Ideal Source Quality Assurance

William B. Yelon, Ph.D.

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Columbia MO 65203

Oct. 8, 2018

U.S. Nuclear Regulatory Commission

Office of NMSS

Mail Stop T5B60

Washington, D.C. 20555-0001

Dear Sirs,

Following is our application for a license for the exempt release of irradiated gemstones. I will provide an electronic copy to Shirley Xu. Also included is a check for $9,400 (as we have a credit of $400). Timely processing will be very much appreciated. (9100)

The application includes an appendix which contains many of the details of the procedure we previously employed, as well as the procedure we intend to apply in the immediate future. Although we hope to not need the older procedure, we request that the information describing it and its basis, (i.e. the appendix) remain proprietary.

I will be happy to provide any additional information you may require and look forward to working with you well into the future.

Yours sincerely,

William B Yelon

William B. Yelon, Ph.D. - RSO

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

1. **A. Renewal-replacement**
   Applicant:
   Ideal Source International LLC

2. **Mailing address of applicant:**
   401 Vandiver
   Bldg 4, Suite 200
   Columbia MO 65202

3. **Name of person to be contacted about this application**
   William B. Yelon Ph.D.
   Telephone number:
   573-529-6820 (mobile)

4. **Specify locations:**
   a. Address where licensed material will be used or possessed
   Ideal Source Quality Assurance
   401 Vandiver
   Bldg 4, Suite 200
   Columbia MO 65201

   b. From which irradiated gems will be distributed to persons exempt from licensing:
   Ostro Minerals (UK) LTD
   ATTN: Mr. Maurice Ostro, Chairman
   62 Grosvenor Street
   London, W1K3JF, United Kingdom

   c. At which records pertaining to possession and distribution of irradiated gems will be maintained:
   Ideal Source Quality Assurance (ISQA)
   401 Vandiver
   Bldg 4, Suite 200
   Columbia MO 65201
   Duplicate copies will be maintained by ISQA's IT support, Dr. Bruce Alspaugh, in electronic form.

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 40 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 are 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. If additional, previously untrained workers are needed (which appears unlikely) 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. Alternatively, the worker may be sent to a short course in radiation safety. It is expected that visitors to the facility will not be exposed to radiation levels above background, and they will not be trained.
Dr. Bruce Alspaugh, the ISQA IT specialist, has been trained to perform testing under the previous license, and has undergone formal RSO training (certificate

attached). He is the only individual, other than William Yelon who has operated in ISQA's offices.

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 in 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.

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 and irradiated diamonds.

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. Diamonds are subjected only to low energy electron irradiation from which no activation is expected.

d. Where and by whom each irradiation will be carried out:
Sadly, Dr Krzysztof Pytel passed away unexpectedly in August 2018. Neutron irradiations will be carried out at the Maria Research Reactor in Poland, under the supervision of Agata Gajewska-Dyszkiewicz and the reactor physicist or at other facilities yet to be determined. Electron irradiation (either after neutron irradiation or unique) will be carried out under the supervision of Hans Hartmann, senior engineer, at appropriate 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 irradiated in Poland 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 not mixing 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. ^{22}Na was identified in a small number of stones subjected to an unusually high energy electron treatment and has been the subject of an amendment to the original license. Although we do not anticipate a repetition of this situation, in our current application, 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 ^{22}Na if the electron energy exceeds the photonuclear threshold. The Al isotope has a long half-life and may be present at a level of order 1 Bq/g. ^{22}Na has been observed in a few stones subjected to the highest energy electron irradiation, although the production route is not clear. No exempt

concentration limits are available in 10 CFR 30 for these isotopes. Using the formula C = ALI/(3000 x 365) (where ALI is the annual limit for ingestion) we arrive at an exempt limit for both isotopes of approximately 13.5 Bq/g. Thus, they 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.

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.

h. Requested possession limit:

It is anticipated that not more than 2×10^6 cts will be present at the release facility at any given moment, and typically the quantities will be more than 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 8×10^6 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, for primary testing and for other related purposes. 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 approved for distribution in 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 sale of approved will detail (at least) size, shape and quantity. In general, a certificate will cover only one type of stone and multiple certificates will be generated for sales of multiple sizes, shapes, etc. However, once approved, stones from different packets of the same type may be combined in inventory, and the certificates will not, in general, specify the shipment(s) from which the stones were tested. No paper certificates will be associated with the transfer of goods from each shipment to Ostro Minerals, but the inventory

of cleared goods (which is updated with each certified sale) will be updated with each shipment.

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 Ostro Minerals LTD or its representatives 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 Ostro Minerals LTD or its designated representative, agent or customer, or returned to the Maria Reactor center. Delivery directly to a customer would be accompanied with printed certificate.

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 primarily 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.
On occasion the Missouri facility will be used for primary testing (principally for third parties), but only after it has been determined that the stones have been stored for sufficient duration to assure that the NRC exempt limits are not normally be exceeded. In the event that a shipment fails testing, it will be stored at the facility for a duration for sufficient time to reach NRC standards prior to release to any third party.

Individuals responsible:

Agata Gajewska-Dyszkiewicz supervises the operation of the gemstone irradiation program at the Maria Reactor. She is assisted by the reactor physicist (Rafał Prokopowicz, PhD- interim), Dariusz Krawczyński 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. Dr. Bruce Alspaugh, who is primarily responsible for maintaining testing results and the exempt release and certificate databases has undergone RSO training and has been trained in the operation of the testing procedures is available to operate the testing in the absence of Dr. Yelon.

A new NaI(Tl) has been installed at Ostro's cutting facility in Thailand. It is supervised by Patty Worawong, Ostro's representative who has been trained by W. Yelon. As soon as approval of this license is announced, Dr. Yelon will work with Patty to be sure that the facility is operated in a safe and

correct fashion. This will be supervised regularly by remote video inspection with frequent QA tests will be implemented to track the reliability of the testing.

Responses relating to paragraph 32.11(b):

a. Product or material:

1. 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.

   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.

   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. Irradiated cut and polished diamonds. We are not aware of any reports of radioactivity in irradiated diamonds, and have seen none in our diamond testing under our previous license. Nevertheless, the NRC has formal responsibility for irradiated diamonds, and testing and certification is required. In general diamonds are treated with 1MeV electrons which do

not induce any radioactivity, but neutron treatment has also been used in the past, and the possibility of activation or contamination cannot be excluded. Testing will insure that treated diamonds do not exceed the NRC limits. This testing will be described briefly in section D 5. With the exception of the following section (Other Gemstones) the remaining discussion is limited to questions concerning the treatment, testing and release of topaz.

3. Other Gemstones: Other gemstones, such as Morganite have been color enhanced through neutron treatment. In general, though, the activities encountered after treatment reach unacceptable limits. If we become aware of potentially useful treatments that produce activities comparable to those encountered in topaz, we may initiate a program to characterize the activation products and develop procedures to permit safe release of those materials. In that event, we will promptly inform the NRC of the results of the development and request formal permission for the release of those products under conditions similar to those applied to topaz.

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 includes a procedure designed to identify and exclude all stones with activity greater than twice the exempt limit. These procedures are available for special testing at customers request (and expense). These procedures, however, are time consuming, expensive (even with the methods previously described) and have severely impacted our competitiveness. We are requesting an exemption from the 1/1000 standards to allow release based on the health risk associated with stones that have not been tested according to this criterion. This justification has been used by at least one other licensee (International Isotopes) to allow them to bypass the 1/1000 criteria.

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 to guarantee that not more than one stone per 1000 has activity equal to or greater than twice the exempt limit (for medium and large stones) is described in the appendix, but will be employed only in special circumstances. The quality assurance programs 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 or by the facility in Thailand, Thailand. Failure of 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, or retraining of operators. Only after the discrepancies are resolved and the sites proven capable of providing consistent, accurate data, will release resume.

f. 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:

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. Every packet of stones will be tested in this fashion prior to shipping to the importer. The sorting procedure described in Appendix A insures that no medium or large stone has activity greater than twice the exempt limit and has been employed by us in the past, However, this procedure is costly and time consuming, and alternative justification has been provided by other licensees for release based solely on the average activity and distribution of activity. We intend to adopt that analysis to allow quicker (but still safe) release. The import facility will verify the concentration of byproduct material in randomly selected packets received from the exporter. The testing of these packets will verify that the activity levels and isotope distributions reported by the export facility are reliable. Any failure of verification will compel a review of the methods of testing and the calibration of the instruments, and release will be suspended until the discrepancies are resolved. This situation arose on rare occasions in the early years of the prior license, which led to retraining of the operators, but none have arisen in the last 5 years of the license. Consequently the frequency of verification will be reduced from its prior level.

QA with regard to the Thailand facility will require that individual (large) stones be identified, tested and the results recorded. Those stones will be forwarded to the Missouri facility for retesting. The procedure requires that agreement be found (within statistical limits) for all the stones sent for testing. Failure will result in shutdown of release from Thailand until the source of discrepancy is identified and resolved.

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.

A new NaI(Tl) testing station has been developed, using a Bridgeport Instruments detector system, and installed at TIE's facility in Thailand, Thailand. The software largely replicates that employed at the irradiator's facility and that at ISQA, although the balance employed is external, rather than integral to the detector. This facility will test stones on a one by one basis after they have been cut from rough according to customer demands. Because of the custom cutting (and the small quantities often demanded) and the need to respond rapidly to market needs, the irradiation and decay of these stones cannot practically be carried out as is customary for "standard" sizes and shapes. Instead, cutting will be carried out only on pieces of rough that have already been determined to have low activity, typically less than the NRC exempt limit.

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).

4. The counting procedures and how external measurements are converted to concentration values:

Previously, we have employed procedures designed to assure that the NRC 1/1000 standard was **strictly** observed. Details of that method remain available in the appendix. Instead, we intend to employ a more liberal method (based on human health risk) for the majority of our production/release. For this reason we request that details of the procedures remain confidential. This is described in detail in Appendix A (proprietary information).

4. Responsibility for the QA procedures:

Agata Dyszkiewicz, under the supervision of the reactor physicist 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. Patty Worawong (under the supervision of William Yelon) will be responsible for release from Thailand.

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.

c. The NRC is also welcome to visit the importers facility during a testing session, providing we can reach accommodation as to schedule, since testing is episodic and not carried out on any regular schedule.

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 performed 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.

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 previously 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. **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 can 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. However, such a requirement has not been imposed on other licensees and we will defer from applying the special sorting procedure, except as requested by our customers.

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. From these numbers it is clear that stones that are yet hotter (at the tail of the ^{182}Ta distribution will also be negligible and restricted to the skin, which is not a sensitive organ. Furthermore, the relatively short half-life of ^{182}Ta assures that long term dosing does not occur.

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.

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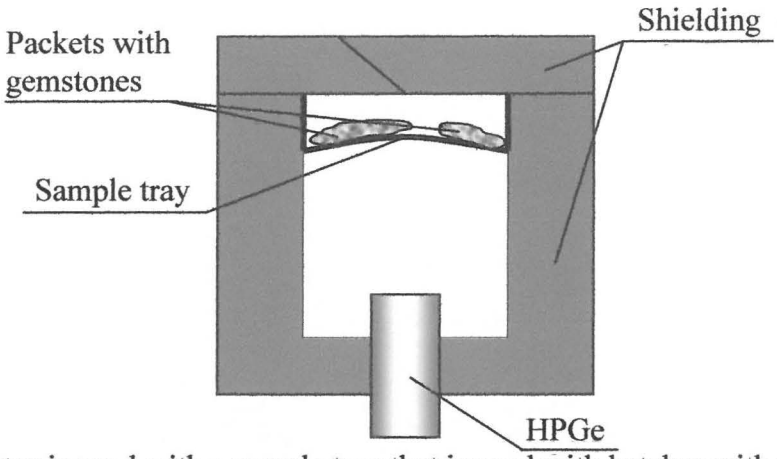
D. The Quality Assurance Program

The quality assurance (QA) program described below includes a novel method for identifying stones (outliers) with activities that will exceed twice the exempt limit at the time that the average activity for a group of stones has decreased to the exempt limit. This will be applied only in special circumstances and the documentation will identify those shipment that strictly comply to the 1/1000 criterion. The identification of the distribution of activities, determination of the required decay time, the selection of outliers and the storage of the various groups of gemstones for the required time all take place at the irradiation facility. The QA program at the import facility consists of verification of the isotope distribution and average activity, and qualitative evaluation of the activity distribution. An essential ingredient in the QA program is the requirement that the results reported by the importer and the exporter must agree, for all tested lots, before the entire shipment is qualified for release. The equipment employed, the calibration and verification procedures, and the method employed for counting and selection of outliers is described below. It must be recognized that it is impractical, if not impossible, to eliminate outliers when the mass of the gemstones becomes small, due to deteriorating signal-to-noise, requiring, in-turn excessive counting times. The applicant is requesting an exemption from the requirement that the activity of not more than 1 stone in 1000 exceed twice the exempt limit. There are no adverse consequences of such an exemption. Justification for this request is provided below.

D.1 Radiation detection equipment:

a. Ge high resolution gamma detector:

The high resolution gamma detector is a Ge detector, Canberra Model GC1020, equipped with Canberra InSpector MCA and associated Genie 2000 software. For the gamma rays of interest and the geometry employed it has approximately 10% efficiency. (see part 5, below). A schematic of the detector and shielding is given in Fig. A1).



The detector is used with a sample tray that is used with batches with mass approximately 100g or greater, while smaller parcels are measured using a small tray that is positioned closer to the detector. The Ge detector is employed for a variety of other purposes, including reactor chemistry and the identification of isotopes produced in other reactor projects.

b. NaI(Tl) detectors:

There are several NaI(Tl) detectors employed by the topaz QA program at the Maria Reactor. These are end window 3"x 3" scintillation detectors equivalent to the Canberra 802 models, with roughly 8.5% resolution. The Al window of the detector is mounted flush with the test bench surface, with the body, shielding and electronics supported from the underside. A schematic side view is shown in Fig. A2.

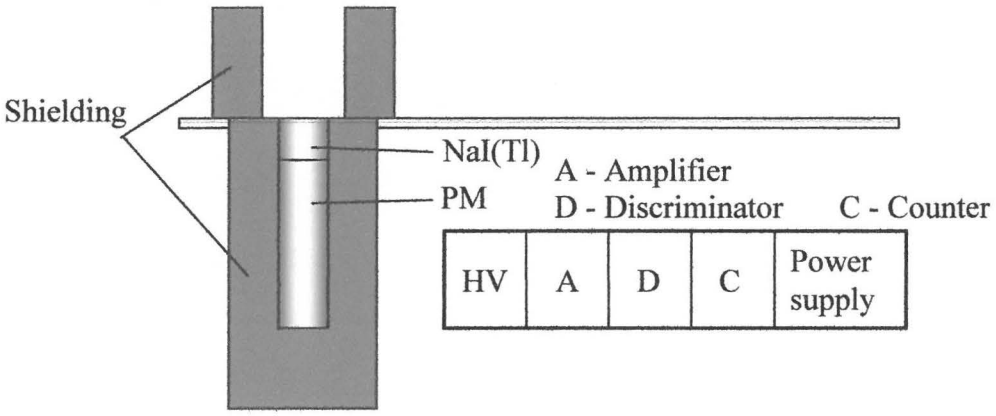


Fig. A.2.

A three sided Pb cave surrounds the space above the detector, enabling samples to be introduced from the front, while minimizing background, especially that coming from the gemstone inventory placed on the bench for counting. The sides of the cave are extended to improve the net shielding. Also mounted on the bench surface is a balance, which is used to measure sample mass. The detector counting is initiated by triggering a micro-switch that is enabled when the balance records a mass greater than a preset threshold. Figure A3 shows a top view of the work surface. Data from the detector system, (mass, counts and specific activity-based on the Ge determined ratio of isotopes) is automatically stored in a dedicated computer connected to each of the NaI(Tl) workstations.

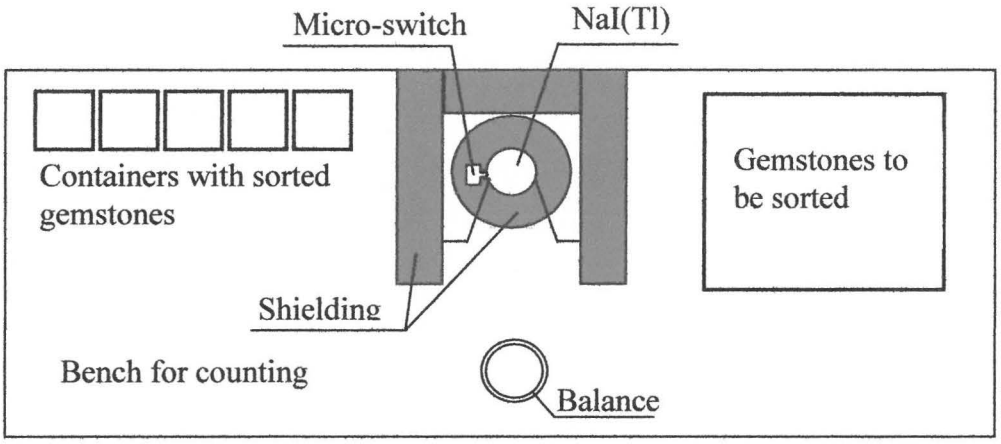


Fig. A.3.

The NaI(Tl) system employed at the importer's facility is closely copied from that in use at Maria, but is also equipped with a dedicated MCA so that gamma-ray spectroscopy can also be carried out to verify the results reported by the exporters QA program. This system was assembled at the Maria facility, calibrated and tested before installation at the importer's facility.

Equipment at the Thailand facility

The Thailand facility is equipped with a NaI(Tl) detection system similar to that installed at the irradiation facility and at the importer's facility. However, the Canberra system originally used is no longer available and, in Thailand has been replaced by a Bridgeport Instrument system using the Morpho software, modified to replicate and extend the importer's system. Instead of an integral balance, however, it has an external balance, coupled to the data acquisition computer. As structured, the operator places the sample on the balance, and when the mass is updated on the computer screen, the operator places the sample on the table directly above the NaI(Tl) detector and clicks on the "measure" icon. After measurement, the system reports a release date, which may be in the past (below the NRC exempt limit), present (at the NRC exempt limit) or future (above the NRC exempt limit).

The shielding of the Thailand facility is identical to that in use at our other facilities, and the performance for the Thailand station will be monitored regularly by comparing its results with those obtained at the Importer's facility on sets of stones provided for QA verification.

c. Beta detection:

The characterization of pure beta activity was accomplished using a plastic scintillation detector, from which it was established that ^{32}P is the only pure beta emitter encountered in these irradiations. The concentration of this isotope is known, *a priori*, from the fluence, (which is measured in every irradiation container using Ni foils) since it arises from the Si in the topaz matrix, No further, quantitative beta counting is planned, but GM detectors are employed to assure that no anomalous beta activity is encountered.

D.2. Calibration of Detectors:

a. Calibration of the Ge detector:

Efficiency calibration of the Ge detector is made with references sources (of ^{152}Eu and ^{241}Am provided by Division of Research and Laboratories, International Atomic Energy Agency, with the rounded overall uncertainty of 2% and 1%, respectively). Calibrated sources for efficiency and self shielding of gemstones are made using beads impregnated with 30 Bq of ^{152}Eu each, which yields 11 gamma ray lines between 121 keV and 1448 keV, the range of interest for quantifying the isotope distribution in topaz. 50 beads are mixed with white (un-irradiated) topaz gemstones in packets of 100, 200, 500, 1000, 1500 and 2000 g, which are then measured in the standard geometry to give the self shielding corrections across the energy spectrum. Interpolated values are used for the specific masses encountered in the measurements. Energy and background calibrations for the detector are monitored weekly.

b. Calibration of NaI(Tl) detectors:

Calibration of the NaI(Tl) detectors uses irradiated gemstones with known activities and isotope distributions derived from the Ge counting. Because of the different half-lives of the predominant isotopes ^{54}Mn, ^{182}Ta and ^{46}Sc, it is possible to provide sources which have only one of these components as the dominant contributor. Calibration includes the following components.

- Absolute calibration of detector efficiency is described below, but after ten years has been found to be unnecessary.
- Calibration of detector stability (energy calibration).semi-annually or as required from failure.
- Background calibration (daily when in use)

i. Absolute calibration of detector efficiency:

The efficiency of the detector for each of the isotopes is established by narrowing the discriminator so that only the single line (for ^{54}Mn and ^{46}Sc) or the high energy lines (^{182}Ta) is accepted by the counting chain. Samples are derived from selected stones, measured with the Ge detector to establish the absolute activity of the selected isotope, and measured in the standard counting geometry. For example, the activity of stones from Nigeria have initial activities dominated by ^{182}Ta, while stones that have decayed for long times are dominated by ^{54}Mn. Several samples with varying activity are used to establish the linearity of the NaI(Tl) system in the counting range of interest.
An example of such calibration of NaI(Tl) detector is shown in Fig. A4.

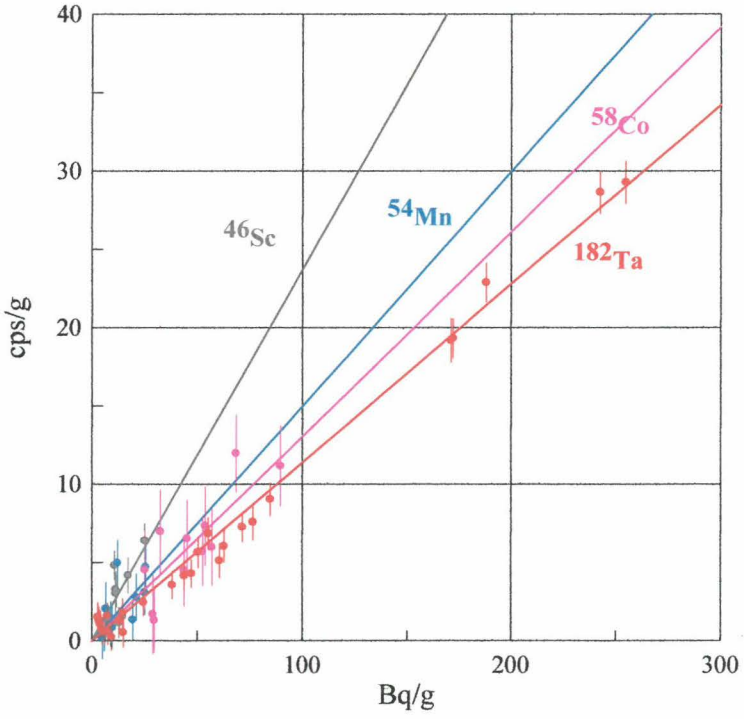


Fig. A.4.

ii. Calibration of detector stability:

The stability of the detectors is monitored periodically using the same ^{152}Eu impregnated beads used for the calibration of the Ge detector. The result must agree with the calibration constants for the instrument within two standard deviations for counting to continue. Otherwise, the problem must be identified and corrected

iii. Background calibration:

The background at each NaI(Tl) station is measured at the start of each day before use. The counting times employed are sufficiently long to permit statistically reliable subtraction of the background from the net counts for the samples, prior to conversion to specific activity. If many batches of stones are to be counted, the background may be monitored more than once a day to insure against a "crumb" or other contaminant close to the detector.

The results of the NaI(Tl) counting are stored in the computer and the cumulative results for a packet of stones can be compared to the results obtained from Ge counting of the same stones. Inasmuch as our original method employs sorting for outliers before the average activity has decreased to the exempt limit, the Ge counting was performed after the NaI(Tl) counting, on the reassembled packet, excluding the outliers identified in the NaI(Tl) sort. (see section D.3.)

D.3. Counting Procedures:

Introduction:

The counting procedures employed by the exporter were previously based on a new method that recognizes that it is easier to identify "outliers" (i.e. those whose activities will exceed twice the exempt limit at the time the average activity for the group reaches the exempt limit) if the sorting takes place at an earlier time, when the activity of those outliers is higher and the statistical accuracy of the counting is better. This, in turn, is possible because of the unusual nature of the distribution of activities, which, apparently has not previously been recognized, or, at least, has not been used for the determination of outliers. Dr. Yelon was a consultant in the preparation of the Alnor-Studsvik license and is fully familiar with the methods developed in that case. The distribution of activities used as the basis for that license accurately reflect the results at the time of release of the majority of stones, but when projected back in time, and presented for the individual (principal) isotopes, the distribution looks quite different, and has features that make it attractive for sorting. In addition, the data imply that (small) batch counting, rather than single stone counting can be employed for medium and large stones, reducing the task of sorting to a more manageable level. It must be recognized, however, that no method can guarantee that very small stones are free of outliers, even when single stone counting is applied. However, the doses associated with batch release of stones based on the NRC limits are negligible compared to permitted doses for large stone satisfying the

exempt limits. For this reason exemption from the 1/1000 criterion is requested. This request will be further justified in this appendix. In spite of this, we continue the discussion to underscore our thorough understanding of the nature of the stones and their activities and to demonstrate the labor intensive nature of the procedure.

The following discussion relates primarily to the basis for the sorting procedure we have previously employed and which will not be the primary release method in the future. Nevertheless, the data have been carefully collected and may provide valuable guidance in the NRC evaluation of our proposal and that that of our competitors.

Distribution of activities:

In the following discussion, T_r refers to the time at which the average activity of the initial collection of stones, with a single geologic origin, size, shape and radiation history, reaches the exempt limit. T_s refers to the time of sorting (counting) to eliminate outliers, A_e refers to the activity given by the exempt concentration of isotopes (using the sum-of-ratios method) and other activities are presented in similar terms, e.g. $2A_e$ refers to stones with twice the exempt concentrations. The discussion focuses on stones from two sources, Rondonia, in Brazil, referred to as RC, and from Nigeria, referred to as NC. These are less pure than stones from Sri Lanka, described in detail in the Alnor-Studsvik license, and, as such require longer cooling times and are more difficult to sort. However, the same considerations apply to Sri Lanka stones, although the relevant "controlling" isotope is ^{46}Sc, rather than ^{182}Ta, as described below. Stones from other origins are similar to one or the other of these families of impurity distributions.

The distribution of total activity for Sri Lanka gemstones was reported in the Alnor-Studsvik license application, based on NaI(Tl) counting. It showed a peaked distribution of activities with a long tail at high activity. The total activity of both the NC and RC stones resembles this distribution but Ge measurements on 200 large stones of each type reveals that the ^{54}Mn activity is peaked, with a relatively narrow spread, while the ^{182}Ta activity more closely resembles a log-normal distribution, with most stones having a very small activity, and with a long tail, reaching several times A_e. These results are presented in units where activity 1 corresponds to the average. It is clear that the average activity of the Ta is dominated by the long tail. It seems likely that the Ta solubility in the topaz matrix is small and that the tail arises from microscopic inclusions of a Ta rich phase while it is likely that the Mn activity is associated with the inclusion of Fe in the topaz structure and is probably limited by its solubility in the phase. The activity reflects the concentration of these inclusions. Fig. A.5. shows the results for the NC stones, while Fig. A.6 shows the results for the RC stones.

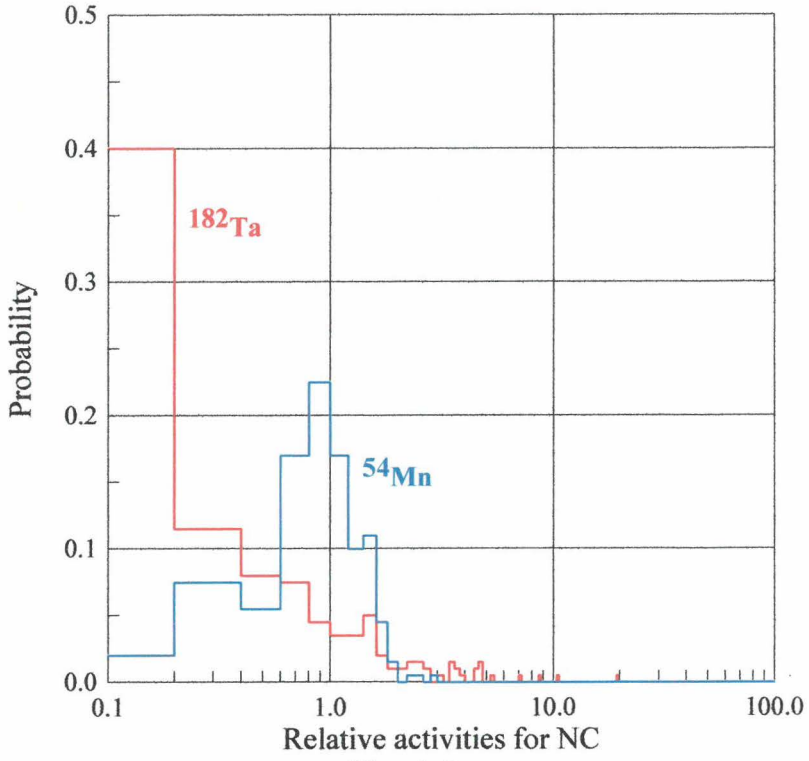

0.5
0.4
0.3
0.2
0.1
0.0
Probability
182Ta
54Mn
0.1
1.0
10.0
100.0
Relative activities for NC

Fig. A.5

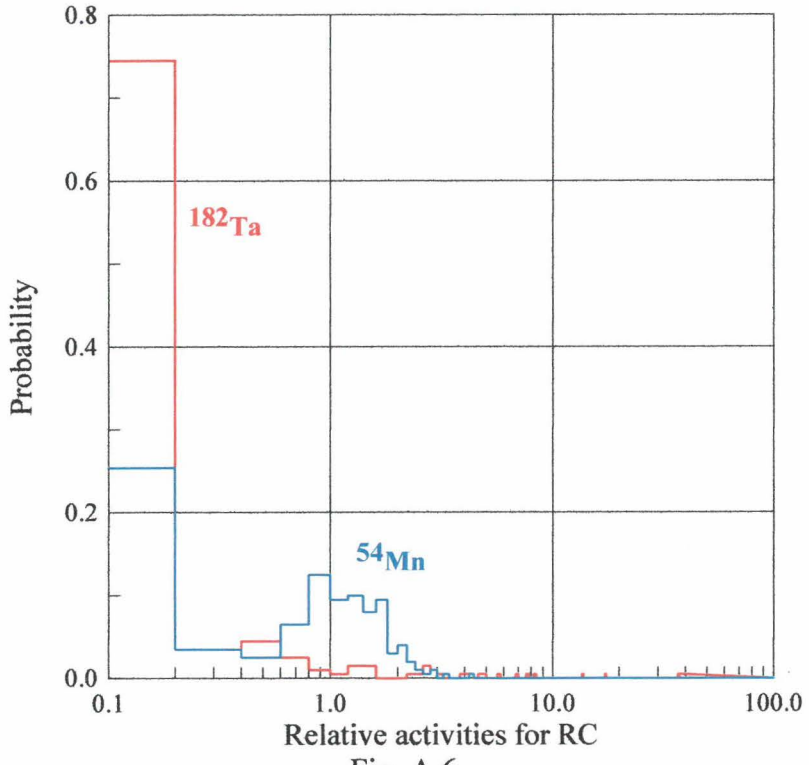

0.8
0.6
0.4
0.2
0.0
Probability
182Ta
54Mn
0.1
1.0
10.0
100.0
Relative activities for RC

Fig. A.6

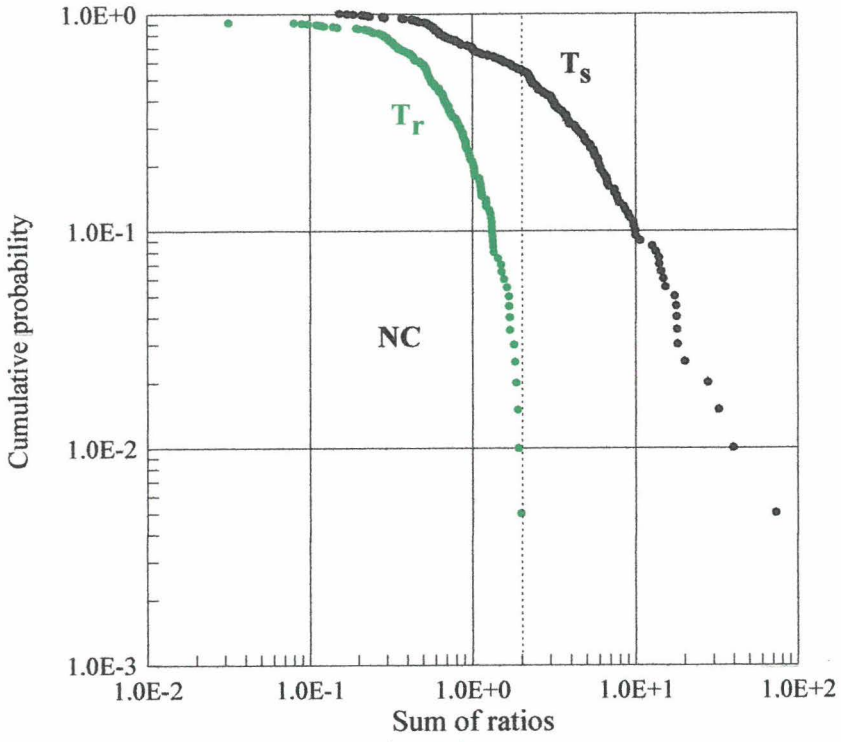


Fig. A.7

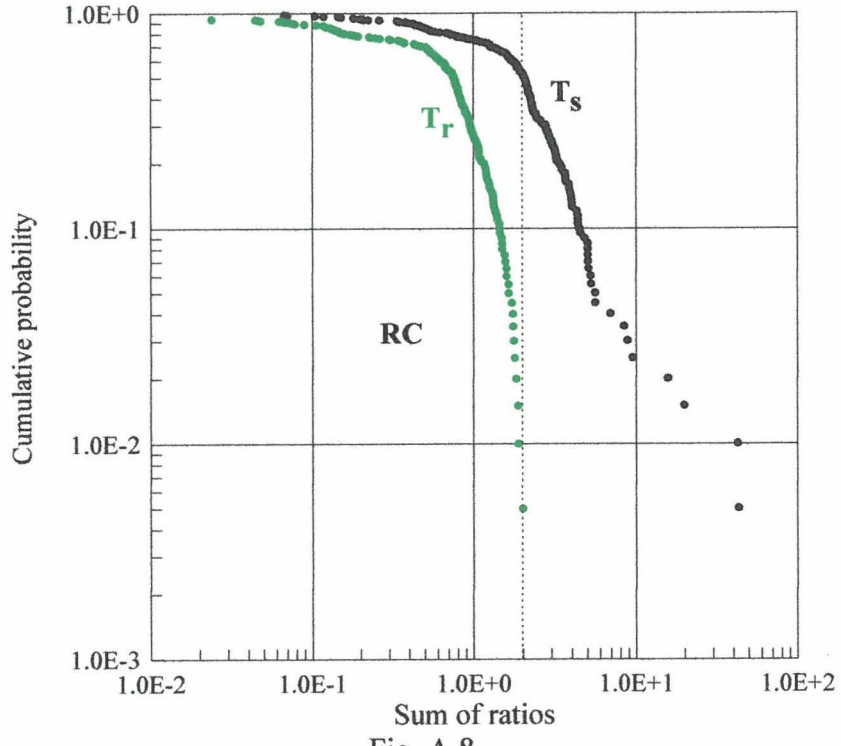


Fig. A.8

Figures. A.7 and A.8 present the cumulative probability distribution of sum-of-ratios at T_r, where T_r is estimated from the generic distribution of isotopes and activities in the different geologic sources, i.e. prior to activity measurement. It is found that about 9% of

the NC stones will have activities greater than $2A_e$ and 4% of the RC stones will exceed that limit as well. Figures A.7 and A.8 show the distribution of activity, at an earlier time, T_s, when the Ta activity dominates the total. At T_s, the sum-of-ratios for stones which will exceed $2A_e$ at T_r have total activity $10A_e$ or greater. It is clear that it is easy to identify and remove these stones at that time. The new distribution (with those stones removed) is also shown in A.8 and A.9 for T_r. Now, no stones remain with activity greater than $2A_e$ and the average activity is less than A_e, thus satisfying NRC requirements. In fact, the distribution of activities, (most stones have low activities) allows not only single stone counting, but small batch NaI(Tl) counting. Any batch containing a single stone with activity $\geq 10A_e$ is easily identified and the outlier eliminated through iterative division of the batch and recounting. This counting would be windowed on the Ta gamma rays to improve the signal to noise (the Mn activity is "noise" in this process). In this case, most batches would pass through without division. Batch sizes will be chosen so that about 10% will show the presence of one (or more) outliers, but the time needed for processing the entire group will be substantially reduced relative to single stone counting. Of course, the counting time required will depend on the size of the stones and the number of stones in the batch, but the high activity of the outliers reduces the risk of missing the outlier, due to statistical error, to near zero. Once the sorting has been completed, the entire group, minus outliers, will be measured with the Ge detector to verify the predicted average activity and isotope distribution. The average for total activity and Ta activity will, of course, be less than the generic activity, but no adjustments to T_r will be made, in order to guarantee the statistical requirements are fulfilled.

Combined Mn-Ta activity:

The procedure described above eliminates stones whose final Ta activity is more than roughly 40% of A_e at T_r, when the Mn activity becomes the major component (~ 55%). However, we must also assure that the few stones with the highest Mn activities do not also contain enough Ta to exceed $2A_e$, with a probability greater than 1/1000. The measurements of individual activities have shown no correlation of Mn and Ta concentrations and also show that (based on the distribution) fewer than 1% of the stones will have Mn activities equal to about 1.5 A_e. Thus, we must be sure that fewer than 10% of the stones have Ta activities greater than 0.5 A_e. Examination of the distribution of ^{182}Ta activities shown in figures A.5 and A.6 show that the average activity of the group is highly skewed by the outliers with many (40-100) times the average activity, and that more than 90% of the stones have activities below the average, thus assuring that this condition is met.

Eventual release of outliers:

Even though their numbers are small, outliers identified by the sorting process will be stored by activity and allowed to decay to the NRC limits, at which time they will be released.

Specific answers to part D.3:

Procedures at the irradiation facility:

a. Selection of samples:

Samples to be sorted for exempt release are packets that, based on the generic distribution of isotopes for that geologic source, and the irradiation history, would have average activity A_e at time T_r. The packet contains only stones of a specific size and shape, and is from a small enough (vertical) section of the irradiation container (which is rotated during the irradiation to homogenize the dose), that all stones are assumed to have the same neutron dose. Counting at the irradiation facility may take place before the average activity has been estimated to reach the NRC exempt limit. Those parcels would be put into storage until they are ready for release, based on the distribution of activities determined during the testing. (See section f. below)

b. Maximum and minimum sample sizes:

In general, samples will consist of groups of stones with the same origin, size, shape and irradiation history. Typical groups will be around 200g. Smaller groups may be encountered as determined by the packing of the irradiation containers. Stones of different sizes and shapes will not be mixed in a test volume, except as they constitute an existing inventory of previously identified "outliers", that have been stored in bins designated for their accurately determined dates of release. This is based on their specific activities and sum-of-ratios from the single stone counting that has accompanied the binary sorting of outliers procedure previously in use.

c. Counting efficiency:

The efficiency for the NaI(Tl) detectors is estimated to be approximately 40% for the high energy gamma rays from ^{182}Ta. Because the mass of the samples undergoing testing will be relatively large (200 gm) the background will be negligible, and it can be assumed that all counts are from the stones. Even using small samples (10 gm) we have found that the system reliably reports the specific activities and sum-of-ratios for those samples.

d. Counting times:

The counting time for each test sample will typically be 30-60 seconds, but will be increased if the uncertainty in the result (2-sigma) exceeds the NRC exempt limit. The program is designed to allow a re-measurement with the statistical error to be reevaluated from the combination of the measurements.

e. Counting geometry:

The NaI(Tl) counters have their end windows flush with the surface of the workbench. The samples are contained in thin wall plastic container with diameter less than the detector diameter and are placed directly on the detector window. The efficiency of the detector is adjusted for the mass of the sample, to account for the self shielding of stones that cover more than a single layer.

f. Time of counting:

The time of counting will depend upon the origin of the stones and the irradiation history. No stones will be tested until the estimated activity (based on historical data) is close to or below the exempt standard. Obviously this will require storage of different stones for different lengths of times. For example, stones from Sri Lanka can be tested in less than 60 days since they have been found free of Ta, while stones from Nigeria require cooling times in excess of one year. Because of the relatively poor color quality of Nigerian stones, they are not expected to constitute a significant component of the inventory.

g. Lower limit of detection:

Although the systems in use at the exporter's facility are well shielded, and capable of low level counting, the sorting method to be employed does not depend upon a very low level of detection. However, in the prior license, which used samples of 10 gm or less, we were easily able to determine specific activities of a few Bq/gm for both ^{56}Mn and ^{182}Ta.

h. Statistical methods for analyzing data, calculating background and lower level of detection and data confidence levels:

(This section was written partially in explanation of the statistical method we applied to small groups of stones in order to identify and remove outliers. Nevertheless, the data contained here applies to the proposed license and demonstrates our thorough knowledge of the activity distribution in topaz.)

The activity curves for the specific isotopes shown in figure A.5 and A.6, show that very few stones in the distribution have activities greater than twice the mean activity, and that a small group of stones will contain not more than a few stones of this type. This allows us to set a conservative threshold for triggering the "alarm" requiring a sorting of the group to identify a potential outlier. The procedure uses the conservative assumption that all stones, except a single outlier have average activity given by the weighted average of the activities of the distribution up to twice the mean activity (the distribution average). (Using a different cut-off has minimal effect on the procedure). The "alarm" level is set at the average activity of that group plus the activity of a minimum outlier, i.e. one whose activity would result in stone with twice the exempt limit at T_r, minus 10%. The counting time would be set such that a group containing such an outlier would not be detected would be at least 4 standard deviations from the alarm limit. If the limit is exceeded, the group is divided in two and each half tested using the same procedure. The outlier can be

uniquely identified by successive division of the group and re-measurement. The detection system automatically records the mass of each parcel and records the specific activity of each smaller group, with the same threshold preserved.

The following paragraph is not relevant to the current application, but is retained for reference.

This is a very conservative procedure; it may produce false positives if two stones with allowed activities are present in the group or if the average activity of the main group exceeds the assumed activity, given by the weighted activity described above. It insures that false negatives will not occur. Once we begin releasing stones using this method, further testing and statistical analysis will be carried out to see if the alarm level could be raised modestly to further reduce false positives, while preserving the reliability of the sorting for outliers. If such changes are made, they will be reported to the NRC in an addendum, allowing for further NRC review.

i. Procedures for minimizing false negatives:

The following paragraph is not relevant to the current application, but is retained for reference.

The principle procedure for minimizing false negatives is the decision to count stones when their activities are much higher than at the time of release. This results in high count rates (resulting in good statistical reliability) and allows the effect of a small (potentially varying) background to be neglected. In addition, the threshold for "alarm" is set at a conservative level, based on the assumption that the stones that make up the main distribution have less than their true average activity. Finally, the statistical 4 sigma test is used. Finally, we note that the distribution of stones to be excluded is sparse. The probability of finding a stone that will produce exactly twice the exempt limit of activity is quite small, and most outliers will have significantly higher activities, making them still easier to identify. We are confident that this procedure will effectively eliminate outliers that would lead to release with $2A_e$ with probability significantly better than 1/1000.

i. Sample calculations:

The following paragraph is not relevant to the current application, but is retained for reference.

The following calculations are shown for example only. We have simplified some assumptions that will be fully taken into account in the actual implementation of the counting procedure, but are ignored or rounded here. If the sorting takes place at a time when the total activities are high, the background can be neglected as we have done in the example below.

Assume that at T_r the mean activity of ^{54}Mn and minor constituents is 50% of A_e (using the sum of ratios). The mean ^{182}Ta activity, will, of course be 50% of A_e at T_r if the release takes place when the average total activity is equal to A_e. (The actual Ta/Mn ratio at T_r varies with geologic origin and duration of irradiation, but these values are typical of the range encountered.) The task, then, is to identify any stone that will contain $1.5A_e$ of ^{182}Ta at T_r, with a probability less than 1/1000 that one such outlier is not identified in the sorting.

Perform the counting at time T_s, such that the ^{182}Ta activity of this outlier is $10A_e$. This converts to counting approximately 250 days before the estimated release date, which is based on knowledge of the generic distribution and radiation history. Assume that the ^{182}Ta distribution average (defined in h. above) is 0.3 A_e at T_r, (i.e. 60% of the mean activity including all the outliers). This corresponds to activity $2A_e$ at T_s.

Assume a group containing 20 stones, 1 outlier with activity $10A_e$ and 19 stones with the distribution average activity $2A_e$. This corresponds to a net activity of $48A_e$, with the single outlier contributing more than 20% of the total activity.

For this type of distribution (which appears to be reasonable for NC stones) we set our "alarm threshold" at 90% of the count rate expected for a group containing exactly one (minimum) outlier and 19 average stones. Assume stones with 1 g mass (5 carat) ea.

For ^{182}Ta, A_e is approximately 15 Bq/g. Thus our group has net activity

$$A_{total} = 48 \times 15 \text{ Bq} = 720 \text{ Bq}$$

Using the high energy gammas from ^{182}Ta, with an 85% yield, and a 40% efficient NaI(Tl) system we expect a count rate

$$C = 720 \times 0.85 \times 0.4 = 245/\text{sec}$$

A 10 second count will, then, give 2450 counts with a standard deviation

$$\sigma = \sqrt{2450} = 49.5$$

The "alarm threshold" set a 90% of the minimum outlier level is

$$C_{alarm} = 0.9C_{net} = 220/\text{sec}$$

For the example of the 10 second count given above, this is 5σ from the expected count, and the system will reliably trigger the alarm, initiating the iterative search for the outlier. Thus, the10 second count is more than sufficient to guarantee that these stones can be successfully sorted in batches of 20.

For larger batches or smaller sizes, longer counting times will be required. It appears that stones as small as about 2 carat can be sorted in this way. For smaller sizes the batch size

must shrink or the counting time grow to unreasonable limits. Counting at the earliest time possible (after the decay of short lived byproducts) can modestly improve the situation, but for a significant percentage of the total production of cut topaz, no practical method can assure the NRC standard of fewer than 1/1000 outliers.

Ten years of experience have shown the method described above to be reliable, but due to the small sample size and the sorting required to identify and remove outliers, is both expensive and time consuming. The method thereby diminishes our competitiveness, vis-à-vis competitors that do not attempt to identify and remove outliers. It does, however, **strictly** comply with the guidelines in NUREG 1556, that not more than one stone out of 1000 exceed 2 times the NRC exempt limit.

Procedures at the Thailand facility:

The Thailand facility has been equipped with a NaI(Tl) detector (Bridgeport Instruments) with programming based on that in use at both the irradiation facility and the importers facility. It has been modified to simplify the user experience by reporting a release date rather than a list of activities (although these data are stored). This date could be in the past, present or future. Any stones (or group of stones) with a future release date would be stored for decay until, at least, that date. Stones with present or past release dates would be eligible for release. The data for those stones will be transmitted to the import facility so that inventory and certification can track the sale of those stones.

The Thailand facility will be used primarily for stones that have been cut from rough in Thailand for special orders, (such as non-standard shapes and color selected rough). Periodically (initially every three months), the Thailand facility will provide the importer with 20 tested pieces (and the related reports) for verification at the importer's facility. Failure of agreement would result in cessation of activity in Thailand until the source of error is determined and remedied. .

Procedures at the importer's facility:

a. selection of samples:

We propose that the licensee's QA facility (the importer) would verify a small percentage of the lots tested. These would be selected at random from a numbered list provided by the exporter. Files containing the identity of the lots would be provided in a read-only file, to assure that the selection was not biased. Lots chosen for verification would be shipped to the importer's facility while the remaining lots would stay with the exporter until the verification procedure was successfully completed. Once the verification was completed, the remainder of the lots would be shipped (with appropriate documentation generated by the exporter, identifying the NRC license and the characteristics of each lot) to the licensee's facility. Upon request, the applicant would provide access to its distribution center for the purpose of allowing the NRC to select material to be tested by the NRC or its contractor, 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. We propose that 5% of the parcels be verified at the importer's facility, with not fewer than 5 parcels per (intended) shipment.

b. Maximum and Minimum sample size:

Typical lots selected by the applicant for verification will contain 1 kg or less of gemstones of a single size, shape, geologic origin and irradiation history. These will be measured on the importer's NaI(Tl) system, using the equipment employed at the irradiator's facility. As with the exporter, verification will be carried out only on single packets of stones (with the exception noted above for mixed, decayed outliers) with masses up to 1000 gm. Sample sizes will not exceed 200 gm, but in cases of small packets, may be considerably smaller. In the past, we have restricted the smallest parcels to 60 gm, because of limitations in the program for determining the probability of outliers, but this limit no longer needs to be applied.

c. Counting efficiency:

The efficiency of the Nai(Tl) system to be employed at the importer's facility replicates the systems currently in use at the exporter's facility and is estimated to be 40% efficiency for the isotopes of interest.

d. Counting times:

At the time of export, the average activity of the stones will be equal to or less than A_e, (about 25Bq/g for the typical Mn/Ta ratio encountered). With 200 g batches, 30-60 second counting will produce of order 40000 net counts, sufficient to establish the average activity, For smaller packets the time may be adjusted to guarantee that the average activity is less than A_e with uncertainty (2-sigma) outside that value.

e. Counting geometry:

The counting geometry is identical to that employed at the exporter's facility (see above).

f. Time of counting:

QA testing at the importer's facility will only take place after the average activity of the lot is less than A_e. No lots should be sent to the importer that will not be immediately releasable as exempt, it the verification is successful.

g. Lower level of detection:

No single stone counting is contemplated at the importer's facility (except to verify results from the Thailand facility); it will be used only to verify that the activities reported by the exporter are accurate. Using 200 g batches with average activity A_e implies that very low level counting is not an issue. Nevertheless the importer will

establish a facility with the lowest background reasonably achievable so that single stone counting on selected large stones can be carried out for testing/quality assurance purposes.

h. Statistical methods:

Statistical analysis at the importer's facility will be limited to calculations of the isotope distribution, average activity and to the distribution of activity based on the variability of the activity measurements for different 200g or smaller batches. Unless unexpected results are encountered, no additional analysis is expected.

i. Procedures for minimizing false negatives:

The following paragraph is not relevant to the current application, but is retained for reference.

The procedures for identifying outliers, and the statistical limits on their identification are spelled out in the procedures for the exporter's facility. Faithfully performed, those procedures should guarantee that no outliers reach the importer's facility. The importer's facility is used only for the purposes of testing that the results reported by the exporter are reliable. Nevertheless, large stones could be counted, (with long counting times) to periodically re-screen a limited number of lots.

j. Diamond testing

Diamonds will be tested in batches of 50 gm or less only at the importer's facility in Missouri. We will require that no evidence of radioactivity above background be observed, since our testing, under the prior license, has shown that electron irradiated stones do not show any activation (as expected). Observation of a signal above background will lead to an effort to decontaminate the stones, followed by recount. If activity is observed after cleaning is more than a few Bq/g, the stones will be returned to the treater without certification. If very low activities are observed, the isotope distribution will be characterized and used to build a data base for future testing. However, we largely expect that no activities will be seen. Once approved for release, a diamond data base will be established for the issuance of certificates to accompany the sales.

k. Sample calculations:

Sample calculations are given for the exporter's facility above. No sorting is to be performed at the importer's facility (except as part of the QA procedures in part 5 below).

5. The QA procedures:

Procedures at the exporter's facility:

a. Standards, frequency and procedures used to perform constancy tests:

The Ge detector is maintained as part of the reactor instrumentation at Maria and, as such, is subject to regular calibration, background tests and other tests needed to assure its performance in compliance with Polish Law, which appears to be as stringent as those required at U.S. facilities.

The NaI(Tl) detectors are subject to daily background and periodic efficiency tests. Secondary standards, derived from the Ge detector are routinely used to establish the performance of the detectors, using the ^{152}Eu beads, developed for calibrating the efficiency of the Ge detector for different mass topaz samples. These are regularly used for calibrating the NaI(Tl) detector for the energy range of interest.

b. Frequency and methods for introducing spiked samples:

The following paragraph is not relevant to the current application, but is retained for reference.

The identification of outliers, already performed, has allowed for the establishment of a "library" of hot stones that can be introduced into a batch for counting, using the same size and shape to disguise their identity. They are marked with a fluorescent dye but are impossible to identify with the naked eye. Failure to remove such a stone (chosen as close to the outlier lower limit as possible), results in a shutdown and recalibration of the NaI(Tl) system. Such spiked samples will be introduced at least once a day, on each counting system, during sorting operations.

Procedures at the importer's facility:

The NaI(Tl) detector(s) at the importer's facility will be subject to daily background, and periodic calibration tests using ^{152}Eu beads. It has been established that the detector efficiency (40%) is stable over 10 years and will only be tested if systematic discrepancies between the export and import facilities appear.

The quality assurance procedure requires that the specific activities reported by the importer for each tested pack agree (within a reasonable statistical limit) with the reported results from the exporter. Of course, those results will also show that the specific activities and sum-of-ratios fall below the NRC exempt limit.The packets to be tested will be randomly selected from a list provided by the exporter.

Request for exemption from the 1/1000 standard

The NRC guidelines, for the issuance of a license to permit the distribution of irradiated gemstones, includes a requirement that not more than one stone out of 1000 exceed two times the exempt activity limit. Our previous license disclosed a method of testing that

would meet this standard without the necessity of single stone counting. Our experience over the license lifetime showed that we were successful in meeting that standard. Despite the improvement the method afforded, vis-à-vis single stone counting, the method was slow and costly, requiring nearly full time utilization of three NaI(Tl) counting stations at the Maria reactor. During this time, however, other licensees have failed to comply with that demanding standard and have argued, on the basis of risk to human health, that the requirement be waived. We were not aware of this situation until we provided (Qualitech-International Isotopes) with spiked samples that were significantly outside that standard, which they approved for release without comment. Discussion with the NRC allegations section led to the realization that the standard had been waived altogether. We are requesting a similar exemption from the 1/1000 standard.

Basis for the requested exemption:

The license application from International Isotopes (Adams Accession Number ML073340395, pages 15-17) provides a detailed analysis of the risk to human health from a modeled exposure and concludes that these are negligible. They conclude **"Based on a study sponsored by the NRC..., the stochastic risks associated with the modeled exposure are of 8.8 x 10^{-11} and 4.3 x 10^{-8} for fatal and non-fatal skin cancers, respectively."** It seems unnecessary to replicate their argument here as it is publicly available through the NRC Adams system.

The following paragraph is not relevant to the current application, but is retained for reference.

~~**Proprietary information**~~
~~**Not to be released to the public without permission**~~

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.

If we examine the activities for ^{54}Mn and ^{182}Ta, given in figure A.6 of aour license application, we find a remarkable result; the ^{182}Ta activity is dominated by the outliers. At the time T_r when the average sum-of-ratios (SOR) is equal to 1, we have the following average activities:

^{182}Ta = 5.6 Bq/g ^{54}Mn = 15.4 Bq/g <SOR> = 1.0

Eliminating those stones with SOR $\geq$ 2, results in an adjusted average activity:

^{182}Ta = 1.9 Bq/g ^{54}Mn = 15.9 Bq/g <SOR> = 0.77.

That is, approximately 2/3 of the total ^{182}Ta activity is accounted for by the outliers (the tail of the distribution) and there is a weak negative correlation between ^{54}Mn activity and ^{182}Ta activity (at least for stones with high Ta activity). This feature is of great value in the sorting.

If we consider stones with mass 0.2 gm, we first note that a 10gm batch will contain (on average) at least one such outlier, and division of the batch will be necessary to effectively sort the lot. Consequently, the initial batch size should be reduced to 5gm for the sorting. We consider the average counts for three conditions, assume a 40% efficient NaI(Tl) system, reporting only the ^{182}Ta activity (spectroscopic mode), and 30 second counting. We further assume that the counting takes place at time T_s such that the Ta activity is 5 times higher than at T_r i.e. slightly more than 2 half lives prior to T_r.

1) The lot contains no outliers. With 25 pieces with average ^{182}Ta activity is equal to 1.9 Bq/g at T_r and 9.5 Bq/g at T_s. The total activity for the lot is then 237.5 Bq

The average count, <C> = 237.5 x 0.4 x 30 = 2850 cts.

2) The lot contains 1 outlier such that at T_r the SOR for that stone would equal 2. This corresponds to a ^{182}Ta activity of 20.3 Bq at T_r and 101.5 Bq at T_s. This results in a total activity (24 x 9.5 + 101. 5) for the lot equal to 329 Bq

The average count, <C> = 329 x 0.4 x 30 = 3948 cts.

3) The lot contains 1 outlier such that at T_r the SOR for that stone would equal 2.5. This corresponds to a ^{182}Ta activity of 27.6 Bq at T_r and 138 Bq at T_s. This results in a total activity (24 x 9.5 + 138) for the lot equal to 366 Bq.

The average count <C> = 366 x 0.4 x 30 = 4392 cts.

Note that at these count rates, the background of approximately 1/sec contributes nothing to the uncertainty.

If we set the threshold for alarm at 3600 counts, more than 5 sigma from the <C> for case 2, we will have less than a one in a thousand chance of missing the outlier. Furthermore, the chance of missing an outlier described in case 3 is infinitesimal.

However, we can take further advantage of our knowledge of the distribution to reduce the risk of false positives (due, perhaps to a stone that will have an SOR somewhat less than 2 at T_r). For the distribution given in fig. A.6, only 4.5 % of the total number have activity above SOR = 2 at T_r and, in fact, not more than about 1 % of the stones will fall within the interval 2 < SOR < 2.5. Consequently, our threshold would be set at 2 x sigma (3824 cts) to assure that the probability that a stone within this activity interval is released is less than one in one thousand. In fact, the total probability of release is equal to the product of the probabilities:

$$P_{total} = P_d \times P_s$$

Where P_d is the probability of finding a stone in that interval (0.01) and P_s is the probability that the stone is missed in the counting (0.05 for a 2 sigma test). In the case described above, that product is 0.0005, i.e. not more than one stone in 2000 in this activity interval will be released. In fact, the probability is still smaller since, only those few stones very close to SOR = 2, will fail the test with a 5% frequency, while those with higher activities will fail less often.

It should be noted for the distribution of activities in NC stones, (Fig. A.5) the problem is more difficult, and we will modify the procedures accordingly for the current inventory. However, it is our intention to use, in the future, only stones from RC origin, or from other sources for which the distribution of activities is, at least, as favorable as the case described above.

Summary: By adjustment of the lot size and counting time, it is possible to meet the NRC criteria that not more than one stone in one thousand with activity equal to or greater than SOR = 2 is released.

Audit Requirements

Insofar as the irradiator has reliably performed under our previous license, we believe that audit frequency for that facility and its personnel can be reduced to bi-annually. The audit would examine whether the procedures spelled out in the license (e.g. vis-à-vis calibration of detectors) are being carried out properly, and whether the personnel are adequately trained for their positions. However, the most important "audit" is that carried out on a routine basis; confirmation of agreement between the irradiator's results and those at the importer's facility. Failure of agreement requires a shutdown of release until the source(s) of disagreement is identified and remedied.

With regard to the facility in Thailand, both the equipment and the personnel are new to the task. Consequently, Dr. Yelon will visit the facility within a short time of license approval to verify the training for Patty Worawong and to train any other individuals expected to carry out testing. He will bring the ^{152}Eu source used in his office to verify the detector performance, and check that the programming will allow for the bookkeeping tasks associated with release, certification and periodic validation of the system performance. Initially the Thailand facility will provide samples to the importer for comparative measurements every three months, and Dr. Yelon will revisit the facility after one year of operation. If the state of the equipment and the level of training remains adequate, the frequency of visits and of verification tests will be decreased, although we intend to compare results from Thailand and Missouri at least twice every year.

We are confident that the facilities in Poland and Thailand can be operated in a manner that assures that the NRC standards are adhered to, and that adequate

documentation is available to assess the production and distribution of blue topaz to the American market.