



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
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TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Discussion of Safety Interlock Requirements and Concepts for Meeting These Requirements, 21 CFR 1040.10(f)(2)

BACKGROUND AND QUESTION: Several manufacturers have asked for elaboration on the safety interlock requirements of the Federal performance standard for laser products (21 CFR 1040.10(f)(2)), for an explanation of how the various interlock requirements relate to one another, and for a functional description of how interlocks may perform in order to satisfy these requirements. Manufacturers have also asked for confirmation whether interlock concepts which they propose to use in their products function as required.

RESPONSE: The Federal Performance Standard for Laser Products, 21 CFR 1040.10 and 1040.11, is applicable to all laser products manufactured on or after August 2, 1976, except as noted. The standard includes a requirement that safety interlocks be provided for each portion of protective housings designed to be removed or displaced during operation or maintenance, if removal or displacement could permit human access to laser or collateral radiation in excess of the limit of the lowest class necessary for the performance of the intended function of the product.

Safety interlocks must satisfy the following criteria in order to comply with the standard:

1. Prevent human access to the laser or collateral radiation upon removal or displacement of the interlocked portion of the protective housing.
2. Preclude removal or displacement of the interlocked portion of the protective housing upon failure of the interlock to prevent human access to the laser or collateral radiation in excess of the required limit.
3. If defeatable, provide an indication of defeat.
4. When defeated, preclude replacement of the removed or displaced portion of the protective housing.

In response to several requests for clarification, several conceptual techniques are discussed for satisfying those requirements. A few specific examples will be given; each will be traced through the requirements with an explanation of how the example complies or fails to comply. In addition, consideration will be given to possible modes of failure which fail to prevent human access to laser or collateral radiation.

1. Prevent human access to the laser or collateral radiation upon removal or displacement of the interlocked portion of the protective housing. For a given product, various schemes may be visualized which will satisfy this requirement. Electrical interlock switches are well known and widely used. For many products the ideal circuit location may be in the primary power lines, however, for others this may be very inappropriate. A non-electrical interlock may be better suited to other products; such may be the case for laser pumped dye lasers. Note, too, that this does not dictate that the interlock must interrupt operation of the laser, but merely prevent access; prevention of access may be more suitably accomplished by introduction of a baffle (or shutter) as the protective housing is removed or displaced.

a. Electrical interlock switches may be conveniently located in proximity to access doors and panels. Such switches may be actuated by the door, panel, or a latch which actuates a leaf spring, push-button or plunger. The switch may be located in a power or control circuit, or may operate a solenoid shutter or baffle in order to prevent human access to radiation upon movement of the protected portion of the housing or latch.

Failure modes that must be considered include:

Failure of the switch contacts to "break or make" upon actuation (switches are more commonly used in a "normally open" mode and are closed by the closure of the housing or operation of the latch. In this case failure to make contact would not be considered a failure in the sense of preventing access to radiation. This is not to imply that there may not be situations in which "normally closed" operation is more suitable); and

Failure of another component although the switch performed as intended (the switch may control the input to a control component - transistor, thyristor or vacuum tube. Such components and their failure modes must be considered part of the interlock).

b. Plug type interlocks such as those used on television sets are very familiar. In the case of television sets the primary electrical power is delivered to the product by a plug which is integrally mounted to the portion of the housing that is to be removed for access to the interior of the set. Removal of the back cover of the set removes all electrical power. The tele-

vision interlock is but one example of this type of interlock. Other types may mount only a portion of a circuit on the removable portion of the housing, while other types may employ a single prong plug to complete a circuit. As with switches, plug interlocks should be placed in the most suitable location and in the most suitable portion of the circuit of the specific product.

Failure modes to be considered include short circuits and other interlock circuit component failures as above.

Since plug type interlocks are likely to require more individual design than switch types, the laser product manufacturer is cautioned to consider the durability of his design and its ability to perform its required function over the useful life of the product.

Latching switches which employ contacts integrally mounted on a latch, so that the latch not only secures the access but also completes the circuit, should be considered an extension of the plug type. Component switches that are actuated by a latch are considered as merely electrical interlock switches (l.a.); only the actuating mechanism is different in this case.

c. Mechanical interlocks use baffles or shutters which may operate in various ways to prevent access to radiation. They can block the radiation from entering the area made accessible by removal of the housing, frustrate a laser cavity, remove an integrally mounted optical component, insert an attenuator, and so forth. Sturdiness of design and component failure modes must be considered.

2. Preclude removal or displacement of the interlocked portion of the protective housing upon failure of the interlock to prevent access. In the determination of the adequacy of an interlock, consideration must be given to all modes of failure which might fail to prevent access. Sticking of a push button or leaf actuator, shorting or welding of switch contacts, failure of another component in an interlock circuit, or a mechanical jamming of a shutter may result in failure to preclude human access to radiation when the housing is removed or displaced. All these modes of failure must be considered when designing an interlock system which will preclude removal or displacement of the interlocked portion of the protective housing upon interlock failure.

a. Electrical interlock switches are subject to all of the failures noted, and therefore, by themselves are inadequate to satisfy the requirement. In order to furnish this level of safety, such switches must be used in conjunction with other devices. For example, the circuit may include an electrically operated latch which keeps the housing secured until the electrical circuit is interrupted by opening of the contacts of the interlock switch or the cessation of laser radiation.

b. Plug type interlocks are not subject to as many types of unsafe failure as switches. Compliance with the prevent access or preclude removal criteria (21 CFR 1040.10(f)(2)(i)(b)) is in general more readily achieved with a plug than a switch interlock. Provided the plug is securely and permanently attached to the housing, sticking or shorting of the contacts will hold the housing in place, and preclude removal. Proper design can preclude socket short circuits or mechanical failure.

c. Mechanical interlocks typically employ a permanent mechanical linkage between the means to prevent access and the protected portion of the housing. As such, sturdiness of design may be sufficient to prevent displacement or removal of the housing in the event of jamming of the shutters or beam blocks.

3. If defeatable, provide an indication of defeat. Before explaining how this criterion may be met, it is necessary to define what is meant by defeatable. Any interlock system, regardless of its complexity, can be defeated by a person with sufficient motivation and cleverness. Therefore, an interlock system will not be considered defeatable merely because such persons may be able to defeat it. For the purpose of determination of compliance, an interlock may be considered to be designed to allow defeat: if its method of defeat is self evident, e.g., pushing a button or leaf spring, installing a clip lead across obvious switch terminals, pulling out a "pull to defeat" plunger, etc., or if instructions for procedures to defeat are contained in the user or service information.

An adequate indication of defeat may be audible or visible, or active or passive, as appropriate to the product.

a. Electrical interlock switches, when defeated, may contain an inherent indication of the condition of defeat. The indication must be clear in its meaning and appropriate for the product and its operating environment. In many cases, the presence of a particular sound level associated with operation may be an obvious indication. However, the visibility of a piece of tape holding a leaf spring depressed, or a clip lead, may not be a clear indication.

b. Plug type interlocks generally require the use of an auxiliary plug or cable for defeat. A familiar example is the television service power cable which permits the set to be operated for testing with the cover removed. The external cable is a visible indication in this case. If the plug merely completes a circuit, a shorting plug may be used for defeat. Any such plug must be readily seen and be clear in meaning when installed.

c. Mechanical interlocks may incorporate integral "flags" which indicate defeat. Alternatively, defeat may be accomplished by means of the installation of a tool which must give suitable indication of defeat.

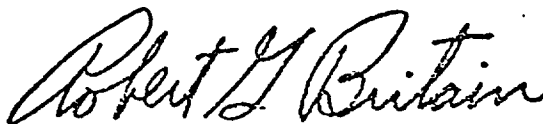
4. When defeated, preclude replacement of the removed or displaced portion of the protective housing. This criterion requires either that the attempted replacement of the housing automatically resets the defeated interlock so that it will prevent human access to radiation the next time the housing is displaced, or that the defeated interlock interferes with the replacement of the housing.

a. Electrical interlock switches may or may not satisfy this criterion. "Pull to defeat" plunger switches generally provide this function and are reset by the replacement of the housing. A tape or clip lead defeated switch would probably fail to comply. If, however, a monitor was used to electrically operate a latch, the latch may impede the replacement of the housing and satisfy this criterion.

b. Plug type interlocks can generally be designed so that they satisfy this criterion. For example, the back of the television set cannot be replaced when the service cable is in place. If a shorting plug is used, it should be of sufficient size to interfere with the replacement of the housing, and in any case would probably do so by preventing seating of the housing mounted portion of the interlock.

c. Mechanical interlocks can be designed to satisfy this criterion. Mechanical shutters which can be reset by replacement of the housing should be used. If a defeating tool is used, it should be of sufficient size to interfere with replacement of the housing.

Please note in conclusion that mention has been omitted of portions of a protective housing which are intended to be removed or displaced for service only. The performance standard requires safety interlocks for access during operation or maintenance. Access, for service only, may be protected by means of either a safety interlock (one meeting the requirements of 21 CFR 1040.10(f)(2)) or a warning label. Attention is directed to 21 CFR 1040.10(g)(6), (7), (8), (9) and (10) for the contents of labels required for portions of a protective housing which may be removed or displaced for operation, maintenance or service.



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