# JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)



# Ocular Evaluation and Disposition after Suspected Laser Exposure (CPG ID:79)

This CPG provides information and instructions for medical providers responsible for service members following a suspected directed energy exposure involving the visual system

Contributors		
COL Mark E Reynolds, MC, USA Lt Col Timothy R. Landis, USAF, BSC		
COL James R Auvil, MS, USA	CAPT Matthew C Rings, MC, FS, USN	
LTC Marcus H Colyer, MC, USA	Heuy-Ching Hetty Wang, Ph.D.	
Lt Col Luanne Danes, USAF, BSC	Rodney L Wood Jr	
Colleen Jenkins	COL Jennifer M. Gurney, MC, USA	
Robert N Kang, OD, PhD	Col Stacy A. Shackelford, USAF, MC	

First Publication Date: 14 Feb 2020

# **TABLE OF CONTENTS**

Introduction	.3
Introduction Clinical Scenarios	
Background	.3
Key Points	.4
Effects Of Exposure	.4
Incident With Temporary Visual Interference Effects	4
Incident With Suspected Ocular Injury	6
Optical Devices	7
Evaluation of Suspected Injury	7
Treatment & Disposition	
Treatment	.7
Teleconsultation Services	8
Asynchronous Consultation Services:	
Disposition	8
Flight Surgeons	8
Other Forward Providers	9
Eye Care Providers	9
Medical Coding	9
Incident Reporting	
Performance Improvement (PI) Monitoring	10

Population Of Interest	
Intent	
Performance/Adherence Measures	
Data Sources	
System Reporting & Frequency	11
Responsibilities	11
References	
Appendix A: Evaluation & Documentation Sheets for Providers	13
Appendix B: Laser Incident Questionnaire	15
Appendix C: Amsler Grid/Foveal Grid Testing Instructions	17

# LEGEND OF FIGURES & TABLES

Figure 1. Spectral response of the eye	5
Figure 2. Effects of laser and other intense/bright light exposures based on distance.	6
Table 1. ICD-10 coding guidance for laser exposures	9

## INTRODUCTION

This Clinical Practice Guideline provides information and instructions for medical providers responsible for Service members following a suspected directed energy (DE) exposure involving the visual system. (Consider: There is little experience in the general medical community with DE and having a high index of suspicious for this type of injury is important. If a DE exposure is suspected – early consultation with ocular care providers is important as is having a full understanding of the physiologic and anatomic effects of this type of injury. Ocular DE injury can result in mission compromise and pose safety hazards to the individual and the unit.) These suspected exposures, presumed caused by a laser or other intense bright light source, can compromise the ability to execute mission essential functions. For the purposes of this guideline, the term laser will also include any light source, visible or invisible, capable of resulting in potential injury. The intent of this guideline is to provide a better understanding of this type of injury and its effects and to establish a care algorithm for first-line providers and follow-on care by eye care providers. This CPG is based on expert consensus

## **CLINICAL SCENARIOS**

- An aircrew making a final approach is exposed to a laser source, leading to temporary flash blindness. Spatial awareness and situational awareness is effected, compromising actions during critical operations. The symptoms resolve without functional or anatomic evidence of damage.
- 2. A mounted service member employs an escalation of force visible laser during operations. The beam is reflected of the turret mirror resulting in close proximity exposure. Central vision is immediately compromised. Evaluation shows decreased vision and retinal edema. This results in a central retinal scar and loss of vision.

because there is little available data on this type of injury. Specifically, it includes the key elements of a Service member's history, examination, disposition, and medical record coding following potential exposures. Service and unit-specific reporting procedures for exposures and possible injuries are also included. Early recognition and treatment of potential injuries is essential to maintain optimal visual performance. In addition, timely reporting is essential to assess the operational impact of these exposures/injuries.

## BACKGROUND

Lasers emit nonionizing radiation in the ultraviolet, visible, and infrared portions of the electromagnetic spectrum. When the eye is exposed to this energy, temporary disruption of visual function or permanent injury may occur.<sup>1</sup> Lasers available for wide scale commercial purchase that emit at visible wavelengths (including red, green, and blue) have been increasingly reported in laser strikes on commercial aircraft. These laser strikes on commercial aircraft have been reported most frequently during takeoff and landing.<sup>2</sup> A review of these civilian aircraft incidents found that while these laser strikes have not resulted in any documented permanent changes in visual functional or structural damage to the eyes, they have been documented to cause immediate visual effects, including flash blindness, glare, and startle that can interfere with critical functions on board the aircraft. Based on reports by civilian pilots that have been directly exposed, recovery of optimal visual function can take from seconds to minutes. However, alterations in visual function can last from several minutes to several hours.<sup>3</sup>

Potential exposures of the visual system to laser threats that are present across the spectrum of military operations are more varied. Laser technology is incorporated into multiple weapons systems from both friendly and hostile forces and presents a threat of temporary visual effects or permanent injury to the eye. Most laser systems designed for military use emit at infrared wavelengths that cannot be seen by the human eye. Visible laser systems also pose a threat to military operations. A review of data from the Defense and Veterans Eye Injury and Vision Registry (DVEIVR) from 2006-2018, found 132 service members with documentation of exposure in the medical record. Of these cases reviewed, five service members found to have permanent damage compromising visual function as a result of exposure.

# **KEY POINTS**

- Ocular exposure to directed energy in the form of lasers can acutely disrupt operational functioning.
- Permanent injury to the eyes and visual system is rare after these exposures.
- Awareness of this type of exposure is critical for all deployed providers.
- Early engagement of eye care specialist is essential to maximize recovery.
- Service members with persistent symptoms or worsening vision complaints require priority evacuation.
- Exposed Service members require comprehensive evaluation by an eye care provider as soon as possible after exposure events.
- Consistent documentation of exposures and injuries will improve treatment recommendations

# EFFECTS OF EXPOSURE

Exposure of the eyes to laser energy generally leads to two categories of effects.

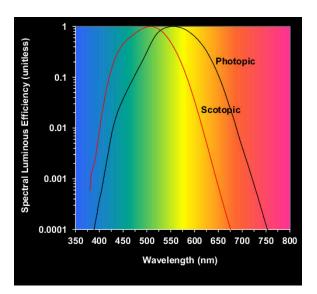
- 1. Visual interference effects
- 2. Ocular injury (persistent anatomic or visual function abnormalities)

# INCIDENT WITH TEMPORARY VISUAL INTERFERENCE EFFECTS

These effects are the result of wavelengths in the visible spectrum (400-700 nm). The wavelength or color of the source is associated with the degree of immediate visual function disruption following an exposure. This is because the human eyes spectral response to color varies across the visible spectrum. We see the color green much better than blue or red. Our response to color even varies with lighting conditions. The vision we use under well-lit, daytime conditions is called photopic vision and under low-light levels, nighttime conditions is called scotopic vision. For example, green light is capable of producing visual function disruption with less relative power than red light at similar distances. Effects include temporary flashblindness, afterimages, and glare. They also include startle, distraction, and disruption, effects that may not directly degrade vision but may have an effect on human performance. These effects are more pronounced when a person is exposed at night or in a dark environment.

#### Figure 1. Spectral Response of the Eye

The standard photopic and scotopic sensitivities of the eye as defined by the Commission internationale de l'éclairage (CIE) or International Commission on Illumination are shown and demonstrate the peak sensitivity to green wavelengths. Note the logarithmic scale of the y-axis.



Visual interference effects include:

- 1. **Flash blindness** A visual interference effect that persists as an afterimage after the source of illumination has ceased.
- 2. **Glare** An obscuration of an object in a person's field of vision due to a bright light source located near the same line of sight.
- 3. **Afterimage** A transient image that persists in one's visual field after a bright source of illumination has been removed.
- 4. **Startle** The involuntary reaction to an unexpected event that alters mental, physical, and visual activities and diverts selected attention away from the normal primary tasks of an individual. The startle response can be broken into four specific categories: Distraction, Disruption, Disorientation, and Operational Incapacitation.
  - Distraction Momentary attention shift from primary tasks due to sudden exposure to a bright light source. This effect may not be readily identified by the Service member and should be asked specifically.
  - Disruption Interference or interruption of critical tasks or task sequences that extend the shift of attention from primary tasks requiring selective attention.
  - Disorientation Losing perspective in the relationship between the direction of travel and surroundings. Can include loss of both spatial orientation and situational awareness.
    Disorientation can occur simultaneously with distraction, disruption, and startle.
  - **Operational Incapacitation** An individual's loss of spatial orientation and loss of situational awareness in reference to the outside world. In the case of aviation, a pilot that becomes

operationally incapacitated should immediately transfer control of their aircraft because they can no longer reliably discern or control the aircraft.

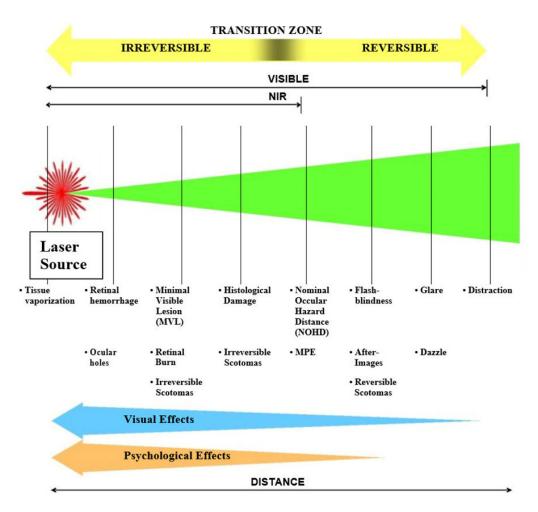
The natural aversion response to bright light sources limits exposure to visible wavelength lasers to about 0.25 seconds. Although exposure may be limited to a fraction of a second by your ability to blink or turn away from the offending light source it does not provide absolute protection from injury.

# INCIDENT WITH SUSPECTED OCULAR INJURY

An ocular injury can result from any laser wavelength if sufficient power is delivered to the eye. The affected structure within the eye varies with wavelength. Lasers emitting in the far ultraviolet, UV-B and UV-C (180-315 nm), and far infrared, IR-B and IR-C (1400 nm - 1 mm), are absorbed by the cornea. Near ultraviolet, UV-A (315-400) wavelengths are absorbed by the lens of the eye. Visible (400-700 nm) and near infrared, IR-A (700-1400 nm) wavelengths are absorbed by the retina. The spectral region 400-1400 nm is commonly referred to as the retinal hazard region. Laser output power, or energy, is an important determinant for injury potential, as is the duration of the exposure and the exposed person's location relative to the laser source exit aperture.

## *Figure 2. Effects of laser and other intense/bright light exposures based on distance.*

Source: AF Laser Injury Guide Book.



## **OPTICAL DEVICES**

Vision enhancement devices, such as Night Vision Devices, provide an additional barrier between the laser and the eyes which can provide a degree of protection. However, they can be more sensitive to interference from intense light sources, both visible and non-visible wavelengths, especially compared to the unaided eye. This can cause difficulty with the device's operation and significantly affect safety.

Optical scopes, or other devices with magnifying optics, may amplify or further focus the light source, leading to more energy delivered to the eye and increased risk of injury.

# **EVALUATION OF SUSPECTED INJURY**

All service members with a laser exposure require evaluation. The form below includes key points for documentation as well as recommended testing and intervals. Generally, service members should be evaluated at least daily until symptoms resolve or evacuation to an eye care provider is available. After evacuation out of theater frequency of follow-up is based on clinical situation, but should occur at a minimum of 1, 3, and 6 months following exposure/injury. Detailed sheets to guide the evaluation for all providers are available in <u>Appendix A</u>. These include sheets to guide initial providers through key history and examination elements, as well as more specialized recommendations for eye care providers. Medical documentation does not replace operational reporting as detailed below. These recommendations may be modified as new information is available through ongoing analysis of exposures and outcomes.

Use of the Laser Incident Questionnaire (<u>Appendix B</u>) enables both medical and operational aspects of the incident to be documented. Exposed/injured service members can expect to undergo more extensive interviews with additional medical, operational, and military intelligence personnel after treatment has been initiated.

## **TREATMENT & DISPOSITION**

## TREATMENT

Initial treatment guidance for suspected ocular injury from laser exposure is limited. Readily identifiable injuries such as corneal abrasions, hyphema or vitreous hemorrhage should be treated using current standards in coordination with an eye care provider. These guidelines can be found in the Eye Trauma: Initial Care, 28 Aug 2019 and Ocular Injuries and Vision-threatening Conditions in Prolonged Field, 01 Dec 2017. In the context of visual dysfunction, available literature suggests early treatment with non-steroidal anti-inflammatory drugs (NSAIDS) and/or systemic corticosteroid therapy.<sup>4,5,6</sup> Treatment of SMs with suspected ocular injury should be considered as follows (if not otherwise contraindicated):

- 1. **Vision 20/40 or better** but not at baseline, visual interference effects lasting more than 2-4 hours: start NSAID (indomethacin by mouth 25mg three times/day can be used if available, or ibuprofen 800mg by mouth three times/day
- 2. **Vision worse than 20/40**, any Amsler grid abnormalities: Consider addition of oral prednisone (0.5 to 1 mg/kg); teleconsultation with eye care provider recommended.

Evaluation by an eye care provider in theater should be obtained if operationally feasible. This decision is best made after discussion with the eye care provider. Teleconsultation for specific treatment decisions when no eye care providers is available.

## **Teleconsultation Services**

- ADVISOR 833-238-7756; DSN 312-429-9089 (select emergency department and callers will be connected to ophthalmology) ADVISOR covers all Combatant Commands
- U.S. Air Force School of Aerospace Medicine Ophthalmology: 937-938-2675
- Naval Aerospace Medical Institute Ophthalmology: 850-452-2933; usn.pensacola.navmedotcnamefl.list.nami-ophthal@mail.mil

## Asynchronous Consultation Services:

- INDOPACOM: Pacific Asychronous TeleHealth (PATH): <u>https://path.tamc.amedd.army.mil/</u>
- EUCOM, CENTCOM, AFRICOM, SOUTHCOM: Health Experts onLine Portal (HELP): <u>https://help.nmcp.med.navy.mil/</u>

## **NOTE**: PATH and HELP links require establishment of an account

Service members (SM) reporting worsening visual acuity or visual symptoms, or a change in exam findings should be considered for priority evacuation to allow for evaluation and care by an eye care provider. SMs with any visual symptoms that persist beyond 24 hours despite initial treatment should be considered for priority evacuation.

All SMs with symptomatic exposures, even those that return to baseline function, should have comprehensive evaluation by an eye care provider in theater or upon redeployment if resources are not available in theater. This post-exposure evaluation should be documented in the electronic medical record.

SMs with repeated exposures (multiple exposures over several days), should be evaluated for symptoms after each incident, and each evaluation documented and treated as an additional exposure.

# DISPOSITION

## Flight Surgeons

Follow Service-specific guidelines for aviation personnel; full references at end of CPG.

- United States Air Force School of Aerospace Medicine Laser Injury Guidebook
- OPNAV Instruction 5100.27B Marine Corps Order 5104.1C, Navy Laser Hazards Control Program<sup>7</sup>
- Army personnel should follow above guidance

**NOTE**: Aviation personnel are only to be returned to duty in accordance with Service-specific aviation guidelines from the above references and local SOPs.

#### **Other Forward Providers**

SMs with exposures that return baseline visual function (with no new or persistent defects on Amsler grid testing, see <u>Appendix C</u>) within 2-4 hours may be returned to full duty without restrictions as long as the SM meets current service-specific standards. Full documentation and incident reporting is required for incidents with transient visual interference effects as well as suspected ocular injuries. Non-aviation personnel may return to duty when visual function returns to baseline and allows for effective execution of MOS-specific duties and operational requirements.

#### Eye care providers

- 1. Whenever feasible and operationally viable, obtain ultrastructural image of the retina as near to point of exposure as possible in SMs with persistent visual complaints. This will serve to further define the severity of injuries, serve as a baseline for visual recovery, and inform ongoing understanding of the spectrum of directed energy injuries as an evolving operational concern.
- 2. Service Members with suspected ocular injuries from laser exposure are eligible for enrollment in the DVEIVR <u>https://vce.health.mil/Vision-Registry/Need-Access</u>. The registry is populated using medical encounter documentation. Only unclassified details of the event should be entered into the medical record. Coding recommendations to facilitate tracking and analysis are listed below.
- 3. Service Members with documented retinal involvement should be referred to a vitreoretinal specialist for further evaluation.

## MEDICAL CODING

The following ICD-10 coding guidance is recommended for laser exposures. Proper documentation and coding of these events allows for optimal tracking and analysis inform and evaluate treatment recommendations. Uniform and consistent medical documentation and coding is essential to proper surveillance and research efforts. This guidance is designed to standardize coding across the MHS.

<b>Diagnostic Position</b>	Code	Comments
Principal/First listed Diagnosis	Initial symptoms (headache, blurred vision, etc.)	Allows for tracking duration/resolution of symptoms longitudinally
Second Diagnosis	Anatomic findings (burn, scar, etc.)	Allows for documentation and tracking of injuries longitudinally
Third Diagnosis	W90.2* Exposure to laser radiation	ICD-10 codes in the range V00-Y99 describe the cause of the morbidity, not the condition itself; this code allows for accurate tracking of laser exposures.
	W90.2XXA Exposure to laser radiation initial encounter	
	W90.2XXD Exposure to laser radiation subsequent encounter	
	W90.2XXS Exposure to laser radiation sequela	

#### Table 1. ICD-10 coding guidance for laser exposures

#### **INCIDENT REPORTING**

- 1. Notify Chain of Command at the earliest level possible.
- 2. Notify the DoD Laser Hotline as soon as time and circumstances permit:
  - DoD Laser Hotline Toll-free: 800-473-3549 (not currently manned 24/7)
  - https://hpws.afrl.af.mil/dhp/OE/ESOHSC/laserinjury/
  - US Army Institute of Surgical Research (MCMR-SRR-O), Ocular Trauma and Vision Restoration,
  - https://usaisr.health.mil/, Trauma Clinic & Civilian Care Coordination Office (CCCO) phone 210-916-2796.
- Notifications as outlined in the Air Force Occupational Safety and Health Standard, AFI48-139 should be made as soon as possible. Field level notification should be made to the Deployed Medical Commander and the Air Expeditionary Wing Commander. Notify the Tri Service Laser Injury Hotline (1-800-473-3549) as soon as time and circumstances permit.
- 4. Medical personnel can coordinate medical guidance for laser injuries from the DoD Laser/EMF Injury Hotline through the ESOH Service Center, (800) 473–3549, DSN 798–3764, commercial (937) 938– 3764, or email esoh.service.center@wpafb.af.mil. Upon examination, if the medical facility suspects or confirms the over exposure, they contact the injured person's commander or supervisor.
- For Army Aviation, Commander, U.S. Army Combat Readiness Center (CSSC–Z), Fort Rucker, AL, at DSN 558–2660/3410, commercial (334) 255–2660/3410 (24-hour phone line), FAX DSN 558–3749, commercial (334) 255–3749 or email helpdesk@crc. army.mil.

## PERFORMANCE IMPROVEMENT (PI) MONITORING

#### **POPULATION OF INTEREST**

All patients with laser eye exposure/injury.

#### INTENT

- 1. Patients in the population of interest are identified as having exposure at first role of surgical care.
- 2. Patients in the population of interest undergo comprehensive evaluation by an eye care provider as soon as possible after exposure events
- 3. Patients in the population of interest have complete documentation of type of laser injury, severity, treatment, and outcomes.

## **PERFORMANCE/ADHERENCE METRICS**

- 1. Number and percentage of patients in the population of interest with documented comprehensive eye exam.
- 2. Number and percentage of patients in the population of interest with complete documentation of type of laser injury, severity, treatment, and outcomes.

#### DATA SOURCES

- Individual Medical Record
- DVEIVR
- DoD Trauma Registry

## SYSTEM REPORTING & FREQUENCY

The above constitutes the minimum criteria for PI monitoring of this CPG. System reporting will be performed annually; additional PI monitoring and system reporting may be performed as needed.

The system review and data analysis will be performed by the Joint Trauma System (JTS) Chief, JTS Program Manager, and the JTS Performance Improvement Branch.

#### RESPONSIBILITIES

It is the trauma team leader's responsibility to ensure familiarity, appropriate compliance and PI monitoring at the local level with this CPG.

#### ACKNOWLEDGMENTS

The JTS extends a special thanks to the voting members of the JTS Committee on Surgical Combat Casualty Care for their contribution to the development and publication of this clinical practice guideline.

## JTS Defense Committee on Surgical Combat Casualty Care (CoSCCC)

JTS Chief: COL Stacy A. Shackelford, MD, FACS, USAF, MC JTS Senior Enlisted Advisor: MSG Michael A. Remley, ATP, SFC, MC, USA DCoT Chair, CoSCCC Chair: COL Jennifer M. Gurney, MD, FACS, MC, USA

#### **Voting Members, Peer Reviewers**

COL Scott B. Armen, MD, FACS, FCCP, FCCM, MC, USAR COL David Aaron Baker, MD, MC, FS COL Jay Baker, MD, MC, USA COL Tyson Becker, MD, MC, USA CDR Randy S. Bell MD, FAANS, MC, USN PO1 Jeffrey D. Bentley, USN USA Lt Col Craig (CJ) Berg, MD, USAF, MC CDR Virginia Schmied Blackman, PhD, RN, USN CAPT Matthew Bradley, MD, MC, USN Col Jeffrey (Scott) Calder, MD, USAF, MC SSG Tommy Chavez, MC, USA LTC John Chovanes, DO, FACS, MC, USAR LTC Jason B. Corley, MD, MC, USA COL Brian Eastridge, MD, MC, USAR LTC Matthew Eckert, MD, MC, USA CAPT Ted Edson, MD, MC, USN CAPT Eric Elster, MD, FACS, MC, USN Col Mark D. Ervin, FS, USAF, MC MAJ Colin Frament, PA, MC, USA COL Tamara Funari, RN, MC, USA

COL Jason Hiles, MD, MC, USA MAJ Keith Jackson, MD, MC, USA SFC Jonathan R. Johnson, ,OPS NCOIC, USA SMSgt Melissa A. Johnson, USAF, MC CDR Michel Kearns, MD, MC, USN Col Peter A. Learn, MD, USAF, MC MAJ Rich Lesperance MD, MC, USA Maj Justin D. Manley, FS, USAF, MC LTC Alex Merkle, USA, PA CAPT Margaret M. Moore, MD, FACS, MC, USNR COL Shawn Nessen, MD, MC, USA SMSgt Jose Arias-Patino, USAF CDR Travis Polk, MD, FACS, MC, USN CAPT Robert Ricca, MD, MC, USN Anne Rizzo MD, FACS Col James B. Sampson, MD, RPVI, FACS, USAF, MC COL Martin Schreiber, MD, MC, USAR COL Jason M. Seery, MD, FACS CAPT Zsolt Stockinger, MD, MC, USN CDR Matthew D. Tadlock, MD, FACS, MC, USN

Lt Col Brian J. Gavitt, MD, MPH, FACS, USAF, MC COL Kirby Robert Gross, MD, MC, USA Maj Andrew Hall, MD, USAF, MC LCDR Jonathan Hamrick, USN CRNA, NMCP VA Maj Regina Tai-see, USAF, MC LTC Eric Verwiebe, MC, USA COL Paul White, MC, USA Col Eveline F. Yao, USAF, MC, CFS

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## **APPENDIX A: EVALUATION & DOCUMENTATION SHEETS FOR PROVIDERS**

Patient		
Identifier		
Date of Injury		
Date of Evaluation		
History		
Element	Description	Result
Exposure description	Color, brightness and duration of light/exposure	
	Other characteristics of light (pulse/flicker)	
	Eye(s) exposed	
	Direct or reflected exposure	
	Activity/tasks at time of exposure and ability to perform tasks.	
	Optical devices in use at the time of suspected exposure (night vision devices, magnifying devices, specific laser protection devices)?	
Presenting Symptoms	Reported symptoms may include: blurred vision, headache, blind spots, shadows, eye pain, eye irritation/burning, etc.	
Time since exposure	How long ago was the exposure?	
Duration of symptoms	Seconds, minutes, hours, ongoing	
Medical/Ocular History	Previous visual function (baseline vision as available (i.e. glasses use)	
	Previous ocular history	
	History of refractive surgery	
	Current medications	
Social History	Tobacco use	
	Examination	
Element	Description	Result
Laterality (OD/OS/OU)	Accomplished at every visit. Document affected eye(s)	
Visual Acuity	Accomplished at every visit. Note whether acuity was taken at near or distance, and whether acuity was accomplished with or without correction; annotate whether spectacles or contacts were used.	

Laser Exposure Medical Documentation: Initial Provider Evaluation		
Amsler grid* testing ( <u>Appendix B</u> )	Accomplished at the initial visit, and at follow-up for previously documented abnormality or where new symptoms are disclosed ; document abnormalities or "normal" in each eye	
Color Vision testing	Accomplished at the Initial visit, and at follow-up for previously documented abnormality or where new symptoms are disclosed performed at follow-up if new abnormality; document abnormalities or "normal" in each eye computerized color vision testing, monocular, with red, green, blue cone testing individually preferred if available (pseudoisochromatic plates are not considered adequate for this testing, but may be used for initial screening)	
Pupils	Document size, shape, and reactivity	
External eye	Evaluate for irritation, burns, corneal opacities; Document abnormalities or "normal" in each eye	
Retinal evaluation	Accomplished at the Initial visit, and at follow-up for previously documented abnormality or where new symptoms are disclosed performed at follow-up if new abnormality; document abnormalities or "normal" in each eye	
Additional evaluation	Flight Surgeons complete additional evaluation and testing required for aviation personnel based on training and Service- specific guidelines.	

\*The Amsler grid is a printed grid pattern with a central dot. It is designed to demonstrate alterations in vision near fixation (the area of highest acuity). See <u>Appendix C</u> for details of use.

## APPENDIX B: LASER INCIDENT QUESTIONNAIRE

The following questions taken from the AFRL-SA-WP-SR-2012-0005, are designed to gather information to assist medical, operational, and intelligence personnel in analysis of laser beam exposure incidents. It should be anticipated that further questions and information will be sought as time allows. Finally, remember to call the Tri-Service Hotline at 1-800-473-3549 or DSN798-3764 as soon as possible.

## 1. Describe the light you saw

- What color(s) was the light(s)?
- How bright was it?
- How long was it on?
- Was it uniform in appearance?
- Did the intensity of the light change?
- Was it constant or did it pulse or flicker? If so, how fast did it pulse or flicker?
- How wide (perhaps using finger widths at arm's length) was the beam at origin?
- How wide on exposure was the light? Did the light fill your cockpit or compartment?
- Was the light emanating directly from a source or was it reflected off a surface?
- Were there any other unusual light sources?
- Have you seen this light(s) before?

## 2. Date, location, and circumstances

a. Date and time (local & Zulu using a 24-hour clock) that the exposure occurred.

local: DDMMYYYY hh:mm

Zulu: DDMMYYYY hh:mm

- Location of exposure (if nonclassified). Describe location preferably using degree decimal (DD), degrees-minutes-seconds (DMS), Universal Transverse Mercator (UTM), or Military Grid Reference System (MGRS).
- c. How far and in what direction was the light source? Was it airborne or surface based?
- d. What was between the light source and your eyes?
- e. What were the atmospheric conditions: clear, overcast, rainy, foggy, hazy, and sunny?
- f. Was any equipment such as windscreens, visors, NVGs, goggles or sensors affected by the light?
- g. What evasive maneuvers did you attempt and did the beam follow you as you tried to move away?

## 3. Effects

- a. How long did you look into the light beam?
- b. Did you look straight into the light beam or off to the side?

- c. What tasks were you doing when the exposure occurred? Did the light(s) hamper you from doing those tasks?
- d. Were both eyes exposed? If not, describe the difference between the light exposure (for example, one eye was shielded or closed, or on the side away from the light beam).
- e. Describe any difference in the effect on either eye.
- f. Was the light so bright that you had to blink or squint, close your eyes, or look away?
- g. Was the light painful? Describe the pain. For how long did the pain persist after the light exposure?
- h. Was vision affected while the light was on? How much of your visual field was affected? What types of things could you see or not see? Did you notice the color of instruments or targets change? Did the changes to your vision remain constant or vary during the exposure? If the light source was mounted on a platform (e.g., aircraft, ground vehicle, or building), how much of the platform was obscured?
- i. Did your vision remain affected after the light was extinguished? If so, for how long and how did you estimate the time? What types of things could you see or not see? Did you notice afterimages ("spots before your eyes")? If so, describe them.
- j. Were there any lingering (i.e. hours or days) visual effects? If so, were the effects continuous or intermittent? Did you have problems reading or seeing in low-light conditions? How long until you were able to see normally again?
- k. Did you notice any reddening, warming, or burns to your skin?
- I. Describe the condition of your vision before the incident. Do you wear glasses?
- m. Are you taking any medications?

# APPENDIX C: AMSLER GRID/FOVEAL GRID TESTING INSTRUCTIONS

An accurate and validated grid for testing with instructions (Aidman Vision Screener) is available through the U.S. Army Public Health Center, Health Information Products e-Catalog: https://usaphcapps.amedd.army.mil/HIOShoppingCart/viewItem.aspx?id=452.

If pre-printed copies are not available, the vision screener may be printed full size for expedient screening.

#### **GENERAL INSTRUCTIONS:**

- 1. Have Service Member wear current glasses or correction if normally used for near vision.
- 2. Evaluate each eye separately under good lighting conditions, begin with the right eye (cover left eye).
- 3. Hold the sheet 40 cm/16 inches from the eye.
- 4. Ask Service Member to:
  - a. Describe the center of the grid (may be unable to see center)
  - b. Determine if all four corners of the diagram are visible.
  - c. Identify any dark, hazy, or missing areas on the grid while SM focuses on central dot. Have SM draw these areas on the chart.
  - d. Identify any distorted or wavy lines on the grid while focusing on the central dot. Have SM draw these areas on the chart.
- 5. Repeat test for left eye (cover right eye).
- 6. Document Amsler grid testing in medical record.

#### Laser Exposure Medical Documentation: Initial Provider Evaluation

-		
Patient		
Identifier		
Date of Injury		
Date of Evaluation		
History		
Element	Description	Result
Exposure description	Color, brightness and duration of light/exposure	
	Other characteristics of light (pulse/flicker)	
	Eye(s) exposed	
	Direct or reflected exposure	
	Activity/task at time of exposure and ability to perform tasks.	
	Optical devices in use at the time of suspected exposure (night vision devices, magnifying devices, specific laser protection devices)?	

Laser Exposure Medica	al Documentation: Initial Provider Evaluation	
Presenting Symptoms	Reported symptoms may include: blurred vision, headache, blind spots, shadows, eye pain, eye irritation/burning, etc.	
Time since exposure	How long ago was the exposure?	
Duration of symptoms	Seconds, minutes, hours, ongoing	
Medical/Ocular History	Previous visual function (baseline vision as available (i.e. glasses use)	
	Previous ocular history	
	History of refractive surgery	
	Current medications	
Social History	Tobacco use	
	Examination	
Element	Description	Result
Laterality (OD/OS/OU)	Every visit. Document affected eye(s)	
Visual Acuity (best corrected)	Accomplished at every visit.	
Amsler grid* testing	Accomplished at the initial visit, and at follow-up for previously documented abnormality or where new symptoms are disclosed ; document abnormalities or "normal" in each eye	
Color Vision testing	Accomplished at the Initial visit, and at follow-up for previously documented abnormality or where new symptoms are disclosed performed at follow-up if new abnormality; document abnormalities or "normal" in each eye computerized color vision testing, monocular, with red, green, blue cone testing individually preferred if available (pseudoisochromatic plates are not considered adequate for this testing, but may be used for initial screening)	
Pupils	Document size, shape, and reactivity	
External eye	Evaluate for irritation, burns, corneal opacities; Document abnormalities or "normal" in each eye	
Retinal evaluation	Accomplished at the earliest role of care with available technology. Repeat testing should be done to monitor for progression based on the clinical situation.	
Ocular Coherence Tomography (OCT	Flight Surgeons complete additional evaluation and testing required for aviation personnel based on training and Service-specific guidelines.	
Automated Visual Field (VF)	Accomplished at the earliest role of care with available technology. Repeat testing should be done to monitor for progression based on the clinical situation.	

#### APPENDIX C: ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

#### PURPOSE

The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of "off-label" uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

#### BACKGROUND

Unapproved (i.e. "off-label") uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing "investigational new drugs." These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.

#### ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the "standard of care." Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

## ADDITIONAL PROCEDURES

#### **Balanced Discussion**

Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

#### **Quality Assurance Monitoring**

With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

#### **Information to Patients**

Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.