Summary Report

Radiological Health Reengineering Workshop

November 15-16, 2000
Holiday Inn Gaithersburg
Gaithersburg, Maryland

December 21, 2000

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Summary Report
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This document summarizes the results of the Radiological Health Reengineering Workshop conducted on Wednesday and Thursday, November 15-16, 2000, at the Holiday Inn Gaithersburg in Gaithersburg, Maryland.

Background

The Food and Drug Administration's Center for Devices and Radiological Health hosted an open public meeting on November 15-16, entitled "Radiological Health Reengineering Workshop," in order to receive public input regarding its radiological health responsibilities. CDRH has been experiencing an increasing disparity between its available resources and its statutory and regulatory responsibilities regarding the reduction of unnecessary radiation exposure of the U.S. population from electronic product radiation sources. In response to this, CDRH has been engaged for about two years in a detailed investigation of its radiological health program ("Radiological Health Reengineering") in order to develop workable solutions to this resource/responsibility dilemma. This public meeting was conducted as a part of those reengineering efforts.

Publicity for the meeting was conducted in a variety of ways. First, CDRH sent letters of invitation to a large number of organizations and individuals, including individual companies with radiological products, relevant trade associations and health professional associations, Federal and State government agencies, etc. (see Appendix 1). Second a meeting notice was published in the Federal Register on November 9, 2000 (see Appendix 2), and detailed information was also provided on the CDRH web site. Third, the Food and Drug Law Institute (FDLI) provided information about the meeting on its web site, and information was also sent for several days to the over 4000 subscribers to FDLI's SmartBrief daily e-mail information service. Finally, FDLI sent a newsletter to over 800 registered members of the Devices and Radiological Alumni containing an article about the meeting and encouraging attendance.

There were 97 registered participants at the meeting, including 34 people from radiological industry or related organizations, 25 people from CDRH itself, and 38 others. The following table lists the types of attendees.

Attendee Type (listed in order of decreasing number of attendees)	Number	Percent of Total
Representatives of Industry, Staff of Trade Associations and Testing Laboratories	34	35.1%
CDRH Staff	25	25.8%
Staff of other Federal Government Agencies	9	9.3%
Staff of other (non CDRH) FDA Components	7	7.2%
Representatives of Academic and Health Care Institutions, Staff of Professional Associations	6	6.2%
Retired Staff of CDRH and BRH (Bureau of Radiological Health)	5	5.2%
Consultants to the Radiological Industry	4	4.1%
Press, FDLI staff	4	4.1%
Representatives of State Governments	3	3.0%
Total	**97**	**100.0%**

Workshop Agenda

All meeting participants were provided with a detailed list of specific information about the workshop, including detailed descriptions of the four breakout session topics (Prioritization, Information Exchange, Standards, and Product Testing) (see Appendix 3 for complete description of breakout sessions). The two-day meeting itself (see Appendix 4 for Agenda) was organized with plenary sessions in the first morning and second afternoon, with four breakout sessions for the first afternoon and second morning. The plenary sessions were co-moderated by Mr. Joseph S. Arcarese, Executive Vice President, FDLI, and CAPT Joanne Barron, Radiological Health Reengineering Team Leader, CDRH. Each meeting attendee was encouraged to participate in at least two of the four breakout session topics. The breakout sessions, in which the bulk of the meeting work was performed, were designed to allow sufficient time for interaction and discussion among all participants. The breakout sessions were moderated by volunteers of former BRH and CDRH staff (see Appendix 5) and by current CDRH staff. The closing plenary session was devoted to a report from each of the four breakout sessions.

Town Hall Forum

In addition to providing the participants with a thorough overview of the problems and issues that occasioned the meeting, the opening plenary session included an unstructured open public forum so that individuals could express themselves on this whole subject area. The following comments were made by the participants:

1. Scientific leadership in radiation

In the past, when radiological emergencies occurred outside of BRH/CDRH's strict statutory radiation responsibilities (e.g., TMI and Chernobyl), FDA and HHS looked to it for scientific leadership in radiation. As part of the radiological health reengineering program, will it be considered whether CDRH ought to be prepared to assume that leadership again in the future, or is it assumed that CDRH will no longer be involved in such a manner?

2. Assistance to States
As CDRH reengineers its own radiological health activities, and as it considers the possibility of shifting additional responsibilities onto the State radiological health programs, will it also consider ways to assist the States with their own resource limitations? CDRH needs to keep aware that the States suffer from the same resource problems that it does.

3. CDRH support of the Consumer Assurance of Radiation Excellence Act
Will CDRH support this Act which would mandate State compliance with the 1981 Act? This would help FDA in assessing compliance because the States would be required to report under the provisions of this new act. The proper use of radiation emitting diagnostic and therapeutic equipment requires proficient operators, in order to assure that the public is not being exposed unnecessarily.

4. Expertise needed to deal with radiation emergencies
Due to dwindling scientific and technical resources on staff, it is becoming increasingly difficult for CDRH to marshal consultants and experts (either at the Federal or the State level) needed to fill the expertise gaps on staff to deal with radiation emergencies in a timely manner. Although there is a Memorandum of Understanding between CDRH and NRC in order to deal with certain kinds of non-electronic product radiation emergencies, and it has been successful, there is not a comparable arrangement for electronic product radiation emergencies. Lengthy delays in responding to these kinds of problems can compromise CDRH's ability to protect the public health.

5. Mandatory reports under P.L. 90-602
A representative of color television set manufacturers expressed concern for the slow speed of exchange of information with CDRH regarding mandatory reports. He said they would like to offer suggestions for alleviate that problem and ways to simplify the testing requirements, and expressed their willingness to participate in a pilot program.

6. Suggestions for reengineering
A representative of the diagnostic imaging industry suggested that the industry has always appreciated the Radiological Health approach to controlling radiation from medical devices, as opposed to the Medical Device Amendments approach. In the case of the former, mandatory reporting is work, but it is not a hurdle to the introduction of new technologies to market. In the case of the latter, however, all of the pre-market controls are hurdles. He felt that Congress, consumers, and the industry itself will always demand that resources be applied to reducing these hurdles, which further diminishes the availability of resources to radiological health programs.

He further suggested that, as CDRH reengineers its radiological health programs, CDRH ought to think globally by leveraging with other agencies and processes around the world, recognizing that it is not the only regulatory agency in the world focusing on these issues. He also suggested that CDRH think seriously about harmonizing its regulatory programs with those with other countries. Finally, he suggested that CDRH seriously consider how it can make use of third parties as a strategy to get the right expertise applied to the issues.

7. Coordination among Federal agencies
There was a strong advocacy for the radiation-related Federal agencies to meet regularly to coordinate their radiation missions, their standards, and their regulations. Different agencies have applied radiation standards in ways never intended, in an attempt to control one problem while exacerbating others, thus diminishing the overall public health.

8. Public education
A representative of a health professional organization advocated that the government do a much better job of making the public aware of the benefits of radiation or the proper balance of benefit and risk. The public continues to have unwarranted fears about radiation that diminish the potential public health benefit. There appears to be no uniform effort in the United States to educate the public, thus leaving the field to extremists. A state government representative claimed that the public accumulates more of its attitudes about radiation from Hollywood than from any other source.

9. Surveillance
Despite the necessity of good surveillance (the finding of problems in the field and in the marketplace) for the protection of the public, CDRH does not have appropriate “sensors” to provide needed information. The Medical Device Reporting program is inadequate for this purpose due to strong reporting disincentives (e.g. fear of liability, protection of privacy). There could be formal connections with appropriate organizations (such as the American Association of Physicists in Medicine) to routinely collect needed data.

10. Reasons for reengineering

The basis for the reengineering program was questioned, whether there was an agency directive pushing it, whether there were regulatory deadlines or other internal time constraints, whether there were budget constraints, or whether there were human health studies indicating either that regulation of radiation exposure was no longer needed, or that there was no longer a need of a radiological health agency equivalent to its former size. There was also the question whether there are plans to merge the CDRH radiation responsibilities with those of another agency.

11. CDRH strategic plan

A CDRH representative explained that the 5 year strategic plan involves a focus on several themes. First, a focus on Total Product Life Cycle is a means of assuring connectivity throughout all CDRH components, in dealing with regulated products from conception to obsolescence. Second, there will be a focus in CDRH as a Magnet for Excellence, whereby it is again seen as place where new graduates can gravitate to, as well as a place that encourages existing staff to learn additional skills. Third, there will be a focus on Meaningful Metrics, measures of performance to demonstrate the success of programs and the efficacy of the resources expended. Fourth, there will be a focus on Knowledge Management, in which CDRH attempts to capture expert knowledge before its staff retire, and studies how information comes into the agency and how it is disseminated.

Summary of Outcomes from the Breakout Sessions

The following section, written by Joanne Barron, summarizes the major consensus suggestions and comments emerging from the breakout sessions.

PRIORITIZATION

Stakeholders confirm the prioritization approach developed by the CDRH Reengineering Team

Participants endorsed and suggested amendments to the criteria for prioritizing products that was developed by the reengineering team. In addition, they developed a Dynamic Prioritization Model (to document the process and its use) and a list of benefits in communicating our priorities and needs.

INFORMATION EXCHANGE

Stakeholders strongly endorse CDRH's role as an information clearinghouse

Participants identified and strongly supported the following activities to improve the efficiency of communications tools and processes:

- establish Federal agency alliances
- conduct periodic meetings with stakeholders
- identify training needs and establish training alliances
- conduct an information needs assessment forum
- develop processes and procedures for (interagency) electronic submissions

They also suggested establishing listserves and web links with possibly a single Federal Radiation page, establishing a database into which stakeholders can report test results and problems for trend analysis, and providing multi-language regulatory packages (CD-ROM) for new manufacturers.

STANDARDS

Stakeholders recommend simplifying & harmonizing standards plus education

Participants suggested changing the process and content of mandatory standards:

- set radiation limits and emphasize major health concerns
- follow IEC format and write in plain English
- make standards apply to classes of products
- avoid duplication of standards and regulatory agencies' requirements

They also concluded that industry and users need education, training, and guidance to supplement standards or sometimes in place of standards:

- create an education program and certify third parties (CDRH)
- determine licensure requirements and competency testing
- educate stakeholders on the standards development process

- conduct workshops (separate for consumer products and medical products) and videoconferencing
- issue agency letters to manufacturers and press releases
- explain more in preambles to standards (Federal Register)

PRODUCT TESTING

Stakeholders recommend improvements and pilot tests on product testing

Participants identified the following activities to improve industry testing and regulatory evaluations of products:

- fund an orphan-instrument development program
- identify test labs to develop instrumentation and test protocols and conduct workshops and a chatroom on modernizing and simplifying testing
- develop specifications outside of mandatory standards and amend standards or grant exemptions to revise instrumentation requirements
- advertise opportunity for manufacturers to discuss alternate testing with CDRH
- conduct a pilot test: reviews by FDA-accredited third parties in lieu of reports

PARTNERSHIPS AND LEVERAGING

Stakeholders agree to partner with CDRH

Twelve participants indicated their willingness to partner with CDRH and some suggested some partnership activities. However, the conference did not produce substantive suggestions about how all these recommendations could realistically be accomplished (i.e. who would do them, how many resources they would entail, where the resources might come from). The participants did not provide a realistic assessment of how these recommendations would compete against all the needs faced by CDRH, assuming that its resources are not unlimited and that any radiological health recommendations need to compete against all other recommendations for resource expenditures.

Appendix 1: Invitation Letter

Food and Drug Administration
Center for Devices and Radiological Health

October 4, 2000

Dear Colleague:

You and your coworkers are cordially invited to participate in a **"Radiological Health Reengineering Workshop"** convened by the Food and Drug Administration (FDA). This open public meeting is being conducted to address an important issue concerning FDA's role in radiological health in an era of declining resources. It is being held on **Wednesday and Thursday, November 15-16, 2000 at the Holiday Inn Gaithersburg** located in Gaithersburg, MD. There is no registration fee for attending, but attendees are requested to preregister, in order to be guaranteed a seat. On-site registrations will be accepted on a space available basis.

The Food and Drug Administration's Center for Devices and Radiological Health (CDRH) has important regulatory responsibilities to protect the public from unnecessary exposure to electromagnetic radiation from electronic products, such as consumer products, industrial products, and medical devices that emit ionizing or non-ionizing electromagnetic radiation or ultrasonic radiation. These responsibilities are in addition to the Center's regulatory responsibilities for all medical devices. As medical device problems and programs have grown in complexity and in public health significance, there has been a gradual shift over the years, moving resources into device activities and away from traditional radiological health programs, so that now radiological health full time staff equivalents are only 6.5% of the CDRH total. As a result, many radiological health activities are either not being done or are not being done very effectively. Furthermore, experienced staff are retiring and replacements (if any) do not possess the same degree of technical capability and scientific knowledge. Consequently, CDRH believes it is appropriate to address this dilemma directly; this workshop is being held as one step in a deliberative process of analyzing how the radiological health responsibilities can be reengineered.

Instructions for Preregistration at Radiological Health Reengineering Workshop
Send registration information (name, title, firm name, address, telephone, fax number, e-mail address, and preferred breakout topics to Mr. Diarra Hall at Laurel Consulting Group, 14504 Greenview Dr., Suite 500, Laurel, MD 20708, telephone 301-490-5500, fax 301-490-7260 by November 3, 2000. Alternatively, you may complete the registration form on the Internet at [http://www.fda.gov/cdrh/reenging/radhlth/index.html].

Date/Time: November 15-16, 2000, starting at 8:30 AM
Location: Holiday Inn Gaithersburg
2 Montgomery Village Ave.
Gaithersburg, MD 20879
Phone: 301-948-8900
Fax: 301-258-1940

Meeting Information:
In keeping with the outreach provisions of the Radiation Control for Health and Safety Act and the Food and Drug Administration Modernization Act, CDRH wants to work with stakeholders to reengineer its radiological health program. This open public meeting is intended to bring together persons representing industry, health professionals and other users of electronic products, government agencies, instrumentation manufacturers and laboratories, and scientific and standards organizations, as well as the general public. The purpose of the meeting is to develop practical plans by which the essential elements of a radiological health program can be continued. Attendees will have the opportunity to participate in their selection of breakout session topics. Please see the attachment for more information about the conference objectives and about the breakout session topics.

We hope that you will participate in this very important event. You will find that the discussions and the networking opportunities will be professionally rewarding, and you will be part of an important program with public health significance for the future.

Sincerely yours,

/s/

Joanne Barron
Radiological Health Reengineering Team Leader
Center for Devices and Radiological Health
2094 Gaither Road (HFZ-342)
Rockville, MD 20850

Enclosure

Appendix 2: Federal Register Announcement

[Federal Register: November 9, 2000 (Volume 65, Number 218)]
[Notices]
[Page 67389]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr09no00-88]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Radiological Health Reengineering; Public Workshop
AGENCY: Food and Drug Administration, HHS.
ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), is announcing a public workshop intended to gather information regarding its radiological health programs. The topic to be discussed is reengineering of electronic product radiation control processes with attention to prioritization, information exchange on new technology and public health issues, standards, and product testing.

Date and Time: The public workshop will be held on November 15 and 16, 2000, 8:30 a.m. to 4:30 p.m.

Location: The public workshop will be held at the Holiday Inn, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Joanne Barron, Center for Devices and Radiological Health (HFZ-342), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-594-4654, FAX 301-594-4672, e-mail: jxb@cdrh.fda.gov.

SUPPLEMENTARY INFORMATION: At the workshop, FDA would like to hear whether certain radiological health programs and processes would benefit from changes and, if so, which changes would be most effective.

The purpose of reengineering the radiological health processes is to make the best use of FDA expertise and resources in performing activities that best fulfill FDA's role in radiation protection. While reengineering provides opportunities to shift priorities, FDA also would like to establish partnerships with others who have a role in radiation protection from electronic products.

During the past 2 years, FDA obtained comments from stakeholders on improvements needed in the radiological health program. Comments received suggested four areas for improvement: (1) Prioritization, (2) information exchange, (3) standards, and (4) product testing. Several FDA teams considered the ideas and now would like public participation in revising the processes. CDRH must prioritize the use of limited resources to effectively and efficiently address these public health concerns. To that end, FDA issues recommendations and guidance and develops

and enforces regulatory performance standards for radiation-emitting electronic products to minimize exposures to unnecessary radiation. FDA develops test methods and tests electronic products to ensure conformance to standards, identify nationwide exposure trends, and provide a basis for analyzing new technologies. FDA and stakeholders need information on product emissions, exposures, use, and health effects as a basis for decisions and actions. CDRH expects this public workshop to benefit the radiological health reengineering effort by developing practical solutions to the following questions:

1. How should CDRH choose and implement specific radiological health activities and set priorities?
2. How can CDRH optimize and improve the development/administration of electronic product radiation standards, recommendations, and guidances?
3. How can CDRH optimize and improve the evaluation of radiation emissions and exposures from electronic products?
4. How can CDRH better communicate and network with partners (States, other Federal agencies, industry, health professionals, standards organizations, etc.) regarding its radiological health program?

FDA will conduct concurrent breakout sessions on each of the four topics during this public workshop.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, fax number, and e-mail address), and written material and requests to make oral presentations to Diarra Hall at Laurel Consulting Group, 14504 Greenview Dr., suite 500, Laurel, MD 20708, 301-490-5500, FAX 301-490-7260 by November 13, 2000; or complete the registration form that is available at http://www.fda.gov/cdrh/reenging/radhlth/index.html.

If you need special accommodations due to a disability, please contact Diarra Hall in advance.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

Dated: November 2, 2000.

Linda S. Kahan,
Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. **00-28694 Filed** 11-8-**00**; 8:45 am]
BILLING CODE 4160-01-F

Appendix 3: Workshop Details

Details about the Radiological Health Reengineering Workshop
Wednesday and Thursday, November 15-16, 2000

Workshop Purpose
The purpose of reengineering the radiological health processes is to make the best use of FDA expertise and resources in performing activities that best fulfill the FDA role in radiation protection. In partnership with stakeholders, CDRH wants to implement:
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- a prioritization process to assure that limited resources are allocated effectively and efficiently to address critical radiation problems.
- an efficient and effective information exchange process on public health concerns, safety information and manufacturer data.
- an optimized process for the development and implementation of radiation product standards and recommendations.
- a consolidated process for gathering, storing, analyzing, and disseminating product test data.

The workshop will include presentations on CDRH radiological health reengineering activities and proposals, a town hall forum for participant comments, and four breakout sessions. Participants will be asked to participate in two breakout sessions on November 15, and then to concentrate on one of the four topics on November 16. The four breakout topics are prioritization, information exchange, standards, and product testing.

Conference Objectives
1. Develop practical solutions to the following questions.
   - How should CDRH choose and implement specific radiological health activities and set priorities? (Constraints include low budget and 60 full-time equivalent personnel.)
   - How can CDRH better communicate and network with stakeholders (states, other federal agencies, industry, health professionals, standards organizations, etc.) regarding its radiological health program?
   - How can CDRH optimize and improve the development/administration of electronic product radiation standards, recommendations, and guidances?
   - How can CDRH optimize and improve the evaluation of radiation emissions/exposures from electronic products?

2. Seek collaboration via leveraging to enhance the overall effectiveness of the FDA/CDRH radiological health program in light of modern technology, fewer resources, competing priorities, and reduced public concern about exposure to radiation sources.

3. Get stakeholders' reaction and buy-in to proposed changes in the FDA/CDRH radiological health program.

Breakout Topic 1: Prioritization
CDRH must prioritize the use of limited resources to effectively and efficiently identify and address public health concerns. CDRH wants to partner with stakeholders to assure the best allocation of these limited resources. We are seeking a practical plan to be implemented jointly by FDA and stakeholders. The workshop will address the following questions:

Day 1

1. For the purposes of a prioritization scheme, what products and technologies are of most concern and why?
2. Who are we (CDRH and stakeholders) trying to protect and from what? (Consider what health effects we are trying to prevent from modern-day products and technologies, e.g., burns, cancer.)
3. How should the prioritization scheme be used?

Day 2

1. How should we (CDRH and stakeholders) prioritize these products and technologies?
2. How and when should CDRH communicate the prioritized products and technologies to our stakeholders?
3. What measures of success should CDRH use for this prioritization scheme? (Consider stakeholder needs, communications and the impact on improved public health.)
4. How should FDA and stakeholders develop, maintain and implement a risk based program?
5. What partners should participate and how?

Breakout Topic 2: Information Exchange

FDA and stakeholders need information on product emissions, exposure, use and health effects to make public health decisions. When FDA and stakeholders exchange information, such as identification of public health concerns, dissemination of safety information, and reports from manufacturers, FDA's public health effort is enhanced. CDRH is seeking a practical plan to improve the efficiency and effectiveness of communications tools and processes. The workshop will address the following questions:

Day 1

1. What are the criteria for identifying a public health concern?
2. When there is a public health concern, what information do we need to collect/analyze and why? (Consider injury data, risk prevention, and stakeholder fears).
3. When there is a public health concern what does each stakeholder group need to know? (When brainstorming consider emergency information, long-term information, trends data versus descriptions, and training versus literature).
4. What surveillance data needs to be obtained and why? How should the surveillance data be used? (Consider data on new technologies, monitoring compliance with standards and guidances, and adverse events).

Day 2

1. How should stakeholders and FDA communicate and network about public health concerns? (Consider what tools and technologies should be used.)
2. How should stakeholders and FDA collect and disseminate public health data and information? (Consider what tools and technologies should be used. This includes the submission of manufacturer reports to CDRH and reports of adverse events.)
3. How should we format the information? (Consider trend analysis, charts, graphs and general presentations.)
4. What measures of success should we use to evaluate the information exchange process?
5. How should we implement an information exchange process? What partners should participate?

Breakout Topic 3: Standards

CDRH develops and enforces regulatory performance standards for radiation-emitting electronic products to minimize exposures to unnecessary radiation. In addition, CDRH makes recommendations relating to hazards and control of radiation. CDRH is seeking a practical plan to optimize the maintenance, development and implementation of standards and recommendations. The workshop will address the following questions:

Day 1

1. What are the principles (e.g., informing patients about the benefits of radiation, protecting children, or providing controls to allow users to minimize exposures) CDRH and stakeholders are trying to achieve in radiation protection standards? (Consider what exposure or use conditions we are trying to prevent).
2. When are mandatory performance requirements necessary and when is it acceptable for performance specifications to be in consensus standards (including international standards)? (Consider purpose, use and compliance with standards.)
3. When should CDRH use guidances in place of standards?

Day 2

1. What measures of success should CDRH use for determining when product performance criteria improves public health? (Consider implementation, distribution, use, effectiveness and harmonization of regulatory and consensus standards and guidances.)
2. How should CDRH and stakeholders work smarter to develop and maintain regulatory and consensus standards? What partners should participate?
3. How should the process of developing and implementing guidances differ from the process for standards?
4. How should CDRH format standards and guidances so stakeholders can easily read, understand and implement them?

Breakout Topic 4: Product Testing

CDRH studies and evaluates radiation emissions and exposures from electronic products, often by testing such products. CDRH uses the test data to assess conformance to standards, determine nationwide exposure trends, analyze new technologies, and evaluate the effectiveness of procedures and techniques for minimizing exposure. CDRH is seeking a practical plan to consolidate and improve the process for gathering, storing, analyzing, and disseminating this data. The workshop will address the following questions:

Day 1

1. What aspects of radiation emissions and safety can be obtained only by a test of a product? (Consider all types of radiation and applications, including consumer, medical, and industrial.)
2. Who needs the testing information? Why and how will the testing information be used?
3. What instrumentation and test methodologies are needed to achieve product testing?

Day 2

1. How should CDRH and stakeholders work smarter to test products? (Consider all types of radiation and applications, including consumer, medical, and industrial.)
2. How should CDRH work with others to obtain reliable testing information and what partners should participate? (Consider industry monitoring and assessment of user practices.)
3. What measures of success should CDRH use for determining when product testing improves public health?
4. How should CDRH consolidate and present the information so that it is useful to stakeholders? (Consider consumer information, exposure trends, industry noncompliance rates or types of outlyers.)

Appendix 4: Workshop Agenda

AGENDA

Radiological Health Reengineering Workshop

Food and Drug Administration,
Center for Devices and Radiological Health

November 15-16, 2000
Holiday Inn Gaithersburg
Gaithersburg, MD.

November 15, 2000

7:30 – 8:30	**Registration**	
8:30 – 8:45	**Welcome**	Joe Arcarese, Food and Drug Law Institute Joanne Barron, Reengineering Teamleader, CDRH
8:45 – 9:00	**Opening Remarks**	David Feigal, Director, CDRH
9:00 – 9:15	**Agenda & Meeting Format**	Joanne Barron
9:15 – 9:45	**Reengineering Background**	Joanne Barron
9:45 – 10:15	**Break**	Meet and Greet CDRH Staff and Managers (Washingtonian Room)
10:15 – 11:00	**Town Hall Forum**	Joe Arcarese
11:00 – 11:45	**Workshop Topics**	Joanne Barron
11:45 – 1:00	**Lunch**	
1:00 – 2:30	**Breakout Session**	(1st topic selection)
2:30 – 2:45	**Break**	
2:45 – 4:15	**Breakout Session**	(2nd topic selection)
4:15 – 4:30	**Day Two Registration**	

November 16, 2000

8:00 – 8:30	**Registration**	
8:30 – 10:00	**Breakout Session**	(3rd topic)
10:00 – 10:15	**Break**	
10:15 – 11:30	**Breakout Session** (cont.)	
11:30 – 12:45	**Lunch**	
12:45 – 2:00	**Breakout Session** (wrap up)	

2:00 – 2:30	**Break**	
2:30 – 2:45	**New Initiatives**	John Villforth, Food and Drug Law Institute
2:45 – 4:00	**Breakout Session Reports**	Facilitators
4:00 – 4:30	**Questions and Answers**	Joe Arcarese & Facilitators
4:30 – 4:45	**Pilots and Partnerships**	Joe Arcarese

Welcome and Refreshment area is located in the Potomac Room. It is open 8:00-4:30 both days. Quiet area and Computers for feedback & evaluations is located in the Seneca Room, 7:30-5:00 both days.

Appendix 5: Workshop Volunteers

Volunteers

At the request of FDLI, the following individuals (former BRH and CDRH staff) volunteered their time and expertise as facilitators and notetakers at the meeting:

Facilitators
Billy Mills
Jack Patterson (Nov. 15th only)
LaVert Seabron
Roger Schneider

Notetakers
Ralph Bunge
Mike Audet
Paul Leggett
Jerre Jensen
Kelly Sauer
Carole Sierka
Carol Vetter (Nov. 15th only)
Ed Manny (Nov. 15th only)

Appendix 6: Prioritization

Possible Inputs to a Prioritization Model

Identified benefit(s)

Identified adverse bio-effect?
Nature of injury
- Tangible
- Intangible
- Probabilistic

Severity of injury

Usage frequency
Usage pattern
- Changing use of product (increasing/decreasing)
- Estimated growth / decline in usage

Use error / human factors
Complex user interface
Complexity of product
How much is known/understood by the user/patient?
Is training readily available for users? Is that a mitigating factor?

Incidence / probability of occurrence (exposure)
Probability of injury, given occurrence (dose response)
Exposed population
- Occupational
- General population
- Patient
- Special sub-population(s) (e.g., pediatric, obstetric)

Knowledge assessment
- Adequacy of known data (e.g. MDR reports)
- Emissions, measurements, dose response
- Reliability of information

History of product
- negative -recalls, litigation – perhaps action needed
- positive - no problems known – perhaps no action needed
- Complaints, problem/injury reports?

How well does the industry police itself?
New industry / many new manufacturers?
Radiation expertise in industry?
How well does the industry train itself?

Emerging technology
Widely variable technology?

Rapidly changing technology?
Software controlled?

Is there current special interest (Congress, public, users)?

- Consumer interest
- Perceived vs. real hazards
- Sense of user control
  - User aware of exposure?
  - Can user decide to accept or refuse exposure?
- Is there an outrage factor?

What has already been done? By whom?

- Who else (other than CDRH) has public health protection / promotion responsibilities?
- Other regulatory agencies
- International or national voluntary standards?
- Mandatory performance standards?
- Existing usage guidelines?

How to Use Prioritization Model

One of many management tools for decision making

Helps to prioritize initiatives
Helps in allocation of resources
Provides structure for the organization
Sharing the priority list allows others to help solve problems on their own (e.g. manufacturer may design out problem up front)
Useful to explain:
- what we do and why
- what we don't do and why

Useful tool for evaluating future problems
Helps with emergency preparedness
Helps maintain consistency
Helps build staff and stakeholder confidence and buy-in
Allows us to be proactive rather than reactive
Helps direct research initiatives to develop information that we need
Process prioritization helps us choose from among available strategies (e.g., guidelines vs. testing)
Promotes voluntary compliance
Can be used to prompt review and updating of existing performance standards guidelines, educational programs, etc.
Can provide dynamic monitoring of new and changing technologies

Appendix 7: Information Exchange

FDA and stakeholders need information on product emissions, exposure, use and health effects to make public health decisions. When FDA and stakeholders exchange information, such as identification of public health concerns, dissemination of safety information, and reports from manufacturers, FDA's public health effort is enhanced. CDRH is seeking a practical plan to improve the efficiency of communications tools and processes.

Suggestions from Day 1 and Day 2 workshop sessions:

Establish/identify a national information clearinghouse on radiation-related issues. (Strong Support)

- Define clearinghouse with stakeholders.
- Query other radiation-related agencies and other organizations.
- Subject-based.
- Who takes the lead? Must be at a high level—probably a Federal agency. It could be done by CRCPD or NCRP or NAS, but it would require funding and staffing.
- It would require periodic meetings with contributors in order to maintain this clearinghouse.
- NRC is investigating an "alliance" –National Materials Working Group. There is an interagency regulatory forum. ISCORS.
- What would be useful to the states would be information on which states have particular expertise for certain issues (e.g. accelerators).
- If the clearinghouse consists only of links, then its usefulness is limited. But it might encourage communication, and as time passes, this could grow with additional functionality.
- Valuable for consumers.

There is a real need for training for states, industry, end users, and FDA in: Basic Radiological Health, Advanced Inspection Techniques, and New Emerging Technologies (the context here is mainly medical) (Strong Support)

- There would be a market for this training in the medical community (the context is the people who perform repair and maintenance in health care facilities)
- Who does this training?
- Would the industry (NEMA) be willing to help train FDA (both headquarters and field), the states, and the medical technologies in new technologies?
- Has CRCPD established minimum training requirements for inspectors? Evaluate existing training. Where is health/medical physics training currently available? Check with HPS.

- Evaluate what training would be of value to industry that is not currently available from other sources.
- Evaluate what modes and electronic systems would be most valuable and efficacious for providing training (e.g., web-based, CD-Rom/DVD, satellite teleconferencing, live face-to-face conferences, "train the trainer").
- Should the Federal agencies be collaborating on this issue?

Develop a discussion forum on the questions of what data (from industry, states, Federal agencies) are absolutely needed and useful. Information needs assessment should be performed. CRCPD has already made some inroads with regards to states data. (Strong Support)

- CDRH should hold a small group discussion with industry, trade associations and states, to discuss what information is or isn't useful. Example: Form 2579 includes a lot of detailed information about specific x-ray machines, but the only information really needed is the number of tubes, location, and registration ID. States have concerns about relocation of equipment. Should the form be simplified to eliminate the information that isn't needed?
- Related problem: Out of date forms should be evaluated in light of electronic submissions, that can be easily updated
- Annual reports, Product Reports, and Supplemental Reports should not have to be submitted routinely, but the manufacturer should be allowed to retain the information and submit these reports only upon request from FDA. Office of Compliance needs to be involved to deal with the issue of Accession numbers for new products.
- Volunteers: CRCPD, Rick Hampton, Bob Turocy, Bob Britain, CEA

Develop processes and procedures to allow electronic submission of required reports/submissions, and evaluate the feasibility of all Federal agencies using compatible reporting software systems. Evaluate using the Mammography model or the FCC model. There is a statutory deadline of 2003 for all Federal agencies to have systems in place for electronic submissions. (Strong Support)

- CDRH already has a pilot program, and other Federal agencies are also investigating this.
- FDA Information Technology group should be queried regarding the FDA plan for this.
- There may be different needs for industry and the states.
- There is no easy way to mandate a single system across the Federal government. Dialogue between agencies is strongly encouraged.

Establish/identify an on-going forum for discussion of radiation issues (national meetings of trade and professional groups). Face to Face discussion. (Some Support)

- CRCPD fulfills this for states.
- Make an effort to get new and different people involved.
- Meetings need to be focused.
- Industry wants new ideas. Focus important.
- Not suggesting more meetings, but better and more focused meetings.
- FDA staff need to be at these meetings. Due to costs, Federal participation is limited.
- Federal agencies need to consider sponsoring and cosponsoring meetings, in order to help guarantee Federal staff participation.

Establish/identify/link to a listserve (contact with CDRH) within a website to allow discussion on: (Some Support)

- Radiation concerns
- Instrumentation and calibration issues.
- Already exists in some fashion: Radsafe; Health Physics Society ("Ask the Expert")—questions parceled out by Genevieve Roessler to experts.
- Need FAQ library

Establish electronic database into which States, industry, and others can report generic testing results to facilitate trend analysis, and to facilitate reporting to legislatures about impending problems. (Little or No Support)

- Takes a lot of up front coordination to assure data consistency—formatting
- Very labor and money intensive to do this.
- Fuzzy suggestion.
- Would this suggestion be satisfied by the National Clearinghouse?

Develop an information packet (written and CD-Rom) for new companies (similar to DSMA packet) with necessary regulatory information. Due to concerns for international usability, this information should be available in several different languages. Training materials should also be considered for inclusion in this packet. (Little or no support)

- There is already a pilot effort between CEA and CDRH on television testing. Probably will be a DVD eventually. There will be a training course at CDRH, and later in San Diego. Later, this course will be available in Spanish. There is the hope that this will involve "train the trainer."

- CDRH should explore other opportunities for cosponsorship of educational materials in English and other languages.
- Credentialing and testing is being discussed.

Evaluate current Federal websites for usability by:
industry, consumers, medical community, states, Federal agencies
(CPSC has an excellent website for consumer complaints). Evaluate the feasibility for consistent/compatible search engines across these websites. (Little or no support as a separate suggestion)

- Questionable value of this suggestion in general.
- Related to No. I.
- Who does this? Independent evaluator? Funding? How would this evaluation be done?
- CDRH needs to maintain its website better (make sure there is only one version of each form [e.g., Form 2877], make forms available in both PDF and Word, search engine doesn't find everything on the CDRH site, and the search engine searches at a higher level and doesn't find all occurrences of the search parameters).
- CDRH should assemble a small group of stakeholders to evaluate its website and offer suggestions on improvements. Volunteers: Rick Hampton, Wayne Myrick. CDRH should solicit other volunteers.

Reporting systems should include a mechanism for feedback, acknowledging receipt of information in a timely fashion. (Little or no Support)

- Industry suggests that CDRH have the same threshold of reporting between MDR vs. Corrections and Removals. CDRH should have discussions with the global community about this issue.

Evaluate current non-Federal radiation websites for usability by: industry, consumers, medical community, states, Federal agencies. Establish criteria for evaluating the credibility of these websites ("Buyer Beware issue"). (Little or no support as a separate suggestion)

Related to No. I and III.

- Not sure this is doable legally.

Prepare a list of radiation website resources to be made available to all stakeholders to include contacts within Federal, state (incl. CRCPD), industry, trade, and professional associations. (Little or no support)

- Related to No. I.

Note: The following suggestions from the above list are areas where the radiation-related Federal Agencies ought to be collaborating between themselves :

- Establish/identify a national information clearinghouse on radiation-related issues.
- Evaluate current Federal websites for usability by industry, consumers, medical community, states, Federal agencies (CPSC has an excellent website for consumer complaints). Evaluate the feasibility for consistent/compatible search engines across these websites.
- Prepare a list of radiation website resources to be made available to all stakeholders to include contacts within Federal, state (incl. CRCPD), industry, trade, and professional associations.
- Develop processes and procedures to allow electronic submission of required reports/submissions, and evaluate the feasibility of all Federal agencies using compatible reporting software systems. Evaluate using the Mammography model or the FCC model. There is a statutory deadline of 2003 for all Federal agencies to have systems in place for electronic submissions.
- There is a real need for training for states, industry, end users, and FDA in: Basic Radiological Health, Advanced Inspection Techniques, and New Emerging Technologies (the context here is mainly medical)

Appendix 8: Standards

WHAT and WHY

- TWO TYPES OF STANDARDS (Have the force of law; mandatory)
  - Product-
    1) Testing methods should be done by manufacturer and 3rd party
    2) Needed: an effective, timely system for notifying those that need to know about the agency's intent to write a new standard- to avoid problems from falling through the cracks make a conscious effort to get interested parties to participate/comment.
    3) FDA should develop simple, non-prescriptive mandatory high risk safety standards, following IEC format
    4) Industry and users should develop voluntary performance standards
    5) FDA should rely on prescriptive guidance using:
       FDA 66P
       Voluntary standards organizations (IEC, ANSI, NAFTA)
       CRCPD
    6) Conscious effort should be made to include in writing process: government, academia, standard groups, manufacturers, consumers, etc.
  - User –
    1) utilization – continuous training
- FDA should set the limits and industry groups should put together test methods such as CEA, ANSI and other consumer groups.
- There should be global harmonization of standards and industry testing, including open workshops before writing a standard.
- FDA standards need to be flexible. What was a problem 20 years ago may no longer be a problem. FDA needs to keep standards up to date such as ANSI- every 5 years with stakeholder input and agreements.
- Look at the issue of enforcement of guidance and standards- shouldn't matter which one if both are enforced.
- Make a dedicated effort to get information to the states quickly.
- FDA sets standards, has educational programs on labeling x-rays and facilities should follow a maintenance schedule, but there may not be a schedule for adjustments being made.
- Use the FDA web site more for updates to Radiology program.
- FDA needs to keep continuously educating the public, industry, end-user and other stakeholders.
- FDA should investigate other agencies such as OSHA and how they handle standards and industry- self-certifications.
- Voluntary compliance vs. regulatory. What is meant by consensus
- Higher risks should have mandatory standards. Calculations and risk- need to look at total population before assessments are made
- Standards are not the solution to every problem.

- CDRH Radiological Health program has no live threatening injuries like medical devices and the public looks at them differently.
- Industry wants mandatory standards to give a "level playing field"
- General public needs reassurance that there is no problem- their perception is that the product is compliant if FDA has standards
- With limited FDA resources to develop new standards, FDA should look to other groups such as IEC to help with consensus standards.
- Product performance is better than protection. We are trying to protect the public and longer-term standards would bear this out.
- Look at 3rd party testing such as Under- writers Lab's.
- Suggestion not to use voluntary guidelines as it gives unfair advantage to those that do not comply.
- How can we get control of end-users, put pressure on manufacturer to do this
- Require Radiological health initial reports to be submitted 90 days before introduction to commerce and require FDA revision and approval before intro into commerce.
- Model guidance documents after the mammography guidance documents- excellent to explain the intent behind the standard.
- Guidance documents can serve many purposes:
    1) Ways to recommend testing
    2) On how to use the product
    3) Covers limits of product use
    4) Guidance can be used as a precursor to a standard and can be put out faster
    5) Guidance is not a substitute for a standard - guidance is voluntary and a standard is mandatory
    6) Good guidance can promote "best practices"
- Definition of standard is that it means mandatory and enforced.
- Standards should be linked to a safety requirement
- CDRH standards are 20-30 years out of date and industry still follows them.
- Example of China that needs guidance and training- shouldn't reply on manufacturer to do that job in foreign countries. FDA should be more active in this area.
- FDA needs to work with the states to help them with guidance and standards.

HOW and WHO

Begin process by setting the criteria (concept) with standard setting organizations.
FDA should emphasize major HEALTH CONCERNS
Review periodically and update appropriately.
Use third party products when possible

WHO:

Government agencies
Users
Academia
Industry
Manufacturers
Writers (in clear, technical language, not legaleez)

TEPPRSSC
Professional societies

HOW:
Follow IEC format
Class of Standards
Regulatory safety standards
OR
Education: 3rd party lab certified by CDRH/FDA
Two steps:
CDRH creates
3rd party plus CDRH
Avoid duplication; keep as simple as possible.

EDUCATION
WHO: All should include third party help, especially FDA
FDA (overall)
States
Manufacturer organizations (testing and use; meaning of compliance)
Operators/users
Professional organizations (use)
Standards organizations (what's available)

HOW: All participating organizations should be educating each other; inform what standards are available.
Conduct surveillance effectively with limited resources.
Video conferencing
Workshops
Licen. Requirements/competency testing
Educate on standard development process
Press releases
Agency letters to manufacturers
Preamble to standards (FR)

GUIDANCE Use to clarify and update issues and rules.
WHO:
FDA
Third parties (NCRA)

HOW:
Good Guidance Practice
FR Notice (notify of availability of guidance)
Address: concern for lack of training of medical/technical stds

GLOBAL HARMONIZATION

- WHO:
  - FDA
  - Manufacturers
  - Third parties

- HOW:
  - Avoid duplicity.
  - Voluntary vs mandatory standards
    - FDA should notify through the FR
  - Participate on committees

ENFORCEMENT:

- Equipment based
- Operator based

Appendix 9: Product Testing

Product testing requirements for consumer products need to be specific by device.

- TV receivers: Standard and testing philosophy needs to be revisited in light of new technology (incorporation of microprocessors). Stage III testing in TV standard is obsolete.
- Microwave ovens: Current product testing by manufacturers needs to continue, but FDA may be able to test only problem cases.
- Medical x-ray and medical laser systems:

  CDRH resources would be more effectively applied to use of **quality systems** within manufacturing organizations rather than product testing (because end product is adequately tested now at user facilities).

  HACCP concepts should be folded into testing philosophy.

Why Test:

- Current FDA requirement (product report, self-certification).
- To assure consumers that products are safe.
- To assure that people are not exposed to unnecessary radiation.
- Integral part of manufacturer quality systems.

Other suggestions:

- FDA should certify industry testers and then reporting requirements could be reduced.
- Consider the feasibility of having measurement methodology in voluntary standards rather than in mandatory standards.

Topics considered important but not discussed further in working sessions:

- Harmonization of standards, with world-wide markets. Developing countries need consistent standards and test protocols
- Expand NEXT, include new technologies and exams, e.g. CT. Also put on WEB site for non-tech audience.

Recommendations:

Fund an orphan-instrument development program

- Industry assn (CEA…)
- WEAC
- NIST (technology transfer act)
- SBIR (Small business incentive research program)

Develop specifications for test instruments (accuracy, reliability) as opposed to incorporation of instrumentation requirements in product standards

- FDA, NIST
- Industry assn (CEA, NEMA…)
- Professional societies (IEEE, AAPM)
- Standards-setting committies
- Testing labs (UL, Korea Lab, ETL..)

- SBIR (Small business incentive research program)

Identify test labs to participate in development of test instrumentation and protocol, e.g. announce in Commerce Business Daily

- FDA
- Industry associations
- NIST
- Professional societies (SPIE, IEEE)

Advertise the continuing opportunity for discussion with CDRH on alternative testing protocol (21CFR 1010.13)

- FDA
- Industry and professional (journals and magazines) e.g. Compliance Engineering

Develop and conduct a chatroom for testing and instrumentation issues (by product area)

- FDA
- Industry associations

Amend performance standards or grant industry-wide exemption to revise instrumentation requirements, FDA. Draft by industry associations or professional societies, test labs.

Conduct workshops to consider

- Alternative testing programs
- Modernize, simplify and optimize current testing

  FDA, industry and trade org (e.g. CEA), NIST, Professional Societies, Test labs

  Industry brings quantitative data to support changes

Conduct a Pilot Test to minimize reporting and delays to market.

Initial report for new manufacturers only . Reviews by FDA accredited third parties will assure ongoing conformance. FDA issues 12 month marketing clearance based on third party's audit.

Third party and company alliances with FDA oversight. With possible input from: NVLAP, NRTL (Nationally recognized testing laboratories), AALA (Am Asc of Laboratory Accreditation)