In May 2004, the Center embarked on an effort to set a new direction for its Radiological Health Program. This direction will increase the Program's relevance to, and impact on, the most pressing current public health problems in the radiological health arena, and anticipate the evolution of medical radiation systems. A Radiological Health Program Core Group was commissioned to consider all previous radiation health program studies and make recommendations for the program's future.

The Core Group submitted its report, *The CDRH Radiological Health Program – Adapting to Current Public Health Needs* to me recently and I have accepted it April 19, 2005 for implementation. The program changes are focused in five areas: Standards, Monitoring, Education, Research and Program Management. The benefits that we expect are that the new Program will:

- Align CDRH efforts with current and evolving public health needs,
- Expand focus on patient and consumer experience
- Allow for a more targeted approach to regulation,
- Increase information dissemination and training, and
- Improve coordination across the radiological health community.

These changes to the Radiological Health Program will offer exciting opportunities for us to have the impact we want on current and evolving public health problems. Offices have already begun some implementation and you can expect to hear more specific information at the Division and Branch levels soon. Please read the report and prepare to join in effecting this new Radiological Health Program as we move forward.

Daniel G. Schultz, M.D.
Director, CDRH

The CDRH Radiological Health Program

- Adapting to Current Public Health Needs - 2005 - 2010

April 2005

The CDRH Radiological Health Program
- Adapting to Current Public Health Needs -
2005 - 2010

I. The Program

Introduction

This document describes how CDRH will fulfill its responsibilities established by the Electronic Product Radiation Control Provisions (EPRC) of the Food Drug and Cosmetic Act to address current public health needs related to electronic product radiation over the period 2005 to 2010. The program also includes responsibilities under the Mammography Quality Standards Act, and activities to assure the safety and effectiveness of medical devices that directly emit or influence the emission of electronic product radiation. First, the history and accomplishments of the radiological health program from its inception in 1960 are briefly described. This is followed by a description of the current situation regarding radiation-emitting electronic products. In view of the current situation, the Mission of the radiological health program is provided and a Vision for the future is stated. Finally, the key program elements for the CDRH radiological health program are described in general terms, along with a construct for program management. Many specific details regarding the implementation of the recommended program elements are not addressed and will be developed by the organizational elements charged to execute the plan. Plans for implementation are to be completed within the next year [see Appendix A] and full implementation is expected within five years. Resulting activities and projects are to be developed under the general guidance of this document and are to be based on the risks to public health posed by the issue to be addressed. The impact of the CDRH radiological health program will be influenced by available resources.

Methodology

In May 2004, a Radiological Health Program Core Group was commissioned by the Center Director to consider all previous radiation health program studies and make recommendations for the program's future. Group members were:

John McCrohan	Office of Communication, Education and Radiation
Tom Ohlhaber	Office of Communication, Education and Radiation
Tom Shope	Office of Science and Engineering Laboratories
Charles Finder	Office of Communication, Education and Radiation
Sean Boyd	Office of Communication, Education and Radiation
Nancy Wynne	Office of Communication, Education and Radiation
David Leslie, Consultant	Schmitt & Leslie, Inc.

Stakeholder information was important and the Core Group solicited input from the following groups throughout the process: FDA's Device Field Committee, Office of Regulatory Affairs, the Regional Radiological Health Representatives (RRHR), and various States. The Core Group met with professional groups such as the American College of Radiology and the Conference of Radiation Control Program Directors.

The Core Group obtained internal information via the creation of five radiation type working groups, the creation of a rad health e-room, and regularly updating senior staff.

Background

In 1960, the National Council on Radiation Protection and Measurement (NCRP) published a statement on television x-ray emission, which read in part: "During the past years, members of the NCRP have investigated the emission of x rays from television receivers. From a genetic point of view even sources of minute radiation are of significance if they affect a large number of people. X rays emitted by home television sets are, therefore, of interest because of the high percentage of the population involved." NCRP clarified and re-emphasized its statement in 1968 to address changes in technology and to encourage "judicious application" of governmental and other controls to ensure control of television x-ray emissions. Other products such as shoe store fluoroscopes were identified as a risk due to the ionizing radiation employed, and concerns were also raised regarding the newly-introduced microwave oven as a consumer product.

The Radiation Control for Health and Safety Act (RCHSA), enacted in 1968, charged the Secretary to implement a program to protect the public from the hazards of radiation from electronic products. Regulatory authorities granted by this legislation included establishment of reporting requirements for electronic product manufacturers, the authority to declare electronic products defective, the ability to recall defective or non-compliant products, the authority to establish requirements for importation of electronic products, and the authority to establish mandatory radiation safety performance standards for electronic products that emit radiation. The law also authorized numerous other activities necessary for identifying the risks from electronic product radiation and developing methods to reduce these risks.

The RCHSA was established in an atmosphere of significant concern regarding unintentional radiation production by consumer products, and in an environment where the potential for radiation exposure from these products had not been adequately addressed in the design and manufacture of many of these products. In addition, the bioeffects or risks presented by some types of product radiation or the level of exposure of the population to these radiations were not fully understood or appreciated. Assessment of some of the product designs of this period indicated that changes in the product designs would lead to significant improvements in the radiation safety performance of the products. Hence, the initial emphasis in the legislation was on product performance standards to assure that manufacturers produce products with enhanced radiation safety.

During the decade of the 1970s, the FDA established radiation safety performance standards for nine types of electronic products judged to provide the most significant public health risks that were amenable to control through product performance standards. Since this time, FDA has relied on these performance standards and the related product reports from manufacturers coupled with limited product testing to control potential hazards from x-ray and other electronic product emissions.

Program Accomplishments

Over the years, the CDRH radiological health program has enjoyed numerous successes and accomplishments.

Performance standards for nine types of products were promulgated and compliance programs tailored to assure compliance with these standards. In the 1960s and the early 1970s the only comprehensive evaluations of the population exposure to diagnostic medical x-ray procedures ever conducted in the United States were completed. In the early years of the program, training programs and other assistance were provided for State radiation control personnel, creating a foundation for many State radiation control programs. Educational activities were conducted to inform consumers and professionals regarding topics related to radiological health through publication of technical reports, scientific studies, public health advisories, guidance documents and recommendations.

Examination referral criteria were developed to reduce inappropriate x-ray examinations. Continual monitoring of x-ray exposure levels through the Nationwide Evaluation of X-ray Trends (NEXT) program and study of specific medical radiology procedures in the Breast Exposure Nation-wide Trends (BENT) and Dental Exposure Normalization Technique (DENT) programs led to nationwide radiation dose reduction.

Technical support was provided for State radiation measurement programs through equipment loans and calibration of instrumentation for x-ray and microwave radiation. Research was conducted into the bioeffects of radiation, radiation measurement methodology, performance testing of products and performance optimization. Post-market surveillance and enforcement of regulatory requirements was accomplished via inspections, voluntary problem reporting, and investigation of accidental radiation occurrences and consumer complaints.

The Current Situation

The advent of a global economy and of manufacturers that market products worldwide has also changed the landscape. Additionally, international, voluntary performance standards have been established for many products, in many cases based on FDA-developed mandatory standards, but often extending beyond radiation safety performance and into appropriate product use. Another significant change has been development of Quality Manufacturing Systems standards for product design and production that have been widely adopted and that have significantly improved the quality of products in many areas. Development has also occurred in terms of greater knowledge regarding quality assurance and quality control for radiation user facilities and in their appropriate application of radiation protection principles.

Significant changes in the technologies of radiation-emitting products, (e.g., digital x-ray imaging systems, cell (wireless) telephones, magnetic resonance imaging, and security screening systems) have also occurred.

Changes have also taken place in terms of radiological health concerns. Earlier, concerns were largely about the types of new electronic products being introduced; such as lasers, microwave

ovens, baggage inspection systems; and the potential for these products' emissions to cause adverse bioeffects. Currently, the concerns are less about product design or performance and are more about the manner in which the products are used.

Developments in modern communication, including the Internet, have created the potential to make radiation protection information widely available.

Significantly reduced resources for the CDRH radiological health program have resulted from competing responsibilities in the area of medical devices (with limited prospects for future increases).

These changes make it important for the CDRH to re-configure its radiological health program to best address the current issues of public health significance in the context of current limited resources.

To successfully address the current public health problems in the radiological health arena, the CDRH radiological health program must shift the focus of existing programs and priorities.

- The program must adapt to the changing standards environment and acknowledge the availability of national and international voluntary consensus standards.
- The program must maintain awareness of radiation-emitting products and act appropriately based on the risks posed by these products. Our awareness must also include today's problems related to product use and not only those problems related to equipment performance.
- The program must provide useful public health information and training to industry, users, the public, and regulators.
- The program must conduct research to address radiation risks, the results of which can be applied in a practical setting.
- And, the program must be managed as an integrated set of activities

Mission

The mission of the CDRH radiological health program is to protect the public from hazardous or unnecessary radiation emissions from electronic products. CDRH does this by addressing all types of radiation from medical and non-medical electronic products, through authorities granted by the EPRC, by the medical device amendments to the Food Drug and Cosmetic Act, and by the Mammography Quality Standards Act. CDRH also assists in the protection of the public during a radiological incident, whether intentional or accidental and supports the FDA radiation emergency response activities. The program works with a wide range of stakeholders including: States and other Federal agencies, professional organizations, academic institutions, users, manufacturers, and consumer groups.

Working together with these groups, CDRH must:

- Maintain awareness of new and existing radiation-emitting products, their manner of use, and their manufacturers,
- Understand relevant bioeffects and the potential risk to health resulting from radiation-emitting product emissions,

- Assess radiation emission levels from various products in various applications,
- Provide direction and guidance to the general public and users of radiation-emitting products to minimize unnecessary radiation exposure,
- Encourage manufacturers to comply with all applicable standards and where necessary pursue regulatory and enforcement action as appropriate for radiation-related public health problems.

Vision

We will reduce unnecessary or hazardous exposure and maintain doses as low as reasonably achievable. We will protect the public by maintaining awareness of developments in science and technology.

We will create a radiological health community of:

- Manufacturers designing products which are safe
- Users aware of how to appropriately employ electronic products and administer radiation,
- Workers able to understand radiation safety and protection principles
- Consumers aware of basic radiation risk and protection concepts and protected from hazardous or unnecessary emissions
- Regulators able to collect and disseminate appropriate information and take action on this information when necessary

CDRH will provide leadership and play a coordinating role to bring together the many and varied interest groups to effectively address the important public health issues related to radiological health.

Program Elements

The following sections address in detail each of the five major CDRH radiological health program elements. Note that the following existing radiological health activities are not addressed extensively in this document: device pre-market review, mammography quality, occupational radiation safety, and radiological emergency response. These programs will continue as currently configured for the present.

The five major CDRH radiological health program elements are:

- Standards
- Monitoring
- Education
- Research
- Program Management

Each of these elements is critical to a comprehensive radiological health program designed to protect the public from hazardous and unnecessary radiation, while ensuring appropriate use of radiation when necessary. Not all activities, products, and program elements are of equal priority within this construct. Monitoring and education are the higher priority program elements

to ensure we are collecting, sharing, and acting upon relevant information regarding products and the hazards related to those products and their use. Medical products are generally of higher priority than non-medical products because of the greater potential impact on the user or patient from appropriate or inappropriate use of a medical device. Products emitting ionizing radiation are generally of higher priority due to the well-known risks posed by exposure to ionizing radiation when compared to the low or unproven risks posed by products emitting low levels of non-ionizing radiation. Activities addressing high risk problems or providing greater impact on public health will be given priority within the CDRH radiological health program.

Standards

Radiation safety performance standards for electronic products are a key component of the Center's radiological health program. These standards establish a common, minimum level of safety-related performance for products subject to the standards. However, as described above, the development of international consensus standards for many radiation-emitting products, the existence of a global market for many of these products, and the rapid pace of technological development related to these products require that FDA revise its approach to performance standards.

The goals of the radiological health program related to product performance standards are:

- Increased use and reliance on international consensus standards
- Establishment of processes to assure conformance with appropriate international standards, as well as mandatory standards when international standards are not available or appropriate.
- Use of performance standards that are enforceable, appropriate for current equipment and that do not inhibit technological advances.

In order to achieve these goals, CDRH must take substantive steps toward use of voluntary consensus standards, while pursuing options to facilitate use and enforcement of such standards.

CDRH will increase participation in development of international and national consensus standards and will encourage U.S. stakeholders to do so as well. Efforts will be made to allow conformance to consensus standards by guidance, and to adopt such standards by reference where appropriate.

CDRH will base enforcement actions related to nonconformance to standards or defective products on risk. While all existing standards will remain, enforcement or standard revision activities related to each will follow the priorities established above.

CDRH will pursue legislative changes to allow adoption and enforcement of voluntary consensus standards. This action will enable CDRH to create an adaptable program and to more easily recognize the role voluntary consensus standards play in assuring product safety. This activity is not required to pursue additional changes in the area of standards described above.

Monitoring

Essential to an effective program, CDRH must be aware of products coming to market, performance of products upon introduction and performance of products subsequent to introduction. Knowledge regarding products comes from ODE reviewers of pre-market submissions and RCHSA product reports. Pre-market reviews of devices address radiation risks. Post-market knowledge comes from normal reporting and partners such as the States and professional groups such as the American College of Radiology (ACR). CDRH must also maintain awareness of the developing knowledge concerning the biological effects of different types of radiation and the magnitudes of public exposures to such radiations.

The goals of the monitoring programs are:

- An appropriate awareness of:
    - radiation emitting electronic products,
    - their manufacturers, and
    - the risk they represent

The following are the high priority activities and program directions that will be undertaken to achieve these goals. In all monitoring efforts, we will maximize use of electronic systems.

CDRH will require only essential manufacturer reporting and only essential information to describe radiation-emitting electronic products. CDRH will revise and where possible, reduce the number and types of reports submitted based on the risk posed by the product. CDRH will reduce the content of the reports to provide information necessary to identify the manufacturer, characterize the product, assess the emissions of the product, and ensure the product complies with applicable requirements.

CDRH will shift its emphasis from product testing to inspections of manufacturers. CDRH will ultimately conduct field and lab tests only on a "for cause" basis. CDRH will prioritize manufacturer inspections to improve coverage of the industry and assess the manufacturer's quality control testing programs, and quality systems under which radiation-emitting products are produced. The States will be encouraged to increase their focus on dose reduction, and to provide data on high risk devices. FDA intends to ultimately cease providing instrument calibration services, while maintaining measurement capability for all radiation types.

CDRH will emphasize assessment of use and exposures by harvesting data from outside sources rather than direct collection or measurement by FDA. This includes collection of adverse event data as well as dose and exposure data and will impact existing monitoring programs conducted by CDRH.

CDRH will establish access to radiation related pre-market applications and tracking systems for the radiological health program, to share information on new radiation-emitting medical devices. Radiological health will be included in orientation for ODE reviewers, and CDRH will develop consistent means to consider the radiation aspects of devices under review for pre-market approval or clearance.

Education

A strong monitoring program must be supported by an educational program capable of disseminating critical information and providing meaningful training to radiological health stakeholders. This is particularly true given that today's problems related to product use are the most significant public health problems in the arena of radiological health. CDRH has a responsibility to play a leadership role in educating those who use radiation-emitting products, as well as educating the public on whom such products are used. This responsibility can best be met by a combination of direct CDRH action and partnering throughout the radiological health community.

In the area of radiological health education CDRH's goals are:

- A public able to make informed choices about their own exposure to radiation-emitting products in the medical, occupational and home setting
- Users of radiation-emitting products able to minimize their own exposures and those of people they expose
- Manufacturers of radiation-emitting products able to understand their responsibilities and sensitive to radiation risk issues
- FDA and State radiation control programs that actively encourage and assist users in minimizing radiation exposure and risk.

CDRH will create a coordinated radiological health education program designed to both disseminate information and support training for the public, users, manufacturers, and regulators.

CDRH will invest in the use of the World Wide Web (web) as an educational tool and, in particular, develop and maintain a comprehensive, user-friendly radiological health web page. CDRH will also make appropriate use of other FDA media [e.g. *FDA Consumer*, *Patient Safety News*] to deliver critical radiological health messages.

CDRH will work with manufacturers, professional societies, and State organizations to assure that radiological health training is made available to those State and Federal personnel who can deliver critical radiological health messages to users and the public. CDRH will work to promote and enhance existing training opportunities while exploring new ways of providing training to, and through our various stakeholders.

Within these areas specific activities must be selected on the basis of risk and targeted to the audience best able to have a positive impact on risk.

Research

CDRH will undertake only those research activities that address high priority questions related to the radiological health responsibilities of FDA. This research will provide independent data for regulatory decision-making when such information is required and not elsewhere available. Research activities will be related to important public health issues or questions and can include activities, as described in the RCHSA, to assess the exposure to and bioeffects of electronic

product radiation, development of testing and measurement methodologies, and development of product evaluation and optimization techniques.

The goal of the radiological health research activities is:

- A research program supporting high priority radiological health activities, conducted in accordance with the highest scientific standards, and publicized in the scientific literature and other appropriate media.

In determining what research activities to undertake, the Office of Science and Engineering Laboratories will utilize the Center-wide Science Prioritization Process to obtain Center review of proposed radiological health related research activities. In this effort, the Science Prioritization Oversight Committee will include one or more representatives with specific expertise and knowledge of the radiological health program. Review of radiation-related research proposals will also include review by the active radiological health components of the Center.

Program Management

Center-wide program management is required to implement the program described in this document. While many of the concepts described will be implemented by CDRH alone, some changes will greatly impact both FDA Field Programs in the Office of Regulatory Affairs (ORA) and State radiation control programs. The ultimate success of our mission and attainment of our vision requires endorsement and active participation by ORA and the States. This effort will require active involvement by Center Senior Managers, in support of and promoting the activities outlined in this document.

The goal for management of the CDRH radiological health program is a clearly delineated management structure with well-defined roles and responsibilities for managers and staff. Appendix A defines roles and responsibilities throughout CDRH, with primary responsibility for the program assigned to the Office of Communication, Education, and Radiation Programs (OCER).

CDRH will establish accountability among Senior Managers and across Offices to address the strategic needs of the program. A standing Radiological Health Management Team will be established to coordinate radiological health activities and direct program resources and priorities within the Center.

Working-level relationships among managers and offices will be established to address day to day operational needs of the program. A standing Radiological Health Coordination Group will be established to monitor program activities, and *ad hoc* groups may be established to develop solutions to specific problems and issues.

OCER retains the responsibility to organize and staff the CDRH radiological health program.

II. Implementation Plan

The following activities will be performed immediately to begin execution of this plan and lay the foundation for the future CDRH Radiological Health program.

Standards Program Element						
Activity	**Office**	**05 Q4**	**06 Q1**	**06 Q2**	**06 Q3**	**06 Q4**
Work to increase CDRH participation on high-priority standards committees. Specifically, CDRH will increase active participation in medical ionizing standards groups involved with dose intensive equipment, such as CT, fluoroscopy, and radiation therapy devices.	OSEL					
Develop a plan for seeking legislative changes to facilitate the use of conformance to identified international standards as enforceable requirements for marketing in the U. S.	OCER					
Draft guidance allowing manufacturers to certify conformance to all or parts of selected voluntary consensus standards in lieu of certification to the U. S. standards. These standards shall include the IEC computed tomography (CT) and ultrasound therapy standards and may also include additional diagnostic x-ray standards. Following the guidance, OCER will initiate the process, including development of a timeline and concept document to adopt these standards by reference as mandatory FDA standards.	OCER					

Monitoring Program Element						
Activity	**Office**	**05 Q4**	**06 Q1**	**06 Q2**	**06 Q3**	**06 Q4**
Draft guidance exempting manufacturers of low-risk electronic products from submitting reports to CDRH. These exemptions include reports for Class I laser, television, and microwave oven products.	OCER					
Work with the Office of Regulatory Affairs (ORA) and State Radiation Control Program Directors to develop and implement a plan to phase out routine laboratory and field test measurements in favor of for-cause testing. Specifically, OCER will eliminate measurement of dose from MQSA inspections, and phase out routine lab and field testing for diagnostic and cabinet x-ray systems; and for laser, sunlamp, television, and microwave oven products. FY 2006 will be a transition year for development of the FY 2007 workplan, associated guidance, and program documentation; with implementation of new programs to occur in FY 2007.	OCER					
Develop a plan to phase out instrument calibration service while maintaining "for cause" measurement capabilities. The plan will address appropriate timeframes, and mitigate impact on ORA and State programs.	OSEL					
Ensure CDRH maintains instrumentation expertise and measurement capabilities for all radiation types.	OSEL					
Develop a plan to collect adverse event data for radiation-emitting electronic products and medical devices. The system will gather information from various groups inside and outside CDRH.	OCER OSB					
Develop a program to collect dose and exposure data from sources outside CDRH. The program will harvest facility collected data through organizations such as; the States, the American College of Radiology, the American Association of Physicists in Medicine, and from the MedSun network.	OCER					

Education Program Element						
Activity	**Office**	**05 Q4**	**06 Q1**	**06 Q2**	**06 Q3**	**06 Q4**
Redesign the radiological health portion of the CDRH web page. The redesign will address all aspects of radiological health as outlined in this plan, to include electronic products, MQSA, and medical devices.	OCER					
Create a coordinated education program for the radiological-health community. This will be a collaborative effort.	OCER					
Research Program Element						
Activity	**Office**	**05 Q4**	**06 Q1**	**06 Q2**	**06 Q3**	**06 Q4**
Integrate the radiological health program into its science prioritization process. Specifically, ensure radiological health research needs are identified and prioritized, and that radiological health program managers are actively involved in the process.	OSEL					
Develop a process to assess and validate on-going radiological health related research activities with input from other Center components.	OSEL					
Conduct research to address radiation risks, and population exposures, radiation measurement methods, and actions to minimize or optimize exposures to radiation.	OSEL					
Program Management Program Element						
Activity	**Office**	**05 Q4**	**06 Q1**	**06 Q2**	**06 Q3**	**06 Q4**
Develop and implement a communication strategy to promote the CDRH radiological health program and identify next steps with various CDRH stakeholders impacted by the changes described by this plan.	OCER					
Establish standing committees as described by Appendix I of this document, and schedule the first meeting of these committees.	OCER OCD					
Develop a resource reallocation plan to optimally configure radiological health program resources to implement the changes described by this plan.	OCER					
Update the Implementation Plan and establish annual objectives and milestones for each Program Element. Reestablish objectives and milestones annually after year one.	OCER					

Appendix A

Program Responsibilities

The consolidation of Office of Compliance (OC) radiological health functions into the Office of Communication, Education, and Radiation Programs (OCER) incorporated a large portion of the CDRH radiological health program under one organization. Major components of the radiological health program now exist within OCER and the Office of Science and Engineering Laboratories (OSEL). However, FTEs supporting radiological health functions remain scattered through other CDRH offices and FDA as a whole. Further, some overlap of authority remains among radiation emitting medical devices, requiring coordination of OCER, OSEL, OC, and/or the Office of Device Evaluation (ODE) efforts to address issues with these products. This document assigns responsibilities to CDRH offices, groups, and individuals to share information of mutual interest, develop program priorities, and address resource allocation. CDRH must clearly establish these expectations and hold individuals accountable to ensure the radiological health program is effectively managed.

Overview
Each office has specific roles and individuals responsible for coordinating and conducting various program activities. Activities may impact the direction of the CDRH radiological health program, focusing on radiation hazards, radiation protection, or radiation safety aspects of a radiation-emitting electronic product or medical device. Activities may impact day to day maintenance of the radiological health program, focusing on of information sharing and processing of assignments. Generally, OCER will manage the program with OCD and OSEL, to establish program priorities, develop the workplan, and allocate program resources. ODE, OC, and OSB have primarily a medical device focus and will provide support as needed to OCER.

Two standing groups will also be formed to coordinate program planning and facilitate information sharing. The CDRH Radiological Health Management Team serves as the management body for program planning and is composed of:

- CDRH Program Coordinator
- OCER Office Director
- Designated OCER program coordinator
- OSEL Office Director
- Designated OSEL program coordinator

The CDRH Radiological Health Coordination Group serves as the information collection and dissemination body for CDRH radiological health functions. The coordination group is composed of one representative (coordinator) from each office at the Division Director or above. Issue Management Groups will also be formed on an ad hoc basis to address emergent radiological health problems or questions, and will be composed of experts representative of appropriate CDRH offices and divisions.

CDRH Offices, Accountable Individuals, and Responsibilities

OCD (Center Director, CDRH Program Coordinator)

- Champion the CDRH radiological health program via Management Team
- Coordinate related office programs and track accomplishments
- Approve CDRH program priorities, develop workplan, and resource allocation
- Integrate Office efforts as required

OCER (Office Director, Office Deputy Director or designated OCER Program Coordinator)

- Conduct CDRH radiological health program
    - Act as exec sec of CDRH Radiological Health Management Team
- Coordinate CDRH inter-office activities
    - Form and Chair CDRH Radiological Health Coordination Group
- Direct and prioritize ORA radiological health activities via Device Field Committee, OC/Field Programs Branch, Risk Based Workplanning Process
- Coordinate outside stakeholder activities
- Manage CDRH radiological health mandatory standards activities
- Conduct CDRH radiological health training and education activities
- Manage CDRH radiological health compliance activities
- Conduct MQSA program
- Manage CDRH exposure monitoring activities
- Conduct CDRH radiation safety, radiation emergency preparedness and response activities
- Provide CDRH radiological health instrumentation calibration, evaluation, and development services for sensitometers and densitometers.
- Support ODE in pre-market review of radiation emitting medical devices
- Provide one representative (in addition to the Chair) to the Radiological Health Coordination Group (RCHG)

OSEL (Office Director, Office Deputy Director or designated OSEL Program Coordinator)

- Conduct CDRH radiological health research activities
- Integrate radiological health priorities into Science Review process
- Provide CDRH radiological health measurement instrument evaluation services.
- Manage CDRH radiological health voluntary standards activities
- Support ODE in pre-market review of radiation emitting medical devices
- Provide scientific expertise and consult in radiation health issues
- Provide one representative to the Radiological Health Coordination Group (RCHG)

ODE (Office-level designated point of contact)

- Conduct device premarket activities on radiation health devices or products
- Provide information on radiation-emitting medical devices under review

- Explore the impact of integrating radiation hazard assessment and radiation protection principles during premarket review
- Coordinate standards activities with OCER and OSE
- Provide one representative to the Radiological Health Coordination Group (RCHG)

OSB (Office-level designated point of contact)

- Provide medical device adverse event reporting
- Provide information on radiation-emitting medical devices under review
- Assist with accidental radiation occurrence reporting
- Facilitate data collection via existing reporting mechanisms
- Support OCER in data collection on radiation emitting devices or products
- Provide one representative to the Radiological Health Coordination Group (RCHG)

OC (Office-level designated point of contact)

- Conduct medical device compliance program
- Provide information on radiation-emitting medical devices or firms under review
- Assist OCER with recall actions
- Transmit OCER radiological health priorities to ORA via Device Field Committee, Risk Based Workplanning Process
- Provide one representative to the Radiological Health Coordination Group (RCHG)

CDRH Groups, Accountable Individuals, and Responsibilities

CDRH Radiological Health Management Team (RHMT) (Chair, CDRH Program Coordinator)

- Establish CDRH radiological health program priorities
- Recommend ORA radiological health program priorities
- Recommend CDRH radiological health resource allocation
- Manage radiological health issues requiring Center Director involvement or input

CDRH Radiological Health Coordination Group (RHCG) (Chair, OCER Program Coordinator)

Composed of one representative (coordinator) from each office at the Division Director or above with responsibility for monitoring office radiological health functions.

- Provide information on radiation-emitting medical devices with other offices
- Identify priority issues or resource needs to be addressed by radiological health management team
- Form Radiological Health Issue Management Groups as needed

Radiological Health Issue Management Groups

- Develop plan and initiate necessary actions to address problems or questions