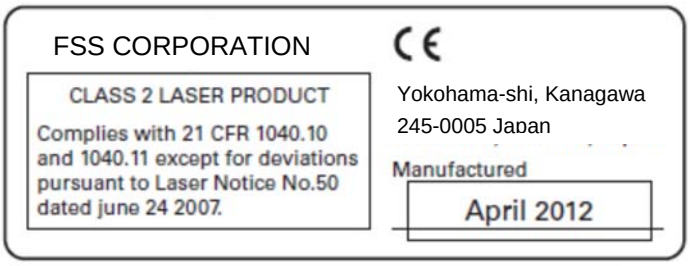
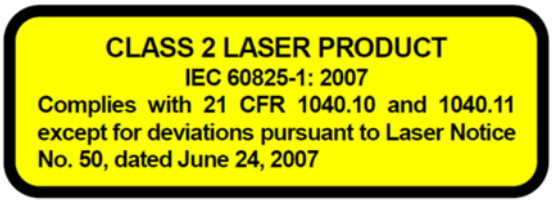
レーザレポート作成に必要な技術資料 (具体例)
(IEC 60825-1, FDA 21CFR 1040.10)

(1) 表示ラベル　Label

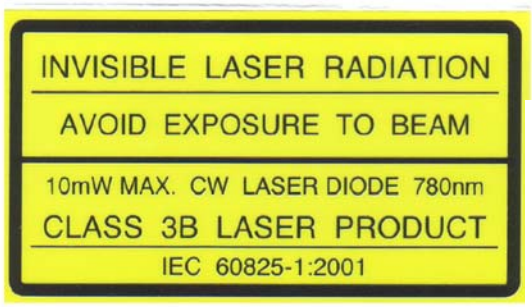
■ Identification label (Laser product)





■ Warning explanatory label

The following warning explanatory label is affixed on the protective housing of the product .
Dimensions: 35mm by 60mm
Letter: Printed (black letters)
with black border on yellow background
Location: On the top of Sensor Unit



■ Laser hazard symbol

The specified laser hazard symbol label is affixed on the top of the Sensor Unit as the following photo.

-Laser hazard symbol-

■ Label for access panel of the sensor unit

The following label for access panel is affixed on the protective housing of the Sensor Unit.

Dimensions: 20mm by 50mm
Letter: Printed (black letters)
with black border on yellow background
Location: On the side of the Sensor Unit

-Caution label-

■ Laser aperture

The following laser aperture label is affixed on the protective housing of the Sensor Unit.
The location of aperture is indicated with the arrow markings.

Dimensions: 26mm by 60mm
Letter: Printed (black letters)
with black border on yellow
background Location: On the Sensor Unit

-Aperture label-

(2) レーザ製品の説明　Laser Product

レーザ照明装置(Laser Illuminator Device)で対象物にレーザを照射してその形状を観察するもので外部DC電源入力(DC12V)をAC100Vに変換するインバータを内蔵、ソーラパネル等で充電した外部蓄電池（DC12V）を接続してAC100V電源を出力する機能を有する。

1) 外観 Appearance

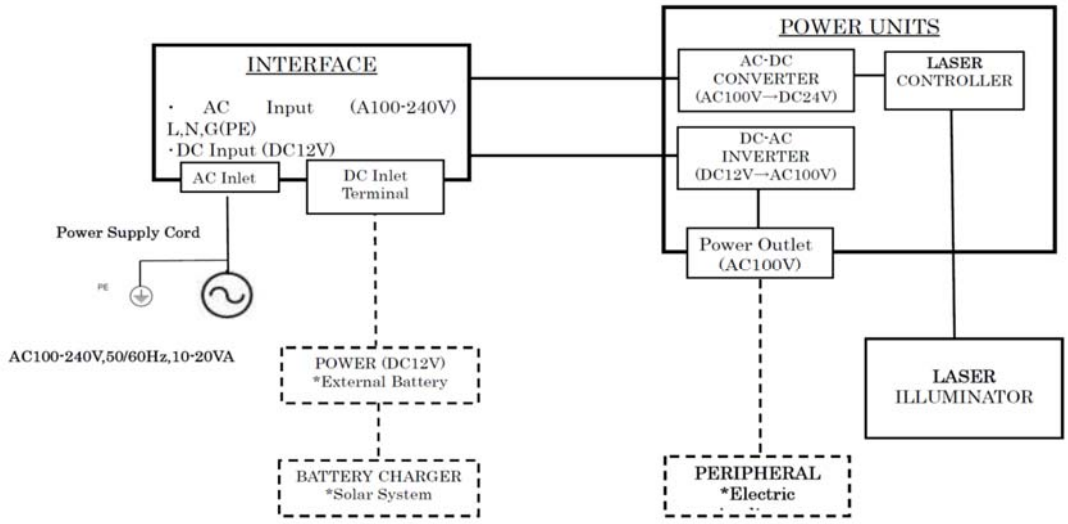
2) 製品仕様　Specifications

Power Source	Input Rating: AC100-240V, 50/60Hz, 10-20VA Electrical Protection: Class Ⅰ Class 2 Laser Product
Power Supply Cord	- For AC100-120V area UL Listed, detachable power cord set, 3-conductor grounding Type SVT, No. 18 AWG, 3 m long maximum, rated at AC125V minimum. - For AC220-240V area Approved according to EU/EN standards, 3-conductor grounding Type H05VV-F, 3 m long maximum, rated at AC250V minimum.
Function	1) Laser Illuminator P= 1mW　λ=650 nm　CW *Source Laser: LD (Laser Diode) (Class 2 Laser Product) 2) AC100V Inverter Input: DC12V *External Battery Output: AC100V, 150VA (150W)
Operating Environment	Temperature: 0 - 40℃, Humidity: 85%RH Max (Non-condensing) Altitude: 2000m Max Pollution: Degree 2 Installation: Category Ⅱ
Dimensions	Approx. 320(W) x 240(D) x 80(H) mm

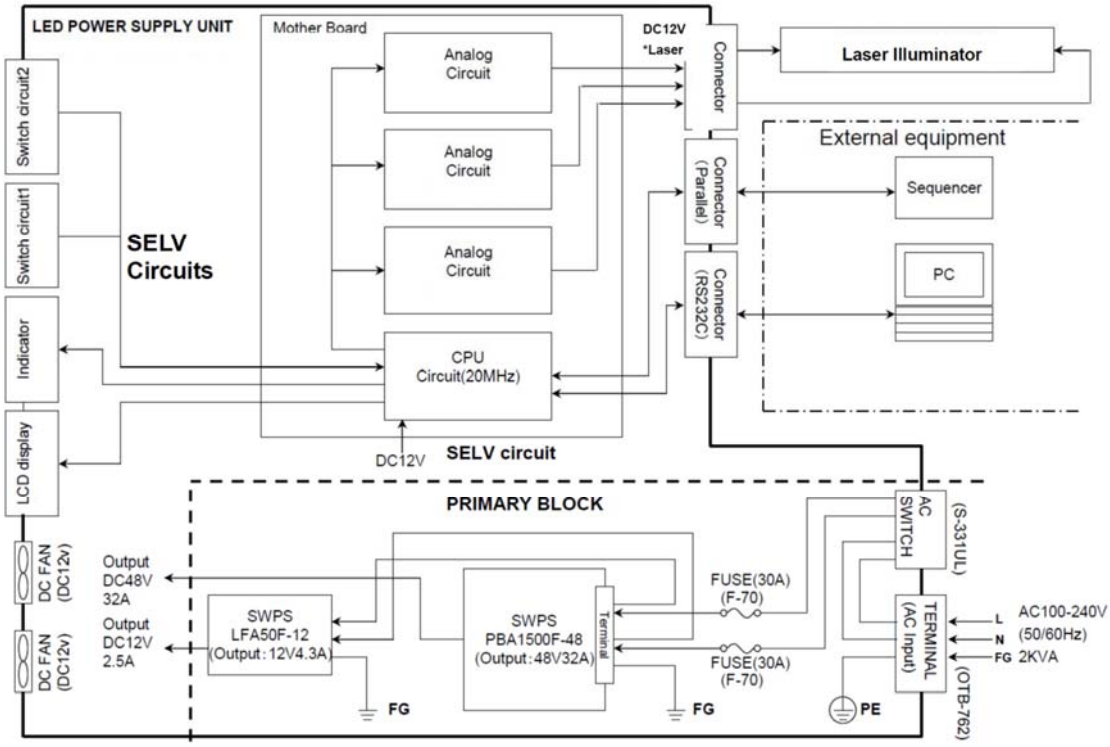
Weight	Approx. 3kg
Applicable Standard	CE Marking Low Voltage Directive: 2014/35/EU EN 61010-1:2010 IEC/EN 60825-1:2014 *Laser EMC Directive: 2014/30/EU EN 61326-1:2013 RoHS Directive: 2011/65/EU EN 50581:2012

3) 電気系ブロックダイアグラム Electrical Block Diagram

■ 特にレーザパワー出力が、その電源の変動や経時変化で変わる恐れのある場合は、要注意！



Electrical Block Diagram (1)



Electrical Block Diagram (2)

4) 取扱説明書 Instruction Manual

■ 取説(Instruction Manual)には、下記の内容を含むこと。

1. Intended product use
2. Explanation of Laser product
3. Laser safety (Residual Risk)
4. Certification and Identification label
5. Laser and caution labels
6. For Safe Use of the Product (Requests of Standards IEC 60825-1 / FDA CDRH)

   *Ex. Class 3B Laser Product

- Control using a key
- Remote interlock connectors
- Safety interlock mechanism
- Laser-emission alarm indication
- Beam shutter *If applicable
- Emergency shutdown switch *If applicable
- Labels

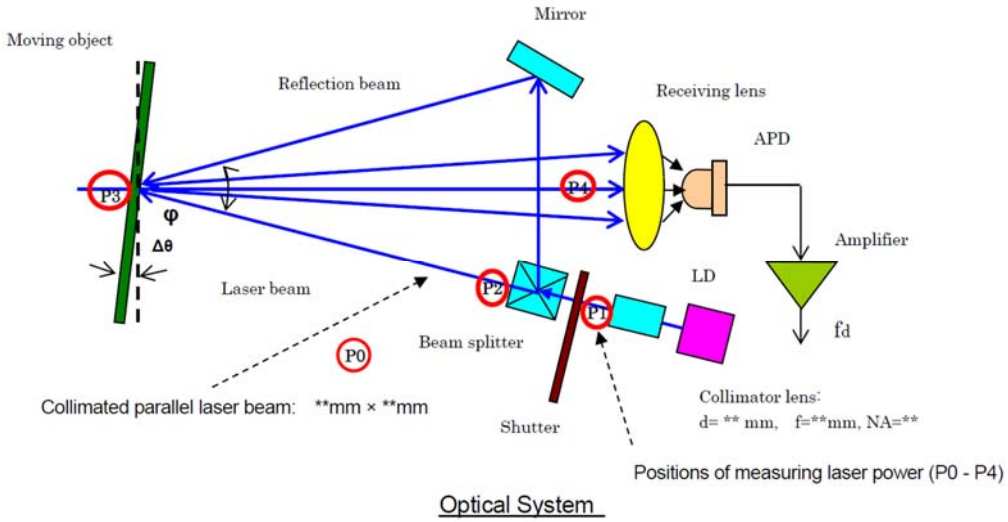
7. Safety Pre-cautions

*Ex. Class 3B Laser Product

- Setup of the laser-controlled area
- Appointment of a laser safety officer

3) レーザ光路図 Optical System for Laser

■ レーザビームの光路をそのレンズ･ミラーなどの光学系、位置関係を図示した資料が必要。



Optical System

4) セットアップ、オペレーション、メンテナンス　Setup / Operation / Maintenance Manual

■ 以下の項目について、マニュアルに記載されていること。

1. Setup procedures include,

- Health and safety rules for users
- Training for safety operation
- Setup environment
- Power supply as to grounding and connection of power cord
- Operation and manipulation
- Safety interlock of the Laser Sensor *If applicable
- Handling the Laser Product
- ON/OFF operations of the laser
- Precautions (Laser Safety)

2. Accessible radiation during setup and operation

【記載例】

An operator could access the laser radiation from the sensor unit during setup and operation because that ….

**Reference: Example*
An operator could not access the laser radiation from the sensor unit during setup and operation because that this sensor provides a function for automatically turning off the laser, such as in a case in which the laser beam being radiated onto the object under measurement is aimed at some other point.)

3. Description of warning in the user manual during setup and operation.

【記載例】

WARNING

This is a laser product corresponding to Class 3B. Read this operation manual carefully, observe the do's and don'ts given in "User's Obligations", by all means, and handle the instrument in advance with the predetermined operating procedures. Failure to observe the precautionary obligations could result in a disorder of the eyes or other part of the body.

The following warning is saying that it should not look directly into the output laser and the reflected laser beam from the sensor unit for safety to eyes.

WARNING

Do not look directly into the window and the reflected laser beam from the object during positioning and measuring.

4. Maintenance only includes cleaning the window glass of the sensor.

【記載例】

CAUTION

Do not use benzoline, paint thinner, alcohol, or the like for cleaning. Such chemicals could damage the coating of the sensor or cause hazing or distortion of the optical system.

5. Description of warning in the user manual during maintenance.

【記載例】

A maintenance person could not access the laser radiation as far as the power switch of the signal processor is off during maintenance. Even if not doing such manners, the laser radiation stops by the workings of the interlock system.

WARNING

Before cleaning the window glass, make sure to switch off the signal processor and unplug the sensor connection cable. Unexpected emission of laser beam is very dangerous.

5) サービス(修理) Service(Repair) Manual

■ 以下の項目について、マニュアルに記載されていること。

1. Setup procedure includes;

- Precautions (Laser Safety)
- Place of Installation
- Power cord connection
- Connection interface cables
- Controlling peripheral instruments
- Other relating matters for laser safety

2. Accessible radiation during service

【記載例】

There are accessible laser radiations during diagnosis of the laser product.
A service person could access the laser radiation (Class 3B, AEL: see Attachment 6) during check of the sensor unit. The service procedures are only allowed of diagnostic working because that all malfunctioning assembly parts have to be returned to the manufacturer's plant.

3. Descriptions for laser safety in the service manual

【記載例】

The pre-cautions are saying that the service should be conducted by an authorized person who is familiar with safety working regarding fire, electric shock and laser hazards with the following caution markings employed by the Doppler sensor.

The summery of pre-cautions for the service person are as follows.

ARNING

1. *Pay attention at High Voltage area.*
2. *Class 3B invisible laser radiation, wear a protective eyeglass.*
3. *Make a protective enclosure to avoid laser radiation.*
4. *Turn off the power when removing cover or checking optical parts.*
5. *Read the user manual in addtion to the service manual when reparing.*

The installation of the instrument is performed by a well-trained engineer according to manufacturing educating system with laser safety instruction.

4. レーザクラス分け Laser Classification

■ 製品仕様書で規定したレーザクラスの資料を提出のこと。

・ **Class 1**
直接ビーム内観察を長時間行っても，またそのとき，望遠光学系を用いても安全であるレーザ製品である。
クラス1は，用いるときに危険性のある放射を被ばくすることのないように完全に囲われた高出力レーザ（組込形レーザ製品）も含む。

・ **Class 1M**
クラス1Mレーザ製品は，裸眼（光学器具を用いない。）で，直接ビーム内観察を長時間行っても安全であるレーザ製品である。

・ **Class 2**
400 nm～700 nm の波長範囲の可視光を放出するレーザ製品であって，瞬間的な被ばくのときは安全であるが，意図的にビーム内を凝視すると危険なレーザ製品。0.25 s の時間基準は，クラスの定義に記載している。これは，多少長めであっても，瞬間的な被ばくによって障害が生じるリスクは非常に小さいという推定に基づいている。

・ **Class 2M**
クラス2M レーザ製品は，可視のレーザビームを出射するレーザ製品であって，光学器具を用いない裸眼に対してだけ短時間の被ばくが安全なレーザ製品である。測定条件3 で規定する測定用の開口直径よりも大きな直径をもつ平行ビームに対しては，双眼鏡のような望遠光学を用いた露光は，MPEを上回り，目の障害を引き起こす可能性がある。

・ **Class 3R**
クラス3R レーザ製品は，放射出力のレベルが，直接のビーム内観察条件に対してMPEを超えるものの，AEL がクラス2 のAEL（可視レーザの場合）の5 倍又はクラス1のAEL（不可視レーザの場合）の5 倍であることから，障害が生じるリスクが比較的小さいレーザ製品である。

・ **Class 3B**
目へのビーム内露光が生じると（NOHD 内において），偶然による短時間の露光でも，通常危険なレーザ製品。
拡散反射光の観察は通常安全である。クラス3B のAEL 近傍のクラス3B レーザは，軽度の皮膚障害又は可燃物の点火を引き起こす可能性がある。ただし，これはビームの直径が小さいか，又は集光したときだけに起こり得る。

・ **Class 4**
クラス4 レーザ製品は，ビーム内の観察及び皮膚への露光は危険であり，また拡散反射の観察も危険となる可能性があるレーザ製品である。これらのレーザは，場合によっては火災の危険性が伴う。

・ **Class 1C**
医療，診断，手術，又は脱毛，しわ取り，にきび取りのような美容への用途として，皮膚又は体内組織にレーザ光を直接照射することを意図したレーザ製品である。出力するレーザ放射は，クラス3R、クラス3B又はクラス4のレベルの場合もあるが，一つ以上の技術的手段によって目への露光を防止するものである。皮膚に対する露光レベルは用途に依存するので，その特徴は製品安全規格で包含する。

5. 保護筐体(ハウジング) Protective Housing

■ 下記の要求を満足する保護筐体とすること（図面、写真の提出が必要）。

1. **一般事項**
各レーザ製品は，所定の位置に設置してある場合には，クラス1 のAEL を超えるレーザ放射（迷走レーザ放射を含む。）に対する人体の被ばく状態を予防するための保護きょう体を，備えていなければならない。
ただし，人体の被ばくが製品の機能の実施上必要である場合は除く。

2. **サービス**
サービスのため取外し又は移動ができインタロックが施されていないレーザ製品の保護きょう体又は保護囲いのいかなる部分も，その部分の取外し及び移動には工具又は工具類を必要とするような方法によって安全化を図らなければならない。

6. レーザ放射インジケータ　Laser Indicator

■ 下記に該当する場合は、レーザ放射インジケータの資料を提出のこと。

波長が400 nm を下回るか，又は700 nm を超えるクラス3R のレーザシステム，並 びにクラス1C,クラス3B及びクラス4 のレーザ システムは，下記を満たさなければ ならない。

- レーザシステムのスイッチがオンになったとき，警告装置は可聴音又は可視光の信号を発するようになっていなければならない。
- 警告装置は，フェールセーフ又は冗長性のある設計でなければならない。
- 警告装置は，保護めがねを通して明らかに見えるものでなければならない。
- 可視光警告装置はクラス1M 及びクラス2M に対するAEL を超えるレーザ放射を被ばくせずに観察できるような位置に設けなければならない。
- 運転制御部及びレーザ開口のいずれも，放射警告装置から2 m 以上離すことができる場合には，それぞれに放射警告装置を備えていなければならない。
- レーザ放出が，2 個以上の出口開口を通して分岐される場合には，可視光警告装置は，レーザ光が放出される出口開口又は開口群を明瞭に表示しなければならない。

7. 検査、及び試験（品質管理）　Inspection / Testing　(Quality Control)

■ FDA(CDRH)は、Laser Product Report (Part 8)で検査及び試験についての要求がありますので下記の要求に従った報告が必要です。(品質管理に関する資料)

8.1 Attach, and identify as attachments to Part 8, samples of documents that describe, specify, or relate to procedures or tests used to ensure compliance of your reported product with the standard, including compliance with all performance, labeling, and informational requirements. These may include:

( ) Specification controls for critical components,
( ) manufacturing and assembly control procedures,
( ) inspection and test control procedures,
( ) assembly and test traveler forms,
( ) inspection and test reports and checklists, and/or
( ) other(s) _____
(specify)

8.2 If formal quality control and testing procedures have not been implemented or are not sufficient to assure that your product(s) will comply with the standard, explain how you assure that your products comply and submit supporting documentation.

NOTE: Section 1010.2(c) requires that certification be based on a test, in accordance with the standard, of each unit or on a program in accordance with good manufacturing practices. Failure to maintain an adequate testing program may result in disapproval of the program by CDRH.

8. 試験機器　Instrumentation

■ FDA(CDRH)は、Laser Product Report (Part 10)でレーザ製品の検査･試験に使用する計測機器の校正記録を要求しています。(試験機器の校正記録)

Describe those tests and controls used to ensure that the reported product will remain in compliance with the Federal laser product performance standard during its useful life. Items to be addressed include:

10.1 List the instruments you use to determine compliance of the reported product with the standard. Describe these instruments or provide copies of specification sheets. Identify each detector's aperture size, if applicable.

.....

10. レーザ光源デバイス(装置)　Laser Device employed by product

■ FDA(CDRH)は、Laser Product Report(Part 2)でレーザ製品に使用しているレーザデバイスが認証されているかどうかの回答を要求しています。 (レーザデバイスの資料)

2.4　Does your product incorporate a noncertified laser product?

(　)Yes　(　)No

If yes, identify the manufacturer(s), brand(s), model(s), and describe the type of product.

_____

11. その他　Others

1) 製造メーカー(国内)と輸入業者(米国)の身元確認書類（サイン付）

***FDA(CDRH)申請用 (LASER PRODUCT REPORT)**

【例】

SAMPLE

LASER PRODUCT REPORT

PART I: MANUFACTURER AND REPORT IDENTIFICATION

1.1 Manufacturer: ***** Co., Ltd.
Address 1. **********
Yokohama 226-8507, Japan

Manufacturing Firm: ***** Co., Ltd., Utsunomiya Plant
Address **********
Utsunomiya-shi, Tochigi 321-0155, Japan

Corresponding official:
Signature: Takao
Name & title: ******** , Vice President
Address ******** ******* Yokohama 226-8507, Japan

Telephone number : +81-45- ********

Firm's Prime Contact or Responsible Person if different from above:
Name & title: ********** ,General Manager

Telephone number : +81-45- ********

1.2 Importing agent (For manufacturers exporting to the U.S., see 21 CFR 1005.25.):

Signature
(Or attach copy of written agreement with agent)
Name & title ******** Vice President
Address ********** Inc
********** IL. 60101, U.S.A.
Telephone number **********

1.3 Report type: (X) Laser Product Report, or

( ) Supplement to CDRH Accession No. _____

submitted on (date) _____

1.4 Date of this report: Month Day, Year

Laser Product Report

Laser Product Report

2）認可書（Accession Letter of FDA CDRH）

【例】

DEPARTMENT OF HEALTH & HUMAN SERVICES — PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND
RADIOLOGICAL HEALTH
10903 New Hampshire Avenue
WO66-4617
Silver Spring, MD 20993

May 1, 2014

Reference: [ ]

[ ]
TOKYO, JAPAN 184-0012

This is to acknowledge receipt of your April 16, 2014, document, which was filed pursuant to the regulations for the administration and enforcement of the Radiation Control for Health and Safety Act of 1968 (title 21, code of Federal Regulations, Subchapter J) as they pertain to Initial Product Report requirements.

Your document has been assigned an accession number of [ ], and has been classified as a(n) Initial Product Report (pursuant to Part 1002, Subpart B of the Regulation referenced above).

Further, the submittal has been assigned an informal subject title of "This submission is a(n) Initial Product Report. These Research, Scientific, Laboratory Laser Products include designated model family [ ] series with model(s) [ ]".

This acknowledgement does not constitute approval of the document. You will be contacted if any questions or comments arise concerning your document.

WARNING:

THE ACCESSION NUMBER ASSIGNED TO YOUR SUBMISSION DOES NOT IMPLY, CONVEY OR CONSTITUTE FDA APPROVAL OF ANY REPORT, APPLICATION FOR VARIANCE OR EXEMPTION, NOTIFICATION, OR ANY OTHER SUBMISSION OR ITS CONTENTS. THE ACCESSION NUMBER IS ONLY AN ACKNOWLEDGMENT THAT FDA HAS RECEIVED YOUR SUBMISSION. IT MAY BE REVOKED BY FDA. ITS DISCLOSURE IS YOUR RESPONSIBILITY. IT IDENTIFIES YOUR SUBMISSION FOR PRODUCTS OR PRODUCT FAMILIES IDENTIFIED IN THIS MESSAGE.

Be advised that failure to comply with FDA regulations may result in notification of affected persons and corrective actions at no cost to the purchaser, pursuant to 21 CFR Part 1003 -- Discovery of Defect or Failure to Comply and 21 CFR Part 1004 -- Repurchase, Repairs, or Replacement of Electronic Products.

Please note that your firm is required to submit an Annual Report to CDRH every year by September 1.

All Radiological Reports may be prepared using FDA's Electronic Submissions software which can be downloaded at http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm. For more information on the FDA's eSubmitter program please see the following websites:

Radiological Health - http://www.fda.gov/Radiation-EmittingProducts/default.htm

Electronic Submissions (instead of paper reports) -
http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm

FDA Electronic Submissions Gateway -
http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

Thank you for your cooperation. If any questions or concerns arise during our review of your report, we will notify you. If you have any questions, contact us at (301) 796-5710.

Sincerely Yours,

Robert J. Doyle
Chief, Magnetic Resonance and Electronic Products Branch
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health