

August 20, 2004

ALL AGREEMENT STATES, MINNESOTA, PENNSYLVANIA

**REQUEST FOR SEALED SOURCE & DEVICE APPROVAL FROM FOREIGN (MEXICAN)
RADIOGRAPHY COMPANIES - (STP-04-061)**

The United States Nuclear Regulatory Commission (NRC), as well as several Agreement States, was contacted by Mr. Carlos Martinez of Naumex, S.A. de C.V., representing four industrial radiography companies in Mexico. The purpose of these contacts was to request NRC or Agreement State "Approval or Certification" of a refurbished exposure device (Model Iriditron 520).

Enclosed for your information is an email to Mr. Martinez providing our response. He was informed that consistent with our guidance, neither the NRC nor the Agreement States issue registration certificates to companies located outside the United States. Mr. Martinez was advised to contact the Mexican regulatory authority, directly and request that they contact the NRC should they desire NRC advice or technical assistance.

We appreciate the prompt notice provided to us by several Agreement States. If you have any questions on this correspondence, please contact me or the individual named below.

POINT OF CONTACT: Lloyd Bolling
TELEPHONE: (301) 415-2327

INTERNET: LAB@NRC.GOV
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***/RA By Dennis M. Sollenberger Acting for/
Paul H. Lohaus, Director
Office of State and Tribal Programs***

Enclosure:
As stated

STP-04-061

August 20, 2004

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***See previous concurrence.**

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From: John Jankovich
To: CONTROL DE CALIDAD, TECNICA RN, MEXICANA DE RADIOGRAFIAS & NAUMEX
Date: 8/11/04 12:58PM
Subject: Re: EVALUATION AMENDED AI 520 DEVICE

Mr. Martinez,

This is a response to your e-mails, dated July 29, and August 3, 2004 (attached below), regarding the registration of the Model Iriditron 520 radiography camera. You indicated that your company modified 76 units by replacing the original lock box with an automatic lock box and, thereby, you intended to meet the requirements in 10 CFR 34.20(c)(2) of the U.S. Nuclear Regulatory Commission (NRC) and you requested an NRC registration certificate as a "reference" for the use of the devices in Mexico.

Please note that the U.S. performance requirements for industrial radiography equipment are described in 10 CFR 34.20, 34.21, and 34.24. The requirements specify that the equipment must be tested in accordance with the provisions of ANSI Standard N432-1980. We are not familiar with the requirements in ISO Standard 3999-1-2000 that you quoted in your e-mail. One obvious difference between the ANSI Standard and the tests conducted on your cameras is the endurance test: ANSI requires 20,000 cycles, your locks were tested for 600 cycles.

Please also note that the NRC conducted, under contract, extensive testing of three models of radiography equipment that are in wide use in the U.S. The test methods, test durations and the test results were published in the NRC Technical Report No. NUREG/CR-6652, "Safety Testing of Industrial Radiography Devices." You may want to consult the report for reference.

The responses to your specific questions in your e-mail dated July 29, 2004, are below.

Question 1. "What kind of certificates can be issued by you for AI 520 to be used in Mexico by a Mexican Licensee?"

Response: The U.S. Nuclear Regulatory Commission does not issue registration certificates to companies located outside the U.S. When a U.S. company wishes to register and distribute a product within the U.S. for use by U.S. licensees, the product must be registered by the NRC or an Agreement State. The NRC or the Agreement States issue the registration certificate on the basis of a safety evaluation of the device which is conducted in accordance with the applicable guidance. The guidance used by the NRC is our technical report entitled "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," NUREG-1556, Vol. 3, Rev.1. The document is accessible at the following web-site: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v3/r1/>. Section 10 in the document lists the technical areas that the NRC staff uses for conducting the safety evaluation. The Agreement States use similar procedures.

Since the Model Iriditron 520 device was modified, a new safety evaluation would be needed in the U.S. for the updated Model Iriditron 520 radiography cameras. The registration issued for the original design would not be acceptable. A safety evaluation would be conducted in response to an application from a distributor, such as yourself, if your business was located in the U.S. However, in your specific case the NRC or the Agreement States cannot conduct such an evaluation because our authority does not extend beyond the U.S.

Question 2. "In the U.S.A. do you have to issue certificates for each exposure device or only for the prototype?"

Response: In the U.S., the registration certificate is issued to the distributor on the basis of a safety evaluation of the prototype tests as well as the other areas subject to safety evaluation that are listed in Section 10 of the guidance document referred to above. The registration certificate is issued for the model in general, not for individual units. Once the registration certificate is issued, the manufacturer is free to distribute as many units as they wish on the commercial market.

Question 3. "If the AI 520 approved prototype was accepted regarding the above authorized cited modification, does Naumex as the Manufacturer/Distributor responsible for the modification made in México, can issue the certificates of compliance for the 76 modified devices if they are going to be used only by three Mexican licensees exclusively in México?"

Response: We are not familiar with the requirements in Mexico and, therefore, unable to answer your question. We recommend that you contact the nuclear regulatory authorities in Mexico directly.

Question 4. "Do you know if the original U.S. manufacturer of the radiographic exposure devices AI Model Iriditron 520 manufactured before 1992 named Automation Industries, Inc. Sperry Products Division, still exists?"

Response: As far as we can determine, this camera was built originally by Automation Industries, and later was registered in the U.S. by Amersham Corporation, and the registration certificate (NR-628-D-807-S) was inactivated in 1992. Amersham has changed the name since the time when the inactive registration was issued; their current name is: AEA Technology, QSA, Inc. The address is the same: 40 North Avenue, Burlington, MA 01803.

In summary, the NRC conducts safety evaluations and device registrations only for U.S. licensees and for devices that are used in the U.S. We suggest that you contact the Mexican regulatory authority, Comisión Nacional de Seguridad Nuclear y Salvaguardias (CNSNS), directly and ask them to request such a review from the NRC. If CNSNS would like to seek NRC's advice on the application, we will consider a request from them for technical support.

If you need further information regarding the requirements or the registration process in the U.S., please contact me by e-mail or call at 301 415-7904.

John Jankovich, Team Leader
Sealed Source and Device Registration

CC: Josephine Piccone; Lloyd Bolling; PKH; Teh; the ; Theodore Sherr