Prism (U.S.A.) Application for NRC Exempt Distribution License

The following information is provided to support NRC Form 313, "Application for Materials License", and it follows the guidance in Appendix G to NUREG-1556, Volume 8.

Please note that for all correspondence associated with this application, a copy should be sent to the following:

Alpesh Jiwani
Prism (U.S.A.) Inc.
22 West 48th St., Suite 1201
New York, NY 10036

The New York State Department of Health has licensing jurisdiction for the Radioactive Materials License for possession of the materials, and the NY State License No. 12-271 is being applied for concurrently.

A. Basic Information
    1. Prism (U.S.A.) Inc.
    2. 22 West 48th St., Suite 1201
       New York, NY 10036
    3. 212-596-4163
    4. Locations
        a. Where gems will be received and possessed is 22 West 48th St., Suite 1201, New York, NY 10036.
        b. From which irradiated gems will be distributed to persons exempt from licensing: same as 4.a.
        c. At which records pertaining to possession and distribution of irradiation gems will be maintained: same as 4.a.

B. Background Information
    1. Describe the material to be imported
        a. Diamonds
        b. Cut and polished gems will be irradiated and imported to Prism U.S.A. Inc.
        c. Process is irradiation with 1.0 MeV electron beam, followed by heating.
        d. The diamonds are irradiated in two locations:
            - By Anand International in Mumbai, India using a 1.0 MeV electron beam accelerator.
        e. No additional irradiation is performed.
        f. Not applicable, as there is no activation of the gems due to low energy electron beam irradiation.
        g. No radionuclides are expected, as there is no activation of the gems due to low energy electron beam irradiation. However, as a precaution, gamma spectroscopy will be used to verify that concentrations are below those listed in 10 CFR 30.70, Schedule A.
        h. A sample batch of diamonds was evaluated using gamma spectroscopy, and the results are included as Attachment 1.
    2. No radioactive materials are expected; and we anticipate having less than 1 microcurie of activity in the diamonds at any time, including natural activity.
    3. Describe the handling of the gems.

a. Since a low energy linear accelerator is used, there will be no radioactive contamination, and therefore there is no specific check for removable contamination. However, an evaluation of each batch of diamonds will be performed to ensure concentration below the limits of 10 CFR 30.70, Schedule A.

b. Processing of the diamonds is as follows:
   - Selection, cut and polishing of the diamonds.
   - Irradiation using a 1.0 MeV electron beam accelerator in Mombai, India.
   - Packaging the diamonds into lots, and sending lots to Prism USA Inc. in New York, NY.
   - Transfer the lot of diamonds to a laboratory vendor to test for radioactivity using gamma spectrometry.
   - After laboratory has determined that concentrations are below10 CFR 30.70, Schedule A values, the diamonds can be distributed as exempt materials.

c. The categories of unlicensed organizations to which irradiated diamonds will be transferred to include the following: wholesaler, manufacturing jewelers, retail jeweler, and individual consumers.

d. Radioactivity above the criteria specified in 10 CFR 30.70 Schedule A is not anticipated; however, if it were to occur, the diamonds would be transferred to a person licensed to receive these materials.

C. Information required by 10 CFR 32.11:

1. A license for possession of radioactive materials from the New York State Department of Health has been applied for concurrently.

   a. The use of a low energy linear accelerator is the primary method for assuring the health and safety of individuals who come in contact with the diamonds, because no activation of the diamonds is expected. The diamonds will be maintained in a secure safe in the office area; however, this is primarily for resource protection and not for radiation protection.

   b. Describe the individuals responsible for the various aspects of the process, and describe the training and experience of each.

      - Irradiation in Mombai, India by Anand International. Responsible individuals are Ashok Majali and D. S. Lavale. Their resumes are included in Attachment 2.

      - Receipt, handling, storing, counting, and controlling release of irradiated gems: These responsibilities are performed by Alpesh Jivani. His resume is included in Attachment 2.

      - Evaluation of radioactivity content: CoPhysics Corporation, Theodore Rahon, CHP, PhD will be supervising the radiological analysis. His resume is attached as Attachment 3.

2. Information required by 10 CFR 32.11(b):

   a. Diamonds will be irradiated and since the energy of the electron beam is low (1.0 MeV), no radioactivity will be induced.

b. Intended use of diamonds is as jewelry.

c. The method of introduction of byproduct material is by electron beam irradiation; however, as previously stated, no activity is expected to be introduced.

d. Initial concentration of radioactive material is expected to be less than the values listed in 10 CFR 30.70, Schedule A, and typically less than 0.00001 microcurie per gram, as analyzed in a batch of 3 grams or greater.

e. Estimated maximum concentration of radioisotopes at the time of transfer to persons exempt from licensing is expected to be less than the values listed in 10 CFR 30.70, Schedule A, and typically less than 0.00001 microcurie per gram.

f. Control methods to assure that no more than the specified maximum concentration is in the product: primary method is use of a low energy accelerator that does not add radioactivity to the gems. In addition, gamma spectroscopy will be performed with detection capability sufficient to assure that the concentrations are less than those specified in 10 CFR 30.70, Schedule A.

g. The estimated time from irradiation to transfer to an unlicensed person is anticipated to be 30 days or longer.

3. 10 CFR 32.11(c) requires reasonable assurance on the following:

a. Concentrations will not exceed the concentrations in 10 CFR 30.70, Schedule A. This will be confirmed by use of gamma spectroscopy at a laboratory vendor experienced in low level counting. The vendor procedure is shown in Attachment 4, and a sample gamma analysis is shown in Attachment 1.

b. No reconcentration will occur because the low energy electron beam is the only irradiation that takes place. Heat treatment of the diamonds takes place after the irradiation, and no radioactivity is induced during the heat treatment.

c. The limits listed in 10 CFR 30.70, Schedule A are used as benchmarks; however, it is anticipated that the actual concentrations in the licensee's gems will be well below those in Schedule A. It is possible to use lower values than Schedule A; however, as the values decrease further, the limitation will become one of long count times and expense for analysis. As stated in the NRC fact sheet for irradiated gemstones, the highest level of radioactivity allowed for distribution under NRC regulations would result in an annual dose of 0.03 millirem. Therefore, reduction of the 10 CFR 30.70, Schedule A values would not provide a substantial dose reduction.

d. The diamonds are intended to be used as jewelry, and are not likely to be incorporated into any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by humans.

D. Information on Quality Assurance (QA) Program

The QA program for laboratory analysis will be contracted to a commercial laboratory. Laboratories to be used include:

- CoPhysics Corporation, located at 1 Commercial Drive, Florida, NY 10921, manager: Theodore Rahon, CHP, PhD. The mailing address for CoPhysics is 1242 Route 208, Monroe, NY 10950. is.

- any NELAP accredited laboratory

The minimum requirements for laboratory QA follow:

1. The instrumentation used is a HPGe detector, with a minimum 8000 channel Multichannel Analyzer. The detector is cooled with liquid nitrogen and is in a minimum 4" thick lead shield.
2. The detector is calibrated annually, with daily source checks when in use. Standards are traceable to the National Institute of Standards and Technology.
3. An example counting procedure is included as Attachment 4. Information requested is provided in the procedure, with additional information and clarification provided below:
    a. Selection of samples: as provided from Prism USA Inc. by lot.
    b. Minimum sample size: 3 grams; Maximum sample size: 400 grams
    c. Counting efficiency determined as per procedures (Attachment 4)
    d. Counting times determined as per procedures (Attachment 4)
    e. The diamonds will fit into one of the following calibrated geometries: 10 ml Petri dish, 200 ml jar, or other geometries routinely used by the laboratory
    f. The time of counting following irradiation is typically 2-6 weeks. The time until transfer to unlicensed persons is estimated at 1-6 weeks following counting.
    g. The lower limit of detection depends on the radionuclide and the parameters selected, including sample size and counting time. An example radioanalytical results report is included as Attachment 1, and shows the results for a 3 gram sample of diamonds. In this instance, the MDA for Eu-152, for example, is 0.7 pCi/g. The MDA for each gamma-emitting nuclide listed in CFR 30.70, Schedule A shall be less than 1/5 of the limits specified in CFR 30.70, Schedule A.
    h. The statistical methods are performed by commercial software manufactured by instrument vendors such as Canberra, Ortec and PGT. The results of calculations are deemed accurate via review of standard, spike, duplicate and other QA checks.
    i. False negatives are kept to a minimum by ensuring that the MDA's of the analysis are less than 1/5 of the values shown in 10 CFR 30.70, Schedule A.
    j. Sample calculations: Gamma spectroscopy calculations are performed by commercial software manufactured by instrument vendors such as Canberra, Ortec and PGT. The results of calculations are deemed accurate via review of standard, spike, duplicate and other QA checks.

    At a minimum, procedures must be sufficient to ensure that:

    a. Measurements are performed on gems are adequate to identify all induced radionuclides.
        - Since the energy of the electron beam is 1.0 MeV and no activation is expected at this low energy, no induced beta emitting or gamma emitting radionuclides are expected. Nevertheless, gamma analysis is performed on the diamonds, and if no significant activity is detected (i.e., all

gamma-emitting nulcides are < 25% of 10 CFR 30.70 Schedule A limits), then it is assumed that no significant activation has taken place, and there is no need to analyze for pure beta emitters.

b. Gems are analyzed to ensure that the concentrations listed in 10 CFR 30.70, Schedule A are not exceeded, including use of the "sum of the ratios" method when multiple radionuclides are present.

- All gems will be evaluated in lots by gamma spectroscopy. The total activity will include any detected radionuclides, and where the results indicate no detection above the MDA, then the MDA value will be used in the "sum of the ratios" calculation.

c. Show that there is only 1 chance in 1,000 that an outlier gem will contain more than twice the appropriate 10 CFR 30.70 maximum value.

- A qualitative response is provided as follows: since the low energy electron accelerator does not induce radioactivity, then there is an extremely low probability of any gem reaching the 10 CFR 30.70 maximum values.

4. Responsibility for the analytical QA program is with the contract laboratory. For CoPhysics Corporation, Theodore Rahon, CHP, PhD, is the individual responsible. His resume is included as Attachment 3.

5. Describe the QA Program:

   a. Constancy tests for counting systems are checked daily on days of use, prior to first use. Description of the method is described in Attachment 4.

   b. Spiked samples are analyzed as described in Attachment 4.

6. Prism USA Inc. will promptly comply with requests from the NRC to monitor the counting techniques, and Prism will ensure that the contractor supports NRC requests as described in NUREG-1556, Volume 8, Appendix G.

   a. Upon request, the applicant will provide samples of irradiated gems to NRC for independent verification of radionuclide identity and concentration. NRC's request will be in writing, signed by the appropriate Regional Administrator or the Director, Office of Nuclear Material Safety and Safeguards. The request will specify who (i.e., NRC representative, NRC contractor, or applicant) will select the samples for independent verification. After analysis, samples will be returned promptly to the applicant.

   b. Upon request, the applicant will analyze qualitatively, quantitatively, or both gems or groups of gems provided by NRC or its contractor. The request will be in writing; signed by the appropriate Regional Administrator or Director, Office of Nuclear Material Safety and Safeguards; will specify the type of analysis requested and techniques to be followed; and will provide instructions for reporting results and for returning gems.

Attachments:

1. Example of Gamma Spectroscopy Report
2. Resumes of persons responsible for irradiation and for gem handling
3. Resume of person responsible for radiological analysis
4. Vendor laboratory procedure for gamma spectroscopy counting and Quality Assurance