Office of Health and Industry Programs

Center for Devices and
Radiological Health

Food and Drug Administration

FY2000 Annual Report

FROM THE DIRECTOR

Every day, 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.

When thinking of OHIP's role in CDRH, **Outreach and Education** always come to mind. Outreach and education are in all aspects of our work – whether we are producing teleconferences, training CDRH staff, working with patients and consumers, 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 appropriate 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;
- other 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.

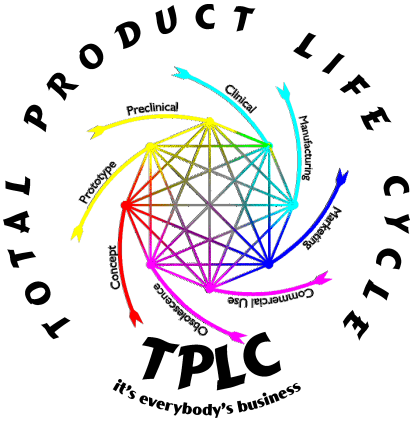
We believe that each of our customers will find programs of interest in our FY2000 Annual Report. We also believe that these programs and our accomplishments reflect changes and improvements that have

been implemented as a result of **OHIP strategic planning**. In 1997, OHIP began implementation of 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 also received many suggestions and comments for changes and improvements. After listening to our customers, 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 fourth 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. We will also be concentrating our efforts on participation in 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.

During the past year, CDRH re-affirmed its **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. Next, CDRH developed a **vision**: ***"Ensuring the health of the public throughout the Total Product Life Cycle."***



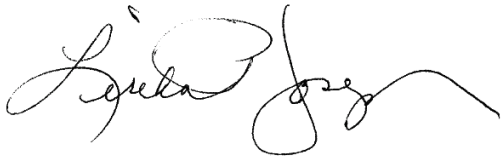
Finally, CDRH has proposed four **strategic goals** to fulfill the vision:

- 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
- to develop **meaningful metrics** to assess our continuing impact on public health and our communication with stakeholders.

OHIP is working with all of CDRH in the first stages of implementing these strategic goals. We are co-leading 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 FY2000 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. As consumers, patients and device-users, we 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, provide extensive information on our website, and collaborate extensively with other CDRH Offices and outside groups to prepare information on important medical device and healthcare issues.

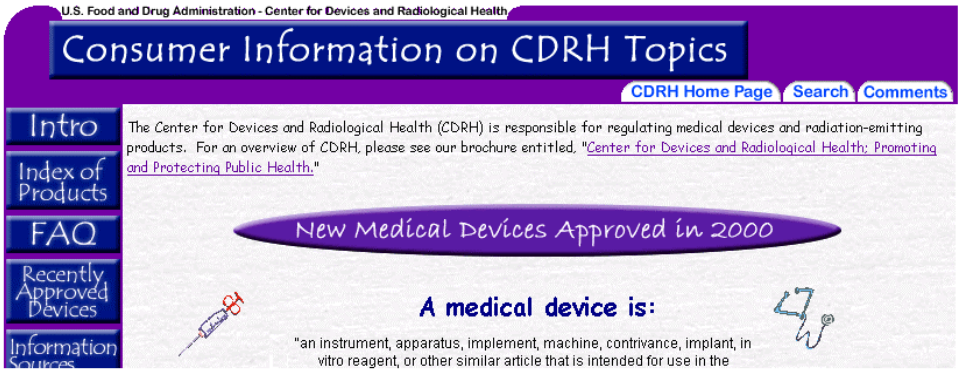
Goals

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 Webpage

Our "Consumer Page" on the CDRH website is one of our most important tools for communicating with consumers and patients. It was created in June 1999 to complement the FDA Consumer Page

http://www.fda.gov/cdrh/consumer/index.shtml



(http://www.fda.gov/opacom/morecons.html). By visiting the CDRH consumer page, you will find:

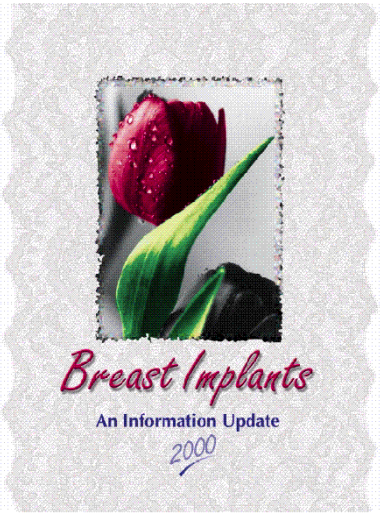
- information on the products that CDRH regulates;
- explanation of the process for obtaining FDA clearance to market a medical device;
- information on newly approved medical devices;
- other consumer literature as well as links to other health related government websites; and
- an easy way to automatically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

Consumer Inquiries

During FY2000, our consumer specialists responded to approximately:

- 4,500 telephone inquiries;
- 2,000 e-mails;
- 700 letters and faxes; and
- 2,700 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.

TMJ Implants

We prepared a webpage to provide consumers with the latest information on approved TMJ implants and those under review. This information is important to patients suffering extreme TMJ symptoms and to their healthcare providers. By visiting the webpage, you will be able to download a copy of the consumer handbook entitled ***"A Consumer Information Update – November 1999."***

http://www.fda.gov/cdrh/consumer/tmjupdate.html

Internet Sales

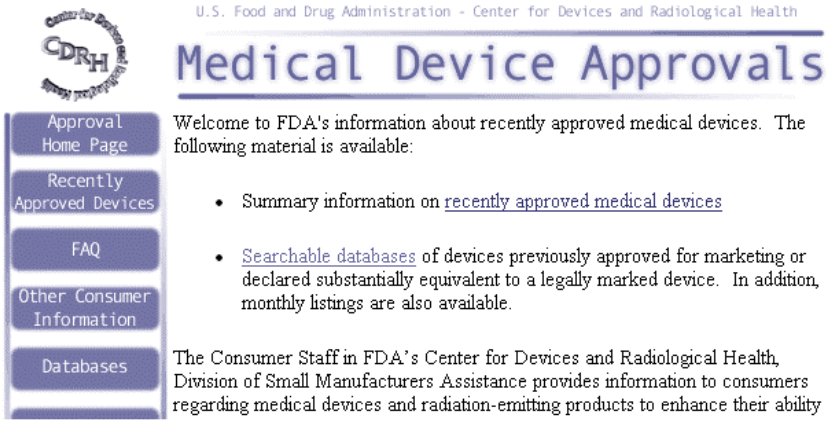
A growing number of medical devices are available for sale on the Internet. We prepared two articles that will provide consumers with information about the benefits and risks they face when purchasing medical devices online. These articles will be available on FDA's webpage **"Buying Medicines and Medical Products Online."**

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

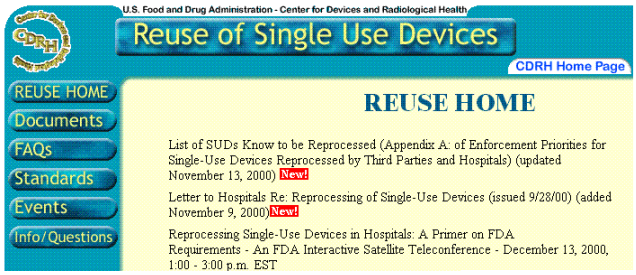
New Device Approvals

In October of 2000, we collaborated with other CDRH Offices to launch a webpage for New Device Approvals. This page includes brief, plain language information on the most recently approved medical devices. Primarily intended for consumers, the page links to other sources of consumer information, Premarket Approval (PMA) databases, and the labeling for these devices.

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



Reuse



Insufficient data exist regarding the safety of reprocessing single-use devices (SUDs). Therefore, on August 14, 2000, FDA announced that it will regulate hospitals and third parties engaged in reprocessing SUDS in the same way that the agency regulates device manufacturers. This policy impacts hospitals, healthcare professionals, and the public. OHIP is working closely with the **CDRH Reuse Steering Committee** to provide up-to-date information on reuse to our stakeholders. Our accomplishments included:

http://www.fda.gov/cdrh/reuse/index.shtml

- Working with the CDRH's Office of Systems and Management, we created a **Reuse Homepage**. It includes CDRH documents on reuse, a listing of standards relevant to reprocessing, frequently asked questions, a calendar of upcoming meetings at which FDA will speak on reuse, copies of previous presentations, and e-mail capability to ask questions or to register to receive updates on reuse. This webpage received more than 50,000 hits in August of 2000, making it the most popular site in FDA.

- A CDRH **interactive satellite teleconference** entitled, "Proposed FDA Strategy for Reuse of Single-Use Medical Devices" was broadcast on November 10, 1999. Industry experts, healthcare professionals, and consumers joined in the interactive discussion on CDRH's proposed strategy on SUDs. The teleconference, produced in our studio, provided a forum for stakeholders and other interested parties to comment and offer alternative approaches to the proposed regulatory strategy. A second teleconference was held December 13, 2000.

- We provided videotaping, artwork, registration, and administrative support for an **open public meeting** on reuse held on December 14, 1999.

- Working with other CDRH staff, a **one-day workshop** on the reuse of SUDs was developed and presented at the annual meeting of the Association for the Advancement of Medical Instrumentation in June 2000.

- A **reuse packet** was mailed to over 6,100 hospitals to inform them about their new responsibilities if they reprocess SUDs. The packet included a cover letter from the Center Director and a copy of the August 14, 2000 guidance document, **"Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals."**

http://www.fda.gov/cdrh/reuse/trifold1.html

- A trifold **reuse brochure** was prepared in a Question and Answer format. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is distributing the brochure. It will also be used at FDA exhibits nationally and will be mailed out in answer to requests for information about the reuse of SUDs. Copies of the brochure are also available on the Reuse Homepage.

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

- To inform consumers about the new CDRH policy on reuse of SUDs, we developed an **informational letter** that was sent to 35 consumer organizations. They, in turn, were asked to inform their membership about the new policy. We also worked with the *FDA Consumer* magazine in publishing **"Reusing Medical Devices: Ensuring Safety the Second Time Around"** (September/October 2000).

Hospital Bed Rails

FDA issued a Safety Alert entitled **"Entrapment Hazard with Hospital Bed Side Rails"** in 1995. Since then, FDA has continued to receive reports of deaths and injuries caused by patient entrapment between the rails of the bed and in the gap between the mattress and side rails. To address this complex problem, we worked with CDRH's **Office of Surveillance and Biometrics** to create a forum for the exchange of information related to patient entrapment associated with hospital beds. The result was the formation of the ***Hospital Bed Safety Workgroup***. The Workgroup includes representatives from the medical bed industry, national healthcare organizations, patient advocacy groups and other federal agencies. As the issues unfolded, possible labeling and compliance issues were identified, so CDRH's Office of Device Evaluation, Office of Compliance, and Office of Science and Technology have participated as well.

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

During FY2000, the Workgroup collaboratively developed a brochure entitled, **"A Guide to Bed Safety."** The brochure discusses bed rail patient safety, considers some of the potential benefits and risks of using hospital bed rails, and gives suggestions on how to meet patients' needs without the use of bed rails. The Workgroup is widely distributing the brochure in hardcopy as well as through the member's websites.

The Workgroup is concurrently addressing several issues related to the entrapment problem and its members are committed to finding a long-term solution. In FY2000, the Workgroup began several projects, including:

- development of a **clinical guidance** describing how clinicians should approach the use of bed rails;
- review of entrapment zones in and around the bed and development of **recommended design limits** for the size of gaps;
- development of an **assessment tool** to determine a bed's compliance with the new recommendations;
- development of a **decision tree** to help in determining whether to keep or replace older beds that do not meet the recommendations; and
- widespread distribution of **information on preventing entrapment** through publication in national journals and presentations at major medical meetings.

Contacts Database

In FY2000, we began testing a "Contacts Database" to support CDRH's outreach programs. The database will be a tool to identify contact information for consumers, health professionals, industry and others interested in medical device issues. The data will be searchable by area of interest and/or affiliation and will provide us with a rapid means of sending information to interested organizations and individuals. When the database is completed, members of the public will be able to use their Web browsers to self register and indicate or change the types of CDRH information they would like to receive.

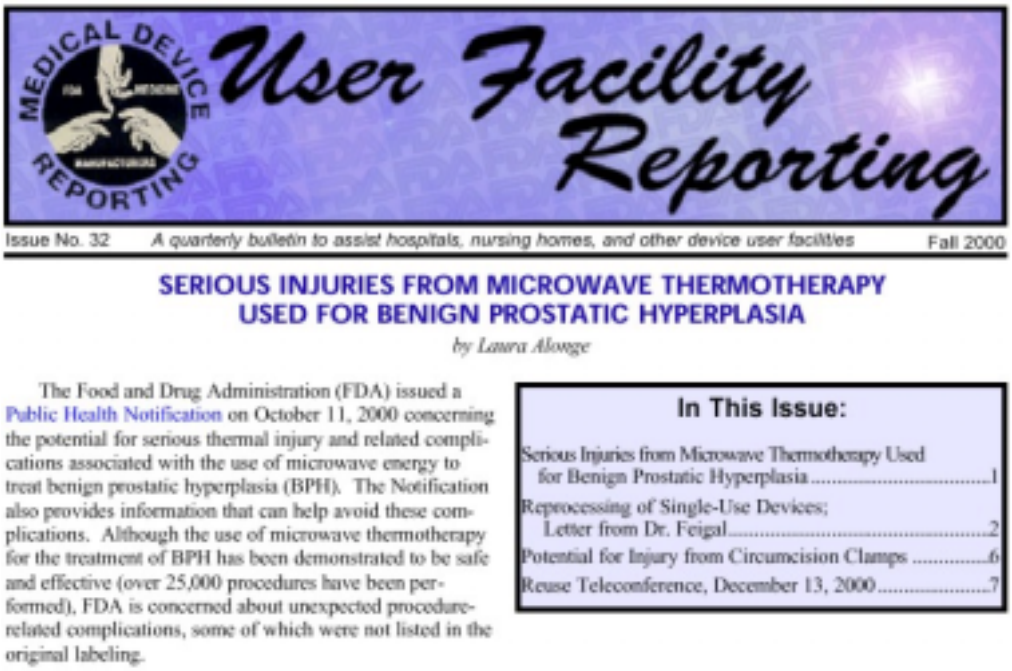
User Facility Reporting Bulletin

In the fall of 2000, we prepared the 32nd 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



MEDICAL DEVICE REPORTING

User Facility Reporting

Issue No. 32 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Fall 2000

SERIOUS INJURIES FROM MICROWAVE THERMOTHERAPY USED FOR BENIGN PROSTATIC HYPERPLASIA

by Laura Alonge

The Food and Drug Administration (FDA) issued a Public Health Notification on October 11, 2000 concerning the potential for serious thermal injury and related complications associated with the use of microwave energy to treat benign prostatic hyperplasia (BPH). The Notification also provides information that can help avoid these complications. Although the use of microwave thermotherapy for the treatment of BPH has been demonstrated to be safe and effective (over 25,000 procedures have been performed), FDA is concerned about unexpected procedure-related complications, some of which were not listed in the original labeling.

In This Issue:

Year 2000 and FDA

The Year 2000 (Y2K) computer "bug" had the potential to affect many of the products that FDA regulates. OHIP served on a CDRH-wide coordinating group responsible for all Y2K issues; played a major role in outreach to health professional organizations, healthcare

facilities, consumers, and manufacturers; participated in the staffing the CDRH Y2K Emergency Operations Team that was on duty during the rollover into the new year; and worked with other CDRH Offices to assure that our "internal" computer systems and databases were Y2K compliant. Our accomplishments included:

- A Public Health Notification letter was developed and sent to the Administrators, Risk Managers, and Biomedical/Clinical Engineers of 67,000 hospitals and healthcare facilities in the U.S. This was followed up with another letter in November 1999 to further encourage facilities to complete their contingency and remediation planning to avoid serious adverse events.

- Information on all CDRH Y2K activities was compiled into a single, comprehensive package. These packages were used in discussions and planning with other government and Congressional staff. Copies were distributed to FDA's nationwide Public Affairs Specialists. Also, distribution was leveraged by working with medical professional organizations for further publication in their journals and newsletters, notices on their webpages, copies to regional, state and local chapters, etc.

- We provided the majority of FDA speakers and coordinated speaker requests for a series of HCFA-sponsored outreach meetings entitled, **"Transition 2000-Y2K Readiness Strategies for Medicare and Medicaid Providers."** The meetings informed healthcare providers about the Y2K issue and methods to prepare for it. Each session featured one speaker from FDA, from a device manufacturer, and from a healthcare facility.

- Through extensive planning, evaluation and documentation, we assured that the database system (MPRIS) for the mammography quality assurance program was Y2K ready.

MANUFACTURER SUPPORT

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 15,000 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.

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.

Small Business Activities

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

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 six FDA field offices, each Center in FDA has a special small business unit.

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 below.

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:** The system used for our call center was updated in FY1999 and work on the system continued in FY2000. As a result of these upgrades, we were able to implement additional customer service features including call queuing. This 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 year round (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 an average of **40,000 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 include access to our e-mail account – dsma@cdrh.fda.gov. We respond to an average of **9,000 e-mail inquiries** per year. Although declining in numbers we still receive an average of **2,500 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 550 requests each year. The link on the left provides instructions on using 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 FY1999 and FY2000 we distributed information on several topics, including a letter to the medical glove industry announcing the Glove Powder Proposal; Y2K leap year announcements; and upcoming workshops/conferences on Reuse of single use devices.

- **Facts on Demand (FOD):** FOD is an automated answering system that allows you to access over 1,200 CDRH publications through your FAX machine. Almost all of the documents available by FOD are more easily available from our webpage. However, FOD is still used by some of our stakeholders. In FY2000 approximately **7,000 guidance documents** were obtained through this system.

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
- 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.

- **Hardcopy:** OHIP is a warehouse to over 1,000 FDA publications. Although approximately 75 percent are accessible electronically, our stakeholders still request hardcopies. Over the last three years hardcopy distribution has decreased by 50 percent. In FY2000, approximately **40,000 publications** were distributed either by hardcopy or on diskette.

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

- **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.

Device Advice Webpage

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.

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

To address these concerns, OHIP designed and implemented ***Device Advice***. 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 for the Code of Federal Regulations (Title 21 CFR).

http://www.fda.gov/cdrh/devadvice/365.html

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 FY1999, we modified topics to include the FDA Modernization Act. In FY2000, we developed two new sections on the Investigational Device Exemption (IDE) that include new information on meetings with FDA, Financial Disclosure of Clinical Investigators, Institutional Review Boards, Quality System requirements and Medical Device Recalls (Corrections and Removals). We are currently expanding the Premarket Approval (PMA) section.

Workshops/Presentations

During FY2000, OHIP partnered with other organizations in presenting eight 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:

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

- Association for the Advancement of Medical Instrumentation (AAMI),
- Canon Communications,
- Regulatory Affairs Professional Society (RAPS),
- Food and Drug Law Institute (FDLI),
- Atlantic Food and Drug Officials (AFDO), and
- Western New York Technical Development Center.

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 Industry and FDA, Medical Glove Guidance Manual. July 30, 1999
- Guidance for Industry and FDA: Regulation of Medical Devices: Background Information for International Officials. April 14, l999
- Draft Guidance for Staff, Industry and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997. June 12, 2000
- Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA). January 6, 1999
- Draft Guidance for Staff, Industry and U.S./EU CABs; Implementation Plan for the MRA between the EU and the USA: Confidence Building Program: Overview, Medical Device Annex, Version 7. June 29, 2000
- Draft Guidance for Staff, Industry and U.S./EU CABs; Implementation Plan for the MRA between the EU and the USA: Confidence Building Program: Procedures, Medical Device Annex, Version 7. June 29, 2000

OHIP plans to update the Premarket Notification 510(k) Regulatory Requirements Manual in FY2001.

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 Third Parties 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 third party program in FY2000:

- the list of eligible devices was updated on June 12, 2000, adding an additional 57 devices;
- in a June 12, 2000 draft guidance document we proposed a pilot program that would make an additional 460 Class II devices eligible for third party review;
- we worked with FDA's Office of Regulatory Affairs to develop an audit program for the Accredited Persons;
- we prepared a Report to Congress on the "Inclusion of Certain Devices Within the Accredited Persons Program - Third Party Review of Clinical Data; and
- we are currently reviewing public comments to the draft guidance document and expect to issue final guidance early in 2001 that will significantly expand the number of devices eligible for the program.

Taken together, updating the list of eligible devices and implementation of the expansion pilot program will represent more than a 300 percent increase in the number of eligible devices.

INTERNATIONAL ACTIVITIES

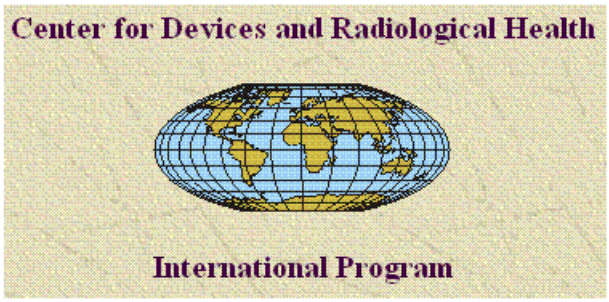
The concept of a **"global marketplace"** is especially true in the case of medical devices. Forty percent of approved device firms have manufacturing facilities abroad. There are approximately 6,000 foreign establishments that export devices to the United States. Device development studies are conducted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

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 FY2000, 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 FY2000, our assistance to foreign manufacturers included:

- answering more than 1,300 telephone inquiries;
- responding to more than 1,100 e-mails and 600 letters and faxes; and
- mailing more than 470 information packages on various medical device issues.

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. Both OHIP and other CDRH staff participate in these activities. During FY2000, they included:

- Brazil – presented a medical device overview;
- People's Republic of China – ten day training program;
- Estonia – presented medical device overview;
- Ghana – presented a medical device overview;
- Japan – six-month foreign visitor training program; and
- Embassy Seminar – presented medical device regulations to several embassy delegations.

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. Recent presentations included:

- India – Medical Gloves and Quality Systems;
- Taiwan – Medical Glove Symposium;
- Mexico – Quality Systems Workshop;
- Russia – Regulating Medical Devices in the U.S.;
- Ukraine – Regulating Medical Devices in the U.S.;
- Akron, OH – International Latex Conference;
- Long Beach, CA International Glove/Barrier Shippers Association; and
- Washington, D.C; PAHO Conference (Pan American Health Organization).

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 worldwide. GHTF members are working to build an international consensus on medical device regulatory policies and practices. The goal is to enhance public health, promote technological innovation, and facilitate international trade. The United States is one of five founding members and a major partner.

OHIP coordinates CDRH participation in GHTF activities:

- In June 1999, the U.S. hosted the 7th annual meeting of the GHTF. The meeting, chaired by CDRH, included more than 300 attendees from all of the member and observer countries. OHIP temporarily reassigned six staff to assist in all aspects of planning and implementing the meeting.

http://
www.ghtf.org

- OHIP led the construction of a freestanding, non-FDA website to facilitate communications among GHTF participants and to serve as a resource to parties interested in GHTF activities.

- OHIP coordinated CDRH participation in the GHTF Annual Conference held in Ottawa, Canada on September 18-22, 2000.

- OHIP participated in the annual conference of the GHTF Study Groups to discuss forthcoming plans for: operations of the study groups; procedures for document review; and discussion of an education campaign for the products of the GHTF.

In FY2001 we will develop procedures to obtain stakeholder comments and FDA concurrence on all GHTF documents.

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 implementation of the medical device annex of the MRA. Our accomplishments include:

- Together with the Commission for the European Community, we prepared the First Annual Report on the Medical Device Annex to the U.S./EC Mutual Recognition Agreement. The report includes background on the MRA and a chronology of accomplishments from May 18, 1998 through December 1, 1999.
- During FY2000, CDRH/OHIP participated in five stakeholders meetings to provide an update on progress of the MRA including confidence building activities and to allow for discussions and clarification.
- OHIP issued two draft guidance documents for public comment on October 3, 2000. These draft guidance documents are based on draft documents prepared jointly by the EC and the FDA (Version 7, June 29, 2000). They describe confidence building activities and related procedures to realize the intention of the MRA in general.

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. Since October 2000, OHIP's Director has served as chairperson of the Council. The Council is pursuing a variety of initiatives to assure and enhance the cost-effectiveness and public health benefits of CDRH's 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 minimum 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). The facilities that meet quality standards are then issued an MQSA certificate. 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-credentialed 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 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

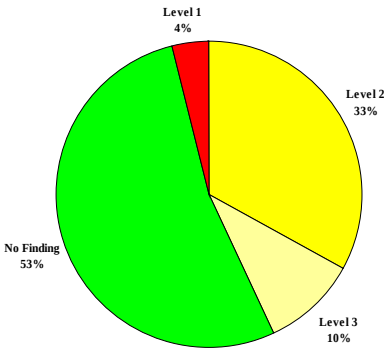
Approximately 10,000 **certified mammography facilities** operate in the United States, including federal and military. To be certified to conduct mammography, each facility must be accredited by an **FDA-approved accreditation body**. At the end of FY2000, the five accreditation bodies and the number of facilities they accredit were:

American College of Radiology (9,178)
State of Arkansas (71)
State of California (464)
State of Iowa (134)
State of Texas (85)

To assure mammographic quality, mammography facilities undergo **annual inspections** by FDA credentialed inspectors[1]. Nearly 10,000 inspections take place each year. Preliminary results from FY2000 are shown in Figure 1:

- fifty-three percent of the mammography facilities had **no adverse findings;**
- only four percent of the inspections found **the most serious type of problems** ("Level 1 finding") – facilities must

Figure 1. Preliminary FY 2000 Inspection Results



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

[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.

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

correct problems or lose their certification; and

- since the beginning of the MQSA program, significant problems at four 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 left). 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.)

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 FY2000, FDA completed audits of all its certified inspectors.

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 FY2000 are listed below.

Digital Mammography: CDRH's Office of Device Evaluation approved the first Full Field Digital Mammography (FFDM) system for commercial use on January 28, 2000. Digital mammography allows interpreting physicians to quickly and easily manipulate the images and may reduce the need for some women to have additional exposures. Digital units are exempt from MQSA accreditation requirements until the accreditation bodies have developed a process

for accrediting them. However, in order for a 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"): The States as Certifiers (SAC) Demonstration Project is in its third year. In this project, certain key MQSA responsibilities have been transferred successfully to the States of Illinois and Iowa. The SAC program authorizes qualified States to certify mammography facilities within their jurisdiction, conduct inspections, and enforce the MQSA quality standards under FDA oversight. The proposed rule to institutionalize the program on a national scale was published on March 30, 2000. Final regulations are expected in 2001.

Comprehensive electronic guidance: During FY2000, all MQSA regulatory guidance materials and documents were compiled into the **MQSA Policy Guidance Help System (PGHS)**. For the first time, mammography facilities and other interested parties have access to a comprehensive online resource accessible through MQSA's webpage. Previously, this information was only available in ten separate documents and there was no way to search through all of the documents at once. 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

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 FY1999-2000, NMQAAC met to discuss the following important issues:

- issuance of guidance on the MQSA final regulations;
- FDA's role in evaluating the competency of mammography personnel;
- implementation of a demonstration project evaluating the feasibility of performing less than annual mammography facility inspections in high quality facilities; and
- certification of Full Field Digital Mammography facilities.

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 baseline 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, 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. 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 this page shows the status of the 1995 through 2001 *NEXT* surveys. During

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 **fluroscopic CT****, procedures incorporate major improvements in survey methodology (electronic submissions, etc.), data entry started.
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.

* 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.

each survey, various types of information are 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

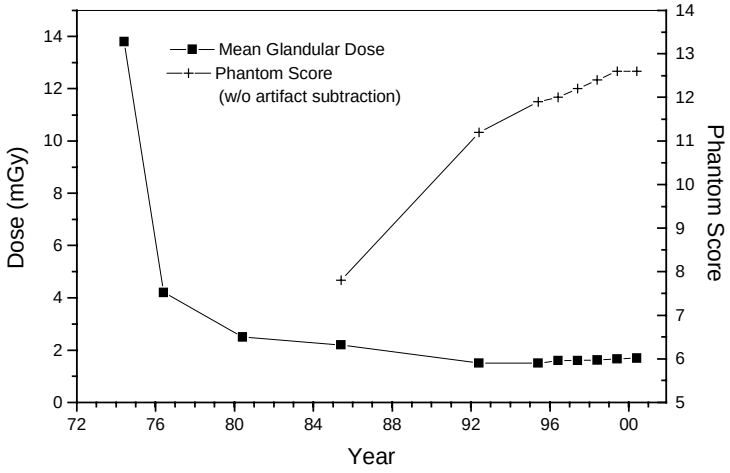
OHIP prepares a comprehensive report on a given year's data that includes tabulations of the results and graphical summaries. These reports are then published by the CRCPD. CRCPD publishes the reports without conclusions or other analyses in order to make the reports widely available and as timely as possible. Instead, the data are available to the radiation community for their own in-depth analysis and publication in technical journals.

During FY1999 and FY2000, OHIP published six analytical works on the *NEXT* data in peer-reviewed journals and conference proceedings. These included articles in Radiology, the Journal of the American Dental Association, and the Proceedings of the Thirty-fifth Annual Meeting of the National Council on Radiation Protection and Measurements (NCRP)[2]. A review of the *NEXT* findings was published in a special edition of the international journal, Applied Radiation and Isotopes in January 1999 (Vol. 50, pp. 247-259).

The uses of *NEXT* data and its impact are illustrated in the figure on the next page. Data points through 1992 were generated using data 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

[2] Specific references as well as a list of *NEXT*-related presentations are included in the Appendix of this report.

well as FDA's MQSA regulatory program in 1992. The MQSA inspection uses the *NEXT* developed protocol for determining the radiation dose and phantom image quality score.



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

As a result of *NEXT* and these actions, the radiation dose women receive from mammography is generally lower and the image quality is 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.

Overall, *NEXT* has established **<u>baseline data and long-term trends</u>** 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); and

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

TEPRSSC

The Technical Electronic Products 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. During FY1999-2000, TEPRSSC discussions included the following important health and safety issues:

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

- Electronic Article Surveillance Systems and their potential interference with implanted medical devices;
- the use of ionizing radiation to scan people for concealed weapons and other contraband;
- wireless medical telemetry and interference with medical devices;
- the development of sunlamp standards associated with international harmonization;
- proposed rulemaking for lasers;
- proposed amendments for computed tomography fluoroscopy;
- *NEXT* computed tomography survey;
- radiological health re-engineering; and
- ultrasound diathermy.

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;
- DOE (Department of Energy);
- HRSA (Health Resources and Services Administration); and
- NASA (National Aeronautics and Space Administration).

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 radiation surveys in these facilities with FDA's Office of Regulatory Affairs (ORA). 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

Goals

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

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 100 surveys were completed in FY2000. Most were conducted in 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. OHIP staff serve as CDRH's Radiation Safety Officer (RSO). The RSO has responsibility for CDRH's radiation safety program to protect the health and safety of all employees and to assure 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 FY1999-2000, the RSO and OHIP accomplished the following:

- developed and implemented a new CDRH Policy for physical security in rooms where radioactive material is stored;
- updated a CDRH policy on the decommissioning[3] of CDRH buildings where radioactive materials were stored or used, and worked with other CDRH staff in decommissioning the Wilkins Avenue building;
- updated CDRH's inventory of electronic generators of ionizing radiation and non-ionizing radiation used for research purposes;
- 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;
- conducted the annual training required of all licensed materials users, as well as training on safety procedures for other CDRH and contract janitorial staff who occasionally work in radiation laboratories;
- facilitated and chaired quarterly radiation safety committee meetings;
- amended CDRH's Nuclear Regulatory Commission (NRC) license from a broad to a specific license;
- disposed of approximately 200 sealed radioactive sources no longer needed for CDRH research programs, four 55 gallon drums of dry waste, and 40 carboys[4] of liquid radioactive waste;
- instituted a program of bi-monthly disposal of liquid radioactive wastes; and
- successfully passed the NRC inspection in early FY2000.

[3] Decommissioning is the formal process for declaring a building "free of radiation hazards" and available for public use.

[4] A "carboy" is a term used for liquid radioactive waste containers. Each carboy typically holds from 5 to 15 gallons of liquid.

During FY1999 and FY2000, 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 or procedural violations 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
Containers of liquid radioactive waste	30	40	6	1
Sealed Drums of dry radioactive waste	3	3	0	0
Drums of "Decay-in-Storage" waste[5]	3	3	1	1
Sealed radiation sources[6]	200	200	3	3

[5] "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.
[6] Does not include generally licensed sources that do not require NRC (Nuclear Regulatory Commission) approval.

REDUCING USE ERROR

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

A November 1999 Institute of Medicine report, **"To Err is Human – Building a Safer Health System,"** estimated that as many as 98,000 people die in any given year from medical errors that occur in hospitals, which is more than die from motor vehicle accidents, breast cancer, or AIDS. Though many of these errors are not related directly to medical devices, some are, and it highlights the importance of addressing errors with the use of medical devices.

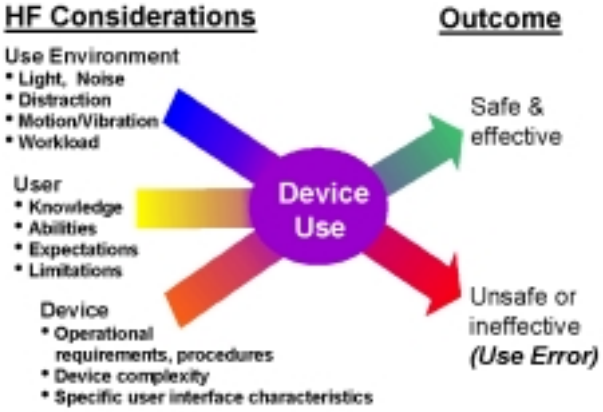
FDA recognizes that most use errors with medical devices are not "inevitable human error." Rather, they are largely influenced by device design and device labeling. OHIP seeks to promote the safe and effective use of medical devices through our Human Factors program, labeling efforts, and patient safety 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 CDRH's premarket, postmarket, and field-inspection regulatory missions.

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

- **Guidance:** In July 2000, we issued a final guidance document, **"Medical Device Use Safety: Incorporating Human Factors Engineering into Risk Management."** It describes how to incorporate Human Factors techniques and theory into risk management during the design and development of medical devices so that intended users are able to use medical devices safely and effectively throughout the product life cycle. It also facilitates review of new device submissions and design control documentation.

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.

- **Webpage:** We posted a webpage on Reducing Use Error. This page provides CDRH staff, manufacturers and others with comprehensive information on the role that Human Factors and labeling can play in reducing use error.

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

- **Device Reviews:** We assisted CDRH's Office of Device Evaluation by providing Human Factors reviews for selected medical device approval applications.

- **Patient Checklist:** We developed a one-page checklist, **"Make Sure the Medical Device You Choose Is Designed for You."** Healthcare professionals and patients can use the checklist to choose a medical device that is best for the patient. It can easily be modified to focus on particular devices for certain patient groups (e.g., patients with arthritis, diabetes, or heart disease). The checklist poses questions in three major categories for patients and healthcare professionals to discuss:
  - Do **you** have limitations that can affect your use of the device?
  - Is the device right for the **environment** where you plan to use it?
  - Are there **device characteristics** that can affect its use?

http://www.fda.gov/cdrh/useerror/you_choose_checklist.html

- **Teleconference:** On June 21, 2000, we broadcast a live, interactive satellite teleconference for risk managers and other healthcare providers. This video teleconference used a case study format in which a panel of risk managers described actual incidents of medical error. They then analyzed the incident for the audience, including lessons to be learned about preventing and managing errors. The audience also had the opportunity to question the panelists. CDRH's Office of Surveillance and Biometrics assisted us in co-sponsoring this teleconference with The American Society for Healthcare Risk Management (ASHRM).

- **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 more fully understand use error in clinical practice. In July 2000, we completed the first phase in which we interviewed Nurses and Risk Managers who are 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 the next phase, we will analyze the results and develop models to help us better understand and prevent use error.

- **International Standards:** OHIP is playing a critical role in the development of national and international standards that will deal with Human Factors considerations and medical devices (see inset). With these efforts, we are updating existing standards and providing new standards that better explain how manufacturers should perform their design activities in an orderly manner that takes into account the needs of device users. When these standards are in place, they will serve as additional Human Factors guidance for the design of medical devices.

Human Factors-Related Standards under Development

- **ANSI/AAMI HEXX: 2000 2CDV**: *Volume 1, HF Design Process* and *Volume 2, HF Design Principles and Specifications*
- **IEC 60601** *Safety Standard for Electrical Medical Devices*
- **IEC 60601-1-6** *Collateral Standard: Usability: analysis, test, and validation of human factors compatibility*
- **ISO 14791** *Risk Management*

- **Inspections and Site Visits:** We are working with FDA's Office of Regulatory Affairs to better understand the types of educational and regulatory information we need to provide manufacturers. In FY2000, we accompanied FDA inspectors on several GMP/QSR (Good Manufacturing Practices/Quality System Regulation) inspections of medical device manufacturers. During directed inspections, we observed investigations of actual adverse events related to

use error. During design control inspections, we gained insight into the extent to which manufacturers were able to include "user needs" and Human Factors in their documentation design controls. We helped inspectors understand how to identify and assess human factors issues contained in complaint handling systems and device history files. Additionally, we received practical feedback from the inspectors on the time and resources required for them to evaluate a manufacturer's Human Factors processes.

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

- **Human Factors Brochure:** In FY2000, we produced a brochure that was distributed widely at professional meetings. The brochure briefly introduces Human Factors in medicine, lists CDRH Human Factors activities, and gives other information resources.

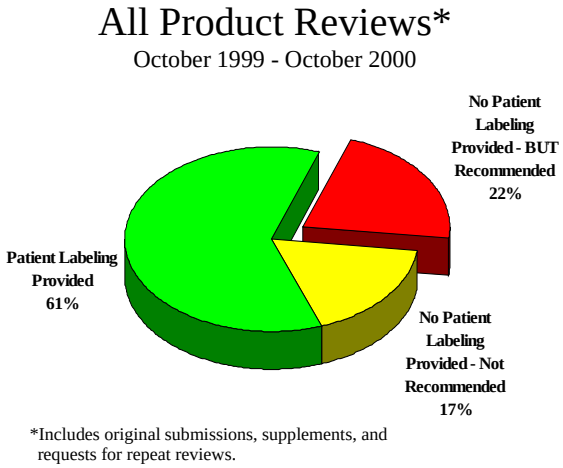
Labeling

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 non-PMA submissions where CDRH's Office of Device Evaluation feels patient labeling needs careful attention. This was the fourth year of an inter-Office agreement for these reviews. Our purpose is to recommend improvements to patient labeling so that the intended patient or caregiver will better understand both the instructions for use and the risk-benefit information provided in the labeling. In cases where patient labeling is not submitted, 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 FY2000, we reviewed approximately 90 submissions.

Out of all reviews, 61 percent of submissions contained patient labeling. **Twenty-two percent did not contain patient labeling, but we recommended that patient labeling be written.** Seventeen percent did not have patient labeling and did not require labeling for the patient.



- Under a contract with a Duke University expert, Model Patient Labeling for Medical Devices is undergoing **Usability Testing**. The model patient labeling for medical devices was developed previously and includes recommendations for both risk/benefit information and instructions for use. This contract will compare labeling developed according to our model with the current labeling for a variety of devices. The results will strengthen the scientific foundation for the CDRH policy on labeling.

- A **Draft Guidance on Medical Device Patient Labeling** was issued. The guidance seeks to assist manufacturers and CDRH reviewers in their review and evaluation of medical device patient labeling. More understandable and usable labeling is essential for patients, family members and other lay persons caring for patients. The draft guidance was issued on March 3, 2000 for public comment. The final guidance will be issued early in 2001. Preparations are underway to provide training for CDRH reviewers on the final guidance.

- A **poster presentation** entitled **"A Patient's Path to Understanding Medical Devices"** was presented at two national meetings of healthcare professionals and stakeholders in promoting patient safety. The presentation details the steps a patient should take to get complete information, including labeling, about a medical device. We developed a brochure based on the poster and are working to make similar information available on our webpage.

- We are working with an FDA-wide Labeling Group to share labeling and advertising/marketing research and policy information. Working with outside experts and stakeholders, the group is also exploring options for leveraging activities in labeling and advertising.

Also during FY2000, OHIP used qualitative research to evaluate labeling-related issues associated with two CDRH programs. Qualitative research attempts to discern a target population's perceptions, opinions, beliefs and attitudes on a given issue or topic. Focus groups are one of the most familiar tools used in qualitative research. The two CDRH programs were:

- **Focus Testing for Tampons:** Working with CDRH's Office of Device Evaluation in November 1999, we coordinated a focus group study consisting of six groups to look at tampon usage and patient labeling. These groups explored:
  - how women select tampons and the role of labeling in tampon selection;
  - women's understanding of the tampon label hierarchy and how they interpret the absorbency terms "light" and "ultra"; and
  - what women know about Toxic Shock Syndrome (TSS) and the effectiveness of patient labeling in providing TSS information.
- **Focus Testing for Latex Gloves:** We helped the CDRH Glove Powder Regulation Working Group in identifying and securing a qualitative research contractor and we provided consultation on the preparation and conduct of focus groups to evaluate warning messages for glove labeling.

Patient Safety

In response to the November 1999 Institute of Medicine (IOM) report on medical error, federal agencies including FDA were asked to participate in a Quality Interagency Coordination Task Force (QuIC) to address concerns raised in the IOM report. The goal of QuIC is to ensure that all federal agencies that purchase, provide, study, or regulate healthcare services are working in a coordinated way toward the common goal of improving the quality of healthcare. QuIC prepared a report to the President entitled **"Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact."** The report lists over 100 actions for federal agencies. Staff from OHIP and from CDRH's Office of Surveillance and Biometrics coordinated CDRH's responses for inclusion into the QuIC report. As a result, the action list includes several items pertaining to medical devices.

We continue to serve on three QuIC workgroups to ensure implementation of the federal action items addressing patient safety:

- **Patient and Consumer Information** – addressing barriers to effective communication with patients about quality. This includes providing federal agencies with information to more effectively help people understand quality issues and how their choices influence the quality of the services they receive. It also includes developing a common vocabulary, or set of terms, for federal agencies to use in communicating with patients and consumers about quality.
- **Improving Information Systems** – exploring how to augment federal efforts to develop a standardized language that will enable computerized comparisons of quality across federal agencies. The workgroup is also examining the potential uses of telemedicine for helping to improve quality of care.
- **Errors Workgroup** – ensuring the implementation of all action items by federal agencies and, where appropriate, providing a forum for collaborative projects among federal agencies.

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 FY2000, 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 20 citizens petitions, with no overdue petitions; and
- publish 100 Federal Register documents. Some of the most significant documents included:
  - **Postmarket Surveillance.** This proposed rule would establish 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 published 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.

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

- **States as Certifiers.** This proposed rule 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).
- **Lay Summaries.** CDRH issued a final rule to require mammography facilities to send patients "lay summaries" explaining the results of their examination. This rule implemented a provision of the Mammography Quality Standards Reauthorization Act.
- **The "Six Year" Rule.** CDRH issued final guidance on implementation of section 216 of FDAMA. This section allows FDA to use data from Premarket Approval (PMA) applications approved more than six years earlier when approving or reclassifying devices.
- **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 withdrew its proposal to require a mandatory standard for apnea monitors. Instead, CDRH issued a draft 510(k) guidance document for apnea monitors and proposed to make this guidance document a special control for these devices.
- **Tracking Amendments.** CDRH issued a proposed rule to implement the CDRH amendments to the tracking provisions of the Federal Food, Drug, and Cosmetic Act.

The regulation workload in FY2000 was consistent with that of previous years. The number of staff assigned to the regulation process has steadily decreased. However, 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 FY2000, OHIP:

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

- Worked with the GGP coordinators across FDA to develop a regulation on GGPs that was published on September 19, 2000. A refresher course was given to update all staff on the revised procedures and changes resulting from the final regulation.
- Created and updated a comprehensive database of all guidance documents issued by CDRH – currently, more than 607 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.
- 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 as well as quarterly updates.

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.
3. To provide advice and assistance to manufacturers in writing labeling in Plain Language.

During FY2000, OHIP:

- continued to sponsor plain language and writing/editing courses for CDRH staff – since these classes were first offered in FY1999, more than 250 staff have participated in classes for
  - regulations writers,
  - letter writers,
  - support staff,
  - reviewers and non-reviewers;
- worked with CDRH's Office of Surveillance and Biometrics to issue CDRH's first proposed rule written in plain language; and,
- 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.

FDAMA

OHIP serves as the CDRH coordinator for implementation of the FDA Modernization Act of 1997 (FDAMA). Each of the CDRH Offices are 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 FY2000, 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:

- Sixty-nine different **courses** were presented for more than 2,600 "students."[7] 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 several weeks.

[7] There were approximately 1,050 CDRH employees in FY2000. 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.

- Sixty-eight **seminars** were held in FY2000. 2,000 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. The speakers at our seminars are national and international experts from FDA, other government agencies, universities, and from the medical device industry.

- We designed, developed, and implemented a new training program for CDRH support staff. Called **Pathways**, it is a voluntary three-year training and development program that will provide support staff with the knowledge and skills needed for their continued professional development. Twenty-one participants from across CDRH are currently enrolled. Applications are accepted on an ongoing basis.

Examples of FY2000 Training for CDRH Staff

- 12-week **Biocompatibility** course included lectures in each type of Biocompatibility test along with case studies to help reinforce the information and policy presented.

- 6-session course in **CDRH software policy and review principles** presented in partnership with CDRH's Office of Device Evaluation and Office of Science and Technology.

- The **Clinical Trials Course** was revised and offered in modular format.

- **Advanced Risk Communication** training was provided as a follow-up to the 2000 FDA Science Forum.

- A monthly series addresses **Quality Systems Issues**, including topics such as "Six-Sigma," Quality and Business Management, and the Quality Management Program instituted by FDA's Office of Regulatory Affairs.

- Held the 5th offering of **Tissue Engineering** to provide cutting-edge information in this technology.

- Collaborated with the Radiological Health Reengineering Team to provide **Training in Radiation Law/Basic Radiation**.

- Webcasts, with recurring playback schedule on issues including: **The Least Burdensome Provisions of FDAMA**, **CDRH Leveraging** and **Developing a Strategic Vision for the Center**.

- Satellite Teleconferences on issues ranging from **Best Practices in Treating Acute Myocardial Infarction; Plain Language, the Write Idea;** to **Time Management**.

- We increased our commitment to explore and implement alternative training technologies that complement traditional instructor-led classes and seminars. Teleconferences, CDROMS, web-based online training, and webcasts allow us to provide greater diversity in the topics that we offer as well as greatly increasing each employee's access to training.

- More than thirty-two **satellite teleconferences** were broadcast throughout CDRH.

- In cooperation with CDRH's Office of Systems and Management, we implemented **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.

- We provided four **multimedia CDROM-based courses** in Anatomy and Physiology.

- CDRH became the first FDA Center to make **SkillSoft** Corporation's Critical Skills Library available for CDRH-wide use. After pilot testing the program in FY2000, this online (web-based) training became available to staff in October 2000. The training library includes over 300 courses in topics such as Management, Supervision, Teamwork, Customer Service, Project and Time Management, Communication, Human Resources, Finance, and Knowledge Management.

- Finally, our **Playback Schedule** has given CDRH employees greatly increased access to training at their desktops and on their own schedule. Webcasts, seminars, courses and teleconferences are being recorded and then "archived" for later playback. Each week, our website on CDRH's Intranet provides employees with a schedule of events that includes live classes and seminars and playbacks of previously recorded events.

360° Training Program

We formed a training team to implement a continuous improvement program, known as the 360° training program. The purpose of the program is to ensure that courses are more rigorously designed, developed, delivered, and assessed to ensure their quality and relevance to program goals. This allows us to "close the loop" between training needs assessment and course development/delivery. In FY2000, the training team focused on needs assessment, training impact assessment, training transfer, performance/evaluation measurement criteria, and benchmarking.

Needs Assessment

We are working to ensure that our training programs meet the needs of all CDRH employees, including supervisors, professionals and support staff. During FY1999, we conducted an extensive "needs assessment." Many important training needs emerged and we began addressing them in FY2000. Examples include:

- In FY2000, we developed a new course, **Case Studies for Non-Managers**, that prepares employees to work productively and proactively on CDRH programs. This seven-session course began during fall 2000.

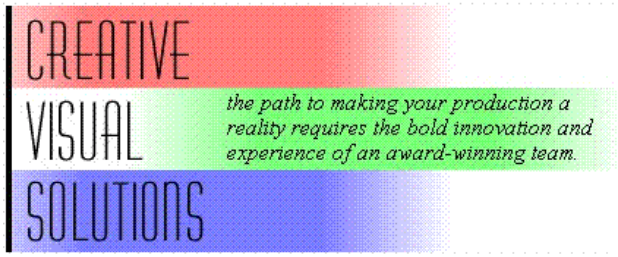
- Some of CDRH's most important training needs identified were communications, interpersonal and professional development skills training. We formed active partnerships with each of CDRH's Offices, greatly increasing our course offerings.

- We instituted a continuous needs assessment program by scheduling open houses for all CDRH Offices. The purpose of conducting these open houses is to update the information from the FY1999 needs assessment and to promote the continued discussion of training needs by CDRH employees.

Benchmarking

To learn more about how other organizations provide training for their employees, we benchmarked against ten government agencies and private organizations. Our goal was to identify, understand and adapt outstanding training practices and processes found outside of CDRH. In comparison with other organizations, we confirmed that we are doing an excellent job in a number of key areas, including needs assessments and training evaluations. We also identified a number of "best practices" that can be implemented in CDRH.

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 FY2000;

- 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 27 medical device panel meetings;
  - we provided video documentation of 35 critical CDRH meetings; and
  - we downlinked 83 programs via CDRH's fiber-optic, closed circuit channel for staff training and professional development available to all CDRH and

CBER (FDA's Center for Biologics Evaluation and Research) employees.

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

In February 2000 we launched a comprehensive website for our television and 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.

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 FY2000:

- We began exploring opportunities to deploy an HHS-wide, multiple channel, digital service that will give all PHS

agencies direct links to each other and to their constituents, including a direct link to consumers.

- 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.

- Along with the Health Resources and Services Administration, we participated in a pilot project to disseminate television programming via digitally compressed satellite broadcasts to personal computers.

- Fiber optic cabling was installed to provide both distribution and programming services to the new Center for Veterinary Medicine (CVM)/Center for Food Safety and Applied Nutrition (CFSAN) College Park facility.

- A long-standing partnership with the Food and Drug Law Institute (FDLI) continued to provide national training and information dissemination on issues critical to CDRH and other FDA Centers.

- 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.

A Patient's Path to Understanding Medical Devices. Presentation (poster) at the American Academy of Family Physicians/Society of Teachers of Family Medicine Annual Conference on Patient Education; and at the FDA/National Patient Safety Consumer Forum. John J. Crowley, Patricia A. Kingsley.

CDRH Hot Topics for 2000 and ***Navigating and Retrieving Valuable Information from the FDA Website.*** Presentation (booth) at The Medical Design and Manufacturing (MD&M) East 2000 Conference, New York, NY. William M. Sutton, Carol M. Fedorchak.

CDRH Overview. Presentation at Baltimore District Conference, Annapolis, MD. August 21, 2000. Nancy M. Leonard.

CDRH Webpage and ***Overview of Medical Device Regulations.*** Presentations at the Pan American Health Organization (PAHO), Washington, DC. October 22, 1999. Frederick B. Winston, Thomas E. Cardamone, William M. Sutton, John F. Stigi.

Central Venous Catheter Tip Placement and Catheter Occlusion. American Journal of Surgery; 108(1):78-79 (2000). Walter L. Scott.

Challenges for FDA (in regard to electronic records and electronic signatures). Presentation at the Drug Information Association Conference, Washington, DC. September 13, 2000. Christine Nelson.

Condoms-Standards and Regulations. Presentation at the International Glove/Barrier Shippers Association, Long Beach, CA. May 1, 2000. Arthur K. Yellin.

Current Issues in Federal Sector Healthcare Law. Presentation at Medical Jurisprudence of the Uniformed Services University of the Health Sciences Section of Medical Jurisprudence and the Air Force Judge Advocate General School, Bethesda, MD. May 2000. Melvin Greberman.

Doses in Radiology: How and Why They Vary. Presentation at the Annual Meeting of the National Council of Radiation Protection (NCRP), Bethesda, MD. Orhan H. Suleiman.

Electronic Imaging in the Health Care Enterprise: Roles of the FDA. Presentation at the American Medical Informatics Association (AMIA), Washington, DC. November 1999. Melvin Greberman.

Electronic Records and Signatures. Presentation at AdvaMed Workshop, Washington, DC. September 26-27, 2000. Christine Nelson.

FDA Guidance for I. V. Catheter Market Clearance. The Journal of Vascular Access Devices; 5(3):18-19 (2000). Walter L. Scott.

FDA International Activities and ***FDA/EU Mutual Recognition Agreement Update.*** Presentations at the Global Harmonization Task Force (GHTF) Annual Conference, Ottawa, Canada. September 2000. Christine Nelson.

Human Factors Considerations in Infusion Pump Use Safety. Presentation at the Infusion Pump Workshop, Minneapolis, MN. September 26-28, 2000. John J. Crowley, Ronald D. Kaye.

Human Factors in Medical Device Use Safety: How to Meet the New Challenges. Presentation at the International Mini-Symposium on Global Challenges for Human Factors and Medical Systems, Conference of the International Ergonomics Association and the Human Factors and Ergonomics Society Annual Meeting. August 2000. Susan K. Meadows, Ronald D. Kaye, C. Richard Sawyer, Peter B. Carstensen, Cornelia B. Rooks.

IDE Process and Expected Information in Protocols. Presentation for the U.S. Army Medical Material Command, Bethesda, MD. October 29, 1999. Frederick B. Winston.

Making Medical Devices Safer. Nursing Spectrum; 11A:21, 20 (1999). Patricia A. Kingsley, C. Richard Sawyer, Peter B. Carstensen.

Mammography in the 1990's: The United States and Canada. Radiology; 210:345-351 (1999). Orhan H. Suleiman, David C. Spelic, John L. McCrohan, Gordon R. Symonds, Florence Houn.

Medical Glove Regulation Overview and ***Quality System Regulation Overview.*** Presentations at the India Latex Conference, Wellington Island, Cochin, India. December 6-8, 1999. Arthur K. Yellin, Anthony E. Rodgers.

Medical Device Update. Presentation at the Latin American Conference, Alexandria, VA. July 11, 2000. Christine Nelson.

Navigating and Retrieving Valuable Information from the FDA Website. Presentation (booth) at The Medical Design and Manufacturing West 2000 Conference, Anaheim, CA. January 17-20, 2000. William M. Sutton.

NEXT Update. Presentation at the 31st Annual Meeting of the Conference of Radiation Control Program Directors, Louisville, KY. David C. Spelic.

Optimization of Viewing Conditions and Phantom Image Quality Evaluations on GE DMR and Full Field Digital Mammography System. Journal of Digital Imaging Vol 13, No.2, Suppl 1, May 2000, pp 226-227. Kishalaya Chakrabarti, Jerry Thomas, Richard V. Kaczmarek, Ronald W. Waynant, Michelle Loscocco.

Overview of the Division of Small Manufacturers Assistance. Presentation at the Association of Medical Diagnostic Manufacturers Meeting, Rockville, MD. September 20, 2000. William M. Sutton.

Overview of FDA; Design Controls Process Validation; Acceptance Activities; and ***Corrective and Preventive Actions.*** Presentations at Association for Advancement of Medical Instrumentation GMP Quality System Requirements and Industry Practice Course, Roslyn, VA. February 28-March 2, 2000. Christine Nelson.

Overview of Medical Device Regulations and ***Export Requirements.*** Presentations at Department of Commerce Seminar, Washington, DC. June 29, 2000. Lynne L. Rice, Thomas E. Cardamone.

Overview of US and European Medical Device Regulations. Presentation at Department of Commerce Seminar, Russia and Ukraine. April 1-9, 2000. Lireka P. Joseph, Lynne L. Rice.

Overview of the Quality System Regulations. Presentation at the Quality Systems Workshop, Mexico City, Mexico. April 11-12, 2000. Joseph V. Puleo, Christine Nelson.

Patient Dosimetry Activities in the United States: the Nationwide Evaluation of X-ray Trends (NEXT) and Tissue Dose Handbooks. Applied Radiation and Isotopes 50 (1999) 247-259. Orhan H. Suleiman, Stanley H. Stern, David C. Spelic.

Phantoms Used for Evaluation of Full Field Digital Mammography Systems. Presentation (poster) at World Congress on Medical Physics & Biomedical Engineering, Chicago, IL. Richard V. Kaczmarek, Jerry Thomas, Kishalaya Chakrabarti.

Preference Studies of Workstation Monitor Performance. Presentation at the Fifth International Workshop on Digital Mammography, Toronto, Canada. June 2000. Jerry Thomas, Kishalaya Chakrabarti, Richard V. Kaczmarek, Michelle Loscocco, Jerry Gaskill.

Preliminary Results of the 1998 Nationwide Evaluation of X-ray Trends Pediatric Survey. Presentation at the American Association of Physicists in Medicine Meeting, Nashville, TN. Albert E. Moyal.

Quality Control Phantoms for Full Field Digital Mammographic Systems. Presentation at Fifth International Workshop on Digital Mammography, Toronto, Canada. June 2000. Jerry Thomas, Kishalaya Chakrabarti, Richard V. Kaczmarek, Michelle Loscocco, Jerry Gaskill.

Radiographic Trends of Dental Offices and Dental Schools. Journal of the American Dental Association; Vol. 130: 1104-1110 (July 1999). Orhan H. Suleiman, David C. Spelic, Burton J. Conway, June C. Hart, Penny R. Boyce, Robert G. Antonsen.

Regulatory Overview; Quality Systems Inspection Technique; Corrective and Preventive Actions; Case Studies; 21 CFR: Part 11; Electronic Records and Signatures; Financial Disclosure for Clinical Investigators; and ***The 510(k) Paradigm.*** Presentations at the Cooperative Workshop with Western New York Technical Development Center, Buffalo, NY. September 26-27, 2000. William M. Sutton; Frederick B. Winston, Joseph V. Puleo.

Regulatory Requirements for Medical Gloves and ***Overview of Quality Systems.*** Presentations at the Medical Glove Symposium, Taipei, Taiwan. March 27-31, 2000. Judith L. Strojny.

Results of a Nationwide Survey of Chest Radiography: Comparison with Results of a Previous Study. Radiology; 215:891-896 (2000). Richard V. Kaczmarek, Burton J. Conway, Robert J. Slayton, Orhan H. Suleiman.

Roles of the FDA: Telemedicine and Website Linkages. Presentations at Mitretek Systems Seminar, McLean, VA; at Washington Metropolitan Distance Learning Association, Washington, DC; and at University at Buffalo Schools of Law, Medicine, and Pharmacy, Amherst, NY. Melvin Greberman.

510(k) and ***Registration and Listing Requirements for Medical Devices.*** Presentations at the International Latex Conference, Akron, Ohio, July 25, 2000. Arthur K. Yellin.

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	Howell, Heather D.	Manny, Edward F.*
Brophy, Linda S.	Jans, Ronald G.	Paras, Peter
Brown, Karen M.	Joseph, Lireka P.	Sullenger, Deborah C.
Evans, Clifford D.	Lewis, Debra Y.*	Vitale, Kimberly J.
Garris, Cynthia I.		

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.	Noland, Bernice E.	Sheehan, Joseph M.
Gilmore, Rosa M.	Olson, Jean M.	Wade, Jennette
Hanna, Myrna A.	Ross, Ronald D.*	

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

* No longer with OHIP as of January 31, 2001

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.
Anderson, Babette 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.
Clingerman, Angela H.
Dennis, Malcolm M.
Divine, Michael P.
Finder, Charles A.
Fischer, Ruth A.
Flanagan, Margaret
Franke, Kathleen A.
Friend, Wesley A.
Gunzburg, Charles R.
Haran, Timothy J.
Hoage, Patricia A.
Jernigan, Vickie H.
Kaczmarek, Richard V.
Marks, Beverly A.*
McCrohan, John L.
Mourad, Walid G.
Moyal, Albert E.
Netzer, Ruth M.*
Pack, Randy F.
Ratskoff, Ellyce F.
Robinson, Denise J.
Shandruk, Petro
Sheridan, Kathleen M.
Sierka, Carole L.*
Slayton, Robert J.*
Smith, Doris A.*
Spelic, David C.
Stern, Stanley H.
Suleiman, Orhan H.
Thompson, Donald L.
Trammell, Dennis L.
Wandell, Evelyn P.
Wei, Stella D.
Wynne, Nancy M.

* No longer with OHIP as of January 31, 2001

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*

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

Division of Small Manufacturers Assistance

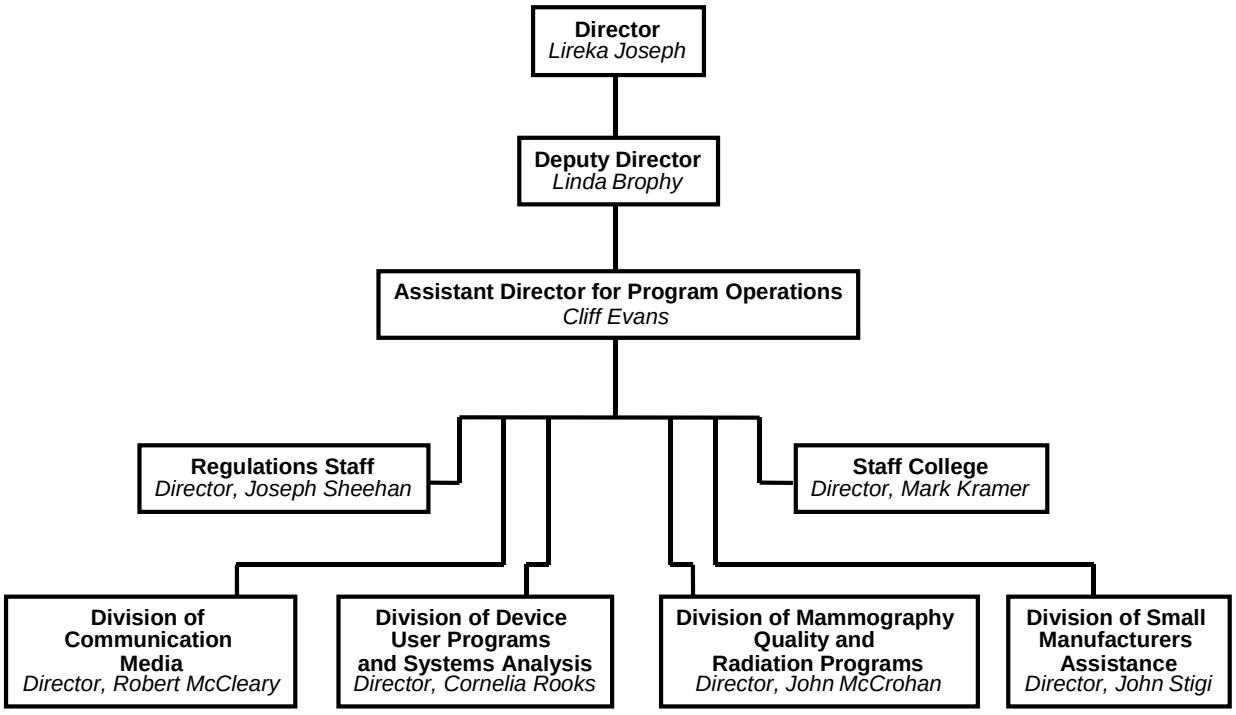
- *educates industry and helps them comply with FDA regulations*
- *educates consumers on medical device and radiation emitting product issues and problems*
- *educates foreign governments on the U.S. regulatory process*
- *supports global harmonization and MRA (Mutual Recognition Agreement) activities*

Alderton, Bonnie J.
Alford, Ardeen S.*
Allen, Gene E.
Auerbach, Jessica B.
Barcome, Althea L.
Benesch, Bryan H.*
Bracey, Alfred
Cardamone Thomas E.
Carland, Deborah C.
Clark, Geoffrey S.
Fedorchak, Carol M.
Freeman, Nancy J.
Greberman, Melvyn
Leonard, Nancy M.
Lowery, Andrew*
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.
Willis, Marcellus E.
Winston, Frederick B.
Yellin, Arthur K.

* No longer with OHIP as of January 31, 2001

OHIP Organization Chart

Office of Health and Industry Programs



Television Design and Development Branch
Chief, Robert Fatula

Deputy Director
Margaret Tolbert

Associate Director
Jay Rachlin

Labeling Research and Policy Development Branch
Chief, Patricia Kingsley

Human Factors Engineering Branch
Chief, Robert Cangelosi

Outreach and Public Participation Branch
Chief, Alvin Thomas

Deputy Director
Helen Barr

Associate Director for Policy & Clinical Affairs
Charles Finder

Associate Director for Administration
Kate Sheridan

Inspection Support Branch
Chief, Kathleen Franke

Information Management and Support Branch
Chief, Tim Haran

Radiation Programs Branch
Chief, Orhan Suleiman

Accreditation and Certification Branch
Chief, Ruth Fischer

Outreach and Compliance Branch
Chief, Nancy Wynne

Deputy Director
Lynne Rice

Associate Director
Al Bracey

Associate Director
Mel Greberman

Associate Director
Tony Rodgers

International Staff
Chief, Chris Nelson

Technical Assistance Branch
Chief, Joseph Puleo

Operations Branch
Chief, Frederick Winston

Regulatory Assistance Branch
Chief, Thomas Cardamone