November 1, 2005

MEMORANDUM TO: George C. Pangburn, Director
Division of Nuclear Materials Safety, RI

FROM: Scott W. Moore, Chief **/RA/ MSD for**
Rulemaking and Guidance Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: RESPONSE TO TECHNICAL ASSISTANCE REQUEST DATED AUGUST 1, 2005, REGARDING GRANDFATHERING OF LINEAR ACCELERATORS MANUFACTURED BY VARIAN ASSOCIATES

ISSUE:

In a technical assistance request (TAR) [ADAMS Accession No. ML052130497] dated August 1, 2005, Region I requested assistance in determining whether various linear accelerators, containing depleted uranium (DU), and manufactured by Varian Associates (Varian) prior to their issuance of a specific license pursuant to 10 CFR 40.34, "Special requirements for issuance of specific licenses," in 1983 can be possessed under the general license in 10 CFR 40.25, "General license for use of certain industrial products or devices."

BACKGROUND:

Section 40.25 provides a general license to persons for the use of certain industrial products or devices containing DU for the purpose of providing a concentrated mass in a small volume of the product or device. Varian received a license, issued by the State of California in 1983, to distribute various models of linear accelerators for use under a general license [ADAMS Accession #ML051310053]. Varian originally applied to the State of California for such authority in 1977 [ADAMS Accession #ML051310058]. Based on a May 20, 2005, email submitted by Varian Medical Systems (formerly Varian Associates), Varian distributed approximately 425 units of various models of linear accelerators containing DU between 1962 and 1980. Additionally, Varian shipped approximately 566 units of two newer models between 1977 and 1983 [ADAMS Accession #ML051510209]. According to a telephone call between Varian and Region I on March 10, 2005 [ADAMS Accession #ML051580456], all the devices manufactured prior to 1983, were manufactured according to the standards outlined in the 1977 license application. These standards were amended into Varian's license in 1983.

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In a response to a TAR (IMAB-1307), dated March 8, 1993, NMSS identified that a § 40.25 general licensee could receive linear accelerators containing DU from other general licensees possessing the DU under 10 CFR 40.25 or its Agreement State equivalent, presuming the linear accelerator was initially distributed or manufactured under § 40.34 or its Agreement State equivalent. However, the 1993 TAR response stated that some linear accelerators are received by specific licensees and if the specific licensee then transfers the linear accelerator to a general licensee, the specific licensee would be in violation of the regulations since a specific licensee cannot distribute to general licensees without authorization to distribute.

In an April 11, 2004, response to a TAR, dated November 23, 2004, NMSS provided clarifications that a specific licensee could transfer linear accelerators to a general licensee if the device was initially manufactured or distributed under a specific license issued pursuant to § 40.34 or its Agreement State equivalent; however, no information was provided regarding devices manufactured prior to implementation of § 40.25 in 1976.

Discussion:

On January 10, 1975, the Atomic Energy Commission issued a proposed rule to amend the source material regulations to include a general license for use of depleted uranium in industrial products or devices [40 FR 2209]. This proposed rule was in response to three petitions for rulemaking (PRM 40-15, PRM 40-16, and PRM 40-17) which requested a broader exemption for such uses. The Commission believed that the general license was more appropriate than an exemption to provide adequate safety in use and to exercise control over disposal or abandonment. The final rule was published on December 6, 1976, with minimal changes [41 FR 53330]. The final rule amended the regulations in 10 CFR Part 40 to include three new sections: § 40.25, § 40.34, and 10 CFR 40.35, “Conditions of specific licenses issued pursuant to § 40.34.” Section 40.25 provides the conditions of use of the general license; whereas, §§ 40.34 and 40.35 provide conditions for the manufacture and initial distribution of devices for use under § 40.25.

Both the proposed rule and final rule are silent on the status of devices manufactured or produced prior to implementation of § 40.25. Under § 40.25, devices, manufactured or initially distributed under a license issued under § 40.34 or an Agreement State equivalent, can be possessed because the conditions believed necessary to safely possess the device under a general license are met. The primary controls in §§ 40.34 and 40.35 used to protect public health and safety include:

(1) The applicant manufacturing or initially transferring the device has a specific license authorizing such activity.

(2) The application included sufficient information to ensure that the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the device provide reasonable assurance that possession, use, or transfer of the depleted uranium in the device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of 10 percent of limits specified in § 20.1201(a).

(3) There are unique benefits resulting from the use of the device.

(4) The licensee maintains the level of quality control required by the license.

(5) The licensee labels or marks each unit to: (a) identify the manufacturer and license number under which the device was manufactured or transferred, and (b) state that the receipt, possession, use, and transfer of the product or device are subject to a general license issued by the U.S. Nuclear Regulatory (NRC) or an Agreement State.

(6) The licensee assures that the depleted uranium has been impressed with the following legend: “depleted uranium”

(7) The licensee furnishes a copy of the general license and Form NRC 244 to each person it transfers the device to for use under § 40.25.

The devices manufactured by Varian prior to 1983, were clearly not manufactured or initially transferred under a specific license issued pursuant to § 40.34 or its Agreement State equivalent because Varian did not receive such a specific license until 1983; therefore, the pre-1983 devices do not readily meet the requirements to be used under the general license in § 40.25. However, in a March 10, 2005, telephone call with Region I, Varian stated that all the devices manufactured prior to 1983, were manufactured according to the standards outlined in the 1977 license application that were eventually amended into Varian’s specific license in 1983. Therefore, Varian devices produced prior to 1983, can be considered to meet many of the objectives of §§ 40.34 and 40.35 conditions as follows:

(1) The applicant produced, manufactured, or distributed the devices under a specific license (albeit not necessarily for use under the general license in § 40.25).

(2) The devices were manufactured to the same standards amended into Varian’s specific license in 1983. Therefore, the design, manufacture, prototype testing, quality control procedures, proposed uses, and potential hazards of the device provide reasonable assurance that possession, use, or transfer of the depleted uranium in the device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of 10 percent of limits specified in § 20.1201(a). Note that the labeling and marking would not be the same due to the changes in labeling requirements resulting from the new rule.

(3) Because the license was granted for the same models, the regulatory agency determined that there was a unique benefit from the use of the depleted uranium in the device.

(4) In a May 6, 2005, telephone call with Region I, Varian indicated that all of the units were labeled and marked to indicate that the devices contained depleted uranium.

As a result, the devices manufactured by Varian prior to 1983, meet all of the objectives of the primary requirements for manufacture under a license issued pursuant to § 40.34 except that the specific labeling required by § 40.35 (b) was not provided and no copies of the general license and a NRC Form 244 were included with the distribution as required by § 40.35 (d) . However, by adding proper labeling to the device and providing a copy of the general license and a NRC Form 244 to the potential general licensee, these devices manufactured by Varian, prior to 1983, may be considered to meet the objectives of §§ 40.34 and 40.35 for all intensive purposes and therefore be acceptable for use under § 40.25.

CONCLUSION:

The available regulatory history of § 40.25 provides no discussion regarding the use of devices under the general license that were manufactured and initially distributed prior to the rules implementation in 1976. Based on telephone discussions with Varian, all the devices manufactured by Varian prior to 1983 were manufactured according to the standards outlined in its 1977 license application that was eventually amended into the specific license in 1983, which allowed distribution of the devices for use by general licensees pursuant to § 40.25. By adding labeling consistent with the requirements in § 40.35 and providing a copy of the general license and an NRC Form 244 to the potential general licensee, all the objectives of the specific license requirement in §§ 40.34 and 40.35 can be considered fulfilled. As a result, there is no reason that devices manufactured by Varian prior to 1983, with the same model number as those approved for manufacture in their 1983 license amendment, should not be able to be used under the general license provisions of § 40.25 after such labeling and documentation is included.

CONCLUSION:

The available regulatory history of § 40.25 provides no discussion regarding the use of devices under the general license that were manufactured and initially distributed prior to the rules implementation in 1976. Based on telephone discussions with Varian, all the devices manufactured by Varian prior to 1983 were manufactured according to the standards outlined in its 1977 license application that was eventually amended into the specific license in 1983, which allowed distribution of the devices for use by general licensees pursuant to § 40.25. By adding labeling consistent with the requirements in § 40.35 and providing a copy of the general license and an NRC Form 244 to the potential general licensee, all the objectives of the specific license requirement in §§ 40.34 and 40.35 can be considered fulfilled. As a result, there is no reason that devices manufactured by Varian prior to 1983, with the same model number as those approved for manufacture in their 1983 license amendment, should not be able to be used under the general license provisions of § 40.25 after such labeling and documentation is included.

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