**Worksheet: NCE Case Studies 4-09**

Tracking Number: NCE-2016-240

# **Nonconforming Event (NCE) Report Form**

 Existing nonconformity

 Potential nonconformity

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| **Date/Time of Nonconformity**: July 2016 | | **Date/Time of Report**: 02 August 2016/0920 | |
| **Personnel Reporting Nonconformity:** | | Biochemistry Supervisor | |
| **Patient’s Name**: (if applicable) | | **Patient ID**: (if applicable) | |
| **Patient’s clinician**: (if applicable) | |  | |
| **Location of nonconformity:** | | Laboratory utility room’s water system | |
| **Brief description of nonconformity:** | | There is no evidence that the water system’s filter was changed per preventative maintenance schedule for the month of July. | |
| **How was the nonconformity discovered?** | | Monthly review of quality records | |
| **Remedial (immediate) action taken:**  I discussed the issue with the biochemistry technologists and was informed that James usually takes care of the matter. James was reassigned to hematology last month. I assigned Biochemistry Technologist #2 to change the filter and note it on the preventative maintenance log. Technologist #2 explained that she did not know how to do this task. After receiving permission from the Hematology Supervisor, I asked James to change the filter. | | | |
| **Report provided to** | | | |
| Supervisor Name: | Biochemistry Supervisor | | Date/Time: 02 August 2016/0920 |

Supervisor must obtain tracking number within 24 hours of receiving the occurrence; write number on top, right-hand corner

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| Gen\_NCE\_F001; v1 | Page 1 of 2 | 03/03/2015 |

# **Nonconforming Event (NCE) Investigation and Management Form**

Tracking Number: NCE-2016-240

Instructions:

* Begin investigation as soon as possible. Determine what, who, when, how, and then why (cause analysis) things went wrong in the process that led to the nonconforming event.
* Classify the event.
* Propose action to correct the problem or mitigate the risks

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| **Supervisor/Manager Investigation (attach pertinent information if required):**  After reviewing previous maintenance logs, only James initials are noted. I spoke with James, and he explained that since he has been assigned to cross-train in hematology, he felt he should not be responsible for a biochemistry task.  I reviewed the biochemistry departmental tasks per workstation, and realized this task was never assigned to a specific workstation. Also, the only documentation I found was the operator’s manual and preventative action log.  Causes - the task was never assigned to a workstation, and documentation and training were missing.  Name: Biochemistry Supervisor Date/Time: 02 August 2016/ 1500 |

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| Classification (check all that apply): | | | | | | | |
| Non-laboratory Error |  | Laboratory Error |  | Laboratory Section: | | | |
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| Pre-examination |  | LIS problem |  | Receiving/Delivery |  | Complaint |  |
| Examination |  | Equipment |  | Waste Management |  | Safety/Injury |  |
| Post-examination |  | Purchasing |  | Environmental Issue/Housekeeping |  | Reference Lab |  |

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| **Proposed correction (attach action plan if approved):**  I propose that James remain responsible for the water filtration system until management can allocate sufficient time for James to develop the necessary SOPs and training/competency forms. Once approved, James instructs the biochemistry staff in proper procedure.  As Biochemistry Supervisor, I will assign this responsibility to Workstation #1 and include this task as part of that workstation’s training and competency. | | |
| QA Officer Comments:  Risk Score Name Date | | |
| NCE Management Database Entry: | | |
| NCE closed and entered into database | Name | Date |

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| Gen\_NCE\_F001; v1 | Page 2 of 2 | 03/03/2015 |

Tracking Number: NCE-2016-241

# **Nonconforming Event (NCE) Report Form**

 Existing nonconformity

 Potential nonconformity

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| --- | --- | --- | --- |
| **Date/Time of Nonconformity**: 9 August 2016/0950 | | **Date/Time of Report**: 9 August 2016/1015 | |
| **Personnel Reporting Nonconformity:** | | Blood Bank Technologist | |
| **Patient’s Name**: (if applicable) Patient #1 | | **Patient ID**: (if applicable) MR2345 | |
| **Patient’s clinician**: (if applicable) | | Dr. Provider | |
| **Location of nonconformity:** | | Blood Bank | |
| **Brief description of nonconformity:** | | Unit # 2 was incorrectly labeled as an O Pos by the referral laboratory when it actually was A Pos blood. | |
| **How was the nonconformity discovered?** | | I received an order and specimen to cross-match 2 units of packed rbc with Patient #1. I selected 2 units of O Pos since Patient #1’s specimen was O Pos. During the immediate spin phase, UNIT #2 had an extremely strong reaction (+4) with the patient’s specimen. I performed a type and Rh on Unit #2 and discovered it was incorrectly labeled as O Pos by the Central Blood Repository Centre. Unit #2 was really A Pos. | |
| **Remedial (immediate) action taken:**  I placed Unit #2 on the bottom shelf in the back with a large sign indicating Do Not Use This Blood and told the supervisor. She requested I write this report. | | | |
| **Report provided to** | | | |
| Supervisor Name: | Blood Bank Supervisor | | Date/Time: 9 August 2016/1120 |

Supervisor must obtain tracking number within 24 hours of receiving the occurrence; write number on top, right-hand corner

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| Gen\_NCE\_F001; v1 | Page 1 of 2 | 03/03/2015 |

# **Nonconforming Event (NCE) Investigation and Management Form**

Tracking Number: NCE-2016-241

Instructions:

* Begin investigation as soon as possible. Determine what, who, when, how, and then why (cause analysis) things went wrong in the process that led to the nonconforming event.
* Classify the event.
* Propose action to correct the problem or mitigate the risks

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| **Supervisor/Manager Investigation (attach pertinent information if required):**  I interviewed the technologist and discovered that she selected 2 appropriate blood units by type and Rh from the blood storage refrigerator as per procedure when performing a cross-match.  She performed the type and Rh on Unit #2 because she never saw such a strong reaction on immediate spin.  I verified the acceptability of her records of her QC, patient’s type and Rh, the immediate spin reactions for Unit #2, and Unit #2’s type and Rh.  The A Pos unit of blood was placed on the O Pos availability shelf because the unit was mislabeled by the Central Blood Repository Centre.  I do not know why the Centre made this mistake, but the catastrophic error was compounded due to a system problem within our organization.  Name: Blood Bank Supervisor Date/Time:9 August 2016/1300 |

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| Classification (check all that apply): | | | | | | | |
| Non-laboratory Error |  | Laboratory Error |  | Laboratory Section: | | | |
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| Pre-examination |  | LIS problem |  | Receiving/Delivery |  | Complaint |  |
| Examination |  | Equipment |  | Waste Management |  | Safety/Injury |  |
| Post-examination |  | Purchasing |  | Environmental Issue/Housekeeping |  | Reference Lab |  |

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| **Proposed correction (attach action plan if approved):**  Because we receive our blood units from the referral laboratory, Central Blood Repository Centre, already labeled with the type and Rh, and to save money on reagents, the Receipt of Blood Products Procedure does not include verifying the label placed on the units with the contents. I recommend that we inspect all incoming units until the Centre can respond to our complaint. | | |
| QA Officer Comments:  Risk Score Name Date | | |
| NCE Management Database Entry: | | |
| NCE closed and entered into database | Name | Date |

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| Gen\_NCE\_F001; v1 | Page 2 of 2 | 03/03/2015 |

Tracking Number: NCE-2016-242

# **Nonconforming Event (NCE) Report Form**

 Existing nonconformity

 Potential nonconformity

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| **Date/Time of Nonconformity**: 11 August 2016/1005 | | **Date/Time of Report**: 11 August 2016/1015 | |
| **Personnel Reporting Nonconformity:** | | Storeroom Keeper | |
| **Patient’s Name**: (if applicable) | | **Patient ID**: (if applicable) | |
| **Patient’s clinician**: (if applicable) | |  | |
| **Location of nonconformity:** | | Storeroom | |
| **Brief description of nonconformity:** | | 3 boxes containing plastic pipette tips were crushed | |
| **How was the nonconformity discovered?** | | I discovered the crushed boxes while unpacking supplies from the XYZ Vendor. | |
| **Remedial (immediate) action taken:**  I called XYZ Vendor to inform them. XYZ’s representative said to discard the crushed boxes. They will send us 3 replacement boxes by the end of the week. I noted the details on the packing invoice and wrote this NCE report as per the SOP. I made a note on the management calendar to expect the replacement boxes by Friday. | | | |
| **Report provided to** | | | |
| Supervisor Name: | Technical Supervisor | | Date/Time: 11 August 2016/1100 |

Supervisor must obtain tracking number within 24 hours of receiving the occurrence; write number on top, right-hand corner

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| Gen\_NCE\_F001; v1 | Page 1 of 2 | 03/03/2015 |

# **Nonconforming Event (NCE) Investigation and Management Form**

Tracking Number: NCE-2016-242

Instructions:

* Begin investigation as soon as possible. Determine what, who, when, how, and then why (cause analysis) things went wrong in the process that led to the nonconforming event.
* Classify the event.
* Propose action to correct the problem or mitigate the risks

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| **Supervisor/Manager Investigation (attach pertinent information if required):**  I discussed the issue with the Storeroom Keeper. He said no other items in this shipment were affected. The Storeroom Keeper does not recall that this has ever been a problem before today, especially with this vendor.  We do not know why the boxes were crushed; they just were.  Name: Technical Supervisor Date/Time: 12 August 2016/0800 |

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| Classification (check all that apply): | | | | | | | |
| Non-laboratory Error |  | Laboratory Error |  | Laboratory Section: | | | |
|  | | | | | | | |
| Pre-examination |  | LIS problem |  | Receiving/Delivery |  | Complaint |  |
| Examination |  | Equipment |  | Waste Management |  | Safety/Injury |  |
| Post-examination |  | Purchasing |  | Environmental Issue/Housekeeping |  | Reference Lab |  |

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| **Proposed correction (attach action plan if approved):** | | |
| QA Officer Comments:  Risk Score Name Date | | |
| NCE Management Database Entry: | | |
| NCE closed and entered into database | Name | Date |

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| Gen\_NCE\_F001; v1 | Page 2 of 2 | 03/03/2015 |

Tracking Number: NCE-2016-243

# **Nonconforming Event (NCE) Report Form**

 Existing nonconformity

 Potential nonconformity

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| --- | --- | --- | --- |
| **Date/Time of Nonconformity**: 11 August 2016/1800 | | **Date/Time of Report**: 11 August 2016/1830 | |
| **Personnel Reporting Nonconformity:** | | Evening-shift Technologist | |
| **Patient’s Name**: (if applicable) | | **Patient ID**: (if applicable) | |
| **Patient’s clinician**: (if applicable) | |  | |
| **Location of nonconformity:** | | Biochemistry Department | |
| **Brief description of nonconformity:** | | The Neonatal Bilirubin Procedure states to add the wrong amount of sulfanilic acid to the working solution (0.1 ml instead of 1.0 ml). | |
| **How was the nonconformity discovered?** | | The new girl was using the procedure as written and her QC values were unacceptable. While watching her technique, I told her that she is using the wrong pipette. She then showed me the procedure she was following while making her working solution. We both agreed that the mistake was probably a typo. | |
| **Remedial (immediate) action taken:**  We made the working solution correctly, and the QC was acceptable. I attached a post-it note to the procedure explaining the amount of sulfanilic acid should be 1.0 ml. | | | |
| **Report provided to** | | | |
| Supervisor Name: | Evening-shift Supervisor | | Date/Time: 11 August 2016/2100 |
| I obtained a tracking number. I left this report for the Biochemistry Supervisor to address in the morning. I also noted the problem in the Change-of-shift Communication Log.  Evening-shift Supervisor  11 August 2016/2115 | | | |

Supervisor must obtain tracking number within 24 hours of receiving the occurrence; write number on top, right-hand corner

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| Gen\_NCE\_F001; v1 | Page 1 of 2 | 03/03/2015 |

# **Nonconforming Event (NCE) Investigation and Management Form**

Tracking Number: NCE-2016-243

Instructions:

* Begin investigation as soon as possible. Determine what, who, when, how, and then why (cause analysis) things went wrong in the process that led to the nonconforming event.
* Classify the event.
* Propose action to correct the problem or mitigate the risks

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| **Supervisor/Manager Investigation (attach pertinent information if required):**  I reviewed the references for the method to confirm the amount of sulfanilic acid is 1.0 ml. This procedure, along with many others, were created at the same time by me. The typo was not caught because the single reviewer was the Quality Manager, who never worked in the biochemistry department.  I reviewed the entire procedure and found another typo involving the wavelength to set the spectrophotometer.  This is a system problem involving documentation. Because the QC was able to detect this error, I believe this error should be classified as a low risk.  Name: Biochemistry Supervisor Date/Time: 12 August 2016/0810 |

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| Classification (check all that apply): | | | | | | | |
| Non-laboratory Error |  | Laboratory Error |  | Laboratory Section: | | | |
|  | | | | | | | |
| Pre-examination |  | LIS problem |  | Receiving/Delivery |  | Complaint |  |
| Examination |  | Equipment |  | Waste Management |  | Safety/Injury |  |
| Post-examination |  | Purchasing |  | Environmental Issue/Housekeeping |  | Reference Lab |  |

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| **Proposed correction (attach action plan if approved):**  Institute a Change Request Form for this procedure and communicate changes to all biochemistry staff. | | |
| **QA Officer Comments:**  Risk Score Name Date | | |
| NCE Management Database Entry: | | |
| NCE closed and entered into database | Name | Date |

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| Gen\_NCE\_F001; v1 | Page 2 of 2 | 03/03/2015 |