ACCE
AMERICAN COLLEGE OF CLINICAL ENGINEERING

2023-2024 Educational Webinar Series

Recall Management Best Practices

March 21, 2024

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About the Moderator

Martin Poulin, P.Eng., FCMBES
Director, Biomedical Engineering
Island Health, Victoria, BC, Canada

- Director of Biomedical Engineering for Island Health, Victoria, BC, on the west coast of Canada.
- 25+ years health technology management
- 5 years in the medical device development industry in Vancouver.
- Master of Engineering in Clinical Engineering from UBC
- Past President of CMBES

Logistics

- All attendees have their microphones muted during the presentation.
- Questions to the panelists must be submitted via the "Q&A" feature in Zoom at any time. They will be addressed at the Q&A portion, slide#39.
- If there is any urgent issue, please use the "chat" feature to communicate with the host/moderator.
- Please remember to complete the webinar evaluation after attending. A link will be provided at the end, slide#40.

Session Description

Review of Recall Management Best Practices to improve patient safety and ensure regulatory compliance. This session will discuss through effective recall response strategies and provides insights from healthcare organizations' recall management journey.

About the Panelist

Tom Toczylowski
Assistant Director, Alerts
ECRI

Tom Toczylowski is the Assistant Director of the ECRI Alerts product, which provides ECRI members with recall and safety notifications to help safely manage medical devices, pharmaceuticals, and other medical products. A proud ECRI employee since 2008, Tom manages a group of writers, editors, and data coordinators who all contribute to ECRI's Alerts, recall management solutions, and inventory management products.

In addition to his many years of experience with medical device safety, recall management software solutions, and equipment data standardization, Tom has maintained a focus on the clinical laboratory and laboratory research. Prior to coming to ECRI, Tom spent several years working in molecular research laboratories at Fox Chase Cancer Center and Thomas Jefferson University.

Best Practices for Recall Management

1. Have a Recall Policy with intention of enforcing it
2. Sponsorship of Recall Management within a hospital, no matter the size.
    1. No support leads to users not monitoring recalls
3. Primary tracker for each area - (SME) but also have a backup for when that person is on PTO or extended leave
4. Maintain up to date user list
    1. Notification sent to head of Recall program regarding employees that have left to maintain up to date list of users
    2. Review list of users anywhere from quarterly to yearly depending on frequency of turnover
5. Training manual with how to track recalls per system you are using
6. Regular reporting to ensure tracking
7. High Completion Rate

Successful Recall Management Key Concepts

- How alerts information is obtained and shared
- How to address and monitor program compliance
- Internal and external documentation needs
- How to report to program participants

Leadership and Sponsorship

- Challenges
  - Executive Sponsorship
  - Involvement of Patient Safety and/or Risk Management
  - Promoting Alerts Management as a Patient Safety Initiative

- Best Practices
  - Involvement of Patient Safety and/or Risk Management department
  - Promoting accountability through effective leadership
    - Sponsorship, Oversight, Awareness, Written Policy, Program Cohesion
  - Establish Alert Evaluation Team

Collaboration

- Challenges
  - Promoting and maintaining participation
    - Overcoming resistance to involvement
    - Avoiding duplication of effort

- Best Practices
  - Cultivate a network of safety advocated
  - Sufficiently documented process
  - New employee onboarding process

Alerts Acquisition and Review

- Challenges
  - Have the right information
    - Externally
    - Internally
  - Reliability of sources
    - Accuracy, Completeness, Timeliness

- Best Practices
  - Obtaining and sharing alerts information
  - Manage internal non-recall incidents
  - Preparatory measures when not following recommendations
  - Ensuring alerts are not missed

Documentation and Reporting

- Challenges
  - Complete, accessible record of how affected
    - Did this alert affect us?
    - Has it been resolved?
    - Who did what and when?

- Best Practices
  - Maintaining complete and accessible documentation
    - Internal needs – i.e., Safety Committee
    - External needs – i.e., FDA, Joint Commission
  - Update policies as needed
  - Feedback to sponsors and participants

Recall Management Measures of Success

Reporting Routines

- Compliance
  - To ensure that users are addressing Alerts
  - ECRI Recommendation: 95% Completion Rate
  - Send to users on a monthly/quarterly basis
- Percent Tracked as Applicable
  - To ensure that users are addressing Alerts correctly
  - ECRI Recommendation: 5-7%
- List of Alerts Tracked as Applicable
  - To report to Safety/Environment of Care Committees

About the Speaker

Shelly Crisler Leacock, MS, CCE, PMP
Biomedical Engineer
VHA Healthcare Technology Management

VA | U.S. Department of Veterans Affairs

SHELLY LEACOCK is a Clinical Engineer with the Department of Veterans Affairs (VA) for over 18 years

- Provides direction and support regarding equipment management, alerts, recalls, incident response, continuing education, medical device safety, and more.

AWARDS

- AAMI Young Professional Award (2014)
- AAMI & Becton Dickinson's Patient Safety Award (2019)

HTM COMMUNITY ENGAGEMENT

- ACCE Board
- AAMI Healthcare Technology Leadership Council
- AAMI Equipment Management (EQ) Standards Committee
- NFPA 99 Medical Equipment Standards Committee
- Medical Device Servicing Community
- ECRI Health Devices Advisory Board

Learning Objectives

1. Learn requirements of an alerts/recalls management process and how to apply them at your hospital or organization.
2. Learn the process that VHA HTM uses for the management of equipment alerts and recalls including the risk and resources evaluation process.
3. Understand the importance of documenting and tracking the corrective actions and their completion.

A Closed-Loop Process for Remediation of Equipment Alerts/Recalls

Agenda

1. Introductions and Background
2. Intake
3. Evaluate
4. Mitigate
5. Continuous Improvement
6. Takeaways
7. Discussion

Veterans Health Administration
Healthcare Technology Management

vacareers.va.gov/job-news-advice/find-fit-tcf-programs gov
www.va.gov
www.usajobs.gov
jobs.aami.org/jobs/

1 | Introductions: VA HTM

1 | Background: High Reliability Organizations

1 | Background: Laws, Regulations, Standards

The **VA Office of HTM** provides policy oversight for the management of medical technology across VA consistent with relevant laws, regulations, industry standards, and accreditation requirements, including:

Safe Medical Devices Act of 1990
Public Law 101-629

Food and Drug Administration
21CFR 803, Medical Device Reporting

Association for the Advancement of Medical Instrumentation
EQ56, Recommended Practice for a Medical Equipment Management Program

The Joint Commission
Standard Environment of Care
EC.02.04.01, EC.03.01.01, EC.04.01.01

National Institute of Standards and Technology

Department of Veterans Affairs
VA policies and standards

1 | Background: Medical Equipment Alerts/Recalls

A medical equipment recall is a method for **correcting or removing** medical devices from use that are in violation of laws administered by FDA or otherwise deemed defective or potentially harmful to patients

CORRECTION means repair, modification, adjustment, relabeling, destruction or inspection of a medical device without its physical removal

Alerts and recalls are initiated by manufacturers, FDA request or order, and healthcare systems

VA initiates and conducts internal alerts/recalls when a safety issue is found at one or more local facilities and there are risk mitigating actions that can be implemented

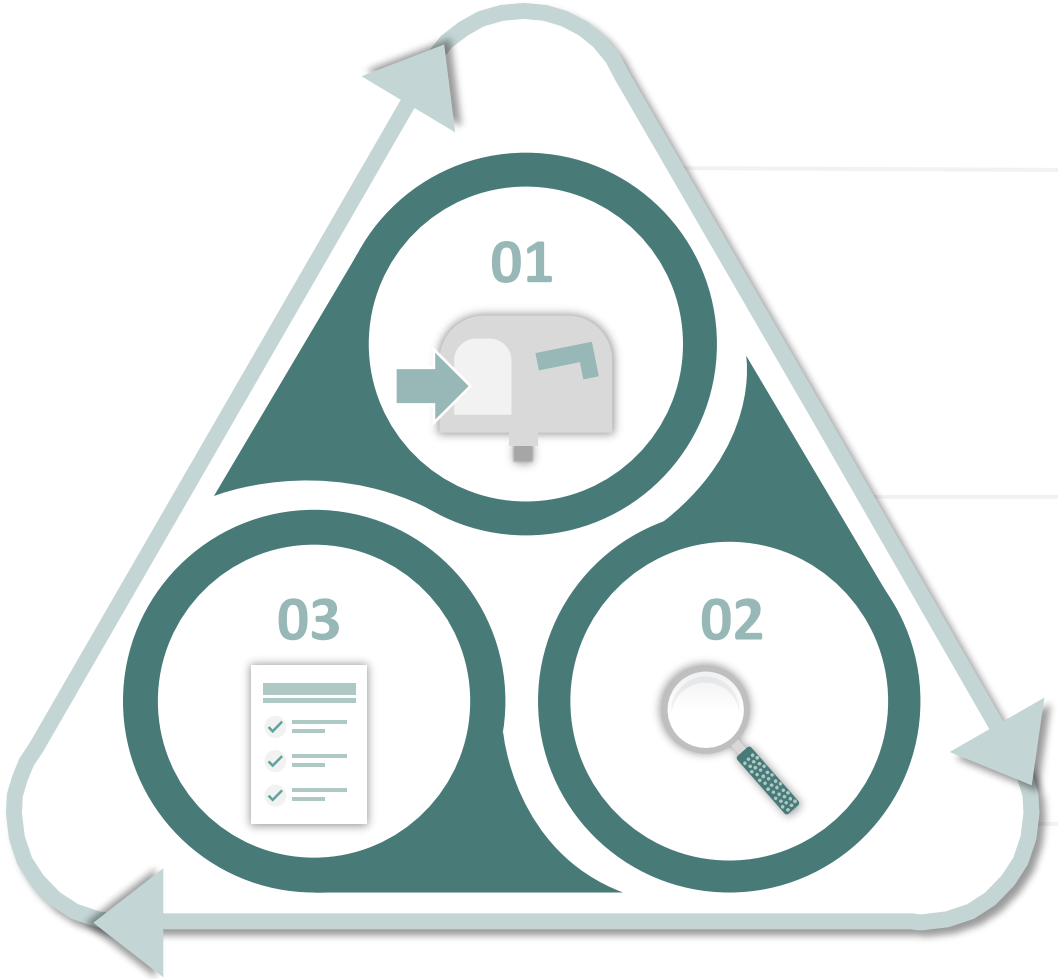
1 | Background: VHA Alerts/Recalls Management Components

ALERTS & RECALLS Management

is a critical patient safety program with key components:

- **Executive sponsorship**
- **Written policies**
- Comprehensive **sources of recalls**
- **Programmatic collaboration** to limit duplicative efforts
- Ability to **target facilities** that have the affected equipment
- **Internal recalls**
- **Specific actions** and **due dates**
- **Closed-loop process**
- Clear and consistent **communication channels**
- **Training events**

Process Overview: Intake, Evaluate, Mitigate



01 INTAKE

Receiving and documenting awareness of an alert or recall, checking applicability against inventory, and identifying mitigating activities

02 EVALUATE

Setting priorities and deadlines for mitigating actions through evaluation and scoring of associated risks and resource needs

03 MITIGATE

Communicating mitigating actions, performing them, and “closing the loop” by tracking, measuring, and reporting their completion

2 | Intake: Research Alerts & Recalls

PROACTIVELY RESEARCH ALERTS & RECALLS

sources

MANUFACTURERS & VENDORS

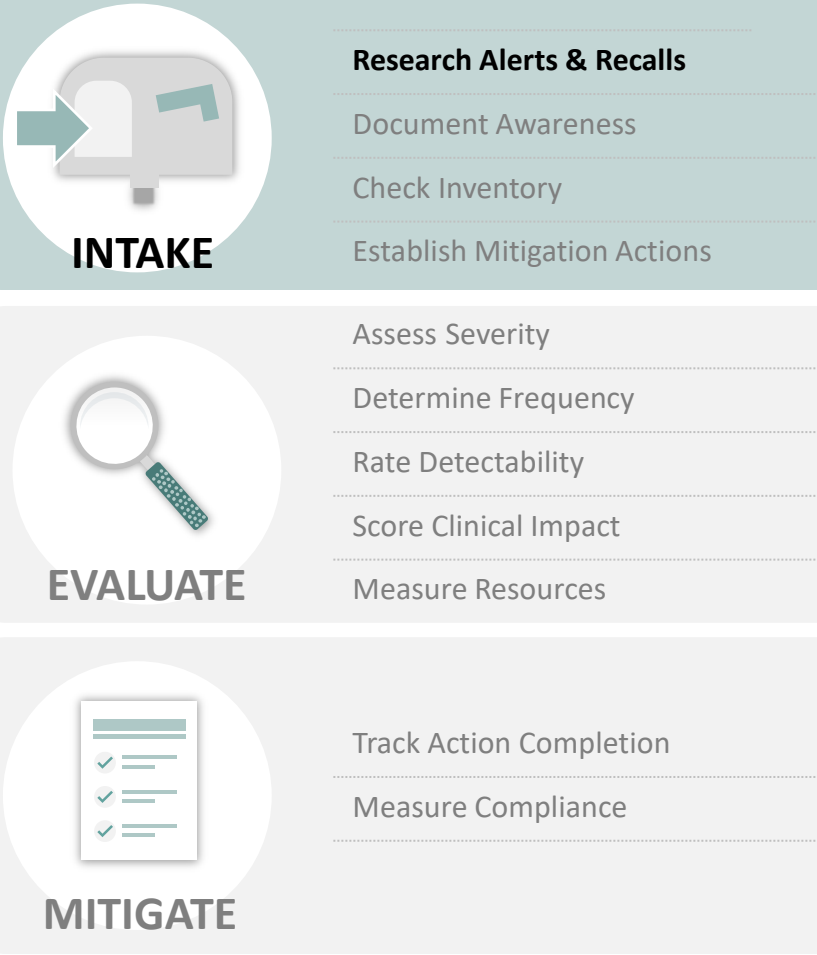
VA HTM departments forward all alerts/recalls to a central POC for processing

PROFESSIONAL ORGANIZATIONS

VA maintains an ECRI Membership and searches postings by ECRI and FDA

INTERNAL INCIDENTS

VA facilities report incidents to a central POC and VA-only recalls are created as needed



2 | Intake: Document Awareness

DOCUMENT ALL ALERTS/RECALLS

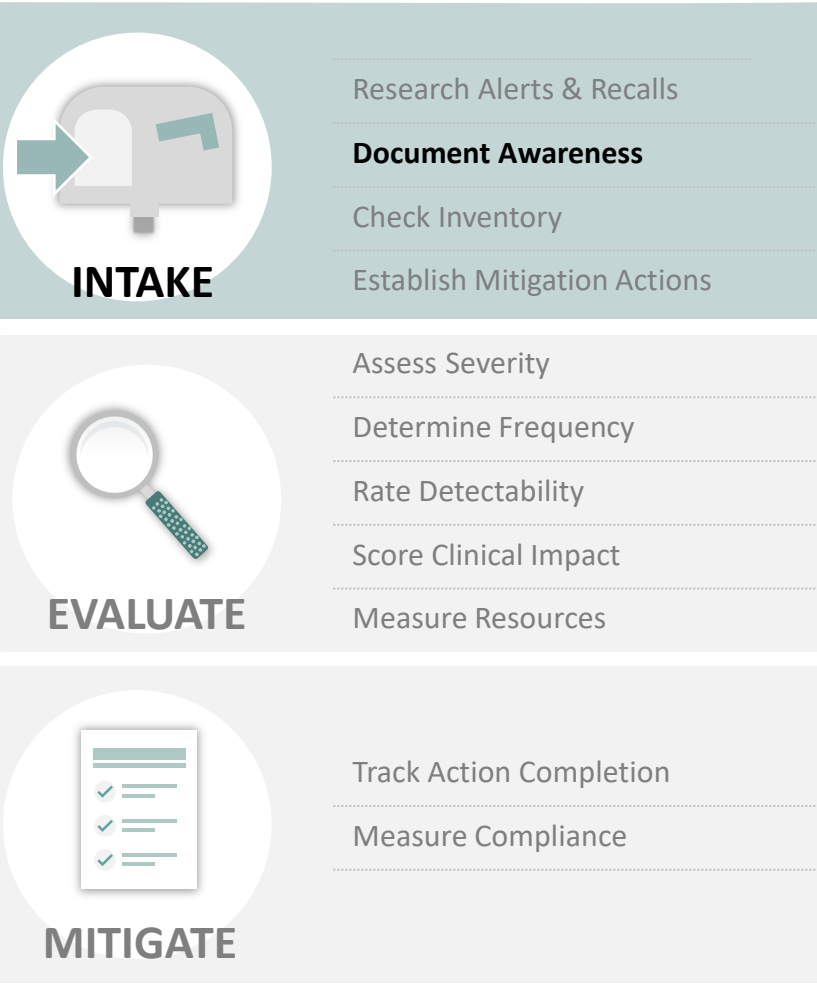
centrally within multi-hospital program

Document Date Received, Priority/Designation, Status

Discard duplicate issues

Confirm applicability to HTM scope of services

Notify other service lines if relevant



2 | Intake: Check Inventory

SEARCH EQUIPMENT INVENTORY FOR THE AFFECTED MODEL

MULTI-HOSPITAL PROGRAMS

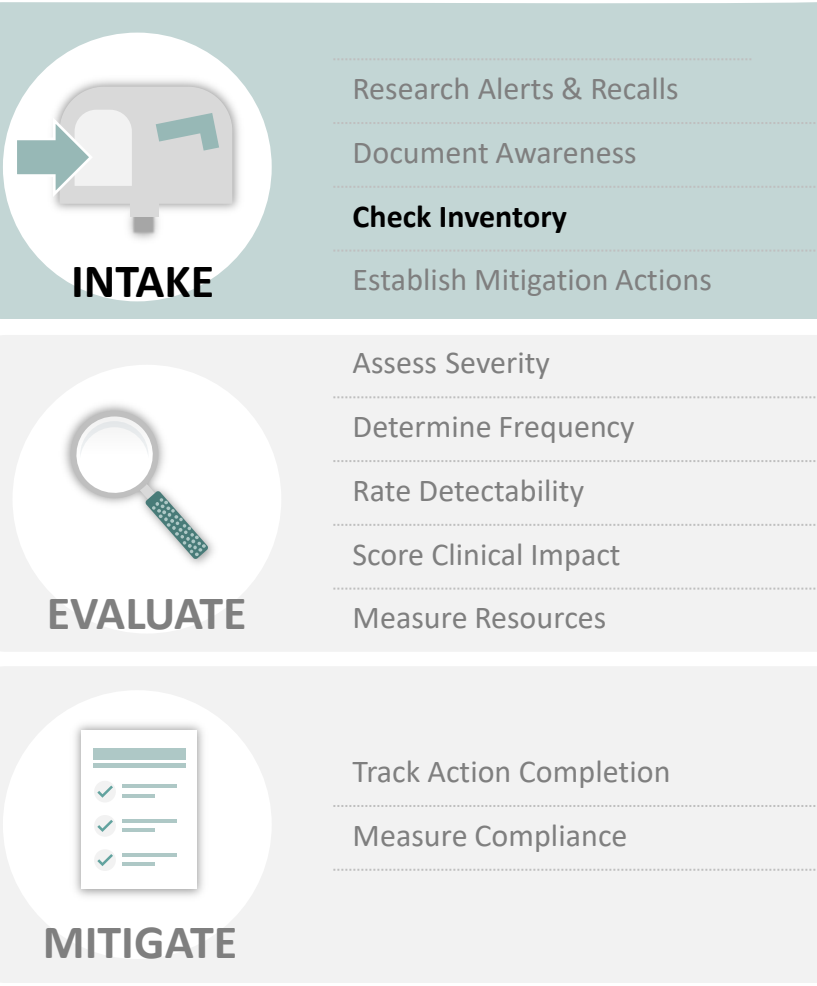
search inventory centrally

STANDALONE FACILITIES

search inventory locally

VA HTM performs nationwide inventory searches and assigns and notifies **only the facilities that have the affected equipment**

A complete and accurate inventory with standard naming conventions facilitates this process!



2 | Intake: Establish Mitigation Actions

IDENTIFY ACTIONS

WHO

Stakeholders responsible for completing actions e.g., HTM, manufacturer, vendor, clinical

WHAT

Mitigating actions e.g., changes to PM procedures, EOC rounds, or other activities

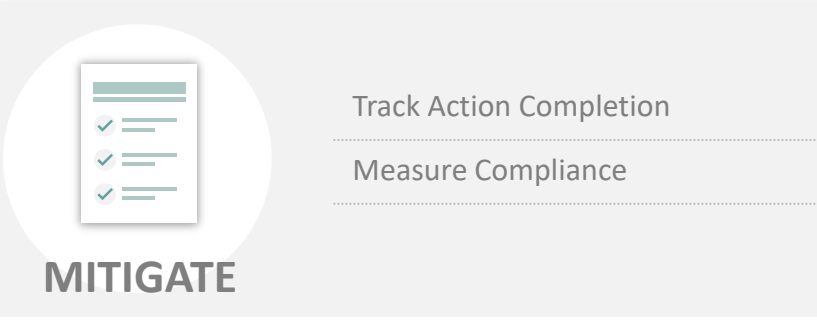
WHEN

Timelines to complete actions e.g., immediate vs. future

FOR ADDITIONAL INFORMATION

Reach out to the manufacturer to understand scope of affected equipment, risk factors, mitigation strategies, and required actions – maintain list of manufacturer contacts

Communicate with other facilities to understand issues they may be experiencing, effectiveness of mitigating actions or questions they have



3 | Evaluate: Assess Severity

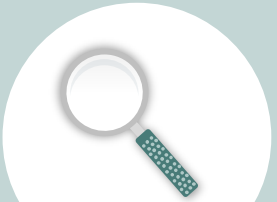
SEVERITY

the degree to which the failure causes harm (injury, illness, or death)

4 | **Catastrophic**	Failure can cause **death,** injury, or illness that **requires medical or surgical intervention to prevent permanent loss of function** in sensory, motor, physiologic or intellectual skills to patient, visitor, or staff.
3 | **Major**	Failure can cause **permanent lessening of bodily function** (including but not limited to sensory, motor, physiological or intellectual) and **disfigurement** to patients, visitors, and staff.
2 | **Moderate**	Failure can cause injury or illness that **requires medical or surgical intervention**, **requiring increased length of care** or loss time from work to patients, visitors, and staff.
1 | **Minor**	Failure causes **no injury or illness** and **requires no medical or surgical intervention** other than first aid treatment. Requires **no increased length of care** or loss time from work to patients, visitors, and staff.

INTAKE

- Research Alerts & Recalls
- Document Awareness
- Check Inventory
- Establish Mitigation Actions



EVALUATE

- **Assess Severity**
- Determine Frequency
- Rate Detectability
- Score Clinical Impact
- Measure Resources

MITIGATE

- Track Action Completion
- Measure Compliance

3 | Evaluate: Determine Frequency

FREQUENCY

the likelihood the failure will occur in your hospital(s) over a defined time

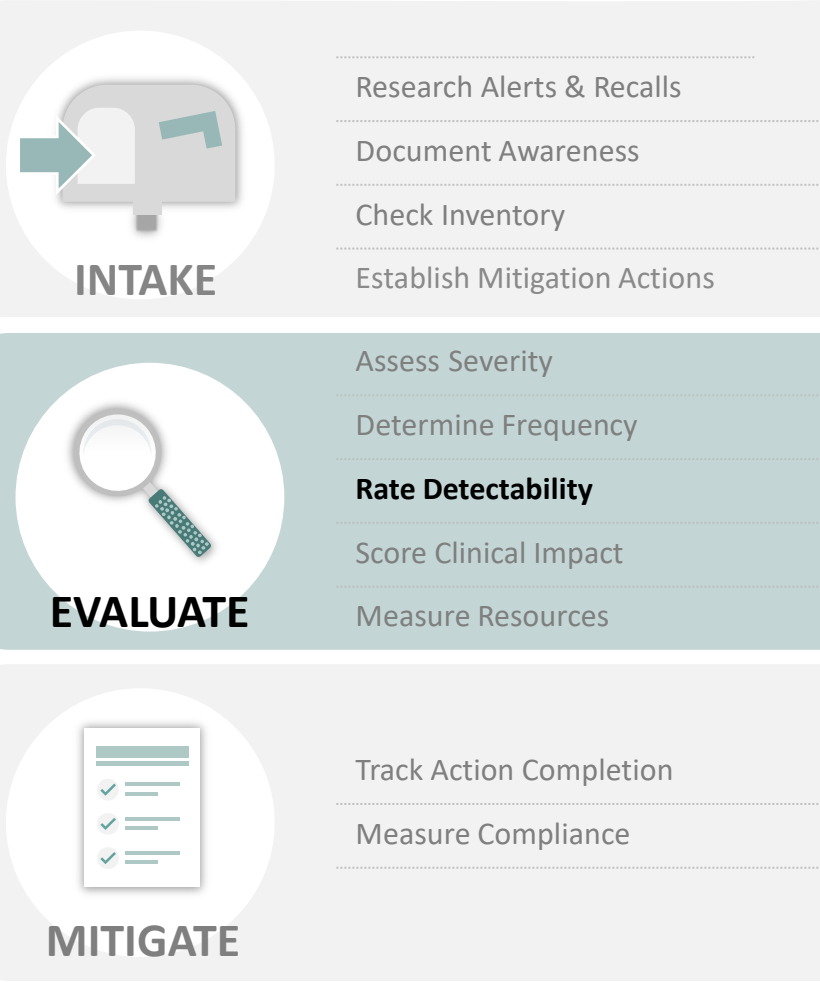
4 | **Frequent**	Likely to occur immediately or within a short period (may happen at a VHA facility **several times in one month**).
3 | **Occasional**	**Probably** will occur (may happen at a VHA facility **several times in three to four months**).
2 | **Uncommon**	**Possible** to occur (may happen at a VHA facility sometime **within the next six months**).
1 | **Remote**	**Unlikely** to occur at a VHA facility **within the next year**.

3 | Evaluate: Rate Detectability

DETECTABILITY

the likelihood of the failure being recognized by users before the failure occurs

3 | **Low**	Vulnerability or defect **will not be identified or detected** by the user.
2 | **Moderate**	Vulnerability or defect **may be discovered prior to injury or use**.
1 | **High**	Vulnerability or defect **will be obvious** to the user and will be d**iscovered before the patient is harmed**.



3 | Evaluate: Score Clinical Impact

CLINICAL IMPACT

the degree to which the failure interrupts clinical operations or functions.

3 | **High**	Vulnerability or defect **interrupts all** clinical operations or functions associated with the affected medical device. Use of affected devices **may not continue and they must be removed from service. Alternative equipment is likely not available.**
2 | **Moderate**	Vulnerability or defect **interrupts some** clinical operations or functions associated with the affected medical device. Use of affected devices **may continue with deactivation of affected features or alternative risk reduction plan.**
1 | **Low**	Vulnerability or defect **does not interrupt** clinical operations or functions associated with the affected medical device. **Use of affected devices may continue.**

3 | Evaluate: Risk Score

PRIORITIZE HIGH RISK RECALLS AND ASSIGN SHORTER DUE DATES

Classified as **High Risk** if **any** of the following apply:

- Overall Risk Score of 32 or greater
- Severity Score of “4” (Catastrophic)
- Clinical Impact of “3” (High)
- FDA Class 1
- Resulted in death(s)

CLINICAL IMPACT VS. DETECTABILITY

SEVERITY VS. FREQUENCY	1	2	3	4	6	9
1	1	2	3	4	6	9
2	2	4	6	8	12	18
3	3	6	9	12	18	27
4	4	8	12	16	24	36
6	6	12	18	24	36	54
8	8	16	24	32	48	72
9	9	18	27	36	54	81
12	12	24	36	48	72	108
16	16	32	48	64	96	144

INTAKE

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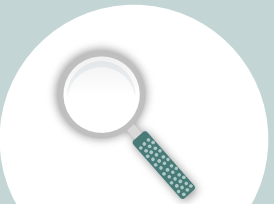
- Document Awareness
- Check Inventory
- Establish Mitigation Actions



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MITIGATE

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- Measure Compliance

3 | Evaluate: Measure Resources

RESOURCES SCORE

CRITERIA

must meet 2 of 3 to be labeled as **HIGH RESOURCES**

1	**NUMBER OF AFFECTED UNITS**	**500+ devices affected**
2	**NUMBER OF AFFECTED FACILITIES**	**50+ sites affected**
3	**COMPLEXITY OF REMEDIATION**	**highly complex remediation** *must meet 4+ subcriteria, requiring:* □ Removal of device from service □ Clinical precautions before remediation □ Replacement/loaner before remediation □ Third-party service on site □ Return of the device to the vendor □ Parts/replacements □ Travel to other hospitals/clinics

HIGH RESOURCES recalls are assigned longer due dates

4 | Mitigate: Track Action Completion

DOCUMENT ACTION COMPLETION

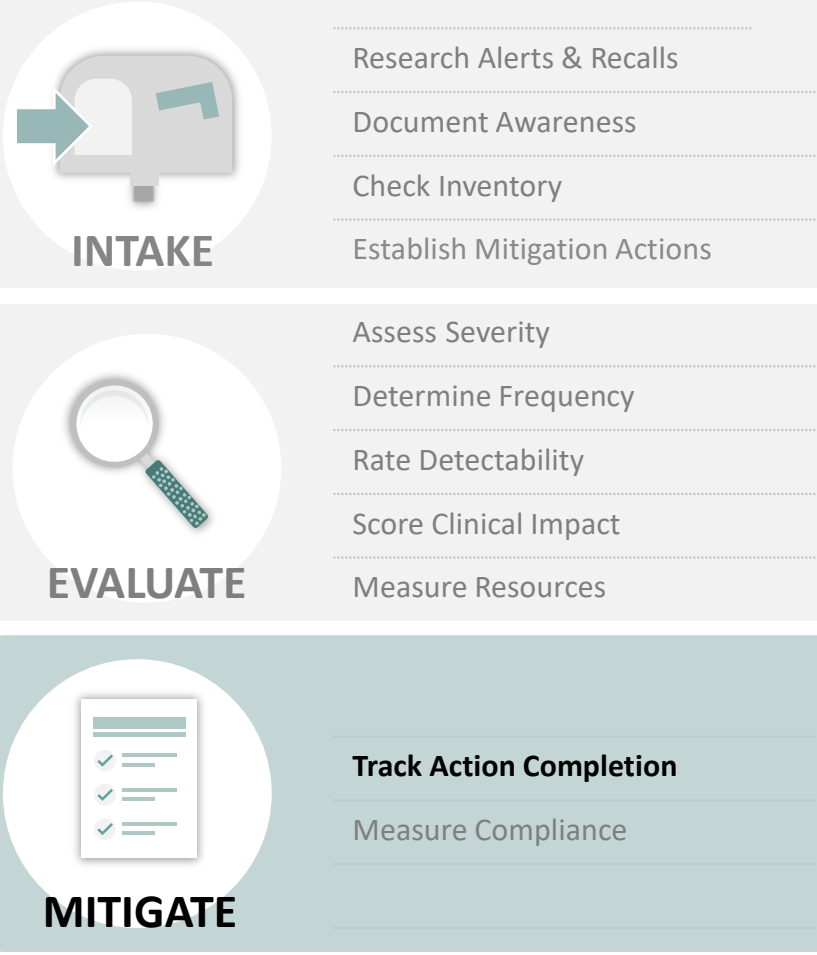
Establish a process for assigning alerts/recall records as open/closed

BENEFITS

Closes the Loop!
confirms mitigation of risk

Supports measurement of compliance
must record date of action completion

Informs evaluations of future alerts and recalls
High Reliability Organization!



4 | Mitigate: Measure Compliance

MEASURE COMPLETION OF ACTIONS

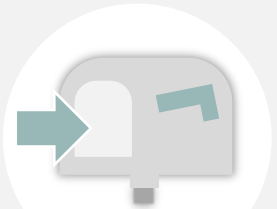
Final Action Compliance

percent complete by the Due Date

$$\frac{\#\text{ of Actions where the Final Action was completed and verified by the Due Date}}{\#\text{ of Actions where the Final Action was Due in a given month or quarter}}$$

Open Overdue Recalls

number of open and overdue Final Actions



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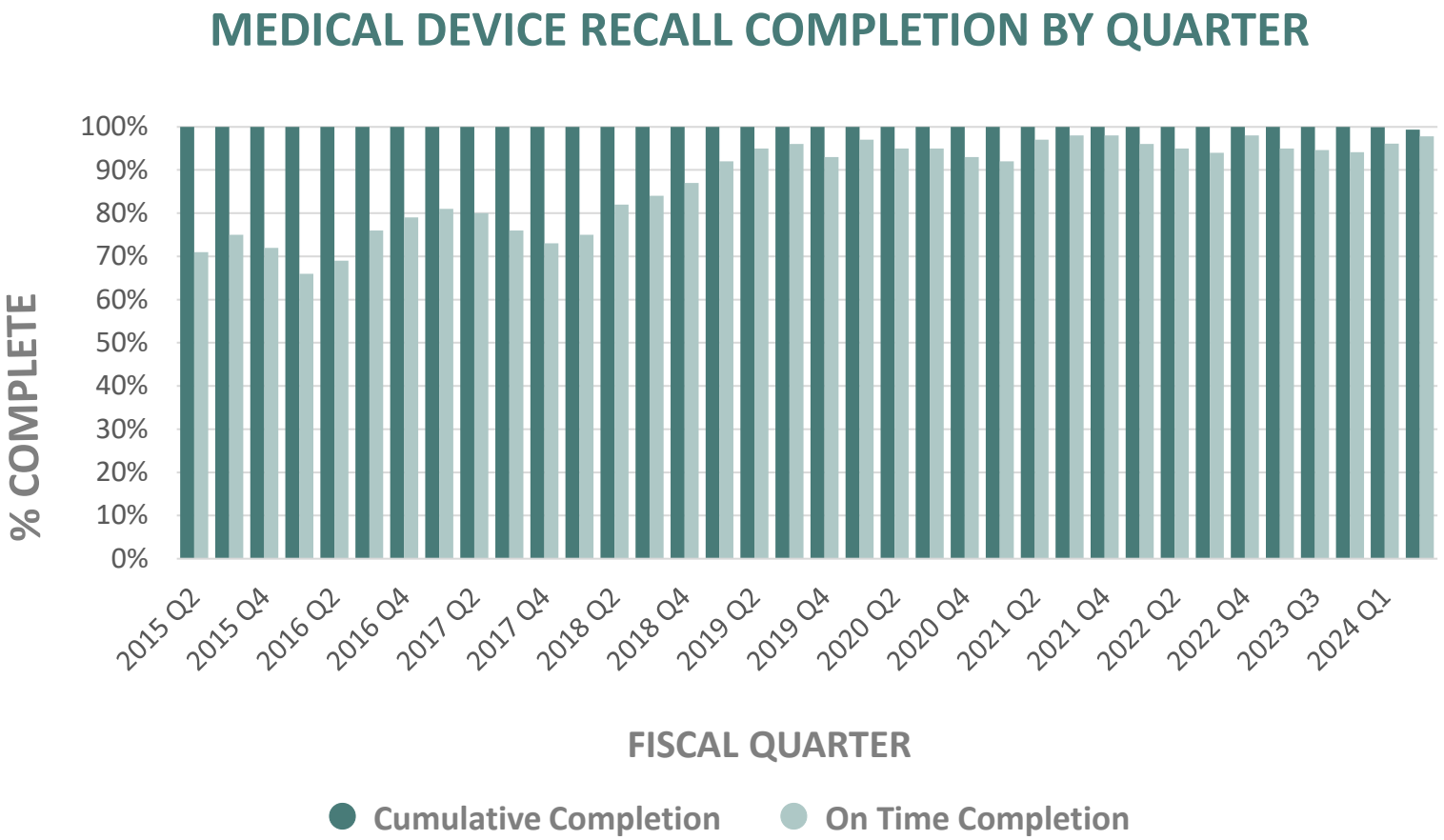
4 | Mitigate: Measure Compliance



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MITIGATE

- Track Action Completion
- **Measure Compliance**

5 | Continuous Improvement

IMPROVE REPORTS

Improve inventory reporting to better target affected sites and develop and provide more real-time reporting for better performance monitoring

IMPLEMENT ENTERPRISE SYSTEMS

Deploy and utilize an enterprise work order system to issue, track, and measure remediating actions

SHARE BEST PRACTICES

Engage with VA HTM Community and larger industry community to share and learn best practices

6 | Takeaways

1. **Establish a program**
   tailor components of an alerts and recalls management program to create standardized policies and functions

2. **Implement a process**
   span phases of Intake, Evaluate, and Mitigate to manage risks, prioritize resources, and monitor performance

3. **Close the loop**
   document and track corrective actions associated with alerts and recalls to ensure their completion

Questions / Comments / Concerns

Please enter your questions/comments/concerns to both speakers in the Zoom Q&A window

Thank you

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