

Similar to Case 1, **Case 2** takes you through an expanded investigation at Riverbend Memorial Hospital. Although you will be provided the basic facts about the case and a completed Event Discovery Report, you will be challenged to think through and organize the information so that you can complete the following steps on your own:

- Fill out the QA SysOp Investigation Report.
- Conduct a root cause analysis by building a causal tree.
- Assign codes to the root causes revealed by that analysis.
- Fill out Root Cause Analysis Report, using causal tree information.

Like Case 1, you must become the QA SysOp at the transfusion service at Riverbend Memorial Hospital in order to complete this exercise. Remember, events that occur at Riverbend are not unique; however, the organizational environment is unlike yours. As you put yourself in the QA SysOp’s position and see how decisions about the events are made, you may disagree with sections of the case “because that’s not how we do it at my hospital.” Try not to get immersed in the event and focus on the illustration of the MERS-TM process.

Materials

You will need a copy of the two code lists (Event Codes and Root Cause Codes) and the RAI tool, you can print them from the Support Materials section of the MERS-TM Web site (www.mers-tm.net/support.html) All other materials are provided.

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Answer Key

An Answer Key is provided to allow you to check your work and get some questions answered. The Answer Key includes the following items:

- QA SysOp Investigation Report information/answers
- Root Cause Analysis Report
- Causal Tree without root cause codes
- Causal Tree with root cause codes

**ABOUT
RIVERBEND
MEMORIAL
HOSPITAL**

Riverbend is a mid-sized hospital, and the transfusion service is a fairly well run operation. The staff work well as a team and many have been employed there for close to 10 years. Like any organization, however, the department does not have a large enough budget and compromises have been made. Plus, miscommunication and disagreements occur among the staff from time to time. So while the processes operate well most of the time, there are plenty of event reports to input into your event reporting program—MERS-TM.

You implemented MERS-TM about six months ago and feel very comfortable with the system. An average of 40 events per month have been reported. The majority of the events are of low risk and are handled as routine investigations (unless a trend is detected). About three to five events each month are handled as expanded investigations.

In the beginning the staff was hesitant about discussing events. Over time, they have realized that the information is not going to be used against them or their coworkers. Confidence in the event reporting system went up significantly after you demonstrated to them how their information was being used to make a needed improvement to the transfusion service.



BACKGROUND It is the morning of Friday, December 21, 2001. The workload has been quite heavy, but is starting to taper off. The staff are ready for the holidays and in a buoyant mood. Some of the staff are on their morning breaks and are starting to set up the conference room for a holiday luncheon.

DISCOVERY At about 10AM, *Elizabeth, the senior technologist*, comes into your office with a completed Event Discovery Report. She is flustered. She said she had volunteered to do the 8 AM Operating Room (OR) refrigerator check for *Susan*, who is on vacation.

However, there was a problem with an antibody identification at the start of the shift that had taken quite a bit of time, plus a few other issues that she had to resolve before going to the OR. This resulted in a one and one-half hour delay of the refrigerator check. She briefly explains what she found.

First, Elizabeth reports that one of the refrigerators contained several units, one of which was an autologous unit for *Mr. Gray*. His surgery was yesterday so she brought the unit back to the transfusion service.

After, she returned the autologous unit to inventory, Elizabeth pulled up Mr. Gray's transfusion record. She saw that two autologous units had been issued to the OR the previous morning.

Elizabeth also saw that one homologous unit of RBCs had been issued to the Intensive Care Unit (ICU) for Mr. Gray at 9:00AM today. She called the ICU to inquire about the unit. The nurse said that it had been administered at 9:15 AM. Elizabeth had told the nurse that one of Mr. Gray's autologous unit's had been located in the OR and was now available should Mr. Gray require additional blood.

Elizabeth adds that it appears that the OR refrigerator check was not performed at the beginning of yesterday's second shift. Technologist initials on the task checklist were absent. She discovered this when she was in the process of putting her own initials on the checklist. She gives you a photocopy of the checklist and a copy of the task assignments for this week.

Although she knows that others were involved in the event, Elizabeth feels terrible. She realizes that she should have reassigned the task to someone else when it became clear she was too busy.

WHAT HAPPENED? *As you begin your investigation, you first think through the event and make notes about what happened.*

Elizabeth had already written the preliminary discovery and occurrence information on the Event Discovery Report worksheet.

You wonder what happened because it is exceedingly rare for units to be left in the OR due to the frequency of checks. In this case, however, the autologous unit remained in the OR refrigerator for almost 24 hours—through three scheduled checks.

Initial discoveries and observations:

1. *The check the OR staff does during clean-up a surgery suite:*
Normally, when blood products are not needed during surgery, someone from the OR returns them to the transfusion service. Other than making a report to the OR manager that the unit had been missed, this failure is outside the scope of your investigation.
2. *The transfusion service's 4 PM check:*
You look at the photocopies of the checklist and task assignment lists Elizabeth had given you. The technologist responsible for checking the OR refrigerators this week for the second shift was **Nancy**. Nancy is conscientious and very reliable. You find it odd that she would not perform her assigned tasks. It would be a few hours before you can talk with Nancy, so you piece together the event the best you can until then.
3. *The transfusion service's 8 AM check:*
The discovery of the event occurred during the today's first shift refrigerator check. However, Elizabeth was one and one-half hours late, performing the check at 9:30 instead of around 8:00 AM. She had already explained the delay (morning workload that she was responsible for as senior technologist) acknowledging that she should perhaps have found another technologist to do the OR check for her.

Follow up with Nancy, the second shift technologist:

Shortly after Nancy arrived for her shift, you ask her if she did the OR refrigerator check the previous evening. Nancy's cheerful expression changes to one of surprise. "I can't believe I forgot to check the refrigerators!" she exclaims. Sensing that last night must have been stressful in some way, you ask her about what was going on. She said that nothing out of the ordinary had happened at work, but she had been very tired. One of her kids was ill and she had been up with him at night.

Pausing, she tentatively said that she had difficulty remembering to check the refrigerator, despite having worked at Riverbend for 6 years. All of her tasks for the evening are listed on one check list except the OR refrigerator check. She did not know if anyone else had the same problem, but asks if you would consider merging the check lists.

You say you will look into it.

CONCLUSION

This event involved two omissions and a delayed action. The event could have been stopped at any one of those points. Fortunately, there was not a bad patient outcome.

**CREATING A
TIMELINE**

Next, you organize the facts about the event into a timeline.

Working forward in time from left to right, you begin with the first failure leading up to the transfusion reaction. You list other major process steps that led up to the event and conclude with the consequent event* on the far right-hand side of the time line.

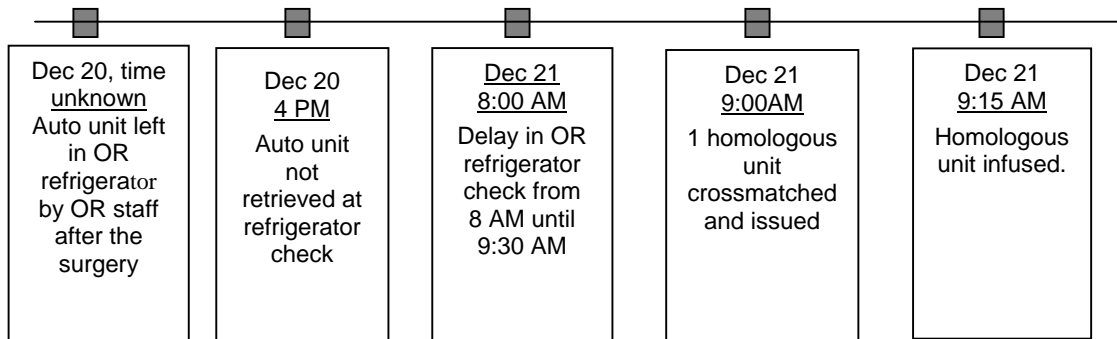
In building a timeline, you include all the major process steps leading up to the event. For the causal tree, you will use only the process steps from the

timeline in which a failure occurred.

**For near miss events, the time line concludes with the discovery of the event. This event was not a near miss and it did impact the patient. Therefore, the timeline concludes with the patient.*

Review the following events in light of the story.

Time Line for the Event



**EVENT
DISCOVERY
REPORT**

See the Event Discovery Report for this case that Elizabeth filled out (page 13 of the Appendix).

As a Riverbend employee, you would then enter the event into the database by first going to the MERS-TM web site and logging into the Database Functions area.

After you submit the information, the system assigns an accession number, which for this case is 350. Keep a record on this number by recording it at the bottom of your worksheet.

If you have a question about how the Event Discovery Report was completed, refer to the directions provided for each form under the Support/Materials section of the MERS-TM web site.

**QA SYSOP
INVESTIGATION
REPORT**

The next form to fill out is the **QA SysOp Investigation Report**. You decide to complete a worksheet version of this form before entering it online.

**Worksheet
Instructions →**

Use the following guide, along with the information you've gathered about the case, to complete the blank QA SysOp Investigation Report (Worksheet) included on page 16 of the Appendix.

An Answer Key is included.



Report Accession Number

Use the accession number assigned to the Event Discovery Report, which is 350.

**(Refer to Event
Code List)**

Event Codes:

1. Consequent (discovery) Code: ___ ___ ___ ___ ___

The spaces provided are broken up into three sections: overall event type, consequent event process code, and consequent event subprocess code.

Event type:

Categorize the event as either a (1) misadventure, (2) no-harm event, (3) near miss with an unplanned recovery, or (4) or a near miss with a planned recovery.

Hint: The unit was compatible, but the event was not discovered until after infusion.

Process code:

Identify *where* in the process the consequent event occurred using the Transfusion Service Event Codes. (First, find the appropriate code category in the list on the left of the page. To the right, you will see a code consisting of two alpha characters and three numeric characters plus a text description. The two alpha characters make up the process code.)

Subprocess code:

Find the text description that best describes the overall event. Write the three numbers in the last three spaces provided for the consequent event code.

2. Initial Antecedent (1st occurrence) Code:

Find the code that best describes the initial antecedent on the Transfusion Service Event Code list.

Hint: The initial antecedent occurred outside the transfusion service.

There should be agreement between the code entered here and question B.5 on the Event Discovery Report.

3. Significant Antecedent (occurrence) Event Code

Find the code that best describes the significant antecedent on the Transfusion Service Event Code list.

This is where you identify the most important antecedent that occurred within the transfusion service. This will be the most likely target for a process improvement, should there be one.

In this case, two of the three antecedents occurred within the transfusion service – the omission of the 4 PM check of the OR refrigerators and the delay of the 8 AM check. The code is the same for each antecedent, although the causes for each are different.

4. Additional Description of the Event:

You use this narrative block to further describe the event. Additional knowledge may be added, or information that is not clear from the initial narrative or codes should be clarified here.

5. Risk Assessment (RAI)

The risk assessment relates to the patient risk – actual or potential.

The Final RAI is used to decide whether or not to do an expanded investigation (root cause analysis) and to determine the extent of follow-up action to recommend.

Using your own expertise and knowledge about this event, use the RAI tool to help work through these questions and arrive at the Final RAI. Your answer may differ from that in the Answer Key.

Initial RAI:

The initial Risk Assessment Index (RAI) includes two components:

- Quantified Estimate of Severity of Patient Harm (QES)
What is your estimate of the potential severity of harm to the patient from getting a compatible stock unit of red cells rather than his autologous unit?
- Quantified Estimate of Probability of Recurrence (QEP). What is the probability of all three checks of the OR refrigerator failing?
- Calculate the initial RAI value

Final RAI:

Using the initial RAI value as the starting point, do the following to arrive at the Final RAI:

- Add 0.1 if the event is a near miss with an unplanned recovery
- Add 0.2 if the event involves a product issued to the patient

6. Organizational risk:

Do you think there was any organizational risk?

7. Follow-up:

Use the RAI tool to determine appropriate follow-up action.

8. If appropriate, describe the long-term preventive action to be taken:

The long-term preventive action field is completed when there is a “quick fix” that can be easily and quickly implemented, or if the event has an obvious solution. It can also be filled in at a later date after an analysis has been completed.

Do you think there is an appropriate long-term preventive action?

If so, what is it?

9. What type of investigation will this event receive?

Using the Final RAI result, Organizational Risk, and your expert judgement, what would you do?

Rough or Linked?

What should you do here?

Notes:

At this time, you make a few notes to yourself about the specifics of the event, who you spoke with and when, patient information, and other relevant details that will not be entered into the database.

BUILDING THE CAUSAL TREE

Now that you have completed the QA SysOp Investigation Report, you will build the causal tree and classify the root causes.

To help organize your information you may wish to create a table (as in Case 1) to help with the transition from narrative to causal tree. If so, use the “Techniques for Organizing Information” page and the blank table found on the pages 11 and 12.

You may also wish to use actual “sticky notes” to record each piece of information while constructing the tree.

Remember, work from left to right, then down when building the causal tree. Look for technical, organizational or human factors that contributed to the event.

Hint: There was no recovery in this event, so you only build the failure side of the tree.

Build Causal Tree

After you’ve built your tree, check out the Answer Key.



Code Root Causes



ROOT CAUSE ANALYSIS REPORT WORKSHEET

You generally do not use the Root Cause Analysis Report worksheet for this part of your MERS process because you enter this information directly into the computer.

However, for this case you use the worksheet as a convenient method for gathering all the information and to practice completing the form.

The narrative boxes you wrote for the causal tree do not need to match your entries on this form exactly. The key point is to make the case understandable to someone who reads it at some point in the future.

Complete the RCA Worksheet

Use the following information to complete the blank Root Cause Analysis Report (Worksheet) found on pages 19-20 of the Appendix.

TECHNIQUES FOR ORGANIZING INFORMATION

There are many methods of moving from an event description to a causal tree. With practice, most people are able to make the mental leap from the event description directly to the tree.

In this case, you choose to use the timeline you created earlier to help organize what you know about the event into a three-column table.

Refer to timeline and table

Table Description:

Left Column	Middle Column	Right Column
Process steps from timeline.	Description of actual failures	Reasons for each failure

Left column

The process steps listed in the time line form the left column of the table. One process step is entered per box.

Middle column

This is where the actual failures are described.

For each process step in which a failure(s) occurred, you create a “sticky note” with a description of the failure. Only one failure is listed per “sticky note.” These failures are the antecedent events. You are careful to provide only objective descriptions.

For process steps in which no failure occurred, nothing needs to be entered into the middle column. You usually make a note explaining why nothing was entered.

The bottom box in the middle row describes how the event was discovered. It is therefore the consequent event.

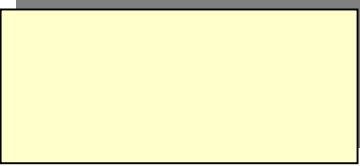
Right column

This is where the reasons for the failures described in the middle column are listed.

For each failure described on a “sticky note” (middle column), describe the reasons uncovered in the investigation. The list can be added to as needed.

If there is no failure described in the middle column, enter N/A in the right column.

The bottom box in this column is paired with the “sticky note” describing the discovery of the event (consequent event). It is not necessary to write anything in this final box because “Why?” is answered by the antecedent events described at the top of the middle column.

Time Line Process Steps	What went wrong (Event code if applicable)	Reasons Why?
<p>DATE What occurred?</p>	 <p>This is the first thing to go wrong (initial antecedent).</p>	<p><i>Why did it happen?</i></p>
	<p>This is the second antecedent.</p>	<p><i>Why did it happen?</i></p>



QA SysOp Investigation Report (worksheet)

Report Accession Number: _____

Event Codes:

1. Consequent (discovery) Code: 2. Initial antecedent (1st occurrence) Code: 3. Significant antecedent (occurrence) Code:

* _____

*Enter 1-4 on the first line: 1=No recovery, harm 2=No recovery, no harm 3=Near miss, unplanned recovery 4=Near miss, planned recovery

4. Additional description of event (optional):

5. Risk Assessment:

Final RAI: _____

6. Organizational Risk:

QES: .99 .90 .75 .50 .25 .10

High Low N/A

QEP: .99 .90 .75 .50 .25 .10

7. Follow up:

Propose action Consider action Monitor External report to other dept/org FDA Reportable

8. If appropriate, describe the long-term preventive action to be taken:

9. What type of investigation will this event receive? Routine Investigation Expanded Investigation

Complete this section only if this event is undergoing a routine investigation.

Rough or Linked?	Rough/Link Cause Code 1	Rough/Link Cause Code 2	Rough/Link Cause Code 3	Rough/Link Cause Code 4	Link to Accession Number
_____	_____	_____	_____	_____	_____

Notes:



Root Cause Analysis Report (Worksheet)

Instructions: This form is to be filled out after a causal tree has been built and the root causes of the event identified. Space has been provided for the consequent event and four antecedent events as well as their descriptions. List the antecedent events in order of occurrence, beginning with the initial antecedent.

Within each antecedent event section, space is provided for up to three root cause codes plus their descriptions. If there are additional root cause codes within a section, indicate so at the end of the section.

Report Accession Number: _____

Consequent Event Code _____	Describe what happened. _____ _____
Initial Antecedent Event Code 1 _____	Describe what happened. _____ _____
Cause Code 1a _____	_____ _____
Cause Code 1b _____	_____ _____
Cause Code 1c _____	_____ _____
Are there additional root cause codes for antecedent event 1? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Antecedent Event Code 2 _____	Describe what happened. _____ _____
Cause Code 2a _____	_____ _____
Cause Code 2b _____	_____ _____
Cause Code 2c _____	_____ _____
Are there additional root cause codes for antecedent event 2? <input type="checkbox"/> Yes <input type="checkbox"/> No	

Root Cause Analysis Report (Worksheet)

Antecedent Event Code 3 _____	Describe what happened. _____ _____
Cause Code 3a _____	_____ _____
Cause Code 3b _____	_____ _____
Cause Code 3c _____	_____ _____
Are there additional root cause codes for antecedent event 3? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Antecedent Event Code 4 _____	
Antecedent Event Code 4 _____	Describe what happened. _____ _____
Cause Code 4a _____	_____ _____
Cause Code 4b _____	_____ _____
Cause Code 4c _____	_____ _____
Are there additional root cause codes for antecedent event 4? <input type="checkbox"/> Yes <input type="checkbox"/> No	



MERS-TM Event Discovery Report (worksheet) Transfusion Service

Instructions: Use this worksheet to collect event discovery/occurrence information, and then enter it into the online database.

Section A – Discovery Information

1. Report date: 12 mo./21 day/2001 year 2. Discovery date: 12 mo./21 day/2001 year 3. Day of discovery: Weekday Weekend/Holiday
4. Discovery time: 12-4 AM 4-8 AM 8-12 Noon 12-4 PM 4-8 PM 8-12 Mid.
5. Discoverer's job description: Clerk House staff MD/DO MLT MT RN LVN/LPN Other
 Supervisor QA/QC Discoverer's name: Elizabeth
6. Where in the institution was the event discovered:
 Trans. Serv. OR ER ICU L&D Clinic Hosp. Ward Other Location Code _____

7. Describe briefly the event you discovered.
Autologous unit of RBCs was left in the OR refrigerator for 24 hours following the patients surgery.

8. How did you discover this event?
During the OR refrigerator check by the transfusion service staff.

9. Where in the process was the event discovered?
- | | | | | |
|--|--|--|---|--|
| <input checked="" type="checkbox"/> Product Check-In | <input type="checkbox"/> Patient/Product Request | <input type="checkbox"/> Order Entry | <input type="checkbox"/> Sample Collection | <input type="checkbox"/> Sample Handling |
| <input type="checkbox"/> Sample Testing | <input type="checkbox"/> Product Storage | <input type="checkbox"/> Product Selection | <input type="checkbox"/> Product Manipulation | <input type="checkbox"/> Available for Issue |
| <input type="checkbox"/> Product Issue | <input type="checkbox"/> Product Administration | <input type="checkbox"/> Miscellaneous | | |
10. Product/Record Action: Product retrieved Product destroyed Record corrected Floor/Clinic notified
 Additional testing Pt. sample recollected Other

Section B – Occurrence Information

1. Date the initial antecedent event occurred: 12 mo./20 day/2001 year 2. Time initial antecedent occurred: 12-4 AM 4-8 AM 8-12 Noon 12-4 PM 4-8 PM 8-12 Mid. 3. Day initial antecedent occurred: Weekday Weekend/Holiday
4. Person involved: Clerk House staff MD/DO MLT MT RN LVN/LPN Other Supervisor QA/QC
Person involved: OR staff-unknown.
5. Where in the process did the initial antecedent (occurrence) event first occur?
- | | | | | |
|---|--|--|---|--|
| <input type="checkbox"/> Product Check-In | <input type="checkbox"/> Patient/Product Request | <input type="checkbox"/> Order Entry | <input type="checkbox"/> Sample Collection | <input type="checkbox"/> Sample Handling |
| <input type="checkbox"/> Sample Testing | <input type="checkbox"/> Product Storage | <input type="checkbox"/> Product Selection | <input type="checkbox"/> Product Manipulation | <input type="checkbox"/> Available for Issue |
| <input type="checkbox"/> Product Issue | <input checked="" type="checkbox"/> Product Administration | <input type="checkbox"/> Miscellaneous | | |
6. Where in the institution did the initial antecedent (occurrence) event occur?
 Trans. Serv. OR ER ICU L&D Clinic Hosp. Ward Other Location Code _____
7. Product Issued? Yes No 8. Product Administered? Yes No

Report Accession Number 350 : Sub-site code (if applicable) _____



QA SysOp Investigation Report (worksheet)

Report Accession Number: 350

Event Codes:

1. Consequent (discovery) Code: 2. Initial antecedent (1st occurrence) Code: 3. Significant antecedent (occurrence) Code:

*2 U T 0 1 0 U T 0 1 2 P C 0 0 5

*Enter 1-4 on the first line: 1=No recovery, harm 2=No recovery, no harm 3=Near miss, unplanned recovery 4=Near miss, planned recovery

4. Additional description of event (optional):

Auto unit left in OR refrigerator due to two omitted checks and one delayed check. Resulted in the patient receiving one unit of homologous RBCs. ICU notified.

5. Risk Assessment:

Final RAI: 0.21

6. Organizational Risk:

QES: .99 .90 .75 .50 .25 .10

High Low N/A

QEP: .99 .90 .75 .50 .25 .10

7. Follow up:

Propose action Consider action Monitor External report to other dept/org FDA Reportable

8. If appropriate, describe the long-term preventive action to be taken:

Look into combining checklists

9. What type of investigation will this event receive? Routine Investigation Expanded Investigation

Complete this section only if this event is undergoing a routine investigation.

Rough or Linked?	Rough/Link Cause Code 1	Rough/Link Cause Code 2	Rough/Link Cause Code 3	Rough/Link Cause Code 4	Link to Accession Number
—	— — — —	— — — —	— — — —	— — — —	_____

Notes:



Root Cause Analysis Report (Worksheet)

Instructions: This form is to be filled out after a causal tree has been built and the root causes of the event identified. Space has been provided for the consequent event and four antecedent events as well as their descriptions. List the antecedent events in order of occurrence, beginning with the initial antecedent.

Within each antecedent event section, space is provided for up to three root cause codes plus their descriptions. If there are additional root cause codes within a section, indicate so at the end of the section.

Report Accession Number: 350

Consequent Event Code <u>2 U T O 1 0</u>	Describe what happened. <u>Patient received one unit homologous RBCs rather than his Autologous unit.</u>
Initial Antecedent Event Code 1 <u>U T O 1 2</u>	Describe what happened. <u>OR staff did not return unused product as outlined in their protocol</u>
Cause Code 1a <u>H E X</u>	<u>Protocol not followed - reason unknown.</u>
Cause Code 1b <u>---</u>	
Cause Code 1c <u>---</u>	
Are there additional root cause codes for antecedent event 1? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Antecedent Event Code 2 <u>P C O O 5</u>	Describe what happened. <u>Second shift did not check DR refrigerator to retrieve any unused products</u>
Cause Code 2a <u> T D</u>	<u>Difficult task to remember as check-off sheet is separate from main check-off sheet.</u>
Cause Code 2b <u>H S S</u>	<u>Forgot to check DR refrigerator. Sleep deprivation contributed.</u>
Cause Code 2c <u>---</u>	
Are there additional root cause codes for antecedent event 2? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	



Antecedent Event Code 3 <u>P C 0 0 5</u>	Describe what happened. <u>Delay in first shift OR refrigerator check until 9:30 (Homologous unit issued 9 AM)</u>
Cause Code 3a <u>H R C</u> Cause Code 3b — — <u>X</u> Cause Code 3c — — —	<u>Technologist was busy, did not ask another tech to perform the check.</u> <u>Heavy workload</u>
Are there additional root cause codes for antecedent event 3? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Antecedent Event Code 4 — — — — —	Describe what happened. _____
Cause Code 4a — — — — — Cause Code 4b — — — — — Cause Code 4c — — — — —	_____ _____ _____
Are there additional root cause codes for antecedent event 4? <input type="checkbox"/> Yes <input type="checkbox"/> No	