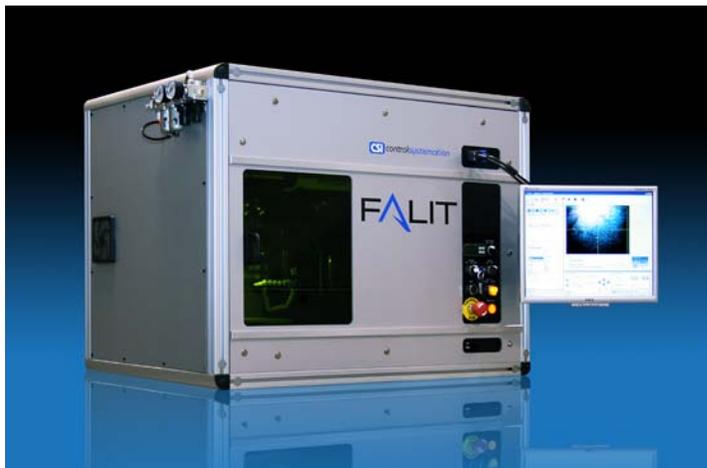


# FALIT



## CDRH REQUIREMENTS GUIDE



**Control Systemation Inc.**

2419 Lake Orange Drive, Orlando, FL 32837

Phone: (407) 926-3500 Fax: (407) 926-3590

[www.controlsystemation.com](http://www.controlsystemation.com)

# INTRODUCTION

This guide covers the CDRH requirements and safety standards that must be met in compliance when using the FALIT Laser System. Diagrams and drawings may be included to assist in the description of components and layout of the FALIT.

## **!! WARNING !!**

It is extremely important to read and understand the Safety section before attempting to operate the FALIT laser system.

Control Systemation Inc. (CSI) welcomes suggestions for future editions of this guide. Please send your comments to:

Attention: Marketing  
Control Systemation Inc.  
2419 Lake Orange Drive  
Orlando, Florida 32837

E-mail: [csisales@controlsystemation.com](mailto:csisales@controlsystemation.com)

Please contact the Field Service department for information regarding the maintenance of the FALIT.

Phone: 407-926-3562, Monday through Friday 8:00 a.m. to 5:00 p.m. EST  
Fax: 407-926-3590, 24 hours a day, seven days a week  
E-mail: [csiservice@controlsystemation.com](mailto:csiservice@controlsystemation.com)

For information about CSI, visit our website at [www.controlsystemation.com](http://www.controlsystemation.com).

# TECHNICAL SUPPORT DIRECTORY

## **Field Service Support**

A qualified maintenance technician should troubleshoot the laser system before contacting the Field Service department. Attempting to isolate the source of the problem will make it easier for the field service technician to assist you. Have the model name and serial number of the laser available when you contact Field Service. This information is located on the supplied Data Sheet for the system.

## **Support by Phone**

The Field Service department can be contacted at (407) 926-3562, Monday through Friday, 8:00 a.m. to 5:00 p.m. Eastern Time. After 5:00 p.m., an answering service will take your message and notify a field service technician of your requirements by the next business day.

## **Support by Fax**

The Field Service department can be contacted by fax at (407) 926-3590, 24 hours a day, including weekends. Faxes received after business hours and on weekends will be responded to the next business day.

## **Support by E-mail**

The Field Service department can be contacted by e-mail at [csisupport@controlsystemation.com](mailto:csisupport@controlsystemation.com).

## **Support by Website**

Visit our website at [www.controlsystemation.com](http://www.controlsystemation.com) to learn more about Control Systemation Inc. (CSI), our laser products, and various applications.

## SERVICE AND MAINTENANCE PROGRAMS

The Field Service department offers several service and maintenance programs that provide expert on-site support from factory trained representatives. Programs may be purchased on a quarterly or annual basis. Contact Field Service for details at (407) 926-3562 or [csisupport@controlsystemation.com](mailto:csisupport@controlsystemation.com).

## ADVANCED MAINTENANCE TRAINING SEMINARS

Advanced maintenance training seminars are held periodically on-site at CSI. Contact Field Service for enrollment information at (407) 926-3562 or [csisupport@controlsystemation.com](mailto:csisupport@controlsystemation.com)

## PARTS REPAIR / SPARE PARTS

If a laser component fails, contact Field Service immediately. Most repairs can be accomplished within 24-48 hours upon receipt of the component. Some power supply units may take additional time to replace/repair because they may require outside vendor participation.

Before returning any parts to CSI for repair/replacement contact Customer Service at (407) 926-3562. You will be supplied with a Return Material Authorization (RMA) number used to track the part during repair and shipping.

Return all components to CSI by United Parcel Service (UPS), Federal Express, or any local carrier that can track your package to:

Attention: (Use your RMA # here)  
Control Systemation Inc.  
2419 Lake Orange Drive  
Orlando, Florida 32837

## REPLACEMENT AND SPARE PARTS

In North America, replacement and spare parts must be ordered directly through CSI. Parts can be shipped overnight at the customer's request. Spare part kits and test equipment kits are also available.

To order parts or a current parts catalog, contact Customer Service at Control Systemation:

Attention: Customer Service  
Control Systemation Inc.  
2419 Lake Orange Drive  
Orlando, Florida 32837

Telephone: (407) 926-3562  
Fax: (407) 926-3590

# SAFETY 1

## Recommendation

Control Systemation Inc. (CSI) recommends the Safety chapter be read thoroughly by all personnel before operating or performing maintenance on the FALIT Laser System.

## Compliance Statement

The FALIT is certified by Control Systemation Inc. as a Class IV product in accordance with Title 21, Code of Federal Regulations, Subchapter J, (21 CFR), and European Standard EN 60825:1992.

Compliance may be verified by contacting:

Office of Compliance (HFZ-312)  
Center for Devices and Radiological Health  
US Department of Health & Human Services  
2098 Gaither Road  
Rockville, MD 20850  
Telephone: (301) 594-4654

## Laser Radiation Wavelength

The FALIT emits infrared laser (IR) radiation at 1,062 nanometers (nm). The IR laser poses the greatest risk of injury if the safety precautions in this guide are not followed. The specifications in the following chart are provided to assist the Laser Safety Officer (see Responsibility of the Laser User on page #6) in evaluating the hazard potential of the laser. These specifications represent the “worst-case” potential for short-term, peak laser emission.

## Protective Eyewear

Recommended Optical Density for Eyewear:  
FALIT Laser System (IR) - 6

Eye protection (goggles or spectacles) must be worn while the FALIT laser is in operation. Exposure to laser radiation may produce eye damage and physical burns. Combustible materials may also be ignited. **Never** look directly into the laser beam path or view it through specular reflection such as glossy materials including metals, glass, items of jewelry. Avoid placing such materials near the beam path.

## Responsibility of the Laser User

The performance requirements are defined by the United States government and the European Union as the responsibility of the laser manufacturer. The responsibility of the user is the safe use of the laser defined in ANSI Z136.1; the American National Standard for the Safe Use of Lasers; and Section Three of EN 60825 - Radiation safety of laser products, equipment classification, requirements, and user's guide.

These standards require the user to appoint a Laser Safety Officer to oversee the use of this equipment. This individual shall have the authority and responsibility to evaluate, monitor, and enforce the control of laser hazards. See the appropriate standard: ANSI Z136.1 in the United States of America and Section Three of EN 60825 in the European Union for the specific responsibilities of the Laser Safety Officer.

ANSI Z136.1 is issued by the American National Standards Institute (ANSI) as a recommended safety guide for the use of laser products in the United States of America. ANSI cannot enforce adherence to the guide. However, OSHA, the Occupational Safety and Health Administration, uses the guide as its inspection standard when it inspects workplaces that use lasers. Therefore, the guide carries the authority of the United States government. It is recommended the procedures outlined in the guide be followed when operating the FALIT and the user contact local and state authorities to determine if any additional regulations may apply.

ANSI Z136.1-2000 may be ordered from:

Laser Institute of America (LIA)  
13501 Ingenuity Drive  
Suite 128  
Orlando, FL 32826-3009  
Telephone: 407-380-1553  
Fax: 407-380-5588  
[www.ANSI.org](http://www.ANSI.org)

EN 60825 is issued by the European Committee for Electrotechnical Standardization (CENELEC) as a safety standard for the manufacture and use of laser products in the European Union. It is enforced individually by the government of each member country of the European Union. For more information, please use the address, phone number, and/or web site below.

CENELEC  
35, Rue de Stassartstraat  
B-1050 Brussels, Belgium  
Tel: +32 2 519 68 71  
Fax: +32 2 519 69 19  
[www.cenelec.org](http://www.cenelec.org)

## Performance Requirements

21 CFR and EN 60825 specify certain performance requirements (features) that must be incorporated into or provided with each laser product for radiation safety purposes. These features with an explanation of their function in the FALIT are described in the following sections.

### !! WARNING !!

Any action which disables, modifies, defeats, or otherwise alters the function or operation of any of the performance requirements automatically voids the Class 1 certification stated above, and places responsibility for compliance with 21CFR and EN 60825 upon the person or organization taking such action.

## 1. Protective Housing

**The laser radiation emitted by a Class IV laser product must be contained within a protective housing at all points where access to radiation is not required during normal operation of the product in the performance of the function for which it was designed. [21 CFR 1040(f)(1) and EN 60825, 4.2].**

Laser radiation generated by the FALIT Laser System originates in the laser module, a sealed unit inside the enclosed head assembly that is not accessible to the user. The assembly, which focuses and manipulates the laser beam at the piece to be lased, is mounted at the end of the head assembly. Laser radiation is completely contained within the enclosed head assembly except where it exits the assembly to impact the piece to be lased. In the standard configuration, laser radiation is emitted downward from the assembly.

The Class 1 workstation consists of a base frame that is covered with panels. It has a door that permits access to the interior. The laser head assembly is mounted on top of the base frame inside the work enclosure.

### !! WARNING !!

The FALIT Laser System must never be run during normal operation with any part of the protective housing open, removed, or displaced.

## 2. Safety Interlocks

**Any part of the protective housing that must be opened, removed or displaced during normal operation of the laser must be interlocked to prevent access to laser radiation. [21 CFR 1040.10(f)(2) and EN 60825,4.3].**

The access door to the work enclosure is protected by two magnetic reed switches, which cause the safety shutter to close and terminate lasing from the FALIT Laser System laser when the door is open. The switch is attached to the enclosure frame, and the actuating magnet is attached to the enclosure door (Figure 1-1). Opening the door releases the switch contacts, removing electrical power from the safety shutter, causing the shutter to close. The use of dual interlock switches provides redundancy, which ensures continued functionality of the interlock circuit in the event of failure of one of the switches.

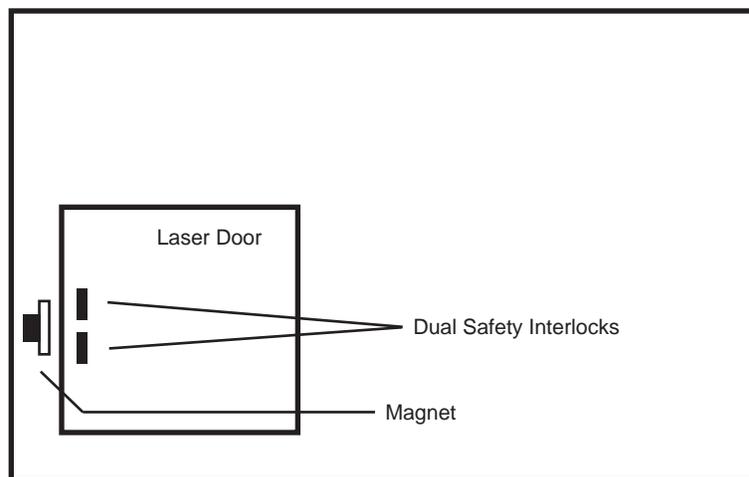


Figure 1-1: Safety Interlock Locations

The interlocks should be tested at least once per week to verify that they are still functional. To test the interlocks, hold the magnet next to only one of the magnetic reed switches and initiate a command to open the shutter. If the shutter opens, the other switch is faulty and must be replaced. Repeat the test with the second switch.

### !! WARNING !!

The interlocks must remain functional at all times during normal operation of the FALIT Laser System. If the interlocks must be turned off during an authorized service functions, such as optical alignment, laser eyewear with that is made for an optical density (OD) of 6.0 at the wavelength of 1,064 nanometers must be worn.

### 3. Beam Attenuator

**A beam attenuator (safety shutter) is not required on Class 1 laser products; however, a shutter is used on the FALIT Laser System in conjunction with the protective housing interlocks to interrupt lasing when the housing is open. [21 CFR 1040.10 (f)(6) and EN 60825, 4.7].**

The safety shutter for the FALIT Laser System marking laser is located inside the laser rail assembly, and is actuated by the switch on the control panel. The enclosure access door interlock switches inhibit safety shutter operation when the door is open. The shutter terminates lasing by blocking the laser beam path and preventing emission of laser radiation out of the laser rail assembly and into the main enclosure. The shutter does not terminate lasing from the laser diode. The shutter should be functionally tested each time the laser is turned on by placing a fire brick or similar beam absorbing material under the output optics, and initiating a START WRITE command. Contact the Control Systemation Field Service Department immediately if the shutter does not operate. Do not operate the laser if the shutter is inoperable!

## !! WARNING !!

Even though the shutter may be blocking the path of the beam, the laser may still be running. Always exercise caution when using the laser with either the shutter in the On or Off positions at all times.

### 4. Master Key Control

**Even though not required for a Class 1 laser, a master key control is provided on the main control panel to enable and disable operation of the FALIT Laser System. The key can be removed from the switch only in the OFF position, and when removed, the laser is disabled. [21 CFR 1040.10(f)(4) and EN 60825, 4.5].**

## !! WARNING !!

The key should be given only to personnel authorized by the Laser Safety Officer to operate the FALIT Laser System laser. The laser should never be left unattended while it is running, or while the key is available and not under the control of an authorized person.

## 5. Location of Controls

**Controls which are necessary for operation of the laser must be located so they can operate without exposure to laser radiation. [21 CFR 1040.10 (f)(7) and EN 60825, 4.8].**

All of the controls used to operate the FALIT are located outside the workstation enclosure (see Figure 1-2). The functions of the controls and indicators on the FALIT Laser System are explained below.



Figure 1-2: Location of Controls

*Left to Right (Top to Bottom)*

**Cold Plate Temperature Control:** Adjustments to the temperature of the internal cold plate can be manually controlled using this display.

**Cold Plate On/Off Switch:** Turns power to the Cold Plate On or Off.

**System Keyswitch:** The keyswitch has three positions -

Power Off - Turns the laser off. The key can be removed only in this position.

Control On - Activates the laser computer system. The FALIT Laser System software can be run in this state.

Laser Start - Activates the laser power supply and internal cooling system.

**Lights On/Off Switch:** The internal light source (mainly used for the vision system) can be manually turned On or Off.

**Reset Button:** From a cold startup, press the RESET button before turning the Key-switch to the ON position.

**Shutter Switch:** Turn the safety shutter switch to the CLOSE position to close the safety shutter and terminate lasing from the FALIT Laser System laser. (The safety shutter does not terminate lasing from the laser diode). Turn the switch to the OPEN position to open the safety shutter and enable lasing.

**Emergency Stop:** The Emergency Stop switch is for emergencies only. It will shut off all safety items in case of an emergency (See Addendum: Start Up and Shut Down Procedure at the end of this document).

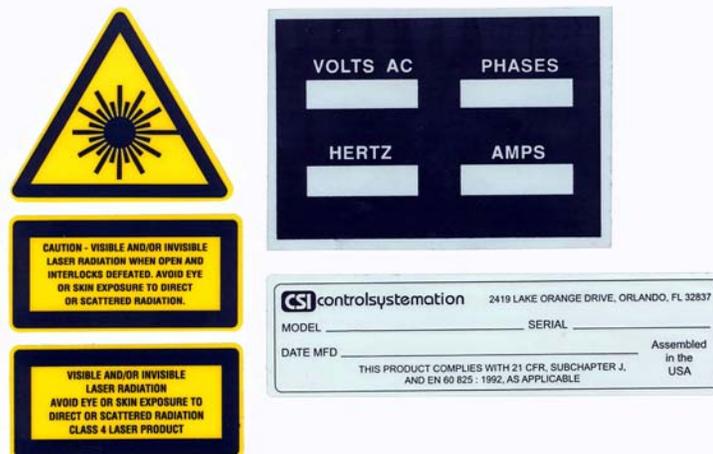
Warning: This can degrade the diodes by shutting the laser and the cooling system down before the diodes have cooled down. The normal shut down procedures will allow the proper cooling before the laser shuts down.

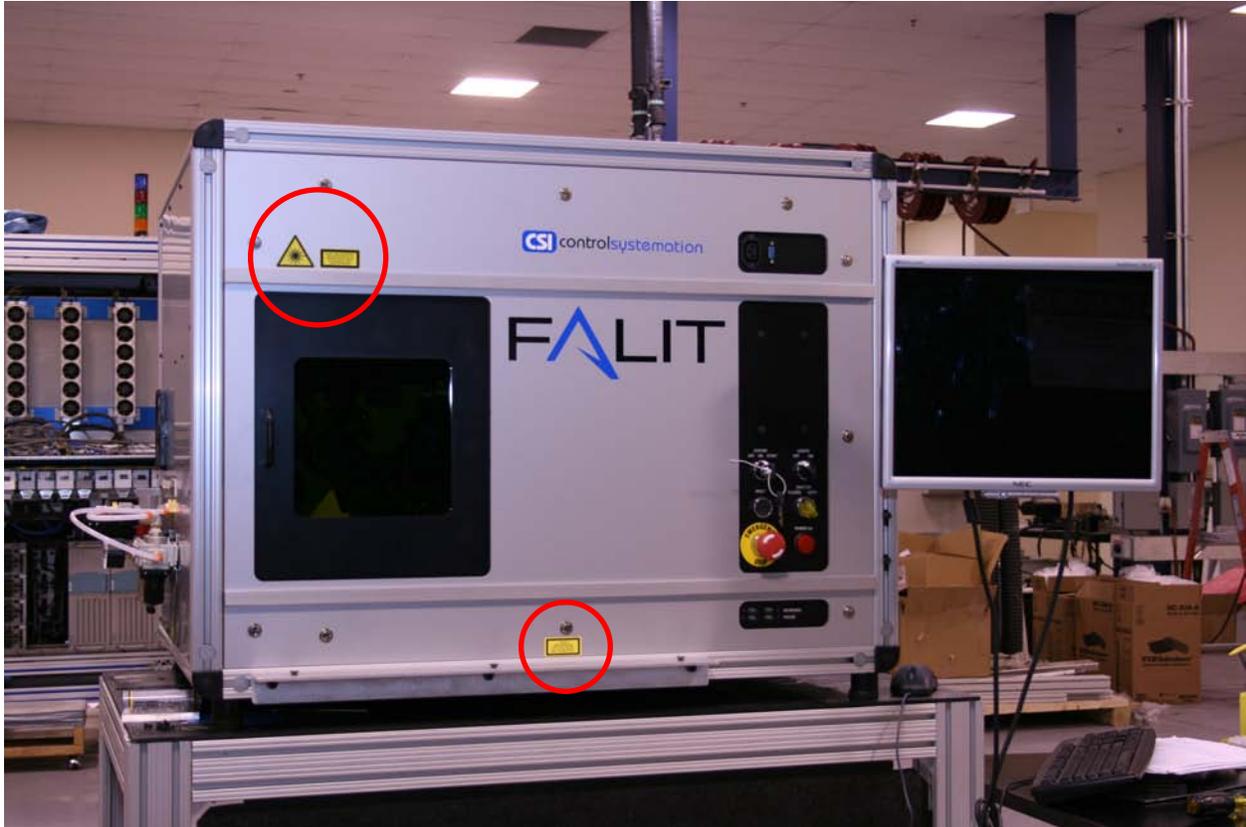
**Power On Indicator:** This light illuminates to indicate that the laser system is capable of emitting laser radiation.

## 6. Labeling

Labels must be affixed to each laser to identify the manufacturer, certify compliance with 21 CFR and EN 60825, provide warnings to the user about the wavelength, level, and location of accessible laser radiation present, and give precautions that should be taken to avoid exposure to the laser radiation. [21 CFR 1040.10(g) and EN 60825, 5].

Under regulations established by the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration, the FALIT laser systems are Class 1 laser products. In compliance with regulations, the locations of the warning labels affixed to the laser are shown on Page #12. Each label is assigned an alphabetical designator. Reproductions of the labels along with corresponding designators are also depicted.





## 7. Documentation

**Instructions must be provided that will enable the user to safely operate and maintain the laser. [21 CFR 1040.10(h) and EN 60825, 6.1].**

It is recommended that the supplied manuals be thoroughly studied by all personnel who have any responsibility for the laser prior to operation. The Operations manual gives instructions for proper operation and maintenance of the FALIT. The manual also provides warnings and cautions that must be observed by the user to prevent unnecessary exposure to laser radiation.

## CLASSIFICATION OF LASER FUNCTIONS

Laser products are classified according to the maximum level of laser radiation within human access during operation only. Levels accessible only during maintenance or service do not affect the classification. Therefore, it is possible for class I or class II products to contain class IV lasers. It is the responsibility of the manufacturer to determine whether specific functions are operation, maintenance, or service. The following definitions apply:

**Operation** - Consists of functions by which the product accomplishes its intended purpose. These may include loading workpieces or documents and setting and manipulating external controls.

**Maintenance** - Consists of functions performed by the user to assure performance. These may include cleaning and replacement of expendables.

**Service** - Usually means repair. Service may be performed by specially trained service personnel or by sophisticated users following instructions specifically indicated as service instructions. Certain maintenance procedures will be considered service if they are infrequent, complex, or highly specialized.

The following chart lists the functions of operation, maintenance, and service associated with the FALIT laser system described in this manual.

### !! WARNING !!

All personnel in the vicinity of the laser while it is in operation must follow all prescribed safety procedures and use appropriate safety equipment. This includes wearing laser eyewear with an optical density (OD) as recommended on **page 5**. Failure to follow these instructions may result in the exposure of personnel to hazardous laser radiation.

## Classification of Laser Functions

Function	Classification	Requires Lasing
Operation of Laser Controls	Operation	Yes
Cleaning Optics	Maintenance	No
Replacements of Electrical Assemblies & Components	Service	No
Replacement of Mechanical Components	Service	No
Replacement of Optical Components	Service	No
Troubleshooting & Repair	Service	See Note
Testing Following Repair	Service	See Note
Optical Alignment/Adjustment	Service	Yes
Programming	Service	No
Connections to Remote Interlock Connector	Service	No
Setup/Fixture Alignment	Service	No
Test Marking (following repair, programming, setup)	Service	Yes

**NOTE:** Some troubleshooting and testing functions will not require the laser to be lasing.

## ELECTRICAL SAFETY

- Disconnect main power line(s) before working on any electrical equipment if it is not necessary for the equipment to be operating.
- Disconnect main power line(s) before changing the laser lamp.
- After disconnecting power, wait at least five minutes for the capacitors to discharge through the bleeder resistors before touching any electrical equipment.
- Do not short or ground the power supply output. The power supply is not electrically isolated from the power line. Protection against possible hazards require proper connection of the ground terminal on the power cable and an adequate external ground. Check these connections at the time of installation and periodically thereafter.
- Never work on electrical equipment unless there is another person nearby who is knowledgeable of the operation and hazards of the equipment and who is competent to administer first aid.
- When possible, keep one hand away from the equipment to reduce the danger of current flowing through the body.
- Always use approved, insulated tools when working on high-voltage circuits.
- Special measurement techniques are required for this system. Ground references must be selected by a technician who has a complete understanding of the system operation and associated electronics.

## ESD (ELECTROSTATIC DISCHARGE) PROTECTION

Connect the M-BNC RF cable in the umbilical cable exiting the DPSS Power Supply/Cooler to the Q-Switch F-BNC connector located on the Laser head. (This provides an initial DC return path between the Laser head and the DPSS Power Supply Cooler.)

The Power Supply/Cooler incoming AC service cable must be connected to the electrical utility service to provide an Earth Ground. The incoming AC service is in the OFF POSITION.

Using a conductive wrist strap and conductive floor mat, remove the ESD electrical jumper, connect the D connector in the umbilical cable from the Power Supply Cooler to the Laser head. Secure the two retaining fasteners at the D connector to the Laser head.

If a conductive wrist strap and conductive floor mat is not available one may place one hand in contact with the metallic portion of the RF BNC connector and proceed as above.

## USE OF COMBUSTIBLE MATERIAL

### !! WARNING !!

A fire or explosion could occur if the laser beam is allowed to contact flammable or combustible materials. Care must be taken to ensure that such materials are kept away from any part of the laser beam path.

## OPTISHIELD

The Hazardous Materials Index Rating is as follows:

Health = 1; Flammability = 0; Reactivity = 1

### Fire and Explosion Hazard

Non-Flammable

Flash Point: Unknown

### Physical Data

% Volatiles: Nil

Color: Light Yellow to Clear Liquid

Odor: Mild

Specific Gravity: 1.02

Solubility: 100% in water

pH of 100% solution (concentrated) 8 to 10; typical 8.5

### Reactivity Data

Stability: Stable

Polymerization: None

Exposure to Other Chemicals: Keep away from concentrated acids

Reactivity in Water: None

### First Aid

Ingestion: Give milk or water, induce vomiting, get medical attention.

Skin: Flush with fresh water, wash with soap and water. Remove contaminated clothes and shoes.

Eyes: Flush with fresh water for at least 15 minutes: get medical attention.

Inhalation: Inhalation should not occur during normal operation. However, should it occur, close container and move to well ventilated area. If irritation persists, get medical attention.

### Special Instructions

Do NOT pressurize container.

Keep container closed at all times when not in use.

Store in cool area above 60 degrees F. Do not allow fluid to freeze.  
Use in well ventilated area. Do not breathe mist or vapor.  
Wash hands thoroughly after handling product.  
Protect eyes with safety goggles or glasses with side shields.

## LASER HAZARDS

There are some highly dangerous laser hazards that should be considered when operating a laser. The collimated beam direct from the laser head or a mirror (without any focusing optics) contains sufficient heat energy to damage eyes, skin, or flammable materials for a considerable distance (possibly hundreds of feet or more) from the source. The focused beam contains much higher power density for marking, cutting or welding, but it is present only in a very localized area near the beam focus. Past the focus, the beam pattern expands significantly, and there is a distance beyond which the power spreads over an area that is so large that the laser beam is no longer hazardous.

### Eye Injury

Because of the high degree of beam collimation, a laser serves as an almost ideal point source of intense light. A laser beam of sufficient power can theoretically produce retinal intensities at magnitudes that are greater than conventional light sources, and even larger than those produced when directly viewing the sun. Permanent blindness can be the result.

### Thermal Injury

The most common cause of laser-induced tissue damage is thermal in nature, where the tissue proteins are denatured due to the temperature rise following absorption of laser energy.

The thermal damage process (burns) is generally associated with lasers operating at exposure times greater than 10 microseconds and in the wavelength region from the near ultraviolet to the far infrared (0.315  $\mu\text{m}$ -103  $\mu\text{m}$ ). Tissue damage may also be caused by thermally induced acoustic waves following exposures to sub-microsecond laser exposures.

With regard to repetitively pulsed or scanning lasers, the major mechanism involved in laser-induced biological damage is a thermal process wherein the effects of the pulses are additive. The principal thermal effects of laser exposure depend upon the following factors:

- 1) The absorption and scattering coefficients of the tissues at the laser wavelength
- 2) Irradiance or radiant exposure of the laser beam.
- 3) Duration of the exposure and pulse repetition characteristics, where applicable.
- 4) Extent of the local vascular flow.

- 5) Size of the area irradiated.

### **Toxic Injury**

Fumes generated from cutting some plastics and other materials can be highly toxic. Any materials being processed should be evaluated to determine what fume collection and filtering are needed to ensure that the Threshold Limit Values (TLVs) for the byproducts are not exceeded.



**Control Systemation Inc.**

2419 Lake Orange Drive, Orlando, FL 32837 Phone: (407) 926-3500 Fax: (407) 926-3590  
[www.controlssystemation.com](http://www.controlssystemation.com)

