

# Developing and Maintaining ISO 17025 Accreditation

for the U.S. National Guard  
Weapons of Mass Destruction  
Civil Support Teams

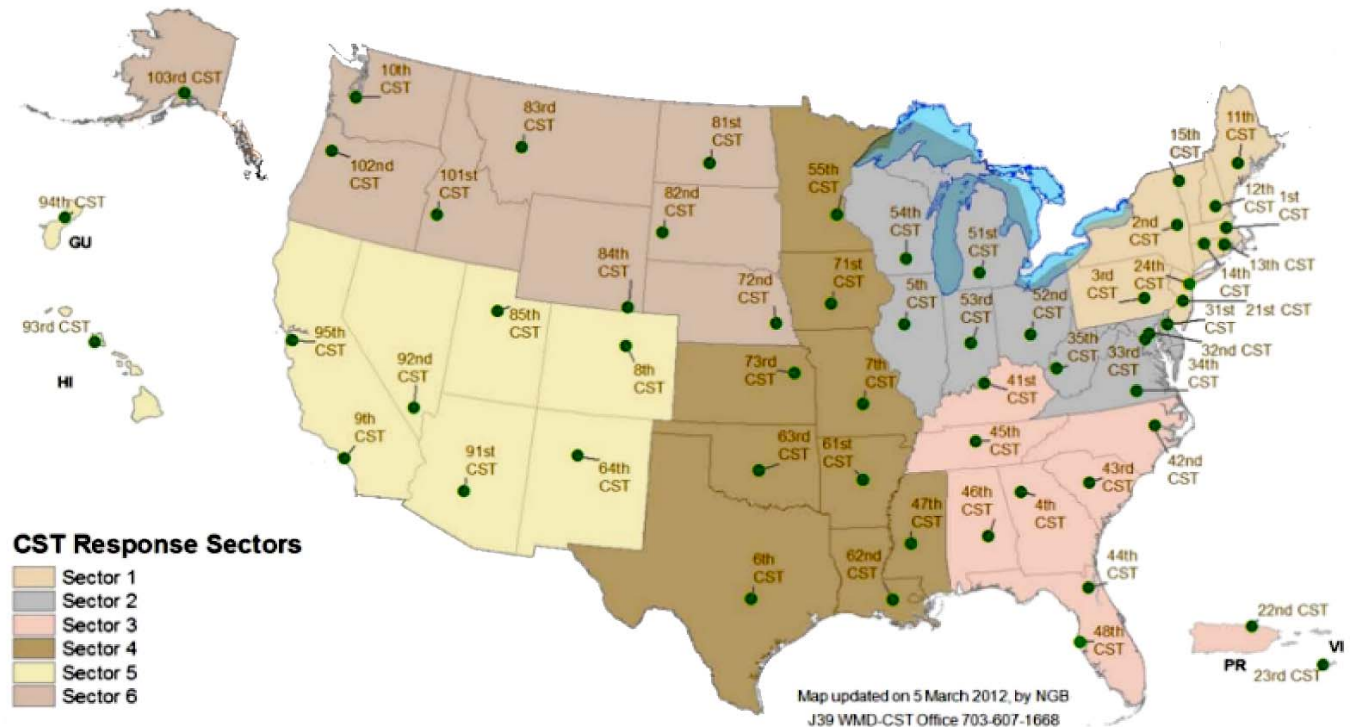
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*Signature Science, LLC*



# Weapons of Mass Destruction—Civil Support Team (WMD-CST) Overview

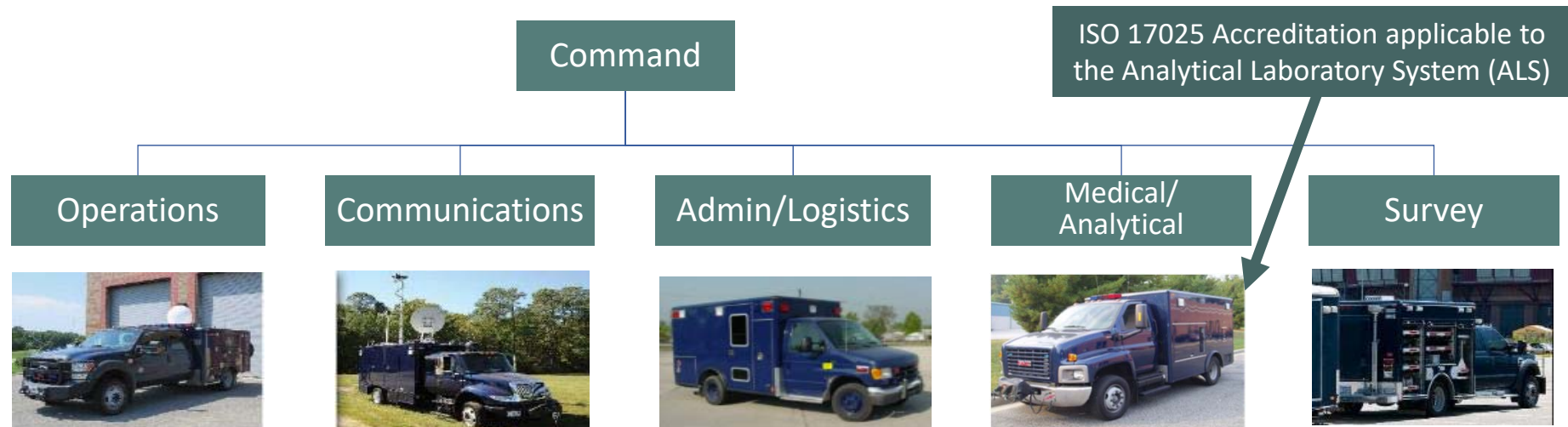
- 57 specialized, active duty, full-time Guard units (one in every state and US Territory (and two in NY, CA, and FL))
- Staffed by 22 ARNG and ANG team members



# WMD-CST Mission and Organization

CSTs support intentional and unintentional releases of chemical, biological, radiological and nuclear (CBRN) or other hazardous agents and natural or manmade disasters that could result in catastrophic loss of life or property

**Identify** agents and substances,  
**Assess** consequences,  
**Advise** on response measures  
**Assist** with additional military support



# WMD-CST ALS Capabilities

## Chemical and biological threat detection

- Glovebox isolation chamber
- Polymerase chain reaction (PCR)
- Electrochemiluminescence (ECL)
- Gas Chromatography – Mass Spectroscopy (GC-MS)
- Fourier Transform Infrared Spectroscopy (FTIR)
- Polarized Light Microscopy (PLM)
- Fluorescence Microscopy (FM)



# The ISO/IEC 17025 Accreditation Initiative

**Launched in 2006 to support the CST mission by**

- Standardizing analytical tactics, techniques, and procedures (TT&P) and enforcing scientific rigor
- Bolstering technical credibility and defensibility of analytical data generated by the WMD-CST laboratories

**A fully accredited program embodies  
the WMD-CST motto:  
*“Always Ready, Always There”***

# Accreditation Challenges

- **Complex joint state and federal military command structure**
  - Federally funded, state controlled
  - Equipment procurement and supply chains belong to DoD Joint Program Office
  - Training responsibilities spread among DoD entities
  - High turnover due to military staffing procedures
- **Unconventional analytical request and contracting process**
  - Not a fee-for-service model
  - Customers may not be familiar with ALS capabilities or analytical processes required to meet mission objectives
  - Rapid response time essential

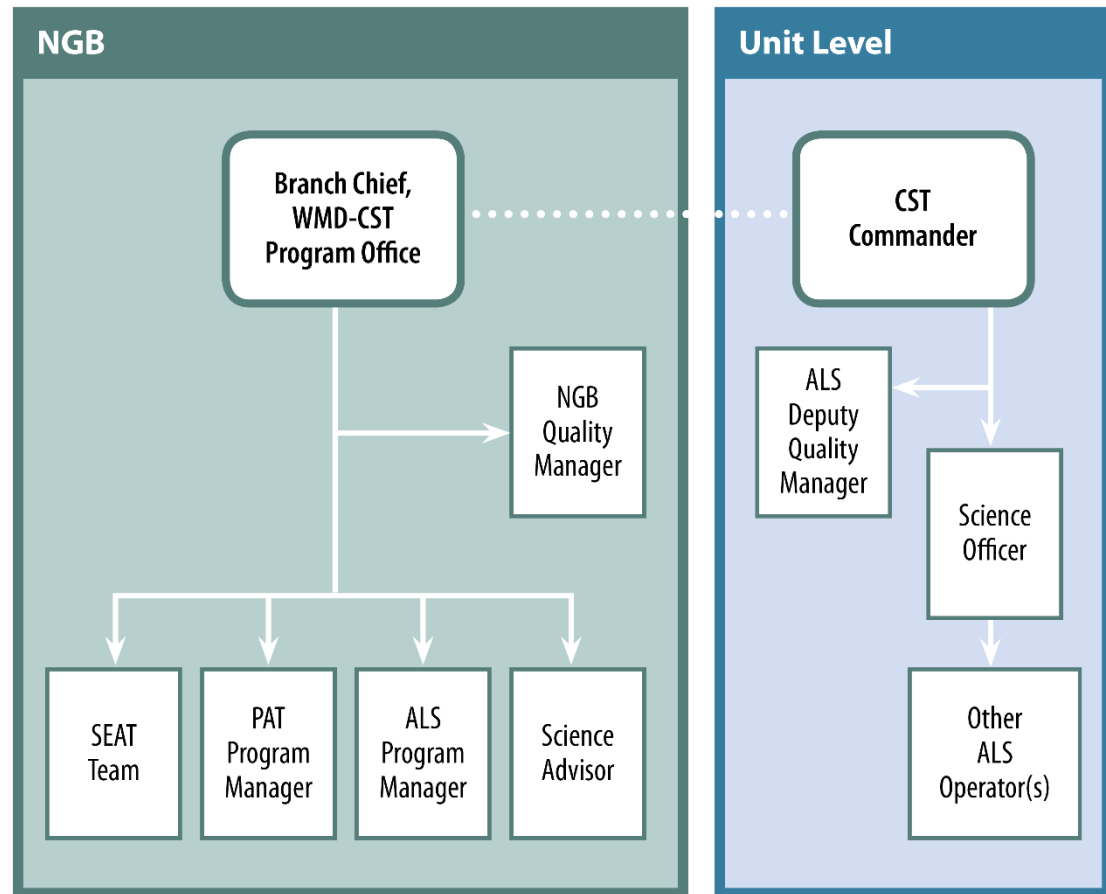
## Accreditation Challenges (continued)

- **Low throughput, high complexity analysis**
  - CSTs might analyze only few samples per response action, but variety of sample types and possible targets are almost unlimited
  - Analysts must be proficient with chemical, biological, and microscopical methods and instrumentation
- **Military incident response paradigm focuses on rapid identification and characterization of chemical and biological threats**
  - Emphasis on correct presence/absence calls rather than quantitative results

## ACCREDITATION APPROACH

# Collaboration

- Worked with A2LA to develop the conceptual approach
  - Adapted a “branch laboratory” accreditation model with centralized and de-centralized components
  - Quality Manager functions split between NGB and WMD-CSTs



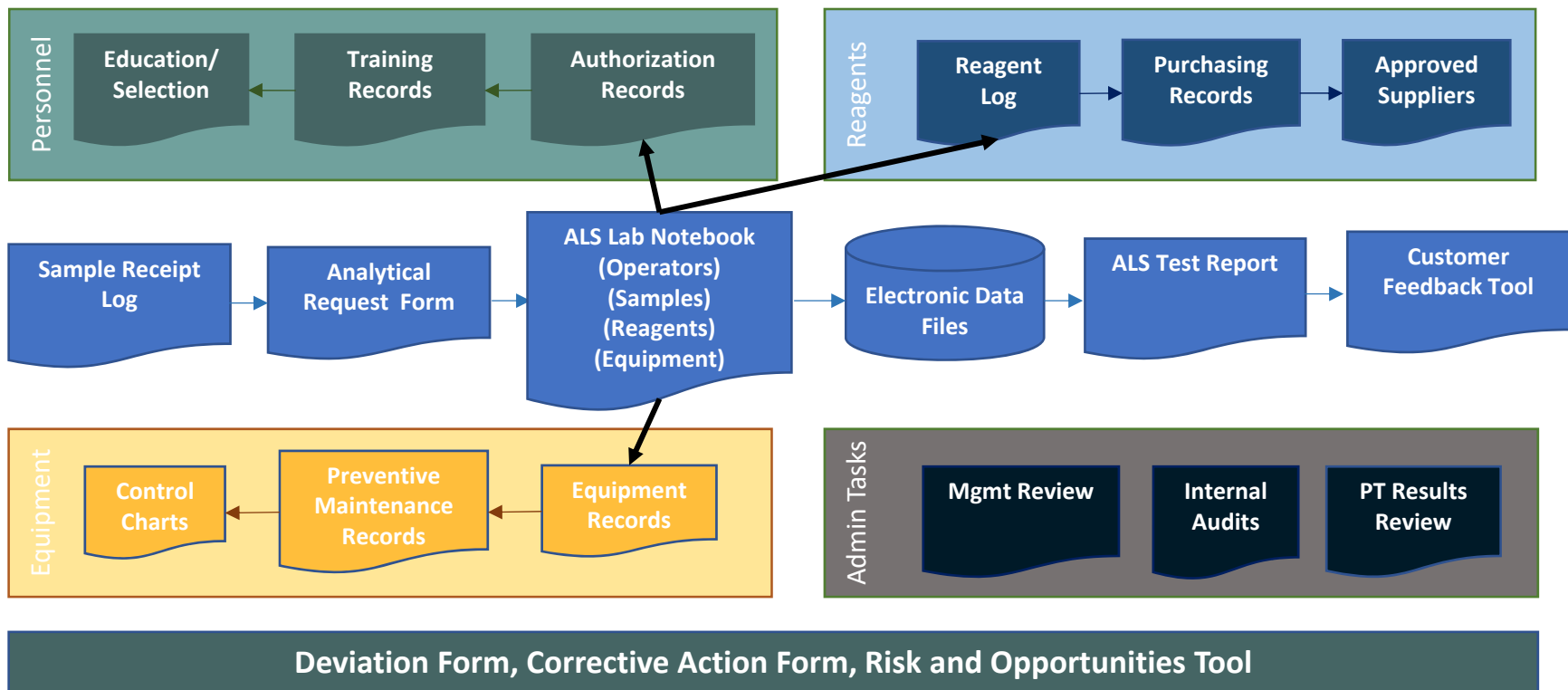
- Set up “Beta Teams” to determine what already existed and what had to be developed



# ACCREDITATION APPROACH

## Standardization

- ISO 17025-compliant Quality Manual and Quality Procedures
- Standardized forms and tools
- Secure website for document control, training records storage, and proficiency test (PT) reporting



## ISO Training

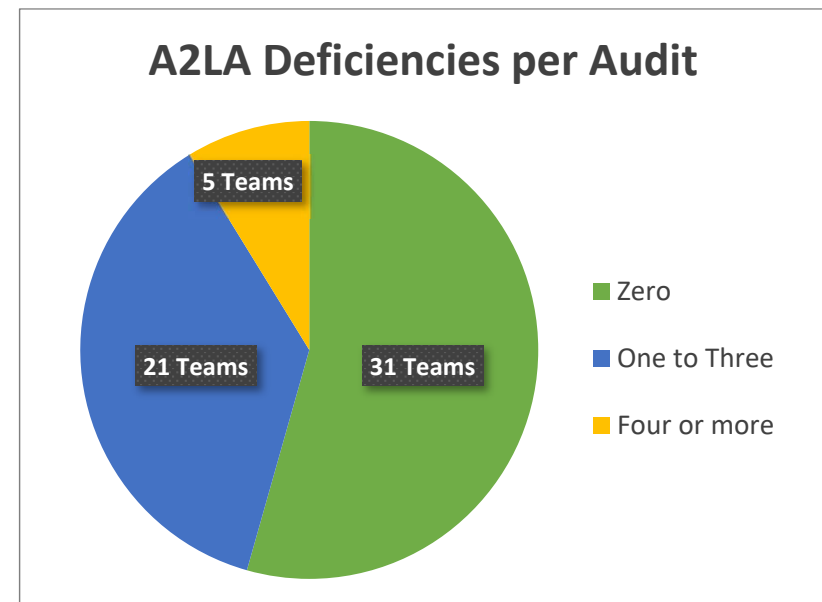
**Developed specialized ISO 17025 training course conducted on an ongoing basis that includes:**

- Overview of ISO 17025 requirements
- Instruction on WMD-CST specific procedures, forms, tools, and checklists
- Auditor training
- Exercises for performing all quality system activities

## ACCREDITATION APPROACH

# SEAT Audits and Readiness Reviews

- Standardization, Evaluation, and Assistance Team (SEAT) performs internal audit function for entire WMD-CST
  - Each team audited biannually at a minimum
  - ALS portion ensures conformance to ISO 17025 and operator competence
- Readiness reviews conducted as needed
  - Ensure team is ready for external accreditation body audits
  - Support teams with significant turnover



## ACCREDITATION APPROACH

# Proficiency Testing

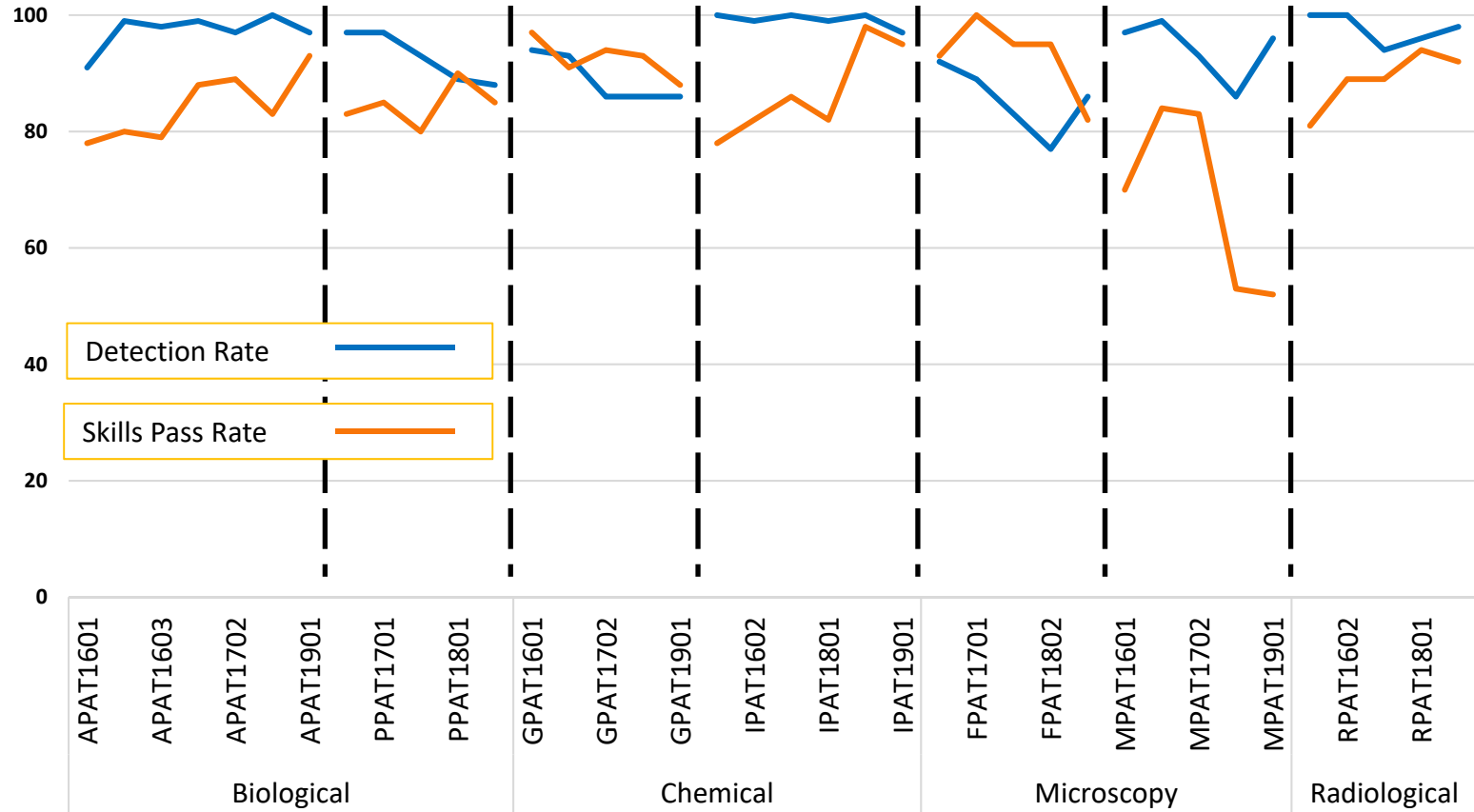
- Comprehensive PT program conducted under the SigSci ISO 17043 PT accreditation
- PTs performed monthly to collectively cover all methods and matrices
  - GC-MS, FTIR, PCR, ECL, and polarized light (PLM) and fluorescence microscopy
  - Liquid, soil/solid, sludge, powder, vegetation, and wipe matrices
  - Radiological data interpretation capabilities
- All analysts participate in each round



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# ACCREDITATION APPROACH

## Proficiency Testing



UPDATES

# ISO/IEC 17025:2017 Transition



UPDATES

# ALS Upgrade



**Updating QMS to apply to both current and updated systems throughout the three-year transition – no QA gaps**

UPDATES

# Website Upgrade

In the process of enhancing website functionality to allow increased automation of ISO 17025 activities

The screenshot displays two parts of the CST DataNet website interface. The top part is a 'WMD-CST Customer Feedback Survey' form, 'Step 1 of 2: Customer/Event Information'. It includes fields for Feedback Date (7/12/2019), CST / Team (dropdown), Event Name, Event Date, and optional fields for Name and Email. The bottom part is a 'WMD-CST Risk Opportunities' table with search filters and a detailed view of a specific risk opportunity.

General Info	Risk/Opportunity Identification	SLLC Review of Risk/Opportunity	NCB Decision on Risk/Opportunity	Status	Action
<b>Id:</b> 17 <b>Date Submitted:</b> 6/14/2019 <b>Organization:</b> 9th CST <b>Name:</b> Nadeau, Daniel <b>Category:</b> QM/QMP/NCB Guidance Document <b>Risk Level:</b> Low Risk	<b>Risk/Opportunity Descriptions:</b> QMP 003: 8.2 Pipettor Check: Any time a pipettor is returned to a WMD-CST after being calibrated or repaired AND in the year between the two-year calibration period, a pipettor check is performed, as follows: • Set the pipettor to the minimum volume, draw up water, and ensure that water is being drawn up and released. • Set the pipettor to the maximum volume, draw up water, and ensure that water is being drawn up and released. The date and initials of the operator performing the check must be recorded in the equipment records and/or ALS notebook. PMCS equipment record sales to only put an X in the box for functionality test.  <b>Recommended Action:</b> Change PMCS equipment record to state Initial and Date for function test or revise QMP-003, section 8.2 to move flexible with location of initials and dates for function check. (ie. Certificate, F-04)	<b>Recommended Actions:</b> Mitigate risk (no CAR required)  <b>Recommended Mitigation:</b> It appears that there may be some confusion on how the PMCS log is supposed to be filled out. If they fill it out as intended there would automatically be initials and dates included with the function test (they would have one set of rows with initials and date the pipette were sent for calibration then another set of rows with initials and date that the function test is performed when the pipettes come back from calibration). Since it appears there was some confusion, we will revise QMP-003 and the PMCS log with NCB approval in the near future. Specifically, we will clarify that initials and dates are needed for the function test in the PMCS log. In addition, we will add the additional locations that function test initials/date can be recorded in the QMP-003 (i.e., certificate, F-04).	<b>NCB Decided Actions:</b> Mitigate risk (no CAR required)  <b>NCB Mitigation Plans:</b> NCB agrees that there must have been some confusion on how the PMCS log is supposed to be filled out. The initials and date are requested before the operator is asked to put an 'X' in the box for: 1) Malfunction, Damage, or Repair; 2) Sent for Calibration; or 3) Performed Pipettor Check. All QMP-003. However, it may help to place the aforementioned rows (i.e. those that request the user's initials and date, Pipettor ID, function test, etc.) at the top of the equipment record, so that recording the operator's initials and date are completed before filling out the remainder of the requested information.  <b>NCB Rationale:</b> After reviewing the equipment record, NCB sees the benefit of moving the location of the 'initials and date for the function check' rows to a more practical	<b>Status:</b> NCB Decision Complete  <b>Date Implemented / Closed:</b>  <b>Plan to Evaluate Effectiveness:</b>  <b>Effectiveness:</b> Edited By rdwright on 6/28/2019 3:47:55 PM Created By daniel.nadeau on 6/14/2019 12:21:51 PM	ikearby