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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 –** ISO 15189:2022  ***6.2.3*** ***Authorization*** *The laboratory shall authorize personnel to perform specific laboratory activities* …..  **6.4.5 Equipment maintenance and repair**  *C (in part) Equipment that is defective or outside specified requirements, shall be taken out of service. It shall be clearly labelled or marked as being out of service, until it has been verified to perform correctly.* |
| **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*.  **Requirement –** SLIPTA  **3.11** Does the laboratory assess the competency of its personnel according to its defined criteria for all relevant activities including the following….  **b** Competency assessments performed according to defined criteria for new hires and existing personnel |
| **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 7.11 Product Expiration** Are all reagents/test kits in use (and in stock) currently within the manufacturer-assigned expiration or within stability?  **ISO 15189:2022 6.6.7 Reagents and consumables -Records** |
| **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 3.3 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 | **Requirements -**  **SLIPTA 11.1** Is the outcome of the review of quality indicators used to improve lab performance?  **ISO 15189:2022 8.8.2 Quality Indicators** |
| **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 Patient identification (*PID)* is required by hospital policy (CCH-269A) and laboratory policy (Recp-Phleb-Pl002) regarding specimen labeling.  **SLIPTA 8.4 Instructions for collection activities**  Are records available to show implementation of the following:  d) Labelling of primary samples in a manner that provides an unequivocal link with the patient from whom they are collected? |
| **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 8.5 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 –** |