

5/13/02

Nuclear Regulatory Commission
Mail Stop T-8F-5
Washington D.C. 20555-001

Attention Seung Lee

RE: Device Registration NR-0668-D-101-E Amendment Request

In response to your e-mail dated 4-18-2002 this letter will address those questions in that letter.

Question # 1. You will find enclosed with this letter a copy of our ISO 9001 Certificate issued to us on August 20, 1999.

Question # 2. Kidde-Fenwal does not purchase sealed sources from Amersham. We have named Amersham in our licenses, certificates and other documents as a alternative to NRD. We would only purchase sealed sources from Amersham if NRD was unable to supply us. We have confirmed that the model numbers are still valid from both suppliers. NRD supplies us with model NRD A-001, and Amersham (now known as AEA Technologies) still supplies Nohmi with model AMMD-1001H. This is a sealed source mounted in a holder.

Question # 3. Kidde-Fenwal purchases these devices already assembled in there holders (sealed sources). The only assembly done here is mounting of the holder into the smoke chamber.

Question # 4. The letter dated November 27, 1991 describes in summary the quality guidelines for these detector assemblies. The procedures that are described in the letter are Kidde-Fenwal's procedures Nohmi Bosai Ltd also employs these procedures in their manufacturing process. We manufacture model CPD7052, and Nohmi manufactures model CPD7051. Each lot received from Nohmi is accompanied by quality conformance documentation, and Kidde-Fenwal performs their own quality conformance test procedures prior to distribution of these detectors in the U.S.

Question # 5. This question is answered in question # 4.

Question # 6. Kidde-Fenwal has been using LTPD of 5% and C=0 for all of the smoke detectors that we manufacture and distribute. One reject would fail the entire lot. Please note that we have been using the table in 10 CFR 32.110 (b)(6) but as stated in the original amendment request, one reject will fail the entire lot no matter what the sample size. The table in 10 CFR allows 1 failure on a sample size of 2,001 to 100,000 pieces. The sampling sizes listed in this table are identical to the table found in NRC's regulatory guide 6.9, page C-6. Kidde-Fenwal will be referencing and following the guidelines in Regulatory Guide 6.9 as well as NUREG 1556 vol.3.

Question # 7. Quality records as they pertain to radioactive materials and radiation safety at Kidde-Fenwal are kept for many years. Records are kept in the office of the Radiation Safety Officer, and date back to the early 80's. Section 4.16 of the Quality manual will be revised.

Sincerely,
William E. Sawyer R.S.O.

Enclosures: Kidde-Fenwal's ISO 9001 Certificate
Blue Print for Model NRD A-001

B-74