THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUN 22 1993

File

The President
The White House
Washington, D.C. 20500

HHS:

Dear Mr. President:

In accordance with Section 540 of the Federal Food, Drug, and Cosmetic Act (previously Section 360D of the Public Health Service Act, 42 U.S.C. 263 l), I am forwarding a copy of the Department's 1992 Annual Report on the Administration of the Radiation Control for Health and Safety Act. Also enclosed are proposed letters for your transmittal of the report to Congress.

The report recommends the repeal of Section 540 of the Federal Food, Drug, and Cosmetic Act which requires the completion of this annual report. All the information found in this report is available to Congress on a more immediate basis through Center for Devices and Radiological Health technical reports, the Radiological Health Bulletin, and other publicly available sources. This annual report serves little useful purpose and diverts Agency resources from more productive activities. The Food and Drug Administration intends to submit a legislative proposal for repeal of the requirement for this annual report (as it has several times in the last decade).

Sincerely,

Donna E. Shalala

Enclosures

- D R A F T -

TO THE CONGRESS OF THE UNITED STATES:

In accordance with section 540 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360qq) (previously section 360D of the Public Health Service Act), I am submitting the report of the Department of Health and Human Services regarding the administration of the Radiation Control for Health and Safety Act of 1968 during calendar year 1992.

The report recommends the repeal of section 540 of the Federal Food, Drug, and Cosmetic that requires the completion of this annual report. All the information found in this report is available to the Congress on a more immediate basis through the Center for Devices and Radiological Health technical reports, the Radiological Health Bulletin and other publicly available sources. This annual report serves little useful purpose and diverts Agency resources from more productive activities.

THE WHITE HOUSE,

This draft xmittal was edited by the Executive Clerk's Office.

The Honorable Thomas M. Foley

Speaker of the House of Representatives

Washington, DC 20515

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Sincerely,

Enclosure

Original incoming from HHS

The Honorable Albert Gore

President of the Senate

Washington, D.C. 20510

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Sincerely,

Enclosure

Clerk's copy 7-7-93

THE WHITE HOUSE

WASHINGTON

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1992 Annual Report on the Administration of the Radiation Control for Health and Safety Act of 1968 Public Law 90-602 April 1, 1993

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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ANNUAL REPORT ON THE ADMINISTRATION OF THE RADIATION CONTROL FOR HEALTH AND SAFETY ACT OF 1968

I. INTRODUCTION AND SUMMARY

The Secretary of Health and Human Services is required by Subchapter C of Chapter V of the Federal Food, Drug, and Cosmetic Act (previously Subpart 3, Part F of Title III of the Public Health Service Act; 42 USC 263b et seq.) (Public Law 90-602) to submit an annual report to the President for transmittal to the Congress on or before April 1 on the administration of the Radiation Control for Health and Safety Act. The detailed information required in the report is outlined in Section 540 of the Federal Food, Drug, and Cosmetic Act (previously Section 360D of the Public Health Service Act).

The Food and Drug Administration, through its Center for Devices and Radiological Health, is responsible for the day-to-day administration of the Radiation Control for Health and Safety Act of 1968. This report provides a summary of the operations of the Center in carrying out that responsibility for calendar year 1992. In reviewing the operations of the Center for Devices and Radiological Health as reported in this document, it should be kept in mind that the day-to-day administration of the Act is only part of the Center's function. Other responsibilities include the administration and enforcement of the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act and the Safe Medical Devices Act of 1990 (not covered in this report).

The report recommends that Section 540 of the Federal Food, Drug, and Cosmetic Act (previously section 360D of the Public Health Service Act, as added by Public Law 90-602) which requires the completion of this annual report be repealed. All of the information found in this report is available to the Congress on a more immediate basis through Center technical reports, the *Radiological Health Bulletin*, and other publicly available sources. We have concluded that this annual report serves little useful purpose and diverts Agency resources from more productive activities.

Manufacturers of electronic products are required by 21 CFR 1002.20 to report accidental radiation occurrences to the Center for Devices and Radiological Health. The Center no longer maintains a Radiation Incidents Registry, since accidental radiation occurrences are reported through the Device Experience Network (DEN) and through the requirements of the Medical Device Reporting (MDR) regulations. During calendar year 1992, the Center received 100 reports of alleged injury from radiation accidents. These data and an active biological research program in the areas of ionizing radiation, RF-microwave, light, sonic products, and other nonionizing radiation sources provide the biological basis for the establishment of safety performance standards and guidelines.

There are nine equipment performance or regulatory standards now in effect. Four Public Notices were published in the FEDERAL REGISTER this year.

Forty-three recall actions, affecting over 61,400 radiation-producing products, were initiated during the 1992 calendar year. Compliance actions involved medical x-ray units, lasers, and sunlamp products.

Ionizing radiation, radiofrequency (RF)-microwave radiation, light, and ultrasound research and development activities are being pursued.

The Center developed technical and consumer-oriented information consisting of in-house technical reports and outside publications. Center staff participated in training sessions, seminars, and symposia and prepared press releases on current health-related issues. A list of publications and presentations is included in the Appendix.

Quality assurance programs, which attempt to assure the high standards of operation established by the performance standards for the manufacture of electronic products, were actively pursued by the Center.

Cooperation between Government and industry was significant. Performance standards and test procedures were developed through the cooperative efforts of the Center and the technical committees and subcommittees of many industrial, professional, and scientific organizations.

The Center for Devices and Radiological Health has been designated by the World Health Organization as a Collaborating Center in three areas: (1) Standardization of Protection Against Nonionizing Radiations, (2) Nuclear Medicine, and (3) Training and General Tasks in Radiation Medicine.

II. SUBJECT AREAS COVERED BY THIS REPORT

Section 540 of the Federal Food, Drug, and Cosmetic Act (previously Section 360D of the Public Health Service Act (42 USC 263 l) as added by Public Law 90-602) directs that the Annual Report shall cover:

(1) A thorough appraisal (including statistical analyses, estimates, and long-term projections) of the incidence of biological injury and effects, including genetic effects, to the population resulting from exposure to electronic product radiation, with a breakdown, insofar as practicable, among the various sources of such radiation.

(2) A list of Federal electronic product radiation control standards prescribed or in effect in such year, with identification of standards newly prescribed during such year.

(3) An evaluation of the degree of observance of applicable standards, including a list of enforcement actions, court decisions, and compromises of alleged violations by location and company name.

(4) A summary of outstanding problems confronting the administration of this subchapter in order of priority.

(5) An analysis and evaluation of research activities completed as a result of Government and private sponsorship, and technological progress for safety achieved during such year.

(6) A list, with a brief statement of the issues, of completed or pending judicial actions under this subpart.

(7) The extent to which technical information was disseminated to the scientific, commercial, and labor community and consumer-oriented information was made available to the public.

(8) The extent of cooperation between Government officials and representatives and other interested parties in the implementation of this subpart including a log or summary of meetings held between Government officials and representatives of industry and other interested parties.

The report required by subsection (a) shall contain such recommendations for additional legislation as the Secretary deems necessary to promote cooperation among the several States in the improvement of electronic product radiation control and to strengthen the national electronic product radiation control program.

III. REPORT BY SUBJECT AREA

APPRAISAL OF INCIDENCE OF BIOLOGICAL INJURY AND EFFECTS

Requirement (1)

Sec. 540 (a)(1): a thorough appraisal (including statistical analyses, estimates, and long-term projections) of the incidence of biological injury and effects, including genetic effects, to the population resulting from exposure to electronic product radiation, with a breakdown, insofar as practicable, among the various sources of such radiation.

Action

Accidental Radiation Occurrences

Manufacturers of electronic products are required by 21 CFR 1002.20 to report accidental radiation occurrences to the Center for Devices and Radiological Health, FDA. All accidental occurrences that are known to the manufacturer, and which arise from the manufacturing, testing, or use of any product introduced or intended to be introduced into commerce, must be reported.

The following is a list of accidental radiation occurrences reported by manufacturers, FDA field offices, consumers/users, and from press sources during calendar year 1992.

IONIZING RADIATION:		NONIONIZING RADIATION:	
Diagnostic X-Ray Systems	25	Tanning Booths/Lamps	13
Linear Accelerators	11	Lasers	9
Therapeutic X-Ray Systems	1	Microwave Ovens	1
Therapy Simulation Systems	1	UV Light	1
		Police Radar	38
Total Ionizing Radiation	38	Total Nonionizing Radiation	62
GRAND TOTAL	100		

CDRH conducts research and risk assessments of the human health effects of emissions from electronic products. This laboratory based research continues to concentrate on the areas of Extremely Low Frequency (ELF) and Ultraviolet (UV) bioeffects. The goal of the research in these areas is to develop scientifically based criteria for the control of exposure of the population to radiations emitted by electronic products and medical devices regulated by CDRH. This program continues to receive outside support from the Office of Naval Research. The UV program is directed largely toward UV activation of Human Immunodeficiency Virus (HIV) and cell membrane damage and has direct implications for our regulation of investigational therapies for HIV using PUVA and photopheresis.

Extremely low frequency (ELF) effects research

The ELF bioeffects program is currently investigating the effects of these electromagnetic fields (EMF) on cellular processes, which may be related to the increased cancer risk suggested by a number of epidemiological studies. Work continued in the areas of transmembrane calcium signaling, oncogene expression, and identification of the protein products of translation under the influence of ELF exposure. State-of-the-art instrumentation was purchased to allow more accurate measurement of the magnetic fields in our exposure systems. A contract is being negotiated for the design and construction of a sophisticated ELF exposure system. A new project to investigate the second messenger response to growth factors related to cellular proliferation was begun. In vivo studies of rates of bone explant resorption were continued in support of regulatory programs involving bone growth stimulators.

Transmembrane calcium signaling was studied using the FACScan flow cytometer and the calcium sensitive fluorescent dye fluo-3. A newly developed solenoidal exposure system was utilized in some of these studies. Studies of the human T-cell leukemia line (Jurkat), stimulated with antibody to CD-3, were examined in 60 Hz fields from 6 gauss to 20 gauss with no differences from unexposed cells observed. These results suggest that Jurkat cells may be insensitive to ELF fields; the studies will be extended to a variety of cell types, including thymocytes which have yielded positive results in similar studies utilizing ^{45}Ca. A new project has been initiated to study calcium signaling in neonatal rat pinealocytes, of interest in connection with the reported effects of ELF exposure on pineal melatonin.

We had previously shown the ability of ELF fields to affect c-myc oncogene expression in the Daudi human leukemia cell line. Recent work has concentrated on the investigation of the effect of magnetic field strength on this expression (a "dose-response" curve). The amount of c-myc RNA transcript was evaluated by northern blot hybridization to a ^{32}P-labeled probe followed by autoradiography and laser scanning densitometry. One hour exposures to 60 Hz fields showed an apparent dose dependence, with increases in c-myc expression ranging from 30 percent at 1 gauss to over 100 percent at 10 gauss.

Work continues on investigating the effects of ELF on cellular protein synthesis. Daudi cells were used in the investigation of the effects of 60 Hz fields: several proteins were expressed at different levels in exposed cells compared to unexposed controls. The variations observed are consistent with those reported by other investigators, and further analysis of the data is planned.

Activation of Human Immunodeficiency Virus by radiation

Since human immunodeficiency virus (HIV)-infected individuals may be exposed to UV radiation from medical devices, studies have been conducted on HIV activation by different types of radiation and drugs. In addition to UV emitted by medical devices, HIV-infected individuals could be exposed to UV from cosmetic tanning devices or certain types of lighting. Since CDRH regulates these devices, we need to understand the effects of the UV emissions from these electronic products on persons infected with HIV. These studies were carried out in vitro with human cells carrying the HIV promoter as well as with the complete virus. They also explored combined effects of UVA radiation and several psoralens (PUVA treatment). Systemic and extracorporeal PUVA therapy is used to treat a variety of diseases in HIV-infected individuals, and the extracorporeal PUVA is being clinically tested as an AIDS therapy.

A study has been completed on the effects of combined treatment with clinically used furocoumarins and UVA radiation on the HIV promoter. Three bifunctional psoralens and four monofunctional angelicins were used in the experiments. It was found that the HIV promoter is activated by both bi- and monofunctional drugs. The activation was observed at cytotoxic doses. The data have been evaluated from the viewpoint of human blood exposures during photopheresis. A manuscript has been prepared for publication, and the results were presented at the American Society for Photobiology (ASP) meeting. The Branch sponsored and organized a colloquium at this meeting on Gene Activation by Radiation.

Activation of the HIV promoter by UVB radiation is being further characterized. Studies of repetitive UV treatments were begun since this is the normal protocol for clinical UV treatments. Kinetics of the promoter post-exposure activation have been determined at four UVB doses. It was found that as the dose increases the promoter activity peak is shifted to later post-exposure times. Fractionation of UVB dose results in reduction of the HIV promoter activation. Experiments on the effects of multiple doses have been initiated. The results were presented as a poster at the ASP meeting.

A collaborative study with the George Washington University on the effects of UVB and PUVA exposure on HIV has been completed. PUVA refers to the combination of psoralen, a photosensitizing drug, and UVA that is used clinically to treat a number of dermatological conditions. Experiments with the complete AIDS virus indicated that UVB doses that were effective in activating the HIV promoter also activated the virus. This suggests that even a single UVB exposure within the erythemal limit for sunlamps can activate HIV. On the other hand, the relatively high PUVA exposures required to activate the HIV promoter were sufficiently cytotoxic to prevent the treated cells from being able to support the viral growth.

Results of the in vitro experiments indicated the need for observations on HIV-infected individuals exposed to UVB radiation and PUVA treatment. For this reason, cooperation was established with the clinicians and scientists of the Johns Hopkins School of Medicine. Five PUVA and one UVB patient have been followed. No significant increase in the HIV titer has so far been related to the PUVA or UVB exposure.

A collaborative study on DNA damage-binding proteins produced in PUVA-exposed cells has been initiated with workers at the National Cancer Institute.

Effects of ultraviolet radiation on blood

The general population receives substantial ultraviolet radiation (UVR) exposure as a result of natural and artificial tanning. Medical applications of ultraviolet lamps and lasers also require research into possible adverse effects of UVR exposure. Such devices are widely used in dermatology clinics, and the current resurgence in the incidence of tuberculosis has caused renewed interest in the use of UVR for air disinfection in medical facilities. Since the CDRH mission includes research to minimize exposure of the population to unnecessary emissions from electronic products, we continue to investigate the mechanisms of UVR damage at the cellular level. This work is essential to the development of scientific criteria to support performance standards for numerous electronic products regulated by CDRH. Depending on the wavelength, a significant amount of UVR may penetrate the skin to the dermis, which contains circulating blood cells. UVA (320-400 nm) and UVB (290-320 nm) are emitted by sunlamps, and UVC (200-290 nm) is emitted by some devices used in dermatology. It is for these reasons, that the Center conducts and supports several studies concerning the effects of blood exposure to UVR.

Research is almost completed on the effects of UVA1-induced plasma membrane and cytoskeletal damage to erythrocytes. Results show that there is a dose-response relationship between UVA1 (340-400 nm) radiation and oxidative damage, i.e., membrane, cytoskeletal damage, and hemolysis. Heinz bodies, indicative of cytoskeletal damage and hemolysis were observed using transmission electron microscopy. We have performed and still are performing studies on the molecular oxygen species responsible for the initiation of photohemolysis via damage to hemoglobin which results in cytoskeletal damage. We have developed a novel approach to measuring relative membrane permeability in RBCs using dye exclusion and flow cytometry. We have discovered that the photohemolytic mechanism has two dynamic aspects to it, one is oxygen independent and the other is oxygen dependent. These results were presented at the 11th International Congress on Photobiology in Kyoto, Japan.

Microwave-induced ocular changes

A collaborative research program with The Johns Hopkins University Applied Physics Laboratory and Wilmer Ophthalmological Institute continued to investigate microwave-induced ocular changes and their mechanism. Past work has shown corneal endothelial lesions, increased iris vascular permeability, and decreased retinal function following relatively low-level microwave exposure. In 1992, these studies were extended to chronic exposures. Chronic effects are studied by 4-hour exposures on 3 consecutive days each week for 10 weeks at 10 mW/cm^2. Both physiological and histopathological techniques are being utilized to investigate the combined effects of microwaves and ophthalmic drugs such as timolol. A related study seeks to investigate the mechanism of the differential cellular effects that have been observed. This work utilizes the B-16 melanoma cell line to determine whether the presence of melanin affects the cytotoxic sensitivity of retinal cells to microwave exposure. These findings on the ocular effects of relatively low-level microwave exposure are particularly relevant to public health protection because they demonstrate the possibility of ocular damage at exposure levels close to and in some cases below currently recommended safety levels.

Effects of microwave exposure on lymphocytes

Our previous studies indicated that exposures to pulsed 2450 MHz microwaves induce blastic transformation of human lymphocytes in vitro at nonheating levels, while continuous wave exposure does not. These studies suggested that the difference in the results may be explained by the larger peak electric field strength induced by pulsed microwaves. Another possibility is that the difference is related to the frequency of modulation, i.e., the pulse repetition rate. Additional investigations are being done to clarify the role of the waveform characteristics in blastic transformation. This line of research is significant to CDRH because no safety standards have been set for pulsed microwave radiation.

Kinetics of low dose rate radiation

When cells are subjected to continuous low dose rate irradiation, they are likely to be arrested in the G2 phase of the cell cycle if the dose rate is above a certain value. This dose rate is termed the "critical dose rate." However, the relationship between this critical dose rate and the various mammalian cell characteristics is poorly understood at the present. CDRH is currently investigating the cell kinetics of G2 arrest from low-dose-rate ionizing radiation. Work to date has shown that the critical dose rate is just the reciprocal of the mitotic delay caused per Gray of high dose rate radiation. In addition to advancing our current understanding of radiobiology, this work is relevant to the evaluation of radiotherapy devices using fractionated doses.

IV. LIST OF RADIATION CONTROL STANDARDS AND RELATED ACTIONS

Requirement (2)

Sec. 540 (a)(2): a list of Federal electronic product radiation control standards prescribed or in effect in such year, with identification of standards newly prescribed during such year.

Action

The following performance standards were in effect in calendar year 1992:

1. A performance standard for television receivers.

2. A performance standard for demonstration-type cold-cathode gas discharge tubes.

3. A performance standard for microwave ovens manufactured for use in homes, restaurants, food vending, or service establishments, on interstate carriers and in similar facilities.

4. A performance standard for diagnostic x-ray systems and their major components.

5. A performance standard for cabinet x-ray systems including x-ray baggage inspection systems.

6. A performance standard for laser products.

7. A performance standard for ultrasonic therapy products.

8. A performance standard for high-intensity mercury vapor discharge lamps.

9. A performance standard for sunlamp products and ultraviolet lamps intended for use in sunlamp products.

The following significant public notices were published in the *Federal Register* in 1992:

1. Notice of Availability: Suggested State Regulations for Control of Radiation, 8th Edition of Volume I (Ionizing Radiation).

2. Notice of Request for Nominations for Voting Members on Public Advisory Panels or Committees: Technical Electronic Product Radiation Safety Standards Committee.

3. Notice: Assuring Radiation Protection; Availability of Cooperative Agreement; Request for Applications.

4. Notice of Request for Nominations for Representatives of Consumer and Industry Interests on Public Advisory Committees or Panels: Technical Electronic Product Radiation Safety Standards Committee.

A listing of each section of the regulations published by the Department of Health and Human Services under Public Law 90-602, with an indication of the date of publication in the *Federal* Register, is given in the Appendix. These regulations are compiled periodically in Title 21 of the Code of Federal Regulations.

V. EVALUATION OF OBSERVANCE OF APPLICABLE STANDARDS

Requirement (3)

Sec. 540(a)(3): an evaluation of the degree of observance of applicable standards, including a list of enforcement actions, court decisions, and compromises of alleged violations by location and company name.

Action

REVIEW AND EVALUATION OF REPORTS AND RECORDS

Regulations issued under the Radiation Control for Health and Safety Act (Subchapter C of Chapter V of the Federal Food, Drug, and Cosmetic Act) and codified in 21 CFR, Chapter I, Subchapter J, require that manufacturers of certain electronic products submit reports and keep records related to electronic product radiation safety, including the applicable radiation testing and quality control programs that the manufacturers conduct. Initial reports and reports of model changes are required from manufacturers of certain classes of products. Manufacturers of microwave ovens, television receivers, cold-cathode tubes, medical and dental x-ray units, cabinet and baggage x-ray units, sunlamps, laser products, mercury vapor lamps, ultrasonic therapy products, and certain other products are also required to establish and maintain records including quality control and testing records.

During 1992, 5,500 initial reports, model change reports, annual reports, exemption requests and supplements to such reports and requests for exemption were received. Four thousand one hundred and thirty reports and supplements thereto were reviewed and evaluated. Over 2,400 pieces of incoming correspondence were received and acted upon.

COMPLIANCE ACTIONS

GENERAL

The compliance and defect investigations of FDA consist of authorized inspections and reviews of record keeping, plant inspections authorized for cause, and plant inspections arranged with manufacturers on a voluntary basis. Compliance with applicable standards is also determined by in-house laboratory analysis products and by reviews of reports and quality control data that the manufacturer is required to submit.

A total of six compliance programs and six program circulars were operational in calendar year 1992. These programs provide guidance for field and headquarters personnel in conducting compliance activities in the following areas: laboratory testing of microwave ovens and imported electronic products; laboratory testing of television receivers, mercury vapor lamps, sunlamps, and ultrasonic therapy equipment; field and laboratory testing of diagnostic x-ray equipment; and field testing of cabinet x-ray equipment, lasers, and suntan booths.

FDA initiated 43 recall actions, affecting over 61,400 radiation-producing products during the 1992 calendar year. The recall actions involved medical x-ray units, lasers, and sunlamp products.

TELEVISION RECEIVERS

FDA processed and reviewed 800 television receiver reports during 1992. The FDA's Winchester Engineering Analytical Center (WEAC) tested 80 television receivers in accordance with the Federal Performance Standard for Television Receivers, 21 CFR 1020.10. Three domestic and six foreign manufacturing facilities were inspected.

At the end of September 1991, a disapproval of a quality control and testing program was issued to a foreign TV manufacturer. For a period of several months, FDA met regularly with the foreign manufacturer to discuss improvements to their quality control and testing program especially checking x-radiation emissions and calibration of testing instruments. This resulted in rescission of the program disapproval.

In an effort to control the widespread abuse by importers of multi-system broadcast TV receivers that are not certified to meet the Federal performance standards, a revised Import-for-Export guidance paper for television receivers was sent to all FDA Import and Compliance offices as well as the television industry. A change in the policy withdrawing the exemption of import-for-export TV products was instituted in order to require all TV receivers imported into the U.S. to be certified to meet the Federal performance standard. In related cases involving multi-system TV receivers, several importers of noncertified multi-system TV receivers have attempted to certify these sets while they are imported under bond. Their certification has been unsuccessful because their quality control and testing procedures were found by FDA to be inadequate. A program disapproval letter was issued to one importer after an unannounced inspection was conducted and several deficiencies were found, and WEAC laboratory test results revealed a more serious Phase III test condition than what the importer was using for certification.

A program disapproval letter was issued to a manufacturer of video display terminals because the firm's x-radiation testing results were inadequate as revealed by WEAC's laboratory results. The firm did not understand the product's radiation characteristics, and their x-radiation testing procedures were found to be inadequate.

An importer of TV products submitted a self-declaration of noncompliance letter to FDA for video display terminals that were illegally imported over five years ago. The products were noncompliant because the terminals lacked the required certification labels and no reports were filed with the FDA. The importer has tested a sample of those terminals for x-radiation emission and submitted the test results to FDA along with the request for exemption from notification to the purchasers. FDA concurred and granted the exemption because no significant x-radiation emission was found under Phase III test conditions.

MICROWAVE OVENS

As part of the enforcement program for the Microwave Oven Performance Standard (CFR 1030.10), FDA maintained and calibrated nearly 100 microwave survey instruments for the Agency's field offices and the Office of Compliance and Surveillance within CDRH. Further, since the FDA field offices rely on cooperation and information from state and local health departments to aid in the enforcement of the oven standard, the Agency provides calibrations of the survey instruments to several local agencies. During fiscal year 1992, FDA calibrated more than 60 survey instruments for the local government agencies.

FDA processed and reviewed 200 microwave oven reports during 1992. The Agency's laboratories tested 97 microwave ovens and 15 prototype ovens for compliance with the Federal Performance Standard for Microwave Ovens 21 CFR 1030.10. Ten domestic and six foreign microwave manufacturing facilities were inspected.

FDA handled several compliance cases this year involving leaking microwave ovens. One firm reported that a leaking microwave oven was discovered during a service call. The leak was the result of a bent cavity face and possible welding defect. A warning letter was issued to the manufacturer requiring field testing to determine the extent of the welding problem among similar ovens in the field. The manufacturer performed a microwave leakage measurement on approximately 50 ovens in the field that were built or fabricated in the same production month, and no other noncompliant units were found. FDA and the manufacturer are continuing to investigate quality control problems with welding.

In another case, an FDA district investigator tested a consumer's microwave oven and found leakage of 7 to 8 mW/cm^2 along the top of the door. The oven was immediately transferred to FDA for laboratory analysis and it was determined that the magnetron inside the enclosure was defective and was emitting a high level of microwave radiation which penetrated through the plastic portion of the control panel on top of the door. A warning letter was issued to the manufacturer, asking the firm to investigate this noncompliance and determine if other ovens in the field had the same problem. This case is still continuing because the manufacturer of the magnetron is researching this problem, and more time and samples are needed to determine the cause of the leaking magnetron.

The State of California Orange County Health Department reported finding a microwave oven that has a broken door gasket and consequently leaks 4 to 7 mW/cm^2, in violation of the microwave performance standard. A warning letter was issued to the manufacturer and the oven was eventually replaced with an equivalent oven.

FDA tested a microwave oven submitted by a foreign manufacturer and found it failed to conceal the required safety interlocks from actuation by a small finger. A warning letter was issued to the firm and the company promptly corrected future production. An exemption from corrective action was approved by FDA for the products currently in use in the U.S. because the possible health hazard was considered negligible.

A foreign inspection of several microwave oven and television manufacturers was conducted by two FDA officers. One microwave oven factory was issued a program disapproval letter based on inadequate quality control and testing procedures for microwave emission testing. This case was resolved after the manufacturer documented significant improvements to the quality control and testing program.

One potential manufacturer of microwave vending machines was visited by FDA to determine the compliance status of their products. It was found, after examining the prototypes, that the product does not meet the microwave oven performance standard. The firm was then notified that they may not introduce products into commerce until the problems are corrected and the initial report is filed.

OTHER MICROWAVE PRODUCTS

In the area of new product development, there are two potential manufacturers of microwave clothes dryers. FDA has met with representatives of one company which is planning to develop working prototypes for field test evaluation. An inspection of the manufacturing facilities is being planned in order to review their prototype designs.

One firm has already met with FDA with the intent to market a microwave disinfection system used to treat infectious waste from hospitals, and an initial report was submitted after the meeting.

Some police personnel have alleged that the traffic radars they used have caused them to develop cancer. In September 1992, FDA coordinated a meeting with the manufacturers of police radars and Agency staff. The purpose of the meeting was to discuss the health and technical aspects of the police radar problem. FDA personnel advised the manufacturers of our interests and responsibilities under the Federal Food, Drug, and Cosmetic Act. A second meeting was held during the International Association of Chiefs of Police to discuss engineering and labeling changes to be implemented in early 1993.

FDA has conducted a review of its computer database on the Medical Device and Laboratory Problem Reporting Program where medical and radiation-emitting device problems are collected from all sources including users and manufacturers. There are 64 complaints on file.

ULTRASONIC THERAPY DEVICES

During 1992, five production units were tested at FDA's Winchester Engineering Analytical Center (WEAC) for conformance with the Federal Performance Standard for Ultrasound Therapy Products, 21 CFR 1050.10. WEAC found one unit had deficiencies in the output power measurements and values. A warning letter was issued to the manufacturer. This case is still active pending their response.

Six domestic ultrasound manufacturing facilities were inspected.

A warning letter was issued to an importer of an ultrasonic therapy product which does not comply with the Federal Performance Standard for Ultrasonic Therapy Products.

The importer has been selling this product for almost a year. A recall (replacement) program is being coordinated between the firm and FDA.

OTHER ULTRASOUND PRODUCTS

FDA personnel reviewed the SEA-DO recommendation for injunction and seizure against a manufacturer of diagnostic ultrasound medical devices for continued product defect problems and Good Manufacturing Practice (GMP) problems following the correction of the radiation defect last September. The seizure recommendation against the firm was withdrawn after a second voluntary recall appeared to correct the power output problems and the injunction could not be supported.

MEDICAL X-RAY EQUIPMENT

During 1992, in support for FDA and contract State inspectors to enforce the diagnostic x-ray performance standard, the Agency calibrated instruments, maintained compliance test kits, and consulted on radiation measurements. The Agency provided 1100 x-ray probe calibrations, performed 450 precalibration and electrical linearity tests, calibrated 100 kVp meters with both single- and three-phase x-ray units, and shipped 800 instruments. Supplies, instrument repairs, and new instruments were provided as needed. There were two thermoluminescent dosimetry evaluations of exposures from computed tomography systems.

FDA and contract State personnel conducted more than 2,700 compliance field tests. Sixteen corrective action plans were approved for manufacturers of more than 4,542 diagnostic x-ray units. Eleven cases of noncompliance were cited, for which the violations provided minimal risk of injury, and no corrective action was required. Four exemptions from corrective action were granted.

Eight quality control and testing programs were disapproved pending further information or requiring a change in the program. Three quality control program disapprovals were rescinded. Five x-ray manufacturing plants were inspected.

FDA laboratory personnel completed testing and reported on seven complete x-ray systems and three diagnostic source assemblies in accordance with the Federal Performance Standard for Diagnostic X-Ray Systems and Their Major Components. FDA personnel tested seven computed tomography x-ray systems and modified the prototype test procedures.

CABINET X-RAY UNITS

No quality control and testing programs were disapproved and no disapprovals were rescinded. One corrective action plan for the manufacturer of cabinet systems was approved and no exemptions were granted in 1992.

FDA performed 23 field tests. Copies of 50 field tests of airport baggage x-ray units were submitted to FDA by domestic air carriers as a courtesy. These reports are not required by FDA. Seven manufacturers were inspected.

LASER PRODUCTS

During 1992, 127 manufacturers of lasers were notified or notified FDA of noncompliances with the Federal performance standard. In response to these, 87 exemptions from notification and corrective action were granted because of the minor nature of the noncompliance or negligible risk of injury; 7 refutations were accepted, and 15 corrective action programs were approved. A total of 138 plant inspections and laser light show installation inspections were conducted and 4 field tests performed. One hundred twenty variances and variance renewals for laser light shows were received; of these, 98 were approved. The remainder are presently under review or have had their files closed.

SUNLAMP PRODUCTS

During 1992, the Ultraviolet Products Staff (UVPS) processed and reviewed 330 sunlamp and sunlamp product and 15 phototherapy product reports from manufacturers. A total of more than 300 sunlamp product field tests were conducted under Compliance Program 7382.002—Field Implementation of the Sunlamp and Sunlamp Product Performance Standard. Seventeen plant inspections were performed by UVPS and field personnel. In response to the above activities, five Corrective Action Programs were approved and one denied, and three Testing and Certification Program Disapprovals and six Declarations of Noncompliance letters were issued. Additionally, contracts were awarded to eight states which will result in these states performing 1,600 compliance field tests of sunlamp products during FY 1993.

MERCURY VAPOR LAMPS

During 1992, 10 reports from manufacturers of certified mercury vapor lamps were reviewed. Fifty-two mercury vapor and metal halide lamps were laboratory tested, resulting in four follow-up letters requiring labeling corrections. Additionally a letter dated May 15, 1992, was issued to manufacturers and importers of tungsten-halogen lamps relating the Agency's concerns about the potential for injury from unnecessary exposure to ultraviolet radiation from certain desk lamp fixtures using tungsten-halogen lamps that are not equipped with proper shields/filters that block the UV emissions.

VI. SUMMARY OF OUTSTANDING PROBLEMS

Requirement (4)

Sec. 540 (a)(4): a summary of outstanding problems confronting the administration of this subchapter in order of priority.

Action

PRIORITY 1. USE OF MAMMOGRAPHY FOR CANCER DETECTION

In 1991, an estimated 175,900 new cases of breast cancer were diagnosed in the United States. Approximately 44,500 women and men died of this disease in 1991. Baby boom generation women are now reaching an age of increased breast cancer risk. As a result, the number of cases and deaths will increase unless detection and treatment measures are more effectively applied. Mammography, if performed properly and interpreted accurately, permits detection of breast cancer at an earlier stage than with any other means, thus significantly increasing the chances of successful treatment.

The mammography examination was studied by the Nationwide Evaluation of X-Ray Trends program in FY 1985 (NEXT 85). The results of this study showed that, in general, the dose to patients during mammography has been reduced to acceptable levels by industry, practitioner, and Government action. However, the data showed that the image quality was less than desirable in some facilities. Image quality is especially important with mammography, as identification of tumors often depends upon detection of subtle changes in tissue density. In an effort to improve image quality, several initiatives were launched. These included development of a voluntary mammography facility accreditation program by the American College of Radiology with Center assistance, actions by several States, and FDA dissemination of information concerning desirable mammography practices to consumers and health professionals.

To evaluate the impact of these efforts, the mammography examination was studied again by the Nationwide Evaluation of X-Ray Trends program in FY 1988 and 1989 (NEXT 88). This study showed some encouraging trends, including the growing use of dedicated mammography units and an improvement in average image quality. The average dose to patients continued in the acceptable range. However, improvements in image quality and dose are still needed in a number of facilities. A draft report of the Government Accounting Office (GAO) also focused on the need for further quality controls.

Further efforts to improve mammography quality were stimulated when the Omnibus Budget Reconciliation Act of 1990 provided for the inclusion of screening mammography among the benefits of Medicare. FDA assisted the Health Care Financing Administration (HCFA) in the preparation of regulations to assure quality performance by the providers of the mammography benefit. Since interim final regulations were published in the *Federal Register* on December 31, 1990, FDA has been assisting HCFA in training inspectors and developing a program for inspection of the facilities for compliance with

the regulations. NEXT is once again evaluating progress in mammography due to these and other efforts during FY 1992 and 1993 (NEXT 92).

CDRH (acting on behalf of the Food and Drug Administration), the National Cancer Institute, and the Centers for Disease Control have also coordinated a combined effort by over 75 professional, citizen, and government groups to develop the National Strategic Plan for the Early Detection and Control of Breast and Cervical Cancer. The goal of this plan, approved by the Secretary of Health and Human Services (HHS) on October 15, 1992, is to mount a unified effort by all interested groups to combat these two serious cancer threats. The assurance of high quality mammography will be a crucial tool in the achievement of this goal. Efforts are underway to implement this plan.

On October 27, 1992, the President signed into law the Mammography Quality Standards Act of 1992. This act requires the Secretary of HHS to develop and enforce quality standards for all mammography of the breast, no matter what the purpose or source of reimbursement. By October 1, 1994, any facility wishing to produce, develop, or interpret mammograms will have to meet these standards to remain in operation. The activities conducted under this act in the coming years may finally lead to achievement of the goal of assuring high quality mammography.

PRIORITY 2. MINIMIZING THE RADIATION DOSE FROM FLUOROSCOPIC EXAMINATIONS

Fluoroscopic examinations are conducted on approximately 22 million people annually. These examinations are among those requiring the highest levels of radiation exposure. Therefore, fluoroscopy has long been believed to contribute substantially to the radiation dose of the population.

For a number of years, CDRH has had concerns about whether these examinations were being conducted in such a way as to minimize the dose while assuring adequate diagnostic information. These concerns are with all aspects of fluoroscopic examinations including the design, functioning, and adjustment of the x-ray system and the manner in which the examinations are conducted (e.g., the types and number of exposures used). Concern also exists that several aspects of fluoroscopic system performance which might be expected to be addressed by the regulatory performance standard have not been controlled to date due to a lack of consensus as to appropriate requirements or a sound technical basis for performance criteria.

Comprehensive information regarding the radiation doses resulting from fluoroscopic examinations and the status of fluoroscopic system and user performance has been unavailable due to the lack of appropriate methods or programs to obtain this information. Such information is necessary before problems can be defined and effective programs developed to address them. Development of appropriate and effective actions must take into account the complex interplay of equipment characteristics and capabilities; the specific examination technique employed; and the training, experience, and preferences of the radiologist.

CDRH is currently developing information regarding fluoroscopic system utilization and performance in order to identify potential actions that could lead to improvements in the conduct of fluoroscopic examinations. A major step forward was taken in May 1989, when development of a method for estimating fluoroscopic doses during the upper gastrointestinal examination was completed. This method and mathematical models representing reference patients were used to develop a handbook for use in estimating absorbed doses to selected tissues from this examination. The handbook has been widely distributed to the radiology community. Such dose information is essential to determine the potential hazard from fluoroscopic examinations and to evaluate the need for and impact of corrective actions.

Other activities underway to develop information regarding fluoroscopy include: 1) evaluating exposure from a fluoroscopic examination during the 1991 NEXT survey, 2) reviewing installation and testing procedures related to exposure rates and imaging performance used by manufacturers, 3) continuing efforts to develop standardized consensus measures of system and component performance, and 4) conducting laboratory and computer simulation studies to investigate the impact of changes in system parameters or design changes on measures of system performance.

In total, these activities are providing the basis for future CDRH actions to help assure that fluoroscopic examinations are conducted in such a way as to minimize unnecessary radiation dose while providing the required diagnostic information.

PRIORITY 3: HAZARDS FROM OPTICAL RADIATION-EMITTING ELECTRONIC PRODUCTS

Performance standards have been previously developed for laser products, sunlamps, and high-intensity discharge lamps. These standards were developed as a result of documented injuries from these products as well as the increasing numbers and use of optical radiation-emitting electronic products to which the general public was (and is) exposed.

From 1979 through the present, the public has been increasingly exposed to laser products. This includes the use of lasers in the music, entertainment, and advertising industries; medical and surgical applications from diagnostic to general surgery and other specialized applications such as laser angioplasty for removal of plaque in the arteries, posterior capsulotomy for the treatment of secondary cataracts, and laser lithotripsy for fracturing kidney and gall stones; optical fiber communications; various industrial applications such as laser robotic controllers for parts and process control and for high power industrial applications (welding, cutting, drilling, etc.); laser-guided machining; industrial time-share multistation systems; consumer products such as laser audio discs; office products such as laser-printers; and in supermarket check-out counters.

In 1992, the use of lasers in medicine continued to expand. The trend towards reduced size and cost of medical laser products also continued to expand. The approval of laser cholecystectomy (gall bladder removal) in 1990 and the use of contact fiber tips point to other types of laporoscopic surgery.

Finally, the advent of laser diodes emitting optical radiation in the visible resulted in the introduction of new products in 1991 that formerly employed helium neon gas lasers. This trend continued in 1992. These new products can be considerably smaller and include lecture pointers, aiming devices for firearms, and patient positioning devices for diagnostic and therapeutic radiology. The small size of these products make it difficult to comply with the requirements of the Laser Product Performance Standard.

As the use of lasers in medical, industrial, and consumer products increases, FDA will continue to monitor the various products for safe radiation levels of exposure to the general public.

The sunlamp products industry continues to manufacture down-sized products directed to the home market with increased promotion and sales through numerous mail order catalogues. Improved technology in the manufacture of ultraviolet lamps, which allows the production of compliant 400W, 1KW, and 2KW lamps without additional filtration, has prompted several foreign sunlamp product manufacturers to introduce full lines of high-pressure units (in the 6KW to 24KW range) that are replacing some of the older low-pressure products in commercial establishments. Due to the higher overall output of these products, the manufacturers are using the reduced exposure time (more sessions per day) as a marketing tool to increase sales and promotion of their products.

A major change is also occurring in the low-pressure ultraviolet lamp manufacturing area of the industry where lamps are being produced with higher output in the UVB range. The associated problems occur when these lamps are inappropriately placed in sunlamp products at the salon level without justification for doing so in accordance with the product's labeling. The sunlamp industry continues to be a dynamic one; continued surveillance and enforcement is needed to assure compliance with the standard.

In 1991, FDA determined that some tungsten-halogen bulbs operating in lamps without protective filters emit high levels of ultraviolet radiation. Similar findings were previously reported in Australia and the United Kingdom. These lamps operate at a higher temperature than conventional incandescent lamps and are able to emit more ultraviolet radiation. In 1992, the Agency evaluated the potential risks that may be associated with the use of these lamps and the need for possible corrective action.

In order to better control the potential hazards that are or may be associated with some of these products, FDA is enforcing the performance standards that have been promulgated. In addition, these performance standards have been amended as deemed necessary in order to take into account changes in the industries regulated. A retrospective review committee established to evaluate the effectiveness and need for amendments or changes to the mercury vapor lamp performance standard completed its work in 1990. The committee concluded that the standard could be more effective in protecting the public from unintended exposure to ultraviolet radiation from broken lamps if the nonsafety mercury vapor lamps were banned. A proposal to ban these lamps was prepared. The Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) was consulted in regard to the proposal. The committee unanimously recommended against the proposed ban. However, they also recommended that other alternatives such as improved labeling, educational efforts, and a partial ban on some of

the non-self-extinguishing safety lamps be considered. These alternatives were explored and studied in 1991.

PRIORITY 4: REDUCTION OF ELECTROMAGNETIC FIELD EMISSIONS

Video Display Terminals (VDT)

In cooperation with several computer VDT manufacturers, FDA agreed that the available research and measurement data concerning VDT electric and magnetic field emissions, at the ELF and VLF bands, were insufficient to draw definitive conclusions about possible human hazards. Because of the lack of scientific knowledge in this area, and the need to protect the public from excessive radiation, the Agency began to work with the VDT manufacturers to reduce ELF and VLF emissions to "as low as reasonably achievable" (ALARA).

FDA scientists continue to participate in the IEEE P1140 working group that is drafting a measurement standard for electric and magnetic fields around VDT products. By the end of FY 1992, the scientists had reviewed and commented upon five drafts of the P1140 document. Much of the effort of the scientists was geared toward ensuring that the document is technically correct in its mention of measurement techniques and instrumentation. FDA scientists have taken the lead in ensuring that several experts in this field are consulted about these points. In addition, the scientists were able to obtain permission to cast votes on all ballots for this document as the representative of FDA.

Police Radar

Police traffic radars were the subject of a recent US Senate hearing. FDA scientists arranged a visit at the Agency by Senator Lieberman's staff researcher and a demonstration by a local police officer. The Agency's scientists made it clear that there is an absence of hard data on biological effects from exposure to these products. This information, and results of recent FDA measurements of the radiation from police radars, were supplied to the Senate staffer. In addition, FDA scientists worked on documents written to brief an Agency representative who was designated to testify before the senate hearing.

The heightened concern by police officers and organizations on the safety issues of police radar resulted in a National Highway Traffic Safety Administration (NHTSA) draft of a brochure on these products. FDA scientists were able to review and offer suggestions on the brochure. However, because of the senate hearing, the Agency decided to circulate its own information sheet to police officers across the U.S. FDA scientists helped draft and review this information sheet also.

After the hearing, FDA called a meeting of the police radar manufacturers to request some changes to the products which would address concerns about excessive exposure to officers. FDA scientists were called upon to offer technical advice on the radiation fields and made a suggestion to keep the operator at least 6 inches away from the active radiator.

Electric Blankets

Public and Congressional concern has heightened in recent years about possible adverse health effects associated with extremely low frequency (ELF) fields such as those produced by electric blankets. In response to this concern, FDA engineers and scientists have established a laboratory to evaluate ELF magnetic and electric fields produced by conventional and low magnetic field electric blankets.

The measured data on magnetic field emissions were found to be in basic agreement with manufacturers' claims for the low magnetic field blankets, indicating that manufacturers have significantly reduced magnetic field emissions in their latest products that incorporate low magnetic field emission technology. However, these new low magnetic field blankets still produce approximately the same electric field as the older, conventional blankets. FDA engineers have developed several methods of reducing electric field emissions from electric blankets and have continued to work on the reliability and electrical safety aspects of these methods. A patent documenting this work has being filed.

VII. ANALYSIS AND EVALUATION OF RESEARCH ACTIVITIES AND TECHNOLOGICAL PROGRESS

Requirement (5)

Sec. 540 (a)(5): an analysis and evaluation of research activities completed as a result of Government and private sponsorship, and technological progress for safety achieved during such year.

Action

IONIZING RADIATION

Image Management and Communication Systems (IMACS) - Over the past decade, the increased use of digital imaging modalities; major improvements in information systems and communications, storage, and display technologies; and the belief that such systems have the potential to facilitate the delivery of more efficient health care have led to the evolution of IMACS in radiology. IMACS are automated and integrated systems that capture medical images and related clinical information, transmit them electronically, display them for interpretation, and archive them for future retrieval. CDRH is particularly interested in the effect of IMACS technology on clinical image quality and is working with national and international programs to facilitate the development and acceptance of standards for the communication of image information over computer controlled networks. CDRH is also coordinating FDA participation in the computer-based patient record initiative announced by the Secretary in October 1992. This will ensure that CDRH IMACS-related activities are coordinated with HHS plans regarding the development and use of computerized patient records and electronic health care networks.

Quantitative Dose Description of Fluoroscopic Examinations - During 1989, CDRH, in collaboration with Johns Hopkins Hospital, developed a method to quantitatively describe fluoroscopic examinations. The procedure involves videotaping the examination while simultaneously recording fluoroscopic technique factors (mA and kVp) on the soundtrack of the videotape. Subsequent analysis using the slow playback mode allows the dynamic examination to be segmented into a series of static x-ray fields. Each field is unique, having a characteristic field size, angular projection, and anatomical center. Knowledge of the mA and kVp along with a calibration curve relating the entrance exposure rate to mA and kVp enables determination of the integral exposure associated with each static field.

Since 1989, activities have been underway to streamline and validate the determination of integral exposure. In addition, tissue dose tables were obtained under a contract with the Medical College of Ohio. The tables were obtained using mathematical models representing a standard male and a standard female and provide estimates of the dose to critical organs per unit of radiation exposure under selected exposure conditions. They can thus be used to analyze clinical exposure data in order to estimate total dose. The tissue dose tables were made generally available through publication of a handbook in June 1992.

Nationwide Evaluation of X-Ray Trends - The Nationwide Evaluation of X-Ray Trends (NEXT) program was established in 1972 to meet the need for a standardized evaluation tool that could be used for year-by-year comparisons of x-ray practices. In its current format, a single examination is selected for study each year. The efforts related to each examination are termed NEXT XX (YYYY) with XX referring to the fiscal year in which work on that examination began and YYYY referring to the name of the examination. Analysis and publication of the results are usually completed in the following fiscal year.

NEXT is a program of the Conference of Radiation Control Program Directors, Inc. (CRCPD), an organization of State and local radiation control programs. CRCPD plans, directs, and conducts NEXT with technical support from CDRH. Each year, a statistically representative national sample of the facilities performing the examination under consideration is selected. State personnel then visit the facilities to collect technique and exposure data that represent the experience of a standard patient undergoing the examination at that facility. This data is then sent to CDRH for analysis and a national picture is obtained of how the examination is being conducted, the levels of exposure being used, the adequacy of film processing and, in the case of the mammography examination, the quality of images being produced. This information is then used by the States and CDRH to determine if there are problems that require action. In later years, the examination may be studied again and the comparison of the data from the two years permits determination of trends and evaluation of the effect of corrective actions.

During 1992, the analysis of the data from NEXT 91 (Fluoroscopic Upper Gastrointestinal) was completed and a scientific paper is being prepared for a peer review periodical. Data collection for NEXT 92 (Mammography) was completed. The NEXT 93 (Dental) phantom and protocol were completed and pilot study results are currently being evaluated. Research and design for the NEXT 94 (Pediatric Radiography) is underway.

Pediatric Phantoms - A project to develop prototype designs for a set of pediatric attenuation phantoms (simulating newborn, 6-year-old, and 12-year-old) for use in x-ray facilities to estimate patient exposure for chest, abdomen, and lumbosacral spine examinations was completed by FDA in cooperation with the Children's Hospital, Washington DC, and through a contract with The Children's Hospital, Boston, MA. Attenuation measurements were made using anatomical phantoms and then matched with acrylic and aluminum materials. The data developed will be used to fabricate a set of prototype pediatric phantoms which will be clinically evaluated. These will be used in future NEXT surveys to provide the first national data on pediatric exposures. Initial evaluation of these phantoms is currently underway at these two institutions.

X-Ray Spectroscopy - Measurements of x-ray spectra from the CDRH calibration systems and from a molybdenum anode tube typical of conventional mammography practice have been carried out and compared to study the suitability of current procedures for calibrating instruments to be used for surveys of mammographic installations. Additional measurements of spectra generated at voltages suitable for general diagnostic radiology have been made in support of the calibration program. Spectra from a tungsten-anode, beryllium window tube have been measured to provide input to a study of alternatives to the molybdenum-anode tube for mammography.

Tungsten-anode tubes have been recommended by several investigators for use in digital mammography. These spectra will support development of a regulatory strategy as well as experimental data useful to researchers in the field.

X-Ray Phantoms - FDA continues to support the activities of the Phantom and Clinical Image Correlation Committee established under the Centers for Disease Control/American College of Radiologists Cooperative Agreement. Materials for the proposed phantom design have been purchased. X-ray equipment for producing images of the prototype and several existing commercial phantoms has been purchased and will be used to evaluate these phantoms and suggest refinements in the phantom design. A computer program for designing tissue substitutes using liquids has been developed. The program explicitly accommodates the change in volume of certain combinations of liquids that occurs when they are mixed. An invited review paper describing computer-based design procedures for tissue substitutes for radiologic applications has been presented at a workshop in Würzburg, Germany, in June.

X-ray Calibrations of Parallel Plate Ionization Chambers - One of the activities the Agency's X-ray Calibration Laboratory is undertaking, as part of its effort to become accredited by the National Voluntary Laboratory Accreditation Program for Secondary Calibration Laboratory for Ionizing Radiation, is the replacement of the existing reference ionization chambers with new parallel plate ionization chambers. The evaluation of the PRM MC3 beryllium window parallel plate ion chamber showed unexpected behavior. To obtain calibration factors independent of x-ray source-to-detector distance, one has to use a reference calibration point both behind the front surface and not at the geometric center of the detector. Further, this reference point is dependent on the beam quality of the incident radiation. The effective center of this chamber varies from 3 to over 8 mm behind the front surface for diagnostic beams. If this chamber is used for superficial therapy, the air kerma rate at the skin could easily be in error by several percent if corrections are not made for this effect.

Report on Calibration Procedures used by Secondary Level Calibration Laboratories - Agency personnel have previously given talks at a workshop on Radiation Protection Instrumentation held at the Harvard School of Public Health, Office of Continuing Education. As a result of these talks, a comprehensive draft document has been prepared on the national measurement system for ionizing radiation. The document discusses how Measurement Quality Assurance programs can be used to relate routine calibrations back to the national standards. This procedure gives assurance that the calibration laboratory has demonstrated its ability to calibrate instruments to within a certain percentage difference of the national standards for specific calibration conditions. The document also discusses calibration procedures used at secondary level calibration laboratories for calibrating instruments in reference x-ray, gamma-ray, beta-particle, and neutron radiation fields. The document discusses the need for in-house quality assurance/quality control programs to monitor calibration equipment. Finally, the document discusses recommendations of the Bureau International des Poids et Mesures for combining Type A and Type B uncertainties.

Mammography Optimization - Collaboration with the Department of Radiology of the National Institutes of Health (NIH) Clinical Center continued on the development of an optimized mammography system. The special high-ratio scanning grid that is a critical

part of the optimized system has been thoroughly tested to determine its primary transmission and scatter rejection performance. The results of these tests, which indicated excellent performance relative to conventional mammography grids, were presented at the Radiological Society of North America meeting in December 1991. Also presented were the results of imaging and dose measurements made with a laboratory system that included the grid.

A few additional mechanical, electrical, and software modifications to the grid were found to be necessary to permit smooth operation during exposures in the medio-lateral orientation. The grid has been shipped to Fischer Imaging for integration into a complete system suitable for clinical use. Preliminary work on a clinical protocol has been started and will continue while Fischer is completing construction of the imaging system.

Fluoroscopy - Agency researchers have continued efforts concentrated on measuring the sensitometric response, the modulation transfer function (MTF), the veiling glare, and the Wiener spectrum of an image intensifier (II) tube. Measurements on the resolution and noise properties of the optically-coupled TV camera used in measuring the II's Wiener spectrum were also completed. These data provided the means to calculate summary measures of imaging performance for the II, i.e., the noise equivalent quanta, NEQ, and the detective quantum efficiency, DQE, as a function of spatial frequency. The results of these experiments will be presented at the Medical Imaging VII (SPIE) Conference in February 1993.

These quantitative data are currently being used to predict the imaging performance of the II in detecting simple objects, e.g., a low-contrast circular disk in an uniform background. Eventually, these experiments will include some directed research on characterizing the visibility of different devices (catheters, etc.) used under fluoroscopic guidance.

Efforts also continued on investigating different methods of improving or maintaining fluoroscopic imaging performance and reducing patient dose. The results of one study on this topic has been completed and submitted for publication. The study presents the dose reduction possibilities of several beam-hardening and K-edge filter materials for the imaging of barium during fluoroscopy.

Agency staff continued active liaison with the American College of Radiology and the American Association of Physicists in Medicine regarding mutual concerns about high-powered fluoroscopy equipment and new interventional procedures. A national workshop or symposium on fluoroscopy, partially supported by FDA, was held in October 1992. The results of research activities on optimizing the performance of fluoroscopic systems have been prepared for publication in a journal.

Information Processing - A poster was presented at the IEEE Medical Imaging Symposium in November 1991 on evaluating limited-angle reconstructions using Bayesian decision variables and the Rayleigh task. A paper was presented at the SPIE meeting on Medical Imaging in February 1992 that showed how human detection performance is well predicted by these Bayesian computational observers. The correlation between human and machine is validation of our machine-based approach to image assessment. A paper on this work was presented at the annual Maxent workshop this summer. An invited

review paper on our framework for image quality assessment has been presented at the annual meeting of the Optical Society of America in September 1992.

Our National Research Council postdoctoral research associate has collected hundreds of SPECT images in collaboration with the Nuclear Medicine Department at the NIH Clinical Center. These images have varying numbers of photons and projections and will be used to experimentally assess the effects of sampling and filtering on the detectability of low-contrast lesions in tomographic images limited by stochastic noise and artifacts. In addition, CDRH scientists have developed a theoretical analysis of the noise and signal in sampled images. A paper on this work was presented at the SPIE meeting on "Mathematical Methods in Medical Imaging."

Two posters summarizing the work of our research associate on sampling effects in tomographic reconstruction were displayed at the IEEE Nuclear Science and Medical Imaging Symposia in November 1991. Papers summarizing the same work have been submitted for publication in the *IEEE Transactions on Medical Imaging*.

CLINICAL APPLICATIONS OF RADIOFREQUENCY ENERGY

Cancer Therapy - Researchers at the University of Arizona's Department of Radiation Oncology in Tucson, continued their clinical evaluation trials of a CDRH-designed and fabricated helical coil radiofrequency (RF) applicator. The clinical investigation involves the thermal enhancement of chemotherapeutic drugs. The helical coil is highly effective in elevating the patient's body temperature uniformly, within 10 to 20 minutes and maintaining it for the required 60 minutes of treatment. Other clinical researchers have expressed interest in using this CDRH-invented device, which received a patent this year.

Organ Preservation - Radiofrequency thawing of body organs after vitrification (solidification without ice crystal formation) is being studied. A cooperative research and development agreement (CRADA) between FDA and the American Red Cross is pending. CDRH personnel designed the hardware for this project. Extremely fast and uniform rewarming (up to 16 degrees Celsius/second) must be accomplished, under pressure, to prevent ice crystals from forming in and destroying the tissue's cells. One version of the applicator has been installed inside the pressure vessel at the American Red Cross Laboratories.

Tissue Characterization(Ultrasound/MR Spectroscopy) - Research in collaboration with Georgetown University Medical Center has continued on multimodality pattern recognition techniques for detection of disease states in tissue. Collection of pilot data on 12 patients using both magnetic resonance spectroscopy (MRS) and ultrasound (US) has begun. Three disease categories are included: hepatitis/cirrhosis, AIDS-related disease processes of the liver, and metastatic disease in liver. US and MRS data have been collected on four patients with hepatitis C and two AIDS patients. A Memorandum of Need (MON) was written to support a multi-year contract for data acquisition on the remaining 68 patients allowed under our approved research proposal involving human subjects. Two new coils are under development to collect data from deeper tissue and improve patient comfort. A paper comparing autoregressive moving average (ARMA), linear prediction, and maximum entropy MRS spectral estimation was presented at the

Society of Photo-Optical Instrumentation Engineers (SPIE) meeting on "Mathematical Methods in Medical Imaging" in July 1992. A paper describing a new algorithm for reconstruction of magnetic resonance spectroscopic images was presented at the Society of Magnetic Resonance in Medicine (SMRM) meeting in August 1992.

A large new software package has been developed and implemented at Georgetown University Medical Center for improving the sensitivity of ultrasonic tissue characterization using radiofrequency data and instrument corrections. Several abstracts have been submitted to the annual international symposium on this subject. They discuss the improved sensitivity and degree of instrument independence. Another abstract submitted addresses the problems due to small patient populations. In addition, a paper which presents a new algorithm for estimation of mean scatterer spacing in human liver has been submitted, revised, and resubmitted to IEEE "Transactions on Ultrasonics, Ferroelectrics, and Frequency Control."

A software package simulating the fusion of data from many diagnostic tests for medical decision-making has been developed for studying the effects of small patient populations. This work was presented to the tissue characterization community in June 1992.

LIGHT PRODUCTS AND DEVICES

The laser product performance standard that became effective August 2, 1976, is being enforced, in part, through continued training for field inspectors and the maintenance, calibration, and further modification and improvement of the instrumentation in the six laser field compliance kits. Also, the CDRH laser calibration facility, which provides the legal basis for measurements used to enforce the laser performance standards, was maintained.

In 1992, CDRH Scientists expanded a study of operating microscopes that are used during cataract surgery. The operating microscopes utilize a bright light source to illuminate the inner portions of the eye during surgery to remove the cataract and to insert an intraocular lens implant. Over 1,000,000 cataract surgeries are performed each year in the United States. This study was a continuation of a study of the optical radiation emissions from ophthalmic instruments that was begun in 1986. The work on operating microscopes demonstrated a clear dose-response relationship between the production of retinal lesions and dose. In 1992, Center Scientists also continued to work with other scientists in developing voluntary consensus standards to limit the optical radiation emissions from ophthalmic instruments.

ULTRASONIC PRODUCTS AND DEVICES

Organ Rewarming - Methods for indefinitely preserving organs for transplantation would be a boon to medicine. Nondamaging techniques for cooling organs (for cryopreservation) have recently been developed but there exists no comparable means of safely warming the organs. FDA has begun a collaboration with a Red Cross Scientist to determine if high intensity ultrasound can be utilized to warm vitrified organs without the

formation of damaging ice crystals. Transducer configurations have been designed and test chambers have been built to determine relevant tissue characteristics at very low temperatures. Time-temperature distributions have been monitored while heating frozen tissue analogues with transducers available in-house.

Sensitivity of Ultrasound Doppler Devices - One of the primary elements in the evaluation of an ultrasound Doppler system is the measurement of its sensitivity. Doppler sensitivity refers to a Doppler system's ability to detect a weak signal deep inside the body. The sensitivity is related to the signal-to-noise ratio of the detected Doppler echo signal reflected from flowing blood cells. Although this measure of Doppler system performance is crucial in the evaluation of ultrasound system efficacy, no industry standards exist for the measurement of this parameter. Hence, a draft guidance document for ultrasound fetal Doppler 510(k) submissions has been written. The document requires manufacturers to make a sensitivity measurement and offers a suggested test method, which follows those described by published methods, but opens a forum for a consensus method to be agreed upon by the standards bodies and by the scientific community. CDRH staff are working to develop an objective, quantitative method for measuring Doppler sensitivity and collaborating with the American Institute for Ultrasound in Medicine (AIUM) Doppler subcommittee in defining a standard method for measurement.

Doppler Evaluations of Valvular Regurgitation - CDRH scientists have been working to quantify medical ultrasound images for diagnosing heart valve disease. The latest experimental work, performed at the National Heart, Lung, and Blood Institute and analyzed at CDRH, has shown that Doppler ultrasound techniques have the potential to accurately quantify leakage through valves. Valve leakage is an important clinical sign of degradation in prosthetic heart valves and in patients' natural valves, indicating potentially serious heart disease. A quantitative, noninvasive method for determining valvular regurgitation would also improve the Center's ability to evaluate valve performance during clinical trials.

The experiments used to assess quantitative ultrasound techniques were performed in vitro, using a model of a defective heart valve. Water forced through a hole mimicked blood leaking backward through a defect in a valve. A flow meter was used to accurately measure the flow rate through the hole for comparison to ultrasound. A commercial ultrasound system designed for clinical medicine was used to form a two-dimensional image of the structure around the hole. The machine's color Doppler flow imaging capabilities were then used to map the velocities of fluid in the jet. The jet of fluid forced through the hole appeared as a flame-shaped image on the ultrasound system monitor. Images of jets were downloaded into a personal computer for analysis.

Analysis of the images from the in vitro model verified that the law of conservation of momentum could be used to quantify a jet of fluid forced through a hole, by evaluating the velocities encoded in the color Doppler images. However, there were significant problems with the analysis when fluid velocities rose above a certain limit (called the aliasing velocity), forming ambiguous colors in the image (and, hence, ambiguous velocities in the analysis). This effect limits the method to velocities significantly lower than the velocities found in real leaking valves. A second analysis method was also evaluated which uses pulsed and continuous Doppler techniques and a theoretical model

of turbulent jet flow, but does not require full 2-D velocity imaging. This method was found to be accurate to somewhat higher velocities, but only when the pulsed Doppler measurements were made more than about 3 centimeters from the hole. Measurements made closer to the hole led to an underestimation of the flow rate in the jet.

It was concluded that Doppler ultrasound techniques have great promise in the accurate quantification of valvular leakage, but that significant further work is needed to improve ultrasonic technology for fast acquisition of velocity information or that new computer routines will be needed to handle the data in ways which overcome the aliasing problem. In vitro studies are underway to evaluate certain potential computer-based solutions.

VIII. COMPLETED OR PENDING JUDICIAL ACTIONS

Requirement (6)

Sec. 540 (a)(6): a list, with a brief statement of the issues, of completed or pending judicial actions under this subchapter.

Action

During 1992 there were no completed or pending judicial actions under this subchapter.

IX. DISSEMINATION OF TECHNICAL AND CONSUMER-ORIENTED INFORMATION

Requirement (7)

Sec. 540(a)(7): the extent to which technical information was disseminated to the scientific, commercial, and labor community and consumer-oriented information was made available to the public.

Action

EXPOSURE EVALUATION AND NEXT INFORMATION

Standards issued by the Joint Commission for Accreditation of Healthcare Organizations requiring that medical facilities have knowledge of the doses given during their examinations helped spur interest in the information available from the Nationwide Evaluation of X-ray Trends (NEXT) program. Concern about the quality of images produced in mammography further raised interest. Several steps were taken to make the NEXT information available. Papers were presented at the 24th Annual Meeting of the Conference of Radiation Control Program Directors in May.

Scientific Exhibits at the Radiological Society of North America (RSNA) in November and published articles in "Radiology" further made available exposure data on mammography examinations. Scientific papers and poster sessions presented at the Commission of European Communities Workshop on Test Phantoms and Optimization in Diagnostic Radiology and Nuclear Medicine held in Würzburg, Germany, made available, to the international communities, exposure data on Chest, Abdomen/L-S spine, Fluoroscopy, and Processing.

RADIOLOGICAL HEALTH SCIENCES LEARNING FILE

FDA continues to provide technical support to the American College of Radiology (ACR) for the development and upgrading of the Radiological Health Sciences Learning File. The Learning File consists of more than 5000 full-sized x-ray films organized into eight major organ systems. Used worldwide in over 120 institutions, the File has been acclaimed as an effective and important method for teaching diagnostic radiology to physicians.

FDA staff participates on the ACR Learning File committee, which was created to assure that the File is current with radiological technology and practice. During 1992, a film and videodisc version of a neuroradiology section was developed. The videodisc format contains all of the x-ray images, patient histories, discussions of radiographic findings, and detailed discussions of the film version of the File. These versions offer instant image and text displays, cost less, and are more compact. Future plans call for developing videodisc sections for all of the Learning File sections.

PUBLICATION DISTRIBUTION

During 1992, CDRH staff responded to several hundred requests for technical publications, pamphlets, brochures, and other educational materials produced by the Center for Devices and Radiological Health. Among the subjects covered by these publications were mammograms, x-rays, tanning, halogen lamps, effects of exposure to extremely low frequency radiation, radar guns used by police, fluorescent lamps, microwave ovens, lasers used in medicine, and quality assurance. These materials were in addition to those distributed as described elsewhere in connection with specific projects.

X. COOPERATION BETWEEN GOVERNMENT AND INDUSTRY AND OTHER INTERESTED PARTIES

Requirement (8)

Sec. 540 (a)(8): the extent of cooperation between Government officials and representatives of industry and other interested parties in the implementation of this subchapter including a log or summary of meetings held between Government officials and representatives of industry and other interested parties.

Action

The Center for Devices and Radiological Health has been designated by the World Health Organization (WHO) as the Collaborating Center for the following areas:

1. Standardization of Protection Against Nonionizing Radiations;

2. Nuclear Medicine; and

3. Training and General Tasks in Radiation Medicine.

As the Collaborating Center for Standardization of Protection Against Nonionizing Radiations, the Center will assist WHO in (1) estimating present levels and trends of human exposure from nonionizing radiation; (2) promoting the establishment of instrument calibration and reference services in various countries; (3) establishing internationally acceptable nomenclature, definition of terms and quantities, and dosimeter methods; (4) training public health personnel; (5) alerting health officials to the need for establishing nonionizing radiation control programs; and (6) stimulating international research on biological effects and development of measuring instrumentation.

As the Collaborating Center for Nuclear Medicine, CDRH is assisting WHO in developing protocols and recommendations for the use of nuclear medicine equipment (e.g., gamma cameras, probes, well counters and rectilinear scanners) in measuring environmental samples of low-level radioactivity emanating from accidents of the Chernobyl type as well as human contamination (in vivo measurements). A draft document was prepared by Center Staff and sent out for review to National and International bodies and a WHO panel. The final manuscript has been sent to WHO for publication.

As the Collaborating Center for Training and General Tasks, CDRH will (1) assist WHO in the collection and distribution of information and teaching aids for the training of medical radiological technicians, radiological engineering technicians, medical physicists, and physicians in all branches of radiation medicine, (2) prepare and issue such material for use in the different WHO projects, and (3) formulate, in collaboration with WHO, recommendations and guidelines for training and for the medical applications ofradiation.

The organization and responsibility of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), established by the Radiation Control for Health

and Safety Act of 1968, provides an excellent format for cooperation between Government, industry, and the public in the development of performance standards under the Act.

The Center has coordinated interagency agreements with nine Federal agencies to provide medical radiation use evaluations of all x-ray installations within those agencies. The agencies are the Bureau of Prisons (Department of Justice), the Coast Guard (Department of Transportation), the Department of Energy, Department of the Army, the National Aeronautics and Space Administration, the National Center for Health Statistics, the National Institute of Occupational Safety and Health, the Indian Health Service, and Hansen's Disease Center (Health Resources and Services Administration). The Center uses the information from these evaluations to maintain a Federal data base in diagnostic radiology, to assess the impact of its training and other educational initiatives, and to monitor the impact of new equipment or techniques in reducing radiation exposure.

Over the past year, radiological surveys were completed at 61 Federal facilities under interagency agreements. The surveys were conducted primarily by, or under supervision of, FDA's Regional Radiological Health Representatives. Over 50 ionization chambers and radiation survey instruments have been calibrated by the Center for the U.S. military services. CDRH staff have also contributed to the training and continuing education of Army health physics personnel through the presentation of material during Army-sponsored courses and seminars. CDRH staff have also provided information on Center programs in quality assurance, referral criteria, film processor evaluation, and automatic exposure control evaluation to other Federal agencies. During 1992, CDRH personnel and the Radiological Health Representatives also conducted courses for Indian Health Service (IHS) and FDA personnel to prepare them to conduct safety surveys of their agency's radiological facilities. The course provides basic information to conduct surveys for radiation protection, equipment use, film processing, and policy development and is planned to be repeated annually.

Additionally, CDRH has made quality assurance test tools available to Federal facilities under the interagency agreements and to the State radiation control programs in support of the Nationwide Evaluation of X-ray Trends (NEXT) program. Test tools fabricated and made available for use by the Federal facilities and for NEXT during 1992 included: 200 mammography phantoms, 150 dental phantoms with cradles, 30 fluoroscopic phantoms and imaging test tools, 30 LucAl chest and 30 abdominal/L-S spine phantoms, 150 screen/film contact test tools and 5,000 darkroom fog test tools. One hundred and fifty densitometers and 150 sensitometers were also calibrated and provided for use by Federal facilities and NEXT.

The data collection for the project entitled, "Body Dose Reduction in I-131 Therapy of Hyperthyroidism" has been resumed in Zagreb, Yugoslavia. After long disruption due to the war, data have now been collected.

The Center was involved in consultations regarding U.S.-Polish scientific cooperation in biomedical sciences. This cooperation will support a study on the "Effects of UVA and UVB Radiation on Blood Cells."

US-CIS COOPERATIVE HEALTH AGREEMENT ON ENVIRONMENTAL HEALTH

CDRH has responsibility for coordination of the United States-Commonwealth of Independent States (CIS, formerly USSR) Cooperative Health Agreement for Environmental Health. The focus of this bilateral cooperation is on physical factors in the environment and relates primarily to the biological effects of electromagnetic radiation including extremely low frequency (50-60 Hz) and radio frequency/microwave exposure. This year the Center sponsored the Eighth US-CIS Workshop on Physical Factors in the Environment. This meeting included participation by 10 CIS and 16 American scientists actively engaged in research on the biological effects of electromagnetic radiation. A new 2-year work plan was jointly formulated by the participating scientists and included planning for joint studies and the continued exchange of information. Following the workshop, the CIS delegation also attended a major international scientific meeting dealing with the biological effects of electromagnetic radiation. It is anticipated that the ninth joint workshop will be held in the CIS in 1993.

STANDARDS ACTIVITIES

CDRH staff participated in the revision of the WHO Environmental Health Criteria Document Number 16 on radiofrequency and microwaves, and the preparation of the International Radiation Protection Association Guideline on Exposure Limits to Electric and Magnetic Fields at 50/60 Hz.

As a member of the American National Standards Institute (ANSI), the Center encourages Federal participation with voluntary standards organizations. Among the projects in which CDRH has been involved are standards for safe use of lasers, the uranium content of dental porcelain, and diagnostic ultrasound equipment. The Center has also worked with the International Electrotechnical Commission (IEC) TC 76 Committee on the development of laser standards and the harmonization of U.S. and international standards in this area.

The Center has representation on the American National Standards Institute (ANSI) Z80 Committee on ophthalmic standards and Z311 Committee for the photobiological safety of lamps and lighting systems. In 1988, a subcommittee of ANSI Z80, in cooperation with CDRH, initiated work to develop specifications for future ophthalmic instrument standards to limit the optical radiation emissions from ophthalmic instruments used for the treatment and diagnosis of disease. This work was initiated, in part, as the result of a CDRH study of optical radiation emissions from hand-held ophthalmoscopes that was conducted in 1986-1987. Further, this activity was extended in 1990 to include liaison with the International Organization for Standardization (ISO) TC 172 in an effort to obtain an international consensus on these important devices. Work on developing specifications and achieving a consensus continued through 1992, and agreement, in principle, was reached on optical radiation limits for ophthalmic instruments within ISO TC-172.

In 1988, CDRH actively participated in the development of the first ANSI Z311 general optical radiation standard for lamps and lamp systems. The first draft standard was submitted for a vote for acceptance to the Z311 committee members in 1988. As a result

of the voting, which was completed in early 1989, the draft standard was revised and resubmitted for a second vote in 1990. A second vote in November 1990 resulted in additional substantive comments and revisions. In 1991, a working group formulated revisions to the standard, which was submitted for a vote in late 1992.

The Center actively participates on the American College of Nuclear Physicians Committee (ACNP) on Standardization of Nuclear Medicine Instrumentation. The Committee is developing user specifications for performance as minimum standards of Single Photon Emission Computed Tomography systems (SPECT) named Operational Guides. The final draft entitled, "Operational Performance of Rotational SPECT Systems," was discussed with the National Electrical Manufacturers Association (NEMA). Finalization is now on hold until joint ACNP-NEMA recommendations for quality control are developed. The final document will include both the Operational Guides and the quality control recommendations.

Ultrasound Standards Development

The voluntary standard, "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment," has been adopted by the American Institute of Ultrasound in Medicine (AIUM) and by the National Electrical Manufacturers Association (NEMA). The standard was written cooperatively by AIUM, NEMA, CDRH, and other clinical and scientific organizations. Its goal is to make device operators aware of the ultrasonic output of their instrument via the real-time display of biologically relevant exposure indices, so that exposures can be minimized easily and effectively, and prudent risk-benefit decisions can be made. By demonstrating compliance with this standard as part of a 510(k) notification, a company can address the issue of equivalent safety via the combination of an on-equipment output display as specified in the standard and a related user education program, rather than by performing a comparison of application-specific exposure levels as has been done in the past. A user education program is essential in achieving this goal, and work has begun on developing the educational message, identifying the clinical target groups, and selecting the most effective means for conveying the message to these groups. Efforts to develop a videotape on the standard and its implications are underway; completion is projected for the spring of 1993.

The standard defines two types of biologically relevant indices for the display: a Mechanical Index (MI) designed to provide a measure of the likelihood for a mechanical event such as cavitation to occur, and a Thermal Index, either soft tissue (TIS), fetal bone (TIB), or cranial bone (TIC), designed to provide an indication of the estimated potential for ultrasonically-induced temperature increase. The standard also calls for devices to incorporate application-specific output default settings, which are set upon power-up, entry of new patient ID data, or change from a nonfetal to a fetal application. To help manufacturers incorporate this standard in a premarket notification, a revised 510(k) guidance document is being prepared by the Center.

CDRH staff have contributed on an international level to International Electrotechnical Commission (IEC) efforts to develop standards for the safety of ultrasound imaging devices and the performance of ultrasound Doppler devices. A major purpose of our involvement is to ensure that these international standards are as compatible as possible

with documents produced by U.S. organizations and with FDA guidelines. A CDRH person has been appointed as Deputy Technical Advisor for the ultrasound project of IEC Subcommittee 62B. She is responsible for coordinating U.S. positions on this standard.

To that end we have encouraged inclusion of mechanical and thermal indices (see above) in the IEC document, "Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment." Efforts are also being made to include more physiologically relevant criteria in the IEC document, "Standard Method of Measuring and Labeling for Ultrasonic Doppler Fetal Heart Beat Detector." These include the characterization of unwanted signal rejection and overall signal detectability at all power levels, and the use of tissue mimicking phantoms as testing devices.

Two subcommittees of the AIUM Standards Committee have made significant progress this year. The Doppler Standards Subcommittee has written a "prefinal draft" of "Performance Criteria for Doppler Ultrasound Devices." This document addresses measurement and test techniques for evaluating the ability of Doppler systems to detect and measure weak blood flow signals or signals that are partially masked by acoustic or electrical noise. The Digital Imaging Subcommittee has authored and edited a second draft of "Objective Methods for Measurement of Performance of Pulse-Echo Ultrasound Equipment." This document will provide information on techniques to measure ultrasound system performance without reliance upon human subjectivity in assessment of image quality.

Other Standards Activities

CDRH staff participated in the preparation of guidelines for exposure to nonionizing electromagnetic radiation under the auspices of the International Radiation Protection Association.

Center staff also served on the Committee for Ultraviolet Emitting Appliances of the International Electrotechnical Commission and the International Committee on Illumination.

INTERNATIONAL STANDARDS ACTIVITIES

Consensus Measurement Methodology for Medical Image Assessment

Three Agency staff members are principal authors of an International Commission on Radiation Units and Measurements (ICRU) report on this subject. After one of these gave a short presentation to the ICRU committee in Manchester, England, in February, we were asked to write a "low-tech" draft summary of the entire report for use by radiologists. This has been completed and submitted. The committee has decided to rename the report to incorporate the words, "A unified approach" (to medical image assessment), thereby subscribing to such an approach developed by Agency imaging scientists. One of this group visited the University of Chicago group in July to make a presentation on measurement methodology and to work out differences related to the report.

CDRH staff participated in the revision of the WHO Environmental Health Criteria Document No. 16 on radiofrequency and microwaves and in the preparation of the International Radiation Protection Association Guideline on Exposure Limit to Electric and Magnetic Fields at 50/60 Hz.

In 1990, the European Committee on Standardization (CEN) formed Technical Committee (TC) 251 to deal with the development of standards in health care informatics. Health care informatics is a relatively new field that includes health care applications of computers, information systems and databases, knowledge based and decision support systems, and telecommunications. It is an expansion of "medical informatics" and includes applications of these and related technologies and systems to clinical and personal health care; health services administration; and planning, research, technology assessment, education, and regulation. In October 1990, the Secretary General of CEN requested that ANSI play a coordinating role for related US efforts to facilitate CEN-US cooperation in the domain of health care informatics. During 1991 and 1992, CDRH has worked with the Agency for Health Care Policy and Research (AHCPR) and ANSI in responding to this request. In particular, CDRH has maintained close liaison with the CEN TC 251 working group on medical imaging. This group is responsible for developing European health care informatics standards for medical imaging technologies. CDRH has facilitated cooperation between this group and related US standards activities, particularly those underway as a collaborative effort of the American College of Radiology and the National Electrical Manufacturers Association. During 1992, CDRH has worked with AHCPR, the National Cancer Institute Radiation Research Program, and the National Library of Medicine to coordinate health care informatics activities related to medical imaging and to explore the potential for collaboration with activities sponsored by the Commission of the European Communities in this area.

CDRH scientists participated in the International Electrotechnical Commission (IEC) 62C Subcommittee deliberations, the deliberations of Working Group 1 concerning problems in radiotherapy, and the deliberations of Working Group 2 on nuclear medicine equipment. The following documents will be further revised: (1) "Functional Performance Characteristics of Radiotherapy Simulators," (2) "Guidelines for Functional Performance Characteristics of Radiotherapy Simulators," and (3) "Amendment No. 2 to IEC Publication 601-2-11 (1987) Safety of Medical Electrical Equipment; Part 2: Gamma Beam Therapy Equipment." The following have been published: IEC #976—Performance Standard for Medical Electron Accelerators, and IEC #977—Performance Guidelines for Medical Electron Accelerators.

CDRH serves now as the secretariat to IEC SC 62C/WG 2 for the development of IEC standards in nuclear medicine. The following have been accomplished by WG 2: The IEC Standard #789 entitled, "Characteristics and Test Methods for Anger-Type Gamma Cameras" has been published (January 1992). The Draft Dose Calibrator Standard has been revised and is now being circulated to member countries for voting as a standard including further comment.

A "new work" proposal by Germany to develop a standard entitled, "Characteristics and Test Methods for Positron Emission Tomography" was approved by IEC and assigned to WG 2. Groundwork to prepare the first draft has been completed.

Additionally, CDRH staff worked with Subcommittee 62B on diagnostic x-ray equipment issues. This work relates to efforts at harmonizing the U.S. (FDA) standards with the international standards. The work of Subcommittees 62A (Common Aspects) and 62D (Electromedical Equipment) also impacts on radiation safety. CDRH personnel also participated in their efforts. Because the Center is becoming more involved with international standards activities, it now has representatives on the U.S. National Committee of the IEC.

NATIONAL CONFERENCE ON RADIATION CONTROL

The 24th Annual National Conference on Radiation Control was held in Orlando, Florida, on May 17-21, 1992. The Conference was sponsored by the Conference of Radiation Control Program Directors, Inc., FDA's Center for Devices and Radiological Health, the Environmental Protection Agency's Office of Radiation Programs, and the Nuclear Regulatory Commission. The American College of Radiology and the American College of Medical Physics also participated in the conference. Topics included radioactive materials, mammography, radon, emergency response, film processing, nonionizing radiation, and environmental radiation. During the year, Center personnel have also participated in the activities of various subgroups of the Conference of Radiation Control Program Directors including Task Forces or Working Groups on Medical Practices, Quality Assurance, NEXT, Training, Nonionizing Radiation, Ionizing Radiation Therapy, Radioactive Materials, Radiation Measurements, and Suggested State Regulations.

BREAST CANCER DETECTION ACTIVITIES

In late spring of 1990, the Assistant Secretary for Health (ASH) asked the Centers for Disease Control (CDC) to take the lead in developing a national plan for coordinating Government and private efforts to reduce mortality from breast and cervical cancer. CDC then asked FDA and the National Cancer Institute (NCI) to work with it in coordinating development of the plan. Representatives of over 75 public, professional, and consumer organizations reviewed drafts of the plan and attended 2 meetings on it. The plan recognizes the range of activities—from primary prevention through screening, followup, and treatment—that are essential for the control of breast and cervical cancer. The plan's focus, however, is on effective early detection and followup. CDRH coordinated FDA participation in the plan's development and represents the Agency on the "steering committee" for the effort. In addition, CDRH had the lead responsibility for the writing of the Breast Cancer Quality Assurance section, one of the six components of the plan. In each of the six component areas, needs that must be met and actions to meet them are identified. On October 15, 1992, the Secretary of Health and Human Services accepted the plan as presented to him by ASH. Efforts are underway to ensure its dissemination and implementation.

After the Omnibus Budget Reconciliation Act of 1990 restored the screening mammography benefit to Medicare with an effective date of January 1, 1991, FDA, along with CDC and NCI, was actively involved in the HCFA efforts in late 1990 to have "interim final" regulations in place by January 1, 1991, to assure the quality of the screening mammography services provided by Medicare. The interim final regulations were published and became effective on December 31, 1990. During 1991, FDA provided significant assistance to HCFA in the analysis of comments received on the interim final

regulations and on the development of final regulations. FDA staff were also active in helping HCFA develop interpretative guidelines to be used by inspectors to assess the compliance with the regulations by facilities desiring reimbursement for screening mammography. The interpretative guidelines became effective on September 8, 1992. Previous to that date, facilities wishing to participate in the Medicare program could "self-attest" that they met the quality standards. After September 8, they have to pass an inspection for compliance with the standards before they can participate. In preparation for these inspections, and for the planned inspections of the 6,500 "self-attested" facilities, HCFA conducted training courses for the inspectors in July and in October 1992. FDA personnel presented the technical components of those training courses.

During 1992, the Agency for Health Care Policy and Research established a mammography panel that was charged with developing recommendations for Quality Determinants in Mammography. The recommendations are to serve as voluntary clinical practice guidelines. CDRH staff members serve as liaison members of this panel.

The results of NEXT 85 (Mammography) indicated that while mammographic doses were, in general, reasonable, the quality of mammography images often left much to be desired. These findings were of concern to the American College of Radiology (ACR). In an effort to minimize this problem, they initiated a voluntary accreditation program for mammography facilities. CDRH personnel have been working with ACR in the development of the accreditation program and the writing of several quality assurance documents for mammography facilities. Over 9,000 facilities have now applied for accreditation with about 30 percent failing to meet the criteria. The quality assurance documents were published in November 1990. A revision and expansion of the documents were developed in 1991 and published in 1992. Preliminary results from NEXT 92 (Mammography) indicate that there has been continued improvement in image quality, dose levels, and image processing in mammography facilities. Darkroom fog (light leaks) have been identified as a new problem, however.

CDC has funded an effort by the ACR to improve quality assurance in mammography. This effort involved the formation of seven committees under an oversight committee to consider the educational needs of technologists, radiologists, and medical physicists in the mammography area, to train reviewers of phantom and clinical images, to work to correlate phantom and clinical image quality measurements, to coordinate the education of medical physicists and State radiation control personnel, and to consider research needs. CDRH staff are involved in the work of several of these committees and will cochair one of them.

CDC also has entered into a contract with the Conference of Radiation Control Program Directors to carry out actions to improve the practice of mammography and the evaluation of mammography facilities. CDRH staff have provided liaison between CDC and the Conference and have provided technical support for the Conference efforts.

During 1991, the United States and eight other countries began to exchange data on physical examination; breast self-examination; and mammography screening equipment, techniques, and quality assurance procedures. This exchange is an outgrowth of a December 1988 workshop cosponsored by FDA and NCI. Participants in the workshop included the World Health Organization, the International Union Against Cancer, and 11

countries. At the 1988 meeting it was agreed that a better understanding of how breast cancer detection is evolving in different countries would be beneficial to all. NCI agreed to coordinate participation of the United States in this effort. On behalf of FDA, CDRH has provided technical support, particularly for the quality assurance components. The initial data exchange was intended primarily to test the viability of the procedures developed. However, it has already revealed some interesting variations in the approaches of the various countries. With respect to quality assurance, it has been found that double reading has been used to a greater extent in other countries than in the United States. The cost/benefit ratio of double reading is currently being debated in the United States and data on the practice elsewhere will influence this debate. International cooperation continued during 1992. In addition, NCI began to support projects in the United States that will help to improve data on early breast cancer detection. CDRH is providing technical support for these projects related to mammography quality assurance.

XI. RECOMMENDATIONS FOR LEGISLATION

Requirement

Sec. 540 (b): The report required by subsection (a) shall contain such recommendations for additional legislation as the Secretary deems necessary to promote cooperation among the several States in the improvement of electronic product radiation control and to strengthen the national electronic product radiation control program.

Action

It is recommended that Section 540 of the Federal Food, Drug, and Cosmetic Act (previously, Section 360D of the Public Health Service Act; 42 USC 263 l) which requires the Secretary of Health and Human Services to submit this annual report to the President for transmittal to Congress be repealed.

It is FDA's view that continuing this reporting requirement is not productive. In March 1986, the U.S. Senate passed the Congressional Reports Elimination Act of 1986 (S.992), which included a provision repealing this requirement. However, this provision was among those that were removed by amendments during deliberations in the House of Representatives. The amended bill (without the provision for repealing this requirement) was enacted into law on August 22, 1986.

All of the information found in this report is available to Congress on a more immediate basis through Center technical reports, the Radiological Health Bulletin, and other publicly available sources. The Department and the Food and Drug Administration have concluded that this annual report serves little useful purpose and diverts agency and, to some extent, department resources from more productive activities.

APPENDIX

TECHNICAL REPORTS AND ARTICLES PUBLISHED OR PRESENTED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH - CALENDAR YEAR 1992

IONIZING PRODUCTS AND DEVICES

Reports and articles:

1. Response of RAW 264.7 murine macrophage cells to UVC radiation. In Vitro Toxicology.

2. Mitotic delay as the determinant for the lowest dose rate of x-irradiation to stop cell proliferation (Proceedings of the Radiation Research Society Annual Meeting).

3. Binary task performance on images reconstructed using Memsys3: Comparison of machine and human observers (Proceedings of the 12th International Workshop on Maximum Entropy and Bayesian Methods in Signal and Image Processing, Paris, France).

4. Task performance on constrained reconstructions: human observer compared with sub-optimal Bayesian performance (Proceedings of the Society of Photo-optical Instrumentation Engineers).

5. Handbook of Selected Tissue Doses for the Upper Gastrointestinal Fluoroscopic Examination (FDA 92-8282).

6. Assessing patient exposure in fluoroscopy (Journal of Radiation Protection Dosimetry).

7. Assessment of entrance-skin-kerma in the united states: the nationwide evaluation of x-ray trends (NEXT) (Journal of Radiation Protection Dosimetry).

8. Automatic film processing: analysis of 9 years of observations (Radiology)

9. Average radiation dose in standard CT examinations of the head: results of the 1990 NEXT survey (Radiology).

10. Patient equivalent attenuation phantoms (Journal of Radiation Protection Dosimetry).

11. Preliminary report of 1992 NEXT mammography survey (Proceedings of the American Association of Physicists in Medicine).

12. Sensitometric technique for the evaluation of processing (S.T.E.P.) (Journal of Radiation Protection Dosimetry).

Presentations

1. Evaluation of medical image compression by Gabor Elementary functions (SPIE Medical Imaging V (poster session) San Jose, CA).

2. Computer-assisted radiology research in the Center for Devices and Radiological Health (Symposium for Computer-Assisted Radiology, Baltimore, MD).

3. Gabor-based neural network medical image compression (International Joint Conference on Neural Networks, Baltimore, MD).

4. Considerations regarding mammography calibrations (Workshop for CRCPD-Accredited Calibration Laboratories, Sacramento, CA).

5. HVL determination at the CDRH lab (Workshop for CRCPD-Accredited Calibration Laboratories, Sacramento, CA).

6. Traceability defined? (Workshop for CRCPD-Accredited Calibration Laboratories, Sacramento, CA).

7. Chairman's Concluding Remarks (Tenth Conference on Radiation and Health, American Statistical Association, Hilton Head, SC).

8. Physics in computerized tomography (Medical Officer's Course in Nuclear Medicine, Bethesda Naval Hospital, Bethesda, MD).

9. Physics in computerized tomography (Spring 1992 Medical Officer's Course in Nuclear Medicine and Radioisotope Techniques, Bethesda Naval Hospital, Bethesda, MD).

10. Measurement problems in diagnostic radiology (Workshop for CRCPD-Accredited Calibration Laboratories, Sacramento, CA).

11. QA/QC overview (Workshop for CRCPD-Accredited Calibration Laboratories, Sacramento, CA).

12. Reference ion chamber for low-energy calibrations (Workshop for CRCPD-Accredited Calibration Laboratories, Sacramento, CA).

13. Summary of other accreditation programs (Workshop for CRCPD-Accredited Calibration Laboratories, Sacramento, CA).

14. What is a calibration, how good is it, and how do I know? (Radiation Protection Instrumentation Course, Harvard School of Public Health, Cambridge, MA).

15. Computational methods for the design of test objects and tissue substitutes for radiologic applications (CFC Workshop of Phantoms, Wurzburg, Germany).

16. Imaging and dose characteristics of a computer-optimized mammography system (Radiological Society of North America, Chicago, IL).

17. Gabor-transform compression of medical images and a task-based quality measure (Annual Fall Meeting of the Biomedical Engineering Society).

18. Comparison of methods for spectral estimation from 1D NMR time signals (Mathematical Methods of Medical Imaging, SPIE, San Diego, CA).

19. Development and test of a new spinal injection phantom (Regional Anesthesia Workshop, Tampa, FL).

20. Risk from fluoroscopy: A comparison with other x-ray examinations (Conference of Radiation Control Program Directors Annual Meeting, Orlando, FL).

21. More Handbooks of Tissue Doses in Diagnostic Radiology (International Congress of the International Radiation Protection Association).

22. Assessing patient exposure in fluoroscopy (24th Annual Conference on Radiation Control).

23. Current status of fluoroscopy (American College of Radiology - FDA Fluoroscopy Conference).

24. Determination of entrance skin exposure (Radiological Society of North America).

25. Does credentialing makes a difference in Mammography? (exhibit at Radiological Society of North America).

26. Patient doses in fluoroscopy (American College of Radiology Symposium on Patient and Personnel Dose Assessment in Diagnostic Imaging).

27. Radiation protection requirements for film (President's Symposium at Annual Meeting of the American Association of Physicists in Medicine).

28. Results of federal and state studies on film processing (Conference on Film Processing in Medical Imaging: A Practical Update for the 90's).

29. Update on federal and state legislation (Radiological Technologist Mammography Symposium).

RADIOFREQUENCY AND MICROWAVES

Reports and articles:

1. Burns associated with the use of microwave ovens (Journal of Microwave Power and Electromagnetic Energy).

2. Microwave-induced changes to the primate eye (Johns Hopkins APL Technical Digest).

3. Frequency domain impedance measure of erythrocytes: constant phase angle impedance characteristics and a phase transition (Biophysical Journal).

4. Effects of continuous (CW) and pulsed (PW) 2450 MHz radiation exposure on spontaneous transformation of the human lymphocytes in vitro (Bioelectromagnetics).

5. Increased sensitivity of the nonhuman primate eye to microwave radiation following ophthalmic drug pretreatment (Bioelectromagnetics).

6. Critical research issues in the area of electromagnetic fields bioeffects (BENER Digest Update).

7. Comparison of the effect of ELF on c-myc oncogene expression in normal and transformed human cells (Annals of the New York Academy of Sciences).

8. Comparison of the effect of ELF on total RNA content in normal and transformed human cells (Annals of the New York Academy of Sciences).

9. Medical device RF susceptibility - Research and proposed standards for infant apnea monitors (Proceedings of the Symposium - Electromagnetic Compatibility Technology Expo).

10. 60 Hz magnetic fields do not affect protein synthesis in a human burkitt lymphoma cell line (Book of Abstracts, First World Congress on Biology and Medicine).

11. Intracellular calcium signalling by human T-leukemic cells exposed to an induced 1 mV/cm 60 Hz, sinusoidal electric field (Proceedings of the First World Congress for Electricity and Magnetism in Biology and Medicine).

12. Improved spatial resolution in chemical shift imaging via autoregressive spectral estimation (Proceedings of the Society for Magnetic Resonance in Medicine Annual Meeting, Berlin, Germany).

13. Comparison of methods for spectral estimation from 1D NMR time signals (Proceedings of the SPIE Conference on Mathematical Methods in Medical Imaging).

Presentations:

1. Guidelines for dynamic magnetic fields from magnetic resonance devices (Workshop on Dynamic Fields, Purdue University).

2. Update on medical device electromagnetic compatibility: EMC problems, their technical assessment, and proposed regulations. (Minisymposium - 1992 International Conference of the IEEE Engineering in Medicine and Biology Society, Paris, France).

3. Medical device RF susceptibility - research and proposed standards for infant apnea monitors (Interference Control Technologies (ICT), Inc. Conference on EMI Control in Medical Electronics, Washington, DC).

4. Electromagnetic field measurements of electric blankets (Annual National Conference on Radiation Control, Orlando, FL).

5. System independence of RF-based tissue characterization features: Results of in vivo clinical trials in liver (International Symposium on Ultrasound Imaging and Tissue Characterization, Arlington, VA).

6. Pulsed microwave-induced ocular changes in the restrained nonhuman primate (Bioelectromagnetics Society (BEMS) First World Congress for Electricity and Magnetism in Biology and Medicine, Lake Buena Vista, FL).

7. The effects of varying the frequency and magnetic field strength on morphologic phenotype of ELF responsive model cell line (First World Congress for Electricity and Magnetism in Biology and Medicine, Orlando, FL).

8. Characterization of immortalized cell lines isolated from a soft tissue tumor derived from a rabbit subchronically exposed to 60 Hz magnetic fields at 1G (First World Congress for Electricity and Magnetism in Biology and Medicine, Orlando, FL).

9. Dose dependent health effects exhibited in rabbits exposed to 60 Hz magnetic fields at 1G and 5G (First World Congress for Electricity and Magnetism in Biology and Medicine, Orlando, FL).

10. The effects of a single intraoperative immersion in various chemical agents and electromagnetic field exposure on onlay bone grafts to the facial skeleton (First World Congress for Electricity and Magnetism in Biology and Medicine, Orlando, FL).

11. Pulsed electromagnetic field exposure interferes with antisense inhibition both in the cytoplasmic and the nuclear compartments of the cell (First World Congress for Electricity and Magnetism in Biology and Medicine, Orlando, FL).

12. TENS conventional and burst modes at moderate intensity fails to influence skin temperature significantly (American Physical Therapy Association Conference, Denver, CO).

13. Medical device RF susceptibility - research and proposed standards for Infant Apnea Monitors (First National Conference on EMI Control in Medical Electronics, Herndon, VA).

14. Measurements of the electrical impedance of living cells in the frequency domain (National Institute of Standards and Technology, Biotechnology Division).

15. Electromagnetic interference, electromagnetic compatibility, and safety standards (Association for the Advancement of Medical Instrumentation Annual Meeting and Exposition, Anaheim, CA).

16. Medical device performance degradation due to electromagnetic interference: Reported problems (EMI Control in Medical Electronics, Herndon, VA).

17. Results of an interlaboratory comparison of prosthetic heart valves (Association for the Advancement of Medical Instrumentation Annual Meeting and Exposition, Anaheim, CA).

18. Medical applications of electromagnetic fields (Second International Workshop on Nonionizing Radiation, University of British Columbia, Vancouver, British Columbia, Canada).

19. Comparison of the effects on gene expression by extremely low frequency electromagnetic fields exposure in normal and transformed human cells (First World Congress for Electricity and Magnetism in Biology and Medicine, Orlando, FL).

20. Pathological evaluation of rabbits subchronically exposed to 60 Hz magnetic fields at 1G and 5G (First World Congress for Electricity and Magnetism in Biology and Medicine, Orlando, FL).

21. An examination of the effects on the strength duration response of nerve tissue with different stimulation conditions (First World Congress for Electricity and Magnetism in Biology and Medicine, Lake Buena Vista, FL).

22. Comparison of the effects of extremely low frequency electromagnetic field exposure to intact human cells or their nuclei without cytoplasmic membrane (First World Congress for Electricity and Magnetism in Biology and Medicine, Orlando, FL).

LIGHT PRODUCTS AND DEVICES

Reports and articles:

1. Effects of ultraviolet and ionizing radiations on the HIV promoter: Lack of correlation between promoter activation and cytotoxicity (Journal of Photochemistry and Photobiology).

2. Adjuvant immunotherapy in melanoma: A new approach (Journal of Surgical Oncology).

3. Optical performance of recentered mono focal intraocular lenses (Journal of Cataract and Refractive Surgery).

4. Detection of action-potential-induced fluorescence changes with an optical fiber carrying excitation light (Journal of Fluorescence).

5. Photobiology and radiobiology: divisions and common ground. In: Photobiology (E. Rikilis, Ed.).

6. Non-nuclear damage and cell lysis are induced by UVA, but not UVB or UVC, radiation in three strains of L5178Y cells (Journal of Photochemistry and Photobiology).

7. Photic maculopathy following extracapsular cataract surgery - A prospective study (American Journal of Ophthalmology).

8. Time resolved reflectivity of ArFl laser irradiated polyamide. (Journal of Applied Physics).

9. Bovine corneal photoablation investigated by time-resolved excimer laser reflectivity (Lasers and Light in Ophthalmology).

10. Photoaging effects on spectral transmittance of plastic filters (Photochemistry Photobiology).

11. Indirect ophthalmoscopes - evaluation for potential hazards (Applied Optics).

12. Lasers in medicine (IEEE Circuits and Devices).

13. Prevalence and demographic correlates of intraocular lens implants in the United States (American Journal of Public Health).

14. UV-A1 induced anuclear damage in mammalian cells. In: Biological Responses to Ultraviolet A Radiation (F. Urbach, Ed.). Valdenmar Publishing, pp. 65-73.

15. Studies on the mechanism of UVA-1 induced hemolysis. In: Biologic Effects of Light (Eds., M.F. Hollick and A. Kligman). Walter DeGruyter, pp. 349-353.

16. Carcinogenesis by long-wavelength UVA and failure of reciprocity. In: Biological responses to ultraviolet radiation (F. Urbach, Ed.). Valdenmar Publishing.

17. Medications that increase sensitivity to light: A 1992 updated and revised listing (FDA Publication).

18. Effects of Two Viral Inactivation Methods of Platelets: Laser - UV Radiation and Merocyanine 540-Mediated. In: Blood Cells. Springer-Verlag, Inc., 18:101-116.

19. Effects of PUVA treatment on human immunodeficiency virus. In: Biologic Effects of Light (Eds., M. Holick and A. Kligman). W. DeGruyter.

20. Optical photons and gene activation: An introduction to the symposium (Photochemistry and Photobiology).

21. Estimation of skin cancer risks from direct exposure to UV radiation emitted by unshielded general purpose lamps (Photochemistry and Photobiology).

22. Skin cancer risk estimate for unshielded UV-emitting lamps (Program and Abstracts, 11th International Congress on Photobiology, Kyoto, Japan).

23. Effects of repeated UVB exposures on the human immunodeficiency virus (HIV) promoter (Photochemistry and Photobiology).

24. Argon fluoride excimer laser ablation of cornea (Procedures of SPIE, Biomedical Optics, Los Angeles, CA).

25. Letter to the Editor, American Journal of Psychiatry.

26. Activation of HIV by UVB radiation and PUVA treatment in vitro: An evaluation of the safety of medical procedures and cosmetic applications (Photochemistry and Photobiology).

27. Activation of the HIV promoter by radiation and drugs (Book of Abstracts, FDA Chapter, Sigma Xi Science Expo, Rockville, MD).

28. Effects of PUVA treatment of human immunodeficiency virus (Book of Abstracts, FDA Chapter, Sigma Xi Science Expo, Rockville, MD).

29. Activation of the HIV promoter by psoralens or angelicins in combination with UVA radiation (Photochemistry and Photobiology).

Presentations:

1. Activation of the HIV promoter and virus treatment involving UV, ionizing radiation, and drugs. Basic Science Research Group, Department of Dermatology, College of Physicians and Surgeons of Columbia University, New York, NY.

2. Activation of the HIV promoter by UVB radiation and PUVA treatment: Experimental data and practical implications (Polish Association for Radiation Research, Warsaw, Poland).

3. Dermatologic concerns related to HIV activation by UVB radiation and PUVA treatment (Department of Dermatology, School of Medicine, Warsaw, Poland).

4. Effects of ultraviolet and ionizing radiation on HIV (Institute of Biochemistry and Biophysics, Polish Academy of Sciences, Warsaw, Poland).

5. Optical photons and gene activation: An introduction to the symposium (American Society for Photobiology Annual Meeting, Marco Island, FL).

6. Argon-fluoride excimer laser ablation of cornea (SPIE, Biomedical Optics, Los Angeles, CA).

7. The role of exposure parameters in activation of the HIV promoter by ultraviolet radiation (Department of Radiobiology and Health Protection, Institute of Nuclear Chemistry and Engineering, Warsaw, Poland).

8. Photic maculapathy following extracapsular cataract surgery (The American Academy of Ophthalmology, Anaheim, CA).

9. Effects of UVB radiation and human immunodeficiency virus (Biologic Effects of Light Symposium, Light Symposium Foundation, Inc., Atlanta, GA).

10. Sociodemographic correlates of intraocular lens prevalence (American Public Health Association Meeting, Atlanta, GA).

11. Lasers in medicine (The Catholic University, Washington, DC).

12. Lasers in medicine (University of Maryland, Baltimore, MD).

ULTRASOUND PRODUCTS AND DEVICES

Reports and articles:

1. Lithotripsy pulse measurement errors due to nonideal hydrophone and amplifier frequency responses. IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control.

2. The relationship of maternal race and insurance status to prenatal ultrasound use in a national population (Maryland Medical Journal).

3. Ultrasound sources and human exposures (International Radiation Protection Association, UBC Press, Vancouver).

4. The acoustic field of near-surface source at intermediate distances: A simple result using matched asymptotic expansions (Journal of Acoustical Society of America).

5. Ultrasound safety standards (International Radiation Protection Association, UBC Press).

6. Relationship of maternal age and geographic region to prenatal ultrasound use: Results from the National Maternal and Infant Health Survey (Procedures of the American Statistical Association Meeting, Boston, MA).

7. Multimodality quantitative tissue characterization using ultrasound and magnetic resonance spectroscopy: Initial results (FDA Chapter, Sigma Xi Science Exposition, Rockville, MD).

8. Calculating heart valve regurgitant jet flows from Doppler ultrasound using conservation of momentum and a mathematical model of the jet. Procedures of the American Society of Echocardiology, Annual Scientific Meeting, Boston, MA).

9. Color Doppler ultrasound quantification of asymmetric valvular regurgitant jets in vitro (Procedures of the American Association of Medical Instrumentation Annual Meeting, Anaheim, CA).

10. ARMA spectral estimation in medical ultrasound and magnetic resonance spectroscopy (FDA Chapter, Sigma Xi Science Exposition, Rockville, MD).

Presentations:

1. Acoustic scattering theories applied to biological tissues (Meeting of the Acoustical Society of America, Salt Lake City, UT).

2. Ultrasound safety standards (Procedures of the International Radiation Protection Association, Nonionizing Radiation Committee 2nd International Nonionizing Radiation Workshop, Vancouver, BC).

3. A machine observer vs. the human observer in the evaluation of image quality (Procedures of the American Association of Physicists in Medicine Annual Meeting, Calgary, Canada).

4. The effects of image artifacts on detectability of low contrast targets (Procedures of the Tissue Characterization Conference, Arlington, VA).

5. 1988 National and Maternal Infant Health Survey: use of home apnea monitors. (American Public Health Association Meeting, Atlanta, GA).

6. Backscatter coefficient estimation in tissue characterization: Autoregressive methods vs. classical methods (International Symposium on Ultrasonic Imaging and Tissue Characterization, Washington, DC).

7. Application of autoregressive-moving average spectral estimation in medical ultrasound and magnetic resonance spectroscopy (National Institutes of Health, Bethesda, MD).

RESEARCH CONTRACTS AND INTERAGENCY AGREEMENTS

Supported by

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

CALENDAR YEAR 1992

1. **Bureau of Prisons, Department of Justice** (FDA 224-92-6003). CDRH provides radiological health and safety surveys, consultation, and educational activities in return for reimbursement of expenses.

2. **Bureau of Prisons, Department of Justice** (FDA 224-92-6004). CDRH provides a Radiological Health Personnel Monitoring Program to personnel occupationally exposed to ionizing radiation in return for reimbursement of expenses.

3. **Centers for Disease Control, National Institute for Occupational Safety and Health** (FDA 224-76-6015). CDRH provides a Radiological Health Personnel Monitoring Program to personnel occupationally exposed to ionizing radiation in return for reimbursement of expenses.

4. **Centers for Disease Control, National Institute for Occupational Safety and Health** (FDA 224-85-6010). Continued surveys of x-radiation-producing equipment and encouragement of radiation reduction principles and practices.

5. **Centers for Disease Control, National Institute for Occupational Safety and Health** (FDA 224-87-6008). NIOSH provides funds, which, when added to other funds, support the activities of CIRRPC through an Interagency Agreement (224-87-6006).

6. **Colorado State University** (223-92-6001). To provide funding for the analysis and publication of life span study of irradiated beagles.

7. **Contracts with State Health Departments.** To provide assistance to State and local radiological health programs in conducting compliance testing of diagnostic x-ray units and systems.

Alabama	223-92-4184	Missouri	223-92-4166
Arizona	223-92-4164	Nebraska	223-92-4185
Arkansas	223-92-4170	New Jersey	223-92-4168
California	223-92-4159	New York	223-92-4167
Colorado	223-92-4177	North Dakota	223-92-4158
Connecticut	223-92-4178	Ohio	223-92-4192
Florida	223-92-4153	Oklahoma	223-92-4165
Hawaii	223-92-4161	Pennsylvania	223-92-4157
Illinois	223-92-4174	Rhode Island	223-92-4176
Indiana	223-92-4175	South Carolina	223-92-4156
Iowa	223-92-4186	Texas	223-92-4163
Kansas	223-92-4187	Utah	223-92-4181
Kentucky	223-92-4154	Virginia	223-92-4160
Louisiana	223-92-4151	Washington	223-92-4162
Maine	223-92-4182	West Virginia	223-92-4172
Maryland	223-92-4169	Wisconsin	223-92-4152
Minnesota	223-92-4155		
Mississippi	223-92-4150		

8. **Centers for Disease Control** (FDA 224-90-6008). CDC provides funds, which, when added to FDA funds, support the activities of the Conference of Radiation Control Program Directors through a cooperative agreement (FD-U-00005-11).

9. **Department of Energy** (FDA 224-87-6006). CDRH provides policy and scientific support to the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC), which acts as a coordinator of Federal research efforts and radiation policy among agencies.

10. **Department of Energy** (FDA 224-88-6054) CDRH provides radiological health and safety surveys, consultation, and educational activities in return for reimbursement of its expenses.

11. **Department of Navy** (FDA 224-87-6018). Investigations of damage to the eye induced by exposure to RF radiation.

12. **Environmental Hygiene Agency, U.S. Army** (FDA 224-85-6011) CDRH provides radiological health and safety surveys, consultation, and educational activities in return for reimbursement of its expenses.

13. **Federal Emergency Management Agency** (FDA 224-81-6003). FEMA provides funds, which, when added to FDA funds, support the activities of the Conference of Radiation Control Program Directors through a cooperative agreement (FD-U-00005-11).

14. **Gillis W. Long Hansen's Disease Center, Health Resources Services Administration** (FDA 224-84-6003). CDRH provides radiological health and safety surveys, consultation, and educational activities in return for reimbursement of its expenses.

15. **Health Resources Services Administration** (FDA 224-87-6007). HRSA provides funds, which, when added to other funds, support the activities of CIRRPC through an Interagency Agreement with the Department of Energy (224-87-6006).

16. **Indian Health Service** (FDA 224-93-6001). CDRH provides a Radiological Health Personnel Monitoring Program to personnel occupationally exposed to ionizing radiation in return for reimbursement of expenses.

17. **Indian Health Service** (FDA 224-88-6062). CDRH provides radiological health and safety surveys, consultation, and educational activities in return for reimbursement of its expenses.

18. **Indian Health Service** (FDA 224-88-6063). IHS provides funds, which, when added to other funds, support the activities of CIRRPC through an Interagency Agreement with the Department of Energy (224-87-6006).

19. **Medical College of Ohio** (FDA 223-91-6007). To provide computer support necessary for the calculation of tissue doses from diagnostic x-ray examinations.

20. **National Aeronautics and Space Administration** (FDA 224-89-6005). CDRH provides a radiological health and safety evaluation, consultation, and educational activities in return for reimbursement of expenses.

21. **National Cancer Institute, NIH** (FDA 224-87-6009). NCI provides funds, which, when added to other funds, support the activities of CIRRPC through an Interagency Agreement with the Department of Energy (224-87-6006).

22. **National Center for Health Statistics** (FDA 224-88-6055) To provide a radiological safety survey and a radiation use evaluation for the medical x-ray systems used in mobile trailers for the National Health and Nutrition Examination Survey III.

23. **National Institute of Standards and Technology** (FDA 224-87-6017). To provide the primary laser instrumentation for in-house comparisons.

24. **National Institute of Standards and Technology** (FDA 224-76-6004). The work performed under this IAG provides FDA with state-of-the-art measurement capability in noncoherent optical radiations and ensures traceability to NIST of FDA measurements obtained for regulatory purposes under P.L. 90-602.

25. **National Institute of Standards and Technology** (FDA 224-91-6003). NIST will provide consultation and calibrations of instruments for measurements of electric and magnetic fields emitted by electric blankets and video display terminals.

26. **Nuclear Regulatory Commission** (FDA 224-76-6006). NRC provides funds, which, when added to FDA funds, support the activities of the Conference of Radiation Control Program Directors through a cooperative agreement (FD-U-00005-11).

27. **Office of Naval Research** (FDA 224-89-6007). CDRH will develop a laboratory research program that will investigate the effects of pulsed magnetic fields on cells utilizing molecular biology techniques. ONR will provide reimbursement for costs associated with the research effort.

28. **Office of Naval Research** (FDA 224-90-6007). To study mechanisms by which pulsed magnetic fields affect protein synthesis.

29. **Sachs Freeman Associates, Inc.** (FDA 223-89-6025). To perform the evaluation of the physical parameters associated with the performance of medical devices and electronic products.

30. **Sachs Freeman Associates, Inc.** (FDA 223-93-6001). To perform evaluation of the physical parameters associated with the performance of medical devices and electronic products.

31. **U.S. Army Harry Diamond Laboratories** (FDA 224-91-6004). To provide CDRH with use of an outdoor electromagnetic compatibility (EMC) test site and high power radiofrequency test equipment to evaluate apnea monitor radio-frequency susceptibility.

32. **U.S. Capitol Police** (FDA 224-76-6017). CDRH provides a Radiological Health Personnel Monitoring Program to personnel occupationally exposed to ionizing radiation in return for reimbursement of expenses.

33. **U.S. Coast Guard** (FDA 224-81-6004). CDRH provides a Radiological Health Personnel Monitoring Program to personnel occupationally exposed to ionizing radiation in return for reimbursement of expenses.

34. **Walter Reed Army Institute of Research** (FDA 224-91-6013). To study the effects of high power pulsed microwaves and ELF fields on human lymphocytes and other cells. CDRH shall conduct studies to identify the conditions of microwave exposure which produce kinetic effects on human lymphocytes.

35. **Walter Reed Army Institute of Research** (FDA 224-86-6008). To perform microwave instrument calibrations in return for reimbursement of expenses.

RESEARCH GRANTS
Supported by
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
CALENDAR YEAR 1992

1. **Assuring Radiation Protection (Conference of Radiation Control Program Directors, Inc.)** (FD 01201). The Conference, through conduct of technical meetings, workshops, and clinics, will develop program recommendations and suggestions in how to maintain as low as reasonably achievable radiation protection systems.

2. **Inner Vision, Inc.** ((FD 01500). The potential commercial applications from this Small Business Innovative Research (SBIR) Grant include the development of useful new techniques and contrast agents for diagnostic imaging.

3. **Princeton X-ray Laser Inc.** (FD 01498). Successful completion of this Small Business Innovative Research (SBIR) Grant will lead to an x-ray microscope which can be used for biological tissue microscopy in a routine manner, with reasonable cost, moderate bulk, and user convenience.

4. **Radiation Protection and Measurements (National Council on Radiation Protection and Measurements)** (FD 00750). To collect, analyze, develop, and disseminate information and recommendations on radiation protection and measurement.

5. **American College of Radiology** (FD 00787). To provide support for the annual fluoroscopy conference and to focus attention on fluoroscopy, and ways to improve it, and the radiation exposure concerns associated with newer equipment and procedures.

6. **American Society for Photobiology** (FD 00885). To provide funding for the annual photobiology conference.

7. **W/L Associates** (FD 00876). To provide funding for the electricity in biology and medicine conference.

LOG OF VISITS TO PUBLIC AGENCIES, MANUFACTURERS' PLANTS; CONSULTATIONS WITH INDUSTRY AND PUBLIC AGENCIES BY STAFF OF THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH CALENDAR YEAR 1992

Date	Agency, organization, or industry	Purpose
1/8	American National Standards Institute (ANSI)	Discuss standards
1/10	Philips	Discuss performance standards
1/13	Office of the Assistant Secretary for Health (OASH)	Discuss mammography legislation
1/16	Health Care Financing Administration (HCFA)	Discuss training
1/19	Annual Biomedical Optics Conference	Participate in conference
1/21	Medstone International Lithotripter System	Discuss PMA for IRIS
1/21	Toshiba	Discuss TV and import regulations
1/22	National Cancer Institute (NCI)	Prepare mammography meeting
1/23	American College of Radiology (ACR) Centers for Disease Control (CDC) Conference of Radiation Control Program Directors (CRCPD)	State inspector education cmtte. meeting
1/23	Nat. Inst. for Standards and Techn.	Discuss laser measurements
1/23-25	CRCPD	NEXT cmtte. meeting
1/26	Noninvasive Assessment of Visual Systems/Ophthalmic Conference	Participate in conference
1/26-30	CRCPD	Executive board meeting
1/27	Raymax	Discuss new devices

Date	Agency, organization, or industry	Purpose
1/28	ACR/CDC	Oversight cmtte. meeting
1/30	Funai	Discuss TV regulations and microwaves
2/3	NATS	Certification of imported TVs
2/3	House staff members	Discuss mammography technical issues
2/4	IBM	Discuss import policy for TVs
2/5-8	CRCPD	Mammography cmtte. meeting
2/7	International Electrotechnical Commission (IEC)	Discuss international standards
2/7-8	CRCPD	Suggested State Regulations (SSR) Part F cmtte. meeting
2/9-11	CRCPD	QA cmtte. meeting
2/10	IARC/WHO	Participate in UV radiation conference
2/20	New England State programs	NEXT training
2/22	SPIE	Present paper at medical imaging meeting
2/25	Piraeus International, Inc.	Discuss TV regulations
2/28	Innovative Defense Systems	Discuss standards for new product
3/1	Roper, Magic Chef	Compliance Inspection - TV products

Date	Agency, organization, or industry	Purpose
3/1-6	Summit Technology, Inc. Candela Laser Corp. Polaroid Corp. Bauer Associates, Inc. Azimuth Corp. Cynosure, Inc. MIT/Center for Advanced Visual Studies	Compliance inspection - laser products
3/2	Assistant Secretary for Planning and Evaluation (ASPE)	Discuss HCFA regulations
3/2-6	INEX Vision Systems Theater Manor F/X Lighting Western Technologies Automation Corp. Brevard Community College Laser Sight, Inc.	Compliance inspection - laser products
3/3	Siemens Medical Laboratory	Discuss 510(k) for x-ray product
3/6	Nuclear Regulatory Commission (NRC)	Discuss NRC/CRCPD relationships
3/6	Central State programs	NEXT training
3/6	AIUM	Participate in digital imaging meeting
3/9	Agency for Health Care Policy and Research (AHCPR)	Discuss panel on mammography
3/11	Samsung	Discuss microwave ovens
3/12	ACR/CDC/CRCPD	State inspector education cmtte. meeting
3/12	NE Bioengineering Conference	Participate and present paper on ELF effects

Date	Agency, organization, or industry	Purpose
3/18	International Standards Organiz.	Participate in ophthalmic standards 172 committee meeting
3/18	I-TEC (re: Hitachi)	Discuss regulations for TVs
3/21	American Academy of Otolaryngology	Present talk on FDA regulations re laser medical products
3/21	IEEE	Participate in SC62A EMC meeting
3/23	ACR/CDC	Phantom and clinical image assessment cmtte. meeting
3/27	HCFA	Discuss HCFA training for state inspectors
4/1-5	CRCPD	Mammography cmtte. meeting
4/5	Becton Dickinson	Discuss laser performance standard
4/7	NCI	Discuss NCI mammography survey
4/8	Kevex X-Ray: Army	Discuss dental x-ray device
4/8	Samsung	Discuss microwave oven
4/9	NEMA	Discuss diagnostic ultrasound reporting requirements
4/15	Bill Regnault	Discuss microwave oven weld problem
4/21	William B. Johnson Co.	Discuss TV product
4/22	AIUM/NEMA	Participate in ultrasound mtg.

Date	Agency, organization, or industry	Purpose
4/26 -5/3	Laserworks Photo Acoustic Technology CR Technology, Inc. Lumonics Marking Systems Los Angeles Laser Light YLS Productions	Compliance inspection - laser products
4/29	New Jersey radiation program	NEXT training
5/4	AIUM	Discuss diagnostic ultrasound regulations
5/4	Control CALC	X-ray calibration training
5/6	Gold Star	Discuss microwave oven compliance
5/6-8	CDC	Mammography QA training for CDC coop. agreement states
5/10	Conf. on Lasers and Electro-Optics	Present paper at conference
5/10	Purdue University	Present paper at workshop on magnetic resonance devices
5/12	Dynatronics	Discuss therapy ultrasound regulations
5/13	Acoustical Soc. of America	Participate and present paper at meeting
5/15-16	CRCPD	Mammography cmtte. meeting
5/15-21	CRCPD	Annual meeting
5/17	Amer. Nat. Conference on Rad. Control	Participate in electric blanket conference
5/17-23	Dynatronics Rich-Mar Dynawave	Compliance inspection - microwave ovens

Date	Agency, organization, or industry	Purpose
5/18	Hellige	Discuss TV regulations
5/20	Samsung	Discuss TV and microwave oven compliance
5/21-23	CRCPD	NEXT cmtte. meeting
5/27	Illinois Dept. of Nuclear Safety	Participate in inspection
6/1	HCFA	Discuss HCFA mammography survey training
6/4	ACR/CDC/CRCPD	State inspector education cmtte. meeting
6/4	Motorola	Discuss TV regulations
6/8	Alisum America The Daavlin Distribution Co. Quality Lamps, Inc. Lighting Supplies	Compliance inspection - laser/sunlamp products
6/10-11	Southeastern State programs	NEXT training
6/12	ACR/CDC	Phantom and clinical image assessment cmtte. meeting
6/12	IEEE	Participate in SC28 ELF meeting
6/14	1st World Congress on Electricity and Magnetism in Biology	Participate in ELF conference
6/15-19	B.C. Medical LTEE, Ltd. Raymax Medical Corp.	Compliance inspection - x-ray systems
6/18	Amer. Society for Photobiology Electromed International L. Keroack Co. Varian Canada	Participate and present paper at conference

Date	Agency, organization, or industry	Purpose
6/19	Amer. Society for Photobiology	Participate in phototherapy meeting
6/22	Sanyo	Discuss microwave oven compliance
6/24	Samsung	Discuss microwave oven weld procedures
6/24-25	National Council for Radiation Protection and Measurements (NCRP)	Mammography cmtte. meeting
6/25	NRC Environmental Protection Agency (EPA)	Discuss relations with States
6/27	ASA	Participate in radiation risks conference
7/6-9	HCFA	Provide mammography training
7/8	Inspectors from FL, LA, NC, SC, MS	Training of State inspectors re sunlamp product compliance issues
7/9	K & K Import Export Co.	Discuss import and TV compliance issues
7/9	EIA Sony Thomson Elec.	Discuss TV compliance issues
7/13	International Comm. on Radiation Units and Measurements	Present paper on medical imaging systems
7/15	Collaborative Rad. Health Laboratory	Discuss long-term radiation project
7/16	NEMA	Discuss proposed fluoroscopic compliance policy guide

Date	Agency, organization, or industry	Purpose
7/20	AHCPR	Mammography panel meeting
7/21	International Symposium on Optical and Applied Sciences	Participate in medical imaging conference
7/28	Nucletron (Kermath)	Discuss compliance issues
7/29	CRCPD	Annual meeting site selection
7/30	IEC	Discuss harmonization on standards for x-ray generators
8/7	ABB Sanitec	Discuss compliance issues for micro-wave heating products
8/7	HHS	Discuss HCFA final regulations
8/7	Senator Lieberman	Hearing on police radar
8/11	Samsung	Discuss microwave oven issues
8/16	AIUM/NEMA	Participate in ultrasound meeting
8/17	MWK Industries	Compliance inspection - laser products
8/17	Philips	Field test - x-ray product
8/17	Mitsubishi	Discuss x-ray product
8/18	Philips	Discuss results of field test

Date	Agency, organization, or industry	Purpose
8/18	Alcon Surgical	Compliance inspection - laser product
8/19	Advanced Interventional Systems	Compliance inspection - laser product
8/20	Laser Products Corporation	Compliance inspection - laser product
8/21	Disney Lane, Anaheim, CA	Compliance inspection - laser product
8/21	Senator Tom Harkin	Discuss trade complaint
8/22	American Association of Physicists in Medicine (AAPM)	Participate in meeting
8/22-28	AAPM	Annual meeting
8/23-9/14	Samsung, Korea Gold Star, Korea Daewoo, Korea Nisshin, Korea Matsushita, Japan Sharp, Japan	Compliance inspections - microwave oven and TV products
8/31	Applied Light Cynosure Cutting Edge General Scanning, TLSI Division Bio-Rad, Microscience Division	Compliance inspections - laser products
9/2-4	Cafe Quick	Compliance inspection - microwave oven product
9/3	Toshiba	Discuss TV regulations and microwave issues
9/3	Public Health Service (PHS)	Prepare mammography meeting
9/8	Congressional staffers	Discuss mammography technical issues

Date	Agency, organization, or industry	Purpose
9/10	Police Radar Manufacturers	Discuss radiation concerns
9/11	Show Laser	Compliance inspection - laser product
9/11	ACR/CDC	Phantom reviewer training cmtte. meeting
9/14-18	Zumback Electronics, Ltd. KLB Labs, Inc. Pegasus Productions Rarefied Media Productions Computed Anatomy, Inc. Science Faction	Compliance inspection - laser products
9/15	Samsung	Discuss microwave oven issues
9/15-16	State (LA, CO, MN, RI, ME) programs	Dental protocol training pilot study
9/16	CRCPD	Participate in workshop
9/16-17	ACR	Discuss fluoroscopy conference
9/17	Gold Star	Discuss TV regulations
9/17	Rockne Krebs	Compliance inspection - laser light show
9/18	Cate Fothergill General Scanning	Discuss new laser product
9/18	Square D	Compliance inspection - laser product
9/21-24	State x-ray personnel	Midwest regional training meeting
9/22-24	Chattanooga Corp. White Consolidated	Compliance inspection - microwave oven product

Date	Agency, organization, or industry	Purpose
9/23	President's Cancer Panel	Attend breast cancer panel meeting
9/23	St. Vincent's Hospital, NY	Participate in UV task force meeting
9/23	Soltron, Inc. (USA)	Discuss compliance issues
9/25	Texas Instruments	Discuss microwave regulations
9/27-29	Menu Master Amana	Compliance inspection - microwave products
10/1	CRCPD	Planning cmtte. meeting
10/1	Whirlpool	Discuss microwave import regulations
10/4	IEC	Participate in IEC 62B WG21 on magnetic resonance imaging
10/4-8	CRCPD	Executive board meeting
10/6	Soltron, Inc.	Discuss compliance issues
10/8	Ansell Corp.	Participate in inspection
10/9	Sharp	Discuss microwave oven issues
10/16-17	ACR	Attend fluoroscopy conference
10/17	AIUM	Participate in ultrasound standards meeting
10/19-23	HCFA	Provide mammography training

Date	Agency, organization, or industry	Purpose
10/23	President's Cancer Panel	Attend breast cancer panel meeting
10/24	Police Radar Manufacturers	Discuss police radar issues and update information
10/27	Potomac Photonic	Discuss new laser product
10/27	EMBS	Participate in EMC meeting
11/2	Light Sources, Inc.	Discuss compliance issues
11/2	Samsung	Discuss microwave oven issues
11/10	Sony Corp.	Discuss compliance issues
11/16	ACR/CDC/CRCPD	State inspector education cmtte. meeting
11/16-20	Texas Instruments/Turbo Chef Corp. Magic Chef	Compliance inspection - microwave products
11/18	HHS/Office of Inspector General	Discuss mammography issues
11/29-12/4	Radiological Society of North America	Present workshops, papers
11/30	Sony Corp.	Discuss compliance issues
12/1	Eve Fitzsimmons, Attorney Laser Concepts	Discuss laser light show issue
12/2	Toshiba	Discuss TV regulations

Date	Agency, organization, or industry	Purpose
12/6-10	Dynatronics Laser Corp. American Micro-Tech, Inc. J.G. Microwave Gerling Labs Thermo Energy Corp.	Compliance inspection - microwave products
12/7	Sony Corp.	Discuss compliance issues
12/9-10	CRCPD	Plan annual meeting
12/10-12	State (LA, CO, MN, RI, ME)	Discuss dental protocol pilot test programs
12/11	Toshiba	Discuss microwave magnetron issues
12/11	Laser Systems Development Corp.	Compliance inspection - laser light show
12/16	Potomac Photonics	Compliance inspection - laser product

21 CFR CHAPTER I, SUBCHAPTER J - REGULATIONS FOR THE ADMINISTRATION AND ENFORCEMENT OF THE RADIATION CONTROL FOR HEALTH AND SAFETY ACT OF 1968

The rules and regulations published under the authority of Public Law 90-602 are codified under Title 21, Chapter I, Subchapter J - Regulations for the Administration and Enforcement of the Radiation Control for Health and Safety Act of 1968. The following is a listing of each Section published under Subchapter J and the *Federal Register* publication where they appeared.

Part	Title	Date of publi-cation	Federal Register source
1000 - GENERAL			
	(Subpart A - General Provisions)		
1000.3	Definitions	1/22/70	35 F.R. 890
	(Subpart B - Statements of Policy and Interpretation)		
1000.15	Examples of electronic products subject to the Radiation Control for Health and Safety Act of 1968	1/22/70	35 F.R. 890
	(Subpart C - Radiation Protection Recommendations)		
1000.50	Recommendation for the use of specific area gonad shielding on patients during medical diagnostic x-ray procedures	7/23/76	41 F.R. 30327
1000.55	Recommendation for quality assurance programs in diagnostic radiology facilities	12/11/79	44 F.R. 71728
1000.60	Recommendation on administratively required dental x-ray examinations	6/17/80	45 F.R. 40976
1002 - RECORDS AND REPORTS			
	(Subpart A - General Provisions)		
1002.1	Applicability	5/28/70	35 F.R. 8363
	(amended)	9/18/71	36 F.R. 18646
	(amended)	11/19/73	36 F.R. 31828
1002.2	Definitions	5/28/70	35 F.R. 8363

Part	Title	Date of publi-cation	Federal Register source
	(Subpart A - General Provisions...Continued)		
1002.3	Records and reports on components	5/28/70	35 F.R. 8363
1002.4	Confidentiality of information	5/28/70	35 F.R. 8364
1002.7	Submission of data and reports	4/5/77	42 F.R. 18061
	(Subpart B - Required Manufacturers' Reports for Listed Electronic Products)		
1002.10	Initial reports	5/28/70	35 F.R. 8364
	(amended)	9/18/71	36 F.R. 18646
	(amended)	5/8/74	39 F.R. 16227
1002.11	Annual reports	5/28/70	35 F.R. 8364
1002.12	Reports of model changes	5/28/70	35 F.R. 8364
	(Subpart C - Manufacturers' Reports on Accidental Radiation Occurrences)		
1002.20	Reporting of accidental radiation occurrences	5/28/70	35 F.R. 8364
	(Subpart D - Manufacturers' Records)		
1002.30	Records to be maintained by manufacturers	5/28/70	35 F.R. 8364
1002.31	Preservation and inspection of records	5/28/70	35 F.R. 8364
	(Subpart E - Dealer and Distributor Records)		
1002.40	Records to be obtained by dealers and distributors	5/28/70	35 F.R. 8365
	(amended)	4/5/77	42 F.R. 18061
1002.41	Disposition of records obtained by dealers and distributors	5/28/70	35 F.R. 8365
	(amended)	4/5/77	42 F.R. 18061
1002.42	Confidentiality of records furnished by dealers and distributors	5/28/70	35 F.R. 8365
	(Subpart F - Exemptions from Records and Reports Requirements)		
1002.50	Special exemptions	5/28/70	35 F.R. 8365
1002.51	Exemptions for manufacturers of products intended for the U.S. Government	5/28/70	35 F.R. 8365

Part	Title	Date of publi-cation	Federal Register source
	(Subpart G - Codes for Reporting Listed Electronic Products)		
1002.61	List of specific product groups	5/28/70	35 F.R. 8365
	(amended)	3/5/75	40 F.R. 10174
	(amended)	7/2/76	41 F.R. 27316
	(amended)	11/9/79	44 F.R. 65352
	(amended)	7/15/80	45 F.R. 47612
1003 - NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY			
	(Subpart A - General Provisions)		
1003.1	Applicability	1/22/70	35 F.R. 891
1003.2	Defect in electronic product	1/22/70	35 F.R. 891
1003.5	Effect of regulations on other laws	1/22/70	35 F.R. 893
	(Subpart B - Discovery of Defect or Failure to Comply)		
1003.10	Discovery of defect or failure of compli-ance by manufacturer; notice requirements	1/22/70	35 F.R. 891
1003.11	Determination by Secretary that product fails to comply or has a defect	1/22/70	35 F.R. 892
	(Subpart C - Notification)		
1003.20	Notification by the manufacturer to the Secretary	1/22/70	35 F.R. 891
1003.21	Notification by the manufacturer to affected persons	1/22/70	35 F.R. 891
	(amended)	10/30/70	35 F.R. 16795
1003.22	Copies of communications sent to pur-chasers, dealers, or distributors	1/22/70	35 F.R. 891
	(Subpart D - Exemptions from Notification Requirements)		
1003.30	Application for exemption from notifica-tion requirements	1/22/70	35 F.R. 891
1003.31	Granting the exemption	1/22/70	35 F.R. 892

Part	Title	Date of publi-cation	Federal Register source
1004 - REPURCHASE, REPAIRS, OR REPLACEMENT OF ELECTRONIC PRODUCTS			
1004.1	Manufacturer's obligation to repair, replace or refund cost of electronic products	1/22/70	35 F.R. 892
1004.2	Plans for the repair of electronic products	1/22/70	35 F.R. 892
1004.3	Plans for the replacement of electronic products	1/22/70	35 F.R. 892
1004.4	Plans for refunding the cost of electronic products	1/22/70	35 F.R. 892
1004.6	Approval of plans	1/22/70	35 F.R. 893
1005 - IMPORTATION OF ELECTRONIC PRODUCTS			
	(Subpart A - General Provisions)		
1005.1	Applicability (amended)	1/22/70 12/12/80	35 F.R. 893 45 F.R. 81739
1005.2	Definitions	1/22/70	35 F.R. 893
1005.3	Importation of noncomplying goods prohibited	1/22/70	35 F.R. 893
	(Subpart B - Inspection and Testing)		
1005.10	Notice of sampling	1/22/70	35 F.R. 893
1005.11	Payment for samples	1/22/70	35 F.R. 893
	(Subpart C - Bonding and Compliance Procedures)		
1005.20	Hearing	1/22/70	35 F.R. 893
1005.21	Application for permission to bring product into compliance	1/22/70	35 F.R. 893
1005.22	Granting permission to bring product into compliance	1/22/70	35 F.R. 893

Part	Title	Date of publi-cation	Federal Register source
	(Subpart C - Bonding and Compliance Procedures...Continued)		
1005.23	Bonds	1/22/70	35 F.R. 894
1005.24	Costs of bringing product into compliance	1/22/70	35 F.R. 894
	(amended)	10/14/77	42 F.R. 55207
1005.25	Service of process on manufacturers	1/22/70	35 F.R. 894
	(amended)	4/16/71	36 F.R. 7215
1010 - PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL			
	(Subpart A - General Provisions)		
1010.1	Scope	12/25/69	34 F.R. 20274
	(amended)	7/31/75	40 F.R. 32252
1010.2	Certification	12/25/69	34 F.R. 20274
	(amended)	9/18/71	35 F.R. 18645
	(amended)	7/31/75	40 F.R. 32252
	(amended)	4/5/77	42 F.R. 18061
1010.3	Identification	12/25/69	34 F.R. 20274
	(amended)	9/18/71	36 F.R. 18645
	(amended)	5/8/74	39 F.R. 16227
	(amended)	7/31/75	40 F.R. 32252
	(amended)	4/5/77	42 F.R. 18061
1010.4	Variances	1/15/74	39 F.R. 13579
	(amended)	8/17/79	44 F.R. 48190
	(amended)	12/29/88	53 F.R. 52683
1010.5	Exemptions for products intended for United States Government use	9/2/77	42 F.R. 44228
	(Subpart B - Alternate Test Procedures)		
1010.13	Special test procedures	12/25/69	34 F.R. 20274
	(amended)	7/31/75	40 F.R. 32252
	(Subpart C - Exportation of Electronic Products)		
1010.20	Electronic products intended for export	12/25/69	34 F.R. 20274
	(amended)	7/31/75	40 F.R. 32252

Part	Title	Date of publi-cation	Federal Register source
1020 - PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS			
1020.10	Television receivers	12/25/69	34 F.R. 20274
	(amended)	12/10/71	36 F.R. 23523
1020.20	Cold-cathode gas discharge tubes	5/19/70	35 F.R. 7699
	(amended)	12/10/71	36 F.R. 23523
1020.30	Diagnostic x-ray systems and their major components	8/15/72	37 F.R. 16461
	(corrections)	9/13/72	37 F.R. 18537
	(corrections)	9/30/72	37 F.R. 20551
	(amendment)	6/12/73	38 F.R. 15444
	(amended)	10/7/74	39 F.R. 36005
	(amended)	2/25/77	42 F.R. 10983
	(amended)	9/2/77	42 F.R. 44230
	(amended)	5/22/79	44 F.R. 29653
	(amended)	8/24/79	44 F.R. 49667
	(amended)	11/30/79	44 F.R. 68822
	(amended)	4/25/80	45 F.R. 27927
	(amended)	8/31/84	49 F.R. 34698
1020.31	Radiographic equipment	8/15/72	37 F.R. 16461
	(amended)	10/7/74	39 F.R. 36008
	(amended)	2/25/77	42 F.R. 10983
	(amended)	5/22/79	44 F.R. 29653
	(amended)	4/25/80	45 F.R. 27927
	(amended)	11/5/82	47 F.R. 50211
	(amended)	8/31/84	49 F.R. 34698
1020.32	Fluoroscopic equipment	8/15/72	37 F.R. 16461
	(amended)	10/7/74	39 F.R. 36008
	(amended)	2/25/77	42 F.R. 10983
	(amended)	9/2/77	42 F.R. 44230
	(amended)	5/22/79	44 F.R. 29653
	(amended)	4/25/80	45 F.R. 27927
	(amended)	11/5/82	47 F.R. 50211
	(amended)	8/31/84	49 F.R. 34698
1020.33	Computed tomography (CT) equipment	8/31/84	49 F.R. 34698
	(amended)	7/31/91	56 F.R. 36098
1020.40	Cabinet x-ray systems	4/10/74	39 F.R. 12985

Part	Title	Date of publi-cation	Federal Register source
1030 - PERFORMANCE STANDARDS FOR MICROWAVE AND RADIOFREQUENCY EMITTING PRODUCTS			
1030.10	Microwave ovens	10/6/70	35 F.R. 15642
	(amended)	12/10/71	36 F.R. 23523
	(amended)	8/7/73	38 F.R. 21262
	(amended)	4/2/75	40 F.R. 14750
	(amended)	11/7/75	40 F.R. 52007
	(amended)	11/28/80	45 F.R. 79028
	(correction)	2/3/81	46 F.R. 10465
	(reconsideration and stay of effective date)	4/24/81	46 F.R. 23233
	(amended)	12/30/83	48 F.R. 57481
1040 - PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS			
1040.10	Laser products	7/31/75	40 F.R. 32252
	(amended)	11/28/78	43 F.R. 55387
	(amended)	8/20/85	50 F.R. 33682
1040.11	Specific purpose laser products	7/31/75	40 F.R. 32265
	(amended)	8/20/85	50 F.R. 33702
1040.20	Sunlamp products and ultraviolet lamps intended for use in sunlamp products	11/9/79	44 F.R. 65352
	(amended)	9/6/85	50 F.R. 36548
1040.30	High intensity mercury vapor discharge lamps	9/7/79	44 F.R. 52191
1050 - PERFORMANCE STANDARDS FOR SONIC, INFRASONIC, AND ULTRASONIC RADIATION-EMITTING PRODUCTS			
1050.10	Ultrasonic therapy products	2/17/78	43 F.R. 7166

MEMBERSHIP OF THE TECHNICAL ELECTRONIC PRODUCT RADIATION SAFETY STANDARDS COMMITTEE (TEPRSSC)

(As of December 31, 1992)

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THE WHITE HOUSE

WASHINGTON

July 15, 1993

File: HHS

Carol Roddy
Office of the Surgeon General
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Carol:

As a follow-up from our meeting last week, I have received information from OMB regarding the status of AFL funding in the reconciliation bill. In addition, OMB provided some basic information about past funding of projects in AFL that may be useful to you in the future.

Although no one knows what will be included in the final bill after conference, it looks as though there is a good possibility AFL funding will continue. I hope this information is helpful as you begin program planning.

I enjoyed visiting with you, Nancy Kirsch, and Evelyn Kappeler and hope you will stay in touch.

Sincerely,

Carol

Carol H. Rasco
Assistant to the President for
Domestic Policy

CHR:rk

MEMORANDUM FOR CAROL RASCO

FROM: Kathi Way

RE: funding for AFL

During our meeting last week with Carol Roddy, we committed to finding the status of AFL funding in the reconciliation process. Attached is a memo from Nancy Ann at OMB providing the information on AFL funding status and types of programs funded.

It appears the money for AFL is included in the Reconciliation Bill going into conference. Also, contrary to the information we were given at the meeting, it seems the funding is fairly flexible and could be used for a different type teen pregnancy prevention program.

I am attaching a "draft" memo you may want to finalize and forward to Carol Roddy with the information they requested.

Roz —
Don't understand there will be an attachment? If so, let's send letter to Roddy w/ the attachment.

--DRAFT--

Carol Roddy
Office of the Surgeon General
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

June 28, 1993

Dear Carol,

As a follow-up from our meeting last week, I have received information from OMB regarding the status of AFL funding in the reconciliation bill. In addition, OMB provided some basic information about past funding of projects in AFL that may be useful to you in the future.

Although no one knows what will be included in the final bill after conference, it looks as though there is a good possibility AFL funding will continue. I hope this information is helpful as you begin program planning.

I enjoyed visiting with you, Nancy Kirsch, and Evelyn Kappeler and hope you will stay in touch.

Sincerely,

Carol Rasco
Assistant to the President