**Handout 2: Upcoming Audit4-48**

**Preparing an Audit Plan for an Upcoming Audit**

You realize an upcoming audit is scheduled to be performed in 2 weeks (July 14-15, 2016). You scheduled a maximum of 2 days to conduct this audit and ½ day (½ day = 4 hours, ¼ day = 2 hours) for an audit preparation meeting.

The purpose of this approved audit is to review the processes required for calibrated equipment to ensure compliance with ISO 15189:2022, WHO-AFRO SLIPTA Checklist; v3, and the Quality Manual; v6. In addition to conformance with the requirements, opportunities for improvement (OFIs) and auditor-in-training will also be addressed.

All sections of the laboratory will be addressed including the Point-of-Care (POC) glucometer testing performed in the emergency department. Currently the Macungie Clinic serves as a drawing station only and has no POC devices to evaluate.

The expected vertical audit time to address the laboratory sections are:

Hematology – ½ day (wbc and hemoglobin)

Chemistry – ½ day (glucose and sodium)

Serology – ½ day (hepatitis C antibody and estradiol)

Molecular Biology – ½ day (HIV viral load)

Microbiology – ¼ day (refrigerator, incubator, sterilizer)

Blood Bank – ¼ day (refrigerator, freezer, water bath)

Histology – ¼ day (microtoner)

POC – ¼ day (glucometer)

Analytes selected by the Technical Supervisor include those with the greatest impact on patient care, very high or very low volume tests, and those with previous testing issues.

The processes to be audited for the analyte/equipment selected include:

All areas: Calibration, Maintenance, Service & Repair, including Contingency Plan

Where applicable - QC, PT, Reagents, Instrument Set-up/Shut-down, Measurement of Uncertainty

|  |  |  |
| --- | --- | --- |
| **Qualified Auditor Pool** | | |
| **Name** | **Availability** | **Currently works in the following sections:** |
| Quality Manager**\*** | √ | Quality Management |
| Tech A\* | √ | Chemistry and Molecular Biology |
| Tech B | √ | Hematology and Serology |
| Tech C |  | Microbiology |
| Tech D | √ | Chemistry |
| Phlebotomy Supervisor\* | √ | Phlebotomy and Reception |
| Hematology Supervisor | maternity | Hematology |
| **\*** Qualified to be lead auditor | |  |
| **Auditors-in-Training** | | |
| Microbiology Receiving Clerk | √ | Microbiology, Phlebotomy, and Reception |
| Chemistry Supervisor |  | Chemistry and Serology |