A Standardized Approach to Root Cause Analysis

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Michigan Department of Health and Human Services - Bureau of Laboratories

Preventing disease • Promoting wellness • Improving the quality of life of Michigan residents

TODAY'S OUTLINE

- MDHHS Background
- Definitions
- ISO/IEC 17025 Requirements
- How MDHHS Complies With the ISO/IEC Requirements
- Examples of Root Cause Analysis Tools
- MDHHS Laboratory Standardized Root Cause Analysis Tool
- Lessons Learned

MDHHS Background

- The Bureau of Laboratories is accredited by two agencies
  - College of American Pathologists (CAP) - for testing performed under the Clinical Laboratories Improvement Amendments (CLIA)
  - American Industrial Hygiene Association – Laboratory Accreditation Programs (AIHA-LAP, LLC) – for environmental lead and food testing under the ISO/IEC 17025 standard

DEFINITIONS

- Nonconformity: A failure to comply with a requirement of an accreditation program(s) or a laboratory's own stated management system requirements.

- Root Cause Analysis: A collective term that describes a wide range of approaches, tools and techniques used to uncover causes of problems.

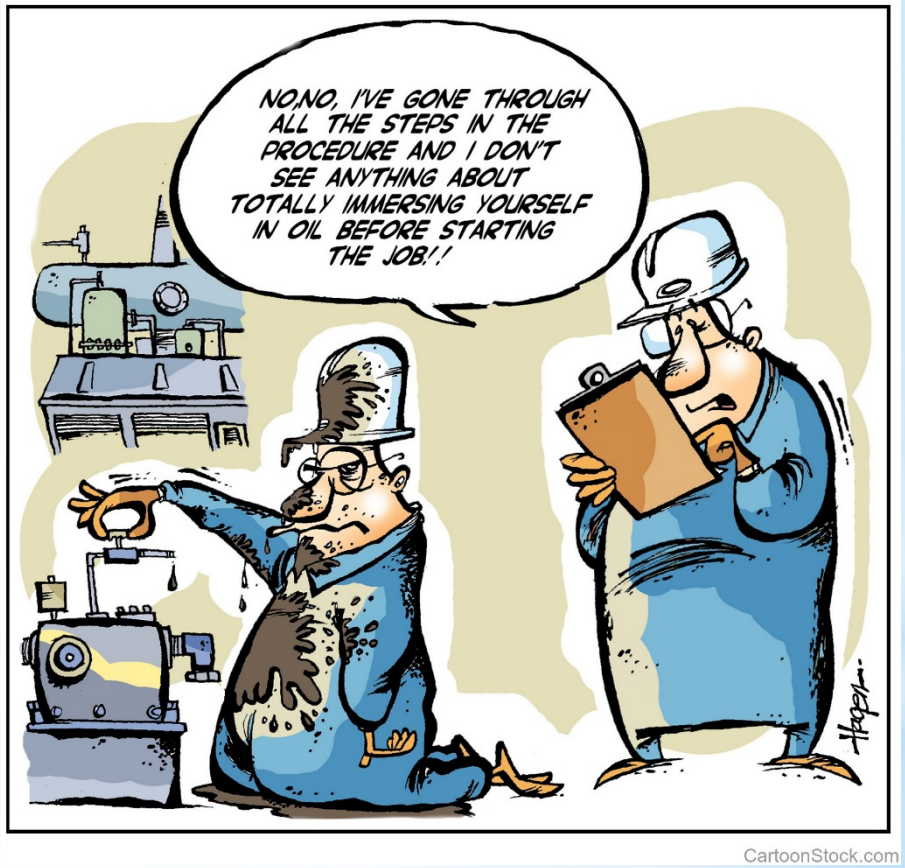
ISO/IEC 17025 REQUIREMENTS

- Customer Complaints

http://www.customerexperienceinsight.com

ISO/IEC 17025 REQUIREMENTS

- When the work being performed does not conform to the procedures

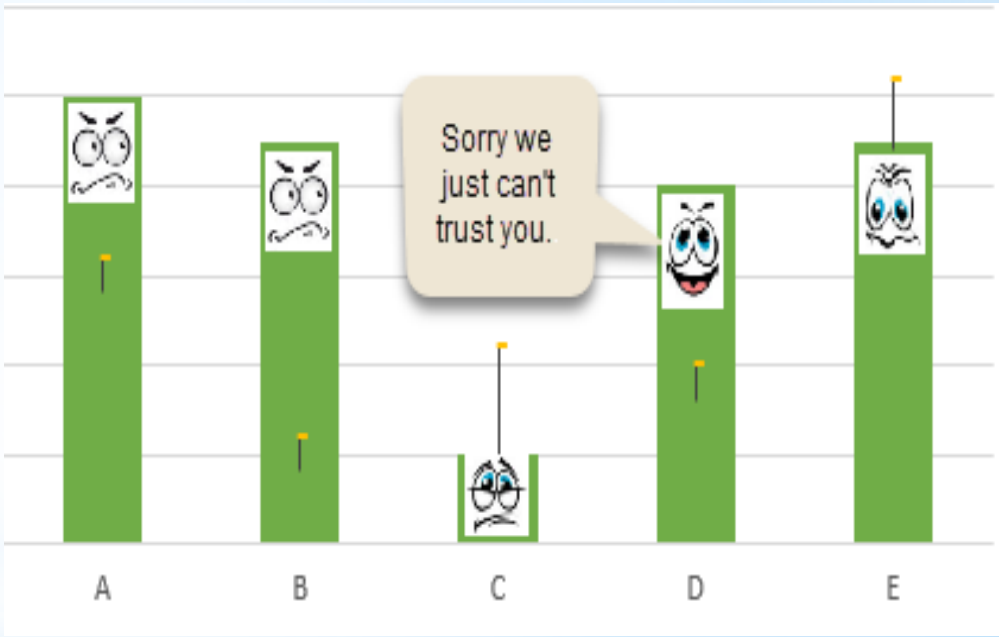


ISO/IEC 17025 REQUIREMENTS

- Audits
  - Internal
  - External

ISO/IEC 17025 REQUIREMENTS

- An outlier from a Proficiency Test (PT)/Round Robin



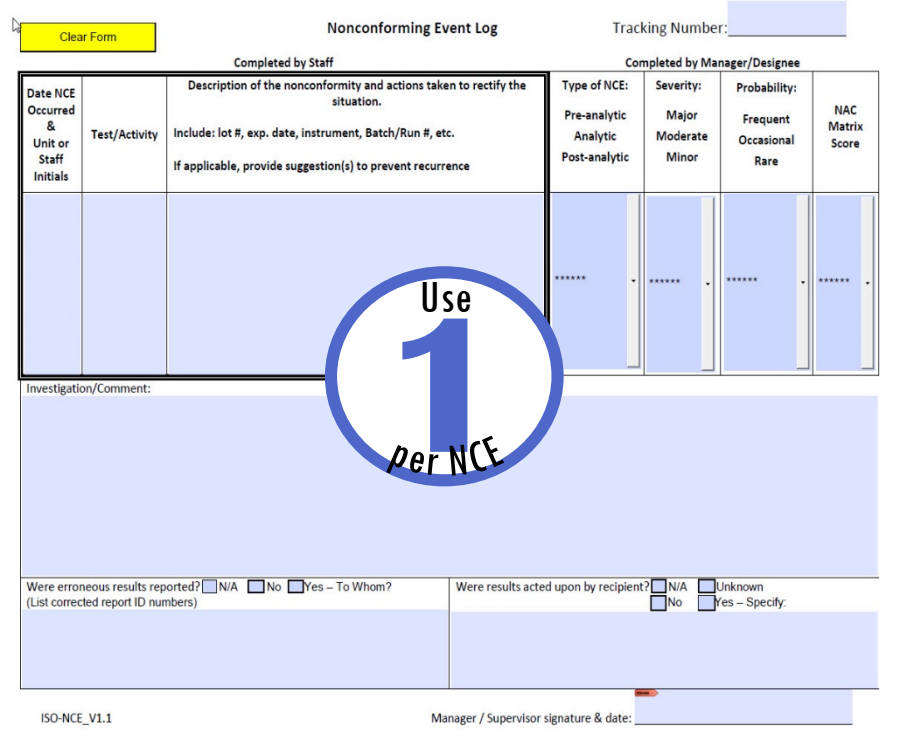
ISO/IEC 17025 REQUIREMENTS

- When a PT round leads to the non-proficient (NP) status of the laboratory.

ISO/IEC 17025 REQUIREMENTS

- To examine the effect of the defect or departure from specified limits on previous tests.

MDHHS LABORATORY COMPLIANCE



- Based off of CLSI Guideline QMS11-A: Management of Nonconforming Laboratory Events; Approved Guideline

MDHHS LABORATORY COMPLIANCE

Minor (Mi) – Low/No Negative Impact	
Sample	• Requisition form information doesn't match sample container information • Sample not received in correct container • No sample received with requisition form • Sample labeling error discovered in the pre-analytic or analytic (prior to running on instrument) phase of testing
LIMS	• Event easily worked around • Samples not 'released to lab' in StarLIMS • Samples not entered/imported into StarLIMS correctly • Samples from one site address having two Group IDs in StarLIMS instead of one • Batch / run assigned to incorrect equipment/instrument
Instrument	• Event easily fixed and documented • Solution / reagent levels weren't adequate and ran out • Instrument not communicating with devices
Results	• Does not affect test results • No increase in TAT • Discovered during data review that the sample was not repeated when it was supposed to be
Moderate (Mo) – Potential Negative Impact	
Sample	• Sample labeling error discovered in the analytic (sample ran on instrument) or post-analytic phase of testing • Not contacting the submitter to obtain required information that wasn't provided or is misleading • Sample received opened • Sample not stored properly
LIMS	• Event can be worked around without large time investment • Sample not suppressed in StarLIMS when it should be • Sample information not entered into StarLIMS correctly • Editing results in StarLIMS
Instrument	• Event can be fixed without large time investment • Sample introduction problems • Auto-sampling probe not sampling correctly
Results	• Event could affect test results IF not caught • PT outlier
Assessments	• Deficiencies acquired from internal and external audits • Customer complaints and issues brought up in the customer survey
Major (Ma) – Negative Impact Present	
Sample	• Sample labeling error discovered after report went out
LIMS	• Time consuming work around • No work around available
Instrument	• Time consuming fix • Out of service and requires intervention from vendor
Results	• Result not valid – unusable • Reports reissued • Reported results on a sample when it was supposed to be repeated/confirmed first • PT result(s) led to a NP status for the laboratory

ii. Probability

	Number of Occurrences	Timeframe
Frequent (F)	≥ 3	Past 30 days
Occasional (O)	2 – 4	Past 60 days
Rare (R)	≤ 1 or first occurrence	Past 90 days

- Prioritizing/Scoring NCEs
  - Severity
  - Probability

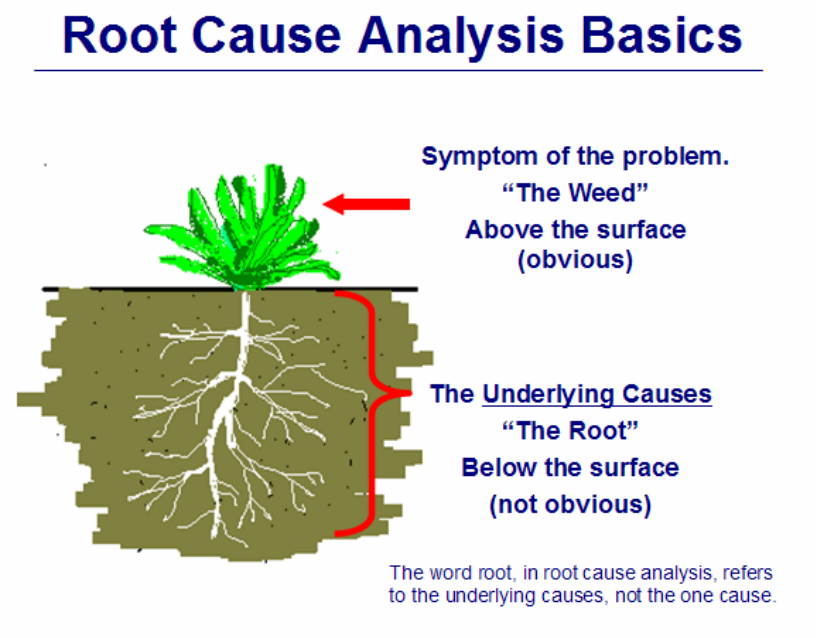
MDHHS LABORATORY COMPLIANCE

NAC

Probability	Severity		
	Major	Moderate	Minor
Frequent	3	3	2
Occasional	3	2	1
Rare	3	2	1

- Nonconformity Assessment Code (NAC) Score
  - 1 = a corrective action plan is optional
  - 2 = requires an informal investigation with corrective action plan
  - 3 = requires a formal investigation with corrective action plan

MDHHS LABORATORY COMPLIANCE



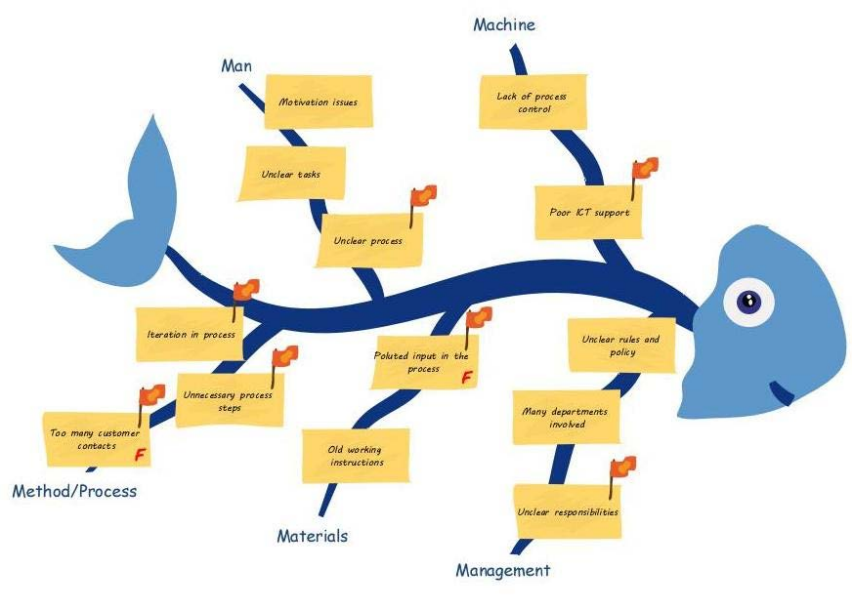
https://dzone.com

- Site Assessment Reveled:
  - Not doing true RCA
  - Identifying symptoms
  - Lacked objective evidence

MDHHS LABORATORY COMPLIANCE

- American Society of Quality (ASQ) Webinars
  - Root Cause Analysis for Beginners, Part 1 – Covered philosophical issues
    - What is RCA
    - Why perform RCA and
    - What factors shape human performance.
  - Root Cause Analysis for Beginners, Part 2 – Covered the practical realm
    - How to collect data for RCA
    - Various tools available to conduct RCA

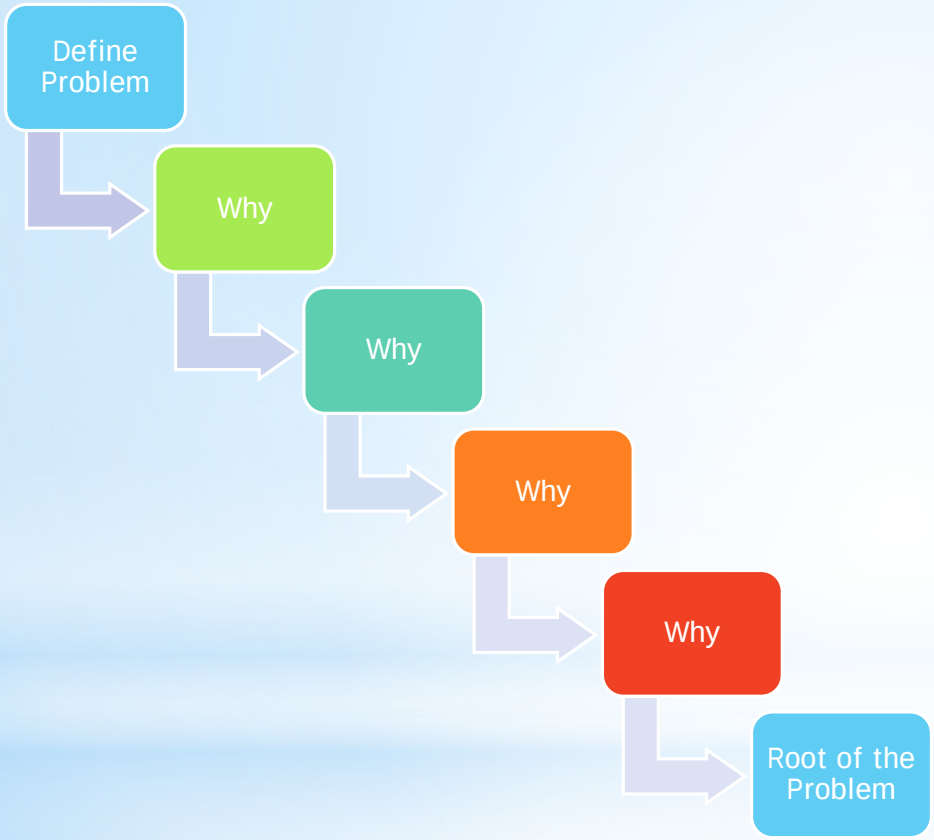
ROOT CAUSE ANALYSIS TOOLS - FISHBONE DIAGRAM



- Useful for initial analysis
- Should be supplemented with another tool when risk of an incorrect solution is high.

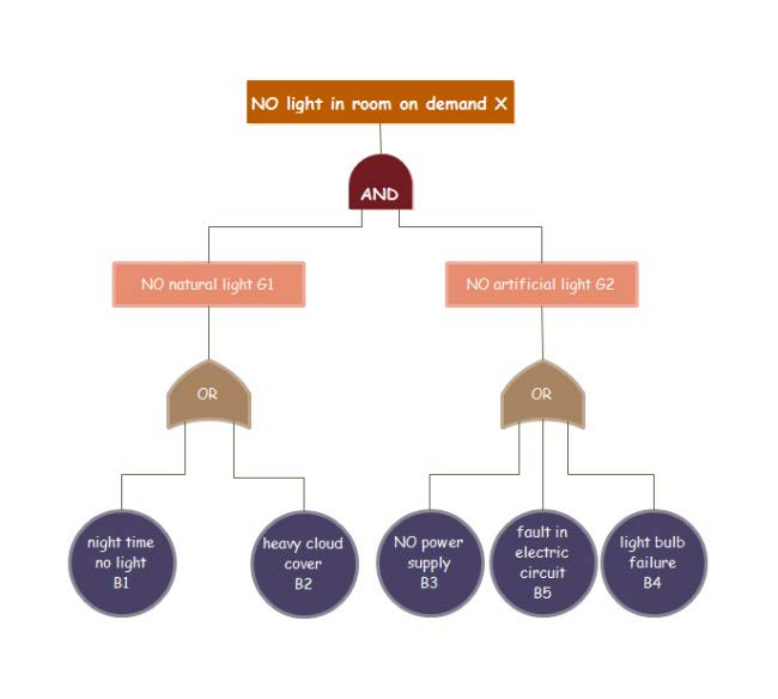
http://blog.bizzdesign.com/leancoach-measure-fishbone

ROOT CAUSE ANALYSIS TOOLS - FIVE WHYs



- Useful for initial analysis
- Should be supplemented with another tool when risk of an incorrect solution is high
- Often used in conjunction with the fishbone diagram

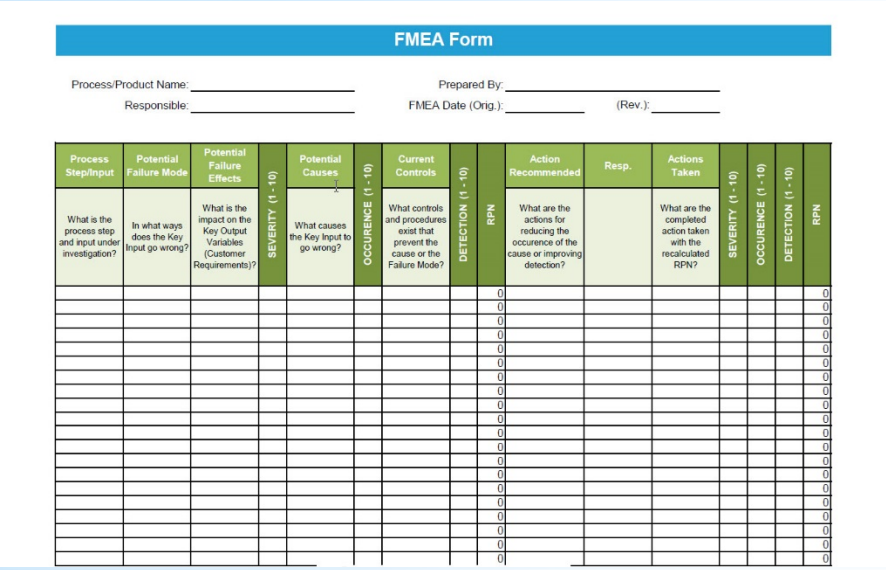
ROOT CAUSE ANALYSIS TOOLS - CAUSE & EFFECT TREE ANALYSIS



http://www.edrawsoft.com

- Combines human errors, equipment failures and external factors that can produce the problem being evaluated
- Can be used as a troubleshooting or a structured guessing approach

ROOT CAUSE ANALYSIS TOOLS - FAILURE MODE EFFECTS ANALYSIS



FMEA Form

Process/Product Name: _____ Prepared By: _____

Responsible: _____ FMEA Date (Orig.): _____ (Rev.): _____

Process Step/Input	Potential Failure Mode	Potential Failure Effects	SEVERITY (1 - 10)	Potential Causes	OCCURENCE (1 - 10)	Current Controls	DETECTION (1 - 10)	RPN	Action Recommended	Resp.	Actions Taken	SEVERITY (1 - 10)	OCCURENCE (1 - 10)	DETECTION (1 - 10)	RPN
What is the process step and input under investigation?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements)?		What causes the Key Input to go wrong?		What controls and procedures exist that prevent the cause or the Failure Mode?		0	What are the actions for reducing the occurence of the cause or improving detection?		What are the completed action taken with the recalculated RPN?				0

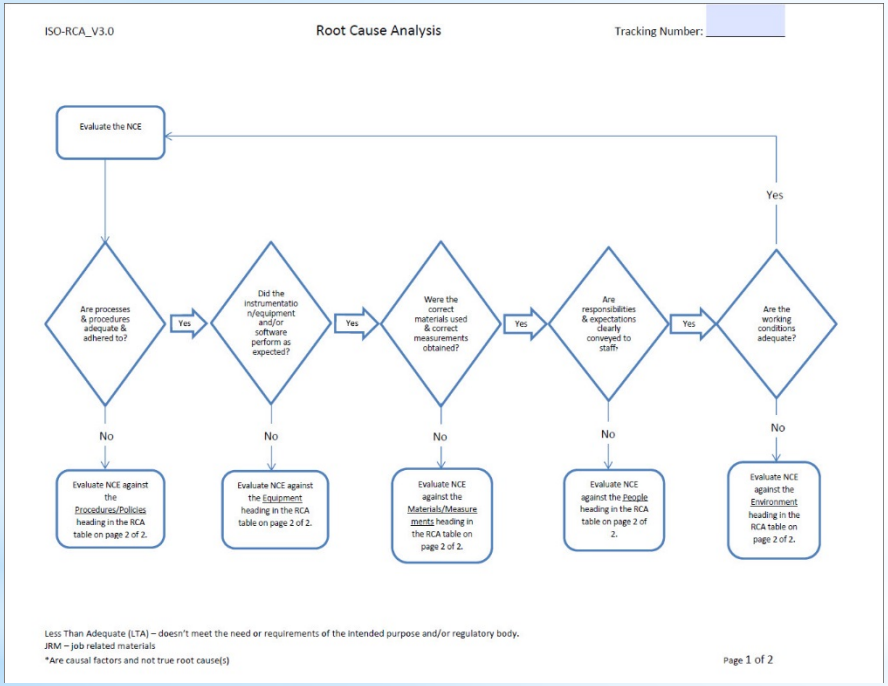
- Identifies the most significant areas of an actual or potential incident
- Useful for analyzing downtime, spare parts, repair work, equipment damage, etc.

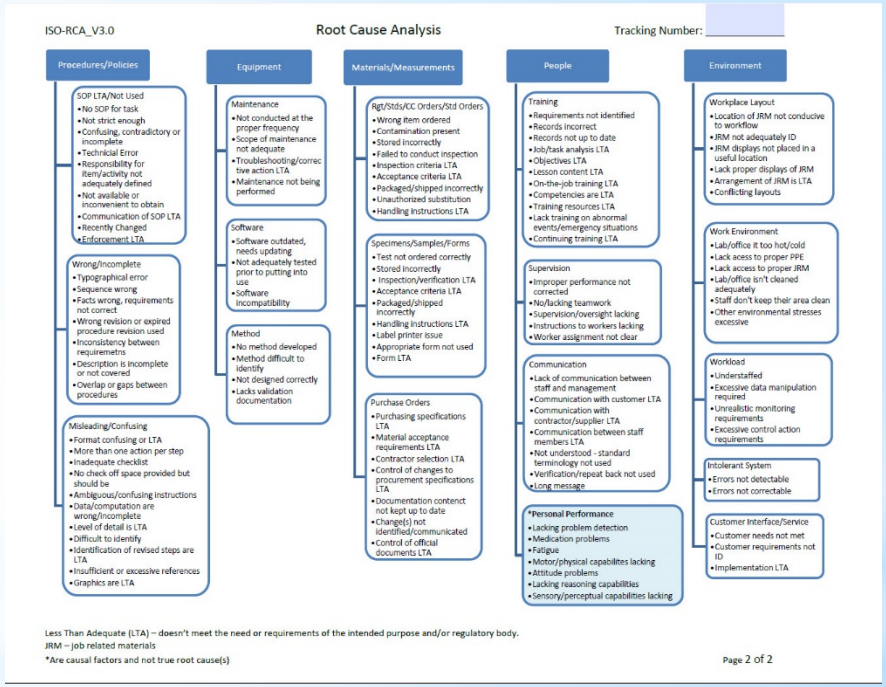
https://goleansixsigma.com

MDHHS LABORATORY RCA TOOL

- Desired features of our RCA tool
  - Applicable to pre-analytic, analytic, and post-analytic phases of testing
  - Didn't take a large amount of time to complete
    - "I don't want to perform brainstorming for each RCA, need something streamlined"
  - Intuitive
    - "I want to be able to look at it and know what to do with it, not have to pull out a procedure each time I have to complete one"
  - STANDARDIZED
    - "Have options listed and staff select all that apply"
  - Comply with regulatory requirements

MDHHS LABORATORY RCA TOOL





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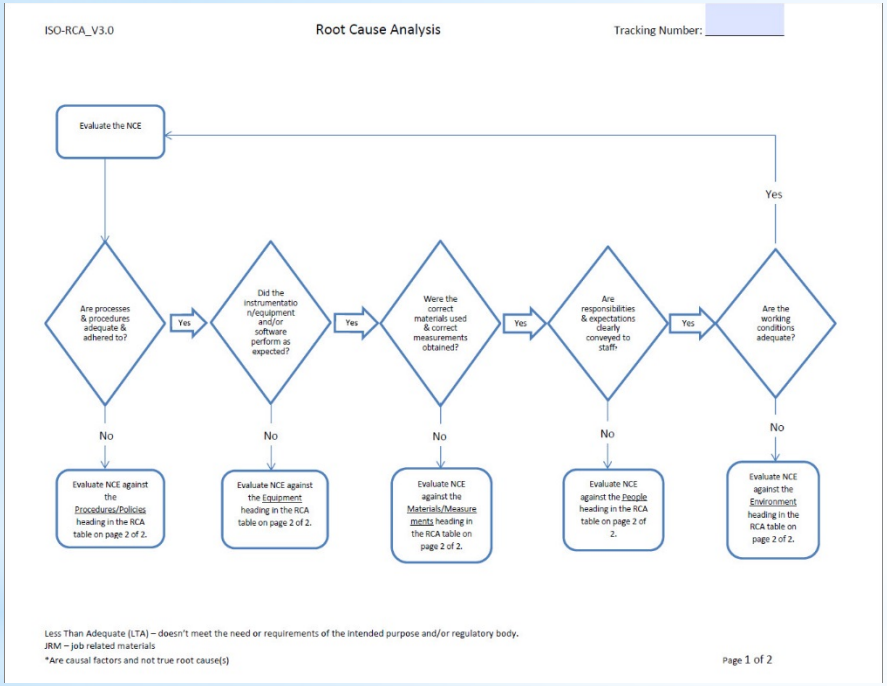

ISO-RCA_V3.0

Root Cause Analysis

Tracking Number: _____

Evaluate the NCE

Are processes & procedures adequate & adhered to?

Yes

Did the instrumentation/equipment and/or software perform as expected?

Yes

Were the correct materials used & correct measurements obtained?

Yes

Are responsibilities & expectations clearly conveyed to staff?

Yes

Are the working conditions adequate?

Yes

No

Evaluate NCE against the Procedures/Policies heading in the RCA table on page 2 of 2.

No

Evaluate NCE against the Equipment heading in the RCA table on page 2 of 2.

No

Evaluate NCE against the Materials/Measurements heading in the RCA table on page 2 of 2.

No

Evaluate NCE against the People heading in the RCA table on page 2 of 2.

No

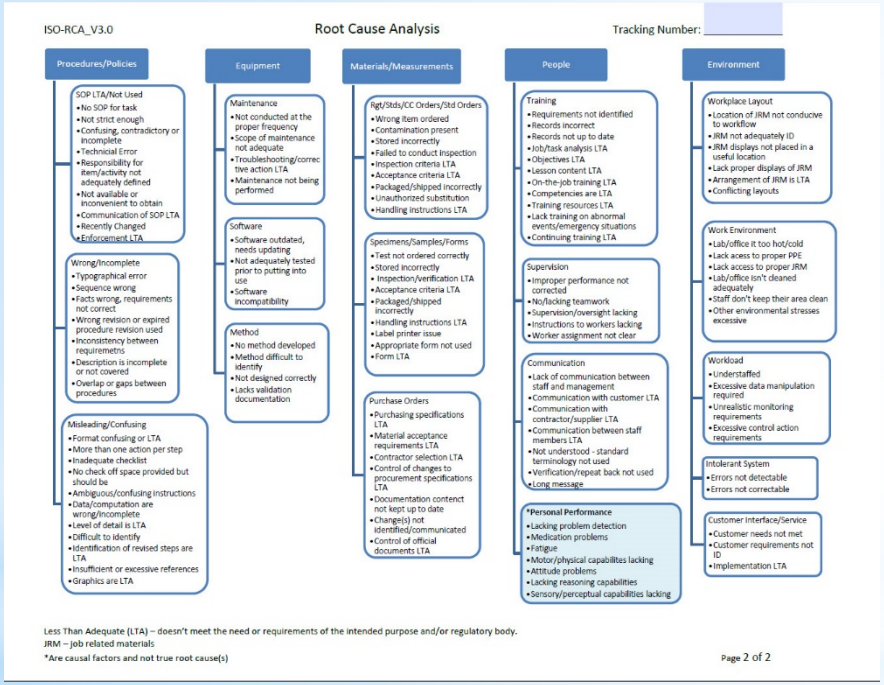
Evaluate NCE against the Environment heading in the RCA table on page 2 of 2.

Less Than Adequate (LTA) – doesn't meet the need or requirements of the intended purpose and/or regulatory body.
JRM – job related materials
*Are causal factors and not true root cause(s)

Page 1 of 2

- Used to identify potential corrective actions
- More than one of the categories can be selected per NCE
  - Procedures/Policies
  - Equipment
  - Materials/Measurement
  - People
  - Environment

MDHHS LABORATORY RCA TOOL



ISO-RCA_V3.0

Root Cause Analysis

Tracking Number: _____

Procedures/Policies

SOP LTA/Not Used
- No SOP for task
- Not strict enough
- Confusing, contradictory or incomplete
- Technicial Error
- Responsibility for item/activity not adequately defined
- Not available or inconvenient to obtain
- Communication of SOP LTA
- Recently Changed
- Enforcement LTA

Wrong/Incomplete
- Typographical error
- Sequence wrong
- Facts wrong, requirements not correct
- Wrong revision or expired procedure revision used
- Inconsistency between requiremetns
- Description is incomplete or not covered
- Overlap or gaps between procedures

Misleading/Confusing
- Format confusing or LTA
- More than one action per step
- Inadequate checklist
- No check off space provided but should be
- Ambiguous/confusing instructions
- Data/computation are wrong/incomplete
- Level of detail is LTA
- Difficult to identify
- Identification of revised steps are LTA
- Insufficient or excessive references
- Graphics are LTA

Equipment

Maintenance
- Not conducted at the proper frequency
- Scope of maintenance not adequate
- Troubleshooting/corrective action LTA
- Maintenance not being performed

Software
- Software outdated, needs updating
- Not adequately tested prior to putting into use
- Software incompatibility

Method
- No method developed
- Method difficult to identify
- Not designed correctly
- Lacks validation documentation

Materials/Measurements

Rgt/Stds/CC Orders/Std Orders
- Wrong item ordered
- Contamination present
- Stored incorrectly
- Failed to conduct inspection
- Inspection criteria LTA
- Acceptance criteria LTA
- Packaged/shipped incorrectly
- Unauthorized substitution
- Handling instructions LTA

Specimens/Samples/Forms
- Test not ordered correctly
- Stored incorrectly
- Inspection/verification LTA
- Acceptance criteria LTA
- Packaged/shipped incorrectly
- Handling instructions LTA
- Label printer issue
- Appropriate form not used
- Form LTA

Purchase Orders
- Purchasing specifications LTA
- Material acceptance requirements LTA
- Contractor selection LTA
- Control of changes to procurement specifications LTA
- Documentation content not kept up to date
- Change(s) not identified/communicated
- Control of official documents LTA

People

Training
- Requirements not identified
- Records incorrect
- Records not up to date
- Job/task analysis LTA
- Objectives LTA
- Lesson content LTA
- On-the-job training LTA
- Competencies are LTA
- Training resources LTA
- Lack training on abnormal events/emeegency situations
- Continuing training LTA

Supervision
- Improper performance not corrected
- No/lacking teamwork
- Supervision/oversight lacking
- Instructions to workers lacking
- Worker assignment not clear

Communication
- Lack of communication between staff and management
- Communication with customer LTA
- Communication with contractor/supplier LTA
- Communication between staff members LTA
- Not understood - standard terminology not used
- Verification/repeat back not used
- Long message

*Personal Performance
- Lacking problem detection
- Medication problems
- Fatigue
- Motor/physical capabilites lacking
- Attitude problems
- Lacking reasoning capabilities
- Sensory/perceptual capabilities lacking

Environment

Workplace Layout
- Location of JRM not conducive to workflow
- JRM not adequately ID
- JRM displays not placed in a useful location
- Lack proper displays of JRM
- Arrangement of JRM is LTA
- Conflicting layouts

Work Environment
- Lab/office it too hot/cold
- Lack acess to proper PPE
- Lack access to proper JRM
- Lab/office isn't cleaned adequately
- Staff don't keep their area clean
- Other environmental stresses excessive

Workload
- Understaffed
- Excessive data manipulation required
- Unrealistic monitoring requirements
- Excessive control action requirements

Intolerant System
- Errors not detectable
- Errors not correctable

Customer Interface/Service
- Customer needs not met
- Customer requirements not ID
- Implementation LTA

Less Than Adequate (LTA) – doesn't meet the need or requirements of the intended purpose and/or regulatory body.
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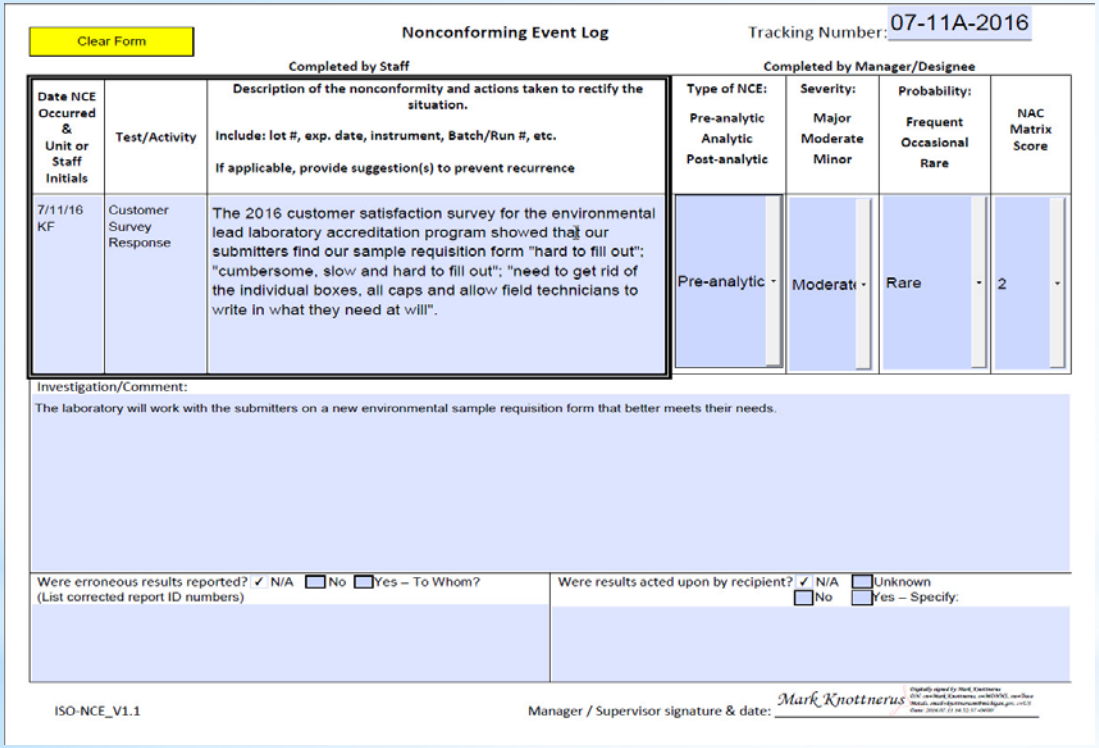
Page 2 of 2

- Drill down on the categories identified as potential corrective actions
- Select and implement the action(s) most likely to eliminate the problem and prevent recurrence

MDHHS LABORATORY RCA TOOL - EXAMPLE



Clear Form

Nonconforming Event Log

Tracking Number: 07-11A-2016

Completed by Staff			Completed by Manager/Designee			
Date NCE Occurred & Unit or Staff Initials	Test/Activity	Description of the nonconformity and actions taken to rectify the situation. Include: lot #, exp. date, instrument, Batch/Run #, etc. If applicable, provide suggestion(s) to prevent recurrence	Type of NCE: Pre-analytic Analytic Post-analytic	Severity: Major Moderate Minor	Probability: Frequent Occasional Rare	NAC Matrix Score
7/11/16 KF	Customer Survey Response	The 2016 customer satisfaction survey for the environmental lead laboratory accreditation program showed that our submitters find our sample requisition form "hard to fill out"; "cumbersome, slow and hard to fill out"; "need to get rid of the individual boxes, all caps and allow field technicians to write in what they need at will".	Pre-analytic	Moderat	Rare	2

Investigation/Comment:

The laboratory will work with the submitters on a new environmental sample requisition form that better meets their needs.

Were erroneous results reported? ✓ N/A ☐ No ☐ Yes – To Whom? (List corrected report ID numbers)

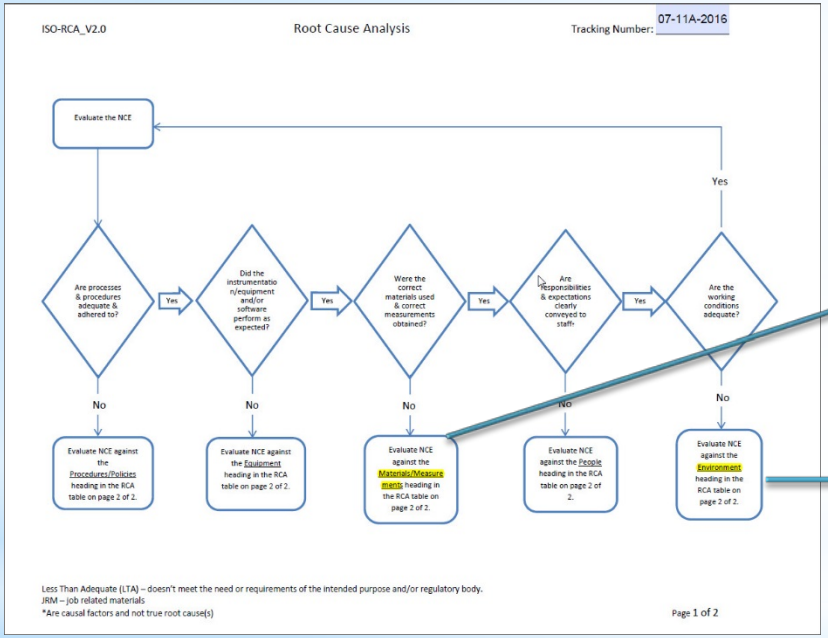
Were results acted upon by recipient? ✓ N/A ☐ No ☐ Unknown ☐ Yes – Specify:

ISO-NCE_V1.1

Manager / Supervisor signature & date: Mark Knottnerus

- NAC Matrix Score = 2
- Informal investigation with root cause analysis

MDHHS LABORATORY RCA TOOL - EXAMPLE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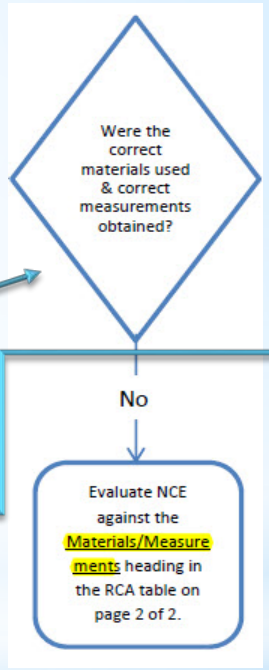

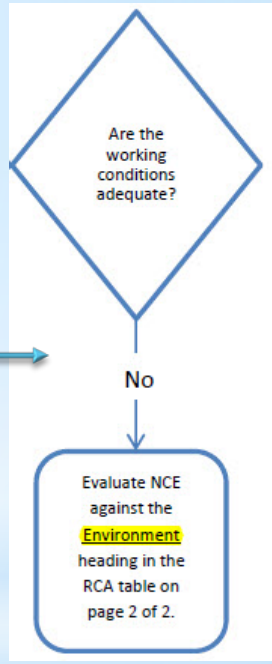

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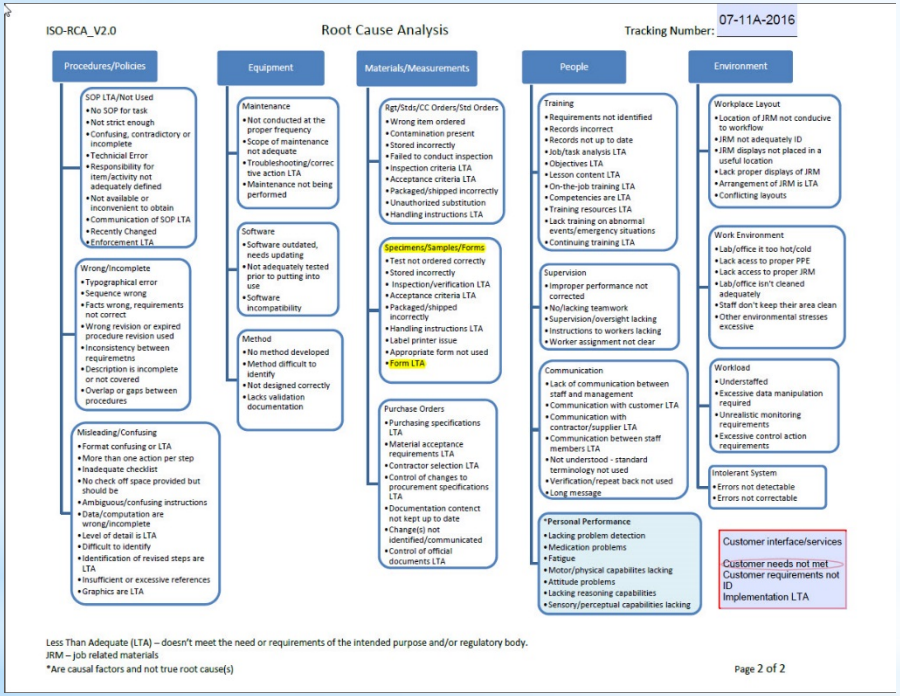

ISO-RCA_V2.0

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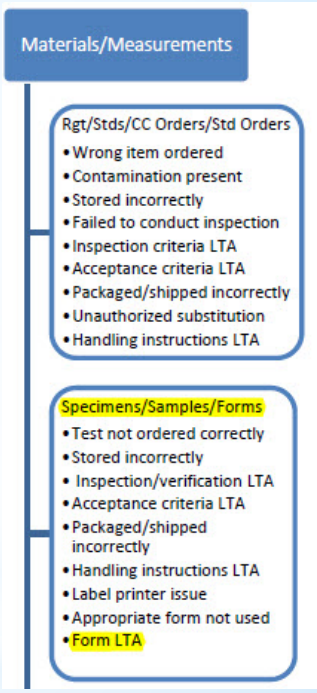
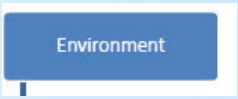
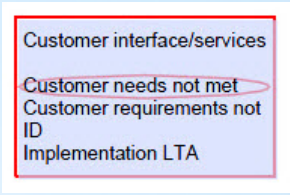


Materials/Measurements

- Rgt/Stds/CC Orders/Std Orders
  - Wrong item ordered
  - Contamination present
  - Stored incorrectly
  - Failed to conduct inspection
  - Inspection criteria LTA
  - Acceptance criteria LTA
  - Packaged/shipped incorrectly
  - Unauthorized substitution
  - Handling instructions LTA
- Specimens/Samples/Forms
  - Test not ordered correctly
  - Stored incorrectly
  - Inspection/verification LTA
  - Acceptance criteria LTA
  - Packaged/shipped incorrectly
  - Handling instructions LTA
  - Label printer issue
  - Appropriate form not used
  - Form LTA

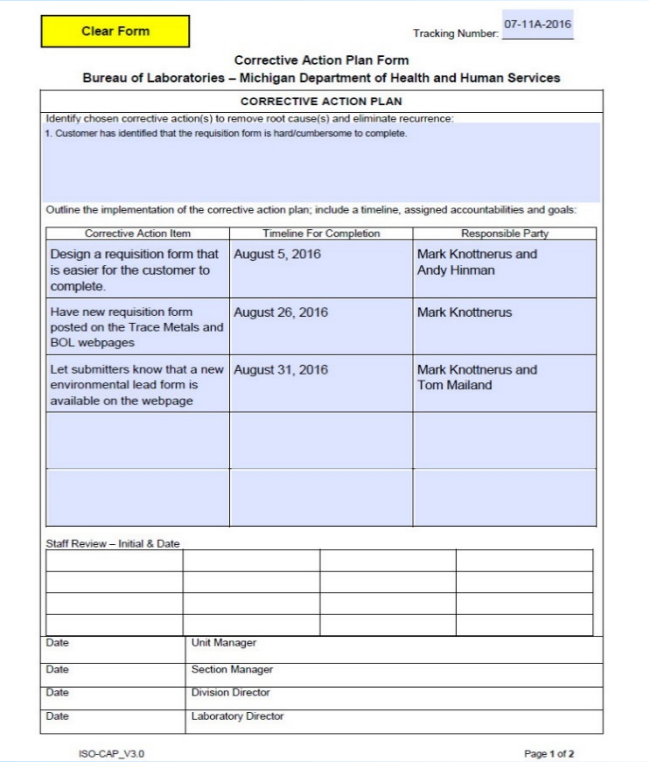


Environment



- Customer interface/services
- Customer needs not met
- Customer requirements not ID
- Implementation LTA

MDHHS LABORATORY RCA TOOL - EXAMPLE



Clear Form

Tracking Number: 07-11A-2016

Corrective Action Plan Form
Bureau of Laboratories – Michigan Department of Health and Human Services

CORRECTIVE ACTION PLAN

Identify chosen corrective action(s) to remove root cause(s) and eliminate recurrence:
1. Customer has identified that the requisition form is hard/cumbersome to complete.

Outline the implementation of the corrective action plan; include a timeline, assigned accountabilities and goals:

Corrective Action Item	Timeline For Completion	Responsible Party
Design a requisition form that is easier for the customer to complete.	August 5, 2016	Mark Knottnerus and Andy Hinman
Have new requisition form posted on the Trace Metals and BOL webpages	August 26, 2016	Mark Knottnerus
Let submitters know that a new environmental lead form is available on the webpage	August 31, 2016	Mark Knottnerus and Tom Mailand

Staff Review – Initial & Date

Date	Unit Manager
Date	Section Manager
Date	Division Director
Date	Laboratory Director

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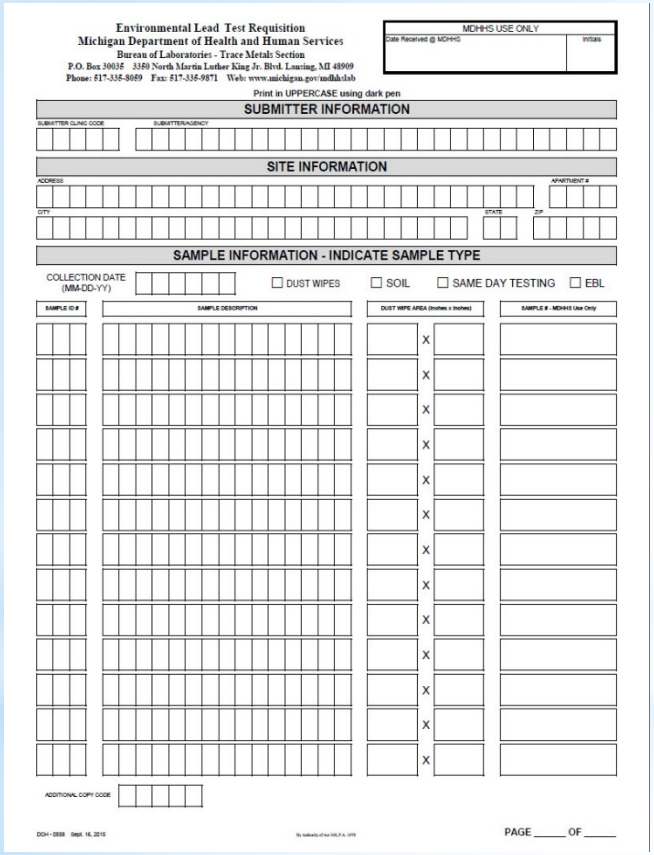
- Corrective Action Plan
  - Outlined what we are going to do, when we are going to do it and who is going to be responsible for doing it
  - Routed for appropriate signatures
- 30 day and 60 day follow ups are scheduled after the return of the paper to the unit.

MDHHS LABORATORY RCA TOOL - EXAMPLE



Environmental Lead Test Requisition
Michigan Department of Health and Human Services
Bureau of Laboratories - Trace Metals Section
P.O. Box 30035 3350 North Martin Luther King Jr. Blvd. Lansing, MI 48909
Phone: 517-335-8059 Fax: 517-335-9871 Web: www.michigan.gov/mdhhslab

MDHHS USE ONLY
Date Received @ MDHHS | Initials

Print in UPPERCASE using dark pen

SUBMITTER INFORMATION
SUBMITTER CLINIC CODE | SUBMITTER/AGENCY

SITE INFORMATION
ADDRESS | APARTMENT # | CITY | STATE | ZIP

SAMPLE INFORMATION - INDICATE SAMPLE TYPE
COLLECTION DATE (MM-DD-YY) ☐ DUST WIPES ☐ SOIL ☐ SAME DAY TESTING ☐ EBL

SAMPLE ID #	SAMPLE DESCRIPTION	DUST WIPE AREA (inches x inches)	SAMPLE # - MDHHS Use Only
		x	

ADDITIONAL COPY CODE

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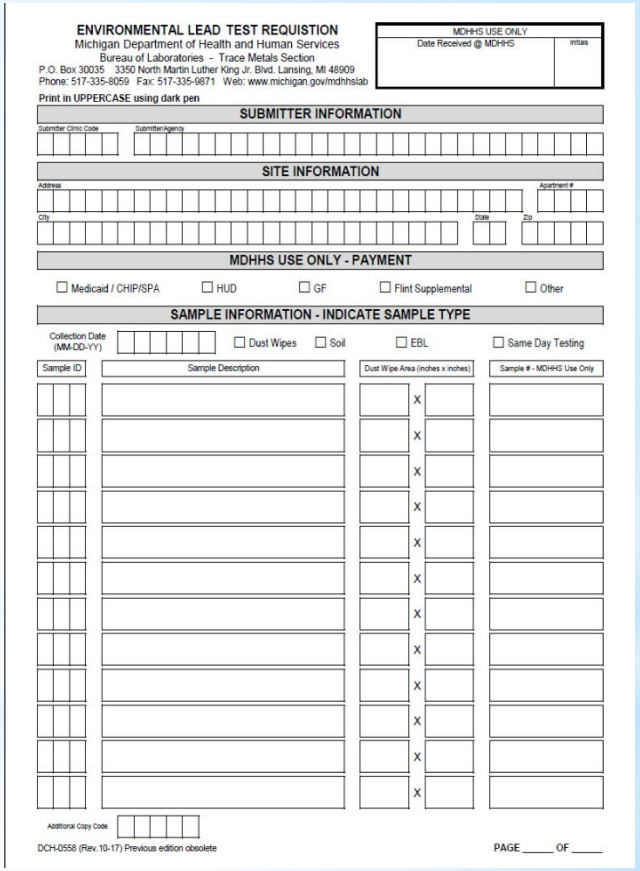

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MDHHS USE ONLY
Date Received @ MDHHS | Initials

Print in UPPERCASE using dark pen

SUBMITTER INFORMATION
Submitter Clinic Code | Submitter/Agency

SITE INFORMATION
Address | Apartment # | City | State | Zip

MDHHS USE ONLY - PAYMENT
☐ Medicaid / CHIP/SPA ☐ HUD ☐ GF ☐ Flint Supplemental ☐ Other

SAMPLE INFORMATION - INDICATE SAMPLE TYPE
Collection Date (MM-DD-YY) ☐ Dust Wipes ☐ Soil ☐ EBL ☐ Same Day Testing

Sample ID	Sample Description	Dust Wipe Area (inches x inches)	Sample # - MDHHS Use Only
		x	

Additional Copy Code

DCH-0558 (Rev.10-17) Previous edition obsolete | PAGE ____ OF ____

http://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5103_71371-364555--,00.html

LESSONS LEARNED

- MUST HAVES
  - Staff input
  - Standardization
- Pilot this in a small section/area of the lab to improve the tools ease of use, prior to implementing labwide.

REFERENCES

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- "Curse of the Super-fish-al." Martin Hedley, Back to Basics, July 2005, www.asq.org
- "Root Cause Analysis: A Framework for Tool Selection" A. Mark Doggett, Humboldt State University, Quality Management Journal, Volume 12, No. 4, 2005, 34-45
- "Getting to the Root of the Problem" Deborah Hopen, Deborah Hopen Associates Inc., James J. Rooney, ABS Consulting. Six Sigma Forum Magazine, November 2014, 27-29.

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