Control Screening

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Q-5

29-31303-01

Betsy Ullrich, Senior Health Physicist
US Nuclear Regulatory Commission
Region 1
475 Allendale Rd.
King of Prussia, PA 19406-1415

Reference: Docket # 030-37738

May 22, 2008

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REGION 1

Dear Ms. Ullrich,

I am writing in answer of your letter dated April 30, 2008 and also to thank you for your inspection visit to our Fairfield, NJ, facility yesterday on behalf of myself and Dr. Georges Vandrish of our affiliate, Scintrex Trace Corp. We appreciate the time that you took with us in explaining the regulatory process. My answers to the questions posed by your letter are below in numerical order:

1. I confirm that I understand that, as an importer/distributor of devices containing radioactive materials in the US, my company, Control Screening, LLC, is considered to be the manufacturer/distributor in the USA for regulatory purposes, and are therefore responsible under US regulations for ensuring that the devices meet the US requirements set forth by the NRC for licensing & registration.
2. Georges Vandrish and I were pleased to have met with you yesterday here at Control Screening, LLC, Fairfield NJ to further our mutual understanding of the process of application(s) and to explain the nature of our business structures and activities.
3. a) the full and correct style of the US applicant entity is Control Screening, LLC. with headquarters at 2 Gardner Rd., Fairfield, NJ 07004; an American limited liability company with American shareholders.
   b) we make use of trade names and trade marks in the course of doing business and these names include 'Control Screening' 'AUTOCLEAR' and 'Scintrex'. Scintrex Trace Corp., located in Ottawa, Ontario, Canada, is our wholly owned affiliate/subsidiary company, who are the designers/manufacturers of the trace detection instruments which incorporate the radioactive components giving rise to the need for regulatory control when imported into the USA.
   c) we confirm that the current name of the manufacturer of the devices subject to NRC regulations is Scintrex Trace Corp. of Ottawa, Canada and that once imported to the USA the 'manufacturer' for American regulatory purposes is Control Screening, LLC. Control Screening, LLC has requested that Shirley

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NMSS/RGN1 MATERIALS-002

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Loquaio and Georges Vandrish of Scintrex Trace Corp. manage the safety program located at Control Screening, LLC in New Jersey in order to extend to us the benefit of their experience & expertise, since they are acquainted with the safe handling of isotope materials. Consistent with the rules and regulations of NRC, Todd Conway is the Radiation Safety Officer at the Control Screening,

LLC facility, listing as an alternate: Jerry Gaudreau, in the event of his absence. SSD registry will be held by Scinrex Trace Corp.

It is noted that the applicant for manufacturer/distributor possession license is: Control Screening, LLC.

4. The individual devices that we will posess/distribute contain nickel 63 sources which do not exceed 100 microcuries. The maximum amount of nickel 63 to be authorized on this license will not exceed a total of 2.0 millicuries at any one time, to include devices possessed at Fairfield and at temporary job sites.
5. a) both the designated RSO; Todd Conway, and the alternate: Jerry Gaudreau, are employees of Control Screening, LLC at the storage site. Todd Conway has been trained by Georges Vandrish in the safe handling of the devices under routine circumstances. Jerry Gaudreau will be similarly trained, which training is routine in nature. In the event of an extraordinary circumstance such as a fire or other disaster, or in the event of a device being received with damage in shipping, we will request the support of Georges Vandrish and Shirley Loquaio. Todd Conway will be authorized to enter the area, manage the inventory and to distribute material. In the event of Todd Conway's absence or incapacity, Jerry Gaudreau will be authorized to similarly enter the area, manage the inventory and distribute the material. Both individuals are located at Fairfield, NJ.
   b) A description of the radiation safety training provided to Todd Conway and other individuals who will handle the devices which contain the nickel 63 sources is as follows: 1) inventory all controlled items
   2) do not dismantle the devices or allow them to be dismantled.
   3) contact Georges Vandrish or Shirley Loquaio if a unit arrives or becomes damaged, or if a building emergency has resulted in any damage to the storage area, or to any temporary job site.
   4) review photographs, drawings, labeling & features of the isotope compontent provided by Scintrex Trace Corp. to obtain a familiarity

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with the component in order to recognize it as part of a damaged or dismantled assembly.

5) review the regulatory requirements for shipping/receiving, DOT procedures, disposal, etc. and instruct individuals in shipping & receiving for recognizing & safety awareness.

6. a) We confirm that authorization for use at temporary job sites is requested by Control Screening, LLC.
b) We confirm our complete understanding of the requirement.
c) Training will be provided to persons who will possess the controlled items at temporary job sites as per the outline of training in # 5, above. Regarding shipping to/from temporary job sites in accordance with 10 CFR Parts 20 and 30; Georges Vandrish will reply separately to this letter. In response to an emergency such as a damage in transport, instruction will be given to notify Georges Vandrish and/or Shirley Locquaio so that they may manage the situation.
d) We understand that at this time the NRC has jurisdiction in New Jersey which is one of the few non-agreement states. However, we are aware that the status of New Jersey is expected to change in the near future. In the event that we decide to conduct an evaluation or demonstration at any temporary job site not under NRC jurisdiction, we confirm that we will file for reciprocity as required according to 10 CFR 150, prior to any such event, according to the requirements of our manufacturer/distributor possession license.

7. We confirm that Control Screening LLC, as manufacturer/distributor, will be responsible for maintaining records, providing quality control, labeling & reports as required by 10 CFR 30.29, noting that an annual report of devices transferred for use pursuant to 10 CFR 30.20 is now required, to include information according to the format of that requirement. As an administrative matter, Georges Vandrish and Shirley Loquaio will provide the reports on behalf of Control Screening, as part of the matrix of reporting requirements scheduled by Scintrex Trace Corp. from time to time in obedience to government requirements.

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8. We confirm that Safe Use, Operating and Emergency procedures will be developed.

9. We confirm that in the event that should any of the sources or devices become radioactive waste, that such waste will be transferred to an authorized radioactive waste broker for appropriate disposal.

10. We confirm that we will correct the intended use to 10 CFR 30.20 'Gas and aerosol detectors containing byproduct material', and that we will comply with the requirements in 10 CFR 32.26, 32.27, 32.28, and 32.29 for manufacturing/distributing the devices, as well as the regulations in 10 CFR parts 19, 20,21,30 and other applicable chapters.

11. We acknowledge that if the exempt distribution license is issued to Scintrex Trace Corp., that license does not authorize possession of licensed materials; therefore any devices to be returned may only be transferred to Control Screening, LLC, holder of the license for possession/distribution in the USA.

We appreciate your efforts in helping us to perfect our license application and process.

Sincerely Yours,

G. Todd Conway, VP, Control Screening, LLC, Fairfield NJ. cc Georges Vandrish

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