IOWA

State Hygienic Laboratory

Initiating Nonconforming Events (NCE) in iPassport

Training Supplemental Guide 2023

By The State Hygienic Laboratory Training & Education Team

Purpose: The purpose of this guide is to provide State Hygienic Laboratory staff with basic steps to follow to initiate a nonconforming (or Non Compliance) event (NCE) in iPassport, the SHL official document management system. This guide is a supplement to the step-by-step video tutorial the SHL training team created. **If you need any clarification on how to correctly complete this process consult with your supervisor or the Quality Manager. For additional guidance you can watch the [Initiating NCE's In iPassport video tutorial](#).**
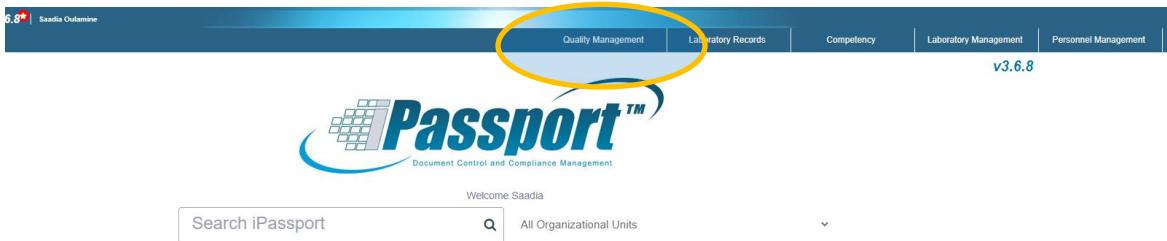
Steps to Initiate a Nonconforming Event

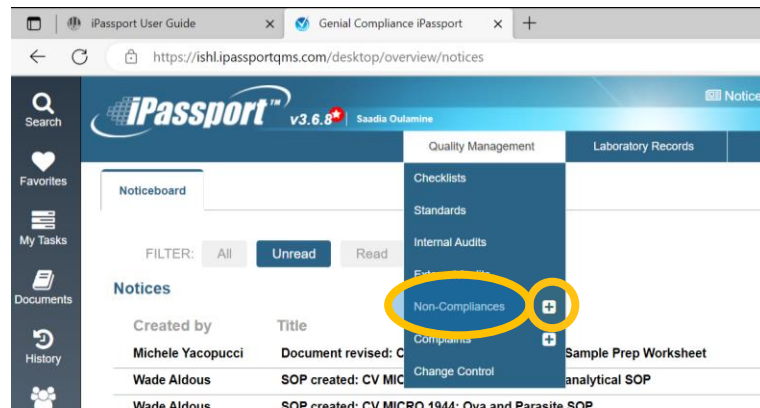**1. Click " Detailed View" on the sidebar**
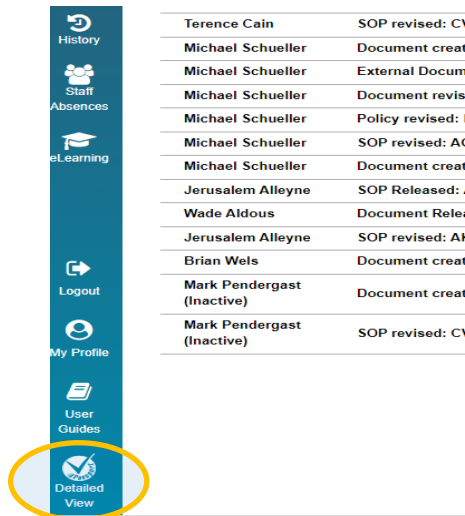
> **Note**
> If you do not have access to the **detailed view**,
> please let your supervisor know.

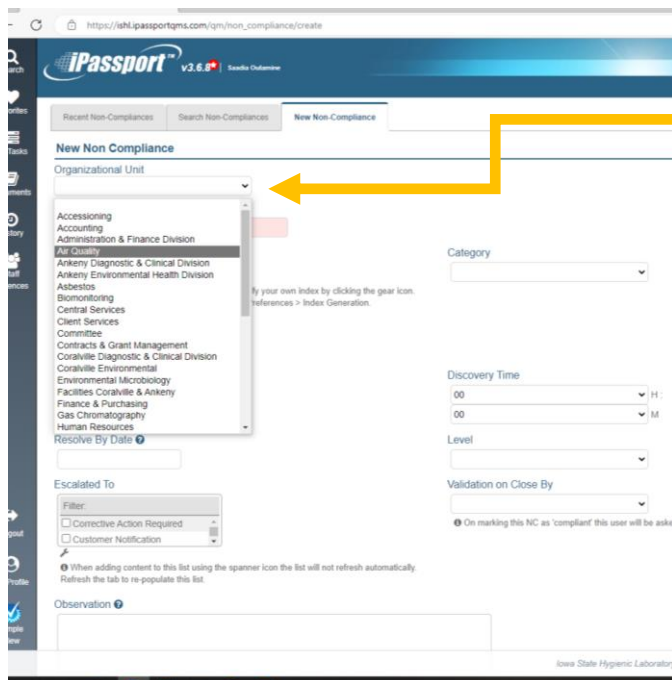2. From the main menu, click **" Quality Management"**

3. Select the **" +"** sign next to the**" Non-Compliances"** from the drop down sub-menu to open a new record
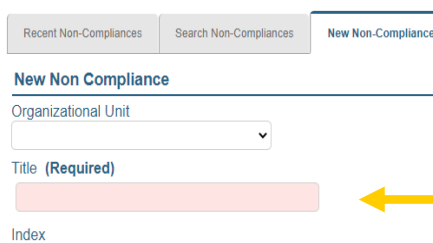
4. Enter the field data required as demonstrated below:

A. Organizational Unit (OU)

Select from the drop down menu the organizational unit which is most closely affected by the NCE.

B. Title

Include the lab location code where the NCE occurred. AK for Ankeny, CV for Coralville, or LK for Lakeside. Then a brief description of the non-compliance.

C. Index

Title **(Required)**

Index

Auto Generate ⚙

ⓘ When creating a non compliance, you can specify your own index by clicking the gear icon.
Configure automatically-generated index's in OU Preferences > Index Generation.

> The index is auto generated. **Do not modify.**

D. Category

> Next select the category which most closely matches the impact of your NCE.

E. Locations

Locations

Filter:

☐ Contracts & Grants Management

> Now select the location or locations that match openElis sections.

F. Non-Compliance Number, Discovery Date & Time

Non Compliance Number

Discovery Date ❓

> This is an optional field if the initiator wants to document the OE number, or the worksheet number associated with the PT sample.

> Select the date the report of the NCE was received by the lab.

Discovery Time

00 H :
00 M

Leave blank unless this is relevant to the NCE. It would only be necessary if a sample exceeded holding time.

G. Resolve By Date

Discovery Date

Resolve By Date

February - 2023-

Sun Mon Tue Wed Thu Fri Sat
29 30 31 1   2   3   4
5   6   7   8   9   10 11
12 13 14 15 16 17 18
19 20 21 22 23 24 25
26 27 28 1   2   3   4

Observation

Set the date by which the NCE needs to be resolved by. Rule of thumb is **30 days** from the discovery date.

H. Level

00 M

Level

0 - Risk - Very Low
1 - Risk - Low
2 - Risk - Medium
3 - Risk - High
4 - Risk - Very High
9 DO NOT USE - HOLD FOR FUTURE USE
9.1 DO NOT USE - HOLD FOR FUTURE USE
9.2 DO NOT USE - HOLD FOR FUTURE USE
9.3 DO NOT USE - HOLD FOR FUTURE USE
9.4 DO NOT USE - HOLD FOR FUTURE USE
Not Assigned for this NCE

Leave the level section blank. This will be addressed by the staff member assigned responsibility for the NCE.

I. Non-Compliance Responsibility

Non-Compliance Responsibility

Filter:
☐ Jennifer Elwood
☐ Jerusalem Alleyne

ⓘ List here the user(s) responsible for reviewing or correcting this non compliance.

Assign non-compliance responsibility. This depends on the nature of the NCE. Technical issues go to the section supervisor. Quality management issues go to the quality manager, and customer service issues go to the client services director.

J. Escalated to

Escalated To

Filter:
☐ Corrective Action Required
☐ Customer Notification

Choose an escalated to option if it applies to your NCE. Note that all failed PT evaluations require a corrective action.

K. Validation on Close By

Level

Validation on Close By

Abby Good
Abby Simbro
Abdullah Jadkarim
Abigail Raymer
Aissa Kergna
Alankar Kampoowale
Allison Hartman
Alyssa Daniel
Alyssa Mattson
Amanda Craft
Amanda Hughes
Amber Arens

e asked to verify that ne NC can be closed

tomatically.

For validation on close by choose the Quality Manager, which is currently Rebecca Blair.

L. Origin

Origin

Complaint
Corrected Report
External audit
External Form
Internal Audit
Internal Process
Lab Accident
Management Review
Outbreak
Preventative Action
Proficiency Testing
Section Identified
Survey

Chose the origin that best matches the NCE.

M. Observation

Staff sences

ⓘ When adding content to this list using the spanner icon the list will not refresh automatically.
Refresh the tab to re-populate this list.

Observation ❓

Use the observation field to explain what went wrong. **Do not include detail on any action taken.**
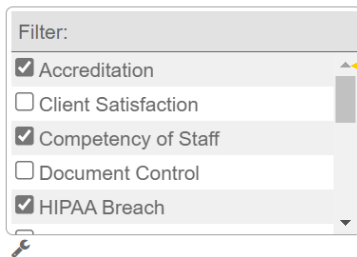
Immediate or Corrective Action Taken?

N. Immediate or Corrective Action Taken
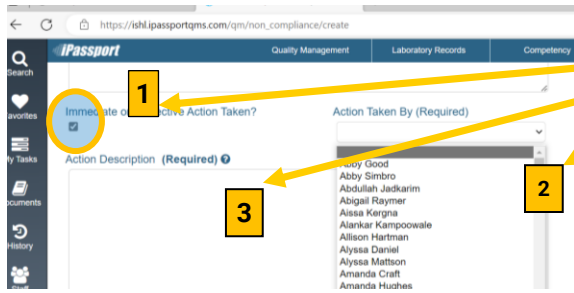
1. **Click the checkbox** if someone has taken action on the NCE being recorded.
2. **Select from the dropdown menu** the staff member that took the action
3. **Then provide detail** of what was done.

O. Non-Compliance Impact

From the dropdown menu, select one or multiple areas impacted by the NCE.

5. When all the details have been added, review the information you entered for accuracy. If you need assistance with double checking your work, consult the Non-Conforming Event (NCE) Management SOP, which is document QA 211in iPassport, and your supervisor or the quality manager if you need help interpreting the NCE initiation policies and procedures. Once you are ready click **Create** in the lower right-hand corner of the screen to submit the NCE.

6. Review the next screen for accuracy. All items with a pencil may be edited. **If you need to change the OU notify your Quality Systems Manager.**

Refer to NCE Below (Example)

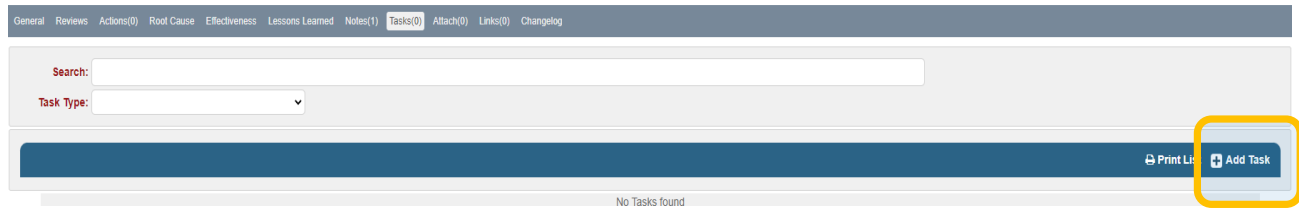## Steps to Assign A Task to The Staff Responsible for the NCE

The final step to initiating an NCE in iPassport, is to assign a task to the individual that was assigned responsibility for the NCE.

1. Click the " **Tasks**" menu tab
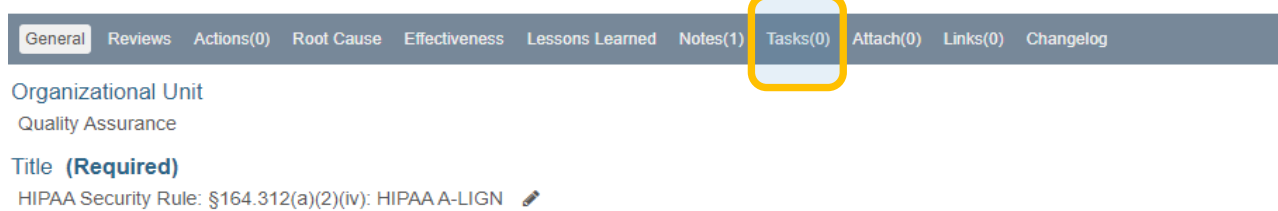
2. Click on " **+ Add Task**" in the new screen that pops up

3. Assign the task to the staff responsible for the NCE**.** The **due date** for this task should be a few days prior to the due date for the completion of the NCE process; this allows the person who is validating the NCE to verify everything has been documented and to request any additional evidence of compliance which supports the implementation of the corrective action plan. The **active date** is the date you are assigning the task.

4. Select medium for priority and copy the Quality Manager and Quality Systems Manager; currently Rebecca Blair and Molly Bradshaw. Then enter the following in the description filed:

    Please complete the root cause analysis and corrective action determination using the template, "NCE Questions to Answer Under Root Cause Tab" found in QA 211. Copy and paste this template in the "Root Cause" tab of this NCE.

5. Scroll down and click " **Create Task**". The staff responsible for the NCE will receive notification from iPassport that this task was assigned to them to complete. You have now completed the NCE initiation process!