COMMANDANT INSTRUCTION 5100.27

Subj: COAST GUARD LIGHT AMPLIFICATION BY STIMULATED EMISSION OF RADIATION (LASER) HAZARD CONTROL POLICY

Ref: (a) Title 21, Code of Federal Regulations (CFR) Part 1040.10, Performance Standards for Light Emitting Products
   (b) ANSI Z136.1, American National Standard for the Safe Use of Lasers
   (c) Title 21, CFR 1010.5, Exemptions for Products Intended for United States Government Use
   (d) Medical Manual, COMDTINST M6000.1 (series)
   (e) Safety and Environmental Health Manual, COMDTINST M5100.47 (series)
   (f) Coast Guard Safety and Occupational Health Council, HQINST 5100.1 (series)

1. PURPOSE. The purpose of this Instruction is threefold:

   a. It provides general information and safety guidance to all Coast Guard employees about the hazards associated with lasers;

   b. It provides specific policy direction for the acquisition of lasers and the approval process for Class 3B lasers, Class 4 lasers and lasers that require an exemption from federal regulations; and

   c. It provides prescriptive guidance on the program elements required for each class of lasers.

2. ACTION. All Coast Guard unit commanders, commanding officers, officers-in-charge, deputy/assistant commandants, and chiefs of headquarters staff elements shall comply with the provisions of this Instruction. Internet release is authorized.

3. DIRECTIVES AFFECTED. None.

5. **BACKGROUND / DISCUSSION.**

   a. **Basic Laser Hazard Awareness.** LASER is an acronym for Light Amplification by Stimulated Emission of Radiation. Reference (a) is the overarching federal regulation for the sale and manufacture of lasers and reference (b) is the accepted industry standard for guidance on the safe use of lasers. References (a) and (b) differ slightly in naming conventions for lasers (Roman numeral for the CFRs (I, II, IIIa, etc) vice alphanumeric for the American National Standards Institute (ANSI) standards (1, 2, 3A, 3R, etc)), but they share the same common definitions and specifications for hazardous potential. For the purposes of this Instruction, lasers will be referenced in accordance with the ANSI convention, and will be broken down into four main classifications based on the hazardous potential:

      (1) **Class 1.** This type of laser is not considered to be an eye hazard, but since the product may actually be a higher power laser housed within an enclosed system, users should use caution if the system is damaged or used outside of the manufacturer’s instructions. While this type of laser does not need specific authorization for use, it still requires a label identifying the classification, should never be pointed directly at someone’s eyes, and should be part of a local unit inventory for awareness purposes.

      (2) **Class 2.** This type of laser is considered a chronic viewing hazard, but still falls under the category of eye safe as long as the period of exposure is extremely short. The hazard increases when viewed through magnification devices (binoculars). This class of laser also requires a caution label in addition to the classification label to bring the users attention to the additional hazard. Similar to the Class 1 laser, this type of laser should never be pointed at someone’s eyes, and should be part of a local unit inventory for awareness purposes.

      (3) **Class 3.** Class 3 lasers are broken down into two categories based on hazardous potential. Units with Class 3 lasers shall maintain and account for their current inventory via the property management system.

         (a) **Class 3A / 3R.** Lasers in this classification may be considered eye safe, but are also likely to be powerful enough to exceed the maximum permissible exposure level for eye damage under normal viewing. They are hazardous if viewed with magnification optics, and require a yellow caution label or red danger label depending on the specifications as defined in reference (a). Operators of this type of laser should ensure everyone in the user area is aware of the hazard, and shall not direct the laser toward anyone potentially using magnification optics.

         (b) **Class 3B.** This type of laser is not considered eye safe. It is considered hazardous under most viewing conditions, and could have diffuse reflection capability (ability to reflect/bounce off a smooth surface and not lose any of the hazardous potential, i.e. easily bounce back to operator). All Class 3B lasers require specific engineering control measures as outlined in reference (a) and must contain a red danger label. They
must also be inventoried and individually tracked at the unit as well as specifically approved in accordance with this Instruction prior to use.

(4) Class 4. This is the most hazardous type of laser. It is not eye safe under any viewing conditions, and most have a diffuse reflection hazard. This type of laser requires significant control measures to include engineering systems, personal protective equipment (PPE), and detailed approved policy guidance/procedures regarding use. In addition to maintaining a current inventory via the property management system, units that use Class 4 lasers will also be required to designate a Laser Hazard Safety Officer (LHSO) for local oversight of the laser safety program. Additional information is in enclosure (1). All Class 4 lasers must be specifically approved in accordance with this Instruction prior to use.

b. **Compliance versus Certification.** All lasers products sold or imported into the United States are required to include certain engineering control measures into their design as defined in reference (a). The burden is on the manufacturer to self verify that their system is in “compliance” with federal regulations prior to market, and to report their findings to the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA). The FDA does not necessarily review all laser submissions for compliance and does not “certify” lasers. Generally unless there is a specific report of a violation, incident, or reason for suspicion, the CDRH will only issue the “Assurance Number”, which indicates that the required reports have been received by the CDRH and that it is authorized to go to market. Note that it is very possible for a manufacturer to submit the paperwork for a hazardous system, with the possibility that it has never been reviewed by a government agency for the methodology behind how it obtained compliance. This is specifically why the Coast Guard has established an internal review process, and why a potential vendor who cannot produce an FDA “Assurance Number” and/or copies of the verification reports submitted to the FDA upon request, should be considered not in compliance until verified otherwise. This concern is particularly relevant for operational laser systems sold to military and law enforcement agencies and should be evaluated fully before obligating the service. Failure to understand this prior to acquisition could expose Coast Guard personnel to unknown risks or result in the Coast Guard assuming the burden for certification, especially if the system is modified in any way to be integrated into a Coast Guard platform.

c. **Exemptions from Federal Regulations.** Some of the engineering control measures from reference (a), most notably the requirement to incorporate a visual or aural emissions indicator into each Class 3B or Class 4 laser system, are not compatible with some of the Coast Guard’s maritime law enforcement and homeland security mission objectives to remain covert during surveillance activities. The Department of Defense (DOD) identified this type of concern in 1976 when they lobbied for and received permission to self-regulate (and exempt) laser systems for the following three reasons: combat, combat training, and lasers classified in the interest of national security. In November 2009, Commandant (CG-113) met with CDRH and attempted to gain inclusion in the DOD exemption status or originate a similar exemption status for the Coast Guard, but was directed to the process defined in reference (c) for a system by system individual review by the CDRH for government use exemptions. In practice, this doesn’t alleviate the need for an internal laser management process as defined by this Instruction for oversight and acceptance of risk; it simply places the final decision external to the organization.
d. **FDA Compliance versus “Safe Use”**. Meeting the requirements of reference (a) alone does not guarantee that a hazardous laser will be used safely. Since the FDA regulation only covers the physical structure and attributes of the engineering control measures of the laser itself, additional administrative and procedural control measures must be instituted to properly manage the operator and environment within which the laser system will be used. While not technically required in legislation, the commonly accepted practice in research, industry and DOD is to adopt the ANSI standards from reference (b) as applicable. Failure to incorporate additional control measures in addition to those required in reference (a) could result in a citation from the Occupational Safety and Health Administration (OSHA) for “Failure to provide a safe workplace”, or a permanent or partially debilitating injury to Coast Guard personnel or the public.

6. **EMERGENCY MEDICAL PROCEDURES AND REPORTING.** After a confirmed or suspected exposure to a Class 3B or Class 4 laser, a Coast Guard employee's continued participation in operations should be determined by the operational commander based on mission urgency and after consultation with the cognizant medical authority (i.e., flight surgeon, unit medical officer or equivalent). The cognizant medical authority will determine whether the affected personnel should be immediately relieved from duty, able to complete the operational duty period or allowed to continue in full duty status. Regardless of duty determination, any Coast Guard employee with a confirmed or suspected exposure to a Class 3B or Class 4 laser will have a diagnostic vision examination by an optometrist or ophthalmologist at the next available opportunity. Many lesions begin to fade or heal with time, making a diagnosis of injury more difficult and symptoms or physical signs of eye injury unapparent. Furthermore, delay in evaluation may later reduce medical treatment options. Documentation of the injury will include a history of the event and a thorough vision and ocular examination. The examination is required to include ocular history, distance visual acuity, Amsler grid (or similar central visual field) test, slit lamp examination, ocular fundus evaluation through dilated pupil, ocular fundus photographs that depict the extent of injury or lack of injury, and photographs of any external or anterior segment injury.

a. **Medical Reporting.** Once the optometrist or ophthalmologist suspects or confirms an acute laser overexposure incident, the member (or representative) must report the laser incident to:

1. The immediate operational chain of command,

2. The Tri-Service LASER Injury Hotline: (800) 473-3549, and

3. Document the incident in the Occupational Medical Surveillance Program (OMSEP) in accordance with reference (d) and this Instruction.

b. **Additional Reporting.** After emergency care is provided, all laser incidents regardless of injury shall be reported via a mishap report in accordance with reference (e). This will ensure operational commanders are able to continually monitor the external threat to our forces for consideration of potential mitigation strategies, as well as educate the workforce as a whole on the hazardous potential of lasers. Additional reporting to appropriate law enforcement officials (internal and external to the Coast Guard) for enforcement action or reporting incidents to the Federal Aviation Administration (FAA) through the nearest controlling agency for incidents involving aircraft operations in U.S. airspace might also be required.
7. **LASER HAZARD CONTROL PROGRAM ELEMENTS.** The following five program elements are required for all Class 3B and Class 4 lasers, regardless of intended use, and constitute the minimum requirements for the Coast Guard Laser Hazard Control Policy. They mirror the basic requirements of DOD laser programs as well as those outlined in the ANSI standards for laser use.

a. **Laser Hazard Control Program Administration/Architecture.** This section identifies the two basic elements needed for successful laser hazard control program administration. The first is the establishment of an organizational regulatory body to address individual certification and authorization issues at the program level. The second is to designate a sufficient number of field level LHSOs to assist in program implementation, management and oversight.

(1) **Laser Hazard Control Standing Committee (LHCSC):** In accordance with reference (f), the LHCSC shall review each new Class 3B and Class 4 laser, or any laser requiring exemption from federal regulations. If, in the opinion of the LHCSC, the technical data and system engineering decisions are deemed to be beyond their capability, the committee shall outsource review to a DOD laser review board or other commercial source as needed prior to submitting any exemption request to the FDA. The LHCSC shall provide a written report and present its recommendation to the CG-Safety and Occupational Health Committee (CG-SOHC). The CG-SOHC will review the documentation and recommend final disposition if needed to higher authority. Commandant (CG-11) will be the administrative lead for issuing and tracking approval documentation. At a minimum, the LHCSC shall consider the following items:

(a) The design of the system to include independent verification of laser classification, determination of Nominal Ocular Hazard Distances and Nominal Hazard Zone, engineering controls required and recommended.

(b) The policy and doctrine required to implement the safe and effective operation of the system. This shall include at a minimum the appropriate inclusion in Operations Manuals (Air Operations, Surface Operations, Flight Manuals, Small Arms Manuals, etc), Training, Tactics and Procedures (TTP) Manuals, Maintenance Manuals, Maintenance Procedure Cards (MPCs), and any required local instructions.

(c) Documentation and training support for the system to include a recommend training program covering all sections of paragraph 7.c and enclosure (2) of this Instruction.

(d) Legal review of the employment and use plan with specific emphasis on the hazardous potential of the system within the proposed operating environment to the general public and marine wildlife. The review shall include an environmental review (NEPA and ESA).

(e) Safety features of the system to include all applied control measures, PPE, standard operating procedures (SOPs), interlock systems, emergency cutoff, use of control areas, etc.

(f) Formal risk assessment of the risk versus gain for acceptance determinations.
(2) **Laser Hazard Safety Officer (LHSO).** Each unit that operates a Class 3B or Class 4 laser shall designate an LHSO in writing. The LHSO shall be knowledgeable in the evaluation and control of laser hazards, both basic and those specific to the systems in the unit’s inventory. They shall have the authority to suspend, restrict, or terminate the operation of a laser system if it is deemed that laser hazard controls are inadequate or if the system is used outside of its intended guidance or environment. To meet this requirement, it is possible, but not necessary for a designated LHSO to attend a DOD or other sanctioned LHSO course to complete their functions. In most cases however, this Instruction, Commandant (CG-113) sanctioned laser training program, and the individual approval guidance from the Commandant (CG-11) via the LHCSC and CG-SOHC should be adequate for the LHSO to perform his/her duties. Commandant (CG-113) and the LHCSC will ensure an appropriate number of individuals in the organization maintain a suitable level of certification to develop and disseminate mandated training programs, this Instruction and program evaluation guidance. In some cases, based on the determination of the LHCSC, a LHSO may be designated to service the needs of a specific geographic region (an example would be if a Sector Safety Manager/Officer fulfilled all of the requirements of this Instruction for subordinate units). The specific responsibilities of a LHSO are listed in enclosure (1).

b. **Laser Radiation Hazard Control Measures.** The mandatory performance specifications for laser products listed in reference (a), 21 CFR 1040.10 are as follows: radiation emission indicator, beam attenuator, safe location of controls, viewing optics as required, scanning safeguards, and manual reset mechanism. These items will produce a potentially safe laser, but as explained in paragraph 5.d of this Instruction, engineering control measures alone will not guarantee the safe use of a hazardous laser. The ANSI standards in reference (b) must be reviewed for incorporation of the most appropriate additional administrative & procedural control measures, and since there is a wide variance of discretionary possibilities, the LHCSC shall be the main focal point for ensuring the proper mix is established. The overall goal for Coast Guard laser systems should be to incorporate as many of the requirements as possible while still remaining operationally effective.

c. **Training and Education.** Initial laser hazard awareness training is required for all Class 3B and Class 4 lasers prior to operational use, and shall be conducted annually thereafter. Training for other classes of lasers is not required, but highly recommended. The Commandant (CG-113) approved laser safety training presentation will be used as a base template for laser safety training. It is the responsibility of the LHSO to incorporate any local instructions and specific operating instructions for the lasers found at the unit into the presentation to ensure a comprehensive training and education module. The specific topics are listed in enclosure (2).

d. **Medical Surveillance.** Medical surveillance is required for personnel working with Class 3B and Class 4 lasers and laser systems in accordance with reference (d) for monitoring for exposure to non-ionizing radiation. Medical Surveillance is not a requirement for personnel working with Class 1, Class 2, or Class 3A / 3R lasers or laser systems. Enclosures (3) and (4) provide definitions and required medical forms. The preplacement examination must be performed before assignment involving risk of exposure to Class 3B or 4 lasers and establishes a baseline for comparison and measurement following an accidental exposure or ocular damage. Termination laser examinations should be completed when the member is no longer working with Class 3B or 4 lasers.
e. **Formal Risk Assessment.** Prior to a Class 3B or Class 4 laser approval determination, each program will be required to conduct a formal risk assessment evaluation. The scope of the assessment will vary depending on the hazard potential of the system and will be determined by the LHCSC. It can range from a general description of how people could potentially be injured to a formal system safety evaluation in accordance with the requirements of MIL-STD-882D, Standard Practices for System Safety Program Requirements.

8. **LASER ACQUISITION POLICY, REQUIREMENTS AND REVIEW PROCESS.**

a. Enclosure (5) depicts the process and decision matrix for Coast Guard personnel purchasing lasers. It is important to stress that as the hazardous potential of the laser system increases, so too will the amount of research, documentation and collaboration required to achieve authorization. As with any complex system acquisition, the earlier in the acquisition cycle that requirements and hazards can be identified, the better chance they stand to be properly engineered, mitigated and fully approved prior to operational use.

(1) For Class 1, Class 2, and Class 3A / 3R Lasers:

   (a) Coast Guard members may purchase lasers for Coast Guard use in this classification, however, the requesting unit and purchasing agent shall ensure that the “FDA Assurance” number is recorded on the purchase request (PR) and/or any other purchasing documentation. This will be considered satisfactory for organizational due diligence for ensuring the requesting unit has researched the hazardous potential of the laser and verified that it is not an illegally manufactured or sold product.

   (b) If the manufacturer cannot provide the assurance number and/or copies of the compliance verification reports submitted to the FDA, then the laser shall not be purchased and Commandant (CG-113) shall be notified for consultation with the FDA.

   (c) The requesting unit shall consider all other aspects of this Instruction for incorporation into local procedures regarding local use of lasers to include (inventory, training, etc).

   (d) While it may not be required in all communities, the requesting unit shall also contact the appropriate program or system managers for operational assets to ensure there are no configuration management control conflicts. For aviation requests, any laser used in the aircraft requires a full Aircraft Configuration Control Board (ACCB) review regardless of class, Commandant (CG-41) must be contacted prior to initiating the purchase.

(2) For Class 3B lasers, Class 4 lasers, or any laser requiring exemption from federal regulations: All lasers in this classification require consultation and review by the LHCSC regardless of their FDA compliance status, and ultimately must be approved by Commandant (CG-11) or higher as determined by the CG-SOHC. For “FDA Compliant” lasers, the LHCSC will make internal recommendations to the CG-SOHC regarding validity of compliance documentation and recommendations for additional administrative and procedural control measure as required. For lasers that will require an exemption, the LHCSC will help prepare the package for CG-SOHC review and coordinate for external review by the CDRH. At a minimum laser use request packages shall contain the following items or sections of a request:
(a) **Detailed System Description.** This section shall include all of the technical specifications and basic operating parameters for use of the laser system. There is no specific format described, but should allow the LHCSC to review and understand the basic physical attributes of the laser and how it will be used in practice. This section should also include a detailed explanation of how the system meets each of the engineering control measures required in reference (a) and if it will not, explain additional control measures that will be required for exemption documentation.

(b) **Approved Employment and Use Plan and other Organizational Policy Documents.** Based on the hazardous potential to Coast Guard personnel and the public, the employment and use plan shall be approved and reviewed by Commandant (CG-094) prior to authorization. This section should also cover other ancillary policy documents that will be required for documentation of “safe use” policy and procedures. (e.g. Air Operations Manual; mission specific Training, Tactics & Procedures (TTP) manuals, and individual flight manuals or operator manuals)

(c) **Formal Risk Assessment of Hazards.** The complexity of this section will be directly proportional to the hazardous potential of the system, the complexity of its intended use, and its operating area. Additional guidance will be coordinated by the Commandant (CG-113) representative or the LHCSC regarding the scope of this evaluation. The end product should clearly explain the probability and severity of all of the possible ways that someone can be injured with the proposed system and offer recommended mitigation strategies for safety concerns.

(d) **Compliance Certification Documentation.** For an “FDA Compliant” laser system, this will include the manufacturer’s self-generated compliance documentation. Depending on the quality of the evaluation, an independent verification through a third party or military laser evaluation service may be required. For new lasers not currently in compliance, an independent verification of the system parameters is required. Commandant (CG-113) representatives can help coordinate with other service laser evaluation services. Note that any modifications or integration of a previously compliant laser into a new system or platform constitutes the requirements for new compliance documentation. (i.e., if a laser system that is “compliant” on a DOD or other government platform is integrated into a Coast Guard platform, the manufacturer, integrator or the Coast Guard is responsible for originating new compliance documentation).

(e) **Laser Hazard Safety Officer (LHSO) Force Plan.** This section needs to explain the program’s intent for LHSOs. There is no requirement to have a DOD or civilian school certified laser safety officer, however the LHSO must be designated as delineated in this Instruction. If the program intends to use regional laser safety officers (from sector or district level), that should be documented here so the reviewing officials have a full level of understanding regarding the breadth and depth of safety oversight provided for each laser system.

(f) **Proposed Training Package Implementation Plan.** This should include the drafts of the presentation material that will augment the Commandant (CG-113) sanctioned basic laser safety presentation. Since the majority of the material from enclosure (2) will be included in the base program, the sponsor’s proposal should focus on system specific
hazards, operating procedures, guiding documents (Commandant Instructions, SOPs, etc.) and associated hazards and mitigation strategies.

(g) Estimate of OMSEP enrollment requirements: This section should be a base estimate of how many people at the unit will be expected to be enrolled in the OMSEP program. Enclosure (3) provides information to help make that determination.

9. RESPONSIBILITIES.

a. Deputy Commandant for Mission Support (DCMS) shall

(1) Ensure that all subordinate support staffs and headquarters units comply with the requirements of this Instruction for new and existing lasers and laser systems, including all acquisition activities.

(2) Ensure staff elements incorporate the requirements of federal law as cited in reference (a) and the program elements of this Instruction at the earliest possible time in the design or purchase of new lasers. If full compliance is not possible because of operational needs, ensure the laser is properly exempted in accordance with this Instruction prior to use. Any deviations from federal law shall also be reviewed by the Judge Advocate General (JAG) & Chief Counsel, Commandant (CG-094).

(3) Designate the Director, Health, Safety and Work-Life, Commandant (CG-11) as the lead agent for the administration of the Laser Hazard Control Program.

(4) Assign members to CG-SOHC and LHCSC as outlined in reference (f). These members will act as the reviewing authority for all Class 3B and Class 4 lasers and make recommendations to higher authority as needed based on the hazardous potential of the system.

b. Deputy Commandant for Operations (DCO) shall

(1) Ensure the program elements of this Instruction are considered in the development of future operational requirements to ensure they can be accounted for in the development and acquisition of new capabilities.

(2) Develop and implement policies and procedures in all applicable doctrine, tactics and operations manuals regarding lasers. Ensure clear operating procedures remain consistent with this Instruction, and in accordance with the final approval documentation of each hazardous Class 3B and Class 4 laser system.

(3) Assign members to CG-SOHC and LHCSC as outlined in reference (f). These members will act as the reviewing authority for all Class 3B and Class 4 lasers and make recommendations to higher authority as needed based on the hazardous potential of the system.

(4) Ensure all operational units that employ the use of lasers and laser systems adhere to this Instruction and any subsequent policies, procedures and standards as developed by higher authority.
c. Coast Guard Force Readiness Command (CG FORCECOM) shall

(1) Designate members as needed to act as representatives on LHCSC and CG-SOHC activities.

(2) Develop a quality assurance mechanism to evaluate compliance with this Instruction and all applicable standards for the safe use of lasers.

d. Judge Advocate General (JAG) & Chief Counsel, Commandant (CG-094) shall:

(1) As a member of the LHCSC, review all requests for laser exemption from federal law as outlined in reference (a), and for all Class 3B and Class 4 lasers used in Coast Guard operations.

(2) Determine if deviations from federal law and the potential injury to the general public and/or marine wildlife are commensurate with mission objectives.

e. Director of Health, Safety and Work-Life Commandant (CG-11) shall

(1) Develop and implement policies and procedures for the administration of the Coast Guard’s Laser Hazard Control Program to include: LHCSC review protocol and support, standardized laser training, medical surveillance, and incident/accident reporting procedures (both medical emergency and safety).

(2) Designate medical and safety staff members from Commandant (CG-11) to maintain an appropriate level of Laser Safety Officer Qualification or certification to ensure professional competence, and maintain liaison with DOD and other government agencies regarding the management of laser radiation hazards.

(3) Designate an appropriate number of staff personnel to act as regional LHSO for field support regarding laser hazard assessments, technical concerns and quality assurance.

f. Units with Class 1, 2, or 3A / 3R lasers or laser systems shall

(1) Conduct an annual laser hazard assessment to identify potential threats. While not mandatory it is recommended to maintain a local inventory of non hazardous lasers for awareness purposes.

(2) Obtain the FDA “Assurance Number” for all Class 1, 2, and 3A / 3R lasers and record it on the Procurement Request (PR) and/or any other procurement documentation necessary to ensure the laser is properly recorded as being FDA compliant. If in question, contact FORCECOM or Commandant (CG-113) for guidance.

(3) Conduct optional laser hazard awareness training in accordance with paragraph 7.c and enclosure (2) of this Instruction if desired.
g.  **Units with Class 3B or Class 4 lasers or laser systems shall**

(1) Designate an LHSO for local level administration of laser hazard controls.

(2) Conduct an annual laser hazard assessment and review the effectiveness of all required control measures as specified in the approval of the system.

(3) Ensure all laser operators and personnel who might work with or around lasers receive approved training upon initial assignment to the unit and annually thereafter in accordance with paragraph 7.c and enclosure (2) of this Instruction.

(4) Assign only qualified and trained personnel to operate lasers and laser equipment.

(5) Maintain an inventory of all lasers in the property management system and submit to Commandant (CG-113) and FORCECOM an annual inventory of all Class 3B and Class 4 lasers, and lasers requiring exemption from federal regulations.

(6) Designate unit personnel who require medical surveillance in accordance with paragraph 7.d of this Instruction.

(7) Provide unit personnel with appropriate laser protective equipment (eyewear, clothing, barriers, screens, etc.) as outlined in the approval of the specific systems.

(8) Ensure laser warning devices and signs are posted in accordance with reference (a) and in the approval of the system to ensure unsuspecting personnel are protected from laser radiation.

(9) Maintain a firing log (sample provided in enclosure (6)) for all Class 3B and Class 4 laser use events. Documentation shall include, at a minimum, a location, azimuth, and start and stop time of each use.

10. **ENVIRONMENTAL ASPECT AND IMPACT CONSIDERATIONS.** This action is not expected to result in any significant adverse environmental impact as described in the National Environmental Policy Act (NEPA) of 1969. The proposed action has been reviewed by the United States Coast Guard and has determined this action to be categorically excluded from further environmental documentation under current USCG Categorical Exclusion #33 in accordance with National Environmental Policy Act Implementing Procedures and Policy for Considering Environmental Impacts, COMDTINST M16475.1 (series), Figure 2-1.

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Enclosures:  (1) Laser Hazard Safety Officer (LHSO) Duties and Responsibilities  
(2) Laser Safety Training Program Elements  
(3) Occupational Medical Surveillance and Evaluation Program (OMSEP) Information  
(4) Coast Guard Laser Class 3 B & 4 Medical Surveillance Form  
(5) Laser Acquisition and Review Process Flowchart  
(6) Sample Unit Class #b or Class 4 Laser Firing Log  
(7) List of Acronyms and Abbreviations
Laser Hazard Safety Officer (LHSO) Duties and Responsibilities

The specific duties of the LHSO are as follows:

(1) Identify all lasers used at the unit and maintain a local inventory.
   a. For Class 3A lasers and below it is not necessary to account for each individual laser, but at a minimum the LHSO shall have an understanding of how they are being used at the unit. Even “eye safe” lasers used in presentations can cause damage if used outside of manufacturer’s guidance.
   b. For all Class 3B and Class 4 lasers, the inventory shall include all of the information in enclosure (1) and shall be forwarded to Commandant (CG-113) and FORCENCOM for auditing and standardization purposes. The inventory shall be verified annually.

(2) Monitor and maintain local oversight over all laser operations at the unit for quality assurance purposes. Be prepared to suspend, restrict or terminate laser operations if needed and report it immediately to the chain of command.

(3) Ensure all Class 3B and Class 4 lasers are properly secured when not in use, and only trained and authorized operators and maintainers have access to them.

(4) Consider creating a local laser instruction or SOP to ensure all of the specific requirements mandated in the system’s approval, this instruction and other Commandant instruction manuals are consolidated in one document.

(5) Ensure the appropriate unit personnel are entered into the Occupational Medical Surveillance and Evaluation Program (OMSEP) in accordance with paragraph 7.d and enclosure (2) of this instruction.

(6) Report all laser injuries or potential injuries via mishap reporting guidance found in reference (e).

(7) Ensure all laser operators and maintainers receive initial and required recurrent laser training prior to working with or near Class 3B and Class 4 lasers. Utilize the Commandant (CG-113) standardized Basic Laser Safety Presentation augmented with specific information on any lasers or laser systems used at the unit. At a minimum, ensure the content of the training is in accordance with paragraph 7.c and enclosure (2) of this instruction.
Laser Safety Training Program Elements

The following are the minimum topics for each class of laser system:

a. For user personnel routinely working with or potentially exposed to Class 3B or Class 4 laser radiation:
   
   (1) Fundamentals of laser operation (physical principles, construction, etc.)
   
   (2) Bioeffects of laser radiation on the eye and skin
   
   (3) Significance of specular and diffuse reflections
   
   (4) Non-beam hazards of lasers (electrical shock, etc)
   
   (5) Laser and laser system classifications
   
   (6) Control measures
   
   (7) Overall responsibilities of member and supervisor
   
   (8) OMSEP and Emergency medical procedures for accidental exposure, to include Cardio Pulmonary Resuscitation (CPR) for personnel servicing or working on lasers with exposed high voltages and/or the capability of producing potentially lethal electrical currents.

b. For units that choose to employ an optional training program for activities involving Class 3B and below lasers:
   
   (1) Simple explanation of a laser
   
   (2) Compare differences of laser light from ordinary light
   
   (3) General explanation of the differences in the various laser classifications
   
   (4) Explain the concept that it is harmless for exposure duration less than the human aversion response time of 0.25 s
   
   (5) Explanation of the potential for collecting and focusing optics to increase the hazard and effects of exposure.
Occupational Medical Surveillance and Evaluation Program (OMSEP) Information

Medical surveillance is required for personnel working with Class 3B and Class 4 lasers and laser systems. Medical Surveillance is not a requirement for personnel working with Class 1, Class 2, or Class 3A lasers or laser systems.

a. Classification of Laser Workers.

(1) Laser Workers. Laser workers are those individuals who routinely work in a laser environment and, therefore, have a higher risk of accidental exposure. Those working with Class 3B or Class 4 lasers are at greatest risk of injury due to such exposures. Laser workers include those who regularly perform laser research, development, testing, and evaluation; individuals who work with or near medical lasers found in operating rooms; and workers who perform routine laser maintenance. Laser workers have a moderate to high risk potential for laser injury.

(2) Incidental Laser Workers. Incidental laser workers are those individuals whose work makes it possible, but unlikely, that they will be exposed to laser energy that could damage the eye. Incidental workers include operators of fielded laser equipment, individuals who oversee laser use, and members who participate in force-on-force laser training exercises. Incidental laser workers are considered to have a low risk potential for laser injury.

b. Laser Medical Surveillance and Assessment.

(1) Laser Workers (Laser Personnel). Laser Personnel shall be included in OMSEP (non-ionizing laser radiation). OMSEP enrollment procedures are described in detail in Chapter 12 of reference (f). Laser workers shall have an ocular and visual history, visual acuity, color vision test, and a central visual fields test (via Amsler Grid or similar macular integrity test) at preplacement and termination. Visual acuity, color vision, and central field tests shall be performed on each eye separately. No further examination is required if the worker’s distance corrected visual acuity is 20/20 in each eye, the color vision test is normal, central visual fields are normal via Amsler grid test or similar macular integrity test and the medical history (for eyes and skin) are normal. Any deviation from the acceptable normals shall be evaluated to determine the reason. This may be done by ocular funduscopic examination or other tests as deemed appropriate by the eye care professional. Baseline funduscopic photography may be useful for documenting the retinal status. This information should be documented on the Laser Class 3B & Class 4 Medical Surveillance Form (See Enclosure 2) (print out the form and attach on an SF-600).

(2) Incidental Laser Personnel. Incidental laser workers shall have each eye screened for visual acuity. They shall not be included in the OMSEP (Laser Medical Surveillance Program).
Coast Guard Laser Class 3 B & 4 Medical Surveillance Form

_____ y/o male/female here for LASER CLASS 3 B or 4 medical surveillance exam

Personal History of
Y/N Major illness or injury
Y/N Hospitalization or surgery
Y/N Cancer
Y/N Back injury
Y/N Alcohol use (6+ drinks per week)
Y/N Have you ever smoked?
Y/N Do you currently smoke (packs/day)
Y/N Heart disease, high blood pressure, stroke
Y/N Current medication use
Y/N Medication allergies
Y/N Photosensitizing medications
Y/N Any reproductive health concerns
Y/N Unusual sensitivity to sunlight
Y/N Skin disease
Y/N Cataracts
Y/N Change or loss of vision
Y/N Eye irritation
Y/N Contact lens use
Y/N Glaucoma
Y/N Lens surgery

Work History of:
Y/N Exposure to non-ionizing radiation (laser, infrared, microwave, ultraviolet)
Y/N Eye injury
Eyes: +/- discharge (L/R) +/- conjunctiva/sclera injected (L/R) +/- swollen/red lid (L/R)
Skin: Rash ___ Erosion ___ Ulcer ___ Pigment ___ Eczema ___ Other ___

Optometry:
Date of most recent refraction (when applicable): ____________________
Current refraction prescription (when applicable): ____________________
Vision screen (visual acuity): Both _______ Left _______ Right _______
External ocular and fundus examination: ____________________

LASER Medical Surveillance Examination (Pre-Placement / Termination)
Is surveillance consistent with exposures Y/N
Are any abnormalities related to exposures / occupation Y/N
Comments on medical history ____________________
Comments on ophthalmologic exam ____________________
Comments on physical exam ____________________
Referral to ophthalmologist or optometrist Y/N
Recommendations: ____________________
Enclosure (5) to COMDTINST 5100.27

Laser Acquisition and Review Process Flowchart

CG Member / Program Desires to Purchase a LASER

Class 1, 2, 3A

FDA COMPLIANT?

YES

DO NOT PURCHASE! SEEK ASSISTANCE FROM CG-113 (LHCSC)

Class 3B or 4

LHCSC MUST Review for SAFETY and REGULATORY COMPLIANCE

The requesting program shall provide:

- Detailed System Description including all engineering, administrative and procedural control measures
- Approved Concept of Operations
- Formal Risk Assessment of Hazards
- Certification Documentation
  - OEM Self Certification, Third party Certification, Previous DOD exemption or FDA exemption
- Laser Hazard Safety Officer (LHSO) plan
- Training Package plan
- Estimate of OMSEP enrollment numbers

IF Full FDA Compliance is NOT Possible for Coast Guard Mission Execution: FDA EXEMPTION REQUIRED

LHCSC Coordinates FDA Exemption via CFR 1010.5

LHCSC Reviews Package and/or FDA Exemption Status Determines if ADDITIONAL Control Measures are Needed Makes Recommendation to CG-SOHC

CG-11 Issues Laser Approval after CG-SOHC Concurrence and Maintains Organizational Inventory of All Approved Class 3B and 4 Lasers
Sample Unit Class 3B or Class 4 Laser Firing Log

<table>
<thead>
<tr>
<th>Command</th>
<th>________________________________</th>
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</thead>
<tbody>
<tr>
<td>Date</td>
<td>________________________________</td>
</tr>
<tr>
<td>System</td>
<td>________________________________</td>
</tr>
<tr>
<td>User</td>
<td>________________________________</td>
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<table>
<thead>
<tr>
<th>Firing #</th>
<th>Start Time</th>
<th>Stop Time</th>
<th>Target Location</th>
<th>Firing Position/Heading</th>
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**List of Acronyms and Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>ACCB</td>
<td>Aircraft Configuration Control Board</td>
</tr>
<tr>
<td>ANSI</td>
<td>American National Standards Institute</td>
</tr>
<tr>
<td>CDRH</td>
<td>Center for Devices and Radiological Health</td>
</tr>
<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
</tr>
<tr>
<td>CG-SOHC</td>
<td>Coast Guard Safety and Occupational Health Council</td>
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<tr>
<td>FAA</td>
<td>Federal Aviation Administration</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>LASER</td>
<td>Light Amplification by Stimulated Emission of Radiation</td>
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<tr>
<td>LHCSC</td>
<td>Lazard Hazard Control Standing Committee</td>
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<td>LHSO</td>
<td>Lazard Hazard Safety Officer</td>
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<td>MPC</td>
<td>Maintenance Procedure Card</td>
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<tr>
<td>OMSEP</td>
<td>Occupational Medical Surveillance Program</td>
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<td>OSHA</td>
<td>Occupational Safety and Health Administration</td>
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<tr>
<td>PPE</td>
<td>Personal Protective Equipment</td>
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<tr>
<td>SOP</td>
<td>Standard Operating Procedures</td>
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<tr>
<td>TTP</td>
<td>Training, Tactics and Procedures</td>
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