Jan 2017

ABC COMPANY

Internal Audit

Audit Plan		
1	Audit Plan Objective	
2	Audit Team Leader	
3	Audit Team Members	
4	Objectives	
5	Pre-Audit Review Meeting	
6	General Requirements	
7	Conclusions	
8	Post Audit Meeting	

AUDIT PLAN	
OBJECTIVE	

AUDIT TEAM LEADER(S)	AUDIT MEMBERS

START DATE:	Time:	Duration:	Location:
REFERENCED PROCEDURES:		REFERENCE DOCUMENTS:	

QUALITY SYSTEM TYPE – PLEASE CHECK ALL THAT APPLY		
☐ ISO/IEC 17025-2005	☐ ANSI/NCSL Z540-1-1994	☐ ANSI/NCSL Z540.3-2006

PRE-AUDIT REVIEW	
Review from Last External Audit dated:	Performed by:
1.	
Review from Last Internal Audit dated:	Performed by:
1.	

AREA(S) AUDITED				
Date		☐	Entire Quality Management System	
Date		☐	Sections	☐ First Quarter
Date		☐	Sections	☐ Second Quarter
Date		☐	Sections	☐ Third Quarter
Date		☐	Sections	☐ Fourth Quarter

General Requirements for the competence of Calibration Laboratories				
NMI REQUIREMENTS		Compliant		Remarks
1.		☐ Yes	☐ No	
2.		☐ Yes	☐ No	
3.		☐ Yes	☐ No	
ANSI/NCSL Z540-1 REQUIREMENTS				
ANSI/NCSL Z540.3 REQUIREMENTS				

Checklist					
Part I: General Requirements for the competence of Calibration Laboratories	**Reference**	**YES**	**NO**	**NA**	**Comments**
4 ORGANIZATION AND MANAGEMENT					
Personnel, who manage, perform or verify work affecting the quality of calibrations is documented.					
Laboratory is adequately supervised and has a technical manager responsible for the technical operation.					
A Quality Manager has responsibility for the quality system and its implementation.					
5 QUALITY SYSTEM, AUDIT AND REVIEW					
The quality manual and related documentation contain procedures for:					
A) the control and maintenance of documents					
B) achieving traceability measurements					
C) the lab's scope of calibrations and verifications					
D) calibration dates and results and expiration date					
E) past maintenance history and planned maintenance					
F) repair, malfunction or damage history					
G) measured value observed from each parameter found to be out of tolerance during calibration / verification					
H) establishing and changing calibration intervals					
The laboratory activities are independently audited at appropriate intervals to verify compliance with the quality system and corrective actions are documented.					

Part I: General Requirements for the competence of Calibration Laboratories	**Reference**	**YES**	**NO**	**NA**	**Comments**
6 PERSONNEL					
Laboratory personnel have the necessary education, training, technical knowledge and experience for their assigned functions.					
7 ENVIRONMENT					
The laboratory shall monitor, control and record environmental conditions as appropriate.					
8 EQUIPMENT AND REFERENCE MATERIALS					
Suitable equipment and reference materials are available to correctly perform the calibrations / verifications					
Instructions, data, standards and manuals are current					
Maintenance procedures are documented					
Broken and defective equipment is identified and labeled					
Calibration, verification and repair records for each piece of equipment are maintained and include:					
A) equipment name					
B) manufacturer's name, type and serial number					
C) location					
D) calibration dates and results and expiration date					
E) past maintenance history and planned maintenance					
F) repair, malfunction or damage history					
G) measured value observed from each parameter found to be out of tolerance during calibration / verification					

Part I: General Requirements for the competence of Calibration Laboratories	**Reference**	**YES**	**NO**	**NA**	**Comments**
9 MEASUREMENT TRACEABLILITY AND CALIBRATION					
A recall or removal program exists to remove from service equipment or standards which has exceeded its calibration interval or is otherwise judged to be unreliable					
Overall program is NIST traceable					
10 CALIBRATION METHODS					
Calibration procedures contain comprehensive details necessary for performing calibrations					
Calibration uncertainties do not exceed 25% of the acceptable tolerance					
11 HANDLING OF CALIBRATED ITEMS					
Each calibrated item is uniquely identified					
The condition as received of the calibrated item is recorded					
Tamper-resistant seals are applied to controls which, if moved, would invalidate the calibration					
12 RECORDS					
Each calibration record contains sufficient information to permit the calibration to be repeated.					
13 CERTIFICATES AND REPORTS					
Reports are accurate, clear and unambiguous and include:					
A) A title, e.g. “Calibration Report” or “Calibration Certificate”					
B) calibration laboratory name and address					
C) unique report identification or number					
D) customer name and address					
E) description of the item calibrated					

Part I: General Requirements for the competence of Calibration Laboratories	**Reference**	**YES**	**NO**	**NA**	**Comments**
F) calibration date					
G) calibration procedure used					
H) deviations from calibration method					
I) measurement results					
J) identification of the person responsible for the report					
K) special limitations if any					
L) a traceability statement					
M) identification of subcontractor performed calibrations					
14 SUBCONTRACTING OF CALIBRATION					
Subcontracted work is always placed with an accredited, audited and competent laboratory					
15 OUTSIDE SUPPORT SERVICES AND SUPPLIES					
Vendor services and supplies are of adequate quality to assure confidence in the laboratory's calibrations					
16 CORRECTIVE ACTIONS					
Documented procedures exist for resolving customer complaints and records are maintained on the resolution					

PART 2: QUALITY ASSURANCE REQUIREMENTS FOR MEASURING AND TEST EQUIPMENT (M&TE)	**Reference**	**YES**	**NO**	**NA**	**Comments**
17 GENERAL REQUIREMENTS					
A system exists to control the calibration/verification of M&TE					
M&TE is recalled or removed when the calibration interval is exceeded, has broken calibration seals or is suspected to be malfunctioning					
Calibration and verification system is audited periodically to ensure compliance to Z540					
18 DETAILED REQUIREMENTS					
M&TE is used in a controlled environment with consideration given to all factors affecting measurement results					
Environmental factors are monitored and recorded and correcting compensations applied to results when necessary					
Calibration intervals are established for all calibrated M&TE					
Temporary calibration interval extensions are documented					
User is notified along with measurement results when M&TE is found to be significantly out of tolerance					
M&TE is labeled to indicate calibration status					
Calibration label includes date calibrated, calibration due date, and the calibration agency					
Limited use or limited calibration items are labeled with the pertinent limitations					
Subcontractors calibration system is accredited and complies with NIST, ISO 10012 and to Z540					

PART 2: QUALITY ASSURANCE REQUIREMENTS FOR MEASURING AND TEST EQUIPMENT (M&TE)	**Reference**	**YES**	**NO**	**NA**	**Comments**
19 Z540 REQUIREMENTS					
Management review is completed at least once a year					
The quality manual and related quality documentation shall contain the laboratory's scope of calibrations					
Subcontracted Z540 calibrations are not performed					
Calibration procedures and their modifications are validated prior to being places in service.					
User is notified along with measurement results when M&TE is found to be significantly out of tolerance					

Action Items *(Include status of items from last review; list new items with responsible individual and due dates)*

1.
2.
3.

Overall Quality Objectives

1.
2.
3.

Calibration Activities

1.
2.
3.

Management Approvals

ABC Company's business and quality system has been reviewed to ensure their continuing suitability and effectiveness in satisfying ISO/IEC 17025:2005, ANSI/NCSI Z540-1and ANSI/NCSI Z540.3 requirements and stated company quality policy, goals and objectives.

Applicable Company Representative | *Date*

Management/Quality Representative | *Date*

POST AUDIT MINUTES OF MEETING	**DATE:**
Audit Team Leader(s)	Audit Team Members
PURPOSE:	SCOPE:
ITEMS DISCUSSED:	
1.	
2.	
AUDIT REPORT	DATE:
COMMENTS AND OBSERVATIONS	
STATEMENT OF DEFICIENCIES	

FOLLOW UP INSPECTION REQUIRED	☐ **YES**	☐ **NO**		**DATE:**
SIGNATURE OF LEAD AUDITOR:				**DATE:**