DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
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IN REPLY REFER TO
BUMEDINST 6470.22B
BUMED-M9
20 Jul 2016

BUMED INSTRUCTION 6470.22B

From: Chief, Bureau of Medicine and Surgery

Subj: NAVY DIAGNOSTIC IMAGING EQUIPMENT PERFORMANCE SURVEY PROGRAM

Ref: (a) Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures, Federal Guidance Report No. 14
(b) National Council on Radiation Protection and Measurements (NCRP) Reports 145, 147, 99, and 102
(c) Navy Diagnostic Imaging Equipment Performance Survey Manual, Navy and Marine Corps Public Health Center (NMCPHC)TM-6470.1
(d) Joint Commission Comprehensive Accreditation Manual for Hospitals
(e) Joint Commission Comprehensive Accreditation Manual for Ambulatory Care
(f) Radiation Health Protection Manual, NAVMED P-5055
(g) BUMEDINST 6470.25
(h) 21, CFR, 1020
(i) 21, CFR, 900
(j) NAVMED P-5132, BUMED Equipment Management Manual
(k) BUMED Memo 5050 Ser M82/13UM80776 of 7 Oct 13
(l) SECNAV M-5214.1
(m) DoD Instruction 6025.18, of 2 December 2009
(n) DoD Instruction 8580.02 of 12 August 2015

Encl: (1) Navy Medicine Radiological Surveyor Responsibilities

1. Purpose. Update guidance for radiation safety management, acceptance and periodic testing of imaging equipment in Navy Medicine. This is a complete revision and must be read in its entirety.

2. Cancellation. BUMEDINST 6470.22A.

3. Scope. This instruction applies to all Naval facilities and commands, ashore or afloat, and Navy Medicine sponsored operations having medical or dental diagnostic imaging equipment.

4. Background. Navy medical and dental diagnostic imaging equipment must comply with Federal regulatory requirements, Navy policies, applicable accreditation standards governing the safe use and proper operation of equipment. Equipment performance surveys and acceptance testing procedures are established to verify compliance with these requirements.

a. Reference (a) provides radiation protection guidance for diagnostic and interventional x-ray procedures. Reference (b) provides procedures and practices for safe operations and shielding design at medical and dental diagnostic imaging equipment sites. Reference (c) provides guidance on procedures for the Navy Diagnostic Imaging Equipment Performance Survey Program. References (d) and (e) require periodic performance evaluation of diagnostic imaging equipment at Joint Commission (JC) accredited facilities. Reference (f) provides Navy ionizing radiation protection standards. Reference (g) outlines the composition, functions and responsibilities of the Navy Medical Physics Advisory Board (MPAB). References (h) and (i) establish Federal performance standards for the manufacture of diagnostic x-ray systems and dedicated mammography systems, respectively. Reference (j) outlines the requirements of the X-ray Acceptance Program, including the scope and responsibilities of the Naval Medical Logistics Command (NAVMEDLOGCOM) and the Biomedical (BIOMED) Engineering Division for the management of medical and dental imaging equipment. Reference (k) promulgates official travel requirements for Navy Medicine activities. Reference (l) is the Navy's Information Requirements Manual. References (m) and (n) provide requirements for safeguarding Personally Identifiable Information (PII) and Health Insurance Portability and Accountability Act (HIPAA) data.

b. Due to the inherent ionizing radiation, radiofrequency (RF) radiation and strong magnetic field health risks to diagnostic imaging patients and equipment operators, support of this program meets the reference (k) "mission critical" criteria to maintain patient/staff safety and meet oversight requirements.

5. Navy Diagnostic Imaging Equipment Performance Survey and Acceptance Testing and Receipt Inspection Program. This program includes personnel qualification standards, structural shielding design, systems evaluation, reporting procedures, receipt and acceptance requirements, and criteria for the safe and effective use of medical and dental diagnostic imaging equipment.

6. Testing periodicity. Diagnostic imaging equipment performance survey and newly installed equipment acceptance testing frequencies must be as follows:

a. Acceptance testing and receipt inspection must be performed on all newly installed diagnostic imaging equipment within 30 days of the completion of installation and before initial clinical use. Radiology Department ultrasonic imaging equipment is subject to a Biomedical Engineering Technician (BMET) receipt inspection prior to clinical use along with the 30-day post-installation acceptance rule.

b. Medical diagnostic imaging equipment (fixed and mobile) ashore must be surveyed annually.

c. Medical diagnostic imaging equipment (fixed and mobile) afloat, in Special Forces support and "IN USE" War Reserve Materiel units must be surveyed within 6 months of scheduled deployment, and must not exceed 24 months between surveys. Hospital ships must be surveyed

within 6 months of scheduled deployment and must not exceed 12 months between surveys. Under unforeseen operational circumstances, hospital ships and afloat units may delay periodic surveys until a suitable port call when/where qualified surveyors can perform the necessary testing.

d. Mammography equipment must be tested and surveyed at the frequency prescribed by the Mammography Quality Standards Act (MQSA) in reference (i).

e. General dental diagnostic imaging equipment (fixed and mobile; ashore and afloat) must be surveyed triennially. Portable and specialized dental imaging equipment, including panographic and dental cone-beam Computed Tomography (CT) units, must be surveyed biennially.

f. Computed Radiology (CR) units must be surveyed at the same periodicity as their companion diagnostic imaging systems.

g. Diagnostic imaging equipment must be surveyed following major component repairs, upgrades (e.g., x-ray tube, generator, detector array, Automatic Exposure Control (AEC) assembly or static/gradient magnetic field coils), or major operating software upgrades. Applicable technologist Quality Control (QC) must be performed before next clinical use. If technologist QC results pass, a qualified surveyor must complete an appropriate evaluation as soon as practicable within 30 days. A post major repair survey may be used to modify or adjust the periodic survey date for an existing piece of medical or dental diagnostic imaging equipment as long as the post repair survey meets the content requirements of a periodic survey. Upon completion of the survey, the qualified surveyor should brief the afloat command on the results of the survey.

h. Accredited imaging equipment (e.g., mammography, CT, magnetic resonance imaging (MRI), treatment planning equipment, etc.) must be accepted and surveyed using methods specified by the accrediting body (e.g., American College of Radiology or American College of Radiation Oncology) and meeting this instruction's minimum periodicity requirements.

i. Therapeutic radiology equipment (e.g., radiation oncology medical linear accelerators) will be evaluated per reference (c).

j. For tracking purposes, the equipment survey periodicity windows are defined as followed:

(1) Annual – 10 to 14 months from the date of the last survey.

(2) Biennial – 24 to 26 months from the date of the last survey.

(3) Triennial – 34 to 38 months from the date of the last survey.

7. Definitions

a. Diagnostic Imaging Equipment. Includes, but is not limited to, the following medical and dental imaging equipment used for the purpose of clinical diagnosis: medical radiography (fixed, mobile and portable systems), fluoroscopy (fixed and mobile systems), CT (fixed and mobile CT), tomography, mammography, breast stereotactic and breast tomosynthesis systems, single-photon emission computed tomography (SPECT) and positron emission tomography (PET) systems, MRI and Radiology Department diagnostic ultrasound (US) systems; Dental intra-oral, panoramic, cephalometric, hand held, and cone beam CT systems. Devices that can produce visible light digital imaging and communication in medicine (DICOM) images, e.g., endoscopes, gastroscopes or colonoscopes, and are used for diagnosis are not included in this category.

b. Diagnostic Imaging Equipment Performance Survey. A set of physics tests performed by a qualified survey or to evaluate diagnostic imaging equipment functionality, compliance with Food and Drug Administration (FDA), American College of Radiology (ACR), JC, Navy, or original equipment manufacturer (OEM) performance standards; functional consistency and ability to produce clinically acceptable images over the equipment's lifetime.

(1) Surveys must assess image quality, patient and operator radiation doses, and unit radiation protection (including sufficiency of intrinsic and associated personnel protective devices and attire such as integrated shielding, lead aprons, gloves, gonad shields, etc.) as applicable.

(2) Surveys performed on the following advanced imaging modalities (i.e., CT, MRI, US, NM, and PET) must contain the elements prescribed by the JC in references (d) and (e).

(3) Surveys performed on advanced imaging modalities (e.g., CT, MRI, US, NM, and PET) must be performed by surveyors qualified as outlined in references (d) and (e). Surveys performed on advanced imaging modalities not specifically covered by the JC must be performed by surveyors qualified as outlined in reference (c).

c. Diagnostic Imaging Equipment Facility Radiation Protection Survey. The radiation protection survey must evaluate the adequacy of structural radiation barriers including operator control booths, and wall and door shielding.

d. Diagnostic Imaging Equipment Acceptance Testing. A comprehensive survey comprised of both the diagnostic imaging performance and radiation protection surveys. A qualified surveyor must perform acceptance testing upon receipt of new diagnostic imaging equipment to ensure that the equipment meets Regulatory and Navy performance standards, and the OEM's specifications. A copy of the acceptance testing results must be provided to the Biomedical Engineering Technician (BMET) performing the receipt inspection for inclusion to the Diagnostic Imaging Equipment Receipt Inspection and Acceptance (RIA) package per paragraph (j).

e. Diagnostic Imaging Equipment Receipt Inspection. A qualified BMET inspection that validates that the terms of the procurement contract have been met, verifies that the system performs per its advertised specifications, verifies the certification (reference: FDA Form 2579) that assembly of a new piece of x-ray equipment has been performed according to the manufacturer's instructions, and certifies that the equipment meets the applicable Federal requirements and standards contained in Title 21 Code of Federal Regulations (CFR) 1020.30 through 1020.33.

(1) The BMET receipt inspection ensures mechanical and electrical safety, proper connectivity to ancillary equipment (e.g., picture archive and communication systems (PACS) and inventory of equipment hardware and software.

(2) A BMET's x-ray system receipt inspection must be conducted in conjunction with the qualified surveyor's comprehensive acceptance testing using the appropriate Department of Defense (DoD x-ray acceptance test protocol.

f. Diagnostic Imaging Equipment RIA Package

(1) The RIA Package must consist of the following:

(a) Qualified surveyor's report

(b) Copy of applicable DoD x-ray acceptance test protocol

(c) Copy of FDA Form 2579

(d) Photographs depicting proper installation and/or assembly of the device

(e) Copy of Defense Medical Logistics Standard Support (DMLSS) equipment record

(2) The RIA package must be submitted to NAVMEDLOGCOM by the equipment receiving activity's BIOMED no later than 5 working days upon completion of the RIA.

g. Qualified Individuals

(1) Qualified BMET. An individual who has successfully graduated from DoD BMET Training (NEC-8410) (or equivalent) and the DoD Radiographic Acceptance Procedures Course (B-326-2030). These individuals are competent to perform initial receipt and post calibration inspections of the specific diagnostic imaging systems covered in course B-326-2030, using system specific DoD Standard Inspection Testing Protocols.

(2) Qualified Diagnostic Medical Physicist (QMP*)*. An individual who is competent to independently provide clinical professional services in diagnostic medical physics. The QMP must be certified in diagnostic physics by the American Board of Radiology (ABR), American

Board of Medical Physicists (ABMP), or Canadian College of Physicists in Medicine (CCPM) and abide by the certifying body's requirements for continuing education. Qualification criteria for medical physicists are established by the ABR, ABMP and the American Association of Physicists in Medicine (AAPM). A qualified medical physicist is a qualified surveyor by definition.

(3) Qualified Medical Health Physicist (QMHP*)*. An individual who is competent to independently provide professional services in ionizing and non-ionizing radiation protection in a clinical or health care setting. The QMHP must be certified by the American Board of Health Physics and have a minimum of 3 years relevant experience in the subfield of medical health physics.

(4) Qualified Surveyor. An individual qualified to conduct diagnostic imaging performance surveys and radiation protection surveys based on the training and experience criteria established in references (c) through (e) and (i), evaluation by the Regional Medical Physicist and approval by the MPAB.

(5) Qualified Shielding Expert. A QMP or QMHP who is competent to design radiation shielding for medical or dental x-ray imaging facilities per reference (b); or an individual qualified, based on the training and experience criteria established in reference (c), and approved by the MPAB.

8. Responsibilities

a. Navy MPAB. A committee of senior Navy physicists that serves as the Navy Diagnostic Imaging and Radiotherapy Board's (NAVDIRB) technical advising body for diagnostic imaging equipment, teleradiology, radiation therapy equipment safety and evaluation, testing equipment, training needs, software recommendations and personnel qualifications. Composition and functions of the MPAB are outlined in reference (g). The MPAB must:

(1) Establish technical standards for acceptance testing and quality assurance procedures for Navy diagnostic imaging equipment including teleradiology systems and digital imaging network-PACS.

(2) Approve changes and updates to reference (c) and associated software.

(3) Evaluate and approve individuals applying as qualified surveyors and shielding designers for Navy diagnostic imaging equipment.

(4) Evaluate and approve new Diagnostic Imaging Survey Equipment (DISE) technology for Navy use.

b. Navy and Marine Corps Public Health Center (NMCPHC must:

(1) Maintain, and distribute reference (c) and any associated software.

(2) Maintain a current list of:

(a) Surveyors and QMPs qualified to evaluate medical and dental diagnostic imaging equipment.

(b) Shielding experts qualified to design and evaluate structural shielding for radiological (x-ray) imaging rooms.

(c) Appropriate types of DISE used for routine diagnostic imaging surveys and acceptance testing.

(3) Coordinate program-related issues and functions for compliance with the requirements of this instruction through Navy Medicine (NAVMED) East and Navy Medicine (NAVMED) West.

(4) Assist NAVMED East and NAVMED West activities in obtaining resources to complete required diagnostic imaging equipment surveys and shielding design evaluations.

(5) Report equipment failures or malfunctions that prohibit continued use, significant medical events, and any identified violations of this instruction to Bureau of Medicine and Surgery (BUMED), Radiation Health Specialty Leader, within 30 days of event.

c. NAVMED East and NAVMED West Regional Medical Physicist must:

(1) Maintain oversight of medical and health physics programs at commands in the respective regions including pertinent medical physics, diagnostic imaging and radiation therapy equipment issues, mammography and other accredited programs, image quality, and patient and occupational radiation exposure associated with medical imaging. Enclosure (1) provides guidance for the regions respective areas of responsibility.

(2) Coordinate and maintain oversight of professional activity of Radiation Health Officers in the region including equipment performance surveys. Periodically review and evaluate qualified surveyor and BMET work product for appropriateness, completeness, and conformance with professional standards.

(3) Perform technical evaluations of diagnostic imaging and radiation therapy equipment requests for the NAVDIRB.

(4) Review the qualifications of assigned prospective surveyor candidates, and selectively recommend qualified surveyors to the MPAB for approval.

(5) Assist regional commanding officers (CO) and officers in charge (OIC) in obtaining necessary resources to complete equipment performance surveys and shielding evaluations.

(6) Authorize region COs and OICs to out-source commercial medical physics services on a case basis when Navy or other DoD physicists are unavailable and the subsequent delay would unduly impair patient care.

(7) Monitor corrective actions for deficiencies identified during diagnostic imaging equipment performance surveys.

(8) Provide NMCPHC regional summary status reports of diagnostic imaging equipment surveys as requested.

d. NAVMEDLOGCOM must:

(1) Notify commands and facilities receiving new and replacement medical and dental diagnostic imaging equipment within 10 working days after the equipment contract award date. For afloat commands, notify the activity through the appropriate type commander within 10 working days after the equipment contract award date.

(2) Contact receiving commands to validate equipment receipt date, and the prospective installation start and completion dates.

(3) Send receiving command's Diagnostic Imaging Equipment RIA Notification Letters within 5 working days after the installation completion date.

(4) Ensure coordination between the surveyor, BMET, and vendor's field service engineer (FSE).

(5) Review x-ray system RIA packages for completeness per reference (j).

(6) Approve, maintain, and distribute reference (j) and associated x-ray System Receipt Inspection Test Protocols.

(7) Approve and maintain a list of qualified BMETs that can perform diagnostic imaging equipment receipt inspection testing.

e. COs and OICs must:

(1) Ensure qualified surveyors perform acceptance testing and periodic performance surveys of medical and dental diagnostic imaging equipment per this instruction.

(2) Ensure that a qualified surveyor evaluates newly installed diagnostic imaging equipment prior to initial clinical use. Under certain conditions when a qualified surveyor is not

readily available to perform acceptance testing of the equipment, and when critical patient care may be adversely impacted, the following diagnostic equipment can be used clinically after BMET completes RIA testing, and written concurrence is provided by a qualified surveyor. However, a qualified surveyor is still required to complete the acceptance testing within the prescribed timeline following the installation or receipt of new equipment:

(a) Dental radiographic (x-ray) units (except cone beam CT).

(b) Medical radiographic (x-ray) units (fixed and mobile, and supported by either digital or CR).

(3) Ensure mammography systems including screening diagnostic, stereotactic biopsy, and tomosynthesis units are surveyed annually or as required under the MQSA in reference (i), by a qualified medical physicist or qualified surveyor meeting MQSA requirements. Navy mammography programs are subject to ACR site visits and random clinical image reviews to assess the program's compliance with accreditation standards. Mammography programs are also subject to FDA inspections per reference (i).

(4) Ensure a qualified shielding expert performs structural shielding design assessments and radiation protection surveys for new facilities housing radiological imaging equipment (x-ray, nuclear medicine, and PET), replacements of such imaging equipment and after major structural renovations to existing rooms housing such equipment. When mobile equipment is to be used routinely in one location (as though fixed), shielding must be evaluated as a fixed radiographic installation.

(5) Maintain system performance survey reports for 3 years. Maintain structural radiation shielding designs for the lifetime of the facility.

(6) Maintain diagnostic imaging equipment RIA packages for the lifetime of the equipment.

(7) Ensure a corrective action report is provided to the qualified surveyor who performed the initial survey and BIOMED providing maintenance support to the activity within 15 working days of receipt of each equipment performance survey report. Provide follow-up corrective action reports to the qualified surveyor, BIOMED, NAVMEDLOGCOM, and responsible medical physicist every 30 days for issues that cannot be corrected within 30 days of the survey report date.

(8) Prohibit use of diagnostic imaging equipment that fails an equipment performance survey, or when it is known that the equipment fails to meet basic radiation safety standards in references (c), (h) and (i), until the deficiency is corrected.

(9) When local command resources are not available to perform the equipment performance survey or shielding design:

(a) For routine periodic surveys, complete the NAVMED 6470/14, Diagnostic Imaging Equipment Survey Request Form, and submit the request to the respective supporting command, as listed in enclosure (1), no later than 45 days prior to the requested survey date. For urgent request due to unforeseen circumstances, submit the Equipment Survey Request Form to the respective supporting command as soon as possible.

(b) Provide the necessary travel funding for equipment performance, radiation protection and acceptance testing surveys.

(c) Request authorization from their respective NAVMED Regions to out-source commercial medical physics services on a case basis when DoD medical physics support is unavailable and the subsequent diagnostic imaging equipment acceptance test, performance survey, structural shielding design assessment or shielding survey delay would unduly impair patient care, or compromise accreditation standards.

(10) Ensure that a qualified BMET is available to support this directive, otherwise, ensure training is provided to the BMET. When local command resources are not available to perform the x-ray system receipt inspection, contact NAVMEDLOGCOM immediately and provide the necessary travel funding.

(11) Ensure that new diagnostic imaging equipment and upgraded or replaced components are recorded in the DMLSS System.

(12) Ensure any equipment that stores personal health information (PHI) - is handled and accessed per reference (m) and (n). This means that anyone accessing the equipment must have authorization to access PHI per reference (n) prior to accessing the equipment. Otherwise the equipment must either be properly erased/wiped of all PHI or a business associate agreement must be entered into between the medical/dental treatment facility and the entity requiring access to the equipment per reference (n). This includes command service agreements and purchase requests with respect to outside organizations/companies accessing equipment for the purpose of service repair or replacement of equipment that may contain PII and HIPPA data.

f. QMPs and qualified surveyors with oversight of commands within their areas of regional responsibility must:

(1) At the request of assigned commands, or as assigned by their respective Regions, conduct equipment performance surveys following references (c), (h), and (i).

(2) If resources are not available to provide services for the requested dates, contact the respective Region for assistance.

(3) Provide a written report with relevant supporting information documenting the equipment performance survey to the requesting command, normally within 30 working days after

completion of the survey, with a copy to file. Critical system problems identified during the survey should be immediately brought to the attention of the medical authority responsible for maintenance of the equipment.

(4) Track corrective actions for discrepancies found during equipment performance survey until corrective actions are completed and verified.

g. Qualified Shielding Experts must:

(1) Assess and/or approve structural radiation shielding design drawings for new facilities housing medical and dental x-ray equipment, and nuclear medicine equipment, prior to installation of the equipment. Shielding designs will also be assessed prior to replacement of existing CT, PET, and NM equipment, and structural modification of facilities housing such equipment.

(2) At the request of the assigned commands, or as assigned by their respective Regions, conduct radiation protection surveys of medical and dental x-ray facilities.

(a) A radiation shielding design evaluation is required when a room is structurally modified to accommodate a new x-ray equipment installation; when the radiographic modality has been upgraded or modified within an existing shielded room; or, when a non-imaging room is changed to support the use of x-ray equipment.

(b) The purpose of the shielding evaluation is to verify existing barriers provide adequate radiation protection per NCRP Reports 145 and 147.

(3) For capital equipment procurement, the prime contracting vendor must ensure a shielding design evaluation is completed by a qualified shielding expert per NCRP Reports 145 and 147 as part of the extended installation work (turnkey or military construction (MILCON)) process.

(4) Design drawings and shielding thickness estimates generated by a vendor or vendor's subcontractor must be assessed and approved by a Navy qualified shielding expert prior to the start of construction of the affected spaces.

(5) Ensure a radiation protection survey of the designed shielding for new radiographic, CT, PET, or NM imaging equipment rooms, and ancillary nuclear medicine spaces is performed following completion of facility construction; after structural modification of an existing radiographic, CT, PET, or NM equipment room or ancillary space; and after replacement of existing CT, PET, or NM equipment. The evaluation must be completed prior to clinical use of the affected space. A copy of this evaluation should be provided to the command operating the system and associated NAVMED Region (M3 and M4) within 30 days after completing the evaluation.

h. Qualified BMETs must:

(1) Assist the supported activity and NAVMEDLOGCOM in coordinating diagnostic imaging equipment receipt inspections and acceptance testing per reference (j).

(2) Ensure the imaging equipment and its components are properly recorded in DMLSS using appropriate nomenclature.

(3) Perform imaging equipment receipt inspections per reference (j) using appropriate x-ray equipment receipt inspection test protocols.

(a) BMETs must only use x-ray system receipt inspection test protocols approved by NAVMEDLOGCOM and the Regional Medical Physicist.

(b) BMETs must only use NAVMEDLOGCOM and Regional Medical Physicist approved test equipment and phantoms to test Navy diagnostic imaging equipment.

(4) Submit the required Diagnostic Imaging Equipment RIA package and supporting documentation to NAVMEDLOGCOM no later than 5 working days after the testing completion date. Maintain the completed RIA package for the lifetime of the unit.

(5) Contact NAVMEDLOGCOM and their NAVMED Region BMET immediately in cases of receipt inspection testing failures that may require additional guidance.

(6) Ensure that survey and acceptance testing results including corrective actions are recorded in DMLSS.

9. Reports. The reports required in this instruction, are exempt from reports control per SECNAV M-5214.1 of December 2005, part IV, paragraph 7k.

10. Publication. NMPHC TM-6470.1 is available at:
http://www.med.navy.mil/sites/nmcphc/occupational-and-environmental-medicine/rhd/Pages/rsoep.aspx

11. Forms

a. NAVMED 6470/14 (01-2015), Diagnostic Imaging Equipment Survey Request Form. Form is available at:
https://navalforms.documentservices.dla.mil/unlocked/NAVMED%206470%2014.pdf

b. X-ray system receipt inspection test protocols are available at: https://gov_only.nmlc.med.navy.mil/int_code03/xray.asp.

C. FORREST FAISON III

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