**Job Aid 5: IA Procedure 4-78**

**Developing an Internal Audit Procedure**

**ISO 15189:2012 4.14.5**

*The laboratory shall have a documented procedure to define the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.13).*

***Commentary***

**When preparing an internal auditing procedure, does the procedure address:**

* The objectives of the overall internal audit program (conformance and performance)
* Identification of the internal audit program coordinator (process owner)
* Scheduling of individual audits to be performed
* Selection of the processes, areas, and functions to be audited
* Dissemination of an annual plan of what to audit
* Auditor selection and a process for determining who can audit what
* Responsibilities for planning and conducting audits
* Reporting of audit results
* Relationship of audit process to the corrective action process and to follow-up
* Audit Closure, including notification

Is there a related procedure addressing *Internal Auditor Competence and Training*?

**When retaining records, consider the following :**

For the Audit Program

* Audit schedules
* Auditor competence and performance evaluation to demonstrate competency
* Feedback from auditors and auditees about the process
	+ Overall satisfaction with the audit program
	+ Competence of lead auditor and auditors
	+ Areas for audit program improvement

For Each Internal Audit

* Audit schedules
* Opening and closing meetings
* Audit plans
* Audit checklists and matrices
* NCE requests or corrective action/preventive action requests, depending on the system employed
* Reports or records of feedback from auditees on actions taken
* Audit follow-up report (evidence of review by management regarding the verification of effectiveness)
* Memo notifying audit closure to top management and the process owner

A complete record of the audit should be maintained even if a nonconformity has not been reported.