

Sample Internal Audit Agenda

Internal Audit Agenda – Best Bet Laboratories

Audit Objectives:

- to monitor compliance of the laboratory to our own quality management system
- to monitor compliance to ISO 15189

Audit Criteria:

The criteria have been defined in the checklist titled Master – Internal Audit Best Best Laboratories. The principle reference document is ISO/IEC 15189:2007 Medical Laboratories—Particular requirements for quality and competence.

Audit Scope:

The audit will encompass all areas of Best Bet Laboratories that perform medical laboratory testing and those areas that provide quality support. All Best Bet staff is required to be available for discussion and to assist the auditors in finding the records needed.

Date(s) of Internal Audit	
Team Leader (Auditor 1)	
Auditor 2	
Auditor 3	
Auditor 4	

DAY ONE				
Activity	Time Needed	Start time	End time	Facility staff required
Opening meeting, led by Team Leader	¾ hour	08:45	09:30	<Lab Director>, <Quality Manager>, Facility administrative representative, all other staff encouraged to attend.
Team Leader: Organization and Management, Personnel	2 hours	09:30	11:30	<Lab Director>, <Quality Manager>, Auditor may need to visit Human Resources
Team Leader: Quality Management System	1 ½ hours	11:30	13:00	<Lab Director>, <Quality Manager>
Auditor 2: Contracts and Referrals	1 ½ hours	09:30	11:00	<Lab Manager>
Auditor 2: Specimen Collection	2 hours	11:00	13:00	Staff in specimen procurement area, Auditor may also visit nursing units.
Auditor 3: Technical Requirements: Hematology area	3 ½ hours	09:30	13:00	<Technical Specialist> (primary contact), Auditor may converse with all staff in area.
Auditor 4: Technical Requirements: Chemistry area	3 ½ hours	09:30	13:00	<Technical Specialist> (primary contact), Auditor may converse with all staff in area.
Lunch	1 hour	13:00	14:00	Audit team only
Team Leader: Document Control	1 hour	14:00	15:00	<Lab Director>, <Quality Manager>,
Team Leader: Internal Audits and Management Review	1 hour	15:00	16:00	<LIS "specialist">, Auditor may converse with available staff in all laboratory areas.
Auditor 2: Point-of-Care Testing	2 hours	14:00	16:00	<POCT "specialist">, Auditor will also visit areas in the hospital where POCT is performed.
Auditor 3: Technical Requirements: Hematology area	2 hours	14:00	16:00	<Technical Specialist> (primary contact), Auditor may converse with all staff in area.
Auditor 4: Technical Requirements: Chemistry area	2 hours	14:00	16:00	<Technical Specialist> (primary contact), Auditor may converse with all staff in area.
End of day one meeting	1 hour	16:00	17:00	Audit team only

DAY TWO				
Team Leader : Complaints and nonconformities	2 hours	08:00	10:00	Quality Manager
Team Leader: External services and supplies, advisory services	2 hours	10:00	12:00	Quality Manager
Auditor 2: Safety	4 hours	08:00	12:00	<Safety officer>, Auditor may converse with available staff in all lab areas
Auditor 3: Technical Requirements: Microbiology area	4 hours	08:00	12:00	<Technical Specialist> (primary contact), Auditor may converse with all staff in area.
Auditor 4: Technical Requirements: Transfusion Medicine area	4 hours	08:00	12:00	<Technical Specialist> (primary contact), Auditor may converse with all staff in area.
Lunch	1 hour	12:00	13:00	Audit team only
Team Leader and Auditor 2 – Prepare reports	2 hours	13:00	15:00	None
Auditor 3: Technical Requirements: Microbiology area	2 hours	13:00	15:00	<Technical Specialist> (primary contact), Auditor may converse with all staff in area.
Auditor 4: Technical Requirements: Transfusion Medicine area	2 hours	13:00	15:00	<Technical Specialist> (primary contact), Auditor may converse with all staff in area.
Final Audit Team Meeting	1 hour	15:00	16:00	None
Closing meeting, led by Team Leader	1 hour	16:00	17:00	<Lab Director>, <Quality Manager>, Facility administrative representative, all other staff encouraged to attend.