April 5, 2012

MEMORANDUM TO: Anne T. Boland, Director
Division of Nuclear Materials Safety, RIII

FROM: Brian J. McDermott, Director ***/RA/ Pamela Henderson for***
Division of Materials Safety
and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

SUBJECT: TECHNICAL ASSISTANCE REQUEST: GENTEX CORPORATION (NEW APPLICANT)

Issue:

This is in response to a Region III Technical Assistance Request (TAR), dated February 7, 2012. The TAR requested a review of Gentex Corporation's submittal to determine if a smoke detection/measuring device can be approved by the NRC and registered in the Sealed Source and Device Registry (SSDR) under 10 CFR 30.32(g)(2) or as a "custom device" for use only by Gentex Corporation.

Action:

A review of the requested action and the additional information supplied by Gentex Corporation demonstrated that the device is acceptable for licensing purposes under 10 CFR 30.32 (g)(2). The device therefore does not need a custom sealed source and device registration. However, even though a custom sealed source and device registration is not required, since the device is not registered in the United States, the device should be authorized for use in the license for the applicant's use alone as a custom user. The term custom user should be used to clearly identify the entity authorized to use the device.

Background:

By letter dated October 28, 2011, forwarding its application, Gentex Corporation (Gentex, or applicant) requested authorization to use a smoke detection/measuring device manufactured by DELTA Electronics Testing in Denmark. The applicant states that the device will be used for measuring smoke density in connection with testing ionization smoke detectors for automatic fire detection systems. The device does not have SSDR approval by the NRC or Agreement State. The applicant wishes to use three devices at its facility. It does not want to distribute this device to other customers. The device contains a nominal 3.5 microcuries of Americium-241 source which can be removed for cleaning.

CONTACT: Lymari Sepulveda, FSME/MSSA
(301) 415-5619

Discussion:

10 CFR 30.32(g) provides in pertinent part that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source either (1) identify the source or device by manufacturer and model number as registered with the Commission under 10 CFR 32.210, or with an Agreement State, or (2) contain the information identified in 10 CFR 32.210. However, as described in NUREG 1556 Volume 3, Rev. 1, "Consolidated Guidance About Materials Licenses, Applications for Sealed Source and Device Evaluation and Registration," section 5.1.3, "Custom Sealed Sources or Devices," sealed sources or devices containing sealed sources built to the unique specifications of a given user need not be registered if they meet certain specified criteria. The authorization to use such sources or devices applies only to the custom user of the product.

Because the DELTA Electronics Testing device does not have SSDR approval, Gentex has submitted an application with information regarding this device. We have reviewed the information provided by the applicant to Region III. This review was conducted following the guidance in NUREG 1556 Vol. 3, Rev.1.

The applicant has stated that the device Model EC-912 would be used to measure smoke particle size when testing smoke detectors. The device has three major components: (1) a measuring ionization chamber, (2) a control cabinet, (3) and a vacuum pump. One of the devices would be mounted on the ceiling and the other two would be mounted on adjacent walls. Access to the area where these devices would be installed is limited to authorized personnel. The device Model EC-912 contains an Americium-241 source with a maximum activity of 3.5 microcuries (130 kBq). The source is constructed of an Americium oxide in gold between two layers of gold and covered with a hard gold alloy. The source is a disk source with dimension of 27 mm in diameter. The source is mounted in a metal holder with sealed edges which make the source inaccessible. The ionization chamber will contain the radiation symbol.

The applicant has provided sufficient information as required by 10 CFR 30.32(g)(2) such that the use of the device may be authorized under its license by license condition. However, because the device is not registered in the United States, the device will be authorized for use in the license by the applicant as for a custom user. The term custom user will be used to clearly identify the entity authorized to use the device.

In addition, it is recommended that the following license conditions, be added to the license: (1) Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holder by the licensee; (2) Sealed sources need not to be tested if they contain only hydrogen-3; or they contain only a radioactive gas, or the half life of the isotopes is 30 days or less, or they contain not more than 100 microcuries of beta-and/or gamma-emitting material or not more than 10 microcuries of alpha emitting material; (3) The licensee must develop and follow a procedure for the maintenance of the device (i.e. to address the changing of the filters); (4) The licensee shall follow the instructions and/or restrictions provided by the manufacturer; (5) The device shall only be used by the custom user, Gentex Corporation; (6) Only qualified personnel are authorized to perform maintenance on the device.

The Region has also requested, in separate correspondence, that we provide text for items 6, 7, 8, and 9 on the license for material use and possession limit. This will be provided in a separate response.

Discussion:

10 CFR 30.32(g) provides in pertinent part that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source either (1) identify the source or device by manufacturer and model number as registered with the Commission under 10 CFR 32.210, or with an Agreement State, or (2) contain the information identified in 10 CFR 32.210. However, as described in NUREG 1556 Volume 3, Rev. 1, "Consolidated Guidance About Materials Licenses, Applications for Sealed Source and Device Evaluation and Registration," section 5.1.3, "Custom Sealed Sources or Devices," sealed sources or devices containing sealed sources built to the unique specifications of a given user need not be registered if they meet certain specified criteria. The authorization to use such sources or devices applies only to the custom user of the product.

Because the DELTA Electronics Testing device does not have SSDR approval, Gentex has submitted an application with information regarding this device. We have reviewed the information provided by the applicant to Region III. This review was conducted following the guidance in NUREG 1556 Vol. 3, Rev.1.

The applicant has stated that the device Model EC-912 would be used to measure smoke particle size when testing smoke detectors. The device has three major components: (1) a measuring ionization chamber, (2) a control cabinet, (3) and a vacuum pump. One of the devices would be mounted on the ceiling and the other two would be mounted on adjacent walls. Access to the area where these devices would be installed is limited to authorized personnel. The device Model EC-912 contains an Americium-241 source with a maximum activity of 3.5 microcuries (130 kBq). The source is constructed of an Americium oxide in gold between two layers of gold and covered with a hard gold alloy. The source is a disk source with dimension of 27 mm in diameter. The source is mounted in a metal holder with sealed edges which make the source inaccessible. The ionization chamber will contain the radiation symbol.

The applicant has provided sufficient information as required by 10 CFR 30.32(g)(2) such that the use of the device may be authorized under its license by license condition. However, because the device is not registered in the United States, the device will be authorized for use in the license by the applicant as for a custom user. The term custom user will be used to clearly identify the entity authorized to use the device.

In addition, it is recommended that the following license conditions, be added to the license: (1) Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holder by the licensee; (2) Sealed sources need not to be tested if they contain only hydrogen-3; or they contain only a radioactive gas, or the half life of the isotopes is 30 days or less, or they contain not more than 100 microcuries of beta-and/or gamma-emitting material or not more than 10 microcuries of alpha emitting material; (3) The licensee must develop and follow a procedure for the maintenance of the device (i.e. to address the changing of the filters); (4) The licensee shall follow the instructions and/or restrictions provided by the manufacturer; (5) The device shall only be used by the custom user, Gentex Corporation; (6) Only qualified personnel are authorized to perform maintenance on the device.

The Region has also requested, in separate correspondence, that we provide text for items 6, 7, 8, and 9 on the license for material use and possession limit. This will be provided in a separate response.

ML120960590

OFFICE	FSME	FSME	FSME	RIII/DNMS
NAME	LSepulveda	JJankovich	KO'Sullivan	3/21/2012
DATE	4/ 5 /2012	4/ 5 /2012	4/ 5 /2012	
OFFICE	OGC	FSME	FSME	
NAME	NLO (via email)	PHenderson	BMcDermott	
DATE	4/ 3 /2012	4/ 5 /2012	4/ 5 /2012	

OFFICIAL RECORD COPY