

ALERTS TRACKER

ECRI European Office
29 Broadwater Road
Welwyn Garden City
AL7 3BQ

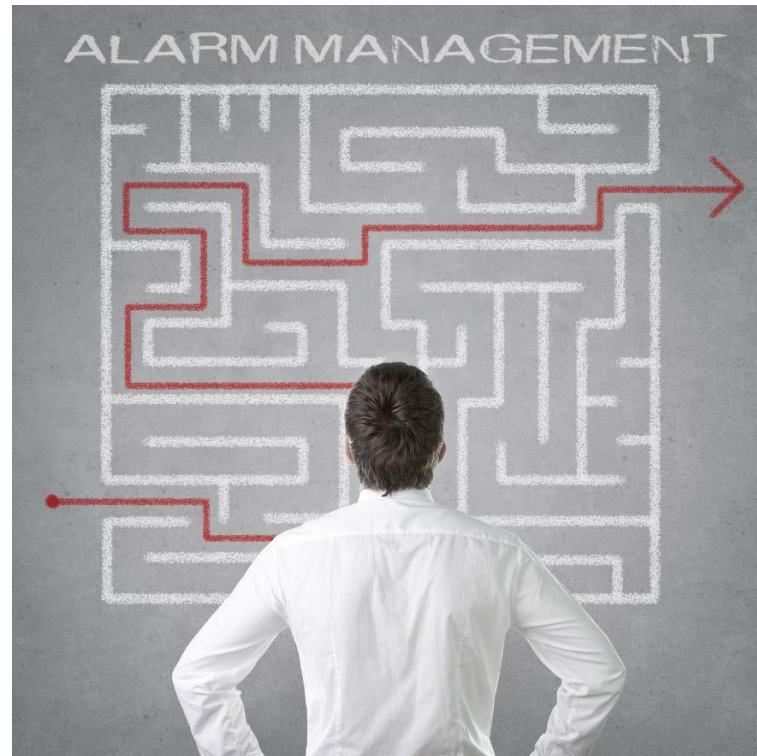
www.ecri.org.uk
info@ecri.org.uk

Alerts Tracker, why is it needed?

An Escalating Burden of Alerts

- ▶ Over 2500 Alerts per year now issued by ECRI

What are your current costs in time, risk and effort?



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The Challenges:-

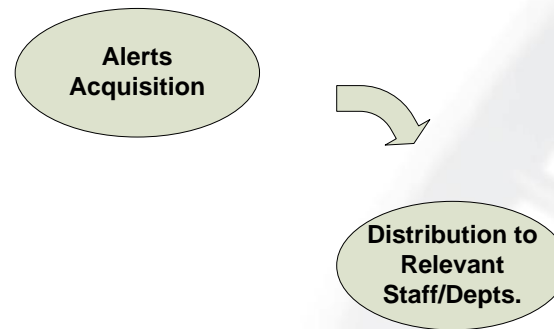
Alerts Management

Alerts
Acquisition

Alerts Acquisition – Multiple Sources

- ▶ Regulatory Agencies
- ▶ Manufacturer's recalls
- ▶ External agencies e.g. ECRI Institute
- ▶ Device users
- ▶ Local alerts

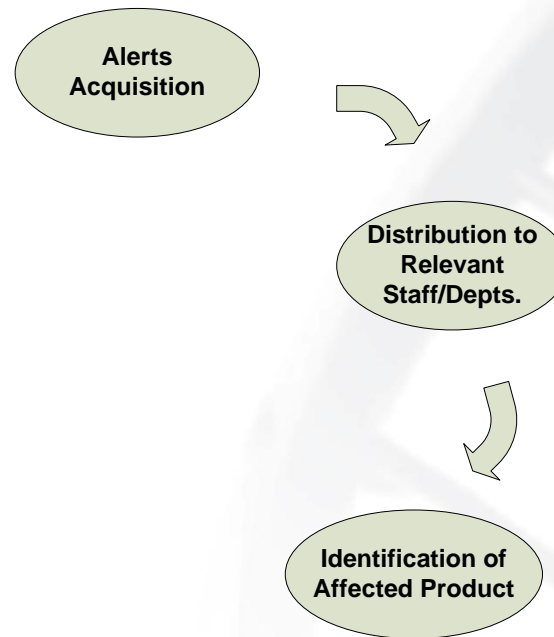
Alerts Management Process



Alerts Distribution

- ▶ Who should receive particular alerts?
- ▶ By what means should the alerts be distributed?
- ▶ Have alerts have been received by particular users?
- ▶ Do any of the alerts apply to that user?
- ▶ Is any action required?

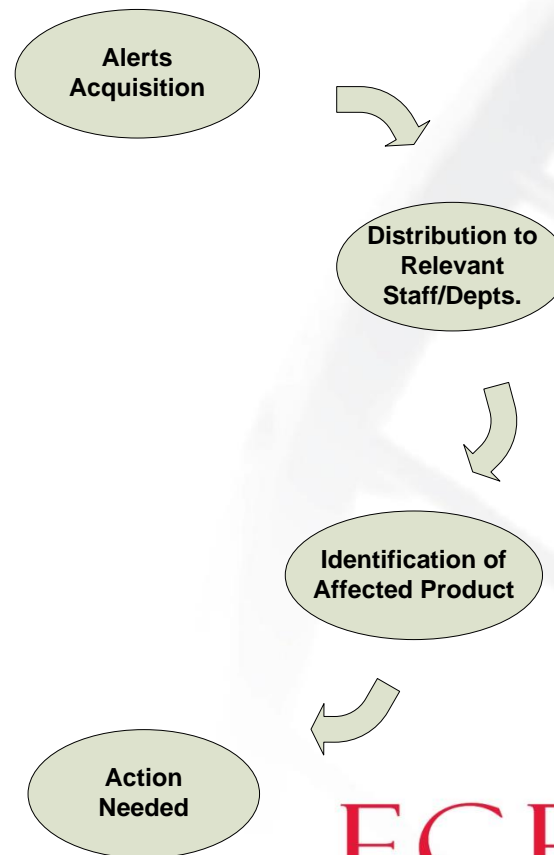
Alerts Management



Identify Affected Product

- ▶ Where are the devices kept/stored?
- ▶ Who has the affected devices?
- ▶ Who individually does the searching?
- ▶ Have all devices been identified?
- ▶ How do administrators direct product searches and identify the appropriate departments?

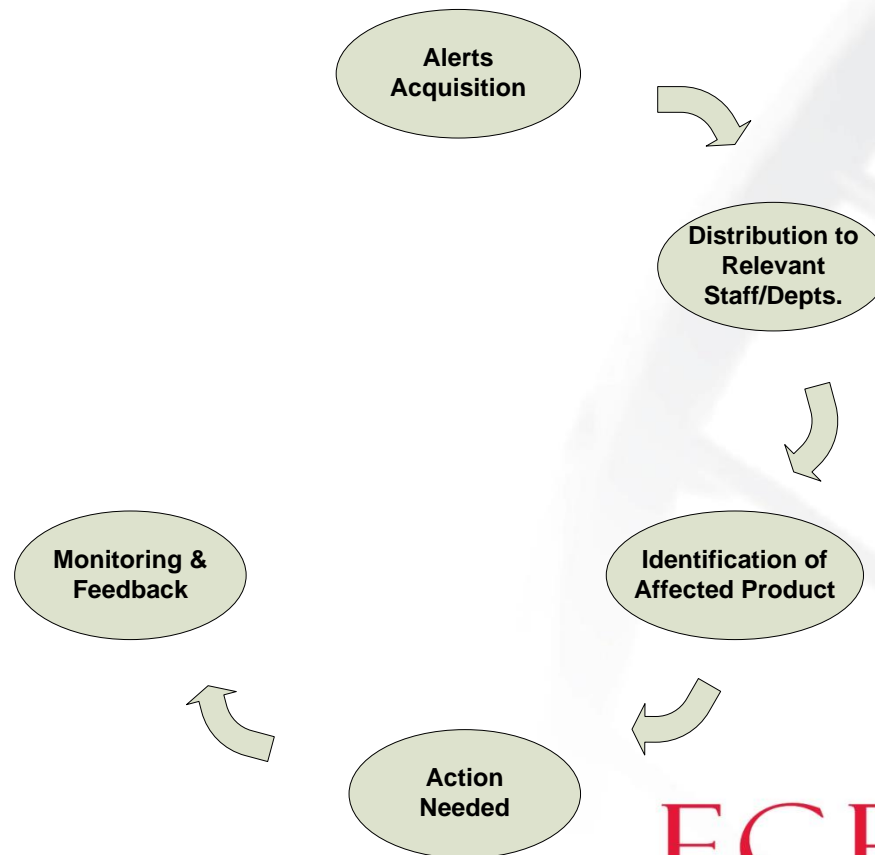
Alerts Management



Action Needed

- ▶ What is required to be done?
- ▶ Who does the work?
- ▶ Are any parts or replacement items required?
- ▶ Does the organisation possess the required skills and/or test equipment?
- ▶ Return or disposal of affected consumables
- ▶ Who accounts for the cost?

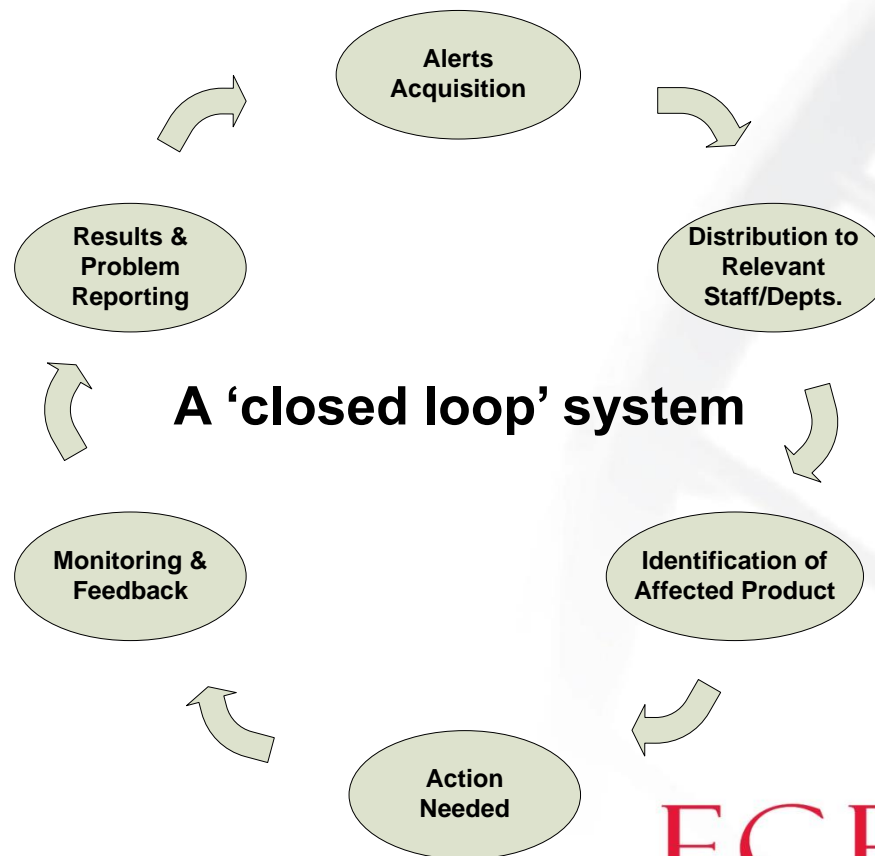
Alerts Management



Monitoring & Feedback

- ▶ Do alerts apply/not apply to assignees/users?
- ▶ Have assignees/users even read their alerts?
- ▶ Have any devices/supplies been identified as applicable to particular alerts?
- ▶ Have all alerts been assigned to at least one assignee/user?
- ▶ Have any required actions been completed?

Complete Alerts Management Process



The Solutions



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Alerts Sources



Hospital



Alerts Tracker

End-Users

What is Alerts Tracker?

- ▶ Interactive Web Service (App. Service Provider model)
 - Secure interactive Web site
 - Nothing to install or update
- ▶ Unlimited users at licensed facilities
- ▶ Two groups of users
 - Tracking users
 - Personalised e-mail notification of alerts
 - Record responses in central data repository
 - Coordinators
 - Configure and manage users
 - Monitor and report on activities of users

Alerts Acquisition

ECRI Institute's *Healthcare Product Alerts*

▶ Product Coverage


- Medical Devices
- Pharmaceuticals
- Blood Products
- Food Products

▶ Sources include:

- Hundreds of member hospitals
- Manufacturers
- ECRI Institute Original Research
- Agencies:- MHRA, NPSA, FDA, JCAHO, USDA, IMA, Health Canada, BfArM, etc.


Weekly Email Notification

From: HDAActionItemsByEmail@ecri.org
To: Vogel, Erica
Cc:
Subject: ECRI Institute Action Items for July 1, 2011



Alerts Tracker Action Items

WEEKLY ALERTS AND NEWS FOR ALERTS TRACKER MEMBERS



The Discipline of Science. The Integrity of Independence.

Note: Please do not reply to this e-mail, as your response will not be received.

- ▶ **Important Alerts Tracker Updates:** The Alert Status tab and the Alert Status Report have been updated to include alert status entries made by Defunct users. This will be beneficial in creating a more complete depiction of an organization's alert status, taking into account actions taken by those who are no longer with the organization or otherwise no longer involved with using Alerts Tracker at the organization.

Coordinators: To cancel multiple outstanding assignments for a Defunct user, access the Coordination tab, click to "Show Defunct Users," and click on the person's name. Next, click on "Terminate Assignments." This section will enable removal of the Defunct users' outstanding unresolved assignments, applying a neutral status to the person's outstanding assignments. You may elect to review particularly the "Applicable Open" status alerts prior to terminating them.

- ▶ For further information regarding *Health Devices Alerts* content, contact one of ECRI Institute's experts by e-mailing HDA@ecri.org or calling (610) 825-6000.
- ▶ For additional important announcements from ECRI Institute, please scroll down to the bottom of this e-mail or [Click Here](#). Announcements were updated on July 1, 2011.

Search	Action Items - Friday, July 01, 2011
Search / Report Preliminary Records	Alerts Assigned to You
Alert Tracking	High Priority A16213 Baxter-Interlink System 4-Way Large-Bore Stopcocks: Packaging May Have Tears and Pinholes, Potentially Compromising Sterility.
Dashboard User Preferences My New Assignments My To Do List	High Priority A16012 Leventon-Dosi-Flow Intravenous Extension Sets: May Leak
Recent Alerts	Your FYI Alerts
Medical Devices	High Priority A16238 Bard-Site-Rite Vision Ultrasound Systems: Internal Fan May Not Meet International Electrotechnical Commission Standard for Radiated Emissions
Help	High Priority A16135 Siemens-Model 10041461 ACUSON S2000 Ultrasound Systems: May Merge Measurements from 2 Patient Reports
HDA Help Alerts Tracking Help Tracker Coordination Help Submit An Alert	

▶ Alerts Tracker assigns each new alert to the appropriate users and notifies them by email.

▶ This email serves two functions:

1. Notification, and
2. Navigation

Automated Alerts Distribution

The screenshot displays the 'Alerts Tracker' interface for 'Health Devices Alerts - Assign Channel/Categories to Users'. The user 'Bob Smith' is selected. Under 'Alerts Channels', 'Medical Devices' is checked. Under 'Alerts Categories', 'Clinical Laboratory/Pathology' is checked. A note indicates that users should select/unselect checkboxes to assign/unassign alerts categories and click on save.

Alerts Tracker

Health Devices Alerts - Assign Channel/Categories to Users

Emergency CHS - Inland Medical Center - Bob Smith

Alerts Channels

Medical Devices Blood Products Food Products
 Pharmaceuticals

Note: Select/unselect check boxes to assign/unassign alerts categories to users and click on save.

Alerts Categories

Select All / Clear All

<input type="checkbox"/> Anesthesia	<input type="checkbox"/> Home Care	<input type="checkbox"/> Otolaryngology
<input type="checkbox"/> Cardiology/Cardiac Catheterization Laboratory	<input type="checkbox"/> Immunohematology/Blood Bank	<input type="checkbox"/> Pain Clinic
<input checked="" type="checkbox"/> Clinical Laboratory/Pathology	<input type="checkbox"/> Infection Control	<input type="checkbox"/> Pediatrics
<input type="checkbox"/> Clinical/Biomedical Engineering	<input type="checkbox"/> Information Technology	<input type="checkbox"/> Pharmacy/IV Therapy
<input type="checkbox"/> Critical Care	<input type="checkbox"/> Internal Medicine	<input type="checkbox"/> Phlebotomy
<input type="checkbox"/> CSR/Materials Management	<input type="checkbox"/> Neurology	<input type="checkbox"/> Physical Therapy/Rehabilitation
<input type="checkbox"/> Dentistry/Oral Surgery	<input type="checkbox"/> NICU	<input type="checkbox"/> Point-of-Care Coordination

- ▶ Includes 50 clinical and professional categories.
- ▶ Our experts apply the appropriate categories to each alert.
- ▶ Coordinators assign users to appropriate channels and categories.

Point and Click Tracking of Actions

- ▶ Users review and respond to alerts on the secure Alerts Tracker website.
- ▶ Documenting actions is simple using drop-down menus and a free text area.

Alert Current Status Details

Status: Applicable - Open
Action Taken: Called Supplier
Action Notes: Called supplier at 800-123-4567...

Alert Tracking

Status: ▾
Action Taken: ▾

Action Notes:

SAVE

CLEAR

ADD COMMENT

STATUS HISTORY

Identification

Alert Details | **Alert Status** | **Email Alert** | **Assignments**

Track this Alert

User Name	Action Taken	Action Note	Status	Status Date
Aldridge (test acct),Richard	None		Assigned - No Action - Viewed	2009-08-18 03:36:09

PRINT

Alert Current Status Details

Status: Viewed
Action Taken: None
Action Notes:

Alert Tracking

Status: <-- Select Status -->
Action Taken: <-- Select Status -->
Not Applicable
Applicable - Open
Applicable - Closed

Action Notes:

SAVE | **CLEAR** | **ADD COMMENT** | **STATUS HISTORY**

Back to Top

1 of 1

Action Needed

Alert Details | **Alert Status** | **Email Alert** | **Assignments**

Track this Alert

User Name	Action Taken	Action Note	Status	Status Date
Aldridge (test acct),Richard	None		Assigned - No Action - Viewed	2009-08-18 03:36:09

PRINT

Alert Current Status Details

Status: Viewed
Action Taken: None
Action Notes:

Alert Tracking

Status:

Action Taken:

Action Notes:

COMMENT | **STATUS HISTORY**

[Back to Top](#)

1 of 1

- <-- Select Action -->
- None
- Notified Users
- Isolated Affected Product
- Called Supplier
- Sent Response to Supplier
- Ordered Part(s)
- Issued Work Order
- Scheduled Service
- Completed Service
- Scheduled Training
- Completed Training
- Assigned
- Other

Real-time Reporting - Coordinators

Health Devices Alerts - Coordinators Search For Acknowledgement Report

Emergency Care Health System - Bayside

! Your search (' Alert type(s): Action Items and Special Reports and alerts with in last 4 weeks') returned 50 record(s).

[Go Back](#) [Back To Search](#) [Export to Excel](#)

Search Results:

November 11, 2005

Acc. No.	Priority	Resolved		Emergency Care Health System - Bayside					
		No	Yes	Bayside	Biomed	Purchasing	Clin Lab	OR	ED
A6706	Critical	0	0						
A6752	High	1	0						
A6712	High	0	1	NA		NA			
A6714	Normal	1	2	A		A		NA	A
A6748	Normal	0	2	A		A			A
A6749	Normal	0	2	NA		NA	NA		
A6752	High	1	0						
A6753	Critical	1	0						

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A6749	Normal	0	2	NA		NA	NA		
A6752	High	1	0						
A6753	Critical	1	0						

These alerts have been found to affect the hospital.

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Search Results:

November 11, 2005

Acc. No.	Priority	Resolved		Emergency Care Health System - Bayside					
		No.	Yes	Biomed	Purchasing	Clin Lab	SR	SD	
A6706	Critical	0	0						
A6752	High	1	0						
A6712	High	0	1	NA		NA			
A6714	Normal	1	2	A		A		NA	A
A6748	Normal	0	2	A		A			A
A6749	Normal	0	2	NA		NA	NA		
A6752	High	1	0						
A6753	Critical	1	0						

This alert has escaped review.

Real-time Reporting - Coordinators

Health Devices Alerts - Coordinators Search For Acknowledgement Report

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A6749	Normal	0	2	NA		NA	NA	
A6752	High	1	0					
A6753	Critical	1	0					

This department is not responding to alerts.

Monitoring for Problems

+ A10461		Critical	Philips—Model MX4000, Model MX4000 Dual, and Model MX6000 Dual Computed Tomography Systems: R-Host Box May Detach from Mount during Gantry Rotation	8/7/2008
+ A10464	A		GE—Model 2259976 Proteus XR/a Radiographic Systems: May Lack Required Warning Label	8/7/2008
+ A10466	NA		Hansen—Artisan Control Catheters: May Develop Leak, Potentially Leading to Adverse Patient Events	7/15/2008
+ A10476	NA		Specialised Orthotic Services—Mojo Wheelbases: Tires May Detach from Wheels, Potentially Causing Loss of Control	7/15/2008
+ A10477	NA	High	ev3—Protégé EverFlex Self-Expanding Stents: Product Number and Size Were Mislabeled	7/21/2008
- A10478	A	High	ev3—IntraCoil Self-Expanding Peripheral Stents: Product Number and Size Mislabeled	7/21/2008

Child Facilities (Emergency CHS - Inland Medical Center)	
Child Facility/Dept.	Status
No child records to display.	

Users (Emergency CHS - Inland Medical Center)		
Name	Status	Status Date
Jim Keller	Assignment Terminated	7/29/2008
Ken Ross	Assignment Terminated	7/29/2008
Erica Vogel	Applicable - Closed	7/30/2008
Ginny User	Assigned - No Action - Not Viewed	7/24/2008
Maria Foster	Not Applicable	7/29/2008
Cory Weaver	Assigned - No Action - Viewed	7/29/2008

Getting the Details

Alerts Tracker

Health Devices Alerts - Current Status of Users

Accession Number: A10464 **Not Prioritized** Last Updated: Thursday, August 7, 2008
D Broadcast Date: Friday, August 8, 2008

GE—Model 2259976 Proteus XR/a Radiographic Systems: May Lack Required Warning Label


Source Document(s):
[20071101GEProteusXRa.PDF](#)
[20080611GEProteusXRaySystems.pdf](#)

Note: Click the User Name hyperlink from the list to view the tracking information for that user.

User Name	Action Taken	Action Note	Status	Status Date
Foster, Maria	None	Administrative Note : Assignment The alert assignment is terminated by - [Cory Weaver]	Terminated	2008-08-08 12:04:46
Smith, Bob	Completed Service	Completed labeling on unit in 4B under WO # 12356.	Applicable - Closed	2008-08-13 09:24:46
Vogel, Erica	None	Administrative Note : Assignment The alert assignment	Terminated	2008-08-13 09:26:44

Getting the Big Picture

Community Hospital

 Aggregated Assignment Results [Chart] for alerts with publication date between 1/1/2008 and 8/1/2008 .

Total Alerts Assigned/Tracked	784	
Applicable	75	10 %
Open	23	3 %
Closed	52	7 %
Not Applicable	567	72 %
Undetermined	142	18 %
Other Assigned Users Not Applicable	142	18 %
No Information	0	0 %
All User Assignments Terminated	0	0 %



Alerts Tracker Service Includes:

- ▶ Consultative Implementation & Training
- ▶ Support for Establishing Sponsorship and Buy-In
- ▶ Ongoing Program Improvement Support
- ▶ On Demand Consultation
 - Alert interpretation support
 - Program and policy development

Summing Up

▶ Simplifies and Streamlines the Process

- Automated Alerts Distribution
- Point and Click Tracking

▶ Facilitates Cooperation

- Information Sharing
- Communication

▶ Ensures Accountability

- Easy, Real-time Reporting