

FDA(CDRH)申請時に必要なユーザーマニュアル

レーザー製品について、米国FDA(CDRH)の認可を得るためには、LASER PRODUCT REPORTを作成して当局に提出することを要求されますが、この時に対象のレーザー製品のユーザーマニュアルが必要となります。このマニュアル(Instruction Manual)に記載する内容について、具体的に解説します。

(1) FDA(CDRH)LASER PRODUCT REPORT の要求

ユーザー、及びサービス情報(マニュアル)のコピーの提出要求は、第4部(PART 4)の「情報に関する要求項目との適合」に記載されています。具体的には、FDA PART 1040.10 (h) の要求内容を反映したマニュアルを提出することが必要で特に、製品の機能、及び安全に関する箇所限定して提出することが出来ます。

LASER PRODUCT REPORT (FORM FDA 3632 (09/20) Guide for Preparing Product Reports for Lasers and Products Containing Lasers)

PART 4: COMPLIANCE WITH THE INFORMATIONAL REQUIREMENTS

- 4.1 Submit copies of user and servicing information (operator and service manuals) for your laser product. If the manuals are very extensive, submit those portions that confirm compliance with Section 1040.10(h) [and 1040.11(a)(2), if a medical laser product] and that permit understanding how your laser product functions.
See Compliance Guide, page 8, for assistance.

Are copies of user and service information attached to this report?

(X)Yes ()No

If "Yes," please identify attachment: _____

If "No," please explain why not _____

NOTE: These materials may also be used in the product description required by Part 5.

【第4部】

<情報に関する要求事項との適合>

- 4-1 ユーザ及びサービス情報 (=マニュアル) の写しを提出のこと。マニュアルが多岐にわたる内容を含む場合には、section 1040.10(h)に適合する旨を確認する箇所と、製品の機能を説明する箇所のみ限定して提出のこと。

(注) ここでの資料は、次の第5部<製品の詳細>の箇所でも、又、必要となる。

写しの添付:

Y e s N o

(2) FDA PART 1040.10 (h) の要求

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER J - RADIOLOGICAL HEALTH

PART 1040 – PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

Sec. 1040.10 Laser products.

.....
(h) **Informational requirements** - (1) User information. Manufacturers of laser products shall provide as an integral part of any user instruction or operation manual which is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each laser product:
.....

※FDA U.S. FOOD & DRUG: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?FR=1040.10>

(3) Instruction Manualに要求される具体的な内容 (例)

下記は、LASER PRODUCT REPORTに記載するマニュアルの要旨(Summary)で製品の取説(Instruction Manual)を添付してFDA(CDRH)に提出が必要となります。対象製品の説明、特にレーザ関連のシステム仕様、機能、及びレーザ安全に関してユーザーに提供する情報が重要なポイントとなります。

※情報提供: リスクアセスメントの残留リスクを考慮してマニュアルに反映

■ Product Summary

The instrument is the product that is connected to the specified product to use.

This instrument is designed as a class 1 laser product according to IEC 60825-1:2014.

The laser system employs LD (laser diode) provided by laser manufacturers.

Product Function and Specifications

Regarding the operations of the laser product, please see the Instruction Manual.

■ Operation and Maintenance Procedures

(1) Operation procedure includes;

1) Safety Precautions

Use sufficient care regarding the following cautions to use this instrument correctly and safely.

2) About Warning Labels

The warning labels of this unit is stuck on the position shown in the following figures of the main body and the optical head. Be sure to follow the directives of the warning labels.

3) Cautions at Transferring and Setting the Unit

This unit which equipped xxx as the anti-vibration platform can be used on a desktop and can also be transferred easily. There are 4 points that need to be followed when transferring and setting the equipment. Describe these points hereinafter.

4) Precautions for Use

Use sufficient care regarding the following cautions to use this unit correctly and safely.

(2) Maintenance procedure includes;

1) Replacement of consumable parts

2) Cleaning

3) After service

4) Transport

The followings are caution/warning relating laser safety.

1. Always turn the power supply Off when performing maintenance of each part. If maintenance is performed with the power On, electric shock may occur and/or the system may be damaged.
2. Customers should never repair this system unless specifically directed in this operation manual or by an authorized representative of our company. Removing or opening covers other than those directed can expose the user to high voltage causing electric shock or burns and causing secondary problems. For consumable part replacement follow the operation manual or directions from an authorized representative of our company.
3. Do not watch directly the laser irradiated from the optics system of Optical Head of this unit. Optical Head is a class 1 laser product. It is safe during normal usage, but be careful not to watch for extended periods of time.

(3) Accessible radiation during operation;

An operator could access the laser radiation from the product during operation of the instrument, however there is no hazardous laser radiation due to Class 1 Laser Product.

See the Instruction Manual in detail.

(4) Warnings relating laser safety

The followings CAUTION/ WARNING are indicated on the instrument.

■ Setup Procedure

(1) Setup procedure includes;

- 1) Place of Installation
- 2) Power cord connection
- 3) Connection Diagram with the product

The above contents are described on "Safety Preparations" in the instruction manual. The followings are caution/warning relating laser safety.

1. Before plugging in or unplugging this system or units connected to this system, be sure to the power for this system and units Off before plugging in or unplugging. If the units are plugged in or unplugged with the power On, electric shock may occur and/or the system may be damaged.
2. Always be sufficiently aware of the environment when installing or using this system. Under the inappropriate environment, this system cannot show original performance, the system may be damaged, or the user may be exposed to dangers such as burns or electric shock. In particular, NEVER use in a combustible environment. There is a large danger and explosion or fire may be induced by spark discharges in relay circuitry, etc.
3. The customer should never modify this system unless specifically contracted to do so with our company. Modifications can lead to system damage and can cause danger to the user. In addition, "Modification" here represents a different state to the system hardware or software from the delivered specifications (or contract details).

(2) Description for a caution in the user manual during the setup.

It's not considered a risk of hazardous laser radiation during the setup.

See the Instruction Manual in detail.

■関連情報 *下記URL

- 1) **FDA LASERPRODUCT REPORT (FDA 21 CFR Part 1040.10 Laser products)**
<https://fujisafety.jp/files/aboutus/c1-12.pdf>
- 2) **レーザーレポート作成に必要な技術資料 (具体例)**
https://fujisafety.jp/files/aboutus/tec_document_for_laser_report.pdf
- 3) **Laser Products and Instruments (U.S. FOOD & DRUG)**
<https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/laser-products-and-instruments>
- 4) **FORM FDA 3632 (09/20) Guide for Preparing Product Reports for Lasers and Products Containing Lasers**
<https://www.google.co.jp/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwiK0sLzNrtAhUtK6YKHRniA78QFjABegQIARAC&url=https%3A%2F%2Fwww.fda.gov%2Fmedia%2F72593%2Fdownload&usq=AOvVaw0PpJEAbw3lljuOxDh1wBrb>

(h) 情報についての要求事項

- (1) 使用者のための情報。 レーザ製品の製造業者は、通常製品に付けて供給する使用者のための指示書又は運転用マニュアルの不可欠な部分として用意するか、又は、もしこれらのものを用意しないときは、以下の情報をすべてのレーザ製品に付けるようにしなければならない。
- (i) この節の(d)項の表 I、II-A、II、III-A、III-B 及び VI の被ばく放出限界を超えるレーザ放射及び副次放射に被ばくを避ける予防措置に関する明らかな警告を含んでいる組立、運転、及び保守に対する適切な指示書、並びにこの節と § 1040.11 項に適合するように製品を維持するために必要な保守のための明細書。
 - (ii) 適切な単位で表したパルス幅、最大放射パワー、並びに適切なきときは、この節の(e)項で決められているこの節の(d)項の表 I の被ばく放出限界を超える各方向において検知され得る被ばくレーザ放射についてのパルス当たりの最大放射エネルギーの大きさについての記述。
 - (iii) レーザ製品に貼付し、又はレーザ製品と共に供給するよう、この節の(g)項及び § 1040.11 項で要求されているすべてのラベル及び危険の警告の読みやすい複製（色は任意）であって、適用される組合せ文字〔この節の(g)(1)(ii)項の図 1、又は(g)(2)(ii)項の図 2〕の中の位置 1、2 及び 3 に要求している情報を含んでいるもの。製品に貼付される各ラベルの対応する位置は指示されていなければならないし、あるいは、もし製品と共に供給されるときには、当該ラベルは製品に貼付されていないで製品と共に供給されたものであることの記述及びそれらが供給される形態と方法についての記述がなされていなければならない。
 - (iv) 「注意—ここで規定した以外の手続きによる制御、又は調整、あるいは作業での使用は、危険な放射被ばくを生ずることがある。」という警告を含んでいるすべての制御、調整、運転に対する手順及び保守をリストしたもの。
 - (v) レーザシステム以外のレーザ製品の場合には、そのレーザ製品がこの節、及び § 1040.11 項に適合しているものであることを保証するためレーザエネルギー源についての両立性要件に関する記述。
 - (vi) この節の(e)(3)(i)項に規定されたような直径 7mm の開口絞りを有するクラス分けされたレーザ製品の場合、もし直径 50mm の開口絞りの使用が、当該製品についてより高いクラス分けのものとなるときは、次の警告を使用者のため情報の中に含めなければならない。

「注意—この製品に光学機器の使用は、眼に対する障害を増すことになる。」

- (2) 購入及びサービスのための情報。 レーザ製品の製造者は、下記の情報を準備するか、もしくは準備させるようにしなければならない：
- (i) 各レーザ製品に関係するすべてのカタログ、仕様書シート及び記述的パンフレットの中に、適切な組合せ文字〔この節の(g)(1)(ii)項の図 1 又は(g)(2)(ii)項の図 2〕の位置 1、2 及び 3 に要求されている情報を含んでいる、当該製品に貼付するようになっているこの節の(g)項で要求されているクラス表示及び警告の読み易い複写（色は任意）。
 - (ii) 準備及び販売のコストを超えないコストで、サービス商社及び販売業者並びに要求に応じその他の者に対して、この節の表 I、II-A、II、III-A、III-B 及び VI の被ばく放出限界を超えるレーザ放射及び副次放射に対し、起こりうる被ばくを避けるために処置すべき明白な警告及び予防措置を含んでいる各レーザ製品のモデルについてのサービス調整及びサービス手順に関する適切な指示書、及び製品をこの節並びに § 1040.11 項との適合を保つために必要な補修計画；そしてこれらのサービス指示書には、放射の被ばく放出レベルを増加させるため製造業者又は、製造業者の代理人以外の者が利用することのできるそれらの制御及び手順を列挙したもの、及び、この節の(d)項の表 I、II-A、II、III-A、III-B 及び VI の被ばく放出限界を超えるレーザ放射又は副次放射に対し人間の被ばく状態が許されるように保護きょう体の移動できる部分の位置をはっきり記述したもの。指示書には、実行すべき各手順及び各手順の順序に関し危険となると分かっているレーザ放射及び副次放射のレベルの被ばくを避けるためサービス要員に対する保護手段、及び要求されているラベルと危険警告の読みやすい複写（色は任意）を含んでいなければならない。

(h) *Informational requirements.*

(1) *User information.* Manufacturers of laser products shall provide as an integral part of any user instruction or operation manual which is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each laser product:

- (i) Adequate instructions for assembly, operation, and maintenance, including clear warnings concerning precautions to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in tables I, II -A, II, III-A, III-B, and VI of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and § 1040.11.
- (ii) A statement of the magnitude, in appropriate units, of the pulse durations(s), maximum radiant power and, where applicable, the maximum radiant energy per pulse of the accessible laser radiation detectable in each direction in excess of the accessible emission limits in table I of paragraph (d) of this section determined under paragraph (e) of this section.
- (iii) Legible reproductions (color optional) of all labels and hazard warnings required by paragraph (g) of this section and § 1040.11 to be affixed to the laser product or provided with the laser product, including the information required for positions 1, 2, and 3 of the applicable logotype (figure 1 of paragraph (g)(1)(ii) or figure 2 or paragraph (g)(2)(ii) of this section). The corresponding position of each label affixed to the product shall be indicated or, if provided with the product, a statement that such labels could not be affixed to the product but were supplied with the product and a statement of the form and manner in which they were supplied shall be provided.
- (iv) A listing of all controls, adjustments, and procedures for operation and maintenance, including the warning "Caution—use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure."
- (v) In the case of laser products other than laser systems, a statement of the compatibility requirements for a laser energy source that will assure compliance of the laser product with this section and § 1040.11.
- (vi) In the case of laser products classified with a 7 millimeter diameter aperture stop as provided in paragraph (e)(3)(i) of this section, if the use of a 50 millimeter diameter aperture stop would result in a higher classification of the product, the following warning shall be included in the user information: "CAUTION—The use of optical instruments with this product will increase eye hazard."

(2) *Purchasing and servicing information.* Manufacturers of laser products shall provide or cause to be provided:

- (i) In all catalogs, specification sheets, and descriptive brochures pertaining to each laser product, a legible reproduction (color optional) of the class designation and warning required by paragraph (g) of this section to be affixed to that product, including the information required for positions 1, 2, and 3 of the applicable logotype (figure 1 of paragraph (g)(1)(ii) or figure 2 of paragraph (g)(2)(ii) of this section).
- (ii) To servicing dealers and distributors and to others upon request at a cost not to exceed the cost of preparation and distribution, adequate instructions for service adjustments and service procedures for each laser product model, including clear warnings and precautions to be taken to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in tables I, II -A, II, III-A, III-B, and VI of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and § 1040.11; and in all such service instructions, a listing of those controls and procedures that could be utilized by persons other than the manufacturers or the manufacturer's agents to increase accessible emission levels of radiation and a clear description of the location of displaceable portions of the protective housing that could allow human access to laser or collateral radiation in excess of the accessible emission limits in tables I, II -A, II, III-A, III -B, and VI of paragraph (d) of this section. The instructions shall include protective procedures for service personnel to avoid exposure to levels of laser and collateral radiation known to be hazardous for each procedure or sequence of procedures to be accomplished, and legible reproductions (color optional) of required labels and hazard warnings.