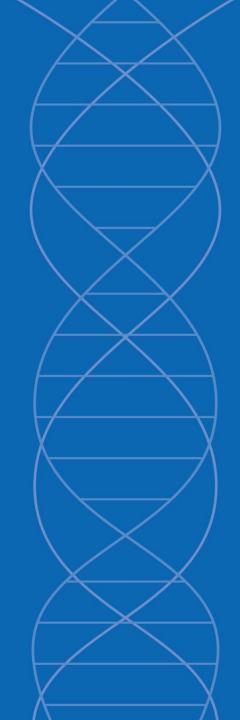


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Incident Reporting





Objectives

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





Definitions

- Nonconformity nonfulfillment of a requirement
- <u>Non-Conforming Event (NCE)</u> 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.
 - <u>External Concern</u> 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

- <u>Corrective Action</u> action to eliminate the cause of a detected nonconformity or other undesirable situation
- <u>Preventive Action</u> action to eliminate the cause of a potential nonconformity or any other potential situation





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Synonyms

CAPA (Corrective action/ Preventive action)	Incid	ent	Nonco	onformity	
Concern , issue, error, problem, event, etc.	Quality c	oncern		customer ncern	
Non con eve	•	O (Occu Variant			

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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



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CAP Lab Gen Checklist

Laboratory General Checklist

08.21.2017

Phase II

GEN.20208 QM Patient Care Services

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.



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



ISO 15189 Standards

4.9 Identification and control of nonconformities

The laboratory shall have a <u>documented procedure</u> 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;
- each episode of nonconformity is documented and recorded, with these records being reviewed at regular specified intervals to detect trends and initiate corrective action.



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 <u>could recur</u> or that there is doubt about the laboratory's compliance with its own procedures, the laboratory shall take action to identify, <u>document and eliminate the cause(s)</u>. Corrective action to be taken shall be determined and documented (see 4.10).



ISO 15189 Standards

4.10 Corrective action

The laboratory shall take <u>corrective action to eliminate the cause(s) of nonconformities</u>. 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.





ISO 15189 Standards

4.11 Preventive action

The laboratory shall determine action to <u>eliminate the causes of potential nonconformities in order to prevent</u> 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

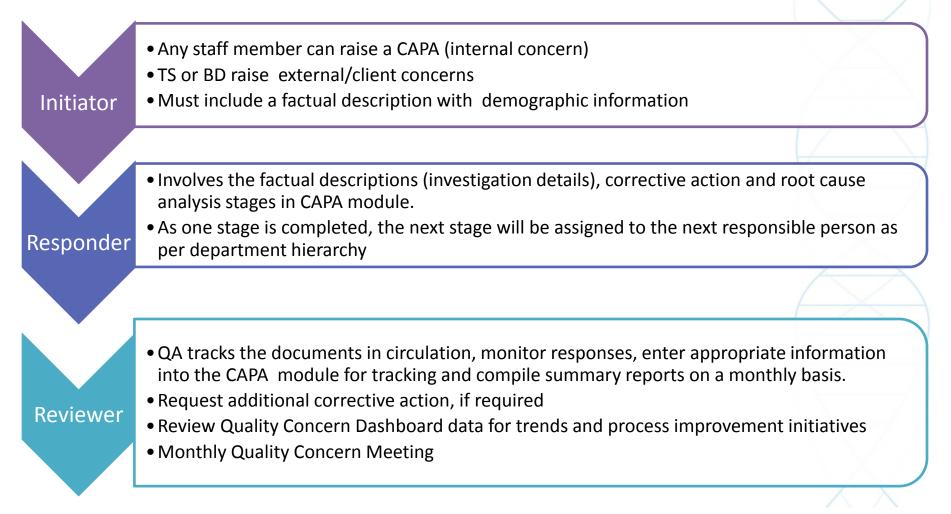
The laboratory shall continually improve the effectiveness of the quality management system, including the pre-examination, examination and post-examination processes, through the use of <u>management reviews</u> to compare the laboratory's actual performance in its evaluation activities, corrective actions and preventive actions with its intentions, as stated in the quality policy and quality objectives. <u>Improvement activities shall</u> <u>be directed at areas of highest priority based on risk assessments</u>. Action plans for improvement shall be developed, documented and implemented, as appropriate. The <u>effectiveness</u> 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





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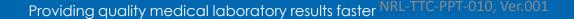
Q-Pulse - CAPA Module Features

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

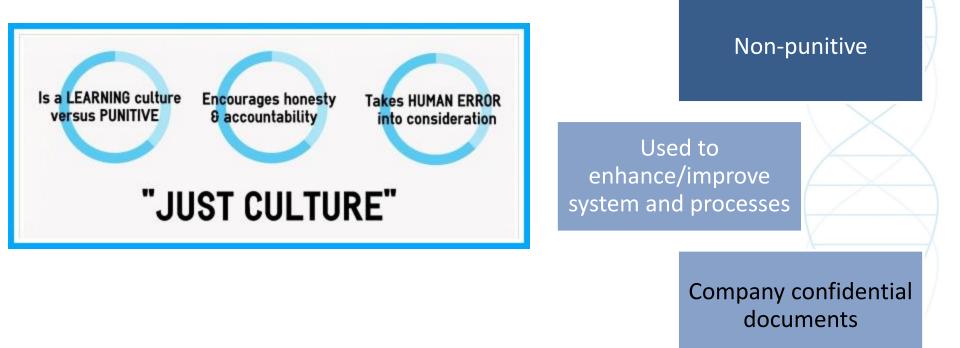
Collected data can be saved as an attachment and serves as an evidence for future reference





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How to handle CAPAs:





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



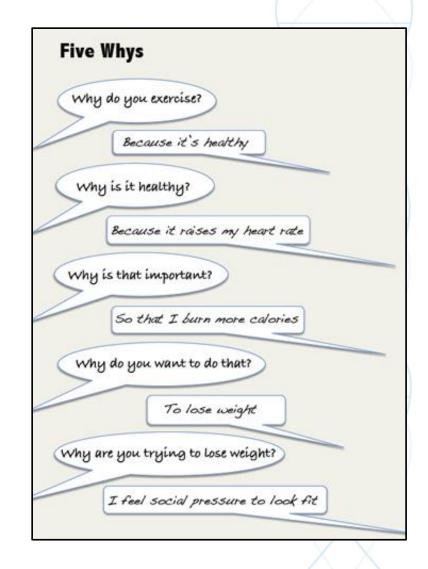


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Root Cause Analysis (RCA)

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.



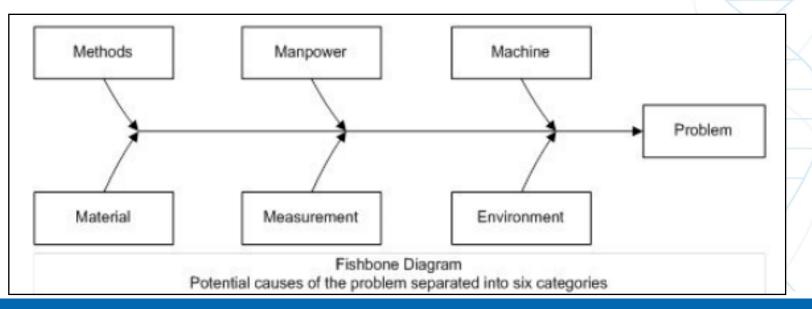
https://advisera.com/9001academy/blog/2016/03/01/how-to-usec-PPT-010, ver.001 root-cause-analysis-to-support-corrective-actions-in-your-qms/



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-useroot-cause-analysis-to-support-corrective-actions-in-your-gms/

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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

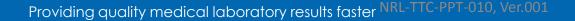
All opened CAPAs which are not addressed within 10 days will be forwarded to the CEO



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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 nontechnical 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

<u>NONCONFORMITY – INCIDENT REPORTING:</u> <u>QUALITY CONCERN REVIEW PROCEURE</u> (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) LaunchPad «Al Omari Lana»	() · 2 · 0 ·	
Modules Station		
Documents	(15) *	
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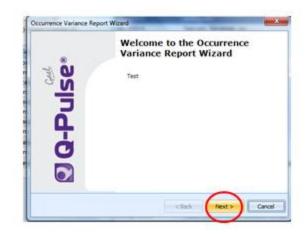


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2. At the top left corner select: File, New, From Wizard, Occurrence Variance Report

Eile	Edit Yiew Actions Window	Help					
1	New	•	Non-Conformance Ctrl+N	- 🗊 📗	VV RY	5	
8	Open Non-Conformance Record	Ctrl+O	From Wizard +	Client Concern		Overall Target Date	Severity
2	Print	Ctrl+P	From Template +	Improvement Id	eas		
	Pregiew	Ctrl+F2	Based on selected	Occurrence Varia	Ince Report		
	Beport Designer	1	Test CAPA raised	Raise Non-Confe	ormance		
	1 NRL-LAB-OVR-15		testing only Testing _Qa	Raise Supplier N	on Conformance	17/09/2015	
	2 NRL-LAB-OVR-13		code XXXX sample missing information not no	tified to client	Closed	17/09/2015	Minor
	3 NRL-LAB-OVR-10		final testing within QA team		Closed	17/09/2015	Minor
	4 NRL-LAB-OVR-8		TE FAIL		Closed		
	5 NRL-LAB-OVR-7		TESting		Open		Minor
10.00			Please record a factual description of the		Open		Minor
	<u>C</u> lose Window	Alt+F4	Delayed IgE report sent to dient.		Closed	08/10/2015	Minor
Arry	* NRL-L	AB-OVR-8	Delayed TAT in CBC		Open	13/10/2015	Minor
Raise	d Date NRL-L	AB-OVR-9	incorrect test ordered		Open	13/10/2015	Minor

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



<u>UU</u>



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- 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"

Page 1 Raised By (Person or Customer) Internal Grundy, Louisa Faised Against Department Abu Dhabi Raised Date 18/10/2015	Raised By (Person or Customer) Internal External Grundy, Louisa ••••• Raised Against Department Abu Dhabi •• Raised Date 18/10/2015 •• ••	Occurrence Variance	Report Wizard	State Cardina Street		23
 Internal External Grundy, Louisa Raised Against Department Abu Dhabi Raised Date 	 Internal External Grundy, Louisa m Raised Against Department Abu Dhabi Raised Date 18/10/2015 18/10/2015 	Page 1				
Grundy, Louisa v ···· Raised Against Department Abu Dhabi v Raised Date	Grundy, Louisa • • • • • • • • • • • • • • • • • • •	Raised By (Persor	or Customer)			
Raised Against Department Abu Dhabi ~ Raised Date	Raised Against Department Abu Dhabi	 Internal 	C External			
Abu Dhabi - Raised Date	Abu Dhabi - Raised Date 18/10/2015 I T	Grundy, Louisa	*			
Raised Date	Raised Date 18/10/2015	Raised Against De	partment			
	18/10/2015	Abu Dhabi		*		
18/10/2015		Raised Date				
10/10/2013	< Back Next > Cancel	18/10/2015	I			
	< Back Next > Cancel					
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				< Back	Next >	Cancel



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 - 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".

(Occurrence Variance Report Wizard
	Page 2
	Accession Number
\Longrightarrow	10-15-270-00055
	Factual Description
⇒	Delay in TAT for CBC result.
	Status
	þpen 🗸
	< Back Next > Cancel



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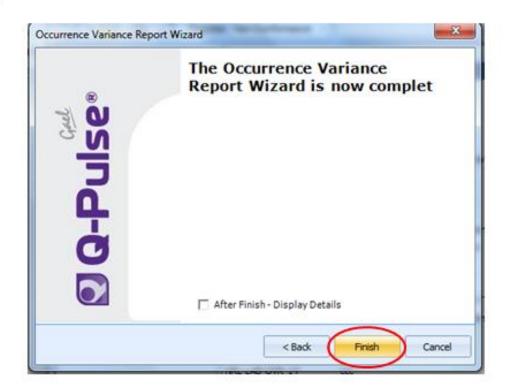
- 6. Use the scroll down button to select the appropriate "Category" for the incident. The use the scroll down button to select the appropriate "Source" of the concern. For example, for internal lab concerns, select Laboratory - Occurrence Variance Report" for external concerns, you can select Customer 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"

0	ccurrence Variance Report Wizard	23
	Page 3	
	Category	
	Delayed TAT -	
	Source	
>	Occurrence Variance Report -	
	Attachment	
	< Back Next >	Cancel





7. Select "Finish"



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

å	The Occurrence Variance Report Wizard is now complet
SID-Puls	Record Created
	Car After Finish - Display Details





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Stage 1 – Factual Description

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

	apulse	
from:		
fo:	Lana Al Omari (NRL)	
ic.		
Subject	New Non Conformance Raised	
🖂 Messag	e Locate Record.qpulse (358 B)	
Locate r	ecord in Q-Pulse Web	
Details:	The following Non Conformance	with resultant actions has been raised:
	2	
Number	r	NRL-LAB-OVR-7
Number	r	NRL-LAB-OVR-7 Customer/Client Concern
	r	
Source Audit	r By (Person or Customer)	
Source Audit Raised		Customer/Client Concern
Source Audit Raised Factual	By (Person or Customer)	Customer/Client Concern Dar Al Shifa Hospital Delayed IgE report sent to client.
Source Audit Raised Factual	By (Person or Customer) Description	Customer/Client Concern Dar Al Shifa Hospital Delayed IgE report sent to client.

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

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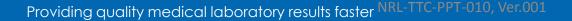




3. Select the OVR which was sent to you in the e-mail.

Eile Edit View Actions W	indow Help				
📄 - 🚰 📚 🙍 Regis	ter Non-Conformance -	- 📬 🔁 🖬 - 🚺 🗋 🗞 🗸 🗟 🦄			
My Actions K	Number	Factual Description	Status	Overall Target Date	Severity
- Overdue (1)	NRL-CCS-3	testing only	Closed		
• Stages Overdue (1)	NRL-CCS-4	Test only. full details, etc	Open		
	NRL-CCS-5	Test CAPA raised	Open		
Search	NRL-CCS-6	testing only	Open		
Source	NRL-CCS-7	Testing _Qa	Closed	17/09/2015	
Any -	NRL-CCS-8	code XXXX sample missing information not notified to client	Closed	17/09/2015	Minor
Ratus	NRL-CCS-9	final testing within QA team	Closed	17/09/2015	Minor
Any -	NRL-LAB-OVR-2	TE FAIL	Closed		
Severity	NRL-LAB-OVR-3	TESting	Open		Minor
Any -	NRL-LAB-OVR-5	Please record a factual description of the variance/incident/event/complaint	Open		Minor
Target Date	NRL-LAB-OVR-7	Delayed IgE report sent to client.	Open	08/10/2015	Minor
Any -	NRL-QA-OVR2	Please record a factual description of the variance/incident/event/complaint	Open		Minor

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 <u>save</u> 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.

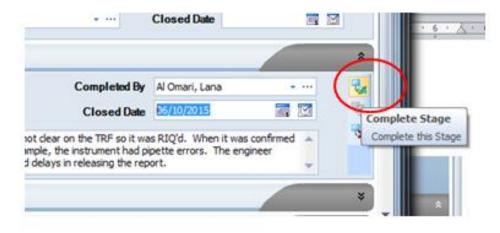
Number	NRL-LAB-OVR-7	Statu	Open	 Raised Date 	06/10/2015	3	1
Source	Client Concern	* Owner	r Al Omari, Lana 👻	Target Date	08/10/2015		1
Factual							
Description	Delayed IgE report sent	to dient.			^		
					-	_	\$
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Raised By	 O Internal O Cus 	tomer Agair	est Department Supplier 	Severit	y Minor	*	
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Factual	Rescription						Ĉ
Owner	Al Omari, Lana	÷ ···	Comple	ted By		•••	₹.
Target Date	08/10/2015		Close	d Date		2	5
Details	On October 2, 2015, th	ere was an test IgE. T	he order was not clear on the TRF	so it was RIQ'd. Wh	en it was confirmed		3
	by CC on Oct 3rd, the t	est was ordered. While	e processing sample, the instrumer er which caused delays in releasing	t had pipette errors.		_	
						-	/



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

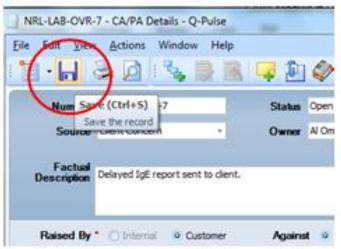
	55				
Owner	Al Omari, Lana	* ***	Completed By	Al Omari, Lana	 -
Target Dale	08/10/2015		Closed Date	06/10/2015	3
Details	by CC on Oct 3rd, the	test was ordered. While pro-	der was not dear on the TRF so it wa cessing sample, the instrument had pi ich caused delays in releasing the rep	pette errors. The engi	9

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





 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.







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Stage 2 – Corrective Action

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

From: To: Cc	qpulse Lana Al Omari (NRL)	
Subject:	A stage target date has bee	n set for the following Non Conformance;
🖂 Message	Locate Record.qpulse (3	58 8)
Locate rec	ord in Q-Pulse Web	
Details: A	stage target date has be	en set for the following Non Conformance;
Number		NRL-LAB-OVR-7
Source		Customer/Client Concern
Factual D	escription	Delayed IgE report sent to client.
Owner		Al Omari, Lana
Target Da	ite	10/8/2015
Туре		Corrective Action
Owner		Al Omari, Lana
Target Da	ate	10/8/2015
Details		





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

LaunchPad (Al Omari, Lana>	1.2.9.	
(*A/PA	×	Ь
Documents	(15) *	
People		
	ඩ Q-Pul se	





- 3. Select the OVR which was sent to you in the e-mail.
- Open the "Corrective Action" and write the details of the corrective action(s) taken to resolve the incident.

V Factual D	lescription			×
V Remedia	Action Taken			×
Correctiv	e Action			Â
Owner	Al Omari, Lana	÷ ···	Completed By	• ··· 😼
Target Date	08/10/2015	i	Closed Date	i 🖾 👘
Details	Engineer was contacted the processed and result was re		rvices and was able to troubleshoot the messa	age error. Sample was

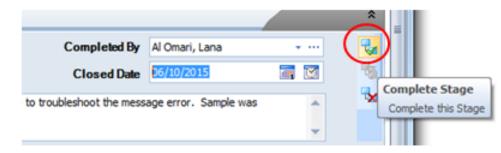




5. Select your name from the "Completed By" prompt and today's date as the "Closed Date".

V Factual	Description					*
V Remedi	al Action Taken					*
Correcti	ve Action					*
Owner	Al Omari, Lana	· ···	Completed By	Al Omari, Lana	*	-
Target Date	08/10/2015	i	Closed Date	06/10/2015		5
Details	Engineer was contacted the processed and result was re	ough support ser eleased to client.	vices and was able to troubleshoot the mess	age error. Sample was	,	*

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







 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.

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Num	ve (Ctrl+5) 7	Status	Open
	ave the record	• Owner	Al On
Factual Description	Delayed IgE report ser	it to client.	



Stage 3 – Root Cause Analysis Stage 4: QA Review

Follow same steps as mentioned in Stage 2 – Corrective Action



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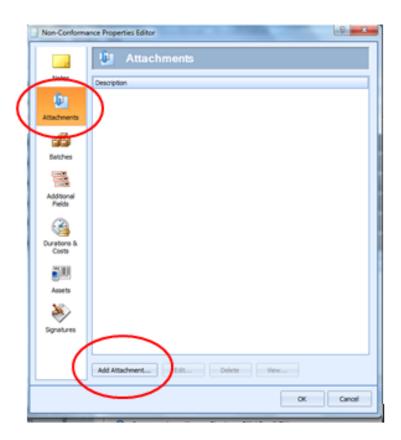
Uploading/ Attaching Documents

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

Properties			*
No additional properties assigned	User/Note	Date/Time 🗸	4
	No Notes Added		View Properties
Madified			



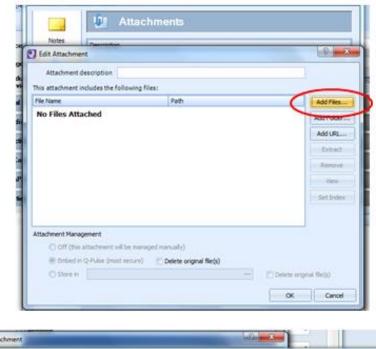
2. Select "Attachments" and then "Add Attachment"







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



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E Desktop	Copy of QA verification Checklist_JCLDC AI Ain_2015	17/09/2015 3:28 PM	Microsoft Excel W
Downloads	QA verification Checklist_AUH AP_2015	13/09/2015 12:26	Microsoft Excel W
1 Recent Places	QA verification Checklist_ CCAD-NRL AP 2015	04/30/2013 10:15	Microsoft Excel W
1 CONTRACTOR (1997)	QA verification Checklist_CoreLab AUH_2015	10/00/2015 5:08 PM	Microsoft Excel W
Giji Libraries	2 QA verification Checklist_DX8 Lab_2015	17/09/2015 12:16	Microsoft Excel W
P Documents	(2) OA verification Checklist HealthPoint General Lab. Blood Back 2015	09/09/2015 11:55	Microsoft Facet W

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

Attachment description	A verification Checklist_AUH AP_2015		
his attachment includes the fo	lowing files:		
File Name	Path		Add Files.
QA verification Cheddist_AUH A	P_2015.xlsx		Add Folder
			Add URL
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Attachment Management			
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The following paper clip icon will show up on the upper right hand corner of the Properties section when there is an attached document.

Attachments	User/Note	Date/Time	This Non-Conformance has Attached File
	No Notes Added		 Image: second sec

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

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Thank You!



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