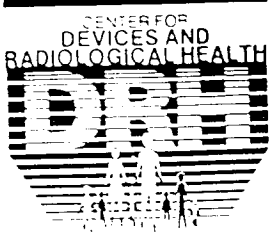
radiological health

Quality Control Guide for Sunlamp Products



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

HHS Publication FDA 84-8234

Quality Control Guide for Sunlamp Products

Office of Compliance

WHO Collaborating Centers for:
- Standardization of Protection Against Nonionizing Radiations
- Training and General Tasks in Radiation Medicine
- Nuclear Medicine

September 1984

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

FOREWORD

In October 1982, the Food and Drug Administration established the Center for Devices and Radiological Health (CDRH) by merging the Bureau of Medical Devices and the Bureau of Radiological Health.

The Center develops and implements national programs to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness and proper labeling of medical devices, to control unnecessary human exposure to potentially hazardous ionizing and nonionizing radiation, and to ensure the safe, efficacious use of such radiation.

The Center publishes the results of its work in scientific journals and in its own technical reports. These reports provide a mechanism for disseminating results of CDRH and contractor projects. They are sold by the Government Printing Office and/or the National Technical Information Service.

Also, CDRH technical reports in radiological health are made available to the World Health Organization under a memorandum of agreement between WHO and the Department of Health and Human Services. Three WHO Collaborating Centers, established under the Bureau of Radiological Health, continue to function under CDRH:

WHO Collaborating Center for Standardization of Protection Against Nonionizing Radiations;

WHO Collaborating Center for Training and General Tasks in Radiation Medicine; and

WHO Collaborating Center for Nuclear Medicine.

We welcome your comments and requests for further information.

John C. Villforth
Director
Center for Devices and
Radiological Health

PREFACE

The Performance Standard for Sunlamp products (21 CFR 1040.20) became effective May 7, 1980. Sunlamps and sunlamp products manufactured on or after that date must conform to the applicable provisions of the standard. In addition, manufacturers are required to certify that their products comply with the standard and to furnish reports, to the Center for Devices and Radiological Health, that clearly substantiate the product's compliance. Because sunlamp products are also medical devices, they are subject to the Medical Device Amendments to the Food, Drug, and Cosmetic Act, including the Good Manufacturing Practices (GMP) regulations developed under the authority of that Act. All manufacturers of sunlamps and sunlamp products must estabish and implement GMPs to ensure that the devices conform to their specifications, and implement quality control procedures to ensure compliance with the Federal performance standard.

This guide has been prepared to assist manufacturers in satisfying the GMP requirements and in developing and implementing quality assurance programs, including appropriate testing. This guide also provides what we believe to be fair and standard criteria by which manufacturers' programs will be evaluated. Because of variation in product designs and manufacturing processes, a detailed step-by-step protocol would be of limited application. The purpose here, therefore, is to set forth a general description of the procedures and philosophy of quality assurance as appropriate for sunlamps and sunlamp products. This document is intended for use in conjunction with the "Reporting Guide for Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products."

We strongly emphasize that the manufacturer may adopt other alternative procedures that are equivalent to, or are as effective as, those methods described in this guide. Each manufacturer's test procedures and testing programs will be evaluated on an individual case-by-case basis. If the alternative procedures constitute good manufacturing practices and provide adequate safeguards to ensure compliance with the standard, the Center for Devices and Radiological Health (CDRH) would have no reason to disapprove such a program.

However, neither the fact that CDRH did not disapprove a testing program, nor the fact that such a program was established pursuant to this guide, relieves a manufacturer from his obligations to comply with the Radiation Control for Health and Safety Act of 1968 and the Food, Drug, and Cosmetic Act as amended.

Walter E. Gundaker
Director
Office of Compliance

CONTENTS

ABSTRACT

Office of Compliance. Quality Control Guide for Sunlamp Products. HHS Publication 84-8234 (September 1984)(pp. 26).

Sunlamp and sunlamp products manufactured on or after May 7, 1980, must conform to applicable portions of a performance standard (21 CFR 1040.20), and their manufacture must be in accord with the medical devices Good Manufacturing Practices (GMP) regulations promulgated under the Food, Drug, and Cosmetic Act (FD&C). This guide is intended to assist manufacturers of these products in satisfying both the GMP requirements and in developing and implementing quality assurance (QA) programs. This guide provides the criteria and the underlying philosophy used by FDA to evaluate manufacturer's QA programs. This document is intended to be used in conjunction with "Reporting Guide for Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products."

QUALITY CONTROL GUIDE FOR SUNLAMP PRODUCTS

1. QUALITY ASSURANCE PROGRAM

1.1 ELEMENTS OF QUALITY ASSURANCE PROGRAM

A viable quality assurance program ensures the performance of a product at a designated level at the time of manufacture and throughout its useful life. It is essential for a manufacturer to establish such a program to ensure compliance of a product with the Federal performance standard and its conformance with design specifications. The adequacy of a specific quality assurance and testing program must be judged solely on its own merits and applicability to the product. The essential elements of a quality assurance program include the following:

1. proper organization, personnel, facilities, and administrative procedures to ensure an objective and defensible program;

2. preproduction evaluation and testing of the product and testing of components and material obtained from other manufacturers;

3. valid measurement techniques, calibrations, and treatment of measurement uncertainties;

4. testing and evaluation of the product during and after production and statistical analyses of data (the establishment of confidence limits and rejection criteria are important components of such an evaluation);

5. procedures to ensure that only accepted units are distributed and 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;

6. an audit procedure to measure the degree of conformance and the effectiveness of the quality assurance program, including product audits;

7. lifetime and reliability testing procedures or other suitable means to determine whether the product will continue to meet its design specifications during its useful life;

8. a continuous review of the product's performance throughout its useful 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;

9. documentation control to assure that all manufacturing, component, and finished product specifications adequately reflect the product design and provide an effective and consistent mechanism for changes of specifications or quality control procedures; and

10. quality control records, including a device master record and a device history record.

1.2 OBJECTIVITY OF PROGRAM

The quality assurance program should be carefully designed and administered to ensure the objectivity of the program. Certain safeguards against personal prejudice and conflicting interests should be built into the system to avoid biased decisions. This may present a problem in small manufacturing firms that employ only a few persons. However, the division of responsibility between production and quality control personnel should be maintained. This may be accomplished, for example, if one person, who is responsible for the receiving, inspection, and accountability of components, is also designated responsible for in-process checks and finished product inspection. Another person should be held responsible for all the production processes. This arrangement (or similar ones) may sustain the objectivity of the quality control program by dividing the responsibilities.

1.3 DOCUMENTATION AND RECORDS

Complete documentation of the quality assurance program must be maintained as required by 21 CFR 1002.30. This should include the description of tests performed, sequence, description of the measurement instrumentation and techniques, 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 all the units produced are not tested, a sampling technique must be used and must be scrupulously documented and followed. Standardized forms for data recording should be used. The forms should provide space for logging all information relevant to the product and the test, including the product model and serial numbers, date of test, date of manufacture, samples per lot, results of test, identification of personnel performing and reviewing the test, model and serial numbers of test instruments, and so forth. A device master record as required by 21 CFR 820.181 must be established for each type of device and include, or refer to the location of, the information concerning:

1. the device specifications, including drawings and component specifications;

2. production process specifications, including the appropriate equipment specifications, production methods, and production procedures;

3. packaging and labeling specifications; and

4. quality assurance procedures and specifications, including quality assurance checks used and the quality assurance apparatus used. The device master record shall be prepared, dated, and signed by a designated individual(s).

A device history record as required by 21 CFR 820.184 must also be maintained and it shall include, or refer to the location of, the information concerning the dates of manufacture, the quantity manufactured, the quantity released for distribution, and any control number used.

Among small manufacturers of sunlamp products, the manufacturing process may be limited to assembling components into the final product, and there should be no problem with communication and managing operations. In this situation, written manufacturing procedures may be reduced to a practical extent. In some cases, training and work experience may be considered valid substitutes for written manufacturing procedures. However, manufacturers must still ensure uniformity of procedures and keep records of test results necessary to ensure the quality of the product.

Records required by the Radiation Control for Health and Safety Act are to be kept for 5 years (21 CFR 1002.31(a)), and for no less than 2 years if required by the Food, Drug, and Cosmetic Act (21 CFR 820.180(b)). Test records, complaints, trends analyses, failure analyses, and audits should be used to identify and provide solutions to quality assurance problems.

1.4 VALIDITY OF MEASUREMENT

A valid program of measurements made as part of quality assurance testing involves periodic evaluation of the test methods and calibration of the instruments. A schedule to recalibrate measuring instruments against an acceptable standard is important to ensure a consistent measurement capability. Calibration services from the instrument manufacturer or other qualified outside sources, with traceability to National Bureau of Standards primary measurement standards, should be used when adequate calibration facilities are not available within a company.

The instrumentation should be carefully specified and selected to ensure that it is capable of performing the tests required by the standard. For example, instruments for ultraviolet (UV) radiation measurements should have sufficient spectral sensitivity in the UV region to measure the anticipated radiation levels from the product. After the measurement instruments have been obtained, they need to be evaluated for proper performance and operation. Control charts and logs of instrument performance and calibrations are essential, as well as service and maintenance schedules. Any changes of the operator, or in the instrument, its components, its techniques of use, calibration standards, or other relevant components of the measurements system should be documented.

1.5 AUDIT PROCEDURES

The purpose of the quality audit is to check the degree of conformance of the quality control procedures and the effectiveness of the quality assurance program, and to ensure that all procedures established are adequate and consistently followed. The quality audits are in addition to the routine quality assurance program and should include, but not be limited to, product audits. A product audit is an independent evaluation of product quality to determine if the product complies with the standards and if the product conforms to design specifications. Random sampling is the only acceptable method in selecting units for product audit. The person responsible for the audit should not have responsiblity for the matter being audited but must have sufficient training and experience in the manufacturing process and testing

procedures. For small manufacturers, a simple checklist with appropriate instructions may suffice. Documentation of audits and their results must be kept; results of findings should be reviewed by management. Audit frequency should be consistent with findings, but the interval between audits should not exceed 1 year.

1.6 PERSONNEL TRAINING

All quality assurance and production personnel shall have the necessary training to perform their assigned responsibilities adequately. They should have a thorough understanding of their jobs and be made aware of defects and errors likely to be encountered in performing their assigned functions.

2. PREPRODUCTION EVALUATION

Preproduction evaluation and testing should include a review of the design, evaluation of components and material obtained from other manufacturers, and engineering and prototype testing to confirm that the product as designed can be manufactured in compliance with the standard and in conformance with the design specifications.

2.1 DESIGN REVIEW

Before the manufacture of the product begins, the product design must be reviewed to determine if the product will comply with the Federal performance standard and other applicable criteria for product safety, including electrical and mechanical safety, as discussed in the Equipment Recommendations (See Appendix A).

This review allows the manufacturer to perform a step-by-step evaluation of the requirements for the product and the means used to fulfill these requirements. In addition to the performance requirements, the conditions and environments under which the product will be used should be considered carefully. For example, if a product is intended to be used at a commercial facility and an alternate timer such as a coin box is permitted, then a mechanism must be incorporated into the coin box to allow the user to terminate exposure before completion of the timer cycle and to prevent the timer from operating continuously in excess of the recommended maximum exposure time. The coin box timer must also provide intermediate exposure times compatible with the recommended schedule. The goggles should be evaluated to ensure adequate eye protection for the user under all possible exposure positions and uses. The location of controls, particularly the radiation emission control, should be convenient for the user to reach in case of emergency. In general, an adequate safety factor regarding the use of the product should be built into the product design, because the product is not only expected to be in compliance at the time of manufacture but also during its entire useful life (see Appendix B for details of compliance requirements).

Further, the manufacturing process must be reviewed to assure that the design basis for the product, components, and packaging is correctly translated into approved specifications.

The approved design specifications must be accurately documented. The manufacturing process must be described in writing and implemented according to the written description in order to ensure the finished product is manufactured according to the approved design. Any changes in the design and/or manufacturing process must be reviewed, approved, and dated before implementation.

2.2 ENGINEERING AND PROTOTYPE TESTING AND EVALUATION

Engineering models and prototypes should be built and tested thoroughly to ensure that the product can be manufactured as designed and be in compliance with the performance standard during the product's useful life.

This testing must include adequate transportation tests, tests of performance under expected 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 must be properly documented, tested, and evaluated in relation to product safety.

3. COMPONENTS AND PRODUCTION TESTING

3.1 COMPONENT EVALUATION AND TESTING

Components should be received, stored, and handled in a manner to prevent damage, mixup, contamination, and other adverse consequences. Components should be inspected, sampled, and tested for conformance to specifications because certain components can affect the compliance of ultraviolet lamps and/or sunlamp products. For example, glass structure or an electrical or mechanical component, such as timer, eyewear, or emission control, will definitely affect the product's compliance. (Tags and labels are also important for compliance.)

Whether such components are fabricated by the manufacturer of the ultraviolet sunlamp or sunlamp product, or purchased from a vendor, proper evaluation of the components is essential in determining if the ultraviolet or sunlamp product will comply with the applicable standard after manufacture. Manufacturers who obtain components from different vendors may choose to rely on a supplier's certificate of analysis and approval in lieu of component testing. These certificates should be made part of the quality assurance documentation.

However, the responsibility for product compliance rests with the manufacturer of the final product rather than with the supplier of components or material. Therefore, any decision to totally rely on a supplier's evaluation must be carefully considered; some type of incoming acceptance examination or testing is recommended. An exception applies to the lamp manufacturers' certification of compliance for their UV lamps. This certification is acceptable because the lamp manufacturers are legally liable for the validity of that certification.

In general, three points must be considered in evaluating components prior to their use in the ultraviolet lamp or sunlamp product.

1. Performance specifications for components should be developed, taking into consideration both the requirements of the performance standard and a tolerance analysis of the product. A tolerance analysis is a calculation of a product's performance range that can result from component variations. Such an analysis would, whenever possible, be experimentally validated.

2. All components should be tested to verify that their performance is within the range of specifications required of them by the manufacturer of the final product. Switches and timers may need to undergo accelerated life testing to ensure reliability. Durability and ruggedness of such components may be appropriately tested under expected environmental conditions. Components also may be appropriately tested after assembly of a subsystem or entire product.

3. If at any time the design specifications or materials of a component 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.

3.2 PRODUCTION TESTING

In designing the production quality assurance and testing program, it is first necessary to identify the parameters that need to be examined or tested in order to determine compliance with the performance standard. The identification and critical nature of these parameters depend to a large extent upon the design, function, and anticipated use of a specific product. Some examples of such parameters are the irradiance ratio, reliability of timers and switches, the inclusion and durability of labels, mechanical construction, electrical safety, and so forth. Some examinations or tests may consist of simple inspections. For example, the product should be inspected to determine that all labels are in the correct positions and properly attached to the product. However, other tests, such as those involving the irradiance ratio of the ultraviolet lamp or sunlamp product and the spectral transmittance of the protective eyewear, 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 a functional test of performance features and inspections, such as tests that confirm the inclusion of labels or instructional material. Quantitative testing refers to the measurement of variable parameters such as the spectral irradiance of the ultraviolet lamp. Individual tests may be designed for each parameter.

Rejection or acceptance criteria need to be determined for different tests. In qualitative tests it is easy to establish the criteria because one is faced with a "has" or "has not" or "functions" or "does not function" situation. The establishment of rejection or acceptance criteria for the quantitative test is more involved. An example is the measurement of ultraviolet radiation from an ultraviolet lamp. The rejection or acceptance

criteria must assure the manufacturer that ultraviolet radiation is within the irradiance ratio limits for sunlamp products as specified in the sunlamp products performance standard, even when the total measurement uncertainty is taken into account. If the testing is not done on every unit, it may be necessary to have more stringent criteria than if every unit were tested.

3.3 QUALITATIVE TESTING

Qualitative testing should be conducted on all of the units produced and should include checks or testing of the following:

1. the presence and secure attachment of a label certifying compliance of the product;

2. the presence, secure attachment, and proper content of the label that identifies the manufacturer and place and date of manufacture;

3. in the case of ultraviolet lamps, the presence, secure attachment, and proper content of the warning label;

4. in the case of sunlamp products, the presence, secure attachment, and proper content of all hazard warning labels;

5. the presence and proper content of instructions to the users;

6. the presence and proper functioning of the timer;

7. the presence and proper functioning of a control that permits users to manually terminate radiation emission from the sunlamp product at any time without disconnecting the electrical plug or removing the ultraviolet lamp;

8. the presence and required number of protective eyewear devices accompanying the sunlamp product; and

9. the proper functioning of the ultraviolet lamps.

3.4 QUANTITATIVE TESTING

Quantitative testing includes the following types of tests:

1. measurement of ultraviolet radiation output to determine if the spectral irradiance is within the expected range for certain types of products (UV-A or UV-B);

2. measurement of the irradiance output within the specified wavelength ranges to determine the irradiance ratio;

3. measurements of protective eyewear spectral transmittance, to determine that it does not exceed the values required by the performance standard; and

4. measurement of timer accuracy to determine that the error is not greater than ± 10 percent of the maximum timer interval.

There are many ways to conduct these measurements. CDRH does not object to any method that would, when correctly executed, yield the correct physical values. Procedures for compliance testing at FDA's Winchester laboratory are provided in Appendix C for manufacturers' reference only.

3.5 TEST CONDITIONS FOR DETERMINATION OF COMPLIANCE

In order for the product to have a valid certification (21 CFR 1010.2), the test on which the certification is based must meet the following conditions:

1. The test must account for all measurement errors and statistical uncertainties in the measurement process and, wherever applicable, for changes in radiation emission or degradation in radiation safety with age of the product.

2. The measurements must be made under operational conditions using procedures that maximize the emission of radiation and with the measuring instrument positioned and oriented so that it will detect the maximum amount of radiation detectable by the instrument. However, the measuring instrument shall be no closer to the product than the minimum-use distance.

3. Such measurements must be made at a test voltage up to 130 root-mean-square volts if the sunlamp product or ultraviolet lamp is designed to operate from nominal 100 to 120 root-mean-square volt power sources. If the sunlamp product or ultraviolet lamp is designed to operate from a power source having some voltage other than from nominal 100 to 120 root-mean-square volts, the measurement must be made at a voltage up to 110 percent of the maximum nominal root-mean-square voltage specified by the manufacturer for the power source.

3.6 SAMPLING, AUDIT AND RECYCLING

3.6.1 Sampling

CDRH recommends testing 100 percent of the products to determine compliance. However, in the case of products built in large quantity on a production line, a sampling plan that randomly allows selection of some units for some tests and inspections may be appropriate. When this is done, it is the responsibility of the manufacturer to demonstrate that the sampling plan will ensure compliance of the product with the standard and with the design specifications. A random sampling scheme must be truly 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 is a more objective basis for random sampling. Examples of sampling plans are contained in Mil-Std-105D and Mil-Std-414 (See Reference 1 and 2).

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.

3.6.2 Product Audit

A product audit is not a GMP requirement; however, it is desirable to establish such an audit to test the validity of the quality control and testing program. A product audit includes testing a previously tested and accepted product to provide a check on the measurement process and the acceptance procedures. A specific sampling procedure should be used to select accepted units that 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.

3.6.3 Recycling

Units or lots that fail to conform to specifications and which are refurbished, repaired, reworked, and so forth, must be subjected to the testing and scrutiny and the same acceptance or rejection criteria to which the original was subjected for the characteristics that may be adversely affected by the reprocessing.

References

1. United States Department of Defense. Sampling Procedures and Tables for Inspection by Attributes. Military Standard 105D (April 29, 1963).

2. United States Department of Defense. Sampling Procedures and Tables for Inspection by Variables for Percent Defective. Military Standard 414 (June 11, 1957).

Copies of these documents (Mil-Std 105D and Mil-Std 414) are for sale by

Superintendent of Documents
United States Government Printing Office
Washington, D.C. 20402

APPENDIX A

EQUIPMENT RECOMMENDATIONS FOR TANNING BOOTHS

The following safety problems are identified, and possible solutions in the form of equipment recommendations are provided for manufacturers of tanning booths or other similar equipment for whole body exposure for tanning purposes. These recommendations are in addition to the requirements of the sunlamp product performance standard.

1. User Positioning in the Booth - The intensity of the radiation to which a user is exposed usually depends upon the distance from the user to the lamp. The intensity of the radiation at contact can be as much as five times higher than that at a distance of 12 inches. Serious burns can occur if the proper exposure distance is not maintained. Installing hand rails, markings on the floor or other suitable physical aids are possible solutions.

2. Timer Error - The ultraviolet radiation intensity usually found inside a tanning booth is relatively high when compared to the sun or the intensities associated with smaller home portable sunlamps. Because of this, allowable exposure times are shorter. Therefore, more accurate control of exposure duration is necessary to decrease the risk of overexposure, and injury. A timer having an accuracy of ±10 percent of any selected timer interval is sufficiently accurate.

3. Protective Eyewear - Exposure of a person's eyes to ultraviolet radiation may result in eye burns, yet persons being exposed need to see well enough to maintain balance and to rapidly locate the door and exit safely, should that be necessary. It is important to provide protective eyewear that protects the eyes from ultraviolet radiation and allows adequate vision.

4. Temperature Control - Operation of sunlamps can increase the temperature in an enclosed booth. A large increase in temperature might cause fainting and subsequent injury. Booths which keep the temperature below 100°F (38°C) would not be cause for concern.

5. Electrical Safety - If potential electrical hazards in the booth are not controlled, users, operators, and service personnel may be seriously injured. Elevated temperatures cause perspiration, which enhances the possibility or severity of an electric shock. Even without perspiration, the skin may come into contact with the interior surfaces which house lamps and ballasts that carry large amounts of current. Without proper circuit design and insulation there is potential for electric shock.

In addition there are potential hazards to operators and service personnel. Changing lamps, turning on the device, and so forth, can be a hazard if the device is not grounded properly and if ground fault protectors are not included. There is also the possibility of a fire due to circuit overloads, wire shortings and use of flammable material. Electrical hazards will be minimized in booths that conform to currently recognized electrical standards for such equipment.

6. Mechanical Construction - The collapse of a booth might cause electrical shock, fire, or direct physical injury. This can be prevented by designing the booth to have enough strength and rigidity to resist the stress of use and to withstand the impact of a falling person.

7. Protection from Lamps - A person can be cut and seriously injured by falling into or bumping against bare sunlamps. This could be prevented by use of physical barriers around the lamps, such as heavy wire grids or ultraviolet transmitting plastics that are sturdy enough to withstand the impact of a falling person.

8. Access and Support - Rapid entrance into or exit from the booth is essential in emergencies. This can be assured by use of doors that open outwardly and are easily opened from both the inside and the outside of the booth. The potential for injuries from falls can be reduced by use of hand rails and by floors that provide adequate traction for wet or dry bare feet.

APPENDIX B

DESIGN CONSIDERATIONS FOR COMPLIANCE WITH THE SUNLAMP STANDARD

A. For Ultraviolet Lamps

(1) Each ultraviolet lamp, unless exempted, must have on the product a permanent label which contains (21 CFR 1040.20(d)(2)) (i) the words "Sunlamp-DANGER-Ultraviolet radiation. Follow instructions." (ii) the model identification and (iii) the words "Use ONLY in fixture equipped with a timer."

(2) Each ultraviolet lamp must be permanently labeled or marked in such a manner that the name of the manufacturer and month and year of manufacture (all of which may be expressed in code) can be determined (21 CFR 1040.20(d)(3)). Labels or marks shall be legible throughout the useful life of the lamp.

(3) When a lamp is sold separately from a sunlamp product, the lamp packaging uniquely associated with an ultraviolet lamp (i.e., innermost lamp packaging) must bear a label or tag that contains the full name and address of the manufacturer, place of manufacture and month and year of manufacture if such a label or tag is not affixed or inscribed on the lamp itself (21 CFR 1040.20(d)(3) and 21 CFR 1010.3(a)). If the lamp is sold under a name other than the manufacturer, the full name and address of the company under whose name the lamp is sold may be set forth, provided sufficient information is furnished to CDRH to allow the Agency to identify the manufacturer. The place of manufacture may be expressed in code. However, no specific place of manufacture identification will be required if the place of manufacture is the same as the address of the manufacturer stated on the label, or if the manufacturer has only one place of manufacture for such lamps and has identified that place of manufacture to CDRH. The month and year of manufacture must appear in full, without abbreviation, as in the following example - Manufactured: March 1980. However, when the date of manufacture is provided in code on the lamp, CDRH will not object to the omission of the date of manufacture on the packaging if the key to the date code and the location of the coded information are provided on the packaging in a manner that will allow the date to be readily decoded. The month and year of manufacture on the packaging must be the same as that which appears on the lamp.

(4) The lamp packaging uniquely associated with the ultraviolet lamp not accompanying a sunlamp product must also bear a label or tag which contains a statement by the manufacturer certifying that the lamp conforms to the requirements of the Federal performance standard for such lamps if the certification label or tag is not affixed or inscribed on the lamp itself (21 CFR 1040.20(d)(3) and 21 CFR 1010.2(b)). The certification statement can be in any of the following acceptable forms:

"Product complies with DHHS radiation performance standard, 21 CFR 1040.20."

"Product complies with DHHS radiation performance standards, 21 CFR Chapter 1, Subchapter J."

"Product complies with applicable DHHS standards under the Radiation Control for Health and Safety Act of 1968."

Other certification statements may be used as long as they are clear and unambiguous.

(5) The ratio of the irradiance within the wavelength range of greater than 180 nanometers through 260 nanometers to the irradiance within the wavelength range of greater than 260 nanometers through 320 nanometers must not exceed 0.003 at any distance and direction from the lamp (21 CFR 1040.20(c)(1)).

(6) The lamp must not be capable of insertion and operation in the "single contact medium screw" and/or "double-contact medium screw" lampholders (21 CFR 1040.20(c)(6)).

(7) Instructions containing information as required by 21 CFR 1040.20(f) must be provided to the purchasers of the lamp not accompanying a sunlamp product.

B. For Sunlamp Products

(1) Each sunlamp product must have a label that contains the information as required by 21 CFR 1040.20(d)(1)(i) through (ix), including the warning statement, designation of the ultraviolet lamp type which is to be used in the product, instructions concerning minimum use distance, a warning to use protective eyewear, recommended maximum exposure time, recommendations for duration, frequency, and spacing of sequential exposures, and a statement of the time it may take before the expected results appear (please note CDRH position on some of these labeling requirements as expressed in the August 24, 1981 memo to sunlamp product manufacturers). The design must clearly define the contents and locations of the labels required in Section 1040.20(d), and their permanence and visibility must be assured.

(2) Each sunlamp product must bear a label or tag that contains the full name and address of the manufacturer, place of manufacture and month and year of manufacture (21 CFR 1040.20(d) and 21 CFR 1010.3(a)). If the sunlamp product is sold under a name other than the manufacturer, the full name and address of the company under whose name the product is sold may be set forth, provided sufficient information is furnished to CDRH to allow the Agency to identify the manufacturer. The place of manufacture may be expressed in code.

However, no specific place of manufacture identification will be required if the place of manufacture is the same as the address of the manufacturer stated on the label or if the manufacturer has only one place of manufacture for such products and has identified that place of manufacture to CDRH. The month and year of manufacture must appear in full, without abbreviation, as in the following example: Manufactured: March 1980.

(3) Each sunlamp product must also bear a label or tag which contains a statement by the manufacturer certifying that the product conforms to the requirements of the Federal performance standard for such products (21 CFR 1040.20(d) and 21 CFR 1010.2(b)). The certification statement can be in any of the following acceptable forms:

"Product complies with DHHS radiation performance standard, 21 CFR 1040.20."

"Product complies with DHHS radiation performance standards, 21 CFR Chapter 1, Subchapter J."

"Product complies with applicable DHHS standards under the Radiation Control for Health and Safety Act of 1968."

Other certification statements may be used as long as they are clear and unambiguous.

(4) The ratio of irradiance within the wavelength range of greater than 180 nanometers through 260 nanometers to the irradiance within the wavelength range of greater than 260 nanomemters through 320 nanometers shall not exceed 0.003 at any distance and direction from the product (21 CFR 1040.20(c)(1)). In meeting this requirement, a manufacturer of sunlamp products may rely on a certification of compliance made by the manufacturer of the ultraviolet lamp.

(5) A sunlamp product must incorporate a timer with multiple timer settings adequate for the recommended exposure time intervals for different exposure distances and expected results of the product. The maximum timer interval shall not exceed the recommended maximum exposure time or 10 minutes, whichever is less. The timer must have an accuracy of $\pm$10 percent of the maximum timer interval.

(6) A sunlamp product must incorporate a control to enable the user to manually terminate radiation emission from the sunlamp product at any time, without disconnecting the electrical plug or removing the UV lamps.

(7) It must be impossible for the sunlamp product to automatically recycle and restart following termination of emission until the product is reactivated manually.

(8) The spectral transmittance of the protective eyewear must not exceed a value of 0.001 over the wavelength range of greater than 180 nanometers through 320 nanometers and a value of 0.01 over the wavelength range of greater than 320 nanometers through 360 nanometers, and must be sufficient over the wavelengths greater than 360 nanometers to enable the user to see clearly enough to read the labels and reset the timer. There is protective eyewear on the market that appears to comply with this requirement. The sunlamp product manufacturer could request a certification by the protective eyewear manufacturer that the product complies with the applicable portion of the standard.

(9) Instructions containing information required by 21 CFR 1040.20(f)(1) must be provided to the purchasers of the product.

APPENDIX C

WINCHESTER ENGINEERING AND ANALYTICAL CENTER

PROCEDURES FOR LABORATORY COMPLIANCE TESTING OF SUNLAMP PRODUCTS AND ULTRAVIOLET LAMPS INTENDED TO BE USED IN SUNLAMP PRODUCTS

February, 1981

FOOD AND DRUG ADMINISTRATION
WINCHESTER ENGINEERING AND ANALYTICAL CENTER

PROCEDURES FOR LABORATORY COMPLIANCE TESTING OF SUNLAMP PRODUCTS AND ULTRAVIOLET LAMPS INTENDED TO BE USED IN SUNLAMP PRODUCTS

February, 1981

INTRODUCTION

The purpose of this document is to establish procedures for laboratory compliance testing of Sunlamp Products and Ultraviolet Lamps intended to be used in Sunlamp Products that are certified by the manufacturer as in compliance with the "Sunlamp Products: Performance Standard" published in 21 CFR Parts 1010 and 1040. The procedures described in this document are applicable to any ultraviolet lamp and product containing such lamps intended for irradiation of any part of the human body by light (of wavelength in air less than 320 nanometers) to induce skin tanning. Definitions of terms used in this document are identical to definitions published in 21 CFR Parts 1000 through 1040.

SPECIAL INSTRUCTIONS

PERFORM ALL OPERATIONS WITH EXTREME CARE. ULTRAVIOLET RADIATION, OZONE AND ELECTRICAL SHOCK ARE ALL HAZARDS INHERENT WITH THESE TESTS.

GENERAL INSTRUCTIONS

1. Laboratory control of sunlamp products and ultraviolet lamps intended to be used in sunlamp products shall be maintained as specified in the FDA Regulatory Procedures Manual, the Analyst Guidance Manual, and Compliance Program 7390.804E "Compliance Testing of Sunlamp Products at WEAC".

2. Upon notification of assignment of a Sunlamp/Ultraviolet lamp sample for analysis the analyst shall arrange with the Sample Custodian to transfer the sample to the testing laboratory.

3. All test data shall be recorded on Analyst Worksheets (FD-431 and FD-431a) and appropriate special data sheets.

4. The sample number shall be acquired from the "Official Seal" (FD-414a) on the sample and verified with the "Collection Report" (FD-464) and be clearly printed on all worksheets. If no "Official Seal" is present on the sample, consult your supervisor.

5. Before breaking the seal and removing the sample from its shipping carton, the analyst shall initiate an Analyst Worksheet (FD-431) in accordance with Chapter 9 of the Analyst Operations Manual.

6. All accompanying materials shall be read and understood before any testing procedures are initiated. Consult your supervisor if any problems are encountered with the materials.

COMPLIANCE TESTING

I. Introduction

The compliance tests delineated in this part are performed on all Sunlamp and Sunlamp Products collected for analysis at WEAC under compliance program 7390.804E.

II. Sunlamp Products

A. Performance

1. Measurement of Irradiance Ratio Limit, Timer Accuracy, and Transmission of Protective Eyewear shall be carried out according to the procedures outlined in Appendices A through C respectively.

2. Radiation Emission Controls

a. Verify that there is a user control on the sunlamp product that will terminate radiation emission at anytime without disconnecting the electrical plug or removing the ultraviolet lamp.

b. Verify that when radiation emission from a sunlamp product has been terminated for any reason, including termination by a timer, the product will not automatically recycle and restart.

B. Labels

1. Identification Labeling

a. Visually examine the identification label for (a) presence, (b) permanence, (c) legibility, (d) accessibility, and (e) correctness.

b. Record the name of the manufacturer and the month and year of manufacture.

2. Certification Labeling

a. Visually examine the certification label for (a) presence, (b) permanence, (c) legibility, (d) accessibility, and (e) correctness.

3. Verify that the following statement is present on the product: "DANGER-Ultraviolet Radiation. Follow instructions. As with natural sunlight, overexposure can cause eye injury and sunburn;

repeated exposure may cause premature aging of the skin and skin cancer. Medications or cosmetics applied to the skin may increase your sensitivity to ultraviolet light. Consult physician before using lamp if taking any medication or if you believe yourself especially sensitive to sunlight."

4. Verify that the following recommendations, directions, warnings and statements are present on the product:

   a. Designation of the ultraviolet lamp type which is to be used in the product.

   b. A recommended minimum use distance specified both in meters and in feet (or inches).

   c. Directions for measuring the minimum use distance.

   d. A warning that exposure at distances less than the minimum use distance is not recommended.

   e. A warning to use protective eyewear whenever the product is energized.

   f. A recommended maximum exposure time in minutes.

   g. A recommendation for duration, frequency, and spacing of sequential exposures.

   h. A statement of the time it may take before the expected results appear.

C. Instructions

Verify that the users' instructions contain the following:

1. A reproduction (color optional) of the label described in 3 and 4 above, prominently displayed at the beginning of the instructions.

2. A prominently displayed statement containing the words: "DANGER - Ultraviolet radiation. Follow instructions. As with natural sunlight, overexposure can cause premature aging of the skin and skin cancer. Medications or cosmetics applied to the skin may increase your sensitivity to ultraviolet light. Consult physician before using lamp if taking any medication or if you believe yourself especially sensitive to sunlight." This requirement may be satisfied by the reproduction of the label described in 3 above.

3. A statement of the maximum number of people who may be exposed to the product at the same time and a warning that only that number of protective eyewear has been provided.

4. Instructions for obtaining repairs and recommended replacement components and accessories which are compatible with the product,

including compatible protective eyewear, ultraviolet lamps, timers, reflectors and filters, and which will, if followed result in continued compliance with the Standard.

III. Ultraviolet Lamps

A. Performance

1. Measurement of Irradiance Ratio Limit shall be carried out according to the procedures outlined in Appendix A.

2. Compatibility of Lamps

a. Determine visually, by physical measurement, or trial that the lamp cannot be inserted into either a "Single-contact medium screw" or "Double-contact medium screw" lampholder.

b. If the lamp can be inserted in either or both lampholder(s), determine if it can be operated.

B. Labels

1. Identification Labeling

a. Visually examine the identification label for (a) presence, (b) permanence, (c) legibility, (d) accessibility, and (e) correctness.

b. Record the name of the manufacturer and the month and year, or codes, of manufacture as marked on the inscribing tags, or labels, or on the packaging.

2. Certification Labeling

a. Visually examine the certification label as required under 1010.2 for: (a) presence, (b) permanence, (c) legibility, (d) accessibility, and (e) correctness.

3. Other labeling, determine the presence of labels on the lamp stating:

a. "Sunlamp-DANGER-Ultraviolet radiation. Follow instructions."

b. The model identification

c. "Use ONLY in fixture equipped with a timer."

4. If the labeling in 1 and 2 above is not permanently affixed or inscribed on the lamp but is on the lamp packaging, determine that the name of the manufacturer and month and year are permanently affixed or inscribed on the exterior surface of the ultraviolet

lamp so as to be legible and readily accessible to view. The name of the manufacturer and month and year of manufacture required to be permanently affixed or inscribed on the exterior surface of the lamp may be expressed in code or symbols.

C. Instructions

Verify that the users' instructions contain the following:

1. A reproduction (color optional) of the label required in 3 above, prominently displayed at the beginning of the instructions.

2. A statement prominently displayed containing the words "DANGER-Ultraviolet radiation. Follow instructions. As with natural sunlight, overexposure can cause eye injury and sunburn; repeated exposure may cause premature aging of the skin and skin cancer. Medications or cosmetics applied to the skin may increase your sensitivity to ultraviolet light. Consult physician before using lamp if taking any medication or if you believe yourself especially sensitive to sunlight."

3. A warning that the instructions accompanying the sunlamp product should always be followed to avoid or to minimize potential injury.

APPENDIX A

TEST PROCEDURE FOR MEASUREMENT OF IRRADIANCE RATIO LIMIT USING THE OPTRONICS 747 SPECTRORADIOMETER AND HP 9825 SYSTEM CONTROLLER

I Initial Start-Up

A. Spectroradiometer Switch On

1. Switch on the Power console, (the unmarked chassis below the calculator).

2. Switch on the Control console. Verify that the pre-amp light below the PM housing on the monochrometer is on. Shutter the PM tube.

3. Switch on the Pacific Photometric Instruments, push the reset and set the control to 2.42, verify that the PM housing fan is operating.

4. Set the following "switches" to the noted position; "Filter wheel", Auto, "Pbs cooler" off, "Response time" 0.3, "jog", normal, "sphere position" off.

5. "Ranging" manual, use push buttons to set to the X10-0 range.

6. Set switches for DC gain, PMT, "Chopper" off.

7. Wavelength stop.

8. Continue with B while the system warms up for 90 minutes.

B. System Controller Switch On

1. Remove any dust covers, especially from the HP 9872A Plotter.

2. Place the 6940B Multiprogrammer in Local mode then switch on.

3. 4880 Coupler on, the "SRQ" Inhibit switch should be out.

4. Turn on the 3455 DVM, 3495A Scanner, 9872A Plotter, 9866B Printer and the 9825 Calculator.

5. Turn on the two Kepco JQE power supplies, Kepco BHK (AC only, DC off) and the Sorenson ACR 3000.

6. Switch the Oriel C73-14 on.

II Set-Up

A. Set 747 signal to -0.001 to 0.001 (X10-0 range) using Zero Offset and manual range change.

B. Set the high voltage to 8.000 (800 volts).

C. Adjust the Zero potentiometer on the pre-amp housing to null out dark current on the 10-4 range.

D. Set to Auto range.

E. Verify that the 3 in. integrating sphere is in place with the aperture towards the reference lamp.

F. Verify that the proper slits are in place, normally they are 1 mm entrance and exit and 2 mm middle.

1. Turn HeNe laser on.
2. Check laser alignment on optical bench.
3. Check that laser is centered on aperture plug and that aperture is normal to laser beam.
4. Remove aperture plug.

III Wavelength Check

A. Enter erase a on the 9825 and press "Execute". Insert tape #14 and press "Load" and "Execute." Enter ldk 1 and press "Execute." Place the sunlamp overlay over the special function keys. Press "clr 704".

B. Switch the 6940 Multiprogrammer to Remote, press "shut down" on the 9825.

C. Set the wavelength to 631.9, select jog mode, .1 nm jog interval and 20 nm/s scan speed.

D. Press "Run" on the calculator, respond to displayed prompts, if no answer is appropriate or for no, press "Continue" without any entry. Start wavelength 632, stop 634.

E. Follow program prompts.

F. Turn laser off.

G. Place the Hg lamp attached to the Oriel C73-14 at the aperture. CAUTION: the lamp housing is hot and the lamp is producing UV.

H. Repeat A thru C using:

1. Set 251.9, start 252, stop 254.
2. Set 311.9, start 312, stop 314.
3. Set 363.9, start 364, stop 366.
4. Set 434.9, start 435, stop 437.
5. Set 544.9, start 545, stop 547.

I. Turn off C73-14 and remove lamp from aperture.

J. Complete the wavelength calibration chart. If the mean deviation is greater than $\pm$.5 nm, make wavelength drive adjustments as described in the Model 747 instruction manual.

IV Calibration Check

A. Place the alignment jig in the standard lamp bi-pin socket. Turn laser on and verify or establish socket alignment so that the beam is centered and normal to the plane of the bi-pin. Turn the laser off.

B. Establish 50 cm distance from sphere aperture to the alignment jig using the 50 cm reference gauge.

C. Set the 10 turn potentiometer located above the plotter to between 4 and 6.

D. Set the radiometer to 199.9 nm, 1 nm jog interval and 50 nm/s scan speed.

E. Place working standard in the socket, place baffles and shields to reduce stray light on the radiometer.

F. Press Run on the calculator. Respond to displayed prompts. Start wavelength 200, end 400, current 7.9.

G. After 15 minutes adjust the potentiometer so that the DVM reading is between .7899210 and .7899999 and press Continue.

H. Compare luminous intensity values at 250, 270, 300, 350 and 400 nm with the working standard values. If they differ by more than 4 percent, a new calibration factor will have to be determined using a standard lamp.

V Sunlamp Test

A. Perform erase a "Execute" on the 9825, insert tape #13 and press "Load" and "Execute", enter ldk 1 and press "Execute".

B. Set up the sample at the specified minimum use distance from the detector aperture, measuring the distance as described in the sunlamp manufacturer's instructions. Gauge rods are available for the most common distances. Another distance may be used, however, it must be no less than the manufacturer's minimum use distance.

C. Lock the timer on. Arange baffles to reduce stray light. Check that the lamp switch is off and plug the 120v sunlamp into the Sorenson supply.

D. Press Run on the calculator, answer the display prompts. Turn the lamp switch on and adjust the variac to 130v using the DVM.

E. After 5 minutes, or the manufacturer's recommended warm-up time, check and adjust the variac as necessary and press "Continue".

F. At the end of the data run respond to the prompts. If plotting is desired make sure there is paper in place on the plotter.

APPENDIX B

TEST PROCEDURE FOR SUNLAMP TIMER ACCURACY

1. Determine maximum timer interval.

2. Compute maximum allowable timer error ($\pm$ 10% of maximum interval).

3. Test accuracy of timer at maximum interval.

   a. Set timer to its maximum.

b. Simultaneously start timer and suitable timing device (stopwatch, clock, etc.).

c. When interval is complete, compute difference between sunlamp timer setting and measured length of time.

d. Compare timer error with maximum allowed error to determine compliance status.

e. Repeat steps a-d.

4. Test accuracy of timer at the one minute setting.

   a. Perform steps 3a-3e above using a setting of one minute instead of the maximum interval setting. If there is no setting for one minute, use the available setting closest to one minute.

5. Test accuracy of the timer at the minimum marked setting, provided it is different from the setting used in step 4 above.

   a. Perform steps 3a-3e above using the minimum marked timer setting instead of the maximum interval setting.

APPENDIX C

TEST PROCEDURE FOR EVALUATION OF PROTECTIVE EYEWEAR

This test is to be performed using a Carey Model 118 Spectrophotometer.

1. Initial set-up control settings.

   Power switch ON

   Function switch 10%T

   Mode switch SB

   Source Select switch VIS

   UV Source switch OFF

   VIS Source switch HIGH

2. Open the sample compartment and remove both cell holders. Place the universal positioning jig in the sample chamber. Clamp the protective eyewear to be tested in the clip and adjust the base and arm so that one lens intercepts the sample beam about half way across the chamber. The sample beam is a thin vertical green light in the front of the chamber. The lens should face left so the beam is incident on the front. Orient the lens so that it is perpendicular to the beam and intercepts the entire beam. A piece of white paper will help to locate the beam and so ensure that the entire beam is intercepted. Make sure no part of the eyewear or positioning jib intercepts any of the reference beam that also runs across the chamber. Close the chamber and turn Source Selelct switch OFF.

3. Set the Source Select switch to UV and the UV Source switch to ON. Note the time to allow a 30 minute warm up of the UV lamp.

4. Control settings for data run.

   Beam interchange switch NORMAL

   Mode switch AUTO SLIT

   Period switch 1

   Function switch 10%T

   Wavelength switch OFF

   Chart switch OFF

   Scan Speed switch 2 nm/sec

   Chart Selector switch 50 nm/inch

   Baseline switch IN

   Baseline UV-VIS switch UV

5. Using the knob on the left side of the cabinet, set the wavelength to 375 nm.

6. Set the chart so that the pen will start on a line. Turn on wavelength and chart drive toggle switches.

7. Turn scan switch to "-". When wavelength reaches 200 nm, turn off.

8. Turn off pen and chart switches and turn mode switch to SB.

9. Open the sample chamber, remove the universal positioning jig and eyewear and replace the cell holders.

10. Put eyewear on. Determine if labels and timer graduations can be read. Also determine if there are light leaks around the eyewear.

☆ U.S. GOVERNMENT PRINTING OFFICE: 1984-421-177:10012

FDA 82-8198	The Role of the U.S. Public Health Service in Radiological Health: 1946-1969 (PB 83-175695, $25.00).
FDA 83-8023	Radiological Health Training Resources Catalog, 1983.
FDA 83-8042	CSU-FDA Collaborative Radiological Health Laboratory Annual Report-1981 (PB 84-108372, $13.00).
FDA 83-8152	Annual Report of the Division of Biological Effects, Bureau of Radiological Health (Fiscal Year 1981) (PB 83-165779, $11.50).
FDA 83-8154	Quality Control Procedures for Field Uniformity Correction Devices in Nuclear Medicine (GPO 017-015-00209-8, $2.75) (PB 83-225764, mf only).
FDA 83-8199	The Performance of a New 915 MHz Direct Contact Applicator with Reduced Leakage - A Detailed Analysis (PB 83-226621, $8.50).
FDA 83-8202	A Microprocessor Controlled Instrument for Measurement and Display of X-Ray Waveforms (PB 83-215509, $10.00).
FDA 83-8203	Suggested State Regulations for Control of Radiation, Volume I - Ionizing Radiation (GPO 017-015-00208-0, $11.00) (PB 83-252569, $34.00).
FDA 83-8204	The Selection of Patients for X-Ray Examinations: Chest X-Ray Screening Examinations (GPO 017-015-00210-1, $4.50) (PB 84-179647, $10.00).
FDA 83-8208	Utilization of Diagnostic X-Ray Examinations (GPO 017-015-00212-8, $4.00) (PB 84-118793, $10.00).
FDA 83-8209	Joint NCDRH and State Quality Assurance Surveys in Nuclear Medicine: Phase 1 - Scintillation Cameras and Dose Calibrators (GPO 017-015-00214-4, $3.75) (PB 84-118405, $10.00).
FDA 83-8210	Source Book of Educational Materials for Diagnostic Medical Ultrasound (GPO 017-015-00211-0, $4.00) (PB 84-118785, $11.50).
FDA 83-8211	Preparedness and Response in Radiation Accidents (GPO 017-015-00213-6, $6.00) (PB 84-104736, $23.50).
FDA 83-8213	Mammographic Phantom Evaluation Project (PB 83-256933, $10.00).
FDA 83-8217	Patient Radiation Exposure in Diagnostic Radiology Examinations: An Overview (PB 84-118264, $22.00).
FDA 83-8218	A Basic Quality Assurance Program for Small Diagnostic Radiology Facilities (PB 84-119098, $17.50).
FDA 83-8219	Checklist for Establishing a Diagnostic Radiology Quality Assurance Program (GPO 017-015-00216-1, $4.00) (PB 84-118801, $10.00).
FDA 83-8220	Suggested State Regulations for Control of Radiation, Volume II - Nonionizing Radiation-Lasers (GPO 017-015-00218-7, $4.00) (PB 84-109669, $11.50).
FDA 84-8152	Annual Report of the Division of Risk Assessment - Fiscal Year 1982 (PB 84-149798, $11.50).
FDA 84-8221	Clarification of the Regulations for Diagnostic X-Ray Equipment (GPO 017-015-00219-5, $4.25) (PB 84-164946, $11.50).
FDA 84-8222	Instrumentation for Nonionizing Radiation Measurement (GPO 017-015-00220-9, $2.00) (PB 84-180603, $8.50).
FDA 84-8223	Computerized Treatment Planning Systems - Proceedings of a Symposium held at Henry Ford Hospital, Detroit, Michigan (PB 84-155118, $23.50).
FDA 84-8224	Quality Assurance in Nuclear Medicine - Proceedings of an International Symposium and Workshop, held in Washington, D.C. April 27-29, 1981 (GPO 017-015-00221-7, $7.00) (PB 84-199306, $19.00).
FDA 84-8225	Routine Compliance Testing for Diagnostic X-Ray Systems (PB 84-190958, $22.00).
FDA 84-8226	Calculation Programs for Routine Compliance Testing of Diagnostic X-Ray Systems (PB 84-167840, $11.50).
FDA 84-8229	Nationwide Evaluation of X-Ray Trends (NEXT) Eight Years of Data (1974-1981) (PB 84-189281, $10.00).
FDA 84-8230	Source Book of Educational Materials for Medical Radiographers - 1984 (GPO 017-015-00222-5, $2.75) (PB 84-208040, $11.50).