**Assignment 1 4-20 Assignment # 1**

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| **Purpose of Assignment #1:**   1. **To analyze investigative records so that the problem can be understood and defined.** 2. **To determine if this problem is a recurring nonconformity by looking for patterns and trends.**   **Instructions:**  **Document Information after evaluating the investigative records on Problem Statement Table (Page 4). Submit completed Problem Statement Table to the facilitator.** |  |

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| **Task #** | **Task to be performed** | **Record Reference** | **Location of Reference** | **Helpful Notes** |
| 1 | Read | *Handout 3: NCE-2016-244* | Stand-alone handout | NCE form has two pages |
| 2 | Refer to | *Step 1: Define the Problem* | *Handout 1: RCA Model 4-17, pages 2-3* |  |
| 3 | Evaluate | Investigative Request form records related to this NCE. | Provided with these instructions, pages 5 and 6. | 2 request forms |
| 4 | Evaluate | *NCE Log* | Provided with these instructions, page 7. | Review the NCE log to determine the frequency of problems occurring |
| 5 | Document the specific and detailed information you have learned about this problem. | *Problem Statement Table* | Provided with these instructions, page 4. | At this point, you are not trying to determine causes or develop solutions, just **clearly define the problem** using the information you currently have in your possession.  Remember to capture new information by keeping your Problem Statement Table current. **Add facts about the problem with each new piece of information you obtain during the diagnostic phase**. Keep your Problem Statement table handy to quickly update when evaluating further information e.g Task 5,6. |
| 6 | Read | *NCE-2016-194*  *NCE-2016-214*  *NCE-2016-219* | Stand alone handout | **These NCE were selected from the NCE log for further investigation**  Always review the NCE Aggregate Log early in a NCE and/or RCA investigation to determine if the current NCE reflects an emerging trend or pattern. |
| 7 | Document the specific and detailed information you have learned about this problem from the related NCEs. | *Problem Statement Table* | Provided with these instructions page 4 | At this point, you are STILL not trying to determine causes or develop solutions, just clearly define the problem using the information you currently have in your possession.  **Remember to capture new information by keeping your Problem Statement Table current.**  Add facts about the problem with each new piece of information you obtain during the diagnostic phase. Keep your problem statement table handy to quickly update. |
| 8 | Listen to the interviews (3) and take notes. Add relevant information to Problem Statement Table | *Interviews and Worksheet: Note page 8* | PPT with interviews embedded –standalone handout  Worksheet: Note page 7 of these instructions | Gather information from the interviews and record notes. |

**RCA Step #1 Define the problem.** You must first understand what happened before attempting to understand the causes.

**Problem Statement Table**

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| **Reported by:** Quality Manager | **Date:** 18 August 2016 |
| **Description of problem as it was reported:**  Dr. Timela did not receive laboratory results on the requested CSF microbiology tests. | |

For all portions below, apply the following rules

* Assume nothing
* Independently verify all facts, if possible
* Do not state symptoms

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| **WHAT exactly is the problem? (Move one step beyond the symptoms)** |
| **WHERE does it occur?** |
| **WHEN does problem happen?** |
| **WHO experiences the problem?** |
| **HOW MUCH does it occur?** |
| **WHY DOES IT MATTER? (i.e., what requirements are violated by the problem?)** |







**Worksheet Assignment 1**

Task 8: Interview points to be documented

1. What information was learned from Dr. Timela’s interview?
2. What information was learned from Tech AA’s interview?
3. What information was learned from LSRC?
4. What information from the interviews should be added to the Problem Statement Table to keep it current?