Director
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington D.C. 20555
USA

24 August 2000

MA/JH
A0678/2000

Dear Sirs

We take the liberty of writing to you because we need your guidance and advice regarding how to fulfil US regulations for sales of a product containing a sealed Americium 241 foil source to customers in the United States.

DELTA is the manufacturer of smoke measuring equipment MIC, type EC-912 (see enclosed Product Data Sheet) which is used for reference measurements of smoke density when the smoke sensitivity of ionisation type fire detectors is tested by manufacturers and test laboratories. The EC-912 instrument is specified in important standards for type testing of smoke detectors such as UL217, UL268 and European Standards EN54-7 and EN54-9 and is essential in the research, production and approval of reliable smoke detectors. The instrument is manufactured in small numbers since the demand is very limited and it is sold to manufacturers of smoke detectors and test laboratories worldwide.

The measuring head of the MIC contains a sealed Americium 241 foil source which ionises the air in the measuring chamber. The foil is manufactured by Nycomed Amersham in England and has the following specifications:

Product code:	AMMV 577
Radioactive isotope:	Am-241
Activity:	129,5 kBq (3,5 μCi) ± 5 %
Average α-energy:	4,5 MeV ± 5 %
Mechanical construction:	Americium oxide embedded in gold matrix which is covered on the alpha emitting face by gold-palladium alloy. The backing is silver with a thin gold interface. The foil is in the form of a circular disc with a diameter of 27 mm.

The Am-241 foil is mounted in a robust holder which covers the rim of the foil and the rear side so that no cut edges of the foil are accessible. The holder is mounted in the measuring head and secured against unauthorised dismounting by a 3 mm allen screw. The label, affixed to the source holder, has the radioactive symbol, the serial number (EC ..) of the measuring chamber and the text "RADIOACTIVE" "Am241" and "3,5 μCi". A warning label, with the following text, is affixed to the measuring head:

> "WARNING. This equipment contains a weak radioactive source. Do not attempt to dismount the unit without following the safety precautions given in the instruction book"

DELTA
Danish Electronics,
Light & Acoustics

Venlighedsvej 4
DK-2970 Hørsholm
Denmark

Tel. (+45) 45 86 77 22
Fax (+45) 45 86 58 98
www.delta.dk
VAT DK 12275110

The safety precautions for the use and cleaning of the measuring head and the radioactive source are given in the instruction manual accompanying each smoke measuring system we deliver. The instruction manual for the last production series is enclosed for your information (see page 4, 23 and 24). The labels are shown in the instruction manual in fig A.1.2 in Annex 1.

The Am-241 foils are mounted in the source holders in our laboratory during the production of the smoke measuring equipment. The mounting is carried out in accordance with our QA procedures which have been approved by the National Institute of Radiation Hygiene in Denmark. After the mounting, a wipe test is carried out on each individual source according to the recommendations and methods described in ISO TR 4826 (1979), clause 2.1.1.: Wipe (smear) test. A copy of a test record sheet is enclosed for your information. The production of the EC-912 smoke measuring equipment is carried out under a license given by the National Institute of Radiation Hygiene (see the enclosed copy of statement from the National Institute of Radiation Hygiene, dated 14 October 1996.

The smoke measuring equipment is produced by Electronics Testing, a division of DELTA Danish Electronics, Light & Acoustics. DELTA is an independent organisation, affiliated to the Danish Academy of Technical Sciences (ATV). Further information about our company can be seen on http://www.delta.dk.

We are not familiar with the conditions which have to be fulfilled by us and/or our customers in the United States in order for them to buy and use our EC-912 smoke measuring equipment. So, we would appreciate your guidance and advice on this matter and information on how to proceed if we need to fulfil more specific requirements. We will be happy to supply further details which you may need.

We thank you in advance for your assistance.

Yours sincerely
DELTA

Morten Avlund
Project Manager, Responsible for Radiation Hygiene
Alarm & Security Systems
ma@delta.dk

Encl.
c.c. KaK, MA