

April 28, 2004

Mr. Allan Sutton  
EHS Manager/Radiation Safety Officer  
Nuclear Medicine  
ADAC Laboratories, a Philips Medical Systems Company  
540 Alder Drive  
Milpitas, CA 95035

SUBJECT: REGULATORY INTERPRETATION REQUEST CONCERNING THE  
SERVICING OF MEDICAL DEVICES BY MANUFACTURER'S /  
DISTRIBUTOR'S SERVICE TECHNICIANS

Dear Mr. Sutton:

I am responding to your letter to Charles L. Miller, Director, Division of Industrial and Medical Nuclear Safety, U.S. Nuclear Regulatory Commission (NRC), dated January 22, 2004, on the above-referenced subject. In your letter, you ask whether a Service Provider Specific License is required to perform routine service procedures at a licensee's facility, while operating under Title 10 of the Code of Federal Regulations (10 CFR) Parts 35.11 and 35.27. Specifically, you ask whether a Manufacturer/Distributor's service person may (1) conduct routine service procedures on a medical device containing a sealed (transmission) source at an NRC or Agreement State facility and (2) may conduct source installations and exchanges on a medical device at a customer's site without a specific license. Please note that the interpretation below applies to NRC's regulations, which is applicable only to non-Agreement States and federal facilities. Agreement States (as defined in 10 CFR Part 150), such as California, have regulations compatible with 10 CFR. You may find a listing of Agreement States, as well as state regulations and contact persons, through the NRC's Office of State and Tribal Program's website: <http://www.hsrdo.nrc.gov/nrc/home.html>.

10 CFR 35.11(b), which describes the criteria for an individual for whom a specific license is not needed, applies only to medical use licensee personnel. The medical use licensee personnel would not be required to have a specific license for the receipt, possession, use, or transfer of byproduct material if they are working under the supervision of an authorized user, as provided in 10 CFR 35.27. 10 CFR 35.11 and 35.27 do not apply to the manufacturer's/distributor's service personnel performing activities on devices located at the customer's facilities.

The manufacturer/distributor would need to obtain a specific license to perform activities that would affect the radiation safety aspects of the sealed source in the device. The general regulatory requirements for this license are in 10 CFR 30.33(a)(3), which requires the applicant for the license to be qualified by training and experience to use the material for the purpose requested. NUREG-1556, Vol. 18, "Program Specific Guidance About Service Provider Licenses", Section 8.7.2, addresses persons described in your letter, namely authorized users providing installation, relocation, removal from service, disposal, radiation surveys, routine and preventive maintenance, adjustment of equipment, training of personnel or repair of devices containing licensed materials. It is the responsibility of the service provider licensee to control

the radiation safety program for its personnel, which includes supervision of the use of the licensed material. If the manufacturer's/distributor's personnel are only performing non-NRC regulated services on the device, such as software upgrades for a CT or PET scanner that do not involve the radiation safety aspects of the transmission source, a license by the NRC or Agreement State is not required.

I trust that the above response addresses your need for clarification. If you have any further questions, please contact Jonathan Rivera of my staff, at (301) 415-5810.

Sincerely,

**R/A R. Torres for**

Thomas H. Essig, Chief  
Materials Safety and  
Inspection Branch  
Division of Industrial and  
Medical Nuclear Safety  
Office of Material Safety  
and Safeguards

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Sincerely,

Thomas H. Essig, Chief  
Materials Safety and  
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Division of Industrial and  
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Office of Material Safety  
and Safeguards

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