

March 3, 1988

GA Technologies Inc.
ATTN: Dr. Keith E. Asmussen, Manager
Licensing and Nuclear
Material Compliance
P.O. Box 85608
San Diego, California 92138

Gentlemen:

This is in reference to your April 9, 1986 and October 31, 1986 applications for a license to be issued pursuant to 10 CFR 32.11 to authorize distribution of irradiated crystalline material to persons exempt from licensing. This is also in partial response to the April 16, 1987 letter, signed by Mr. James R. Edwards, General Counsel and Secretary of your organization.

We regret the delay in processing your application. However, as you probably know, your application and two other similar requests were precedent-setting and required consultation with the Commission. During our review of the issues, we have appreciated the assistance provided by you and the members of your organization. The information provided by telephone, letter and in the May 6, 1987 meeting between members of the NRC staff and Dr. William Whittemore and Mr. Norval Carey of GA Technologies has been very helpful in clarifying some practical and technical issues associated with your application.

The Commission has recently directed the staff to process applications such as yours. Licenses, if granted, will not be subject to the prohibition in 10 CFR 32.11(c) against distribution of products intended for application to human beings. However, all other requirements of 10 CFR 32.11, 30.14, and 30.70 (copies enclosed) must be met.

Following the Commission's decision, the NRC staff prepared Enclosure 2 to assist domestic reactors with the preparation of their applications. We have reviewed your October 31, 1986 application, which was submitted in substitution for your April 9, 1986 application. As a result of our review, we find that your application either does not address the matters described in Enclosure 2 or addresses them incompletely. Some specific examples are outlined below.

- o It is not clear whether all of the activities described in Item A.4 of Enclosure 2 to this letter will be conducted at the 10955 John Jay Hopkins Drive address in San Diego.
- o As a research reactor in class 104 status, you have not provided information to demonstrate that less than 50 percent of the annual cost of owning and operating the facility is devoted to the production of materials, products, or energy for sale or commercial distribution, or to the sale of services, other than research and development or education or training." See 10 CFR 50.21-22. This must be demonstrated not only before we can issue you a license pursuant to 10 CFR 32.11, but also on an annual basis after such a license is issued.

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- o Item 5.b of your application indicates that radioactive material will be in "[s]olid forms contained within crystalline material." Later in the application you refer to irradiated topaz. Although the language of Item 5.b. of your application is sufficiently general to include topaz, it is also broad enough to include other gems and other types of crystalline material. Please be advised that, at this time, we are only considering authorized distribution of cut, polished, and finished irradiated topaz to persons exempt from licensing. If your application is to include other gems in addition to topaz, specific information related to the other gems will be required as is the case for topaz.
- o You propose to use a value of two nanocuries per gram as the maximum specific activity of gems released to persons exempt from licensing. In support of your choice of this value, you indicated that it is used by the International Atomic Energy Agency (IAEA), the U.S. Department of Transportation (DOT), and regulatory agencies in Europe and Asia. You are correct that, for purposes of safe transportation, materials with a specific activity lower than two nanocuries per gram are not regulated by either IAEA or DOT. However, the limit for purposes of transportation does not imply that the distribution of gems containing up to two nanocuries per gram to members of the public is acceptable.

The two nanocuries per gram value exceeds the limits specified in 10 CFR 30.70. For example, the exempt concentration limit in 10 CFR 30.70 for tantalum-182, the principal radionuclide in your gemstones, is 0.4 nanocurie per gram. Note that this is the maximum concentration for tantalum-182, assuming that it is the only radionuclide present, and it is one-fifth of your proposed limit. A review of Table 1 in Enclosure 2 to your application indicates that, if only tantalum-182 is considered, 13 of the 19 specimens have concentrations exceeding the limit in 10 CFR 30.70.

Information in Enclosure 2 to your application also indicates that irradiated gemstones may contain other radionuclides, such as scandium-46, antimony-124 and 125, and cadmium-109, in addition to tantalum-182. In cases such as this, where a combination of radionuclides is present, Note 2 in 10 CFR 30.70 specifies that the concentration limit for the combination is to be derived by "the sum of ratios" method and the sum shall not exceed unity. Thus, it would be necessary to identify and quantify the various radionuclides and to ensure that the "sum of the ratios" does not exceed unity. As specified in 10 CFR 32.11(c), you will need to provide assurance not only that the concentration levels in 10 CFR Section 30.70 are not exceeded, but also that lower concentrations are not feasible. (See Item C in Enclosure 2 to this letter.)

- o Although you indicate gems will be grouped by size for counting, it is not clear if they are also grouped according to geologic origin and/or type(s) of irradiation received. It also is not clear what constitutes a "given lot" (as used on page 3 of Enclosure 3 of your application); what types of quality control (QC) will be exercised in the precutting stage; and whether this QC would offset our concern.
- o Item B.2.g. of Enclosure 2 to this letter requests identification of all radionuclides with half-lives greater than 2 hours and classification of each as "major" or "minor." It is not clear whether the listing of radionuclides in Enclosure 2 to your application is complete; even if it is, the radionuclides are not classified as requested.

In addition, it is not clear how we can be assured that the information in Enclosure 2 to your application on radionuclides, their activities, and concentrations is representative of topaz to be irradiated in the future.

- o Although your application mentions washing of irradiated stones to remove "tactile" contamination, it does not describe procedures to be used to ensure that each gem is free of removable contamination; see Item B.3.a. of Enclosure 2 to this letter.
- o Your application presents some apparently conflicting information about the disposition of irradiated gems whose concentrations exceed your criteria. Item 11 of the application indicates that such stones "can" be disposed of with reactor waste, but does not necessarily imply that they will be disposed of in that manner. On page 4 of Enclosure 3 to your application you mention twice that "rejected" stones will be held for further decay and evaluation.
- o Your license and its supporting information should be a "stand alone" document (i.e., a document that does not reference other licenses for important information, such as training and experience of personnel). Thus, you should correlate the names of your staff members with their responsibilities under this license and submit documentation of their training and experience, particularly in handling and analyzing low-levels of byproduct material, use of equipment, procedures and statistical analyses appropriate for levels of activity not to exceed those specified in 10 CFR 30.70; and the control procedures, accountability and record-keeping responsibilities under this license. Experienced reactor operators, nuclear engineers, or nuclear physicists do not necessarily have the needed training and experience.

- o Although your application provides some of the information requested in Item D of Enclosure 2 to this letter, it is incomplete and not sufficiently detailed for us to reach a decision about its adequacy. For example, we need more information about: the shielding surrounding your NaI(Tl) and plastic scintillator detectors; the configuration of the detectors to provide 4 pi geometry, and the calibration of these systems. We note that in describing your instrumentation you use the phrase "or equivalent." If you wish to have the flexibility to use "equivalent" equipment, then your application must describe the minimum features of such equipment.

It is not clear to what instruments (i.e., G-M only; GM, NaI(Tl) and plastic scintillators) you are referring in Item 9 of your application where calibration is described briefly.

Also your application does not provide all of the information requested in Item D.3. of Enclosure 2 to this letter for your counting procedures. We need a clear description of the analyses done on irradiated gems and their sequence, being sure that the information requested Items D.1., 2., and 3. is provided for each type of analysis.

- o Your "Safety Analysis" should be revised to include the information requested in Items E.2. and E.3. of Enclosure 2 to this letter.

Please review Enclosure 2 to this letter and provide the information requested in Section II; it is not necessary to provide responses to Items A.1., 2., 3., and 6., B.1.b., and F. Please submit your response in duplicate, refer to Control No. 019643, and mail to:

U.S. Nuclear Regulatory Commission
Medical, Academic, and Commercial Use
Safety Branch (Mail Stop OWFN-6H3)
ATTN: Mr. Michael Lamastra
Washington, DC 20555

We note that you have requested that Enclosures 1B, 2, 3B and 4 be withheld from public disclosure because they are "company confidential," were developed at GA Technologies' expense, and, if released, "would cause substantial harm to GA Technologies Inc.'s competitive position." The information contained in Enclosure 4, although interesting background information, is not needed in order to make a licensing decision and can be returned to you. The information contained in Enclosures 1B, 2, and 3B is needed in order to make a licensing decision. Based on past experience, we do not believe that the types of information contained in these enclosures (e.g., type of gems to be irradiated; radionuclide content, activity, and concentration; counting systems) constitute proprietary information that can be withheld from public disclosure.

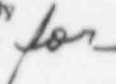
You may: (1) withdraw your request for withholding the specified documents from public disclosure, (2) modify your request (e.g., narrow the request), or (3) ask that we proceed with a legal review of your original or modified request. Please inform us in writing of your decision.

We are prepared to expend the necessary resources to expedite review of your application if we receive your reply to this letter within 45 calendar days of the date of this letter. Please let us know if you need more time to prepare your response. If we do not receive your response within 45 calendar days of the date of this letter or by the date agreed upon when you request an extension of time, we will assume that you do not wish to pursue your request for a license at this time. If you do choose, you may reactivate your application (without paying any additional fee) by responding to this letter within one year of the date of this letter.

If you have any questions or wish to arrange a meeting, please call me at (301)492-3416.

Sincerely,

Original Signed By
PATRICIA C. VAGGA



Michael A. Laniastra, Section Leader
Commercial Use Section
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety

Enclosures:

1. 10 CFR Parts 30 and 32
2. Information Needed from a
Domestic Reactor. . .

cc w/o enclosures:

Mr. James R. Edwards
General Counsel and
Secretary
GA Technologies Inc.
P.O. Box 85608
San Diego, CA 92136

Dr. Keith Asmussen

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Dr. Keith E. Asmussen

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