

Internal Audit

Take a Close Look at Yourself

The purpose of this worksheet is to provide a step-by-step guide to prepare for accreditation to ISO 15189. It contains:

- ✓ What ISO 15189 Requires
- ✓ How to Meet ISO 15189 – A step-by-step guide
- ✓ The “Am I Ready for Accreditation?” Checklist

This guide will focus on concepts relating primarily to the following clauses of ISO 15189:

What ISO 15189 Requires

4.14 Internal Audits

- 4.14.1 You must conduct internal audits of all aspects of your laboratory service at regular intervals (once every twelve months). This includes both managerial and technical elements, with particular emphasis on areas of critical importance to patient care.
- 4.14.2 Your internal audits must be formally planned by the quality manager. Personnel cannot audit their own work. Procedures for conducting the internal audit must be documented. You must undertake appropriate corrective or preventive actions following the internal audit and these must be recorded and carried out within an agreed upon time.
- 4.14.3 The results of internal audit must be submitted to laboratory management.

How to Meet ISO 15189 - A Step-by-step Guide

Step	To Do	Responsible Person	Date Completed
1	Complete a gap analysis of your current internal audit process		
2	Plan for a new or revised internal audit program for your laboratory		
	a. Prepare an internal audit schedule		
	b. Identify potential auditors		
	c. Ensure the team of auditors has training		
	d. Create a policy, map a process, write detailed procedures		
	e. Create related templates: agenda, checklists		
	f. Set up record system		

3	Train staff covering the following points		
	a. The reasons for implementing the program		
	b. Establish a culture of no blame. Promote the program in a positive light		
	c. Practice using “open-ended” questions		
	d. Ensure an understanding of the requirements		
4	Conduct an internal audit		
	a. Set an audit date		
	b. Convert all processes and procedures to “current”		
	c. Set the agenda and share it with auditors and staff		
	d. Share the checklists with auditors and staff		
	e. Conduct an opening meeting		
	f. Perform the audit		
	g. Conduct a closing meeting		
6	Follow-up after the audit		
	a. Document nonconformities		
	b. Conduct root cause analysis		
	c. Develop and record action plans		
	d. Measure effectiveness of corrective actions		
	e. Ensure records are complete		
7	Submit to management review		
8	Follow-up after the management review		
	a. Record action plans with responsibilities, timelines		
	b. Ensure action plans are completed		
	c. Communicate results with staff		

The Am I Ready for Accreditation? Checklist

Clause	What to look for	YES	NO
4.14.1	Do you have a policy statement in your quality manual that addresses internal audits?		
	Has the frequency and schedule for internal audits been defined?		
	Does your internal audit plan cover both managerial and technical elements of your laboratory service? Can you demonstrate this with a checklist template?		
	Can you demonstrate that cumulative results of audits from one year to the next are considered?		
	Can you demonstrate that your internal audits emphasize areas critically important to patient care?		
4.14.2	Do you have a documented process and procedures for internal audits?		
	Does your internal audit procedure include a description of the records that will be kept of the audit?		
	Do you have properly trained internal auditors on staff or available to you from other labs?		
	Do your internal audits possess the necessary interpersonal skills?		
	Can you demonstrate that personnel never audit their own work and that your audit team members are objective?		
	Can you demonstrate that each of the main elements of your quality management system is subject to internal audit at least once every twelve months?		
	Have you created checklists?		
	Have you promoted the concept of internal audit to staff?		
	Do you have records of internal audit follow-up activities?		
4.14.3	Can you demonstrate that results of your internal audit were shared with management?		

	<p>Do you have the following records from your last internal audit?</p> <ul style="list-style-type: none">• Agenda• Records of opening and closing meetings• Audit report• Corrective and preventive action taken• Evidence of review by management• Evidence of verification of effectiveness of corrective action• Evaluation of auditor competence		
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