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Incident Reporting

Objectives

- Define incident reporting
- Understand importance of raising/reporting incidents as per accreditation standards
- Review the CAPA module guidelines in Q-Pulse

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Definitions

- **Nonconformity -** nonfulfillment of a requirement

- ***Non-Conforming Event (NCE)* –** an occurrence that does not conform to the laboratory's policies, processes and/or procedures, does not conform with applicable regulatory or accreditation requirement; or has the potential to affect (or has affected) patient, donor or employee safety.
  - ***External Concern* –** a complaint, an unresolved problem or issue communicated by a client**.** The complaint or opportunity may be service related, or may involve a pre-analytical, analytical testing, or post analytical process.
    - recorded by the Technical Service (TS) or Business Development (BD) teams.
  - ***Internal Concerns* –** a complaint or unresolved problem, issue or opportunity for improvement identified by personnel
    - recorded by personnel for documentation purposes

- ***Corrective Action*** – action to eliminate the cause of a *detected* nonconformity or other undesirable situation

- ***Preventive Action*** - action to eliminate the cause of a *potential* nonconformity or any other potential situation

Synonyms

CAPA (Corrective action/ Preventive action)

Incident

Nonconformity

Concern , issue, error, problem, event, etc.

Quality concern

Client/customer concern

Non conforming event

OVR (Occurrence Variant Report)

CAP Lab Gen Checklist

****REVISED**** ***08/17/2016***

COM.04000 **Written QM Program** **Phase II**

The laboratory has a written quality management (QM) program.

NOTE: The program must ensure quality throughout the pre-analytic, analytic, and post-analytic (reporting) phases of testing, including patient identification and preparation; specimen collection, identification, preservation, transportation, and processing; and accurate, timely result reporting. The program must be capable of detecting problems in the laboratory's systems, and identifying opportunities for system improvement. The laboratory must be able to develop plans of corrective action based on data from its QM system.

All QM requirements in the Laboratory General Checklist pertain to the laboratory.

Evidence of Compliance:

- ✓ Records reflecting conformance with the program as designed **AND**
- ✓ Results of quality surveillance

CAP Lab Gen Checklist

GEN.20208 **QM Patient Care Services** **Phase II**

The QM program includes a process to identify and evaluate errors, incidents and other problems that may interfere with patient care services.

NOTE: There must be an organized process for recording of problems involving the laboratory that are identified internally, as well as those identified through outside sources such as complaints from patients, physicians or nurses. The process must be implemented in all sections of the laboratory, and on all shifts. Any problem that could potentially interfere with patient care or safety must be addressed. Clinical, rather than business/management issues, should be emphasized. The laboratory must record investigation and resolution of these problems. Laboratories must perform root cause analysis of any unexpected event involving death or serious physical or psychological injury, or risk thereof (including "near misses" and sentinel events). Laboratories must be able to demonstrate appropriate risk-reduction activities based on such root cause analyses.

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CAP Lab Gen Checklist

GEN.20325 **Employee and Patient Quality Communication** **Phase II**

The laboratory has a procedure for employees and patients to communicate concerns about quality and safety to management.

NOTE: The investigation and analysis of employee and patient complaints and suggestions, with corrective or preventive action as appropriate, should be a part of the laboratory quality management program and be specifically addressed in laboratory quality management records.

Evidence of Compliance:

✓ Records of employee and patient complaints (if any) with appropriate follow up

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ISO 15189 Standards

4.9 Identification and control of nonconformities

The laboratory shall have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination or post-examination processes.

The procedure shall ensure that:

a) the responsibilities and authorities for handling nonconformities are designated;

b) the immediate actions to be taken are defined;

c) the extent of the nonconformity is determined;

d) examinations are halted and reports withheld as necessary;

e) the medical significance of any nonconforming examinations is considered and, where appropriate, the requesting clinician or authorized individual responsible for using the results is informed;

f) the results of any nonconforming or potentially nonconforming examinations already released are recalled or appropriately identified, as necessary;

g) the responsibility for authorization of the resumption of examinations is defined;

h) each episode of nonconformity is documented and recorded, with these records being reviewed at regular specified intervals to detect trends and initiate corrective action.

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ISO 15189 Standards

NOTE Nonconforming examinations or activities occur in many different areas and can be identified in many different ways, including clinician complaints, internal quality control indications, instrument calibrations, checking of consumable materials, interlaboratory comparisons, staff comments, reporting and certificate checking, laboratory management reviews, and internal and external audits.

When it is determined that nonconformities in pre-examination, examination and post-examination processes could recur or that there is doubt about the laboratory's compliance with its own procedures, the laboratory shall take action to identify, document and eliminate the cause(s). Corrective action to be taken shall be determined and documented (see 4.10).

ISO 15189 Standards

4.10 Corrective action

The laboratory shall take corrective action to eliminate the cause(s) of nonconformities. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

The laboratory shall have a documented procedure for:

a) reviewing nonconformities;

b) determining the root causes of nonconformities;

c) evaluating the need for corrective action to ensure that nonconformities do not recur;

d) determining and implementing corrective action needed;

e) recording the results of corrective action taken (see 4.13);

f) reviewing the effectiveness of the corrective action taken (see 4.14.5).

NOTE Action taken at the time of the nonconformity to mitigate its immediate effects is considered "immediate" action. Only action taken to remove the root cause of the problem that is causing the nonconformities is considered "corrective" action.

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ISO 15189 Standards

4.11 Preventive action

The laboratory shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

The laboratory shall have a documented procedure for:

a) reviewing laboratory data and information to determine where potential nonconformities exist;

b) determining the root cause(s) of potential nonconformities;

c) evaluating the need for preventive action to prevent the occurrence of nonconformities;

d) determining and implementing preventive action needed;

e) recording the results of preventive action taken (see 4.13);

f) reviewing the effectiveness of the preventive action taken.

NOTE Preventive action is a proactive process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints (i.e. nonconformities). In addition to review of the operational procedures, preventive action might involve analysis of data, including trend and risk analyses and external quality assessment (proficiency testing).

ISO 15189 Standards

4.12 Continual improvement

The laboratory shall continually improve the effectiveness of the quality management system, including the pre-examination, examination and post-examination processes, through the use of management reviews to compare the laboratory's actual performance in its evaluation activities, corrective actions and preventive actions with its intentions, as stated in the quality policy and quality objectives. Improvement activities shall be directed at areas of highest priority based on risk assessments. Action plans for improvement shall be developed, documented and implemented, as appropriate. The effectiveness of the actions taken shall be determined through a focused review or audit of the area concerned (see also 4.14.5).

Laboratory management shall ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care. When the continual improvement programme identifies opportunities for improvement, laboratory management shall address them regardless of where they occur. Laboratory management shall communicate to staff improvement plans and related goals.

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Designated Responsibilities

Initiator

- Any staff member can raise a CAPA (internal concern)
- TS or BD raise external/client concerns
- Must include a factual description with demographic information

Responder

- Involves the factual descriptions (investigation details), corrective action and root cause analysis stages in CAPA module.
- As one stage is completed, the next stage will be assigned to the next responsible person as per department hierarchy

Reviewer

- QA tracks the documents in circulation, monitor responses, enter appropriate information into the CAPA module for tracking and compile summary reports on a monthly basis.
- Request additional corrective action, if required
- Review Quality Concern Dashboard data for trends and process improvement initiatives
- Monthly Quality Concern Meeting

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Q-Pulse - CAPA Module Features

- Each event is traceable to a unique tracking number
- Security feature wherein reported event can only be accessed by the involved personnel and administrative staff named on the incident report (secondary and primary users)
- Sends e-mail notification and reminders to responsible persons
- Collected data can be saved as an attachment and serves as an evidence for future reference

How to handle CAPAs:

Non-punitive

Used to enhance/improve system and processes

Company confidential documents

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CAPA Process

Once an event is detected
the following actions are observed:

REMEDIAL/IMMEDIATE Action = Alleviate the concern (respond to as much of the concern as possible according to the event details gathered)

Isolated event?

- Can stop at immediate/ remedial

- Recurring event?
  - Implement corrective/preventive action based on root cause analysis

Notify all necessary stakeholders

Document the incident in

CAPA module of Q-Pulse

Examples of remedial action:

- ✓ Provision of status of results on turnaround around time delay
- ✓ Sample recollection
- ✓ Issuance of corrected / revised report
- ✓ Implement an interim work process

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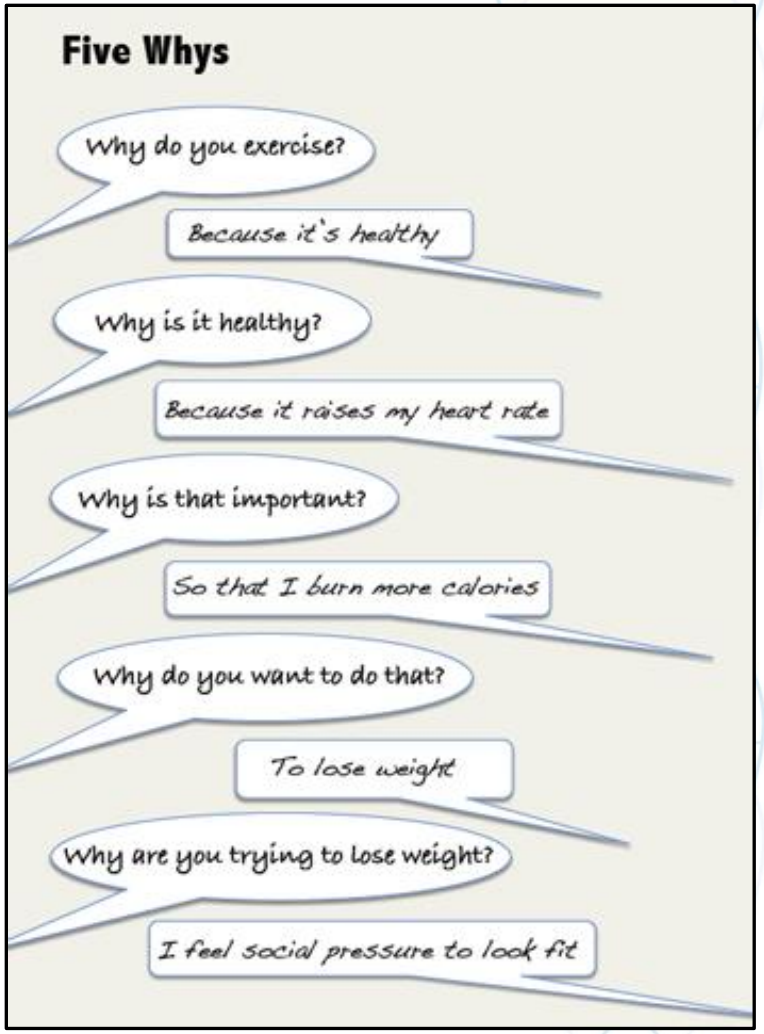
Root Cause Analysis (RCA)

5 Whys:

- Simplest RCA tool
- Start with your problem and ask "why" until you come to the ultimate cause.
- This may take more or less than five "whys," but five questions will commonly come to the root of the problem.

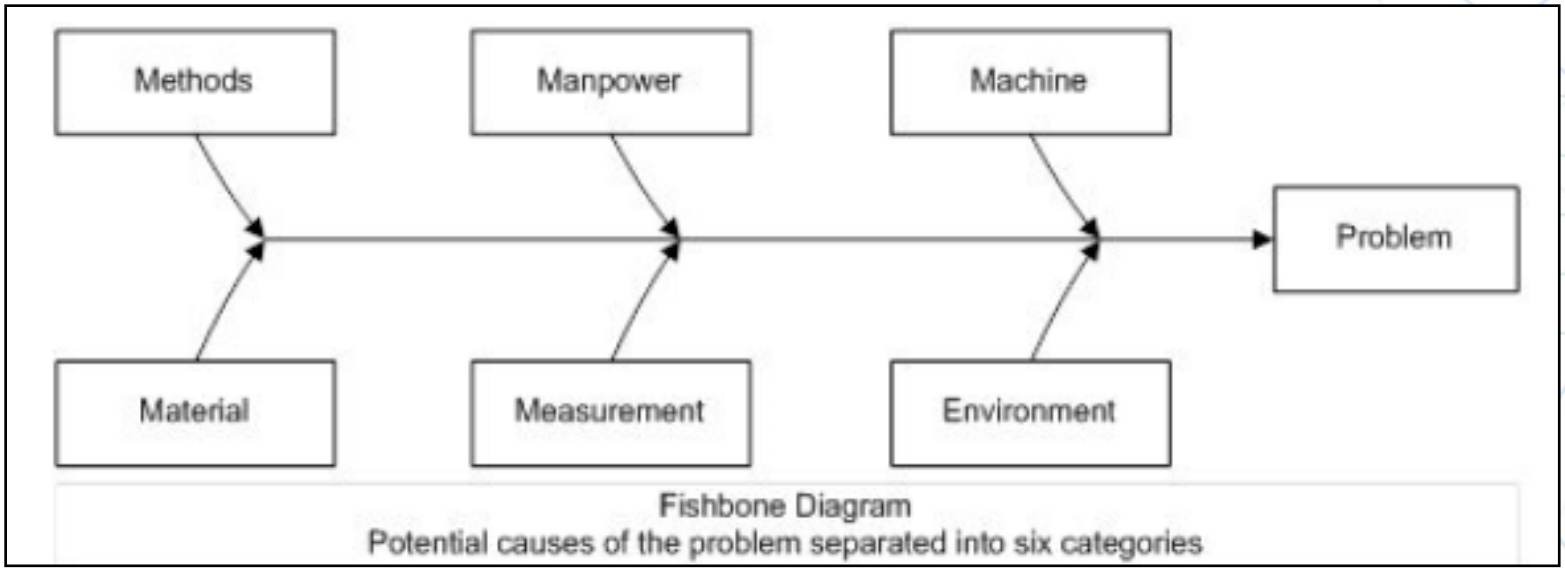


https://advisera.com/9001academy/blog/2016/03/01/how-to-use-root-cause-analysis-to-support-corrective-actions-in-your-qms/

Root Cause Analysis (RCA)

Fishbone diagram:

- Often called "cause and effect diagrams" and is considered a basic tool of quality used in RCA
- This tool was first created by Karou Ishikawa in 1968 and is used as a method to organize a team to **brainstorm** the possible causes of a problem.



https://advisera.com/9001academy/blog/2016/03/01/how-to-use-root-cause-analysis-to-support-corrective-actions-in-your-qms/

Response Time

- Responder should provide an **initial investigation response within 72 hours** after creation of the CAPA.
  - This should include a detailed factual description of events which led to the incident with a proposed corrective action
- If this timeframe is not adhered to, escalation procedure is put into place:

If no response is received within 3 days the staff line manager will be notified

If no response is received within 4 days the QA Director will be notified

If no response is received within 5 days the Chief Medical Officer (CMO) will be notified

All opened CAPAs which are not addressed within 10 days will be forwarded to the CEO

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Closure of a Recorded CAPA

- Closure of CAPA is facilitated and documented by Quality Assurance (QA) Department in the CAPA module.
- Closure is done when no further actions are needed or necessary to correct the event.
- There is no defined timeframe for closure of CAPAs due to potential complexity of corrective/preventive actions suggested and implemented; however it is **encouraged to attempt to close incidences within 30 days** from the time the incident was raised.
- Quality Assessment Reports can be provided upon client requests for a formal written response of the concern.

Benefits of Incident Reporting

- Improvement of performance for both technical and non-technical areas
- Raises attention to resources needed
- Promotes consideration for possible lessons learned
- Provide prevention of occurrence to other facilities by encouraging standardization

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NRL References

NONCONFORMITY – INCIDENT REPORTING: QUALITY CONCERN REVIEW PROCEURE (NRL-QA-SOP-006)

CAPA MODULE in Q-PULSE INSTRUCTION GUIDELINES (NRL-QA-GDL-008)

Very important for repeated errors!!!

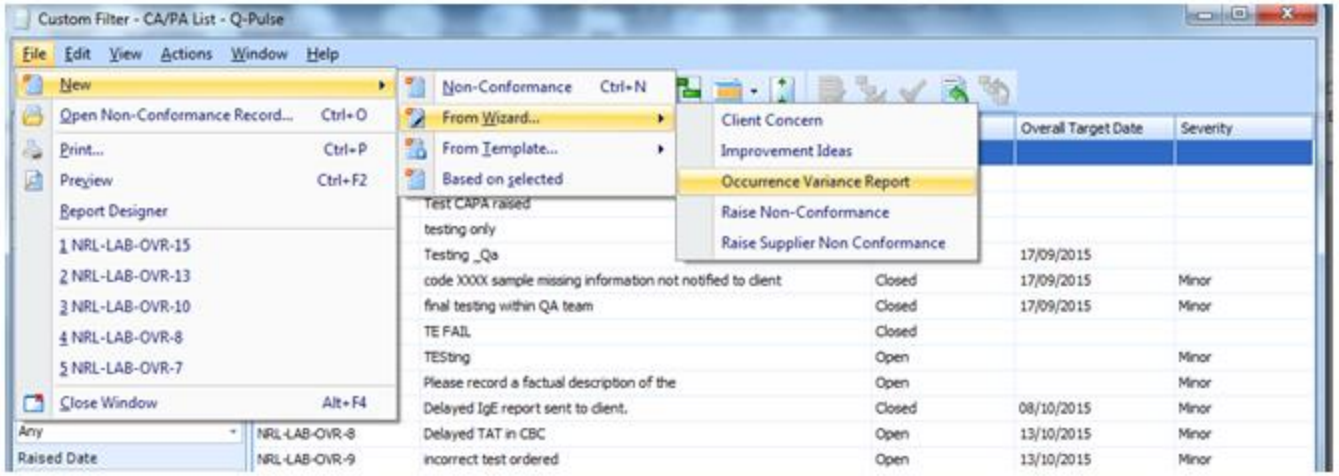
ERROR CATEGORIZATION AND CORRECTIVE ACTION NRL-QA-SOP-063

How to Raise a CAPA in Q-Pulse

a. Secondary User:

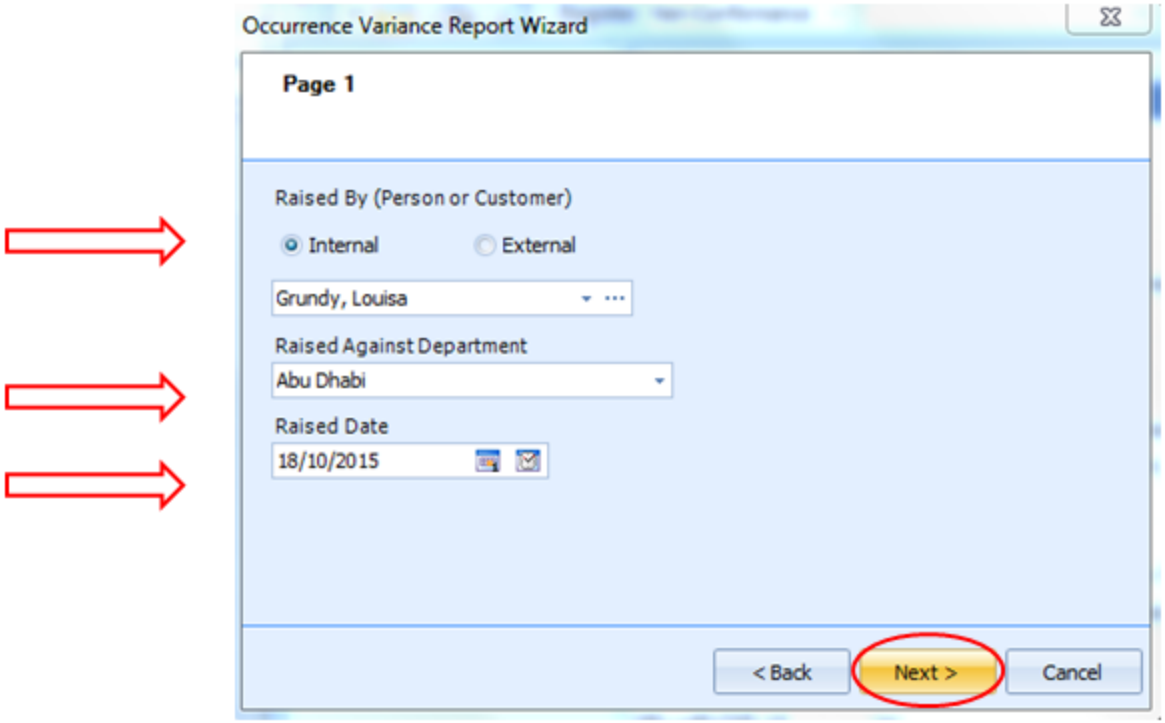
1. Log into Q-Pulse using your username and password. Select the **"CAPA"** module.

2. At the top left corner select: **File, New, From Wizard, Occurrence Variance Report**

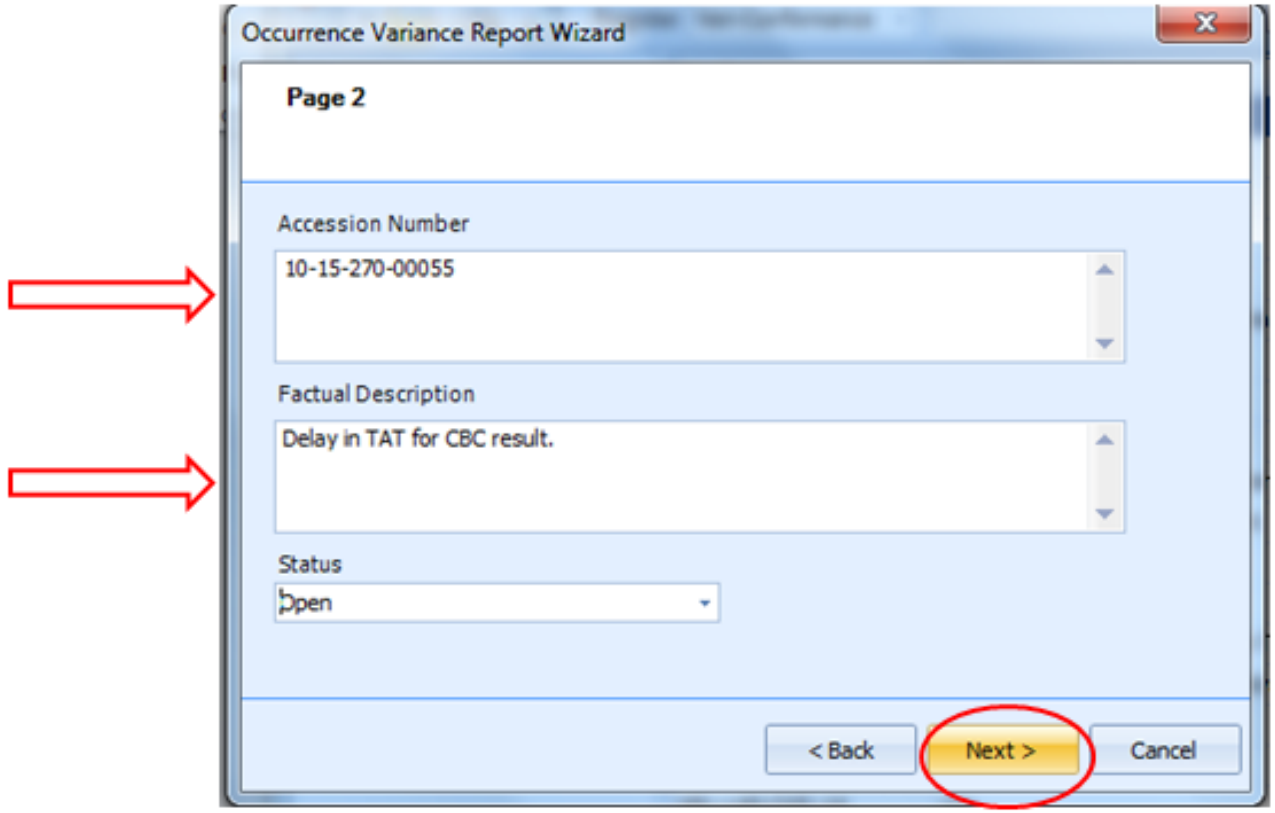


3. On-line wizard will open. Select Next:

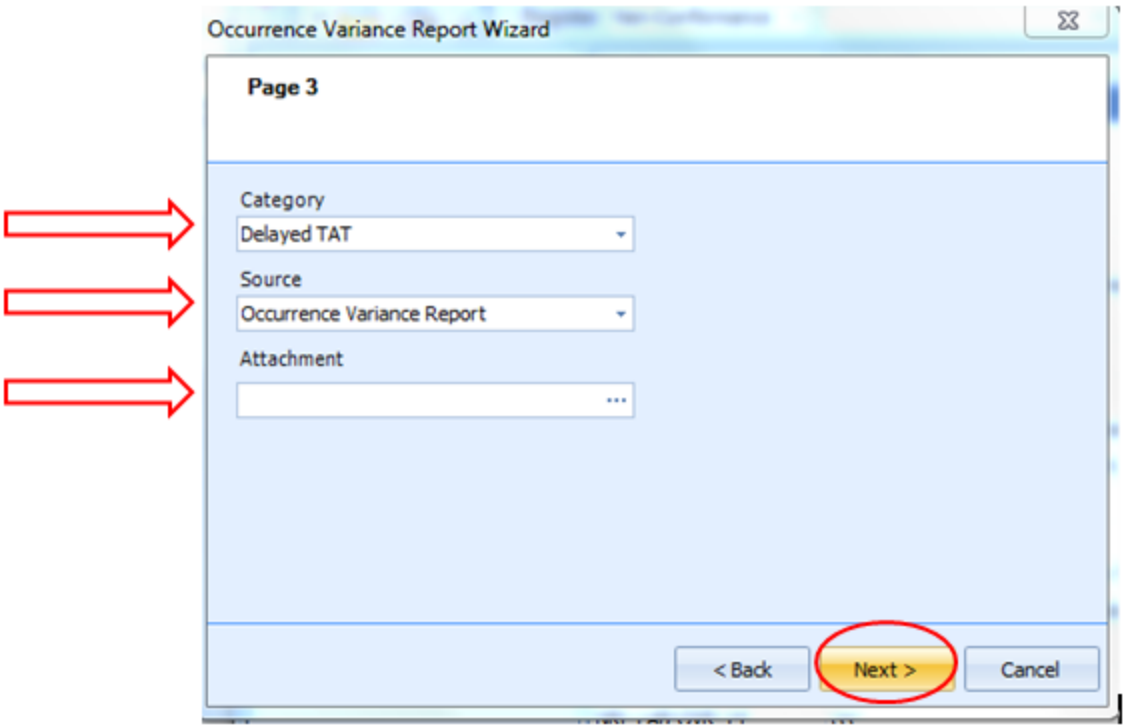
4. Select "internal" or "external" concern. For all "internal concerns" select your name at the "..." prompt as the person raising the concern. For external concerns scroll through the various customers at the "..." prompt to select the client who is raising the complaint.
   - At the "raised against department" prompt, use the drop down menu to select where the concern originated from (which department).
   - Select the "raised date".
   - Select "Next"



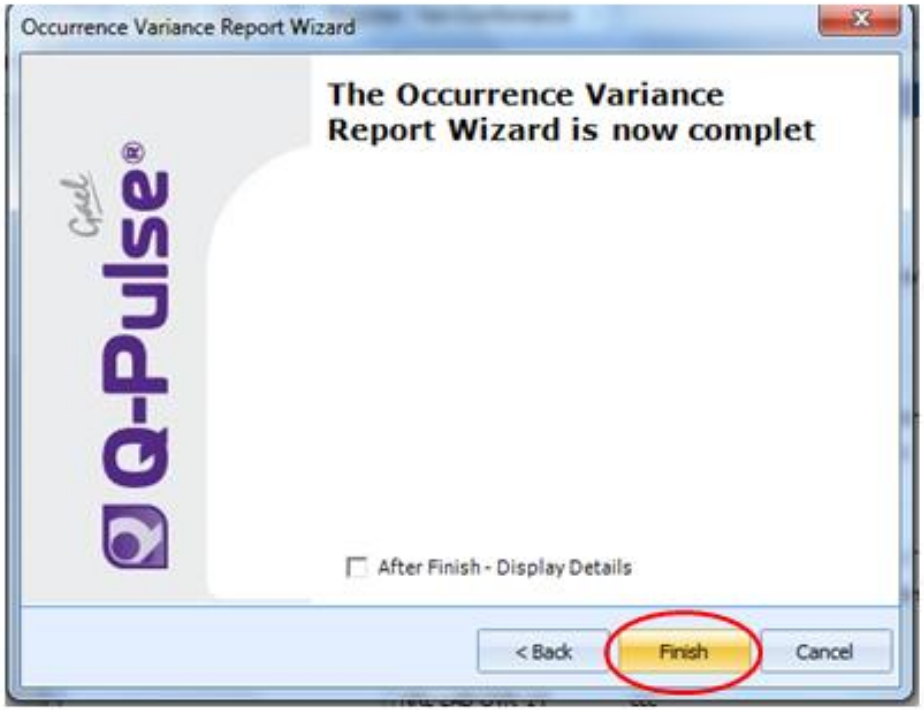
5. Enter the accession number(s) and/or other patient demographic information, a brief factual description of the concern. Leave the status as "open". Then select "Next".



6. Use the scroll down button to select the appropriate "Category" for the incident. The use the scroll down button to select the appropriate "Source" of the concern. For example, for internal lab concerns, select Laboratory – Occurrence Variance Report" for external concerns, you can select Customer Care – Client Concern.
   - If there are any attachments, such as copy of TRF or any other supporting document, kindly attach using the "..." prompt under "Attachment".
   - Select "Next"



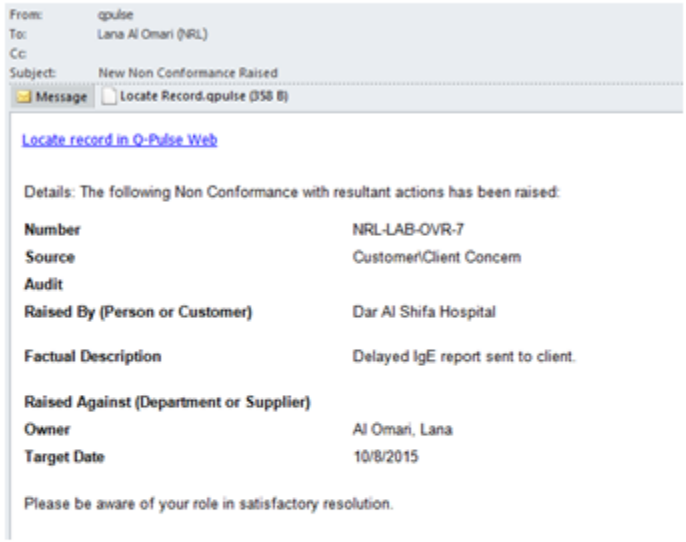
7. Select "Finish"



8. The CAPA/OVR will be assigned a number. Select "Ok". QA department will receive a notification that this OVR has been created.

Stage 1 – Factual Description

1. The person assigned to start the investigation for the "Factual description" part of the incident report will be e-mailed.



From: qpulse
To: Lana Al Omari (NRL)
Cc:
Subject: New Non Conformance Raised
Message | Locate Record.qpulse (358 B)

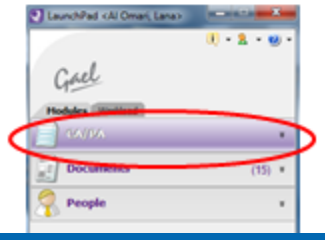
Locate record in Q-Pulse Web

Details: The following Non Conformance with resultant actions has been raised:

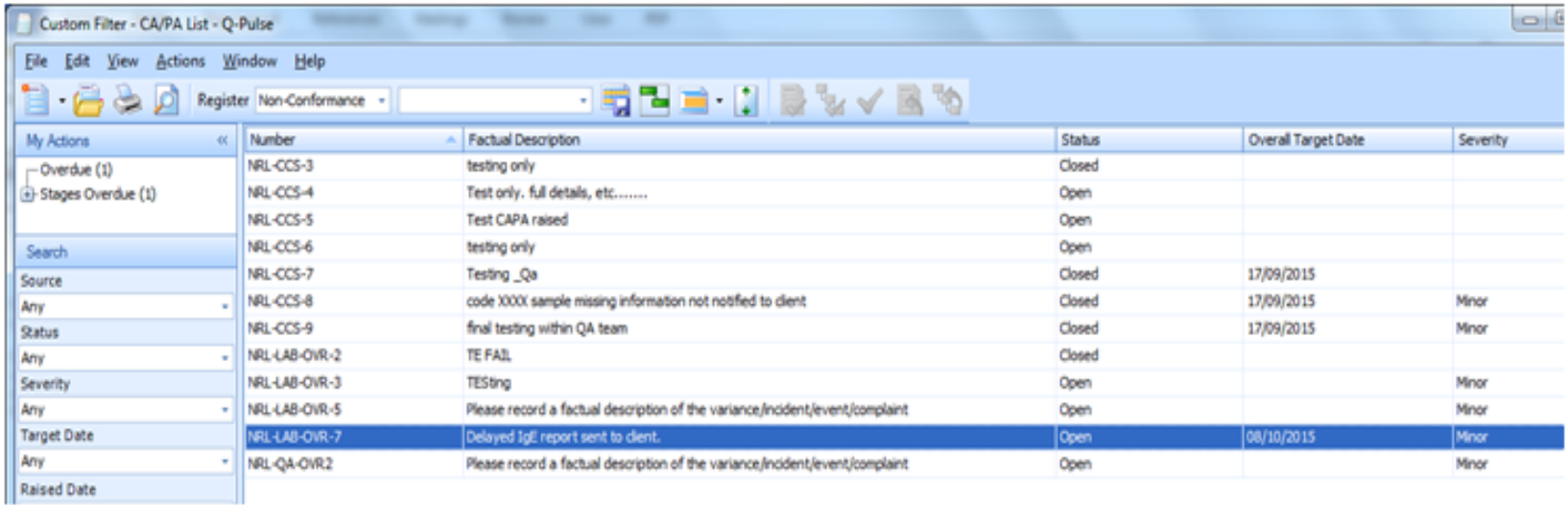
Number	NRL-LAB-OVR-7
Source	Customer\Client Concern
Audit	
Raised By (Person or Customer)	Dar Al Shifa Hospital
Factual Description	Delayed IgE report sent to client.
Raised Against (Department or Supplier)	
Owner	Al Omari, Lana
Target Date	10/8/2015

Please be aware of your role in satisfactory resolution.

2. Log into Q-Pulse using your username and password. Select the **"CAPA"** module.

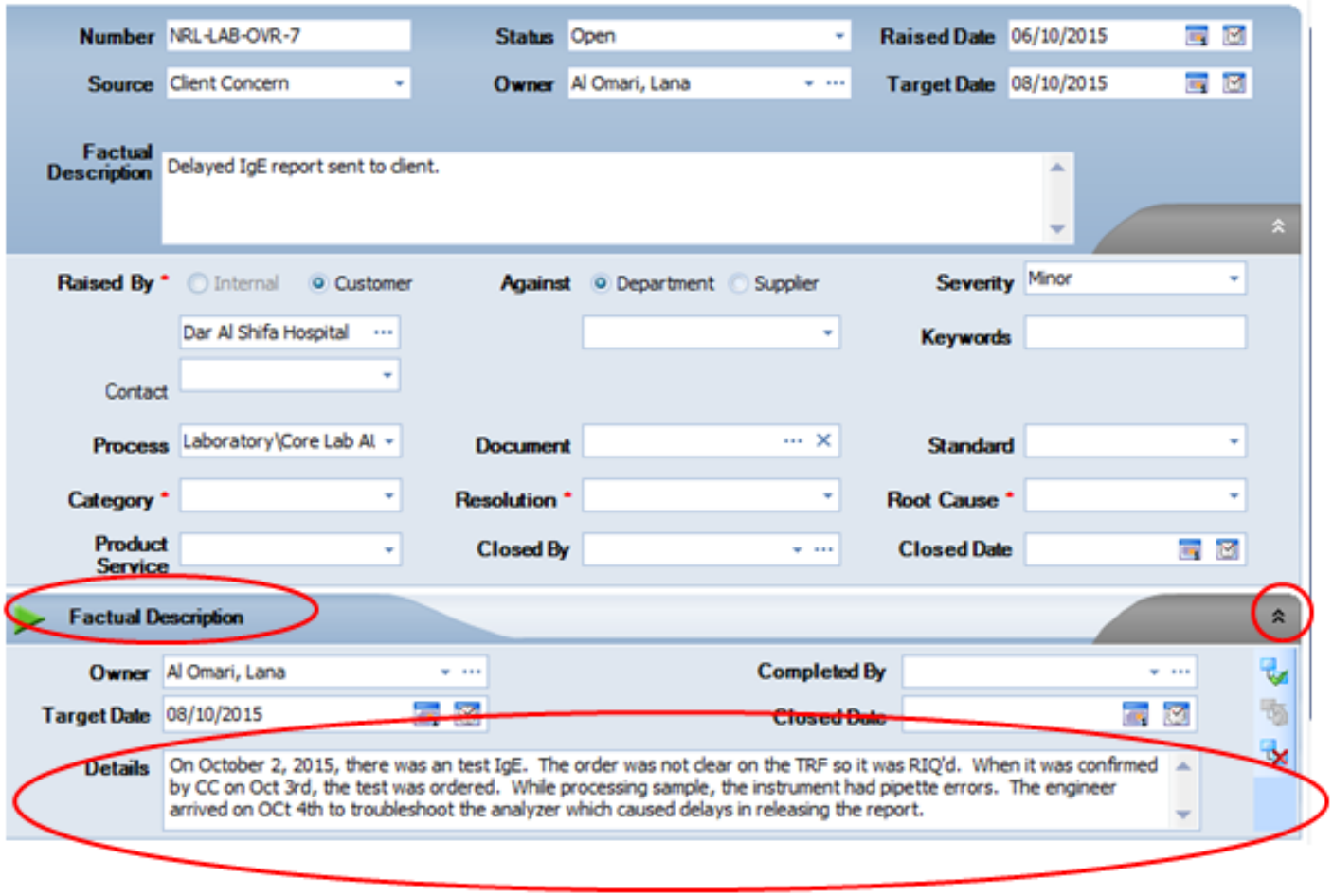


3. Select the OVR which was sent to you in the e-mail.

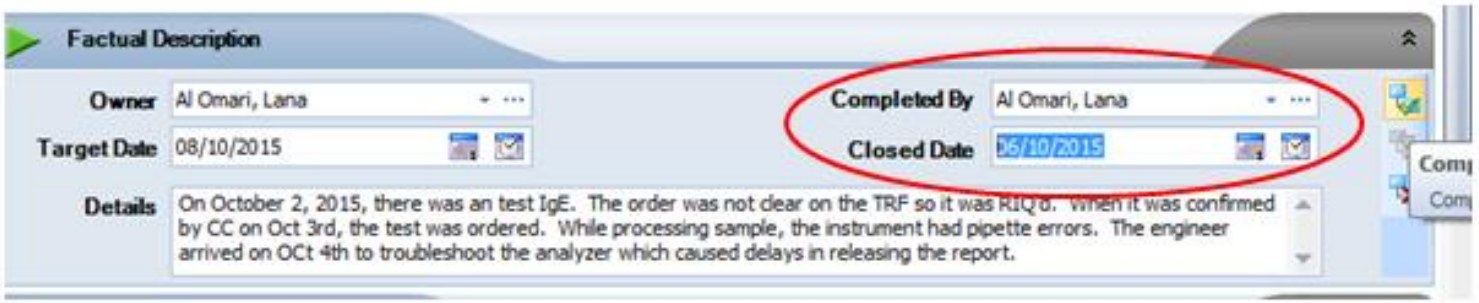


Note: If you are not the correct person who should be assigned to the incident, you can select the correct person from the "Owner" category and save accordingly. The correct person will be notified through e-mail and can continue with the below mentioned steps.

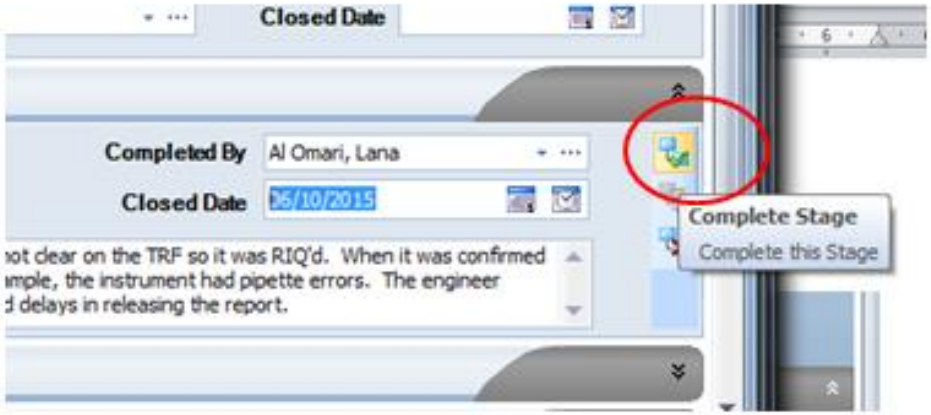
4. Open the **"Factual Description"** and provide a detailed explanation of the incident.



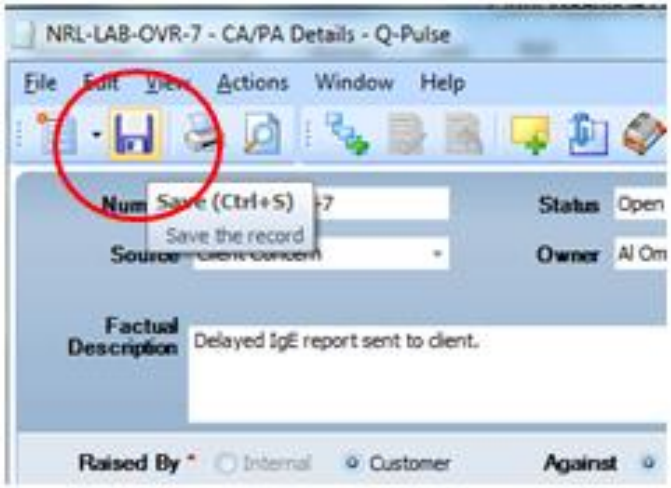
6. Select your name from the **"Completed By"** prompt and today's date as the **"Closed Date"**.



7. Select the **"Complete Stage"** button on the left of the screen.

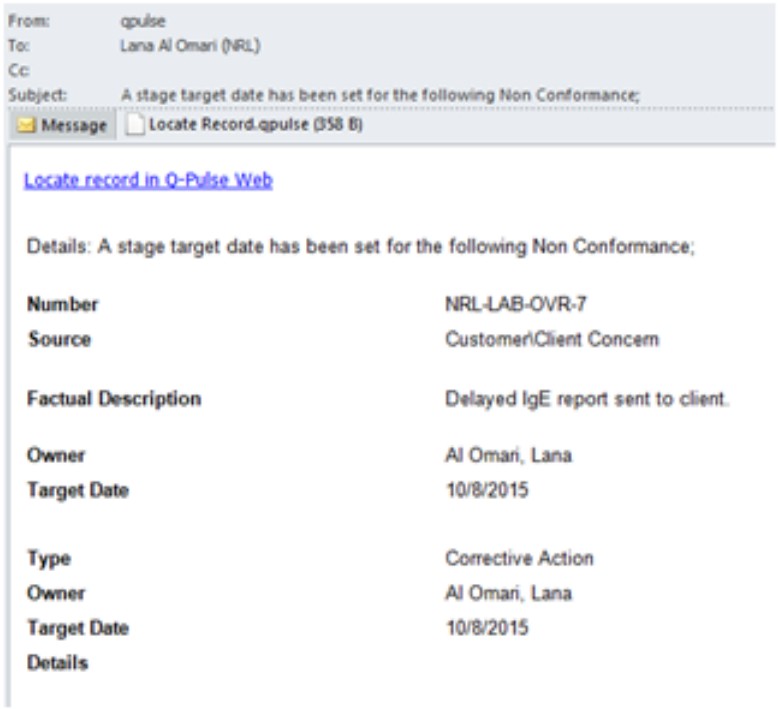


9. Select the **"Save"** button on the top left of the screen (a window will open to enter your username and password – then select "sign"). The person assigned will get an e-mail notification for necessary action.



Stage 2 – Corrective Action

1. The person assigned to stage 2 for the **"Corrective Action"** will receive an e-mail notification.



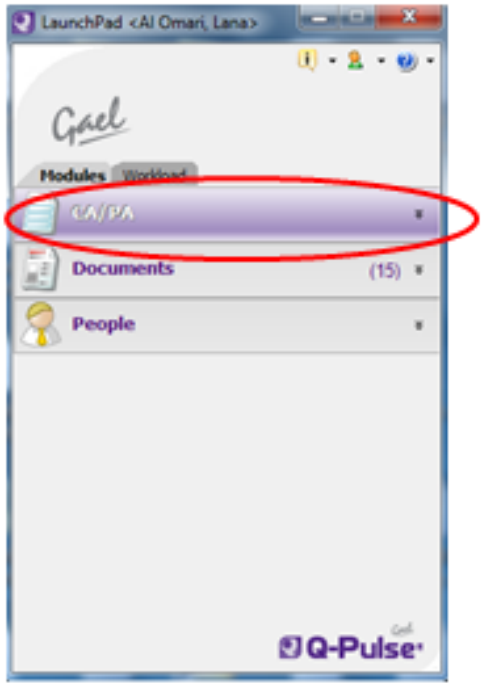
From: qpulse
To: Lana Al Omari (NRL)
Cc:
Subject: A stage target date has been set for the following Non Conformance;
Message | Locate Record.qpulse (358 B)

Locate record in Q-Pulse Web

Details: A stage target date has been set for the following Non Conformance;

Number	NRL-LAB-OVR-7
Source	Customer\Client Concern
Factual Description	Delayed IgE report sent to client.
Owner	Al Omari, Lana
Target Date	10/8/2015
Type	Corrective Action
Owner	Al Omari, Lana
Target Date	10/8/2015
Details	

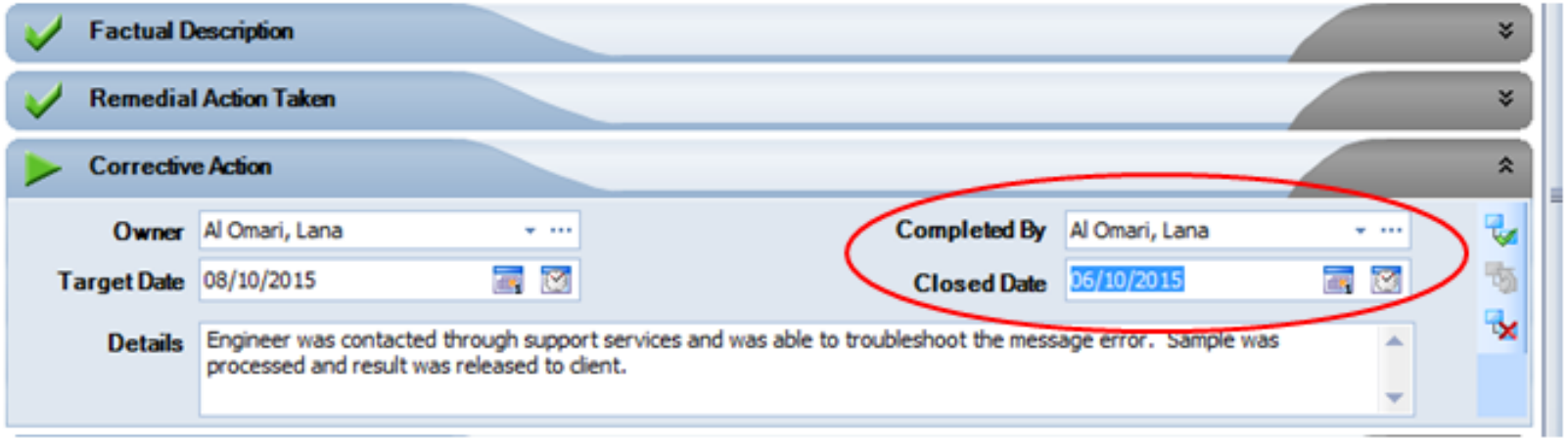
2. Log into Q-Pulse using your username and password. Select the **"CAPA"** module.



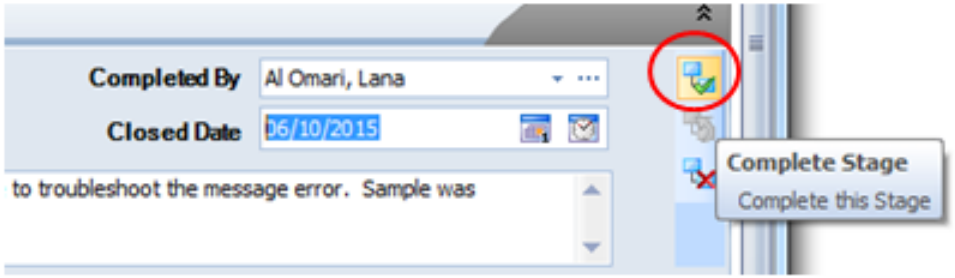
3. Select the OVR which was sent to you in the e-mail.

4. Open the **"Corrective Action"** and write the details of the corrective action(s) taken to resolve the incident.

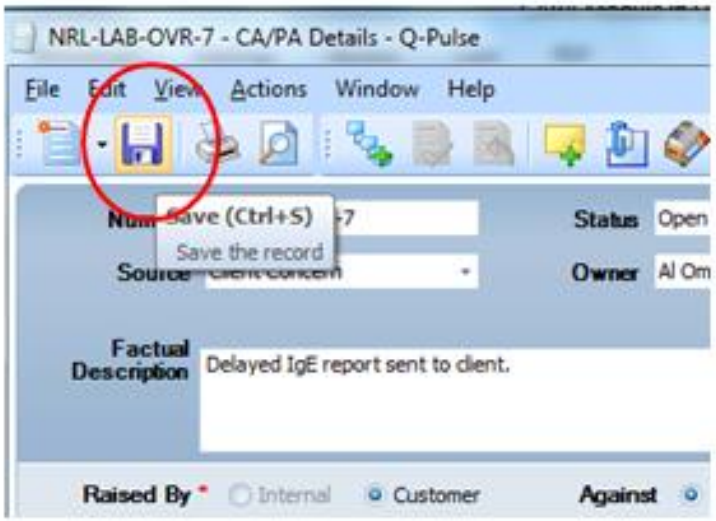
5. Select your name from the **"Completed By"** prompt and today's date as the **"Closed Date"**.



6. Select the **"Complete Stage"** button on the left of the screen.



8. Select the **"Save"** button on the top left of the screen (a window will open to enter your username and password – then select "sign"). The person assigned will get an e-mail notification for necessary action.



Stage 3 – Root Cause Analysis
Stage 4: QA Review

Follow same steps as mentioned in Stage 2 – Corrective Action

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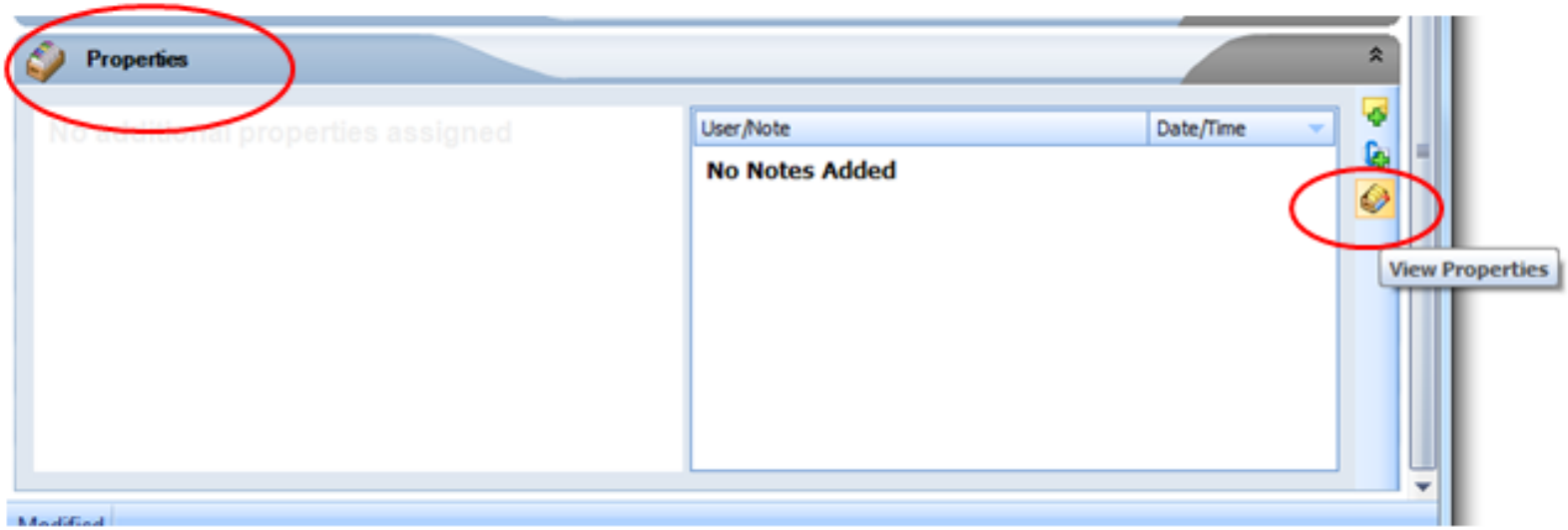
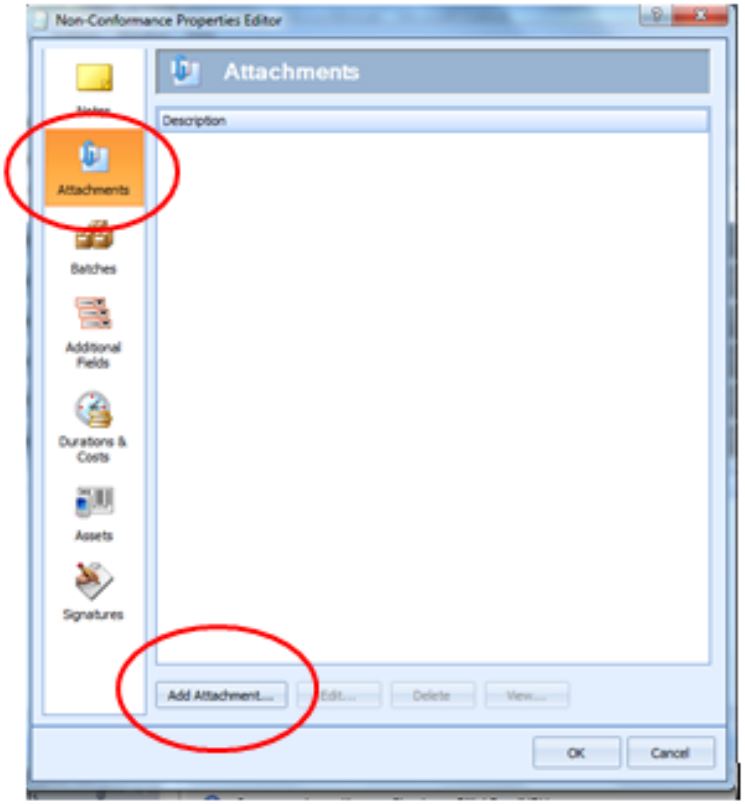
Uploading/ Attaching Documents

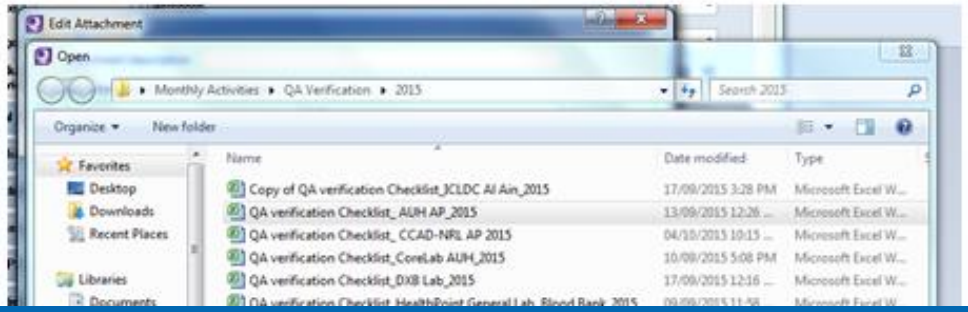
1. Open **"Properties"** section and then select the **"View Properties"** button on the right hand side of the screen.



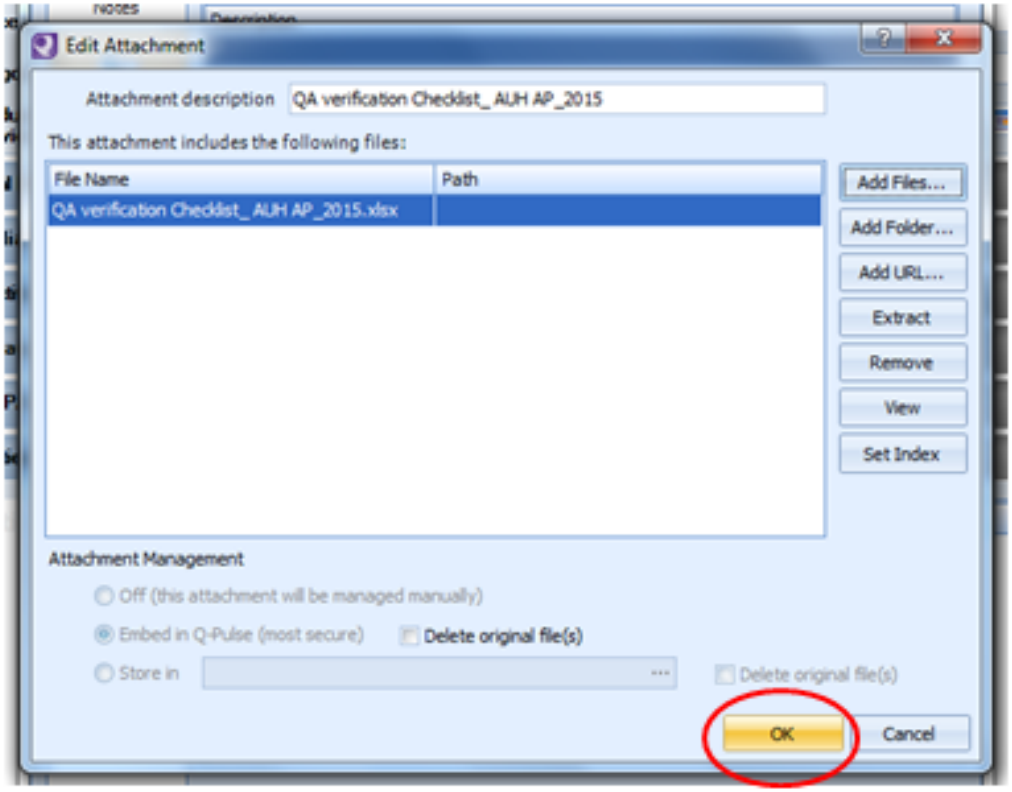
2. Select **"Attachments"** and then **"Add Attachment"**



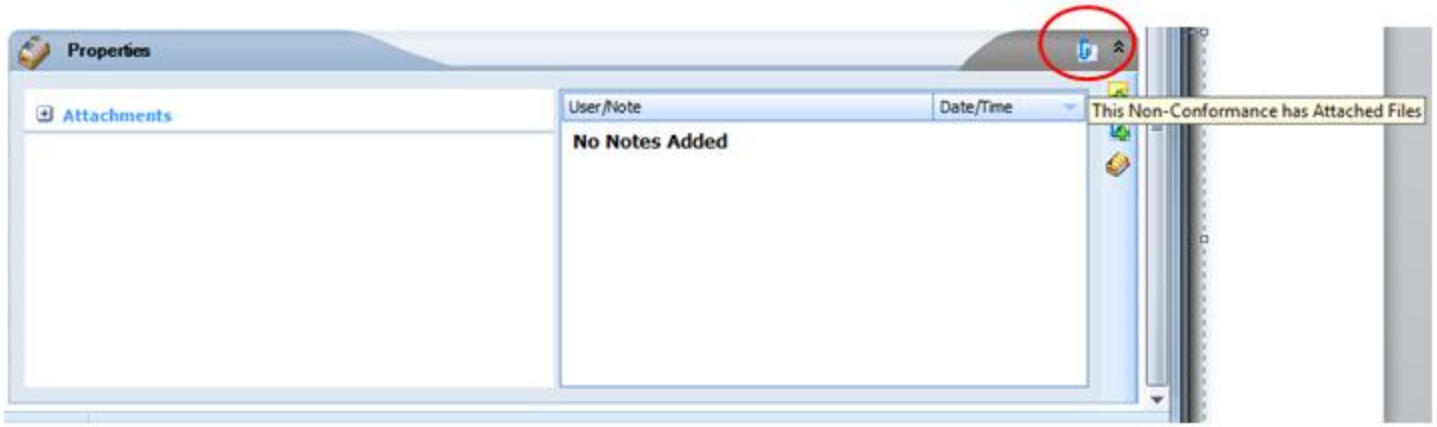
3. Select **"Add Files..."** button. And choose the document you want to upload. Then select **"Open"**.



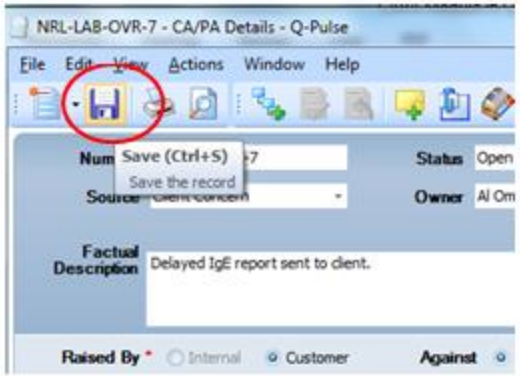
4. The attachment will be listed. Select "OK". Then select "OK" again.



5. The following paper clip icon will show up on the upper right hand corner of the Properties section when there is an attached document.



6. Select the **"Save"** button on the top left of the screen (a window will open to enter your username and password – then select "sign").



Thank You!