April 15, 1991

TELEDYNE ISOTOPES
50 VAN BUREN AVENUE
WESTWOOD, NEW JERSEY 07675
(201) 664-7070

See Rpt

U.S. Nuclear Regulatory Commission
Medical, Academic, and Commercial
Use Safety Branch
Attn: Michael Lamastra
Mail Stop OWFN 6-H3
Washington, D.C. 20555

re: Docket No. 030-31965
U.S. NRC License No. 29-00055-16E

Dear Mr. Lamastra:

Based on recent conversations with a major wholesaler, there is a need for a "clearing house" for domestic and imported gemstones from many different sources. We feel that Teledyne Isotopes can meet this requirement with some minor modifications to our existing license. Therefore, Teledyne Isotopes requests an amendment to the above referenced license to incorporate the following changes, additions, and deletions.

I have enclosed an updated copy of our Radiation Safety Code & Quality Control Manual which incorporates all of the changes as well as a DRAFT copy which indicates to you exactly what changes have been made by showing deletions crossed out and additions in bold italic type. Also enclosed is a check in the amount of $280.00 to cover the cost of this licensing action.

1) We request that we be authorized to accept any type of gemstone for analysis and distribution. Because we will be counting every gemstone for beta and gamma activity, either individually or in small groups, and will not be relying on the origin nor type of irradiation to the stone to determine its releasability, there is no need to limit the type of stone that we may accept. We want to be able to accept gemstones from importers, wholesalers, or anyone who would want their gemstone analyzed. We do not want to be limited to topaz as other types of stones may be subjected to this type of treatment in the future. Therefore, please change condition 7A to read "Irradiated processed gemstones", and in conditions 9A and 14 change the word "topaz" to "gemstones".

2) We request that the requirement for a Certificate of Origin and a Certificate of Irradiation be removed from the license conditions. Because of the need to have "street" gemstones analyzed, many clients will not have this type of certification available nor do we need this information as explained in Item 1 above. Furthermore, it is prudent to have the stones counted by a service such as ours to prevent unnecessary exposure to the public.

3) We request the removal of the Acid Wash Certification as we will treat the stones as contaminated until the results of the rinsing performed at Teledyne Isotopes are known.

4) Please change Condition 11 to: "Licensed material shall be distributed by, or under the supervision of, persons authorized in writing by the Radiation Safety Committee."

5) Finally, we request authorization to ship gemstones that do not meet the specified limits to overseas clients that can receive them. This is in addition to our option store and/or dispose of these types of gemstones.

If you have any questions, please call or fax them to the attention of the undersigned. Thank you.

Sincerely,

TELEDYNE ISOTOPES

Steven A. Black, R.S.O., Manager
Radiological Services Department

SAB:jk
Enc.

Log ..... Agreement Ltr
Receipt .....
Check No. 4711
Amount 280
Fee Category 3I
Type of Fee Amdt
Date Check Rec'd 4/15/91
Date Completed 4/23/91
By: .....

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PDR FOIA
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III-13.0 SPECIAL PROCEDURES FOR THE DISTRIBUTION OF IRRADIATED GEMSTONES TO PERSONS EXEMPT FROM LICENSING

This section of the RSC & QCM covers the transfer of irradiated gemstones to persons exempt from licensing.

III-13.1 *Facility Name, Address, License Number(s), Contact, and Locations*

Address: Teledyne Isotopes
50 Van Buren Avenue
Westwood, NJ 07675

License: U.S. NRC License 29-00055-06 and 29-00055-16E

Contact: Steven A. Black, R.S.O., Manager of Radiological Services
201-664-7070 x225
FAX: 201-664-5586

Location: To be distributed from the address identified above. In addition, all records will also be maintained at the above address.

III-13.2 *Background Information*

III-13.2.1 This license request is for the distribution of irradiated gemstones. Our US NRC License 29-00055-06 will cover the possession and use (analysis) of the radioisotopes prior to their distribution to persons exempt from licensing.

The expected quantity of gemstones delivered to Teledyne Isotopes is expected to be 40,000 gemstones per month. If a typical gemstone is 0.5 carat (0.1 gram) then 40,000 gemstones weigh approximately 4,000 grams. The handling and storing may necessitate having the equivalent of 18 months of gemstones (72,000 grams) at any one time. The possession limit specified in Teledyne Isotopes' U.S. NRC License 29-00055-06 for each radionuclide of interest is at least a factor of 50 times the anticipated maximum cumulative activity of all the gemstones for this project in Teledyne Isotopes' possession at any one time.

III-13.2.2 The gemstones will have been cut, ground and polished prior to being sent to our facility for radionuclide measurement.

III-13.2.3 Because we will not be using statistics to determine if a stone may be released, we will accept any gemstone to determine if the activities are below the specified limits for release to persons exempt from licensing.

III-13.2.4 Deleted.

III-13.2.5 Below is a list of all radionuclides with half-lives greater than 2 hours induced in gemstones and each is classed as a "major" or "minor" contributor to the total activity.

Table III-13.2.0 Radionuclides Commonly Found in Gemstones

Radionuclide	Half-life	Contributor to Total Activity
Na-22	2.60 Y	major
Sc-46	83.85 D	major
Mn-54	312.50 D	major
Co-58	70.78 D	major
Ta-182	114.50 D	major
P-32	14.28 D	minor
S-35	87.90 D	minor
Cr-51	27.70 D	minor
Fe-59	44.50 D	minor
Co-60	5.27 Y	minor
Zn-65	243.80 D	minor
As-74	17.78 D	minor
Sr-85	64.84 D	minor
Rb-86	18.60 D	minor
Y-91	58.51 D	minor
Nb-95	34.97 D	minor
Zr-95	64.02 D	minor
Sn-113	115.10 D	minor
Sb-124	60.20 D	minor
Sb-125	2.77 Y	minor
Ba-133	10.74 Y	minor
Cs-134	2.06 Y	minor
Ce-139	137.50 D	minor
Ce-141	32.50 D	minor
Hf-181	42.39 D	minor
Ir-192	74.02 D	minor
Hg-203	46.59 D	minor
Pa-233	27.00 D	minor

III-13.3 *Handling of Gems*

III-13.3.1 After receipt and initial radiation survey at Teledyne Isotopes as described in III-13-4.1 below, the gemstones will be soaked in a rinse solution of water and detergent to check for removable contamination. The rinse solution will be agitated prior to being analyzed by beta counting and gamma ray spectroscopy. We do not expect the rinse solution to have appreciable activity. If any activity is detected greater than twice background in the solution, it will be disposed as radioactive waste (See Section II-8.0 of the RSC & QCM).

III-13.3.2 For each batch of gemstones received from a client the following steps for the radionuclide measurements will be followed:

The gemstones will be loaded into standard geometry containers for which gamma ray detectors (high resolution germanium and NaI) have been been calibrated using radioactive standards traceable to National Institute of Standards & Technology (NIST). The aggregate weight of the gemstones in each container will be determined and recorded. Each container will be marked with appropriate identification to maintain traceability of origin. The details of the counting techniques are described in Appendix A (proprietary information).

III-13.3.3 We will transfer these gemstones only to wholesalers, manufacturing jewelers, or the client who supplies us with the gemstone.

III-13.3.4 After completion of the gamma counting and the beta counting a final calculation will be performed to verify that the sum of the ratios of the activity of each radionuclide (gamma emitters and pure beta emitters) divided by the corresponding NRC release limit does not exceed unity. The gemstones which are too high in radioactivity for immediate release to persons exempt from licensing will be stored in a secured area for radioactive decay. Those gemstones which are projected to still be too high in radioactivity after two years will either be 1) retained by Teledyne Isotopes until they decay sufficiently to be released, 2) disposed as radioactive waste,3) shipped to a licensed facility, or 4) exported from the United States as instructed by the client.

III-13.4 *Information Required by 10 CFR 32.11*

III-13.4.1 Information Required by 10 CFR 32.11 (a)

III-13.4.1.1 Upon the arrival of a batch of gemstones at the shipping/receiving department of Teledyne Isotopes, a member of the health physics department will perform a survey of the package and contents according to Section II-4.3 of Teledyne Isotopes Radiation Safety Code and Quality Control Manual (TWL-0312-451).

The gemstones will then be transferred to a safe which is located within a restricted area of the building. The area is accessible only through one door which has a controlled card entry system. In addition, there is a passive infrared motion detection system with an external alarm and telephone communication with the local police department.

No more than ten thousand gemstones will be removed from the above safe for radionuclide measurement during any one period of time. These gemstones will be either secured in another safe outside the controlled area described above, or under the constant surveillance and immediate control of one of the persons listed in the section below, or an additional well trained and responsible person assisting one of those persons listed. The method of training laboratory personnel is described in the Quality Control Manual, TWL-0032-365 (Proprietary Information), a copy of which is submitted with this request. Each

person involved in this project will wear a quarterly personnel TLD badge which will be processed by the Teledyne Isotopes TLD Department .

III-13.4.1.2 The overall supervision of the radionuclide measurement of the gemstones will be provided by the Manager of Environmental Services. QA/QC will be provided by the QA/QC Manager who reports directly to the company president.

Ms. L. Tyndall is the supervisor of the gamma ray spectroscopy laboratory. She has been in that capacity most of the 10 years of her employment at Teledyne Isotopes. She is responsible for the daily scheduling of the work load and the calibration of the instruments.

Ms. B. Rowland is the manager of the radon measurement laboratory. Ms. Rowland has been with Teledyne Isotopes for two years and has extensive experience with NaI counting.

Mr. A. Skaar designed and continues to enhance the gamma ray spectroscopy laboratory which consists of 21 high resolution germanium detectors and 24 NaI detectors. He has assembled high quality detectors and data acquisition systems and provides software programs to meet expanding market needs.

Resumes of the above persons and an organization chart for Teledyne Isotopes are provided in Appendix D.

III-13.4.2 Information Required by 10CFR32.11 (b)

III-13.4.2.1 By-product material will be induced into the gemstone, usually topaz, a mineral of chemical composition $Al_2SiO_4[F,OH]_2$. Most of the induced activity, other than production of P-32 from Si-30, is due to activation of impurities within the gemstone rather than to the intrinsic elemental content and the production of activity is in all cases unintentional.

III-13.4.2.2 The gemstone will be colored by radiation and used for jewelry. The by-product material is unintentional and will decay to nearly negligible levels after one year. The by-product material will be permanently contained within the gemstones and can not be reconcentrated.

III-13.4.2.3 By-product material is induced in the gemstone by irradiation at a nuclear reactor, or by other methods not known to the client and/or Teledyne Isotopes.

III-13.4.2.4 Immediately after irradiation the concentration of activity is quite high due to the presence of Na-24 produced by fast neutron (n,α) activation of Al-27, which is a constitutional component of the material. After approximately 4 weeks, the short-lived species have decayed and the activity level of the gamma emitting species (Mn-54, Sc-46 and Ta-182) is generally found to be less than or equal to 20 Bq/g. In addition, P-32 contributes to the specific activity, but the 14-day half-life for this nuclide reduces its importance after a short storage at the irradiation facility.

III-13.4.2.5 At release to persons exempt from licensing, the maximum concentration of isotopes will be less than the concentration corresponding to the sum of ratios allowed in 10CFR30.70. The details of the counting procedures and expected activities are provided in Appendix A (Proprietary Information).

III-13.4.2.6 The activity will be characterized by high resolution gamma counting with Ge or Ge(Li) detectors and beta counting with a low background gas proportional detectors for selected samples in each irradiation unit. Gamma counting with NaI(Tl) detectors will be made on all the material before release to persons exempt from licensing. The details of the counting procedures are provided in Appendix A (Proprietary Information).

III-13.4.2.7 The time interval between completion of irradiation and transfer to unlicensed individuals depends on the irradiation dose, which is related to the size of gemstones and to the desired depth of color as well as to the distribution of impurities in the starting material. The time interval between the end of irradiation and the transfer of the material to unlicensed persons will not be less than 90 days and in general substantially longer.

III-13.4.3 Information Required by 10CFR32.11 (c)

III-13.4.3.1 The QA program is designed in accordance with NRC specifications, such that any gemstones which have higher than allowed activity are identified and stored until the activity has decreased to acceptable levels.

III-13.4.3.2 No reconcentration of activity is expected to occur in the gems.

III-13.4.3.3 After 30 days the largest gems, which have received the lowest irradiation dose, are on average substantially below the allowed concentrations of activity. On the other hand, smaller gems, which receive higher doses, are on average close to the limit and require longer decay times. Imposition of lower limits would significantly affect the ability to carry on a normal commerce in these gems, in which color treatment is carried out in response to specific market conditions for color quality.

III-13.4.3.4 It is difficult to envisage circumstances under which these gemstones would be incorporated into any product designed for ingestion. Neither is it likely that the material could be inhaled, even in the unlikely event that the gemstones were pulverized.

III-13.4.3.5 For information concerning doses, please refer to Appendix E: Calculation of Doses to Persons Exposed to Irradiated Gemstones at Levels Below Exempt Concentrations (Proprietary Information).

III-13.5 *Information on Quality Assurance (QA) Program*

III-13.5.1 The principal market for the radiochemical services provided by Teledyne Isotopes is the nuclear power industry. The QA/QC programs at Teledyne Isotopes were designed and are maintained in compliance with 10CFR 50, Appendix B and U.S. NRC Regulatory Guide 4.15. Between 15-20 audits are performed annually by our clients on the Environmental Analysis Department. A copy of the Quality Assurance Manual, IWL-0032-395 (Proprietary Information) and a copy of the Quality Control Manual IWL-0032-365 (Proprietary Information) are included as part of this application. Teledyne Isotopes has participated in the U.S. EPA inter-laboratory comparison program for 20 years.

III-13.5.2 The radiation detection equipment used to identify and quantify the radioactivity induced in the gemstones includes:

III-13.5.2.1 High resolution gamma detectors (high purity germanium and lithium-drifted germanium) for identification and quantification of gamma-emitting nuclides of small batches of gems.

III-13.5.2.2 NaI (Tl) detectors to quantify the gamma-emitting nuclides on up to 10 gemstones at a time, based on the activity determined by GeLi counting.

III-13.5.2.3 Low background gas proportional detectors for the quantification of beta-emitting nuclides.

The details of the counting methodology of each of these three types of systems are described in Appendix A (Proprietary Information). Lists of the radiation detection equipment and the associated shielding are described in Appendix B (Proprietary Information).

III-13.5.3 The frequency, standards and procedures used to calibrate the radiation detection equipment are specified in Appendix C (Proprietary Information).

III-13.5.4 The counting procedures and how external measurements are converted to concentration values are described in Appendix A (Proprietary Information).

III-13.5.5 The responsibility for the QA program will be shared between Dr. Martin and Mr. Guenther. Dr. Martin will be responsible for the technical QA aspect of the program. His resume gives his academic background and employment status. He was trained in the detection and analysis of low-levels of radioactivity while stationed at McClellan Air Force Base, California as a Nuclear Research Officer (rank of Captain) from 1967 to early 1970. He has 23 years of experience in this specialty, three while in the US Air Force and twenty at Teledyne Isotopes.

The QA/QC Manager is responsible for performing internal audits, verifying that sufficient controls and calibrations are performed and assuring that all programs are documented and controlled. Other responsibilities are described in Mr. Guenther's resume.

III-13.5.6 The QA program used to assure reliable data is described in the QA Manual, IWL-0032-395 (Proprietary Information), the QC Manual, IWL-0032-365 (Proprietary Information), and in the section "counting with NaI detectors" in Appendix A (Proprietary Information).

III-13.5.7.1 Upon request, Teledyne Isotopes will provide samples of irradiated gemstones to NRC for independent verification of radionuclide identity and concentration. The request from the NRC should be in writing, signed by the appropriate Regional Administrator or the Director, Office of Nuclear Material Safety and Safeguards and should specify who (the NRC representative, the NRC contractor or the applicant) will select samples. After analysis, samples should be returned promptly to the applicant and should remain in the possession of the NRC until returned to Teledyne Isotopes.

III-13.5.7.2 Upon request, Teledyne Isotopes will analyze qualitatively and/or quantitatively gemstones or groups of gemstones provided by the NRC or its contractor. The request from the NRC should be in writing, signed by the appropriate Regional Administrator or Director, Office of Nuclear Material Safety and Safeguards, will specify the type of analysis requested and techniques to be followed, and will provide instructions for reporting results and for returning gemstones.

III-13.6 *Information Needed to Support a Request for Exemption From a Portion of 10 CFR 32.11 (c)*

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

Please refer to Appendix E for the worst case calculated doses.

As each stone or group of stones will be analyzed quantitatively, we do not expect any outliers with activities higher than those used in the above calculations.

The following information will be supplied as a package insert when first distributed under this license:

> "The stone in this piece of jewelry has been subjected to neutron irradiation to enhance its color and beauty. There are minute levels of residual radioactivity residing within the stone that will not pose a hazard to the wearer if used in an ornamental manner. These stones have been distributed pursuant to a license granted by the U.S. Nuclear Regulatory Commission."

TELEDYNE ISOTOPES

III-13.0 SPECIAL PROCEDURES FOR THE DISTRIBUTION OF IRRADIATED GEMSTONES TO PERSONS EXEMPT FROM LICENSING

This section of the RSC & QCM covers the transfer of irradiated gemstones to persons exempt from licensing.

III-13.1 *Facility Name, Address, License Number(s), Contact, and Locations*

Address: Teledyne Isotopes
50 Van Buren Avenue
Westwood, NJ 07675

License: U.S. NRC License 29-00055-06 and 29-00055-16E

Contact: Steven A. Black, R.S.O., Manager of Radiological Services
201-664-7070 x225
FAX: 201-664-5586

Location: To be distributed from the address identified above. In addition, all records will also be maintained at the above address.

III-13.2 *Background Information*

III-13.2.1 This license request is for the distribution of irradiated gemstones. Our US NRC License 29-00055-06 will cover the possession and use (analysis) of the radioisotopes prior to their distribution to persons exempt from licensing.

The expected quantity of gemstones delivered to Teledyne Isotopes is expected to be 40,000 gemstones per month. If a typical gemstone is 0.5 carat (0.1 gram) then 40,000 gemstones weigh approximately 4,000 grams. The handling and storing may necessitate having the equivalent of 18 months of gemstones (72,000 grams) at any one time. The possession limit specified in Teledyne Isotopes' U.S. NRC License 29-00055-06 for each radionuclide of interest is at least a factor of 50 times the anticipated maximum cumulative activity of all the gemstones for this project in Teledyne Isotopes' possession at any one time.

III-13.2.2 The gemstones will have been cut, ground and polished ~~and will have undergone an acid wash~~ prior to being sent to our facility for radionuclide measurement.

III-13.2.3 ***Because we will not be using statistics to determine if a stone may be released, we will accept any gemstone to determine if the activities are below the specified limits for release to persons exempt from licensing.*** ~~The gemstones will have been exposed only to neutron irradiation by a US NRC licensed facility. One such facility is the Research Reactor Facility at the University of Missouri, Research Park, Columbia, Missouri. No other irradiation or treatment will be performed. Teledyne Isotopes will require that a Certificate of Irradiation, specifying that the gemstones have only been exposed to neutron irradiation, be supplied by the irradiation facility with each batch of gemstones.~~

III-13.2.4 ***Deleted.*** ~~The manufacturing jeweler, for whom Teledyne Isotopes is to perform the radionuclide measurements, purchases gemstones of Sri Lanka origin only. The manufacturing jeweler will provide a copy of the Certificate of Origin that accompanies each batch of gemstones through U.S. Customs. Thus, there should be no significant variations in induced radionuclides due to gemstones' origin or type of irradiation received.~~

III-13.2.5 Below is a list of all radionuclides with half-lives greater than 2 hours induced in gemstones and each is classed as a "major" or "minor" contributor to the total activity.

Table III-13.2.0 Radionuclides Commonly Found in Gemstones

Radionuclide	Half-life	Contributor to Total Activity
Na-22	2.60 Y	major
Sc-46	83.85 D	major
Mn-54	312.50 D	major
Co-58	70.78 D	major
Ta-182	114.50 D	major
P-32	14.28 D	minor
S-35	87.90 D	minor
Cr-51	27.70 D	minor
Fe-59	44.50 D	minor
Co-60	5.27 Y	minor
Zn-65	243.80 D	minor
As-74	17.78 D	minor
Sr-85	64.84 D	minor
Rb-86	18.60 D	minor
Y-91	58.51 D	minor
Nb-95	34.97 D	minor
Zr-95	64.02 D	minor
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Cs-134	2.06 Y	minor
Ce-139	137.50 D	minor
Ce-141	32.50 D	minor
Hf-181	42.39 D	minor
Ir-192	74.02 D	minor
Hg-203	46.59 D	minor
Pa-233	27.00 D	minor

III-13.3 *Handling of Gems*

III-13.3.1 ~~The neutron irradiation facility will perform an acid wash of the gemstones prior to shipment to Teledyne Isotopes. Teledyne Isotopes will require that a Certificate of Compliance, from the irradiation facility documenting that the acid wash has been performed per the written procedure, accompany each batch of gemstones.~~ After receipt and initial radiation survey at Teledyne Isotopes as described in III-13-4.1 below, the gemstones will be soaked in a rinse solution of water and detergent to check for removable contamination. The rinse solution will be agitated prior to being analyzed by beta counting and gamma ray spectroscopy. We do not expect the rinse solution to have appreciable activity. If any activity is detected greater than twice background in the solution, it will be disposed as radioactive waste (See Section II-8.0 of the RSC & QCM).

III-13.3.2 For each batch of gemstones received from ***a client*** ~~the irradiation facility~~ the following steps for the radionuclide measurements will be followed:

The gemstones will be loaded into standard geometry containers for which gamma ray detectors (high resolution germanium and NaI) have been been calibrated using radioactive standards traceable to National Institute of Standards & Technology (NIST). The aggregate weight of the gemstones in each container will be determined and recorded. Each container will be marked with appropriate identification to maintain traceability of origin. The details of the counting techniques are described in Appendix A (proprietary information).

III-13.3.3 We will ***transfer*** ~~transferal~~ these gemstones only to wholesalers, ~~or~~ manufacturing jewelers, ***or the client who supplies us with the gemstone.***

III-13.3.4 After completion of the gamma counting and the beta counting a final calculation will be performed to verify that the sum of the ratios of the activity of each radionuclide (gamma emitters and pure beta emitters) divided by the corresponding NRC release limit does not exceed unity. The gemstones which are too high in radioactivity for immediate release to persons exempt from licensing will be stored in a secured area for radioactive decay. Those gemstones which are projected to still be too high in radioactivity after two years will either be 1) retained by Teledyne Isotopes until they decay sufficiently to be released, 2) disposed as radioactive waste, ~~or 3) shipped back to the irradiation facility.~~ ***3) shipped to a licensed facility, or 4) exported from the United States as instructed by the client.***

III-13.4 *Information Required by 10 CFR 32.11*

III-13.4.1 Information Required by 10 CFR 32.11 (a)

III-13.4.1.1 Upon the arrival of a batch of gemstones at the shipping/receiving department of Teledyne Isotopes, a member of the health physics department will perform a survey of the package and contents according to Section II-4.3 of Teledyne Isotopes Radiation Safety Code and Quality Control Manual (IWL-0312-451).

The gemstones will then be transferred to a safe which is located within a restricted area of the building. The area is accessible only through one door which has a controlled card entry system. In addition, there is a passive infrared motion detection system with an external alarm and telephone communication with the local police department.

No more than ten thousand gemstones will be removed from the above safe for radionuclide measurement during any one period of time. These gemstones will be either secured in another safe outside the controlled area described above, or under the constant

surveillance and immediate control of one of the persons listed in the section below, or an additional well trained and responsible person assisting one of those persons listed. The method of training laboratory personnel is described in the Quality Control Manual, IWL-0032-365 (Proprietary Information), a copy of which is submitted with this request. Each person involved in this project will wear a quarterly personnel TLD badge which will be processed by the Teledyne Isotopes TLD Department .

III-13.4.1.2 The overall supervision of the radionuclide measurement of the gemstones will be provided by ***the Manager of Environmental Services,*** ~~Dr. David Martin.~~ QA/QC will be provided by ***the QA/QC Manager who reports directly to the company president.*** ~~Jeffrey Guenther.~~

Ms. L. Tyndall is the supervisor of the gamma ray spectroscopy laboratory. She has been in that capacity most of the 10 years of her employment at Teledyne Isotopes. She is responsible for the daily scheduling of the work load and the calibration of the instruments.

Ms. B. Rowland is the manager of the radon measurement laboratory. Ms. Rowland has been with Teledyne Isotopes for two years and has extensive experience with NaI counting.

Mr. A. Skaar designed and continues to enhance the gamma ray spectroscopy laboratory which consists of 21 high resolution germanium detectors and 24 NaI detectors. He has assembled high quality detectors and data acquisition systems and provides software programs to meet expanding market needs.

Resumes of the above persons and an organization chart for Teledyne Isotopes are provided in Appendix D.

III-13.4.2 Information Required by 10CFR32.11 (b)

III-13.4.2.1 By-product material will be induced into the gemstone, usually topaz, a mineral of chemical composition $Al_2SiO_4[F,OH]_2$. Most of the induced activity, other than production of P-32 from Si-30, is due to activation of impurities within the gemstone rather than to the intrinsic elemental content and the production of activity is in all cases unintentional.

III-13.4.2.2 The gemstone will be colored by radiation and used for jewelry. The by-product material is unintentional and will decay to nearly negligible levels after one year. The by-product material will be permanently contained within the gemstones and can not be reconcentrated.

III-13.4.2.3 By-product material is induced in the gemstone by irradiation at a nuclear reactor, ***or by other methods not known to the client and/or Teledyne Isotopes.***

III-13.4.2.4 Immediately after irradiation the concentration of activity is quite high due to the presence of Na-24 produced by fast neutron (n,α) activation of Al-27, which is a constitutional component of the material. After approximately 4 weeks, the short-lived species have decayed and the activity level of the gamma emitting species (Mn-54, Sc-46 and Ta-182) is generally found to be less than or equal to 20 Bq/g. In addition, P-32 contributes to the specific activity, but the 14-day half-life for this nuclide reduces its importance after a short storage at the irradiation facility.

III-13.4.2.5 At release to persons exempt from licensing, the maximum concentration of isotopes will be less than the concentration corresponding to the sum of ratios allowed in

10CFR30.70. The details of the counting procedures and expected activities are provided in Appendix A (Proprietary Information).

III-13.4.2.6 The activity will be characterized by high resolution gamma counting with Ge or Ge(Li) detectors and beta counting with a low background gas proportional detectors for selected samples in each irradiation unit. Gamma counting with NaI(Tl) detectors will be made on all the material before release to persons exempt from licensing. The details of the counting procedures are provided in Appendix A (Proprietary Information).

III-13.4.2.7 The time interval between completion of irradiation and transfer to unlicensed individuals depends on the irradiation dose, which is related to the size of gemstones and to the desired depth of color as well as to the distribution of impurities in the starting material. The time interval between the end of irradiation and the transfer of the material to unlicensed persons will not be less than 90 days and in general substantially longer.

III-13.4.3 Information Required by 10CFR32.11 (c)

III-13.4.3.1 ~~The starting material, which is exclusively of Sri Lanka origin, is chosen to minimize activation of the gems.~~ The QA program is designed in accordance with NRC specifications, such that any gemstones which have higher than allowed activity are identified and stored until the activity has decreased to acceptable levels.

III-13.4.3.2 No reconcentration of activity is expected to occur in the gems. ~~The gemstones will only be neutron-irradiated and not followed by any other irradiation.~~

III-13.4.3.3 After 30 days the largest gems, which have received the lowest irradiation dose, are on average substantially below the allowed concentrations of activity. On the other hand, smaller gems, which *receive* ~~require~~ higher doses, are on average close to the limit and require longer decay times. Imposition of lower limits would significantly affect the ability to carry on a normal commerce in these gems, in which color treatment is carried out in response to specific market conditions for color quality.

III-13.4.3.4 It is difficult to envisage circumstances under which these gemstones would be incorporated into any product designed for ingestion. Neither is it likely that the material could be inhaled, even in the unlikely event that the gemstones were pulverized.

III-13.4.3.5 For information concerning doses, please refer to Appendix E: Calculation of Doses to Persons Exposed to Irradiated Gemstones at Levels Below Exempt Concentrations (Proprietary Information).

III-13.5 *Information on Quality Assurance (QA) Program*

III-13.5.1 The principal market for the radiochemical services provided by Teledyne Isotopes is the nuclear power industry. The QA/QC programs at Teledyne Isotopes were designed and are maintained in compliance with 10CFR 50, Appendix B and U.S. NRC Regulatory Guide 4.15. Between 15-20 audits are performed annually by our clients on the Environmental Analysis Department. A copy of the Quality Assurance Manual, IWL-0032-395 (Proprietary Information) and a copy of the Quality Control Manual IWL-0032-365 (Proprietary Information) are included as part of this application. Teledyne Isotopes has participated in the U.S. EPA inter-laboratory comparison program for 20 years.

III-13.5.2 The radiation detection equipment used to identify and quantify the radioactivity induced in the gemstones includes:

III-13.5.2.1 High resolution gamma detectors (high purity germanium and lithium-drifted germanium), for identification and quantification of gamma-emitting nuclides of small batches of gems.

III-13.5.2.2 NaI (Tl) detectors to quantify the gamma-emitting nuclides on up to 10 gemstones at a time, based on the activity determined by GeLi counting.

III-13.5.2.3 Low background gas proportional detectors for the quantification of beta-emitting nuclides.

The details of the counting methodology of each of these three types of systems are described in Appendix A (Proprietary Information). Lists of the radiation detection equipment and the associated shielding are described in Appendix B (Proprietary Information).

III-13.5.3 The frequency, standards and procedures used to calibrate the radiation detection equipment are specified in Appendix C (Proprietary Information).

III-13.5.4 The counting procedures and how external measurements are converted to concentration values are described in Appendix A (Proprietary Information).

III-13.5.5 The responsibility for the QA program will be shared between Dr. Martin and Mr. Guenther. Dr. Martin will be responsible for the technical QA aspect of the program. His resume gives his academic background and employment status. He was trained in the detection and analysis of low-levels of radioactivity while stationed at McClellan Air Force Base, California as a Nuclear Research Officer (rank of Captain) from 1967 to early 1970. He has 23 years of experience in this specialty, three while in the US Air Force and twenty at Teledyne Isotopes.

The QA/QC Manager Mr. Guenther is responsible for performing internal audits, verifying that sufficient controls and calibrations are performed and assuring that all programs are documented and controlled. Other responsibilities are described in Mr. Guenther's resume.

III-13.5.6 The QA program used to assure reliable data is described in the QA Manual, IWL-0032-395 (Proprietary Information), the QC Manual, IWL-0032-365 (Proprietary Information), and in the section "counting with NaI detectors" in Appendix A (Proprietary Information).

III-13.5.7.1 Upon request, Teledyne Isotopes will provide samples of irradiated gemstones to NRC for independent verification of radionuclide identity and concentration. The request from the NRC should be in writing, signed by the appropriate Regional Administrator or the Director, Office of Nuclear Material Safety and Safeguards and should specify who (the NRC representative, the NRC contractor or the applicant) will select samples. After analysis, samples should be returned promptly to the applicant and should remain in the possession of the NRC until returned to Teledyne Isotopes.

III-13.5.7.2 Upon request, Teledyne Isotopes will analyze qualitatively and/or quantitatively gemstones or groups of gemstones provided by the NRC or its contractor. The request from the NRC should be in writing, signed by the appropriate Regional Administrator or Director, Office of Nuclear Material Safety and Safeguards, will specify the type of analysis requested and techniques to be followed, and will provide instructions for reporting results and for returning gemstones.

III-13.6 *Information Needed to Support a Request for Exemption From a Portion of 10 CFR 32.11 (c)*

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

Please refer to Appendix E for the worst case calculated doses.

As each stone or group of stones will be analyzed quantitatively, we do not expect any outliers with activities higher than those used in the above calculations.

The following information will be supplied as a package insert when first distributed under this license:

> "The stone in this piece of jewelry has been subjected to neutron irradiation to enhance its color and beauty. There are minute levels of residual radioactivity residing within the stone that will not pose a hazard to the wearer if used in an ornamental manner. These stones have been distributed pursuant to a license granted by the U.S. Nuclear Regulatory Commission."

III-13.0 SPECIAL PROCEDURES FOR THE DISTRIBUTION OF IRRADIATED GEMSTONES TO PERSONS EXEMPT FROM LICENSING

This section of the RSC & QCM covers the transfer of irradiated gemstones to persons exempt from licensing.

III-13.1 *Facility Name, Address, License Number(s), Contact, and Locations*

Address: Teledyne Isotopes
50 Van Buren Avenue
Westwood, NJ 07675

License: U.S. NRC License 29-00055-06 and new 'E' license to be issued

Contact: Steven A. Black, R.S.O., Manager of Radiological Services
201-664-7070 x225
FAX: 201-664-5586

Location: To be distributed from the address identified above. In addition, all records will also be maintained at the above address.

III-13.2 *Background Information*

III-13.2.1 This license request is for the distribution of irradiated gemstones. Our US NRC License 29-00055-06 will cover the possession and use (analysis) of the radioisotopes prior to their distribution to persons exempt from licensing.

The expected quantity of gemstones delivered to Teledyne Isotopes is expected to be 40,000 gemstones per month. If a typical gemstone is 0.5 carat (0.1 gram) then 40,000 gemstones weigh approximately 4,000 grams. The handling and storing may necessitate having the equivalent of 18 months of gemstones (72,000 grams) at any one time. The possession limit specified in Teledyne Isotopes' U.S. NRC License 29-00055-06 for each radionuclide of interest is at least a factor of 50 times the anticipated maximum cumulative activity of all the gemstones for this project in Teledyne Isotopes' possession at any one time.

III-13.2.2 The gemstones will have been cut, ground and polished and will have undergone an acid wash prior to being sent to our facility for radionuclide measurement.

III-13.2.3 The gemstones will have been exposed only to neutron irradiation by a US NRC licensed facility. One such facility is the Research Reactor Facility at the University of Missouri, Research Park, Columbia, Missouri. No other irradiation or treatment will be performed. Teledyne Isotopes will require that a Certificate of Irradiation, specifying that the gemstones have only been exposed to neutron irradiation, be supplied by the irradiation facility with each batch of gemstones.

III-13.2.4 The manufacturing jeweler, for whom Teledyne Isotopes is to perform the radionuclide measurements, purchases gemstones of Sri Lanka origin only. The manufacturing jeweler will provide a copy of the Certificate of Origin that accompanies each batch of gemstones through U.S. Customs. Thus, there should be no significant variations in induced radionuclides due to gemstones' origin or type of irradiation received.

III-13.3 *Handling of Gems*

III-13.3.1 The neutron irradiation facility will perform an acid wash of the gemstones prior to shipment to Teledyne Isotopes. Teledyne Isotopes will require that a Certificate of Compliance, from the irradiation facility documenti. , that the acid wash has been performed per the written procedure, accompany each batch of gemstones. After receipt and initial radiation survey at Teledyne Isotopes as described in III-13-4.1 below, the gemstones will be soaked in a rinse solution of water and detergent to check for removable contamination. The rinse solution will be agitated prior to being analyzed by beta counting and gamma ray spectroscopy. We do not expect the rinse solution to have appreciable activity. If any activity is detected greater than twice background in the solution, it will be disposed as radioactive waste (See Section II-8.0 of the RSC & QCM).

III-13.3.2 For each batch of gemstones received from the irradiation facility the following steps for the radionuclide measurements will be followed:

The gemstones will be loaded into standard geometry containers for which gamma ray detectors (high resolution germanium and NaI) have been been calibrated using radioactive standards traceable to National Institute of Standards & Technology (NIST). The aggregate weight of the gemstones in each container will be determined and recorded. Each container will be marked with appropriate identification to maintain traceability of origin. The details of the counting techniques are described in Appendix A (proprietary information).

III-13.3.3 We will be transferal these gemstones only to wholesalers or manufacturing jewelers.

III-13.3.4 After completion of the gamma counting and the beta counting a final calculation will be performed to verify that the sum of the ratios of the activity of each radionuclide (gamma emitters and pure beta emitters) divided by the corresponding NRC release limit does not exceed unity. The gemstones which are too high in radioactivity for immediate release to persons exempt from licensing will be stored in a secured area for radioactive decay. Those gemstones which are projected to still be too high in radioactivity after two years will either be 1) retained by Teledyne Isotopes until they decay sufficiently to be released, 2) disposed as radioactive waste, or 3) shipped back to the irradiation facility.

III-13.4 Information Required by 10 CFR 32.11

III-13.4.1 Information Required by 10 CFR 32.11 (a)

III-13.4.1.1 Upon the arrival of a batch of gemstones at the shipping/receiving department of Teledyne Isotopes, a member of the health physics department will perform a survey of the package and contents according to Section II-4.3 of Teledyne Isotopes Radiation Safety Code and Quality Control Manual (IWL-0312-451).

The gemstones will then be transferred to a safe which is located within a restricted area of the building. The area is accessible only through one door which has a controlled card entry system. In addition, there is a passive infrared motion detection system with an external alarm and telephone communication with the local police department.
Ten thousand gemstones will be removed from the above safe for radionuclide measurement during any one period of time. These gemstones will be either secured in another safe outside the controlled area described above, or under the constant surveillance and immediate control of one of the persons listed in the section below, or an additional well trained and responsible person assisting one of those persons listed. The

method of training laboratory personnel is described in the Quality Control Manual, IWL-0032-365 (Proprietary Information), a copy of which is submitted with this request. Each person involved in this project will wear a quarterly personnel TLD badge which will be processed by the Teledyne Isotopes TLD Department.

III-13.4.1.2 The overall supervision of the radionuclide measurement of the gemstones will be provided by Dr. J. D. Martin. QA/QC will be provided by Jeffrey M. Guenther.

Ms. L. Tyndall is the supervisor of the gamma ray spectroscopy laboratory. She has been in that capacity most of the 10 years of her employment at Teledyne Isotopes. She is responsible for the daily scheduling of the work load and the calibration of the instruments.

Ms. B. Rowland is the manager of the radon measurement laboratory. Ms. Rowland has been with Teledyne Isotopes for two years and has extensive experience with NaI counting.

Mr. A. Skaar designed and continues to enhance the gamma ray spectroscopy laboratory which consists of 21 high resolution germanium detectors and 24 NaI detectors. He has assembled high quality detectors and data acquisition systems and provides software programs to meet expanding market needs.

Resumes of the above persons and an organization chart for Teledyne Isotopes are provided in Appendix D.

III-13.4.2 Information Required by 10CFR32.11 (b)

III-13.4.2.1 By-product material will be induced into the gemstone, usually topaz, a mineral of chemical composition $Al_2SiO_4[F,OH]_2$. Most of the induced activity, other than production of P-32 from Si-30, is due to activation of impurities within the gemstone rather than to the intrinsic elemental content and the production of activity is in all cases unintentional.

III-13.4.2.2 The gemstone will be colored by radiation and used for jewelry. The by-product material is unintentional and will decay to nearly negligible levels after one year. The by-product material will be permanently contained within the gemstones and can not be reconcentrated.

III-13.4.2.3 By-product material is induced in the gemstone by irradiation at a nuclear reactor.

III-13.4.2.4 Immediately after irradiation the concentration of activity is quite high due to the presence of Na-24 produced by fast neutron (n,α) activation of Al-27, which is a constitutional component of the material. After approximately 4 weeks, the short-lived species have decayed and the activity level of the gamma emitting species (Mn-54, Sc-46 and Ta-182) is generally found to be less than or equal to 20 Bq/g. In addition, P-32 contributes to the specific activity, but the 14-day half-life for this nuclide reduces its importance after a short storage at the irradiation facility.

III-13.4.2.5 At release to persons exempt from licensing, the maximum concentration of isotopes will be less than the concentration corresponding to the sum of ratios allowed in 10CFR30.70. The details of the counting procedures and expected activities are provided in Appendix A (Proprietary Information).

III-13.4.2.6 The activity will be characterized by high resolution gamma counting with Ge or Ge(Li) detectors and beta counting with a low background gas proportional detectors for selected samples in each irradiation unit. Gamma counting with NaI(Tl) detectors will be made on all the material before release to persons exempt from licensing. The details of the counting procedures are provided in Appendix A (Proprietary Information).

III-13.4.2.7 The time interval between completion of irradiation and transfer to unlicensed individuals depends on the irradiation dose, which is related to the size of gemstones and to the desired depth of color as well as to the distribution of impurities in the starting material. The time interval between the end of irradiation and the transfer of the material to unlicensed persons will not be less than 90 days and in general substantially longer.

III-13.4.3 Information Required by 10CFR32.11 (c)

III-13.4.3.1 The starting material, which is exclusively of Sri Lanka origin, is chosen to minimize activation of the gems. The QA program is designed in accordance with NRC specifications, such that any gemstones which have higher than allowed activity are identified and stored until the activity has decreased to acceptable levels.

III-13.4.3.2 No reconcentration of activity is expected to occur in the gems. The gemstones will only be neutron-irradiated and not followed by any other irradiation.

III-13.4.3.3 After 30 days the largest gems, which have received the lowest irradiation dose, are on average substantially below the allowed concentrations of activity. On the other hand, smaller gems, which require higher doses, are on average close to the limit and require longer decay times. Imposition of lower limits would significantly affect the ability to carry on a normal commerce in these gems, in which color treatment is carried out in response to specific market conditions for color quality.

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