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| **Worksheet 2: Writing Nonconformities 4-70** | |
| **Directions:** Decide if the scenario described should be cited as a nonconformity. If so, then write a problem statement for the scenario. | |
| 1 | **Requirement –**  **SLIPTA 1.5** **Authorization** How the laboratory will: 1) document authorization levels for the different tasks and roles  **SLIPTA 5.13 Equipment Repair Monitoring and Documentation** Are repair orders monitored to determine if the service is completed? Does the laboratory verify and document the equipment is in proper working order before being put it back into service? |
| **Evidence –**  The analytical staff expressed frustration with the bioengineers arriving after-hours and leaving before ensuring the instrument is properly functioning. When reviewing service reports between June 2015 – January 2016, 9 out of 10 service reports from the biochemistry and hematology sections reflect a phlebotomist signature accepting the service rendered. 6 of the 10 service orders required follow-up visits to fix the original problem resulting in an additional 10 days of equipment downtime. |
| **Non-Conformance –** |
| 2 | **Requirement –**  CCHL’s Training and Competency Policy (QGen-Comp-Pl003) states that a score of 100% must be achieved to be determined *competent*.  **SLIPTA 1.5** **Competency Assessment** How the laboratory will: 1) assess the competence of personnel to perform assigned managerial or technical tasks; 2) assess ongoing competency; 3) establish competency criteria; 4) provide feedback to persons assessed; 5) schedule retraining based on the assessment outcome; 6) keep records of competency assessments and outcomes?  **SLIPTA 3.8 Staff Competency Assessment and retraining** Is there a system for competency assessment that covers the following? a) Are competency assessments performed according defined criteria? b) New hires, c) Existing staff, and d) Retraining and re-assessment where needed |
| **Evidence–**  8 of the 10 competency records reviewed for the XYZ analyzer demonstrate a re-grading that then achieves a 100% score. Of those 8, 7 achieved an initial score of greater than 90%. However, 1 of the records (May 13, 2016) had an initial score of 43%. with no retraining performed. Because the re-grading resulted in 100% through the use of recommendations, retraining was not considered necessary. |
| **Non-Conformance –** |

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| 3 | **Requirement –**  **SLIPTA 7.10 Product Expiration** Are all reagents/test kits in use (and in stock) currently within the manufacturer-assigned expiration or within stability? |
| **Evidence–**.  Date of Audit May 2, 2016  Pharmacy prepares the sodium citrate anticoagulant for the blue top tubes that have been previously washed. All 8 blue top tubes in the phlebotomy section have an expiry date printed by the manufacturer of 10-2007. |
| **Non-Conformance –** |
| 4 | **Requirement –**  **SLIPTA 3.2 Organizational Chart and External/Internal Reporting Systems**  Is an organizational chart available that indicates the relationship between the laboratory and its parent organization? |
| **Evidence–**  When asked to see the organogram, the quality manager presented an organizational matrix instead that depicted reporting relationships and organizational structure. |
| **Non-Conformance –** |
| 5 | **Requirement -**  **SLIPTA 11.5** Is the outcome of the review of quality indicators used to improve lab performance? |
| **Evidence–**  Your lab measures only TATs and these are met 100% of the time because they are very generous. |
| **Non-Conformance –** |

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| 6 | **Requirement –**  The *PID* is required by hospital policy (CCH-269A) and laboratory policy (Recp-Phleb-Pl002) regarding specimen labeling.  **SLIPTA 8.1 Information for patients and users**  Are guidelines for patient identification, specimen collection (including client safety), labelling, and transport readily available to persons responsible for primary sample collection? |
| **Evidence –**  3 phlebotomists and the Phlebotomy Head of Section (HoS) were interviewed but no one knew what the *PID* was. Whatever it is, 10 out of 10 specimens probably don’t have it since only the last name was written on each tube. |
| **Non-Conformance –** |
| 7 | **Requirement –**  **SLIPTA 8.2 Does the laboratory adequately collect information needed for examination performance?** f) Date of sample collection (And time of collection where relevant – where time has an impact on the result) |
| **Evidence –**  All10 CD4 tubes examined were labelled with the date and time, except for 1 tube which was missing the year. |
| **Non-Conformance –** |