Laser Light Show Annual Report

Created From “Guide For Preparing Annual Reports...” 21 CFR 1002.7
Revised September 1995

From -

Name:

Address:

Phone:

Date:

To CDRH,

Please accept this annual report to fulfill reporting requirements under Title 21 of the Code of Federal Regulations (CFR), Parts 1002 and 1003 which specify Reporting and Notification requirements.

Please address any questions or correspondence to the above.

Part 1. Identification Of Manufacturer

1a. Report Date:

1b. Company Name:

1c. Address

1d. Name/Position of Person Filing This Report:

1e. Signature:

1f. This Annual Report is submitted in accordance with 21 CFR 1002.13 for the period July 1, 20_____ through June 30, 20_____.

Part 2. Production Status

( ) Products were manufactured during this period and the firm is still in business. If you check this, complete and mail this entire report.

( ) No products were manufactured during this period but the firm is still in business and expects to manufacture in the future. If you check this, complete Part 6 and mail pages 1 and 4.

( ) No products were manufactured during this period and the firm is now out of business. If you check this, complete Part 6 and mail pages 1 and 4.

( ) Products were manufactured during this period but the firm is now out of business. If you check this, complete and mail this entire report.

Part 3: Current Production Tabulation

3.1 All Laser Products Used

3.1a. Accession Number:

3.1b. Family Designation:

3.1c. Model Numbers:

3.1d. Product Function:

3.1e. Class:

3.1f. Active:

3.1g. Discontinued:

3.1h. Plant:

3.2 Laser Light Shows

3.2a. Accession number:

3.2b. Projector Family Designation(s):

3.2c. Permanent Or Touring:

3.2d. Class:

3.2e. Lasing Media:

3.2f. Number Of Shows Performed:

3.2g. Discontinued:

Part 4. Procedures for Quality Control and Testing

The written procedures for assessing and controlling radiation safety have been reviewed. (These include prototype testing, incoming materials testing, assembly testing, retesting after repair, and service testing.) The procedures for maintaining quality control testing equipment have also been reviewed. All procedures are up-to-date, complete, and accurate.

( ) YES ( ) NO

The reports provided to CDRH for each model family currently in production have been reviewed and the procedures contained in them are up-to-date, complete, and accurate.

( ) YES ( ) NO

If you answered "no" to either question, provide the current procedures in a supplement to the appropriate model family report.

Part 5: Summary Of Test Results

5a. Model Number Or Name Of Show:

5b. Number Produced:

5c. Performance Requirements:

5d. Labels:

5e. LLSV Conditions:

Part 6. Correspondence Concerning Radiation Safety

The number of letters received from users, dealers, or others about possible radiation exposure or safety-related failures during use of the product was _____.

Attach a copy of each letter.

The number of letters received from dealers, distributors, or others concerning the need for repair, adjustment, or replacement of a part to maintain radiation safety of the product was _____.

Attach a summary of correspondence or a sample. Identify any trends in failed components or adjustments needed during servicing.

The number of notices or brochures sent to users, dealers, or service personnel on precautions or actions to be taken to maintain radiation safety of the product was _____.

Attach a summary of correspondence or a sample.

Part 7. Distribution Records

Production facility shipping records and dealer records (when returned) are maintained at _____.

Products can be traced from these records by:

( ) Model
( ) Serial Number
( ) Date of Manufacture
( ) Other, specify: