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

Implementation guide - Appendices

Mandatory reporting of medical device adverse events by healthcare facilities

Version 1.0, July 2025

Contents

Appendix A: State and territory centralised or de-centralised reporting approaches for public healthcare facilities

The following information is accurate as at June 2025, it is subject to change at the discretion of the individual state or territory.

State or Territory	Centralised or de-centralised approach
Western Australia	De-centralised
Victoria	De-centralised
ACT	De-centralised
Northern Territory	Centralised
South Australia	Centralised
Tasmania	Centralised
NSW	Centralised
Queensland	Centralised

Public hospitals located in states and territories opting for a de-centralised approach are required to submit medical device adverse event reports directly to us.

Public hospitals located in states and territories opting for a centralised approach are required to submit medical device adverse event reports to their state/territory health department. Reports from all facilities within these jurisdictions will then be consolidated at a state level prior to bulk submission to us.

Private facilities are required to submit medical device adverse event reports directly to us. Should private hospital operating groups choose to centralise reporting from their facilities, this will be communicated with hospitals within the network.

Please contact your jurisdiction’s health department or private hospital network to confirm the arrangements for your healthcare facility.

Appendix B: Medical device adverse event report examples

Example 1

Scenario:

A patient presents to hospital with pain, swelling and inflammation to their knee. The patient had a polyethylene knee insert component implanted on 15 May 2023. There was wear to the insert which led to mild metallosis in the patient. A revision surgery was performed on 26 June 2024 and the polyethylene insert was replaced. Minor harm occurred to the patient.

Example report below:

	Data Fields	Description	Example 1
Mandatory Fields	**HEALTHCARE_FACILITY_IDENTIFIER** ALPHANUMERIC (8 Character Limit)	An alphanumerical identification code using a Hospital Provider Number for each healthcare facility. The TGA will provide the identifier to facilities.	0123456A
	DATE_OF_USE dd/mm/yyyy format	the date the reportable medical device was used, removed or exchanged with another device. If the date of original use of the device is unknown, please provide the date the incident occurred.	15/05/2023 *(this is the date of the device implantation)*
	INCIDENT_DESC Free text description of the incident (500 character limit)	A description of the incident being reported including as much information as possible without providing identifiable data. Information can be a simple high-level summary such as ‘death during use’, ‘screw snapped’, ‘device migrated’ or for deterioration ‘excessive blood loss during use’, ‘seroma resulting from breast implant’.	There was wear to the polyethylene insert which led to mild metallosis in the patient. A revision surgery was required.
	DEVICE_DESCRIPTION Free text entry to describe the medical device if known (500 character limit)	The name and description of the device (including trade name, model number, etc if known).	Knee insert component.
	MANUFACTURER Free text entry to identify the manufacturer of the reportable medical device if known (500 character limit)	If known, the name of the manufacturer must be included with any report made. ‘Unknown’ should be used if the manufacturer is not known.	Unknown
Conditional Fields	Additional information (conditional fields) must be provided in the following specific circumstances: · For incidents that involve the death or serious deterioration in the condition of a person: · The date of the incident (if known). · If a person has died, the date of death (if known). · If there has been a serious deterioration in the condition of a person, the date the deterioration began (if known) or the date the deterioration was first identified. · For a near miss the date an action was taken to avoid the use of the reportable device (i.e. the date a decision was made to not use the device or cease using the device).		
	DATE_OF_INCIDENT dd/mm/yyyy format	The date the incident occurred if the incident was a day, or more, after the use of the reportable medical device	24/06/2024 (*in this example, this is the date the patient presented to the facility with symptoms)*
	DATE_OF_DEATH dd/mm/yyyy format	If a person has died, the date of death (if known).	-

	Data Fields	Description	Example 1
	DATE_OF_DETERIORATION dd/mm/yyyy format	If there has been a serious deterioration in the condition of a person, the date the deterioration began (if known) or the date the deterioration was first identified.	-
	DATE_OF_INTERVENTION dd/mm/yyyy format	For a near miss the date an action was taken to avoid the use of the reportable device (i.e. the date a decision was made to not use the device or cease using the device).	26/06/2024 *(this is the date of revision surgery)*
	DATE_OF_TREATMENT dd/mm/yyyy format	The date of the treatment administered to the individual at the time the adverse event occurred	-
Optional Fields	**FACILITY_REPORT_ID** Dependent on organisation field to associate a report ID number from their incident management system.	An ID number used by your facility to refer to the report made.	orth254544
	TREATMENT_DESC Free text description detailing the treatment of the individual using the reported medical devices (500 character limit)	A high-level description of the treatment the individual was receiving for a serious deterioration in their health	Patient had revision surgery. The polyethylene insert was replaced.
	UNIQUE_DEVICE_IDENTIFIER Alphanumeric format from UDI organisations	Unique Device Identifier (UDI) code of the medical device.	S123
	LEVEL_OF_HARM NUMERIC (1 character limit) 1 = Death 2 = Serious harm 3 = Temporary harm 4 = Minor harm 5 = No harm to individual (near miss)	Level of harm the person received as a result of the incident expressed as a single value.	4

Example 2

Scenario:

A patient was in the operating theatre having abdominal surgery on 28 January 2025. During the surgery, the tip of the inlet surgical forceps with fine tip broke while in use in abdomen. All the parts of the forceps were retrieved without harm to the patient. The surgery time was prolonged and the patient was under anaesthetic for longer than anticipated but had no complications recovering post surgery. This may be interpreted as minor harm (harm score 4) due to the extended surgery time or as a near miss (harm score 5) as no harm was caused to the patient from the forceps breaking.

Example report below:

	Data Fields	Description	Example 2
Mandatory Fields	**HEALTHCARE_FACILITY_IDENTIFIER** ALPHANUMERIC (8 Character Limit)	An alphanumerical identification code using a Hospital Provider Number for each healthcare facility. The TGA will provide the identifier to facilities.	0012345A
	DATE_OF_USE dd/mm/yyyy format	the date the reportable medical device was used, removed or exchanged with another device. If the	28/01/2025 *(this is the date the device was used)*

	Data Fields	Description	Example 2
		date of original use of the device is unknown, please provide the date the incident occurred.	
	INCIDENT_DESC Free text description of the incident (500 character limit)	A description of the incident being reported including as much information as possible without providing identifiable data. Information can be a simple high-level summary such as 'death during use', 'screw snapped', 'device migrated' or for deterioration 'excessive blood loss during use', 'seroma resulting from breast implant'.	Tip of forceps broke while in use in abdomen. All parts retrieved.
	DEVICE_DESCRIPTION Free text entry to describe the medical device if known (500 character limit)	The name and description of the device (including trade name, model number, etc if known).	Inlet surgical forceps with fine tip
	MANUFACTURER Free text entry to identify the manufacturer of the reportable medical device if known (500 character limit)	If known, the name of the manufacturer must be included with any report made. 'Unknown' should be used if the manufacturer is not known.	ABC Medical Manufacturing
Conditional Fields	Additional information (conditional fields) must be provided in the following specific circumstances: · For incidents that involve the death or serious deterioration in the condition of a person: · The date of the incident (if known). · If a person has died, the date of death (if known). · If there has been a serious deterioration in the condition of a person, the date the deterioration began (if known) or the date the deterioration was first identified. · For a near miss the date an action was taken to avoid the use of the reportable device (i.e. the date a decision was made to not use the device or cease using the device).		
	DATE_OF_INCIDENT dd/mm/yyyy format	The date the incident occurred if the incident was a day, or more, after the use of the reportable medical device	28/01/2025 (*this is the date the forceps broke during surgery)*
	DATE_OF_DEATH dd/mm/yyyy format	If a person has died, the date of death (if known).	-
	DATE_OF_DETERIORATION dd/mm/yyyy format	If there has been a serious deterioration in the condition of a person, the date the deterioration began (if known) or the date the deterioration was first identified.	-
	DATE_OF_INTERVENTION dd/mm/yyyy format	For a near miss the date an action was taken to avoid the use of the reportable device (i.e. the date a decision was made to not use the device or cease using the device).	28/01/2025 *(this is the date the broken forcep tip was removed from the patient)*
	DATE_OF_TREATMENT dd/mm/yyyy format	The date of the treatment administered to the individual at the time the adverse event occurred	-
Optional Fields	**FACILITY_REPORT_ID** Dependent on organisation field to associate a report ID number from their incident management system.	An ID number used by your facility to refer to the report made.	surg123456
	TREATMENT_DESC Free text description detailing the treatment of the individual using the reported medical devices (500 character limit)	A description of the treatment the person was receiving when the incident occurred.	- Broken forcep tip was removed from patient without incident, but did extend surgery time.

	Data Fields	Description	Example 2
	UNIQUE_DEVICE_IDENTIFIER Alphanumeric format from UDI organisations	Unique Device Identifier (UDI) code of the medical device.	ABC123
	LEVEL_OF_HARM NUMERIC (1 character limit) 1 = Death 2 = Serious harm 3 = Temporary harm 4 = Minor harm 5 = No harm to individual (near miss)	Level of harm the person received as a result of the incident expressed as a single value.	4 minor harm; or 5 near miss (either classification would be acceptable in this situation)

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Device Vigilance and Policy	July 2025

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