



DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
7700 ARLINGTON BOULEVARD
FALLS CHURCH, VA 22042

IN REPLY REFER TO
BUMEDINST 6700.44
BUMED-M4
25 Nov 2014

BUMED INSTRUCTION 6700.44

From: Chief, Bureau of Medicine and Surgery

Subj: NAVAL LABORATORY EQUIPMENT REVIEW BOARD

1. Purpose. To establish a Naval Laboratory Equipment Review Board (NAVLERB) within the naval service to evaluate new and emerging medical laboratory technologies. To recommend short and long range planning, policy, governance, and acquisition strategies for laboratory equipment, and related support equipment, including military construction (MILCON) projects.

a. Medical laboratory equipment types include, but are not limited to the following: chemistry, hematology, urinalysis, microbiology, blood bank, histology, cytology, and esoteric testing. This instruction does not apply to research laboratory equipment.

b. If uncertainty regarding equipment that qualifies as medical laboratory equipment types arises, contact Naval Medical Logistics Command (NAVMEDLOGCOM), Expense Equipment Program Manager, (301) 619-3083, or via e-mail at: NMLC-CentralFundedReceiving@med.navy.mil, for clarification.

2. Scope. The NAVLERB will serve as an advisory board to the Chief, Bureau of Medicine and Surgery (BUMED), thus informing, drafting, and recommending policy for Budget Submitting Organization 18 medical laboratory equipment within Navy Medicine. The NAVLERB will be the Navy Medicine agent for the evaluation of medical laboratory equipment. All individual or group medical laboratory equipment acquisitions with a value of \$3,000 or more, all cost per test/reportable contracts, equipment leases, interfacility test transfers, reference laboratory contracts, and medical laboratory equipment maintenance for Navy Medicine will be reviewed by the NAVLERB to ensure standardization and quality are in line with strategic and operational objectives. The NAVLERB is the appointed representative of the Chief, BUMED when called upon or directed to participate in Office of the Assistant Secretary of Defense (Health Affairs) and quad-service forums that evaluate and assess technology, coordinate policy development, technology implementation, and acquisition issues.

3. Background. The establishment of the NAVLERB provides Navy Medicine with a technically and clinically educated board composed of clinical, scientific, and administrative personnel participating in the decision process to identify and introduce new laboratory technologies, to evaluate cost effective alternatives, and to determine appropriate equipment replacement cycles.

4. Procedure. All recommendations for medical laboratory equipment purchases shall be coordinated by NAVMEDLOGCOM who will in turn forward all requests to the NAVLERB, a board composed of laboratory officers appointed by the Specialty Leader. A concentrated,

focused approach is essential to determine which emerging technologies should be introduced to Navy Medicine and how best to upgrade or replace existing technologies. To manage the number of requests and to address issues of policy, the NAVLERB will convene at least once a quarter at NAVMEDLOGCOM or by virtual/teleconference methods. The Chair will also coordinate ad hoc meetings or electronic voting between quarterly meetings as the Chair sees fit to draft policy and to review urgent equipment request packages. Equipment requests must be received at NAVMEDLOGCOM at least 30 days prior to the meeting date to allow adequate time for review and processing.

a. The decision to begin a request for equipment typically begins with the local command's recommendations for medical laboratory equipment or other testing solutions needed to support the laboratory's scope of required testing and procedures. The commanding officer's recommendation is forwarded via regional chain of command to NAVMEDLOGCOM who will in turn forward all requests to the NAVLERB. Medical laboratory equipment requests could also be generated by senior level working groups as needed (i.e., Joint Program Executive Office).

b. During quarterly meetings, NAVLERB members will provide unbiased clinical and technical evaluations of local command requests. The NAVLERB approach to the equipment decision making process will focus on an effort to enhance, optimize, and improve Navy health care services.

5. Policy. The NAVLERB will advise the Chief, BUMED, on medical laboratory equipment standards, facility-specific equipment criteria, patient safety, equipment life cycle management, and replacement prioritization.

a. Based on platform and specific mission requirements where applicable and in conjunction with the Defense Medical Materiel Program Office (DMMPO) for operational medical unit equipment, the NAVLERB will coordinate with NAVMEDLOGCOM to create and maintain "equipment of choice" packages to serve as guides to the field on selecting equipment within NAVLERB standards. Maintaining and disseminating these packages is intended to aid in standardizing equipment throughout Navy Medicine and to aid in expediting equipment requests from the field and acquisitions of such equipment.

b. The NAVLERB will review all requests for equipment covered by this instruction, regardless of funding sources. The NAVLERB will thoroughly evaluate command requests, advise on prioritization of equipment purchases, and forward final recommendations to Chief, BUMED.

c. The NAVLERB is made up of subject matter experts. As such, it is the appropriate body to draft relevant and needed policy for consideration by BUMED leadership. Members shall route all discussions on policy through the Board Chair. The Board Chair then determines the best means to consolidate the opinion of the NAVLERB and draft a document for the consideration of BUMED leadership. Policy issues of interest would include test result quality,

personnel and equipment issues, training gaps, and equipment issues, patient and staff safety concerns, quality improvement efforts, inter-service and inter-agency cooperation, business rules and other financial considerations, issues related to electronic storage of laboratory information, workflow management, and clinical care. Additionally, other advisory boards from BUMED may request the opinion of the NAVLERB and its subject matter experts.

6. Mission and Function. The NAVLERB is vested with the responsibility for leadership and direction of Navy laboratory strategic planning activities. It shall:

a. Direct planning for acquisition of all medical laboratory equipment, establishment of cost per test/reportable contracts, equipment leases, interfacility test transfers, reference laboratory contracts, and medical laboratory equipment maintenance for all Navy Medicine's facilities.

b. Review all equipment requirements to ensure conformance to laboratory strategic plans; and provide liaison with other Services as necessary.

c. Technically and clinically evaluate emerging laboratory technologies for potential adoption by Navy Medicine; oversee technical evaluations and facilitate programming acquisition and schedule fielding of equipment as appropriate.

d. Provide technical expertise and input to large multiyear contracts to ensure "Best Value" procurement of medical laboratory equipment and actively participate in equipment evaluation.

e. Provide technical approval authority on all medical laboratory equipment requests referred for action. This technical approval will be based on analysis of the requesting command's mission, emerging standard of care, staffing, workload, location, cost effectiveness, and conformance with Navy Medicine strategic objectives. These technical approvals will be submitted as acquisition recommendations to the Chief, BUMED.

f. Provide recommendations to the Chief, BUMED, on strategic plans for laboratory and capital equipment procurement.

g. Provide the Chief, BUMED with draft documents for consideration to address gaps in policy for laboratory equipment.

h. As needed, coordinate with the appropriate subject matter, technical, and acquisition experts, in providing guidance, in the form of "units of choice" packages based on platform. The packages will be defined in terms of equipment performance specifications. These packages will be timely, satisfactory in quality, and of sufficient utility that they facilitate a move toward greater standardization, cost effectiveness, and efficiency throughout Navy Medicine laboratory services.

i. Provide assistance to the field in preparing business case analyses. The Chair will direct board members to aid such requests as he or she deems necessary.

j. Provide subject matter assistance to the field and to BUMED on issues related to test quality, facility design, electronic laboratory information storage, workflow, and workload distribution.

k. Provide recommendations on best business practices for coordinating and conducting receipt of medical laboratory equipment and necessary validation procedures.

7. Membership

a. Voting Members. A quorum of greater than 50 percent of members is required for a vote. A passing vote requires a simple majority of all voting members. The following persons are voting members unless replaced by a designee:

- (1) Chair: Specialty Leader for Medical Technology.
- (2) Specialty Leader for Anatomic Pathology.
- (3) Assistant Specialty Leader for Medical Technology.
- (4) Head of Navy Blood Program.
- (5) Defense Medical Materiel Program Office (DMMPO) Laboratory Officer.
- (6) Senior Laboratory Officer from Navy Medicine East, appointed by Chair.
- (7) Senior Laboratory Officer from Navy Medicine West, appointed by Chair.
- (8) Junior Laboratory Officer from Navy Medicine East, appointed by Chair.
- (9) Junior Laboratory Officer from Navy Medicine West, appointed by Chair.
- (10) Commanding Officer, NAVMEDLOGCOM.
- (11) Laboratory Officer, Navy Medicine Information Systems Support Activity.
- (12) Laboratory Officer, Fleet Forces Laboratory.

b. Ad Hoc Non-voting Members. The following persons are non-voting members unless directed by the Chair to vote in their areas of expertise (the Chair may appoint a subject matter expert in lieu of any of the ad hoc members as needed):

- (1) Microbiology Representative (when discussing Microbiology equipment).
- (2) Navy Marine Corps Public Health Center Representative (when discussing Public Health lab equipment).

(3) Head, Capabilities System Branch, Capabilities Development & Integration.

(4) Laboratory Officer representative from command with equipment request(s) being reviewed by the board

c. Non-voting Members. Clinical, technical, and administrative experts and other key personnel. These may include, but are not limited to:

(1) Recorder/administrative coordinator (provided by NAVMEDLOGCOM).

(2) Subject matter expert(s), including:

(a) Expense Equipment Program Manager (NAVMEDLOGCOM).

(b) Investment Equipment Program Manager (NAVMEDLOGCOM).

(c) Clinical Engineers.

(d) Equipment and Technology Management.

(e) MILCON Equipment Planner(s)/BIOMED.

(f) Health Facilities Planning Project Officer(s).

8. Roles and Responsibilities

a. Chair, NAVLERB. Convene the NAVLERB once every quarter or as necessary to review technological innovations, equipment, and facility requests for routine and emergent equipment replacement or upgrades and healthcare provider recommended changes in practices, procedures, and policies. Submit meeting minutes to Chief, BUMED, for comment and approval.

b. Commanding Officer, NAVMEDLOGCOM. Provide the NAVLERB recorder or administrative coordinator. Receive, review, and prepare Navy Medicine facility equipment request packages submitted for board action. Provide other administrative assistance to the Chair as requested.

9. Records Management. Records created as a result of this instruction, regardless of media and format, shall be managed per SECNAV M-5210.1 of January 2012.



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<http://www.med.navy.mil/directives/Pages/BUMEDInstructions.aspx>