

Complaints, Servicing, and FDA Reporting

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Outline

- Setting the Stage
- Servicing
- Complaints
- Medical Device Reports
- CAPA
- Design Changes
- 510(k) Change Analysis
- Corrections and Removals
- Summary and Conclusions
- Questions

Setting the Stage

Our Approach to the Problem

Paradigm Case #1

- Jim, a service technician, is at a customer's site, a hospital, performing scheduled periodic maintenance.
- A nurse stops by and says, "Did anybody tell you about the problem we had with this unit the other day? The patient got into trouble, but we intervened, and she is fine. We expected an alarm, but didn't get one."
- The technician says, "I ran the diagnostics today, and there were no problems. Let us know if it happens again."

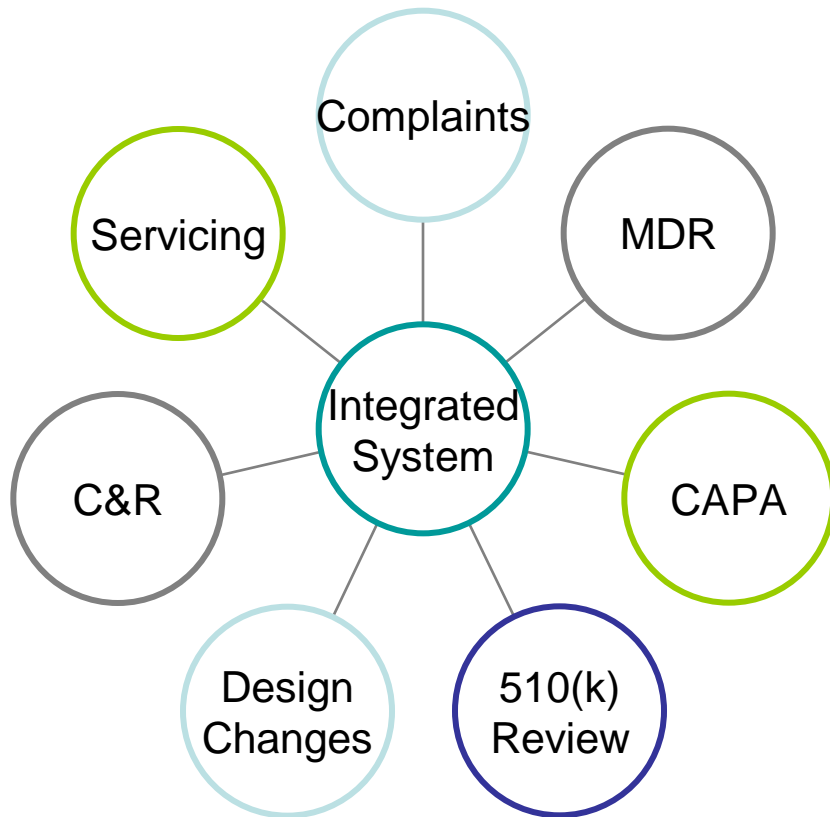
Paradigm Case #2

- Fred, a QA Data Analyst says to Mary, the QA/RA Director, “I’ve been doing some analysis of the actuator arm bearing. The reliability prediction was an MTBF of 185,000 actuations, but we are only getting 65% of that. Looks like we might have a problem.”
- Mary responds, “Keep an eye on it, but we probably don’t need to do anything until we have more data.”

Question

- In these two paradigm cases, did the parties handle the issues correctly?
- We will use these paradigm cases to illustrate the systems and some of their requirements:
 - Servicing
 - Complaints
 - Corrective and Preventive Action
 - Medical Device Reporting
 - Design Changes
 - 510(k) Change Analysis
 - Corrections & Removals

An Integrated View



- The Radial Diagram has an Integrated System at the hub, with associated systems around it.
- Our focus is in three areas
 - System Interrelationships
 - Records
 - Reporting (to FDA)

System Interrelationships

- Each of the systems in the radial diagram touch one or more of the others
- As we look at system, we will show the interrelationships with diagrams

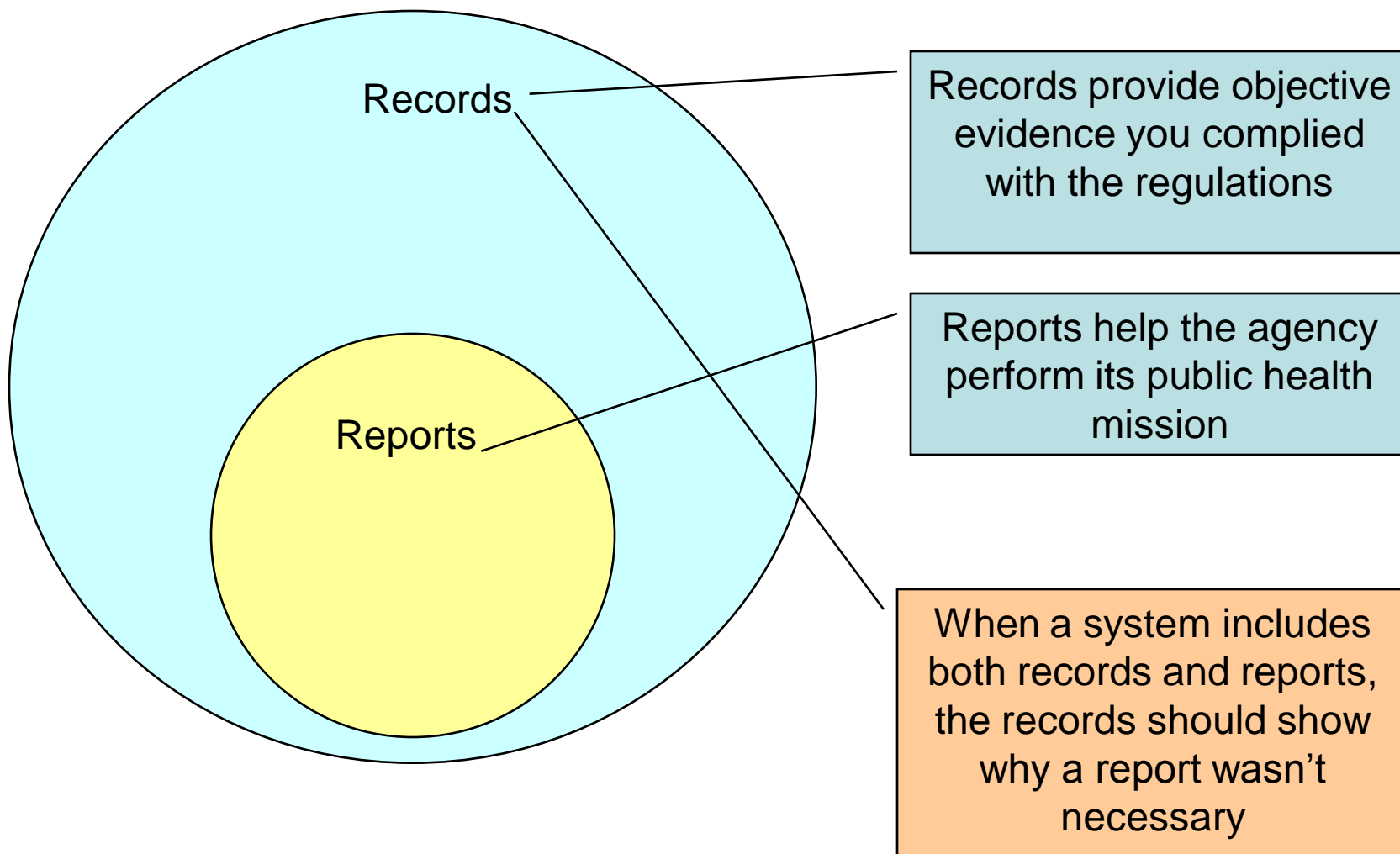
Records

- We characterize records in two dimensions
- Trigger
 - What activities cause you to initiate a record?
- Content
 - What kinds of information belong in the record?
 - We don't look at the details here, only an overview

Reporting (to FDA)

- We characterize reporting in three dimensions
- Trigger
 - What activities cause you to make a report?
- Timing
 - How long do you have from the trigger until the report is due?
- Content
 - What kinds of things go into a report?
 - We don't look at the details, only an overview

Records and Reports



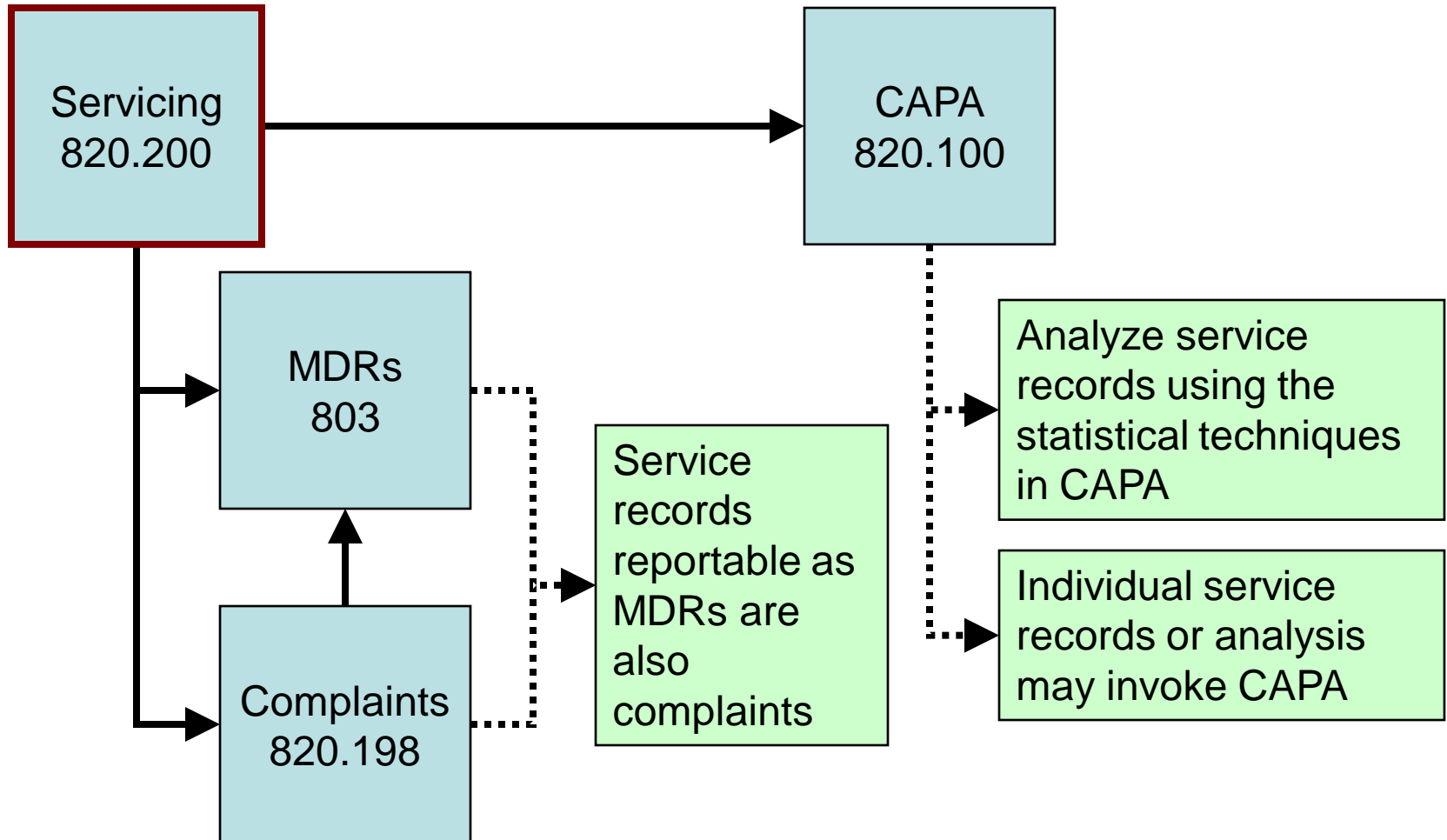
Servicing

21 CFR 820.200

Servicing Definition

- Definitions
 - Neither QSR nor ISO 9000:2005 define servicing
- Limitations
 - QSR limits servicing to those cases where it is a “specified requirement”
- Convention
 - QSR uses the term “service reports”.
 - We use reports for “information reported to the FDA”
 - We use records for “information retained by the manufacturer”

Servicing Interrelationships



Servicing Records - Individual

- Trigger
 - Servicing records are kept for every servicing event
- 820.200 defines the minimum content of an service records
 - Name of the device
 - Identification or control numbers
 - Date of service
 - The servicer's name
 - Service performed
 - Test and inspection data

Servicing Records – Umbrella

- 820.200 does not define the content of umbrella records.
- These records are the result of analysis by appropriate statistical technique
 - The analysis follows the same methodology as the umbrella records in CAPA

Servicing Reports

- Servicing does not require reporting to the FDA
- However, servicing could result in an MDR
 - MDRs are reportable

Servicing Summary

Records	Reports
Maintain a record of every service activity, including the specified data elements	Servicing is not reported to FDA
Maintain records of service report analysis using appropriate statistical methodology	Service analysis is not reported to FDA

Paradigm Case #1

- Jim, the service technician said that he ran the diagnostics as part of the service call.
 - The diagnostics are “test and inspection data” and should be included in the service record
- We will defer the conversation with the nurse until we analyze Complaints and MDRs

Paradigm Case #2

- Fred, the QA Data Analyst, is presumably analyzing “service [records] with appropriate statistical methodology in accordance with 820.100.”
- Fred may have found a problem and that problem may be a complaint.
 - We will defer the problem until we analyze complaints

Warning Letter
Fall Prevention Technologies
August 27, 2008

- Failure to assure that service reports include applicable test and/or inspection data following the completion of service, as required by 21 CFR §820.200(d)(6).
- For example, 19 of the 19 service records reviewed did not have documentation reflecting that the device was tested or inspected after the repair to ensure the device met its specifications.

The Problem

This manufacturer failed to recognize the record keeping requirements in the regulations.

Warning Letter
Crystal Care International, Inc
May 22, 2009

- Failure to establish and maintain instructions and procedures for performing and verifying that the servicing meets specified requirements, as required by 21 CFR 820.200(a).
- Specifically, your firm does not have any procedures for servicing.

The Problem

This manufacturer failed to recognize that servicing procedures must be documented.

Warning Letter
Crystal Care International, Inc
May 22, 2009

- Failure to analyze service reports with appropriate statistical methodology, as required by 21 CFR 820.200(b).
- Specifically, your firm does, not have any procedures for analyzing service reports. In addition, the service reports were not analyzed following appropriate statistical methods.

The Problem

This manufacturer failed to implement the requirements to analyze service records using statistical methodology.

Note: The warning letter also cited this company for failure to have CAPA procedures

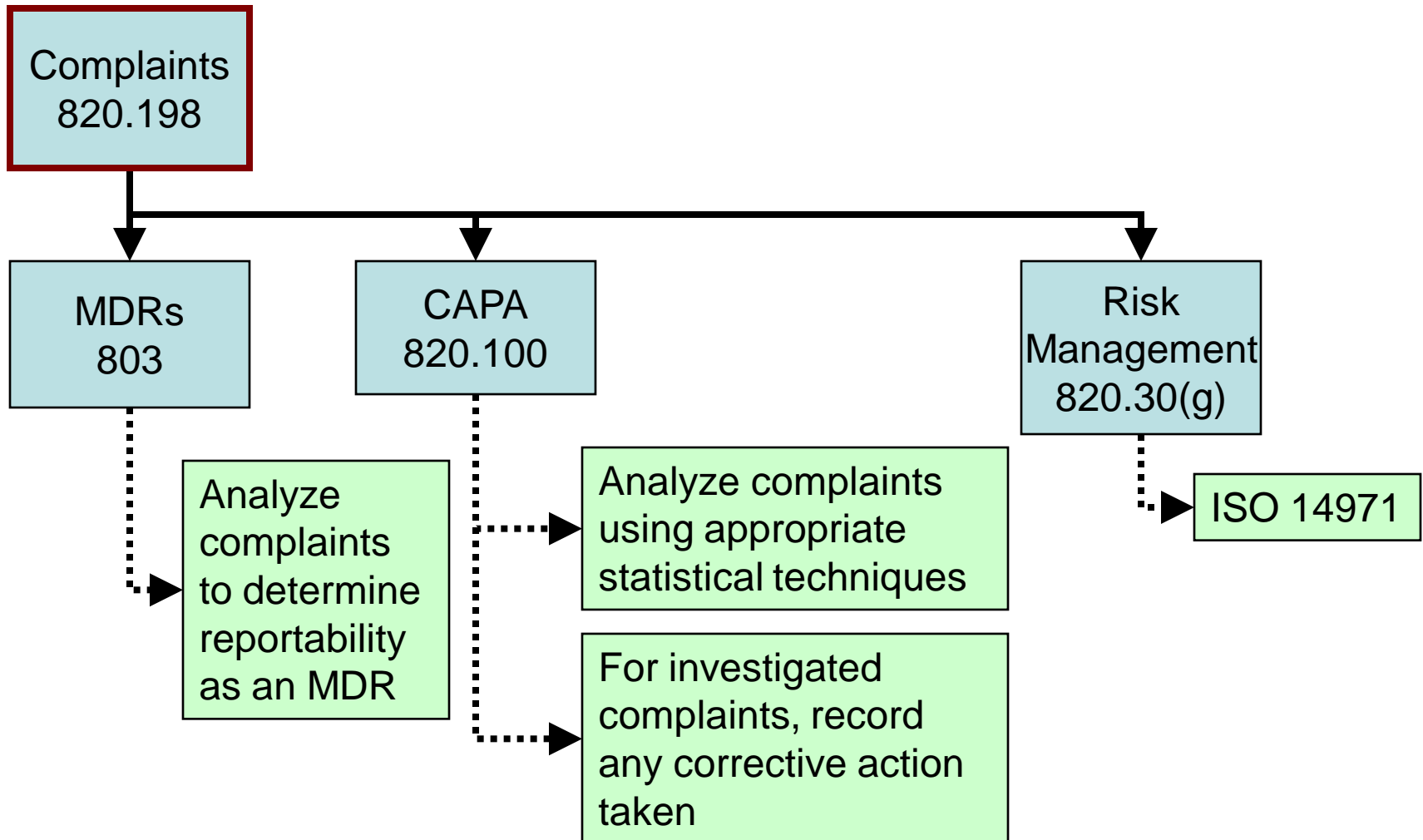
Complaints

21 CFR 820.198

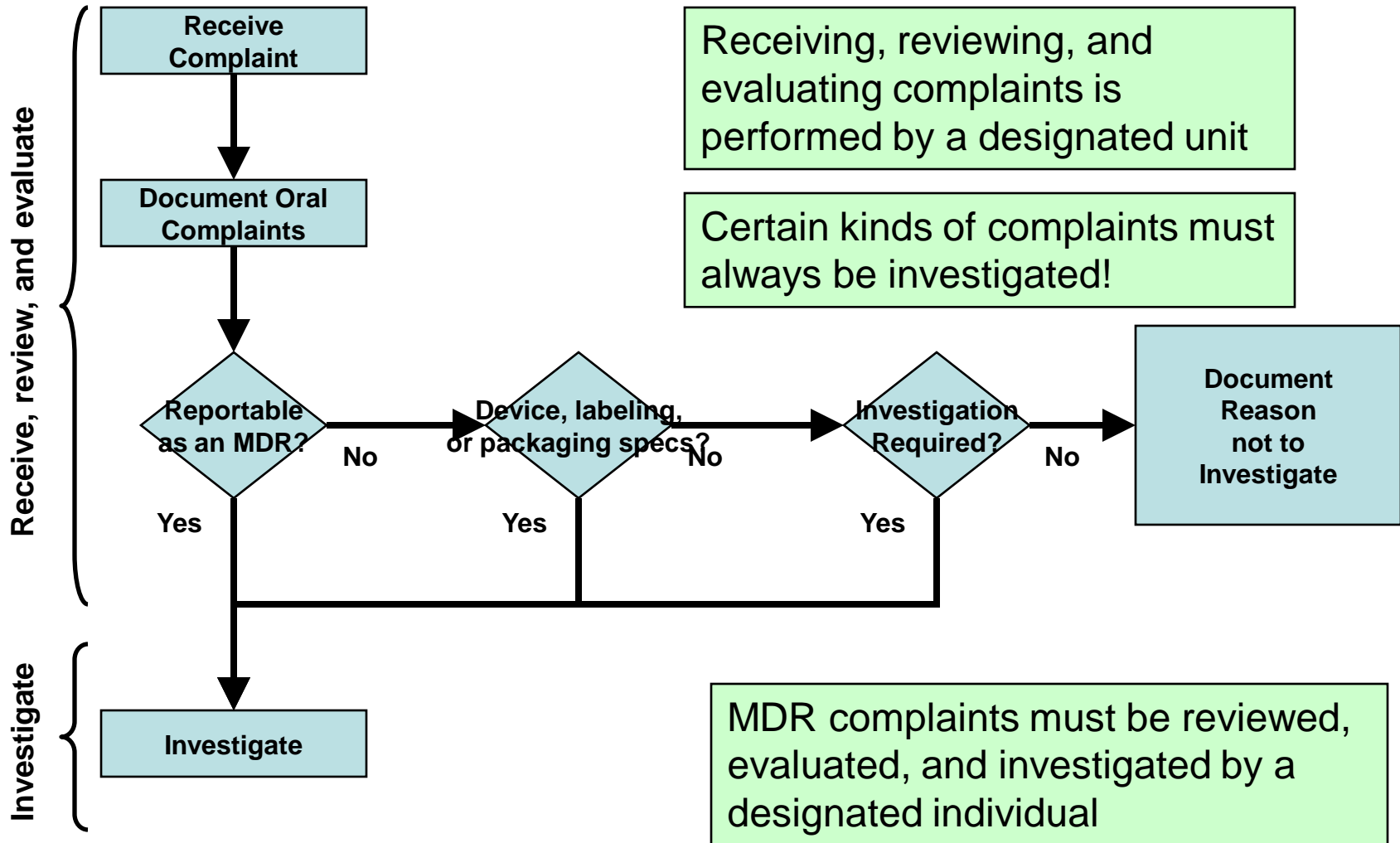
Complaints Definition

- 820.3(b) defines a complaint
- *Complaint* means
 - any written, electronic, or oral communication
 - that alleges deficiencies related to the
 - identity,
 - quality,
 - durability,
 - reliability,
 - safety,
 - effectiveness, or
 - performance
 - of a device after it is released for distribution.

Complaints Interrelationships



Complaints Flow – Investigate



Reviewing MDR Complaints

- 820.198(d) says, “Any complaint that represents an event [reportable as an MDR] shall be promptly reviewed, evaluated, and investigated by a designated individual(s)”
- 803.20(c)(2) says that the decision **not** to report is made a person qualified to make a medical judgment. “Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers.”

Complaints Records – Individual

- The Complaint System generates three groups of records
 - Record not to investigate
 - Record of the investigation
 - Record of an MDR investigation

Complaints Records – Umbrella

- 820.198 does not have a specific requirement for umbrella compliant records
- 820.100 (CAPA) requires analysis of complaints to identify existing and potential causes of nonconforming product using appropriate statistical methodology

Record Not To Investigate

- This record contains:
 - The reason no investigation was made
 - The name of the individual responsible for the decision not to investigate.
- Caution
 - Make sure the decision maker is a member of the formally designated unit for receiving, reviewing, and evaluating complaints



Record Of The Investigation

- This record contains:
 - The name of the device
 - The date the complaint was received
 - Device identification or control numbers used
 - The name, address, and phone number of the complainant
 - The nature and details of the complaint
 - The dates and results of the investigation
 - Any corrective action taken
 - Any reply to the complainant

- **Caution**



You should include the name of all investigators

Record Of An MDR Investigation

- This record contains:
 - All the information required for every investigation
 - Whether the device failed to meet specifications
 - Whether the device was being used for treatment or diagnosis
 - The relationship, if any, of the device to the reported incident or adverse event
- The MDR Investigation Records have to be in a separate portion of the complaint files or be clearly identified
- Cautions
 - You should include the name of all investigators
 - You should ensure the investigators are designated to investigate MDR related complaints
 - Reportable events require more documentation defined in the MDR regulations



Complaints Reports

- Complaints does not require reporting to the FDA
- However, complaints could result in an MDR
 - MDRs are reportable
 - Potentially reportable MDRs must be investigated by a designated individual

Complaints Summary

Records	Reports
Record of the decision not to investigate a complaint	This decision is not reported to FDA
Record of a complaint investigation	Neither complaints nor investigations are reported to FDA
Record of an MDR complaint investigation	If the investigation results in an MDR, the information may be reported
Statistical analysis of complaints is covered in CAPA (820.100)	No required reports

Paradigm Case #1

- The nurse said, “We expected an alarm, but didn’t get one.”
 - Jim, the service technician, just received an oral complaint.
 - A complaint is ... oral communication that alleges deficiencies related to the ... effectiveness or performance of a device ...
 - The case doesn’t have to be proved, only alleged. The evaluation and investigation will determine the facts.
- We defer the Nurse’s patient comments until we complete our analysis of MDRs.

Paradigm Case #2

- Fred, the QA Data Analyst noted that the actuator arm bearing is only meeting 65% of the target MTBF of 85,000 actuations
 - Fred’s analysis just generated a complaint
 - A complaint is any ... communication that alleges deficiencies related to the ... durability or reliability ... of a device
 - Fred’s report should be entered into the Complaint system as an allegation of a reliability deficiency

Warning Letter

Ohio Medical Corporation

July 22, 2009

- Failure to maintain complaint files ... 21 CFR 820.198(a).
- For example six customer inquiries ... that were received for warranty repairs on devices that were not working should have been designated as complaints; however, the inquiries are not found in the complaint log because the inquiry database has separate categories for "Warranty Repair" and "Complaints". The complaint handling procedure ... does not clearly define the categories used by Customer Service to ensure that all complaint inquiries are correctly classified ...

The Problem

This manufacturer didn't recognize that warranty claims can also be complaints. The software required one or the other, not both.

Warning Letter

Philips Medical Systems

April 8, 2008

- Failure to adequately establish and maintain procedures for receiving, reviewing, and evaluating complaints, as required by 21 CFR 820.198(a).
- For example, your "Complaint Handling Process" neither addresses software defects as a source of potential complaints nor requires a review of software defects identified as "potential hazards" as potential candidates for the complaint system. In addition, because this procedure states that a complaint is a "statement expressing dissatisfaction," a communication will not be reviewed and evaluated as a complaint if the customer does not allege "dissatisfaction," even if this communication would otherwise qualify as a complaint under 21 CFR 820.3(b).

The Problem

This manufacturer tried to apply a colloquial definition of customer complaints – dissatisfaction. They didn't realize that there is a technical definition that differs from the colloquial meaning.

Medical Device Reports

21 CFR Part 803

MDR Definitions

- The definition of an MDR reportable event is not simple.
 - We need to look at more than definition.
 - We won't define some terms (such as a user facility or importer) that isn't relevant to our role as a manufacturer
- We will make things more simple when we look at 5 day and 30 day reports

MDR Definitions

Think of hospitals
and nursing homes

MDR reportable event (or reportable event) means:

(1) An event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or **serious injury**; or

(2) An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices:

(i) May have caused or contributed to a death or serious injury,
or

(ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

MDR Definitions

Serious injury means an injury or illness that:

- (1) Is life-threatening,
- (2) Results in permanent impairment of a body function or permanent damage to a body structure, or
- (3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

MDR Definitions

Caused or contributed means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:

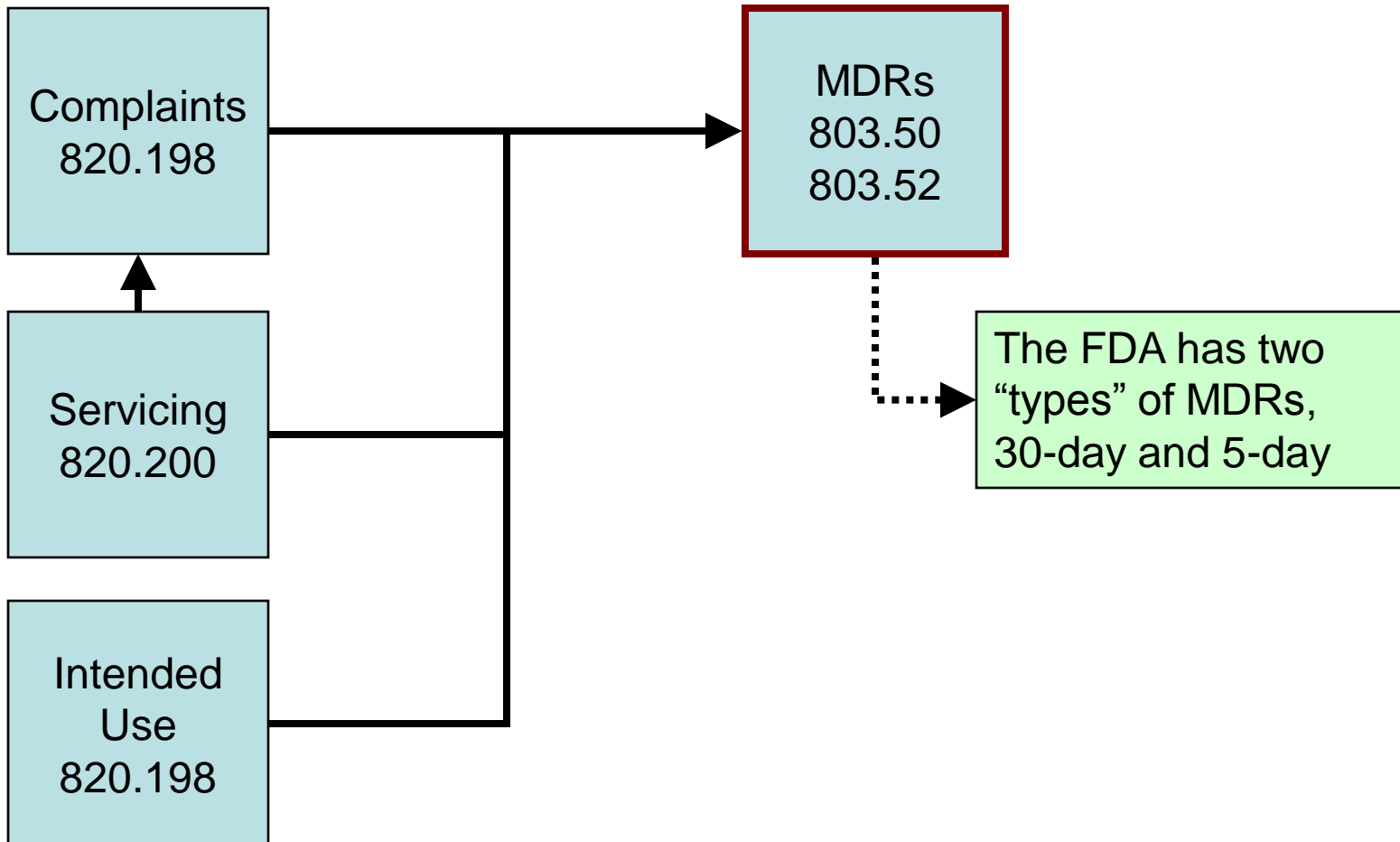
- (1) Failure;
- (2) Malfunction;
- (3) Improper or inadequate design;
- (4) Manufacture;
- (5) Labeling; or
- (6) User error.

MDR Definitions

Malfunction means the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed, as defined in 801.4 of this chapter.

{801.4} The words *intended uses* or words of similar import ... refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article.

MDR Interrelationships Manufacturers



MDR Records

- MDR Records are called "MDR event files"
- MDR event files may have pointers to other records, instead of maintaining duplicates in the file.
- The MDR event files contain:
 - Information related to the adverse event
 - Documentation of deliberations and decision making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable
 - Copies of all MDR forms and other information related to the event that you submitted
 - Information related to other entities such as an importer, distributor, or manufacturer.

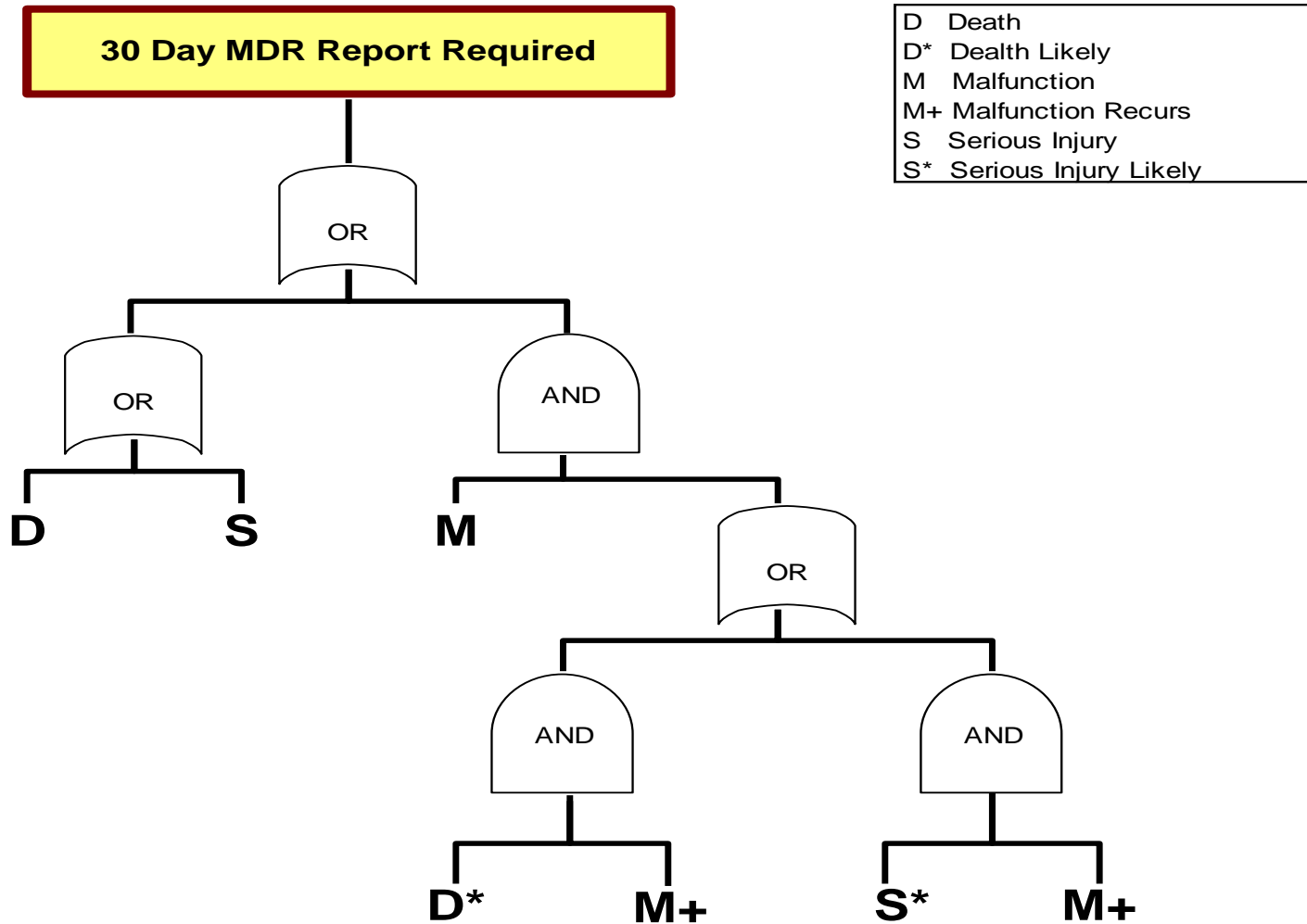
30 Day MDR

- We will apply our standard analysis method to the 30 day MDR: Trigger, Timing, Content
- The report is **triggered** when you “receive or otherwise become aware of information” that meets certain criteria
- The **timing** is 30 calendar days after the trigger
- The **content** is summarized later

Fault Tree Analysis

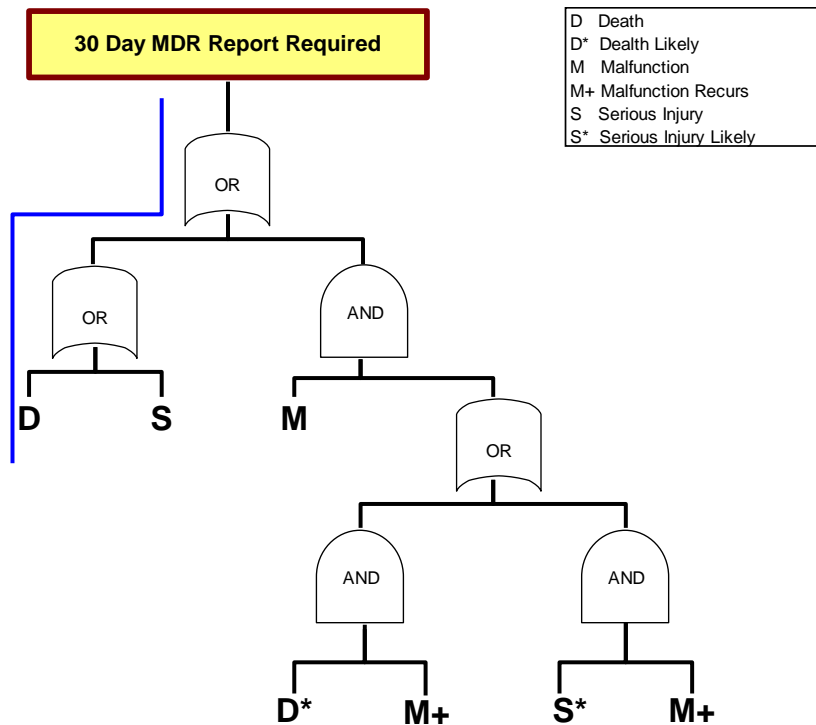
- We use Fault Tree Analysis (FTA) as a pictorial approach.
- FTA uses a “logic diagram” to determine when an event, the top event, occurs.
- For this presentation, the top event is the requirement to report to FDA.

30 Day MDR Trigger



30 Day MDR Trigger

An Explanation of the Symbols



- The Blue Line shows a path to a 30 day report
 - A Serious Injury (S) sets the lower OR to true
 - The lower OR sets the upper OR to true
 - The upper OR results in a 30 day MDR to FDA

30 Day MDR Timing

- The clock starts when you “receive or otherwise become aware of information” that creates the trigger.
- In practice, you will also recognize this as a complaint (820.198), so the clock starts “the date the complaint was received”
- You must report to FDA no later than 30 calendar days after the trigger
- Caution
 - The date the complaint was received is required in the complaint record
 - A complaint that must be reported to FDA as an MDR is promptly reviewed, evaluated, and investigated
 - Make sure the dates align



30 Day MDR Content

- Include all information reasonably know to you including:
 - Any information that you can obtain by contacting a user facility, importer, or other initial reporter
 - Any information in your possession
 - Any information that you can obtain by analysis, testing, or other evaluation of the device.
- You must also provide information missing from user facility or other initial reports.
- If you don't have all the information, file an initial report and follow-up with a supplemental report

30 Day MDR Content

- The MDR requires a lot of information, which is grouped as follows:
 - Patient information
 - Adverse event or product problem
 - Device general information
 - Initial reporter information
 - Manufacturer's information (contact *etc.*)
 - Device information specific to the event

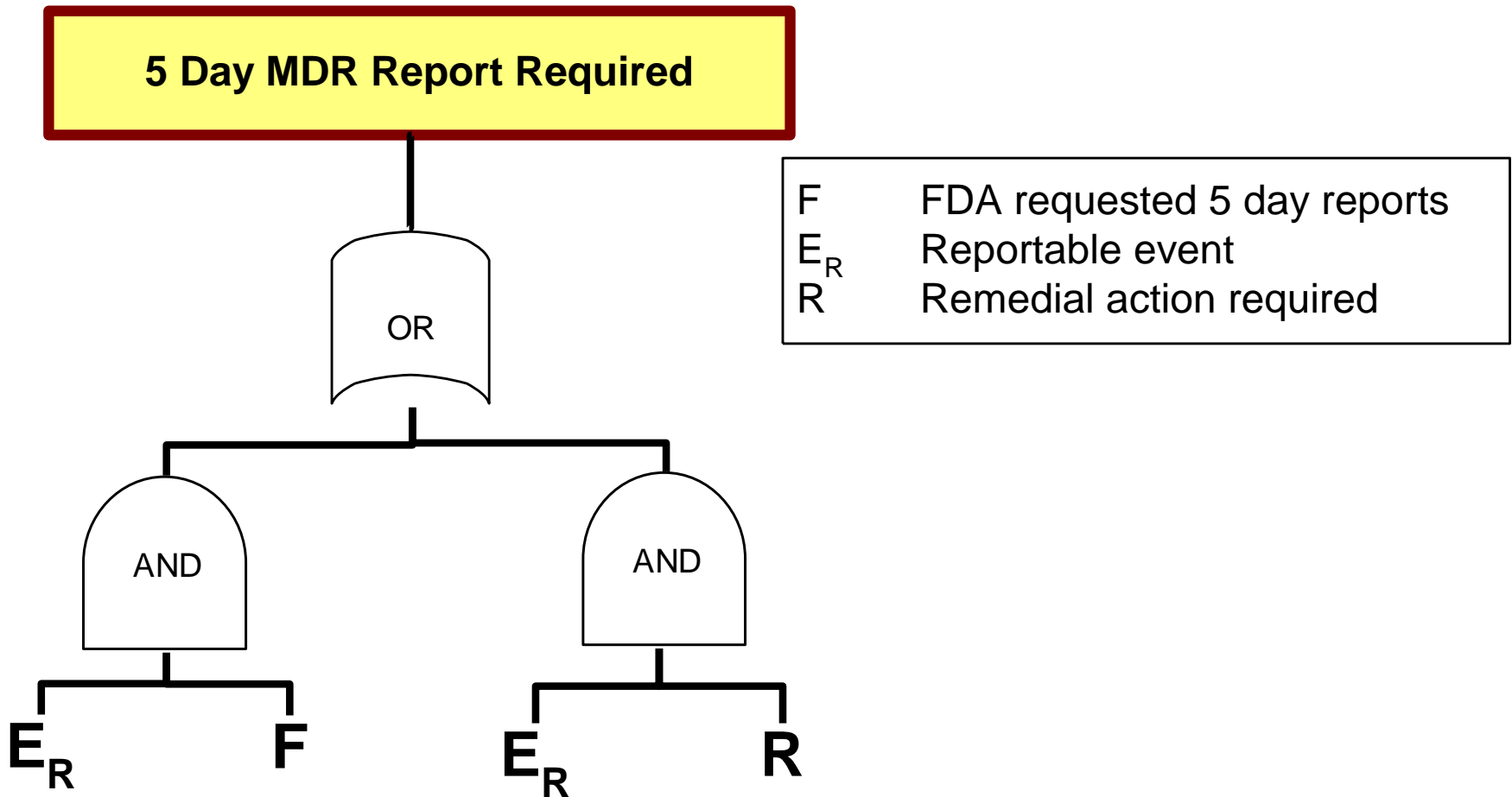
5 Day MDRs

- Make a 5 day report when:
 - An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.
 - You may become aware of the need for remedial action from any information, including any trend analysis
 - FDA requests 5 day reports

Definitions

- *Remedial action* means any action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event.
- From Part 806 (Corrections & Removals) *Risk to health* means
 - (1) A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or
 - (2) That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.

5 Day MDR Trigger



5 Day MDR Timing

- The clock starts when you become aware that an MDR reportable event necessitates remedial action
- In practice, this means the trigger is any decision to fix the problem. The decision could be taken:
 - As part of complaint investigation
 - As part of CAPA
 - As part of Management Review
- You must report to FDA no later than 5 work days after the trigger
 - *Work day* means Monday through Friday, except Federal holidays.

5 Day Report Content

- The content is the same in both the 5 day and 30 day reports at the level described earlier.
- The detailed information may have some differences

Summary – MDRs

Records	Reports
Each MDR event must be maintained in a record including decisions not to report	The decision not to report is not reported to FDA
Each MDR event should be associated with a complaint file	30 day MDRs are reported to FDA
	5 day MDRs are reported to FDA

Paradigm Case #1

- The nurse said, “The patient got into trouble, but we intervened, and she is fine. We expected an alarm, but didn’t get one.”
 - The hospital should submit a user facility report to FDA and notify the manufacturer.
 - The technician received an oral complaint, and because of the nurses comment “we intervened and she is fine” should mark it as a potential MDR complaint.
 - The technician should start to get information on the event.
 - The 30 day clock started with the conversation!

Paradigm Case #2

- Fred has uncovered a potential reliability problem that is a complaint.
- Be cautious because the device has probably malfunctioned, or the service tech would not replace the bearing early. Because it is a reliability problem, the malfunction is likely to recur.
- If this problem “would be likely to cause or contribute to a death or serious injury” you have triggered a 30 day MDR
- If all of the above is true and you decide to “take remedial action” you have triggered a 5 day MDR.

Warning Letter

Duro-Med Industries

June 11, 2008

- Failure to submit an MDR within 30 days of receiving or otherwise becoming aware of information that reasonably suggested that a marketed device may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a)(1).
- Specifically, MDRs were not submitted for the following complaints:
 - The complainant reported that while a physician's assistant was breaking the compress (Compress Instant Ice Junior) to mix the inner ingredients together, the mixture squirted out of a previously unknown slit in the corner of the unit into the eye of the physician's assistant. The physician's assistant went to the emergency room and was diagnosed with a burned cornea.
 - This complaint involved the Compress Instant Ice Junior which was activated in the usual manner, but then leaked into the patient's eye. The eye was lavaged and the patient was treated by the ophthalmologist the next day.
 - This complaint involved the Compress Instant Ice Junior where the end user received frostbite on the lower back after using the cold pack for approximately 15 minutes. The complaint summary indicated that the end user did not follow the instructions for use.

The Problem

The warning letter doesn't provide an explanation of why these complaints were not reported as MDRs. Sometimes manufacturers don't recognize the meaning of serious injury.

Warning Letter

Care Rehab and Orthopaedic Products

April 22, 2008

- Failure to submit an MDR within 30 days of receiving or otherwise becoming aware of information that reasonably suggested that a marketed device may have caused or contributed to a serious injury as required by 21 CFR 803.50(a)(1).
- [Y]ou have 30 days from receipt of any information that reasonably suggests that a reportable MDR event has occurred, to submit an MDR report to the FDA. Before the 30 day time frame has expired, the device manufacturer must determine whether the information it has received or become aware of reasonably suggests that a reportable MDR event has occurred and the event should be reported. In this case, the complaint dated 7/2007 ... indicated that the patient was "severely burned," which reasonably suggests a serious injury occurred. If your firm decides not to report an event, you must explain the justification for not reporting and file your documentation in the MDR event file. Your firm cannot wait past the 30 day timeframe until your investigation is complete to file a report. In this case, the follow-up information was received on 1/24/2008 which is past the 7/2007 injury report date by approximately six months.

The Problem

The manufacturer didn't recognize the requirement to file within 30 days regardless of the state of the investigation.

Warning Letter

Care Rehab and Orthopaedic Products

April 22, 2008

- Failure to document your decision not to file an MDR as required by 21 CFR 803.18(e).
- We have reviewed your response for the complaint dated 2/2007. Your investigation into the injury revealed that the patient did not suffer a serious injury as first reported to your firm. You determined that, since an injury did not actually occur, you did not need to file an MDR with the agency. We have concluded that your response is inadequate because you made the decision not to file an MDR based on information received from the patient negating a claim of a serious injury, however you did not document this decision in your MDR event file.

The Problem

The manufacturer didn't keep the required records. When reports are involved the records need to include the decision and rationale not to report.

Corrective and Preventive Action

21 CFR 820.100

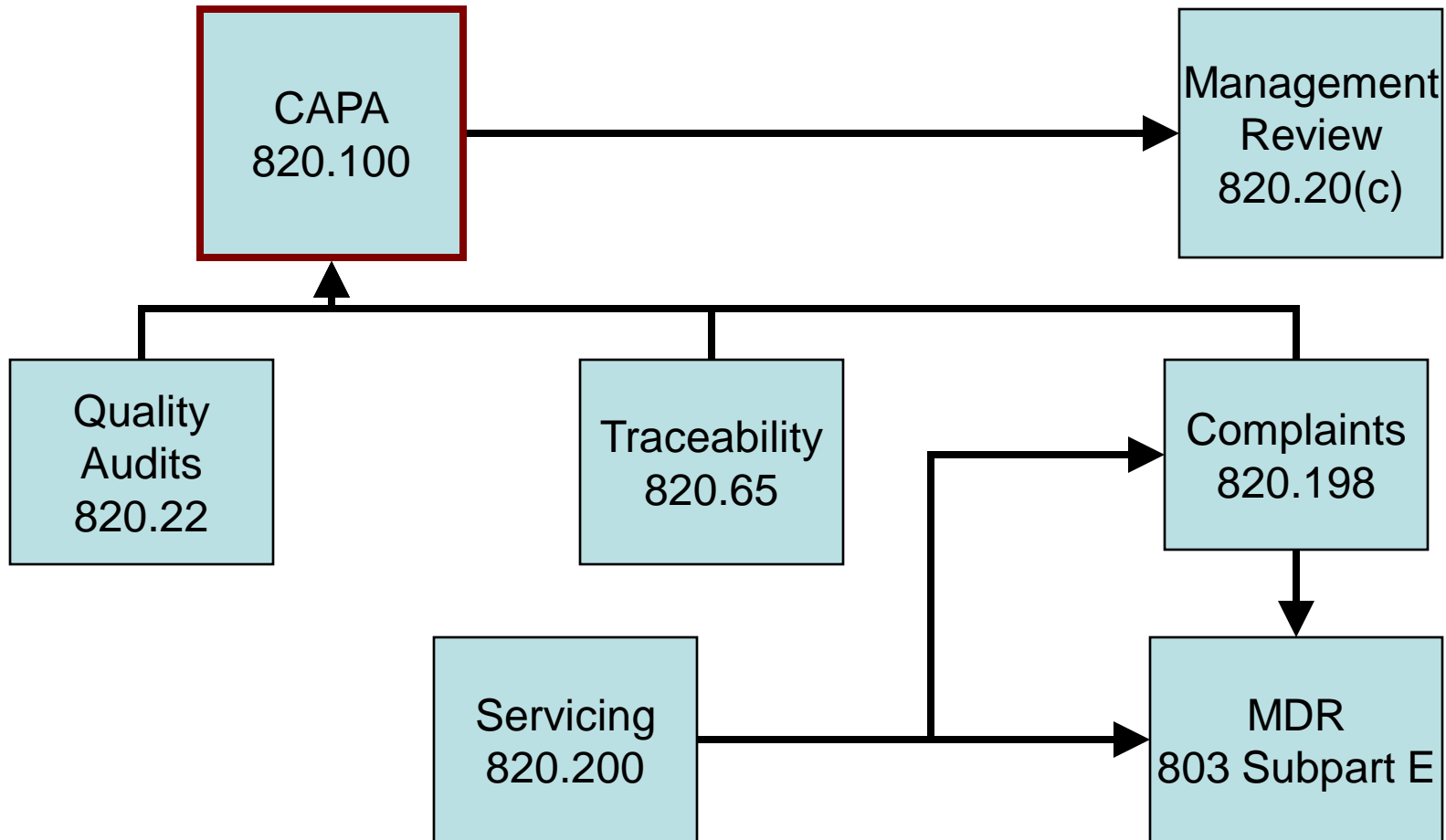
CAPA Definitions

- Our definitions come from ISO 9000:2005 because QSR doesn't define the terms
 - corrective action* – action to eliminate the cause of a detected nonconformity or other undesirable situation
 - preventive action* – action to eliminate the cause of a potential nonconformity or other undesirable potential situation
 - correction* – action to eliminate a detected nonconformity

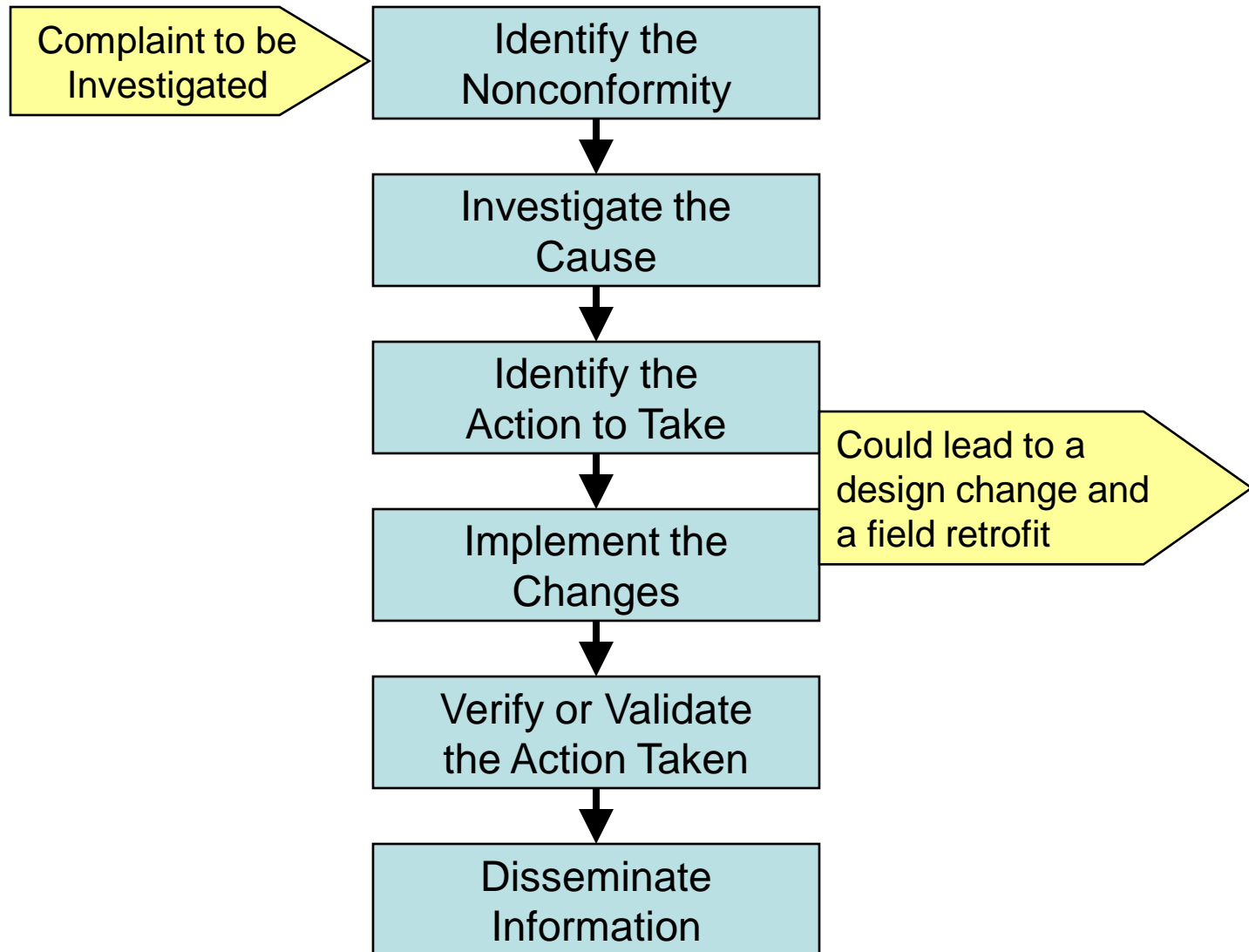
CAPA Approach

- The CAPA system is the framework for complaint investigation
 - Use corrective action for individual complaints, each one alleges a nonconformity
 - Use preventive action for “statistical analysis” of complaint data to help prevent recurrence

CAPA Interrelationships



CAPA Flow



The CAPA Investigator

- Assign an appropriate investigator
 - For internal quality problems, this is usually the process owner.
 - MDR/Complaints must be reviewed, evaluated, and investigated by a designated individual {820.198(d)}
 - Part 820 does not list any specific qualifications for the investigator
 - If the investigation concludes that an MDR is not required, the decision is made by a person who is qualified to make a medical judgment {803.20(c)(2)}
 - 803.20(c)(2) says a person qualified to make medical judgments includes physicians, nurses, risk managers, and biomedical engineers.

CAPA Records – Individual

- Keep records of everything you do in the CAPA process
 - In particular, record changes in methods and procedures needed to correct and prevent identified quality problems
 - CAPA records should link to complaint records
- These are complaint investigation records, so they must link back to the complaint
 - Record of the investigation
 - Record of an MDR investigation

CAPA Records – Umbrella

- CAPA requires that you analyze service reports, complaints and returned product to identify existing and potential causes of nonconforming product or other quality problems.
 - You must apply appropriate statistical methodology to the analysis
- The service report analysis should correspond to (and even be the same as) the service report analysis in 820.200
- CAPA has an umbrella analysis for complaints that is not in the complaints section of QSR.

CAPA Reports

- The FDA does not require any specific reports for the CAPA process
 - Don't forget that CAPA can lead to many other record keeping and reporting requirements

Summary – CAPA

Records	Reports
<p>Keep a record of everything involved in the CAPA process</p> <p>Pay special attention to “recording changes in methods and procedures needed to correct and prevent identified quality problems”</p> <p>Link the CAPA records to the complaint records and <i>vice versa</i></p>	<p>CAPA is not reported to FDA</p>
<p>There is an umbrella analysis requirement for complaint records</p>	<p>CAPA is not reported to FDA</p>
<p>There is an umbrella analysis requirement for service records</p>	<p>CAPA is not reported to FDA</p>

Paradigm Case #1

- Recall that the nurse stated that they expect an alarm.
 - The **Investigation of the Cause** revealed that a set of rare conditions occurred that inhibited the alarm
 - For Identify the **Action to Take**, the decision is to make a software design change
 - The design change will be applicable to all new production
 - The design change will also be a field retrofit, applied as soon as possible, *i.e.*, special service calls

Paradigm Case #2

- Recall that we observed an actuator arm bearing with a lower than expected reliability
- The **Investigation of the Cause** revealed that the initial bearing selection was made on a cost/reliability trade-off.
- For **Identify the Action to Take**, the decision is to replace the bearing with a higher purchase cost but higher reliability bearing
 - The design change will be applicable to all new production
 - The design change will be a direct replacement for failed bearings

Warning Letter

Torbot Group Inc., Jobskin Division

April 14, 2008

- Failure to implement your corrective and preventive procedures to assure the sources of quality data are analyzed to identify existing and potential causes of nonconforming product or other quality problems. [21 C.F.R. § 820.100(a)] Specifically, ... failure to analyze ... complaints to identify trends and determine if a failure investigation was needed ...
 - A total of 36 of the 210 complaints on the Glove to Wrist device ... were returned due to the wrong product being shipped. This trend was not identified, no investigation was performed, and no corrective action was taken.

The Problem

The manufacturer didn't implement appropriate statistical analysis of the complaints, and missed a trend in the data.

Warning Letter

Eagle Parts and Products

November 14, 2008

- Failure to evaluate whether a complaint represents an event that is required to be reported to FDA under Part 803 (Medical Device Reporting) of FDA's regulations; failure to properly review, evaluate and investigate complaints that involve the possible failure of a device; and/or failure to promptly review, evaluate and investigate complaints that represent an event which must be reported to FDA under Part 803, as required by 21 CFR 820.198. Specifically,
 - [An] incident Report resulted from a report that the seat broke off of [a] powered wheelchair. The patient was not injured, but the malfunction could have resulted in patient injury. The investigation does not appear to be sufficiently thorough or adequate to meet the requirements of the regulation.
 - [A call from a dealer] reported that a patient's powered wheelchair battery charger started smoking and caught fire. The patient was not injured, but the malfunction could have resulted in patient injury. There is no documentation to show that the incident was investigated.

The Problem

This is a lack of investigation. These are MDR complaints that should have been investigated in the CAPA system.

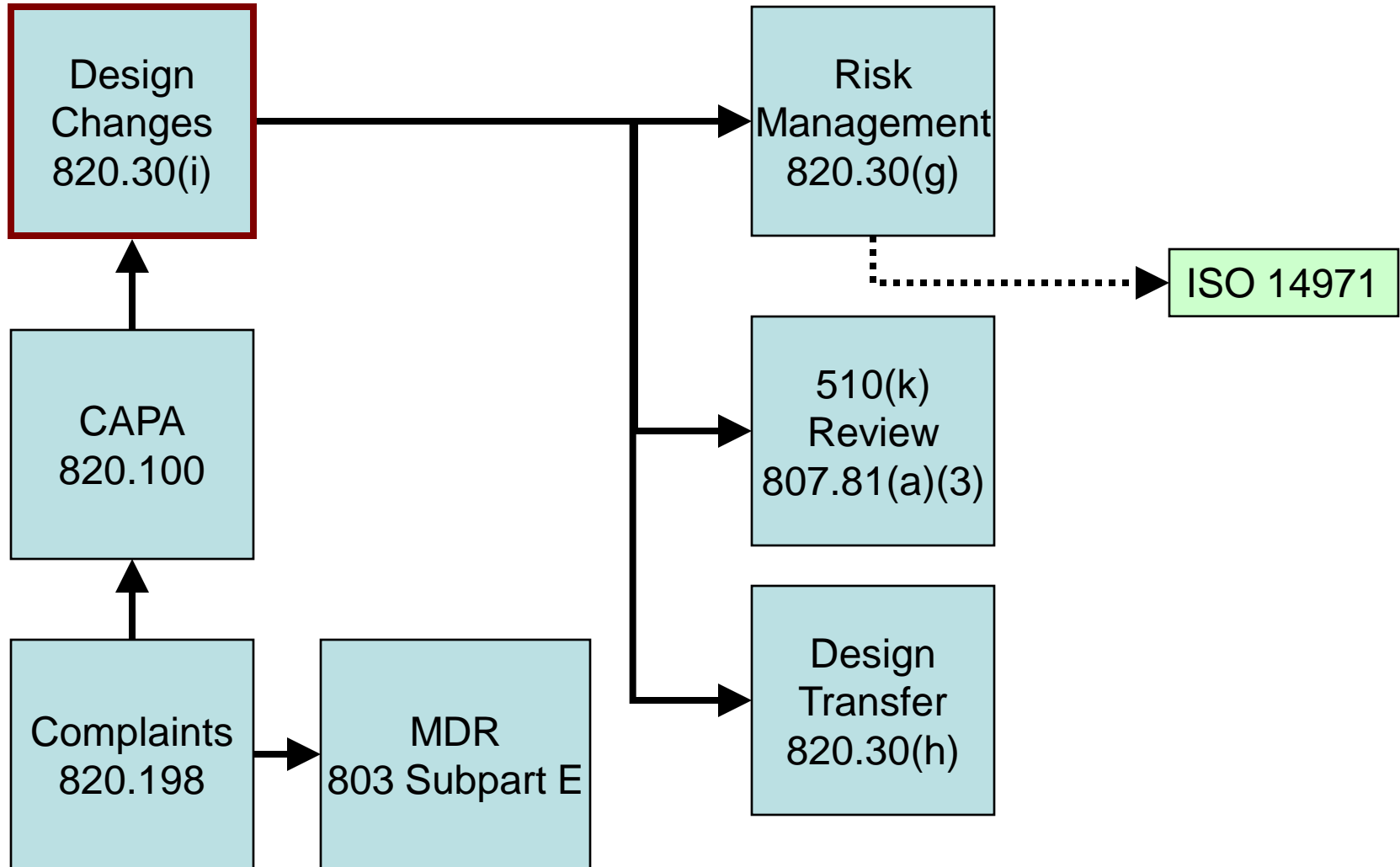
Design Changes

21 CFR 820.30(i)

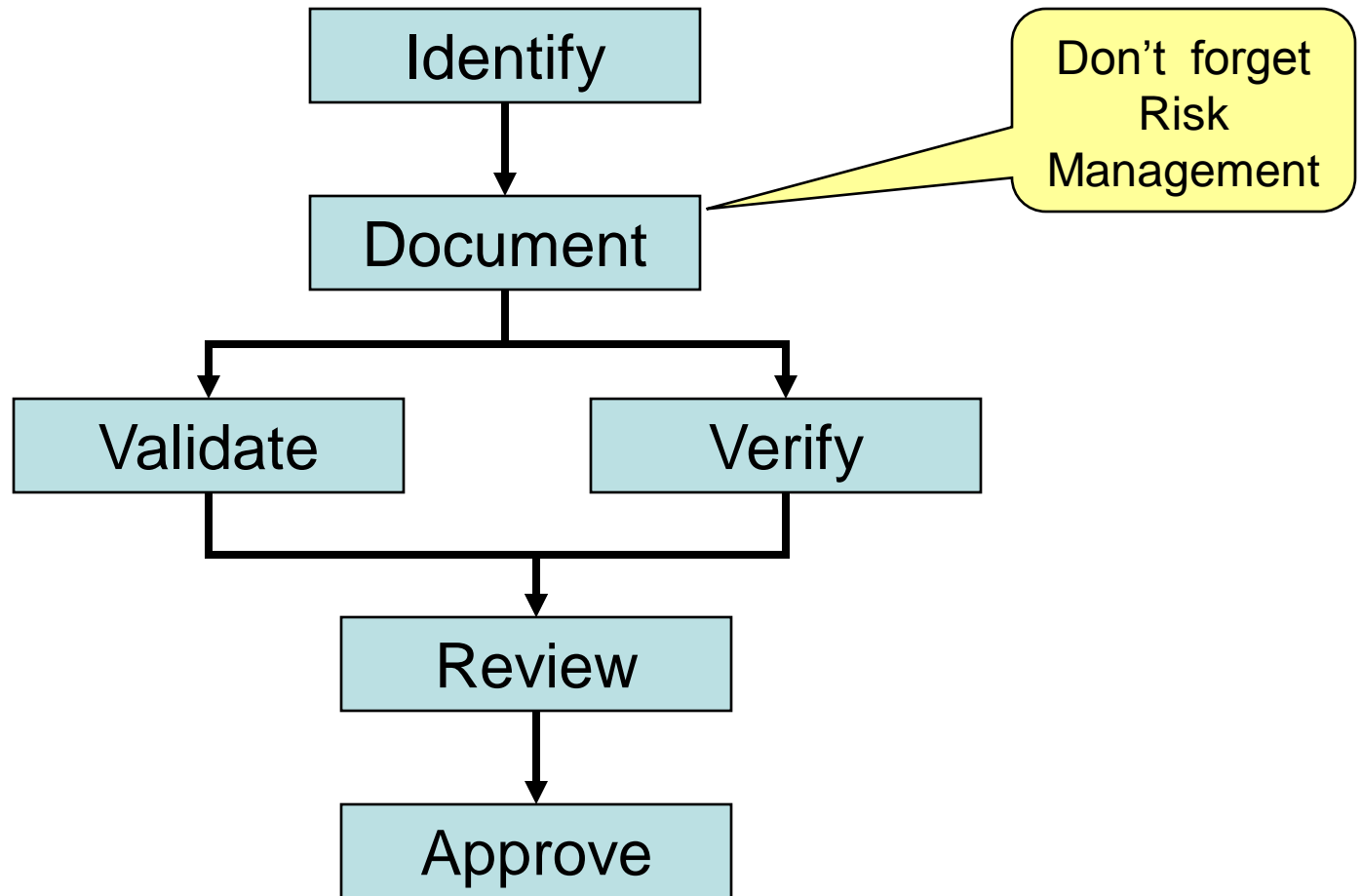
Design Change Requirements

- 21 CFR 820.30(i) requires, “Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.”

Design Change Interrelationships



Design Change Process Flow



Records – Design Change

- Individual
 - The individual records relate to the design change, but include the whole extent of design records
- Umbrella
 - There are no umbrella records associated with design changes

Reports – Design Change

- The FDA does not require Design Change reports
 - Every Design change should be evaluated against 510(k) criteria, which may require a “report” – a new 501(k)

Summary – Design Changes

Records	Reports
Keep all the records associated with design control including verification, validation, design review, and approval	Design change is not reported to FDA
Keep records associated with Risk Management (ISO 14971)	Risk Management is not reported to FDA

Paradigm Case #1

- The design team applied the Design Change methodology and produced the required documentation.
 - The Design Output will include an immediate software change for production units
 - The Design Output will also include a field retrofit package to be installed by Service Technicians without delay
- We will evaluate any required reports after we analyze Corrections and Removals

Paradigm Case #2

- The design team applied the Design Change methodology and produced the required documentation.
 - The new bearing will go into production after the existing stock is used up
 - The new bearing will be installed in field units when the current bearing fails
- We will evaluate any required reports after we analyze Corrections and Removals

Warning Letter
Behavioral Therapeutics, LLC
April 24, 2008

- Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30. For example, the following changes were made to the Good Vibrations device without review, approval, or documentation:
 - A reset button was added to the teacher unit
 - The charting software was revised
 - The voltage to the vibratory motor was lowered to reduce the noise level on the receiving unit
 - You have not provided any evidence of establishing or maintaining a Design History File.

The Problem

This manufacturer didn't recognize and apply the QSR requirements that apply to design changes.

Warning Letter

Cardinal Health 414 LLC

May 28, 2008

- Failure to establish design change control procedures for the identification, documentation, validation and/or verification, review, and approval of design changes before implementation. [21 CFR § 820.30(i)]
- Specifically, between 2003 and 2006, design changes were made to the Secure Safety Insert System. Verifications and/or validations, design reviews, design releases, and design approvals were not performed for any of these changes.
 - The molding operation was changed to improve the visibility of the biohazard symbol on the cap
 - The interlock of the cap into the tube was changed to improve the pull strength testing
 - Short caps were added to accommodate different size syringes.

The Problem

This manufacturer didn't recognize and apply the QSR requirements that apply to design changes.

510(k) Change Analysis

21 CFR 807.81(a)(3)

510(k) Change Analysis Requirements

- 21 CFR 807.81(a)(3) requires a premarket notification submission to the Food and Drug Administration at least 90 days before introduction or delivery when:

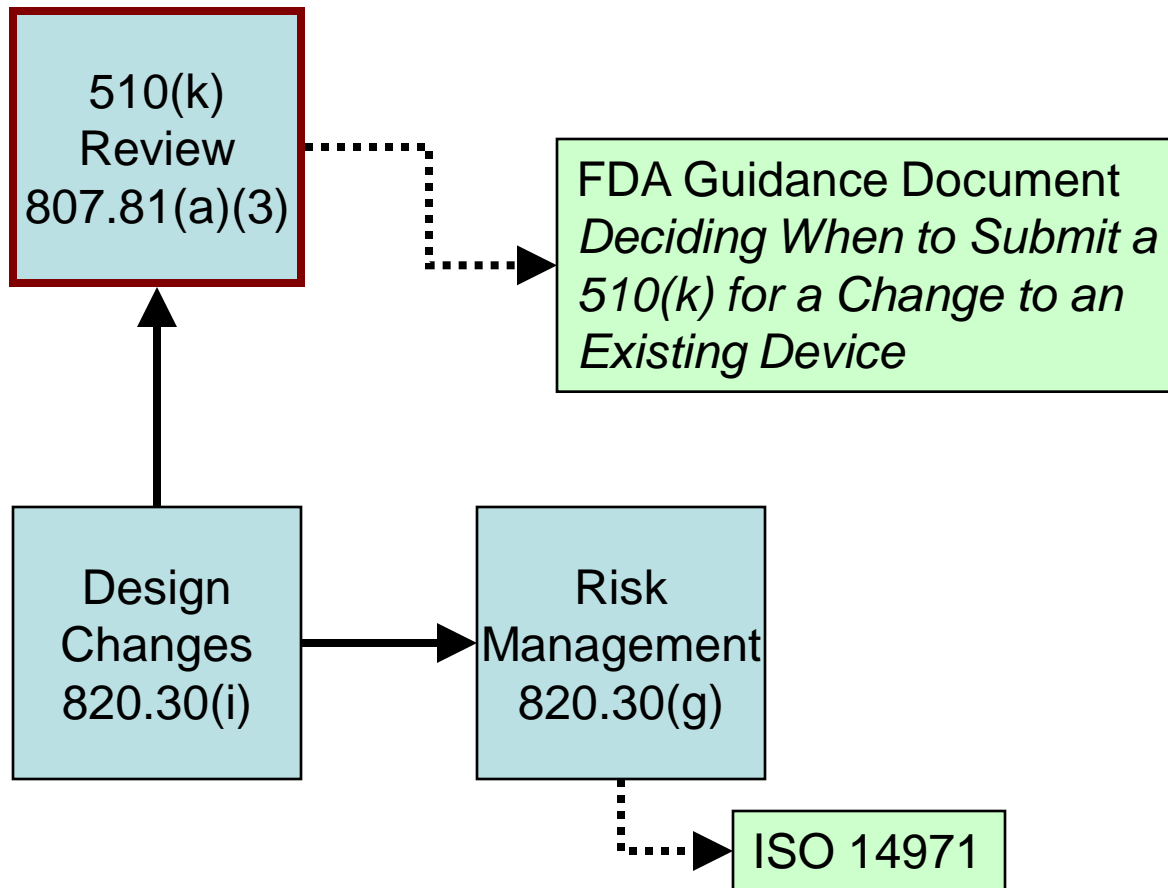
The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

- (i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, *e.g.*, a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.
- (ii) A major change or modification in the intended use of the device.

510(k) Change Analysis Definitions

- *Material change* includes any change or modification in the labeling or advertisements that affects the identity or safety and effectiveness of the device. These changes may include, but are not limited to, changes in the common or usual or proprietary name, declared ingredients or components, intended use, contraindications, warnings, or instructions for use. Changes that are not material may include graphic layouts, grammar, or correction of typographical errors which do not change the content of the labeling, changes in lot number, and, for devices where the biological activity or known composition differs with each lot produced, the labeling containing the actual values for each lot.

510(k) Change Analysis Interrelationships



510(k) Analysis Records

- Keep records that document your decision to submit or not submit a 510(k) revision for the change
- Minimum documentation should include:
 - Written analysis of the questions in the FDA Guidance Document *Deciding When to Submit a 510(k) for a Change to an Existing Device*
 - Written documentation in the ISO 14971 Risk Management File that shows the changes do not exceed the criteria for risk acceptability defined in the Risk Management Plan

510(k) Analysis Reports

- If the device is about to be significantly changed or modified in design, components, method of manufacture, or intended use, then file a revision to the 510(k)

Summary – 510(k) Analysis

Records	Reports
Document the responses to the questions and your conclusions in the FDA guidance document	The “report” to FDA is the revised 510(k)
Keep records associated with Risk Management (ISO 14971)	

Paradigm Cases #1 & #2

- The 510(k) analysis did not reveal a significant change or modification in either case
- The Risk Management analysis shows that the risk remains acceptable

Warning Letter
C Change Surgical LLC
September 24, 2008

- The design changes made to the electrical circuitry of the IntraTemp™ Solution Warmer could significantly affect the safety or effectiveness of the device, and therefore, constitute significant changes or modifications that require a new 510(k) submission (see 21 CFR 807.81 (a)(3)(i)). These changes include:
 - A ... was added due to reports of current leakage from the device
 - The fuse was changed ...
 - A user controlled temperature feature was added to the device
 - The out of range temperature lights were modified.

The Problem

We don't know what analysis this manufacturer performed before introducing the design changes, but the FDA believes they are significant, and requires a new 510(k) submission.

Corrections and Removals

21 CFR Part 806

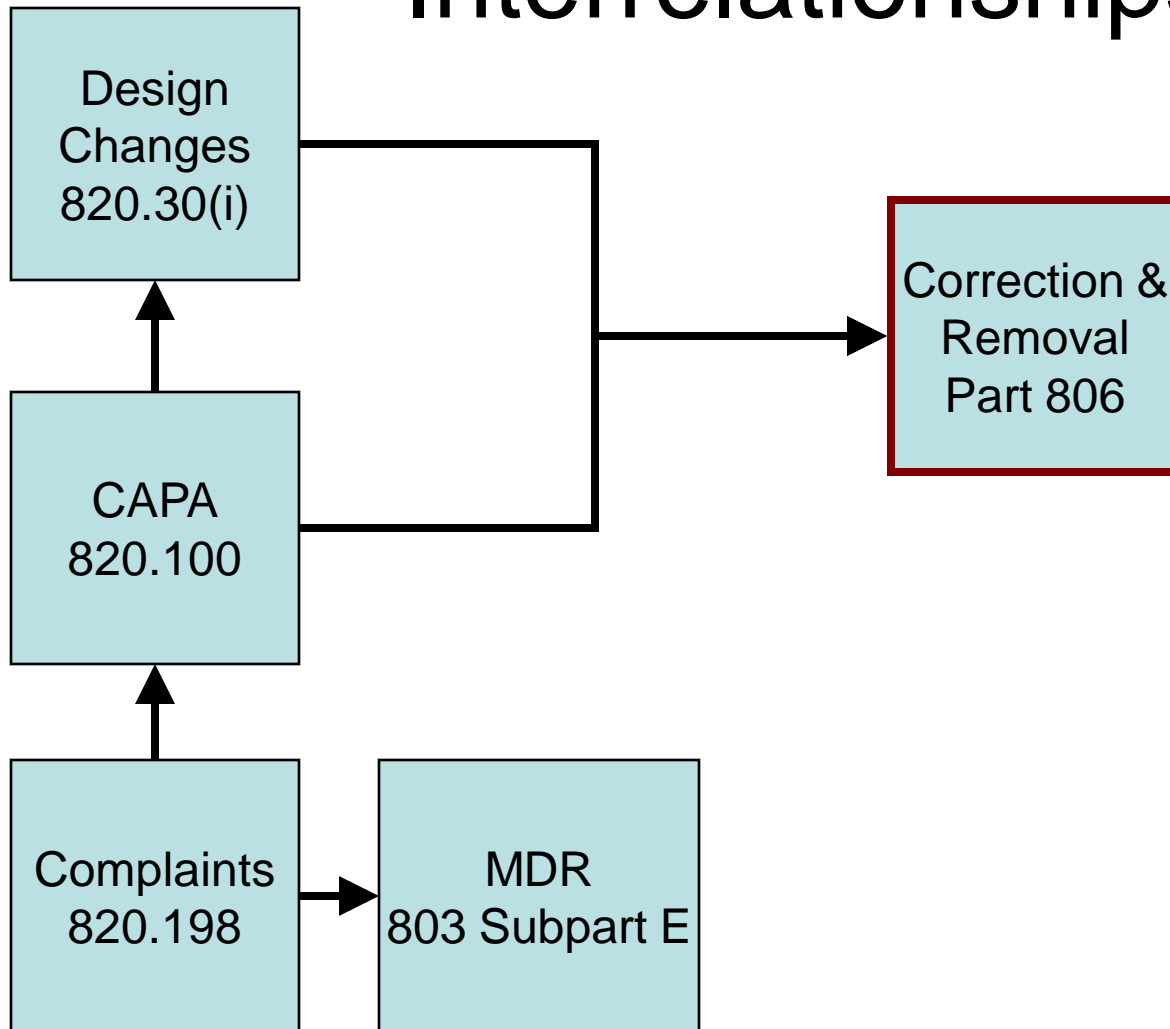
Corrections and Removals – Definition

- The regulations define a number of terms we will need for the analysis, but the basic one are:
 - *Correction* means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location.
 - *Removal* means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

Explanation

If you fix it on site, it is a correction. If you fix it someplace else, it is removal. There are minor differences in reporting, which we ignore here.

Correction & Removal Interrelationships



Correction & Removal – Record

- 806.20 defines the requirements for correction and removal records. Every device manufacturer or importer must keep records of C&R not reported to FDA.
- The C&R records contain:
 - The brand name, common or usual name, classification, name and product code if known, and the intended use of the device.
 - The model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.
 - A description of the event(s) giving rise to the information reported and the corrective or removal action that has been, and is expected to be taken.
 - Justification for not reporting the correction or removal action to FDA, which shall contain conclusions and any follow-ups, and be reviewed and evaluated by a designated person.
 - A copy of all communications regarding the correction or removal.
- Caution
 - The decision not to report must be reviewed and evaluated by designated person
 - Many of the same skills in review and evaluation of complaints and MDRs apply



Correction & Removal – Report Trigger

- The trigger is the decision to initiate a correction or removal.
- C&R Reporting has exceptions
 - If you reported under Part 803 MDRs or Part 1004 Repurchase, Repairs, or Replacement of Electronic Products you don't have to report under Part 806
- C&R Reporting has exemptions
 - Don't report if you only improve quality
 - Don't report market withdrawals
 - Don't report routine servicing
 - Don't report stock recoveries
- Caution
 - The exceptions and exemptions have technical qualifications that you must understand



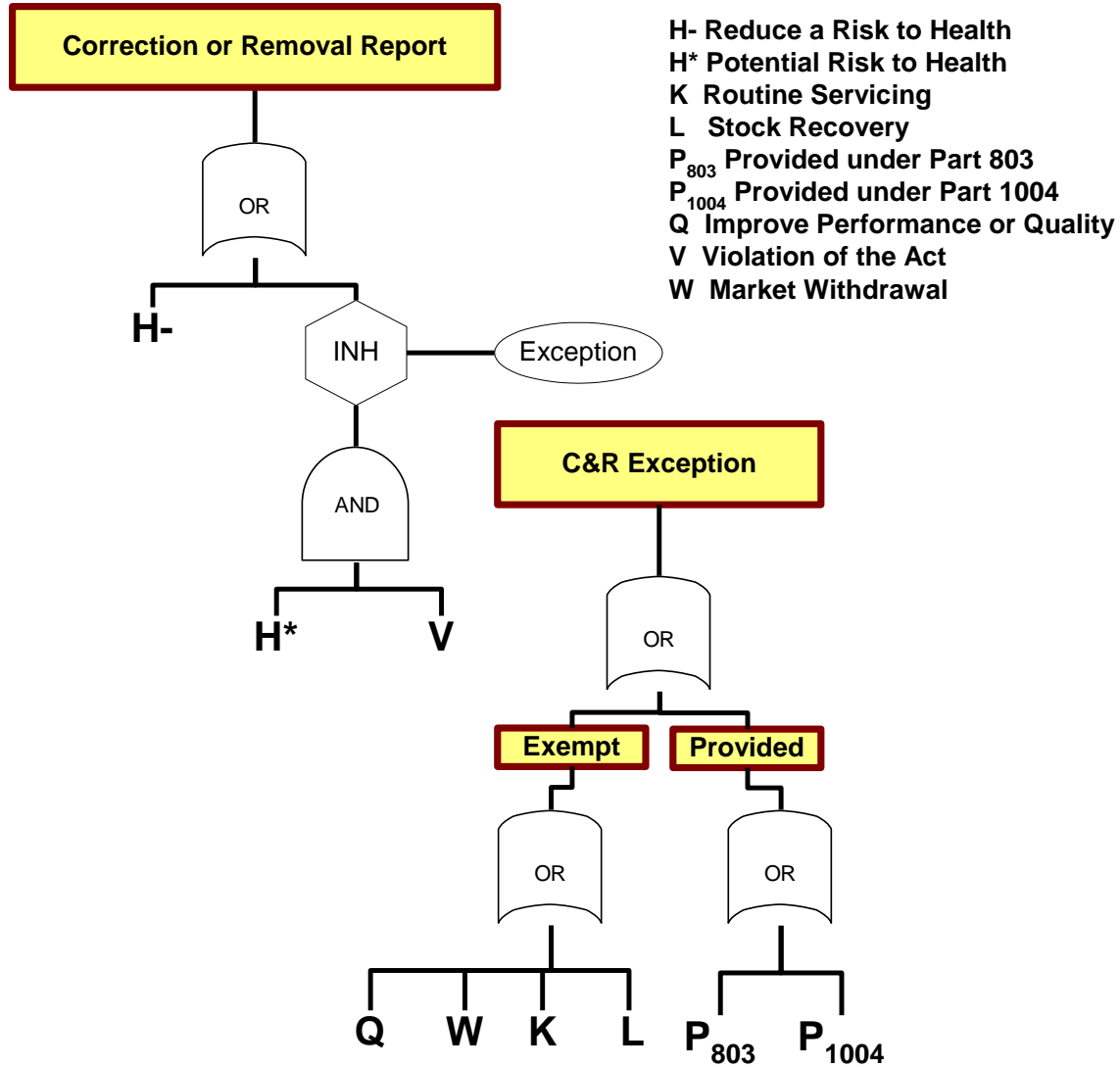
Correction & Removal – More Definitions

- *Market withdrawal* means a correction or removal of a distributed device that involves a minor violation of the act that would not be subject to legal action by FDA or that involves no violation of the act, e.g., normal stock rotation practices.
- *Routine servicing* means any regularly scheduled maintenance of a device, including the replacement of parts at the end of their normal life expectancy, e.g., calibration, replacement of batteries, and responses to normal wear and tear. Repairs of an unexpected nature, replacement of parts earlier than their normal life expectancy, or identical repairs or replacements of multiple units of a device are not routine servicing.

Correction & Removal – More Definitions

- *Stock recovery* means the correction or removal of a device that has not been marketed or that has not left the direct control of the manufacturer, i.e., the device is located on the premises owned, or under the control of, the manufacturer, and no portion of the lot, model, code, or other relevant unit involved in the corrective or removal action has been released for sale or use.
- *Risk to health* means
 - (1) A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or
 - (2) That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.

Correction and Removals Trigger



Corrections and Removals Timing

- 806.10(b) says, “The manufacturer ... shall submit any report required ... within 10-working days of initiating such correction or removal.”
- The word “initiate” is not defined in this part.
- Caution
 - Initiate could include the decision to make the change.
 - 5 day MDRs could have the same trigger event
 - See the distinction between risk to health and serious injury on the next slide



Severity

- MRDs involve *serious injury* defined in 803.3 as an injury or illness that
 - (1) Is life-threatening,
 - (2) Results in permanent impairment of a body function or permanent damage to a body structure, or
 - (3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.
- C&R involves *risk to health* defined in 806.2(j) as
 - (1) A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or
 - (2) That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.

Correction & Removal Report Contents

- The name, address, and telephone number of the manufacturer
- Name, title, address, and telephone number of the manufacturer's representative conducting the correction or removal.
- The brand name and the common name, classification name, or usual name of the device
- The intended use of the device
- Marketing status of the device
- The model, catalog, or code number of the device and the manufacturing lot number, serial number or identification number
- A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken.
- Any illness or injuries that have occurred with use of the device.
- The number of devices manufactured or distributed subject to the C&R
- The date of manufacture or distribution
- The expiration date or expected life
- The names, addresses, and telephone numbers of all domestic and foreign consignees
- A copy of all communications regarding the correction or removal and the names and addresses of all recipients of the communications
- If any required information is not immediately available, a statement as to why it is not available and when it will be submitted.

C&R Summary

Records	Reports
<p data-bbox="112 464 794 706">Maintain records of every change to any device in the field.</p> <p data-bbox="112 856 900 1006">Include the reasons not to report the C&R</p>	<p data-bbox="981 464 1729 621">Report, when required every C&R</p>

Paradigm Case #1

- We decided to change the software in every device. The Service Techs will visit the device, load the new software, and run the required tests.
 - We classified this as a correction (not a removal)
 - We believed this is an MDR reportable event
 - We filed a 30 day MDR on the 25th day because we had not concluded the investigation
 - We decided to take remedial action so we filed a 5 day MDR the day after we made the decision
 - We recognized the decision will reduce a risk to health so we also filed a Corrections Report
 - We recognized that each software upgrade generates a service record

Paradigm Case #2

- We analyzed our decision to replace the bearing with a longer life type.
 - The bearing failure did not make a serious injury likely, so we did not file an MDR.
 - Our complaint file documents the decision
 - The bearing failure did not pose a risk to health so we did not file a correction or removal report
 - Our correction and removal file documents the decision
 - We recognized that each bearing replacement should be included in a service record

Warning Letter
GE Healthcare Integrated IT Solution
August 12, 2008

- Failure to submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer to remedy a violation of the act caused by the device which may present a risk to health, as required by 21 CFR 806.10(a)(2).
- For example, your correction to apply a software patch for the Centricity Perinatal Monitoring System problem of non-identifiable patient information being added to an incorrect file was not reported to FDA. A letter describing this issue was sent to customers on July 20, 2007, and patches are available beginning in August 2007.

The Problem

The Warning Letter did not state a reason for the failure to file a report. I speculate that the manufacturer didn't realize there was a requirement.

Warning Letter
AliMed Corporation
August 19, 2008

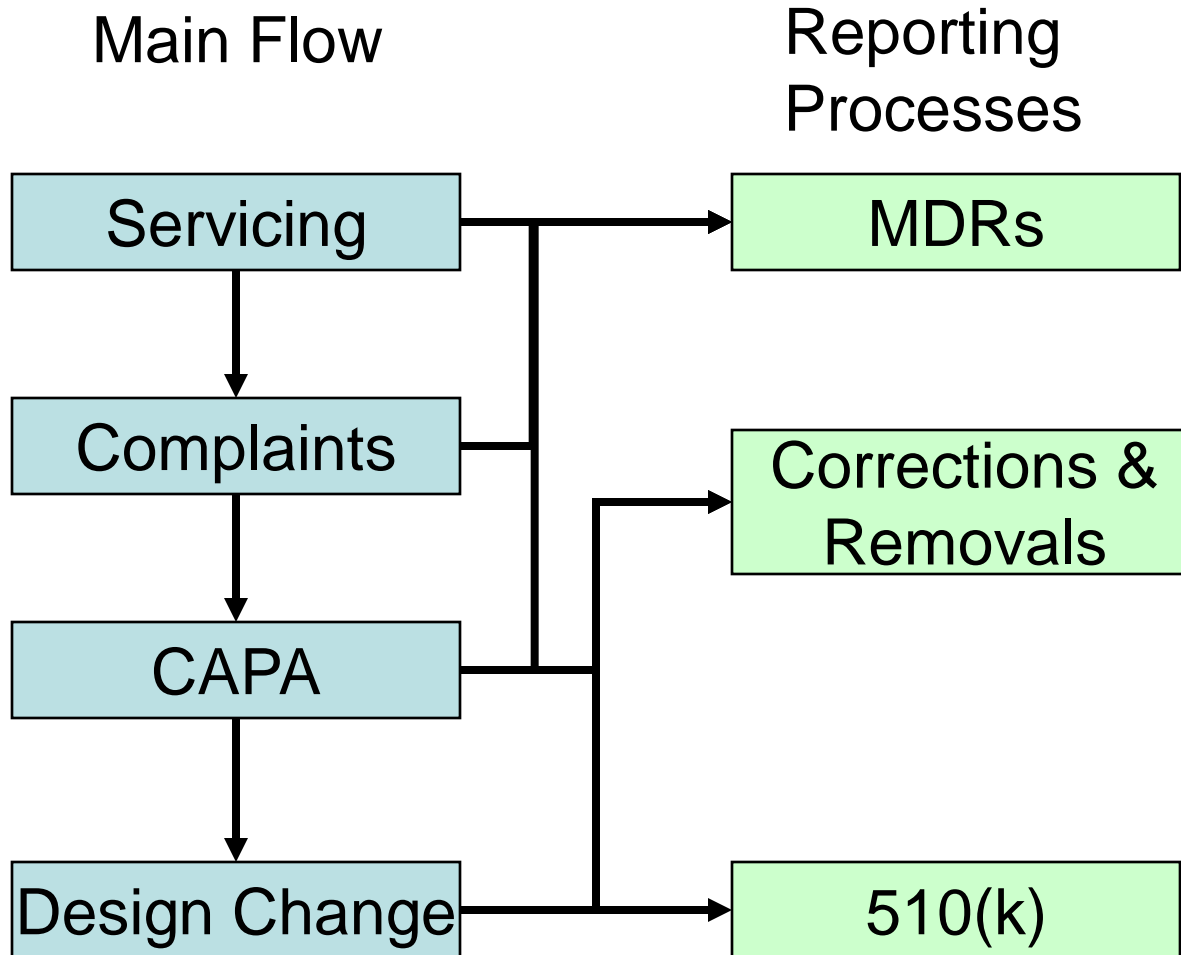
- Failure to contain the following information, not required to be reported to FDA under 21 CFR 806.10, in records of corrections and removals ...
- Specifically, your firm's recall file consists only of the notification letter and distribution lists. [People in your firm] tried to find more information in their email but were unable.

The Problem

The Warning Letter did not state a reason for the failure to maintain the required records, with the specified data elements. I speculate that the manufacturer didn't realize there was a requirement.

Summary & Conclusions

Summary



We followed two service actions through the main flow and showed that each step requires records.

In addition, some steps link to reporting activities. These require records when reporting isn't required.

Conclusions

- Recognize that these Quality Management System processes are linked
- Create a comprehensive and unified implementation
- Recognize that in many cases, the decision maker must be a “designated” person



Questions