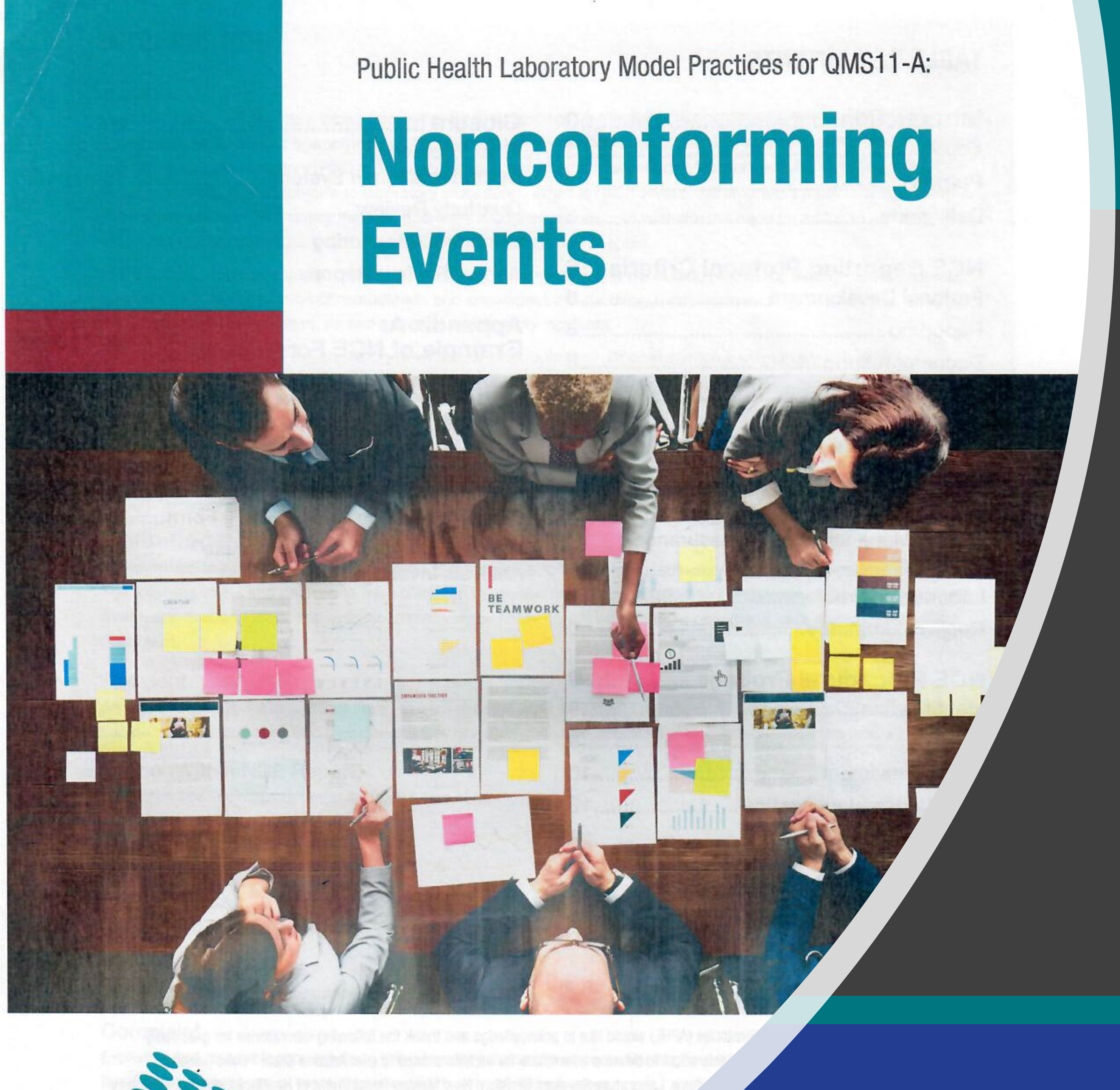
Nonconforming Events

Quality Improvement Forum

Kathy Hochul
Governor

Richard A. Ball
Commissioner

Cynthia Mangione
Food Laboratory



Non-conforming Events Tool

- Follows very closely what is done in the NYS AGM Food Laboratory

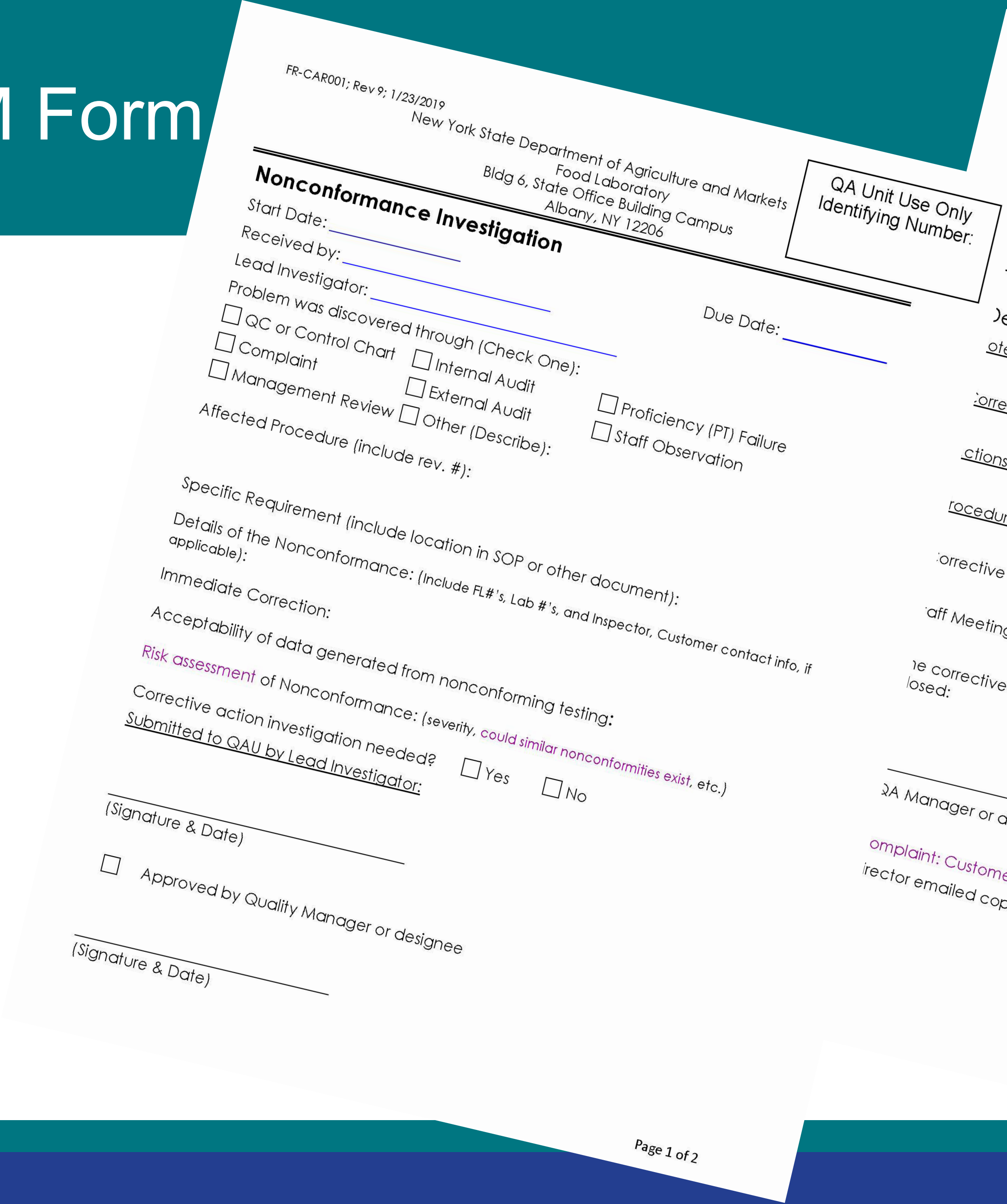
- Pg 6 – **Protocol Development**: NCE reports are not used to document personnel issues. Job titles used.
- Pg 6 – **Documentation**: College of Pathologist - Completed NCE be put in training binder.

NEW YORK STATE OF OPPORTUNITY. | Agriculture and Markets

Non-conforming Events - Tool

- Pg 8 **Supervisors/Managers**
  - Authorize the resumption of work and to follow up on actions taken within their departments.
- NYS AGM GP-4-08 Control of Nonconforming Testing, Complaints & Corrective Actions
  - 5.1.7 If work has been halted, the QAU has the authority to determine if/when testing can resume. This shall be done after consultation with the supervisors/section heads.
- **Quality Committee**
  - While NYS AGM Food Lab does have an ISO committee review of non-conforming work really happens at the management review meetings.

NYS AGM Form



FR-CAR001; Rev 9; 1/23/2019

New York State Department of Agriculture and Markets
Food Laboratory
Bldg 6, State Office Building Campus
Albany, NY 12206

QA Unit Use Only
Identifying Number:

Nonconformance Investigation

Start Date:
Received by:
Lead Investigator:
Due Date:

Problem was discovered through (Check One):

☐ QC or Control Chart ☐ Internal Audit
☐ Complaint ☐ External Audit ☐ Proficiency (PT) Failure
☐ Management Review ☐ Other (Describe): ☐ Staff Observation

Affected Procedure (include rev. #):

Specific Requirement (include location in SOP or other document):

Details of the Nonconformance: (Include FL#'s, Lab #'s, and Inspector, Customer contact info, if applicable):

Immediate Correction:

Acceptability of data generated from nonconforming testing:

Risk assessment of Nonconformance: (severity, could similar nonconformities exist, etc.)

Corrective action investigation needed? ☐ Yes ☐ No

Submitted to QAU by Lead Investigator:

(Signature & Date)

☐ Approved by Quality Manager or designee

(Signature & Date)

Page 1 of 2

FR-CAR001; Rev 9; 1/23/2019

New York State Department of Agriculture and Markets
Food Laboratory
Bldg 6, State Office Building Campus
Albany, NY 12206

QA Unit Use Only
Identifying Number:

Corrective Action Investigation

nvestigation Details (List contributing causes, if any.):

Cause Analysis: (Root cause - if eliminated would prevent the problem from recurring.)

Develop Corrective Action Plan

otential Corrective Actions:

orrective Action Selected:

ctions required to implement corrective action and dates completed:

rocedure updates, if applicable, including revision #:

orrective actions communicated to pertinent personnel by (initial/date) via:

aff Meeting ______ Memo ______ E-mail ______

ne corrective action plan has been fully implemented. This Corrective Action is losed:

QA Manager or designee & date)

omplaint: Customer notified of investigation completion/outcome, if applicable ☐

irector emailed copy of completed CAR form: ☐

Page 2 of 2

Agriculture and Markets

NYS AGM Form

Appendix A: Example NCE Form

- Event
- General incident details
- Problem reported by
- Other personnel titles involved
- Sample and error identification
- Sample accession numbers
- Sample submitted by
- Submitting facility name
- Name of facility POC/Phone email

FR-CAR001; Rev 9; 1/23/2019

New York State Department of Agriculture and Markets
Food Laboratory
Bldg 6, State Office Building Campus
Albany, NY 12206

QA Unit Use Only
Identifying Number:

Nonconformance Investigation

Start Date: ______________ Due Date: ______________

Received by: ______________________

Lead Investigator: ______________________

Problem was discovered through (Check One):

☐ QC or Control Chart ☐ Internal Audit ☐ Proficiency (PT) Failure
☐ Complaint ☐ External Audit ☐ Staff Observation
☐ Management Review ☐ Other (Describe):

Affected Procedure (include rev. #):

Specific Requirement (include location in SOP or other document):

Details of the Nonconformance: (Include FL#'s, Lab #'s, and Inspector, Customer contact info, if applicable):

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

NYS AGM Form

Appendix A: Example NCE Form

- Pre-analytical error type(s)
- Analytical error types(s)
- Post-analytical error type(s)
- Other error type(s)

FR-CAR001; Rev 9; 1/23/2019

New York State Department of Agriculture and Markets
Food Laboratory
Bldg 6, State Office Building Campus
Albany, NY 12206

QA Unit Use Only
Identifying Number:

Nonconformance Investigation

Start Date: ____________ Due Date: ____________

Received by: ____________________

Lead Investigator: ________________________

Problem was discovered through (Check One):

☐ QC or Control Chart ☐ Internal Audit ☐ Proficiency (PT) Failure
☐ Complaint ☐ External Audit ☐ Staff Observation
☐ Management Review ☐ Other (Describe):

Affected Procedure (include rev. #):

Specific Requirement (include location in SOP or other document):

Details of the Nonconformance: (Include FL#'s, Lab #'s, and Inspector, Customer contact info, if applicable):

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

NYS AGM Form

Appendix A: Example NCE Form

- Immediate action(s) taken
- Description of incident
- Did this issue require notification
- Name of individual(s) notified
- Supporting documentation

Details of the Nonconformance: (Include FL#'s, Lab #'s, and Inspector, Customer contact info, if applicable):

Immediate Correction:

Acceptability of data generated from nonconforming testing:

Risk assessment of Nonconformance: (severity, could similar nonconformities exist, etc.)

Corrective action investigation needed? ☐ Yes ☐ No

Submitted to QAU by Lead Investigator:

____

(Signature & Date)

☐ Approved by Quality Manager or designee

____

(Signature & Date)

NYS AGM Form

Appendix B: Example CAR Form

- CAR category

Problem was discovered through (Check One):

☐ QC or Control Chart ☐ Internal Audit ☐ Proficiency (PT) Failure
☐ Complaint ☐ External Audit ☐ Staff Observation
☐ Management Review ☐ Other (Describe):

- Impact to patient care – NA
- Problem identification
  - Description
  - Immediate correction
- Approval signatures

Submitted to QAU by Lead Investigator:

(Signature & Date)

☐ Approved by Quality Manager or designee

(Signature & Date)

FR-CAR001; Rev 9; 1/23/2019

New York State Department of Agriculture and Markets
Food Laboratory
Bldg 6, State Office Building Campus
Albany, NY 12206

QA Unit Use Only
Identifying Number:

Corrective Action Investigation

Investigation Details (List contributing causes, if any.):

Cause Analysis: (Root cause - if eliminated would prevent the problem from recurring.)

Develop Corrective Action Plan

Potential Corrective Actions:

Corrective Action Selected:

Actions required to implement corrective action and dates completed:

Procedure updates, if applicable, including revision #:

Corrective actions communicated to pertinent personnel by (initial/date) via:

Staff Meeting ________ Memo ________ E-mail __________

The corrective action plan has been fully implemented. This Corrective Action is closed:

(QA Manager or designee & date)

Complaint: Customer notified of investigation completion/outcome, if applicable ☐

Director emailed copy of completed CAR form: ☐

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

NYS AGM Form

Appendix B: Example CRE Form

Section II Part B

- Cause of the problem (root cause investigation)
- Systemic correction(s)

FR-CAR001; Rev 9; 1/23/2019

New York State Department of Agriculture and Markets
Food Laboratory
Bldg 6, State Office Building Campus
Albany, NY 12206

QA Unit Use Only
Identifying Number:

Corrective Action Investigation

Investigation Details (List contributing causes, if any.):

Cause Analysis: (Root cause - if eliminated would prevent the problem from recurring.)

Develop Corrective Action Plan

Potential Corrective Actions:

Corrective Action Selected:

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

NYS AGM Form

Appendix B: Example CRE Form

Section II
- Approval Signatures

Section III
- Supervisory Follow-up/Verification of Corrective Action
- Approval Signatures

Section IV
- Continued monitoring
- Approval Signatures

Actions required to implement corrective action and dates completed:

Procedure updates, if applicable, including revision #:

Corrective actions communicated to pertinent personnel by (initial/date) via:

Staff Meeting ________ Memo ________ E-mail ___________

The corrective action plan has been fully implemented. This Corrective Action is closed:

____

(QA Manager or designee & date)

Complaint: Customer notified of investigation completion/outcome, if applicable ☐

Director emailed copy of completed CAR form: ☐

Non-conforming Event

FR-CAR001; Rev 8; 11/23/2016

New York State Department of Agriculture and Markets
Food Laboratory
Bldg 6, State Office Building Campus
Albany, NY 12206

QA Unit Use Only
Identifying Number:
18-CAR-21

Nonconformance Investigation

Start Date: 6/13/18

Due Date: 3/15/18

Received by: Cynthia Mangione

Lead Investigator: A[redacted]

Problem was discovered through (Check One):

- ☐ QC or Control Chart
- ☐ Internal Audit
- ☐ Proficiency (PT) Failure
- ☐ Complaint
- ☐ External Audit
- ☒ Staff Observation
- ☐ Management Review
- ☐ Other (Describe):

Affected Procedure (include rev. #):
MICRO-MTH-320 MicroSEQ *Listeria monocytogenes* on the ABI 7500 Fast (Rev 7, 1/12/18)

Specific Requirement (include location in SOP or other document):
6.9.3.3 A supervisor shall be notified immediately after a positive PCR result has been obtained. The supervisor shall notify the customer of the result stressing that this is a preliminary finding and that it needs to be confirmed. Supervisors shall give an estimated time for completion of confirmation, if requested by the customer.

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

Non-conforming Event

Details of the Nonconformance: (Include FL#'s, Lab #'s, and Inspector, Customer contact info, if applicable):

Sample: Tuna Salad
Sample ID: 18B05672
Sample FL: 183810016
Est. No: 61[redacted]
Insp: 831 – Carl Edgar

Sample screened positive for L. mono on 6/8/18. The analyst notified the supervisor however the supervisor was not in the laboratory that day so the customer was not notified. See attachments 1 and 2.

Immediate Correction: None taken – apologize to the customer when confirmation notification wás sent. See attachment 2.

Acceptability of data generated from nonconforming testing:
All data deemed acceptable.

18 CAR 21 Attachment 1

Mangione, Cynthia (AGRICULTURE)

From:	[redacted]
Sent:	Wednesday, June 13, 2018 10:02 AM
To:	Mangione, Cynthia (AGRICULTURE)
Subject:	FW: Positive sample

From: [redacted]
Sent: Thursday, June 07, 2018 5:07 PM
To: [redacted]
Cc: Lovelace, Amy (AGRICULTURE) <Amy.Lovelace@agriculture.ny.gov>; Koch, Chelsea (A
<Chelsea.Koch@agriculture.ny.gov>
Subject: Positive sample

18B05672, a tuna salad, is presumptive for *L. mono*.

18 CAR 21 Attachment2

Mangione, Cynthia (AGRICULTURE)

From:	[redacted]
Sent:	
To:	Luker, John (AGRICULTURE); Sawyer, Erin (AGRICULTURE)
Cc:	Koch, Chelsea (AGRICULTURE); Lovelace, Amy (AGRICULTURE); Olsen, Peter (AGRICULTURE); Ishida, Maria (AGRICULTURE); Oglesby, Debra V (AGRICULTURE); Mangione, Kurt J (AGRICULTURE); Mangione, Cynthia (AGRICULTURE); Sauders, Brian (AGRICULTURE); agr.sm.RRT
Subject:	Confirmed Positive L. mono
Attachments:	FL-1838310016 Report.pdf

Hi all,

Realizing this may be the first time you have heard about this (I was out last Friday with a sick kiddo and didn't realize a presumptive notification wasn't sent to the whole distribution list...), but:

Sample **18B05672 (FL- 183810016)**, tuna salad, collected by Carl Edgar on 6/5/18 from [redacted] has confirmed positive for the presence of *L. monocytogenes*.
See attached for scanned copy of the report.
PFGE and WGS will be started this week.

Hard copy is on the way over.

Thanks,

Nonconforming Event

- Do you think this requires a root cause investigation?

NCE

Why no root cause?

- Self imposed rule – done as a courtesy.
- Customers do not require it.

FR-CAR001; Rev 8; 11/23/2016

New York State Department of Agriculture and Markets
Food Laboratory
Bldg 6, State Office Building Campus
Albany, NY 12206

QA Unit Use Only
Identifying Number:
18-CAR-21

Evaluation of Nonconformance: (severity of problem, i.e. minor, moderate, severe, etc.)

Minor.

The sample screened positive very late on Thursday afternoon. The analyst notified the supervisor at 5:07 PM (see attachment 1). There was no supervisor in the lab at the time, so notification was done via email. The supervisor received notification on her phone and was unable to determine if the customer was also included on the email.

This requirement is one imposed by the laboratory itself so that inspectors are poised to move quickly to remove contaminated food from store shelves if a sample confirms out positive. It is a convenience for our customers and does not have any impact of the quality of the data generated. Holding off notification until confirmation is completed would be a scientifically sound, although conservative, course of action.

Often analysts notify supervisors of presumptive positive results verbally. If the direct supervisor is not in the lab another supervisor is notified (ex. if the food section supervisor is out, the dairy supervisor is notified) who passes notification onto the customer. Because of the great communication within the Microbiology section, customer notification is rarely a problem. This seems to be an isolated case and no changes to the management system are deemed necessary.

Corrective action investigation needed? ☐ Yes ☒ No

Submitted to QAU by Lead Investigator:

[redacted] 6/13/18

(Signature & Date)

☑ Approved by Quality Manager or designee

6-13-18

(Signature & Date)

Traceability

- Sample usually delivered via courier – UPS/NYS courier
- Local inspectors will hand deliverer their samples

FR-CAR001; Rev 8; 11/23/2016

New York State Department of Agriculture and Markets
Food Laboratory
Bldg 6, State Office Building Campus
Albany, NY 12206

QA Unit Use Only
Identifying Number:
18-CAR-16

Nonconformance Investigation

Start Date: 5/30/18 Due Date: 5/31/18

Received by: Nina [redacted]

Lead Investigator: Cynthia Mangione

Problem was discovered through (Check One):

- ☐ QC or Control Chart
- ☐ Internal Audit
- ☐ Proficiency (PT) Failure
- ☐ Complaint
- ☐ External Audit
- ☒ Staff Observation
- ☐ Management Review
- ☐ Other (Describe):

Affected Procedure (include rev. #):
GP-5-07.1 Sample Receipt, Storage, and Disposal - Microbiology

Specific Requirement (include location in SOP or other document):

5.2.11.1 All receiving information including but not limited to, the received date and time, receiving analyst, temperature at receipt (if applicable), and a way to tie this information to the sample shall be kept.

Note: Receiving information can be tied to samples by FL number, Inspector number, or other identifying information. Extra care shall be taken so that receipt information for each sample is clearly identified.

5.2.11.1.1 This can be done by hand writing all information and attaching it to the Sample Import log (once printed) or the sample's bench worksheet once the sample has been imported.

Traceability

Details of the Nonconformance: (Include FL#'s, Lab #'s, and Inspector, Customer contact info, if applicable):
Sample No.: 18B05270, 18B01871
FL No.: 969619, 969620
Insp. No.: 133 – C. Angell

Sample No.: 18B05272 – 18B05283
FL No.: 961958, 961948, 961952-961957, 961960-961963
Insp. No.: 137 – C. Martin

Original observations were thrown away after they had been entered into the LIMS.

Traceability

- Do you think this requires a root cause investigation?

Traceability

Why not root cause?

- Analyst self reported – they knew there was a problem. Not re-occurring problem.

FR-CAR001; Rev 8; 11/23/2016

New York State Department of Agriculture and Markets
Food Laboratory
Bldg 6, State Office Building Campus
Albany, NY 12206

QA Unit Use Only
Identifying Number:
18-CAR-16

Immediate Correction: None needed. All information was captured in LIMS. Analyst who mistakenly threw away original observation indicated that she had done so. No additional training needed.

Acceptability of data generated from nonconforming testing:
All data acceptable. No impact of result data from this non-conformance.

Evaluation of Nonconformance: (severity of problem, i.e. minor, moderate, severe, etc.) Minor

Corrective action investigation needed? ☐ Yes ☒ No

Submitted to QAU by Lead Investigator:

5.31.18

(Signature & Date)

☑ Approved by Quality Manager or designee

5/31/18

(Signature & Date)

Traceability

QA Unit Use Only
Identifying Number:
18-CAR-18

FR-CAR001; Rev 8; 11/23/2016

New York State Department of Agriculture and Markets
Food Laboratory
Bldg 6, State Office Building Campus
Albany, NY 12206

Nonconformance Investigation

Start Date: 6/1/18 Due Date: 6/29/18

Received by: Cynthia Mangione

Lead Investigator: Debbie Oglesby

Problem was discovered through (Check One):

- ☐ QC or Control Chart
- ☐ Internal Audit
- ☐ Proficiency (PT) Failure
- ☐ Complaint
- ☐ External Audit
- ☒ Staff Observation
- ☐ Management Review
- ☐ Other (Describe):

Affected Procedure (include rev. #):
WI-700 Completed Report Form Check Off Instructions (Rev 3, 5/9/18)

Specific Requirement (include location in SOP or other document):

Separating Instructions

3. FR-FL003 sample information forms have only one copy of the sample information form and the sample results form. Staple the sample information form on top of the sample results form and file in the laboratory.

Traceability – Root Cause Analysis

Details of the Nonconformance: (Include FL#'s, Lab #'s, and Inspector, Customer contact info, if applicable):

Lab ID Number	FL Number	Product	Inspector	Date Received	Analysis
18B04412	18EN2695	Pickled veggies	Massachusetts	02-May-18	CAMPY
18B04413	18EN2696	Bread	Massachusetts	02-May-18	CAMPY
18B04414	18EN2697	Chicken, cooked	Massachusetts	02-May-18	CAMPY
18B04415	18EN2699	Cucumber	Massachusetts	02-May-18	CAMPY
18B04416	18EN2701	Chili sauce	Massachusetts	02-May-18	CAMPY
18B04417	18EN2702	Swordfish	Massachusetts	02-May-18	CAMPY
18B04418	18EN2693	Pate, chicken liver	Massachusetts	02-May-18	CAMPY
18B04419	18EN2694	Mayo, homemade	Massachusetts	02-May-18	CAMPY
18B04421	18EN2698	Cilantro	Massachusetts	02-May-18	CAMPY
18B04422	18EN2700	Jalapeno	Massachusetts	02-May-18	CAMPY

Due to a problem with the Promega DNA extraction kits used on unofficial samples sent in from Massachusetts a notice needed to be added to samples results reports. No results reports could be found in the laboratory's files. It was determined that both results reports and the SIF were sent to Massachusetts. No copies were kept for the laboratory's files.

Traceability

- Do you think this requires a root cause investigation?

Traceability

- Root cause analysis needed because we felt it could happen again.

FR-CAR001; Rev 8; 11/23/2016

New York State Department of Agriculture and Markets
Food Laboratory
Bldg 6, State Office Building Campus
Albany, NY 12206

QA Unit Use Only
Identifying Number:
18-CAR-18

Due to a problem with the Promega DNA extraction kits used on unofficial samples sent in from Massachusetts a notice needed to be added to samples results reports. No results reports could be found in the laboratory's files. It was determined that both results reports and the SIF were sent to Massachusetts. No copies were kept for the laboratory's files.

Immediate Correction:
Duplicate results reports will be printed, signed and filed in the laboratory's files. A copy of the SIF will not accompany these results report since they were sent back to the sampler.

Acceptability of data generated from nonconforming testing:
Not a data generating issue. All results are ok to report.

Evaluation of Nonconformance: (severity of problem, i.e. minor, moderate, severe, etc.)
Moderate – this problem could have been missed but for fact that these reports needed to be amended.

Corrective action investigation needed? ☒ Yes ☐ No

Submitted to QAU by Lead Investigator:

Delia Vaine Oglesby 6/15/18
(Signature & Date)

☑ Approved by Quality Manager or designee

Cynthia Mayne 6.15.18
(Signature & Date)

6.15.18

Traceability – Root Cause Analysis

FR-CAR001; Rev 8; 11/23/2016

New York State Department of Agriculture and Markets
Food Laboratory
Bldg 6, State Office Building Campus
Albany, NY 12206

QA Unit Use Only
Identifying Number:
18-CAR-18

Corrective Action Investigation

Investigation Details (List contributing causes, if any.):

Analysis was done for Campylobacter for the Massachusetts Public Health Laboratory. Reports were completed and sent to the secretary for filing and mailing (to MA). As per WI-700 the FR-FL003 and one copy of the results report should have been stapled together and filed in the laboratory's file, while the other copy of the results report should have been mailed to MA.

When MA was contacted, they reported that they had received both copies of the results report.

The secretary was unaware of the procedure for dealing with these special types of samples.

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

Traceability – Root Cause Analysis

Root Cause: (To qualify as a root cause it must be a) Specific, b) Reasonable, c) Under management's control, and d) by eliminating this cause there would be a high probability of preventing recurrence of the same non-conformance.)

Office staff are no longer responsible for "checking off" samples, however, they are doing all the separating and filing of reports. The samples in question are unusual. The supervisor instructed office staff to mail the samples to MA to assure that the correct customer received results (in the past MA results had been sent to the wrong customer), however, there was no additional instruction given on separation or filing. The staff person who did this was not aware that a "separation" step was needed.

Develop Corrective Action Plan

Potential Corrective Actions:

1. Update WI-700 Completed Report Form Check Off Instructions (Rev 3, 5/9/18) to clarify how this type of sample report needs to be handled and how this should occur.

Corrective Action Selected:

Update WI-700 Completed Report Form Check Off Instructions

Actions required to implement corrective action and dates completed:

Update WI-700 Completed Report Form Check Off Instructions

Procedure updates, if applicable, including revision #:

WI-700 Completed Report Form Check Off Instructions (Rev 3, 5/9/18)

Traceability – Root Cause Analysis

FR-CAR001; Rev 8; 11/23/2016

QA Unit Use Only
Identifying Number:
18-CAR-18

New York State Department of Agriculture and Markets
Food Laboratory
Bldg 6, State Office Building Campus
Albany, NY 12206

Completed: 6/21/18

NOTE: Because of how the work is currently being divided up in the laboratory it was decided to pull the separating instructions out of WI-700 and create an entirely new set of instruction just for the separating: WI-722 Competed Report Form Separating Instructions.

Corrective actions communicated to pertinent personnel by (initial/date) via:

Staff Meeting ________ Memo ________ E-mail 6/21/18 CMM CMM

The corrective action plan has been fully implemented. This Corrective Action is closed:

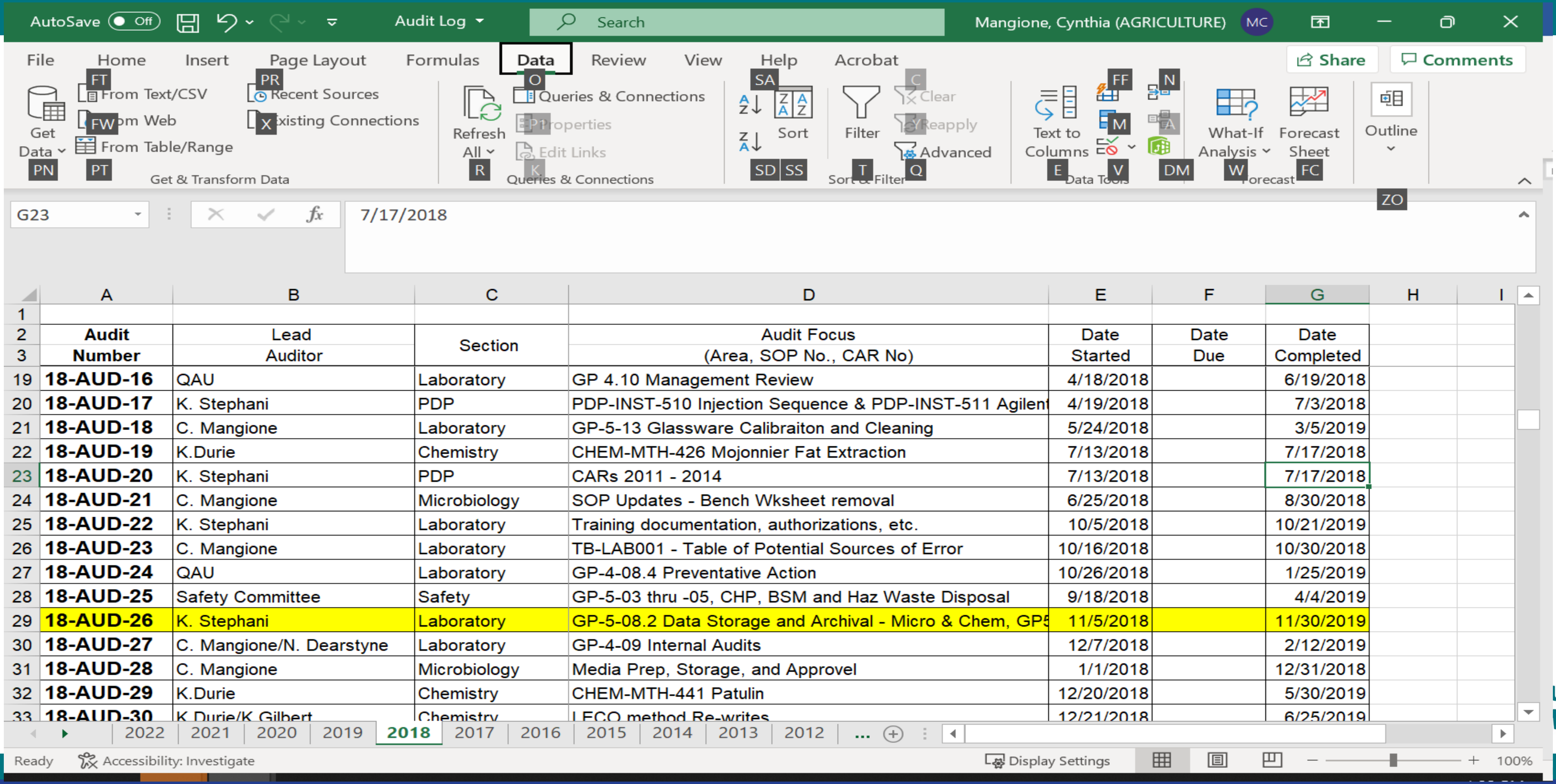
6/25/18

(QA Manager or designee & date)

Director emailed copy of completed CAR form: ☑

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

Traceability – Root Cause Analysis



Audit Number	Lead Auditor	Section	Audit Focus (Area, SOP No., CAR No)	Date Started	Date Due	Date Completed
18-AUD-16	QAU	Laboratory	GP 4.10 Management Review	4/18/2018		6/19/2018
18-AUD-17	K. Stephani	PDP	PDP-INST-510 Injection Sequence & PDP-INST-511 Agilent	4/19/2018		7/3/2018
18-AUD-18	C. Mangione	Laboratory	GP-5-13 Glassware Calibraiton and Cleaning	5/24/2018		3/5/2019
18-AUD-19	K.Durie	Chemistry	CHEM-MTH-426 Mojonnier Fat Extraction	7/13/2018		7/17/2018
18-AUD-20	K. Stephani	PDP	CARs 2011 - 2014	7/13/2018		7/17/2018
18-AUD-21	C. Mangione	Microbiology	SOP Updates - Bench Wksheet removal	6/25/2018		8/30/2018
18-AUD-22	K. Stephani	Laboratory	Training documentation, authorizations, etc.	10/5/2018		10/21/2019
18-AUD-23	C. Mangione	Laboratory	TB-LAB001 - Table of Potential Sources of Error	10/16/2018		10/30/2018
18-AUD-24	QAU	Laboratory	GP-4-08.4 Preventative Action	10/26/2018		1/25/2019
18-AUD-25	Safety Committee	Safety	GP-5-03 thru -05, CHP, BSM and Haz Waste Disposal	9/18/2018		4/4/2019
18-AUD-26	K. Stephani	Laboratory	GP-5-08.2 Data Storage and Archival - Micro & Chem, GP5	11/5/2018		11/30/2019
18-AUD-27	C. Mangione/N. Dearstyne	Laboratory	GP-4-09 Internal Audits	12/7/2018		2/12/2019
18-AUD-28	C. Mangione	Microbiology	Media Prep, Storage, and Approvel	1/1/2018		12/31/2018
18-AUD-29	K.Durie	Chemistry	CHEM-MTH-441 Patulin	12/20/2018		5/30/2019
18-AUD-30	K.Durie/K.Gilbert	Chemistry	LECO method Re-writes	12/21/2018		6/25/2019

Equipment

18-PAR-03 – 18-CAR-14

Details of the Nonconformance:

Throughout the month of April, the MDP-022 control strain was being run concurrently with routine samples and controls for 18-VAL-02.

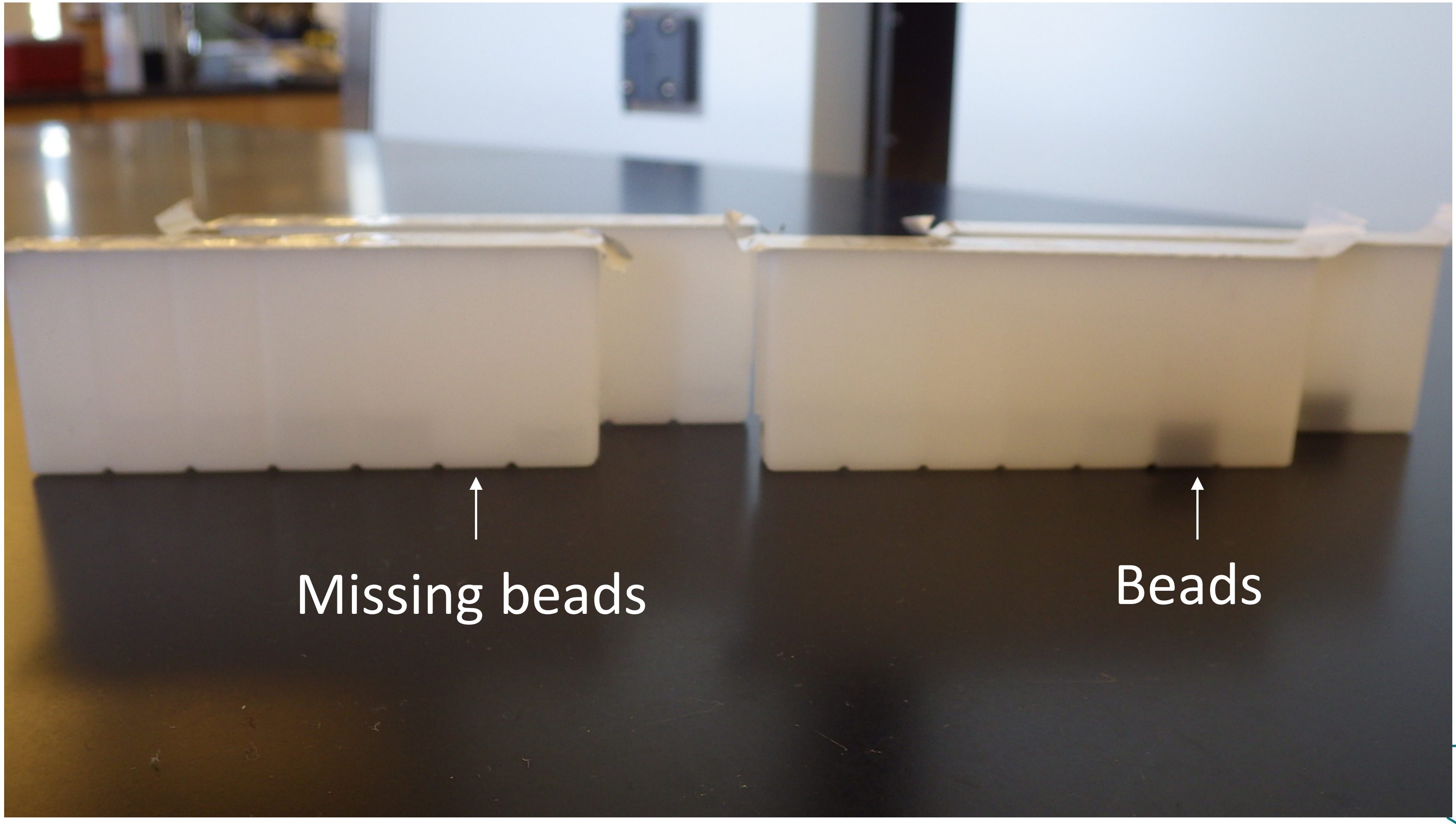
On Friday, 5/4/18, the final week of 18-VAL-02, LM-MDP-022 strain screened negative, and the LM-2 was positive on the ABI 7500 FAST. See attachment 1. The DNA (LI-1, LM-2, and MDP-022) was frozen over the weekend. On Monday, 5/7/18, to troubleshoot the MDP strain, the controls were re-run and results were the same. See attachment 2. The controls were re-extracted and re-run, yet this time the LM-2 was negative and the LM-MDP-022 was positive on the ABI. See attachment 3. The DNA was re-run and the results were the same. See attachment 4.

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

Equipment

Go to 18-CAR-14

Equipment

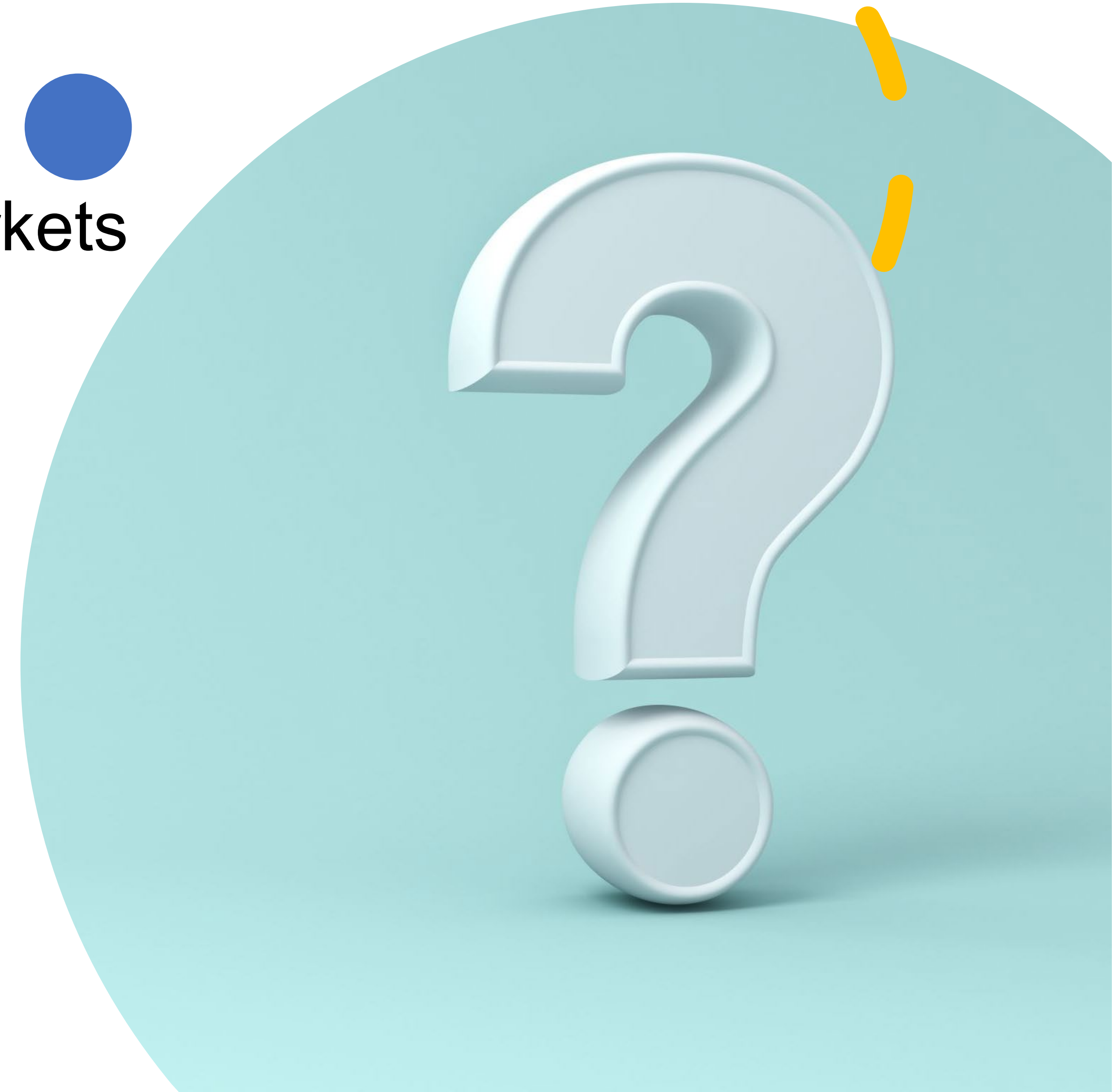


NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

Equipment

Agriculture and Markets

Cynthia Mangione
NYS Department of Agriculture and Markets
Food Laboratory
cynthia.mangione@agriculture.ny.gov



DCLS

Division of

Consolidated Laboratory Services

DGS

DEPARTMENT OF GENERAL SERVICES

Occurrence Management

Presented by: Jennifer McGee

QA Senior Scientist

Occurrence Management Workflow in Qualtrax

- DCLS utilized the following document:
  - CLSI QMS 11- Non-conforming Event Management
- APHL Public Health Laboratory Model Practices for QMS11-A: Non-conforming Events
  - Follows CLSI document
  - Probability and severity

Occurrence Management Workflow

- DCLS uses Qualtrax to document and record non-conforming events or potential non-conforming events in a workflow called Occurrence Management
- Occurrence – A non-conformance or potential non-conformance
- Occurrences are recorded as:
  - No Action/Administrative Action
  - Correction
  - Corrective Action
  - Preventive Action

Occurrence Management Workflow

- No Action – A non-conformance due to no fault of the laboratory or no systemic factor that contributed to the error, or would lead to a similar error occurring in the future (i.e. low probability/low severity)
- Administrative Action – A non-conformance due to a personnel issue
- Preventive Action – A potential non-conformance in which actions are put into place to prevent the occurrence

Occurrence Management Workflow

- Correction – A non-conformance in which the probability and severity does not warrant a full corrective action with root cause analysis
- Corrective Action – A non-conformance in which the probability and severity warrants a full investigation with root cause analysis
- Root Cause – The condition or event(s) that, if corrected or eliminated, would prevent the reoccurrence of a non-conformance. Also known as the "why" the non-conformance has occurred (corrective)
  - The root cause is a factor that caused the non-conformance and should be permanently eliminated through process improvement

Occurrence Management Initiation

Occurrence Management

ID
Current Step is Initiation
History

Initiation

OM - How to use the Occurrence Management Workflow
Workflow Job Aid

OM - DCLS Groups (Required)

OM - Group Manager (Required)

Show Available Users

OM - DLO (Required)

Show Available Users

OM - Date Incident Discovered (Required)
Date Discovered=the date the error or event was identified

Show Calendar

OM - Date Incident Occured (Required)
Date Occurred=date the error or event took place

Show Calendar

Occurrence Management Initiation

Occurrence Management

ID
Current Step is Initiation
History

Initiation

OM - How to use the Occurrence Management Workflow
Workflow Job Aid

OM - DCLS Groups (Required)
ORGANICS
ORGANICS

OM - Group Manager (Required)
Ashley Pierce (20443) Remove

Show Available Users

OM - DLO (Required)
Ed Shaw (548) Remove

Show Available Users

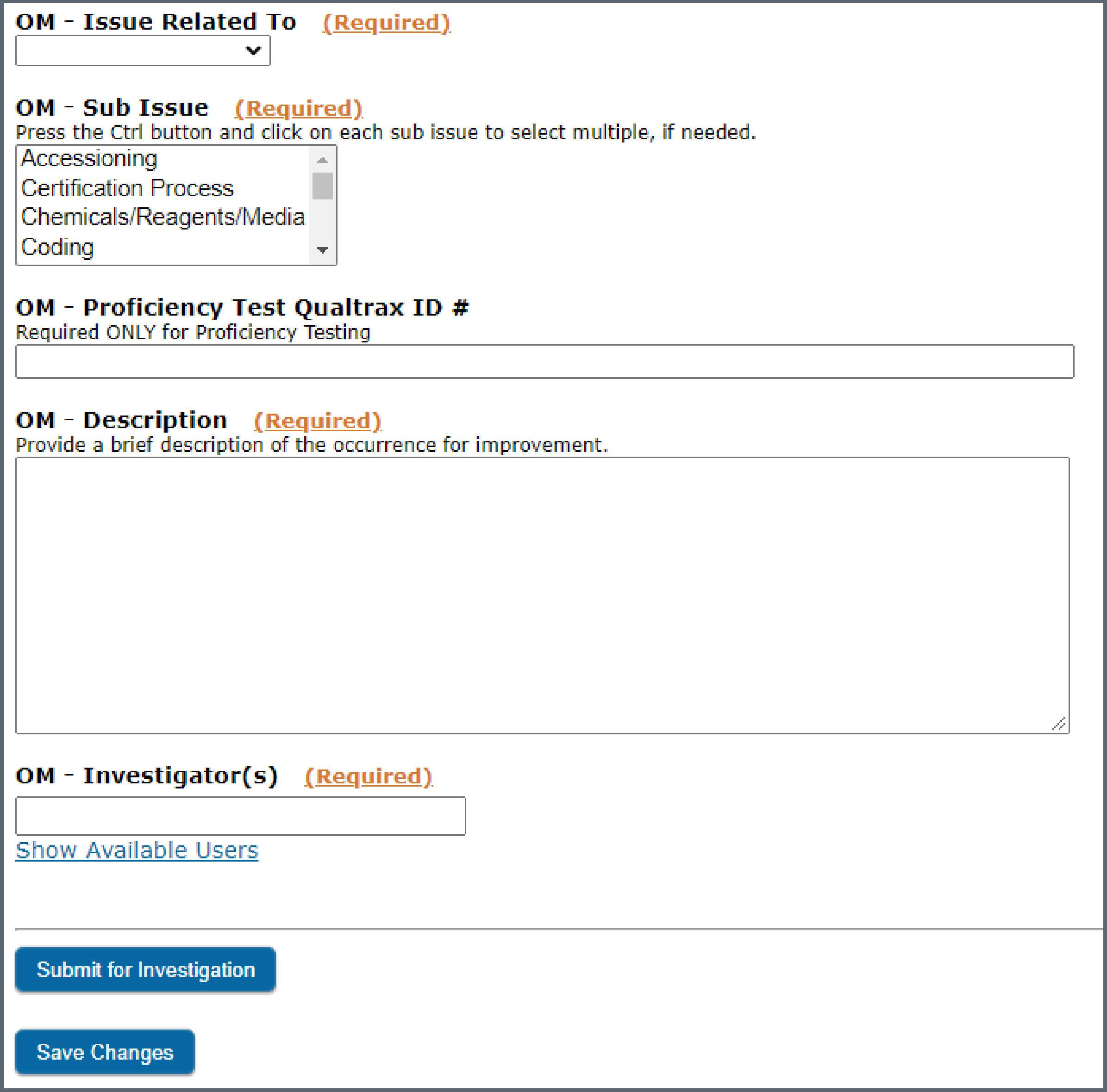
OM - Date Incident Discovered (Required)
Date Discovered=the date the error or event was identified

3/7/2022
Show Calendar

OM - Date Incident Occured (Required)
Date Occurred=date the error or event took place

3/4/2022
Show Calendar

Occurrence Management Initiation



Occurrence Management Initiation

ISSUE RELATED TO	SUB ISSUE
Environment	Equipment, Quality Control Failure, Chemicals/Reagents/Media, DI Water Quality, Quality Control
LIMS	Coding, Customer Issue, Interface
Quality Management	Certification Process, Internal or External Audit, Document Management, Management Review, Monitors
Reagents/Standards	Chemicals/Reagents/Media, DI Water Quality, Quality Control, Traceability, Labeling
Specimen/Sample	Courier, Holding Times, Labeling, Sample Issue, Customer Issue, Traceability, Quality Control
Testing Personnel	Accessioning, Internal Issue, Competency
Test Results	Proficiency Test, Reporting, Traceability, Customer Issue, Quality Control
Test System	Equipment, Quality Control Failure

Occurrence Management Initiation

OM - Issue Related To (Required)
Quality Management
Quality Management

OM - Sub Issue (Required)
Press the Ctrl button and click on each sub issue to select multiple, if needed.
Proficency Test
Monitors
Proficency Test
Quality Control
Quality Control Failure

OM - Proficiency Test Qualtrax ID #
Required ONLY for Proficiency Testing
12345

OM - Description (Required)
Provide a brief description of the occurrence for improvement.
Overall PT passing score of 98.2% for ERA WS-123 PT study.

Benzene has an unacceptable result of non-detect.

Benzene acceptance limits for ERA WS-123 PT study: 0.00-7.00 µg/L.

OM - Investigator(s) (Required)
Jennifer Mcgee (21066) Remove

Show Available Users

Submit for Investigation

Save Changes

Occurrence Management Investigation

Occurrence Management

ID 24797
Current Step is Investigation
Needs to be processed by (Jennifer Mcgee)
History

Investigation

OM - How to use the Occurrence Management Workflow
Workflow Job Aid

OM - DCLS Groups
ORGANICS
ORGANICS

OM - Group Manager (Required)
Ashley Pierce(20443) Remove

Show Available Users

OM - DLO
Ed Shaw(548) Remove

Show Available Users

OM - Date Incident Discovered
Date Discovered=the date the error or event was identified

3/7/2022
Show Calendar

OM - Date Incident Occured
Date Occurred=date the error or event took place

3/4/2022
Show Calendar

OM - Issue Related To
Quality Management
Quality Management

OM - Sub Issue
Press the Ctrl button and click on each sub issue to select multiple, if needed.
Proficency Test

Labeling
Management Review
Monitors
Proficency Test

Occurrence Management Investigation

Occurrence Management

OM - Proficiency Test Qualtrax ID #
Required ONLY for Proficiency Testing
12345

OM - Description (Required)
Provide a brief description of the occurrence for improvement.
Overall PT passing score of 98.2% for ERA WS-123 PT study.

Benzene has an unacceptable result of non-detect.

Benzene acceptance limits for ERA WS-123 PT study: 0.00-7.00 µg/L.

OM - Investigator(s) (Required)
Jennifer Mcgee(21066) Remove

Show Available Users

OM - Evidence (Required)
Provide the details about the occurrence along with supporting records, documents or processes that were observed.

OM - Regulatory Body

OM - DCLS/Standard Requirement (Required)
Press the Ctrl button and click on each requirement to select multiple, if needed.
Quality Manual
SOP
Standard/Reference Method
Other

OM - Requirement Explanation (Required)
Provide additional information related to the DCLS/Standard Requirement such as the SOP title/ID #, Reference Method title/ID #, or Standard requirement.

Occurrence Management Investigation

Occurrence Management

OM - Proficiency Test Qualtrax ID #
Required ONLY for Proficiency Testing

12345

OM - Description (Required)
Provide a brief description of the occurrence for improvement.

Overall PT passing score of 98.2% for ERA WS-123 PT study.

Benzene has an unacceptable result of non-detect.

Benzene acceptance limits for ERA WS-123 PT study: 0.00-7.00 µg/L.

OM - Investigator(s) (Required)
Jennifer Mcgee(21066) Remove

Show Available Users

OM - Evidence (Required)
Provide the details about the occurrence along with supporting records, documents or processes that were observed.

PT failure due to a transcription error and no second review in place for manual entry of results. The following items were reviewed during the investigation to determine the cause. All applicable records were acceptable.
- Acceptable QC data
- Acceptable calibration curve
- Acceptable control charts
- Acceptable instrument maintenance logs
- All reagents and materials were within specifications
- Analyst competency up to date
- A second review of the PT data was completed prior to submitting results to the PT provider
- Reviewed PT data and Benzene would have passed had there not been a transcription error and if a second review was in place of the manual entry

Occurrence Management Investigation

Occurrence Management

OM - Regulatory Body
TNI
TNI

OM - DCLS/Standard Requirement (Required)
Press the Ctrl button and click on each requirement to select multiple, if needed.
SOP
Quality Manual
SOP
Standard/Reference Method
Other

OM - Requirement Explanation (Required)
Provide additional information related to the DCLS/Standard Requirement such as the SOP title/ID #, Reference Method title/ID #, or Standard requirement.

Per Proficiency Testing (Qualtrax ID # 1772), an occurrence management is required if a PT is deemed a "failure" by an AB or PT provider. The recommended course of action shall be a corrective action. refer to Occurrence Management (Qualtrax ID # 29272) for specifics.

OM - Additional Records
(optional)
Choose File No file chosen

Occurrence Management Investigation

Occurrence Management

OM - Probability & Severity
Probability & Severity Job Aid

OM - Probability (Required)

OM - Explanation for Probability (Required)
Provide an explanation for why the probability was chosen

OM - Severity (Required)

OM - Explanation for Severity (Required)
Provide an explanation for why the severity was chosen

OM - Recommended Course of Action (Required)

OM - Explanation for Recommended Course of Action (Required)
Provide an explanation for why the recommended course of action was chosen

Determining Probability

Probability – The likelihood of an occurrence happening

Probability Ranking	Examples / Explanations Consider Volume and Frequency of Testing
High	Frequent failures or occurrences - extremely likely or happens often, such as once per week
Moderate	Few failures or occurrences - highly likely or happens occasionally, such as once per month
Low	Infrequent failures or occurrences - unlikely or rarely happened before, such as once per year to every few years

Occurrence Management Investigation

Occurrence Management

OM - Probability (Required)
Low
Low

OM - Explanation for Probability (Required)
Provide an explanation for why the probability was chosen
Reviewed PT records for the past 3 years with no failures.

Determining Severity

Severity – The measure of consequences of an occurrence (i.e. impact on public health or customer confidence)

Severity Ranking	Issue Related To	Examples / Explanations
High: Results will cause or have caused a public health emergency, backordered or unobtainable resources required, work stoppage, severe property damage or loss of client confidence, results in amended report/tests	*Environment*	Temperature or humidity out of range - include other resulting effects to determine severity
	LIMS	Time consuming work around or no work around available
	Quality Management	Starting or completing work without director (or designee) approved procedure, validation or EUA, Quality Monitor threshold exceeded the 3rd or greater time, Management review findings - include other resulting effects to determine severity
	Reagents/ Standards	Backordered or unobtainable resources required, incorrect labeling discovered after results reported leading to amended report or retesting
	Specimen/ Sample	Missing/lost/misplaced sample, incorrect storage temperature, request for new sample due to lab error
	Testing Personnel	Testing performed & results released by analyst during lapse of competency
	Test Results	Invalid/unusable result, reports reissued with incorrect results, results released prior to confirmation testing, delayed reporting of abnormal/critical results, PT sample/survey fail per PT provider or by the accreditation body
	Test System	Time consuming fix or placed out of service and requires vendor in-house support/service, equipment failure causing release of incorrect result(s)

Determining Severity

Severity Ranking	Issue Related To	Examples / Explanations
Moderate: Results may cause a public health emergency, additional resources required, significant work delays, substantial property damage or damaged client reputation, amended report at fault of lab	*Environment*	Temperature or humidity out of range - include other resulting effects to determine severity
	LIMS	Reports sent to wrong location, sample labeling error discovered after testing started but prior to reporting, failing to contact client to obtain required missing information or clarification for unclear information, result amendment due to lab error
	Quality Management	Missed/late lab document reviews WITH document issue findings, Quality Monitor threshold exceeded the 2nd time, Management review findings - include other resulting effects to determine severity
	Reagents/ Standards	Testing performed with expired sample container/media kit/collection devices, Equipment/material recall affecting test results, Incorrect labeling discovered during testing but prior to results reported
	Specimen/ Sample	Sample delivery delay, lab error resulting in requesting another sample
	Testing Personnel	Lapse in competency of the only analyst for the method, samples not tested during lapse but caused delay in testing
	Test Results	Specimen preparation error, result of testing released prior to QC run completion or review, delayed reporting of results due to instrument or QC issues, PT results w/ z-score >3 or PT sample/survey fail per DCLS
	Test System	Sample introduction problems, auto-sampling probe not sampling correctly

Determining Severity

Severity Ranking	Issue Related To	Examples / Explanations
Minor, Low or None: No Public health emergency, impact to resources, work delay, property damage, client inconvenience or can result in temporary discomfort, amended report at no fault of lab	*Environment*	Temperature or humidity out of range - include other resulting effects to determine severity
	LIMS	Data entry errors other than patient misidentification/test results, requisition form information doesn't match sample container information, samples not released to lab in LIMS, amendment of results due to client error
	Quality Management	Missed/late lab document reviews without document issue findings, Quality Monitor threshold exceeded the 1st time, Management review findings - include other resulting effects to determine severity
	Reagents/ Standards	Incorrect labeling discovered prior to use in testing
	Specimen/ Sample	Unlabeled or mislabeled sample received, inadequate specimen volume received for testing, sample not received/received in wrong collection device
	Testing Personnel	Lapse in competency the 2nd/3rd analyst for the method (no samples processed by analyst during lapse)
	Test Results	Delay of normal results report due to issues other than equipment or QC, discovered during data review that all necessary testing not completed (i.e. repeat testing for confirmation), PT results w/ z-score between 2 & 3 if issue is discovered
	Test System	Batch/run assigned to incorrect equipment/instrument, run started with inadequate instrument supplies to perform tests

What Severity ranking would you choose?

A. High

B. Moderate

C. Low

Occurrence Management Investigation

Occurrence Management

OM - Severity (Required)
High

High

OM - Explanation for Severity (Required)
Provide an explanation for why the severity was chosen

PT failure could lead to accreditation suspension from the accrediting body if the same analyte fails 2 out of 3 studies.

Determining Recommended Course of Action

Recommended Course of Action			
	High severity	Moderate severity	Low severity/Unlikely Risk
High probability	Corrective action	Corrective action	Corrective action / Correction
Moderate probability	Corrective action	Corrective action / Correction	Correction / No action
Low/Rare probability	Corrective action / Correction	Correction	No action

What Course of Action would you take?

A. No Action / Administrative Action

B. Correction

C. Corrective Action

D. Preventive Action

Occurrence Management Investigation

Occurrence Management

OM - Recommended Course of Action (Required)

Corrective Action

Corrective Action

OM - Explanation for Recommended Course of Action (Required)

Provide an explanation for why the recommended course of action was chosen

A corrective action is required by the accreditation body for a failed PT study.

Occurrence Management Investigation

Occurrence Management

OM - Immediate Correction
Used ONLY for Corrective Actions. State the immediate correction(s) taken to fix the issue.

OM - Root Cause (Required)
Required ONLY for Corrective Actions. State the factor(s) that would prevent the reoccurrence. This is the "why" the incident occurred.

Occurrence Management Investigation

Occurrence Management

OM - Immediate Correction

Used ONLY for Corrective Actions. State the immediate correction(s) taken to fix the issue.

A review of the PT data packet including QC data, calibration curve, and instrument logs was performed. There were no obvious problems observed. The PT result was correct from the instrument print out in the data packet.

Occurrence Management Investigation

Occurrence Management

OM - Root Cause (Required)

Required ONLY for Corrective Actions. State the factor(s) that would prevent the reoccurrence. This is the "why" the incident occurred.

There is no second review in place for manual entry of PT results to the PT Provider.

Occurrence Management Investigation

Occurrence Management

OM - Correction/Action Plan

Required ONLY for Preventive Actions, Corrections, and Corrective Actions. Can be used for documenting purposes for No Actions/Administrative Actions

Add Row

Action (Required)	Personnel (Required)	Proposed Due Date (Required)	Dat
	Show Available Users	Show Calendar	Show Caler

Date Completed	Evidence Document(s)	Comments
Show Calendar	Choose File No file chosen	

Occurrence Management Investigation

Occurrence Management

OM - Correction/Action Plan

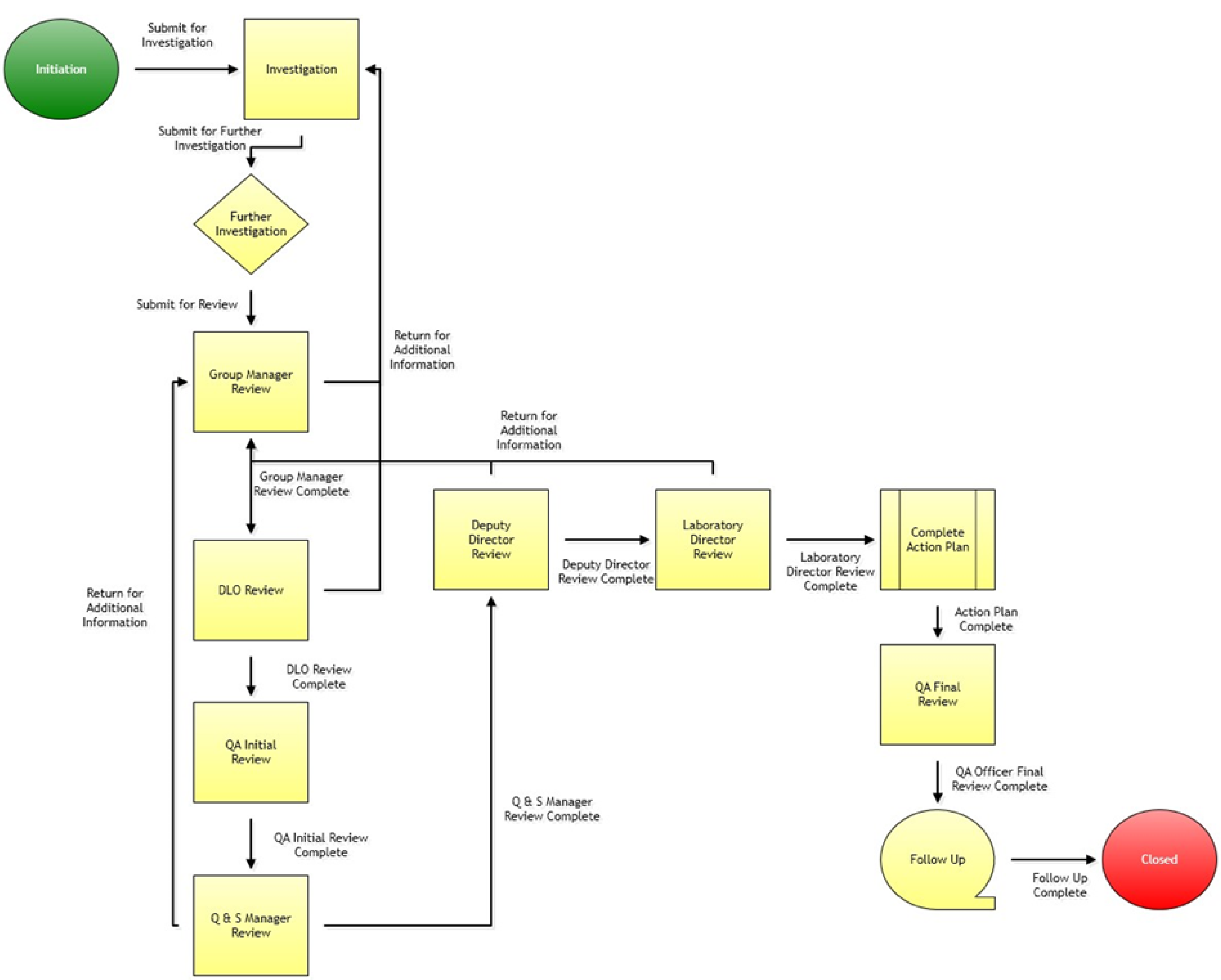
Required ONLY for Preventive Actions, Corrections, and Corrective Actions. Can be used for documenting purposes for No Actions/Administrative Actions

Add Row

Action (Required)	Personnel (Required)	Proposed Due Date (Required)	Date
Create a PT review form for reviewing PT result submissions that includes a second review of the study summary against the data results submitted to the PT provider.	Jennifer Mcgee (21066) Remove Show Available Users	4/15/22 Show Calendar	Show Calend
Update applicable SOPs to include the PT results review form.	Jennifer Mcgee (21066) Remove Show Available Users	4/15/22 Show Calendar	Show Calend
Perform a training for the review analyst when entering PT results to the PT provider.	Jennifer Mcgee (21066) Remove Show Available Users	4/15/22 Show Calendar	Show Calend

Occurrence Management Approval

4. Corrective Action



Complete the Action Plans

OM - Correction/Action Plan

Required ONLY for Preventive Actions, Corrections, and Corrective Actions. Can be used for documenting purposes for No Actions/Administrative Actions

Add Row

Action (Required)	Personnel (Required)	Proposed Due Date (Required)	Date Completed
Create a PT review form for reviewing PT result submissions that includes a second review of the study summary against the data results submitted to the PT provider.	Jennifer Mcgee(21066) Remove Show Available Users	4/15/22 Show Calendar	4/1/22 Show Calendar
Update applicable SOPs to include the PT results review form.	Jennifer Mcgee(21066) Remove Show Available Users	4/15/22 Show Calendar	4/15/22 Show Calendar
Perform a training for the review analyst when entering PT results to the PT provider.	Jennifer Mcgee(21066) Remove Show Available Users	4/15/22 Show Calendar	4/1/22 Show Calendar

60 Day Follow Up

OM - Reoccurrences (Required)
Please select if any reoccurrences have occured. If so, please place new workflow # in the next text field.

OM - Reoccurrence ID #

OM - Explanation of Reoccurrence(s)

Summary

- This process allows for identifying, analyzing, correcting and documenting non-conforming events
- If it isn't documented…it didn't happen
- APHL Public Health Laboratory Model Practices for QMS11-A: Non-conforming Events is an excellent resource to use

Questions?

Jennifer McGee
QA Senior Scientist
Richmond, VA
804-648-4480 ext. 400
DCLS_QA@dgs.Virginia.gov