

Calibration & Supplier Audits

ASQ Merrimack Section
04/02/09

Outline

- Survey
- Objective
- Reference Terms
- Traceability and Requirements Conformance
- Calibration Requirements
- Calibration Certificates
- Customer Requirements
- Non-Conforming Measurements
- What to look for in a supplier Audit

Survey

How many attendees:

How many companies are represented:

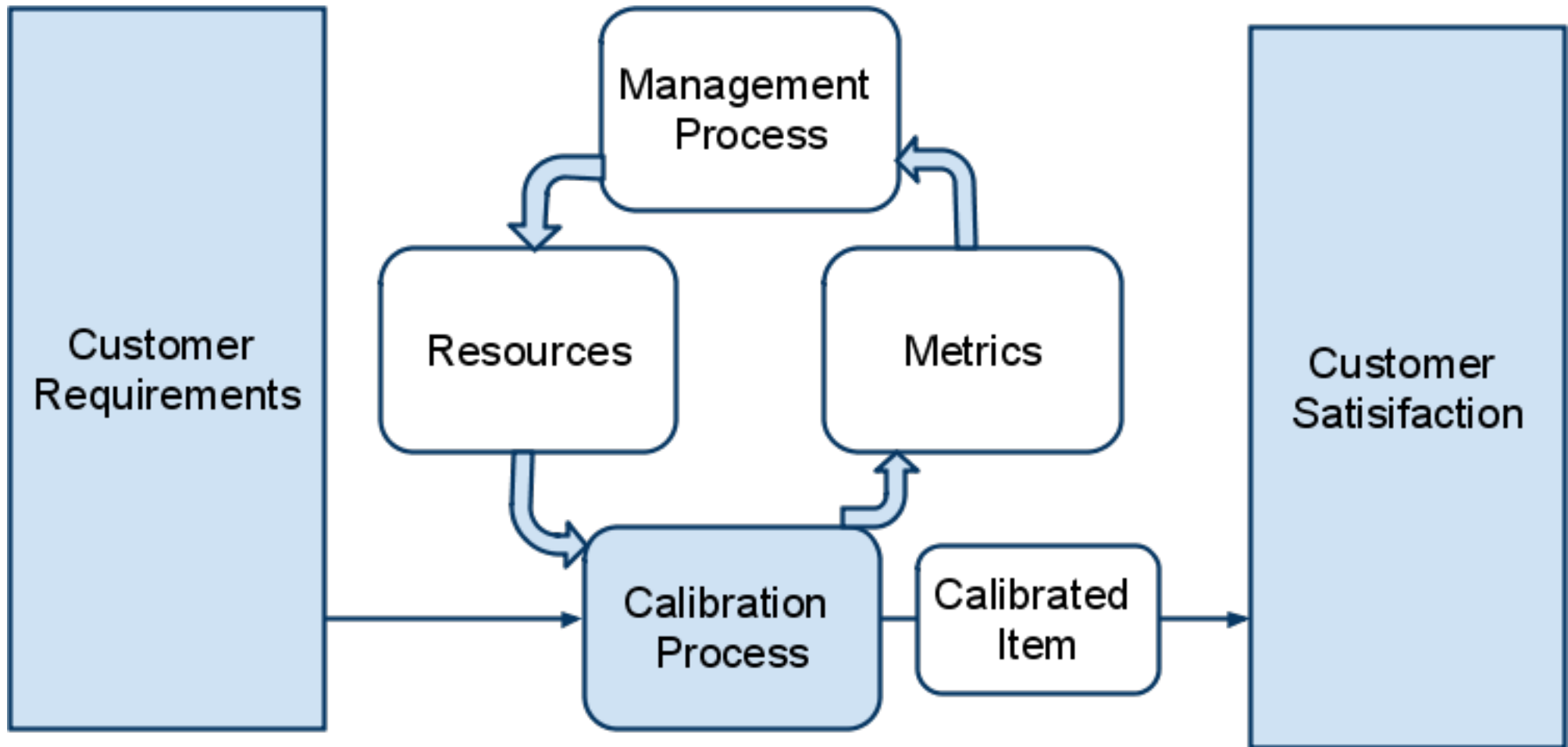
How many metrologists or calibration specialists :

How many are from companies that outsource their calibrations:

How many attendees perform external audits for a living:

How many audit a suppliers calibration lab during a supplier audit:

Objective



Terms that I will be using

- Metrology
- Calibration
- Traceability *
- 17025 *
- Z540 *
- TS
- Calibration Process
- Uncertainty
- GUM
- Calibration Standards
- PMEL - ASQ CCT
- Calibration Certificate *
- OOT *

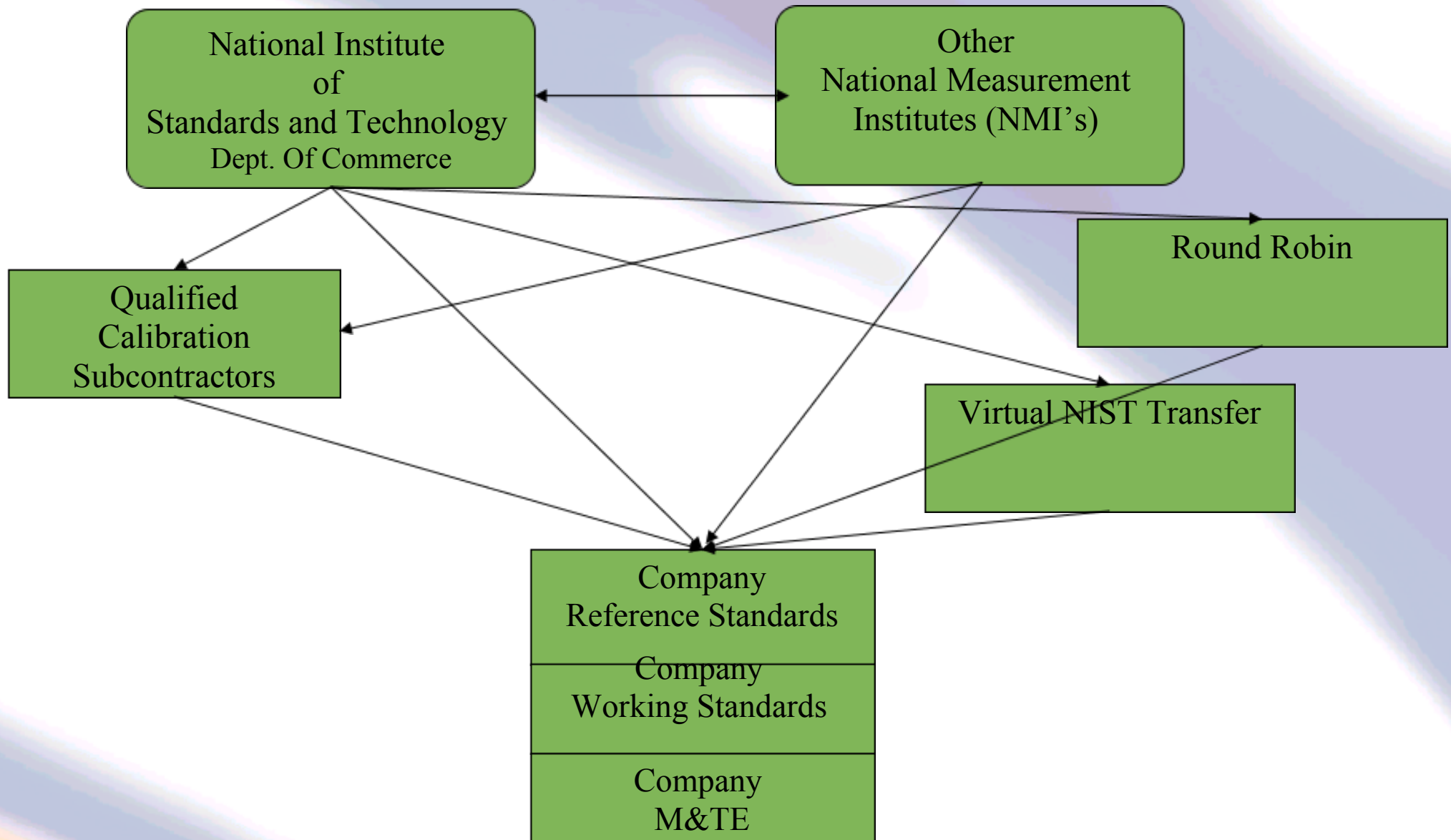
* Additional slides

Traceability

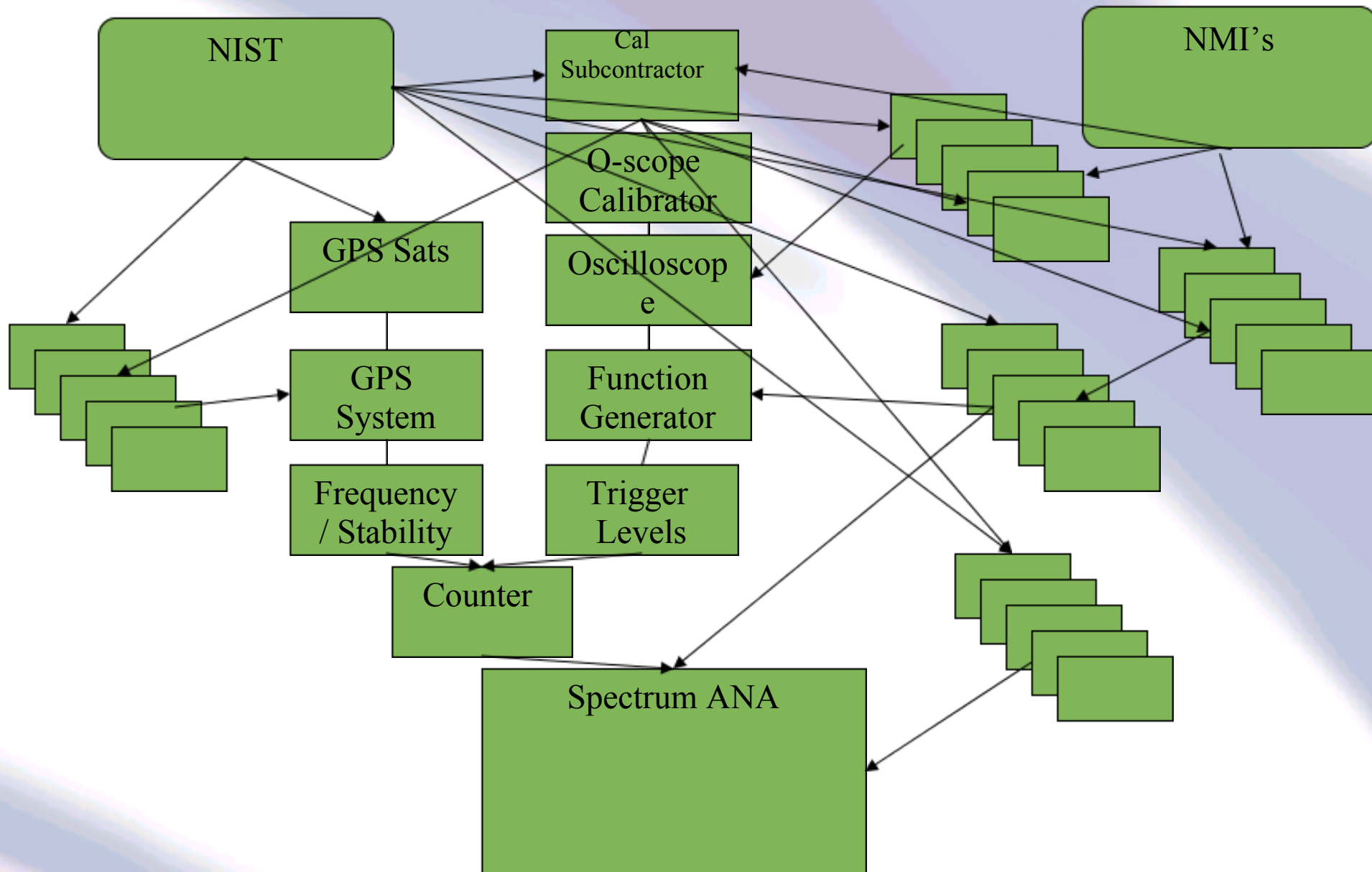
Traceability

- Relate measurements to stated references
- Traceability Elements
 - Unbroken Chain of Comparisons
 - Stated Uncertainty
 - Documentation
 - Competence
 - Reference to SI Units
 - Recalibration at appropriate intervals

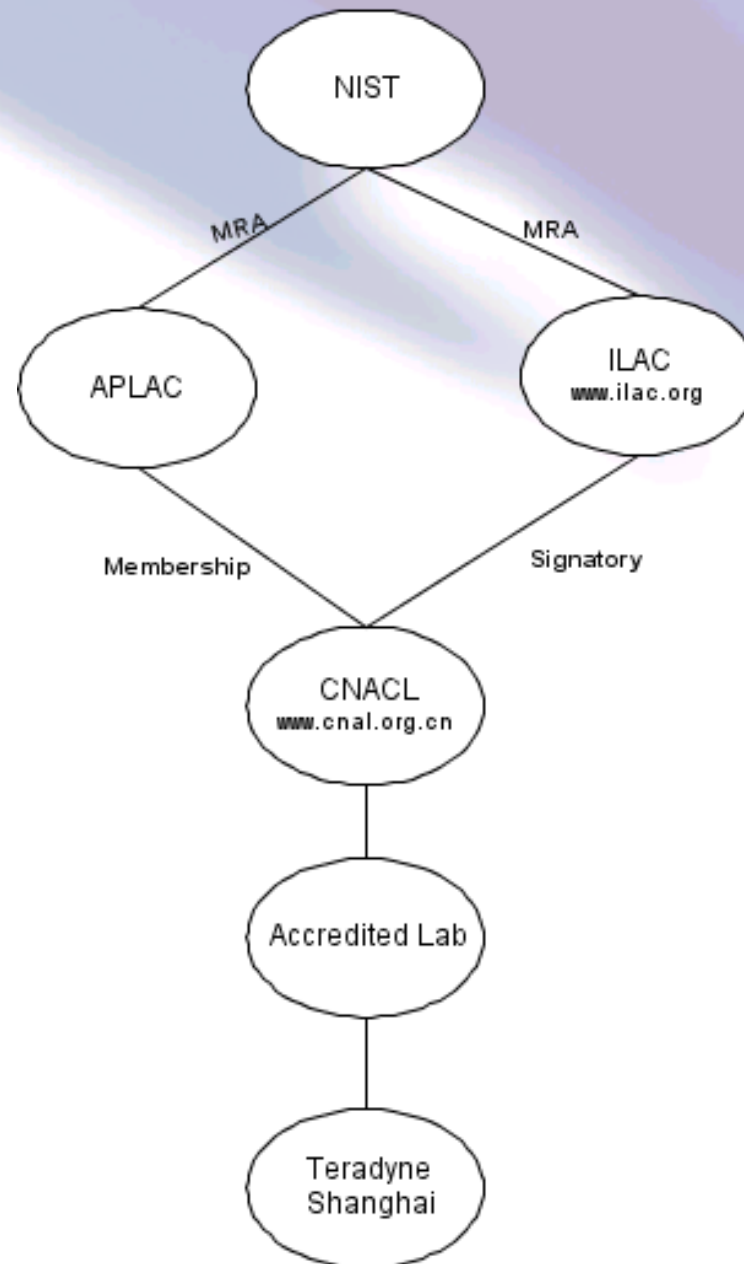
Traceability Simplified



Traceability - Real World



China Traceability

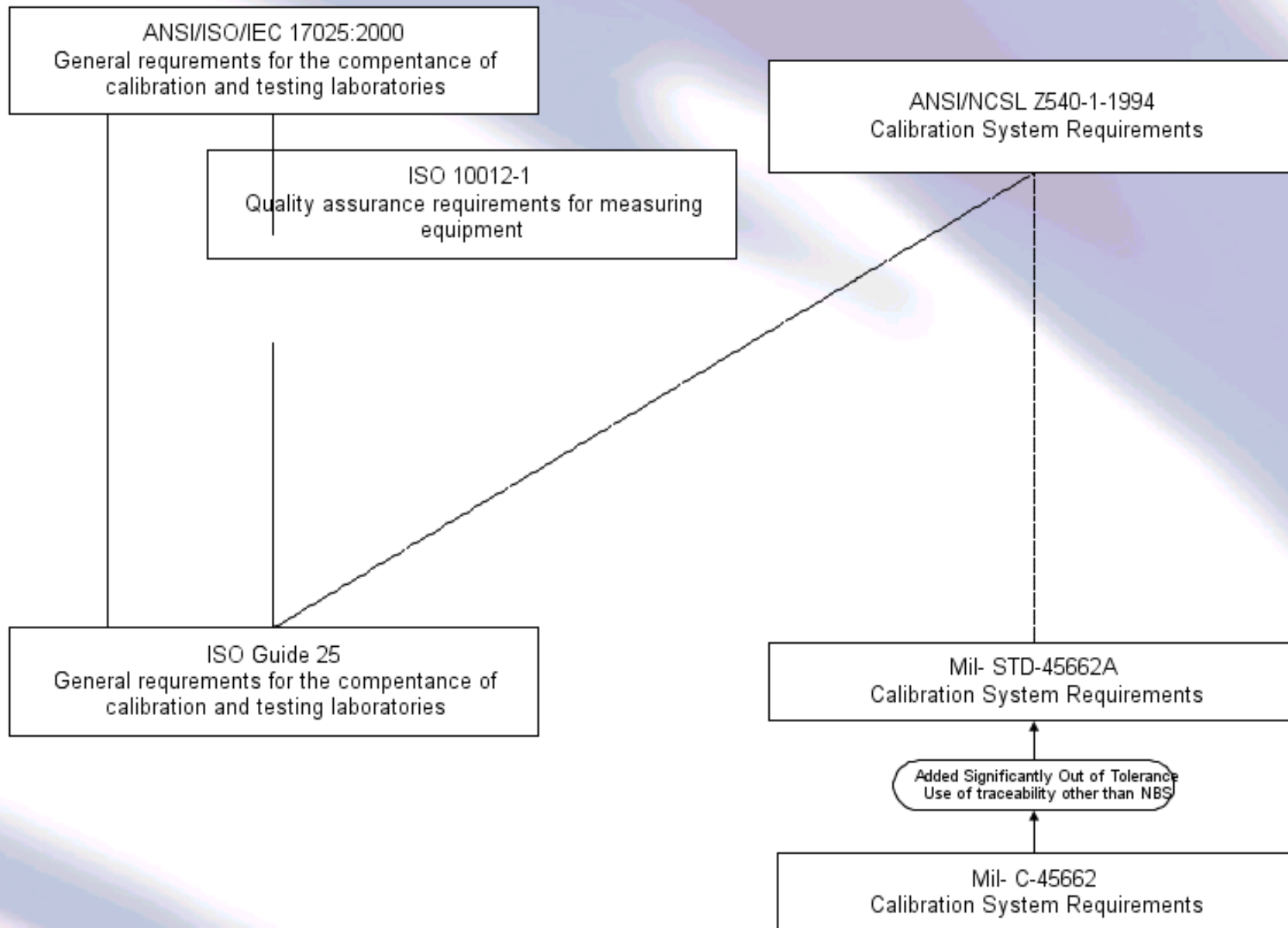


Traceability Statement

Traceability to National Standards

All equipment under the control of company X has been calibrated with equipment where measurements are traceable to national standards of measurement at NIST, NORAMET and EUROMET members or other recognized standards laboratories.

Evolution of Standards



Calibration Standards Documents

- 17025 > ANSI/ISO/IEC 17025:2005
 - General Requirements for the Competence of Testing and Calibration Laboratories
 - Originally issued in 1999
 - International Accreditation available through NIST, A2LA, ... from the US and international certification bodies similar to ISO scheme.
 - Recent version correlated to ISO 9001
- Z540 or .3 > ANSI/NCSL Z540.3-2006
 - Requirements for Calibration of Measuring and Test Equipment
 - Successor to MIL-STD-45662C
 - No 3rd. Party accreditation available.
 - Not applicable to testing laboratories

Compliance to Specifications

Metrology Laboratory Compliance to National and International Standards

All equipment is calibrated and controlled in accordance with Company xxx procedures that are in compliance with ANSI/NCSL Z540-1-1994 and ANSI/ISO/IEC 17025:2000.

What should be on a Calibration Certificate

- Statement of Traceability
- Statement of Compliance with Standards
- Name and location of Cal provider
- Temp - Humidity-Other at time of calibration
- Calibration method (procedure)
- Manuf., Model, Serial No., Control No.
- List of Calibration Equipment used at time of cal with due dates
- Unique document number
- Date of Calibration

Other Items

- Statement of Uncertainty
- Statement that cert should not be reproduced
- Recall Frequency -Not for ISO 17025 unless requested by customer
- Data - Generally only supplied if requested or required for use

Type	Found	Traceability	Compliance
Lowest Level	Distributor or imports ~ Extek	None Inexpensive or Statement Traceable to NIST	None
ISO 9001	Agilent Production and others	Traceable to NIST or other NMI's	ISO 9001
Z540	Agilent Option and Others	Traceable to NIST or other NMI's	Z540
ISO 17025	Agilent Optional. Tek-Fluke Standard	Traceable to NIST or other NMI's	ISO 17025
ISO 17025 Accredited	Agilent Optional, Fluke Std and Optional	Traceable to NIST or other NMI's	Accredited to ISO 17025

Sample of OEM's and Compliance availability

Vendor	ISO 9001	Z540 Compliant	17025 Compliant	17025 Accredited
Agilent	Standard	Optional	Optional	Limited Items
Fluke			Standard	Standard on some items. Limited on Others
Keithley		Standard		Optional on Some Items
Tektronix		Standard	Standard	
Extek	None	None		

Agilent Calibration Offerings

Agilent 3458A

3 levels of Calibration Available

Agilent Calibration Per Incident	US\$ 495.72
ANSI Z540-1-1994 Calibration Per Incident	US\$ 788.19
ISO 17025 Compliant Calibration Per Incident	US\$ 945.83

Out-of-Tolerance

- Must be reviewed for Impact to Customer calibrations
- Must be reviewed for Root Cause
- Action must be taken
 - Change in recall cycle
 - Elimination of items
 - Limitation of measurements
- Must be documented

What to look for in an audit

- Documented Process
 - Seperate from but referenced to QMS
- Traceability Statement
- Standards compliance statement
- Purchase of Calibration services meeting compliance requirements
- Calibration Certificates available
 - Certificates are reviewed
 - Certificates meet requirements
- OOT % > 0
- CA Process for OOT Measurements or other non-conformances
- Metrics

Further Information

The Metrology Handbook ASQ Press

NCSLI Website <http://www.ncsli.org/>

NIST Website <http://www.nist.gov/index.html>

NVLAP <http://ts.nist.gov/standards/accreditation/index.cfm>

A2LA Website <http://www.a2la.org/>

Agilent Metrology Forum <http://metrologyforum.tm.agilent.com/?cmpid=98921>

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