

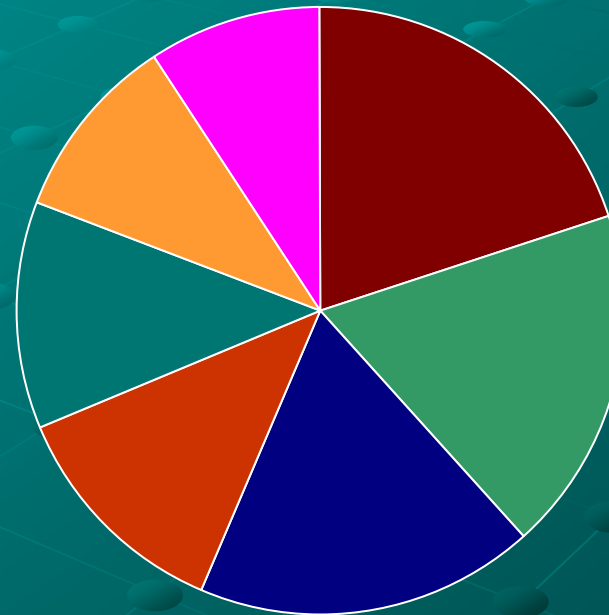
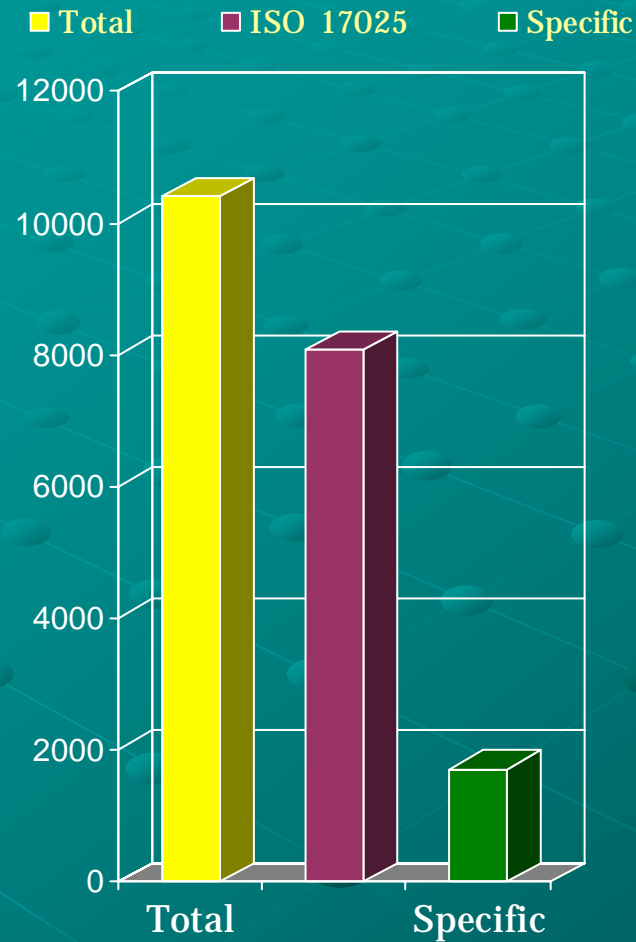
# Most Commonly Cited Deficiencies

Presented by Elizabeth Carbonella  
Automotive Testing Expo  
Novi, MI  
October 2008



# Deficiencies

September 2006 through May 2008



- A2LA Traceability Policy-907**
- Section 5.4-836**
- Section 5.5-817**
- Section 4.6-557**
- A2LA PT Policy-538**
- Section 4.14-458**
- Section 4.13-409**

## **A2LA Policy on Measurement Traceability**

- ❖ **Current Version-May 2006-deficiencies are being written even though waivers may have been granted previously**
- ❖ **This is cited whenever an unaccredited calibration source is used and/ or whenever a calibration certificate does not contain an endorsement by the accrediting body**
- ❖ **Exceptions may be granted**

## Requesting an Exception to the A2LA Traceability Policy

- ❖ Equipment name, model, and identification number
- ❖ Parameter and range of calibration needed
- ❖ Key words used in any website search for an accredited calibration provider
- ❖ List all sources investigated (e.g. specific accreditation body websites, hardcopy directories, state metrology labs, etc.)
- ❖ Reverse traceability study-objective evidence that the measurement being provided by your present calibration provider is traceable to the SI

# ISO 17025 section 5.4

## Test and Calibration Methods and Method Validation

- ❖ Common problems in this area include lack of method validation and improper or incomplete estimates of measurement uncertainty

$$u_0 = \sqrt{s_1^2 + s_2^2 + s_3^2 + s_4^2}$$

- ❖ Some documents that can be used for guidance:

P103-Policy on Estimating Measurement Uncertainty for Testing Laboratories

ISO *"Guide to the Expression of Uncertainty in Measurement"*

- ❖ The requirement is to have and apply a procedure

# ISO 17025 section 5.5 Equipment

- ❖ Lack of proper equipment required by the standard
- ❖ Lack of up-to-date calibration
- ❖ Failure to check equipment when it is received after calibration, maintenance, or repair

# **ISO 17025 section 4.6**

## **Purchasing Services and Supplies**

- ❖ A2LA's interpretation of services includes calibration providers and proficiency testing providers
- ❖ Deficiencies in this area include failure to check incoming materials, failure to request accredited calibrations or consumables to meet specific standards, failure to evaluate suppliers or include them on an approved vendor list

## **A2LA Proficiency Testing for ISO/IEC 17025 Laboratories**

- ❖ A2LA requires that labs have a 4-year proficiency testing plan
- ❖ Labs must participate in two proficiency testing activities per year, covering all the major sub-disciplines in four years
- ❖ New applicants must successfully participate in at least one available activity prior to accreditation

# ISO 17025 section 4.14

## Internal Audits

- ❖ The standard requires a procedure and a pre-determined schedule
- ❖ The audit must cover 3 areas. Compliance with 17025, your own management system and your testing activities must be shown with objective evidence
- ❖ The internal audit should have evidence of the specific records that were checked

# ISO 17025 section 4.13

## Control of Records

- ❖ Be sure to keep sufficient records to complete a data audit
- ❖ Original observations must be recorded
- ❖ With the use of technology be sure to have procedures in place to secure original observations

# Resources

- ❖ [www. A2LA.org](http://www.A2LA.org)  
Understanding ISO/IEC 17025
- ❖ Call us at :301-644-3248  
and speak with your Accreditation Officer

# Questions



# For Further Information:

Contact: Elizabeth Carbonella

Phone: 301-644-3219

Email: [Ecarbonella@A2LA.org](mailto:Ecarbonella@A2LA.org)

Website: [www.A2LA.org](http://www.A2LA.org)

Fax: 301-662-2974

5301 Buckeystown Pike, Suite 350

Frederick, MD 21704-8307