s22 [redacted]
To: NOJA, Marcelle
s22 [redacted]
Subject: RE: Subject: Formal Complaint – s11C [redacted] [SEC=OFFICIAL:Sensitive, ACCESS=Personal-Privacy]
Date: Wednesday, 8 April 2026 11:09:45 AM
Attachments: image001.png

OFFICIAL:Sensitive//Personal-Privacy

Thank you Marcelle

I acknowledge your considerations s47F [redacted] If you require any assistance for you or your staff please do not hesitate to reach out.

Kind regards

s22 [redacted]

OFFICIAL:Sensitive//Personal-Privacy

From: NOJA, Marcelle <Marcelle.Noja@health.gov.au>
Sent: Tuesday, 31 March 2026 10:58 AM
s22 [redacted]
s22 [redacted]
Subject: FW: Subject: Formal Complaint – s11C [redacted] [SEC=OFFICIAL:Sensitive, ACCESS=Personal-Privacy]

OFFICIAL:Sensitive//Personal-Privacy

Hi s22 [redacted]

I am writing to advise of a complaint received by the TGA with allegations that a member of the public's complaint was not handled appropriately. Whilst this specific package of documents does not name staff, other communication submitted by s11C [redacted] and that have been subject to FOI have named TGA staff.

I note the complaints made, and can confirm I have assessed the complaints in line with the Department's complaint handling procedure and the Medical Device Branch complaints handling documentation (also attached for your reference).

s47F [redacted]

s47F [redacted]

s47F [redacted]

Happy to discuss.
Marcelle

Dr Marcelle Noja

Assistant Secretary – Medical Devices Surveillance Branch

Medical Devices and Product Quality
Health Products Regulation Group
Australian Government Department of Health, Disability and Ageing
T: s11C [redacted] | E: marcelle.noja@health.gov.au
PO Box 9848, Canberra ACT 2601, Australia

Executive Support: s22 [redacted]

Making flexibility work *- if you receive an email from me outside of normal business hours, I'm sending it at a time that suits me. Unless I reach out to you via IM, phone or text, I'm not expecting you to read or reply until normal business hours.*

OFFICIAL:Sensitive//Personal-Privacy

From: s11C [redacted]
Sent: Sunday, 29 March 2026 7:17 PM
To: NOJA, Marcelle <Marcelle.Noja@health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; IRIS <IRIS@health.gov.au>
Cc: regulatory.legal@health.gov.au
Subject: Subject: Formal Complaint – s11C [redacted]

clicking on URLs contained within an e-mail message that has been sent to you by an unfamiliar sender.

Subject: Formal Complaint – s11C (DIR Follow-Up)

Dear IRIS Team,

Dear Dr Noja,

Please find attached my formal complaint concerning the s11C , including prior Device Incident Report submissions dated 21 January 2024 and 15 February 2024, and supporting material.

The complaint raises concerns regarding discordant serology and potential false-negative outcomes, and seeks clarification as to the regulatory assessment and any action taken in response.

I would appreciate confirmation of receipt and advice as to the next steps.

Kind regards,
s11C

From: NOJA, Marcelle
s22 [redacted]
Subject: FW: Subject: Formal Complaint – s11C [redacted] [SEC=OFFICIAL:Sensitive, ACCESS=Personal-Privacy]
Date: Tuesday, 31 March 2026 10:58:23 AM
Attachments: s11C [redacted]
MDB SOP 5 Complaints & Appeals - Version 1.0.DOCX
image001.png

OFFICIAL:Sensitive//Personal-Privacy

Hi s22 [redacted]

I am writing to advise of a complaint received by the TGA with allegations that a member of the public's complaint was not handled appropriately. Whilst this specific package of documents does not name staff, other communication submitted by s11C [redacted] and that have been subject to FOI have named TGA staff.

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s47F [redacted]

s47F [redacted]

Happy to discuss.

Marcelle

Dr Marcelle Noja
Assistant Secretary – Medical Devices Surveillance Branch

Medical Devices and Product Quality
Health Products Regulation Group
Australian Government Department of Health, Disability and Ageing
T: s11C [redacted] | E: marcelle.noja@health.gov.au
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Sent: Sunday, 29 March 2026 7:17 PM
To: NOJA, Marcelle ; LAWLER, Tony ; IRIS
Cc: regulatory.legal@health.gov.au
Subject: Subject: Formal Complaint – s11C [redacted]

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I would appreciate confirmation of receipt and advice as to the next steps.

Kind regards,
s11C [redacted]

Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Medical Devices QMS

Standard Operating Procedure

Name of procedure	Complaints and Appeals
Applicable to	Medical Devices Branches
Number	MDB SOP 5
Written by	s22 [redacted]
Authorised	John Jamieson Assistant Secretary, Medical Devices Authorisation Branch Marcelle Noja Assistant Secretary, Medical Devices Surveillance Branch
Date issued	[Publish Date]
Version no.	1.0

Purpose

This SOP documents requirements for staff to ensure complaints and appeals are managed consistently, fairly, effectively, efficiently, and according to Departmental, HPRG and legislative requirements and frameworks.

Scope

This SOP applies to the specific action required to be taken by Medical Devices Branch staff upon receipt of:

- a complaint
- an appeal to an initial decision
- notification from the Internal Decision Review team an appeal raised under section 60 of the *Therapeutic Goods Act 1989*, regulation 48 of the *Therapeutic Goods Regulations 1990* and regulation 10.7 of the *Therapeutic Goods (Medical Devices) Regulations 2002* regarding an initial decision made requires review.

This procedure does not apply to complaints raised internally by staff of the Department of Health and Aged Care (the Department) or complaints considered out of the Department's portfolio responsibilities.

Definitions

A complaint is defined as an express statement of dissatisfaction about the Department where a response is sought and is reasonable to expect or legally required.

An appeal is defined as a request for reconsideration of an initial decision given by the Secretary.

Responsibility

Assistant Secretary MDAB/MDSB	To support an effective complaints management process. To drive change and improvement in response to process review, reporting and analysis. To ensure effective local procedures are implemented. Including the conduct of quality assurance reviews or self-audits. To review and respond to complaints escalated to tier 3, or where an internal review is requested. To refer any allegations of criminal misconduct to Fraud Control and Investigation Branch and misconduct to People Branch.
MDSAP Assessment Program Manager (APM)	To record complaints and other feedback received on the MDSAP Concern Resolution Report (CRR) Log. To assist in gathering the information relative to the appeals case. To assist in drafting the Appeal Decision notification letter and sends it to the AO. To ensure the implementation of the Appeal Decision made by the Regulatory Authority Council (RAC).

AuCAB Program Manager	To review and respond to complaints received regarding the AuCAB program. To assist in gathering the information relative to the appeals case. To assist in drafting the Appeal Decision notification letter and sends it to the AuCAB.
MDAB and MDSB Directors	To conduct the initial assessment, triage, investigation and response to complaints received. To manage and respond to complaints assessed as escalation tier 1 and 2. To report on issues and concerns arising from the complaints handling area. To provide access to ongoing training and support for complaints staff. To work with staff to identify strategies to manage unreasonable complainant behaviour. To implement a robust quality assurance and complaint review process. To ensure reviews or self-audits are conducted on the effectiveness of the implemented complaints management process every 2 years. To report on established KPIs to the executive.
EL2 Internal Decision Review delegate	To conduct internal decision review in a fair, impartial, and equitable manner. To complete internal decision reviews in the required 60 (calendar) days.
MDAB and MDSB staff	To record and handle complaints and appeals in an appropriate, transparent and timely manner in accordance with documented requirements. To demonstrate exemplary complaint handling practices. Be professional in all interactions and effectively recognise and respond to complainants' needs. To respond to all complainants in accordance with Health's Service Charter as documented in the Complaints Management Policy. To follow the APS Values and Code of Conduct when engaging with complainants, their delegate or advocate.

Contents

Procedure

Complaints

The Department has established a complaints management policy. It aims to ensure that staff are managing complaints consistently, effectively and efficiently. To do this the FAIR principles are applied. These are summarised below.

Complaints may be received from members of the public, the Department's customers and clients or external stakeholders, via verbal or written communication. They may involve:

- Services provided
- Services delivered by third parties and funded by the Department
- Programs, schemes and projects
- Investment of Commonwealth monies
- Policies and related materials
- The conduct of staff towards external stakeholders
- The complaints management process.

Complaints may be made either directly, by the complainant, their delegate or, advocate, or anonymously.

Applying the FAIR principles

Fairness and objectivity

All complaints will be treated fairly, with respect, investigated impartially, managed transparently and as required by the Privacy Policy.

Accessibility and visibility

Information on the complaints handling process is clear and publicised and ensures accessibility to all persons and the opportunity to render a complaint through a range of channels. Refer to appendix B of the Complaints Management Policy for specific entry points.

Integration and efficiency

Responsibilities are clearly defined. Divisions and teams will collaborate to resolve complaints. This will include other Government entities or third parties if required.

Complaints data and feedback will be used to inform change and improve service delivery. Data will include report volumes, complaint reasons, and actions taken to address identified root causes of complaints.

Responsiveness and accountability

Staff will act responsibly, ethically, professionally and accountably and will actively respond to the needs of vulnerable people to ensure full access to the complaints process.

A consistent and systematic approach will be applied to all complainants, including those who behave in an unreasonable manner.

Complaints management model

The Department maintains the central Complaints Management Policy. The process, management, monitoring and reporting of complaints is the responsibility of business areas.

If you receive or are involved in investigating or responding to a complaint refer to MDB WI 5.1 and MBD WFLOW 5 for details on how to proceed.

Key requirements for receiving and managing complaints

Accessibility

Lodging a complaint must be accessible, free and practical for all members of our community. Staff must apply the no wrong door policy and assist people to find the right complaint pathway.

If the complainant, their delegate or advocate indicates they are:

- Deaf, or have a hearing or speech impairment staff must provide information on the National Relay Service. Send the web link https://www.accesshub.gov.au/sites/default/files/documents/using-national-relay-service-nrs.pdf or provide the phone number 1300 555 727.
- A non-English speaker staff must provide information on the Australian Government translating and interpreting service. Send the link https://www.tisnational.gov.au/en/Our-services/Interpreting-services/Immediate-phone-interpreting or provide the phone number 131 450.

Records

Accurate records of complaints must be maintained in the Department's electronic document and records management system (TRIM). Complaint information should be restricted to authorised staff only on all systems where information is held. Access controls should be applied to CM/ TRIM folders and mailboxes containing complaints information. Where possible, complaints should be de-identified in complaint reporting and data collection.

Personal information must be managed as required by the *Privacy Act 1988,* the Privacy Policy and the *Archives Act 1983* and classified in accordance with the Protective Security Policy framework. The minimum document classification for a record relating to a complaint is *Official*.

Escalation

The complaint management policy has 4 escalation tiers:

Escalation tier	Person responsible	Requirements
1	Section Director	• Initial receipt • Simple complaint • Assessed as low risk impact
2	Director or Complaints Team Leader	• Complaint unresolved at tier 1 or • Complex complaint
3	AS or FAS	• Unresolved at tier 2 or • Complex complaint
4	External review	• Referred for review by an external entity e.g., Commonwealth Ombudsman

Refer to Summary Flowchart – Complaints for process steps and Appendix 1 – Escalation tiers.

Internal review

When a complainant is dissatisfied with the outcome or believes the complaints procedure may have been unfair, a request for internal review can be submitted, verbally or in writing. If you receive a request for review, ensure the original complaint is identified and the reason for review recorded. The internal review is to be referred to the Assistant Secretary of the relevant branch for review and action.

Unreasonable complainant conduct

Unreasonable conduct by complainants will not be tolerated and may result in staff ending communication with the complainant, their delegate or advocate. This includes unreasonable persistence, demands, lack of cooperation, arguments and unreasonable behaviour. Refer to the Unreasonable complainant conduct fact sheet for further guidance.

Key performance indicators

The complaint management policy has key performance indicators (KPIs) established for each phase of the process:

Process phase	Requirement	Timeframe (working days)
Record	from allocation to the designated official	5
Acknowledge	from receipt of complaint	5
Respond	Tier 1	10
	Tier 2	20
	Tier 3	40
Resolve	Tier 1	20
	Tier 2	40
	Tier 3	80
Communicate resolution	from completion of the investigation or review phase	5

Refer to Appendix 1 – Escalation tiers.

Reporting and analysis

Regular reporting on the functioning of the complaints process is required. The report should include:

- Number of complaints
- Causes and outcomes

- Trends and emerging issues
- Performance of complaints management against KPI's
- Any other relevant complainant data (e.g. geographic, demographic, cohort information).

Note: Data must be de-identified.

Process review

Areas that respond to complaints are required to conduct a review, or self-audits, every 2 years, to determine the effectiveness of the established process. The results and progress in implementing any identified outcomes are reported to the responsible management.

The review must include an evaluation of:

- The number and nature of complaints
- Compliance with the Complaints Management Policy and local procedures
- Accuracy and effectiveness of capturing, recording and internal reporting complaints.
- Time taken to manage and resolve complaints
- Correctness of recording complaints.

Note: Reporting, analysis, and process review activities are currently considered out of scope, and dependent on implementation of the complaints management process by HPRG.

Complaints relating to MDSAP

Complaints relating to the quality of the Medical Device Single Audit Program (MDSAP) work products, processes and services at the Regulatory Authorities, an Auditing Organization, or at a Medical Device manufacturer are managed by the MDSAP Assessment Program Manager in DMQS as per MDSAP QMS P0011: Complaints and/or Customer Feedback Procedure.

Feedback and complaints relating to therapeutic goods manufacturer audits

Feedback relating to our audits of a therapeutic goods manufacturer's QMS is received via the website feedback form. The form allows manufacturers to provide constructive feedback (positive and areas that need improvement) on the planning, conduct and communication of audits. If a manufacturer wants to give feedback on an audit, provide the website address https://www.tga.gov.au/resources/resource/forms/inspection-and-audit-feedback-forms to the requestor.

If the website cannot be accessed by the requestor, email the form directly to them and cc in DMQS using QMS.certificates@tga.gov.au. Ask the requestor to return the completed form to this email address.

Where the feedback received is an express statement of dissatisfaction it meets the definition of a complaint and is managed as per this SOP and MBD WFLOW 5.a. Refer to MDB WI 5.1 if you receive or are involved in investigating or responding to a complaint.

Complaints relating to AuCAB Program

Complaints relating to the AuCAB Program processes and services are managed by DMQS. Refer to MDB WI 5.1 for receipt of complaint, then refer the case to the AuCAB Program Manager in DMQS.

Appeals

Internal decision review

The Internal Decision Review team within the HPRG Regulatory Legal Services Branch coordinate internal reviews for initial decisions made under the:

- *Therapeutics Goods Act 1989*, section 60
- *Therapeutic Goods Regulations 1990*, regulation 48
- *Therapeutic Goods (Medical Devices) Regulations 2002*, regulation 10.7.

The Decision Review Coordinator allocates reviews to approved EL2 staff nominated by their Branch Head and recorded as a delegate. Refer to the instrument of delegation specific to HPRG positions for delegations. Reviews are allocated in a fair, impartial, and equitable manner. Internal review delegates must not have been involved in the making of the initial decision or be the initial decision maker's line manager.

If you become aware that a request for review has been (or has the potential) to be made, contact the Decision Review Coordinator by emailing decision.review@health.gov.au. Include in the email any relevant details (e.g. application number, persons contact details, the current information known relating to the request or communication). The Decision Review Coordinator (Regulatory Legal Services Section) monitors and coordinates requests for review.

If you receive a query regarding the making of a request, the progress or status of a current review or require advice on what constitutes a reviewable initial decision contact the Internal Decision Review team by email to decision.review@health.gov.au. Refer to the Decision Review SharePoint site https://healthgov.sharepoint.com/sites/DecisionReview for further information.

Overview of the decision review process

Initial decision

An initial decision must be made. Persons must be informed that the initial decision is a reviewable decision. Refer to https://healthgov.sharepoint.com/sites/DecisionReview for statements included with initial decisions.

Request

Within 90 calendars days after the notice is given in writing, published in the Gazette or on the TGA website, whichever is earlier, a request to the Minister to reconsider the decision must be made.

Review

Receipt of the request is confirmed by written acknowledgment from the Internal Decision Review team.

The Minister or delegate undertakes the review request.

Outcome

The outcome of the review can:

- Confirm the initial decision
- Revoke the initial decision (overturn the initial decision)
- Revoke and substitute the initial decision with a new decision
- Remit the initial decision. This applies only to section 60 reconsideration. Further assessment fees are required to be paid and a new initial decision is made, taking into account the 'new' information provided.

If the initial decision was published in the Gazette or TGA website the particulars of the decision upon reconsideration must be published.

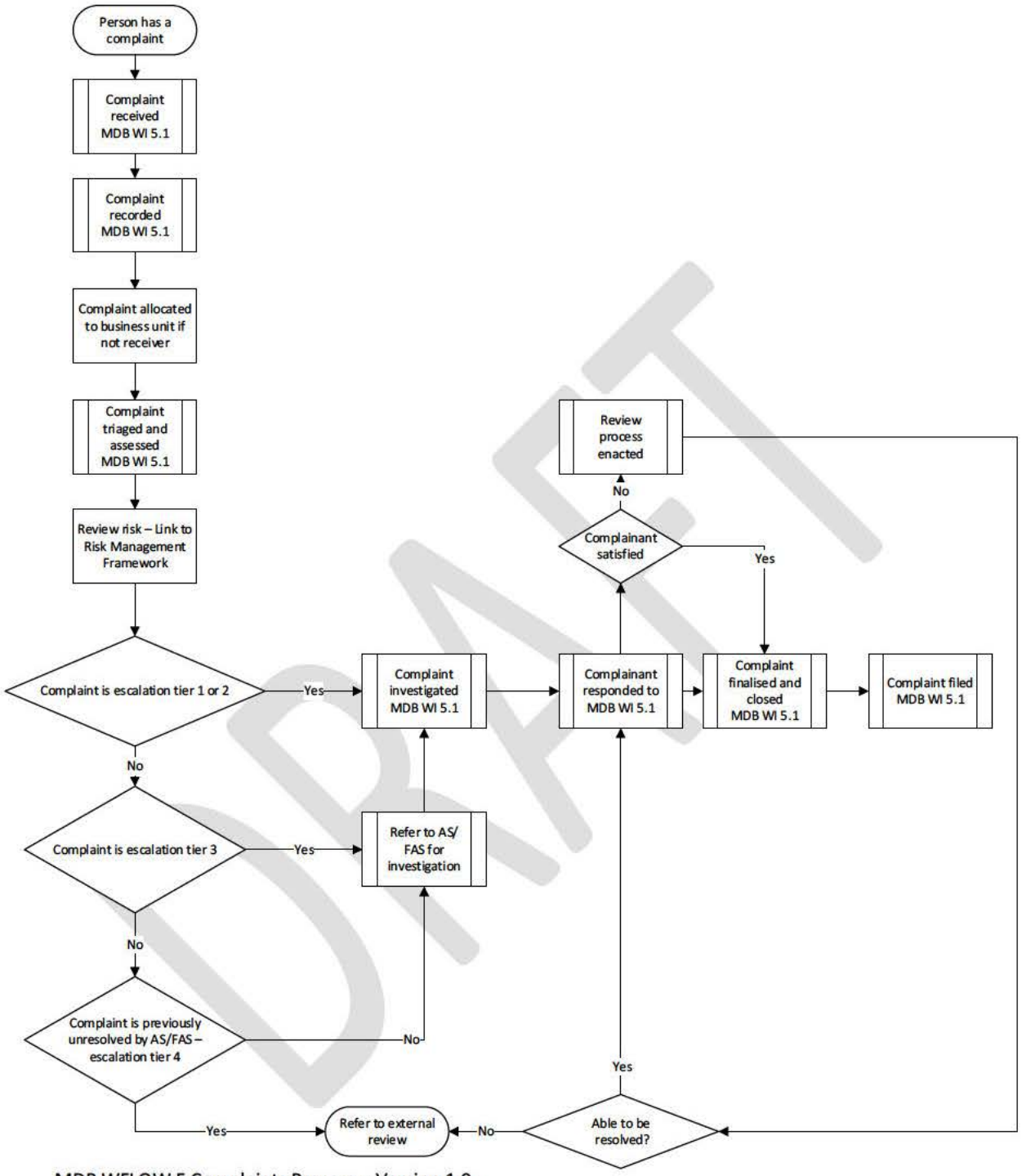
The outcome of a decision on review is required within 60 (calendar) days from the date the request and must be provided in writing.

If the persons requesting the review are dissatisfied with the decision an application to the Administrative Appeals Tribunal for review of the reconsideration can be made (subject to the Administrative Appeals Tribunal Act 1975).

MDSAP appeals

Appeals related to MDSAP assessment activities are managed by the MDSAP Assessment Program Manager in DMQS as per the procedure MDSAP AS P0021.

Summary Flowchart – Complaints



MDB WFLOW 5 Complaints Process – Version 1.0

References

Complaints Management Policy November 2023

Vulnerable People Factsheet (Complaints) September 2023

Privacy Policy (October 2022)

APS Values

APS Code of Conduct

TGA customer service standards

Using the National Relay Service (NRS)

Translation and Interpreting Service immediate phone interpreting

Commonwealth Ombudsman Better Practice Complaint Handling Guide (17 February 2023)

Commonwealth Ombudsman Fact Sheet Unreasonable complainant conduct

Protective Security Policy Framework

Managing Complaints SharePoint page

ISO 9001: 2015 Quality management systems – Requirements

AS/NZS 10002-2022 Guidelines for Complaints Handling in Organisations

ISO 17021-1: 2015 Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements

Privacy Act 1988

MDSAP QMS P0011: Complaints and/or Customer Feedback Procedure

MDSAP Assessment Procedures and Forms

Therapeutic Goods Act 1989

Therapeutic Goods Regulations 1990

Therapeutic Goods (Medical Devices) Regulations 2002

Administrative Appeals Tribunal Act 1975

Decision Review SharePoint page

Delegations and authorisations instruments

Guidance for requesting reconsideration of an initial decision (March 2023)

Inspection and audit feedback forms

TGA quality management system audits and certification Guidance for manufacturers of medical devices (December 2023)

Appendices

Appendix 1 – Escalation tiers

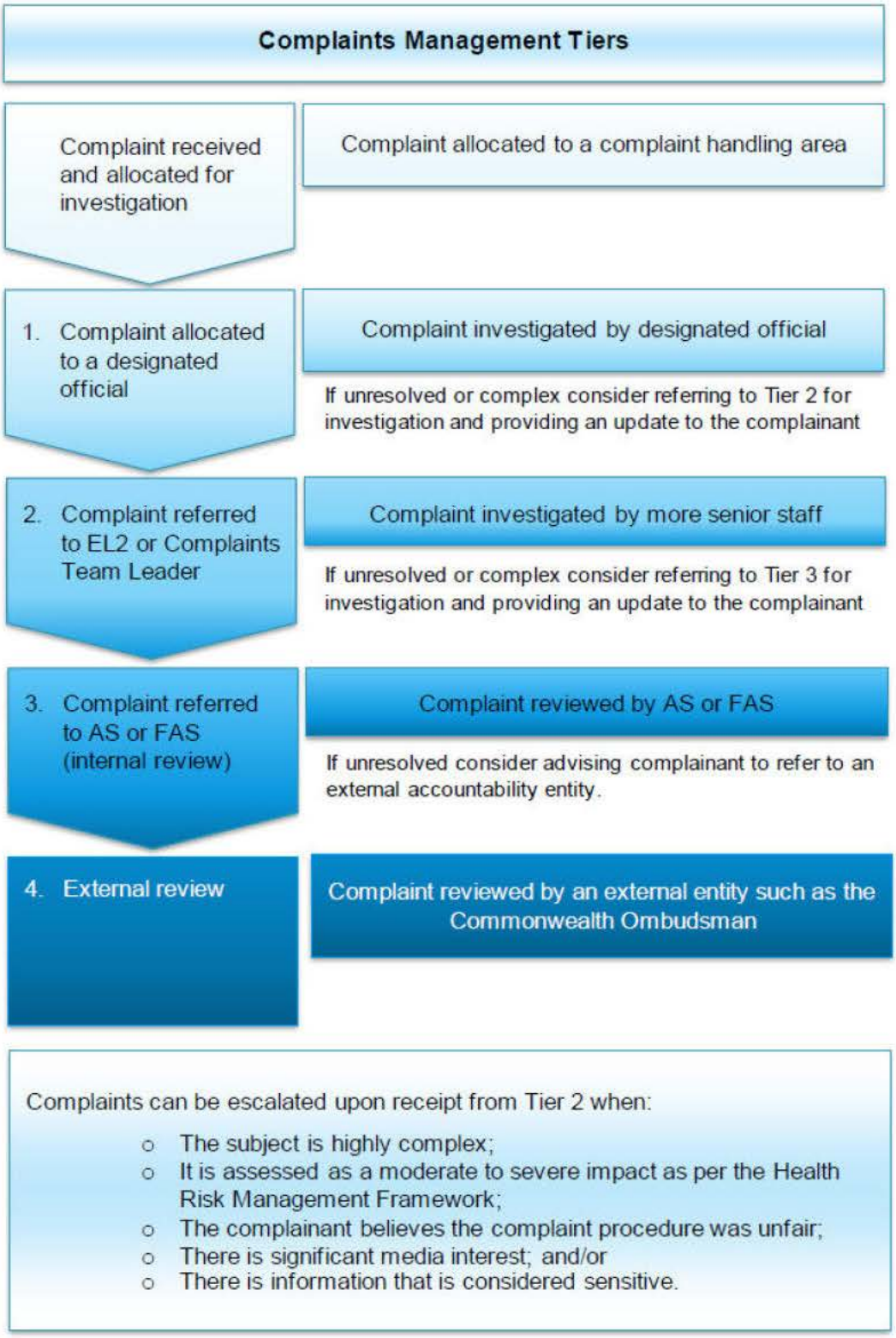
Appendix 2 – Key performance indicators

Version history

Version	CM/ TRIM Reference	Description of change	Authors	Effective date
V1.0	D24-410474	New document.	s22 [redacted]	

Appendix 1 – Escalation tiers

Escalation Tiers

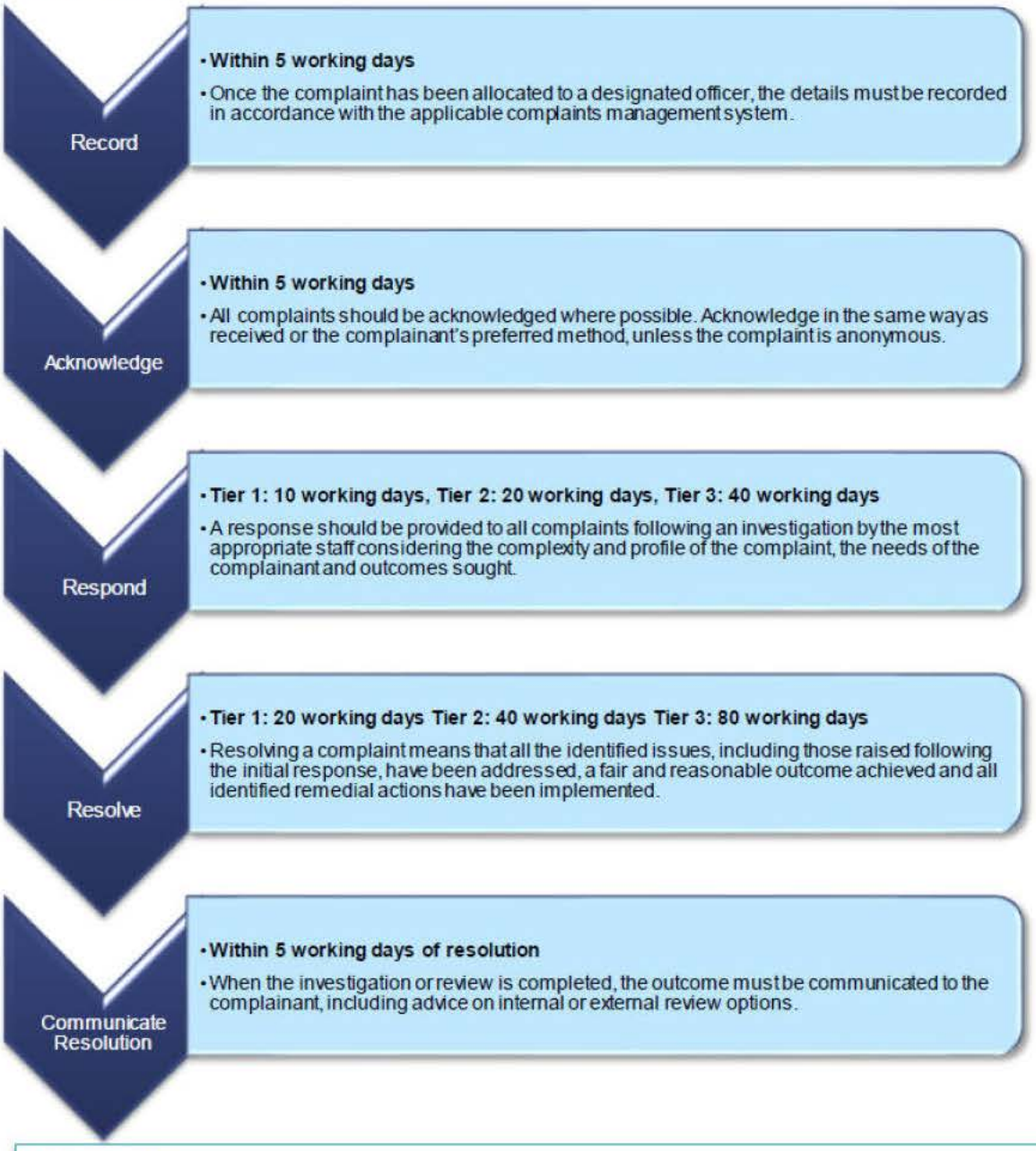


Source: Complaints Management Policy November 2023

Appendix 2 – Key performance indicators

Key Performance Indicators

Health receives complaints ranging from the straightforward, which can be resolved in days, to the highly technical or sensitive which require thorough investigation and analysis. Complaint handling areas should establish Key Performance Indicators (KPIs) that reflect the nature of complaints managed. The model below provides guidance areas must consider when establishing KPIs.



Please note:

- Timeframes noted above refer to days from receipt by Health unless stated otherwise.
- Timeframes noted above to respond to and resolve complaints may be exceeded for individual complaints due to their complexity, risk profile and sensitivity; and for third parties due to access to information.
- Automatic responses can be generated to acknowledge that emails have been received.

Source: Complaints Management Policy November 2023

Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Medical Devices QMS

Work Instruction	
Name of procedure	Team review of Device Incident Reports
Applicable to	Medical Devices Program– Devices Post Market Monitoring Section
Number	DPMMS WI 1.11
Written by	s22 [redacted]
Authorised	s22 [redacted] Director, Devices Post Market Monitoring Section
Date issued	29 July 2025
Version no.	2.2

Guidelines

Medical device incident reports are received from consumers, health professionals, and sponsors either electronically through the medical device incident reporting (MDIR) scheme or by email, or printed copies of the MDIR form.

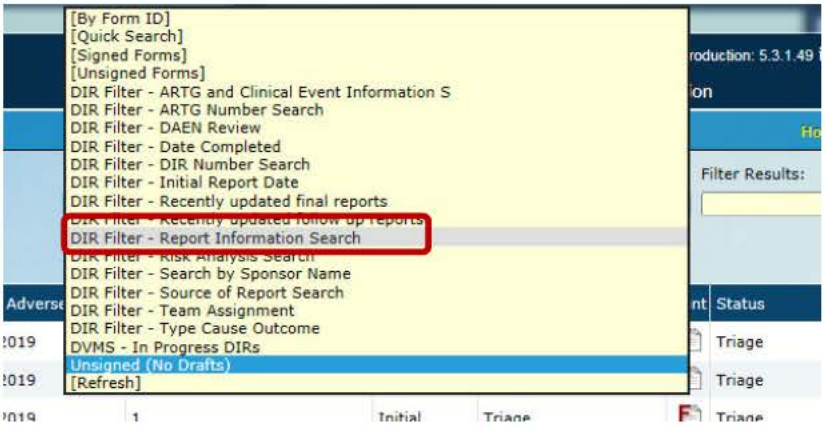
The Team Review (DIRE) meeting usually occurs weekly following the risk assessment and triage process of device incident reports (DIRs) as a forum to review and discuss considerations about reports flagged for discussion. The Team review report is distributed to all team members as well as representatives from the Devices Clinical Surveillance Section on the Friday prior to the meeting (at 2pm). During the meeting, each report is discussed. Attendees provide inputs and advice about whether a report is to be investigated, and a decision will be recommended to the relevant team leader based on device classification.

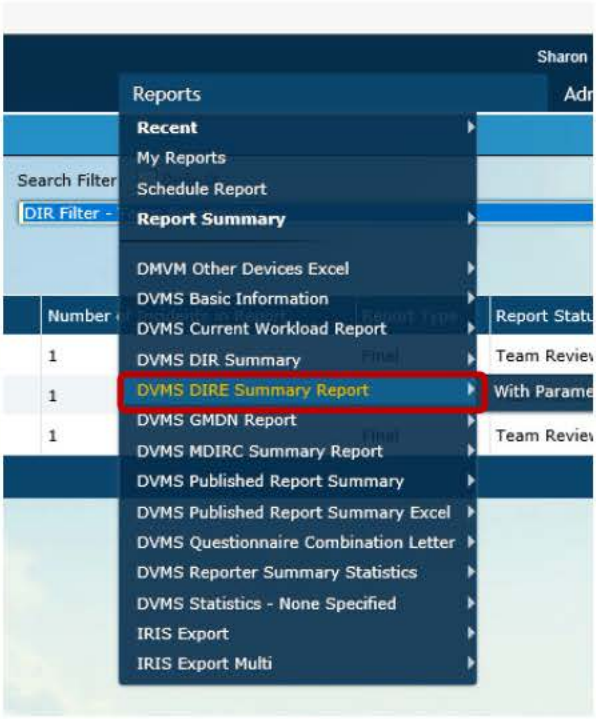
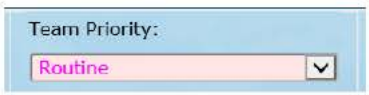
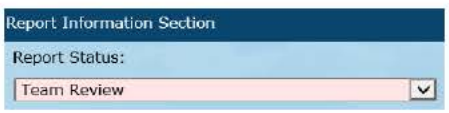
This Work Instruction documents processes:

- Before the team meeting
- After the Team meeting

This Work Instruction does not include instructions on the receipt or processing of the device incident reports (DIRs) or the investigation process following the risk assessment process. These are described in DPMMS WI 1.1 and DPMMS WI 1.3, respectively. Administrative procedures carried out by DST can be found in the DPMMS SOP 12 series.

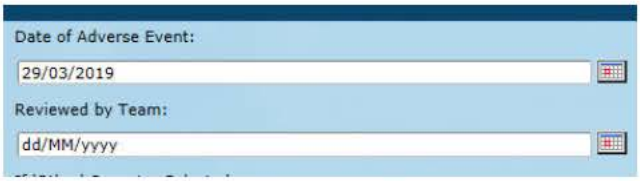
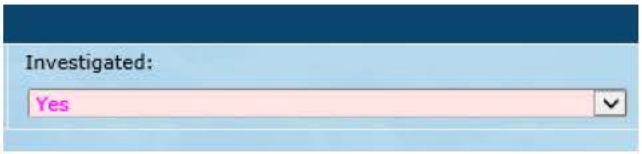
Before the team meeting

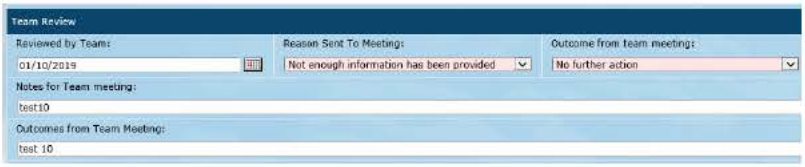
#	Step	Responsible
1.	**Open the InfoLeader database** From the home page of IRIS select the DIR tile: 	IRIS Triager
2.	Use search bar and select 'Report Information Search': Click on the Flow tab 	IRIS Triager
3.	Select 'Team review' in the Report Status, untick the date of final report.  Press 'Run'.	IRIS Triager

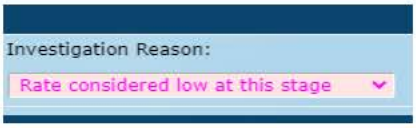
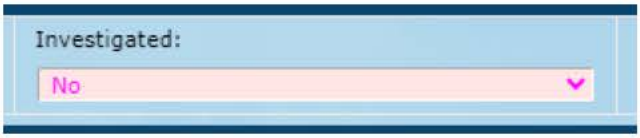
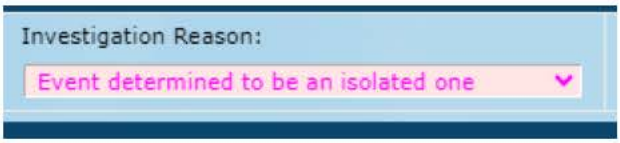
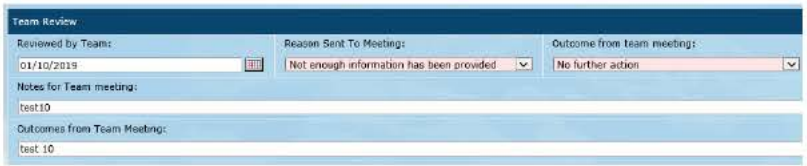
#	Step	Responsible
4.	Hover over reports and select 'DIRE summary Report'. 	IRIS Triager
5.	Once the report is generated count how many DIRs are in it to ensure you have captured them all. If any are missing search for the DIR as the triager may have answered the below steps incorrectly and update accordingly, then re-run the report. The key areas to look for are: • A Final date has been added on the Report Information page  • 'Routine' is selected in the Risk Analysis page under the team priority drop down box  • Report status has been set to Team Review  • The overall status has been set to Team Review and assigned to OPR Administration User 	IRIS Triager

#	Step	Responsible
6.	In the report change the heading to Team Meeting Report and include the date of the team meeting: Team Meeting Report – XX/ Month/202X	IRIS Triager
7.	Tidy the report format and ensure all the information is present. **Note:** Some boxes may need to be expanded. Click on the box within the report information and adjust the size as required Safety System. Details of Similar Events: There have been no other similar events reported. ***** End of DIR 59139 *****	IRIS Triager
8.	For each report insert a text box after the report and include the words from the risk analysis page in section 'Notes for team meeting':  Example in report: ***** End of DIR 103974 *****  	IRIS Triager
9.	Once completed save the document to your desktop and then send to the section and allocated clinical evaluators in an email.	IRIS Triager

After the Team meeting

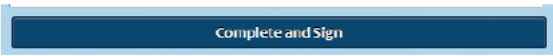
#	Step	Responsible
10.	On the Report Information page put the date the DIR was reviewed in the 'Reviewed by team' area.  a. Change the Report status to 'Active' if it is for investigation. b. Change the report status to 'Complete' if it is to be closed. <table><tr><th>If</th><th>Then</th></tr><tr><td>The DIR needs investigation</td><td>Go to step 12</td></tr><tr><td>The DIR does not need investigation</td><td>Go to step 13</td></tr></table>	IRIS Triager
11.	On the Risk Analysis page fill out all tabs in the Report status. If the Device required investigation, select 'YES' on the drop down on the Risk Analysis page.  Choose an Investigation reason from the drop-down box under that heading depending on what was discussed at the team review meeting.  	IRIS Triager

#	Step	Responsible
	Fill out all the parts in the 'Reviewed by team' section, including: • The date of review • Outcome of the meeting drop down box • Outcome from team meeting  Press 'Save'.	
12.	In the Flow tab change the status to: Investigation. Then assign the DIR to team leader of the associated team assignment or nominated investigator (if unsure, this can be found in Risk Analysis, under Report Status) with the following:  Words when sending to the Team Leader: *This investigation was assigned to your team at the team meeting. Click the [F] button to view the details.* Words used by the Team Leader when sending to the investigator: *This investigation was assigned to you at the team meeting. Click the [F] button to view the details.* *Please add your questions in the comments box after reassigning (in the 'Status' drop down box) to Device Support Team (in the 'Assigned to Role' drop down box) by DATE* *Make sure you include the following on your return wording "Upon return please send to XXXX"]*	IRIS Triager
13.	If the Device does NOT require investigation: On the Risk Analysis page fill out all areas in the Report status, as sometimes the other drop-down boxes are missed when sent to meeting. If the Device does NOT require investigation, select No' in the drop down on the Risk Analysis page. 	IRIS Triager

#	Step	Responsible
	Choose a reason for not investigating from the drop-down box under that heading depending on what was discussed at the team review meeting. An example is below. 	
14.	On the Risk Analysis page fill out all tabs in the Report status. If the Device required investigation, select 'NO' on the drop down on the Risk Analysis page.  Choose an Investigation reason from the drop-down box under that heading depending on what was discussed at the team review meeting.  Fill out all the parts in the 'Reviewed by team' section, including: • The date of review • Outcome of the meeting drop down box • Outcome from team meeting  Press 'Save'.	IRIS Triager
15.	In the flow, do not change the status in the flow. Send to the Triager who initially sent the report to the meeting for closure with the following words: *This DIR was assigned to you at the DIRE meeting to close. Click the [F] button to view the details.*	IRIS Triager

Investigator to Close

<table>
<tr><th>#</th><th>Step</th><th>Responsible</th></tr>
<tr><td>16.</td><td>Proceed as follows:<table><tr><th>If</th><th>Then</th></tr><tr><td>The DIR is a User/HCP report</td><td>Go to step 17</td></tr><tr><td>The DIR is a Sponsor report</td><td>Go to step 19</td></tr><tr><td>The DIR is from a Competitor and is not being investigated</td><td>Send to DST to close after completing steps 17 and 19</td></tr><tr><td>The DIR is an amended final report</td><td>Follow DPMMS WI 1.17</td></tr></table></td><td>Investigator</td></tr>
<tr><td>17.</td><td>Fill in the Investigation Summary:
a. Investigation findings
b. Investigation conclusion
c. Investigation outcomes
As this is a user report leave the Summary section empty.</td><td>Investigator</td></tr>
<tr><td>18.</td><td>In the flow send to the device support team with the following:
Please close with standard User or HCP report wording
Thanks</td><td>Investigator</td></tr>
<tr><td>19.</td><td>Fill in the Investigation Summary:
a. Investigation findings
b. Investigation conclusion
c. Investigation outcomes
As this is a sponsor report fill out the ‘Summary Findings’ with:
No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate. The TGA expects both you and the manufacturer to undertake relevant processing, analysis and investigation of all incidents in accordance with your documented procedures.</td><td>Investigator</td></tr>
</table>

#	Step	Responsible
20.	On the sponsor page in the section of Additional comments (at the bottom) write: *DIR closed XX/XX/202X*	Investigator
21.	On the Report Information page (first one) press the complete and sign button. 	Investigator

Version history

Version	CM/ TRIM Reference	Description of change	Authors	Effective date
V1.0	D19-6241978	New WI	s22	28 Oct 2019
V1.1	D21-2293088	Update to include extra information and workflows Addition of step 19 and small changes to formatting	s22	17 Mar 2021
V2.0	D21-3302938	Update to include extra information to reflect current practice Update to the WI sequence Updated to current template	s22	4 Dec 2024
V2.1	D25-287035	Correction of step reference in step 16 and inclusion of direction for closing an amended final report included	s22	18 Feb 2025
V2.2	D25-3129458	Updated to current template to incorporate machinations of government changes and align formatting Hyperlinks within document replaced with cross references to step numbers and headings for ease of future updates.	s22	29 July 2025

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Medical Devices QMS

Work Instruction	
Name of procedure	Searching for the ARTG Number of a Medical Device
Applicable to	Medical Devices Branches – Devices Post Market Monitoring Section
Number	DPMMS WI 12.6
Written by	s22 [redacted]
Authorised	s22 [redacted] Director, Devices Post Market Monitoring Section
Date issued	7 February 2025
Version no.	1.0

Guidelines

Medical Device Incident Reports (DIRs) are received from consumers, health professionals, and sponsors either electronically through the medical device incident reporting (MDIR) scheme or by email, or printed copies of the MDIR form.

When users submit Medical Device Incident Reports, they may not identify an ARTG number. It is the responsibility of the Device Support Team (DST) member to attempt to find the applicable ARTG number, based on the information provided. This work instruction explains different ways of finding an ARTG number.

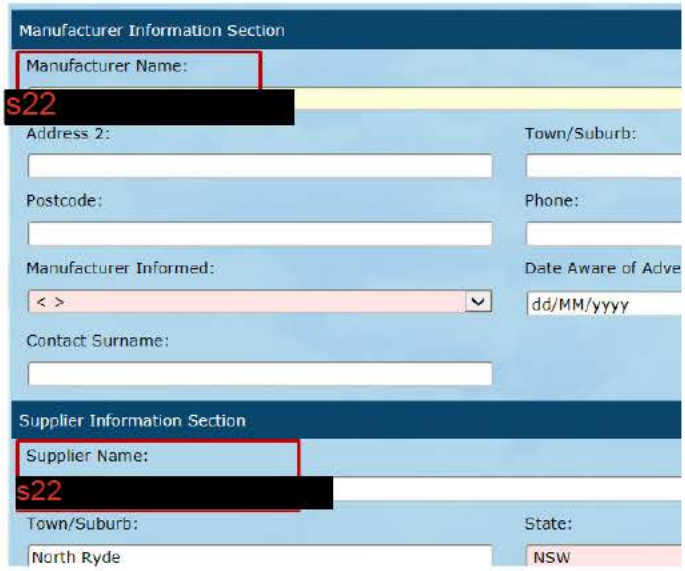
This work instruction provides 3 methods for locating an ARTG number:

1. The Register in Lotus/ IBM Notes
2. Devices In Tray in Lotus/ IBM Notes
3. Searching InfoLeader

IMPORTANT:

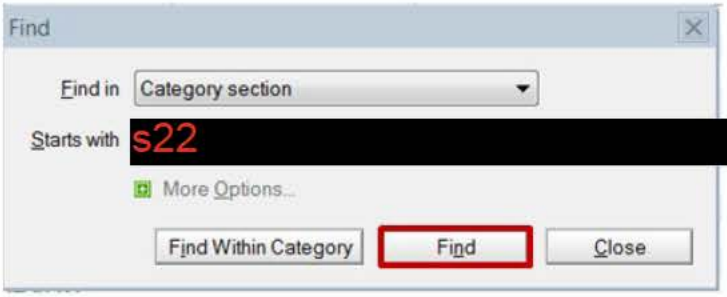
- You must have requested and obtained access to Lotus Notes before attempting to use this application to search for an ARTG entry (See Appendix A).
- If the search takes longer than 5 minutes, consult with the DST Team Leader for ARTG selection or appropriate action.

Procedure/Process

#	Step	Responsible
1.	Check the 'Search Device ARTG field' in InformationLeader. If it is blank, proceed to Step 2. 	Device Support Team (DST) / Investigator
2.	Check the 'Brand Name:' and 'Initial Device Description:' fields for any defining details. 	Device Support Team (DST) / Investigator
3.	Check if the reporter has provided the details of the 'Supplier Name' and or 'Manufacturer Name'. 	Device Support Team (DST) / Investigator

#	Step	Responsible
4.	Also read through the 'Clinical Event Information:' field to check for any defining or important applicable information regarding the device.  You can also refer to the original copy of the attached User Report for any possible information removed in relation to sponsor or manufacturer details.	Device Support Team (DST) / Investigator
5.	**The Register within IBM Notes** See Appendix A if you have not previously used Lotus Notes. Click on 'Register'. 	Device Support Team (DST) / Investigator

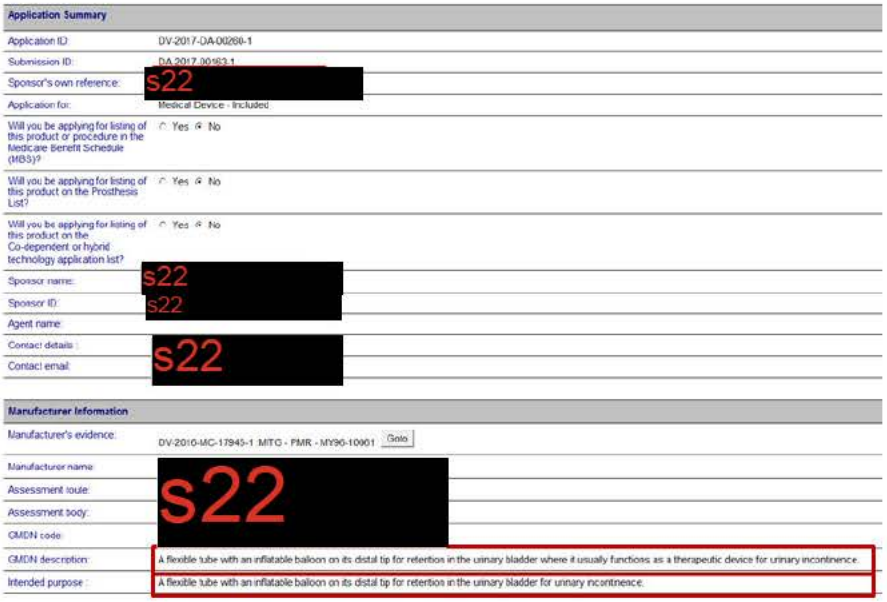
#	Step	Responsible
6.	Expand the Devices drop-down and click 'Medical Devices'. 	Device Support Team (DST) / Investigator
7.	Copy and paste or type in some of the details of the device as well as the supplier or manufacturer name in the 'Search for' field. Press the Search button or Enter key on your keyboard to show results. 	Device Support Team (DST) / Investigator
8.	Check to see if any of the results match the reported device. Ensure the Sponsor and or Manufacturer are correct as well. If there are no results or the results do not quite match, use alternative word variations with the information from the report and if still not confident with the results, follow the next step/s for other search methods. **Note:** Sometimes it is easy to find the ARTG number in this first check, however it is common not to immediately find it as the device may be under a general GMDN term and not a specific device name.	Device Support Team (DST) / Investigator

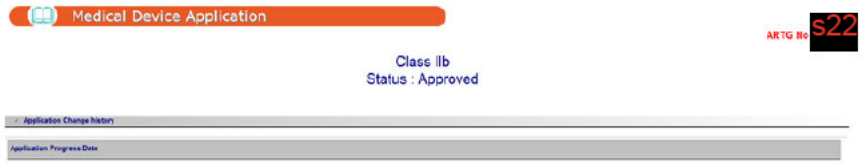
#	Step	Responsible
9.	Expand the Manufacturers drop-down at the bottom of 'The Register' and click 'of Current Entries'. 	Device Support Team (DST) / Investigator
10.	Close any search field (x at the top right of the screen) and start typing the manufacturer name in full. A 'Find' dialogue box will appear, and your typed words should appear in the 'Starts with' field. 	Device Support Team (DST) / Investigator
11.	Click on the 'Find' button or press the 'Enter' key on your keyboard. 	Device Support Team (DST) / Investigator
12.	Locate the **exact** manufacturer name in the list (ensure it is the correct name as they can be slightly different, and ensure the country matches the manufacturer details) and expand the selection under the name.	Device Support Team (DST) / Investigator

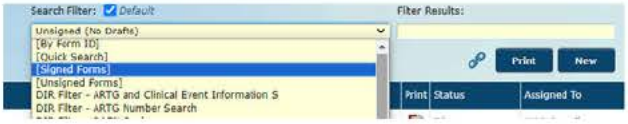
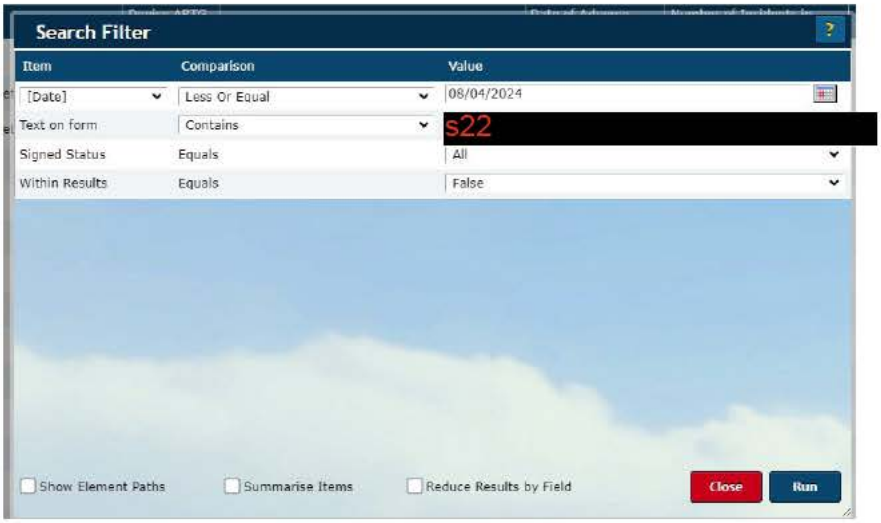
#	Step	Responsible
	s22	
13.	Locate the supplier or sponsor's name underneath. s22	Device Support Team (DST) / Investigator
14.	Click on the 'D' to expand the list of Devices this supplier or sponsor has ownership of. s22 (M is for Medicines if this appears in your search.)	Device Support Team (DST) / Investigator

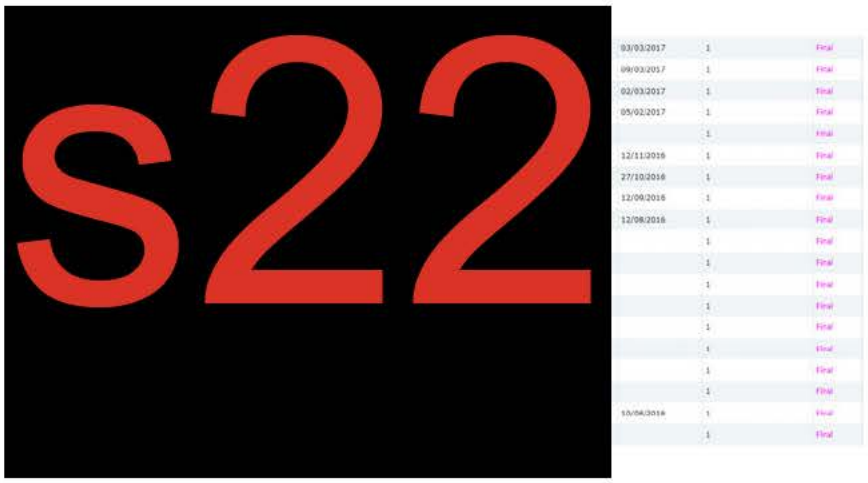
#	Step	Responsible
15.	Check the list to see if you can find the applicable ARTG number. If you are not confident with the results, follow the next step/s for other search methods. s22	Device Support Team (DST) / Investigator
16.	**Search Devices In Tray** Go to the 'Notes Home' view. 	Device Support Team (DST) / Investigator

#	Step	Responsible
17.	Click on 'Medical Devices' and then click on 'Devices In-tray'. 	Device Support Team (DST) / Investigator
18.	Click on 'Approved' under 'In Tray Main'. 	Device Support Team (DST) / Investigator
19.	Copy and paste, or type in, some of the details of the device and the supplier, or manufacturer, name in the 'Search for' field. Press the 'Search' button or 'Enter' key on your keyboard to show any results. 	Device Support Team (DST) / Investigator

#	Step	Responsible
	s22	
20.	Double click each of the results to open the device application details. Check that the Sponsor and or Manufacturer name match your information.  The ARTG number will be at the top right of the form.  **Note**: If the details **do not match**, refer to the Team Leader for ARTG entry selection or appropriate action.	Device Support Team (DST) / Investigator

#	Step	Responsible
21.	If the details **match**: Copy the ARTG number at the top right of the form: 	Device Support Team (DST)
22.	Go back to the Register. 	Device Support Team (DST)
23.	Paste the ARTG number into one of the search fields and click the magnifying glass icon or hit the Enter key on your keyboard to search. 	Device Support Team (DST)
24.	If the ARTG entry is 'Active' and you are satisfied with the result, then this is the number you use for the purpose of the search.  If the purpose was to look up the ARTG number for an InformationLeader report, copy and paste the ARTG number into the InformationLeader report, save and flow onto the appropriate team triage member. When you are still uncertain you can include a note to the investigator in the flow 'Please confirm ARTG number'.	Device Support Team (DST)

#	Step	Responsible
25.	If there are no results or the number is Inactive, refer to the DST Team Leader for ARTG selection and appropriate action.	Device Support Team (DST)
26.	**Search in InformationLeader** Open an additional InformationLeader and select Quick Search from the drop-down menu. 	Device Support Team (DST)
27.	In the 'Date Field select from the drop-down list 'Less or Equal'. From the information you have been provided in the User Report, you can enter in the 'Text on form' field either a model number, serial number, or device description. Then select 'Run'. 	Device Support Team (DST)

#	Step	Responsible
28.	Once the list has populated, choose the ARTG number which most closely matches the information that has been provided (Manufacturer, Sponsor, Initial Device Description etc). 	Device Support Team (DST)
29.	Copy the ARTG number from InformationLeader and paste it in IBM notes register search fields to verify the ARTG number. If you are satisfied with the result, this is the number you will use for the device incident report.	Device Support Team (DST)
30.	Copy and paste the ARTG number into the InformationLeader report, save and flow onto the appropriate team triage person as required. When you are still uncertain include a note to the investigator in the flow 'Please confirm ARTG number'.	Device Support Team (DST)
31.	This completes the process of Searching for the ARTG Number for a device.	Device Support Team (DST)

Version history

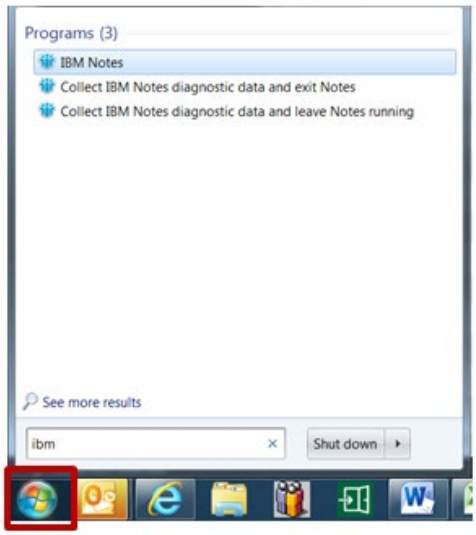
Version	TRIM Reference	Description of change	Authors	Effective date
V1.0	D24-2360263	New Work Instruction	s22	7 Feb 2025

Appendix A: Accessing Lotus Notes

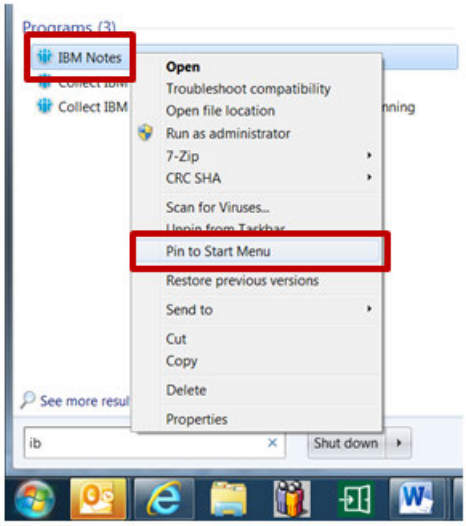
Ensure you have access to IBM Notes. If you do not, discuss obtaining access with your Team Leader.

When opening IBM Notes for the first time:

- Find the IBM Notes program in the Start menu.



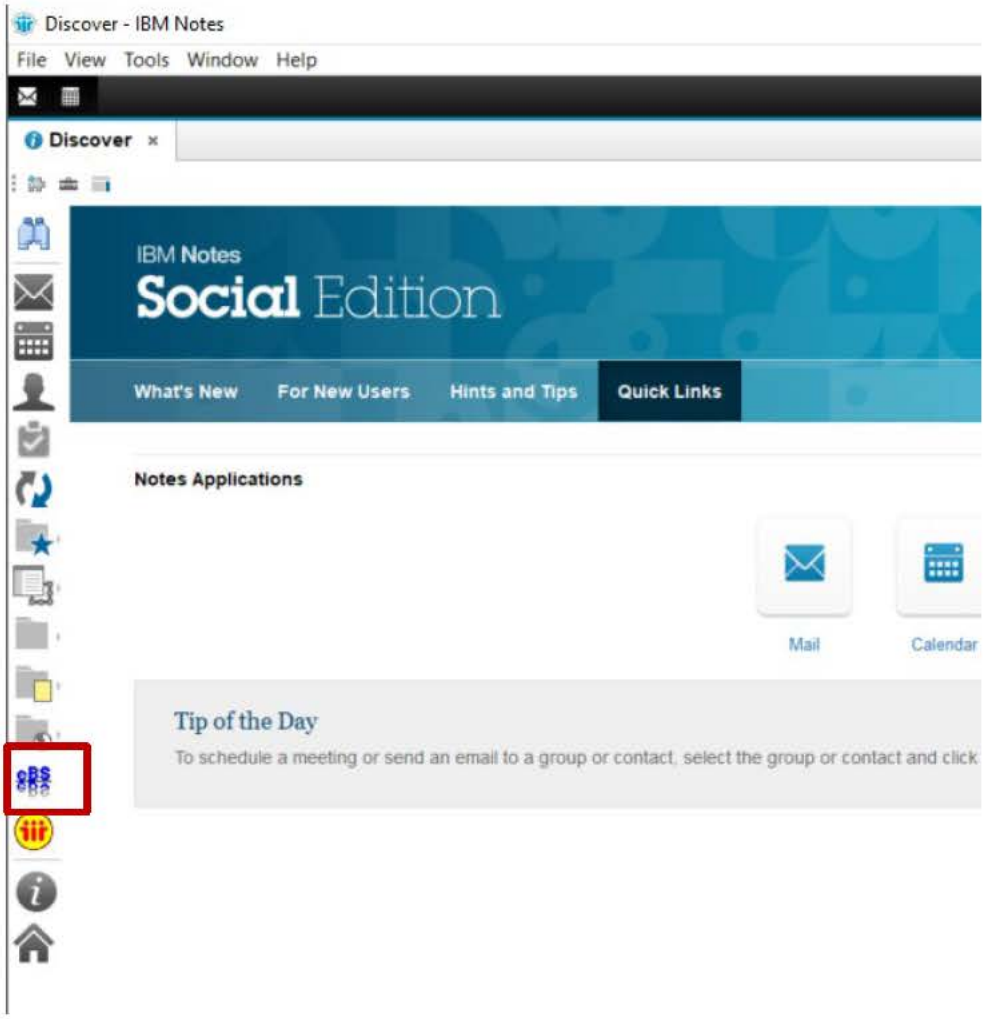
- Pin the program/icon to your footer taskbar menu.



- Click on the IBM Notes icon in your footer taskbar menu to open the program.

- Enter the password you have been provided.

- Click on the  icon on the left side menu. Follow the steps in this WI to search IBM Notes applications in this WI.



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Medical Devices QMS

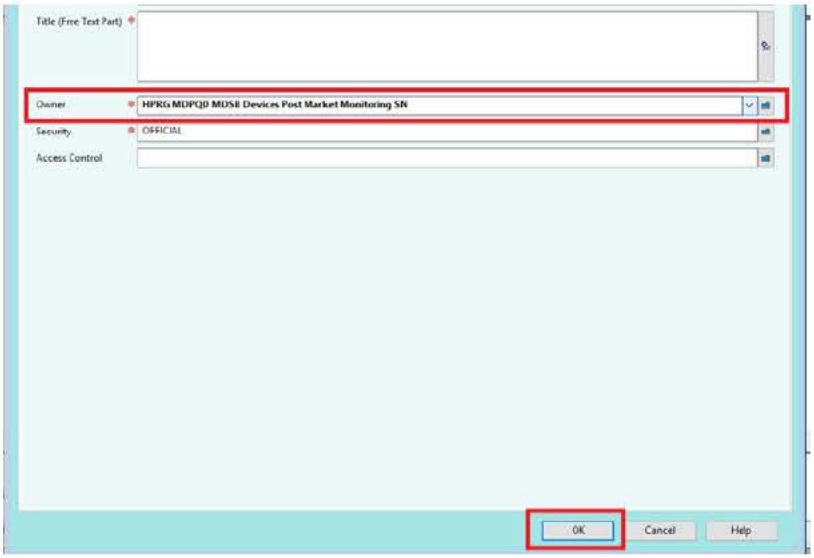
Work Instruction	
Name of procedure	Creating a CM file using DPMMS file naming convention for DIR triage and investigations
Applicable to	Medical Devices Branches – Devices Post Market Monitoring Section
Number	DPMMS WI 17.1
Written by	s22 [redacted]
Authorised	s22 [redacted] Director, Devices Post Market Monitoring Section
Date issued	05 March 2026
Version no.	1.1

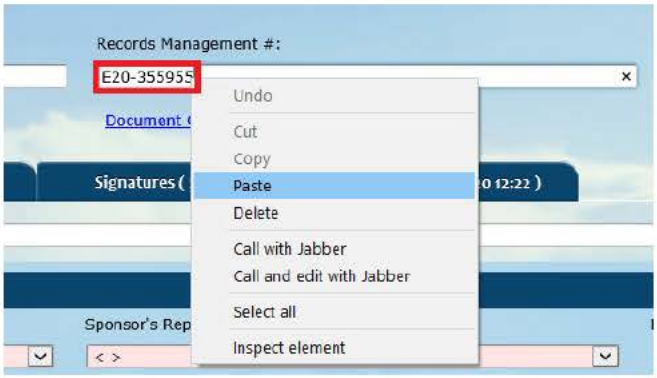
Guidelines

The purpose of this document is to ensure consistency of the file naming convention for Content Manager (CM) containers created and used in DPMMS for device incident report (DIR) investigations and post market investigations.

DPMMS naming convention in CM for DIR triage and investigations

#	Step	Responsible
1.	Create a digital file using the CM Quick Reference Guide.	DPMMS Staff
2.	Name the file using the fields, as follows for 'Classification': THERAPEUTIC GOODS REGULATION – Investigations	DPMMS Staff
3.	In the Title (Free Text Part) field, enter the DIR naming convention as follows: *DIR [number] – ARTG ID – Sponsor Name – Device Description* For example: THERAPEUTIC GOODS REGULATION – Investigations s22  If the matter involves too many ARTG numbers for the title, utilise the most representative ARTG numbers (up to 5). E.g. the key components of a joint system, or sponsors with perceived major market share.	DPMMS Staff

#	Step	Responsible
4.	Ensure the 'Owner' section is 'HPRG MDPQD MDSB Devices Post Market Monitoring SN'. Then select OK. 	DPMMS Staff
5.	Select 'Related Records'. Right click and 'add related record'. Search under the 'With record' section for the appropriate Placeholder. Include the CM File 'Alternatively within' (E.g. DPMMS – DIR Investigations – Q4 2025). Click 'OK' to save the related record and click OK again to generate the Digital File. See CM helpcard -Relate Records.	DPMMS Staff
6.	Right click on the Record Number and copy text. 	DPMMS Staff

#	Step	Responsible
7.	Paste the record number into the Records Management #: field within the DIR in InfoLeader.   Select 'Save'.	DPMMS Staff
8.	This completes the process for creating a CM Record Number for a Device Incident Report (DIR).	DPMMS Staff

Version history

Version	CM/ TRIM Reference	Description of change	Authors	Effective date
V1.0	Published - D25-5368934 DRAFT - D24-2244189	Relocated in QMS from DPMMS WI 1.33 V1.0 (D21-2476166) to DPMMS WI 17.1 V1.0 Updated to current template to incorporate machinations of government changes and align formatting References to TRIM updated to Content Manager (CM) after May 2025 update and change to intranet references New template. Minor formatting changes. Guidelines remained from previous version. Hyperlinks repaired Added step to ensure Digital File is placed within a Placeholder.	s22	1 December 2025
V1.1	Published - D25-5368934 DRAFT - D24-2244189	Document title updated from 'Creating a CM file using DPMMS file naming convention' to 'Creating a CM file using DPMMS file naming convention for DIR triage and investigations'.	s22	05 March 2026

Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Medical Devices QMS

Work Instruction	
Name of procedure	Risk Assessment and Triage of Medical Device Incident Reports
Applicable to	Medical Devices Branches — Devices Post Market Monitoring Section
Number	DPMMS WI 1.2
Written by	s22 [redacted]
Authorised	s22 [redacted] Director, Devices Post Market Monitoring Section
Date issued	22 August 2025
Version no.	3.2

Background

Medical device incident reports (DIRs) are received from consumers, healthcare professionals, and sponsors either electronically through the medical device incident reporting (MDIR) scheme or by email, or printed copies of the MDIR form.

The TGA receives three main types of adverse event reports:

Initial report	Sponsor only
Initial Final Report	Sponsor only
Final reports	Sponsor and User/Healthcare Professionals

This work instruction covers the risk assessment and triage of 'Final reports' from Sponsors and User reports (submitted by Healthcare Professionals, patients, carers, etc).

This document is divided into the following sections:

- Completing the ‘Risk Analysis’ page in InfoLeader
- Closing a DIR after Triaging
- Team Review
- Duplicate Reports
- Overseas and Medicine Reports
- Referral to another Section of the TGA

Processes that are specific to the work of the Devices Support Team (DST) can be found under DPMMS SOP 12.

Information regarding the DIRs is stored in the InformationLeader database (Infoleader).

This platform is also used to undertake and record the risk assessment and triage of the DIRs. Information to inform the risk assessment can be found in the IRIS Triage Tool application in Qlik Sense.

Training videos for the Risk assessment and triage of DIRs are available in the Triage Training CM/ TRIM Container (E17-42700) or via your QMS SharePoint page.

Using this Work instruction

This is a lengthy work instruction due to the complex nature of the decision-making process required to triage a device incident report. It may be useful to turn on the Navigation Pane from the ‘View’ tab to be able to see the key sections of this document.

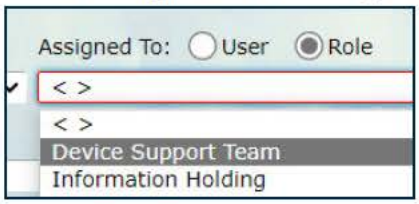
References to steps have been bookmarked and you are able to link to the step by using Ctrl-Click on the blue step references.

Procedure

Selecting the Device Incident Report for Assessment

#	Step	Responsible
1.	Open the InfoLeader database: http://ileader.production.tga.gov.au/InformationLeaderAD?domain=production Hover over 'Requests' in the top navy-blue banner.  Then click 'Device Incident Report' to display a more detailed inbox view. Select the DIR that you are going to assess by clicking on it. Ensure you read any information DST has provided with the DIR (located in the Flow tab within the DIR) before starting the triage. Progress the DIRs as follows:	Triager/ Investigator

If the DIR is:	Then
an initial final/final Sponsor or User report.	Go to step 2.
an amended final	Go to DPMMS WI 1.17.
related to a clinical trial, special access (SAS) product, or authorised prescriber (AP) product (will not contain an ARTG).	Identify the clinical trial, SAS, or AP reports and go to step 5.
a literature article	Go to step 6.
a Medicine or Overseas report	Send to DST to close.

<table>
<tr><th>#</th><th>Step</th><th>Responsible</th></tr>
<tr><td>2.</td><td>For sponsor DIRs, review the report and confirm it includes:
an ARTG number and the sponsor has not indicated this was supplied under SAS or through a clinical trial notification (CTN)
information in the device analysis results
completed details of similar events
AOANJRR report for orthopaedic joint DIRs
the full journal article for incidents reported from a journal article
<table><tr><th>If the information:</th><th>Then</th></tr><tr><td>is missing</td><td>Go to step 3 to push back the DIR to DST.</td></tr><tr><td>is incomplete
has more than one device
has more than one clinical event
similar event rates are not consistent with the TGA database; or
the triager is unable to conduct a risk assessment.</td><td>Go to step 4 to initiate a Triage request for information (Triage RFI).</td></tr><tr><td>is complete</td><td>Go to step 7.</td></tr></table></td><td>Triager/ Investigator</td></tr>
<tr><td>3.</td><td>Assign the DIR to the Device Support Team (DST) for pushback to the sponsor to obtain more information:
i. Click on the Flow (Triage) tab.
 
ii. In ‘Assigned To: Role’ option, select Device Support Team
 
iii. In the ‘Comments:’ box, enter the reason why this DIR requires a push back to the sponsor.
Note: Provide the exact wording for your question to DST in this box.
iv. Select ‘Save’ and this DIR will be sent to DST for pushback.
  </td><td>Triager/ Investigator</td></tr>
</table>

#	Step	Responsible
4.	**Triage request for information** (Triage RFI) A triage RFI requests or clarifies information in the report from the sponsor to assist with the triager's decision about the report. Assign the DIR to the member of the DST responsible for Triage RFIs who will email the sponsor to obtain more information: **Note**: Check with the DST Team Leader if you are unsure who is responsible for Triage RFIs. i. Click on the Flow (Triage) tab.  ii. In 'Assigned To: Keep as 'User' and use the drop-down arrow to select the relevant member of the DST  iii. In the 'Comments:' box, enter the words: iv. *Please go back to the sponsor as a triage RFI (via email) and ask the following:* v. (add the exact wording for your questions) vi. Click 'Save' to flow the DIR to the relevant DST member to action  	Triager/ Investigator
5.	**Clinical Trials/SAS/AP Reports** For reports associated with a clinical trial or those that are SAS/AP devices, the following additional pathways are to be followed once the risk assessment is completed: • **Clinical Trial** reports are not investigated by DPMMS. If there has been a death or permanent injury, notify the medical officers in MDAB via email. Attach a PDF copy of the DIR and email to both: DevicesClinical@health.gov.au s22 [redacted] @Health.gov.au – The clinical team will advise whether further action is required or not. – Please specify a 2 week timeframe for the response.	Triager/ Investigator

<table>
<tr><th>#</th><th>Step</th><th>Responsible</th></tr>
<tr><td></td><td>
Note: the TGA has limited scope to require further information from the sponsor of a clinical trial report.
<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>the medical officer's advice is to take further action</td><td>Discuss this with your team leader.</td></tr>
<tr><td>the medical officer's advice is to close the report</td><td>The DIR can be closed.

After closing, flow the DIR back to DST via the Flow tab and ask them to notify Clinical trials of the report at clinical.trials@health.gov.au.</td></tr>
<tr><td>if there have not been a death or permanent injury but the event is unusual</td><td>Consider sending the report to the DIRE meeting.</td></tr>
</table>
Note: For Clinical Trials only, information is not published in DAEN and not investigated. Complete Report Status section (Risk Analysis Page) with:
– Website publication: No
– Investigated: No
– Investigation Reason: Device not returned (or other appropriate entry)

• SAS/AP reports should be treated as normal reports and closed or investigated based on the risk assessment.
– Go to step 7 and follow the processes in this work instruction for these types of reports.
– Once the DIR is triaged, attach a PDF copy of the DIR and email DevicesClinicalDelegate@health.gov.au for their awareness of the report.
</td><td></td></tr>
<tr><td>6.</td><td>
Journal/Literature article
In the clinical event section on the Report Information page, use the following convention to reference the journal:

"This report of [insert adverse event(s)] is in reference to [insert name of article, author] published in [insert name of journal, year, issue, date, page]".

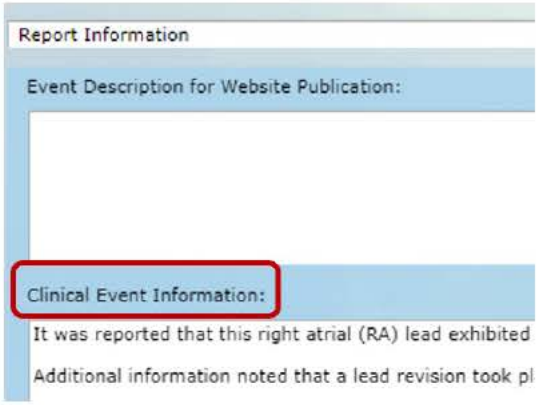
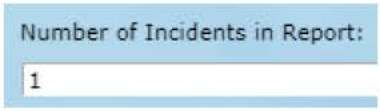
Example:

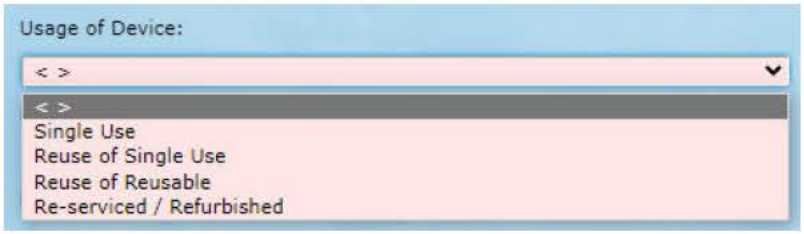
This report of periprosthetic fracture is in reference to

"Periprosthetic fractures: epidemiology and current treatment –
</td><td>Triager/ Investigator</td></tr>
</table>

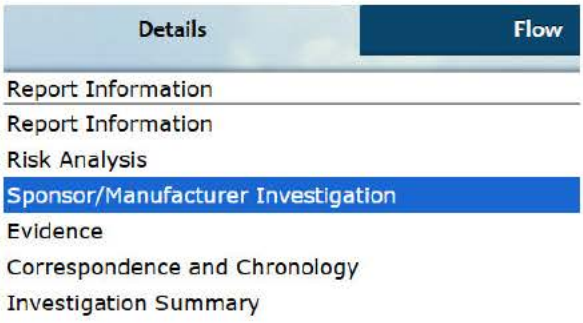
#	Step	Responsible
	Capone et al;" published in Clinical Cases of Mineral Bone *Metabolism. 2017 May-Aug; 14(2): 189–196.(if known you may include the DOI number)* **Note:** For journal article DIRs, multiple clinical events and multiple incidents may be submitted under one DIR. E.g., If an article mentions 3 reports of pain, 2 for infection, 4 for migration. Confirm the Number of Incidents in the Report reflects the event description and amend if required. Enter all the clinical events mentioned under the 'Problems Observed' and 'Clinical Signs Symptoms and Conditions' headings on Investigation Summary page. Enter standard sponsor closure words. Complete the risk analysis page as normal.	

Completing the 'Report Information' page in InfoLeader

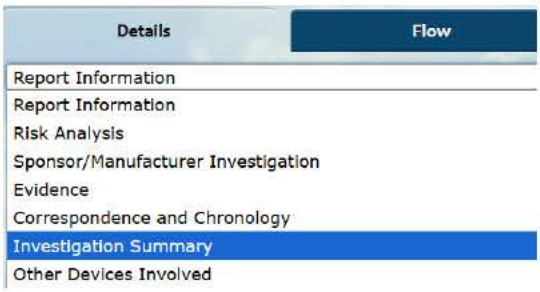
#	Step	Responsible
7.	In InfoLeader, select the 'Details' tab on the 'Report Information' page:  Read the 'Clinical Event Information' section to determine the reported adverse event.  Make note of the 'Number of incidents in Report' and ensure this is reflected in the event description.  **For User reports only**: if required, review the redacted information by accessing the .pdf file of the Original User Report from the attachments section on the form.  If triaging a user report and there are concerns about patient/reporter safety or those close to the patient/reporter, discuss sensitive closing words with the TL of the class of device for the Investigation Summary. If referral to clinical is required, Go to step 14 Referral during triage.	Triager/ Investigator

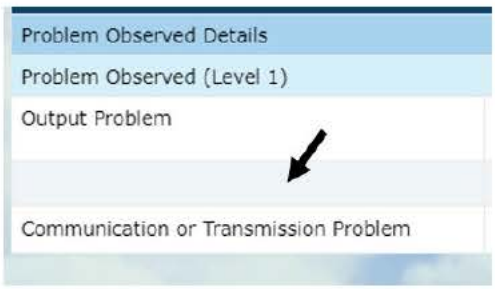
#	Step	Responsible
8.	The information entered in 'Event Description for Website Publication' is published on the Database of Adverse Event Notifications (DAEN) on the TGA website, as part of the TGA medical device safety monitoring program. Therefore, it should not contain any personal information. • A good DAEN description should be concise, not include any identifying information and simply outline what adverse event occurred. • Any comments that are emotive, prejudicial, inappropriate, confidential or exceedingly lengthy should be removed. • Ensure any device analysis and actions taken by the sponsor and/or manufacturer are not included in the "Event Description for Website Publication".	Triager/ Investigator
9.	Ensure all the information in the Device Information Section is complete and verify the ARTG number is accurate. If you change the ARTG number in a **User report**, check yellow text boxes populate with information relevant to the new ARTG number (e.g., class of device, GMDN code/text, manufacturer information). **Note:** brand name and initial device description will not update automatically. You will need to copy the GMDN text and paste that after the hyphen in brand name and initial device description.  For **sponsor reports**, if the ARTG entered is inconsistent with the device in the clinical event information, discuss with your TL as a Triage RFI may be required. Ensure that the 'Usage of Device' is completed: 	Triager/ Investigator

Sponsor/Manufacturer Investigation page

#	Step	Responsible
10.	Navigate to the 'Sponsor/Manufacturer Investigation' page using the drop-down menu in the Details tab.  Review the information provided by the sponsor and manufacturer. Consider the evidence when completing the investigation summary page and the risk assessment page. Consider the following: • Device analysis results • Corrective/Preventative Actions • Details of similar events • Additional comments **Note**: The details of similar events reported by the manufacturer should relate to the clinical event (instructions in step 22).	Triager/ Investigator

Completing the 'Investigation Summary' page

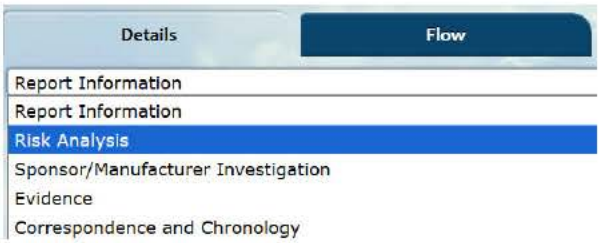
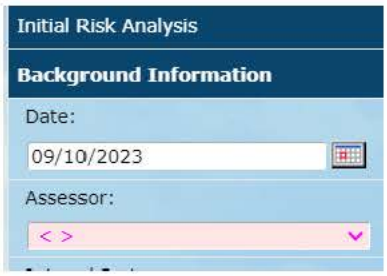
#	Step	Responsible
11.	Navigate to 'Investigation Summary' page using the drop-down menu in the Details tab. 	Triager/ Investigator
12.	Complete drop-down selections for: • *Problem Observed (Annex A)* • *Clinical Signs and Symptoms (Annex E)* • *Health Impact (Annex F)* Create new records by clicking on the 'N' icon located at the right of the heading bar for each category.   Refer to the appropriate codes in DPMMS GUIDE 1.2.a (D25-1121098) that are from '*IMDRF/AE WG/N43 Terminologies for categorized Adverse Event Reporting (AER) terms, terminology and codes Annexes A-G consolidated workbook*'. Save the selection by pressing the  button at the right of the 'Problem Observed' heading bar. The terms selected for 'Problem Observed', 'Clinical signs and symptoms and conditions', and 'Health impact' **must** be based on the clinical event description alone.	Triager/ Investigator

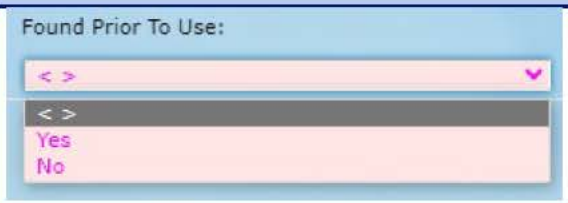
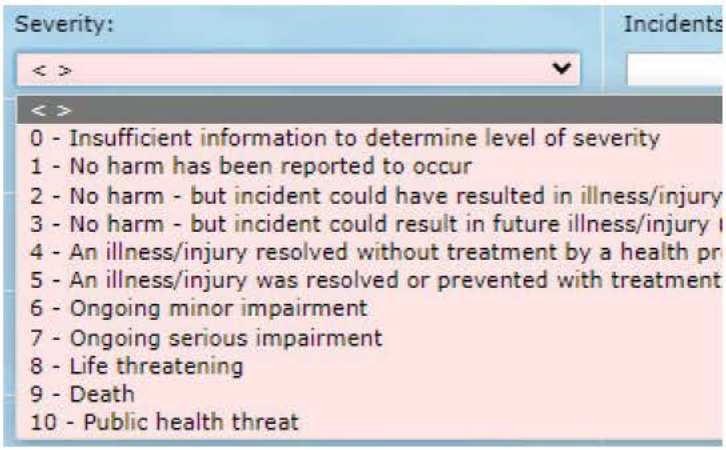
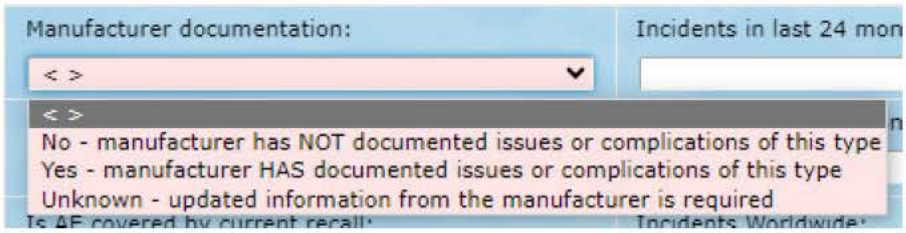
#	Step	Responsible
	Note: The information entered in the fields in this step will be disclosed to the sponsor upon closing the DIR and care must be taken to ensure accuracy and consistency.	
13.	**To delete an entry within the investigation summary page:** To delete an unwanted record containing text, click on the field you want to delete then press the D button. However, to delete an empty field containing no text (as shown below), first click on a field that contains text, select the arrow buttons <, or > to move to the empty field, then delete it with the D button. 	Triager/ Investigator
14.	**Referral during triage** Based on the information within the **final** report the investigator may consider that referral to technical or clinical assessors is required to ensure that a thorough risk assessment is undertaken. Referral may be made to clinical for the purposes of support to complete sensitive reports (e.g. drafting closing words).	Triager/ Investigator

If	Then use
Referral to Devices Clinical Surveillance Section required (Sponsor reports)	DPMMS FORM 1.2.a
Referral to Devices Clinical Surveillance Section required (information that may indicate there may be a safety concern for the reporter or those people around them)	DPMMS FORM 1.2.a

#	Step		Responsible
	Referral to IVD section required	DPMMS FORM 1.2.a	
	Referral to TGA laboratories required	DPMMS FORM 1.2.a	
	Referral to Recalls required to confirm the Manufacturer's action meets the definition of a market action under the PRAC.	Please include the following words in an email: I am seeking advice as to whether the actions taken by the sponsor in this DIR report meets the definition of a market action under the PRAC. • DIR [Number] • Description of events: • Description of Preventative actions taken by Sponsor: • 1. [Add what they have done] • Please attach a PDF copy of the DIR Please confirm if the action taken by the sponsor/ manufacturer meets the definition of a recall action.	

Completing the 'Risk Analysis' page in InfoLeader

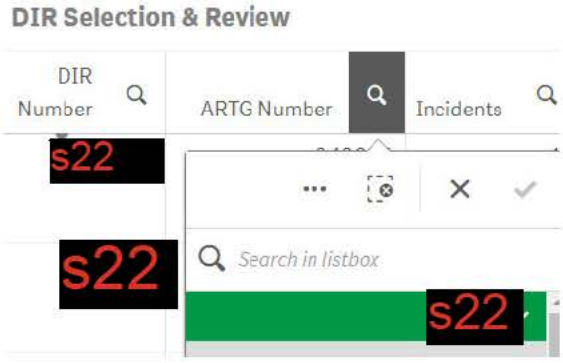
#	Step	Responsible
15.	Navigate to the 'Risk Analysis' page: 	Triager/ Investigator
16.	Under the heading 'Initial Risk Analysis', select the date as the day you are conducting the risk assessment, and select your name as the 'Assessor' from the drop-down selection.  **Note:** if an 'Initial Risk Analysis' has been completed, click the 'N' at the bottom right of the screen to generate an 'Additional Risk Analysis.' Update the auto-filled fields with new details reflecting the latest information. 	Triager/ Investigator
17.	Select the 'Injured Party' from the drop-down selection, with tick boxes, based on the clinical information. 	Triager/ Investigator
18.	Select response to the 'Found Prior to Use' question.	Triager/ Investigator

#	Step	Responsible
		
19.	Select the response to the 'Reusable' section. 	Triager/ Investigator
20.	Select the appropriate 'Severity' of the clinical outcome, with consideration to the definitions below:  See Appendix 6 for Severity definitions.	Triager/ Investigator
21.	Select the appropriate drop-down response for the 'Manufacturer Documentation'. Based on the sponsor/manufacturer information/documentation provided in the DIR or as part of a previous DIR, select the response as follows: 	Triager/ Investigator

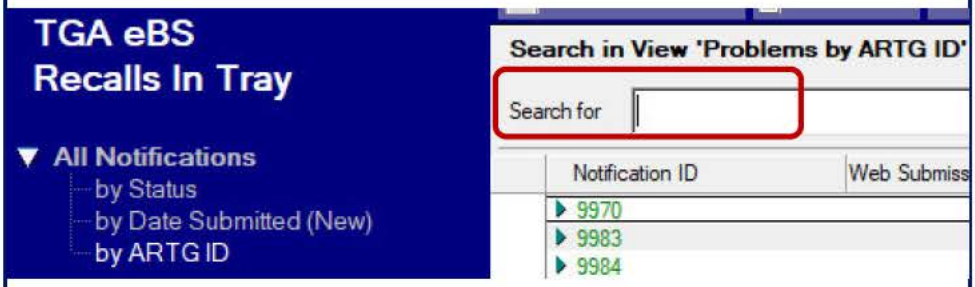
<table>
<tr><th>#</th><th>Step</th><th>Responsible</th></tr>
<tr><td>21
cont.</td><td>
<table>
<tr><th>If</th><th>Then select</th></tr>
<tr><td>The manufacturer states in the device analysis, that the issue or complications have been documented in their instructions for use (IFU), labelling and/or risk management in the Sponsor/Manufacturer investigation section of the DIR.</td><td>‘Yes’</td></tr>
<tr><td>The manufacturer states the issues or complications have not been documented in their IFU, labelling and/or risk management documents.</td><td>‘No’</td></tr>
<tr><td>You are not aware if this information is included in the manufacturer’s documentation.</td><td>‘Unknown’</td></tr>
</table>
Note: Please do not refer to IFUs published on the internet. The IFU should be provided in the DIR or the sponsor should have referred to the IFU in the Sponsor/Manufacturer investigation section.
</td><td></td></tr>
<tr><td>22.</td><td>Open Qlik and go to the IRIS Triage tool.

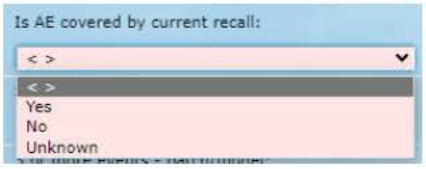
Enter the ARTG number that relates to the DIR.

If the report does not require or is without an ARTG number, you will not be able to source information for recalls or similar events in this manner. You may need to obtain this information via the device description.

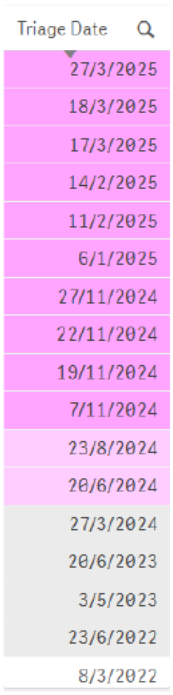
 

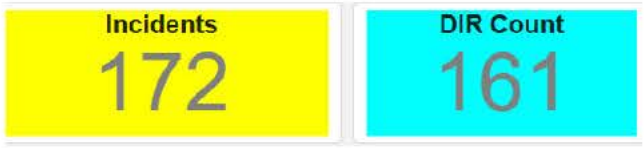
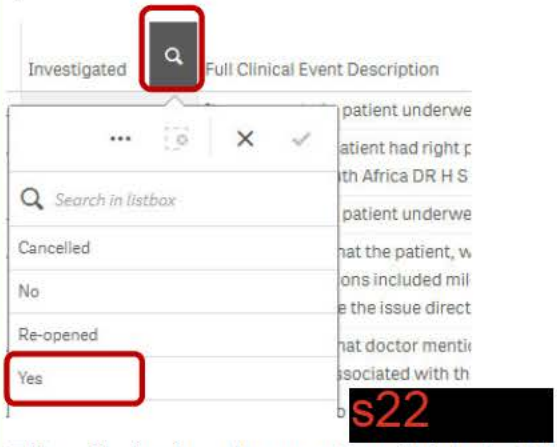
Note: Some devices are reclassified. For these situations, the ARTG number entered should be based on when the device was implanted/supplied. The old ARTG number can be searched using the Reclassified ARTG entries Qlik Sense application.</td><td>Triager/ Investigator</td></tr>
</table>

#	Step	Responsible
23.	Refer to the 'Recalls List' information in the Qlik database and the TGA eBS 'Recalls In Tray' (IBM Notes) to identify similar incidents to the one currently reported. • Qlik: Click on any recalls  • Recalls In Tray (IBM Notes) Search by typing the ARTG number, brand or device name in the search bar in the recalls database.  **Note:** The recall should only be noted if it is related to the model and issue. If the market action is for a specific model/lot/batch, and you need to verify whether the device in your DIR is part of the market action, check the TGA eBs Recalls Intray in IBM and review attachments in 'Supporting Information' tab. 	Triager/ Investigator

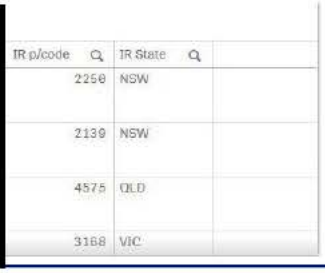
#	Step	Responsible
24.	Select the relevant drop-down option in the 'Device Recalls' box in InfoLeader:  If this is a report without an ARTG number, such as SAS and/or custom made or the ARTG is unknown, select 'No recalls for similar incidents in Australia' and go to step 26.	Triager/ Investigator
25.	Indicate whether the Adverse Event is covered by any current recall actions, by selecting the appropriate response from the drop-down options:  If a Recall is listed in Qlik (step 23) make sure you select the appropriate response, by first conducting a search in IBM notes with the recall number or the ARTG entry. This will ensure the information, such as the recalled batch or lot numbers, are the same as the ones included in the DIR. Use the information supplied in the Report Information and Sponsor/Manufacturer Investigation pages to confirm the response.	Triager/ Investigator

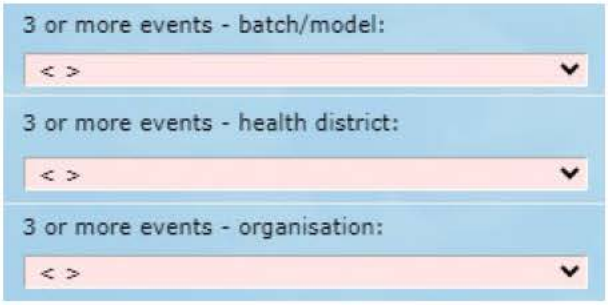
If	Then select
The Sponsor/Manufacturer has stated this device is covered under the recall action.	'Yes'
Or the sponsor has not stated the ARTG is part of a recall, however the ARTG, Batch or Model numbers match with information in IBM Notes.	'No'
This device is not covered under the recall action i.e., Different model number.	'Unknown'

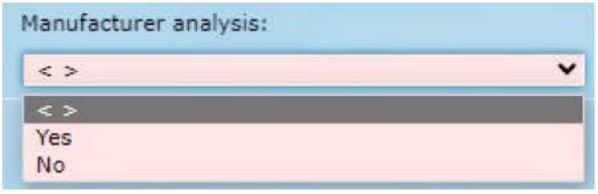
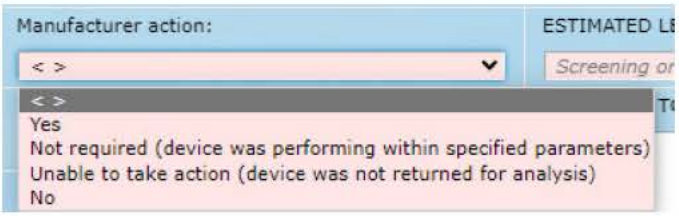
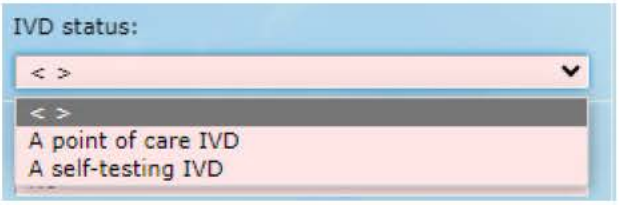
#	Step	Responsible
26.	 Select all DIRs within the last 6 months by selecting the DIRs that are highlighted dark pink from the Triage Date column. • Dark pink indicates DIRs with report dates within the previous 6 months from current date. • Light pink indicates DIRs with report dates within the previous 12 months from current date. • Grey indicates DIRs with report dates within the previous 3 years from current date.	Triager/ Investigator
27.	Read through the event descriptions and select the DIRs that have similar events to the DIR you are currently assessing. The maximum number of Similar events is '*More than 10 Incidents*'. Therefore, you only need to identify up to 11 similar (non-duplicate) events in this column. DIR Selection & Review  **Note**: A 'similar event' is not defined in the legislation or TGA's guidance and sponsors may define it differently. The section's guidance is that an event is likely to be considered as similar based on clinical presentation i.e., If the clinical event description mentions same/similar clinical signs/symptoms/conditions, or it mentions same/similar problems of the device.	Triager/ Investigator

#	Step	Responsible
	The count boxes at the top of the Qlik application will provide you with a count of how many DIRs have been selected and how many incidents have occurred within those DIRs:  **Note**: If the DIR that you are assessing is included in the DIR list, reduce the count of incidents by one. If you are assessing the report on the same day that it has been submitted, the DIR will not appear in Qlik and a reduction in the counts will not need to be made. The exception is that where there are multiple incidents in the DIR you are assessing, you will need to increase the incident count accordingly.	
28.	Check to see whether there are any investigations for the ARTG you are searching. To do so, you first need to clear the date filter by clicking the 'x' 	Triager/ Investigator
29.	Next, click the magnifying glass of the Investigated column, then select 'yes'  This will display all current and historic DIRs that have been investigated for that ARTG number. If one of the DIRs details the same/similar clinical event, please consult Appendix 9 on next steps.	Triager/ Investigator

<table>
<tr><th>#</th><th>Step</th><th>Responsible</th></tr>
<tr><td>30.</td><td>In InfoLeader, select the appropriate option in the ‘Similar events’ drop-down list:
 

<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>The DIR is without ARTG number, for example the report is from consumer/health professional or is for a SAS/AP device</td><td>Select ‘0 incidents’</td></tr>
<tr><td>A single DIR contains multiple incidents</td><td>Consider the first incident as the current and count the others when completing this field.</td></tr>
</table>
Note: It is important to note that this question asks for the number of incidents found in Qlik, not the number of DIRs. This is because one DIR may contain several incidents. Multiple incidents within the DIR under assessment will also not be recorded in QLIK until the day after the DIR was reported.</td><td>Triager/ Investigator</td></tr>
<tr><td>31.</td><td>Where THREE (3) or more similar incidents have occurred, ‘Click on the ‘DIR Links review’ in Qlik to determine whether they appear to be related to the same:
• product batch, model
• health district; and/ or
• health service organisation.
s22

</td><td>Triager/ Investigator</td></tr>
</table>

#	Step	Responsible
	If there are fewer than three similar incidents you do not need to complete these questions. Go to step 33.	
32.	Complete the Similar events section to identify local clusters of events by selecting from the drop-down options for each of:  **Note:** To select yes the batch/model number should be the same as the one in the DIR you are undertaking the risk assesment. If you are unable to clearly determine this information, mark each cluster as 'unknown'.	Triager/ Investigator
33.	**NJRR Data Review** If the report does not require NJRR Data, go to step 34 If the report is for an orthopaedic implant, then the information from the Australian National Joint Replacement Register (NJRR) must be attached and reviewed when assessing the risk for these types of devices. The report is found in the attachments to the report.  This document shows whether the revision rate for the implant is in line with the revision rate of similar implants to indicate the need for investigation of the device. If the level is outside that which is expected, further investigation may be required. Discuss with the TL for this class of device. See Appendix 3 for examples determining NJRR data. **Note:** details of similar events provided from sponsors are often inconsistent with Qlik results. This is because we look for similar events based off the ARTG number in Qlik, while sponsors usually provide rates based on the implant catalogue number. This is why triagers must review the NJRR report to identify any concerns regarding revision rates.	Triager/ Investigator

#	Step	Responsible
34.	For all report types, complete the 'Manufacturer analysis' and 'Manufacturer action' questions by selecting the appropriate drop-down option. For Manufacturer analysis, consider if the manufacturer has conducted any sort of analysis to establish the root cause of the device problem. This should be based on: i. Was the device returned? and/or ii. Did a field service engineer (FSE) or technical service engineer (TSE) visit the site to check the problem?  For Manufacturer action, consider if the manufacturer performed any processes to address the incident observed in the DIR. This may include analysis of a returned medical device and introducing corrective and preventative actions (CAPA) or initiating a recall action to mitigate risk. 	Triager/ Investigator
35.	If the incident relates to an in vitro diagnostic (IVD) device: Select the appropriate option from the drop-down selection.  See Appendix 7 for definitions.	Triager/ Investigator
36.	**Number of potential contributing factors** The 'Number of potential contributing factors' box is automatically filled from the response completed in the 'Specific factors identified' option. Consider if there are any reasonable grounds for suspicion by a qualified professional (e.g., bio-mechanical engineer, technician, nurse, medical practitioner, other health professional) about possible	Investigator/ Triager

<table>
<tr><th>#</th><th>Step</th><th>Responsible</th></tr>
<tr><td></td><td>contributing factors to the reported incident (e.g., patient-related, treatment-related or mechanical).

After evaluating the information presented, answer the following question:

‘At this stage of the assessment, does the incident appear to have any potential contributing factors?’

<table><tr><th>If the answer is</th><th>Then</th></tr><tr><td>No</td><td>Go to step 37.</td></tr><tr><td>Yes</td><td>Document the suspected ‘factors’ by selecting the appropriate options from the drop-down box selection, using Appendix 4 as a guide.</td></tr></table>
Note: These factors have been organised across the product lifecycle.</td><td></td></tr>
<tr><td>37.</td><td>Number of sensitivities identified

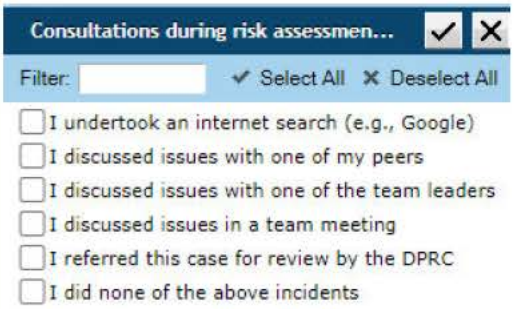
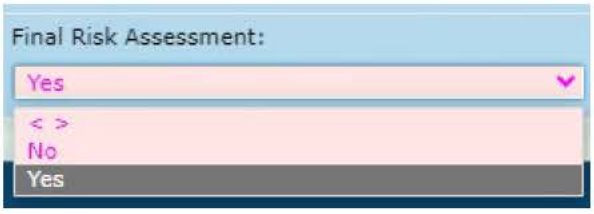
The ‘Number of potential sensitivities’ box is automatically filled from the response completed in the ‘Specific sensitivities identified’ option.

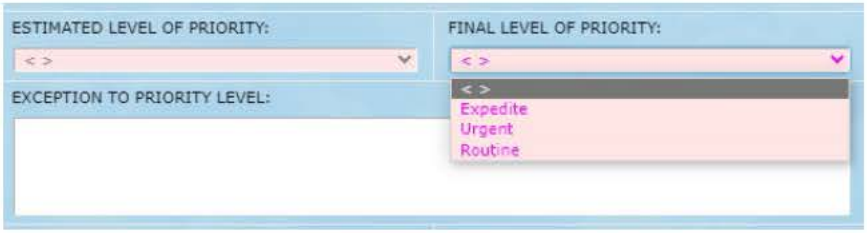
Consider if there are any current sensitivities for other stakeholders about the reported incident.

After thinking about the information presented, answer the following question:

‘At this stage of the assessment, does the incident appear to have any potential sensitivities?’

<table><tr><th>If the answer is</th><th>Then</th></tr><tr><td>No</td><td>Go to step 38.</td></tr><tr><td>Yes</td><td>Document the ‘potential sensitivities’ by selecting the appropriate options from the drop-down box selection, using Appendix 5 as a guide.</td></tr></table></td><td>Investigator/ Triager</td></tr>
</table>

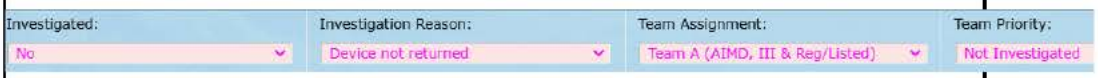
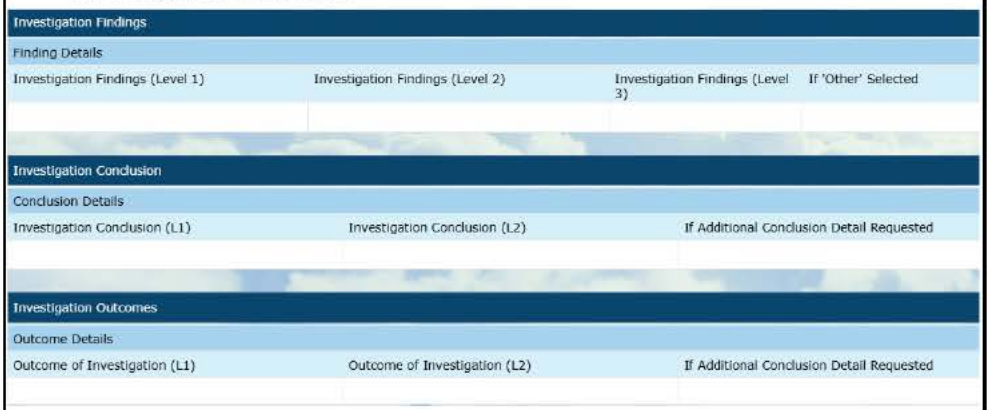
#	Step	Responsible
38.	Consultations during risk assessment. Use the drop-down options to document any consultations that were undertaken during the risk assessment in relation to this incident. This will often be an internet search, or a discussion with your peers or team leaders. 	Investigator/ Triager
39.	Change the Final Risk Assessment option to Yes. 	Investigator/Triager
40.	Ensure you read steps 41 - 43, and their applicable appendices, before making any determinations on the level of investigation or priority of investigation. These need to be read in conjunction with one another.	
41.	**Level of investigation** The estimated level of investigation and level of priority will be calculated once you press the Calculate risk button:  The automatically generated level of investigation will be presented under the calculate Risk button.	Investigator/ Triager
42.	Determine if the level of investigation appears appropriate to manage the incident report. See Appendix 2 for final levels of investigation.	Investigator /Triager

#	Step	Responsible
43.	Select the 'Final' level of investigation from the drop-down selection.  If the 'Final' level of investigation differs from the estimated level of investigation, a reason must be provided in the 'Exception to the investigation level' free text area.	Investigator/ Triager
44.	**Level of Priority** The automatically generated level of Priority will be presented below the level of investigation boxes following clicking on the 'Calculate Risk' button. Determine if the level of priority appears appropriate to manage the incident report; See Appendix 8.	Investigator/ Triager
45.	Select the 'Final' level of priority from the drop-down selection. If the 'Final' level differs from the estimated level of priority a reason must be provided in the exception to the priority level free text area for that decision.  	Investigator/ Triager
46.	Determine if the report type is required to be included in the DAEN for publication and mark accordingly (Yes or No).  The report can be published on the website once it is a final report and contains information in all the mandatory fields. The following DIR types **do not get published on DAEN**: • Clinical trials • Duplicate • Overseas • Medicine	Investigator/ Triager

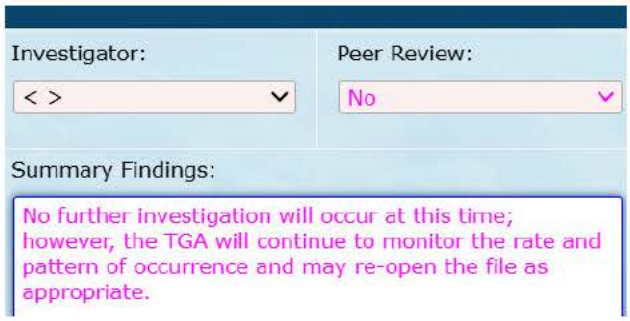
<table>
<tr><th>#</th><th>Step</th><th>Responsible</th></tr>
<tr><td></td><td>
Quarterly
Continue to the next step to continue completing the risk analysis.

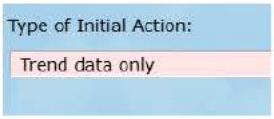
If you believe the DIR has been submitted by the Sponsor in error (e.g., new information received indicates it was not their device, they submitted the DIR by mistake, or the event did not occur), select No after discussion with your Team Leader.
</td><td></td></tr>
<tr><td>47.</td><td>
Action the DIR according to the following:
<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>The DIR can be closed</td><td>Go to step 48.</td></tr>
<tr><td>The DIR is to be expedited or urgent</td><td>Refer to DPMMS WI 1.21.</td></tr>
<tr><td>The DIR requires team review/possible investigation</td><td>Go to step 59 and complete steps 59 - 64 by Midday Friday for the DIR to be included in the DIRE meeting held on the following week.</td></tr>
<tr><td>The DIR may be included in an ongoing investigation.</td><td>Contact the Investigator/Team Leader of the ongoing investigation.</td></tr>
</table>
</td><td>Investigator/ Triager</td></tr>
</table>

Closing a DIR after Triaging

#	Step	Responsible
48.	Remain on the Risk Analysis page of the DIR.	Investigator/ Triager
49.	Complete the following fields on Risk Analysis page: Investigated = No A selection still needs to be made under '*Investigated reason.*' Team priority should remain as '*Not Investigated*' 	Investigator/ Triager
50.	Go to *Investigation Summary* page of the Device Incident report.	Investigator/ Triager
51.	Using DPMMS GUIDE 1.2.a IMDRF Terminologies A-G (D25-1121098) complete drop-down selections for: • *Investigation Findings* (Annex C of the IMDRF codes) • *Investigation Conclusion* (Annex D of the IMDRF codes) • *Investigation Outcome*  **Note:** Press the 'N' on the extreme right of each subheading for the drop-down lists to appear.  Press 'Save' button on the top right of the Device Incident Report.	Investigator/ Triager

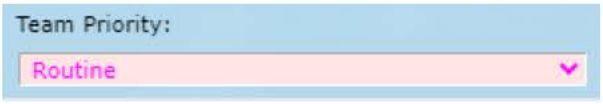
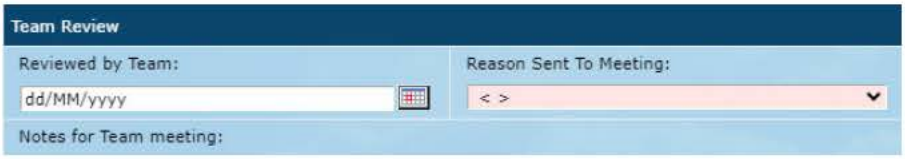
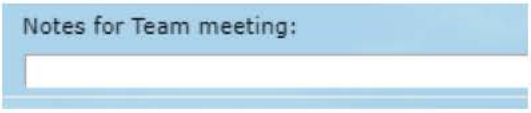
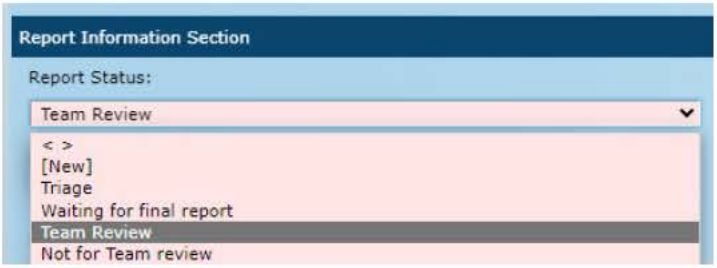
<table>
<tr><th>#</th><th>Step</th><th>Responsible</th></tr>
<tr><td>52.</td><td>Check the source of the report in Report Information Section of the DIR.<table><tr><th>If</th><th>Then</th></tr><tr><td>The source of the report is a User / HCP</td><td>complete steps 53 - 55</td></tr><tr><td>The source of the report is a Sponsor</td><td>complete steps 56 - 58</td></tr></table></td><td>Investigator/ Triager</td></tr>
<tr><td>53.</td><td>Check the attachments of the DIR to confirm an ‘acknowledgement letter’ has been sent to the user/HCP by DST. 

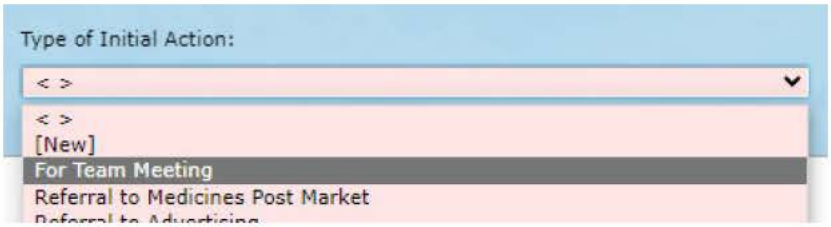
If no sensitive or specific words are needed, please enter standard sponsor words in the Summary Findings section:
“No further investigation will occur at this time; however, the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.” 
If the clinical event relates to a known/sensitive issue covered in DPMMS customised words (see E17-6582) enter the relevant words in the summary findings.
Note: Before entering the customised words in your DIR, read them in full to check the content is relevant to the clinical event in your DIR.</td><td>Investigator/ Triager</td></tr>
</table>

#	Step	Responsible
	Note: Do not send the HCP specific closure words UNLESS the DIR is submitted by a HCP for urogynae mesh device, in this case include the Urogynaecological Mesh Closing Words for Health Care Professionals. • If you think the DIR requires closing with sensitive words, discuss with the TL of the device class. If the TL agrees, draft and get approval of the words prior to entering them into the Summary Findings section.	
54.	On the report information page (first one): • change the Report status to 'Complete ' • Select 'Trend data only' for type of initial action  	Investigator/ Triager
55.	In the Flow tab, assign the DIR to DST and request they close the user report. • For user reports with standard closing words, please ask DST to close the user report with a letter to the sponsor.  • For user reports with specific/sensitive words, please ask DST to send a letter to the reporter and to the sponsor and to close the user report.	Investigator/ Triager
56.	For **sponsor reports**, complete the 'Summary Findings' using the following words: Non-NJRR reports use standard words: *"No further investigation will occur at this time; however, the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate."*	Investigator/ Triager

#	Step	Responsible
	For orthopaedic joint reports with NJRR data use: "*National Joint Replacement Register (NJRR) was reviewed, no further action at this stage, the TGA will continue to monitor.*" Press 'Save' on the top right of the DIR.	
57.	Select 'Trend data only' in the type of initial action on Report Information Search page.  Press 'Save' button on the top right of the Device Incident Report.	Investigator/ Triager
58.	Press the complete and sign button on the Report Information Section page 	Investigator/ Triager

Team Review

#	Step	Responsible
59.	**Note:** ensure you have completed all relevant steps of the risk assessment before initiating the process of sending to DIRE In the Risk Analysis page in the field titled 'Team Priority' mark the report as 'Routine'. 	Investigator/ Triager
60.	Under the field titled 'Team Review' complete the reason sent to the meeting from the list in the drop-down box.  Press the 'Save' button.	Investigator/ Triager
61.	Under the field titled 'Notes for Team Meeting' add the information found in Qlik (e.g., # of similar reports, recalls, PMRs, etc.) and any information supporting the reason for sending this report to the team meeting.  Example format: *"0 DIR's, 0 Recalls & 0 PMR's. - Sent to the meeting for xxx"*	Investigator/ Triager
62.	Go to the 'Report Information Section' and select the Report status as 'Team Review'. 	Investigator/ Triager

#	Step	Responsible
63.	In the area marked 'Type of Initial Action' select 'For Team Review' in the drop-down box: 	Investigator/ Triager
64.	Go to the 'Flow' tab and change the report status to 'Team Review' and the role to 'OPR Administration User'. 	Investigator /Triager

Duplicate Reports

#	Step	Responsible
65.	If a report has been found to be a duplicate, a risk assessment is not required.	Investigator/Triager
66.	To determine of a report is a duplicate you should look at both reports simultaneously to determine if all of the following are the same: • Sponsor's reference number • Date of adverse event • Submitting report / initial reporter • Device name • Model number • Serial number • Clinical event details • Patient details (e.g., age, gender, weight, or patient history) At a minimum, you must have the date of adverse event, device name, model, and reporter name – if no, see step 48. Make sure to check the comments section as the sponsor sometimes submits identical reports for the same event.	Investigator/Triager
67.	Always have the team leader review to confirm it is a duplicate. Be aware that it may require an email from DST to the sponsor to determine. If this is the case send the report back to DST in the Flow tab with the following in the comments box: *'Please ask the sponsor if this report is a duplicate of DIR XXXX as they read the same. Many thanks.'*	Investigator /Triager
68.	Once confirmed that the DIR is a duplicate, flow the DIR to DST via the Flow tab with the following in the comments box: *'Please close this DIR as it is a duplicate of DIR XXXX. Many thanks'* The DIR will be then closed by DST.	Investigator/ Triager

Overseas and Medicine Reports

#	Step	Responsible
69.	If you have identified in your triaging that the report is for **Medicine** or is an **Overseas** report, please send it back to DST to close. **Note:** No risk analysis is required.	Investigator/ Triager

Referral to another Section of the TGA

#	Step	Responsible
70.	Referring to areas such as Advertising or Regulatory Compliance **does** require a risk analysis before flowing to DST to refer. Note that if the DIR covers multiple issues, DPMMS is still responsible for safe and performance issues. Please follow all other directions for risk assessment above before sending to DST.	Investigator/ Triager
71.	Include in the investigation summary the appropriate option: • Referred to Advertising section of the TGA. • Referred to Regulatory Compliance section of the TGA. • Referred to Recalls section of the TGA.	Investigator/ Triager

Appendices

Version history

Version	CM / TRIM Reference	Description of change	Authors	Effective date
V1.0		Original work instructions	s22	10/04/2014
V1.1		Updates	s22	04/05/2015
V1.1		Updates	s22	25/08/2016
V1.2		Rework	s22	
V1.3	D17-56605	Updates and rework	s22	25/7/2017
V2.0	D19-6004093	Update to new QMS format and numbering convention. Updated risk assessment and triage process, introduction of Qlik, and extraction of these processes from the larger work instruction.	s22	13 Feb 2020
V2.1	D20-915613	Addition of background section Update to step 1 New step 4 Removal of what was step 9 in previous version Update to step 19 New step 40, step 45, step 50 and step 51.	s22	21 Jul 2020
V2.2	D21-2292032	Update to information and addition of workflow references Addition of step 60.	s22	17 Mar 2021
V3.0	D23-3759303	Updated to new template Rework of the work instructions to reflect current process. Clarify data entry requirement for certain fields in InfoLeader. Update of triage process by removing steps not relevant to the triaging of Final or Initial Final reports and moving steps to other locations.	s22	29 May 2025

Version	CM / TRIM Reference	Description of change	Authors	Effective date
		Removed Handover of Investigation to another Investigator Update text (proofreading and formatting) and images (adding and updating images to reflect current version of InfoLeader). Insertion of bookmarks/ cross references for referral to step numbers within the WI to allow ease of updating the WI in the future. Update to Dept name and Coat of Arms post election References to TRIM updated to Content Manager (CM) after May 2025 update and change to intranet references Term 'Program' removed when referencing MDAB and MDSB as it has different meaning in Dept context – directed by FAS		
V3.1	D25-2505185	Correction of reference to URPTG to PRAC in step 14 Correction of step references in steps 45 and 50 to correct steps	s22	12 June 2025
V3.2	D25-2580840	Addition of steps 28 and 29, and Appendix 9 to direct triager/ investigator on triaging reports where the reported incident is already under investigation. Inclusion of referral to DPMMS WI 1.21 for urgent or expedited reports Minor clarification of directions to staff in some steps.	s22	22 Aug 2025

Appendix 1. Flow of Reports through the IRIS Information database

Reports are reviewed in IRIS database in the following way:

Triage	The report is marked as triage when it first arrives into the database and signifies that it needs to be reviewed by one of the triage officers in the section. In this workflow request status, the incident will be visible to the Device Support Team (DST) Team Leader and Office of Product Review (OPR) Administration Users.
Awaiting final report	The report is marked as 'Waiting for final' after it has been reviewed by a triage officer in the section. This occurs at the initial and follow-up stage of the workflow process. In this workflow request status, the incident will be visible to the DST Team Leader and OPR Administration Users.
Final report:	The report is marked as 'Final' after all the information required to make it a final report has been reviewed by the Support Administration team. The report will be reviewed by a triage officer in the section and determination is made by the triage officer to send to a team meeting for review as to whether further investigation is required or closed by the triage officer as no investigation is required based on the information within the report. Closed reports are used for trending purposes. In this workflow request status, the incident will be visible to the DST Team Leader and OPR Administration Users.

Appendix 2. Final Level of Investigation

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Screening Only	Applicable if this is an initial or follow-up sponsor report that does not need to be expedited OR if this is a user or final sponsor report requiring no further level of investigation.
Level 1 Investigation	To collect additional information (that has not already been requested from product sponsors for example the IFUs or we are querying something about the information such as the rates) in order to remove doubt that may have been raised in the Risk Assessment. The additional information may include similar adverse event information or copies of the instructions for use. Outcomes of a Level 1 Investigation may include Case Closure, a Level 2 Investigation, or a Level 3 Investigation.
Level 2 Investigation	Detailed investigation of a single report (Device Incident Report). Outcomes of a Level 2 Investigation may include Case Closure, a Level 3 Investigation, or other actions determined by the investigator and Director of DPMMS.
Level 3 Investigation	Investigation of a group of reports and incidents that appear to be related (Device Incident Investigation). The outcomes of a Level 3 Investigation may include Case Closure, or further actions determined by the investigator and Director of DPMMS.

Appendix 3. Determination of revision rate/ NJRR data

Back to step 33


s22

Back to step 33

Appendix 4. Potential contributing factors

Back to Step 36

These factors have been organised across the product lifecycle.

Potential contributing factor	Comment
Compatibility of device - patient characteristics.	This refers to the potentially inappropriate device selection, or ongoing use of the device for a patient given their individual characteristics. Patient characteristics may have been known before the device was used or may emerge as the device has been used.
Choice of device - off-label from original purpose.	This refers to a mechanical fault that is suspected to be related to the way the device is designed.
Production of device – manufacture/batch.	This refers to a mechanical problem in the general device manufacture, or the manufacture of a specific product batch.
Supply of device – packaging.	This refers to problems in device packaging that may compromise the products ability to be safely or effectively used.
Supply of device - transport/storage.	Is the problem that has occurred as a result of product transport or storage prior to use?
Use of device – according to IFUs.	Was the device implemented or used in a manner intended by the manufacturers (as documented in their Instructions for Use)?
Use of device - fit for purpose.	Was the device fit-for-use in the manner for which it was intended by the product manufacturer?
Use of device - interaction with other equipment.	This refers to suspicions that the device performance may be compromised due to planned or unplanned adverse interactions with other equipment (including hardware, software or other interfacing devices or products)

Potential contributing factor	Comment
Use of device - operator/user error.	This refers to potentially incorrect or inappropriate use of a device as recommended by the manufacturer (includes exposure to situations that are contra-indicated for the device by product manufacturers). May also refer to inappropriate monitoring of the device in accordance with manufacturer instructions.
Management of device - performance over time.	This refers to an unplanned deterioration in device performance over time (within the documented lifecycle of the product by the manufacturer).
Management of device - regular updates/repairs/maintenance.	This refers to failure to update (e.g., software/hardware), undertake routine maintenance and/or required repairs to a device to maintain upkeep in accordance with manufacturer's instructions.
Management of device - end of life cycle.	Has the device exceeded its recommended life-span?
'**Other factors**'	If there are 'Other factors', please note these in the 'Exception to investigation level' section of Risk Analysis page in Info Leader.

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Appendix 5. Potential sensitivities

Back to step 38

Sensitivity	Comment
Device is difficult to substitute	There are no readily available alternative devices currently included on the ARTG (note: this is about device availability not interventions required to change any devices).
Device used with high-risk populations	Devices are used with populations who are at risk of death or serious deterioration in health as well as those that have serious chronic conditions or are a vulnerable patient group such as diabetes, kidney failure or are a neonate.
Device used in high acuity clinical environments	Device is used with patients who require active close monitoring in hospital (HDU, ICU, ED, Theatre, Cardiac Cath Labs, Radiological procedure areas etc).
Device uses new technology	Device involves recently introduced technology (over the past 2 years) OR a change of technology that has not been previously associated with this product.
New evidence about device efficacy	Recent investigations or scientific studies have challenged previous evidence about the effectiveness or safety of a medical device.
Public interest/requests for information	More than one question or query has been received by the TGA from members of the public (via telephone, written letter, email correspondence, etc.). Freedom of information requests may have been received on behalf of members of the public (e.g., lawyers). **Note:** this does not include current or previous incident reports from users (these are counted in the number of incidents section of the risk assessment, OR if they are current, they are to be identified as Enquiries/investigations/actions by the TGA).
Media interest/requestions for information	The device is a subject of current attention by Australian or overseas media (newspapers, online, television programs, radio commentary, documentaries, podcasts, etc.). Freedom of information requests may have been received from media organisations.

Sensitivity	Comment
Industry interest/requests for information	Concerns have been expressed by industry or other professional bodies (e.g., device manufacturers, sponsors, professionals etc.).
Investigations/requests by government	This may involve a formal government inquiry (e.g., Senate Inquiry), questions or comments raised in government correspondence (e.g., department briefs, email correspondence, etc.), or requests for preparation of a briefing to members of parliament (e.g., questions on notice, Ministers, or other Standing Committees).
Enquiries/actions by other jurisdictions	Further information or concerns have been raised by other jurisdictions (e.g., State/Territories, National Bodies).
Enquiries/investigations/actions by the TGA	Information about the device has been received from other TGA areas (e.g., Recalls, Laboratories, Medicines etc.), further information has been requested by TGA executive (typically emails or meeting action items), or the device or incident is currently the subject of investigation and/or has been referred for further review by the TGA.
Potential for current incident to become sensitive	This issue is expected to become sensitive to one or more stakeholders. Please make appropriate notes about any potential in Info Leader.

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Appendix 6. Severity definitions

Back to step 20

0	**Insufficient information to determine level of severity.** Select this if there is insufficient information at the point of initial or follow-up assessment from Sponsor Reports, but must not be used in rating Final Sponsor Reports.
1	**No harm has been reported to occur.** The event has resulted in no impact upon the individual (although temporary disruption to clinical care may have occurred).
2	**No harm – but incident could have resulted in illness/injury (near miss).** The event **had** the potential to result in a time-limited or permanent change and/or requiring minor adjustments to daily living by the consumer/user. If changes had occurred, intervention would have been required.
3	**No harm – but incident could result in future illness/injury (ongoing risk).** The event **has** the potential to result in a time-limited change to body structures or functions in the future. If changes occur, they are expected to spontaneously resolve.
4	**An illness/injury resolved without treatment by a health professional (or by self-management).** The event has resulted in a **temporary** illness or injury that **has or will resolve by itself**.
5	**An illness/injury was resolved or will be resolved with treatment by a health professional.** Illness or injury will only be resolved with medical treatment by a health professional. There may be minor impairments involving ongoing illness or injury, temporary changes, and minor adjustments to daily living for the individual.
6	**Ongoing minor impairment.** The event has resulted in illness or injury associated with permanent change to body structures or functions. **This includes impairments where intervention has been planned or has occurred to reverse the ongoing impact upon the injured party**. Minor impairments involve ongoing illness or injury, permanent changes, and minor adjustments to daily living for the individual.
7	**Ongoing serious impairment.** The event has resulted in ongoing illness or injury associated with permanent change to body structures or functions, which might result in major adjustments to daily living for the injured party. **This includes impairments where intervention has been planned or has occurred to reverse the ongoing impact upon the consumer/user**. Serious impairments involve ongoing illness or injury, permanent changes, and major adjustments to daily living for the individual.
8	**Life threatening.** The event resulted in a condition that would have been fatal without medical intervention.
9	**Death.** The event has led to the death of a person. If the death was not related to the device or the adverse event associated with the device, then this severity should not be selected
10	**Public health threat.** Events of a similar nature may occur to others creating an imminent risk of death, serious illness, or serious injury. A ‘public health threat’ relates to the potential impact of the current incident upon **other** people, or more than one person using the same or a similar medical device.

Appendix 7. IVD status

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Point of Care IVD	Testing performed outside the laboratory environment, near to or at the side of the patient, that is not done under the supervision of a trained laboratory professional. For example, a blood glucose test performed by a nurse.
Self-testing IVD:	Any device intended by the manufacturer for use by lay persons. For example, a pregnancy test used at home.

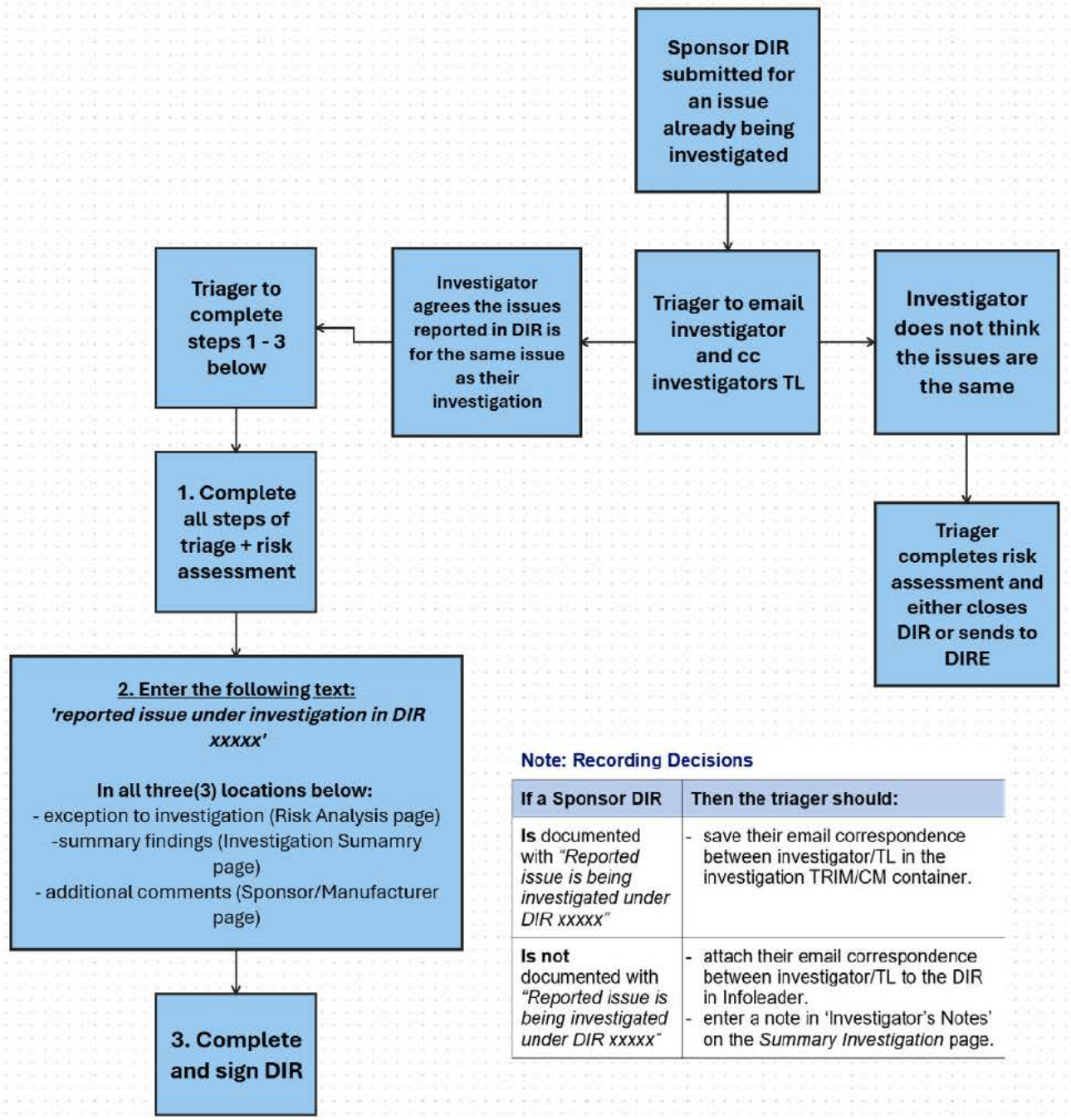
Appendix 8. Final Level of Priority

Back to Step 44

Urgent	Responses refer to those requiring an immediate follow-up such as an event that would have immediate health impacts on the wider community. The sponsor is sent the details of the report and asked to return requested information and/or samples with a completed questionnaire within 48 hours of receipt of the TGA letter of request. The reporter is notified that the incident is being investigated as a high priority.
Expedited	Responses refer to those requiring a quicker follow-up such as those that might need a recall sooner rather than later or where the event could have serious impact to individuals based on the severity identified in the report. The sponsor is sent the details of the report and asked to return requested information and/or samples with a completed questionnaire within 5 working days of receipt of the TGA letter of request. This allows for at least preliminary investigation to take place before reporting back to the TGA. The details of the questionnaire are updated into the database and the scanned copy of the questionnaire is uploaded into the database. The reporter is notified that the incident is being investigated as a high priority.
Routine	Responses require a standard follow-up such as obtaining the manufacturers analysis to assist in an investigation. This usually denotes the severity noted in the report is not extreme in nature. The sponsor is sent the details of the report and asked to return requested information and/or samples with a completed questionnaire (if required) within 20 working days of receipt of the TGA letter of request if the matter is to be investigated. The reporter is notified by form letter that the incident is being investigated.

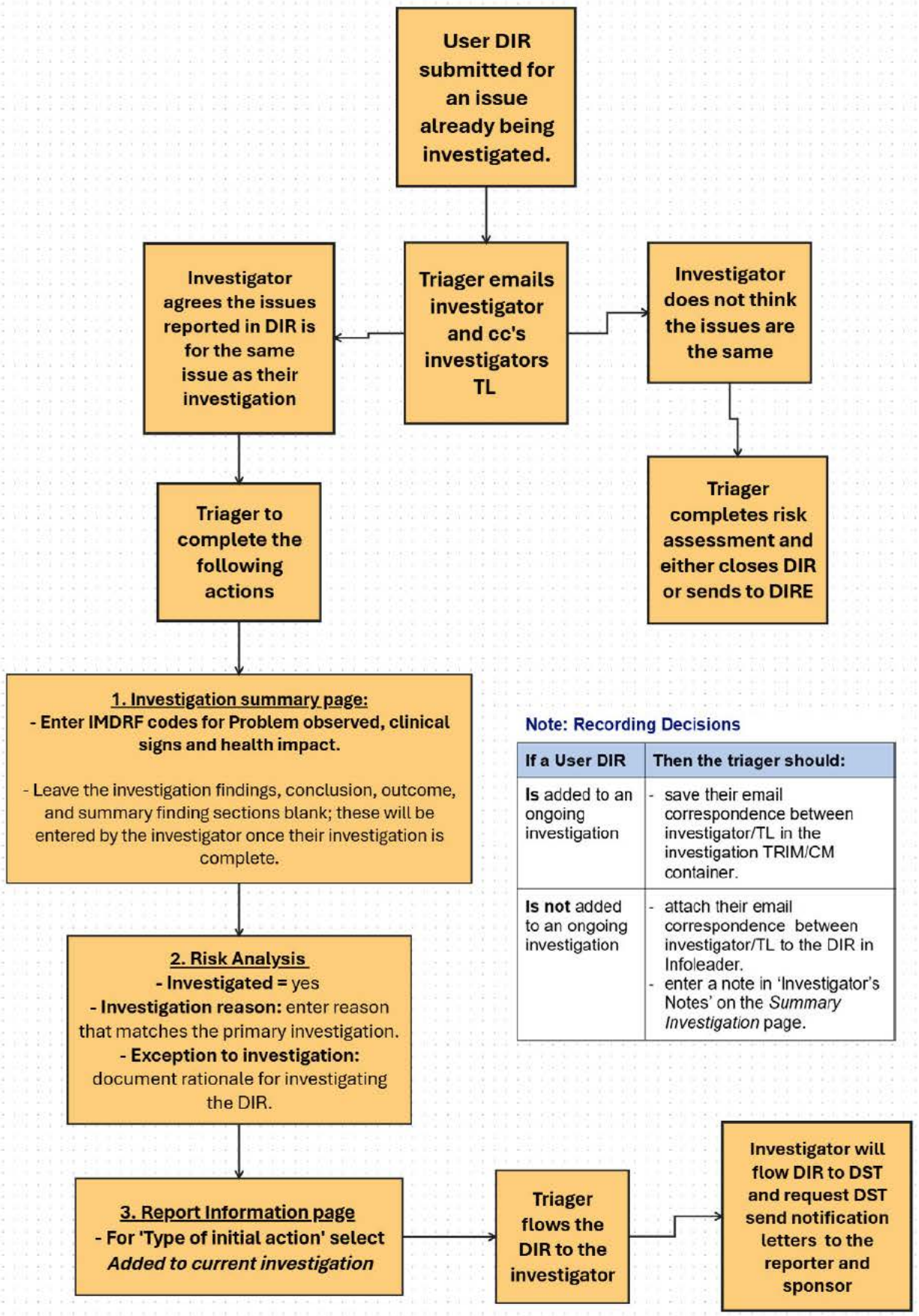
Appendix 9. Management of a DIR submitted for an issue & ARTG are already under investigation

Back to step 29



Note: Recording Decisions

If a Sponsor DIR	Then the triager should:
Is documented with *"Reported issue is being investigated under DIR xxxxx"*	- save their email correspondence between investigator/TL in the investigation TRIM/CM container.
Is not documented with *"Reported issue is being investigated under DIR xxxxx"*	- attach their email correspondence between investigator/TL to the DIR in Infoleader. - enter a note in 'Investigator's Notes' on the *Summary Investigation* page.



Note: Recording Decisions

If a User DIR	Then the triager should:
Is added to an ongoing investigation	- save their email correspondence between investigator/TL in the investigation TRIM/CM container.
Is not added to an ongoing investigation	- attach their email correspondence between investigator/TL to the DIR in Infoleader. - enter a note in 'Investigator's Notes' on the *Summary Investigation* page.

Back to step 29

Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Medical Devices QMS

Work Instruction	
Name of procedure	Processing a Web User Device Incident Report (DIR) in the MDIR for Triage
Applicable to	Medical Devices Branches Devices Post Market Monitoring Section
QMS Reference	DPMMS WI 12.7
Written by	s22 [redacted]
Authorised by	s22 [redacted] Director, Devices Post Market Monitoring Section
Date issued	[Publish Date]
Version no.	1.0

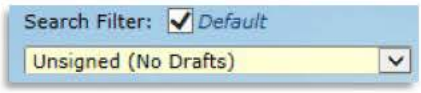
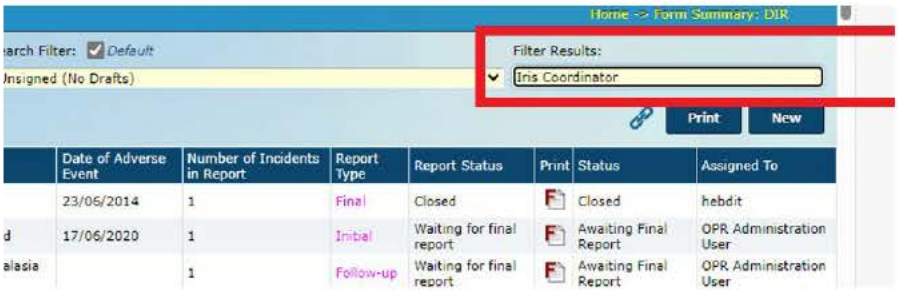
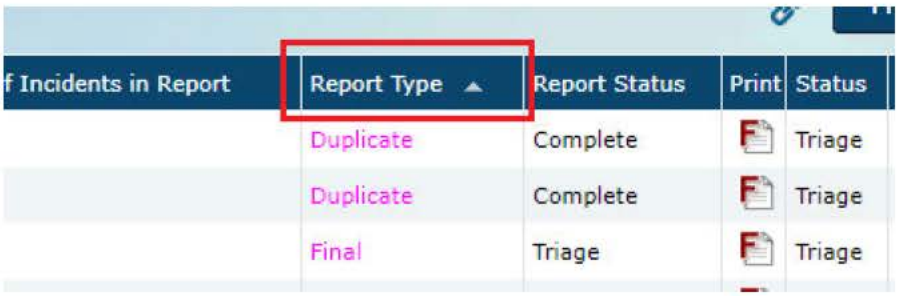
Guidelines

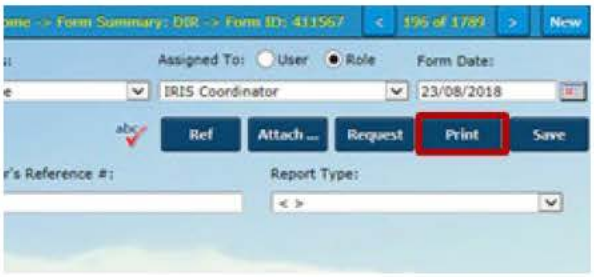
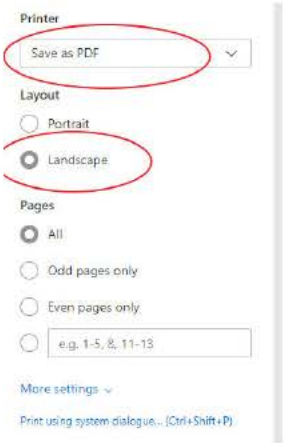
Medical device incident reports (DIRs) are received from consumers, health professionals, and sponsors either electronically through the medical device incident reporting (MDIR) scheme or by email, or printed copies of the MDIR form.

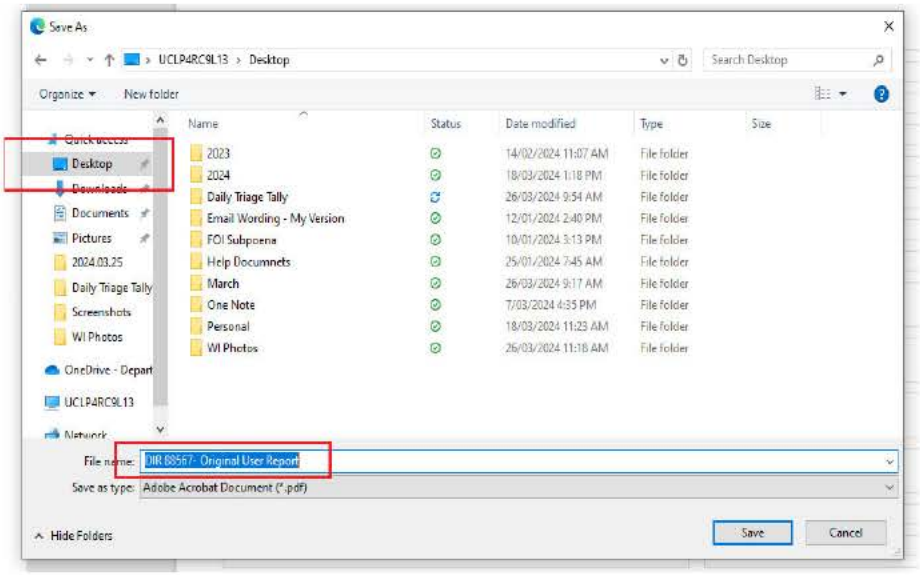
Users and healthcare professionals notify the TGA of adverse medical device incidents, using the website form. The Device Support Team reviews and processes these reports in information leader before sending to the investigator for further risk assessment.

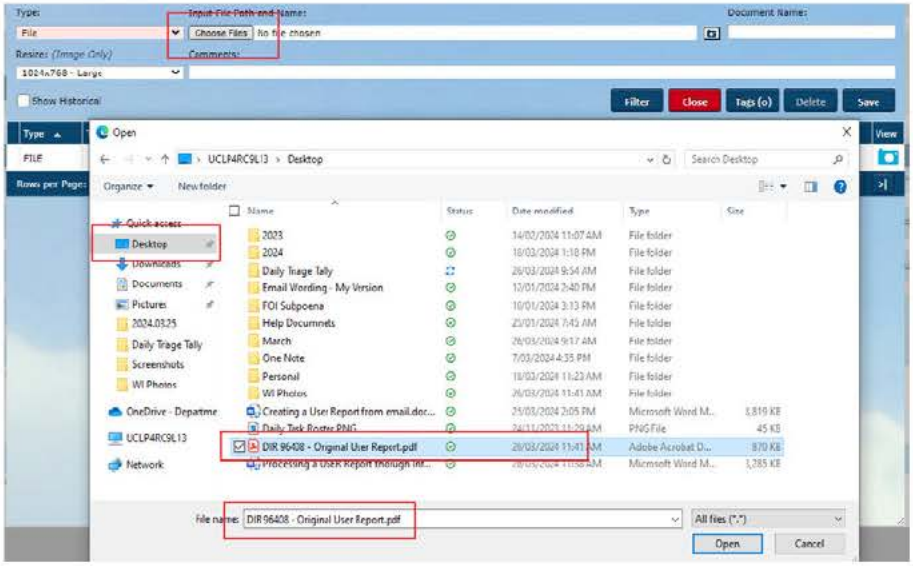
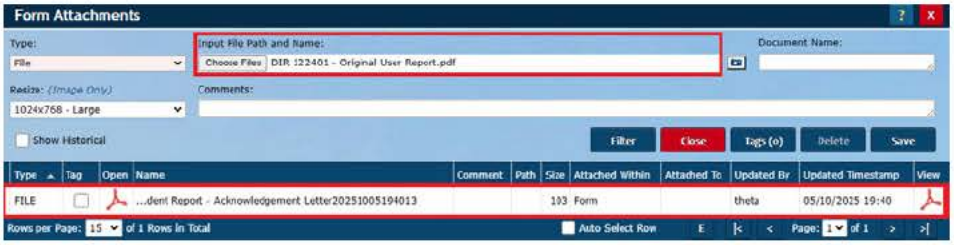
This work instruction document provides instructions on how to process a User Device Incident Report (DIR) received from a Healthcare professional, User or Patient.

Procedure/Process

#	Step	Responsible
1.	In InformationLeader, from the Search Filter: drop down menu, single click to select 'Unsigned (No Drafts)'. 	Device Support Team (DST)
2.	Search 'IRIS Coordinator' in the Filter Results tab. Press Enter. 	Device Support Team (DST)
3.	Click on 'Report Type' to sort in ascending order and group the different report types together. 	Device Support Team (DST)
4.	To identify a User Report look for report type 'Final' with no Device ARTG entered. Click on report to open.  s22	Device Support Team (DST)

#	Step	Responsible
5.	Verify the source of report is not a sponsor. Select from drop down options if source is vacant "< >". 	Device Support Team (DST)
6.	Click the 'Print' button on the top right corner of the DIR form. It is important to save the original details provided by the user for future use. 	Device Support Team (DST)
7.	Once the 'Form Details – Internet Explorer' pop-up opens, select the Print Tab.  Save as a PDF ensuring it is in Landscape layout.  Press 'Save'.	Device Support Team (DST)

#	Step	Responsible
8.	Save the original copy to your Desktop, following the naming convention • DIR ##### - Original User Report and then click Save.  A PDF copy of the report will generate and open, close the PDF and continue processing the report in Infoleader.	Device Support Team (DST)
9.	Click on the 'Attach…' button to open attachments pop up box.  	Device Support Team (DST)
10.	Select the 'File' option from 'Type:' drop-down menu.  	Device Support Team (DST)

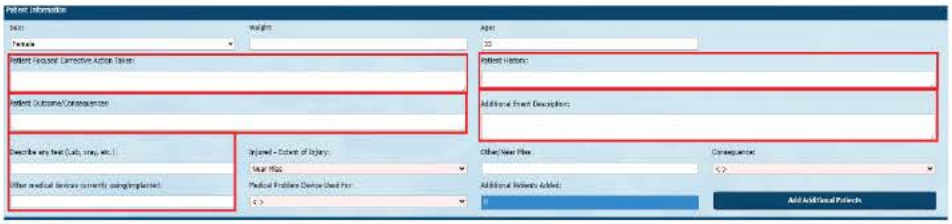
#	Step	Responsible
11.	Click the 'Choose File…' button to open a pop-up box and click on 'Choose File' to Upload. Select and open the downloaded DIR pdf document on your Desktop to attach. 	Device Support Team (DST)
12.	Once the file title appears in the 'Browse…' field, click 'Save'. Confirm the file has attached to the report, as shown below, before selecting the 'Close' button. Before Save:  Note: As the report was submitted online, the system should have sent an Acknowledgement Letter. This file should be visible on this section.	Device Support Team (DST)

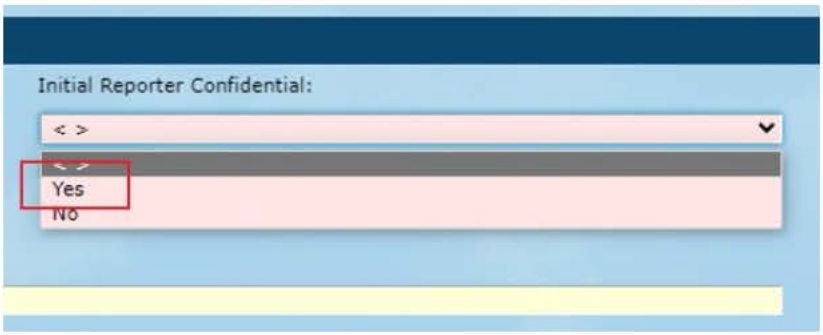
#	Step	Responsible
13.	After Save you should see the PDF in the Attachments as seen below. 	
14.	On the Report Information page (drop-down menu) under the Report Information Section, click the arrow on 'Reporter consents to contact by sponsor' and select 'No'. **Note**: Care must be taken to protect reporter's confidentiality. 	Device Support Team (DST)
15.	Ensure the 'Source of Report' has been entered. If a source of report has not been entered, try to identify the source of report using reporter details. If no source of report can be identified select 'Other'. 	
16.	Remove all text in 'Event Description for Website Publication' field.	Device Support Team (DST)

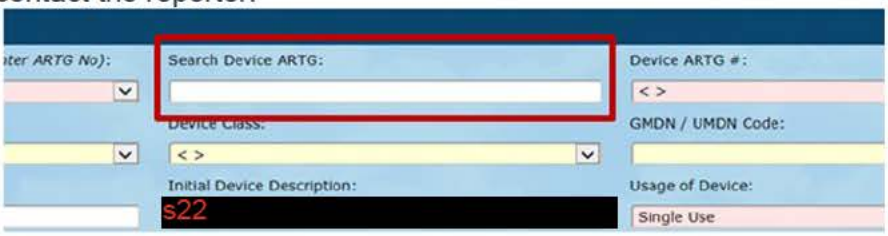
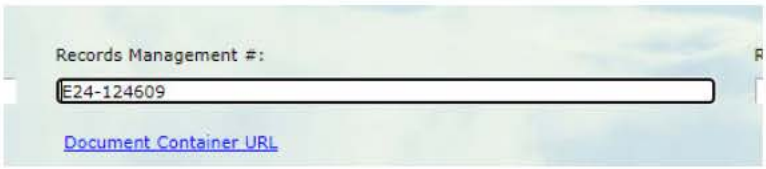
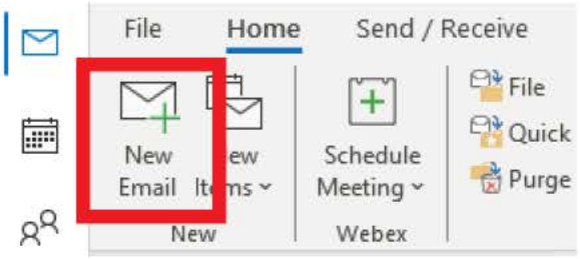
#	Step	Responsible
	Event Description for Website Publication: s22 [redacted] Clinical Event Information: s22 [redacted]	
17.	Redact the 'Clinical Event Information:' field to remove and replace any references to: **Information** / **Replace with** him/her, he/she → 'patient' or 'customer' specific dates (Ex: Birthdates; Death dates) → [Date Redacted] names of people → [Name Redacted] addresses → [Address Redacted] **Any remaining information must not allow a particular facility or person to be identified as a copy of this information is provided to the sponsor.** Correct any obvious spelling and formatting errors.  If a reference to BIA ALCL or SCC has been mentioned in the report, follow steps 23 - 36 for requesting pathology reports.	Device Support Team (DST)
18.	Redact the 'Patient Information section' field to remove and replace any references to:	Device Support Team (DST)

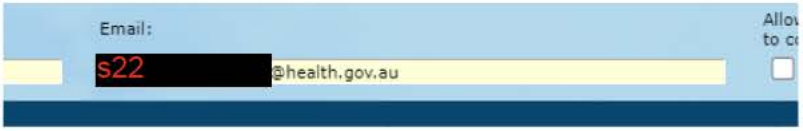
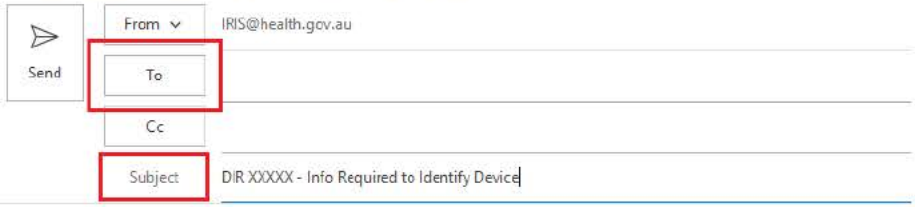
<table>
<tr><th>#</th><th>Step</th><th>Responsible</th></tr>
<tr><td></td><td>
<table>
<tr><th>Information</th><th>Replace with</th></tr>
<tr><td>him/her, he/she</td><td>‘patient’ or ‘customer</td></tr>
<tr><td>specific dates (Ex: Birthdates; Death dates)</td><td>[Date Redacted]</td></tr>
<tr><td>names of people</td><td>[Name Redacted]</td></tr>
<tr><td>Addresses</td><td>[Facility Redacted]</td></tr>
</table>
Any remaining information must not allow a particular facility, company or person to be identified as a copy of this information is provided to the sponsor.

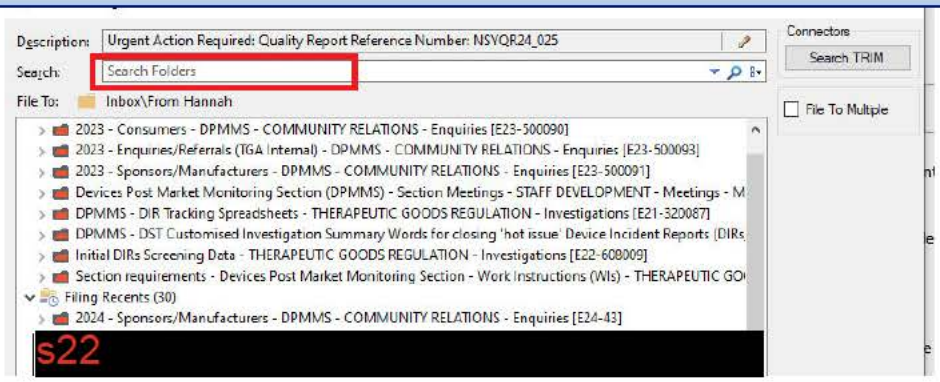
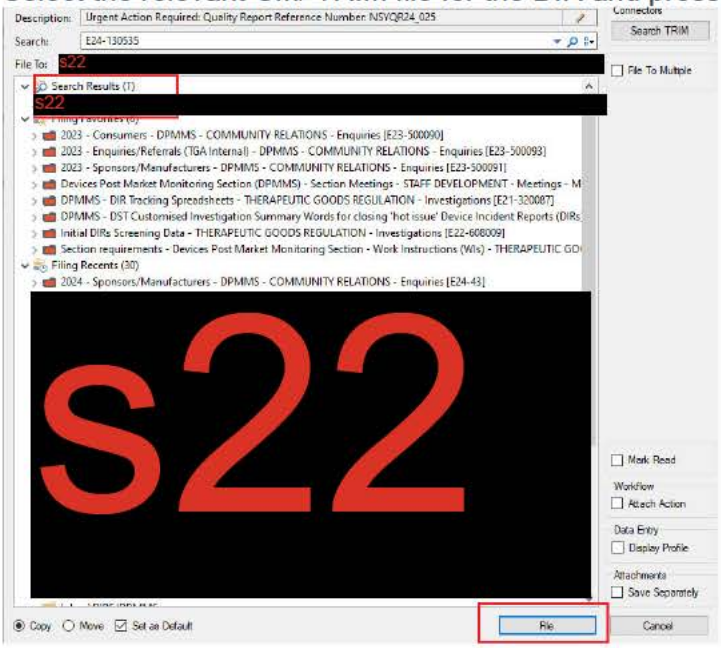
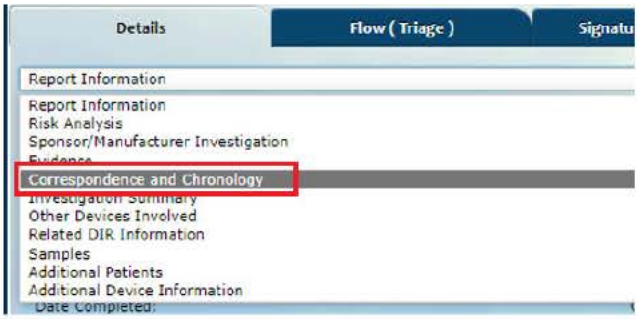
Correct any obvious spelling and formatting errors.

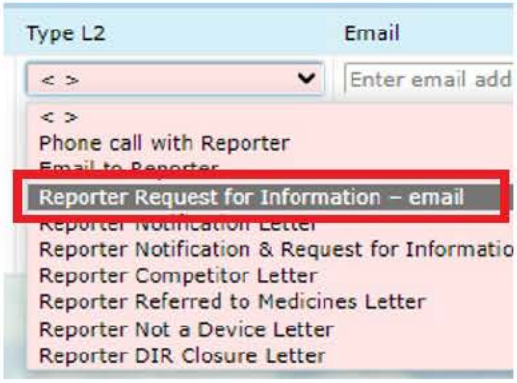

</td><td></td></tr>
<tr><td>19.</td><td>Any information from ‘Patient Information’ section can be cut and pasted into ‘Clinical Event’ section. Ensure all information is carried across.
 </td><td></td></tr>
<tr><td>20.</td><td>Under the ‘Submitting Reporter Section’, correct any grammatical or formatting errors. The details from this section generate onto letters and therefore need to be correctly formatted.</td><td>Device Support Team (DST)</td></tr>
</table>

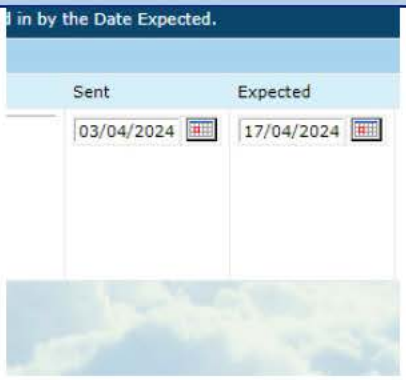
#	Step	Responsible
		
21.	Go to 'Initial Reporter Section' to change 'As Above' drop-down menu. Select 'Yes' if the Submitting reporter is the same as the initial reporter. Otherwise, select 'No'. 	Device Support Team (DST)
22.	Always select 'Yes' for 'Initial Reporter Confidential' field, even if the details are the same as above. 	Device Support Team (DST)
23.	Search for ARTG number by following DPMMS WI 12.6 - Searching for an ARTG Number. Enter the ARTG number in the 'Search Device ARTG' field and press 'Enter' to populate other device fields automatically. Go to step 37.	Device Support Team (DST)

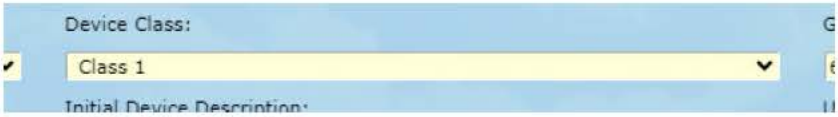
#	Step	Responsible
	If a device cannot be identified or further information is required from the reporter contact your team leader and then follow steps 23-36 to contact the reporter. 	
24.	Create a CM/ TRIM container to save all correspondence. Follow DPMMS WI 17.2 – Creating a CM/ TRIM folder for DPMMS records Once created, copy, and paste the number in the 'Records Management #:' field.  Press 'Enter', then press 'Save'.	Device Support Team (DST)
25.	Go to Outlook and select New Email. 	Device Support Team (DST)
26.	Select the 'From' tab and select the IRIS email address. Check that you are not sending from your personal work email. This ensures that the response is promptly picked up by the DST member monitoring the Iris inbox.	Device Support Team (DST)

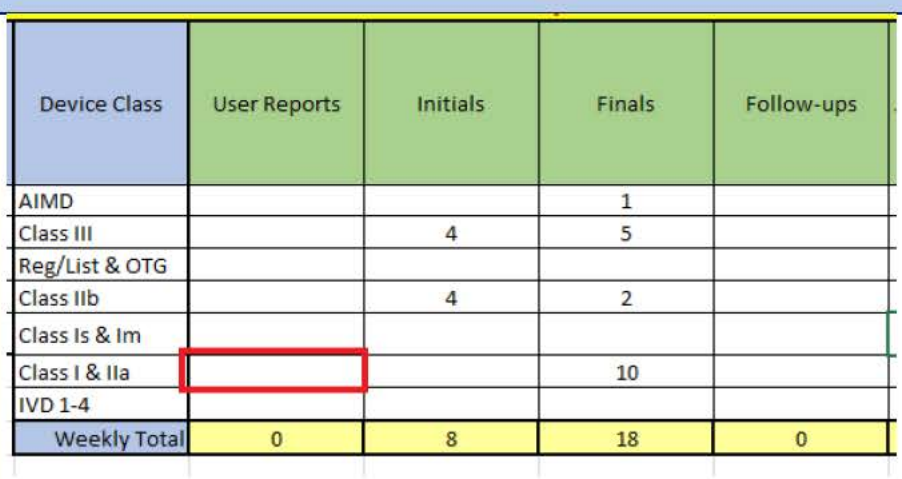
#	Step	Responsible
	 Copy and paste the Submitting Reporter's email address from InfoLeader into the 'To' tab.  In the email Subject write 'DIR XXXXX (The Report Number) – Information Required to Identify Device.' 	
27.	Draft an email to the reporter asking for more information that they might have about the device or other required information, to help with device identification or completing the report. (e.g., Model Number, Serial Number, Brand Name, Photographs, Pathology reports for BIA ALCL cases etc). For an example with standard words that are used, please refer to point 45.	Device Support Team (DST)
28.	Press 'Send' and a pop box will appear. Paste the 'TRIM Record Number' into the 'Search' Tab to locate the correct CM/ TRIM file.	Device Support Team (DST)

#	Step	Responsible
		
29.	Select the relevant CM/ TRIM file for the DIR and press 'File'. 	Device Support Team (DST)
30.	Return to InformationLeader. In the drop-down menu within the 'Details tab', select 'Correspondence and Chronology'. 	Device Support Team (DST)

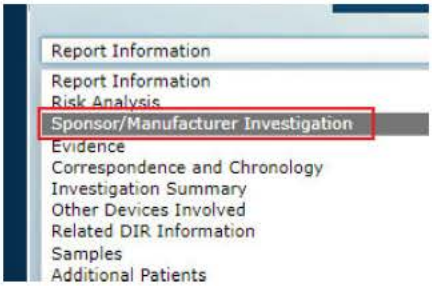
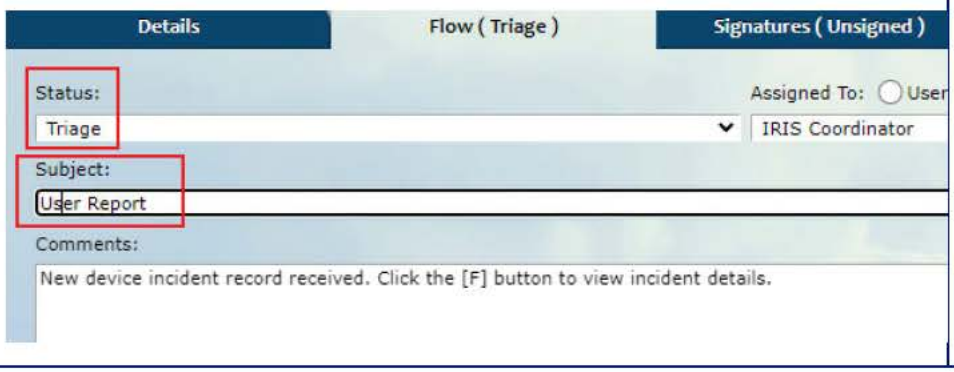
#	Step	Responsible
31.	Click on 'N', located on the right side of the page. 	Device Support Team (DST)
32.	In the 'Type L1 field' select 'Reporter Routine Correspondence'.  In the 'Type L2' field, Select 'Reporter Request for Information – email'. 	Device Support Team (DST)
33.	For the 'Expected Date', give the Reporter 10 working days to respond to our email taking into account any public holidays.	Device Support Team (DST)

#	Step	Responsible
		
34.	In the 'Notes' field, enter the content of the email along with the date sent and CM/ TRIM file number.  Press 'Save'.	Device Support Team (DST)
35.	Click the 'Flow' tab. 	Device Support Team (DST)
36.	Leave the status as 'Triage'. Next to 'Assigned To' select 'Role' and then 'OPR Administration User' from the drop down menu. 	Device Support Team (DST)
37.	Write 'User Report – Please see Comments' in the Subject text box. Write a brief summary of Information requested from reporter in the Comments text box.	Device Support Team (DST)

#	Step	Responsible
	 Press 'Save'. This step completes the process of sending an email to the reporter to identify a device. Once information is received from the reporter enter the ARTG number as mentioned in step 20 and then proceed to step 37.	
38.	Return to the Report Information page. a. Copy the text from 'Initial Device Description' field and paste after the existing text in 'Brand Name' field.  b. Copy the text from 'GMDN / UMDN Text' field and paste this after all the text in 'Brand Name' field separated by hyphen (-).  c. Copy all the text from 'Brand Name' field and paste in the 'Initial Device Description' field to replace the existing text. These fields should be the same.  Press 'Save'.	Device Support Team (DST)
39.	Go to your 'Daily Triage Tally' on Desktop and record it against the correct Device Class under the 'User Reports' column. 	Device Support Team (DST)

#	Step	Responsible
		

Device Class	User Reports	Initials	Finals	Follow-ups
AIMD			1	
Class III		4	5	
Reg/List & OTG				
Class IIb		4	2	
Class Is & Im				
Class I & IIa			10	
IVD 1-4				
Weekly Total	0	8	18	0

40.	Go to 'Sponsor/Manufacturer Investigation' page from the drop-down menu to ensure the Sponsor details were prepopulated after adding the ARTG number. 	Device Support Team (DST)
41.	Click the 'Flow (Triage)' tab. 	Device Support Team (DST)
42.	Make sure the 'Status' is always 'Triage'. Write 'User Report' in the 'Subject:' field. In the comments text box add a note for the Investigator to verify the selected ARTG number. 	Device Support Team (DST)

#	Step	Responsible
43.	Assign the report in InformationLeader to an Investigator using the User Reports Triage Flow Excel Spreadsheet. Select 'User' next to the 'Assigned To:' field 	Device Support Team (DST)
44.	Open the drop down menu and select the investigator's name and press 'Save'. 	Device Support Team (DST)
45.	Example of standard words used for letters requesting Reporters for for information Dear **XXXXX**, Thank you for your Device Incident Report that you have submitted to the Therapeutic Goods Administration (TGA) in relation to the **XXXXXXX** device. The aim of the Medical Device Incident Report Investigation Scheme (IRIS) is to improve the standard of medical devices and to reduce the number and severity of incidents with devices in Australia, through voluntary cooperation between medical device users, industry and government. While suppliers and/or manufacturers are responsible for their products, the Scheme can play an important role in ensuring effective and efficient resolution or prevention of incidents. In addition to reporting safety	Device Support Team (DST)

#	Step	Responsible
	issues, everyone is encouraged to report any issues of the quality and efficacy of medical devices. However, without specific information about the device, an investigation would difficult. We have been unable to clearly identify the device you mention in your Device Incident Report **DIR XXXXX**. Could you please provide more information to assist with this initial stage of our review of this device? This information should include but is not limited to: 1. Model number 2. Serial number 3. Brand name of your particular XXXXX device If unsure, your GP may be able to provide this information to you. Please don't hesitate to contact our team on s22 [redacted] if you have any questions.	
46.	This completes processing a User Report through InformationLeader.	Device Support Team (DST)

Version history

Version	CM/ TRIM Reference	Description of change	Authors	Effective date
V1.0	D24-2360243	New Work Instruction- based on long standing draft D22-5749987	s22	

Users Medical Device Incident Report eg Doctors, Nurses, Patients, Public

What should be reported? A medical device is any material instrument, apparatus, machine, implement, contrivance, implant etc (including any component, part or accessory) which is used in health care and includes in-vitro diagnostics.
Typical problems include deficiencies in labelling, instructions or packaging, defective components, performance failures, poor construction or design. Suggestions for rectifying the problem or improving product performance would be appreciated.

What should you do with the device? **Please keep the device and its associated packaging until you are contacted by the TGA.**

What happens to your report? The report will be investigated and discussed with the manufacturer/supplier. You may be contacted for further information. The report may also be reported to other Health Authorities. If action is considered necessary, it may involve any of the following:

1. Recall - removal of goods from sale or use, or their correction, for reasons relating to safety, performance or quality.
2. Safety Alert – information relating to the correct use of the device to inform those responsible for the device, or affected by the problem.
3. Report in a TGA News Bulletin (a communication produced by the TGA and distributed in Australia and New Zealand to convey information on medical devices) or other appropriate journal(s).

Medical device manufacturers or suppliers should submit reports via the online sponsor portal.

A	**Product Identification**	*Please provide all available details*			Date of Report:	
1.	Brand/Trade Name					
2.	Device Description *(eg Urinary Catheter)*					
3.	Device Identification	Model	Serial Number	Batch Number	Lot Number	Software (Version)
4.	Relevant Dates	Purchase (*Approximate*)	Expiry	If Device is Implantable *(eg pacemaker, venous port etc)* Date of Implant		Date of Explant
5.	Manufacturer's name address & telephone					
6.	Supplier's name address and telephone					
B	**Reporting the Problem**	*Please provide all available details*				
7.	Has the supplier been informed of the problem?	☐ YES ☐ NO	If YES Date Contacted	If YES add contact details Name		Phone / Fax
						( )
8.	Where is the device now?	☐ Place of use ☐ With Reporter ☐ With Supplier ☐ With Patient	Please **Do Not** discard the device or related consumables & packaging	Contacts for access to device Name		Phone / Fax
						( )

9.	Is this device supplied sterile?	☐ YES ☐ NO	Is this device reusable?	☐ YES ☐ NO	Is this device single use?	☐ YES ☐ NO	

C	**Problem Description**	*Please provide all available details* *If you do not have enough space please add information onto another sheet of paper or into the body of your email.*
10.	Add a brief description of the problem. Include what led to, or contributed to the problem.	
11.	Add a brief description of the consequences or outcome of the problem.	*Please add sketches and pictures if necessary and/or available*

12.	Patient Information	Gender		Age		Weight (Kg)	

Patient History

D	**Reporter**	*Please provide all available details*
13.	Do you want your identity to remain confidential? *If **YES** your name & contact details will not be disclosed to manufacturers or suppliers without your permission. TGA will contact you if more information is needed.*	☐ YES ☐ NO A report without contact details cannot be processed. Name Position / Occupation Department, Institution & Address Phone ( ) Fax ( ) email

E	**Initial Reporter**	*Please provide all available details*
14.	Do they want their identity to remain confidential? *If **YES** their name & contact details will not be disclosed to manufacturers or suppliers without their permission. TGA will contact them if more information is needed.*	☐ YES ☐ NO If **YES or NO** add contact details below Name Position / Occupation Department, Institution & Address Phone ( ) Fax ( ) email

F	**TGA Feedback**	*Please provide all available details*
15.	Who can TGA contact for more information regarding this incident?	☐ Reporter ☐ Initial Reporter ☐ Other Appropriate Person *Name* | *Name* | *Name* | Phone & Fax: *Phone:* ( ) *Fax:* ( )

G How to submit Post, Fax or email your completed form to:

	✉ Post to		email / intranet	Fax to	Phone
Australian Reporters **TGA**	**Reply Paid 100** Medical Device IRIS TGA, PO Box 100 Woden ACT 2606 AUSTRALIA	**Courier delivery:** TGA 27 Scherger Drive, Canberra Airport, ACT 2609 AUSTRALIA	IRIS@health.gov.au https://www.tga.gov.au/safety/reporting-problems	**(02) 6203 1713**	**FREE HOTLINE 1800 809 361**
New Zealand Reporters **MEDSAFE**	Product Safety Team, MEDSAFE Ministry of Health Deloitte House 10 Brandon Street PO Box 5013 Wellington NEW ZEALAND		devices@moh.govt.nz	**(04) 819 6806**	**(04) 819 6800**

Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Medical Devices QMS

Standard Operating Procedure

Name of procedure	DPMMS Records Management
Applicable to	Medical Devices Branches - Devices Post Market Monitoring Section
Number	DPMMS SOP 17
Written by	
Authorised	s22 [redacted] Director, Devices Post Market Monitoring Section
Date issued	[Publish Date]
Version no.	N.n

Purpose

To ensure that all records produced by DPMMS are retained in line with Medical Devices' QMS and the Departmental and HPRG requirements.

Scope

This SOP applies to all records produced by DPMMS relating to activities associated with the ?? of therapeutic goods and, in particular, records produced to support a regulatory decision made by a Delegate.

Responsibility

Director, DPMMS	To ensure all staff are aware of their record management responsibilities. To monitor staff under their supervision to ensure that they understand and comply with the Department's records and information management policy and procedures. To support and foster a culture within the Section that promotes good record and information management practices and information literacy. To review and approve changes to this standard operating procedure (SOP).
Assistant Directors, DPMMS	To monitor each team of the Section adhere to procedures to ensure records are retained according to this SOP. To train team members in these procedures.
All DPMMS employees and contractors	To be aware of and understand the Department's record keeping policies and requirements. To ensure that their access, use and control of records comply with the extensive legislation that is relevant to the Department. To ensure that records are classified with the correct Security Classification and Dissemination Limiting Markers.

Procedure

#	Step	Reference
1.	All records shall be handled in accordance with the Medical Devices Records Management procedure.	MDB SOP 3
2.	All records must be created and saved in a digital format by default.	
3.	The default system for recording decisions is Content Manager (formerly TRIM HPE). CM/ TRIM folders will be created for each application received. All email correspondence related to an application, application checklist, supporting documentation provided by sponsors, assessment reports and other relevant documents will be saved in the corresponding CM/ TRIM folder. CM/ TRIM files will be named according to DPMMS CM/ TRIM File Naming Convention.	CM/ TRIM CM/ TRIM help cards DPMMS WI 17.4 DPMMS WI 17.1
4.	Viewing and monitoring of all Medical Device and Other Therapeutic Goods applications will be done in Work management (WM). For easy identification of application status, naming of applications in WM will be done following DPMMS WM naming convention.	DPMMS WI 17.2 DPMMS WI 17.3

Version history

Version	CM/ TRIM Reference	Description of change	Authors	Effective date
V1.0	Published - Click or tap here to enter text. DRAFT - D24-2233723	New SOP		

Add rows as required.
'Version number' increments by whole number for major change to document and by decimal increment for minor changes.
'Description of change' for new documents should state 'New SOP/WI/Policy' as relevant.
'Authors' to be actual names not just Branch or Section.

From: IRIS
To: s22
Subject: FW: Formal Request under the Therapeutic Goods Act 1989 (Cth) — Failure to Act on Evidence of False-Negative Discordant Results — s11C
Date: Tuesday, 13 January 2026 2:56:14 PM
Attachments: RE Attention to managers LEGAL - NEW COMPLAINT FULL REVIEW NEEDED with ... (161 KB).msg

Hi s22,

I don't believe any action is required given legals responded on behalf of the TGA previously (email attached). I am still sharing with you to check in case any acknowledgement or response is required.

Regards,

s22

From: s11C
Sent: Wednesday, 24 December 2025 8:28 AM
To: IRIS <IRIS@health.gov.au>; Recalls <Recalls@health.gov.au>; regulatory.legal@health.gov.au
Subject: Re: Formal Request under the Therapeutic Goods Act 1989 (Cth) — Failure to Act on Evidence of False-Negative Discordant Results — s11C

Subject: Follow-up: Continuing Inaction on Formal Request dated 20 October 2025 — Failure to Decide under the Therapeutic Goods Act 1989 (Cth)

To:
IRIS@health.gov.au
recalls@health.gov.au
regulatory.legal@health.gov.au

From:
s11C

Date: 24.12.2025

Dear Sir / Madam,

I refer to my **Formal Request dated 20 October 2025** addressed to the Therapeutic Goods Administration, invoking the powers and obligations of the Secretary under the **Therapeutic Goods Act 1989 (Cth)** in relation to:

s11C

That correspondence set out **documented evidence of false-negative and discordant results causing patient injury**, supported by TGA Device Incident Reports (including s11C), expert evidence from s11C and peer-reviewed validation data. The letter made **specific, numbered regulatory requests** including the creation of additional DIRs, manufacturer clarification, enforcement assessment, and public-safety notification.

As at the date of this letter:

- I have **not received any written acknowledgment addressing the substance** of the requests;
- No decision, interim decision, or reasons for decision have been provided; and
- No timeframe has been communicated for regulatory assessment or risk evaluation.

I acknowledge that I was s11C for serious medical treatment, which temporarily limited my ability to pursue correspondence. That circumstance does not, however, affect the TGA's obligation to act within a **reasonable time** once a formal request engaging statutory powers has been made.

Request for Formal Position

Accordingly, I now formally request that the TGA **provide a written response within 14 days** of the date of this letter, stating clearly:

1. Whether the TGA has **decided** to act or not act on the requests made on 20 October 2025;
2. If a decision has been made, the **reasons for decision**, including any risk assessment relied upon; or
3. If no decision has yet been made, the **statutory basis for the delay** and a concrete timeframe for determination.

For the avoidance of doubt, continued silence or non-substantive correspondence will be treated as a **failure to make a decision** or a **deemed refusal**, enlivening rights of judicial review under the **Administrative Decisions (Judicial Review) Act 1977 (Cth)** and associated relief in the **Federal Circuit and Family Court of Australia (Division 2)**.

This correspondence is sent **without prejudice** to any current or future proceedings and is intended to afford the TGA a final opportunity to respond **lawfully and transparently** before court action is commenced.

I respectfully request that all further correspondence be in writing.

Yours faithfully,

s11C
Affected patient and complainant

On 20 Oct 2025, at 10:48 am, s11C > wrote:

s11C

Date: 20 October 2025

To:
The Director
Devices Post-Market Monitoring Section
Therapeutic Goods Administration
Department of Health, Disability and Ageing
PO Box 100 Woden ACT 2606 Australia
✉ IRIS@health.gov.au
CC: recalls@health.gov.au | regulatory.legal@health.gov.au

Subject:

Formal Request under the Therapeutic Goods Act 1989 (Cth) — Failure to Act on Evidence of False-Negative Discordant Results — s11C

Dear Sir / Madam,

I write to formally invoke the powers and obligations of the **Therapeutic Goods Administration (TGA)** under **Part 4-6** (*Cancellations and Suspensions*) and **Part 4-9** (*Public Notification and Recalls*) of the *Therapeutic Goods Act 1989 (Cth)*, concerning a series of **In Vitro Diagnostic (IVD) devices** proven to have generated **false-negative and discordant results** for *Borrelia burgdorferi sensu lato* infection.

The TGA's own **Device Incident Report** s11C for the s11C confirms that multiple false-negative results were reported, yet **no further investigation**

occurred, and the file was closed pending "monitoring"

Appendix 23 s11C recorded a *false-negative result questioning validation performed*, and the patient outcome as *injury*.

It is submitted that, once such evidence of harm exists, the duty to act falls squarely on the **TGA** and the **sponsors** of the IVDs under the *essential-principle obligations* (Schedule 1, Therapeutic Goods (Medical Devices) Regulations 2002*), not on the **RCPA** or professional colleges.

New Evidence Requiring Immediate Regulatory Action

Recent evidence from s11C confirms:

s11C

This expert statement demonstrates that the s11C lacks **VlsE B. garinii** antigens, producing false-negative results that other assays detect. In at least **six confirmed cases**, including my own, this deficiency directly led to **clinical injury and delayed diagnosis of neurological Lyme disease**.

Furthermore, comparative research (*Best et al., 2017*) validated the s11C raising potential breaches of **s 18 Australian Consumer Law (misleading or deceptive conduct)**.

Formal Requests under the Therapeutic Goods Act 1989 (Cth)

1. **Regulatory Investigation and DIR Generation**
    - That the TGA immediately **creates separate DIRs** for each identified false-negative discordant result produced by the s11C
2. **Manufacturer Clarification and Scientific Verification**

- That the TGA formally request from s11C [redacted] full disclosure of:
  • inclusion/exclusion of *B. garinii VlsE* antigens in validation/calibration;
  • the interpretive criteria used to define positivity thresholds;
  • any post-market verification or re-validation addressing antigenic deficiencies; and
  • s11C [redacted]

3. **Regulatory Enforcement Action**

   - That the TGA assess whether the sponsors s11C [redacted] and others) have breached essential-principle obligations under **s 41ML** and **s 41MN**, and whether a recall or public-safety notification should be initiated under **s 41KA**.

4. **Public Notification and Patient Safety**

   - Given the evidence of harm and the potential cohort of over 1 400 patients tested with these IVDs, that the TGA issue an official safety alert and direct the sponsors to notify all affected clinicians and patients.

Legal Basis for Reviewability

Any decision by the TGA **not to act, or to decline recall/public notification**, constitutes a **reviewable "initial decision"** under **s 60(1)–(2)** of the *Therapeutic Goods Act 1989 (Cth)*, and is therefore subject to **internal reconsideration and Administrative Appeals Tribunal (AAT)** merits review.

Summary

The evidence now available clearly establishes:

- Confirmed false-negative and discordant results causing documented injury;
- A demonstrable device-design flaw (absence of *B. garinii VlsE* antigen and over-stringent interpretive criteria); and
- Regulatory contradiction between the TGA's own device-cancellation s11C [redacted] under s 41GL(d)) and its inaction on related s11C [redacted] devices.

Under the TGA's *Procedure for Recalls, Product Alerts and Product*

Corrections (2025), these facts trigger mandatory risk assessment and potential recall action.

Please acknowledge receipt of this letter and confirm whether the TGA intends to open a new investigation or issue a recall notification. Failure to act will necessitate a formal application for review under s 60 of the Act and subsequent AAT proceedings.

Yours faithfully,
s11C
Lead Complainant and Affected Patient

<Appendix 23
s11C _Reporter_Complete_Letter_2024_04_08.pdf>

<Appendix 22 - ICPMR Lyme serology testing data 1.pdf>

<Annexure C TGA DIRs.docx>

<TGA formal DIR requests .docx>

s11C

<final EuroLineScan_v2.pdf>

<Appendix 20 - s11C (1) 2.pdf>

<s11C +Lyme+Test_sc.xlsx>

From: Regulatory Decision Review
To: s22
Cc: s22 ; NOJA, Marcelle; s22 ; s22 ; s22 ; s22 ; s22 s22 ; Regulatory Decision Review
Subject: RE: Attention to managers, LEGAL - NEW COMPLAINT FULL REVIEW NEEDED with TOP MANAGEMENT - 10 000 patients involved -class action CCEMS:05720001885 - can not be dismissed - a reply [SEC=OFFICIAL]
Date: Friday, 24 October 2025 5:43:52 PM
Attachments: image001.png
image002.png
image004.png

OFFICIAL

Dear s22,

Thanks for your support to prepare the draft email.

I have sent an email to s11C from decision review inbox.

Kind Regards

s22

Decision Review Team

Legislation Advice and FOI Branch | Regulatory Legal Services Division
Health Products Regulation Group
Australian Government Health, Disability and Ageing
T: s22 | E: decision.review@health.gov.au
Location: Level 2 (North) 27 Scherger Drive Fairbairn ACT 2609
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

OFFICIAL

From: s22 @health.gov.au>
Sent: Friday, 24 October 2025 4:41 PM
To: Regulatory Decision Review <Decision.Review@health.gov.au>
Cc: s22 @Health.gov.au>; NOJA, Marcelle <Marcelle.Noja@health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>;

s22 @health.gov.au>; s22 @health.gov.au>

Subject: RE: Attention to managers, LEGAL - NEW COMPLAINT FULL REVIEW NEEDED with TOP MANAGEMENT - 10 000 patients involved -class action CCEMS:05720001885 - can not be dismissed - a reply [SEC=OFFICIAL]

OFFICIAL

Hi s22

Many thanks for raising earlier this week.

Most grateful if you could please send the following response to s11C, from the decision review email address:

Dear s11C

Clarification of cancellation basis

In relation to your email below and the request for clarification in relation to the basis for the cancellation of s11C as set out in our email to you of 26 August 2025, entry s11C was cancelled pursuant to paragraph 41GL(d) of the *Therapeutic Goods Act 1989*.

Paragraph 41GL(d) of the Act enables the Secretary to cancel the entry of a kind of medical device from the Register if the person [in relation to whom the kind of device is included in the Register] requests in writing the cancellation of the entry of the kind of device from the Register.

This is consistent with the advice provided to you by s22 on 11 July 2023.

Request for statement of reasons

We also note your email of 20 October 2025 requesting, under section 13 of the *Administrative Decisions (Judicial Review) Act 1977* (the ADJR Act), a statement of reasons in relation to the following (excerpted from your email of 20 October 2025):

- The **decision not to issue a recall or product-safety notification** following the confirmed cancellation of s11C under s 41GL(d);
- The **decision or omission not to open a regulatory investigation** into the s11C, notwithstanding the device-incident data establishing multiple false-negative and discordant results; and

- The **closure of the above DIRs without enforcement action**, which, in substance, determines the ongoing regulatory status of these Class II IVDs and directly affects the health and legal rights of affected patients.

The first purported decision you have referred to is a delegate not requiring a recall or the issue of a product safety notification with respect to the devices. The provision you have referred to, section 13 of the ADJR Act, only applies to decisions that have been made. No decision to exercise a recall power has been made, and as a result the Secretary is not required to provide a statement of reasons for the first purported decision under section 13 of the ADJR Act.

The second and third purported decisions you have referred to are not decisions made under any provision of the TG Act. They are internal deliberative processes of the Department that do not involve a decision under an enactment. They are therefore not a decision to which this Act applies for the purposes of section 13 of the ADJR Act, and as that term is defined in subsection 3(1) of the ADJR Act. The Secretary is therefore not required to provide any statement of reasons with respect to the second and third purported decisions.

Summary

We hope the above is of assistance.

As we have endeavoured to explain that the reconsideration of initial decisions process under the *Therapeutic Goods Act 1989*, and now the statement of reasons process under the ADJR Act, do not apply to the matters you have raised, we do not propose to engage in further correspondence with you on these matters.

Regards

s22

s22
Principal Lawyer, Special Adviser
Legislation, Advice and FOI Branch
Regulatory Legal Services Division

Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing
T: s11C M: s11C | E: s11C @health.gov.au
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

OFFICIAL

From: Regulatory Decision Review <Decision.Review@health.gov.au>
Sent: Tuesday, 21 October 2025 10:25 AM
To: s22 @health.gov.au>
Cc: Regulatory Decision Review <Decision.Review@health.gov.au>; s22 @Health.gov.au>
Subject: FW: Attention to managers, LEGAL - NEW COMPLAINT FULL REVIEW NEEDED with TOP MANAGEMENT - 10 000 patients involved -class action CCEMS:05720001885 - can not be dismissed - a reply [SEC=OFFICIAL]

OFFICIAL

Dear s22,

Decision review team has received below email including attached file from s11C s11C as a response to our email sent to him on 26 August 2025.

s11C has sent another email attached above where he requested statement of reasons and **c**larification of reviewable decision.

We would be grateful for your comments regarding his request and approach to respond back to s11C .

Kind Regards

s22

Decision Review Team

Legislation Advice and FOI Branch | Regulatory Legal Services Division
Health Products Regulation Group
Australian Government Health, Disability and Ageing
T: s22 | E: decision.review@health.gov.au
Location: Level 2 (North) 27 Scherger Drive Fairbairn ACT 2609
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

OFFICIAL

From: s11C

Sent: Thursday, 16 October 2025 4:09 PM

To: Regulatory Decision Review <Decision.Review@health.gov.au>

Subject: Re: Attention to managers, LEGAL - NEW COMPLAINT FULL REVIEW NEEDED with TOP MANAGEMENT - 10 000 patients involved -class action CCEMS:05720001885 - can not be dismissed - a reply [SEC=OFFICIAL]

OFFICIAL

Subject: Re: Reconsideration of the decision to cancel s11C s11C

Dear s22 ,

Thank you for your detailed clarification and for confirming that the decision to cancel s11C was made **by a delegate of the Secretary pursuant to paragraph 41GL(d) of the *Therapeutic Goods Act 1989 (Cth)***.

This confirmation is extremely helpful for my ongoing investigation into the reliability and regulatory compliance of the s11C in-vitro diagnostic devices used for Lyme-disease testing. The formal basis of cancellation under section 41GL(d)—failure to comply with essential-principle obligations—provides important context for understanding the extent of the device's performance and validation deficiencies.

However, I am concerned by an earlier statement from s22 , Medical Devices Investigator, who advised me by email on **11 July 2023** that "s11C was cancelled by the sponsor with the effective date of 29 June 2022." That advice directly conflicts with your clarification that the **decision was made by a delegate of the Secretary under paragraph 41GL(d)**. The discrepancy raises serious questions as to how this information was represented within the Department and to affected parties.

Given the gravity of this inconsistency—and the potential implications for patient safety, regulatory transparency, and the integrity of Commonwealth decision-making—I respectfully request that the Department note this matter for internal review or investigation under its established integrity processes. I would also appreciate advice as to whether a **public statement of reasons or summary of the 2022 cancellation decision** is available for citation in ongoing proceedings.

I again thank the Decision Review Team for its assistance and clarification, which have been invaluable to ensuring accurate understanding of the regulatory record.

Kind regards,

s11C

OFFICIAL

On 26 Aug 2025, at 4:14 pm, Regulatory Decision Review <Decision.Review@health.gov.au> wrote:

Dear s11C

1. We write in reply to your e-mail below.

2000671 - Discontinue (Provider) (signed by s11C).pdf

2. Regarding the document 2000671 - Discontinue (Provider) (signed by s11C).pdf, it appears to be a document held by s11C . The TGA is a part of the Commonwealth Department of Health, Disability and Ageing. We do not have access to the document, are unaware of its contents, and so are unable to comment on it.

Reconsideration of the decision to cancel s11C

3. You correctly note that s11C was cancelled effective 29 June 2022. The decision to cancel was made by a delegate of the Secretary pursuant to paragraph 41GL(d) of the *Therapeutic Goods Act 1989* (Cth) (**TG Act**).
4. Subsection 60(2) of the TG Act relevantly provides that Subject to this section, a person whose interests are affected by an initial decision may, by notice in writing given to the Minister within 90 days after the decision first coming to the person's notice request the Minister to reconsider the decision.
5. As we understand it, you are not a person whose interests are affected by an initial decision, as that concept is legally understood.
6. Furthermore:
    a. the decision to cancel first came to your notice on (at the latest) 11 July 2023 when you received the e-mail from the TGA;
    b. the TG Act does not provide for the extension of the 90-day period; and
    c. thus, even if you were a person whose interests were affected by an initial decision, the 90-day period for requesting the Minister to reconsider the decision expired in October 2023, nearly 2 years ago.

Reconsideration of decisions regarding your device incident reports

and post market safety concerns regarding the s11C assay

7. None of the various decisions involved in dealing with your device incident reports and post market safety concerns regarding the s11C assay is an initial decision for the purposes of subsection 60(2) of the TG Act; see the definition of ***initial decision*** in subsection 60(1) of the TG Act. Section 60 of the TG Act only provides for review of decisions under the TG Act that are initial decisions as defined in subsection 60(1). It does not provide a general avenue of review for every decision taken within the TGA.

Future steps

8. We hope the above has explained why there is no basis for the application of section 60 in connection with the matters you have raised, and thank you for writing.

Kind Regards

s22

Decision Review Team

<image001.png>

Legislation Advice and FOI Branch | Regulatory Legal Services Division

Health Products Regulation Group
Australian Government Health, Disability and Ageing
T: s22 | E: decision.review@health.gov.au
Location: Level 2 (North) 27 Scherger Drive Fairbairn ACT 2609

PO Box 100, Woden ACT 2606, Australia

<image002.png> <image003.gif> <image004.png>

The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s11C
Sent: Tuesday, August 19, 2025 1:20 PM
To: Regulatory Decision Review <Decision.Review@health.gov.au>
Cc: IRIS <IRIS@health.gov.au>; Devices <devices@tga.gov.au>
Subject: Re: Attention to managers, LEGAL - NEW COMPLAINT FULL REVIEW NEEDED with TOP MANAGEMENT - 10 000 patients involved -class action CCEMS:05720001885 [SEC=OFFICIAL] - can not be dismissed - a reply

To: Decision.Review@health.gov.au
Cc: IRIS@health.gov.au; devices@tga.gov.au
Subject: s11C [redacted]
[redacted]
[redacted]
[

<Decision.Review@health.gov.au> wrote:

Dear s11C ,

Many thanks for your correspondence, and raising the concerns noted.

It does not appear that the concerns noted involve a decision of a kind covered by the definition of an initial decision in subsection 60(1) of the Therapeutic Goods Act 1989, for which internal merits review may be requested under section 60. As such, it would not be possible to purport to progress this matter as a request for reconsideration.

The TGA continues to monitor the safety and performance of medical devices in Australia, including to ensure that approved devices meet all the requirements of their approval. The TGA takes a risk-based approach to post-market monitoring, including in relation to adverse events.

Kind Regards

s22

Decision Review Team

<image001.png>

Legislation Advice and FOI Branch | Regulatory Legal Services Division

Health Products Regulation Group
Australian Government Health, Disability and Ageing
T: s22 | E: decision.review@health.gov.au
Location: Level 2 (North) 27 Scherger Drive Fairbairn ACT 2609

PO Box 100, Woden ACT 2606, Australia

<image002.png>

<image003.gif>

<image004.png>

The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: [redacted]
Sent: Tuesday, August 12, 2025 4:07 PM
To: Regulatory Decision Review <Decision.Review@health.gov.au>
Subject: Fwd: Attention to managers, LEGAL - NEW COMPLAINT FULL REVIEW NEEDED with TOP MANAGEMENT - 10 000 patients involved - class action CCEMS:05720001885 [SEC=OFFICIAL]

To: [Minister's reconsideration email / Departmental inbox for s 60 requests]
Cc: IRIS@health.gov.au; devices@tga.gov.au
Subject: s11C [redacted] **Request for Reconsideration Under Section 60 of the Therapeutic Goods Act 1989**

Dear Minister,

I request **reconsideration under section 60 of the Therapeutic Goods Act 1989** of the Therapeutic Goods Administration's position communicated in correspondence dated **11 July 2025** (Devices Post-Market Monitoring, IRIS), which stated there was "no decision to review under section 60" in relation to my device incident report(s) and declined further action. This request is made **within 90 calendar days** of that correspondence first coming to my notice.

Decisions identified

For the purposes of s 60, I identify the following as the **initial decision(s)** (or, alternatively, decisions to take no further action) to be reconsidered:

1. The TGA's **decision not to take regulatory action or open/post-market review** of the s11C [redacted] and related IVDs used in NSW, as communicated in TGA IRIS correspondence; and
2. The TGA's **refusal to treat my request as a reviewable decision** and to notify me of merits review rights, instead asserting there was "no decision to review under section 60."

Reasons for reconsideration

I respectfully submit the above should be set aside and substituted for the following reasons:

1. **Error in characterisation**
   The IRIS closure/"no further action" position constitutes an **initial decision** (or a decision refusing to make a decision) affecting my interests. Treating it as non-reviewable is an **error of law**.
2. **Failure to consider relevant scientific information**
   Evidence including Best et al. (2017) and my attached test dossier shows materially **low sensitivity** and **antigenic gaps** for the IVDs at issue

(e.g., omission of non-U.S. Borrelia antigens), inconsistent with the **Essential Principles** and acceptable clinical performance for Class II IVDs.

3. **Unreasonableness / public health risk**
   The decision not to investigate or review, despite credible evidence of **false negatives and diagnostic harm**, is **Wednesbury-unreasonable** and contrary to the protective objects of the Act.
4. **Procedural unfairness**
   I was not notified of **review options** in the correspondence. In the alternative, if the Department maintains there was no "initial decision", I ask the Minister to **treat this as a request to make a decision** and to notify me of review rights.

Orders/outcomes sought

I ask that the Minister (or delegate) on reconsideration:

- **Set aside** the "no further action / no review" position and **substitute** a decision to:
  a) Initiate a **post-market review/investigation** of the s11C [redacted] and related assays used by NSW public providers;
  b) Require the **sponsor(s)** to produce validation data, CAPA, PMS findings, and risk assessments addressing **sensitivity** and **antigen coverage** in Australian cohorts;
  c) Consider **regulatory action** (conditions, suspension, or cancellation) if performance is inadequate; and
  d) Provide me with a **statement of reasons** and notification of any **further review rights**.

Contact for correspondence

Please send all correspondence regarding this s 60 request to:s11C [redacted] (preferred) and copy **[your phone number]** for urgent contact.

Dated and signed statement (s 60 requestor)

I, s11C [redacted], hereby **request reconsideration under section 60 of the Therapeutic Goods Act 1989** of the TGA decisions identified above. I am directly affected as a patient whose diagnosis and care were impacted by the IVDs in question. The components of the decision to be reconsidered are: (i) the decision not to investigate or take regulatory action regarding the identified IVDs; and (ii) the refusal to recognise a reviewable initial decision and to notify review rights. My **reasons** are set out in this email and supported by the attached documents.

Signed: /s/ s11C
Date: 12 August 2025
Email: s11C
Address: [postal address]

Attachments (indexed)

1. **TGA IRIS email dated 11 July 2025** (Devices Post-Market Monitoring) ❖ ❖no decision to review❖ wording.
2. **Earlier IRIS correspondence** closing DIR(s) / stating ❖no further investigation planned.❖
3. **Best et al., 2017 (Pathology/RCPA)** ❖ performance of serological assays (low sensitivity; antigenic scope issues).
4. **Personal test dossier**: consolidated results demonstrating false-negative/discordant outputs across relevant assays (with indices and dates).
5. Any **clinical letters** or expert statements corroborating diagnostic impact and harm.

Thank you for your prompt attention to this request. Please confirm receipt.

Yours faithfully,
s11C

Begin forwarded message:

From: IRIS <IRIS@health.gov.au>
Subject: RE: Attention to managers, LEGAL - NEW COMPLAINT FULL REVIEW NEEDED with TOP MANAGEMENT - 10 000 patients involved - class action CCEMS:05720001885 [SEC=OFFICIAL]
Date: 11 July 2025 at 8:51:21 am GMT+8
To: s11C

Dear s11C ,

Thank you for your further enquiry to the Therapeutic Goods Administration (TGA).

The TGA did not undertake any regulatory decision

against the device incident report number s11C. Consequently, there is no decision to review under section 60 of the Therapeutic Goods Act 1989.

We have already provided you with all the publicly available information on this matter. Therefore, it is unlikely that the TGA will be able to respond to any further correspondence from you regarding these same issues.

Thank you for your understanding.

Regards

s22
Assistant Director

<image005.png>

Devices Post Market Monitoring Section | Medical Devices Surveillance Branch
Australian Government, Department of Health, Disability and Ageing
Therapeutic Goods Administration

Melbourne Office

Phone: s22

PO Box 100, Woden ACT 2606
www.tga.gov.au

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

---------- Original Message ----------

-

Dear Therapeutic Goods Administration,

I am writing to formally request an **internal review under section 60 of the Therapeutic Goods Act 1989** in relation to the TGA's failure to investigate or take regulatory action following my complaint regarding a potentially defective in vitro diagnostic (IVD) medical device specifically, a Lyme disease diagnostic product sponsored by s11C and/or associated entities.

I submitted a complaint to the TGA's IRIS (Incident Reporting and Investigation Scheme) concerning serious issues with the performance and validation of this diagnostic device. To date, I have not received any substantive response, nor has there been any indication that the matter has been appropriately assessed or actioned.

I respectfully assert that this **lack of action constitutes a decision not to act**, and I now request an internal review on the following grounds:

1. **Error of Law** – The failure to respond or initiate regulatory steps constitutes a failure to comply with the TGA's statutory duty to monitor and ensure the safety and efficacy of devices listed on the ARTG.
2. **Failure to Consider Relevant Information** – The TGA has not considered critical evidence submitted regarding analytical limitations, false negative risks, and the device's intended use limited only to *Borrelia afzelii* antigens posing a direct risk to Australian patients.
3. **Procedural Unfairness** – The prolonged delay in response has denied the complainant procedural fairness and the right to have legitimate safety concerns investigated in a timely manner.
4. **Public Health Risk** – The ongoing distribution of this IVD product may be exposing thousands of patients to misdiagnosis and consequent harm, particularly in cases of late-disseminated or neuroborreliosis infections.

Please treat this as a **formal request for internal review** of the inaction/decision under **section 60 of the Therapeutic Goods Act 1989**. I would appreciate written confirmation of receipt and advice regarding the timeframe for conducting the review.

I am attaching:

- My original complaint submission;
- Supporting documentation regarding the device's deficiencies;
- A summary of evidence indicating harm, non-validation, and

device limitations.

Should you require any further information or clarification, I am happy to provide it promptly.

Thank you for your attention to this matter.

---------- Forwarded message ---------
From: s11C [redacted]
Date: Sat, 11 May 2024 at 21:32
Subject: Attention to managers, LEGAL - NEW COMPLAINT FULL REVIEW NEEDED with TOP MANAGEMENT - 10 000 patients involved -class action
To: IRIS <IRIS@health.gov.au>

Dear Sir or Madam,

According to the current letter of complaint and below substantiated materials s11C [redacted] *insists that for each discordant result a separate DIR report is generated and an official investigation commences on a properly and timely manner to avoid further injuries.*

All DIRs needs to be fully *reviewed* and put in the system accordingly

From: Regulatory Decision Review
To: s22 s
Cc: s22 ; Regulatory Decision Review
Subject: RE: Formal Request under the Therapeutic Goods Act 1989 (Cth) — Failure to Act on Evidence of False-Negative Discordant Results — s11C
Date: Friday, 23 January 2026 5:30:19 PM
Attachments: image001.png
image003.png
image005.png
image006.png

OFFICIAL:Sensitive//Legal-Privilege

Dear s22 ,

I am writing to confirm that I have sent the email to s11C

Kind Regards
s22
Decision Review Team

Legislation Advice and FOI Branch | Regulatory Legal Services Division
Health Products Regulation Group
Australian Government Health, Disability and Ageing
T: s11C | E: decision.review@health.gov.au
Location: Level 2 (North) 27 Scherger Drive Fairbairn ACT 2609
PO Box 100, Woden ACT 2606, Australia

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OFFICIAL:Sensitive//Legal-Privilege

From: s22 @Health.gov.au>
Sent: Friday, 23 January 2026 3:50 PM
To: Regulatory Decision Review <Decision.Review@health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: Formal Request under the Therapeutic Goods Act 1989 (Cth) — Failure to Act on Evidence of False-Negative Discordant Results — s11C .

OFFICIAL:Sensitive//Legal-Privilege

Hi s22 ,

We would be grateful if you could send the following response to s11C below email from the Regulatory Decision Review inbox attaching the **attached** email:

> *Dear* s11C
>
> *We responded to your request on 24 October 2025. A copy of the response is **attached**. Your most recent email argues that there has been a failure to make a decision which is capable of review under the ADJR Act. Section 7 of the ADJR Act only allows such an application where the decision-maker 'has a duty' to make the relevant decision. The TG Act does not impose a duty on the Secretary to make a decision or purported decision of a kind referred to in your email of 20 October 2025. There is, further, nothing in the ADJR Act or the TG Act that provides for any kind of deemed refusal in these circumstances. You are therefore not entitled to any relief under the ADJR Act of the kind referred to in your email below.*
> *If you are genuinely considering commencing court proceedings, you should be aware that can have serious consequences. Those include that you are likely to be liable for the Secretary's costs of the proceeding if you are unsuccessful (which, for the reasons outlined in this and previous correspondence, would be the case). You should seriously consider obtaining legal advice before taking such a step.*
> *For the reasons set out in our email of 24 October 2025, we will not be engaging in any further correspondence on this matter.*
>
> *Yours sincerely,*

Thanks,

s22
Senior Lawyer
Dispute Resolution and Litigation | Regulatory Legal Services Division
Health Products Regulation Group/Therapeutic Goods Administration (TGA)
Australian Government Department of Health, Disability and Ageing
T: s11C | E: s11C
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OFFICIAL:Sensitive//Legal-Privilege

From: s11C
Sent: Wednesday, 24 December 2025 8:28 AM
To: IRIS <IRIS@health.gov.au>; Recalls <Recalls@health.gov.au>; regulatory.legal@health.gov.au
Subject: Re: Formal Request under the Therapeutic Goods Act 1989 (Cth) — Failure to Act

on Evidence of False-Negative Discordant Results — s11C [redacted]

Subject: Follow-up: Continuing Inaction on Formal Request dated 20 October 2025 — Failure to Decide under the Therapeutic Goods Act 1989 (Cth)

To:
IRIS@health.gov.au
recalls@health.gov.au
regulatory.legal@health.gov.au

From:
s11C [redacted]

Date: 24.12.2025

Dear Sir / Madam,

I refer to my **Formal Request dated 20 October 2025** addressed to the Therapeutic Goods Administration, invoking the powers and obligations of the Secretary under the **Therapeutic Goods Act 1989 (Cth)** in relation to:

s11C [redacted]

That correspondence set out **documented evidence of false-negative and discordant results causing patient injury**, supported by TGA Device Incident Reports (including s11C [redacted] expert evidence from s11C [redacted], and peer-reviewed validation data. The letter made **specific, numbered regulatory requests** including the creation of additional DIRs, manufacturer clarification, enforcement assessment, and public-safety notification.

As at the date of this letter:

- I have **not received any written acknowledgment addressing the substance** of the requests;
- No decision, interim decision, or reasons for decision have been provided; and
- No timeframe has been communicated for regulatory assessment or risk evaluation.

I acknowledge that I was **admitted to hospital from 4 November 2025 to 3 December 2025** for serious medical treatment, which temporarily limited my ability to pursue correspondence. That circumstance does not, however, affect the TGA's obligation

to act within a **reasonable time** once a formal request engaging statutory powers has been made.

Request for Formal Position

Accordingly, I now formally request that the TGA **provide a written response within 14 days** of the date of this letter, stating clearly:

1. Whether the TGA has **decided** to act or not act on the requests made on 20 October 2025;
2. If a decision has been made, the **reasons for decision**, including any risk assessment relied upon; or
3. If no decision has yet been made, the **statutory basis for the delay** and a concrete timeframe for determination.

For the avoidance of doubt, continued silence or non-substantive correspondence will be treated as a **failure to make a decision** or a **deemed refusal**, enlivening rights of judicial review under the **Administrative Decisions (Judicial Review) Act 1977 (Cth)** and associated relief in the **Federal Circuit and Family Court of Australia (Division 2)**.

This correspondence is sent **without prejudice** to any current or future proceedings and is intended to afford the TGA a final opportunity to respond **lawfully and transparently** before court action is commenced.

I respectfully request that all further correspondence be in writing.

Yours faithfully,

s11C
Affected patient and complainant

On 20 Oct 2025, at 10:48 am, s11C > wrote:

s11C

Date: 20 October 2025

To:
The Director
Devices Post-Market Monitoring Section
Therapeutic Goods Administration

Department of Health, Disability and Ageing
PO Box 100 Woden ACT 2606 Australia
✉ IRIS@health.gov.au
CC: recalls@health.gov.au | regulatory.legal@health.gov.au

Subject:

Formal Request under the Therapeutic Goods Act 1989 (Cth) — Failure to Act on Evidence of False-Negative Discordant Results — s11C [redacted]

Dear Sir / Madam,

I write to formally invoke the powers and obligations of the **Therapeutic Goods Administration (TGA)** under **Part 4-6** (*Cancellations and Suspensions*) and **Part 4-9** (*Public Notification and Recalls*) of the *Therapeutic Goods Act 1989 (Cth)*, concerning a series of **In Vitro Diagnostic (IVD) devices** proven to have generated **false-negative and discordant results** for *Borrelia burgdorferi sensu lato* infection.

The TGA's own **Device Incident Report** ([redacted]) for the [redacted]) confirms that multiple false-negative results were reported, yet **no further investigation occurred**, and the file was closed pending "monitoring"

Appendix 23 [redacted]. Similarly, s11C [redacted] recorded a *false-negative result questioning validation performed*, and the patient outcome as *injury*.

It is submitted that, once such evidence of harm exists, the duty to act falls squarely on the **TGA** and the **sponsors** of the IVDs under the *essential-principle obligations* (Schedule 1, Therapeutic Goods (Medical Devices) Regulations 2002*), not on the **RCPA** or professional colleges.

New Evidence Requiring Immediate Regulatory Action

Recent evidence from s11C [redacted] (author of file [redacted]*+Lyme+Test_sc.xlsx*) confirms:

s11C [redacted]

s11C

This expert statement demonstrates that the s11C lacks **VlsE B. garinii** antigens, producing false-negative results that other assays detect. In at least **six confirmed cases**, including my own, this deficiency directly led to **clinical injury and delayed diagnosis of neurological Lyme disease**.

Furthermore, comparative research (*Best et al., 2017*) validated the s11C , raising potential breaches of **s 18 Australian Consumer Law (misleading or deceptive conduct)**.

Formal Requests under the Therapeutic Goods Act 1989 (Cth)

1. **Regulatory Investigation and DIR Generation**
    - That the TGA immediately **creates separate DIRs** for each identified false-negative discordant result produced by the s11C and related confirmatory IVDs s11C
2. **Manufacturer Clarification and Scientific Verification**
    - That the TGA formally request from s11C full disclosure of:
      • inclusion/exclusion of *B. garinii VlsE* antigens in validation/calibration;
      • the interpretive criteria used to define positivity thresholds;
      • any post-market verification or re-validation addressing antigenic deficiencies; and
      • s11C .
3. **Regulatory Enforcement Action**
    - That the TGA assess whether the sponsors (s11C , and others) have breached essential-principle obligations under **s 41ML** and **s 41MN**, and whether a recall or public-safety notification should be initiated under **s 41KA**.
4. **Public Notification and Patient Safety**

- Given the evidence of harm and the potential cohort of over 1 400 patients tested with these IVDs, that the TGA issue an official safety alert and direct the sponsors to notify all affected clinicians and patients.

Legal Basis for Reviewability

Any decision by the TGA **not to act, or to decline recall/public notification**, constitutes a **reviewable "initial decision"** under **s 60(1)–(2)** of the *Therapeutic Goods Act 1989 (Cth)*, and is therefore subject to **internal reconsideration and Administrative Appeals Tribunal (AAT)** merits review.

Summary

The evidence now available clearly establishes:

- Confirmed false-negative and discordant results causing documented injury;
- A demonstrable device-design flaw (absence of *B. garinii VlsE* antigen and over-stringent interpretive criteria); and
- Regulatory contradiction between the TGA's own device-cancellation (s11C under s 41GL(d)) and its inaction on related s11C devices.

Under the TGA's *Procedure for Recalls, Product Alerts and Product Corrections (2025)*, these facts trigger mandatory risk assessment and potential recall action.

Please acknowledge receipt of this letter and confirm whether the TGA intends to open a new investigation or issue a recall notification. Failure to act will necessitate a formal application for review under s 60 of the Act and subsequent AAT proceedings.

Yours faithfully,
s11C
Lead Complainant and Affected Patient

<Appendix 23
s11C _Reporter_Complete_Letter_2024_04_08.pdf>

<Appendix 22 - ICPMR Lyme serology testing data 1.pdf>

<Annexure C TGA DIRs.docx>

<TGA formal DIR requests .docx>

s11C [redacted]

<final EuroLineScan_v2.pdf>

<Appendix 20 - s11C [redacted] (1) 2.pdf>

<s11C [redacted]+Lyme+Test_sc.xlsx>

From: Regulatory Decision Review
To: s22
Cc: Regulatory Decision Review
Subject: FW: Attention to managers, LEGAL - NEW COMPLAINT FULL REVIEW NEEDED with TOP MANAGEMENT - 10 000 patients involved -class action CCEMS:05720001885 - can not be dismissed - a reply [SEC=OFFICIAL]
Date: Wednesday, 21 January 2026 10:58:52 AM
Attachments: image001.png
image002.png
image004.png

OFFICIAL

Hi s22 ,

Please see the below email that was sent to s11C from our end. The link of the container E26-38214 related to all communications.

Kind Regards

s22

Decision Review Team

Legislation Advice and FOI Branch | Regulatory Legal Services Division
Health Products Regulation Group
Australian Government Health, Disability and Ageing
T: s22 | E: decision.review@health.gov.au
Location: Level 2 (North) 27 Scherger Drive Fairbairn ACT 2609
PO Box 100, Woden ACT 2606, Australia

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OFFICIAL

From: Regulatory Decision Review <Decision.Review@health.gov.au>
Sent: Friday, 24 October 2025 5:40 PM
To: s11C
Cc: Regulatory Decision Review <Decision.Review@health.gov.au>
Subject: RE: Attention to managers, LEGAL - NEW COMPLAINT FULL REVIEW NEEDED with TOP MANAGEMENT - 10 000 patients involved -class action CCEMS:05720001885 - can not be dismissed - a reply [SEC=OFFICIAL]

Dear s11C

Clarification of cancellation basis

In relation to your email below and the request for clarification in relation to the basis for the cancellation of s11C on 29 June 2022 – as set out in our email to you of 26 August 2025, s11C was cancelled pursuant to paragraph 41GL(d) of the *Therapeutic Goods Act 1989*.

Paragraph 41GL(d) of the Act enables the Secretary to cancel the entry of a kind of medical device from the Register if "the person [in relation to whom the kind of device is included in the Register] requests in writing the cancellation of the entry of the kind of device from the Register".

This is consistent with the advice provided to you by s22 on 11 July 2023.

Request for statement of reasons

We also note your email of 20 October 2025 requesting, under section 13 of the *Administrative Decisions (Judicial Review) Act 1977* (the ADJR Act), a statement of reasons in relation to the following (excerpted from your email of 20 October 2025):

- The **decision not to issue a recall or product-safety notification** following the confirmed cancellation of s11C under s 41GL(d);
- The **decision or omission not to open a regulatory investigation** into the s11C, notwithstanding the device-incident data establishing multiple false-negative and discordant results; and
- The **closure of the above DIRs without enforcement action**, which, in substance, determines the ongoing regulatory status of these Class II IVDs and directly affects the health and legal rights of affected patients.

The first purported decision you have referred to is a delegate not requiring a recall or the issue of a product safety notification with respect to the devices. The provision you have referred to, section 13 of the ADJR Act, only applies to decisions that have been made. No decision to exercise a recall power has been made, and as a result the Secretary is not required to provide a statement of reasons for the first purported decision under section 13 of the ADJR Act.

The second and third purported decisions you have referred to are not decisions made under any provision of the TG Act. They are internal deliberative processes of the Department that do not involve a decision under an enactment. They are

therefore not a 'decision to which this Act applies' for the purposes of section 13 of the ADJR Act, and as that term is defined in subsection 3(1) of the ADJR Act. The Secretary is therefore not required to provide any statement of reasons with respect to the second and third purported decisions.

Summary

We hope the above is of assistance.

As we have endeavoured to explain that the reconsideration of initial decisions process under the *Therapeutic Goods Act 1989*, and now the statement of reasons process under the ADJR Act, do not apply to the matters you have raised, we do not propose to engage in further correspondence with you on these matters.

Kind Regards

s22

Decision Review Team

Legislation Advice and FOI Branch | Regulatory Legal Services Division
Health Products Regulation Group
Australian Government Health, Disability and Ageing
T: s22 | E: decision.review@health.gov.au
Location: Level 2 (North) 27 Scherger Drive Fairbairn ACT 2609
PO Box 100, Woden ACT 2606, Australia

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From: s11C
Sent: Thursday, 16 October 2025 4:09 PM
To: Regulatory Decision Review <Decision.Review@health.gov.au>
Subject: Re: Attention to managers, LEGAL - NEW COMPLAINT FULL REVIEW NEEDED with TOP MANAGEMENT - 10 000 patients involved -class action CCEMS:05720001885 - can not be dismissed - a reply [SEC=OFFICIAL]

OFFICIAL

Subject: Re: Reconsideration of the decision to cancel s11C

Dear s11C,

Thank you for your detailed clarification and for confirming that the decision to cancel s11C was made **by a delegate of the Secretary pursuant to paragraph 41GL(d) of the *Therapeutic Goods Act 1989 (Cth)***.

This confirmation is extremely helpful for my ongoing investigation into the reliability and regulatory compliance of the s11C in-vitro diagnostic devices used for Lyme-disease testing. The formal basis of cancellation under section 41GL(d)—failure to comply with essential-principle obligations—provides important context for understanding the extent of the device's performance and validation deficiencies.

However, I am concerned by an earlier statement from s22, Medical Devices Investigator, who advised me by email on **11 July 2023** that 's11C was cancelled by the sponsor with the effective date of 29 June 2022." That advice directly conflicts with your clarification that the **decision was made by a delegate of the Secretary under paragraph 41GL(d)**. The discrepancy raises serious questions as to how this information was represented within the Department and to affected parties.

Given the gravity of this inconsistency—and the potential implications for patient safety, regulatory transparency, and the integrity of Commonwealth decision-making—I respectfully request that the Department note this matter for internal review or investigation under its established integrity processes. I would also appreciate advice as to whether a **public statement of reasons or summary of the 2022 cancellation decision** is available for citation in ongoing proceedings.

I again thank the Decision Review Team for its assistance and clarification, which have been invaluable to ensuring accurate understanding of the regulatory record.

Kind regards,
s11C

OFFICIAL

On 26 Aug 2025, at 4:14 pm, Regulatory Decision Review <Decision.Review@health.gov.au> wrote:

Dear s11C,

1. We write in reply to your e-mail below.

2000671 - Discontinue (Provider) (signed by s11C).pdf

2. Regarding the document '2000671 - Discontinue (Provider) (signed by s11C).pdf', it appears to be a document held by s11C The TGA is a part of the Commonwealth Department of Health, Disability and Ageing. We do not have access to the document, are unaware of its contents, and so are unable to comment on it.

Reconsideration of the decision to cancel s11C 544

3. You correctly note that s11C was cancelled effective 29 June 2022. The decision to cancel was made by a delegate of the Secretary pursuant to paragraph 41GL(d) of the *Therapeutic Goods Act 1989* (Cth) (**TG Act**).
4. Subsection 60(2) of the TG Act relevantly provides that 'Subject to this section, a person whose interests are affected by an initial decision may, by notice in writing given to the Minister … within 90 days after … the decision first coming to the person's notice … request the Minister to reconsider the decision.'
5. As we understand it, you are not 'a person whose interests are affected by an initial decision', as that concept is legally understood.
6. Furthermore:
    a. the decision to cancel first came to your notice on (at the latest) 11 July 2023 when you received the e-mail from the TGA;
    b. the TG Act does not provide for the extension of the 90-day period; and
    c. thus, even if you were a person whose interests were affected by an initial decision, the 90-day period for requesting the Minister to reconsider the decision expired in October 2023, nearly 2 years ago.

Reconsideration of decisions regarding your device incident reports and post market safety concerns regarding the s11C assay

7. None of the various decisions involved in dealing with your device incident reports and post market safety concerns regarding the s11C assay is an 'initial decision' for the purposes of subsection 60(2) of the TG Act; see the definition of ***initial decision*** in subsection 60(1) of the TG Act. Section 60 of the TG Act only provides for review of decisions under the TG Act that are initial

decisions as defined in subsection 60(1). It does not provide a general avenue of review for every decision taken within the TGA.

Future steps

8. We hope the above has explained why there is no basis for the application of section 60 in connection with the matters you have raised, and thank you for writing.

Kind Regards

s22

Decision Review Team

<image001.png>

Legislation Advice and FOI Branch | Regulatory Legal Services Division

Health Products Regulation Group
Australian Government Health, Disability and Ageing
T: s22 | E: decision.review@health.gov.au
Location: Level 2 (North) 27 Scherger Drive Fairbairn ACT 2609

PO Box 100, Woden ACT 2606, Australia

<image002.png> <image003.gif> <image004.png>

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From: s11C
Sent: Tuesday, August 19, 2025 1:20 PM
To: Regulatory Decision Review <Decision.Review@health.gov.au>
Cc: IRIS <IRIS@health.gov.au>; Devices <devices@tga.gov.au>
Subject: Re: Attention to managers, LEGAL - NEW COMPLAINT FULL REVIEW NEEDED with TOP MANAGEMENT - 10 000 patients involved -class action CCEMS:05720001885 [SEC=OFFICIAL] - can not be dismissed - a reply

To: Decision.Review@health.gov.au
Cc: IRIS@health.gov.au; devices@tga.gov.au
Subject: s11C — Request for reconsideration under s 60 TGA Act (reviewable actions evidenced)

Dear Decision Review Team,

Thank you for your email of 19 August 2025. I do not accept that there is “no initial decision” capable of reconsideration under s 60 of the *Therapeutic Goods Act 1989*.

I hold two contemporaneous documents showing that, at the relevant time, **regulatory actions were in fact taken** in relation to the s11C Lyme disease IVD:

1. **"2000671 – Discontinue (Provider) (signed by s11C).pdf"** — referenced as the attachment to "Document 90" within s11C records (internal email trail produced to me). This evidences the discontinuation of the provider's use of the device in 2020–2021.
2. **TGA confirmation that s11C was cancelled** (removed from the ARTG) **effective 29 June 2022**, as advised by your officer, s22

Taken together, these establish that **(a)** the device was discontinued by the provider, and **(b)** the entry was cancelled/removed from the ARTG. Those are **substantive regulatory outcomes**. At minimum, TGA's acceptance/recording of the ARTG cancellation and closure of my DIR(s) with "no further action" constitute **decisions affecting my interests**. The position that there is "no decision" is untenable in light of the evidence above.

Request:
Pursuant to s 60, I again request **reconsideration** of the TGA's actions/inaction in handling my device incident reports and post-market safety concerns regarding the s11C assay. If you maintain that the earlier "no further action" notifications and the ARTG cancellation outcome are not reviewable "initial decisions", please:

- Identify the **precise decision pathway and delegate action** by which s11C was removed (including the date, delegate, and instrument recorded); and
- Provide a **statement of reasons** explaining why that outcome and the DIR closure(s) do not constitute reviewable initial decisions under s 60, notwithstanding their clear regulatory effect.

Given the seriousness of the alleged diagnostic failures and patient harm, this matter cannot be dismissed as involving "no decision". Please treat this email and the attached materials as part of my formal request for reconsideration under s 60, and acknowledge receipt.

Kind regards,
s11C

Attachments:
A. Extract showing "Document 90" with attachment title: *2000671 – Discontinue (Provider) (signed by s11C).pdf*.
B. TGA email (s11C) confirming s11C **cancelled effective 29 June 2022**.

> On 19 Aug 2025, at 1:05 pm, Regulatory Decision Review <Decision.Review@health.gov.au> wrote:
>
> Dear s11C ,
>
> Many thanks for your correspondence, and raising the concerns noted.
>
> It does not appear that the concerns noted involve a decision of a kind

covered by the definition of an 'initial decision' in subsection 60(1) of the Therapeutic Goods Act 1989, for which internal merits review may be requested under section 60. As such, it would not be possible to purport to progress this matter as a request for reconsideration.

The TGA continues to monitor the safety and performance of medical devices in Australia, including to ensure that approved devices meet all the requirements of their approval. The TGA takes a risk-based approach to post-market monitoring, including in relation to adverse events.

Kind Regards

s22

Decision Review Team

<image001.png>

Legislation Advice and FOI Branch | Regulatory Legal Services Division

Health Products Regulation Group
Australian Government Health, Disability and Ageing
T: s22 | E: decision.review@health.gov.au
Location: Level 2 (North) 27 Scherger Drive Fairbairn ACT 2609

PO Box 100, Woden ACT 2606, Australia

<image002.png>

<image003.gif>

<image004.png>

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From: s11C
Sent: Tuesday, August 12, 2025 4:07 PM
To: Regulatory Decision Review <Decision.Review@health.gov.au>
Subject: Fwd: Attention to managers, LEGAL - NEW COMPLAINT FULL REVIEW NEEDED with TOP MANAGEMENT - 10 000 patients involved - class action CCEMS:05720001885 [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside

To: [Minister's reconsideration email / Departmental inbox for s 60 requests]
Cc: IRIS@health.gov.au; devices@tga.gov.au
Subject: s11C [redacted] **— Request for Reconsideration Under Section 60 of the Therapeutic Goods Act 1989**

Dear Minister,

I request **reconsideration under section 60 of the Therapeutic Goods Act 1989** of the Therapeutic Goods Administration's position communicated in correspondence dated **11 July 2025** (Devices Post-Market Monitoring, IRIS), which stated there was "no decision to review under section 60" in relation to my device incident report(s) and declined further action. This request is made **within 90 calendar days** of that correspondence first coming to my notice.

Decisions identified

For the purposes of s 60, I identify the following as the **initial decision(s)** (or, alternatively, decisions to take no further action) to be reconsidered:

1. The TGA's **decision not to take regulatory action or open/post-market review** of the s11C [redacted] and related IVDs used in NSW, as communicated in TGA IRIS correspondence; and
2. The TGA's **refusal to treat my request as a reviewable decision** and to notify me of merits review rights, instead asserting there was "no decision to review under section 60."

Reasons for reconsideration

I respectfully submit the above should be set aside and substituted for the following reasons:

1. **Error in characterisation**
   The IRIS closure/"no further action" position constitutes an **initial decision** (or a decision refusing to make a decision) affecting my interests. Treating it as non-reviewable is an **error of law**.
2. **Failure to consider relevant scientific information**
   Evidence including Best et al. (2017) and my attached test dossier shows materially **low sensitivity** and **antigenic gaps** for the IVDs at issue (e.g., omission of non-U.S. Borrelia antigens), inconsistent with the **Essential Principles** and acceptable clinical performance for Class II IVDs.
3. **Unreasonableness / public health risk**
   The decision not to investigate or review, despite credible evidence of **false negatives and diagnostic harm**, is **Wednesbury-unreasonable** and contrary to the protective objects of the Act.

4. **Procedural unfairness**

   I was not notified of **review options** in the correspondence. In the alternative, if the Department maintains there was no "initial decision", I ask the Minister to **treat this as a request to make a decision** and to notify me of review rights.

Orders/outcomes sought

I ask that the Minister (or delegate) on reconsideration:

- **Set aside** the "no further action / no review" position and **substitute** a decision to:

  a) Initiate a **post-market review/investigation** of the s11C [redacted] and related assays used by NSW public providers;

  b) Require the **sponsor(s)** to produce validation data, CAPA, PMS findings, and risk assessments addressing **sensitivity** and **antigen coverage** in Australian cohorts;

  c) Consider **regulatory action** (conditions, suspension, or cancellation) if performance is inadequate; and

  d) Provide me with a **statement of reasons** and notification of any **further review rights**.

Contact for correspondence

Please send all correspondence regarding this s 60 request to:s11C [redacted] (preferred) and copy **[your phone number]** for urgent contact.

Dated and signed statement (s 60 requestor)

I, s11C [redacted], hereby **request reconsideration under section 60 of the Therapeutic Goods Act 1989** of the TGA decisions identified above. I am directly affected as a patient whose diagnosis and care were impacted by the IVDs in question. The components of the decision to be reconsidered are: (i) the decision not to investigate or take regulatory action regarding the identified IVDs; and (ii) the refusal to recognise a reviewable initial decision and to notify review rights. My **reasons** are set out in this email and supported by the attached documents.

Signed: /s/ s11C [redacted]
Date: 12 August 2025
Email: s11C [redacted]
Address: [postal address]

Attachments (indexed)

1. **TGA IRIS email dated 11 July 2025** (Devices Post-Market Monitoring) — "no decision to review" wording.
2. **Earlier IRIS correspondence** closing DIR(s) / stating "no further investigation planned."
3. **Best et al., 2017 (Pathology/RCPA)** — performance of serological assays (low sensitivity; antigenic scope issues).
4. **Personal test dossier**: consolidated results demonstrating false-negative/discordant outputs across relevant assays (with indices and dates).
5. Any **clinical letters** or expert statements corroborating diagnostic impact and harm.

Thank you for your prompt attention to this request. Please confirm receipt.

Yours faithfully,
s11C

Begin forwarded message:

From: IRIS <IRIS@health.gov.au>
Subject: RE: Attention to managers, LEGAL - NEW COMPLAINT FULL REVIEW NEEDED with TOP MANAGEMENT - 10 000 patients involved - class action CCEMS:05720001885 [SEC=OFFICIAL]
Date: 11 July 2025 at 8:51:21 am GMT+8
To: s11C

Dear s11C

Thank you for your further enquiry to the Therapeutic Goods Administration (TGA).

The TGA did not undertake any regulatory decision against the device incident report number s11C. Consequently, there is no decision to review under section 60 of the Therapeutic Goods Act 1989.

We have already provided you with all the publicly available information on this matter. Therefore, it is unlikely that the TGA will be able to respond to any

further correspondence from you regarding these same issues.

Thank you for your understanding.

Regards

s22 [redacted]
Assistant Director

<image005.png>

Devices Post Market Monitoring Section | Medical Devices Surveillance Branch
Australian Government, Department of Health, Disability and Ageing
Therapeutic Goods Administration

Melbourne Office

Phone: s22 [redacted]

PO Box 100, Woden ACT 2606
www.tga.gov.au

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

---------- Original Message ----------

Dear Therapeutic Goods Administration,

I am writing to formally request an **internal review under section 60 of the Therapeutic Goods Act 1989** in relation to the TGA's failure to investigate or take regulatory action following my complaint regarding a potentially defective in vitro diagnostic (IVD) medical device—specifically, a Lyme disease diagnostic product

sponsored by s11C and/or associated entities.

I submitted a complaint to the TGA's IRIS (Incident Reporting and Investigation Scheme) concerning serious issues with the performance and validation of this diagnostic device. To date, I have not received any substantive response, nor has there been any indication that the matter has been appropriately assessed or actioned.

I respectfully assert that this **lack of action constitutes a decision not to act**, and I now request an internal review on the following grounds:

1. **Error of Law** – The failure to respond or initiate regulatory steps constitutes a failure to comply with the TGA's statutory duty to monitor and ensure the safety and efficacy of devices listed on the ARTG.
2. **Failure to Consider Relevant Information** – The TGA has not considered critical evidence submitted regarding analytical limitations, false negative risks, and the device's intended use limited only to *Borrelia afzelii* antigens—posing a direct risk to Australian patients.
3. **Procedural Unfairness** – The prolonged delay in response has denied the complainant procedural fairness and the right to have legitimate safety concerns investigated in a timely manner.
4. **Public Health Risk** – The ongoing distribution of this IVD product may be exposing thousands of patients to misdiagnosis and consequent harm, particularly in cases of late-disseminated or neuroborreliosis infections.

Please treat this as a **formal request for internal review** of the inaction/decision under **section 60 of the Therapeutic Goods Act 1989**. I would appreciate written confirmation of receipt and advice regarding the timeframe for conducting the review.

I am attaching:

- My original complaint submission;
- Supporting documentation regarding the device's deficiencies;
- A summary of evidence indicating harm, non-validation, and device limitations.

Should you require any further information or clarification, I am happy to provide it promptly.

Thank you for your attention to this matter.

---------- Forwarded message ---------
From: s11C >

Date: Sat, 11 May 2024 at 21:32
Subject: Attention to managers, LEGAL - NEW COMPLAINT FULL REVIEW NEEDED with TOP MANAGEMENT - 10 000 patients involved -class action
To: IRIS <IRIS@health.gov.au>

Dear Sir or Madam,

According to the current letter of complaint and below substantiated materials s11C [redacted] *insists that for each discordant result a separate DIR report is generated and an official investigation commences on a properly and timely manner to avoid further injuries.*

All DIRs needs to be fully *reviewed* and put in the system accordingly

Begin forwarded message:

From: IRIS <IRIS@health.gov.au>
Subject: s11C **- Reporter Complete Letter - 8 April 2024 [SEC=OFFICIAL]**
Date: 8 April 2024 at 9:56:08 am AEST
To: s11C

Dear s11C,

Good morning!

Thank you for your device incident report (DIR) to the TGA. Please find attached the DIR investigation completion letter.

Thank you.

Kind regards,
s22
Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring | Medical Devices Surveillance Branch

Medical Devices and Product Quality Division | Health Products Regulation Group

Therapeutic Goods Administration (TGA)

Australian Government, Department of Health and Aged Care
Email: IRIS@health.gov.au
Phone: DST s22
Phone: IRIS 1800 809 361
Post: 27 Scherger Drive, Canberra Airport, ACT 2609
Courier: 1 Tindal Lane, Canberra Airport, ACT 2609
www.tga.gov.au

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We

pay our respects to them and their cultures, and to all Elders both past and present.

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Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx, using a TGA eBusiness Service (eBS) user name and password. MDIR guidance documents and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website.
MDIR Technical assistance is available via s22 [redacted] or email (IRIS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via: https://apps.tga.gov.au/prod/mdir/udir03.aspx
For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.

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