

1 April 1998

MEMORANDUM FOR Director, Medical Logistics

FROM: AFMLO/FOM
1423 Sultan Drive, Suite 200
Fort Detrick, Maryland 21702-5006

SUBJECT: Contract Requirements for All Diagnostic Radiology Systems

The Safe Medical Devices Act (SMDA) requires extensive record keeping on the maintenance of medical equipment. Since AFMLO is responsible for providing policy and guidance for all calibrations, it is our intent to ensure that all x-ray calibrations are properly documented. In order to accomplish this, all vendors contracted to perform x-ray system maintenance are requested to complete DD Form 2164, "X-Ray Verification/Certification;" AF Form 2025, "Post-Calibration Radiation Inspection Record (PCRI)/Radiographic;" and AF Form 2026, "Post-Calibration Radiation Inspection Record (PCRI)/Fluoroscopic," or provide equivalent calibration documentation on their forms. This policy has been in effect since 1 October 1993.

To ensure appropriate calibration documentation is provided, the following paragraphs are recommended for inclusion in the statement of work or AF Form 9, "Request for Purchase."

- a. Recommend the description of services on the contract be written to state "preventive maintenance, calibration, and all intervening service calls" instead of "preventive maintenance and remedial services."
- b. The contractor will complete DD Form 2164, "X-Ray Verification/Certification," or provide manufacturer's documentation which verifies the following on both radiographic and fluoroscopic modes:
 - (1) All documentation will include the calibration results of kVp and MA in accordance with the manufacturer's calibration instructions or specifications. In the absence of manufacturer-specific instructions, the 25, 50, and all hundreds Milliampere (mA) stations (i.e., 100, 200, 300, 400, 600 or 640, 700 or 720, etc.) on both radiographic and fluoroscopic modes will be validated by written verification. These mA stations will be tested at 60, 80, and 120 kVp. Tolerance standards at all kVp/mA combinations will be \pm kVp, \pm 5 percent of the mA observed. All exposures below 100 mA should be accomplished at a 1- or 2-second time base.
 - (2) The linearity will be documented at the mA/kVp combinations mentioned above in milliroentgen (MR) format (see AF Forms 2025 and 2026).

(3) Conduct testing of half-value layer, time verification, and all collimation checks in relation to light field to rad offset, field size versus indicators, field size versus receptor offset, and field size auto for both table horizontal and chest receptor (see AF Forms 2025 and 2026).

If contracts for 1 October 1998 have already been submitted to your Contracting Office, ensure the above information is incorporated as an amendment.

If you have any questions regarding this request, please contact the undersigned at DSN 343-4040.

ALAN J. CHRISTIAN
Senior Staff Maintenance Manager