QUALITY CONTROL PRACTICES for COMPLIANCE with the FEDERAL LASER PRODUCT PERFORMANCE STANDARD



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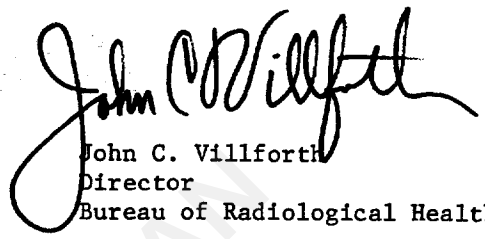
FOREWORD

The Bureau of Radiological Health conducts a national program to limit man's exposure to ionizing and nonionizing radiations. To this end, the Bureau (1) develops criteria and recommends standards for safe limits of radiation exposure, (2) develops methods and techniques for controlling radiation exposure, (3) plans and conducts research to determine health effects of radiation exposure, (4) provides technical assistance to agencies responsible for radiological health control programs, and (5) conducts an electronic product radiation control program to protect the public health and safety.

The Bureau publishes its findings in appropriate scientific journals and technical report and note series prepared by Bureau divisions and offices.

Bureau publications provide an effective mechanism for disseminating results of intramural and contractor projects. The publications are distributed to State and local radiological health personnel, Bureau technical staff, Bureau advisory committee members, information services, industry, hospitals, laboratories, schools, the press, and other concerned individuals. These publications are for sale by the Government Printing Office and/or the National Technical Information Service.

Readers are encouraged to report errors or omissions to the Bureau. Your comments or requests for further information are also solicited.



John C. Villforth
Director
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PREFACE

The Performance Standard for Laser Products (21 CFR 1040.10 and 1040.11) becomes effective August 2, 1976. Lasers and products containing lasers manufactured on or after that date must conform to the applicable provisions of the standard. In addition, manufacturers will be required to certify that their products comply with the regulations and to furnish reports to the Bureau of Radiological Health which clearly substantiate the product compliance.

This document has been prepared in order to assist manufacturers in developing and implementing quality control and testing programs which are in accordance with good manufacturing practices and which assure compliance with the standard and adequacy of safeguards against hazardous electronic product radiation. Because laser products may operate over a large variety of wavelengths, emission durations, and spatial characteristics, a detailed step-by-step protocol would be of very limited application. The purpose here, therefore, is to set forth a general description of the procedures and philosophy of quality control as appropriate for laser products, beginning from the concept and ending after final testing of the product.

The guide incorporates what is considered to be good manufacturing practice and also provides fair and standard criteria by which all manufacturers' programs will be evaluated. This document is intended for use in conjunction with the "Guide for Submission of Information on Lasers and Products Containing Lasers Pursuant to 21 CFR 1002.10 and 1002.12" (July 1976).

It should be strongly emphasized, however, that this guide does not preclude other alternative procedures that the manufacturer may adopt that are equivalent to, or as effective as, those methods in this document. Each manufacturer's test procedures and testing programs will be considered on an individual case-by-case basis. If the manufacturer has established alternative procedures that are still within the limits of good manufacturing practice, and that assure the adequacy of safeguards against hazardous electronic product radiation and compliance with the standard, the Bureau of Radiological Health would have no reason to disapprove such a program.

Neither the failure of the Bureau to disapprove a testing program, nor the fact that such a program was established pursuant to this guide relieves a manufacturer from his obligation to comply with the Radiation Control for Health and Safety Act of 1968 and any subsequent regulations. Additionally, this guide should not be interpreted as a limitation of the Food and Drug Administration's authority to disapprove a manufacturer's testing program pursuant to 21 CFR 1010.2.



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ABSTRACT

General principles and practices for the administration and conduction of a program of quality control for the manufacture of lasers and products containing lasers are presented for guidance in establishing programs to assure compliance with the Federal Performance Standard for Laser Products.

The specific areas of administration and recordkeeping; testing before, during and after production; measuring instruments selection and calibration criteria; sampling criteria and sales and service information are treated in relation to performance and informational requirements of the standard.

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1.0 INTRODUCTION

A viable quality control program ensures the performance of a product at a designated level throughout its useful life, and is essential to demonstrate the compliance of a product with the Federal Performance Standard.

This document outlines some general quality control practices to assist manufacturers of laser products in ensuring the compliance of a product with the Federal Performance Standard for Laser Products. As such it should not be considered to be complete or adequate for all cases. The adequacy of a specific quality control and testing program must be judged solely on its own merits and applicability to the product. The essential elements of a quality assurance program are the following:

(a) Proper organization and administrative procedures to ensure an objective and defensible program.

(b) Preproduction evaluation and testing of the product and testing of components and material obtained from other manufacturers.

(c) Valid measurement techniques, calibrations, and treatment of uncertainties.

(d) Evaluation of the product during and after production and statistical analysis of data. The establishment of confidence limits and rejection criteria are important components of such an evaluation.

(e) Procedures to ensure that any rejected units, if modified and recycled back into the production sequence, undergo the same level of scrutiny as other units that have been found acceptable.

(f) An audit procedure to randomly select completed and tested units for retest as a check on the effectiveness of the quality control and testing program.

(g) Life and reliability testing procedures which determine whether the product will continue to meet its design specifications during its useful life.

(h) An ongoing review of the product performance throughout its production life and a procedure to ensure that any problems discovered are corrected, and that appropriate design changes are made to eliminate them from subsequent units produced.

2.0 ADMINISTRATION OF A QUALITY ASSURANCE PROGRAM

2.1 Objectivity of Program

The quality assurance program should be autonomous in order to be objective. Conflicting duties of personnel can be detrimental to objective evaluation of products. For example, the personnel responsible for maintaining production schedules may be less inclined to reject large numbers of unacceptable units.

2.2 Records and Uniform Procedures

The quality assurance program should be based on standardized tests. Specific written test procedures and standardized forms for data recording should be used. The forms should provide for logging all information relevant to the product and the test such as the product model and serial numbers, date of test, date of manufacture of unit, sample lot, results of test, names of personnel performing and reviewing the test, model and serial numbers of test instruments, a place for calculations, and so forth.

2.3 Validity of Measurements

A valid program of measurements made as part of quality assurance testing involves:

(a) A thorough evaluation and error analysis of the test methods and instruments including calibration uncertainties, drifts and other instrument performance characteristics, errors introduced by the data analysis, and so forth.

(b) Participation in intercomparisons with other organizations performing similar measurements, and

(c) Records of instrument calibrations. This involves a periodic recalibration of measuring instruments against a standard and the maintainance of control groups of test instruments to be used as controls.

2.4 Documentation

A complete written documentation of the quality assurance program should be available. This should include the description of tests performed, description and evaluation of the measurement instrumentation and techniques, the sequence in which tests are performed, detailed uncertainty evaluations of the measurements, the rejection criteria or confidence limits used and the justification for the particular choice of such limits, methods of data analysis, sampling plans, etc. If a sampling technique must be used, it must be scrupulously documented and followed. Quality assurance testing of all units manufactured is urged. Any sampling plans must be defensible under the most critical scrutiny.

2.5 Audit Procedures

Audit procedures should be developed and documented to act as a further check on the test procedures. Random sampling is the only acceptable method in selecting units for audit testing. The audit should be independent of the quality assurance tests.

3.0 MEASUREMENT QUALITY ASSURANCE

3.1 Measurement Program

The credibility of all measurements made as part of a quality control program is one of the more important considerations in evaluating that program. It is therefore imperative that manufacturers carefully plan their measurement facilities and techniques. Some considerations that should go into this planning are enumerated here, however, they are not exhaustive and do not cover all parameters. Detailed planning to assure credible measurements and proper treatment of uncertainties is the responsibility of the manufacturer.

3.2 Instrumentation Selection

The instrumentation should be carefully specified and selected to ensure that it has the capabilities required for a particular test. Instruments for optical radiation measurements should have suitable sensitivity to measure the anticipated radiation levels from the product and acceptable linearity and temporal drift characteristics, temporal response, environmental stability, spectral sensitivity, durability, and noise characteristics. The degree of automation which should be considered is based on the volume of testing and the level of training of the operator.

3.3 Instrumentation Characterization

Once the measurement instruments have been obtained they need to be thoroughly characterized to ensure specified performance. Characterization is used to develop quantitative estimates of instrument related errors or uncertainties. Linearity of instruments for optical radiation measurements should be confirmed over the dynamic range to be covered in testing. Short term and long term temporal response characteristics should be evaluated. If the instruments are to be used in an uncontrolled environment, one should determine the temperature dependence of the instrument response over the range of temperature at which the instrument will actually be used. Wavelength drives and readouts should be checked for accuracy and repeatability in instruments as applicable. Other relevant features of the instrumentation such as frequency response, bandwidth, and so forth should also be characterized. The characterization of the instrumentation will yield quantitative estimates of its capabilities and constraints. These estimates will be useful when one performs an error analysis on the instrument to estimate the uncertainties that are associated with the measurements. It must be noted that as a product emission approaches the limits of the class in which it is intended to function, measuring precision and accuracy become increasingly more important.

3.4 Calibrations and Experimental Design

Much of the burden of credible measurements falls on the validity of calibrations and the design of measurement procedures. Test instruments should be calibrated against standards or reference instruments calibrated by the National Bureau of Standards. Use of standards or reference

instruments calibrated by secondary calibration laboratories against standards obtained from NBS may be acceptable. It is imperative, however, that the manufacturer has valid documented estimates of the uncertainties that are introduced at each stage of the calibration process.

Although a manufacturer has reference standards in his laboratory, it may be useful to calibrate a set of working standards for use in the routine quality assurance measurements. Working standards can be either sources or detectors. The calibration of working standards should be performed according to statistically designed scheme. Working standards should be calibrated periodically and each calibration should consist of a set of measurements. Working standards should be calibrated in groups. It may also be useful to maintain a set of control samples which are calibrated with the working standards, but not used for routine measurements. Repeated calibrations of the control standards will provide a check on the measurement system and should also reveal any gross misbehaviors of the reference standard itself. Calibrations should be done in such a manner that each working standard, reference standard control standard has been measured several times in the same order to yield credible measurements.

Control charts and logs of instrument performance and calibrations are essential. Any changes in the instrument or its components, techniques, standards, operator or other relevant components of the measurements system should be recorded.

Another aspect of measurement assurance is the participation of the manufacturer in intercomparisons with other laboratories making similar measurements. The National Bureau of Standards, and other organizations such as ASTM, conduct such measurement assurance programs in some measurement areas. Participation would lend further credibility to the measurement uncertainties claimed by the manufacturer.

3.5 Uncertainties

Any calibration of a standard source or detector will have an uncertainty assigned to the measurements, relative to absolute units, i.e., the Systeme Internationale (SI) units. Estimating this uncertainty is not trivial and consists of several phases. For example, let us assume that a manufacturer has a reference standard obtained from a secondary calibration laboratory who, in turn, had calibrated this reference standard against standards obtained from NBS. Vague and undefined claims of "traceability to NBS" are unacceptable to the Bureau of Radiological Health. The uncertainty which the manufacturer would assign to his measurements would have the following components:

(a) The uncertainty with respect to SI assigned by NBS to the standard supplied to the secondary calibration laboratory. This uncertainty is with regard to the internationally defined unit of measurement and is normally supplied by NBS with its calibrations.

(b) The transfer uncertainty (see d below) assigned by the secondary calibration laboratory in transferring the calibration to the reference standard it supplies to the manufacturer. In addition to this, the manufacturers should also request from the secondary laboratories the NBS uncertainty relative to SI if the transfer uncertainty of the secondary laboratory is presented as relative to NBS only.

(c) The transfer uncertainty assigned by the manufacturer to calibrations of the working standards against the reference standard.

(d) The uncertainty generated in the measurement of the samples with respect to the working standard.

With respect to (a) above, the National Bureau of Standards supplies uncertainty statements regarding the uncertainties associated with its calibrations with respect to SI. Each other component (b, c and d above) of uncertainty has at least the following subcomponents: the precision or repeatability of the measurements, systematic uncertainties based upon experimental and/or theoretical characterization of the instrumentation and a complete error analysis of the measurements, any uncertainties that may be introduced in the method of data reduction or analysis.

Quantitative estimates of all these uncertainties should be obtained and recorded since they are required in determining a product's compliance with the laser product performance standard. The question then arises as to how these uncertainties should be combined to provide defensible estimate of the final uncertainties that can be assigned by the manufacturer to measurements for determination of compliance. There are several ways in which this can be done. A simple way is to combine them linearly and obtain an arithmetic sum of the percent uncertainties as an indication of the maximum error in the measurements. There are more sophisticated ways to combine uncertainties. If the various uncertainties can be shown to be independent, one could combine them in quardratures, i.e., take the squre root of the sum of the squares. The uncertainties which are not independent may be combined in other ways. Details on these are available in statistics text books that cover the combination of different types of variances.

Measurement assurance programs that NBS may conduct or participate in would provide a good mechanism for achieving an estimate of uncertainties.

4.0 PRE-PRODUCTION EVALUATION

The preproduction evaluation and testing should be conducted to include a review of the design to ensure that the design will yield a product in compliance with the performance standard, evaluation of critical components and material obtained from other manufacturers for use in the product, and engineering and prototype testing and evaluation to confirm that the product can be manufactured in compliance with the standard.

4.1 Design Review

Before the manufacture of the product begins, the product design must be analyzed to ensure that the finished product will comply with the Federal Performance Standard. If the product is intended to be of a certain class (Classes I through IV as enumerated in the laser standard), its electrical and mechanical design should be such that the product will be in compliance with the requirements for products in that class. The aspects of the laser standard that must be considered in any review of the design to include at least:

(a) The accessible emission limits of laser radiation from the product must be less than the accessible emission limits of the lowest class necessary for the product to perform its intended function. Be aware of requirements for lasers emitting beams of a single wavelength, multiple wavelengths in the same range, multiple wavelengths in different ranges, and the dual limits for Class I products which are contained in (21 CFR 40.10(d)).

(b) The requirements (21 CFR 1040.10(f)) regarding protective housing, safety interlocks, key actuated master control, laser emission indicator, beam attenuator, viewing optics, location of controls and specific requirements for products which emit scanned laser radiation should be kept in mind during the review of product design.

(c) The design must clearly define the contents and locations of the labels required in Sections 1010.2, 1010.3 and 1040.10(g), and their permanence and visibility must be assured.

(d) The design must also comply with the requirements for specific purpose laser products as applicable. Medical laser products, surveying, leveling and alignment laser products, and demonstration laser products must comply with 21 CFR 1040.11(a),(b), and (c), respectively.

4.2 Evaluation of Critical Components

Many components of a product affect the level of accessible laser radiation which may be generated or emitted either by direct action or by failure. These may be optical, electrical, or mechanical parts. Whether such components are fabricated by the manufacturer of the laser product or purchased from a vendor, proper evaluation is essential to

determine that the product will comply with the applicable standard when completed. Critical components are those which affect the spatial or spectral quality or quantity of the radiation emission from the product or in any way affect its radiation safety characteristics. Such components would typically include reflectors, attenuators or shutters, warning devices, emission indicators, energy source components, interlocks and other switches, labels, and so forth. In accordance with 21 CFR 1040.10(a), the responsibility for product compliance rests with the manufacturer of the final product and not the supplier of components or material except as indicated therein. The testing of all critical components is, therefore, an important responsibility of the manufacturer. Important aspects of evaluation of these critical components prior to their use in the product include:

(a) Performance specifications for the critical components should be developed taking both the requirements of the performance standard and a tolerance analysis of the product into consideration. A tolerance analysis is a calculation of the range of performance of a product that can result from variations that can occur in components. Such an analysis should, whenever possible, be experimentally validated.

(b) All critical components should be tested to verify that their performance is within the range of specifications required for them by the manufacturer of the final product. Many of the tests of critical components may not be possible or feasible after these components have been incorporated into the product. For example, switches and interlocks may need to undergo accelerated life testing to ensure reliability; durability and ruggedness may be appropriately tested under extreme environmental conditions. Wherever possible, a 100 percent testing of components is recommended. If this is not possible or feasible, sampling procedures may be used. The sampling plan must be of demonstrable validity.

(c) If at any time the design specifications or materials of any critical components are changed, the design of the entire product should be reviewed to ensure that the change does not in any way affect the compliance of the product with the performance standard.

4.3 Engineering and Prototype Testing and Evaluation

Engineering models and prototypes should be tested thoroughly and exhaustively to assure that the product can be manufactured in compliance with the performance standard, and that it will remain in compliance under all forseeable conditions during its useful life. This would include adequate transportation tests, tests of performance under expected and adverse environmental conditions, use and abuse testing and accelerated life tests. A consistent effort is required to keep drawings and prototypes up-to-date and accurate. Any design changes should be properly documented, tested and evaluated in relation to radiation emission and safety.

Sections 5 and 6 of this document should be consulted for more detailed guidance on types of tests, test parameters, test conditions, and testing procedures.

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5.0 PRODUCTION TESTING

5.1 Design of the Production Quality Control and Testing Program

After a manufacturer has verified through design review and prototype that a product can be manufactured in compliance with the performance standard, he must design and establish a production quality control and testing program which will ensure that each individual laser product manufactured complies with the standard. In designing the production quality control and testing program, it is first necessary to identify the parameters that need to be measured or tested in order to determine compliance with the laser performance standard. The identification and criticality of these parameters depend to a large extent on the design, function, and anticipated use of a specific product. Some examples of such parameters are the accessible radiation levels, collateral radiation level, reliability of interlocks, switches and warning indicators, the quality of the mechanical and optical components, and the inclusion and durability of labels. Specific tests should be designed to take into consideration all the relevant parameters. Some such tests may be simple inspection. For example, the product should be inspected to determine that all labels are in the correct postions and properly attached on the product. However, other tests, such as those involving the power or energy measurement of the accessible laser radiation as well as the collateral radiation, are more complicated and require design of test methods and the use of defensible measurement instrumentation and techniques.

Testing will be of two types: qualitative and quantitative. Qualitative testing refers to functional tests of performance features and inspections such as those to confirm the inclusion of labels or instructional material. The quantitative testing refers to the measurement of variable parameters such as the accessible emission level which can be measured. Individual tests may be designed for each parameter. Wherever applicable, the measurement facility for each of these tests should be subjected to the measurement quality assurance as detailed in Section 3 of this document. Testing plans should be documented and the use of checklists and standardized forms is urged for logging and analysis of data.

Sets of rejection criteria will need to be determined for the different tests. In qualitative tests it is easy to establish these criteria since one is faced with a "has" or "has not", or "functions" or "does not function" type of a situation. The establishment of rejection criteria for the quantitative tests is more involved. For example,

consider measurements of the accessible laser radiation from a product intended to be a Class I product. The rejection criteria will have to be such that even when the total measurement uncertainty (discussed in Section 3.5) is taken into account the accessible laser radiation is still less than the accessible emission limits for Class I products as specified in the laser standard. If the testing is done on less than 100 percent of the production, it may be necessary to have more stringent rejection criteria.

5.2 Qualitative Testing

Qualitative testing should be conducted on a 100 percent basis and include checks and testing of the following:

5.2.1 The presence and secure attachment of a label certifying compliance of the product.

5.2.2 The presence, secure attachment and proper content of the label bearing identification of the manufacturer and place nd date of manufacture.

5.2.3 The presence, secure attachment and proper content of all hazard warning labels including classification, aperture and removable protective housing labels.

5.2.4 The integrity of the protective housing not only before, but most importantly, after installation on the product. The inspection should be directed to verify at least that there are no holes, cracks or other paths which give access to laser or collateral radiation. Human access as defined within the context of the standard and its preamble not only includes direct exposure but also exposure which may become accessible by means of insertion of a specifically defined probe. Evaluation of the adequacy of the protective housing is to be made in view of these criteria.

5.2.5 The presence and proper function of interlocks to ensure that:

a. they have been installed in the quantity and locations specified in the design,

b. they operate and perform the intended function of preventing human access to laser and collateral radiation upon removal or displacement of the interlock protected portion of the protective housing (this should be tested actively on each unit in order to verify not only proper functioning of the interlock itself but also its proper integration into the overall control logic of the system),

c. removal or displacement of the protected portion of the housing is prevented upon failure of the safety interlocks to prevent human access to laser and collateral radiation as required upon removal or displacement of the interlocked portion of the protective housing (an active test is in order with the interlock logic disabled or defeated), and

d. visual or aural indicators of interlock defeat will operate and function properly

5.2.6 The presence of a remote control connector if the product is in Class III or IV, and a functional test to verify that interruption of the circuit connecting its terminals does in fact prevent human access to laser and collateral radiation as required.

5.2.7 The presence and proper functioning of the required number of emission indicators for Class II, III or IV products. Functional testing of the indicator(s) on Class III or IV products should include measurement of the time interval between activation of the emission indicator(s) and initiation of the laser radiation.

5.2.8 The presence and proper functioning of the beam attenuator re-required for Class II, III, or IV products. If the beam attenuator is not totally opaque, the actual level of transmitted laser and collateral radiation must be measured to verify that it is below the limits of Class I or Table III of 1040.10(d).

5.2.9 The presence and proper functioning of the safeguard required for scanning laser products. Functional testing should include interruption of or a change in the scan velocity or amplitude to verify that the safeguard operates to prevent human access to laser radiation in excess of the limit that is applicable to the scanned radiation. If the safeguard operates by cessation of the radiation, simple functional testing will suffice. If, however, the safeguard operates to adjust the level of laser radiation, measurement of the actual level of laser radiation will be required under all conditions of scan alteration.

5.2.10 Functional testing of any shutter or variable attenuator incorporated in any viewing optic, viewport or display screen to include:

a. the physical presence and proper operation of the shutter or attenuator, and

b. the prevention of shutter opening or attenuator variation upon failure of the means incorporated into the product to prevent human access to transmitted laser or collateral radiation in excess of the accessible emission limits of Class I and Table III of paragraph (d) of section 1040.10.

5.2.11 The presence and proper functioning of the means incorporated into the product to measure the level of laser radiation of medical laser products of Class III or Class IV, intended for irradiation of the human body. The calibration of this means shall be determined by measurement of laser radiation under Section 5.3.5.

5.3 Quantitative Testing

Quantitative testing includes the following types of tests:

5.3.1 Measurement of the maximum accessible levels of all laser radiations for the purpose of determination and verification of the classification of the product as well as maximum output. The precision and accuracy of the measurements must be such to assure that the product cannot be operated to emit laser radiation levels higher than the maximum accessible emission limit of that class which is used to determine the required performance features and labeling of the product. Therefore, as a product can be operated at a level approaching the limit of its class, measurement error and uncertainties become increasingly critical. Note that measurements for classification are to be made with all controls and adjustments listed in the operation, maintenance and service instructions adjusted to maximize the emission of radiation during operation.

Except for demonstration laser products and surveying, leveling, and alignment laser products for which the standard specifies maximum emission levels, failure of the measurements to assure that the product cannot exceed the maximum accessible emission limit of one class requires that the product be classified within the lowest of the higher class(es) for which such assurance is possible and subject to all of the labeling and performance requirements appropriate to that higher class.

5.3.2 Measurement of the maximum accessible levels of collateral radiation. Determination of the presence of and the measurement of the levels of collateral optical and x-radiation are necessary to determine compliance with the standard. The nature of the product may be such as to preclude the necessity of production testing of individual units; e.g., the use of a properly interlocked protective housing may contain all collateral radiation making it inaccessible. If the level of collateral radiation is of such nature that variations between units are not anticipated, measurements made on the prototype with occasional spot checks of production units may suffice.

As with laser radiation, the level of collateral radiation must be determined for the purposes of compliance with all adjustments and controls adjusted to produce maximum radiation.

5.3.3 The level of laser and collateral radiation transmitted by viewing optics, viewports or display screens. Because of the individual variability of lasers and optical components that might be used in such subsystems, measurements of individual units are considered to be appropriate in this case. Note that measurements are to be made with all adjustments and controls adjusted to produce maximum radiation.

5.3.4 The level of laser radiation accessible upon removal or displacement of noninterlocked or defeatably interlocked portions of the protective housing to confirm or verify the appropriateness of warning labels required by Section 1040.10(g)(6) and (7) of the performance standard. If these levels are well below the upper limit of the appropriate class level, measurements made on the prototype with occasional spot checks of production may suffice.

5.3.5 Calibration of the means incorporated into Class III or IV medical laser products for measurement of the level of laser radiation intended for irradiation of the human body.

5.3.6 Measurement of accessible laser radiation as a result of scanning failure or other failure causing a change in either scan velocity or amplitude, if applicable.

5.3.7 Measurement of laser radiation transmitted through beam attenuators.

5.3.8 Any other quantitative measurements required to assure compliance with the standard.

5.4 Test Conditions

All testing must be conducted under the test conditions and measurement parameters specified in Section 1040.10(e). The following additional guidance is offered:

5.4.1 The product should be carefully evaluated to determine the conditions which maximize the accessible emission levels including start-up, stabilized emission and shutdown of the laser product in order to assure worst case testing.

5.4.2 Tests for classification must be made with all controls and adjustments listed in the operation, maintenance and service instructions adjusted to maximize the accessible emission level of radiation during operation. The product is considered to be operating as long as there is no clear indication of malfunction.

5.4.3 Other measurements of accessible laser radiation must be made with all controls and adjustments listed in the operation, maintenance and service instructions adjusted to maximize the emission of radiation during operation, maintenance or service as appropriate. For example, measurements made of laser radiation made accessible upon removal or displacement of non-interlocked portions of the protective housing must be made when all controls including service controls are adjusted for maximum radiation.

5.4.4 Measurements must be made at points in space in which human access is possible in the product configuration which is necessary to determine compliance. For example, in determining compliance with the requirements of Section 1040.10(g)(6) it would be necessary to conduct measurements at points in space made accessible upon removal or displacement of the non-interlocked portion of the protective housing.

5.4.5 When making laser and collateral radiation measurements, the measuring instruments must be positioned and oriented to maximize the measured quantity.

5.4.6 If the laser product is not equipped with its own energy source, measurements must be made with the laser coupled to a compatible energy source or type of energy source which produces the maximum emission level of accessible radiation. The laser energy source or type of laser energy source must be that specified in user instructions or operation manuals as required by Section 1040.10(h)(1)(v).

5.4.7 Except for scanned laser radiation, measurements of radiant power (W) or radiant energy (J) are to be made using instruments and procedures which will include the maximum power or radiant energy incident within a circular aperture stop having a diameter of 80 millimeters. This is not necessarily to be construed as requiring that the measuring instruments themselves have a collecting aperture of 80 millimeters. A smaller aperture may also be adequate to collect or account for all of the emission as required. If however, the extent of the radiation field equals or exceeds that dimension, the emission level measurement must account for the total and maximum which could be collected by an 80-millimeter circular diameter aperture. This could be accomplished by focusing the radiation into a smaller measurement instrument aperture. Similar reasoning applies to the 7-millimeter aperture for measurements of radiance, integrated radiance, irradiance, and for scanning laser products.

5.4.8 The instruments which are used for measurement of the radiometric quantities of radiation may often not be adequate to provide sufficient information regarding the temporal characteristics of the emission to

determine the proper classification of the product. For example, a quasi continuous wave laser, the output power of which may appear to be quite stable when observed using a thermo-electric radiometer, can often be seen using a wide bandwidth detector and oscilloscope to consist in reality of a train of short pulses. Such pulses may be the result of power supply characteristics, relaxation oscillations within the laser resonant cavity, mode locking, and so forth. Modulation of these types is not to be considered as necessarily undesirable and may in fact be necessary for the product to accomplish its intended function. The effect, however, may be that a product may exceed the class limit of its long term average emission when considered in terms of the individual composite pulses The point to be made is that the measurements for the determination of classification must be capable of accounting for such modulation if it is present. Manufacturers of laser products which incorporate lasers as components should be aware that the product may introduce optical feedback to the laser which can affect its temporal characteristics.

5.5 Sampling, Audit and Recycling

5.5.1 Sampling

All products must comply with the applicable requirements of the laser performance standard. The Bureau of Radiological Health recommends 100 percent testing of products for the determination of compliance. For some tests and inspections a sampling plan may be appropriate i.e., use of a sampling procedure whereby release of noncomplying products may be prevented by testing less than 100 percent of the units produced. When this is done, it is the responsibility of the manufacturer to demonstrate the validity of the sampling plan in ensuring compliance of the product with the standard. A sampling scheme must be random, i.e., the probability of a unit being selected is the same for all produced units. The so called "random" selection of units from a production line based on a judgment of randomness by an individual does not constitute true random sampling. A scheme that is based on generating random numbers or other specified statistical schemes are a more objective basis for random sampling. Examples of sampling plans are contained in Mil-Std-105D and Mil-Std-414.

In addition to random sampling to test for compliance, any systematic problem areas may warrant testing; e.g. at the beginning of a production run, or at the beginning of each day, or when a new assembler begins work on a product, and so forth.

5.5.2 Audit

An audit is a testing of a previously tested and accepted products to provide a check on the measurement process and the acceptance procedures. A specific sampling procedure (see discussion in Section 5.5.1) should

be used to select accepted units which should be subjected to all the tests and inspections of the product quality assurance program. Repeated failures of audited samples indicate problems in the product design or the quality assurance program which must be traced and corrected.

5.5.3 Recycling

Units or lots which are rejected during the quality assurance and are subsequently corrected may be recycled into the production line. Corrected units should be subjected to all of the testing and scrutiny and the same acceptance or rejection criteria as other units.

6 LIFE TESTING

The standard for laser products specifies in Section 1040.10(e) that compliance is required for the useful life of the product. Accelerated life testing is necessary to assure the continued performance of critical components and assemblies. Primary concern is with products which may increase in radiation emission or degrade in radiation safety with age. Although lasers generally decrease in output with age, the aging of other components may nevertheless increase the level of accessible emission or degrade the radiation safety of the product. Such may include: deterioration or warping of protective housings, the failure of interlocks, deterioration of optical coatings of attenuators, and so forth. It is necessary that components and products be adequately specified and tested to preclude such occurrences and that periodic accelerated life testing of such components or products be conducted to assure the continued robustness of the product.

During the production of the product, units should be randomly selected at adequate intervals for accelerated life testing to ensure that characteristics have not be inadvertently introduced which could adversely affect the product's compliance throughout its useful life. Procedures should also be established to identify, review, and promptly correct any problems with the product reliability related to laser radiation safety that may occur during the use of the product. It is important that product reliability information obtained during use be fed back to engineering and quality control for evaluation and design modification.

7 INFORMATIONAL REQUIREMENTS

7.1 Operating Manuals

The manufacturer should verify that the user information supplied with the product is up-to-date, reflecting all pertinent changes or modifications relating to radiation safety which may have been incorporated and contain:

7.1.1 Adequate instructions for assembly, operation, and maintenance, including clear and specific warnings, instruction on avoidance of exposure to laser and collateral radiation, and an adequate maintenance schedule for continued product compliance.

7.1.2 A complete statement of the radiation characteristics of the product.

7.1.3 Reproductions and locations of all warning and identifying labels.

7.1.4 A listing of all controls, adjustments and procedures including a precautionary statement.

7.1.5 Identification of compatible energy sources, if applicable.

7.2 Brochures, Catalogs and Advertisements

Sales literature should be checked to confirm that it contains a reproduction of the required warning logotype.

7.3 Service Publication

Service literature should be checked to confirm that it contains adequate radiation safety instruction including:

7.3.1 Adequate instructions for service adjustments and procedures, including clear and specific warnings and instructions on avoidance of exposure to laser and collateral radiation and an adequate maintenance schedule for continued product compliance.

7.3.2 A listing of controls and procedures for increasing accessible emission levels.

7.3.3 A description of the location of displaceable portions of the protective housing that could allow access to higher levels of laser and collateral radiation.

7.3.4 Reproductions of all required labels and hazard warnings.

7.4 Other Informational Requirements

The specific informational requirements are contained in Section 1040.10(h). This listing is intended to provide only an indication of the areas which must be considered.