Adverse event reporting for medical devices

Incident Report Investigation Scheme (IRIS) for medical devices
A scheme intended to help maintain the standard of devices used in healthcare through voluntary cooperation between users, government and industry through the investigation of adverse events and incidents.

IRIS inSite
- A TGA initiative to support IRIS, and encourage adverse event reporting by health professionals
- TGA establishes direct relationship with a hospital to facilitate increased quantity and quality of adverse event reports
- Involves three key actions: Recognise, Retain, and Report.

What is a medical device adverse event / incident?
- An event associated (caused or partially attributable) with the use (or misuse) of a medical device.
- An event that resulted in, or could have resulted in (had effective intervention not taken place) serious injury, illness or death to patient, healthcare worker or other person.
- Faults that may affect the quality, timeliness and cost-effectiveness such as, problems with getting the device to operate, repeated repairs, device design and difficulty of use.

What do medical device sponsors need to do?
Sponsors have mandatory obligations to report the details of events associated with their device(s) that have resulted, or could have resulted, in serious injury or death.

When to report

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Timeframe</th>
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<tbody>
<tr>
<td>Serious public health threat or concern that will require prompt action to reduce the hazard</td>
<td>Within two (2) days of becoming aware of the issue</td>
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<tr>
<td>Death or serious injury</td>
<td>Within ten (10) days of becoming aware of the event</td>
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<tr>
<td>Event that might have led to serious injury or death</td>
<td>Within thirty (30) days of becoming aware of the event</td>
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How do sponsors report adverse events?
- Preferred method of reporting is online via TGA’s Business Services portal
- Sponsors need to log in with their user name and password
- Enter as much detail as possible into the online form – there are mandatory fields.
- After you have submitted the report, the Device Incident Report (DIR) number will be available.
- You can save or print your report.

Need more information? www.tga.gov.au email: devices@tga.gov.au