



ALERTS | RiskClear & RiskClear Direct | User Guide

2025

Written by Giselle Latta (RN)



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INTRODUCTION

The TGA issues alerts to advise consumers, health professionals and industry about new safety information regarding therapeutic products.

NSQHS & Aged Care Standards advisories, issued by the Australian Commission on Safety and Quality in Health Care (the Commission), provide formal guidance and direction on the interpretation and/or assessment of the NSQHS & Aged Care Standards. The NSQHS & Aged Care Standards Advisories are routinely reviewed to ensure they remain current.

Management may also wish to send out Staff Communications for such things as new policies requiring reading and acknowledging or staff memos.

Communicating these Alerts to key-staff in a timely manner and receiving feedback regarding any actions taken is fundamental to providing a safe and informed hospital environment.

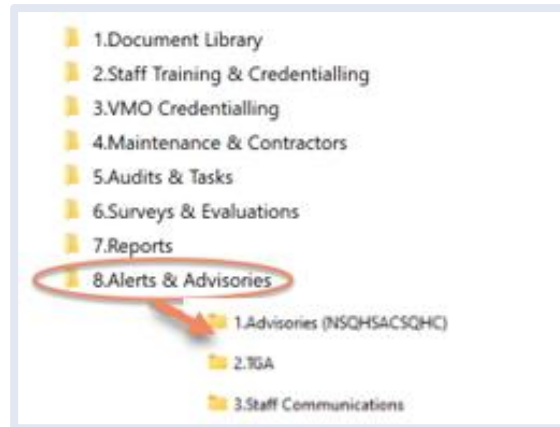
New Alerts is found on the **Quality Tab** of RiskClear. **Responding to Alerts can be done via RiskClear or RiskClear Direct** (where you are a notifyee/recipient).



1- SETUP OF TGA/ADVISORY/STAFF COMMUNICATION ALERTS

1.1 - NETWORK FOLDERS FOR ALERTS

Any documents related to TGA Alerts or Commission Advisories released can be saved on your Network – see example below:

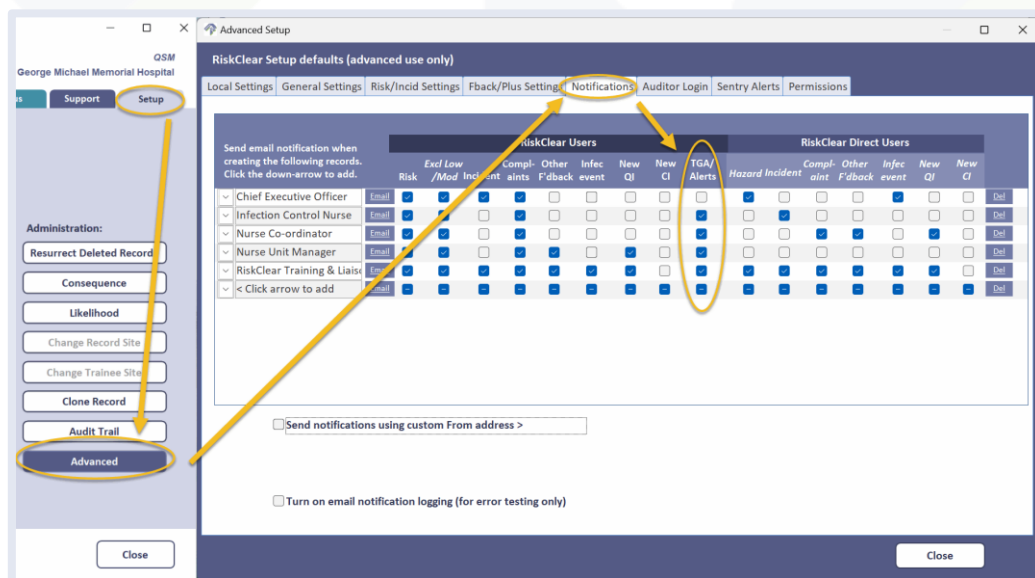


1.2 - ACCESS TO CREATE NEW RECORDS

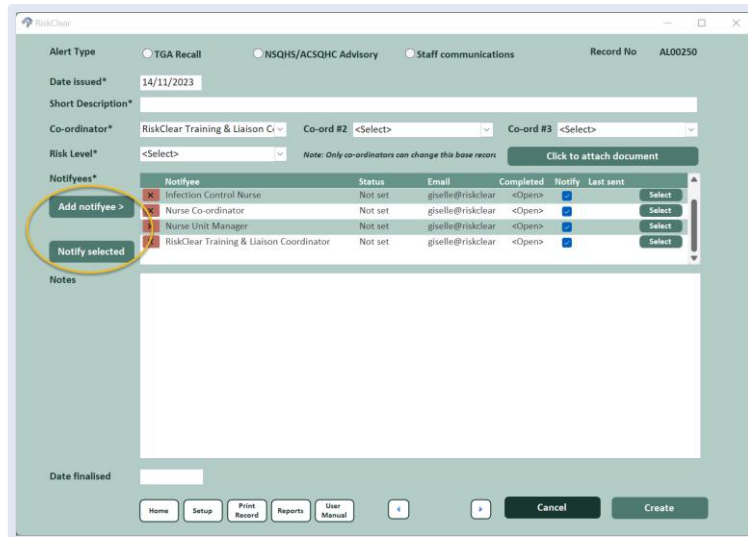
Staff who currently have access to create Alerts records can create new records in this function. This access is granted by ticking the **"TGA/Advis"** box in **Setup > Advanced > Permissions**. Everybody else will be able to access the record to action it.

1.3 - SETTING UP NOTIFYEES

From the **"New Alert/Advisory"** screen (on the Quality Tab) click: **"Add Notifyee"** then select applicable staff from that list, they will then appear listed as below.



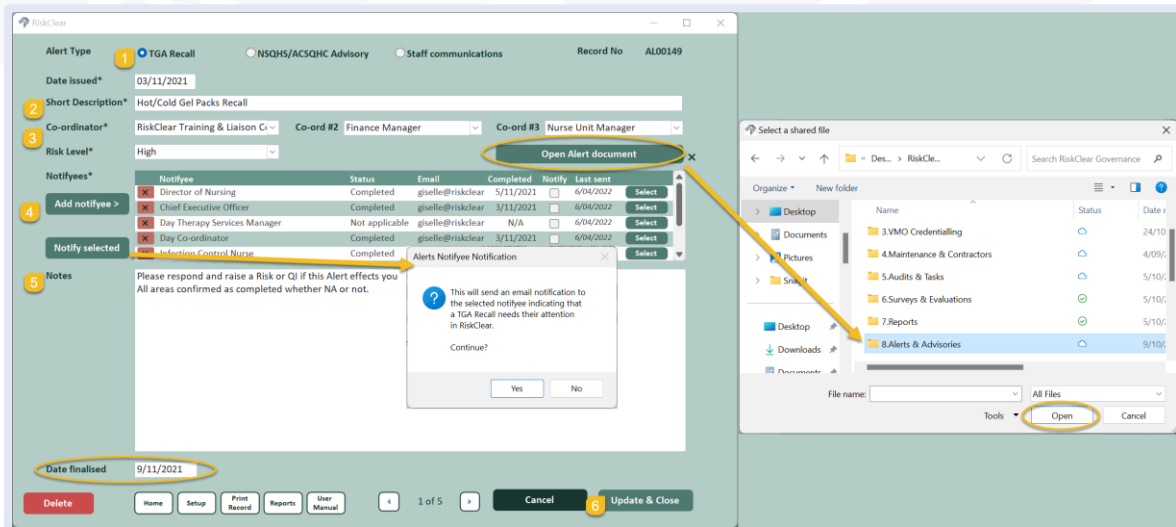
To set up notifications for TGA/Advisory Alerts so that you don't have to individually add each notifyee every time you raise a TGA/Alert, go to Setup **(1)** **Advanced** **(2)** **Notifications** **(3)**, and tick the **TGA/Alerts** **(4)** box for each person you wish to receive TGA/Alerts Notifications (e.g. the Director of Nursing for each Hospital Site).



2 - TGA ALERTS

2.1 - SENDING A TGA ALERT

To alert appropriate staff of an Advisory, go the **Quality Tab** and click **"New Alert"** - the following screen will appear:



1. Select **"TGA"**
2. Complete the ***Mandatory Fields**
3. **"Link"/**Open any TGA related documents from the saved **folder on your Network** – it can be just one or multiple TGAs
4. Click **"Add Notifyees"** (or this may already be done via **Advanced/Notifications** -refer to Section 1.3 of this Guide)

5. Click **"Notify Selected"** – a dialogue box will appear, select **"Yes"**
6. As the TGA Coordinator you can also add any notes and then click **"Create"**

The following Email Alert will be sent to all Notifiees listed above.

There's an alert needing your attention



RiskClear Notifications <notifications@riskclear.com.au>
To: giselle@riskclear.com.au

↩ Reply
↩ Reply All
➡ Forward
⋮

Wed 3/11/2021 11:31 AM

An alert with the title 'Recall of Hot / Cold Gel Packs Batch 43561F' dated 3 Nov 2021 record number AL00152 needs your attention in RiskClear.

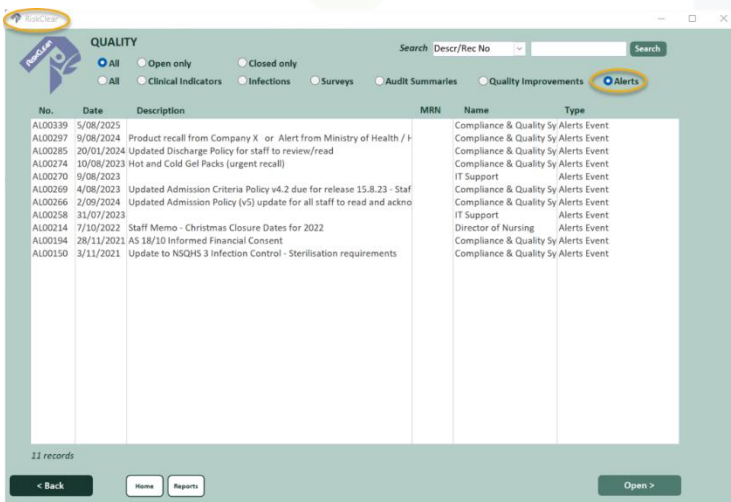
To access it, open RiskClear, click the **Quality** tab, open record AL00152, then select your name from the list.

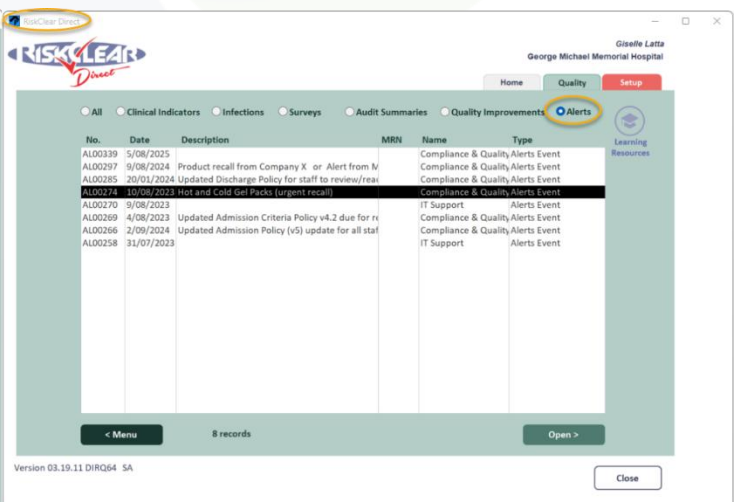
If you have any queries, please contact the Quality Services Manager on giselle@riskclear.com.au.

2.2 - RESPONDING TO A TGA ALERT THAT YOU HAVE RECEIVED

If you receive a TGA Alert (see below) via email that requires your attention >

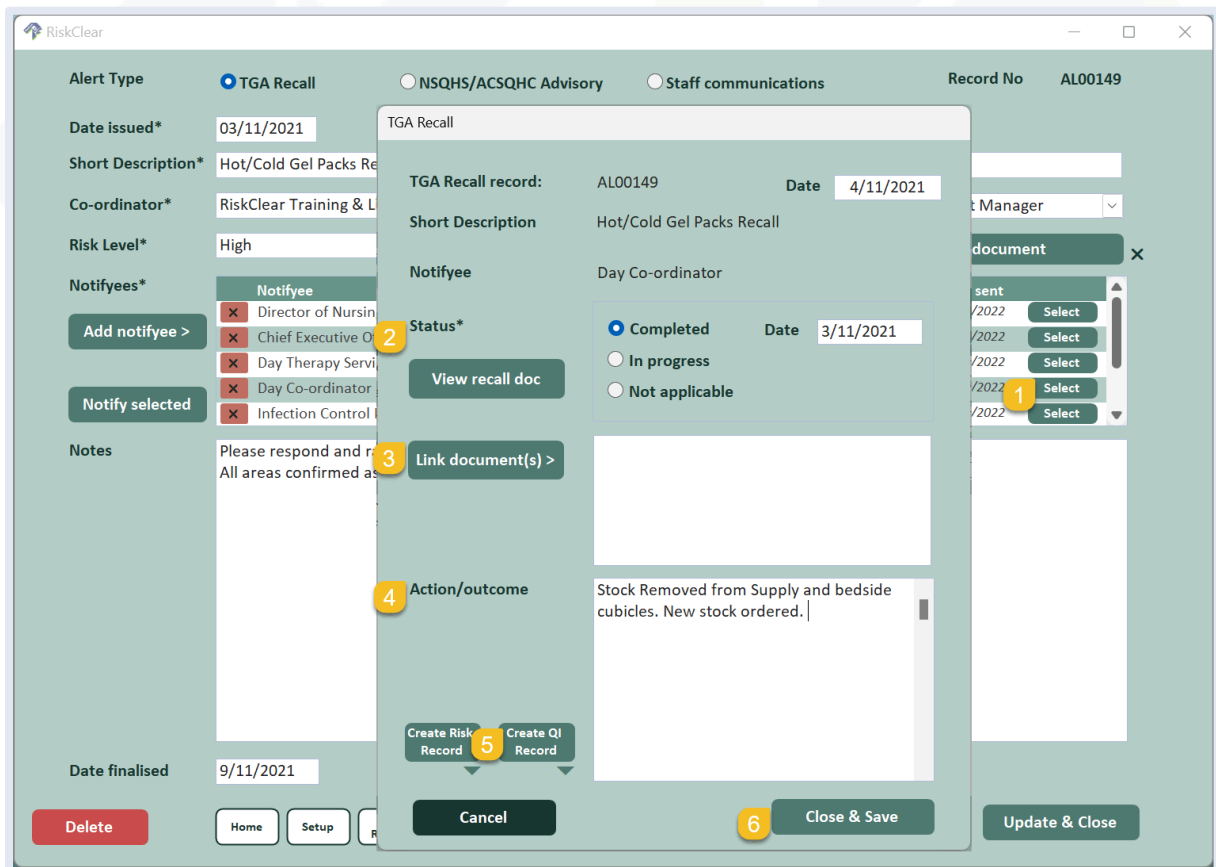
Open RiskClear or RiskClear Direct > go to the **Quality Tab** > **Search Quality** and find the Alert Record (e.g. AL 00152).





Open the Alert Record:

1. Select your name from the List and the following Window will open. Click **"View Recall doc"** to read through the TGA notice/information
2. Complete the **"Status"**
3. **"Link"** any Documents (e.g. evidence)
4. Complete the **"Action/Outcome"** section
5. You can, where necessary, raise a **Risk** and/or **Quality Improvement Record** if the TGA Alert warrants it
6. Click **"Close"**



The screenshot shows the RiskClear application window with a TGA Recall record form. The form is titled "TGA Recall" and has a Record No. of AL00149. The form is divided into several sections: Alert Type, Date issued, Short Description, Co-ordinator, Risk Level, Notifyees, Notes, and Action/outcome. The "Status" section is highlighted with a yellow circle and the number 2. The "Link document(s)" button is highlighted with a yellow circle and the number 3. The "Action/outcome" section is highlighted with a yellow circle and the number 4. The "Create Risk Record" and "Create QI Record" buttons are highlighted with a yellow circle and the number 5. The "Close & Save" button is highlighted with a yellow circle and the number 6. The "View recall doc" button is highlighted with a yellow circle and the number 1.

Alert Type: ☒ TGA Recall ☐ NSQHS/ACSQHC Advisory ☐ Staff communications **Record No:** AL00149

Date issued*: 03/11/2021

Short Description*: Hot/Cold Gel Packs Recall

Co-ordinator*: RiskClear Training & L

Risk Level*: High

Notifyees*:

Notifyee	Action
Director of Nursing	☒
Chief Executive Officer	☒
Day Therapy Services	☒
Day Co-ordinator	☒
Infection Control	☒

Notes: Please respond and... All areas confirmed as...

Status*: ☒ Completed ☐ In progress ☐ Not applicable **Date:** 3/11/2021

Link document(s) >

Action/outcome: Stock Removed from Supply and bedside cubicles. New stock ordered.

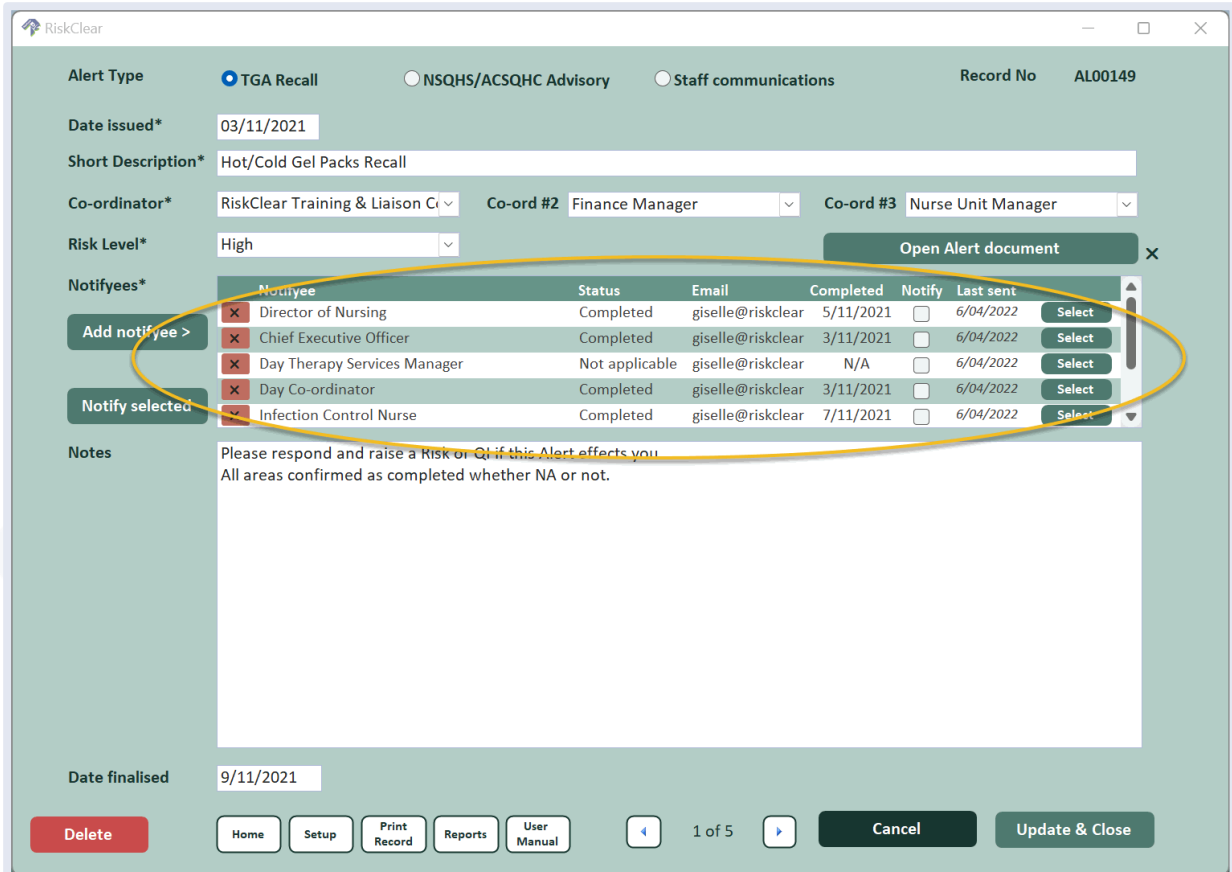
Create Risk Record **Create QI Record**

Date finalised: 9/11/2021

Buttons: Delete, Home, Setup, Cancel, Close & Save, Update & Close

2.3 - ALERT COORDINATOR RESPONSIBILITIES

The Notifiees List on the Main **TGA/Alerts Screen** will update the status accordingly letting the **Alert Coordinator** know the status of the alert (e.g. completed, in progress or not applicable). The **Alert Coordinator** can also send a reminder to any late responders by ticking the “**Notify Box**” and clicking “**Notify Selected.**”



RiskClear

Alert Type: ☒ TGA Recall ☐ NSQHS/ACSQHC Advisory ☐ Staff communications Record No: AL00149

Date issued*: 03/11/2021

Short Description*: Hot/Cold Gel Packs Recall

Co-ordinator*: RiskClear Training & Liaison C Co-ord #2: Finance Manager Co-ord #3: Nurse Unit Manager

Risk Level*: High Open Alert document

Notifiees*

Notifiee	Status	Email	Completed	Notify	Last sent	
☒ Director of Nursing	Completed	giselle@riskclear	5/11/2021	☐	6/04/2022	Select
☒ Chief Executive Officer	Completed	giselle@riskclear	3/11/2021	☐	6/04/2022	Select
☒ Day Therapy Services Manager	Not applicable	giselle@riskclear	N/A	☐	6/04/2022	Select
☒ Day Co-ordinator	Completed	giselle@riskclear	3/11/2021	☐	6/04/2022	Select
☒ Infection Control Nurse	Completed	giselle@riskclear	7/11/2021	☐	6/04/2022	Select

Notes: Please respond and raise a Risk or QI if this Alert effects you. All areas confirmed as completed whether NA or not.

Date finalised: 9/11/2021

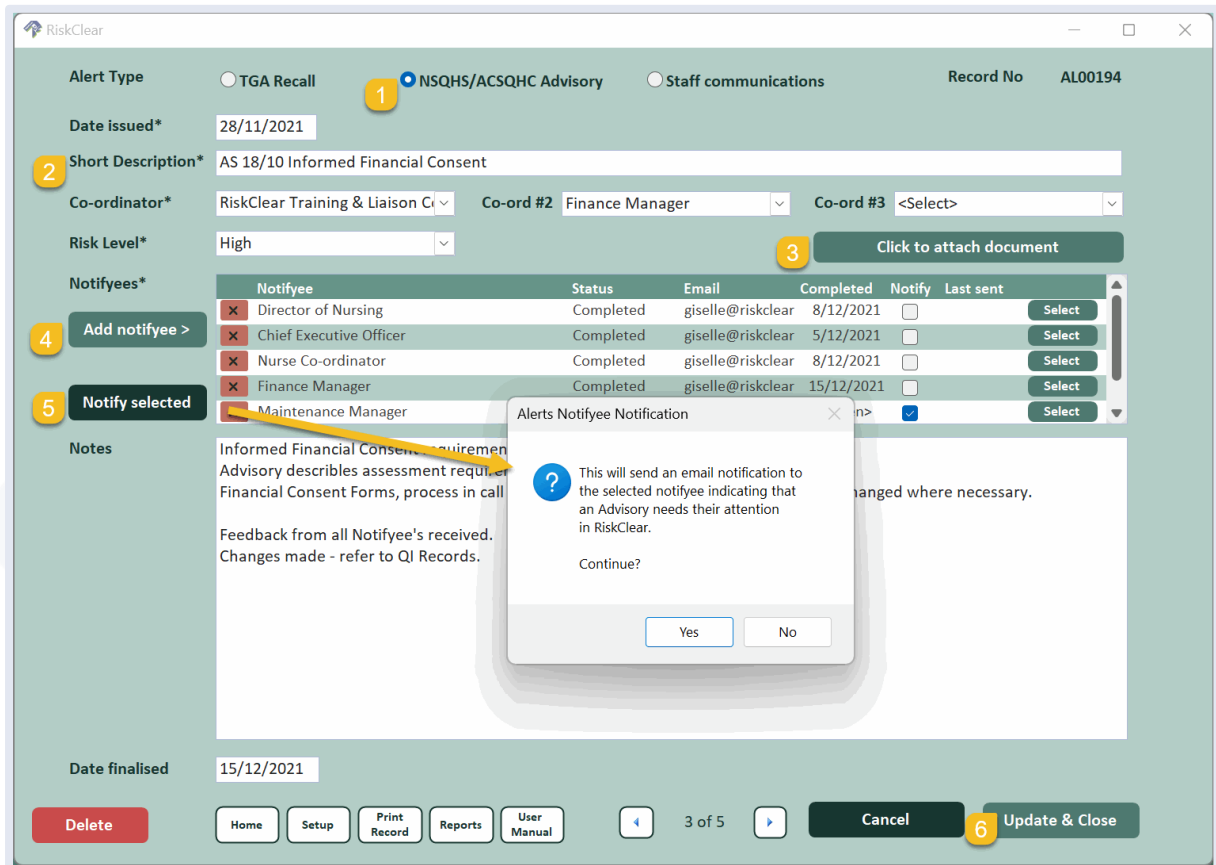
Buttons: Delete, Home, Setup, Print Record, Reports, User Manual, 1 of 5, Cancel, Update & Close

Once all responses from the Notifiees have been received, the **Alert Coordinator** can enter the “**Date Finalised**” and “**Update & Close**” the Alert.

3 - ADVISORY ALERTS

3.1 - SENDING AN ADVISORY ALERT

This process is like sending a TGA Alert to alert appropriate staff of an Advisory Alert, go to the **Quality Tab** and click **"New Alert"** - the following screen will appear:



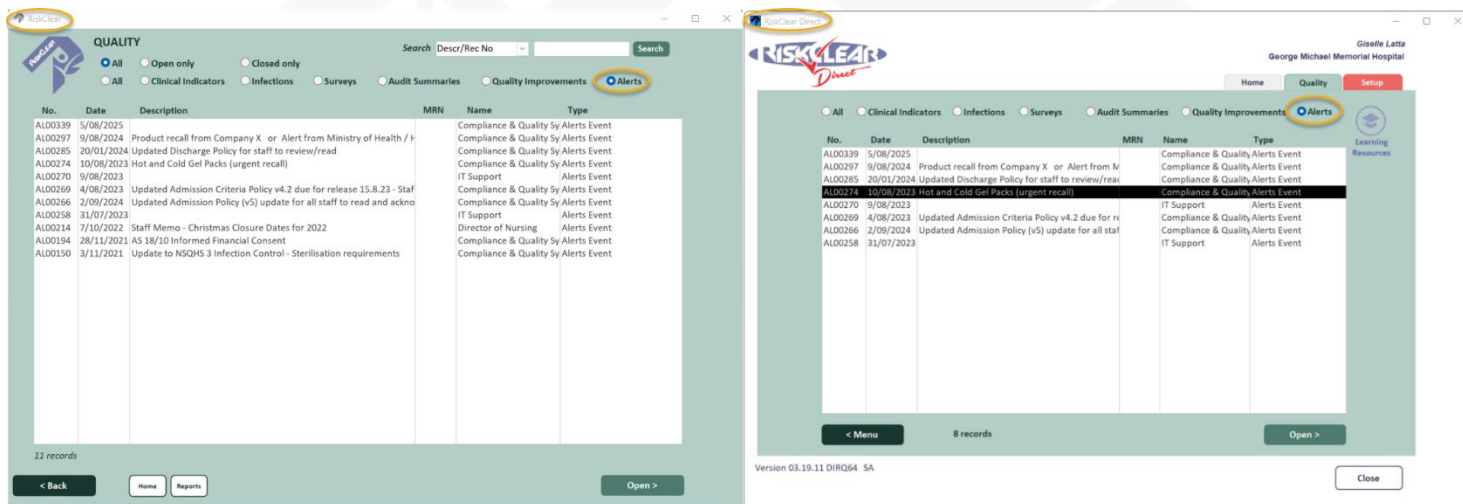
The screenshot shows the 'New Alert' form in the RiskClear system. The form is for an 'NSQHS/ACSQHC Advisory' (Alert Type). The 'Date issued' is 28/11/2021. The 'Short Description' is 'AS 18/10 Informed Financial Consent'. The 'Co-ordinator' is 'RiskClear Training & Liaison C'. The 'Risk Level' is 'High'. The 'Notifies' list includes: Director of Nursing, Chief Executive Officer, Nurse Co-ordinator, Finance Manager, and Maintenance Manager. A modal dialog 'Alerts Notifiee Notification' is displayed, asking for confirmation to send an email notification to the selected notifyee indicating that an Advisory needs their attention in RiskClear. The dialog has 'Yes' and 'No' buttons.

1. Select **"NSQHS/ACSQHC Advisory"**
2. Complete the ***Mandatory Fields**
3. **Link/Open** any Advisory related documents from the **saved folder on your Network** – it can be just one or multiple Advisories
4. Click **"Add Notifies"** (or this may already be done via **Advanced/Notifications** -refer to Section 1.3 of this document)

- Click **"Notify Selected"** – a dialogue box will appear, click yes
- As the Alert Coordinator you can also add any notes and the click **"Close"**

3.2 - RESPONDING TO AN ADVISORY ALERT THAT YOU HAVE RECEIVED

If you receive an Advisory Alert via email that requires your attention, open RiskClear or RiskClear Direct, go to the **Quality Tab > Search** and find the Alert Record (e.g. AL 00152)

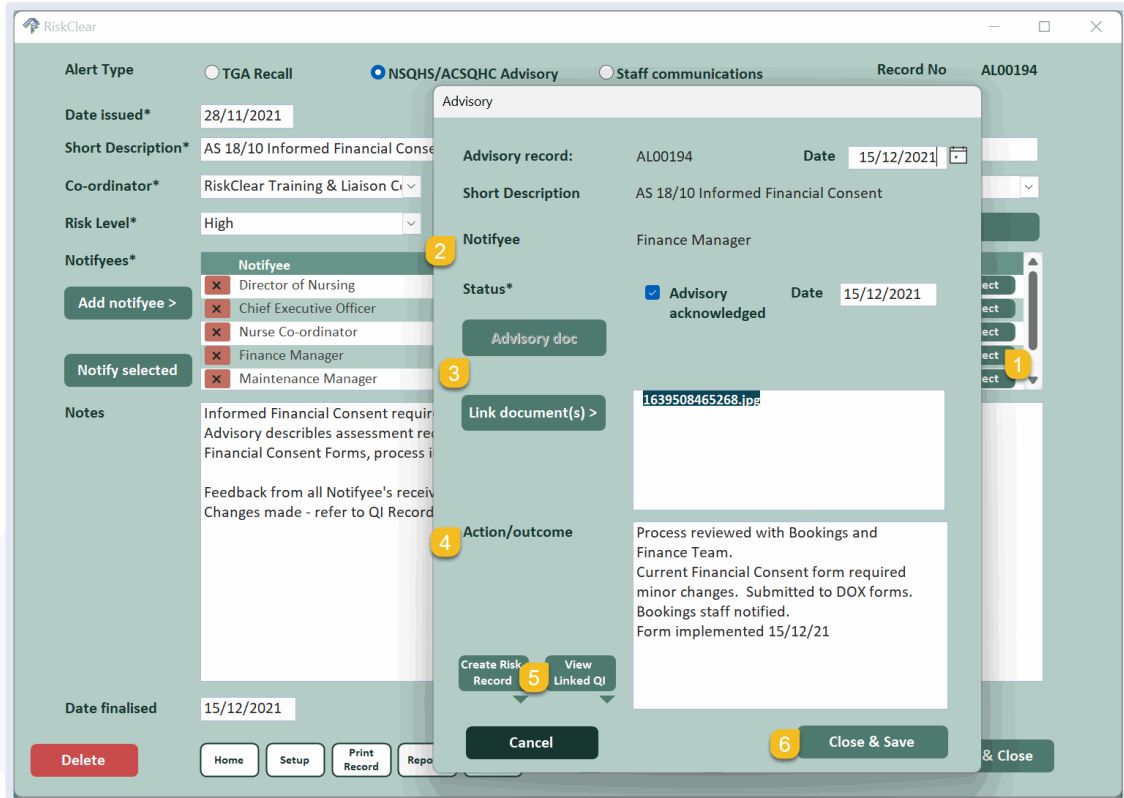


The left screenshot shows the RiskClear interface with the 'Alerts' tab selected. It displays a list of alerts with columns for No., Date, Description, MRN, Name, and Type. The right screenshot shows the RiskClear Direct interface with the 'Alerts' tab selected, displaying a similar list of alerts. Both interfaces include a search bar and navigation buttons.

Open the Alert Record:

- "Select"** your name from the List (e.g. Infection Control Nurse) and another window will open
- Click **"View Advisory doc"** to read through the /information and tick the box to say the Advisory has been acknowledged – a date box will appear for you to complete also
- "Link"** any Documents (e.g. evidence) that you may wish to provide
- Complete the **"Action/Outcome"** section

5. You can, where necessary, raise a **Risk** and/or **Quality Improvement Record** if the Advisory Alert warrants it
6. Click **“Close”**

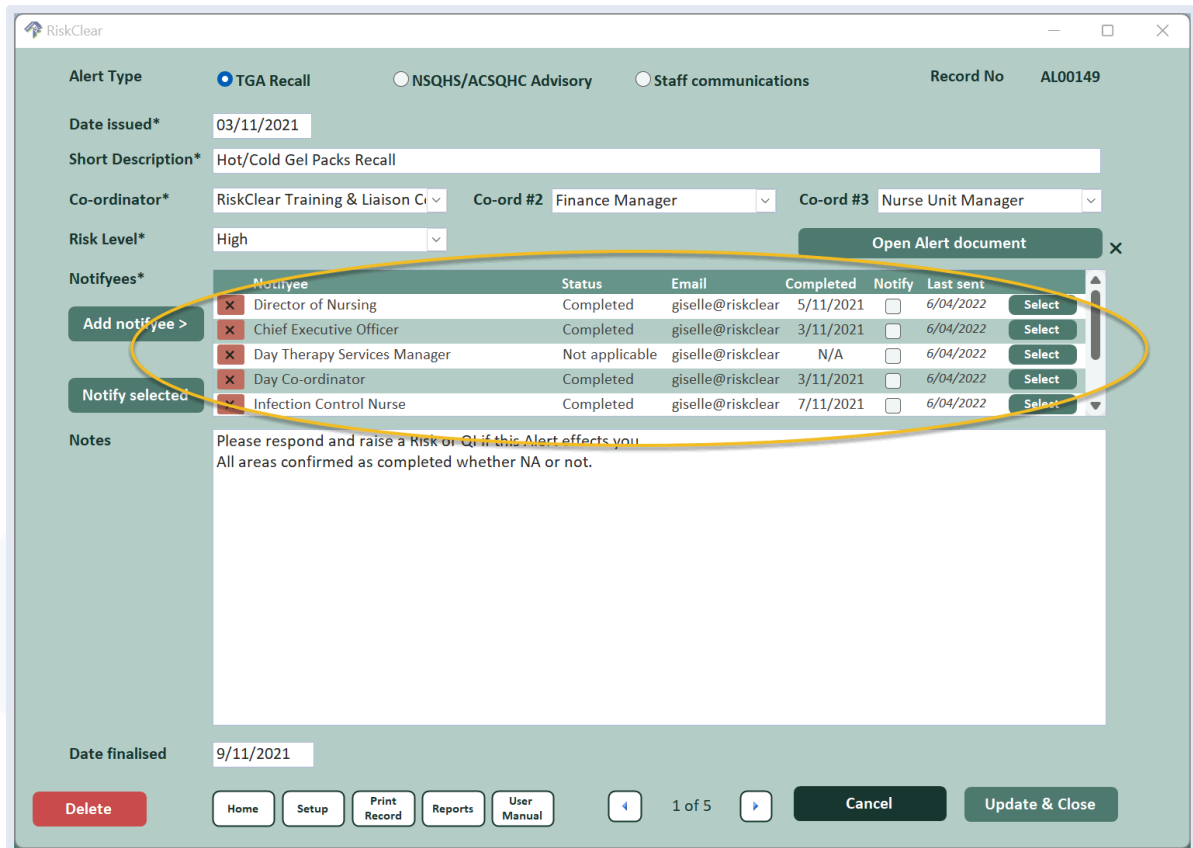


The screenshot displays the RiskClear 'Advisory' form. The main form on the left includes fields for Alert Type (TGA Recall, NSQHS/ACSQHC Advisory, Staff communications), Date issued (28/11/2021), Short Description (AS 18/10 Informed Financial Consent), Co-ordinator (RiskClear Training & Liaison C), Risk Level (High), and a list of Notifieses (Director of Nursing, Chief Executive Officer, Nurse Co-ordinator, Finance Manager, Maintenance Manager). A 'Notes' section contains text about informed financial consent and feedback. The 'Date finalised' is 15/12/2021. A modal window titled 'Advisory' is open, showing details for record AL00194, dated 15/12/2021, with a short description of 'AS 18/10 Informed Financial Consent' and a notifyee of 'Finance Manager'. The status is 'Advisory acknowledged'. A document link '1639508465268.jpg' is shown. The 'Action/outcome' section describes a process review with the Finance Team. At the bottom of the modal, there are buttons for 'Create Risk Record' and 'View Linked QI'. The main form has a 'Close & Save' button at the bottom right.

3.3 - ALERT COORDINATOR RESPONSIBILITIES

The Notifieses List on the Main **TGA/Alerts Screen** will update the status accordingly letting the **Alert Coordinator** know the status of the alert (e.g. completed, in progress or not applicable). The **Alert Coordinator** can also send a reminder to any late responders by ticking the **“Notify Box”** and clicking **“Notify Selected”**.

Once all responses from the Notifyees have been received, the **Alert Coordinator** can enter the **“Date Finalised”** and **“Update & Close”** the Alert.



Alert Type ☒ TGA Recall ☐ NSQHS/ACSQHC Advisory ☐ Staff communications **Record No** AL00149

Date issued* 03/11/2021

Short Description* Hot/Cold Gel Packs Recall

Co-ordinator* RiskClear Training & Liaison Co **Co-ord #2** Finance Manager **Co-ord #3** Nurse Unit Manager

Risk Level* High **Open Alert document** X

Notifyees*

Notifyee	Status	Email	Completed	Notify	Last sent	
X Director of Nursing	Completed	giselle@riskclear	5/11/2021	☐	6/04/2022	Select
X Chief Executive Officer	Completed	giselle@riskclear	3/11/2021	☐	6/04/2022	Select
X Day Therapy Services Manager	Not applicable	giselle@riskclear	N/A	☐	6/04/2022	Select
X Day Co-ordinator	Completed	giselle@riskclear	3/11/2021	☐	6/04/2022	Select
X Infection Control Nurse	Completed	giselle@riskclear	7/11/2021	☐	6/04/2022	Select

Notes Please respond and raise a Risk or Q if this Alert effects you. All areas confirmed as completed whether NA or not.

Date finalised 9/11/2021

Buttons: Delete, Home, Setup, Print Record, Reports, User Manual, 1 of 5, Cancel, Update & Close

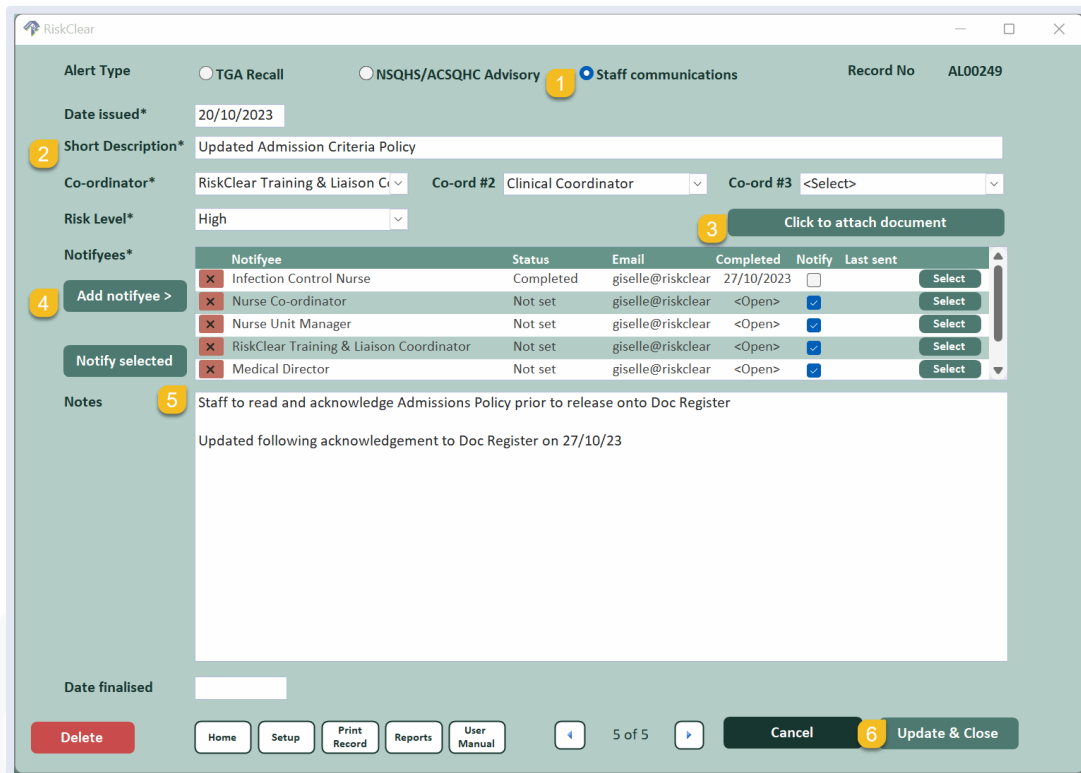
4 - STAFF COMMUNICATION ALERTS

4.1 - SENDING A STAFF COMMUNICATION ALERT

This process is like that of sending a TGA/Advisory Alert. To alert appropriate staff of a **Staff Communication**, go the **Quality Tab** and click **“New Alert”** - the following screen will appear:

1. Select **“Staff Communications”**
2. Complete the ***Mandatory Fields**
3. **Link/Open** any related documents from the **saved folder on your Network** – e.g. Staff Memo, or a new policy needing reading and acknowledging
4. Click **“Add Notifyees”** (or this may already be done via **Advanced/Notifications** - refer to the **“Setting Up Notifyees”** section of this document)

5. Click **"Notify Selected"** – a dialogue box will appear, click yes.
6. As the Alert Coordinator you can also add any notes and then click **"Close"**



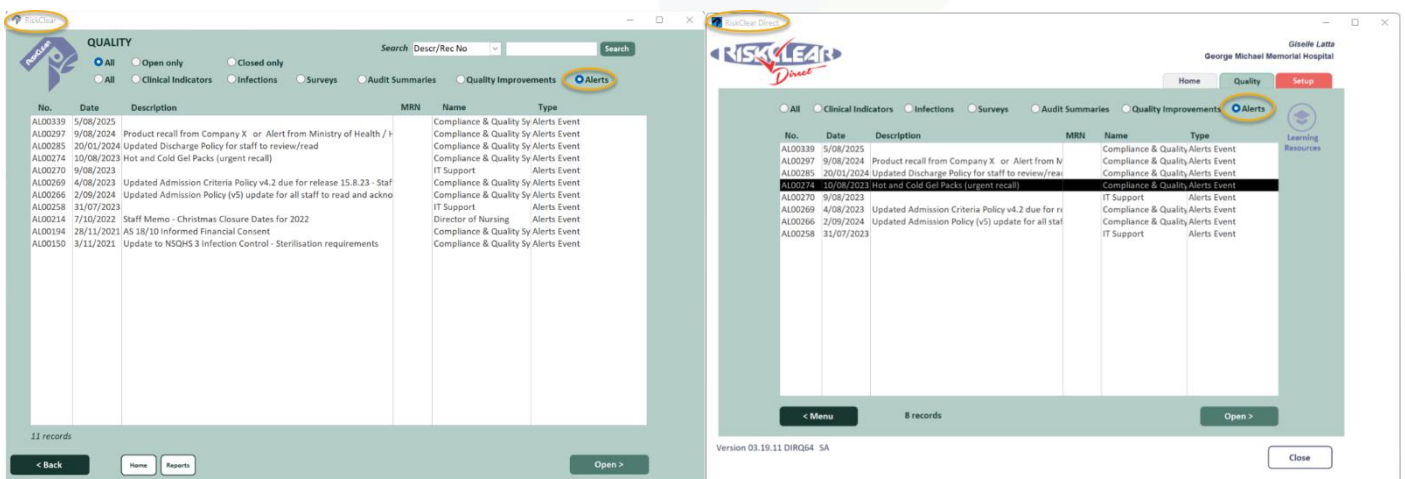
The screenshot shows the 'Alert Type' form in RiskClear. The 'Alert Type' is set to 'Staff communications'. The 'Date issued' is 20/10/2023. The 'Short Description' is 'Updated Admission Criteria Policy'. The 'Co-ordinator' is 'RiskClear Training & Liaison C' and the 'Co-ord #2' is 'Clinical Coordinator'. The 'Risk Level' is 'High'. The 'Notifyees' table shows the following:

Notifyee	Status	Email	Completed	Notify	Last sent	Action
Infected Control Nurse	Completed	giselle@riskclear	27/10/2023	☐		Select
Nurse Co-ordinator	Not set	giselle@riskclear	<Open>	☒		Select
Nurse Unit Manager	Not set	giselle@riskclear	<Open>	☒		Select
RiskClear Training & Liaison Coordinator	Not set	giselle@riskclear	<Open>	☒		Select
Medical Director	Not set	giselle@riskclear	<Open>	☒		Select

The 'Notes' section contains the text: 'Staff to read and acknowledge Admissions Policy prior to release onto Doc Register' and 'Updated following acknowledgement to Doc Register on 27/10/23'. The 'Date finalised' field is empty. The bottom of the form has buttons for 'Delete', 'Home', 'Setup', 'Print Record', 'Reports', 'User Manual', 'Cancel', and 'Update & Close'.

4.2 - RESPONDING TO A STAFF COMMUNICATIONS ALERT THAT YOU HAVE RECEIVED

If you receive a Staff Communications Alert (see below) via email that requires your attention, open RiskClear, go to the Quality Tab and find the Alert Record.

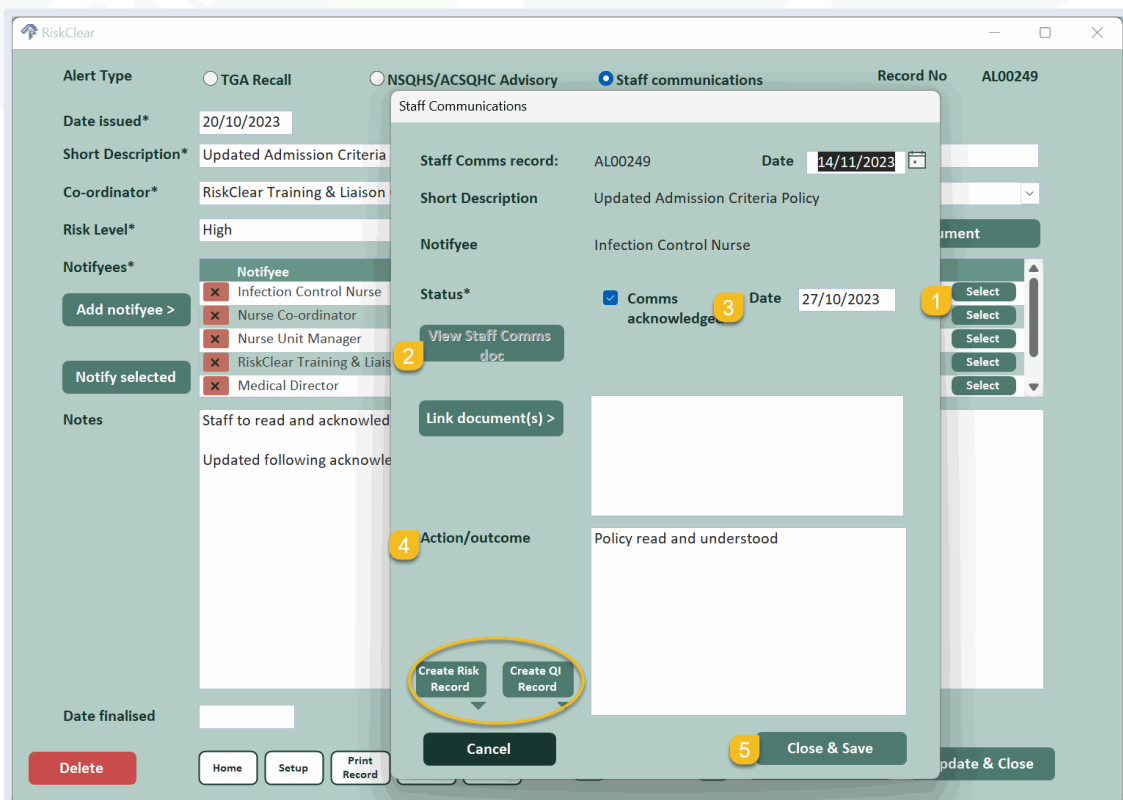


The left screenshot shows the 'QUALITY' tab in RiskClear. The 'Alerts' filter is selected, and a list of alert records is displayed. The right screenshot shows the 'Alerts' tab in RiskClear. The 'Alerts' filter is selected, and a list of alert records is displayed. Both screenshots show the 'Alerts' filter selected in the top navigation bar.

Open the Alert Record:

1. **"Select"** your name from the List (e.g. Nurse Coordinator) and another window will open
2. Click **"View Staff Comms Doc"** to read through the /information and tick the box to say the Communication has been acknowledged – a date box will appear for you to complete also
3. **"Link"** any Documents (e.g. evidence) that you may wish to provide
4. Complete the **"Action/Outcome"** section
5. You can, where necessary, raise a **Risk** and/or **Quality Improvement Record** if the Advisory Alert warrants it

Click **"Close"**

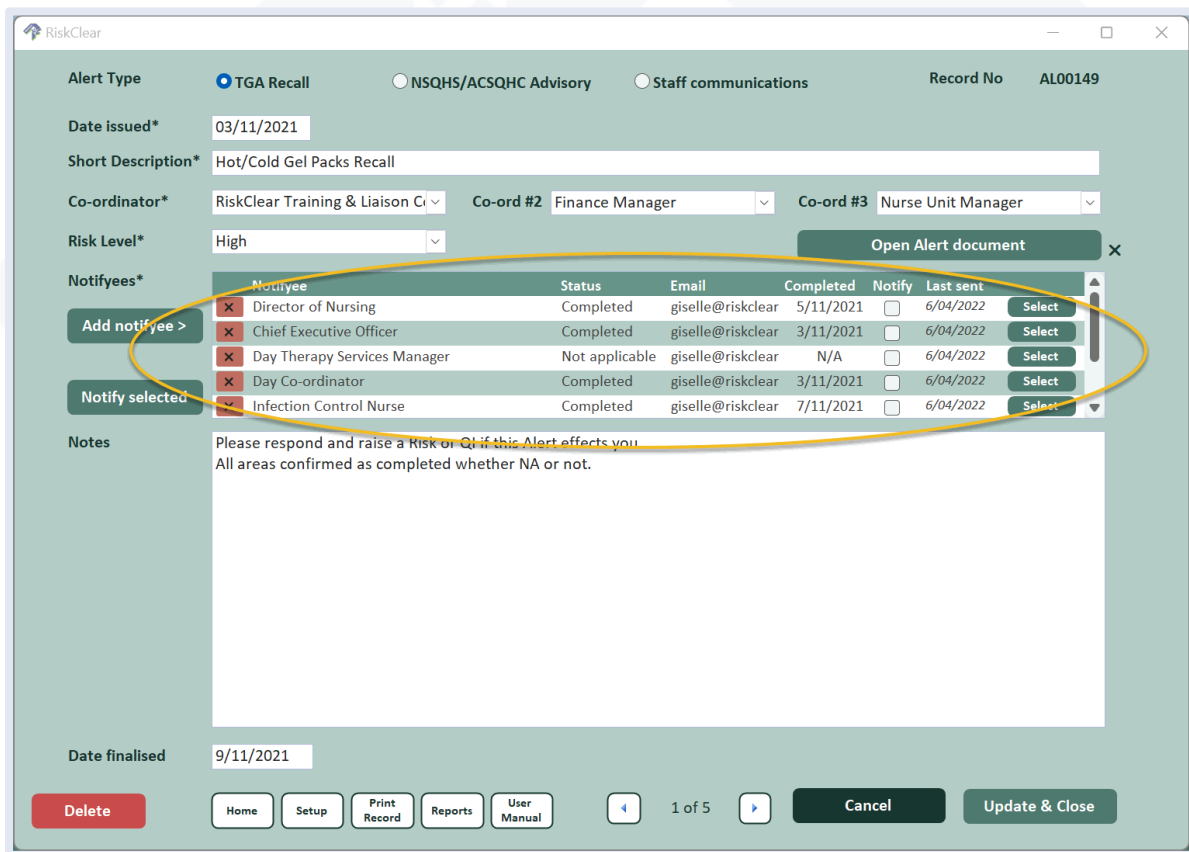


The screenshot shows the RiskClear Staff Communications form. The form is titled "Staff Communications" and has a "Record No" of AL00249. The "Alert Type" is set to "Staff communications". The "Date issued*" is 20/10/2023. The "Short Description*" is "Updated Admission Criteria". The "Co-ordinator*" is "RiskClear Training & Liaison". The "Risk Level*" is "High". The "Notifies*" section lists "Infection Control Nurse", "Nurse Co-ordinator", "Nurse Unit Manager", "RiskClear Training & Liaison", and "Medical Director". The "Notes" section contains "Staff to read and acknowledge" and "Updated following acknowledge". The "Action/outcome" section contains "Policy read and understood". The "Status*" section has a checkbox for "Comms acknowledged" which is checked, and a "Date" field set to 27/10/2023. The "Link document(s) >" section is empty. The "Create Risk Record" and "Create QI Record" buttons are circled in red. The "Close & Save" button is highlighted with a red circle and the number 5.

4.3 - ALERT COORDINATOR RESPONSIBILITIES

The Notifyees List on the Main **TGA/Alerts/Staff Communications Screen** will update the status accordingly letting the **Alert Coordinator** know the status of the alert (e.g. completed, in progress or not applicable). The **Alert Coordinator** can also send a reminder to any late responders by ticking the **"Notify Box"** and clicking **"Notify Selected."**

Once all responses from the Notifyees have been received, the **Alert Coordinator** can enter the **"Date Finalised"** and **"Update & Close"** the Alert.



RiskClear

Alert Type: ☒ TGA Recall ☐ NSQHS/ACSQHC Advisory ☐ Staff communications Record No: AL00149

Date issued*: 03/11/2021

Short Description*: Hot/Cold Gel Packs Recall

Co-ordinator*: RiskClear Training & Liaison Co-ord #2: Finance Manager Co-ord #3: Nurse Unit Manager

Risk Level*: High

Open Alert document

Notifyees*

Notifyee	Status	Email	Completed	Notify	Last sent	
☒ Director of Nursing	Completed	giselle@riskclear	5/11/2021	☐	6/04/2022	Select
☒ Chief Executive Officer	Completed	giselle@riskclear	3/11/2021	☐	6/04/2022	Select
☒ Day Therapy Services Manager	Not applicable	giselle@riskclear	N/A	☐	6/04/2022	Select
☒ Day Co-ordinator	Completed	giselle@riskclear	3/11/2021	☐	6/04/2022	Select
☒ Infection Control Nurse	Completed	giselle@riskclear	7/11/2021	☐	6/04/2022	Select

Notes: Please respond and raise a Risk or QI if this Alert effects you. All areas confirmed as completed whether NA or not.

Date finalised: 9/11/2021

Buttons: Delete, Home, Setup, Print Record, Reports, User Manual, 1 of 5, Cancel, Update & Close

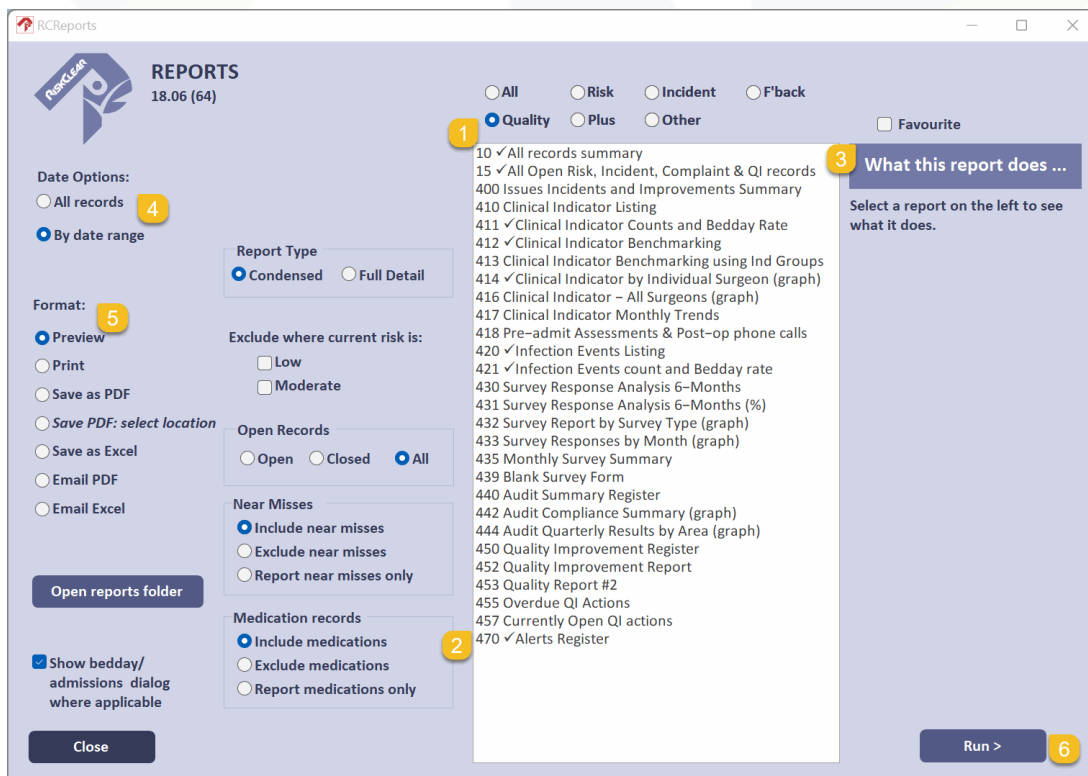
5 - REPORTS

5.1 - REPORT 470 ALERTS REGISTER

Report 470 Alerts Register can be run to show all TGA Recalls, Alerts/Staff Communications according to the date range and Open/Closed filter used. Displays data between two dates or All records.

To Run Report 470, do the following:

1. Click **"Quality"**
2. Select **Report 470** from the list
3. **"Tick"** the favourite box if you will be using it regularly
4. Select your **Date Range** or **All Records** and your **Report Format**
5. Select **Open**, **Closed** or **All Records**
6. Click **"Run"**



RCRReports

REPORTS
18.06 (64)

Date Options:

☐ All records

☒ By date range

Format:

☒ Preview

☐ Print

☐ Save as PDF

☐ Save PDF: select location

☐ Save as Excel

☐ Email PDF

☐ Email Excel

Open reports folder

☒ Show bedday/ admissions dialog where applicable

Close

Report Type

☒ Condensed ☐ Full Detail

Exclude where current risk is:

☐ Low

☐ Moderate

Open Records

☐ Open ☐ Closed ☒ All

Near Misses

☒ Include near misses

☐ Exclude near misses

☐ Report near misses only

Medication records

☒ Include medications

☐ Exclude medications

☐ Report medications only

☐ All ☐ Risk ☐ Incident ☐ F'back

☒ Quality ☐ Plus ☐ Other

☐ Favourite

What this report does ...

Select a report on the left to see what it does.

10 ✓ All records summary
15 ✓ All Open Risk, Incident, Complaint & QI records
400 Issues Incidents and Improvements Summary
410 Clinical Indicator Listing
411 ✓ Clinical Indicator Counts and Bedday Rate
412 ✓ Clinical Indicator Benchmarking
413 Clinical Indicator Benchmarking using Ind Groups
414 ✓ Clinical Indicator by Individual Surgeon (graph)
416 Clinical Indicator - All Surgeons (graph)
417 Clinical Indicator Monthly Trends
418 Pre-admit Assessments & Post-op phone calls
420 ✓ Infection Events Listing
421 ✓ Infection Events count and Bedday rate
430 Survey Response Analysis 6-Months
431 Survey Response Analysis 6-Months (%)
432 Survey Report by Survey Type (graph)
433 Survey Responses by Month (graph)
435 Monthly Survey Summary
439 Blank Survey Form
440 Audit Summary Register
442 Audit Compliance Summary (graph)
444 Audit Quarterly Results by Area (graph)
450 Quality Improvement Register
452 Quality Improvement Report
453 Quality Report #2
455 Overdue QI Actions
457 Currently Open QI actions
470 ✓ Alerts Register

Run >

Report 470 Alerts Register – EXAMPLE ONLY

George Michael Memorial Hospital - Alerts

1 Jul 2020 to 31 Jan 2022

Record No: AL00149			
Alert Type: TGA Recall	Risk Level: Moderate	Date issued	3/11/2021
Short Description		Date Closed	(Currently open)
Hot/Cold Gel Packs Recall			
Coordinator(s)			
Quality Services Manager, Finance Manager, Nurse Unit Manager			
Notes			
Please respond and raise a Risk or QI if this Alert effects you			
Doc Link C:\Users\Gisele\Documents\Query3.xlsx			
7 notifyee(s)			
Nurse Unit Manager	Status Not set	Last Notification	3/11/2021 11:
Action-Outcome (No outcome)			
Linked QI No: (No links)	Linked Risk No: (No links)	Date Completed	(still open)
Nurse Co-ordinator	Status Not set	Last Notification	3/11/2021 11:
Action-Outcome (No outcome)			
Linked QI No: (No links)	Linked Risk No: (No links)	Date Completed	(still open)
Infection Control Nurse	Status In-progress	Last Notification	3/11/2021 11:
Action-Outcome Checking Batch No's			
Linked QI No: (No links)	Linked Risk No: (No links)	Date Completed	(still open)
Day Co-ordinator	Status Completed	Last Notification	(not notified)
Action-Outcome Stock Removed from Supply and bedside			
Linked QI No: (No links)	Linked Risk No: (No links)	Date Completed	3/11/2021
Day Therapy Services Manager	Status Not applicable	Last Notification	(not notified)
Action-Outcome (No outcome)			
Linked QI No: (No links)	Linked Risk No: (No links)	Date Completed	(still open)
Chief Executive Officer	Status Completed	Last Notification	(not notified)
Action-Outcome Stock removed			
Linked QI No: (No links)	Linked Risk No: 3846	Date Completed	3/11/2021
Director of Nursing	Status Not applicable	Last Notification	(not notified)
Action-Outcome N/A			
Linked QI No: (No links)	Linked Risk No: (No links)	Date Completed	(still open)

RiskClear Reports

Page 1 of 2

Thursday, 4 November 2021