

November 27, 2000

John P. Jankovich
United States Nuclear Regulatory Commission
Division of Industrial and Medical Nuclear Safety
Washington, DC 20555

RE: Registry Number NR-0547-D-101-E

Dear Mr Jankovich:

As discussed with you by telephone on November 15, System Sensor is requesting an amendment of this Device Registration to add product manufactured in two additional System Sensor facilities in Xi'an, China and Trieste, Italy. The Xi'an and Trieste facilities are completely owned, controlled, and operated by System Sensor. Products manufactured in Xi'an and Trieste will be completed, labeled, and packaged in Xi'an and Trieste, respectively.

All commitments made in documents referenced in the device registration shall apply to products manufactured in Xi'an and Trieste. The product is the same as product manufactured in St. Charles and Juarez and uses the same NRD A-001 source. The previously submitted quality control program shall be audited by System Sensor following the previously submitted standard operating procedure QP 17, Internal Quality Audits. The results of the quality audits shall be maintained in St. Charles, Illinois.

Product will be shipped to St. Charles or El Paso for distribution, as currently authorized. Upon receipt in St. Charles or El Paso, package labels will be compared with shipping documents to verify that the shipment contains the product described in the device registration. System Sensor shall audit product for labeling requirements in 10 CFR 32.29(b)(3) in accordance with Regulatory Guide 6.9. Sampling shall be random and in accordance with the schedule in Appendix C to Regulatory Guide 6.9.

All production and Quality Control/Quality Assurance (QC/QA) stages, except the above described audits for compliance with labeling requirements, will be completed in Xi'an and Trieste. The (QC/QA) Program is the same as the program described in our application for registration of the above referenced device and as is currently applied to activities in St. Charles, Illinois and Juarez, Mexico.

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System Sensor will perform quarterly audits of the Quality Control Program in its Xi'an and Trieste facilities. Copies of QC/QA records will be forwarded to St. Charles quarterly. Records of these audits shall be retained and shall be available for inspection at St. Charles. Current records that have not been received at the time of an inspection will, upon request, be made available in a timely manner.

The St. Charles Quality and Regulatory Assurance Department will perform an on-site audit of the referenced elements of the Xi'an and Trieste QC/QA programs annually. Records of these annual audits will be available for inspection in St. Charles.

The requested action is fee exempt. To minimize response time, if you have any questions or require additional information, please contact our consultant, Eli Port, at 847-965-1999.

Sincerely,



Andrej Nikolic
Radiation Safety Officer / Regulatory Compliance Supervisor

Cc: Eli Port

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