January 9, 2008

Mr. Duncan White,
Division of Materials Safety and State Agreements,
Office of Federal and State Materials and Environmental Management Program,
Mail Stop T-8E24,
U.S. Nuclear Regulatory Commission,
Washington, DC, 20555-0001

**Re: Revised Application for License for the Distribution of Exempt Materials**

Dear Mr. White:

PAJ appreciates your comments on our original radioactive materials license application, and we are pleased to submit these revised documents for your consideration. This submission contains three documents:

- The revised radioactive materials license application
- A revised Technical Basis Document
- A summary of the manner in which PAJ addressed each comment made during NRC review of our original documents.

PAJ would like to note that the survey methodology outlined in this license application and the attached TBD is intended to be performed using hand-held survey instruments and does not include the use of gamma spectroscopy. The attached TBD demonstrates that our proposed survey methodology is sufficient to detect the presence of any single radionuclide, even the most limiting case, at the exempt concentration limit specified in 10 CFR 30.70. PAJ's intention is that the receipt surveys are screening surveys, to detect the presence of radionuclides that are present at concentrations that exceed exemption limits. As such, survey records for received gemstones in which the results are lower than these levels will be logged as "< MDA". If the screening survey indicates higher levels of radioactivity, the gemstones may be sent for quantitative analysis at a facility licensed to perform such analyses or they may be stored by PAJ until radioactivity concentrations have decayed to levels lower than these screening criteria.

PAJ also notes that this approach appears consistent with both regulatory requirements and with screening criteria for alpha- and beta-emitting radionuclides. For example, alpha spectroscopy or liquid scintillation counting to identify and quantify alpha- and beta-emitting radionuclides has not been requested of other licensees, in spite of the fact that neutron irradiation is capable of inducing both alpha- and beta-emitting radionuclides in irradiated gemstones. The use of screening criteria, including counting with a GM "pancake" detector is adequate to screen irradiated materials for the presence of all of these radioactivities.

In addition, we note that the introduction to NUREG 1556 vol. 8 states:

*"This document provides assistance to applicants and licensees in preparing license applications. It also describes the methods acceptable to NRC license reviewers in implementing*

*the regulations and the techniques used by the reviewers in evaluating the applications to determine if the proposed exempt distribution activity is acceptable for licensing purposes.*

*The guidance contained herein does not represent new or proposed regulatory requirements, and licensees will not be inspected against any portion of it. Additionally, regulatory compliance with all applicable regulations is not assured by licensees who adopt any portion of, or apply the principles described in, this guidance."*

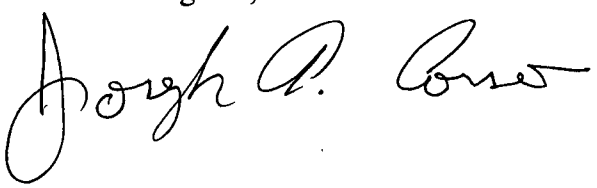
PAJ's interpretation of this, especially the second paragraph, is that it represents guidance ***suggested*** by the NRC to show compliance with the regulatory requirements of 10 CFR 30. This is consistent with the previously stated observations regarding the detection and quantification of alpha and beta emitters.

Thus, it appears as though the intent of this section of NUREG 1556 vol. 8 is to assure the NRC and the public that items released into the public domain do not exceed exempt concentrations; the methodologies outlined in the PAJ license application, as supported by the TBD, are adequate to provide this assurance, even without identifying each individual nuclide. In addition, nuclide identification and quantification may be performed via gamma spectroscopy (performed by a licensed facility) when screening surveys that show the presence of radionuclides present in excess of exemption concentration limits. Thus, the proposed survey screening methodology is sufficient to meet both the letter and the intent of the regulations. Gemstones that do not meet these screening criteria will be returned to the vendor, held until screening criteria are met, or sent to a licensed facility for quantitative analysis.

10 CFR 32.11 states that the licensee should "Provide…initial concentration of the byproduct material in the product or material…." However, as written, this section of the regulations does not specify that such concentrations must be stated in units of pCi/gm, Bq/gm, or any other units of radioactivity concentration. Every analytical method has a lower detection limit, and results are neither expected nor reported for concentrations less than this limit. Accordingly, PAJ feels that it is appropriate to state that gemstones distributed to the public will contain radionuclide concentrations that are lower than the exempted concentrations noted in 10 CFR 30, and that the exact concentrations will vary from gemstone to gemstone. Analytical results will be reported as less than exempt concentration limits, and raw data will be kept on file for review.

We are eager to complete this radioactive materials license application as quickly as possible to minimize the economic losses that recent regulatory changes have caused. To that end, please feel free to contact us at your earliest opportunity with any questions or comments you may have.

With best regards,



## Reply to specific NRC comments

The following table summarizes PAJ's response to the comments made by the NRC during review of the PAJ radioactive materials license application and the attached Technical Basis Document. Some points are discussed in greater detail in the section following this table.

| NRC Comment | PAJ reply |
|---|---|
| A 1 | PAJ has been issued a radioactive materials license by the State of Texas. A copy of this license is attached to this letter. |
| A 2 | Radiological screening procedures that are based on the technical basis document are sufficient to identify irradiated gemstones that contain radionuclides in excess of exemption criteria. These procedures have been revised to reflect NRC comments on the TBD and this reply to these comments. Gemstones that do not pass these screening criteria (those that are above the MDA) will returned to the vendor, held until screening criteria are met, or will be analyzed by a licensed facility to identify and quantify the nuclide(s) present. |
| A 3 | PAJ concurs that exposing neutron-irradiated gemstones to accelerator-produced radiation may result in an increase in radioactivity in such gemstones. As discussed in the TBD, gemstones that are treated in accelerators at sufficiently high energies as the last processing step will be surveyed prior to release as exempt materials. This section of the license application has been revised to reflect the language cited in your comments. |
| A 4 | The process described in the revised license application and in the revised Technical Basis Document is adequate to identify the presence of any single radionuclide that is present at or above exemption limits. |
| B | The license application has been modified to include a more detailed description of record-keeping procedures and to specify that the required reports will be filed annually. |
| C 1 | Neutron-irradiated gemstones that have been distributed by an NRC-licensed facility are required to be found in compliance with 10 CFR 30, in order to be released to the public as exempted materials. Once found to be exempt, such gemstones do not require further characterization. This part of the TBD was phrased poorly and was not intended to imply that neutron-irradiated gemstones are anything other than byproduct materials. It was simply intended to state that, once found to be exempt, there is no need for further licensing or surveys, provided that the gemstones are not subjected to any further processing that is capable of inducing radioactivity. |
| C 2 | This point is discussed in greater detail in the text following this table. |
| C 3 | Major and minor radioactivities are now defined in the TBD and in the license application. |

| | |
|---|---|
| C 4 | With the exception of P-32 and C-14, none of the nuclides noted decay only by beta emission; all other nuclides are detectable using gamma-sensitive survey meters. Assuming a lower counting efficiency to account for self-absorption, we find that the number of counts per minute from P-32 is detectable using hand-held counting instruments. In addition, the proposed counting procedure has been modified to produce a lower detection limit by utilizing a shielded detector to reduce background count rate, using a larger sample size to increase the total amount of radioactivity present, and utilizing a longer counting time; these changes cause a significant improvement in the counting statistics and detection limits, as shown in the revised TBD. This is described in greater detail in the revised TBD.<br><br>S-35 is a more problematic case because of the lower energy and the lower counting efficiency. However, although S-35 has been identified in neutron-irradiated gemstones (presumably via the S-34 (n, $\gamma$) reaction, its presence has not been reported in accelerator-irradiated gems and it is not expected to be formed. This is discussed in greater detail in the revised TBD.<br><br>Finally, we also note that neutron-irradiated gemstones must be released for exempt distribution by the neutron processing center, which will (presumably) determine that levels of S-35 and other low-energy betas are lower than exemption limits. As such, PAJ is not required to attempt to characterize beta emitters from reactor-irradiated gemstones that have been processed by a licensee. |
| C 5 | These editorial changes have been made as suggested – thanks! |

**Food irradiation versus gemstone irradiation**

In the TBD it was noted that the FDA has accepted irradiated food as suitable for human consumption, provided the radiation energy does not exceed 7.5 MeV, because radiation at such energies is incapable of inducing radioactivity. The NRC comment on this part of the TBD has several parts, each of which is addressed separately.

1. *The elemental composition of food materials differs considerably from that of gemstones*
   It is true that food consists primarily of hydrogen, nitrogen, carbon, and oxygen. However, food contains a great many impurities, many of which are identical to those found in irradiated gemstones. In fact, the abundance of impurity elements in food (i.e. nutrients) can have considerable overlap with the chemical impurities found in gemstones. Some of these "impurities" include iron (red meats, spinach, eggs, soybeans, etc.), calcium (milk and dairy products), and essential elements such as sodium, sulfur, and potassium (essential elements found in all organisms). Micronutrients that are necessary for human life (and that are also found in many foods) include boron (found in all plants), cobalt (vitamin B12), chlorine (salt), chromium (found in mammalian tissues and required for sugar metabolism), copper (found in many shellfish), iodine (sea salt, seafood, seaweed), selenium (nuts, cereal grains, meat, fish, eggs), zinc (found in most animal proteins), and others. In addition to these vital nutrients, foods contain a wide variety of other elements – including uranium radium, thorium, and other heavy elements

that are summarized nicely in Eisenbud and Gesell's book on environmental radioactivity. All of these elements are present in irradiated foods, and all are activation targets. In fact, food materials may contain a higher abundance of these "impurities" than do gem-quality minerals because a high abundance of impurities can cause opacity, murkiness, and other factors that cause a loss of value. Accordingly, it is reasonable to assume that food irradiation offers the same opportunities for radioactivity induction as do gemstones.

Incidentally, it is interesting to note that the activation threshold energy for deuterium (which is naturally present at 0.01% of hydrogen and, therefore, is present in foods in very high concentrations compared to the impurities we detect in gemstones) is only 2.22 MeV. In spite of this, the FDA considers is acceptable to ingest foods exposed to radiation energies of up to 7.5 MeV. It is also interesting to note that hydrogen (and deuterium) is very rare in gemstones.

2. *The radiation dose administered to gemstones is 3-6 orders of magnitude greater than that administered to food*
   This is true. However, in the TBD we note that there is a threshold energy for activation of at least 7.5 MeV (with the exception of gemstones containing beryllium, for which the activation threshold energy is 1.66 MeV). If the irradiator energy is less than this activation energy, ***no*** radioactivity will be induced, regardless of the overall dose to which the gemstones have been exposed. This is described in detail in the revised TBD.

   ***Accordingly, it seems appropriate to consider that gemstones (with the exception of beryl-group gemstones and zircons) irradiated with accelerator energies of less than 7.5 MeV cannot be made radioactive and, therefore, are not byproduct materials.***

   The TBD and the license application only address byproduct materials – materials that have been made radioactive by exposure to a man-made source of radiation. As such, for gemstones that are exposed only to irradiator energies less than the activation threshold, the integrated radiation dose to which the gemstones have been exposed is irrelevant.

3. *Food is normally irradiated via bremsstrahlung radiation generated in a target, while gemstones are exposed directly to the electron beam.*
   According to references cited in the TBD, exposure of materials to high-energy electron radiation is primarily due to induced bremsstrahlung[1]. This is confirmed by Weeks and O'Shea (1998), who state "Electrons can produce radioactivity via conversion of their kinetic energy into electromagnetic energy (photons) followed by the subsequent absorption of those photons by nuclei." Further in this paper, the authors state that electrons can also directly cause activation via direct excitation of the nucleus, but that "The cross section for activation of materials (by this process) was observed to be roughly 100 times less than the photon activation cross sections." As such, the forms of interaction are virtually identical in both foods and gemstones, with the exception of the

[1] According to Auditore et al. (2004), Cossairt (1996, and personal communication in 2007), and documents published by the IAEA, high-energy electrons striking a target generate high-energy photons via bremsstrahlung, and these bremsstrahlung photons can then produce neutrons via the photo-neutron effect.

outermost layer of the gemstones (where the radioactivity is easiest to detect), and those layers that are exposed to direct electron radiation have an activation cross-section that is about 2 orders of magnitude lower than for photon activation. In addition, the previous comment regarding exposure to radiation below threshold energies remains relevant. These are discussed in greater detail in the revised TBD.

**Summary of response to NRC comments**

NRC comments A1, A3, C1, C3, and C5 have been corrected in the revised documents that are attached.

NRC comments A2, A4, and B all pertain to the ability to identify and quantify individual radioactivities in irradiated gemstones so that PAJ may release these gems as exempt from regulation. The NRC has suggested that PAJ obtain gamma spectroscopy equipment to perform this assessment. PAJ notes that the procedures outlined in the revised TBD are adequate to identify the presence of radionuclides listed in 10 CFR 30.70 at exempt concentration limits and that any gemstones that do not meet these screening criteria will be returned to the supplier, stored until radionuclide concentrations drop to below screening criteria, or sent to a licensed facility for quantitative analysis. The procedures outlined in the TBD and in the license application (as revised according to NRC comments) are adequate to demonstrate compliance with 10 CFR 30.

PAJ has addressed NRC comment C2 (regarding food irradiation) by noting that:

1. Food items do, indeed contain measurable concentrations of the same chemical elements found in gemstones
2. There is a photo-neutron activation threshold energy below which radioactivity formation is impossible, and that (with the exception of beryllium) energy is less than 7.5 MeV for all elements that have been observed as impurities in those gemstones that are irradiated; making the total administered radiation dose irrelevant to the induction of radioactivity.
3. The scientific literature states unequivocally that the most important interaction between high-energy electrons and irradiated materials is that of bremsstrahlung photons, and that the activation cross-section for electron activation is lower by a factor of about 100.
4. Accordingly, it is appropriate to apply the FDA threshold activation energy of 7.5 MeV to irradiated gemstones, with the exception of those in the beryl group.

In response to NRC comment C4, PAJ notes that, with the exception of P-32 and S-35, all radionuclides that have been reported in irradiated gemstones emit gamma as well as beta radiation, obviating the impact of self shielding. In addition, PAJ notes that, even with substantial self-shielding and subsequent loss of counting efficiency, it is possible to detect exempted concentrations of P-32 in irradiated gemstones. Finally, PAJ notes that, while S-35 has been reported in neutron-irradiated gemstones, such gemstones will be analyzed and released for exempt distribution by an NRC licensee and do not require further characterization by PAJ. For those gemstones that are accelerator-irradiated, PAJ further notes that the formation of S-35 is highly unlikely owing to the low abundance of target atoms, the high threshold activation energy, and the fact that the scientific literature does not report the presence of these elements in the gemstones that are irradiated. In addition, we note that sulfur-containing minerals are almost invariably too soft and too ugly to be considered gemstones. Accordingly, references to S-35

have been removed from the TBD, and counting efficiencies and expected beta count rates are now noted only for P-32 – the only nuclide for which beta counting is necessary.

Based on all of the above, PAJ feels that the following statements remain scientifically appropriate and are consistent with regulatory compliance:

1. Gemstones exposed to electron or photon radiation with an energy of less than 7.5 MeV (1.66 MeV in the case of beryl-group gems) are not byproduct materials and do not require regulation.
2. Regulations do not require that every nuclide be identified and quantified, provided that PAJ can offer reasonable assurance that nuclides do not exceed exempt concentration limits. This interpretation of the regulations is consistent with the NRC's stance regarding the identification and quantification of alpha- and beta-emitting nuclides.
    a. In fact, regardless of detection methodology, it is accepted practice to note that radionuclide concentrations are "< MDA" when radionuclide concentrations are lower than the instrument sensitivity. Gemstones found to contain radionuclide concentrations above exempt concentration limits will not be released for sale; thus it is not necessary to identify every nuclide present.
3. The methods outlined by PAJ in the attached revised license application and TBD are adequate to detect the presence of radionuclides in irradiated gemstones that are at the exempt concentration limits.
4. Finally, PAJ proposes to use handheld survey instruments to perform screening of incoming shipments containing irradiated gemstones, noting that these techniques are sufficient to show the presence or absence of radionuclides at the exemption limit. Any gemstones that do not meet these screening criteria will be sent for further analysis to identify and quantify the nuclide(s) that are present.

Department of State Health Services

# RADIOACTIVE MATERIAL LICENSE

Pursuant to the Texas Radiation Control Act and Texas Department of State Health Services (Agency) regulations on radiation, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the Agency now or hereafter in effect and to any conditions specified below.

| LICENSEE | This license is issued in response to correct an error |
|---|---|
| 1. Name: PAJ INC<br>DBA PRIME ART & JEWEL | |
| 2. Address: ATTN JOSEPH CORSO<br>18325 WATERVIEW PKWY<br>DALLAS TX 75252 | 3. License Number: L06115 — Amendment Number: 01 |
| | PREVIOUS AMENDMENTS ARE VOID |
| | 4. Expiration Date: October 31, 2017 |

RADIOACTIVE MATERIAL AUTHORIZED

| 5. Radioisotope | 6. Form of Material | 7. Maximum Activity* | 8. Authorized Use |
|---|---|---|---|
| A. Any radioactive material with atomic number from 1 to 83 | A. Solid in gemstones | A. No single radionuclide to exceed 2 mCi<br>Total: 20 mCi | A. Possession of radioactive activation products in gemstones incident to distribution pursuant to USNRC Exempt distribution license. |
| B. Any radioactive material with atomic number from 84 to 96 | B. Solid in gemstones | B. 1 μCi total | B. Possession of radioactive activation products in gemstones incident to distribution pursuant to USNRC Exempt distribution license. |

* Ci-Curies mCi-Millicuries μCi-Microcuries nCi--Nanocuries

9. Radioactive material shall only be stored at:

| Site Number | Location |
|---|---|
| 000 | Dallas – 18325 Waterview Pkwy. |

10. Each site shall maintain documents and records pertinent to the operations at that site. Copies of all documents and records required by this license shall be maintained for Agency review at Site 000.

11. This license does not authorize distribution of radioactive material. Distribution can only be authorized by a United States Nuclear Regulatory Commission (USNRC) Exempt Distribution License.

12. The individual designated to perform the functions of Radiation Safety Officer (RSO) for activities covered by this license is Joseph Corso.

13. The licensee shall comply with the provisions (as amended) of Title 25 Texas Administrative Code (TAC) §289.201, §289.202, §289.203, §289.204, §289.205, §289.251, §289.252 and §289.257.

Department of State Health Services

# RADIOACTIVE MATERIAL LICENSE

| LICENSE NUMBER | AMENDMENT NUMBER |
|---|---|
| L06115 | 01 |

14. The licensee shall conduct a physical inventory every six months to account for all radioactive material received, and possessed under the license. The records of the inventories shall be maintained for inspection by the Agency for three years from the date of the inventory and shall include the radionuclide, number of curies, location of each source of radiation, the name of the individual making the inventory, and the date of the inventory.

15. The licensee is required to notify and supply the Agency with a copy of the USNRC Exempt Distribution License when issued.

16. Survey instruments used to determine radioactive content of gemstones shall have documentation verifying the instrument/detector sensitivity is appropriate for the isotopes present in the gemstones.

17. Except as specifically provided otherwise by this license, the licensee shall possess and use the radioactive material authorized by this license in accordance with statements, representations, and procedures contained in the following:

    applications dated September 6, 2007, and October 24, 2007,
    letters dated October 10, 2007, October 24, 2007 and October 30, 2007, and
    facsimile dated October 24, 2007.

    Title 25 TAC §289 shall prevail over statements contained in the above documents unless such statements are more restrictive than the regulations.

RRF:rrf

FOR THE DEPARTMENT OF STATE HEALTH SERVICES

Date November 6, 2007

Michael L. Dunn, Chief
Industrial Licensing Program