Change 142
Manual of the Medical Department
U.S. Navy
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To: Holders of the Manual of the Medical Department

1. **This Change** adds a new section to Chapter 14, Special Activities - Section IV, Clinical Laboratory and Anatomic Pathology Services.

2. **Background.** This section has been developed by the Specialty Leaders to the Navy Surgeon General for Medical Technology/Pathology and includes Clinical Laboratory and Anatomic Pathology Services. Articles include: Applicability, General Guidance, Accreditation Policies, Laboratory Management, Laboratory Personnel, Responsibilities of the Specialty Leaders for Pathology and Medical Technology, and Inspection and Disposition of Laboratory Files and Records.

3. **Action**

   a. Add new Section IV to Chapter 14.

   b. Record this Change 142 in the Record of Page Changes.

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Medicine and Surgery

Chapter 14

Special Activities

TRANSPLANTATION SUPPORT

NAVY BLOOD PROGRAM

AVIATION PHYSIOLOGY PROGRAM

CLINICAL LABORATORY AND
ANATOMIC PATHOLOGY SERVICES

Chapter 14
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Sections Page

Section IV
CLINICAL LABORATORY AND ANATOMIC PATHOLOGY SERVICES

14-15 Applicability

(1) This section applies to all Navy facilities worldwide that operate a medical laboratory (clinical and/or anatomic pathology). This section applies to Active Duty and Reserve Components and to medical laboratories operated under the executive agency of the U.S. Navy. This section does not apply to facilities that perform testing only for forensic purposes; research laboratories that test human specimens but do not report patient-specific laboratory results for the diagnosis, prevention, or treatment of any disease, or the assessment of health for individual patients; or laboratories that solely perform drug-of-abuse testing that are certified by the National Institutes on Drug Abuse.

14-16 General Guidance

(1) Each medical laboratory must follow Department of Defense (DoD) standards of laboratory practice defined in the DoD Clinical Laboratory Improvement Program (DoD CLIP) manual for registration, certification, proficiency testing, patient test management, quality control, personnel, quality improvement, and inspection. Each command must ensure that laboratories are inspected and accredited by the College of American Pathologists (CAP), the Joint Commission (JC), or other accreditation programs approved by the Office of the Secretary of Defense for Health Affairs through the Center for Clinical Laboratory Medicine (CCLM). Transfusion

Services and Blood Donor Centers will be accredited by the American Association of Blood Banks and registered with the Food and Drug Administration.

(2) Each commander, commanding officer, and officer in charge will ensure the CLIP registration of all medical laboratories within their command and any assigned subordinate clinics. CLIP registration is accomplished per DoD guidance available from the CCLM.

(a) This includes centralized laboratories (such as the laboratory department), but also includes all decentralized laboratories in the facility where medical laboratory tests are performed. Examples of common decentralized medical laboratories in medical treatment facilities (MTFs) include the following: medical laboratory tests performed in the intensive care unit, critical care unit, or emergency department; other medical clinics, such as the obstetric clinic or the occupational health clinic; in vitro medical laboratory tests performed by respiratory therapy or nuclear medicine; medical laboratory tests performed by nursing or other non-laboratory staff on inpatient wards; and medical laboratory tests performed by non-laboratory personnel as part of medical screening programs or health fairs.

(b) Each commander, commanding officer, and officer in charge determines the requirement and operational need for each decentralized laboratory assigned to the command and is required to register all medical laboratories with the CCLM.

14-17 Accreditation Policies

(1) All U.S. Navy hospital-based medical laboratories located in fixed MTFs, including their assigned clinic laboratories, must be accredited by the Commission on Inspection and Accreditation of the CAP. Onsite accreditation inspections are required at least biennially.

(2) All fixed MTF/clinic decentralized laboratories not accredited by the CAP will be accredited by and follow the laboratory guidelines of JC. The required biennial JC survey of laboratories by a qualified medical technologist inspector will be waived if all laboratories assigned to the MTF/clinic have been inspected and accredited by the CAP.

(3) Laboratories not located at hospitals or branch medical/health clinics (e.g., Environmental Preventive Medicine Units, Naval Medical Research Units, Navy Research Labs, etc.) will be inspected biennially and accredited by the CAP, JC, or the Commission on Office Laboratory Accreditation.

14-18 Laboratory Management

(1) Each commander, commanding officer, and officer in charge must designate a Laboratory Department Head. This can be either a Medical Corps (pathologist) or Medical Service Corps (Medical Technologist/Medical Laboratory Scientist) officer. The MTF/command must also designate a Laboratory Director (who may assume the additional duty as Head, Laboratory Department). The Laboratory Director must meet qualifications as outlined per the DoD CLIP manual and CAP requirements. If the MTF/command does not have a staff member that meets the DoD CLIP and CAP Laboratory Director education and experience requirements, the MTF/command will consult with the Specialty Leader to the Navy Surgeon General for Pathology to assign a pathologist from another MTF to serve as the Laboratory Director or pathology consultant.

(2) In situations where there is no assigned pathologist or laboratory officer, the MTF/command will consult with the Navy Surgeon General's Pathology/Medical Technology Specialty Leaders to assign oversight responsibilities.

(3) The Laboratory Director is charged with duties as defined by the CLIP manual. The Laboratory Director, working with the laboratory staff, will ensure quality medical laboratory services throughout the organization, keeping abreast of new or modern developments in the medical laboratory field and operation of the MTF medical laboratories in compliance with Federal laws; accreditation standards defined by JC, the CAP, the CLIP; and standards of practice within the community. In doing so, the Laboratory Director will:

(a) Assist and advise health care providers on the cost-effective use of timely, quality medical laboratory services to aid in the medical screening, prevention, and diagnosis or treatment of disease, including monitoring of therapy.

(b) Conduct and document inspections and assist visits for all medical laboratories within the MTF, including medical laboratories in all outlying clinics assigned to the MTF and all medical clinics supported by the MTF. The assigned person/ command will perform periodic assist visits (at least monthly for laboratories within close proximity, quarterly for laboratories located in geographically distant locations). If these visits are performed by a laboratory officer/medical technologist, the designated laboratory director/pathologist, must perform an on-site visit at least annually. Recurring problems and trends not corrected by the department will be referred to the appropriate Chain of Command for notification and correction.

(c) Maintain adequate reference materials (such as books, periodicals, atlases, computer-assisted instructional material, etc.) and knowledge-based information systems for use by laboratory personnel and other professional staff served by the laboratory.

(d) Provide technical expertise and guidance, on-site monitoring as necessary, and centralized laboratory support for MTF laboratories that fail regulatory laboratory proficiency testing. Under the plan of action submitted to the CCLM, approve the decision to resume patient testing in the MTF medical laboratory for analyses or subspecialties that scored as a two-time proficiency testing failure. The decision to allow the resumption of testing belongs to the CCLM.

(e) Disseminate information to professional staff concerning advances in laboratory medicine, use of laboratory services, laboratory input to clinical practice guidelines adopted by the MTF, and related matters. Appropriate media (for example, hospital/ laboratory information systems, electronic mail, memorandums, etc.) will be utilized to disseminate information concerning available laboratory services, acceptable specimen requirements, methods of obtaining service, the cost of laboratory tests ordered, the reference ranges for all laboratory tests provided, and items of interest to the medical staff.

(f) Represent the laboratory services on various committees used by the MTF to improve information management, utilization management, and patient outcomes.

(g) Provide an adequate number of qualified, competent staff to perform the laboratory workload and to provide technical consultation and supervisory duties. An analysis of laboratory staffing needs should be performed on a periodic basis utilizing the Navy Laboratory Staffing Standard. Laboratory workload and staffing information is reported monthly to CCLM and the Specialty Leader to the Navy Surgeon General for Medical Technology utilizing the format designated by CCLM.

(h) The Laboratory Director also provides for orientation, in-service training, and continuing education for all personnel assigned to the clinical laboratory.

(4) ***Note***. The Laboratory Director can assign these duties in writing to qualified personnel [i.e., other pathologists, laboratory officers, or medical technologists (medical laboratory scientists)] but retains all responsibilities inherent in the Laboratory Director role. The Laboratory Director must periodically review and validate the performance of any duties thus delegated.

14-19 Laboratory Personnel

(1) The Head, Laboratory Department and Laboratory Director will ensure that only properly qualified personnel whose competency has been assessed will perform and report the results of laboratory testing. Qualifications for testing personnel will be based on laboratory test complexity (waived, moderate, or high complexity) and will meet the requirements of the current CLIP manual.

(2) Local, onsite training of military or civilian personnel to perform waived complexity laboratory testing only is permitted. In these cases, prior to analyzing patient specimens and reporting patient results, the personnel must be trained appropriately for the laboratory testing performed with a formal training program, not solely limited to on-the-job training. Documentation of training, skills, and competency assessment for these individuals will be maintained in a competency assessment file per CAP and JC standards.

(3) Provider Performed Microscopy (PPM), a special subset of moderately complex laboratory analyses, may be performed by privileged providers when authorized by the MTF commander, commanding officer, and officer in charge and if they have been competency assessed. In such cases, the PPM lab must be registered with CLIP and approved procedures for PPM tests must be instituted.

Note. CLIP defines providers as physicians, nurse practitioners, and physician assistants ONLY. Nurses and Independent Duty Corpsman are not defined as providers in the CLIP manual and cannot perform PPM testing independently.

14-20 Responsibilities of the Specialty Leaders for Pathology and Medical Technology

(1) In addition to the duties defined in the BUMED Instruction 5420.12 series covering Specialty Leaders, the Pathology and Medical Technology Specialty Leaders will:

(a) Establish standards and issue policy for implementation of quality clinical laboratory testing within all medical laboratories under the executive agency of the U.S. Navy.

(b) Receive and evaluate CAP accreditation inspection reports and proficiency testing results.

(c) Evaluate corrective actions for clinical laboratory facilities whose proficiency testing or performance criteria fall outside CLIP or CAP regulations/standards. With a plan of corrective action, approve the request to CCLM to resume patient testing for failed analyses at any Navy medical laboratory.

(d) Perform workload and staffing analysis on a regular basis to assess staffing needs across the Navy. Recommend billet moves based upon analysis of results.

(e) Analyze utilization of laboratory resources and assess laboratory performance indicators throughout the Navy. Develop laboratory business plans that optimize use of laboratory resources, consolidate laboratory testing as appropriate and consider the regionalization of the purchase or lease of laboratory equipment/analyzers.

(f) Serve as consultants to MTF commanders, commanding officers, and officers in charge to assist in the resolution of concerns regarding laboratory quality, laboratory staffing, or any other issues regarding the efficacy of laboratory services.

(g) The Pathology Specialty Leader will ensure that each hospital with a pathologist(s) maintains anatomic pathology support as required by the hospital's mission. When a hospital has only one pathologist, the Specialty Leader will ensure anatomic pathology does not lose current capability during the pathologist's absence. The preferred method is to have cases requiring pathologist interpretation, excluding autopsies and frozen sections, sent to the closest MTF. The Pathology Specialty Leader will ensure that a backfill or a mutually agreed upon alternative plan is provided when requested by the MTF commander, commanding officer, or officer in charge.

14-21 Inspection and Disposition of Laboratory Files and Records

(1) ***Inspection.*** Laboratory files and records will be subject to inspection by inspectors (accreditation organizations, other Government entities, and the CCLM) and higher echelon commanders at all times.

(2) ***Disposition.*** Disestablishing facilities shall follow the guidance contained in SECNAV Manual 5210.1, Department of the Navy Records Management Program, Records Management Manual for the disposition of official records.