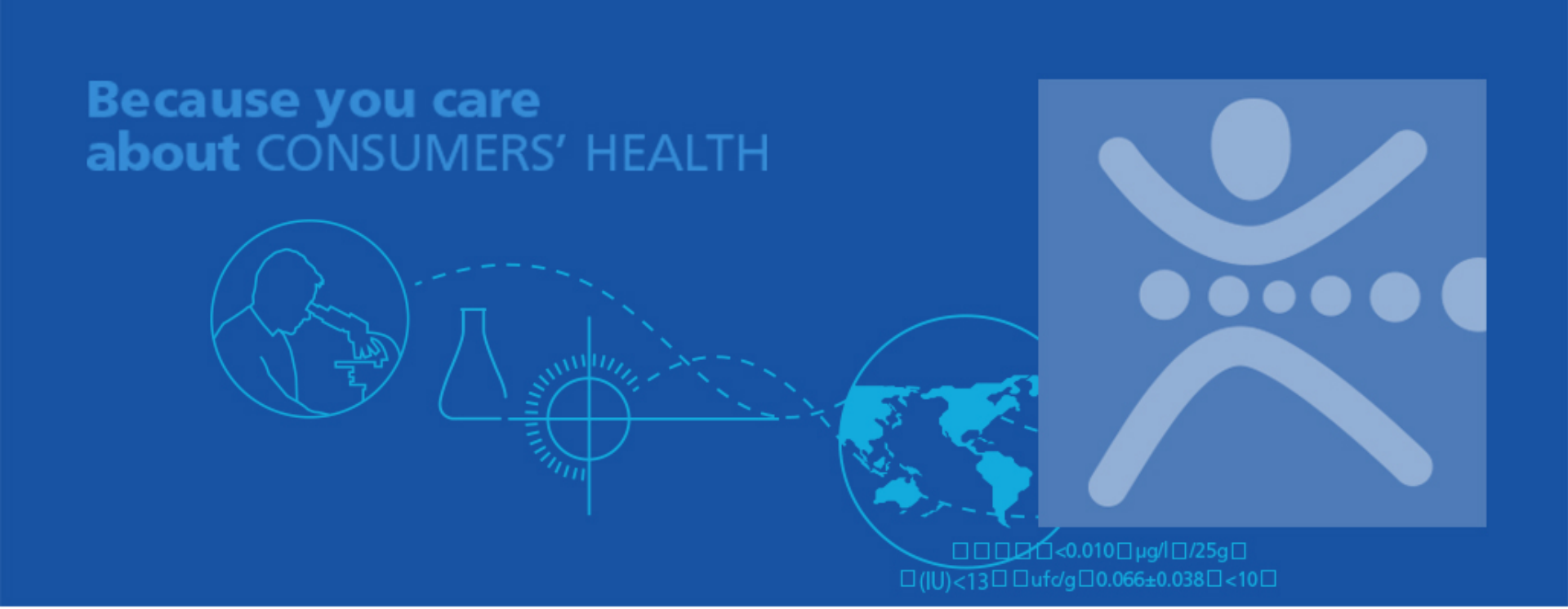

Responding in Time to the New Structure and Components of ISO/IEC 17025:2017

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MERIEUX NutriSciences

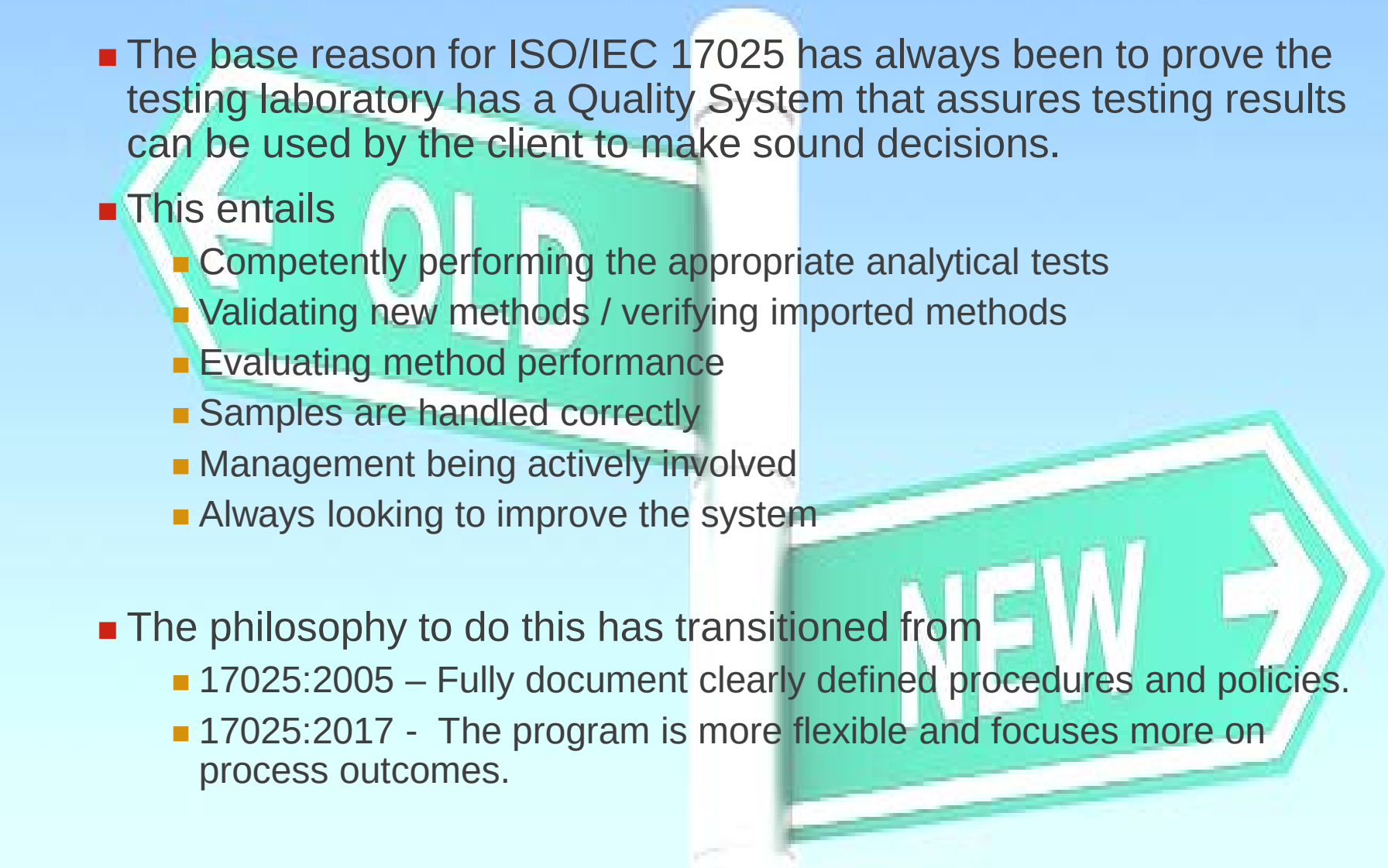
CONTENTS

2005 versus 2017

- 2005
  - George W. Bush
  - Tom Cruise jumped on Oprah's couch
  - Jennifer Aniston divorced Brad Pitt
  - Carrie Underwood won American Idol
  - Ave gas price = $2.34
  - ISO/IEC 17025:2005 released
- 2017
  - Donald Trump
  - Warren Beatty reads the wrong Best Picture winner, 'La La Land' didn't win — 'Moonlight' did.
  - Jennifer Aniston divorced Justin Theroux
  - Trent Harmon won American Idol
  - Ave gas price = $2.36
  - ISO/IEC 17025:2017 released

ISO/IEC 17025:2017

- The base reason for ISO/IEC 17025 has always been to prove the testing laboratory has a Quality System that assures testing results can be used by the client to make sound decisions.
- This entails
  - Competently performing the appropriate analytical tests
  - Validating new methods / verifying imported methods
  - Evaluating method performance
  - Samples are handled correctly
  - Management being actively involved
  - Always looking to improve the system
- The philosophy to do this has transitioned from
  - 17025:2005 – Fully document clearly defined procedures and policies.
  - 17025:2017 - The program is more flexible and focuses more on process outcomes.



Structure of the Standards

17025:2005	17025:20017
1 Scope	1 Scope
2 Normative References	2 Normative References
3 Terms & Definitions	3 Terms & Definitions
4 Management Requirements 5 Technical Requirements	4 General Requirements 5 Structural Requirements 6 Resource Requirements 7 Process Requirements 8 Management Requirements
Annex A – 9001 Cross References	Annex A – Metrological traceability
Annex B – Guidelines for Applications	Annex B – Management System
Bibliography	Bibliography

Some Good News

- If your lab is accredited to ISO 17025:2005, then most of your quality system elements comply with the new standard.
- A common opening step is to create a list of which portions of the 17025:2017 quality standard are met by your accredited 17025:2005 quality system.
  - Good News: some accrediting bodies can provide this list!

What Carried Over

17025:2005	17025:20017
4 – Management	
4.1 Organization	Section 5 – Structure
4.2 Management System	8.2
4.3 Document Control	8.3
4.4 Requests & Tenders	7.1
4.5 Subcontracting	6.5
4.6 Purchasing	6.6
4.7 Service to Customer	Throughout 17025:2017
4.8 Complaints	7.9
4.9 Nonconforming Work	7.10
4.10 Improvement	8.5, 8.6
4.11 Corrective Action	8.7
4.12 Preventive Action	Removed
4.13 Records	7.5, 7.11, 8.4
4.14 Internal Audits	8.8
4.15 Management Review	8.9

What Carried Over

17025:2005	17025:20017
5 – Technical	
5.2 Personal	6.2
5.3 Accommodation & Environment	6.3
5.4 Methods	7.2
5.5 Equipment	6.4
5.6 Traceability	6.6, 7.6
5.7 Sampling	7.3
5.8 Handling of Test & Calibration Items	7.4
5.9 Quality Assurance	7.7
5.10 Reporting	7.8

New Definitions

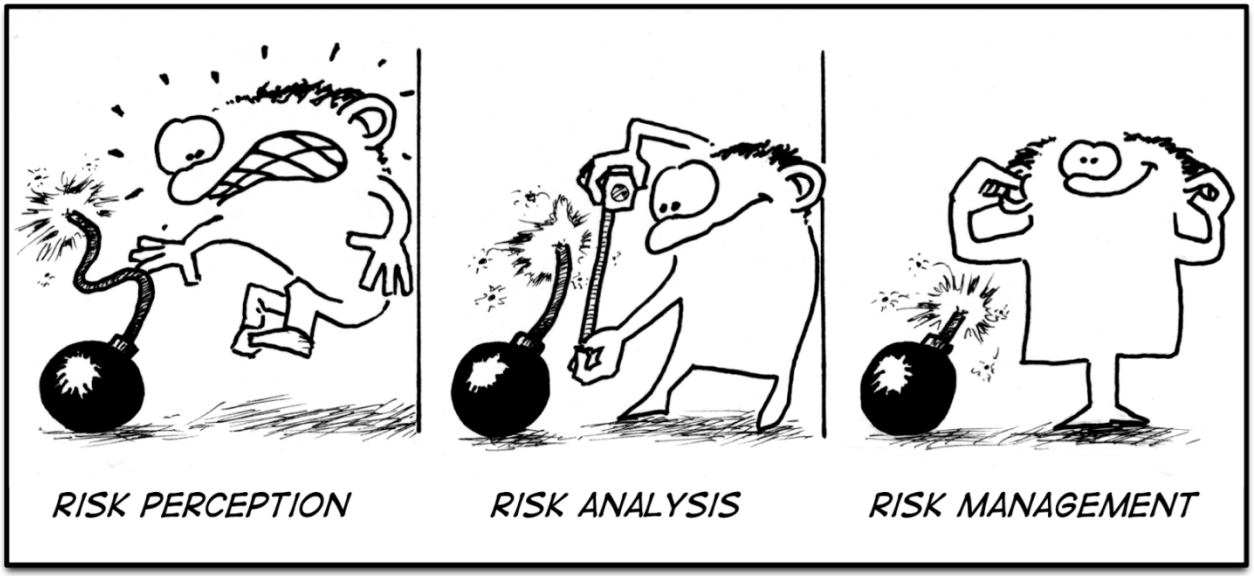
- “Laboratory” has been defined as:
  - Body that performs one or more of the following activities:
    - Testing
    - Calibration
    - Sampling, associated eith subsequent testing or calibration
    - Note: In the context of the 17025:2017 document, “laboratory activities” refer to the three above mentioned activities
- Terms such as Quality Manual, Quality Manager, Deputies, and Subcontracting have been removed
  - Your program can still have these items and roles.

Major Upgrades

- The updated standard covers technical changes and newer information documentation that have developed since 17025:2005 was adopted. The main changes include:
  - 17025:2017 focuses on the results of the processes instead of the a list of actions “to be done”.
    - Can customize response to identified issue.
  - 17025:2017 better accounts for electronic forms of documentation, communication, and data storage. Definitions and terminology has been updated electronic versions.
  - 17025:2017 incorporates a risk-based approach.
  - The scope of 17025 has been revised to cover all laboratory activities including testing, calibration and the sampling associated with subsequent calibration and testing.

Risk-Based Thinking

- Risk-based thinking is a theme throughout ISO 17025:2017.
  - As stated in the standard, “this has enabled some reduction in prescriptive requirements”.
  - Section 8.5 Option A specifies the laboratory must:
    - consider risks associated with lab activities;
    - plan how to address them; and
    - evaluate the effectiveness (outcomes) of these actions.
    - Also “actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results”.
- With corrective actions, such as arising from a nonconformity, the determined risks must be considered in the response.
  - Risk is a part of 7.10 Nonconforming Work of ISO 17025:2017.
  - The response to the nonconformance “are based upon the risk levels established by the laboratory”.
    - Make sure to have proof (aka records).


RISK PERCEPTION
RISK ANALYSIS
RISK MANAGEMENT

So What is Risk....

- Risk is comprised of the:
  - probability the unwanted event can occur.
  - severity of harm when the event occurs.
- Addressing the identified priority risks accomplished by:
  - reducing the probability of its occurrence, or
  - reducing the severity of the associated harm.
- Points to factor in:
  - Every process contains elements of risk
  - There is risk when a process does not perform as intended, something that is always a possibility.

Section 8.5

- **8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities** in order to:
  - a) give assurance that the management system achieves its intended results;
  - b) enhance opportunities to achieve the purpose and objectives of the laboratory;
  - c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;
  - d) achieve improvement.
- **8.5.2 The laboratory shall plan:**
  - a) actions to address these risks and opportunities;
  - b) how to:
    - — integrate and implement the actions into its management system;
    - — evaluate the effectiveness of these actions.
- **8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.**

Some Other New Things

- **6.2.5 The laboratory shall have procedure(s) and retain records for:**
  - a) determining the competence requirements;
  - b) selection of personnel;
  - c) training of personnel;
  - d) supervision of personnel;
  - e) authorization of personnel;
  - f) monitoring of competence of personnel.
- **6.2.6 The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:**
  - a) development, modification, verification and validation of methods;
  - b) analysis of results, including statements of conformity or opinions and interpretations;
  - c) report, review and authorization of results.

Some Other New Things

- Risk identification and responses (4.1, 8.5, 8.9)
- Confidentiality Requirements (4.2)
- Requirements for monitoring of service providers (6.6)
- Statements of Conformity (Measurement Uncertainty and Precision) (7.1 & 7.8.6)
- Method verification (7.2)
- Heftier Complaint Process (7.9)
- LIMS systems (7.11)

NEW THINGS

Some New Things

- Complaints (7.9)
  - A separate documented process to receive complaints, how to evaluate, and working on resolution.
  - Acknowledge receiving the complaint, show progress, and report outcome.
- Corrective Action
  - Nonconformities do occur
  - Preventive Action is no longer in 17025
- Measurement Uncertainty
  - This is now part of method validation (not a separate item). Also a part of conformance
  - Well defined

Timing

- Each Accrediting Body has a slightly different approach but are generally following:

- New applications received prior to September 30, 2018 will be accepted and assessed to either version of the standard.
- All applications received after September 30, 2018 will be assessed to ISO/IEC 17025:2017.
- Any new applicant assessed and accredited to the 2005 version will be required to undergo an on-site verification audit during their first-year surveillance assessment to the 2017 version of the standard (2017).
- Two versions of relevant documents related to laboratory accreditation will be maintained until November 30, 2020.

Summary

- ISO/IEC 2017 contains
  - adaptations for technology and information handling improvements
  - many of the same portions as in the 2005 version
  - some new approaches that need to be incorporated into your quality system
- Resources are available
    - Accrediting bodies
    - Training sessions
    - AOAC Annual Meeting Wednesday 29 Aug 1:00
- It’s time to get started!

Scenario #1

Microbiology

- Daily process control for E. coli by VRB failed. Expected mean = 200 CFU/g E. coli with acceptable range of 50 to 400 CFU/g. The result was 10 CFU/g.
  - The plate had other colonies on it that were atypical.
  - All client samples were within their normal ranges including several samples that had typical counts that confirmed properly.
  - There hasn't been a failure of this test's SPC for many weeks.
  - The sterility test for that batch of media passed.
  - The negative control for the batch passed.
  - Sterility for glass/plasticware passed
  - Productivity and selectivity of media passed
  - Temperature logs were within specification

Chemistry

- Daily process control for vitamin A Expected mean = 200 IU/100g with acceptable range of 150 to 250 IU/100g. The result was 110 IU/100g.
  - The chromatogram for LCS and samples had other peaks on it that were atypical.
  - All client samples were within their normal ranges including several sample with typical levels.
  - There hasn't been a failure of this test's SPC for several weeks.
  - All reagents were properly prepared.
  - The negative control for the batch passed.
  - Glassware properly cleaned.

Conclusion

Microbiology

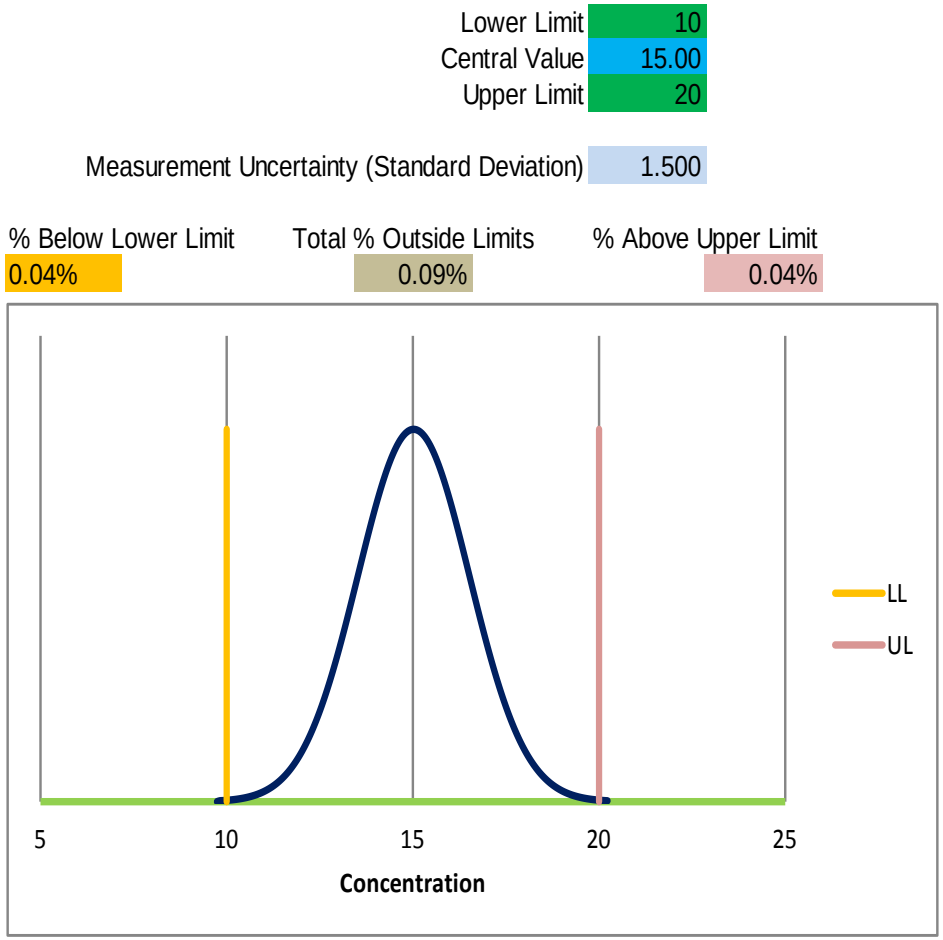
- There was a contamination in setting up the SPC. This contamination organism outgrew the target and caused lower counts of E. coli. Since all of the other QC passed, including the media used, and client samples showed the ability to grow normal levels of the target the risk is low if data is released.
- Does this mean okay to release?

Chemistry

- There was a contamination in setting up the SPC. A co-eluting compound was present in the LCS material and this contaminant degraded and lowered the measured vitamin A peak area. Since all of the other QC passed, including examining reagents etc., and client samples exhibited normal levels of vitamin A, the risk is low if data is released.
- Does this mean okay to release?

Scenario #2

- The laboratory tests a raw material that is used in the production process for water (moisture) by Karl Fisher. The water must be ≥ 10 mg/g and ≤ 20 mg/g.
  - Karl Fisher method was developed in-house
  - Measurement uncertainty was evaluated as 1.5 mg/g.
  - Lab calculates the probability of the true value being outside the specification of 10 mg/g and 20 mg/g to be less than 0.09%.



What are possible causes of the higher than expected OOS results?
What can the laboratory do?

Conclusion

- The laboratory did not consider the impact of using the method in the long term (over a year). This is the “long term” uncertainty component.
- The high humidity in the summer and low humidity in the winter were enough to impact the method performance. The environmental humidity caused the measurement uncertainty to be 2.2 mg/g. The probability of OOS results is actually 2.3%.

Lower Limit	10
Central Value	15.00
Upper Limit	20
Measurement Uncertainty (Standard Deviation)	2.200

% Below Lower Limit	Total % Outside Limits	% Above Upper Limit
1.15%	2.30%	1.15%