Medical Device Problem Reporting

ECRI Editorial

ECRI to Clinical Engineering Departments: “Heads Up! . . . FDA’s Potential Regulation of Servicers, Remarketers, and Refurbishers Could Affect You”

Guidance Article

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- Problem Reporting and Its Benefits
- Problem Reporting within the Hospital
- Problem Reporting to Outside Organizations
- Mining the Databases for Information
- The Future of Problem Reporting

Guidance Article

Digital Film Processing: A Comparison of Wet and Dry Processing Methods

Product Review

The Laser Institute of America’s Laser Hazard Evaluator

ECRI Problem Reporting System

Hazard Report
- Sparking from and Ignition of Damaged Electrosurgical Electrode Cables

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- Identifying Reported Medical Device Problems Using ECRI’s Health Devices Alerts Database

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ECRI to Clinical Engineering Departments:

“Heads Up! . . . FDA’s Potential Regulation of Servicers, Remarketers, and Refurbishers Could Affect You”

U.S. hospitals need to track a new regulatory initiative under consideration by the Food and Drug Administration (FDA). FDA is currently reviewing whether organizations that refurbish, rebuild, recondition, service, or remarket medical devices should be subject to Good Manufacturing Practices. Unless the agency appropriately defines the terms “remarket” and “refurbish” and/or excludes healthcare facilities, hospital clinical engineering departments, which service medical equipment, could be subject to FDA’s requirements.

Is regulation of hospital-based, clinical engineering services warranted? We think not. Very few reported adverse device incidents involve service, maintenance, repair, or calibration errors. But will these services be subjected to the regulations nonetheless? We hope not. But it’s still too early to tell.

The Status of the Regulatory Initiative

FDA has yet to issue regulations for device refurbishing and servicing. But on December 23, 1997, the agency published in the Federal Register an advanced notice of proposed rulemaking (ANPR) to gather information about the need for regulation. The deadline for comments was June 29, 1998. However, FDA is hoping to gather additional comments on the ANPR at a conference on September 17 and 18 in Reston, Virginia. A working group, which will include ECRI, will meet at the end of the conference to further explore the issue. (Details about the conference, organized by the Association for the Advancement of Medical Instrumentation [AAMI] and FDA, are presented on page 292.) After considering all the comments, FDA will decide whether to proceed with a proposed regulation.

ECRI’s Commentary

On regulating medical device servicing . . . In response to FDA’s request for information on the need for regulation, ECRI conducted an extensive search of its database of medical device problem reports, the world’s largest such database. Our searches reviewed more than 750,000 records from 1976 to April 1998, with only 0.17% of all the capital equipment records being related to any of the remarketing or other servicing activities addressed in the ANPR. ECRI reviewed the incidents and doubts that any of them could have been prevented with regulation.

ECRI has also conducted independent investigations of thousands of device accidents since 1971. Of these cases, only an extremely small number (approximately 12) were related to error with service and maintenance.

On applying the regulation to in-house clinical engineering activities . . . In comments to FDA, ECRI said the agency’s ANPR focuses almost exclusively on activities related to remarketers of medical devices. But the agency does not clarify whether the activities of many hospital clinical engineering departments — which service, inspect, perform preventive maintenance on, and repair medical devices — would be covered by the regulation. If FDA defines remarketers as entities that take title to and sell previously owned medical devices, then most healthcare facilities would not fall within this definition. But if FDA fails to define remarketers in a way that excludes healthcare facilities — or if it does not otherwise exclude healthcare facilities — FDA regulation of hospital clinical engineering departments is a possibility.

ECRI is concerned that including in-house clinical engineering departments in the regulations could do more harm than good. Servicing-related regulation will likely redirect clinical engineering’s energies away from its cost-saving and safety-enhancing activities toward a function with little apparent or demonstrable benefit. For example, regulation of service-related activities could decrease the time personnel have to spend on other functions, such as device user education. By far, adverse device incidents are most often related to user error — not service-related problems. Regulation will also reduce the time these departments can spend with functions such as ensuring the purchase of the right equipment, avoiding acquisition of unnecessary technology, and keeping unsafe technology out of the hospital.

In summary . . . Based on the results of our detailed database searches spanning 20 years, and on ECRI’s monitoring of medical device problems and hazards for more than 30 years, we do not believe that a servicing-related safety problem exists or that regulation of hospitals’ servicing activities is needed.
Medical Device Problem Reporting for the Betterment of Healthcare

Given that there are nearly 5,000 individual classes of medical devices, tens of thousands of medical device suppliers, and millions of healthcare providers around the world, device-related problems are bound to happen. But effective problem reporting can help reduce or eliminate many of these problems — not only within an institution, but also potentially around the world. In this article, we trace the problem reporting process from its beginnings in the hospital to its global impact in making critical information available throughout the healthcare community.

Problem Reporting and Its Benefits

An Incident
A nurse observes that an infusion pump is associated with an underdelivery of medication to a patient and sends the device for repair. The biomedical engineering department examines the device, finds it to be working properly, and returns it to service. The same scenario has been repeated several times before.

End of incident? Probably not. The reason for the occurrence is still a mystery. Was the user not familiar with how to program the pump? Was the pump inherently difficult to program? Was the pump’s software faulty? Or might the problem have been caused by misinstallation of, or damage to, the disposable infusion set — a separate device altogether? With none of these questions answered, the problem could recur in a week or a month or a year — and the next time it happens, perhaps a patient will suffer a reaction or even die.

What should be an automatic follow-up to this — or any other — incident is prompt reporting of the problem to the appropriate staff in the hospital and also, perhaps, to the supplier, ECRI, and the appropriate government agency.

What Is Problem Reporting?

Put simply, problem reporting is the communication of a device deficiency or user-related issue to those who are likely to provide or contribute to a constructive response. An effective problem reporting system accurately determines which problems should be reported and provides a mechanism to make, act on, and track reports, and to track any corrective actions. Several different types of problem reporting systems have evolved during the past few decades. They can be grouped broadly into three areas:

- In-house incident reporting systems
- Private, nongovernmental systems, such as ECRI’s Problem Reporting System and User Experience Network™ (UEN™)
- Systems maintained by government agencies, such as the U.S. Food and Drug Administration’s (FDA) Medical Device Reporting (MDR) system and the U.K.’s Medical Devices Agency (MDA), which is charged with meeting the vigilance requirements of the European Union’s (EU) Medical Devices Directive (MDD)

The common goal of these systems is to help reduce the likelihood, seriousness, and recurrence of medical device problems.

The Benefits of Problem Reporting

Within the hospital, an effective reporting system not only helps prevent problems from recurring but also helps meet the requirements of the government, insurers, or certifying bodies (such as the Joint Commission on Accreditation of Healthcare Organizations [JCAHO] in the United States). It also helps lower the institution’s liability profile. But reporting device-related problems also has much broader ramifications and can ultimately benefit the entire healthcare community. (As an example of how effective problem reporting and investigation can help other hospitals, see “Two Case Histories” on page 278.)

For example, disseminating information about device problems outside the hospital prompts the publication of information about those problems. This serves to notify others that the problem exists, possibly helping them avoid the problem altogether, and can prompt an informed person or organization to develop a solution. Medical journals often print letters and case reports describing a problem that arose while using a device and providing recommendations on how the problem can be avoided. A few governments (notably the...
Two Case Histories

Below, we present two case histories that together demonstrate the need for careful, effective reporting and investigation of problems.

Case History 1

Early one summer, a hospital submitted a problem report to ECRI regarding a serious case of subcutaneous emphysema that occurred during arthroscopy of a patient's knee joint. Subcutaneous emphysema is a condition in which gas accumulates between the layers of a patient's tissues.

In this particular procedure, the surgeon used an arthroscopic irrigation/distention device — a disposable diaphragm pump powered by compressed nitrogen gas — to expand the knee joint with saline. This provided a working space for the surgeon to observe joint structures and use arthroscopic instruments. Hospital personnel believed that the irrigation/distention device malfunctioned and forced gas into the patient's subcutaneous tissues. Unfortunately, the disposable pump had been discarded at the end of the case.

In response to the hospital's problem report, we assessed the design of the product for possible hazards. While we had some concerns, we found nothing that clearly implicated the device as the cause of the patient's subcutaneous emphysema. Additionally, after searching our databases, we found no other reported incident involving this device. We therefore decided to monitor the product, and we discussed our safety concerns with the manufacturer.

Case History 2

In the fall of the same year, a hospital asked ECRI to investigate a case of subcutaneous emphysema that occurred during arthroscopy of a shoulder joint. In arthroscopic surgery, surgical power tools are frequently used to drill, cut, or shave bone or cartilage; an arthroscopic shaver, powered by compressed nitrogen, was used in this procedure. Because the shaver was the only gas-powered device used in the procedure, the hospital suspected it as the source of the problem.

Our investigation at the hospital revealed that, under certain conditions of use, the shaver could leak pressurized gas into the patient. Interviews with hospital personnel and review of the procedure revealed that the shaver had been operated under conditions that could potentially cause gas leakage. The supplier was notified of the potential for such an incident, and recommendations were made to improve the design of the shaver to prevent gas leakage under these conditions.

Moreover, this wealth of published information is also easily retrievable through databases such as FDA's Manufacturer and User Facility Device Experience (MAUDE) and MDR systems, ECRI's HDA database,* Index Medicus, Grateful Med, and MEDLINE. Purchasing managers, for instance, can glean from these databases the relative number and types of problems associated with a particular device, making it easier to select a reliable model. Similarly, accident investigators, lawyers, and risk managers need to know about problem trends to help identify the causes of accidents and ways to prevent them.

Consider the incident described at the beginning of this article. If the problem were appropriately reported, then risk management, nursing, and pharmacy staff might review procedures for using the pump and identify a lack of training that led to the incident. The supplier might realize that the instructions for using the pump are too complex or confusing. ECRI might alert others to the potential for such an incident and provide specific recommendations to prevent it, while strongly encouraging the supplier to address the problem. The government might require corrective measures to prevent similar problems in the future. This government action could be logged into a number of problem reporting databases throughout the world and help identify trends in incidents involving the device in question.

* For detailed information about this database, see the Talk to the Specialist article “Identifying Reported Medical Device Problems Using ECRI's Health Devices Alerts Database” on page 302.
with the surgeon and nurses confirmed that the surgeon’s methods produced the conditions necessary to cause gas to be forced into the operative space. Further, we believed that the design of the shaver handpiece likely contributed to the gas leakage. Subsequent discussion with the manufacturer confirmed this.

As soon as our investigator observed the gas leaking from the shaver, he suspected that the same type of shaver might have been used in the previous case. Upon returning to ECRI, he contacted the first hospital and found that the same model of shaver had been used for the knee case. Investigation at the first hospital revealed similar shaver handpiece gas leakage and usage practices. Also, our review of articles in the clinical literature and discussions with the physicians who authored those articles uncovered other cases of subcutaneous emphysema that occurred during procedures employing the same model of shaver. Notably, neither the physicians nor the peer reviewers for their articles considered the nitrogen-powered shaver a potential source of the subcutaneous gas. The type of shaver used was not even identified in the articles.

With the permission of the two hospitals, we contacted the shaver manufacturer to discuss our findings. The manufacturer quickly recalled the handpieces and modified them to minimize the risk of gas leakage into the patient.

Outcome and Lesson

The patient in the knee arthroscopy case sued the hospital and the manufacturer of the arthroscopic shaver. ECRI testified on behalf of the hospital, and a settlement favorable to the hospital was reached. Appropriately, the irrigation/distention device manufacturer was not involved in the suit.

Because the source of the subcutaneous emphysema had not previously been identified — even though the problem had been discussed in the literature — the ailment continued to recur, and at least one patient suffered harm because of it. Not until a careful, thoughtful investigation examined all possible causes, including all devices used in the procedure, was a solution uncovered. As a result of this investigation, ECRI helped two hospitals, contributed to improved product safety, and vindicated a falsely accused manufacturer.

While it may not always be feasible for individual hospitals to conduct such a comprehensive inquiry, these case histories demonstrate the need for hospitals to commit themselves to effective investigations and accurate reporting.

Problem Reporting within the Hospital

Who Should Report

Problem reporting is not the exclusive province of any department or specialty. Anyone who is involved with or who discovers a problem should report it internally — not just physicians and nurses, but also engineers and any other staff members who use or maintain medical devices.

Every healthcare institution should carefully instruct its personnel about the importance of immediately reporting any device-related adverse incident or product defect, as well as facilitating any subsequent investigation. ECRI has published a poster — reproduced on page 282 — that instructs healthcare workers on the steps to take following an incident. These instructions include securing the equipment involved and preserving the scene so that an investigation can be conducted. All staff members should be made aware of these instructions.

What Should Be Reported

Reportable Problems and Outcomes

A problem can be defined as an event that is unexpected within the normal use of a medical device and that causes or could potentially cause harm or difficulty. Healthcare workers need to be aware of what sorts of device-related events and outcomes should be reported.

Health-Threatening Problems

Obviously, any incident or device problem that directly harms a patient or caregiver must be reported. Examples are administering the wrong dosage of a potent medication and the occurrence of an airway fire during a tonsillectomy. Some problems hold a less obvious potential for harm but still require reporting. These include mislabeled packaging and a device failure detected during setup; either could cause injury or death.

During ECRI’s 27 years of investigating medical device problems and accidents, we have identified the causes and adverse outcomes of most types of device
problems. From these, we have identified nine basic types of problems that should be reported. We have also identified the serious outcomes that can result from these incidents. These problems and outcomes are listed below.

**Difficulties and Nuisances**

Difficulties are problems involving ease-of-use issues, increased maintenance, repeated repair requests, higher costs, or other nuisances. They include incomplete distribution of service bulletins and poor seals leading to device corrosion. Difficulties generally do not pose a significant risk of harm but should be reported internally and often externally to improve the quality, timeliness, and cost-effectiveness of care.

Sometimes the difference between a serious problem and a minor difficulty is not readily apparent. Consider the infusion pump problem described at the beginning of this article. While the problem did not

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### Reportable Medical Device Problems and Outcomes

#### Reportable Problems

The vast majority of medical device problems can be categorized as one or more of the following types; examples of these problems are given in parentheses.

1. **User error** — the most common cause of device “failures” and accidents — which includes the following:
   - A. Misassembly of the device or associated devices (infusion set inserted incorrectly into infusion pump)
   - B. Inappropriate reliance on an automatic feature (alarm, bubble detector, automatic stops on an x-ray gantry)
   - C. Accidental misconnections (plugging ECG leads into power cord)
   - D. Incorrect clinical use (using electrosurgery to perform a circumcision)
   - E. Misreading of instructions or misunderstanding of device features (putting a laser in Ready mode when it should be in Standby)
   - F. Failure to follow instructions (patient disregarding instructions from a nurse, physician not following manufacturer directions)

2. **Device failure**, which includes the following:
   - A. Poor design (inadequately tested operating principles, lack of user friendliness)
   - B. Labeling error (mislabeled connectors)
   - C. Manufacturing defect (open cold-solder joints, retained mold flashing that blocks an opening, improper sealing of a package)
   - D. Software deficiency (year-2000 problem, programming bugs)
   - E. Random component failure (shorted capacitor)

3. **Device interaction** (electromagnetic interference, intubation lubricant blocking the lumen of a tracheal tube)

4. **Maintenance error** (misconnected or misinstalled medical compressed-gas lines)

5. **Packaging error** (wrong size component contained in package)

6. **Tampering/sabotage** (“pulling the plug” on a terminal patient)

7. **Support system failure** (water in medical compressed-air piping)

8. **Environmental factor** (a device that is inoperative at temperature extremes)

9. **Idiosyncratic patient reaction** (latex allergy)

#### Reportable Outcomes

The above problems can cause one or more of the following adverse outcomes, which should also be reported:

- Crushing
- Electrocution
- Embolism (gas or particulate)
- Exsanguination
- Failure to receive therapy
- Hypo/hyperthermia
- Infection
- Lesion (e.g., puncture, cut, thermal burn, pressure sore)
- Medication overdose or underdose
- Suffocation or barotrauma
cause a patient injury, it certainly had the potential to do so. And in any event, the time and effort wasted in checking the pump created a difficulty. Should it be reported internally? Yes. Externally? Probably — so that others can be made aware of it and perhaps even diagnose the cause. Discussing such an event with a knowledgeable third party (e.g., risk manager, ECRI) can help determine its reportability.

What to Include in a Report

A problem report should allow readers to identify the device, the problem, and the actual or potential outcome or difficulty.

Identifying Information

To begin with, the patient’s name and physician and the device user’s name should be recorded. (Note, however, that if the report will be sent to an outside agency, patient and staff confidentiality and liability issues may arise. Facilities need to have policies in place addressing these issues — as well as the other confidentiality issues described below.)

The device or its packaging will typically be labeled with the device’s name, supplier, serial number, model number, catalog number, lot number, or other specific identifiers; all these should be reported. The report should also include the age of the device and the date it was last inspected and/or serviced, the expiration date of a disposable device, how long the device was in use, the facility’s history of use of the product line, and the date of the incident. These items are not only important for initial record keeping but also help define the type of problem (e.g., manufacturing defect, user error, adverse clinical effect) and provide perspective on the incidence of the problem. Any accessories used with the device should also be listed and described. Finally, the reporter should also provide his or her complete address, telephone number, fax number, and e-mail address so he or she can be contacted for further detail if needed. (Note, however, that e-mail transmissions may not be secure, and the advisability of sending sensitive information by this method should be carefully considered.)

Description of the Incident

A clear and complete description of the incident is critical to the report’s usefulness. Such a description explains what happened, how it happened, why it happened, when it happened, where it happened, what the outcome was, and any other information that could be pertinent. Without all this information, the report becomes next to useless in helping to prevent future problems.

What constitutes a comprehensive description depends on the complexity of the problem. Most reports can be defined in one or two short paragraphs. (An example of a concise yet comprehensive report is presented below.) In a few cases, a simple descriptive sentence is all that is needed: “The cannula was found to be broken in its package.” In contrast, some problems require a full-page description supplemented with photographs or drawings.

(continued on page 283)
Accidents Happen — An Immediate Action Plan

Immediately after every significant incident:

✓ Take emergency measures to minimize and care for injury to, discomfort of, and threat to life of patients or personnel (e.g., thermal burns, electric shock, contusions, lacerations, fractures, cardiac arrhythmias, interruption of normal respiration, loss of consciousness).

✓ Take appropriate action to minimize damage to equipment and the environment.

✓ Notify the attending physician who has legal responsibility for the patient.

✓ Impound all equipment attached or contiguous to the injured party in the same room or areas. Do not disconnect or change the relative physical positions of equipment or connecting cables, except as absolutely necessary to avoid further injury or damage. Retain and preserve any disposable products that may have been involved (e.g., drapes, electrodes), as well as their packaging materials.

✓ Follow ECRI’s Action Plan for Handling Medical Device Hazards, Recalls, and Internal Incidents (printed in the Health Devices Alerts—Action Items binder).

✓ Call ECRI, +1 (610) 825-6000, for telephone assistance or on-site investigation, if needed.
Unfortunately, problem reports are too often sketchy and vague, which can create difficulties in identifying trends or otherwise applying the information the reports provide. The medical device databases are replete with reports stating only that the device "broke." Some reports, on the other hand, provide exhaustive detail about the patient’s prior condition, the procedure, or follow-up treatment, but fail to explain the basic problem that caused the incident. Although irrelevant details should be avoided, the more essential details the report contains, the more useful it will be.

Complicating the picture, however, is the fact that too much detail can raise liability concerns. While most internal problem reporting systems provide a degree of confidentiality, the occurrences described in a report may be so specific that the actual incident will be identifiable by parties outside the institution (e.g., a lawyer or expert witness reviewing a problem reporting database). The information in the report can be potentially damaging in any subsequent legal action, especially if the information is preliminary or inaccurate. Therefore, reports should be reviewed by risk management or legal counsel (if deemed necessary) before being sent out of the facility.

Who Receives the Report and the Actions They Take

Table 1 lists the potential recipients of problem reports and what types of problems should be reported to each. Problems are typically reported first to the facility’s risk manager or other problem reporting coordinator. (The procedures and protocols for reporting to this individual are outlined in “An Action Plan: Handling Medical Device Hazards, Recalls, and Internal Incidents” in the front matter of your HDA Action Items binder.) This person ensures that there is a system in place to evaluate the problem, act on it to prevent its recurrence within the facility, and report it as required or requested by outside agencies. Some facilities have a dedicated risk manager. Others use the operating room supervisor, biomedical engineering director, chief engineer, purchasing manager, or head nurse as the problem reporting coordinator. Still others give such staff members the authority to report problems directly to outside agencies.

Depending on the specifics of the problem (e.g., severity, potential for litigation), the risk manager or problem reporting coordinator must ensure that certain actions are taken and that the efforts of various groups are coordinated, as listed here.

- Review and follow up on the internal report form.
  - Contact the problem’s reporter for more detail on the problem.
  - Have the biomedical engineering staff impound the device, including disposables, until its performance can be reviewed. If appropriate, consider quarantining other similar devices pending preliminary investigation results.
  - If the model name is unfamiliar, ask the purchasing manager or the clinical engineering department to identify the supplier of the problem device(s).
  - Contact the supplier’s quality assurance manager or regulatory affairs officer to report the problem and, if appropriate, coordinate repair or replacement of the problem device.
  - Review ECRI’s HDA database for similar problems.
  - If appropriate, have an independent third party investigate the problem.

- Based on the preceding steps, evaluate the problem and identify the cause.
- Document any investigation findings.

<table>
<thead>
<tr>
<th>Reporting to . . .</th>
<th>Type of problem</th>
<th>Difficulty or nuisance</th>
<th>Serious injury or illness (actual or potential)</th>
<th>Death (actual or potential)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility’s risk manager or problem reporting coordinator</td>
<td>Is . . .</td>
<td>Required in most facilities</td>
<td>Required in most facilities</td>
<td>Required in most facilities</td>
</tr>
<tr>
<td>Supplier (e.g., manufacturer, sponsor*)</td>
<td>Recommended</td>
<td>Recommended; required in United States</td>
<td>Recommended; required in United States</td>
<td></td>
</tr>
<tr>
<td>Government agency (e.g., U.S. FDA, U.K. Adverse Incident Centre)</td>
<td>Requested</td>
<td>Recommended for healthcare institutions;** required for manufacturers</td>
<td>Required**</td>
<td></td>
</tr>
<tr>
<td>ECRI</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Recommended</td>
<td></td>
</tr>
</tbody>
</table>

* “Sponsor” is a term used in a number of countries to denote a company that manufactures or imports a medical device. In some countries, any foreign firm’s products must be sold through a sponsor.

** In the United States, healthcare institutions are required to report if a device has or may have caused or contributed to the death, serious illness, or serious injury of a patient in the facility.
• Make recommendations for corrective actions to prevent future occurrences.
  — Develop preventive policies or procedures.
  — Have the chief physician or head nurse review these new policies or procedures.
  — Have the nurse educator or clinical educator set up user education programs.
• Ensure that corrective action is taken.
  — Have the risk manager or safety committee order the implementation of preventive procedures.
  — Follow up to ensure that preventive recommendations are implemented, and verify that they are effective.
• Complete any required regulatory reports (e.g., FDA MedWatch Mandatory Form 3500A).
  — Determine what to report and how to report it; be judicious in making this determination (e.g., consult legal counsel).
  — If a report was not submitted to a regulatory agency, internally document the reasons.
• Provide a report summarizing the problem and its resolution to
  — the safety committee, quality assurance office, and others who may be concerned about the problem;
  — regulatory agencies as required (e.g., annual reports to FDA); and
  — ECRI.
• Retain appropriate documents and materials.

The Importance of Timely Reporting

Regardless of the type of event, the speed of its reporting can have significant consequences. For example, stocks of disposable devices are used up quickly, and any problem involving a specific device lot needs to be promptly addressed to help prevent other occurrences. Problems that are very likely to recur or cause serious injury or death also require fast reporting.

Some governments have time specifications for reporting. For example, in the United States, FDA requires healthcare facilities, under penalty of fines, to report some types of device incidents within 10 working days of their becoming aware that a specific device caused the incident. Similarly, the EU and Canada require manufacturers to report incidents within 10 days. Timely methods for alerting other governments to serious, widespread problems are being developed by the Global Harmonization Task Force, which is working to make various countries’ problem reporting systems as compatible as possible.
FDA provides two MedWatch forms for problem reporting: Form 3500A, which is used for mandatory reporting “by user-facilities, distributors, and manufacturers,” and Form 3500, which is used “for voluntary reporting by health professionals of adverse events and product problems.” (The identity of facilities filing many of the MedWatch reports would have become public knowledge had not ECRI and FDA urged legislators to change the law — the Modernization Act of 1997 — to provide anonymity for database reporters. This change was enacted just before the MAUDE database was made public.) ECRI has set up a Computerized Problem Reporting System through which healthcare facilities and users can electronically file MedWatch forms with FDA or manufacturers. ECRI forwards the forms and automatically files the required annual reports.

Once FDA receives a report from the healthcare facility or the manufacturer, it enters the report in its database. Health hazards and trends are identified, an assessment is conducted, and additional information may be requested from the user or the manufacturer. Manufacturers are required to investigate, evaluate,
Contact Information for Problem Reporting Agencies

Below, we list the contact information for some of the major problem reporting systems throughout the world.

**Australia**

The Director
Therapeutic Devices Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Phone: (008) 809-361, (06) 239-8682
Fax: (06) 239-8687

**Canada**

Therapeutic Products Directorate
Medical Devices Bureau
Room 1605
Main Statistics Canada Building
Tunney’s Pasture, P.L. 0301H
Ottawa, Ontario K1A 0L2
Phone: (800) 267-9675
Fax: (613) 954-0941

**France**

Ministère de l’Emploi et de la Solidarité
Secrétariat d’Etat à la Santé
Direction des Hôpitaux
Bureau des dispositifs médicaux EM1
8 avenue de Ségur
75350 Paris 07 SP
Fax: 01-40-56-50-89
Web site: http://www.hosmat.com

**Germany**

Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)
General-Pape-Strasse 62-66
D-12101 Berlin
Fax: 49-30-786-30-65

Deutsches Institut für Medizinische Dokumentation und Information
Weissbahnstrasse 27
Postfach 42 05 80
Phone: (0221) 4724-1, (0221) 4724-270
Fax: (0221) 411429
Web site: http://www.dimdi.de

**Japan**

Pharmaceutical and Medical Safety Bureau
Minister’s Secretariat
Ministry of Health and Welfare
7-3 Ichigayahonmuracho
Shinjuku-ku, Tokyo 162

**New Zealand**

Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
Phone: 64 4 496 2176

**United Kingdom**

MDA Adverse Incident Centre
Medical Devices Agency
Hannibal House
Elephant and Castle
London SE1 6TQ
Phone: (0171) 972 8080
Fax: (0171) 972 8109

**United States**

MedWatch
The FDA Medical Products Reporting Program
Food and Drug Administration, HF-2
5600 Fishers Lane
Rockville, MD 20852-9787
Phone: (800) 332-1088
Fax: (800) 332-0178
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**Worldwide**

Problem Reporting System
ECRI
5200 Butler Pike
Plymouth Meeting, PA 19462-1298
United States
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and identify the underlying cause of each problem reported to them. Often the manufacturer initiates solutions to the problem, and FDA typically relies on the manufacturer's conclusions to close the problem's file or start any needed regulatory action (e.g., recall, retrofit).

Depending on an incident's nature and severity, FDA occasionally publishes Notices, Public Health Advisories, or Safety Alerts to make healthcare providers, facilities, and organizations aware of the problem. Notices are letters sent to healthcare professionals and organizations involved in a particular problem. Public Health Advisories are widely distributed statements about a problem, its risks, and general recommendations for its prevention. Safety Alerts are also widely distributed but specifically address high-risk problems involving death or serious injury. Problems reported to FDA are also communicated through the FDA Medical Bulletin, the U.S. Centers for Disease Control and Prevention's Morbidity and Mortality Weekly Report, the American Journal of Nursing, the Journal of the American Medical Association, and ECRI's Health Devices Alerts. And some problems also result in medical device recalls, either voluntarily by the manufacturer or imposed by FDA.

**JCAHO's Sentinel Event Program**

In early 1996, JCAHO released its Sentinel Event Policy,* which encouraged healthcare organizations to voluntarily report certain events to the organization. This policy defines a sentinel event as "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof." It also describes the steps by which a hospital should uncover the root causes of problems to improve its quality of care, which goes a step beyond FDA reporting requirements. JCAHO's attempts to enforce this policy have created some controversy, and the future of the policy is not clear.

**The European Union's Medical Devices Directive**

The EU recently enacted the MDD, which requires EU member states to establish vigilance systems for monitoring medical device problems. These systems will eventually be harmonized, and the information from them will be shared throughout the EU. Incidents, as the EU calls medical device problems, are defined as device-related events that cause, or have the potential to cause, death, injury, deterioration of health, or unreliable test results. They are reported to the local Competent Authority — usually a national regulatory body — which has the governmental authority to act on the problems as it sees fit. Reports are required from manufacturers and are voluntary from users. (For more background on the MDD, see the Talk to the Specialist article “Medical Devices and CE Marking” in Health Devices 27[6], June 1998.)

The U.K.'s Competent Authority, for example, is MDA. One of MDA's agencies is the Adverse Incident Centre (AIC), established in 1987 as the National Reporting and Investigation Centre. AIC actively solicits and collects user reports on incidents (called adverse incidents in the United Kingdom) and on minor faults and discrepancies that may indicate poor quality assurance with a device. AIC received 5,383 reports in 1997 and anticipates that this number will increase by about 500 reports each year. AIC typically deals with routine reports by working with the supplier to understand the problem and how to correct it. More serious reports are actively investigated by both AIC and experts within MDA. This type of investigation may result in Hazard Notices, Safety Notices, or Safety Action Bulletins that communicate the problem and its corrective measures to U.K. healthcare facilities, manufacturers, and — possibly in the future — appropriate journals.

In addition to member states of the EU, other countries are cooperating with the MDD, even though they are not bound by its provisions. These countries include signatories of the European Free Trade Agreement, Australia, and Canada.

**ECRI's Problem Reporting System**

ECRI founded the concept of medical device problem reporting in 1971 and continues it today by encouraging voluntary problem reports from its network of member institutions and other contacts around the world. Hospitals in this network — or anyone else wishing to report a device problem — can complete our Problem Reporting Form (reproduced on pages 288 and 289 and included in your Health Devices binder) and mail or fax it to ECRI. (As an alternative, we also accept copies of FDA MedWatch forms.) Upon receipt, the report is quickly reviewed for seriousness and likelihood of recurrence. Dangerous problems receive immediate action. Other, less critical problems are cross-checked in our problem reporting, HDA, and FDA databases for similar reports. (One tool for classifying these reports

*This policy is not to be confused with an FDA project often referred to as the "sentinel project." The FDA effort is actually a pilot study called DeviceNet, also started in 1996, to evaluate the feasibility of using a subset of well-trained, educated users as problem reporters rather than relying on mandatory reporting from all users. This study relies on a few "sentinel" hospitals that have been trained to give FDA good-quality information under the MDR regulations.
ECRI's User Experience Network™
Problem Reporting Form

Complete this form and return it to ECRI to report a hazard or problem related to the use of medical devices or equipment. Telephone reports are also acceptable, but should be followed by a completed form. The identity of the reporting individual or institution will not be revealed without your permission. Please type or write legibly.

Personal and Institutional Identification (Confidential)
Name: ___________________________ Date: ___________________________
Title: ___________________________
Department: ___________________________
Institution: ___________________________
Address: ___________________________

Telephone: ___________________________ Fax: ___________________________ E-mail: ___________________________
Alternate contact: ___________________________ Telephone: ___________________________

May we identify you to the manufacturer and/or supplier of the device(s) involved?  □ Yes  □ No

Device Identification
Please be as specific as possible in identifying the devices involved. Please add any other information that might be helpful, and omit any items that are not known or that appear to be irrelevant to this particular problem.
Type(s) of device(s) involved: ___________________________

Manufacturer: ___________________________ Model: ___________________________
Serial/lot no.: ___________________________ Expiration/use before date: ___________________________
How long in use? ___________________________ Date last inspected or serviced: ___________________________
Condition: ___________________________

If requested, will you send the affected device to ECRI for examination?  □ Yes  □ No

Were other devices involved? (If yes, please identify all other units on the reverse side of this form, including the information listed above.)  □ Yes  □ No

Are other units of the same model similarly affected?  □ Yes  □ No

If a single-use device was involved, had it been reprocessed at any time before the incident?  □ Yes  □ No

Problem Description
Date problem occurred: ___________________________

Could (or did) the described problem result in injury?  □ Yes  □ No  □ Unknown

Please use the reverse side of this form or separate sheets to describe the hazard or problem in detail.

Instructions: When describing the problem, be sure to include how it was discovered, any action you took, and the response of any suppliers or manufacturers. Attach copies of any related correspondence, when possible. Sketches, photographs, or copies of portions of operating manuals are often helpful in describing the problem, especially if the affected device is not available for examination at ECRI. (Sending the device to ECRI is not typically necessary.) Retain all disposable accessories involved in an incident.

(continued on the reverse)

Please return the completed form to ECRI at the following address:
5200 Butler Pike, Plymouth Meeting, PA 19462-1298, USA
Telephone +1 (610) 825-6000  •  Fax +1 (610) 834-1275  •  E-mail problemreport@ecri.org

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ECRI’s User Experience Network™
Problem Reporting Form
(continued)

Detailed Problem Description
Describe the hazard or problem in detail below or on separate sheets. Be sure to include how the problem was discovered, any action you took, and the response of any suppliers or manufacturers. Copies of this sheet or additional sheets may be used if necessary. As described on the front, attaching supporting materials such as related correspondence, sketches, or photographs may be helpful in describing the problem. Please type or write legibly.

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Signature: ________________________________________________________________

Submitting the Report
Please return the completed form to ECRI at the address below.

5200 Butler Pike, Plymouth Meeting, PA 19462-1298, USA
Telephone +1 (610) 825-6000 • Fax +1 (610) 834-1275 • E-mail problemreport@ecri.org
In our weekly triage meeting, experienced engineers and scientists sort the recently received reports into four categories:

1. Problems that call for further investigation. These reports are assigned to an engineer or scientist knowledgeable about the involved device or technology. This person further reviews our databases for other information on the problem and contacts the reporter and supplier in an effort to resolve the problem and prevent its recurrence. (We do not divulge any information about the reporter or the facility to anyone except the supplier, and then only if it is appropriate and the reporter agrees.) The involved device may be examined, similar devices may be tested, and the device’s design may be reviewed. However, many problems are concluded through telephone discussions, and the report files are closed but retained in our database.

2. Isolated incidents. These are events that appear unlikely to recur (e.g., the device was operated under unusual circumstances, the problem involved a random component failure). Information on these incidents is maintained in ECRI’s problem reporting database so that trends can be identified if similar reports are received.

3. Known complications. These are problems that have a known history of occurrence. They will often have been described in the literature. Users should read the literature to become aware of the potential problems associated with the use of any given device.

4. New problems — that is, those of a type never before reported. These are evaluated and then sorted into either of the first two categories.

Some investigated reports result in conclusions that need to be communicated to the healthcare community. A problem that presents an immediate and serious danger of a widespread nature is quickly acted on and results in an ECRI Hazard Bulletin, which is sent to all Health Devices System members, all hospitals in North America, and most ministries of health around the world. Problems that are likely to cause harm are described in a Hazard Report published in Health Devices. Problems that are unlikely to cause harm but that will cause some difficulty or nuisance are defined in a UEN article, also published in Health Devices. (See the Reporting Policies box on page 301 for more detail.)
on these types of problem reports.) Some problem report investigations prompt the supplier to distribute a voluntary statement about the problem and its corrective action; these statements are abstracted in HDA (as are all Hazard Reports and most UEN articles).

To date in our 27 years of doing this work, ECRI has published more than 25 Hazard Bulletins, about 800 Hazard Reports, and more than 300 UEN articles. These have resulted in hundreds of improvements to medical devices and the avoidance of countless deaths and injuries.

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**Mining the Databases for Information**

**The Utility of Database Information**

Problem reporting databases around the world contain valuable information that healthcare institutions can use to identify trends in medical device incidents and solve specific device-related problems. For example, as described earlier, ECRI’s Problem Reporting System relies on database searches to help define the seriousness of problems, as well as the likelihood of their recurrence. We also use information from our databases to provide guidance to callers who have device questions, to define evaluation criteria, to identify generic device problems for our Healthcare Product Comparison System reports, and to determine purchasing considerations for SELECTplus™ reports.*

**Challenges in Identifying Data Trends**

Certain difficulties inherent in problem reporting can present challenges to effective trending of database information.

**Lack of a Unified Database**

In an ideal world, every problem report from across the globe would be held in a single consolidated database. Unfortunately, such a database does not yet exist. The largest centralized repository of problem reporting data is ECRI, whose databases contain almost 850,000 citations. We are working to merge our databases with those of countries such as Australia, Canada, and the United Kingdom. And, as noted, the Global Harmonization Task Force is working along similar lines. Perhaps someday these efforts will result in a single unified repository for problem reports accessible from anywhere in the world.

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* For information on the Healthcare Product Comparison System and our SELECTplus™ services, contact ECRI’s Communications Department at (610) 825-6000, ext. 888.

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**Overreporting**

Overreporting is the filing of more than one problem report describing the same problem or incident. This can happen if a problem is separately reported to ECRI, the supplier, and FDA, ending up as three separate database citations. Or a device’s market share can skew the statistics: a particular model may have no greater rate of problems than any other but still be the subject of a greater number of reports because it is more widely used.

Overreporting suggests a greater incidence of a problem than actually exists. Although this might occasionally prove beneficial — by allowing a serious problem to be identified and remedied all the more quickly — it is more likely to overload problem reporting systems with extraneous data. Most systems can do little to cross-check for overreporting. Therefore, it is important that data be interpreted by persons — such as investigators — who are knowledgeable about the devices and about the specific types of incidents and how they occur.

**Underreporting**

On the other hand, a particular problem may not be reported by everyone who experiences it, leading to the conclusion that the problem is not as great as it really is. For example, suture needles are known to fail from several understood causes, yet these failures are infrequently reported because “everyone knows” that needles break occasionally. As a result, the actual reasons for some of the failures may never be identified and therefore may never be corrected.

In late 1997, FDA stated that it receives about 100,000 medical device reports a year, but the agency considers this number just the tip of the medical device problem iceberg. Based on information from our contacts throughout the world healthcare community, ECRI agrees that medical device problems are grossly underreported. Accurate reporting of every problem — which requires adequate staffing of the problem reporting function and, in some cases, enforcement within or from outside the hospital — would help eliminate underreporting and improve the quality of healthcare.

**Failing to Attribute the Problem to the Correct Device(s)**

Often, several devices are involved in an incident. Careless investigating or reporting could result in all these devices being reported as “causing” the incident, when in fact only a single device, or perhaps the interaction between two devices, was the source of the problem. Such carelessness results in both overreporting and misreporting — overreporting because the same incident is
cited several times, and misreporting because the actual cause of the incident is not identified.

This difficulty can be minimized by meticulous investigation of the incident (by an independent third party if warranted), clear understanding of the roles of every device involved in the incident, and accurate reporting that cites only the root-cause device or devices.

**Identifying Subtle Trends**

Trends in problem reporting data are sometimes obvious but more often are not. Obvious trends can be seen, for example, in multiple reports of broken (and unsterile) packaging in specific lots of a product or early failure of a brand of defibrillator batteries. On the other hand, reports of “underdose” and “overdose” involving a particular infusion pump could have any number of causes: they could be separate problems, or they could be caused by poor infusion data entry, complex software, battery failure, use of the wrong infusion set, or several other difficulties. Without clear, detailed reports or significant, knowledgeable investigation, specific trends cannot be easily identified from these sorts of problems.

**The Future of Problem Reporting**

With experience comes wisdom. In the United States, problem reporting has evolved over three decades into a tool that has been wisely used by the healthcare community to reduce deaths, injuries, and costs. And this evolution will continue. New computer systems and programs are enabling faster reporting and better data analysis. Other countries are developing their own problem reporting systems, often adapting to their own needs the methods established by ECRI and FDA. Efforts — such as those of the Global Harmonization Task Force — to link various agencies’ problem reporting systems may soon allow a problem reported in Australia to alert device users in Russia to the problem and inform them of how to avoid it. Eventually, problem trends will be quickly identified and prevented from growing.

But this will not happen without the continued reporting efforts of the nurses, physicians, and engineers who work with the devices and see the problems firsthand. All these individuals must be encouraged to clearly report problems and see to it that those problems are corrected.

**AAMI/FDA Conference to Explore the Potential Regulation of Device Servicing and Remarketing**

As mentioned in the ECRI Editorial in this issue, the Association for the Advancement of Medical Instrumentation (AAMI) and the U.S. Food and Drug Administration (FDA) are organizing a conference to explore the potential regulation of medical device refurbishers, rebuilders, reconditioners, servicers, and remarketers. ECRI will be one of the cosponsors of the event. The outcomes of this conference, along with the comments already received in response to FDA’s December 1997 advanced notice of proposed rulemaking (ANPR), will provide the basis for deciding what regulatory approach, if any, should be pursued.

The conference will be held on September 17 and 18 in Reston, Virginia. For registration information, interested parties can contact AAMI’s customer service department at (800) 332-2264. Additional information about the conference, including a preliminary conference program, is also available through AAMI’s Web site (http://www.aami.org).
Digital Film Processing: A Comparison of Wet and Dry Processing Methods

Traditional film-based imaging has always relied on film processing that uses liquid chemicals—a method sometimes referred to as wet film processing. As digital imaging has become available for modalities ranging from radiography to magnetic resonance imaging, however, a digital-based processing method called dry film processing has been devised. Dry film processing transfers digital information to film using heat or a combination of heat and light, and the images are processed by the films themselves. In this article, we present an overview of each film processing method, along with a comparison between the methods as they are used by laser imagers and other imager types.

A Brief Overview of Digital Film Processing Methods

Methods for Developing an Image on Film

Medical imaging has always used film as a medium for image production, even after the advent of digital imaging techniques. And for a time, traditional chemical-based processing—a method called wet film processing because it employs liquid chemicals—was the only means available for processing these digital images. For example, wet processing was used by the laser imagers originally devised in the mid-1980s. These imagers produce high-resolution film images from digital data provided by a wide variety of diagnostic devices—including computed tomography, magnetic resonance imaging, ultrasound, and digital radiography systems— as well as from picture archiving and communication systems (PACS). (Refer to the article on page 294 for a brief discussion of laser imager operation.)

More recently, however, some laser imagers, as well as other types of imagers, have employed a new method—called dry film processing—that eliminates the need for liquid chemicals. Dry systems offer a number of advantages over wet systems. For example, they create no hazardous wastes, and they eliminate the cost and labor associated with using chemicals. However, as we discuss in this article, they also have several drawbacks compared with wet film systems. Therefore, facilities need to weigh the advantages and disadvantages of each system before making a purchase.

Wet and Dry Film Processing Methods

Wet Processing

Traditional—wet-processed—films used by laser imagers have three layers. A cross-section of a typical film is shown in Figure 1. The uppermost layer is the

* Digital radiography systems were profiled in a Technology Overview published in our last issue (Health Devices 27[7], July 1998).
supercoat — a gelatin layer that acts as a protective outer covering. The base, which constitutes most of the film’s thickness, is made from a plastic and is used to provide support and structure for the imaging layer of the film. Finally, the bottommost layer, the emulsion, actually records the image. This layer consists of an emulsion of crystalline silver halide particles in a gelatin matrix. Sulfur-containing compounds, such as allylthiourea, are also incorporated in this matrix. When the film is manufactured, these compounds react with the silver halide to produce silver sulfides (AgS), which migrate to the surface of the silver halide particles and form what is called a sensitivity speck.

Exposure of the film takes place as follows: As the laser imager scans its beam across the film (exposing the film one line at a time to create a high-resolution image), some areas receive greater light intensities than others, corresponding to the digital input from the imaging modality. When the laser beam strikes the silver halide particles, some of them break down into bromine atoms, silver ions, and free electrons. The free electrons are attracted to and captured by the sensitivity specks. These specks then attract silver ions. The ions combine with the free electrons to form silver atoms, which are trapped on the sensitivity speck. The greater the intensity of the laser beam that strikes the silver halide, the more silver atoms are created and captured by the sensitivity specks. These silver atoms will form the dark areas of the x-ray image.

Once a film has been exposed, it undergoes a series of processing steps, including development, fixing, washing, and drying, to produce a visible image. These steps are shown in Figure 2. The entire process is performed outside the laser imager — either by hand or, more commonly, using an automatic film processor.

Development involves placing the exposed film in a developer solution consisting of reducing agents, alkalis, sodium sulfite, bromide, and additional image-enhancing agents. The developer solution reduces some of the remaining silver ions in the film into silver atoms. This process amplifies the exposed image 100 million times, allowing it to become visible. The greater the concentration of silver atoms present in a film area, the more rapidly silver ions will be converted into additional silver atoms in those areas. This intensifies image contrast.

Once the film has been developed, it is placed in a fixer solution that removes all the additional silver ions in the film without removing the silver atoms. Fixing prevents the film from undergoing further development. The film is placed in water to wash off any remaining fixing chemicals; then, finally, it is dried.

Digital Image Production Using Laser Imagers and Alternative Devices

Laser imagers operate similarly to the laser printers commonly used with computer systems. But while printers accept digital input from computers, laser imagers receive their data from medical imaging devices. And instead of outputting data on paper as printers do, laser imagers produce high-resolution films that are developed to produce images.

The first step in image production is transferring digital data from a medical imaging device to the memory of the laser imager, where it is stored and formatted, with the image data reordered to be printed line by line. A roller system in the imager moves a sheet of film into the laser path. The laser scans horizontally across the film to create a single high-resolution line. The film is then advanced, and another laser scan is made. This process is repeated until an entire image is exposed on the film.

Wet and dry imagers use different types of film and development methods. While wet-processed film requires development once it has been exposed by the imager — this is done either manually in a darkroom or automatically by a film processor — dry-processed film is automatically developed by the imager itself, which exposes, develops, and fixes the film using only the chemicals already present in the film.

The introduction of dry film processing has expanded digital film processing beyond laser imagers. While many dry film processing imagers still rely on lasers, some expose films thermally in a process similar to that used in some fax machines. In these imagers, a heat source, such as a thermal head, scans the film line by line. Other imagers rely on dye-sublimation technology to produce images.

Dry Processing

While wet film processing follows a specific procedure, dry film processing encompasses a variety of methods. Currently, there are two primary types of dry film processing: photothermographic and thermographic. Photothermographic films are exposed
using light and developed using heat, whereas thermographic films use heat for both exposure and development. Both film types are readily available.

**Photothermographic Processing**

Photothermographic films are exposed by a scanning laser in the same manner as is used in wet processing. Once exposed, however, the films remain inside the imager, where they are heated to temperatures exceeding 100°C (212°F). The heating causes light-insensitive silver salts — typically silver behenate — in the film to migrate to the sensitivity specks. This process is temperature-dependent and slows as the film heating is discontinued. Both the developer and fixer chemicals are contained in the film itself. Once the silver salts have migrated, the developer and fixer chemicals convert the salts into silver atoms and then fix the film so that no further development occurs. All the unused developer, fixer, and silver salts remain in the film for its entire lifetime. This can cause problems when storing film and can affect the film’s useful lifetime, since, under certain circumstances, it is possible for films to be reexposed.

**Thermographic Processing**

Heat, not light, is used to expose thermographic film. Either thermal heads — similar to those found in fax machines — or lasers expose the film as they are scanned over its surface. The heat is delivered in short bursts whose temperature corresponds to the data from the imaging modality; the degree of film exposure is proportional to that temperature.

Several basic mechanisms are used to form the images on thermographic film. In some instances, silver behenate is released and developed by heating, in a process similar to that occurring in photothermographic films. In other cases, dye or dye-acid combinations are released in response to heating. These dyes diffuse into the film to create an image. This process is called dye sublimation. Another technique uses heat to fuse carbon particles contained in the film. As more heat is delivered, more particles are fused. The fused particles remain on the exposed film in the form of an image, while unfused particles are removed. Variations of all these techniques are used in thermographic processing.

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**Comparing Wet and Dry Processing Systems**

The following discussion outlines the relative advantages and disadvantages of wet and dry image processing systems. The overall results are summarized in the table on page 296.

**Chemical Storage and Waste Disposal Requirements**

Wet film processing involves hazardous chemicals and wastes — including developer, fixer, and wastewater. These substances require special care and attention and are subject to a number of environmental restrictions. In the United States, for example, the procedures for purchasing, storing, and disposing of chemicals must be consistent with Occupational Safety and Health Administration and Environmental Protection Agency requirements. Dry film processing, on the other hand, does not require hazardous chemicals or produce hazardous wastes. This is its most significant advantage over wet film processing.

With wet film processing, the recovery of silver — the primary by-product of this processing method — is a particular environmental concern. Silver must be recovered from the wastewater before the water is released into the environment. This step is required by national and local environmental regulations, with
fines of thousands of dollars per day imposed on violators. Therefore, facilities need to maintain a silver recovery system on-site.

As hazardous waste removal and treatment costs continue to escalate, wet film processing may become less practical. However, several suppliers have developed wet-film-processing laser imagers that are “environmentally optimized” — that is, they greatly reduce the production of waste by-products such as wastewater. While these imagers do not eliminate waste entirely, they may solve enough environmental problems that facilities can continue to use wet film processing. This will allow facilities to retain the processing infrastructures (equipment, plumbing, etc.) already in place, eliminating the significant start-up costs of dry film processing (see the discussion of Costs, below).

**Time and Labor Requirements**

The actual processing of wet films requires little or no additional time or labor compared with dry films, as long as an automatic film processor is used. However, wet processing does entail replacing and replenishing chemicals, as well as the paperwork and wastewater testing involved in managing hazardous wastes (as discussed above). And for facilities that still perform some degree of manual processing in a darkroom, additional labor is required.

Because of the need for plumbing and drainpipes, wet film laser imagers must be kept in a fixed location; this means that films must be transported between the processing and imaging systems. In contrast, dry film imagers are much more easily transported than wet film systems. Therefore, they can often be placed close to imaging systems, eliminating the need to go to a darkroom or other location to retrieve images.

**Space Requirements**

The facilities for wet processing require considerable space. If films are processed manually, darkroom space is required. Even if a darkroom is not used, space must be allocated to plumbing and ventilation, as well as to the storage of chemicals and waste products. On the other hand, the infrastructure for wet film processing is already in place in most facilities. Therefore, most hospitals do not require further expansion unless additional wet systems are being added.

Dry film imagers and processors are small, taking up at most a few square meters of floor space. And because they require only an electrical outlet, they can be placed in convenient locations near the imaging systems.
be placed nearly anywhere within a facility. Some new dry processing systems are even designed to fit on tabletops.

**Film Storage and Handling**

The archival quality of wet-processed film — that is, how long it can be stored without image degradation — has long been established. These films can be stored at temperatures exceeding 100°F (38°C), at high relative humidities, and in bright light for extended periods of time without degrading in quality. In many instances, they can be stored for 100 years or longer.

In contrast, the lifetime of dry-processed film is unknown. The process has been in use for only about 10 years, so there is not yet adequate experience from which to judge the film’s archival quality. Also, no test method is available to reliably predict the lifetime of this film. (Well-known photographic tests are available to determine the archival quality of wet-processed film.)

Furthermore, environmental conditions will affect films that have been dry processed. For example, if a film is left on an activated light box for too long, or inside an automobile during a hot day, a phenomenon called print-up occurs. Print-up is essentially a reduction in film contrast occurring as the light areas of the film darken while the darker areas lighten. As a result, dry-processed films must be stored under closely monitored environmental conditions, which may require renovation of existing storage spaces. For instance, exposed films must be stored at temperatures no greater than 21°C (70°F) and in controlled humidities.

In addition, rough or careless handling can damage dry-processed films. For example, the emulsion of dry-processed film is more likely to separate from its base because of rough handling than that of wet-processed film. Wet-processed films, on the other hand, are highly durable and rarely experience physical damage.

**Costs**

Wet film itself is usually less expensive than dry film. This cost difference may amount to only a few percent — but because the average facility purchases large volumes of film, the savings may in some cases balance the costs of purchasing and disposing of chemicals (which can be considerable). This brings the costs of wet and dry processing closer together.

However, wet-processing imagers create expenses in addition to film and chemical costs. For example, either the facility will have to pay the utility costs required to run a darkroom or it will have to purchase automatic film processors. While automatic processors eliminate the need for a darkroom, their purchase increases the overall expenses of the radiology unit compared to dry imagers. And, as noted, wet imagers still require plumbing and other utilities.

Thus, some facilities will find that operating a dry processor is less expensive than operating a wet-processing system. However, most facilities are already using wet systems, and the costs of switching to dry processing can be significant. For one thing, dry film imagers are expensive. For another, entirely new film stocks will need to be purchased. In addition, facilities will need to get rid of old film, chemicals, film processing equipment, silver recovery systems, and other equipment and materials.

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**Choosing a Processing Technology**

**Selecting a Film Processing System**

Facilities considering the purchase of a new laser imager or dry film processing system should carefully consider the advantages and disadvantages of each type of system as outlined in the table on page 296. A life-cycle cost analysis should be performed for each of the alternatives. The cost of film, chemicals, waste disposal, utilities, facilities renovations, and labor should be included, in addition to capital equipment costs. The costs of converting from a wet to a dry system should also be considered.

Facilities finding that their dry film processing system costs are likely to be less than or similar to existing wet film processing costs should consider conversion to the dry systems because dry systems offer space and labor savings as well as the elimination of hazardous wastes. However, facilities should recognize that film durability and lifetime may be compromised for the sake of those added advantages. Some facilities may have to add temperature and humidity regulation to their storage areas to preserve the contrast in dry-processed films.

On the other hand, facilities that believe they will spend less by retaining wet film processing should consider doing so. This will keep them from having to alter the existing infrastructures that support processing and waste handling. Additionally, environmentally optimized wet film laser imagers can further help reduce wastes and serve as an adequate replacement for existing wet systems.

**The Future of Film Processing**

Although the use of dry film imagers is increasing, the total elimination of wet-processing laser imagers probably will not occur in the near future, especially
with the introduction of environmentally optimized wet systems. However, dry film imagers will soon account for a significant majority of imager sales.

With the growing use of PACS and teleradiology systems and the introduction of digital radiography, it may seem that all film processing, wet or dry, will soon be eliminated, since images can now be archived digitally. However, teleradiology systems are only starting to gain acceptance. Furthermore, many radiologists still prefer films over high-resolution monitors. Therefore, film processing will still be necessary for some time to come.

Bibliography

Eastman Kodak Company:
The Laser Institute of America’s Laser Hazard Evaluator

The Laser Institute of America recently developed a software program, the Laser Hazard Evaluator, to help analyze the risks involved in using most types of lasers. In this article, we review the uses and characteristics of the Laser Hazard Evaluator and present ECRI’s judgment of its merits.

Calculating Laser Hazards

The hazards of laser use are well known. Most hospitals have a laser safety officer (LSO) who is responsible for managing these hazards. The LSO is charged with, among other things, fulfilling the requirements of Standard Z136.3 of the American National Standards Institute (ANSI) and the Laser Institute of America (LIA).* These requirements include analyzing the hazards present in any laser treatment area.

Usually, the hazards posed by a laser system can be gauged simply by reviewing information provided by the laser’s supplier. On occasion, however, there may be a need to confirm a supplier’s safety recommendation or assess the hazards associated with a third-party supplier’s delivery system. In such cases, it may fall to the LSO to analyze the system for potential risks. This will likely require performing the complex calculations of laser performance and effects given in another ANSI standard, Z136.1.** The process is likely to be daunting for the LSO, who may not perform such calculations frequently enough to keep from getting rusty.

The Laser Hazard Evaluator

To help LSOs evaluate laser hazards, LIA — a nonprofit professional society dedicated to fostering lasers, laser applications, and laser safety worldwide — developed a software program called the Laser Hazard Evaluator. The program is a graphical display that runs in Windows 3.0, Windows 95, and Windows NT. It is designed to help determine whether a particular set of laser operating parameters could prove hazardous to persons inadvertently exposed to the laser’s energy — for example, from a misaimed or reflected beam.

Program Operation

The program’s main screen display (see Figure 1) shows a laser source and a cross-section of target tissue; these are used to demonstrate potential tissue damage. Because Z136.1 risk calculations are used primarily to assess the possible risk to the eye or to skin, the program will display either an eyeball or a volume of skin.

* ANSI/LIA. American national standard for the safe use of lasers in health care facilities. Orlando (FL): LIA; 1996. ANSI Z136.3-1996. For more details about the responsibilities of LSOs under this and other standards, see the Talk to the Specialist article “Laser Safety Officer” in Health Devices 25(9), September 1996.


Figure 1. Sample screens indicating injury to the retina of the eye (top) and to the skin.
The user first sets the values (e.g., wavelength, power, exposure duration) characteristic of the laser type to be modeled. The wavelength can be set in three different ways: by selecting a laser type, by selecting from a list of commonly used wavelengths, or by using a slider button to select from the entire available range. For eye hazard assessment, the screen interposes an eyewear filter in the beam. To indicate the type of eyewear intended for use in the treatment area, the user can set the filter’s optical density (OD) by means of another slider button.

The user then clicks on the FIRE button, and a representation of the beam appears. (For wavelengths in the visible range, the selected beam is displayed in the appropriate color, which is a nice enhancement.) The program instantly calculates the effect the beam will have on the target tissue. If no injury will result, the display does not change. If damage is likely, the display changes to indicate the areas where damage will occur. On the eye display, injury occurs either at the cornea (as would happen with, for example, a CO₂ laser) or at the retina (as would happen with visible-light lasers; this is the injury shown in Figure 1). On the skin display, injury is represented identically regardless of the laser type or wavelength.

The program can also generate a report (both viewable and printed) of all the variables that were set on the display screen, as well as certain values calculated from those variables — for example, the laser irradiance, the minimum OD of laser eyewear needed to protect the eyes, and the nominal hazard distances for both unprotected skin and eyes. (See Figure 2 for a typical report screen.) These calculations can reduce the number of Z136.1 calculations the LSO must perform. In addition, the programmed setups can be saved to a file and easily retrieved for review or recalculation.

### Program Capabilities

The program allows system variables to be set over a wide range. For example, wavelengths are available from 180 nm (far ultraviolet) to 11,000 nm (far infrared). In addition, because the program was developed for industrial and military as well as medical uses, the power range available (1 mW to 1,000 MW) is vast — far greater than is needed to assess any medical application.

The model can accommodate most applications likely to be in clinical use. Continuous-wave modes for a wide range of durations can be represented, as can common pulsatile modes. The program can also simulate superpulse or complex pulse modes — for example, Q-switched — particularly if critical variables such as the energy and duration of the component pulses are known or can be derived. In addition, diffuse and reflected emissions can be modeled.

### ECRI’s Judgment

This is a user-friendly program, especially for those to whom such abbreviations as MPE (maximum permissible exposure), NHZ (nominal hazard zone), and NOHD (nominal ocular hazard distance) are readily recognizable. Its authors obviously sought to provide a program that effectively carries out the risk assessments called for in Z136.1. (However, the software includes a disclaimer making it clear that the program is not intended to serve as an “expert” that replaces a knowledgeable LSO.)

ECRI believes that the program’s principal utility lies in providing a good starting point or backup for the LSO or anyone else doing laser assessment. It permits users to quickly establish “ballpark” values for laser hazards or to confirm the validity of their own assessment of those hazards. The program can also serve as an excellent educational tool, since the ease with which a variable can be changed — resulting in an immediate display of the change of risk — allows the user to gain a rapid feel for the boundaries within which a laser system can be safely used.

We recommend the purchase of this program.
Reporting Policies

We encourage our members, healthcare providers, patients, and manufacturers to report all medical device-related incidents and deficiencies to us so that we can determine whether a report reflects a random failure or one that is likely to recur and cause harm. These reports can be generic or model specific. Although many of these reports do not result in a Hazard Bulletin ("pink sheet"), Hazard Report, or User Experience Network™ (UEN™) article, we inform the reporting party of our database search findings, as well as of our findings and opinions when appropriate. As soon as we become aware of device hazards and problems, we inform the manufacturers and invite them to respond constructively. We add all reports, including those that are not published, to our internal confidential databases to track trends of device failure or lot-specific defects.

A Hazard Report describes a possible source of peril, danger, or difficulty. We publish reports about those units in which we have identified a fault or design feature that might, under certain circumstances, place patients or users at risk, providing recommendations on how to correct or avoid the problem. Publication of a Hazard Report on a specific brand name and model of device in no way implies that competitive devices lack hazardous characteristics.

When deciding whether to discontinue using a device that ECRI believes poses a risk, hospital staff should balance the needs of individual patients, the clinical priorities, and the availability of safer or superior products against the information we provide in a Hazard Report. Clinical judgment is more significant than an administrative, engineering, or liability decision. Users often can take precautions to reduce the possibility of injury while waiting for medical equipment to be modified or replaced.

UEN articles describe problems that we believe are unlikely to pose a significant risk of harm. Typically, they include the hospital’s report and ECRI’s comment; when appropriate, we also include the manufacturer’s response and recommendations for corrective action. Most of these reports describe common or nuisance problems that can be corrected with an available modification or revised operating or maintenance procedures.

Please send problem reports to us in a letter or by using one of the problem reporting forms in your black Health Devices binder behind the yellow tab. The binder front matter describes the three forms — ECRI’s yellow Problem Reporting Form and FDA’s MedWatch forms (yellow, voluntary; white, mandatory), which we can forward to FDA for you through our Computerized Problem Reporting System (CPRS). You can also send reports to ECRI by fax; our fax number is (610) 834-1275. Or you can telephone your report directly by calling (610) 825-6000, Monday through Friday, 9:00 AM to 5:00 PM, eastern time. The identity of the reporting individual or institution is never revealed without permission.

Member hospitals may reproduce Hazard Reports and UEN articles for internal distribution only. This policy does not apply to other articles appearing in Health Devices, unless noted otherwise.

Hazard Report

Sparking from and Ignition of Damaged Electrosurgical Electrode Cables

Cables/Leads, Electrosurgical Unit [11-496]
Electrodes, Electrosurgical, Active, Foot-Controlled [16-206]

Problem

ECRI has received reports from several member hospitals describing incidents of sparking from or ignition of electrosurgical electrode cables used during various surgical procedures. In some cases, sparking severed the electrode cable. In others, the cable ignited, starting a fire that spread to nearby surgical drapes. These incidents caused delays in treatment and, in a few cases, injuries to staff members and to the patient. Medical device reporting databases contain numerous recent reports of other such events.

Discussion

Understanding the Problem

Electrosurgical electrode cables connect the electrosurgical generator either to the active handpiece (e.g., forceps) used to treat the patient or to the return electrode used to complete the circuit between the patient and the generator. These cables can be damaged in many ways — some that result in only superficial damage to the cable insulation (e.g., cracks, tears), and others that result in the breaking of some or all the conductor wires within the insulation. Damage to only the cable insulation is unlikely to cause significant problems. For one thing, it may be noticed by staff before the cable is used. In addition, it is unlikely (although possible) that gaps in the cable insulation alone will result in the types of problems described in this report. Rather, sparking and ignition are most likely to occur as a result of damage to the cable’s conductor wires — damage that, as discussed below, is not always easy to detect.

When conductor wires within a cable become severed, current may be able to arc across the break. Because the arcing may allow the device to continue operating — albeit on an intermittent basis (as the severed wires move into and out of close proximity) — staff may not notice the break. The arcing can quickly generate sufficient heat to melt the insulation and, in some cases, could even cause the cable to ignite. With less severe breaks, in which only a few strands of the conductor wires have been severed, sparking and ignition can still occur because the current passing through the unaffected wires may be sufficient to melt these remaining strands, severing the wire. In both
situations, the problems reported by our member hospitals can result.

Unfortunately, damage to the cable’s conductor wires will not necessarily result in any outward sign that the cable has been compromised. For example, reusable cables are subjected to repeated flexing and sterilization, two processes that can damage the conductor wires without causing a break in the cable’s insulation. And any type of cable (single-use or reusable) can be subjected to physical abuses, such as being pinched between the edges of two carts, that can cause the conductor wires to break in places along the cable’s length while the insulation that encases the wires remains intact. Thus, avoiding the types of problems described in this report will require that relevant staff know how to identify potentially damaged cables, preferably before they are used (see Dealing with the Problem, below).

Staff should note that incidents of cable damage resulting in sparking and fire are much less likely to occur with cables that connect the return electrode to the electrosurgical unit (ESU) than with cables that are connected to the active electrode for two reasons: (1) Most return electrode cables are integral to the dispersive electrode and thus are disposable; as such, they are not subjected to the actions — most notably repeated flexing and sterilization — that are most likely to result in cable damage. (2) If a return electrode cable breaks, the ESU’s return electrode contact quality monitor or cable continuity monitor will shut off any current and then alarm, reducing the likelihood of sparking or fire.

Dealing with the Problem

Detecting damaged cables before they are used requires routine inspections — both during cleaning (for reusable cables) and before use. As part of the inspection, personnel should do the following:

- Visually examine the cable. A visual examination should reveal any significant insulation damage, which will usually take the form of cracks, nicks, abrasions, holes, or tears in the covering of the cable. Although insulation defects themselves are not likely to result in sparking or fire, they could be a sign that the conductor wires have also been compromised, and thus should not be ignored.

- Manually flex the cable. This manual inspection is needed to help identify breaks in the conductor wires, which may not be accompanied by corresponding breaks in the insulation. Conductor wire breaks are evidenced by increased flexibility of the cable at the break point, which is often the point where the cable joins an end connector.

Talk to the Specialist

In this column, we provide answers to questions frequently asked of ECRI’s specialists. Members of either the Health Devices System or the SELECTplus™ Program are encouraged to contact ECRI’s experts to pose questions such as these or to seek assistance on healthcare technology issues.

Identifying Reported Medical Device Problems Using ECRI’s Health Devices Alerts Database

Question: Before purchasing a device, we try to determine whether current users of the model have experienced any problems with it. How can we quickly obtain this type of information?

Answer: ECRI’s Health Devices Alerts (HDA) database — the world’s largest database on medical device hazards, problems, and recalls — is the best source for identifying reported problems with medical devices. The HDA database includes abstracts of clinical, technical, and legal literature; published medical device related problems from ECRI’s international medical device Problem Reporting System; information received directly from manufacturers and distributors; and reports from governmental and international sources such as the U.S. Food and Drug Administration (FDA), the U.K. Medical Devices Agency (MDA), the Australian Therapeutic Goods Administration (TGA), and Health Canada. The database is updated weekly and contains more than 850,000 records compiled since 1977.

Comprehensive custom searches of the HDA database can be obtained by any of three methods:

1. Health Devices System members receive three free custom searches each subscription year.** To request a search, complete one of the Database Search Request cards included in the front of your Health Devices binder, or contact Lisa Polillo at ECRI, (610) 825-6000, ext. 763.

* FDA reports in the HDA database include those from the Device Experience Network (DEN), Medical Device Reporting (MDR) system, and Problem Reporting Program (PRP). Soon the database will also incorporate information from the Manufacturer and User Facility Device Experience (MAUDE) system.

** ECRI can also provide additional database searches for a fee. Refer to the front of your Health Devices Alerts — Action Items binder for more details.
Another way to avoid the problem is to recognize that reusable cables have a finite lifetime and should be replaced before they cause a problem. This lifetime will vary depending on the cable’s usage, but can be determined from tracking, routine inspection, inventory control, and purchasing records. The presence of adequate strain relief (e.g., flexible boots around the point of greatest strain on the end connector and cable) will lengthen the amount of time that reusable cables can be used before they become susceptible to failure.

Supplier Recommendations

Most suppliers of ESUs, active electrodes, cables, and associated devices specifically warn users to inspect cables before use and before sterilization for damage such as breaks, cracks, or nicks in the insulation or for loose connectors. If such damage is found, the cable should not be used.

Some suppliers recommend that a pre-use activation test of the setup be performed just before patient use. This test will identify broken cables or intermittent connections. Readers should recognize, however, that these tests may not uncover cables that are damaged slightly enough to still allow low-power operation but that will melt or arc during high-power use.

Conclusion

While damaged or broken cables are a known risk, the recurrence of these problems suggests that some hospitals are not routinely performing pre-use (and cleaning) inspections of reusable cables.

Recommendations

1. Alert electrosurgical device users and central supply personnel to the need to inspect reusable electrosurgical cables, as discussed in this report, before use and during cleaning.

   A. Instruct users to inspect cables before use and to perform an activation test of the setup just before application to the patient. ([User manuals or instructions for the ESU or handpiece typically provide details of such activation tests.]

   B. Instruct central supply personnel to inspect cables before sterilization for excessive cable flexibility, for loose or broken connectors, and for nicks, breaks, cracks, holes, or other damage.

   Cables that are damaged — or that appear to be damaged — should be removed from service and either repaired or replaced.

   NOTE: We focus on reusable cables in this report because single-use cables are not likely to be subjected to the repeated actions that are most likely to result in cable damage. However, any type of cable can be damaged by one-time physical abuses, and single-use cables should likewise be examined before use.

2. Track reusable cables and determine their expected lifetimes based on their use, replacement rate, and failure rate. Replace reusable cables when they reach their expected lifetime (e.g., three months when used three or more times weekly).