

Radiological Health Reengineering Information Surveillance and Exchange Process Case Study

Executive Summary

Purpose

The purpose of this case study was to develop and test a process to improve the acquisition, analysis and dissemination of information on radiological health issues or problems.

The development and testing of this process included:

- ✓ selection of a radiological health product;
- ✓ definition of the problem;
- ✓ determination of data needed to address the problem;
- ✓ design of a process to acquire, analyze and share information;
- ✓ determination of goals and metrics for the new process;
- ✓ testing of the new process; and
- ✓ preparation of a report to the Radiological Health Council on describing the process, how leveraging played a part in this process, and how metrics were achieved.

Background

In accordance with sections 532 and 903 of the Federal Food, Drug, and Cosmetic Act (FFDCA), the FDA must maintain liaison with, and receive information on, present and future potential electronic product radiation emissions from Federal agencies, State agencies, professional organizations, industry, industry/labor associations, and other organizations.

The Radiological Health Reengineering team identified a need to improve the Center's process of acquiring, analyzing, and disseminating information on radiological health issues or problems. This information might include investigation of new products, new uses for old products, measurement of radiation emissions or leakage, health effects, risk, adverse event reports, and probable population exposed.

The Information Surveillance and Exchange Process case study is a product of the Radiological Health Reengineering Information Sub-team (Phase 1), as a case study in improving communication and awareness regarding radiological health issues.

Methodology

The case study team consisted of representatives from OC, OSM, OSB, OST, and OHIP. Their expertise included radiation science, management, medicine, research science, and engineering.

A multidisciplinary effort is required to meet the public health challenges posed by electronic products that emit ionizing radiation. Because of the fractured nature of the Radiological Health Program within CDRH, representation from each office is required to assure adequate communication within the Center.

The case study team:

- ☞ Identified a need to obtain and disseminate additional information for a radiation-emitting electronic product or issue. (The case study team questioned the applicability of the current federal standard for radiation emissions from televisions.)
- ☞ Reviewed the current Federal performance standard (21 CFR 1020.10) for radiation emissions for the electronic product.
- ☞ Defined the problem with the product or issue. (These questions were found to be adequate in addressing the stated issue: Is the leakage rate set by the standard of 0.5mR/hour appropriate, too conservative, or too relaxed? Are there sufficient assurances that the products are meeting the standard?)
- ☞ Evaluated the current understanding of the product or issue to determine what kind of data would be required. (Case study team determined required data needs, such as product usage, quality assurance, exposure, potential effects of new technology.)
- ☞ Identified leveraging bodies to obtain the required information needed to resolve the issue. (Three federal and 8 non-federal leveraging bodies were identified.)
- ☞ Surveyed potential leveraging bodies.
- ☞ Analyzed data, identified significant findings and developed and proposed options to address the issue.

Findings

The case study team identified significant findings in the areas of the information surveillance and exchange process and case study results:

Process

- ❖ Participation of all applicable CDRH offices is essential for the success of this process.
- ❖ Outside leveraging bodies need to be willing to participate.
- ❖ Survey was found to be a valuable tool in acquiring needed information.
- ❖ Data collection is limited to 9 or less outside leveraging groups without OMB clearance.

Case study

- ❖ The Federal performance standard for TV products is over 30 years old, and is based on scientific data from 1959.

- ❖ Loss of expertise in radiation science among manufacturers and federal regulators is of concern.
- ❖ Developments in technology pose challenges to the current Federal performance standard for TV products.
- ❖ The duration of potential radiation exposure was confirmed.
- ❖ Shift of product manufacturing to offshore facilities provides unique challenges in assuring product compliance.
- ❖ Potentially relevant voluntary standards were identified. Manufacturers indicated a willingness to collaborate with CDRH in possible revisions/updates to existing performance standard.

Options

Implementation of the following options could enhance the overall efficiency and effectiveness of the information surveillance and exchange process for radiological health issues:

Process

- ✓ Form a standing committee to address and resolve radiological health issues presented to CDRH.
- ✓ Obtain feedback from participating leveraging groups regarding appropriate Agency recognition (e.g. certificates, honorable mention on the CDRH web site, and access to data generated).

Case study

- ✓ Enforce current performance standard.
- ✓ Allocate resources to increase the number of offshore manufacturer inspections.
- ✓ Allocate resources to increase the number of WEAC product tests, particularly for large-screen and projection televisions.
- ✓ Work collaboratively with industry to evaluate the adequacy of performance and consensus standards based on the developments in technology.

Reporting

The case study team briefed the Radiological Health Council on January 6, 2000 and the Radiological Health Reengineering Core Group on January 10, 2000 regarding the status of the case study. The results of the case study were discussed with the CDRH Deputy Director for Science on March 14, 2000. A brief presentation was made to staff during a brown bag discussion on March 28, 2000.

A final report was provided to the Radiological Health Council in April 2000. Case study results were presented to the CDRH Center Director on April 11, 2000.

