



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

April 30, 2008

Docket No. 030-37738
Control No. 142231

License No. 29-31303-01

Granville Todd Conway
Vice President
Control Screening
2 Gardner Road
Fairfield, NJ 07004

**SUBJECT: CONTROL SCREENING, REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 142231**

Dear Mr. Conway:

This is in reference to your letter dated March 5, 2008 applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. Confirm that you understand that, as the initial importer and distributor of devices containing radioactive materials in the United States, this company is considered by the NRC to be the initial manufacturer/distributor of the devices, and is responsible for ensuring that the imported devices meet the requirements as described in NRC regulations, license, and the Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Device (SSD Registry).
2. Because you are an applicant for a new license, we will meet with you at your site in Fairfield, New Jersey, prior to issuing the new license. An individual from our office will contact you within the next several weeks to schedule an appointment for this meeting.
3. In Items 2 and 3 of the application, the name of the company is listed as "Control Screening".
 - a. In other areas of the application, you referred to the company as "Control Screening of New Jersey". Confirm the correct name of the company which should be listed on your license for possession of radioactive materials in Fairfield, New Jersey
 - b. A search of the internet identified a website address "www.controlscreening.com" but the website itself discussed a company named "AUTOCLEAR". The website describes Scintrex Trace as a division of AUTOCLEAR, and as a subsidiary of Control Screening. Explain the relationship between Control Screening, Scintrex Trace Corporation, and AUTOCLEAR.
 - c. The application stated that the Canadian manufacturer of the devices you plan to distribute is Scintrex Trace Corporation located in Canada, and that Scintrex

Trace Corporation employees (Shirley Locquiao and Georges Vandrish) would manage the safety program at Control Screening of New Jersey. However, your application included a copy of an terminated exempt distribution license, formerly issued to CPAD Technologies Inc. located in East Syracuse, New York, and a copy of an inactive Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Device (SSD Registry) issued to CPAD Technologies Inc. located in East Syracuse, New York for an Ion Mobility Detector manufactured by CPAD Technologies Inc. located in Ottawa, Canada. We understand that you have submitted an application for a new exempt distribution license, and an application for a new SSD Registry, to the NRC. Confirm the current name of the manufacturer of the devices which Control Screening plans to distribute, and state the name of the company which will holds the SSD Registry when it is issued.

Please note that, throughout the remainder of this request for additional information, the applicant for the manufacturer/distributor possession license is referred to as "Control Screening".

4. Item 5 of the application states that the individual devices will contain nickel-63 sources not to exceed 100 microcuries. State the maximum amount of nickel-63 to be authorized on the manufacturing/distribution possession license. This amount should include the total activity you expect to possess at any one time, in all devices and/or sources possessed at the Fairfield, New Jersey location and at temporary job sites; in storage, use, waste, etc.
5. Item 7 of the application states that Shirley Locquiao and George Vandrish will be responsible for the radiation safety program at Control Screening of New Jersey. Item 7 later states that the distributor will not require any training on how to handle a radioactive source, and that only Todd Conway will handle the E5000 device. Item 8 states that only Todd Conway will be authorized to enter the area, to manage the inventory, and to distribute material.
 - a. Specify the individual who will be named as the Radiation Safety Officer for the manufacturer/distributor possession license. If that individual is not located in Fairfield, New Jersey, and/or is not a Control Screening employee:
 - (l) Describe: how control over the radiation safety program that will be delegated to the consultant-RSO; the relationship that will exist between the consultant-RSO and your institutional management for funding the radiation safety program and related regulatory requirements; the consultant-RSO's minimum amount of on-site time (hours per week/month/quarter, as applicable) performing RSO duties; and the availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements.

- (ii) Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.
 - (iii) Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant-RSO with limited authority.
 - b. Describe the radiation safety training that will be provided to Todd Conway and any other individuals who will handle the E5000 devices, and any sources, containing radioactive material at the Fairfield, New Jersey location and at temporary job sites. Although the risks from the sources are low, individuals who are present in the area and/or handle the license materials should know such information as: how to recognize the sources/devices containing radioactive materials; limitations for activities with the sources/devices (can they remove sources from the device?); regulatory requirements for transfers, posting, labeling, disposal, Department of Transportation (DOT) shipping requirements etc; and any other appropriate topics. Confirm that any ancillary personnel working in areas such as shipping/receiving, maintenance, etcetera will be appropriately instructed in recognizing and handling the devices, and their limitations for working with or around the devices.
- 6. Item 7 states that Scintrex Trace requests that the license authorize demonstration and evaluation of the E5000 Detection System at temporary job sites.
 - a. Confirm that authorization for use at temporary job sites is requested by Control Screening.
 - b. Confirm that you understand that when devices are possessed and used at temporary job sites, the devices are possessed under the manufacturer/distributor specific possession license and are required to be possessed and used in compliance with all applicable regulations and license conditions.
 - c. Describe the training that will be provided to persons who will possess and use the devices at temporary job sites. Submit the procedures you will use to: ensure that devices are appropriately shipped or transported to/from temporary job sites; used and secured in accordance with 10 CFR Parts 20 and 30 at temporary job sites; respond in the event of an emergency (such as a damaged device arriving at a temporary job site); and other such activities.
 - d. The NRC can authorize possession and use at temporary job sites only at locations where the NRC has jurisdiction (non-Agreement States and federal facilities.) The NRC regulations for granting reciprocity to Agreement State license holders who want to work in non-Agreement States are in 10 CFR 150; all Agreement States should have similar regulations. Confirm that you will file for reciprocity in accordance with the regulations of any Agreement State in which you wish to perform activities at a temporary job site, prior to performing any

demonstration or evaluation activities with your devices that are possessed under the manufacturer/distributor specific possession license.

7. Item 9 of the application states that special facilities are not required, and that Scintrex Trace plans to maintain records in accordance with 10 CFR 32.51. However, 10 CFR 32.51 is applicable only to generally-licensed devices distributed pursuant to 10 CFR 31.5, and Scintrex is not the applicant for this license. Confirm that Control Screening, as the initial importer and manufacturer/distributor authorized to possess the material under a specific license, will be responsible for maintaining records and providing quality control, labeling, and reports as required by 10 CFR 32.29. Please note that these regulations were revised recently to require an annual report of devices transferred for use pursuant to 10 CFR 30.20 and to specify the information to be included in the report.
8. In the NUREG-1556, Volume 12, Appendix C checklist, Item 10 "Safe Use of Radionuclides and Emergency Procedures" has both the "NA" (not applicable) circled, and a checkmark in the box for "description attached" for the statement "Develop and maintain procedures for safe use and emergencies. State that such procedures have been developed." In the attachment for this section, only Quality Assurance is addressed. Safe use procedures should be developed, applicable to the scope of the program. In this case, normal use appears to be one or more individuals may handle multiple devices during receiving, inventory, storing, handling, and transfer/shipping; emergencies may be issues such as receiving devices damaged in transit or response to fire or other building event. Confirm that Safe Use, and Operating and Emergency procedures will be developed.
9. Item 11 states that waste management is not applicable because Scintrex Trace will not open the detectors. However, if damaged devices are received by Control Screening or an event such as a building fire occurs, the sources in the devices may be considered radioactive waste. Radioactive waste may not be exported, in accordance with 10 CFR 110.23(a)(1). Confirm that if any of the sources or devices become radioactive waste, that such radioactive waste will be transferred to an authorized radioactive waste broker for appropriate disposal.
10. On page 3 of the attachment "Application for License", Item 2 states that the device type is intended for use pursuant to 10 CFR 32.36. Confirm that you will correct this to 10 CFR 30.20, "Gas and aerosol detectors containing byproduct material", because this is the regulation that allows users to possess the devices and be exempted from NRC regulations. As the initial manufacturer/distributor in the United States, Control Screening must comply with the requirements in 10 CFR 32.26, 32.27, 32.28 and 32.29 for the manufacturing and distribution of these devices, as well as the regulations in 10 CFR Parts 19, 20, 21, 30 and other applicable chapters.
11. The sample labels provided on pages 6 and 7 of the attachment "Application for License" state that the licensee is Scintrex Trace Corporation. If the manufacturer/distributor specific possession license is issued to Control Screening, the labels will need to list the NRC licensee name, as required by 10 CFR 32.32.29(b)(1)(iii) and 32.29(b)(2)(ii). If the exempt distribution license is issued to Scintrex Trace

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Corporation, the labels may be acceptable. However, the exempt distribution license does not authorize possession of licensed materials, so any devices to be returned may only be transferred to the Control Screening license which will authorize possession.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material; Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 142231. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5040.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Elizabeth Ullrich

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Georges Vandrish, Ph.D., Radiation Safety Specialist

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SUNSI Review Complete: EUllrich

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