration limits.

3. *Methods for achieving minimum detectable activities (MDAs)*

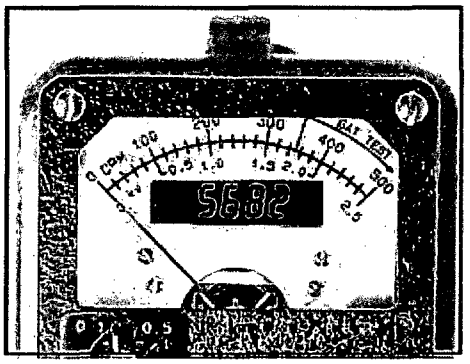
With regard to your reply to questions 3.a. and 3.d., we request that you provide additional information about the instruments that you intend to use.

a. *In 3.a. you state: "The meter to which the probes will be attached will be used to indicate the total number of counts (the integrated counts) over the counting period." This seems to indicate that the two probes will be attached at the same time. What would be the meaning of the combined count, considering that the efficiencies of the two meters are different, as well as their energy responses?*

Two separate counts will be performed, one count with each detector. This will be accomplished by performing one count with one detector, recording the results, changing probes, and performing a second count with the second detector.

b. *In 3.d. you state: "Although a rate meter will be used, the meter will be used to measure the integrated counts over a 5-minute counting period. Thus, the meter will not be used in rate meter mode and the response time of the meter will not affect the sensitivity of the measurement system." Please explain how you will obtain the integrated count from the rate meter.*

Ludlum produces and sells an attached scalar feature that records integrated counts for various periods of time. PAJ has obtained meters that include this scalar feature, which will be used to record integrated counts as noted earlier. Please note the image below, from the Ludlum Instruments catalog.



Part No. 4464-114

Portable Scaler Option

SCALER: 5 1/2 digit LCD display with 0.25"(0.64 cm) digits, overflow arrow, and colons to indicate when a count is in process. *(Cannot be used with Model 16.)*
RANGE: 0-199999 counts
COUNT: Pushbutton in handle to initiate scaler count
COUNT TIME: Selectable times of 0.1, 0.5, 1, 2, or 10 minutes
NOTE: If customer wishes to modify existing instruments, use part no. 4464-127. *(Only portables with serial numbers greater than 69769 can be modified.)*

c. *Based on your reply to our question 3.f., it is our understanding that you intend to determine the MDA using the most conservative case shown in the table on page 9 of your reply (page 11 of your revised TBD). Please verify this. Does this take into account the possibility that other nuclides may be present that are not listed in the table (as discussed in 1.a., above)?*

This assessment is correct on both points.

4. *Additional questions, clarifications, and comments*

a. *It is our understanding, based on the references to NRC documents (NUREGS) you have cited, that the analysis and methodology described in your submittals are*

applicable to topaz, and not other types of gemstones. Please confirm that the type of gemstone you intend to analyze is topaz, or if this is not the case, please describe the other gemstones that you intend to analyze and state how the methodology you have described is applicable to those gemstones.

PAJ's license application states that it is intended to apply to any irradiated gemstones. However, the scientific literature (and NRC documents) primarily address blue topaz, which is why the references cited in the TBD topaz. The methodology described in the PAJ license application, the Technical Basis Document, and other communications is acceptable to detect induced radioactivity in any irradiated gemstones, not just blue topaz.

b. *Will all electron-irradiated gemstones be analyzed, or only those electron-irradiated gemstones that were irradiated with an electron beam energy above 7.5 MeV?*

Because only gemstones that are irradiated with electron beams whose energy exceeds 7.5 MeV may become activated, gemstones irradiated with lower-energy electron beams are not byproduct material and do not require licensing. Accordingly, PAJ does not need to survey gemstones irradiated with electron beam energies of less than 7.5 MeV. **However, given the concerns raised by the NRC on this issue, PAJ is willing to perform surveys on all electron-irradiated gemstones to demonstrate that activation products are not present.**

c. *How will detector efficiency be determined of the final setup to verify that it is at least 5%?*

Detector efficiency will be determined for radiations of relevant energies during instrument calibration by the calibration facility. Instrument efficiency can be determined by placing a radioactive sealed source of known strength in the counting setup and positioning the probe and source in the same positions as during counting, and the net count rate (cpm displayed – background count rate) will be determined. The counting efficiency is equal to the net cpm divided by the source activity (using the conversion factor that 1 μCi = 2.22×10^6 dpm). The results of these measurements will be recorded by PAJ to confirm that detector efficiency is greater than 5% for the radiations of interest.

d. *In addition to the ongoing quality control measures you have stated, it is recommended that you perform a weekly chi-square test.*

Noted. This requirement will be added to the PAJ procedures.

e. *If you expect long production (counting) runs, e.g., in excess of 6 to 8 hours, it is recommended that you perform the source strength check more frequently than daily.*

For "d" and "e" above, please indicate whether these recommendations will be implemented, or an alternative means of achieving these goals is proposed.

PAJ receives only a few shipments daily, and does not expect to have long counting runs. If counting is required over a prolonged period of time, or if more than 6 hours passes between performing initial checks and the need to perform further counting, PAJ will perform additional source checks. This requirement will be added to the PAJ counting procedure.

Best regards,

Joe Corso, RSO
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