Change 153
Manual of the Medical Department
U.S. Navy
NAVMED P-117

23 Oct 2015

To: Holders of the Manual of the Medical Department

1. **This Change**

a. Updates article 14-11, Mission and Elements of the NAOPP, article 14-11(2)(b), Operational Physiology Program. This change deletes "with Marine Expeditionary Forces" and replaces it with "in support of operational forces."

b. Updates article 14-14, Naval Aerospace Physiology Program Planning Committee (NAP^3C), article 14-14(2)(d). This change deletes "The ten senior aerospace/operational physiologist lieutenants shall elect this individual for a 2-year term" and replaces it with "All post-internship NAOPs below the rank of O-4 must be eligible to vote to elect this individual for a 2-year term."

2. **Action**

a. Remove pages 14-8 and 14-10 and replace with enclosure (1).

b. Record this Change 153 in the Record of Page Changes.

M. L. NATHAN
Chief, Bureau of
Medicine and Surgery

Change 143
Manual of the Medical Department
U.S. Navy
NAVMED P-117

8 Jul 2013

To: Holders of the Manual of the Medical Department

1. **This Change** updates the title of MANMED Chapter 14, Special Activities, Section III from Aerospace/Operational Physiology Program to Naval Aerospace/Operational Physiology Program (NAOPP).

2. **Background**

a. Revised article 14-10, paragraph (2) to include a description of the role of the Aerospace Physiologist as an Operational Physiologist.

b. Revised article 14-11, subparagraph (2)(b), Operational Physiology Program which describes the purpose of the establishment of new operational physiology billets within the U.S. Marine Corps structure.

c. Changed the acronym for the Naval Aerospace/Operational Physiology Program from NAPP to NAOPP.

d. Added the term operational in all instances where Aerospace Physiologist is noted (i.e., Aerospace/Operational Physiologist vice Aerospace Physiologist).

e. Refined the Junior Officer Representative (JO Rep) election criteria to the Naval Aerospace Physiology Program Planning Committee (NAP^3C), article 14-14, subparagraph (2)(d).

3. **Action**

a. Remove and replace the following with enclosure (1):

(1) Chapter 14, Special Activities cover page

(2) Chapter 14, Contents page

(3) Chapter 14, entire Section III, Aerospace/Operational Physiology Program.

b. Record this Change 143 in the Record of Page Changes.

M. L. NATHAN
Chief, Bureau of
Medicine and Surgery

Change 142
Manual of the Medical Department
U.S. Navy
NAVMED P-117

22 Oct 2012

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.

M. L. NATHAN
Chief, Bureau of
Medicine and Surgery

Chapter 14

Special Activities

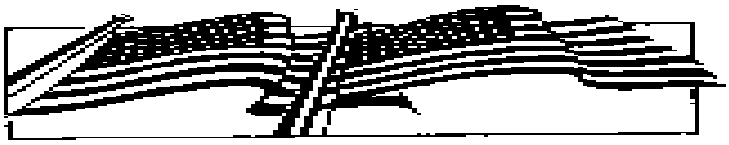
TRANSPLANTATION SUPPORT

NAVY BLOOD PROGRAM

NAVAL AEROSPACE/
OPERATIONAL PHYSIOLOGY
PROGRAM

CLINICAL LABORATORY AND
ANATOMIC PATHOLOGY SERVICES

Chapter 14
CONTENTS



Sections Page

Section I.	Transplantation Support	14-1
Section II.	Navy Blood Program	14-2
Section III.	Naval Aerospace/Operational Physiology Program (NAOPP)	14-7
Section IV.	Clinical Laboratory and Anatomic Pathology Services	14-13

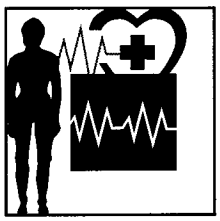
Section I

TRANSPLANTATION SUPPORT

Article		Page
14-1	Support	14-3
14-2	Organ Procurement Organization	14-3
14-3	Procedures	14-4
14-4	Living Donors	14-4
14-5	Point of Contact	14-4

14-1 Support

(1) Organ and tissue donation is encouraged and supported. There is no objection to an active duty Navy member executing a declaration of intent to donate organs or tissues after death under the Uniform Anatomical Gift Act. Coercion or the appearance of coercion of donors or their next of kin will be avoided.



14-2 Organ Procurement Organization

(1) A formally constituted civilian organization created to coordinate and recover organs and tissues for a specific type of transplantation or a special geographic area.

(2) Navy military treatment facilities (MTFs), through military transplant centers, will participate in the congressionally established National Organ and Tissue Procurement Network that facilitates and coordinates organ and tissue donation, the recovery of donated organs and tissues, and the matching of donors and recipients.

14-3 Procedures

(1) See BUMEDINST 6300.8 for specific procedures.

14-4 Living Donors

(1) Active duty Service members may donate, but there are criteria that govern this. Refer to section 14-3 above for specific information.

14-5 Point of Contact

(1) The Army/Navy Transplant Team is available to answer any questions concerning the Organ and Tissue Donor Program and can be reached at Commercial: (202) 782-6462 or DSN: 662-6462. The address is:

Walter Reed Army Medical Center
ATTN: MCHL-RMA
6825 16th Street, NW
Washington, DC 20307-5001

Section II

NAVY BLOOD PROGRAM

Article		Page
14-6	Mission	14-5
14-7	Organization	14-5
14-8	Key Functions	14-5
14-9	Related Information Sources	14-6

14-6 Mission

(1) The Navy Blood Program manages the collection, production, distribution, use, and disposition of all blood products within the Navy Medical Department.

14-7 Organization

(1) ***Bureau of Medicine and Surgery.*** The Chief, Bureau of Medicine and Surgery directs the Navy Blood Program.

(2) ***Worldwide Navy Blood Program.*** The Navy Blood Program is organized into regional area blood systems. The structure of these area blood systems is based on blood donor availability, blood product demand, and shipping distance factors. The configuration of these systems is unique to the blood program and should not be confused with other medical department regional organizations. One MTF within each area blood system is designated as the system director.

(3) ***Other Blood Bank Facilities.*** The blood service units outside of the 48 contiguous United States are organized directly under the respective unified command.

14-8 Key Functions

(1) ***BUMED-273***

(a) Serves as executive agent for coordination and management of all Navy blood banking matters.

(b) Serves as Navy representative to the Armed Services Blood Program Office.

(c) Serves as liaison to the Food and Drug Administration (FDA) for the Chief, BUMED and Navy facility MTFs. Reviews and prepares FDA correspondence, annual reports, and new blood product application packages.

(d) Directs the distribution of Navy blood resources to support local emergencies, as well as mobilization and contingency requirements levied by the DoD Armed Services Blood Program Office.

(e) Directs and monitors readiness capability of blood donor centers to collect, process, and distribute blood for contingencies. Evaluates personnel staffing and donor base capabilities and initiates organizational and manpower changes to improve readiness posture.

(f) Coordinates the review of all blood program agreements for collection of blood aboard Navy and Marine Corps installations to ensure reciprocity, legality, propriety, and adequacy of exchange rates.

(g) Reviews and takes appropriate action on all contractual agreements for exchange of unexpired blood products.

(h) Reviews all Navy and Marine Corps Authorized Medical Allowance Lists having blood program elements and makes recommendations for updates or changes.

(i) Manages pre-positioned frozen blood deployment and inventory aboard casualty receiving treatment ships and Navy blood depots worldwide.

(j) Initiates and maintains directives related to the managerial aspects of the Navy Blood Program. Develops and disseminates policy to MTFs on changes with Federal regulatory requirements and national standards. Writes and develops standard policies and procedures.

(k) Performs public information functions for Navy blood banking.

(l) Monitors Navy R&D projects and coordinates special studies on the preparation and use of blood components. Coordinates with FDA to obtain approval and licensure of new products, technologies, and equipment and manages the implementation within the Navy.

(m) Serves as referral agent and coordinator for technical blood banking matters.

(n) Coordinates maintenance of the Navy Blood Establishment License with FDA to manufacture blood products.

(o) Directs and monitors compliance of Navy blood banks with policies, requirements, and standards of the Navy Blood Program, Armed Services Blood Program, Federal regulatory agencies and national accrediting agencies. Ensures the safety, purity, and potency of blood products is maintained in fixed facilities and aboard ships via report reviews, technical assist visits, on-site audits, and personnel interviews.

(p) Maintains and monitors Navy Blood Quality Assurance Program and Plan. Analyzes tracks, and trends root cause and statistical data on FDA error and accidents occurring at MTFs. Monitors blood product manufacturing process to ensure compliance with good manufacturing practices required by Federal or State law and industry standard.

(q) Manages the Navy Transmitted Disease Look Back Program. Serves as liaison with naval facilities, blood donors, transfusion recipients, civilian blood agencies, and other service blood programs to collect and evaluate look back information.

14-9 Related Information Sources

(1) ***Blood Bank Operational Report, NAVMED 6530/1*** or appropriate DoD equivalent. Submit quarterly.

(2) ***Related Publications***

NAVMED P-5101, Technical Manual of the American Association of Blood Banks

NAVMED P-5120, Standards for Blood Banks and Transfusion Services

NAVMED P-5123, Operational Procedures for Military Blood Donor Centers and Armed Services Whole Blood Processing Laboratories

CFR, Title 21, parts 600-799 and parts 200-299 Food and Drug Administration, Department of Health and Human Services

(3) ***Related Directives and Instructions***

DoD Directive 6000.12, Health Services Operations and Readiness

DoD Instruction 6480.4, Armed Services Blood Program (ASBP) Operational Procedures

OPNAVINST 6530.2 series, Donor Support of Department of the Navy Blood Program

OPNAVINST 6530.4 series, Department of the Navy Blood Program

Section III
NAVAL AEROSPACE/OPERATIONAL PHYSIOLOGY PROGRAM

Article		Page
14-10	Naval Aerospace/Operational Physiology Program (NAOPP)	14-7
14-11	Mission and Elements of the NAOPP	14-7
14-12	Implementation and Management of the NAOPP	14-8
14-13	Responsibilities for the NAOPP	14-9
14-14	Naval Aerospace Physiology Program Planning Committee (NAP^{3}C)	14-9

14-10 Naval Aerospace/Operational Physiology Program (NAOPP)

(1) ***Purpose.*** The Bureau of Medicine and Surgery (BUMED) directs the NAOPP. This applies to all commands and personnel who administer or participate in the NAOPP or any of its elements.

(2) ***Background.*** BUMED established the NAOPP in 1978 to comply with the Chief of Naval Operations (CNO) task to provide support to the Aircrew Survivability Enhancement Program. Aerospace physiologists and their assistants had historically participated in the aeromedical/survival training of naval aviation personnel, and in the development and introduction of aircrew systems (particularly aircrew personal protective equipment). In the late 1970s, the role of the aerospace physiologist expanded to provide support to the Naval Aviation Safety Program, primarily through the establishment of the Aeromedical Safety Officer (AMSO) Program. The NAOPP provided the central management necessary to support these diverse functions. The Naval Aviation Physiology Program Planning Committee (NAP^{3}C) was established in 1981 to provide a steering council of senior aerospace physiologists for strategic planning and program management. In 1994, the CNO appointed BUMED as the Training Agent (TA) for the Naval Aviation Survival Training Program (NASTP). As the role of the Naval Aerospace Physiology expanded to human performance enhancement for non-aircrew personnel, the name was changed in 2007 to Naval Aerospace/Operational Physiologist and new billets with the Fleet Marine Force were established. This resulted in the addition of the Operational Physiology Program Element.

14-11 Mission and Elements of the NAOPP

(1) ***Mission.*** The mission of the NAOPP is to support operational readiness through education, training, aeromedical and human performance support, acquisitions, and research, development, testing and evaluation (RDT&E).

(2) ***Program Elements.*** The NAOPP consists of five major elements, each providing key support to the operational readiness of the Fleet.

(a) ***NASTP.*** The purpose of the NASTP is to prepare all prospective and designated aeronautical personnel, selected passengers, project specialists, and other authorized individuals in the aeromedical

aspects of flight and survival. These aspects include human factors and physiological threats related to the flight environment, physiological elements to enhance flight mission performance, mishap prevention, mishap and hostility survival, aircrew systems applications, and correct emergency egress and rescue procedures. NASTP requirements are CNO directed, BUMED is assigned as the TA. Implementation follows the BUMED NASTP Standard Operating Procedures (SOP) Manual. The NASTP includes Quality Assurance and Revalidation (QA&R) of the Naval Air Warfare Center Training Systems Division (NAWTSD) Orlando-managed NASTP training devices and associated equipment. A Training Management Team (TMT) is chartered to prioritize resources to meet Fleet training requirements.

(b) ***Operational Physiology Program.*** The purpose of the Operational Physiology Program is to provide specialized consultation, assistance, technical liaison, evaluations, training and recommendations directly to and working directly in support of operational forces. Operational Physiologists generally serve in the Operations, Training, or Safety Departments.

(c) ***AMSO Program.*** The purpose of the AMSO Program is to provide specialized consultation, assistance, technical liaison, evaluations, training, and recommendations directly to and working directly with the Navy and Marine Corps aviation community. AMSOs serve multi-faceted roles within safety, operations, and training departments.

(d) ***Fleet Air Introduction and Liaison of Survival Aircrew Flight Equipment (FAILSAFE) Program.*** The NAVAIR-sponsored FAILSAFE Program augments and facilitates the introduction of new and modified items of Aviation Life Support Equipment (ALSS) to Fleet aviation. The FAILSAFE program interfaces with all facets of aircrew system acquisition including: requirements identification; design research; development; testing and evaluation; Fleet introduction; modifications; maintenance; training (maintainers and users); life cycle support; and use. A memorandum of understanding exists between BUMED and NAVAIR governing the program.

(e) ***System Acquisitions and RDT&E.*** System acquisitions and RDT&E is supported by NAOPPs in aircrew system requirements, human performance, operational readiness, and survival systems arenas. Aerospace/operational physiologists are detailed to medical research centers/facilities, Naval Air Systems Commands, HQMC Aviation Weapon System Requirements Branch, and line communities.

14-12 Implementation and Management of the NAOPP

(1) ***Implementation.*** The mission is accomplished by means of:

(a) Management and implementation of the components of the NAOPP in compliance with CNO (N98) and Commander Naval Air Forces policies through AMSOs, aerospace safety corpsmen (AMSCs), and aerospace/operational physiologists and their assistants at aviation survival training centers (ASTCs) throughout the Navy and Marine Corps.

(b) Support of aeromedical and aircrew systems acquisition and RDT&E programs.

(c) Professional and technical career development of officers, enlisted personnel, and civilians assigned to support the NAOPP. Naval aerospace/operational physiologist officer career progression goals are established and available, as is a formalized BUMED-approved Aerospace/Operational Physiologist Internship Program for mentoring first tour officers.

(d) A BUMED NASTP standard operating procedures manual and Job Qualification Requirements (JQR) for all training evolutions/devices have been established and are in place ensuring safe implementation of high risk training.

(e) Established NASTP safety, standardization, training quality assessments, and QA&R Program of inspections for all ASTCs.

(f) Support to human performance enhancement, force preservation, and mishap prevention through training and education.

(2) ***BUMED Management.*** The NAOPP is managed by the Director, Aerospace/Operational Physiology.

14-13 Responsibilities of the NAOPP

(1) ***Chief, BUMED.*** BUMED is assigned as the NAOPP manager and by CNO as the NASTP TA. To fulfill responsibilities it shall:

(a) Coordinate the implementation of training requirements with the CNO, Commandant of the Marine Corps, Commander Naval Air Forces, and Naval Air Systems Command.

(b) Sanction training, prioritize the major claimant's requirements, and expedite programs for all NAOPP elements.

(c) Act as the central point of contact in matters pertaining to NAOPP program policy and safety.

(d) Approve the curricula developed for training aerospace/operational physiologists and aerospace physiology technicians.

(e) Assign a specialty leader for matters pertaining to the personnel required to support the NAOPP including acquisition, education, officer and enlisted billet distribution, and officer billet nominations.

(f) Advise Commander, Naval Air Forces on the impact of new systems and technology on aircrews in areas such as night vision devices, laser devices and weapons, chemical, biological, and radiological threats, Gravity-Tolerance Improvement Program, anthropometry, etc.

(2) ***Naval Survival Training Institute (NSTI)*** is assigned training responsibilities by BUMED and is assigned by OPNAV as the NASTP course curriculum model manager. To fulfill these responsibilities, NSTI shall:

(a) Develop and issue policies and procedures for safe and efficient implementation of the NASTP.

(b) Develop and maintain NASTP curricula.

(c) Compile and analyze data relating to training workload and safety.

(d) Conduct annual safety, standardization, training quality assessments, and QA&R inspections of ASTCs.

(e) Provide professional training for enlisted (Corpsman) leading to designation aerospace medical/physiology technicians (NEC HM-8406/8409).

(3) Naval Aerospace Medical Institute (NAMI) is assigned aeromedical training responsibilities and shall:

(a) Provide professional training for officers leading to designation as an aerospace/operational physiologist (subspecialty 1836).

(b) Provide professional training for enlisted (Corpsman) leading to designation as aerospace medical/physiology technicians (NEC HM-8406/ 8409).

14-14 Naval Aerospace Physiology Program Planning Committee (NAP^{3}C)

(1) ***Purpose***

(a) Implement the principles and processes of continuous quality improvement within the NAOPP using participatory management tools. Specifically, the NAP^{3}C shall serve as the executive steering council (ESC) for the NAOPP. Members shall serve as assigned by the NAOPP chairman.

(b) Improve communications within the subspecialty by serving as a conduit of information and status reports for programs and projects to the program manager and specialty leader.

(c) Refine career pathways for aerospace physiologists. Coordinate with commands in reviewing billet requirements, distribution of billets, and career progress offered by each billet. Provide counsel to the program manager and specialty leader on the personal and educational requirements, as well as the career development for all aerospace/operational physiologists. Periodically review the established career progression pathway for aerospace/operational physiologists.

(d) Review requirements for members requesting to pursue Duty Under Instruction (DUINS). This would include the number of aerospace/operational physiologists in Full-Time In-Service Training (FTIST) and Full-Time Out-Service Training

(FTOST), types of degrees considered appropriate, and recommendations to the DUINS Board, specialty leader, and program manager.

(e) Recommend standardized internship training requirements for first tour aerospace physiologists. Monitor and periodically review the Internship Program to ensure it is remaining responsive to the needs of the individuals, the NASTP, and the operational forces in developing high caliber Naval officers, Medical Service Corps (MSC) officers, and aerospace/operational physiologists.

(f) Make recommendations on the training and distribution of aviation physiology technicians (NEC HM-8406/8409). Review JQRs for all billets following the guidelines in OPNAVINST 1000.16 series.

(g) Provide criteria for screening applicants for the aerospace/operational physiology subspecialty, i.e., minimum educational requirements, levels of experience, etc., to the specialty leader.

(h) Assist program manager and specialty leader in the implementation and monitoring of the QA&R Program. Provide the program manager or TA with recommendations on the procurement, modification, and maintenance of all training devices used in the NASTP via the TMT.

(i) Advise and assist the program manager and specialty leader in the management of the NASTP.

(j) Establish criteria for the awards provided by the NAOPP and vote for recipients in recognition of superior contributions. Periodically review the established NAOPP awards criteria and selection process procedures.

(k) Provide input on any other issues concerning the NAOPP as requested by the program manager or specialty leader.

(2) ***Membership.*** The membership shall consist of senior aerospace/operational physiologists assigned to key billets within the NAOPP and a junior officer representative (JO Rep).

(a) All members are full voting members.

(b) The NAP^{3}C members are designated as such by assignment by the NAOPP manager.

(c) The NAP^{3}C chairman shall be the aerospace/operational physiologist assigned to BUMED as the NAOPP manager.

(d) The JO Rep shall be a lieutenant willing to serve (lieutenants in the internship program and outside the continental United States (OCONUS) billets are excluded). All post-internship Naval aerospace operational physiologists below the rank of O-4 shall be eligible to vote to elect this individual for a 2-year term. Votes may be tallied virtually by the incumbent JO Rep.

(3) ***Meetings.*** The NAP^{3}C will meet formally at least twice annually (in person or virtually) and otherwise stay in communication via electronic means.

(a) These meetings will be held in conjunction with other regularly scheduled program meetings when possible.

(b) The JO Rep serves as the recording secretary for the committee and will submit the minutes to the Chairman for approval.

(c) Meeting minutes will be distributed to all active duty aerospace/operational physiologists and other interested parties as requested.

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Section IV
CLINICAL LABORATORY AND ANATOMIC PATHOLOGY SERVICES

Article		Page
14-15	Applicability	14-13
14-16	General Guidance	14-13
14-17	Accreditation Policies	14-14
14-18	Laboratory Management	14-14
14-19	Laboratory Personnel	14-15
14-20	Responsibilities for the Specialty Leaders for Pathology and Medical Technology	14-16
14-21	Inspection and Disposition of Laboratory Files and Records	14-16

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.