UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 18, 1997

Mr. Michael Avnet
Hemisphere Forwarding
7 Cerro Street
Inwood, NY 11696

Dear Mr. Avnet:

This letter is in response to Mr. John Sinnott's letter dated May 27, 1996, with enclosures thereto, to Ms. Susan Greene, in reference to Models EI100BUS, EI100SUS, and EI100LUS. We are still in the process of evaluating your request. However, in order to continue our evaluation, the following information is necessary:

1. Please clarify who the distributer will be: EI Company, LTD or Hemisphere Forwarding.

2. In accordance with 10 CFR 32.29, the labels for the device and the point of sale package must contain the identification of the person licensed under 10 CFR 32.26 to transfer the detector for use pursuant to 10 CFR 32.20. Your application currently reflects the EI Company, LTD as the person to be licensed under 10 CFR 32.26. However, if the distributer is determined to be Hemisphere Forwarding, this company would then be required to be identified on the label attached to the device and point of sale package. Please provide the wording of the labels if the distributer is another person other than the EI Company, LTD.

3. Please demonstrate that the label attached to the base of the device will be visible when removed from its mounting base.

4. In drawing number D10009, Base - EI100L, it lists three materials that may be used for the base (Polystyrene Dow 492U, ABS Cycolac T 2500, T 27649, and Mor [illegible] to ABS 448 + 1% Armostat 575). Which of these materials were used as the base material in the devices that were used in the prototype testing? For those materials that were not used in the models prototype tested, please demonstrate that these materials would react in the same or better manner than the material used in the tests.

5. Does the source manufacturer, Nuclear Radiation Developments Corporation (NRD), provide the foil source only or does it also insert the foil source into the ion chamber? If NRD provides only the foil source, then your quality assurance procedure number QP 1027 should be revised to be consistent with Regulatory Guide 6.9, Appendix C. Specifically, each ion chamber should be leak tested prior to final packaging instead of lot tolerance percent defective (LTPD) 5%. Please provide a revised copy of quality assurance procedure QP 1027.

4. Please provide engineering drawings of the cover for each model, including the materials of construction and methods of attachment to the bases.

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5. Your assessment on dose commitments addressing the requirements in 10 CFR 32.27 references a report written by the National Radiological Protection Board, Board Statements on Approval of Consumer Goods Containing Radioactive Substances, NRPB, Vol. 3: No. 2, 1992. Please provide us a copy of this report so that we can verify the calculations and assumptions made in addressing the requirements in 10 CFR 32.27.

Please provide the requested information as soon as possible. If I you have any questions, please contact me at (301) 415-5723 or Mr. Douglas Broaddus at (301) 415-5847.

Sincerely,

Brian W. Smith, Health Physicist
Sealed Source Safety Section
Medical, Academic, & Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

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