



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

June 16, 2003

Mr. Timothy Brandon
Radiation Safety Officer
GE Ion Track
205 Lowell Street
Wilmington, MA 01887

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR THE GE ION TRACK
EXPLOSIVE AND NARCOTIC DETECTOR DEVICES (CASE 03-22)

Dear Mr. Brandon:

This refers to your requests dated March 10 and May 12, 2003, for an amendment to the sealed source and device registration NR-399-D-102-E for GE Ion Track explosive and narcotic detector devices.

In order to complete our safety evaluation for the five models listed in the application (i.e., Itemizer II, Itemizer 3, Vapor Tracer 2, Entryscan 3, and VTEX) we need the information identified in Enclosure 1 to this letter. Additional information requested by this letter should be submitted in a written response within 30 days of the date of this letter. If a written response is not received within this time period, the staff will consider the application as "abandoned" for failure to provide the requested information "without prejudice" to the re submission of the application.

In view of the fact that Ion Track Instrument, Inc. (presently GE Ion Track) did not have an active exempt product distribution license since October 28, 1999, we must inactivate Registration Certificate NR-0399-D-102-E for the Model 97 and 97A/VIXEN gas and aerosol detectors. For the five new models listed above, we will issue another registration certificate. Regarding the Model 97 and 97A/VIXEN gas and aerosol detectors, we need the additional information that is listed in Enclosure 2.

T. Brandon

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If you have any questions regarding this matter, we would be pleased to meet with you and your staff. I may be contacted at (301) 415-6195.

Sincerely,



David Tiktinsky, Senior Project Manager
Regulatory Guidance Branch
Division of Industrial and Medical
Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure 1: Information request for Model Nos. Itemizer II, Itemizer 3, Vapor Tracer 2, Entryscan 3, and VTEX

Enclosure 2: Information request for Model Nos. 97 and 97A/VIXEN

cc: Rosalyn Jones

T. Brandon

-2-

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/RA/

David Tiktinsky, Senior Project Manager
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Enclosure 1: Information request for Model Nos. Itemizer II, Itemizer 3, Vapor Tracer 2, Entryscan 3, and VTEX

Enclosure 2: Information request for Model Nos. 97 and 97A/VIXEN

cc: Rosalyn Jones

SS&D Case FILE 03-22

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OFFICE	IMNS	E	MSIB	C	MSIB	E	MSIB		
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DATE	05/ 1/2003		05/3/2003		06/12/2003		6/12/03		

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*see previous concurrence

** concurred by Email

Enclosure 1

REQUEST FOR ADDITIONAL INFORMATION (RAI) FOR REGISTRATION OF MODEL NOS.
ITEMISER II, ITEMISER III, VAPOR TRACER 2, ENTRYSCAN 3, and VTEX
EXPLOSIVES AND NARCOTICS DETECTION DEVICES

GE Ion Track submitted an application to Nuclear Regulatory Commission (NRC) notifying change of locations and requesting a name change from Ion Track Instrument to Ge Ion Scan. Additionally, GE Ion Scan requested the addition of their Models Itemiser II, Itemiser III, Vapor Tracer 2, EntryScan 3, and VTEX to an existing registration certificate NR-399-D-102-E which authorizes the distribution of Model 97, 97A/VIXEN.

GE Ion Track requested the removal of Leakmeter 200 from their license. This product is produced by ITI Qualitek of Billerica, MA which was formerly a part of Ion Track, but is now a separate entity and has listed the Leakmeter 200 on its SS&D registration certificate No. NR-1128-D-101-E. In view of the fact that Ion Track Instrument, Inc. (presently GE Ion Track) did not have an active exempt product distribution license since October 28, 1999, we must inactivate Registration Certificate NR-0399-D-102-E for the Model 97 and 97A/VIXEN gas and aerosol detectors. For the five new models listed above, we will issue another registration certificate, assuming satisfactory resolution of the items contained in this letter.

Each new Model to be added to the registration contains a single 10 mCi (Ni-63) source. This quantity is below the exempt quantity defined by the 10 CFR 30.70 Schedule B. The radioactive sources were provided by AEA Technologies and the application states that GE Ion Track is procuring sealed sources from Isotope Product Laboratories, who purchased the nickel production portion from DuPont Pharmaceutical of Billerica, MA.

Table 4 of the ISO 2919:1999 Section 6.2 lists some typical applications, together with minimum performance requirements which can be used to evaluate a sealed source or a dedicated source in a device assembly. GE Ion Scan is requested to submit additional information to clarify the following issues:

1. MANUFACTURE OF DEVICES

In Paragraph 2, Page 2 of your application, you indicated that there will be two other facilities manufacturing the devices. Please delineate the components that these manufacturers will fabricate and install. Please describe clearly whether these facilities are separate legal entities or are these subsidiaries of GE Ion Scan and what is their working relationship with GE Ion Scan?

Previously Ai Cambridge Limited, Cambridge, England manufactured the devices for Ion Track Instruments. Please advise whether you have discontinued the procurement from this source or are you planning to continue import of devices manufactured by Ai Cambridge Limited.

2. DESCRIPTION & CONSTRUCTION

Please specify for each device the drawing numbers and component numbers that provide the tamper resistant features to ensure that the module/detector holding the source, cannot be removed from the device.

3. LABELING

Please provide a revised label drawing to show the name of the company has been changed to GE Ion Track from Ion Track Instrument, Inc. Please confirm that products to be distributed under your license will carry labels of GE Ion Track only and will be in compliance with 10 CFR 20.1905 and 32.29.

4. QUALITY ASSURANCE

Please provide a copy of your current ISO 9001 registration certificate. Please provide details regarding the QA oversight, scope and the extent of GE Ion Track QA control over the other two manufacturers of the devices that you have requested to be added to the registration.

The discussion should include: a) GE Ion Tracks plans regarding the allocation of device serial numbers; and b) how you would foster consistency at three facilities in design, procurement, design changes, quality control, corrective actions, record keeping and reporting requirements.

5. PROTOTYPE TESTING

Drop tests were performed on light mobile devices. You have requested the addition of fixed, mobile and portable devices in which some can only be used indoors while other can be used outdoors. Please justify how the results of prototype tests conducted in 1994 apply to all the devices that are requested to be added to the registration.

The original model and tests were conducted for devices for detecting sulfur hexafluoride and refrigerants. Please state how the design and the dissimilar materials of construction of the prototype test units were found acceptable to demonstrate the performance of the five models in the applications which are designed to detect a variety of explosives, drugs and chemical agents.

6. ACQUISITION OF SAMPLES

In Appendix E of your application, you have included a Schematic of ITMS Detector. Please provide the sample induction pump system specifications and exhaust system details.

7. REMOVAL OF LEAKMETER 200

GE Ion Track requested the removal of Leakmeter 200 from Ion Track Instrument, Inc. license as this product is produced by ITI Qualitek of Billerica, MA which was formerly a part of Ion Track Instrument, but is now a separate entity and has listed the Leakmeter 200 on its SS&D. Please be advised that this device was added to ITI Qualitek registration NR-1128-D-101-E which was issued on May 11, 2001.

8. LEAK TEST REQUIREMENTS

Please provide the results of the leak tests that were performed at the 12-month frequency on these devices that are required by the registration certificate MA-0399-D-104-G. We request the test results for all units of all models that were distributed under this registration.

Enclosure 2

REQUEST FOR ADDITIONAL INFORMATION FOR THE MODEL 97 AND 97A/VIXEN GAS
AND AEROSOL DETECTORS

Please provide the following information for both models:

- The total number of the products sold; the number of products still in use;
- The services (including source replacement and availability) the registration certificate holder will still provide to users of the product or the identification of an entity that will provide services;
- A commitment that the registration certificate holder will no longer commercially distribute the product; and,
- Verification that no changes were made to the product since its initial registration or last amendment.