**SUSPICIOUS LASER PRODUCT PROTOCOL** (**SLaPP**)

This form contains a self-directed documentation process which assists in the disposition of laser-based products which appear to be non-compliant.

|  |  |
| --- | --- |
| **Person Completing Form/POC** |  |
| **Organization** |  |
| **Address** |  |
| **City, State, Zip** |  |
| **Phone/FAX/Email** |  |
| **Product Description** |  |
| **Model/Stock Number/Serial No** |  |
| **Manufacturer** |  |
| **Address** |  |
| **Phone/FAX/Email** |  |
| **Purchase Price** |  |
| **Purchase Date/Delivery Date** |  |
| **Third Party Assembler/POC** |  |
| **Organization** |  |
| **Address** |  |
| **City, State, Zip** |  |
| **Phone/FAX/Email** |  |

Upon suspicion of non-compliance and/or safe laser device or product, complete the following steps. POC **must** initial each step, supervisor/manager **must** sign completed form.

|  |  |  |  |
| --- | --- | --- | --- |
| **STEP ID** | **TASK** | **COMPLETED**  (POC Initials) | **NOTES** (keep track of call dates/times with vendors) |
| **01** | **DEACTIVATE/REMOVE POWER FROM PRODUCT**- This includes physical separation of power cords and batteries from product | \_\_\_\_\_\_\_\_\_\_ |  |
| **02** | **SEQUESTER INTO A SECURE AREA**- Transfer into an appropriate area or container and secure with lock. | \_\_\_\_\_\_\_\_\_\_ |  |
| **03** | **CREATE ISOLATED SECURE AREA TO PERFORM TESTS**- Create and isolate into a Laser Controlled Area (LCA) | \_\_\_\_\_\_\_\_\_\_ |  |
| **04** | **TAKE PICTURES**- Take pictures to document device or product- do so with a scaling element in frame | \_\_\_\_\_\_\_\_\_\_ |  |
| 04a | **Front** (port aimed camera) | \_\_\_\_\_\_\_\_\_\_ |  |
| 04b | **Rear** (port aimed away from camera) | \_\_\_\_\_\_\_\_\_\_ |  |
| 04c | **Top** (port on right side) | \_\_\_\_\_\_\_\_\_\_ |  |
| 04d | **Right Side** (port on right side) | \_\_\_\_\_\_\_\_\_\_ |  |
| 04e | **Left Side** (port on left side) | \_\_\_\_\_\_\_\_\_\_ |  |
| 04f | **Other** (any other photos to capture safety issues) | \_\_\_\_\_\_\_\_\_\_ |  |
| **05** | **TAKE MEASUREMENTS**  Using appropriate Photometer-based test equipment, and as stipulated by 21CFR1040.10/.11 (e- Tests for determination of compliance) and/or IEC/EN60825 (Section 5- Determination of the accessible emission level and product classification), test emission five (5) times | \_\_\_\_\_\_\_\_\_\_ | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | **Mfg** | **Model** | **Stk #** | **S/N** | **Cal Date** | | **Meter** |  |  |  |  |  | | **Sensor** |  |  |  |  |  | |
| 05a | Test Data Point 01 | \_\_\_\_\_\_\_\_\_\_ |  |
| 05b | Test Data Point 02 | \_\_\_\_\_\_\_\_\_\_ |  |
| 05c | Test Data Point 03 | \_\_\_\_\_\_\_\_\_\_ |  |
| 05d | Test Data Point 04 | \_\_\_\_\_\_\_\_\_\_ |  |
| 05e | Test Data Point 05 | \_\_\_\_\_\_\_\_\_\_ |  |
| **06** | **MAKE DETERMINATION**  Does the product emit what was advertised (and is stated on labeling and documentation?)  Are the labels correct and in the proper locations (should show in photos captured in **04**  If BOTH YES, then introduce into organization with the proper tracking and cognizance (supervisor/manager signature in Notes section). If not, continue to **07** below. | ◎YES ◎NO  ◎YES ◎NO  \_\_\_\_\_\_\_\_\_\_ |  |
| 06a | Pictures of labeling | \_\_\_\_\_\_\_\_\_\_ | |  |  |  |  | | --- | --- | --- | --- | | **Mfg** | **Conformity** | **Warning Logotype** | **Aperture** | |  |  |  |  | |
| **07** | **NOTIFY THIRD PARTY ASSEMBLER, DISTRIBUTOR AND/OR VENDOR**  Let the assembler/distributor/vendor know the product, as you have determined, is NOT compliant to US and/or EU standards.  Manufacturers are required to submit laser product reports to FDA/CDRH if they intend to sell in the US. CDRH will assign a unique tracking number to the reports, referred to as Accession numbers.  Do they have an accession number? If YES (record in Notes)  Will they take the product back and correct the issues?  If BOTH YES, then return to vendor. If not, continue to **08** below.  *(it may be possible that installation results in a modification of the original product under 21CFR1040.10(i).)* | ◎YES ◎NO  ◎YES ◎NO  \_\_\_\_\_\_\_\_\_\_ |  |
| **08** | **ALERT APPROPRIATE AGENCIES**  Contact the appropriate federal, state, and local authorities | \_\_\_\_\_\_\_\_\_\_ |  |
| 08a | (FDA-CDRH)   |  |  | | --- | --- | | **PHONE** | 800-638-2041 ((DICE) CDRH Communications) | | **EMAIL** | cdrhdeviceallegations[@fda.hhs.gov](mailto:radhealthcustomerservice@fda.hhs.gov) | | **MAIL** | U.S. Food and Drug Administration Center for Devices and Radiological Health Document Mail Center – WO66-G609 10903 New Hampshire Avenue Silver Spring, MD 20993-0002 | | **Both EMAIL and MAIL** | Submit with header on a letter containing the form or a cover sheet may include: “Laser Products Trade Complaint – Please forward to the Branch Chief for Magnetic Resonance and Electronic Products in OIR/DRH” | | **NOTE** | An assessment of the laser product should be made to the rest of the FDA general and laser performance standard (21CFR1010; 1040.10(f), (g), (h), and (i); & 1040.11. Alternatively, IEC 60825-1, Edition 2 may be used as per LN 56: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/laser-products-conformance-iec-60825-1-ed-3-and-iec-60601-2-22-ed-31-laser-notice-no-56> | | \_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_ |  |
| 08b | (State/Local)-Contact specific state and/or local authorities as necessary.   |  |  | | --- | --- | | **PHONE** |  | | **EMAIL** |  | | **MAIL** |  | | \_\_\_\_\_\_\_\_\_\_ |  |
| **09** | **DETERMINE DISPOSITION**  Discuss state of compliance with all stakeholders involved with its selection, acquisition, integration, and use. | \_\_\_\_\_\_\_\_\_\_ |  |
| 09a | If it is determined the product is non-compliant and/or unsafe (and manufacturer will not make compliant), but it will be used under specific circumstances, then a permanent, indelible label bearing the words “**THIS PRODUCT IS NON-COMPLIANT WITH US AND INTERNATIONAL STANDARDS, WILL NOT LEAVE THIS FACILITY, AND SHALL NOT BE INTRODUCED INTO COMMERCE**” shall be applied on a prominent surface in a position such that it does not expose the reader to the emission of the laser. | \_\_\_\_\_\_\_\_\_\_ |  |
| 09b | Review and determine if any action is required as per 21CFR1003 (Notification of Defects or Failure to Comply) and/or 21CFR1004 (Repurchase, Repairs, Or Replacement of Electronics Products). If so, coordinate with any/all stakeholders. | \_\_\_\_\_\_\_\_\_\_ |  |
| **10** | **NOTE DECISION AND DISPOSITION**  In order to ensure a complete process, note final disposition in note field, attach communications (email, physical letter) or note who, date, time) | \_\_\_\_\_\_\_\_\_\_ |  |

**LSO/** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(or other authorized reviewer) Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name

**Supervisor/Manager** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name