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William B. Yelon Ph.D.
1309 Overhill Ct.
Columbia MO 65203

July, 13, 2007

Division of Industrial and Medical Nuclear Safety
Office of Nuclear Materials Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C 20555-0001

Dear Sirs,

Enclosed is an application from Ideal Source International, LLC, for a license for the importation and release of topaz gemstones with activities below the exempt limits specified in 10CFR. We are simultaneously submitting a license application for possession of radioactive material (category 3P) to region 3. Although the location of the facility in Columbia MO to be used for the QA program is presently unspecified in our application, I am in the process of negotiation for a small property that would be used for office and laboratory. I will notify the NRC of the location as soon as it is established.

The application describes a novel method for the identification of outliers. This work would be carried out at the off-shore irradiation facility. The facility in Missouri would be used to verify the procedures applied at the irradiation facility to guarantee that NRC regulations are met. This appears to be more logical than importing and screening stones that may have high activities, and that would require long term storage in a location less secure than readily available in the irradiation facility.

I hope you find our application satisfactory. I will be happy to answer any questions about our methods and to respond to any concerns that the NRC may express relative to the adequacy of any aspect of our program.

Yours sincerely,

William B Yelon

William B. Yelon, Ph.D.
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NRC FORM 313 (10-2005) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40 — U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 — EXPIRES: 10/31/2008
APPLICATION FOR MATERIAL LICENSE	Estimated burden per response to comply with this mandatory collection request: 4.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)* [X] A. NEW LICENSE [ ] B. AMENDMENT TO LICENSE NUMBER ______ [ ] C. RENEWAL OF LICENSE NUMBER ______	2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)* Ideal Source International LLC 65 West 39th St. 17th Floor New York NY 10018
3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED Columbia Mo To be determined	4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION William B Yelon Ph.D. TELEPHONE NUMBER (b)(6)

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE. attached	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9. FACILITIES AND EQUIPMENT. See	10. RADIATION SAFETY PROGRAM.
11. WASTE MANAGEMENT.	12. LICENSE FEES *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY 3B AMOUNT ENCLOSED $ 8700

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
William B Yelon, QA Manager	William Yelon	7/17/07

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

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A. Basic Information: (numbering according to NRC form 313)

1. **A. New License.**
   Applicant:
   Ideal Source International LLC

2. **Mailing address of applicant:**
   55 West 39th St. 17th Floor
   New York, NY 10018
   Phone # 212-575-5800

3. **Name of person to be contacted about this application**
   William B. Yelon Ph.D.
   Telephone number:

Exemption 6

(b)(6) [redacted]

4. **Specify locations:**
   a. Address where licensed material will be used or possessed
   Location in Columbia, Missouri,
   To be determined.

   b. From which irradiated gems will be distributed to persons exempt from licensing:
   Ideal Source International LLC
   55 West 39th St. 17th Floor
   New York, NY 10018
   Phone # 212-575-5800

   c. At which records pertaining to possession and distribution of irradiated gems will be maintained:
   Records, containing "historical data" about the gemstones, including date of irradiation, size, shape, activity levels reported by the exporter and activity levels measured in the verification process will be maintained in Columbia MO at the applicant's QA facility, (under the supervision of William Yelon). Duplicate records will be maintained at the applicant's offices give above. They will also maintain records relating to the exempt distribution, once the QA process has been completed and stones released for distribution.

5. **Radioactive Material**
   A: Element and mass number:
   Elements 3-92, mass numbers 7-238,
   Consisting primarily of ^{182}Ta, ^{54}Mn, ^{46}Sc, ^{96}Ge and ^{58}Co, but may contain other isotopes in very low (usually undetectable) levels.

B: Chemical or physical form:
Radioactive elements contained in topaz gemstones, produced through neutron and/or electron irradiation. No loose, concentrated, radioactive byproducts will be encountered. No removable contamination is expected.

C: Maximum amount:
8×10^6 Bq total activity

6. **Purpose for which licensed material will be used:**
Importation and exempt release of irradiated topaz gemstones with specific activities below exempt limits specified by 10 CFR.

7. **Individual responsible for radiation safety program and their training experience:**
William B. Yelon, Ph.D.
Professor Yelon has a Ph.D. in physics and over 30 years of experience as a researcher and research manager at research reactors, including the HFR at Brookhaven National Lab., the Institute Laue-Langevin in Grenoble, France and the University of Missouri Research Reactor, in Columbia MO. As such he has been thoroughly trained in the principles of radiation, radiation detection and radiation protection. He has specialized in neutron detection (and discrimination of neutron and gamma radiation) and in the use and detection of high intensity (KCi) gamma-ray sources. He is thoroughly familiar with the use of a variety of radiation detection equipment including beta-gamma detectors, NaI detection and high resolution (Ge) gamma counting. He has trained numerous students in safe practices in a research reactor environment. He has assisted in the development of the topaz irradiation program at the Maria Reactor, including the design of shielding to minimize the induced radioactivity and participated in the design of the counting systems used to determine the isotopic distribution of the isotopes and the specific activities of the irradiated stones.

8. **Training for individuals working in or frequenting restricted areas.**
No high radiation areas are expected, restrictions related only to secure storage of topaz gemstones prior to their exempt release.
Workers at the facility will be trained in the principles of radiation, detection and radiation protection, using one of the many manuals available on-line, such as the "RADIATION SAFETY TRAINING AND REFERENCE MANUAL" found at www.**safety.caltech.edu/manuals/radiation_safety_training_manual**.pdf.
Lectures will be given by Professor Yelon and an exam will be administered to assure that the workers understand the material presented. A score of at least 80% will be required on the exam. It is expected that visitors to the facility will not be exposed to radiation levels above background, and they will not be trained. However, they will carry self-reading ionization chambers.

9. **Facilities and equipment**:
see attached pages.

10. Radiation safety program:

Imported material will be stored in a secure, shielded vault and only material removed for counting will be unshielded and available for manipulation. These will typically be in quantities of 2 Kg or less, per parcel. All workers will carry self-reading ionization chambers that will be monitored at least on arrival and at the end of the work shift and at any other time that the worker leaves the facility. The workers will be required to leave the chambers at the work site to avoid accidental exposure or mishandling of the chambers in another environment. Radiation detectors will also be mounted at several locations within the facility and periodically monitored for total dose in the work area. Workers will be limited to the time that can be spent inside the vault and storage will be organized in order to minimize the time needed to locate any specific parcel. Only stones that meet the U.S. exempt release limits will be sent to the facility for verification, and once cleared will be shipped to customers as quickly as possible, minimizing the total isotope inventory at the facility. Although no removable contamination is expected, workers will wear latex gloves and lab coats while handling stones and will be required to leave the coats behind and wash hands prior to exiting.

11. Waste management:

No radioactive waste is expected other than stone fragments. Even though the activity of these fragments should be below the exempt limits, these will be periodically packaged and returned to the neutron irradiation facility for ultimate disposal.

B. Background information:

1. Material to be imported:

a. Type of gems:
Topaz minerals.

b. Processing before irradiation:
Only cut and polished gemstones will be sent to the licensee for U.S. distribution.

c. Irradiation:
Topaz will have been subjected to one of the following treatment processes, 1) neutron irradiation only, 2) neutron irradiation followed by electron irradiation, or 3) electron irradiation only. Gemstones may be heated after the final irradiation step to remove unwanted color centers.

d. Where and by whom each irradiation will be carried out:
Neutron irradiations will be carried out at the Maria Research Reactor in Poland, under the supervision of Krzysztof Pytel, Ph.D. Electron irradiation (either after neutron irradiation or unique) will be carried out at

Studer Draht und Kabelwerk AG, located in Daniken, Switzerland, under the supervision of Hans Hartmann, senior engineer, or at other European electron beam irradiation facilities.

e. Additional treatment:
No additional treatment will be carried out after importation into the United States.

f. Handling to ensure grouping by geologic type, irradiation history, etc.
The gemstones are always separated by size, shape and geologic origin in individual packets. The irradiation containers have been designed in order to allow packets of arbitrary volume to be included and maintained as distinct units. Unlike other neutron irradiation facilities, some efficiency is sacrificed by <u>not mixing</u> large and small stones (to fill the interstices), thus assuring that each packet represents a unique origin and radiation history. In addition, the containers are rotated in such a way as to provide a uniform dose to the entire contents, thereby minimizing the variation in specific activity within each packet. After irradiation, the identity of each packet is preserved, for counting and storage, until the release criteria have been reached.

g. Identification of all radionuclides included in gems:
Immediately after release from the reactor the activity of topaz is dominated by ^{24}Na, and it is not possible to identify isotopes with half-lives of less than several days, due to this interference and the need to minimize handling of the stones until the ^{24}Na has decayed. After (typically) 10 days decay, high resolution gamma ray counting identifies the major isotopes ^{182}Ta, ^{54}Mn, ^{46}Sc, and to a lesser extent, ^{58}Co. Other isotopes may be present at low levels (well below exempt concentrations), including ^{122}Sb and ^{124}Sb. ^{32}P is also present and is identified by beta counting. Topaz that has been irradiated by electrons may also initially contain ^{26}Al and ^{96}Ge, if the electron energy exceeds the photonuclear threshold. The Ge isotope has a short half-life and is not present at release. The Al isotope has a long half-life and is present at a level of order 1 Bq/g. No exempt concentration limits are available in 10 CFR 30 for this isotope. Using the formula C = ALI/(3000 x 365) (where ALI is the annual limit for ingestion) we arrive at an exempt limit for this isotope of approximately 13.5 Bq/g. Thus, the ^{96}Ge, may contribute a minor portion of the total sum of ratios, used to determine the release date for large gemstones subject to both neutron and high-energy (> 10 MeV electron) irradiation.

h. How information in part g was obtained:
The data above have been derived from High Resolution Gamma Counting using an intrinsic Ge detector, maintained in the Maria Reactor

Laboratory and used for numerous tasks such as reactor chemistry. Beta activity has been studied using plastic scintillator detection. No pure beta emitter, other than ^{32}P has ever been observed. This activity is intrinsic to every radiation, arising from the Si in the topaz minerals. As such, the contribution of the ^{32}P to the total activity can be calculated based solely on the fluence and decay time.

In addition to the historical data used to estimate the generic distribution of isotopes in stones of differing origins, every packet is subjected to high resolution germanium counting. These data are, in turn, used to establish the average distribution and concentration of isotopes. This information is used, in turn, to establish the date by which the activity will have reached the exempt limit (for U.S. release) or any other arbitrary level. It has been found, of course, that the relative and absolute concentrations of these isotopes varies significantly with the geologic origin of the stones, and this "generic" information is used for irradiation planning. However, each packet is treated as unique, and release is based on the specific results of the Ge counting and not the generic impurity distribution.

i. Requested possession limit:
It is anticipated that not more than 2 x 10^6 cts will be present at the release facility at any given moment, and typically the quantities will be an order of magnitude smaller. Assuming an average of 20 Bq/g, specific activity (with ^{54}Mn representing the dominant isotope at release), we request a possession limit of 8 x 10^6 Bq.

2. Handling of gems:

a. Procedures to assure that removable contamination is not present:
The irradiation containers are dry, filled with He gas (leak test and heat exchange improvement purposes) and the stones are packaged in aluminum foil packets, that contain only one size and shape stone, from one geologic origin. The high resolution Ge counting, which is used to determine the release date, is also used to verify the absence of removable contamination, which could arise from e.g. a leak in the container, allowing pool water to come into contact with the stones. In that case the distribution of isotopes observed would be qualitatively and quantitatively different from the generic distribution, showing e.g ^{60}Co, ^{95}Zr and ^{95}Nb. In such a case, the stones will be washed by means of ultrasonic cleaner and re-measured. Only when the generic distribution is seen can we be confident that no removable contamination is present. Although stones have been swiped, in the past, to check for removable contamination, no trace has been seen when the Ge counting reports "standard" results.

b. Processing at the importer's facility:
The importer's facility will be used for a number of important functions (below), related to license activities. No activities will be undertaken that could result in the release, re-concentration or other modification to the activities of the gemstones, or to their physical integrity (such as heating).

1. Quality assurance:
The importer's facility will maintain a counting lab that will be used to verify the results reported by the exporter. In particular, the distribution of isotopes and average activities of selected packets of stones will be re-determined and compared with the data supplied by the exporter (corrected for decay).

2. Record keeping:
Records of all stones shipped to the U.S. under the NRC license will be maintained at the importer's facility. Included in these records will be stone size and shape, geologic origin, packet mass, date of shipment, distribution of isotopes and average specific activity as determined by the exporter, and similar data from the importer's quality assurance program, if the particular packet was selected for verification.

3. Documentation:
The importer's facility will generate certificates attesting that the packets that have successfully passed the quality assurance program meet the U.S. limits for exempt release, and can be used in commerce without further certification. A unique certificate will accompany each packet of stones and will detail (at least) size, shape, quantity and geologic origin.

4. Storage and shipping:
Stones received by the importer will be stored at the facility in a secure and shielded location until the verification process is completed. As soon as possible thereafter, the stones would be shipped to Ideal Source International LLC for distribution to unlicensed individuals.

c. Organizations that will receive exempt gemstones from the import facility:
It is currently anticipated that the gemstones that have cleared the importer's QA program will be shipped only to Ideal Source International, LLC or its designated representative or agent.

d. Gemstones that exceed the exempt limits:
If the procedures described in this application are faithfully and accurately carried out, the import facility should never possess material exceeding the exempt concentrations of radioactive elements. If the QA procedure carried out by the importer fails to reproduce the results reported by the irradiation facility, then that packet will be isolated and all import

activities halted until the origin of the discrepancy is identified (e.g. calibration error, weighing errors, etc). If the error rests with the exporter and not the importer, then the stones will be returned and the release dates readjusted to account for the systematic error that caused the misestimate. Thus, there is no intention of holding gemstones with activity exceeding the specified criteria at the importer's facility.

C. Information required by 10 CFR 32.11

1) **Responses relating to paragraph 32.11(a)**

a. ***Facilities and procedures are adequate to protect health and pose no danger to life or property:***
The proposed facility will only receive topaz that has previously been determined to have specific activity below the exempt limit for the specific isotope distribution in those stones. Nominally, then, the material has been determined to be exempt from licensing. However, it is recognized that the accumulation of low activity (and low dose) stones, if amassed, could present a small dose hazard to the workers in the import facility. For that reason, the individual packets of stones, each representing a unique size, shape and treatment history, will be stored in a well shielded vault and removed for verification purposes only a few packets at a time. The storage facility will be organized in such a way that individual packets can be found quickly, minimizing the time needed for personnel to spend in a "less than minimum dose" environment, that will be open only for the removal (or replacement) of the packets selected for verification. Thus, only a small quantity of stones (a few kilograms) will be unsecured (i.e. not in a locked facility) at any time. Shipments that pass the verification process at the import facility will be shipped to distributors as quickly as possible, keeping the inventory of irradiated merchandise to the lowest possible level. Workers at the facility will receive training in radiation, radiation detection and radiation protection. The procedures designed for the release of stones may allow for an operation with only one or two workers (supervised by Prof. Yelon, who will be responsible for the total operation of the facility). If necessary, access to the facility will be limited by key or electronic access, even during work hours, to prevent unauthorized removal. Since the specific location of the import facility has not yet been fixed, the details will evolve, but will be fully implemented before the first stones are received for exempt release. If necessary, the licensee will provide additional information to the NRC at that time.

b. Individuals responsible:
Dr. Krzysztof Pytel supervises the operation of the gemstone irradiation program at the Maria Reactor. He is assisted by his wife, Beatrice Pytel, MSc. who manages the High Resolution Gamma Detector facility, by Alina Koziel,

MSc. who supervises the NaI detector laboratory and by other, well-trained staff. The senior staff have been at the Maria Reactor for many years and have extensive experience in irradiations, low level counting with a variety of instruments, and safe handling of radioactive material. Jointly they will be responsible for the Quality Assurance program at Maria. At the present time only Prof. Yelon is identified as responsible for the full operation of the import facility, including the handling, storing and counting of the gemstones to be released as exempt. His experience has been described in part A section 7. He will notify the NRC of the names and training of additional personnel responsible for the protection of the public safety, as they are hired.

2) Responses relating to paragraph 32.11(b):

a. Product or material:
Cut and polished topaz, chemical formula $Al_2SiO_4[F,OH]_2$. Byproduct introduction is the unintended consequence of the (fast) neutron irradiation (or electron irradiation) needed to introduce or modify color centers, producing a blue color from previously colorless stones.

b. Intended use:
The byproducts introduced are unintended, but, with the exception of ^{32}P (which arises from the Si in the matrix), are the inevitable consequence of activation of the impurities in the stones. Shielding has been optimized to minimize this activation, but most is due to the same fast neutrons that are required to produce the color centers. The colored gemstones are used for jewelry in rings, bracelets, pendants, earrings, etc.

c. Method of introduction:
Topaz will have been subjected to one of the following treatment processes, 1) neutron irradiation only, 2) neutron irradiation followed by electron irradiation, or 3) electron irradiation only. Gemstones may be heated after the final irradiation step to remove unwanted color centers. No additional treatment will be carried out after importation into the United States.

d. Initial concentration of byproduct material:
The initial concentration of byproduct material depends on the geologic origin of the stones and the treatment conditions (neutron dose). For the highest purity stones (available only in limited quantities from a specific origin), the initial activity (after two to four weeks decay for ^{24}Na and other short-lived isotopes) may be as low as the exempt limits, and consists of small quantities of ^{54}Mn, ^{182}Ta and ^{46}Sc, while for the least pure material, subjected to high doses (i.e. small sizes), the initial concentration reaches as high as 20 times the exempt limit. For this category of topaz, the initial activity tends to be dominated by ^{182}Ta, decreasing by about a factor of 8 after one year in storage. By that time, the activity tends to be dominated by the longer-lived ^{54}Mn.

e. **Estimated maximum concentration of the radioisotopes at the time of exempt release:**

The Quality Assurance (QA) program described in Appendix A provides that the average activity in each lot of stones is less than or equal to the exempt limit, based on the sum of ratios criterion. The isotopes that contribute to the activity vary with the geological origin of the stones, but consist primarily of ^{54}Mn and ^{182}Ta for stones from Brazil and Nigeria, while stones from Sri Lanka contain primarily ^{54}Mn and ^{46}Sc. Furthermore, the QA procedure described in Appendix A is also designed to identify and exclude all stones with activity greater than twice the exempt limit. An exemption from the requirement that not more than one stone in 1000 have activity greater than twice the exempt limit, is requested for <u>small stones</u>. The justification for this request is given in Appendix A.

f. **Control method:**

Quality assurance (QA) procedures, described in detail in Appendix have been developed to guarantee that the average activity in the stones is less than or equal to the exempt limit based on the sum-of-ratios criterion. Selection of stones after irradiation guarantees that not more than one stone per 1000 has activity equal to or greater than twice the exempt limit (for medium and large stones). This quality assurance program makes use of both high resolution gamma detection and NaI(Tl) counting at the irradiation facility. All packets of stones shipped to the Unites States will be verified with these methods prior to shipping. The importer will maintain a separate QA facility using only NaI(Tl) gamma counting. Measurements by the importer will confirm both the isotope distribution and average activity reported by the shipper and small batch counting will provide limited data on the spread of activities, further confirming the absence of stones with activity greater than twice the exempt limit. Failure to agreement between the shipper's reports and the importers QA results will compel a shutdown of release, while the sources of error are investigated. This may require re-calibration of counters or balances. Only after the discrepancies are resolved and the two sites capable of providing consistent, accurate data, will release resume.

g. **Estimated time between treatment and release:**

As described in part C.2.d. above, the time between treatment and release will vary substantially depending upon the origin of the stones and the treatment history. Historic data will be used to estimate the decay time needed for each batch of stones, using dose history and information about geologic origin. Release could be as short as 45 days for the purest stones and as long as two years for the least pure. It is unlikely that irradiation leading to longer decay would be employed, due to the economic cost associated with long term storage (and lack of access to the market).

3. **Responses relating to paragraph 32.11(c)**

a. ***The concentration of byproduct material will not exceed the concentrations specified in 10 CFR 30.70:***

The detailed gamma analysis of the irradiated gemstones allows us to accurately establish the total activity that corresponds to a sum of ratios less than or equal to one, while the sorting procedure described in Appendix A insures that no medium or large stone has activity greater than twice the exempt limit. Every packet of stones will be tested in this fashion prior to shipping to the importer. The import facility will verify the concentration of byproduct material in randomly selected packets received from the exporter. Inasmuch as the entire license rests on the successful application of the counting procedures described in Appendix A, no deviations from agreement between the irradiation facility and the import facility will be accepted. Thus, any result not in compliance with the expected result, will lead to a cessation of release activities and consultation to establish the source of discrepancy. Only after the questions have been resolved and agreement established, will release be resumed.

b. ***Reconcentration will not occur:***

No treatment of stones that could lead to reconcentration is planned at the importers facility or outside that facility prior to exempt release. Therefore, reconcentration of radioactivity will not occur.

c. **Use of concentrations lower than those specified in 10 CFR 30.70 is not feasible:**

As described above, using the levels specified in 10 CFR 30.70 leads to protracted decay periods up to 2 years for certain types of irradiated gemstones. The use of lower concentrations would further lengthen the required decay period, all but "killing" the market in these products. It is clear that for the topaz market to operate efficiently, the time between initial demand and supply to the customer be reasonable. Even at the present two-year limit, that market does not work well, and most commerce is in stones that have shorter decay times.

d. **The product or material is not likely to be incorporated into food, beverage, drug, cosmetic or other commodity designed for ingestion:**

The market in irradiated topaz is more than 20 years old and we are not aware of any case in which the material has been used for purposes other than those for which it is intended, i.e. ornamentation. Thus, these potential alternative uses remain exceedingly unlikely.

D. Information on the Quality Assurance Program

1. Radiation detection equipment used to identify and quantify the induce radioactivity:

The exporter (irradiator) maintains the following equipment:

- High resolution gamma detector (Ge) for identification of isotopes and determination of average activity.
- NaI(Tl) detectors for selection (and removal) of stones with activities exceeding twice the exempt limit.
- Plastic scintillator detector for the identification of pure beta emitters.
- GM counters to quantify the beta activity.

The import facility will maintain the following equipment:

- NaI(Tl) detectors to characterize the isotope distribution and to determine the average activity and (qualitatively) the activity distribution.
- GM counters for beta measurements.
- Pocket ionization chambers for personnel dosimetry.

Details of the radiation detection equipment and shielding are provided in Appendix A (proprietary information).

2. The frequency, standards and procedures used to calibrate radiation detection equipment:
This is specified in Appendix A in conjunction with the equipment description (proprietary information).

3. The counting procedures and how external measurements are converted to concentration values:
This is described in detail in Appendix A (proprietary information).

4. Responsibility for the QA procedures:
Dr. K. Pytel is responsible for the QA program at the treatment (export) facility. Dr. William Yelon is responsible for the QA procedure at the import facility. Their qualifications have been discussed in parts A.7. and C.1.b. above.

5. The Quality Assurance (QA) program used to assure reliable data:
The QA program is described in detail in Appendix A (proprietary information).

6. Commitment to the NRC to promptly comply with requests by the NRC designed to monitor the counting techniques.

a. Upon request, the applicant will provide samples of irradiated stones to NRC for independent verification of radionuclide identity and concentration. The request should be made in accordance with the procedures described in the "Consolidated Guidance About Materials Licenses" page 31, section 6.a.

b. Upon request, the applicant will analyze qualitatively, quantitatively or both, gems or groups of gems provided by the NRC or its contractor. The applicant does not claim to be able to identify all stones with activity equal to twice the exempt limit, but will demonstrate its ability to fulfill the procedures described in its QA program. The request should be made in accordance with the procedures described in the "Consolidated guidance about materials licenses" page 31, section 6.b.

E. Request for exemption from portion of 10 CFR 32.11:

1. If the NRC considers gems to be products intended for application to human beings, then an exemption from this portion of requirements in 10 CFR 32.11(c) is requested.

2. **Dose calculations:**

Dose calculations were carried out for a 5g (25ct) stone, using an idealized geometry of a disk, 1cm diameter, thickness 0.45 cm, density 3.55g/cm^3. Gamma doses were calculated using the Mshield code, while the beta doses were calculated with a code written by Dr. Pytel (beta_dose) (available upon request). For the beta dose calculation, the stopping power data were taken from the NIST web page:
http://physics.nist.gov/PhysRefData/Star/Text/contents.html
The decay characteristics were extracted from the BNL web site:
http://www.nndc.bnl.gov/nudat2/indx_dec.jsp
The calculations were carried out by Dr. Pytel, who routinely performs such calculations in support of the programs at the Maria Reactor.

We consider two limiting cases, one in which ^{54}Mn is the dominant isotope at release, and a second in which ^{182}Ta is the dominant isotope. In the former case, the beta yield is only 2 x 10^{-5}, while in the latter it is nearly 100%. Thus, the beta dose for the limiting case of ^{54}Mn may be neglected.

Assuming an individual wears the gemstone without interruption for the first year after release (and that the stone does not move in relation to the individual's body), the following results are obtained.

Isotope	**^{54}Mn**	**^{182}Ta-gamma**	**^{182}Ta-beta**
Exempt limit	**37Bq/g**	**14.8Bq/g**	**14.8Bq/g**
Dose (D = 0.01 cm)	**419 mrem**	**138 mrem**	**185 mrem**
Dose (D = 4.0 cm)	**7.0 mrem**	**2.3 mrem**	**5.6 mrem**

These results are highly exaggerated compared to realistic situations, inasmuch as it is unlikely that an individual would wear a stone of this size continuously or that the location of the stone relative to the body would remain invariant. Even a ring of that size would likely be removed and the mounting of the stone would distance it from the individual, and partially shield the radiation. Furthermore, this dose is highly localized to the skin and not to the whole body, leading to the conclusion that such an exposure does not constitute a meaningful risk. In addition, the simplified geometry exaggerates the dose, since mounted stones normally have their narrow end closest to the body, and the largest surface (the table) away from the body.

3. **Doses for outliers with twice the exempt concentrations:**
   Outliers with twice the exempt concentration will, of course, result in doses equal to twice those shown above. It should be noted, however, that the sorting procedure described in detail in Appendix A will easily identify such outliers if the masses are as great as used for the model calculations. These doses are still acceptable, given the conservative nature of the assumptions. In fact, it is reasonable to set a more conservative limit for outliers, for such large stones, and we would be able to identify them through out QA program, if the NRC were to request such an adjustment.

Responses to e-mail request for additional information on application for new exempt distribution license
Email from Anthony Kirkwood, Sept. 12, 2007

William B. Yelon

1. **Notification regarding possession license:**

At this moment I believe that all questions have been answered. Kevin Null from Region III will be visiting the facility in Columbia, MO on Wed. Sept. 19. I hope the license will be issued shortly after his visit and will notify NRC H.Q. as soon as the license is received.

2-a. Methods to assure that no more than the specified concentration is introduced into the product.

Topaz is a natural mineral, subject to variability in the impurities, which affects the concentration of byproduct material introduced into the stones during a typical irradiation (which averages in the range of 10^{17} /cm^2 (fast neutrons). At the time of irradiation the principle isotope ^{54}Mn will have a concentration of 1-3 times the exempt concentration (depending on the origin and dose), while the ^{182}Ta concentration will range from 0.5 to 100 times the exempt concentration. This variability is the principle reason behind the need to sort topaz for outliers. Our method assures that at release no more than 1 stone per thousand exceeds twice the exempt limits based on the sum-of ratios (SOR).

Note that the concentration of isotopes can be affected strongly by the nature and thickness of shielding used to eliminate thermal and some of the epithermal neutrons, as well as the effects of re-moderation of fast neutrons in the irradiation space. We have invested a great deal of time and effort in attempting to optimize the shielding, including investigation of the effect of Ta screens, and Hf foils to eliminate epithermal neutrons. We believe that there is little room to further reduce the concentrations of by-product material, at the time of irradiation.

It should be further noted that the by-product material in topaz is unwanted and is the inadvertent result of the fast neutron irradiation used to create the color centers that make the treatment valuable. Other cases of exempt distribution involve the deliberate production of known concentrations of radioactive isotopes used for their radioactive properties (e.g. in tritium dial watches or in smoke detectors). Thus, the control over production that is required in those cases cannot be maintained in the case of topaz, and, thus, the control must be exercised after production and before release.

2-b. Dose estimates appear to be higher than in NUREG-1717.

The apparent discrepancies between the doses calculated in our application and those given in NUREG-1717 are due to a number of factors, which when properly taken into account, actually show good agreement between the two results.

With regard to the whole body gamma dose, our result shows, e.g. for ^{182}Ta, at a distance (d) of 4.0 cm, a dose of 2.3 mrem. The value in table 2.2.11 of NUREG-1717 is given as 0.1 mrem. However, the basis for that calculation is for a distance of 10.0 cm, and exposure 8 hours per day, versus the 24 hour exposure assumed in our application. The dose is proportional to $1/d^2$, leading to a factor of 1/6.25 in our reported doses for the 10 cm case, with an additional factor of 3 for the time, resulting in a net reduction by a factor of 18.75. This reduces our reported 2.3 mrem to 0.12 mrem, in complete agreement with the data of table 2.2.11. Likewise, by adjusting the ^{54}Mn gamma dose by the same factor, we arrive at a dose of 0.37 mrem, in complete agreement with the value in table 2.2.11 (0.4 mrem).

With regard to the beta dose, we report 185 mrem for ^{182}Ta, versus 30 mrem reported in table 2.2.11. Applying the same time correction (1/3) reduces our result to 60 mrem, within a factor of two of the 2.2.11 result. This is already within the error limits for calculating beta doses, but an additional factor actually brings these two results into better agreement. Our calculation uses a disk shaped reference stone, with a 1 cm diameter, whereas the data in table 2.2.11 is based on a spherical reference stone. It is obvious that the relative dose of the sphere will be lower than for a disk, as the area of the sphere in contact with the skin is small, while that for the disk is large. With this in mind, it is clear that our calculated doses are in good agreement with those tabulated in Table 2.2.11 of NUREG-1717.

Finally, we note that the application for license previous filed by Alnor/Studsvik (and issued) arrives at approximately the same results as we have found and reported in our application.

In summary, <u>our results are in accord with NUREG1717</u>!

3-a. Submit calculations that demonstrate that 0.2 gram stones that exceed twice the exempt concentration limit can be excluded from the one in one thousand screening criteria.

(submitted on a separate page-contains proprietary information)

3-b. Public dose limits will not be exceeded when the 0.2 gm irradiated gemstones are transferred to the public.

If one assumes that one stone per thousand is released at twice the exempt concentration, the dose received by an individual wearing that stone will still be 1/15 of the doses calculated for a 30 ct (6 gm) stone in NUREG-1717, resulting in a negligible dose both to the whole body (photon) of less than 0.008 mrem, and to the skin (beta) of 2 mrem. The collective dose equivalent will be increased only by one part in 1/1000, from 1 mrem to 1.001 mrem. In both cases these represent no concern.

4. Certain portions of the application are marked as proprietary.
We will submit, under separate cover, the required affidavit. The proprietary information describes a method for identifying and eliminating outliers, which, to the best of our knowledge, has not previously been described or used. As such, it represents a significant improvement over others methods in use, and allows us to lower the cost of sorting and better insure that the one in one thousand criteria is met.

Appendix A

The information contained in this appendix should be considered as proprietary material and should be used and disclosed by the NRC only as requested for evaluation of the license application to which it is attached.

Table of Contents

D. The Quality Assurance Program

Exemption 4

(b)(4)

Pages 20 through 36 redacted for the following reasons:

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(b)(4)

(b)(4)

Exemption 4

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 <u>only after</u> 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.

Ja) 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). Our proposed method checks all of the stones in each selected parcel, by means of small batch counting, calculation (from the total measurements for that parcel) of the isotope concentrations and sum-of-ratios for that parcel, as well as statistical analysis (from the distribution of activities of the small batches) of the probability that a stone exceeds a sum-of-ratios equal to 2. We have further committed to rejecting the entire lot if either of these tests fails, as this would constitute a failure of the sorting system in use, either at the Ideal Source Quality Assurance office or in Poland. Until the source of the failure is identified, all shipments will cease, to be resumed, if necessary after resorting, or storage for additional decay. This appears to be a somewhat more 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 cm^2. 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.