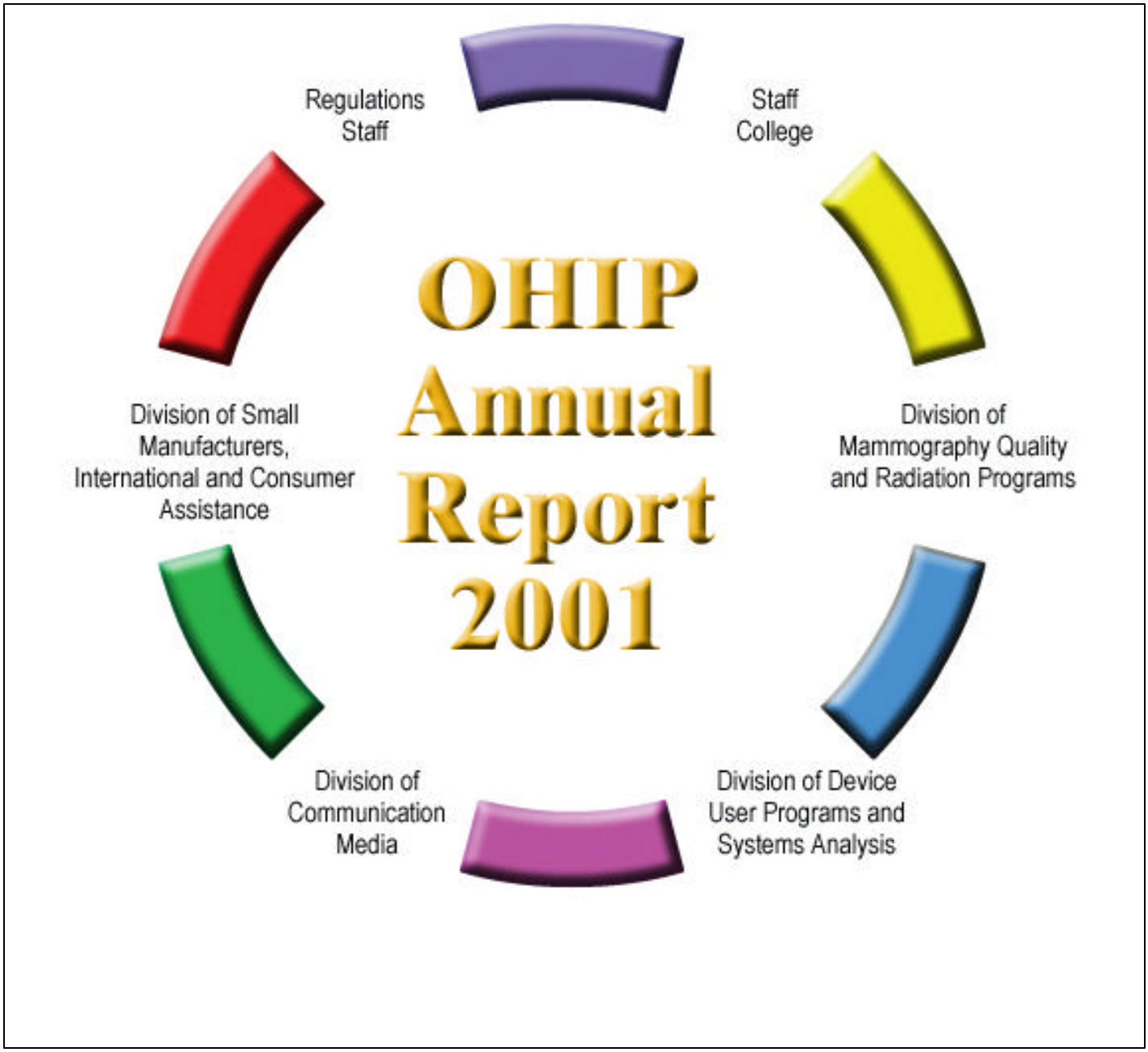


Office of Health and Industry Programs

Center for Devices and Radiological Health

Food and Drug Administration

Department of Health and Human Services

From the Director

The Office of Health and Industry Programs (OHIP) provides services that directly affect the lives of millions of Americans. As one of the Offices within the Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration (FDA), we specialize in program-based communication, education, radiological health, mammography quality, and reduction of use error.

Outreach and education are in all aspects of OHIP's work. This is evident whether we are producing teleconferences, training CDRH staff, working with patients/consumers/health professionals, assuring high quality mammography, conducting radiation safety surveys, answering device industry questions, or writing regulations. As we carry out our programs, we emphasize collaboration both within and outside CDRH. Coalition building, public participation, and information exchange allow us to obtain input from all relevant and concerned sources and to leverage and multiply our resources to protect the public health.

Because of the breadth of our role within CDRH, OHIP serves a wide variety of customers, including:

- domestic and foreign manufacturers of medical devices and radiation-emitting electronic products;
- domestic and foreign government agencies engaged in public health and the regulation of medical devices;
- healthcare professionals and healthcare facilities, as well as the organizations that represent them;
- consumers and patients, including all women in the United States who receive mammograms; and
- CDRH staff who benefit from training and professional development activities.

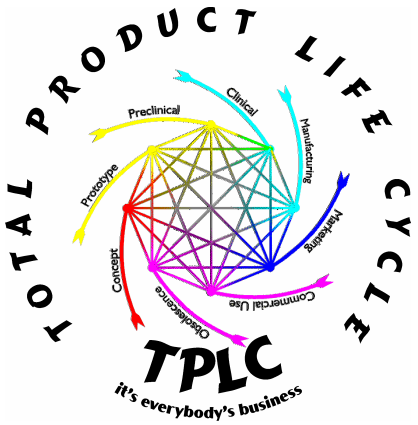
We think that each of our customers will find programs of interest in our FY2001 Annual Report. We think our programs and our accomplishments reflect changes and improvements implemented as a result of OHIP strategic planning. In 1997, OHIP implemented an ambitious five-year strategic plan.

As a first step, we received specific feedback from our customers in all of our program areas. While our customers were generally satisfied with our services, we received many suggestions and comments for changes and improvements. In response to this feedback, OHIP developed four specific goals:

- to use collaboration and cooperation whenever appropriate to improve the quality and effectiveness of CDRH programs, to enhance the satisfaction of our customers, and to use CDRH resources most effectively;
- to consistently produce high quality and timely products and services;
- to identify, develop, implement and evaluate innovative and cost-effective approaches to accomplish vital new OHIP, CDRH and FDA initiatives; and
- to maximize OHIP's use and development of human and fiscal resources.

OHIP is now in the fifth and final year of our strategic planning process. As reflected in our Annual Report, OHIP's four goals are now tightly integrated into our programs and daily operations. During the coming year, we will continue to update and refine our strategic plan and concentrate our efforts on the CDRH strategic plan. As the plan is implemented, it will provide broad principles and goals that CDRH will commit itself to over the next several years.

Our work is guided by the CDRH mission and vision. Mission: ***to promote and protect the health of the public by ensuring the safety and effectiveness of medical devices and the safety of radiological products***. Vision: ***"Ensuring the health of the public throughout the <u>Total Product Life Cycle</u>."***



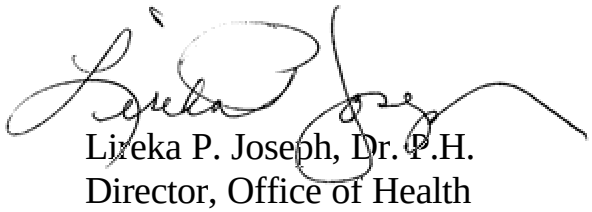
During this past year, OHIP has worked toward the CDRH mission, vision and strategic goals. These goals include the following:

- to apply the **total product life cycle** model across all CDRH activities;
- to serve as a **magnet for excellence** in attracting and retaining a diverse workforce who want to help us fulfill our public health mission;
- to **manage knowledge** in support of the total product life cycle model; and
- **measure** and **communicate** our public health impact.

OHIP continues to work with all of CDRH to implement these strategic goals. We co-lead the magnet for excellence goal group and we lead outreach efforts inherent in all four goal groups. Together with you, our stakeholders, we are preparing a roadmap for the future of OHIP and for CDRH. For more detailed information on the CDRH strategic plan, visit the CDRH website at http://www.fda.gov/cdrh/ocd/strategic.html.

We welcome your review of OHIP's FY2001 Annual Report and your comments on our programs and future directions.

Sincerely,



Lireka P. Joseph, Dr. P.H.
Director, Office of Health
and Industry Programs, CDRH

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USER EDUCATION

CDRH regulates medical devices and radiation-emitting electronic products that touch upon every phase of our lives. Medical devices are an integral part of our healthcare system. Radiation-emitting electronic products include cell phones, microwave ovens, television sets, video display terminals and many other products that are routinely encountered in every day life.

The users of medical devices and radiation-emitting electronic products include patients and consumers, as well as caregivers and healthcare professionals. These users all need accurate and up-to-date information. Providing this information is an important part of CDRH's public health mission. Within CDRH, OHIP plays a key role in user education. We respond to inquiries from individual consumers and patients, and work together with other CDRH Offices and outside groups to provide information on important medical device and healthcare issues. We accomplish this through a wide variety of outreach methods including the internet, public meetings, and print media.

Goals

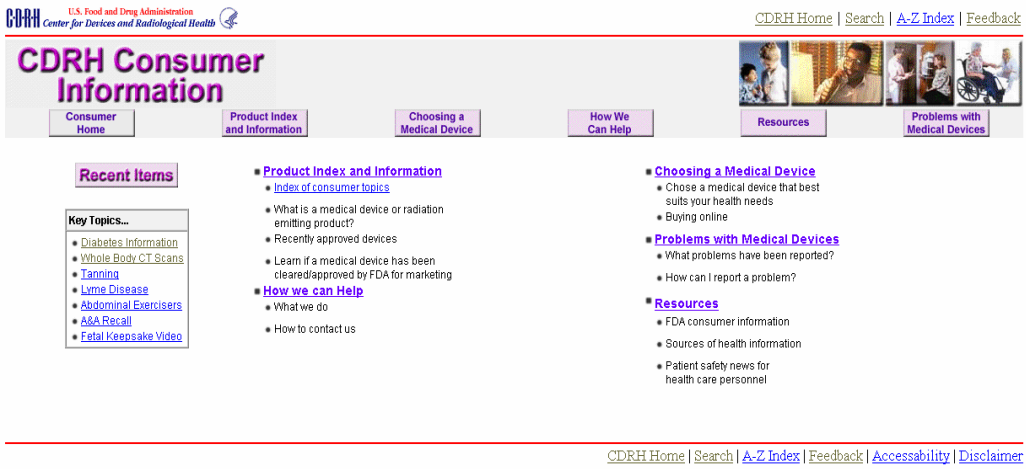
1. To prepare and disseminate accurate information for consumers, patients and others who use medical devices and radiation-emitting electronic products.
2. To respond to consumer and patient inquiries and concerns in a timely and caring manner.

Consumer Assistance

OHIP is responsible for providing consumers with information needed to make informed decisions on the use of medical devices and radiation-emitting electronic products. We accomplish this by answering consumer inquiries and by developing information that addresses specific, high interest issues. For example, in FY 2001 OHIP represented CDRH at a Regional Risk Management Pilot Workshop on "Safe Medical Treatments-Everyone Has a Role." This workshop was held in conjunction with FDA's New Jersey District and the Center for Drug Evaluation and Research (CDER). It provided a forum for consumers to discuss involvement in their own medical care.

Consumer Webpage

Our "Consumer Page" on the CDRH website is one of our most important tools for communicating with consumers and providing consumer-related information.



Click here to visit the CDRH Consumer Information Page

The CDRH consumer page includes the following:

- information on the products that CDRH regulates;
- explanation of the process for obtaining FDA clearance to market a medical device;
- information on newly approved medical devices;
- other consumer literature as well as links to other health related government websites; and
- an easy way to automatically e-mail your questions to OHIP.

Consumer Inquiries

During FY2001, our consumer specialists responded to approximately:

- 3,600 telephone inquiries;
- 3,000 e-mails;
- 500 letters and faxes; and
- 4,180 requests for information packages on various medical device issues.

Breast Implant Information

We collaborated with other CDRH Offices in preparing and distributing a brochure entitled, "**Breast Implant Risks - November 2000**." The brochure alerts the prospective breast implant recipient of the known consequences of breast implant surgery. It describes fifteen known consequences and presents pictures of three frequent adverse outcomes. Both the brochure on risks as well as the FDA handbook entitled, "**Breast Implants - An Information Update 2000**" can be downloaded from the consumer page on the CDRH website.

http://www.fda.gov/cdrh/breastimplants/indexbip.html

Internet Sales

A growing number of medical devices are available for sale on the Internet. This year, we posted three articles about the sale of medical devices on the FDA webpage, **"Buying Medicines and Medical Products Online."** These articles include a general article providing advice for buying medical devices on-line and an article devoted to the on-line sale of in-vitro diagnostic products. The third article is a Question & Answer piece about buying contact lenses on the Internet, by phone or by mail. The article stresses the importance of having a current, correct prescription and receiving regular check-ups.

http://www.fda.gov/oc/buyonline

New Device Approvals

During FY 2001, we collaborated with other CDRH Offices to maintain a webpage for New Device Approvals. This page includes brief, plain language information on the most recently approved medical devices. OHIP provided plain language review of 55 one-page summaries for this webpage, which is primarily intended for consumers. The page links to other sources of consumer information, the Premarket Approval (PMA) database, and the patient labeling for these devices.

http://www.fda.gov/cdrh/mda

Medical Device Recall Webpage

OHIP and the Office of Compliance prepared a consumer-friendly version of medical device recalls for the CDRH website. This page provides brief information about CDRH recalls and includes Class I medical device recalls (those with the highest level of risk) and some Class II and III recalls with general public interest. At present, the page contains products recalled during calendar year 2001. As CDRH classifies new recalls, OHIP will post them to this webpage for public access.

http://www.fda.gov/cdrh/recalls

Whole-Body Computed Tomography (CT) Screening Webpage

OHIP led a CDRH working group in developing a webpage on whole-body CT scanning. Some medical imaging facilities are promoting this new use of CT. It is marketed to healthy individuals who have no symptoms or suspicion of disease as a preventive or proactive health-care measure. However, the effectiveness of whole-body CT screening has not been demonstrated scientifically. This webpage is intended to provide information regarding the appropriateness of whole-body CT screening to individuals considering such a procedure. Geared toward consumers and health professionals, it includes:

http://www.fda.gov/cdrh/ct/

- information on the use of whole-body CT screening;
- explanation of what CT is and how it works;
- information on radiation risk;
- brief description on radiation quantities used to indicate patient dose;
- brief explanation on the regulatory status of CT; and
- extensive resource list and links to other CT related sites.

Reuse

The reprocessing of single-use devices (SUDs) by hospitals and third parties continues to be an important public health issue. During FY2001, CDRH conducted an extensive outreach program to educate hospital SUD reprocessors about their regulatory responsibilities. The outreach program included:

- a brochure summarizing FDA's regulatory requirements – the brochure was sent to 6,000 hospitals in the U.S.;
- a consumer article released through the North American Precis Syndicate, Inc. (NAPS) to over 10,000 newspapers;
- four guidance documents (premarket clearance, labeling, medical device reporting, and frequently-asked-questions) to further clarify the regulatory requirements;
- featured articles in the *User Facility Reporting Bulletin* and *FDA Consumer Magazine;* one entire issue of the *Bulletin* was devoted exclusively to SUDs reuse;
- an extensive reuse website that includes the many important polices, letters, and documents about SUDs reuse;
- a list-serve subscription to alert readers about important issues and policies;
- a reuse speaker's kit distributed to all FDA Field Personnel/Public Affairs Specialists to use as a tool in their educational efforts with hospitals; and
- two medical Device Reuse Workshops – Orlando, FL on May 10-11 and Phoenix, AZ on May 30-31.

http://www.fda.gov/fdac/features/2000/500_reuse.html

Diabetes Webpage

In August 2001, OHIP began leading an agency-wide effort to develop a web page on diabetes. This project supports the HHS effort to address racial and ethnic disparities in health care, as diabetes disproportionately affects many minority populations. The Diabetes Webpage is the Center's first disease-specific webpage. The page is expected to bring together information about all FDA regulated medical products used in the diagnosis and treatment of diabetes. The goal of the webpage is to provide the unique information the Agency has about the many FDA

http://www.fda.gov/diabete

regulated products used by patients with diabetes and their caregivers. We hope the outcome will be healthier lives for the rapidly growing number of Americans that are diagnosed with diabetes. We collaborated with FDA's Office of Women's Health and the American Diabetes Association. Links to other government and non-profit organizations will be included to augment FDA's information. The page will be a working document and we will continue to add information targeted to populations which are disproportionately affected by diabetes.

Hospital Bed Safety

OHIP led a multidisciplinary group to address the safety issues of hospital beds and patients vulnerable to entrapment. The group included representatives from the US and Canadian governments, national health care organizations, manufacturers of hospital beds, patient advocate groups and medical researchers. This group is working to reduce the number of patient deaths and injuries from hospital bed entrapments in all care settings, including hospitals, nursing homes, and private homes. The CDRH-led Hospital Bed Safety Workgroup developed hospital bed guidance that defines the recommended limits for gaps or openings in hospital bed rails. The guidance also provides procedures for clinicians to assess whether a bed meets the recommended limits. In addition, the workgroup has developed an assessment tool for facilities to determine if an opening falls outside the recommended limits. Other projects nearly completed include a Correction Action Guide to assist facilities in modifying the beds determined to be at risk for entrapment, and Clinical Recommendations for caregivers to use when assessing their patients' need and use of bed rails. As a result of these efforts, CDRH developed a website to report the work of the Hospital Bed Safety Workgroup, increase awareness of the entrapment issue and educate the public on the problems related to this issue.

http://www.fda.gov/cdrh/beds/index.html

User Facility Reporting Bulletin

In the winter of 2001, we prepared the 37th issue of the **User Facility Reporting Bulletin**. First issued in 1992, the Bulletin is published quarterly. The Bulletin provides user facilities with:

- important information on preventing adverse events with medical devices;
- directions for reporting adverse events to the FDA; and
- feedback on reported problems.

When first published, the Bulletin had a printed circulation of over 75,000. In order to make more efficient use of resources and technology, the Bulletin is now available solely on our website.

http://www.fda.gov/cdrh/fusenews.html

MANUFACTURER SUPPORT

Goals

1. To provide technical assistance in meeting FDA requirements for medical devices and radiation-emitting electronic products.
2. To develop informational materials and to provide accessible, efficient channels for distributing information to manufacturers.
3. To respond to manufacturer inquiries in a comprehensive and timely manner.

Safe and effective medical devices are crucial to our healthcare system. FDA regulated medical devices include over 100,000 different types of products in more than 1,700 product categories. They range from simple everyday articles such as thermometers, tongue depressors and heating pads to more complex devices such as pacemakers, defibrillators and kidney dialysis machines. Overall, medical devices are becoming increasingly complex. Improved, life-saving devices are using innovations such as microprocessor control, artificial intelligence, miniaturization and remote operation.

Members of the medical device industry are just as diverse as the products that they manufacture:

- there are approximately 14,000 manufacturers of medical devices worldwide;
- more than 70 percent of medical device manufacturers are small enterprises with fewer than 50 employees; and,
- more than 40 percent of device firms manufacture abroad.

This complexity and diversity present a challenge to FDA as a regulatory and public health agency. They also present a challenge to the medical device manufacturers who must comply with FDA regulations. Better communication between FDA and manufacturers opens the door for improved understanding, provides for a better working relationship, and results in quicker access to devices by the public.

Small Business Activities

FDA has instituted a number of activities aimed specifically at increasing communication with the small business community. In addition to Small Business Assistance Programs that reside in each of the five FDA regional offices, each Center in FDA has a special small business unit.

http://www.fda.gov/ora/fed_state/small_business/sb_guide/intro.html

Within CDRH, OHIP serves as a focus for small business concerns. We strive to:

- identify ways in which FDA requirements can protect and promote the public health without being unfair or unduly burdensome to small business;
- encourage greater participation by small firms in the regulatory process itself, especially at the early stage when comments are sought on proposals that impact on the device industry; and
- educate CDRH staff on the needs of medical device manufacturers and potential problems they face in meeting FDA's regulatory requirements.

General Information Package

We provide 2,000 **General Information Packages** each year to new companies entering the device industry. To obtain a copy of this package, fax your request to **301-443-8818**.

The specific types of assistance that we provide to small businesses are similar to those that we provide to other domestic and foreign manufacturers of medical devices. These are discussed in more detail in the following pages.

Assisting Manufacturers

The most fundamental assistance that OHIP provides to manufacturers involves our response to individual inquiries, questions and concerns. We do this through several mechanisms, including:

- **Automated Call Center:** We maintain an automated call center to provide superior customer service. The call center advises the caller of their place in the queue and the average wait time. While in queue the caller hears messages about issues of interest to CDRH stakeholders. The caller can stay on the line or select another option, such as leaving a voice mail or making another choice from the main menu. This system is available 24 hours per day (see inset) and offers manufacturers the opportunity to speak directly to a device specialist who can answer their questions and direct them to the needed information. We typically receive and respond to an average of 35,000 telephone inquiries per year.

OHIP/CDRH

Division of Small Manufacturers Assistance

800-638-2041
301-443-6597
Automated Assistance available 24/7

Device Specialists
available M-F
8 a.m. to 5 p.m., EST

- **E-mail:** All of our webpages for manufacturers, and many other CDRH webpages, include access to our e-mail account – dsmica@cdrh.fda.gov. We respond to over **12,000 e-mail inquiries** per year. In addition, we receive approximately **2,200 written/fax inquiries** per year.

- **510(k) Status Program:** We assist manufacturers in determining the status of their pending premarket notification applications (510(k)). Requests for this service have decreased dramatically as CDRH eliminated the backlog of 510(k) applications. However, we still receive approximately 500 requests each year. The link to the left provides instructions on this program.

http://www.fda.gov/cdrh/dsma/510_stat.html

- **Broadcast Fax:** OHIP uses an automated fax system to rapidly distribute important CDRH information to our industry. We also distribute information to stakeholder organizations such as AdvaMed, RAPS, and FDLI who then provide a multiplier effect. During FY 2001, we distributed information on several topics, including upcoming workshops/conferences on Reuse of single use devices, HACCP, and the Global Harmonization Study Group 1 "Medical Device Classification" document.

- **Facts on Demand (FOD):** FOD is an automated answering system that allows you to access over 700 CDRH publications through your FAX machine. Almost all of the documents available by FOD are more easily available from the CDRH webpage. However, stakeholders still use FOD to obtain publications. In FY 2001, approximately 8,000 publications were obtained through this system. We continue to maintain this system by adding new guidance documents as they become available and removing the outdated documents.

CDRH
Facts on Demand

800-899-0381
301-827-0111

Catalog available on your fax machine after dialing the above number and:

- Press "1" to enter the system and obtain documents; or
- Press "2" to obtain instructions for using the system
- Press "INDX" (4639 on the keypad) to request an index for all documents.

The index can also be found at http://www.fda.gov/cdrh/dsma/fod.html.

- **Publication Distribution:** OHIP is a warehouse to over 1,000 FDA publications. Although approximately 80 percent are accessible electronically, our stakeholders still request hardcopies. In FY 2001, approximately 50,000 publications were distributed either by hardcopy or on diskette.

- **Manufacturers Assistance Webpage:** Our webpage is a comprehensive source of information for manufacturers. It provides easy access to the services we offer, issues of interest to manufacturers and copies of manuals and guidance documents. The site received 54,600 hits in FY 2001. In response to the large volume of this type of work performed by the division, OHIP officially renamed the Division of Small Manufacturers Assistance (DSMA) to the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) in July 2001 in an effort to more accurately describe the services we provide.

http://www.fda.gov/cdrh/dsma/dsmamain.html

Device Advice Webpage

http://www.fda.gov/cdrh/devadvice

Early on, we recognized both the advantages and the limitations of providing extensive information for manufacturers on our website. Often, just having "access" to all of our information doesn't make it easy to find the particular document or information that you are seeking. Further, while you might find a particular document, you might not be aware of related documents or information. To address these concerns, OHIP designed and implemented ***Device Advice***. This webpage has been a successful source of information and received 59,326 hits in FY 2001. With ***Device Advice***, you can determine:

- whether the product you want to market is
  - a radiation-emitting electronic product,
  - a medical device,
  - both a radiation-emitting electronic product and a medical device, or,
  - neither a radiation-emitting electronic product nor a medical device;
- the FDA reporting requirements and standards that may apply for a radiation-emitting electronic product;
- the classification of the product, if it is a medical device;
- the process for obtaining appropriate clearance to market the medical device; and
- information on any other requirements that might apply to your product.

> ***Device Advice*** is an **interactive system** that will guide you through the process of obtaining FDA clearance to market a medical device and to meet FDA requirements for radiation-emitting electronic products.

Device Advice can also be used as a resource linking to regulatory manuals, precedence correspondence, import/export requirements, CDRH databases and a complete index of the Code of Federal Regulations (Title 21 CFR).

OHIP device specialists programmed the first "version" of Device Advice in 1998. Since then, it has consistently been one of the ten most used CDRH webpages. In FY 2001, we modified topics to include the following information:

- IDE Supplements
- PMA Supplements and Amendments Section
- Import for Export
- CLIA Section within the 510(k) Section
- CBER 510(k) Reviews
- Corrections and Removals
- Sunglass Guidance
- Quality Systems
- International Organization for Standardization (ISO)

Workshops/Presentations

http://www.fda.gov/cdrh/dsma/workshop.html

During FY 2001, OHIP partnered with other organizations in presenting 12 workshops for manufacturers. The workshops allow us to meet with manufacturers face to face and to exchange information on topics such as regulatory requirements, Quality Systems, and import and export requirements. Our partners in presenting the workshops included the following organizations:

- Association for the Advancement of Medical Instrumentation (AAMI)
- Canon Communications
- Regulatory Affairs Professional Society (RAPS)
- Association of Medical Diagnostic Manufacturers (AMDM)
- AdvaMed
- Medical Alley
- American Society for Quality (ASQ)

Developing Guidance for Manufacturers

In addition to facilitating manufacturers' access to all CDRH guidance documents, OHIP staff also prepare guidance documents in their areas of expertise. These guidance documents may be prepared entirely within OHIP or in collaboration with staff from other CDRH Offices. Recent guidance documents include:

- Draft Guidance for Staff, Industry and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997. February 2, 2001.
- Sunglasses, Spectacle Frames, Spectacle Lens and Magnifying Spectacles. June 19, 2001.

Accredited Persons Program

http://www.fda.gov/cdrh/thirdparty

OHIP administers the Accredited Persons Program for CDRH. This program allows manufacturers to use "Third Parties" to conduct initial review of premarket notification (510(k)) submissions for low (Class I) to moderate (Class II) risk devices. The Accredited Persons (AP's) are individuals or organizations who meet qualifications and requirements established by FDA and who are then "accredited" to do these reviews. This program has the potential to provide manufacturers with more rapid clearance decisions for their devices. At the same time, FDA would be able to focus its resources on higher risk devices.

Both FDA and the medical device industry have been disappointed that the Accredited Persons Program has not been used more. Therefore, OHIP has worked closely with the Office of Device Evaluation to significantly expand the scope of the AP program in FY2001. Specifically, the following efforts took place in order to address this concern:

- In February 2001, we implemented an expansion pilot that allows AP's to review Class II devices for which there are no device-specific guidance documents. Implementation of the pilot expanded the number of eligible devices to 674 by adding over 450 Class II devices.

Implementing the expanded pilot program represents more than a 300% increase in eligible devices. Also, there was an increase in third party submissions of 510(k)s by AP's of almost 130% in FY 2001.

- In February 2001, we issued a final guidance document that includes criteria allowing for the review of the Class II pilot devices, entitled Guidance for Staff, Industry and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997.

- In June 2001, we conducted the second training session for third parties since the Accredited Persons Program began in 1998.

- In July 2001, we drafted a letter that was issued on September 17, 2001 from Secretary Thompson to Congresspersons W.J. Tauzin and Edward Kennedy advising them that we reached milestones that exceed those in the "sunset provision of FDAMA. This provision specifies that authorization of the program will end 5 years from the date of the letter.

INTERNATIONAL ACTIVITIES

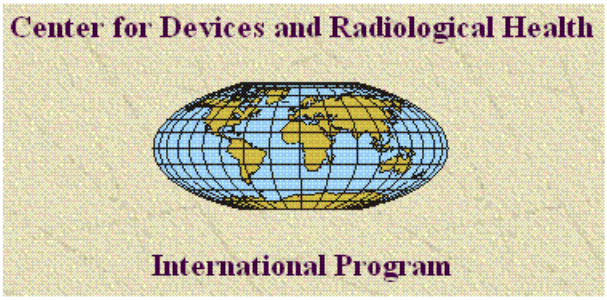
The concept of a "global marketplace" is especially true in the case of medical devices. Forty percent of approved device firms have manufacturing facilities abroad. There are approximately 6,000 foreign establishments that export devices to the United States. Device development studies are conducted worldwide. As a result, post-marketing vigilance for medical device problems is becoming a worldwide network. The inspection methods used by national regulatory agencies are converging in an effort to assure a consistent regulatory process across continental boundaries.

Goals

1. To assure the safety and effectiveness of imported medical devices by assisting foreign manufacturers to comply with U.S. medical device regulations.
2. To direct U.S. firms to sources of information on foreign requirements for medical devices.
3. To support global harmonization activities.

Foreign Manufacturers of Medical Devices

http://www.fda.gov/cdrh/international



During FY2001, OHIP continued to provide manufacturer support to foreign firms bringing medical devices into the United States. In addition, there were significant developments in activities associated with the Global Harmonization Task Force and the U.S./European Mutual Recognition Agreement. Our International Programs webpage was designed to consolidate information on CDRH's international activities in a single location. OHIP uses the same mechanisms to support foreign manufacturers as those used for domestic manufacturers. During FY2001, our assistance to foreign manufacturers included:

- answering more than 1,500 telephone inquiries;

- responding to more than 1,500 e-mails and 500 letters and faxes; and
- mailing more than 470 information packages on various medical device issues.

In addition, the International Programs Webpage received 10,674 hits throughout the year.

Regulatory Training and Assistance

OHIP coordinates the education of foreign governments on the U.S. medical device regulatory process. This may involve seminars and presentations or arrangements for more in-depth learning experiences while at CDRH. OHIP and other CDRH offices participate in these activities. During FY2001, they included:

- Russian Ministry of Health – presented medical device overview;
- Argentina Ministry of Health – presented medical device overview;
- Philippines Department of Health – two month training;
- South Africa Department of Health – one week training;
- Australia Therapeutic Goods Administration – presented medical device overview;
- Finland National Technology Agency – presented medical device overview;
- Danish Consulate – presented medical device overview;
- Japan Ministry of Health – presented medical device overview;
- Mexican Government – presented medical device overview; and
- Canada – presented medical device overview.

International Conferences

As with OHIP's educational efforts for the domestic device industry, we also participate in international conferences to promote compliance with U.S. medical device regulations. During FY 2001, OHIP participated in 18 international industry professional conferences. Recent presentations include:

- Japan – Overview of the US/EC Mutual Recognition Agreement;
- Germany – Overview of Quality Systems;

- Malaysia – Global Harmonization;
- China – US Regulatory Requirements;
- Singapore – Overview of Quality Systems; and
- Canada – Overview of Medical Device Regulation.

Global Harmonization

GHTF
GLOBAL HARMONIZATION TASK FORCE
Working Towards Harmonization In Medical Device Regulation

The Global Harmonization Task Force (GHTF) is comprised of government and industry representatives from the United States, Canada, the European Union, Japan, and Australia. Representatives from other countries also attend meetings and conferences, and participate in discussions of issues. GHTF members are working to build an international consensus on medical device regulatory policies and practices. The goal is to encourage convergence of medical device regulation worldwide to facilitate international trade, promote technological innovation, and enhance public health.

- In October 2000, OHIP participated at a GHTF seminar for embassy/consulate representatives sponsored by FDA's Office of International Programs (OIP).

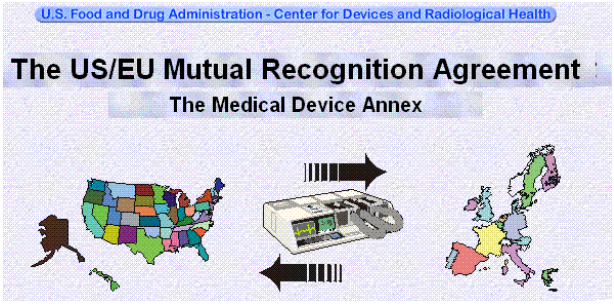
- OHIP participated in CDRH post-staff briefing on GHTF study group activities.

http://
www.ghtf.org

- OHIP coordinated CDRH participation in a videoteleconference to brief Brazilian regulatory officials on the GHTF's structure, goals, and procedures, as well as the study groups, their focus, and guidance documents.

- OHIP coordinated plans for CDRH representatives to attend the 9th Annual Conference of the GHTF in Barcelona, Spain in October 2001. However, the conference was cancelled due to the events of September 11, 2001.

U.S./European Mutual Recognition Agreement



http://www.fda.gov/cdrh/mra

The United States and the European Commission (EC) have signed a mutual recognition agreement (MRA). The MRA covers a variety of "product sectors" that include telecommunication equipment, electromagnetic compatibility (EMC), pharmaceutical good manufacturing practice (GMP), electrical safety, recreational craft, and medical devices. With regards to medical devices, the MRA relies on independent third parties from each exporting country to audit medical device manufacturers and to conduct product reviews according to the importing parties' requirements. To that end, the MRA may enhance FDA's ability to ensure that the health and safety of U.S. consumers are protected.

OHIP leads CDRH's implementation of the medical device annex of the MRA. In FY2001, our accomplishments include:

- Together with the Commission for the European Community (CEC), we prepared the Second Annual Report on the Medical Device Annex to the MRA. The report includes background on the MRA and a chronology of accomplishments from December 1, 1999 through December 1, 2000.

- Together with other CDRH offices, we participated in three stakeholders meetings to provide an update on progress of the MRA including confidence building activities and to allow for discussions and clarification.

- Published a Federal Register notice announcing the availability of Version #7 of the MRA Draft Implementation Plan.

- OHIP sent summaries, checklists and supporting evidence for 8 U.S. Conformity Assessment Bodies (CABs) to the CEC.

- A representative from OHIP taught a course on FDA's Quality System Regulation sponsored by AAMI in Frankfurt, Germany for designated European Union (EU) CAB auditors and EU Designating Authorities as part of confidence building.

- Two OHIP representatives participated at U.S. Department of Commerce (DOC) sponsored seminars in four U.S. cities to promote the MRA.

- Prepared and presented to the EU a proposed expansion of the eligible device list for premarket review. Adoption of the new tables I and II would increase the number of eligible devices from 97 to over 500.

- CDRH and ORA, led by OHIP, worked with the CEC to edit Version #10 of the MRA Implementation Plan.

- Continued to work to facilitate the Third Party Review Board's review of EU CAB dossiers to verify conformance with FDA criteria. Reviews of dossiers from four EU CABs are nearing completion.

RADIOLOGICAL HEALTH PROGRAMS

Radiological health is an important part of CDRH's public health mission. We assure the safety of consumer and industrial radiation-emitting electronic products. We promote the safe use of radiation in medicine by reducing unnecessary radiation exposure and by improving diagnostic image quality. However, CDRH resources for radiological health are at an all-time low. Reallocation to medical devices, personnel attrition and changes in product technology are just some of the factors involved. Within CDRH, a Radiological Health Council has been formed to revitalize our radiological health programs. The Council continues to pursue a variety of initiatives to assure and enhance the cost-effectiveness and public health benefits of CDRH radiological health programs.

Within OHIP, nearly one-third of our staff are involved in radiological health programs. As described below, we are using third parties, cooperative programs with the States, leveraging and other innovative approaches to address important public health problems.

Mammography Quality

OHIP implements the Mammography Quality Standards Act of 1992 (MQSA). Congress enacted MQSA to ensure that all women have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages.

Each year, approximately 180,000 women are diagnosed with breast cancer. Approximately one woman in nine will develop breast cancer in her lifetime. Early detection and prompt treatment of breast cancer has been demonstrated to reduce mortality by one-third in women over fifty. Mammography (x-ray examination of the breast) is the best tool available for the early detection of breast cancer. ***It is essential that all mammographic examinations be of the highest quality.***

Under MQSA, every mammography facility must meet baseline national quality standards. Mammography facilities include breast clinics, radiology departments in hospitals, mobile vans, private radiology practices, and other doctors' offices. For each facility, an FDA-approved accreditation body conducts a thorough review of the mammography facility's equipment, personnel (interpreting physicians, radiologic technologists, and medical physicists), and practices (including clinical image quality). We issue an MQSA certificate to facilities that meet the quality standards. Certification can be renewed as long as the facility remains properly accredited and demonstrates continued compliance with MQSA quality standards through annual inspections performed by FDA-trained Federal or State inspectors. Only MQSA certified facilities can lawfully provide mammography services.

Goals

1. Assure consistent availability of high quality mammographic examinations, nationwide.
2. Update regulations and standards to reflect new technology.
3. Fulfill CDRH's statutory obligations under the MQSA Final Rule in the most cost-effective manner.

MQSA Webpage

There are many facets to enforcement of the Mammography Quality Standards Act. Detailed information on all aspects of the MQSA program can be found at the Mammography Program website. This includes a list of all certified mammography facilities that is searchable by zipcode or State.

http://www.fda.gov/cdrh/mammography

Examples of documents currently available on the webpage (link on previous page) include:

- FDA's Mammography Program: An Overview;
- Mammography Quality Standards Act;
- Federal Register Notices;
- Mammography Quality Standards Reauthorization Act of 1998;
- *Mammography Matters* newsletters;
- policy guidance documents;
- listing of certified mammography facilities;
- Mammography Facility Performance Reports;
- Speaker's kit: *MQSA Final Regulations;*
- MQSA Program Accomplishments; and
- consumer-specific information.

Assuring Quality Mammography

Approximately 9,500 certified mammography facilities operate in the United States, including federal and military. To be certified to conduct mammography, each facility must be accredited by an FDA-approved accreditation body. At the end of FY2001, the five accreditation bodies and the number of facilities they accredit were:

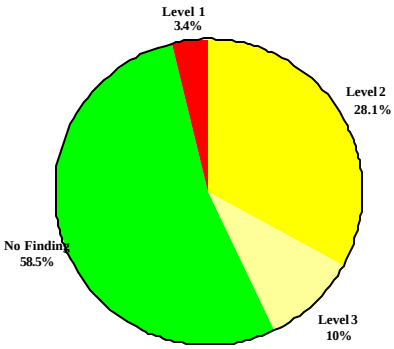
- American College of Radiology (8,752)
- State of Arkansas (75)
- State of California (465)
- State of Iowa (140)
- State of Texas (126)

To assure mammographic quality, mammography facilities undergo annual inspections by FDA trained inspectors[1]. FY2001 was the second full year of inspections under the MQSA Final Regulations. Nearly 9,300 inspections take place each year. Results from FY 2001 are shown in Figure 1 on the following page.

[1] The MQSA inspection program includes FDA inspections of federal facilities performing mammography. MQSA-like inspections are also performed for the Veterans Health Administration (VHA) through an Interagency Agreement.

- 58.5% of the mammography facilities had no adverse findings;
- about 3.4% of the inspections found the most serious type of problems ("Level 1 finding") – facilities must correct problems or lose their certification; and
- Level 1 and Level 2 percentages were lower, the Level 3 remained constant, and the "no findings" percentages were higher than the previous year.

Figure 1. Preliminary FY 2001 Inspection Results



- Inspectors can issue three levels of findings. Level 1 represents the most serious noncompliance with MQSA standards. Level 2 represents moderate noncompliance. Level 3 represents minor noncompliance.
- Regardless of the level, a facility must correct all deficiencies found during an inspection.

Since the beginning of the MQSA program, significant problems at eleven facilities led FDA to require that patients and physicians be notified of concerns related to the quality of their mammographic examinations (see link to Mammography Facility Performance Report at right). In each case, the patients and referring physicians served by these facilities were notified about the image quality problems at the facilities and were advised of the health risk. As a result, the patients and referring physicians were able to arrange for appropriate healthcare followup. (Note: State actions against mammography facilities are reported separately.)

http://www.fda.gov/cdrh/mammography/99report.html

As part of its continued efforts to assist MQSA inspectors to maintain consistent and uniform performance, FDA established an Inspector Quality Assurance Program. This program requires inspectors to conduct a minimum of 12 inspections yearly, obtain 15 continuing education units in mammography-related training (MEU's) over a three-year period, and undergo an annual audit by an FDA MQSA-certified auditor. In FY2001, FDA completed audits of every certified inspector.

Improving the MQSA Program

The mammography program strives to provide better value, improved customer service, and improved public health. Some of the major innovations during FY2001 are listed below.

- **Digital Mammography:** CDRH's Office of Device Evaluation approved the first Full Field Digital Mammography (FFDM) system, the GE Senographe 2000D, for commercial use in January 2000. A second FFDM unit, the Fischer SenoScan, was approved in September 2001. The new technology promises to enhance mammography by reducing the need for some women to have additional exposures, while allowing interpreting physicians to quickly and easily manipulate the images. At this time digital units are exempt from MQSA accreditation requirements. However, the accreditation bodies are developing a process for accrediting FFDM units. For an MQSA certified facility to lawfully use the FFDM system, it must:

  - maintain its accreditation status for at least one screen-film unit;
  - submit an application with required information to FDA;
  - ensure that any interpreting physician, medical physicist, or radiologic technologist has eight hours of initial training in the new modality before using it clinically;
  - provide a satisfactory FFDM equipment evaluation;
  - follow the manufacturer's guidelines for quality assurance and quality control tests; and
  - receive approval from FDA.

- **States as Certification Agencies ("States as Certifiers"):** This project successfully transferred certain key MQSA responsibilities to the States of Illinois and Iowa. The program authorizes qualified States to certify mammography facilities within their jurisdiction, conduct inspections, and enforce the MQSA quality standards under FDA oversight. The Department of Health and Human Services (DHHS) released the final regulations for publication on January 18, 2002.

- **Comprehensive electronic guidance:** All MQSA regulatory guidance materials and documents are now compiled into the MQSA Policy Guidance Help System (PGHS). Mammography facilities and other interested parties now have access to a comprehensive online resource accessible through MQSA's web page. Users of the PGHS can search for answers to specific policy questions through an indexed list of topics and key words. For example, by selecting a particular subject, such as "revocation of accreditation" or "accreditation and certification," the user will find the regulatory citation, any relevant guidance documents, and any other appropriate information and references.

http://www.fda.gov/cdrh/mammography/guidance-rev.html

MPRIS Web Applications

In response to numerous requests from State programs to provide more open access to the Mammography Program Reporting Information System (MPRIS) database, we developed 'modified view-only' versions of the two web-based MPRIS applications: (1) the Certification Accreditation Support System (CASS); and (2) the Facility Noncompliance Tracking and Management System (FaNTMS).

Using the CASS web application, current facility and unit certification and accreditation information and reports are now available to the States and the Districts on-line at any time. The State Facility Listing Report in CASS, which can be exported, replaced the monthly printed report that became rapidly outdated and was expensive for the Division to print and mail. The user is also able to print reports for an individual facility.

FaNTMS was also modified especially for view-only use. Using FaNTMS, a State inspector or supervisor is able to search for inspections in their State using several criteria. They may also view noncompliance and general inspection information and print or export a variety of reports such as the Inspection Detail and Post-Inspection Reports. FaNTMS provides complete descriptions of each report and on-line help is also available. In the Spring of 2001, a third version of FaNTMS was released designed for use by SAC States. This version has all the features of the FDA version, such as entering and editing correspondence and closing out noncompliances and inspections, except that the view of MPRIS data is limited to the SAC State.

NMQAAC

The National Mammography Quality Assurance Advisory Committee (NMQAAC) is a committee established by MQSA to advise FDA on the implementation of the MQSA program. During FY-2001, NMQAAC met to discuss the issuance of guidance on the MQSA final regulations, and the appropriateness of current inspection follow up actions. At the meetings, the committee received updates on:

- certification of Full Field Digital Mammography facilities;
- facility satisfaction survey; and
- current facility inspection findings.

NEXT

NEXT (Nationwide Evaluation of X-ray Trends) is a collaborative State-Federal survey program conducted by the Conference of Radiation Control Program Directors (CRCPD) and FDA. *NEXT* is the sole mechanism in the United States for acquiring and updating nationally representative data on medical x-ray exposures, image quality, and related clinical practice.

Hands-on training for NEXT x-ray surveyors at the National Naval Medical Center in Bethesda, Maryland

Goals

1. Develop standardized test protocols and imaging phantoms for a variety of x-ray examinations and train State radiation control personnel in their use.
2. Determine the average radiation dose and image quality from representative clinical x-ray examinations in the U.S.
3. Monitor trends in patient dose, image quality, and relevant clinical factors.

CRCPD's *NEXT* Committee serves as the steering and coordinating group for the program, exercising general oversight and providing a cadre of State radiation control staff who conduct the annual surveys. OHIP provides scientific and technical support for all phases of *NEXT*. This support includes training of surveyors, including presentations from CDRH staff on new technologies and survey procedures and hands-on surveyor training at local clinical facilities.

The *NEXT* program represents a twenty-seven year partnership between FDA and the States. Since 1998, *NEXT* training for State surveyors has been partially supported by the American College of Radiology through funding to the CRCPD.

Annual Surveys

Under *NEXT*, the surveys for a given year are directed at a single x-ray procedure and are conducted in a national cross section of clinical facilities.

***NEXT* Annual Surveys**

Survey Year	Type(s) of X-ray Examination (N = no. of facilities surveyed)	FY2000 Accomplishments
1995	Abdominal and Lumbo-sacral spine radiography N=204 (abdomen) N=319 (l-s spine)	Tabulation and graphical analysis of data completed, reviewed and currently in press by CRCPD.
1996	Upper gastrointestinal fluoroscopy N=352	Analysis completed for under-table x-ray tube systems; draft data summary completed.
1997	Mammography* N=7,676 (1995) N=10,746 (1996) N=11,086 (1997)	Published major study in *Radiology* on mammography in the 1990s in the U.S. and Canada.
1998	Pediatric radiography N=387	Surveys, data entry and preliminary analysis completed.
1999	Intraoral cephalometric, and panoramic dental radiography N=342	Surveys completed, data entered, and analysis proceeding.
2000	Computed tomography (CT)	Survey protocols modified to collect data on fluoroscopic CT**; incorporates major improvements in survey methodology; data analysis proceeding.
2001	Adult chest examination	Previously surveyed in 1994, the 2001 survey will include procedures for new digital imaging systems and flat panel systems, draft protocol completed, training dates set.
2002	Adult Abdomen and Lumbosacral Spine	Repeat of survey conducted in 1995. Surveyors will be equipped with laptop software that will perform all calculations previously done by hand.

* the data used in the *NEXT* analysis were obtained from facility inspections performed under the Mammography Quality Standards Act.

**There have been reports in the literature that prolonged irradiation during fluoroscopic CT may lead to patient skin injury. The modified protocol will collect quantitative data on the prevalence of this procedure and associated patient exposure.

Thus, the survey results for a given year represent a statistically valid "snapshot" of x-ray exposure and related factors for that examination in the U.S. The table on the previous page shows the status of the 1995 through 2002 *NEXT* surveys. During each survey, specific information is collected, including radiographic technique factors, patient x-ray exposure, x-ray beam quality, image quality, film processing quality and darkroom fog.

Choosing a different x-ray examination from year to year provides data on a variety of radiographic procedures while minimizing the workload during any one year. By repeating *NEXT* surveys for a particular x-ray examination every few years, the data can be used to identify trends or changes over the course of time.

NEXT Survey Results

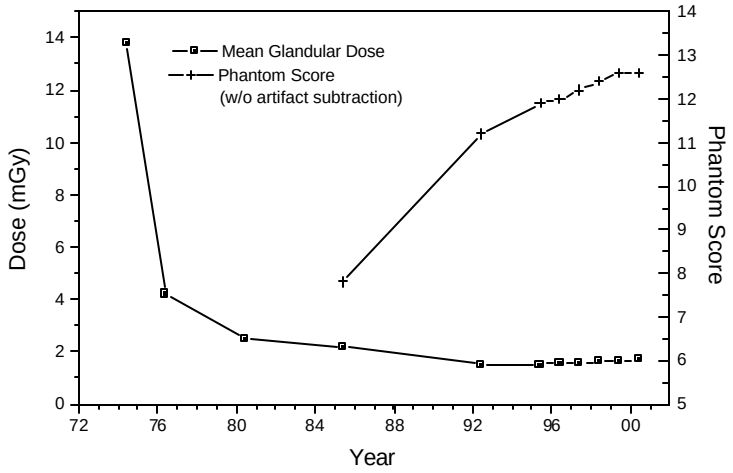
OHIP prepares a comprehensive report on a given year's data that includes statistical tabulations and graphical summaries. These reports are then published by the CRCPD without conclusions or other analyses in order to make the reports widely available and as timely as possible. OHIP also publishes interpretive analyses of *NEXT* data in peer-reviewed scientific, technical, and medical journals.

During FY 2001, OHIP gave presentations at several professional meetings including the FDA Science Forum, the annual meeting of the American Association of Physicists in Medicine (AAPM), and the annual meeting of the Radiological Society of North America (RSNA). Of special interest to the professional community were the results of the 2000 survey of computed tomography (CT). This modality has seen much technological advancement in the past decade as well as broader applications that have renewed concern about patient exposure safety.

The applications of *NEXT* data and their impact are illustrated in the figure on the next page. Data points through 1992 were generated from *NEXT* surveys supplemented with information from the literature. The data since 1995 has been collected using MQSA inspection data.

The results of the *NEXT* mammography surveys identified concerns with patient dose and image quality. These were factors in ACR's development of its Mammography Accreditation Program in 1988 as well as FDA's MQSA regulatory program in 1992. The MQSA inspection uses the protocol that had been developed in the *NEXT* program for determining the radiation dose and phantom image quality score.

As a result of the *NEXT* program and these ensuing developments, the radiation dose women receive from mammography is generally lower and the image quality better than at any other time since we began recording such information. Other data collected during these surveys show marked improvement in darkroom conditions, also contributing to improved image quality. While patient dose has been increasing slightly since 1995, that increase is primarily associated with changes in technical measures to improve image quality.



Average patient dose and phantom image quality scores during mammographic examinations.

Overall, *NEXT* has established baseline data and long-term trends for seven diagnostic examinations. These data:

- provide a standard of practice against which facilities can compare their radiation levels in order to maintain safe and state-of-the-art radiation levels (It is a common practice for many State x-ray surveyors to provide x-ray facilities with a brochure so that the facility can compare its x-ray survey results with the *NEXT* data.).

- have been used as a standard for comparison during inspections by the Joint Commission on Healthcare Organizations (JCAHO);

- are currently being adopted by the American Association of Physicists in Medicine (AAPM) and the ACR as reference values for standards of practice in patient radiation exposure.

TEPRSSC

The Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) is an important advisory committee to CDRH and FDA. Established under the Radiation Control for Health and Safety Act of 1968, TEPRSSC is charged with providing advice and consultation to the Commissioner of Food and Drugs on the technical feasibility, reasonableness, and practicality of developing performance standards for electronic products. TEPRSSC may also recommend electronic product radiation safety standards to the Commissioner.

FDA has performance standards for lasers, sunlamps, microwave ovens, ultrasound medical equipment, and diagnostic x-ray systems. In addition to these existing standards, FDA has the authority to promulgate mandatory safety standards for a wide array of products for which mandatory standards do not exist, such as cellular telephones and x-ray people scanners.

OHIP provides the Executive Secretary for the committee as well as programmatic support. Summaries of recent TEPRSSC meetings are available on our website. In May 2001, the 28th Annual Meeting of TEPRSSC convened to discuss important health and safety issues associated with:

http://www.fda.gov/cdrh/teprsc.html

- digital medical x-ray modalities such as digital radiography, computerized radiography, and computed tomography;
- the use of ionizing radiation to scan people for concealed weapons and other contraband;
- cellular telephones;
- the development of sunlamp standards and international harmonization;
- proposed rulemaking for lasers;
- proposed amendments for fluoroscopy;
- computed tomography pediatric examinations, dose-index display, standardization of nomenclature, tube-current modulation, x-ray field limitation, possible regulatory approach, and whole-body screening;
- non-medical radiation products such as television sets, microwave ovens, and lasers.

Federal Facilities Inspections

OHIP manages a Federal Facilities Inspection program that provides radiation protection services to diagnostic x-ray facilities run by various federal agencies. The federal agencies participating in this program include:

- Department of Justice (Bureau of Prisons);
- U.S. Coast Guard; and
- NASA (National Aeronautics and Space Administration).

Goals

2. Assess federal facility compliance with the Presidential Directive of 1978, "Radiation Protection Guidance for Federal Agencies for Diagnostic X-rays."
3. Educate facility personnel in methods to reduce radiation exposure while improving image quality.

CDRH also has an Interagency Agreement with the Indian Health Service to provide survey equipment, calibration services, training, and assistance with technical issues related to radiation use and control.

OHIP coordinates with FDA's Office of Regulatory Affairs (ORA) to conduct radiation surveys in all of these facilities. ORA staff, either the FDA Regional Radiological Health Representatives (RRHRs) or FDA x-ray auditors, perform the actual surveys. The ORA staff have special training and experience in radiation physics and are qualified to provide facilities with information on how to reduce radiation exposure during medical radiographic procedures. This information ranges from recommending x-ray techniques to methods for optimizing film processing and enhancing image quality. The RRHRs are also available for phone consultation to assist facilities with other problems that might arise in their x-ray facilities.

OHIP provides administrative support and overall coordination for the program. This support includes negotiating Interagency Agreements with the participating federal agencies. These Agreements fund FDA's program implementation for the purchasing and inventorying of survey

equipment and supplies, and for conducting surveys. Each radiation survey is followed up with a report to the x-ray facility and to the headquarters liaison for that federal agency. The report contains test results, cites deficiencies if any, and makes recommendations for improving the quality of the diagnostic x-ray services at the facility.

Approximately 90 surveys were completed in FY2001. Most were conducted in the Bureau of Prisons or U.S. Coast Guard facilities. Almost all surveys recommended minor changes that resulted in a reduction in unnecessary radiation exposure and improved image quality.

All of the participating federal agencies review these reports and require their x-ray facilities to make changes and improvements as recommended by the FDA. At Bureau of Prisons facilities, these reports become an integral part of the records reviewed by auditors from the Joint Commission on Accreditation of Healthcare Organizations when they evaluate and accredit the facility.

Radiation Safety

In carrying out its regulatory science mission, CDRH uses laboratories that employ radiation-emitting products and radioactive materials. CDRH's Radiation Safety Officer (RSO) is a member of OHIP's staff. The RSO is responsible for CDRH's radiation safety program. This includes protecting the health and safety of all employees and assuring that CDRH complies with all government regulations on the safe use of radioactive materials.

Goals

1. Assure the safety of employees and contractors working in CDRH radiation laboratories.
2. Assure CDRH compliance with federal regulations governing the use and control of radiation-emitting electronic products and radioactive materials.

During FY2001, the RSO and OHIP accomplished the following:

- conducted quarterly surveys of all radiation laboratories, annual audits of all radiation programs and licensees and unannounced surveys of CDRH radiation laboratories;

- calibrated 22 radiation survey instruments on a semi-annual basis;
- conducted the annual training required for all licensed materials users;
- facilitated and chaired quarterly radiation safety committee meetings.

During FY2001, there were no incidents that resulted in harm or overexposure to individuals working in CDRH laboratories. Our laboratory inspections and audits also indicate that we are meeting our goals. Where minor problems were identified, corrective actions have been taken and will be monitored during future reviews.

The improvements in CDRH's radioactive waste practices, begun in FY1999, were particularly important accomplishments. As shown in the following table, they have led to continuing, significant reductions in the amounts of hazardous materials stored by CDRH. These practices have resulted in improved radiation safety, better accountability of radioactive materials, reduced workload for monitoring sealed radiation sources, and reduced costs for physical storage.

Radioactive Waste and Sealed Radiation Sources Stored by CDRH

	FY1997	FY1998	FY1999	FY2000	FY2001
Containers of liquid radioactive waste	30	40	6	1	1
Sealed Drums of dry radioactive waste	3	3	0	0	0
Drums of "Decay-in-Storage" waste[2]	3	3	1	1	0
Sealed radiation sources[3]	200	200	3	3	3

REDUCING USE ERROR

People make errors all the time – it's an aspect of being human. Errors made while using medical devices can lead to hazards which can impact patients, family members, and healthcare providers. Hazards associated with device use are a common and serious problem. Evidence from

[2] "Decay-in-Storage" – is a standard practice to store containers of short-lived radioactive waste until the radioactive materials have decayed so that the waste can be released as non-radioactive.
[3] Does not include generally licensed sources that do not require NRC (Nuclear Regulatory Commission) approval.

researchers suggests that the frequency and consequence of hazards resulting from medical device use error far exceed those arising from device failures. Therefore, it is essential to ensure safe and effective device use if hazards are to be controlled effectively.

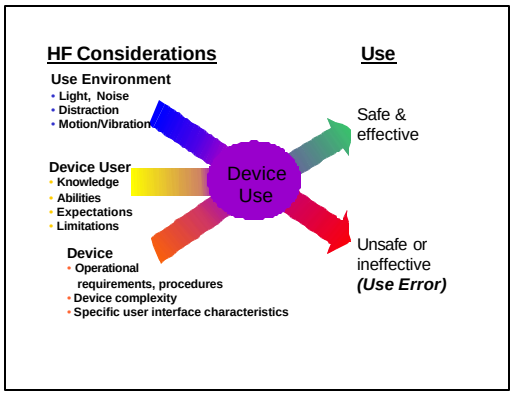
FDA recognizes that most use errors with medical devices are not "inevitable human error." Rather, they are largely influenced by device design and device labeling. OHIP seeks to promote the safe and effective use of medical devices through our Human Factors program, labeling efforts, and patient safety activities.

Goals

1. To support the medical device industry's successful application of human factors principles in order to reduce medical device use error.
2. To expand the science base and continued advocacy for the effective communication of labeling information to patients and healthcare professionals.

Human Factors

Human Factors (HF) is a science devoted to the interaction of people and equipment. "Human Factors," "human engineering," "usability engineering," and "ergonomics" are often used interchangeably. In the field of medicine, the objective of Human Factors is to improve human performance and reduce the likelihood of use error and patient injury.



Human Factors has been used extensively by the military, the transportation industry and in some consumer areas. It is now being applied to address use error problems in medicine. Human Factors analysis and testing should be applied throughout the entire life-cycle of a medical device. Our Human Factors efforts impact on the Center's premarket, postmarket, and field-inspection regulatory missions.

We assisted the Center's Office of Device Evaluation by providing several Human Factors reviews for PMA and 510(k) devices.

Human Factors Considerations can result in Medical Devices with:

- Intuitive operation and low reliance on manuals;
- Easy-to-read displays;
- Easy-to-use controls;
- Positive and safe connections;
- Effective alarms; and
- Easy repair and maintenance.

- **Guidance:** In July 2000, we issued a final guidance document, Medical Device Use Safety: Incorporating Human Factors Engineering into Risk Management. This document has received positive feedback from industry representatives. Its content provided the basis for the 2001 teleconference: "Integrating Human Factors Engineering into Medical Device Design and Development." Recent HF guidance efforts include a HF section of the new guidance (being written) for glucose monitors which contains specific considerations for glucose monitors. This effort also included the incorporation of HF perspectives into the software validation component of the glucose monitor guidance document.

http://www.fda.gov/cdrh/humfac/1497.html

- **Teleconference:** On February 14, 2001, we broadcast a live, interactive satellite teleconference: Integrating Human Factors Engineering (HFE) into Medical Device Design and Development. The audience included risk managers, device manufacturers, and other health care providers. The focus was the role of the medical device industry in reducing errors involving medical device use, a.k.a. “use error”. The teleconference included two panels. The first panel was composed of representatives from CDRH who discussed the regulatory implications of HFE and the extent to which human factors is considered as part of the overall review performed by CDRH. The second panel was composed of experts on HFE from the medical device industry. This panel discussed integration of HFE into design and development processes for medical devices for the purpose of making devices safe for users. At the end of the teleconference, panelists responded to questions from a nationwide audience. Questions that were not answered at the time of the teleconference are posted on our website (link on previous page).

http://www.fda.gov/cdrh/Useerror/teleconf101100.html

- **Research - PROUD 2000:** The Prioritization and Reduction of Use Error in Devices 2000 project is part of OHIP’s overall strategy to address deaths and injuries resulting from the use of medical devices. There is still much to be learned before we can fully understand use error with medical devices. In 2000, we completed the first phase in which we interviewed Nurses and

other actual device users. We collected information on problematic devices, methods for analyzing device use error, organizational influences on use error, and overall issues that affect use error (i.e., training, staffing, workload issues). During 2001, to coincide with the IVD TPLC effort, the next phase of PROUD began with a series of discussion/focus groups consisting of glucose meter users. The results of this undertaking were directly applicable to the recent HF guidance contributions for glucose monitors, and ultimately provided useful information to the public about glucose meter use considerations via a diabetes web site. The next activity will involve discussion groups with clinical engineers regarding use problems with devices used in hospitals.

- **National Standards:** OHIP played a key role in the development of the American National Standard ANSI/AAMI HE74:2001, Human factors design process for medical devices published in 2001. This standard will be given FDA recognition and will serve as a human factors engineering design guidance for medical devices.

- **International Standards:** OHIP is leading the development of an international standard (IEC 60601-1-6, collateral standard: Usability: Analysis, test and validation of human factors compatibility) that describes how manufacturers must carryout design activities to address the needs of the device users to minimize dangerous error. The 1st Committee Draft was circulated for national committee comments in the Spring of 2001. This standard serves as the primary basis for the international standard IEC 60601-1-6, collateral standard: Usability: Analysis, test and validation of human factors compatibility which is currently being developed.

http://www.fda.gov/cdrh/humfac/hfbrochure.html

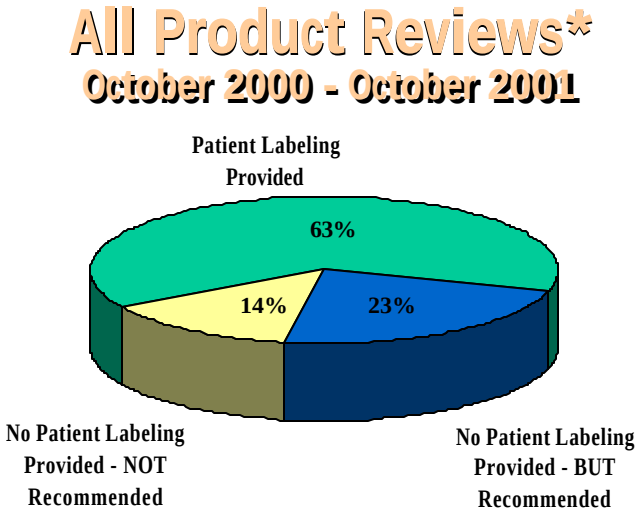
- **Human Factors Brochure:** In FY2001, OHIP updated the Human Factors Brochure and distributed it widely at professional meetings. The brochure briefly introduces Human Factors in medicine, lists CDRH Human Factors activities, and gives other information resources. All of the information from the brochure is available from our webpage.

Labeling

Improved patient labeling on medical devices allows the patient or caregiver to better understand both instructions for use and risk-benefit information. Our accomplishments included:

- We review patient labeling for all new Premarket Approval (PMA) submissions and also for non-PMA submissions if CDRH's Office of Device Evaluation thinks that patient labeling needs review. This was the fifth year that OHIP performed these reviews. In cases where patient labeling is not submitted, OHIP reviewers determine whether patient labeling will contribute to reducing use error or allow the patient to make a more informed choice concerning their healthcare. During FY2001, we reviewed 141 submissions.

Of the 141 reviews, 63% of submissions contained patient labeling. 23% did not contain patient labeling, but we recommended that patient labeling be written. 14% did not have patient labeling and we did not recommend labeling for the patient.



*Includes original submissions, supplements, and requests for repeat reviews.

http://www.fda.gov/cdrh/ohip/guidance/1128.pdf

- **A Draft Guidance on Medical Device Patient Labeling was** issued. In April 2001, we issued a guidance document titled, "Guidance on Medical Device Patient Labeling; Final Guidance for Industry and Reviewers". The guidance can be found at the website to the left of this page. It is designed to assist manufacturers in their development of patient labeling to help make it understandable to and usable by patients (or family members or other lay persons caring for patients). The guidance is also designed to assist Center reviewers in their review and evaluation of medial device patient labeling. This guidance offers:

  - A suggested sequence and content for patient labeling;
  - Information on readability and writing for increased comprehension;
  - Principles to apply to the appearance of text and graphics; and
  - Guidelines on pretesting patient labeling with the target audience.

Patient Safety

During 2001, OHIP participated in the Errors Workgroup and the Patient and Consumer Information Working Group of the Quality Interagency Coordinating Committee (QuIC) on patient safety. The QuIC is coordinated by the Agency for Healthcare Research and Quality.

http://www.fda.gov/opacom/factsheets/5steps.html

ENGLISH

The Patient and Consumer Information Working Group of the QuIC finalized the brochure "5 Steps to Safer Health Care" in English (www.fda.gov/opacom/factsheets/5steps.html) and Spanish (www.ahcpr.gov/consumer/cincorec.htm). This publication is designed to help patients actively participate in their health care. Specifically, the five steps to follow are:

- Speak up if you have questions or concerns.
- Keep a list of all the medicines you take.
- Make sure you get the results of any test or procedure.
- Talk with your doctor and health care team about your options.
- Make sure you understand what will happen if you need surgery.

The Errors Working Group tracked the progress of the participating QuIC agencies in completing the patient safety action items identified in the Institute of Medicine Report on Medical Errors and coordinated a response to the President on the status of the action items. CDRH prepared summary updates on the CDRH action items related to adverse event reporting, human factors, and patient education.

Additionally, as part of CDRH's interest in increasing the awareness of medical students about patient safety issues with the use of medical devices, a medical school curriculum content outline was developed and piloted with medical students under a grant to the Cleveland Hospital Foundation. CDRH is pursuing additional partnerships to further develop the curriculum model into an interactive educational program or web-based program that can be utilized in the clinical setting by a variety of healthcare practitioners.

http://www.ahcpr.gov/consumer/cincorec.htm

SPANISH

REGULATIONS AND GUIDANCE

OHIP plays an essential role in the development of all CDRH regulations and Federal Register documents, as well as in the management of Good Guidance Practices.

Regulations

Goals

1. To manage all aspects of CDRH's regulations development process.
2. To serve as regulatory experts on CDRH teams addressing medical device or radiological health issues.
3. To coordinate the development, review, and submission of all Federal Register publications for CDRH, including citizen petitions.

In FY2001, OHIP lawyers and paralegal staff were instrumental in allowing CDRH to:

- meet all statutory requirements associated with implementation of the FDA Modernization Act of 1997 (FDAMA);
- respond to 16 citizens petitions, with no overdue petitions; and
- publish 46 Federal Register documents. Some of the most significant documents being finalized include:

http://www.fda.gov/cdrh/fedregin.html

- **Postmarket Surveillance.** This final rule establishes procedures for FDA and manufacturers on the postmarket surveillance requirements. *This was CDRH's first "Plain Language" rule (see below) and it was the first rule for which CDRH is accepting comments on the Internet.*

- **510(k) -FOI rule (Freedom of Information).** We are finalizing a proposed rule to require submitters of premarket notifications to send FDA a version of the 510(k) with trade secret and confidential commercial information deleted. This rule, if implemented, would save FDA the time of deleting this information when responding to FOI requests.

- **States as Certifiers.** FDA has finalized a rule that would transfer aspects of FDA's role as a Certifier of mammography facilities to qualified States. The rule fully implements a provision in the Mammography Quality Standards Act (MQSA).

- **Mass Reclassification.** CDRH issued a final rule to reclassify 28 class III devices into class II. This is a major step toward completion of the review of the pre-1976 Class III devices.

- **Apnea Monitors.** CDRH is finalizing a 510(k) guidance document for apnea monitors and is making this guidance document a special control for these devices.

- **Tracking Amendments.** CDRH issued a rule to implement the FDAMA amendments to the tracking provisions of the Federal Food, Drug, and Cosmetic Act.

The regulation workload in FY2001 was consistent with that of previous years. In order to maintain a high level of output and quality, OHIP continued to implement improvements and changes identified through CDRH-wide reengineering of the regulation process.

Good Guidance Practices

Goals

1. To provide coordination and leadership for CDRH's GGP process.
2. To work with CDRH's Office and Division GGP contacts to ensure that CDRH guidance documents comply with the GGP regulation.
3. To assure easy access to CDRH guidance documents over the Internet.

Good Guidance Practices (GGPs) are FDA's policies and procedures for developing and issuing guidance documents. Guidance documents describe FDA's interpretation of, or policy on, a regulatory issue. They are typically prepared for FDA staff, applicants/sponsors and/or the public. The GGP policy standardizes the development process for guidance documents, provides opportunities for public comment, and clarifies the use of guidance documents. Each FDA Center is charged with implementing its own GGPs. OHIP leads implementation, administration, and monitoring of GGPs within CDRH.

In FY2001, OHIP:

http://www.fda.gov/cdrh/ggpmain.html

- Created and updated a comprehensive database of all guidance documents issued by CDRH – currently, more than 642 guidance documents prepared under GGPs.
- Worked with CDRH's Office of Systems and Management to provide a searchable version of the database available on the CDRH webpage. This database can be viewed on the website to the left.
- Updated and revised the Standard Operating Procedures (SOP) Manual for GGPs, providing CDRH authors with detailed instructions, templates and checklists.
- Worked with CDRH's GGP contacts to publish an annual listing of all guidance documents.

Plain Language

On June 1, 1998, the President issued a directive that the federal government's writing must be in plain language. Basically, plain language means that our documents must be clear and easy to read.

Within CDRH, OHIP is responsible for coordinating the implementation of plain language in all of our written communications, including regulations and guidance documents.

Goals

1. To assure that CDRH's written communications are clear and easy to read.
2. To provide advice and assistance to CDRH staff on writing in Plain Language.

Language.

During FY2001, OHIP:

- Continued to sponsor plain language and writing/editing courses for CDRH staff – since these classes were first offered in FY1999, more than 325 staff have participated in classes for:

  - regulations writers,
  - letter writers,
  - support staff,
  - reviewers and non-reviewers;

- Edited documents and webpages to assure the language used is clear and simple. Examples of these include:

  - ***Metal Detectors and Other Security Systems***
    We edited a document about the safety of metal detectors and other security systems found in airports and building entrances. The document answers questions about safe passage through security systems by the public and by pregnant women. It also discusses the risks of electromagnetic interference with implanted medical devices such as pacemakers, implantable cardioverter defibrillators, and infusion pumps.

  - ***Wireless Telephones***
    We collaborated with other CDRH offices and the Federal Communications Commission to design and develop a web site to provide information about wireless telephones. This web site evaluates health and safety concerns about radiofrequency energy, wireless phones, and wireless base stations.

- Continued to assure that new CDRH documents are written in plain language and that plain language is incorporated into existing CDRH documents as they are updated and revised.

- Provided plain language review for 55 one-page summaries written by CDRH about newly approved and cleared devices which include new and emerging technologies.

FDAMA

OHIP serves as the CDRH coordinator for implementation of the FDA Modernization Act of 1997 (FDAMA). Each of the CDRH Offices is committed to implementing the provisions of FDAMA, as evidenced by a record of:

http://www.fda.gov/cdrh/modact/modern.html

- more than 24 final guidance documents and eight final rules;
- three Reports to Congress;
- routine updates to the list of recognized consensus standards;
- implementation and proposed expansion of the Accredited Persons Review Program (discussed elsewhere in this report); and
- implementation of the Least Burdensome provisions of FDAMA.

Throughout all of these efforts, OHIP has provided support for regulations and guidance development as well as extensive training and education for CDRH staff on FDAMA provisions. The Least Burdensome Provisions of FDAMA were the topic of CDRH's first webcast.

CDRH STAFF COLLEGE

OHIP provides all CDRH employees with comprehensive professional and technical training through our Staff College. Our products include classroom training, live satellite teleconferences, webcasts, online coursework, and a variety of seminars and lectures.

Goals

1. To partner with all CDRH Offices in offering high quality, practical training solutions that meet CDRH's evolving needs and priorities.
2. To provide individual employees with management, professional development and scientific/technical training opportunities that enhance their job performance and maximize their career potential.

Training Highlights

During FY2001, we provided CDRH employees with extensive training opportunities, including: in-depth training on scientific and technical issues; CDRH programs and policy; the use of plain language in all CDRH communications; and training in communication, interpersonal, and professional development skills (see next page for examples). This training was presented in a variety of settings and formats:

- Over 100 different courses were presented for more than 2,800 "students."[4] Depending upon the topic and training objectives, individual courses can require a commitment of from four to forty hours. The longer courses may spread over a period of several weeks.

[4] There were approximately 1,050 CDRH employees in FY2001. Individual employees take advantage of several training opportunities during the year. Therefore, the number of "students" or "attendees" is greater than the number of employees.

- Fifty-six high quality, seminars were held in FY2001. Over 1,700 employees attended these seminars. "Staff Updates" are scheduled on a flexible basis to address current or upcoming issues. "Science Grand Rounds" are held monthly to keep CDRH staff up-to-date on the latest medical device and radiation issues. This year, we added 5 Radiological Seminars and 1 Law Seminar Series. The speakers at our seminars are national and international experts from FDA, other government agencies, universities, and from the medical device industry.

- Staff College continued to evaluate the impact of training on job performance. During FY01, impact surveys were conducted on several courses. The survey results indicate that classroom learning is applied to Center work products.

Examples of FY2000 Training for CDRH Staff

- **Home/Self Care Technology:** This one-day course addressed home/self care devices; one of the most important emerging technologies/trends identified in the Future Trends Study.
- **Risk Management:** This comprehensive course in Risk Management for CDRH Staff also address HACCP principles. Internal, industry and academic faculty delivered the course.
- **Epidemiology:** In conjunction with OSB's Epidemiology staff, a new, semester-long course in Epidemiology was offered Fall 2000.
- **Anatomy and Physiology:** This 8-week course was held for the first time in FY'01 and provided staff with a comprehensive overview of human anatomy and physiology.
- **Human Factors:** In partnership with OHIP/DDUPSA, this course was developed as a refresher course in Human Factors.
- **Biocompatibility Case Studies:** We continued to offer quarterly updates to the previously held 12-week course on biocompatibility, which was presented in Spring 2000. The updates give reviewers the opportunity to apply and reinforce knowledge gained about specific biocompatibility testing in the review and evaluation of medical device submissions.
- **Surfaces in Biomaterials:** As a precursor in Biomaterials course scheduled for FY'02, the annual Surfaces in Biomaterials foundation Hemocompatible Surfaces Workshop was broadcast to CDFH employees via videoconferencing in August 2001.
- **Designing Cardiovascular Devices: Science Technology and Applications** was offered for the first time in June 2001.
- **FOIA & Privacy Act Briefing** updated participants with knowledge and understanding of the FOIA and Privacy Acts.
- **Plain Language/Technical Writing:** A total of 114 employees attended our FY01 offerings. Three sessions were offered of a new course on Reviewing and Editing the Writing of Others for a total of 88 employees.
- **SkillSoft Training**: a web-based, self-directed learning program with over 400 online courses was launched Center-wide in FY01.
- OHIP offered an extensive program of over 100 **video playbacks** of recently recorded training and educational programs. The CDRH Learning Channel now has programming continuously available.
- **Pathways Program for Administrative & Support Staff:** We continued to administer and market this program, which recognized its first Graduate in Spring 2001. The following courses were offered specifically for the Pathways program: Achieving Professional Goals Together, Teaming Up for Success, and Managing Support Staff.

- We continued to expand science-related satellite and audio teleconference offerings. Sixteen satellite teleconferences were offered and attended by over 300 CDRH employees.

- We continued to utilize CenterNet Live. This uses webcast technology to bring important seminars, lectures and presentations to every desktop computer in CDRH. Webcasting provides every CDRH employee with the flexibility to participate in important events "live" or at a later date through our playback schedule.

- CDRH maintained availability of offerings from SkillSoft Corporation's Critical Skills Library. This program has been a great success and is frequently used as pre-assigned reading for many of our courses.

360° Training Program

The Staff College Training team continues to implement a "360 degree Training Program" in CDRH. The program has ensured that courses are more rigorously designed, developed, delivered, and assessed to ensure their quality and relevance to program goals. During FY'01, the training team continued to focus on needs assessment, training impact assessment, training transfer, evaluation, Staff College performance/evaluation measurement criteria, and benchmarking.

Electronic Course Evaluations

The pilot of electronic course evaluations conducted in FY'01 has been extremely successful with positive feedback from respondents throughout CDRH, as well as improved productivity of Staff College employees. OHIP will continue to conduct online course evaluations, impact surveys, and needs assessments and explore new ways to make use of this technology to improve the efficiency of CDRH training operations.

CDRH Manager Core Competencies and Learning Pathways

During FY'01, OHIP's Staff College played a lead role in addressing the Center's Strategic goal of becoming a Magnet for Excellence. Reaching this goal involves a proposal of developing and establishing core competencies and learning pathways for CDRH managers. The Magnet for Excellence Goal Group and nominated supervisors from throughout the Center continue to work on the development of this project. The project involves identifying the core competencies applicable to CDRH managers – basic knowledge and management/supervisory skills needed to excel and make CDRH a "magnet for excellence." The group will also develop "learning pathways" (a suggested core curriculum of courses) that build the knowledge and skills needed to address those competencies.

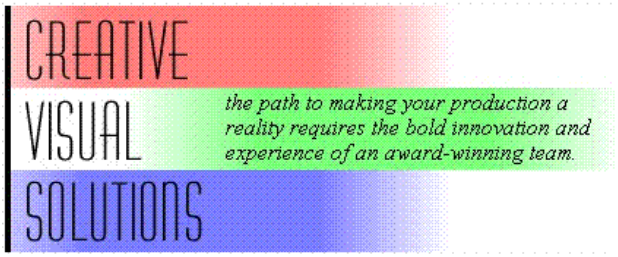
CDRH Mentoring Program

During FY'01, OHIP's Staff College lead the Magnet for Excellence project plan proposal of developing a formally structured mentoring program for new supervisors. A subgroup of the Magnet for Excellence Goal Group, along with nominated employees throughout the Center, engaged in work to develop this project with guidance from an external consultant. The program will help develop a skilled and talented pool of employees whose competencies align with the CDRH strategic mission.

Workplace Assessment

In FY'01, in conjunction with a subgroup of the Magnet for Excellence Goal Group, OHIP's Staff College assisted with the logistical aspects for an external consultant to conduct a workplace assessment survey to be conducted during FY'02. When the survey is completed, CDRH managers will receive feedback on survey results about their effectiveness in helping to build and to retain a strong workforce. OHIP will continue to assist the external consultant with coordinating workshops for managers as a follow-up to the FY'02 survey results.

TELECONFERENCE/VIDEO PRODUCTION



OHIP operates a broadcast quality television studio on behalf of CDRH and FDA. The studio is a uniquely powerful tool for outreach on a wide variety of topics. The primary medium for outreach has become production and presentation of "live teleconferences," although we continue doing videotaped programming on a limited basis.

Goals

1. To provide the infrastructure and expert knowledge needed to effectively use audio and video in support of CDRH, FDA and other government public health programs.
2. To evaluate, recommend and support new techniques and technologies for improved training, education and information exchange.

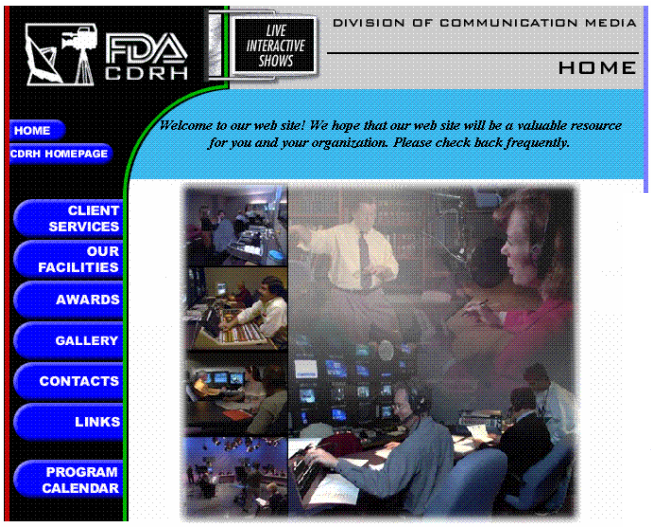
The television studio continues to provide excellent "value" to CDRH and FDA. Studio operations and capital expenditures, other than personnel costs, are completely funded by chargebacks to the other components of FDA and other government agencies sponsoring the programming. As a result, during FY2001;

- CDRH programming was produced with minimal program dollars.
- The same facilities and equipment used for teleconferences and video production were available to CDRH for other purposes:

  - we provided technical video support for Center-sponsored medical device panel meetings;
  - we provided video documentation of critical CDRH meetings and training events; and

- we provided 8 hours of mission-related programming every day to CDRH employees via the CDRH fiber-optic network, including 32 educational and training programs received live via satellite and delivered simultaneously.

Our website for the television and video services continues to be a comprehensive source of information regarding our television and related video services. Developed in cooperation with CDRH's Office of Systems and Management, it provides up-to-date information on television programs currently in production, programs scheduled for broadcast, and opportunities to secure programs previously broadcast. It also provides other PHS agencies with a greater understanding of the facilities and services available to them.



http://www.fda.gov/cdrh/ohip/dcm

Another important feature of our website is a "program calendar" that provides information about, and serves as a marketing tool for, individual CDRH/FDA teleconferences. The program calendar:

- notifies a potential audience of a scheduled event;
- creates a temporary data base of downlink sites;
- provides answers to frequently asked questions related to downlink operations;
- allows for interactive exchange both before and after the distance learning broadcast; and
- results in a database that significantly enhances our ability to accurately target marketing information for all programming activities.

Also during FY2001:

- We used the enhanced ability of our facility and the expertise of our staff to provide new services to CDRH and FDA that allow audio and video to be digitized and used as streaming media on the Web and for the production of CD copies of television productions.

- A new series of monthly educational and informational programs aimed at health-care providers has been instituted in concert with other CDRH components. The program, "FDA Patient Safety News", is currently distributed to four medical networks reaching a combined audience of 4,700 hospitals. Each program features stories on new medical devices recently approved for by FDA, recent FDA notifications about safety problems with devices, tips on protecting patients when using medical devices, and important product recalls. The show also features a "Journal Scan" section, in which we highlight interesting articles on patient safety in the medical literature. Playback schedules and 24/7 network operation produce 15,000 airings per month of each title.

- In collaboration with OSM, "FDA Patient Safety News" has its own dedicated website where interested persons can review the stories that have appeared on the broadcasts, get more information on any of the topics we cover in the broadcasts, and report problems they've encountered with FDA-regulated products directly to CDRH. That site is located at fda.gov/cdrh/psn.

- We began a series of monthly broadcasts to all FDA employees featuring the Acting FDA Commissioner. This series of programs, titled "A Conversation with the Commissioner", allows timely information to be imparted as well as interactive communication between the commissioner and any guests appearing on the program and the FDA workforce. These programs are also made available on the FDA website as archived media for viewing at any time from the employee's desktops.

- DCM facilitated the first ever joint teleconference between FDA and NTEU. The success of this collaborative effort generated a second teleconference to address union-related issues.

- Plans are currently underway to inaugurate a CFSAN video network that will be made available to all employees in the new Greenbelt CFSAN headquarters building. This network will operate in the same fashion and with identical equipment to the current CDRH and CBER fiber channels that are currently managed and operated by OHIP.

- We continue to explore, evaluate and implement new tools and technologies that allow information and educational programming to be delivered to CDRH employees either individually, in groups of varying sizes, interactively, and/or on an "as-needed" basis. Our mechanisms of delivery have expanded beyond videotape to include CD-Rom, DVD, and streaming media.

- On-location video recordings of lectures, panel discussions, training classes, and other informational programs were used in a variety of training and learning situations, including rebroadcast to all CDRH staff.

- We continued our working partnership with the Office of Regulatory Affairs (ORA) to provide training and other programming on a wide variety of FDA issues.

APPENDIX

Publications and Presentations

OHIP's programs may involve formal publications or presentations in various scientific and professional settings. This listing reflects the variety and diversity of our programs.

Activities of NEXT – Past, Current, and Future. Presented to the *33rd Annual meeting of the Conference of Radiation Control Program Directors*, Anchorage, Alaska, April 29-May 2, 2001. Companion paper published in *Proceedings of the 33rd National Conference on Radiation Control*, CRCPD Publication 01-7, August, 2001; pg 88. PowerPoint document available at http://www.crcpd.org/proceedings.htm. Mary Ann Spohrer, David Spelic.

Breast Implant Risks. FDA Brochure. November 2000. Nancy Leonard, Mary Ann Wollerton

CDRH Regulatory Requirements and Quality Systems. 8 Presentations at the FDA Medical Device Reuse Workshop; Orlando, FL.; May 10-11, 2001; Joseph Puleo; Frederick B. Winston

CDRH Regulatory Requirements and Quality Systems. 8 Presentations at the FDA Medical Device Reuse Workshop; Phoenix, AZ.; May 30-31, 2001; Joseph Puleo; Frederick B. Winston

Chapter 2, Radiation Safety. *Efficacy and Radiation Safety in Interventional Radiology*, (World Health Organization, Geneva, 2000). P. Shrimpton (Rapporteur), C. Sharp (Chairman), D. Mohlkert, V. Neofotistou, H. Schibilla, T. Schmidt, S. Stern, R. Veit, and M. Zankl.

Comparison of Photometers in Measuring DICOM Part 14 Conformance. Medical Physics, 28, 1248(2001). B. Drinkwine, J. Thomas, M. Loscocco, K. Chakrabarti, R. Kaczmarek, I. Ilev, R. Waynant.

Comparison of Photometers in Measuring DICOM Part 14 Conformance. Scientific exhibit presented at the *2001 meeting of the American Association of Physicists in Medicine*, Salt Lake City, UT. Medical Physics, Vol. 28, No. 6, June 2001 (Abstract), p. 1248. B. Drinkwine, J.Thomas (USUHS), K. Chakrabarti, R. Kaczmarek (CDRH), M. Loscocco (JRCAB, Ft Detrick, MD).

Continual Quality Control Monitoring of High Resolution Diagnostic Monitors. Medical Physics, 28*, 1248(2001).* M. Loscocco, J. Thomas, B. Drinkwine, K. Chakrabarti, R. Kaczmarek, D. Davis.

Continuous Quality Control Monitoring of High Resolution Diagnostic Monitors. Scientific exhibit presented at the *2001 meeting of the American Association of Physicists in Medicine,* Salt Lake City, UT. Medical Physics, Vol. 28, No. 6, June 2001 (Abstract); p. 1248. M. Loscocco (JRCAB, Ft Detrick, MD), J. Thomas, B. Drinkwine (USUHS), R. Kaczmarek, K. Chakrabarti, (CDRH) D. Davis (Naval Medical Center, San Diego, CA*).*

Division of Small Manufacturers, International and Consumer Assistance (DSMICA) Overview. Presentation at the Association of Medical Diagnostic Manufacturers (AMDA) Workshop; Rockville, MD.; April 25, 2001; William Sutton

Effect of CNR and SNR on Phantom Image Quality in GE Senographe Full Field Digital Mammography System. Medical Physics, 28, 1247(2001). K. Chakrabarti, R. Kaczmarek, J. Thomas, B. Drinkwine, M. Loscocco.

Effects of CNR and SNR on Phantom Image Quality in the G.E. Senograph 2000D FFDM System. Med. Phys. Vol. 28, No. 6, June 2001 (Abstract); p. 1247. Scientific exhibit presented at the 2001 meeting of the American Association of Physicists in Medicine, Salt Lake City, UT. Medical Physics, Vol. 28, No. 6, June 2001 (Abstract), p. 1247. K. Chakrabarti, R. Kaczmarek (CDRH), J. Thomas, B. Drinkwine (USUHS).

Establishment Registration and Medical Device Listing. CDRH User Facility Reporting Bulletin, Issue 34, Spring 2001; Frederick B. Winston

Estimated Benefits of Proposed Amendments to the FDA Radiation-Safety Standard for Diagnostic X-Ray Equipment. Poster S3, *2001 FDA Science Forum: Science Across the Boundaries,* Washington, DC, February 15-16, 2001 (Abstract no. 189, http://vm.cfsan.fda.gov/~frf/forum01/A189S03.htm; entire paper, http://www.fda.gov/cdrh/radhlth/021501_xray.html). S.H. Stern, S.A. Tucker, R.M. Gagne, and T.B. Shope, Jr.

Equipment Evaluation and QC Test Requirements for Full Field Digital Mammography Systems Invited Presentation at the Digital Mammography Workshop. Nov. 15, 2001, University of California, Los Angeles, CA. Published in Newsletter of American Association of Physicists in Medicine. K. Chakrabarti.

FDA Launches a Tool to Create Effective Medical Device Patient Labeling: Seeks FDA-Industry Partnership in Its Use. Food and Drug Law Institute Update Magazine, Volume 56, Issue 4, Page 13-15. July/August 2001. Silberberg, Paula G.

Global Harmonization. 6 Presentations for the Asian Harmonization Working Party; Malaysia; September 6-7, 2001; Christine Nelson; Judy Strojny

Guidance on Medical Device Patient Labeling; Final Guidance for Industry and Reviewers. http://www.fda.gov/cdrh/ohip/guidance/1128.pdf. April 19, 2001. Silberberg, Paula G.

Hospital Bed Safety Work Group: Highlights. Article in *User Facility Bulletin*, Summer 2001, Issue Number 35, pages 5-6; M. Pijar & M. Wollerton.

The Impact of MQSA On the General Practice of Radiology: Regulated versus Unregulated Environments. Scientific paper and exhibit presented at the *2001 meeting of the American Association of Physicists in Medicine*, Salt Lake City, UT. Medical Physics, Vol. 28, No. 6, June 2001 (Abstract); p. 1257. O.H. Suleiman.

Issues Relevant to Medical Physicists Under MQSA's Final Regulations. Presentation at the *Medical Technology Management Institute workshops*, Feb. 18, June 10, and Sept. 30, 2001. Mourad, W.

Medical Device Regulatory Requirements. Presentations at Hood College, Frederick, MD.; July 11, 2001; William Sutton

Mammography Equipment Evaluations (MEE) Under MQSA's Final Regulations, poster presentation at the *American College of Medical Physicists Meeting* in Hershey, PA, June 4-6, 2001. Mourad, W.

Medical Physicists Role in Full Field Digital Mammography Facilities. Presentation at the *American Association of Physicists in Medicine 43rd Annual Meeting*, July 22-26, 2001, Salt Lake City, UT. Medical Physics, 28, 1243(2001). K. Chakrabarti.

MPRIS Overview and Demonstration. Presentation to *CRCPD*, April 2001. Haran, T.,

MQSA Update. Continuing education presentation for radiologic technologists at the *"A Day of MQSA"* meeting in Atlanta, GA, July 31, 2001. M. Divine.

Nationwide Evaluation of X-ray Trends: Summary of the 1996 Fluoroscopy Survey. Submitted to *CRCPD* for publication. Richard Kaczmarek.

The Nationwide Evaluation of X-ray Trends: Twenty-five Years of NEXT. Scientific exhibit presented at the *2001 FDA Science Forum: Science Across the Boundaries,* (abstract no. 249, February 15-16, 2001, Washington DC. http://vm.cfsan.fda.gov/~frf/forum01/A249S02.htm). D. Spelic, R. Kaczmarek, O. Suleiman, S. Stern.

Navigating the CDRH Website. Presentation at the Medical Alley: Managing your Submissions and Web Presence Workshop; Minneapolis, MN.; December 13, 2000; Frederick B. Winston

Navigating the CDRH Website. Presentation (booth) at the Medical Design and Manufacturing (MD&M) West 2000 Conference; Anaheim, CA.; January 8-10, 2001; Frederick B. Winston; Carol Fedorchak

Navigating the CDRH Website. Presentation (booth) at the Medical Design and Manufacturing (MD&M) East Conference; New York, New York, June 5-7, 2001; William Sutton, Carol Fedorchak

NEXT 2000 Protocol for Survey of Computed Tomography (CT). December 18, 2000. (*CRCPD* publication available at http://www.crcpd.org/intro1.htm, posted August 3, 2001). S.H. Stern, D.C. Spelic, R.V. Kaczmarek.

Optimization of Viewing Conditions and Phantom Image Quality Evaluations on GE DMR and Full Field Digital Mammography (FFDM) System. J. Digital Imaging, 13, 226(2000). K. Chakrabarti, J. A. Thomas, R. V. Kaczmarek, R.W.Waynant and M. F. Loscocco.

Overview of Medical Device Regulations. 8 Presentations for the Canadian Manufacturers; November 14, 2000; Montreal, Canada; Frederick B. Winston, William Sutton

Overview of Medical Device Regulations. 8 Presentations for the Canadian Manufacturers; November 16, 2000; Halifax, Canada; Frederick B. Winston, William Sutton

Overview of the Division of Small Manufacturers, International and Consumer Assistance (DSMICA); Global Harmonization; Mutual Recognition Agreement. Presentations for San Diego Graduate Students; Rockville, MD.; August 27, 2001; Christine Nelson

Overview of Medical Device Regulations; CDRH Electronic Communications Systems. 8 Presentations for the Canadian Government; Ottawa, Canada; May 31, 2001; Ron Parr, Christine Nelson

Overview of Medical Device Regulations; Global Harmonization; Mutual Recognition and Overview of Radiological Health. Presentations for Embassy Seminar (Representatives for Medical Device Industry); Rockville, MD.; October 2000; William Sutton; Christine Nelson, Walter Snesko

Overview of Medical Device Regulations and Quality Systems Presentations at Hood College, Frederick, MD.; July 9, 2001; Frederick B. Winston

Overview of Quality Systems. 17 Presentations for the Government of Singapore; November 2-3, 2000; Singapore; Judy Strojny

Overview of Quality Systems Requirements for Process Validation.. Presentation at the Association for the Advancement of Medical Instrumentation (AAMI) Process Validation Workshop; Dallas, TX; December 13-15, 2000; Christine Nelson

Overview of Quality Systems Regulations. Presentation at the Association for the Advancement of Medical Instrumentation (AAMI) GMP/QS Requirements and Industry Practice Workshop; Sanibel Island, Fl.; October 16-19, 2000; Christine Nelson

Overview of Quality Systems. Presentation at the Association for the Advancement of Medical Instrumentation (AAMI); Frankfurt, Germany; April 23-27, 2001; Christine Nelson

Overview of U.S./EC Mutual Recognition Agreement Medical Device Annex. Presentation at the Medical Design and Manufacturing (MD&M) East Conference; New York, New York, June 6, 2001; William Sutton

Overview of U.S./EC Mutual Recognition Agreement Medical Device Annex. Presentation at the Mass MEDIC Exporting Medical Devices to Europe; New Frontiers and Opportunities Workshop; Boston, MA; June 7, 2001; Christine Nelson

Overview of U.S./EC Mutual Recognition Agreement Medical Device Annex. Presentation at the Regulatory Professional Society (RAPS) and the Department of Commerce Workshop; San Francisco, CA; June 12, 2001; William Sutton

Overview of U.S./EC Mutual Recognition Agreement Medical Device Annex. Presentation at the Medical Alley: Exporting Medical Devices to Europe; Minneapolis MN.; June 14, 2001; Christine Nelson

Overview of Quality Systems. Presentation at the American Society for Quality (ASQ) Workshop; St. Paul, MN.; July 16-17, 2001; Christine Nelson

Overview of U.S./EC Mutual Recognition Agreement Medical Device Annex and Where do IVD's Fit In. Presentation at the FDA/IVD Roundtable, Rockville, MD.; July 24, 2001; Christine Nelson

Overview of U.S./EC Mutual Recognition Agreement Medical Device Annex and Where Do IVD's Fit In. Presentation at the AdvaMed Conference; Washington, D.C., August 23, 2001; Christine Nelson

Overview of the U.S./EC Mutual Recognition Agreement; Presentation at the Japan Association for the Advancement of Medical Equipment (JAMME) International Seminar; August 27-31, 2001; John Stigi

Preference Studies of Workstation Monitor Performance. Proceedings of the *5th International Workshop on Digital Mammography*, June 11-14, 2000, p 612-616, Medical Physics (2001). M.F. Loscocco, J.A. Thomas, K.Chakrabarti, and R.V. Kaczmarek.

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OHIP Staffing and Organization

OHIP includes the Office of the Director, two Staffs and four Divisions.

Office of the Director

- *provides overall leadership and direction*
- *provides administrative and ADP support to all OHIP programs*

Barr, Wes	Garris, Cynthia I.	Sullenger, Deborah C.
Brophy, Linda S.*	Howell, Heather D.	Paras, Peter
Brown, Karen M.	Jans, Ronald G. *	Vitale, Kimberly J.
Dennis, Malcolm M.	Joseph, Lireka P.	
Evans, Clifford D.	Marshall, J. Lowell	

Regulations Staff

- *develops and advises on the preparation of Federal Register documents, including proposed and final regulations and notices*
- *coordinates the preparation, review and processing of responses to citizen petitions*

Cassis, Domini H.	Hanna, Myrna A.	Olson, Jean *
Fischer, Ruth A.	Knight, Jacqueline E.	Sheehan, Joseph M.
Gilmore, Rosa M.	Noland, Bernice E.	Wade, Jennette

Staff College

- *develops and delivers training programs, courses, seminars and lectures*
- *provides satellite telecasts and distance learning programs on a variety of topics*

Brier, Marjory F.	Kramer, Mark D.*	Nakon, Kimberly K.
Gerhold, Susan H.	Morch, Cecile, A.	Sauer, Patrice A.
Hanna, Mary R.	Nesseler, Steven E.	Stewart, Laura L.

* No longer with OHIP as of 3/31/02

Division of Communication Media

- *produces videotapes and teleconferences – from script development to completed program – using in-house resources*
- *delivers satellite productions to CDRH, FDA, and national audiences to promote the mission and messages of CDRH and FDA*

Bailey, David W.
Boyce, Wallace C.
Butler, Bruce E.
Fatula, Robert H.
Frederic, Kenton P.
Jefferson, Arnette L.
Kogok, Richard A.*
McCleary, Robert F.
Monica, Stefan F.
Richards, Barbara A.
Rose, Stanley C.
Scimonelli, Glenn M.
Silverman, Laurie
Vinson, Jeanine M.

Division of Mammography Quality and Radiation Programs

- *implements the Mammography Quality Standards Act, including the certification and annual inspection of all mammography facilities*
- *supports collaborative activities that help protect the public from unnecessary exposure to electronic product radiation*
- *administers the CDRH radiation safety office*

Abernethy, Scott D.
Akey, Catherine L.
Ali, Fiad M.
Appleby, Suzanne E.
Ashby, Kimberly A.
Barr, Helen J.
Belella, Stephanie L.
Bennaugh, Nancy T.
Boyce, Penny R.
Burkhart, Roger L.
Chakrabarti, Kishalaya
Chesemore, Kaye F.
Chissler, Pamela G.
Choy, Joanne K.
Divine, Michael P.
Finder, Charles A.
Flanagan, Margaret
Franke, Kathleen A.
Friend, Wesley A.
Gunzburg, Charles R.
Haran, Timothy J.
Hoage, Patricia A.
Jernigan, Vickie H.
Kaczmarek, Richard V.
McCrohan, John L.
Mourad, Walid G.
Moyal, Albert E.
Pack, Randy F.
Ratskoff, Ellyce F.
Robinson, Denise J.
Shandruk, Petro
Sheridan, Kathleen M.
Spelic, David C.
Stern, Stanley H.
Suleiman, Orhan H.
Thompson, Donald L.
Trammell, Dennis L.
Wandell, Evelyn P.
Wei, Stella D.
Wynne, Nancy M.

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Division of Device User Programs and Systems Analysis

- *provides human factors and systems analysis to reduce use error by evaluating device design, instructions for use, and patient labeling in premarket and postmarket reviews*
- *conducts and advises on qualitative research to help construct risk messages and analyze internal processes*
- *develops information and outreach for health professionals and consumers*

Appel, Sherrie
Cangelosi, Robert J.
Carstensen, Peter B.
Clayton, Carol M.
Houchins, Donna E.*
Lowe, Nancy S.
Kaye, Ronald D.
Kingsley, Patricia A.*
McCracken, Jack E.
Meadown, Susan K.
Mendelson, Laurel S.
Mendelson, Michael
Pijar, Mary Lou
Rachlin, Jay A.
Rooks, Cornelia B.
Sawyer, C. Richard
Scott, Walter L.
Seligson, Edith D.
Silberberg, Paula G.
Thomas, Alvin W.
Tolbert, Margaret T.
Weiss, Ruth
Wollerton, Mary Ann

Division of Small Manufacturers, International and Consumer Assistance

- *educates industry and helps them comply with FDA regulations*
- *educates consumers on medical device and radiation emitting product issues and problems*
- *educates foreign governments on the U.S. regulatory process*
- *supports global harmonization and MRA (Mutual Recognition Agreement) activities*

Alderton, Bonnie J.
Alford, Shirley *
Allen, Gene E.
Auerbach, Jessica B.
Barcome, Althea L.
Bracey, Alfred
Cardamone Thomas E.
Clark, Geoffrey S.
Fedorchak, Carol M.
Freeman, Nancy J.*
Greberman, Melvyn*
Leonard, Nancy M.
Lucas, James E.
Nelson, Marie C.
Park, James J.
Parr, Ronald P.
Pritchard, Lisa M.
Puleo, Joseph V.
Raines, Joyce A.
Rice, Lynne L.
Rodgers, Anthony E.
Snesko, Walter M.
Stellar, Barbara P.
Stigi, John F.
Strojny, Judith L.
Sutton, William M.
Taylor, Tawana V.
Watts, Crystal
Weller, Phyllis S.
Weiner, Deborah C. *
Willis, Marcellus E. *
Winston, Frederick B. *
Yellin, Arthur K.

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OHIP Organization Chart