

## Safety Alert Broadcast System Policy Directive

**Summary** This policy directive outlines the NSW Ministry of Health's approach to the communication and management of State-wide patient safety issues raised from sources which include: the Incident Information Management System (IIMS), Reportable Incident Briefs (RIB)s, Root Cause Analysis (RCA) reports, Health Care Complaints Commission (HCCC), Coroners reports, Information from Health Services, the Australian Commission for Safety and Quality in Healthcare, and other jurisdictions, Safety alerts and product recalls / notices issued by the Food and Drugs Administration (FDA), Therapeutic Goods Administration (TGA) and UK Medicines and Healthcare Products Regulatory Agency (MHRA).

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**Applies to** Local Health Districts, Board Governed Statutory Health Corporations, Chief Executive Governed Statutory Health Corporations, Specialty Network Governed Statutory Health Corporations, Affiliated Health Organisations, Public Health System Support Division, Dental Schools and Clinics, NSW Ambulance Service, Ministry of Health, Private Hospitals and day Procedure Centres, Public Hospitals

**Distributed to** Public Health System, NSW Ambulance Service, Ministry of Health, Private Hospitals and Day Procedure Centres

**Audience** Clinical Staff;Directors of Clinical Governance;Chief Executive Officers

Secretary, NSW Health

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is mandatory for NSW Health and is a condition of subsidy for public health organisations.

## **SAFETY ALERT BROADCAST SYSTEM POLICY DIRECTIVE**

### **PURPOSE**

The NSW Ministry of Health Safety Alert Broadcast System (SABS) is the mechanism to provide a systematic approach to the distribution of patient safety information to the NSW health system and includes a mechanism to ensure the required action and management of patient safety issues by health services.

The SABS includes three tiers of notifications to provide NSW health services with early warnings of issues, namely:

- Safety Alert
- Safety Notice
- Safety Information

### **MANDATORY REQUIREMENTS**

#### **Safety Alerts**

Local Health Districts / Specialty Health Networks must:

- Distribute the SAB to staff identified in the Alert (and other staff as relevant)
- Acknowledge receipt of the SAB within the defined timeframe
- Ensure completion of required actions within the designated timeframe
- Submit required responses to the CEC within the designated timeframe.

#### **Safety Notices**

Local Health Districts / Specialty Health Networks must:

- Distribute the SAB to staff identified in the Alert (and other staff as relevant)
- Consider the relevance of the information to the Local Health District
- Review relevant policies and procedures to address the issues
- Identify any actions required and implement those actions
- Submit required responses to the CEC within the designated timeframe.

#### **Safety Information**

Local Health Districts / Specialty Health Networks must:

- Distribute the SAB to all staff
- Consider the relevance of the information to the Local Health District
- Identify any actions required and implement those actions (if appropriate)
- Submit required responses to the CEC within the designated timeframe.

## IMPLEMENTATION

### NSW Clinical Excellence Commission is responsible for

- assessment of information received and production of SABS document
- distribution of SABS notifications to NSW health services in a timely manner
- monitoring State-wide implementation of requested actions
- providing reports to the Clinical Risk Action Group (CRAG) on compliance of mandatory actions with SABS
- reviewing the SABS Policy Document in accordance with PD2009\_029, Policy, Guideline and Information Bulletin Distribution System for the NSW Ministry of Health.

### Chief Executives are responsible for establishing an efficient and effective process for

- receipt, distribution, implementation and effectiveness for SABS notifications,
- ensuring distribution of SABS notifications to the appropriate people within the health service
- acknowledging receipt of SABS Safety Alerts within a time frame defined at the time of release, ideally within 2 days.

### Directors of Clinical Governance are responsible for

- ensuring implementation of nominated action/s, where relevant
- monitoring the effectiveness of the SABS within the health service.

## REVISION HISTORY

Version	Approved by	Amendment notes
May 2013 (PD2013_009)	Director General	Changes in Policy reflect transfer of SAB function from MOH to CEC and replaces PD2006_102
November 2006 PD2006_102	Director General	New policy.

## ATTACHMENTS

1. Safety Alert Broadcast System Policy Directive

## Safety Alert Broadcasts System Policy Directive



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**Issue date:** May-2013

PD2013\_009

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## 1 BACKGROUND

### 1.1 About this document

The NSW Ministry of Health and the Clinical Excellence Commission are made aware of issues affecting patient safety from a variety of sources. These include but are not limited to:

- a. Incident Information Management System (IIMS) incident notifications
- b. Reportable Incident Brief (RIB) information and Root Cause Analysis (RCA) reports
- c. Health Care Complaints Commission (HCCC) and Coroners reports
- d. Information from Health Services, the Clinical Excellence Commission (CEC), the Australian Commission on Safety and Quality in Healthcare, and other jurisdictions
- e. Safety alerts, product recalls and notices issued by organisations including the Therapeutic Goods Administration (TGA), international authorities such as the US Food and Drugs Administration (FDA) and the UK Medicines and Healthcare Products Regulatory Agency (MHRA).

This Policy Directive outlines the NSW Ministry of Health's approach to the communication and management of statewide patient safety issues raised through these sources.

The Safety Alert Broadcast System (SABS) aims to:

- a. Provide a coordinated approach to the management and distribution of patient safety information within NSW Health Services
- b. Ensure that SABS notifications have been received by the Chief Executive of each Local Health District / Specialty Health Network or service and that appropriate distribution of the information occurs
- c. Monitor NSW Health service implementation of risk management strategies.

SABS policy does not apply to:

- a. Public Health alerts issued by the Chief Health Officer (CHO) about environmental health issues, food safety, or consumer products or public health events related to communicable diseases such as SARs or pandemic influenza
- b. Corporate alerts relating to areas such as equipment (other than medical devices), power supply and information technology
- c. WorkCover alerts and notices.

**Compliance with this policy is mandatory for all health service staff.**

Private health facilities should review the information provided in SABS and implement any action as appropriate to ensure patient safety.

## 1.2 Key definitions

<b>CEC</b>	A board governed statutory health corporation established under the Health Services Act as part of the NSW Patient Safety and Clinical Quality Program (PSCQP). It builds on the foundation work carried out by the Institute of Clinical Excellence established in 2001.
<b>Clinical Governance</b>	Clinical governance can be considered as the responsibility of governing bodies to demonstrate sound strategic and policy leadership in clinical safety and quality, to ensure appropriate safety and quality systems are in place and to ensure organisational accountability for safety and quality.
<b>The Ministry</b>	NSW Ministry of Health.
<b>DCG</b>	Director, Clinical Governance.
<b>Health Services</b>	For the purposes of this policy, the term “health services” refers to Public Health Organisations, Justice and Forensic Mental Health Network and the Ambulance Service of NSW
<b>HCCC</b>	Health Care Complaints Commission.
<b>IIMS</b>	Incident Information Management System
<b>IRR</b>	Information Risk Rating
<b>Local Health Districts, Specialty Health Networks and Services</b>	Organisations constituted under the <i>Health Services Act 1997</i> that are principally concerned with the provision of health services to residents within a designated geographic area and/or service type
<b>Private Health Facilities</b>	Private health facilities licensed under the <i>Private Health Facilities Act 2007</i>
<b>Public Health Organisations (PHO)</b>	This term refers to Local Health District, statutory health corporations or an affiliated health organisation in response of its recognised establishments and recognised services as defined in the <i>Health Services Act 1997</i> .
<b>PSCQP</b>	Patient Safety and Clinical Quality Program (PD2005_608)
<b>RIB</b>	Reportable Incident Brief
<b>RCA</b>	Root Cause Analysis
<b>SABS</b>	Safety Alert Broadcast System
<b>TGA</b>	Therapeutic Goods Administration

## 2 SABS NOTIFICATIONS

The SABS notifications provide a systematic three-tiered approach to the distribution, prioritisation and management of patient safety information. This includes a standardised system for monitoring the implementation of required actions by health services.

The three notifications issued under the SABS use the following colour coding to indicate the level of urgency.

1. **Safety Alert** (Red)
2. **Safety Notice** (Amber)
3. **Safety Information** (Green)

### 2.1 Safety Alert (Red)

The aim of the **Safety Alert** is to quickly disseminate information to Local Health Districts (LHDs) / Specialty Health Networks about a safety matter needing **immediate attention and action**. The Safety Alert will specify **mandatory** action/s to be taken by health services and the timeframes in which such actions should occur and assign responsibility for action. The colour coding for Safety Alerts is **RED**. This Alert takes precedence over any contrary policy/procedure/guideline contained in a Policy Directive or Guideline. On receipt of a Safety Alert, LHDs / Specialty Health Networks are to ensure local policies/procedures/guidelines comply with the information contained therein.

### 2.2 Safety Notice (Amber)

The aim of the **Safety Notice** is to inform Local Health Districts / Specialty Health Networks about potential quality and safety issues requiring **risk assessment at the local level** to determine appropriate action/s regarding any identified problems. The colour coding for Safety Notices is **AMBER**.

### 2.3 Safety Information (Green)

The aim of the **Safety Information** is to disseminate quality and safety information to health services to ensure lessons learned from State-wide, national and international sources are shared across the NSW Health System in an active manner. The Safety Information may include items such as updates on State-wide initiatives implemented under the NSW Patient Safety and Clinical Quality Program, information about Policy Directives and Guidelines and access to the most current information focusing on clinical quality and patient safety issues and research. The colour coding for Safety Information is **GREEN**.



## Safety Alert Broadcast System Policy Directive



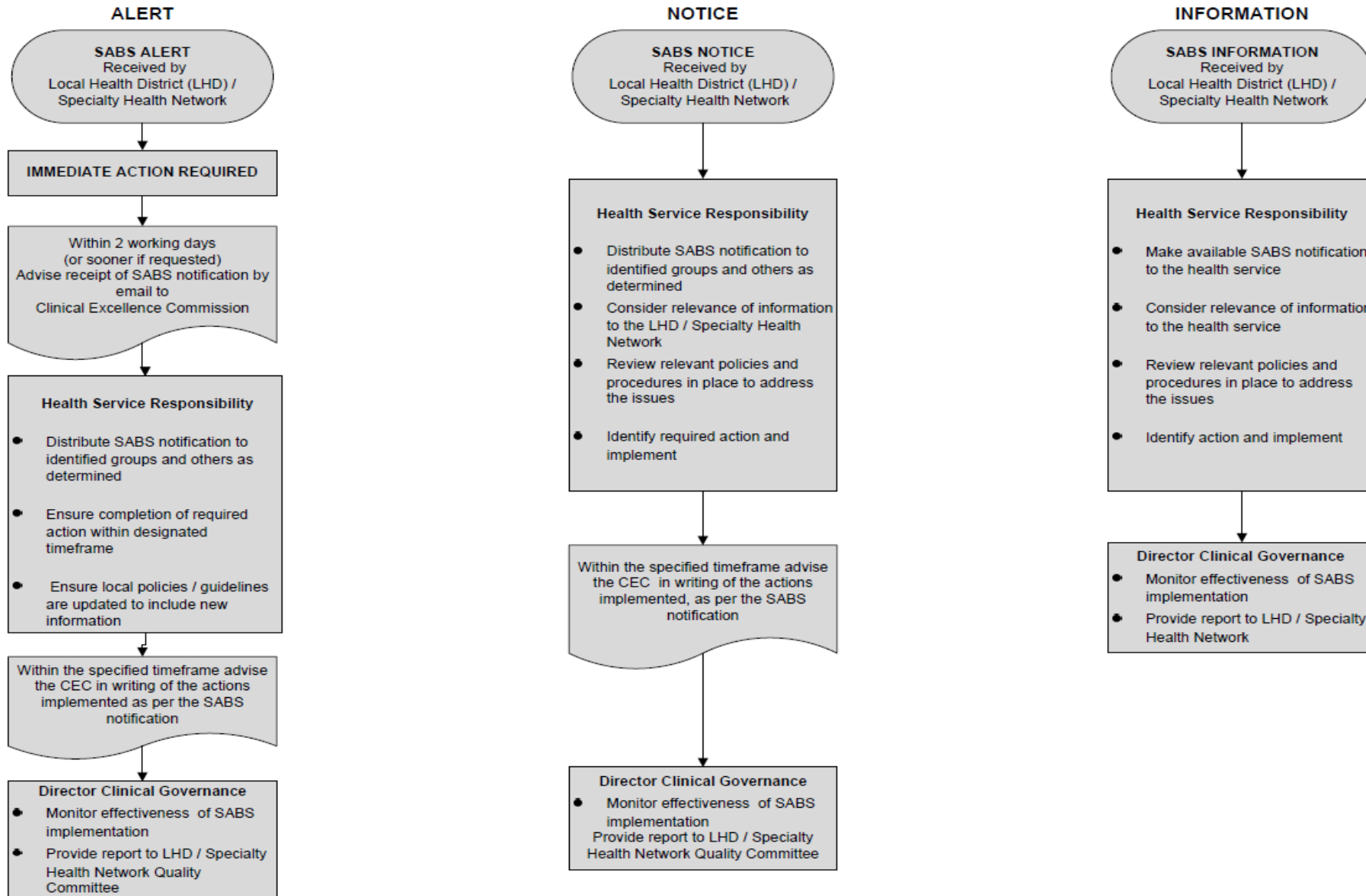
**Table 1** Easy Guide to health service responsibilities for receipt and management of a SABS notification

SABS document	Aim	Distribution strategy*	Health service response on receipt of SABS document
<b>Safety Alert</b>	Alert LHDs/ Specialty Health Networks to a safety matter needing <b>immediate attention and mandatory action</b> .  The colour coding for Safety Alerts is <b>RED</b> .	The CEC distributes SABS to: <ul style="list-style-type: none"> <li>The Chief Executive; and</li> <li>The officer responsible for designated action/s (indicated on the SABS).</li> </ul> The LHD / Specialty Health Network distributes SABS to: <ul style="list-style-type: none"> <li>staff identified in the Alert; and</li> <li>other relevant staff.</li> </ul>	<ul style="list-style-type: none"> <li>Acknowledge receipt within a defined time frame, usually 2 working days.</li> <li>Ensure completion of required action/s within designated timeframe.</li> <li>Ensure local policies and guidelines are updated to include new information if required.</li> <li>Submit required responses to the CEC within the designated timeframe at <a href="mailto:quality@cec.health.nsw.gov.au">quality@cec.health.nsw.gov.au</a>.</li> </ul>
<b>Safety Notice</b>	Informs LHDs / Specialty Health Networks or services about potential quality and safety issues requiring <b>risk assessment at the local</b> level to determine appropriate action regarding any identified problems.  The colour coding for Safety Notices is <b>AMBER</b> .	The CEC distributes to: <ul style="list-style-type: none"> <li>The Chief Executive; and</li> <li>The officer responsible for suggested action/s.</li> </ul> The LHD / Specialty Health Network distributes SABS to: <ul style="list-style-type: none"> <li>staff identified in the Notice; and</li> <li>other relevant staff.</li> </ul>	<ul style="list-style-type: none"> <li>Consider relevance of information to the LHD / Specialty Health Network or service.</li> <li>Review relevant policies and procedures in place to address the issues.</li> <li>Identify required action/s and implement.</li> <li>Submit required responses to CEC within the designated timeframe at <a href="mailto:quality@cec.health.nsw.gov.au">quality@cec.health.nsw.gov.au</a>.</li> </ul>
<b>Safety Information</b>	Disseminates quality and safety news to LHDs / Specialty Health Networks or services to ensure lessons learned are shared across health services. May include updates on initiatives implemented under the NSW Patient Safety and Clinical Quality Program, information about policy directives and guidelines and provide access to the latest information and research focusing on clinical quality and patient safety.  The colour coding for Safety Information is <b>GREEN</b> .	The CEC distributes to: <ul style="list-style-type: none"> <li>The Chief Executive and the Director of Clinical Governance.</li> </ul> The LHD /Specialty Health Network ensures: <ul style="list-style-type: none"> <li>the availability of Safety Information to all staff.</li> </ul>	<ul style="list-style-type: none"> <li>Consider relevance of the information to LHD/ Specialty Health Network.</li> <li>Identify any action/s and implement (if any).</li> </ul>

**Safety Alert Broadcast System Policy Directive**



**SABS PROCESS**



**IMPLEMENTATION & EVALUATION**

### 3 DISTRIBUTION OF SABS NOTIFICATIONS TO LOCAL HEALTH DISTRICTS / SPECIALTY HEALTH NETWORKS

The Clinical Excellence Commission will ensure that the SABS notification is distributed by the following process:

1. Email to all Chief Executives
2. Copy of the email to each Chief Executive nominated person
3. Copy of email to all Directors of Clinical Governance
4. Copy of email to position assigned responsibility for action in the SABS document
5. Copy of email to Director, Private Health Care for distribution to licensed private health facilities
6. Copy of email internally to Clinical Excellence Commission staff
7. Copy of email to Corporate Governance and Risk Management Branch
8. Copy of email to Strategic Relations and Communications Branch.

Available on the Department's website <http://www.health.nsw.gov.au/quality/sabs>

#### 3.1 Distribution of Safety Alerts out of normal business hours

The CEC will contact the Chief Executive by telephone should there be need to disseminate a Safety Alert or an emergency drug recall out of business hours. The distribution of the formal Safety Alert will be on the first day of the CEC's normal business hours.

#### 3.2 Local Health District / Specialty Health Network Distribution of SABS notifications

Each SABS notification will include a recommended distribution list for use by the CEC. Local Health Districts/ Specialty Health Networks are responsible for ensuring an effective internal distribution strategy is in operation.

#### 3.3 Local Health District / Specialty Health Network or Services request for response from SABS notification

When Local Health Districts/ Specialty Health Networks are required to respond back to the CEC, then it is the **responsibility of the Chief Executive** or equivalent of that entity to ensure that:

- a. Responses back (where requested) are received within the stipulated timeframe
- b. A system is developed so that only one response from each Local Health District/ Specialty Health Network is returned back to the CEC.

The response should be emailed to the CEC at [quality@cec.health.nsw.gov.au](mailto:quality@cec.health.nsw.gov.au)

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### 3.4 Local Health District/ Specialty Health Network responsibility for actions arising from SABS notification

When LHDs / Specialty Health Networks are required to take action resulting from a SABS notification then it is the **responsibility of the Director of Clinical Governance** to ensure that:

- a. the nominated actions have been implemented in the stated timeframe
- b. a written response has been returned to the CEC (where requested) of the actions taken arising from the SABS notification
- c. the response should be emailed to the CEC at [quality@cec.health.nsw.gov.au](mailto:quality@cec.health.nsw.gov.au) the Directors of Clinical Governance are to report the implementation status of actions arising from SABS notifications to the local peak Quality Committee.

### 3.5 Review of SABS Notifications

All Safety Alerts will have a mandatory review date consistent with other Policy Directives. This review establishes if the document remains active, requires updating or is obsolete.

The Clinical Excellence Commission will review and update all Safety Alerts and Notices as new information becomes available.

## 4 EVALUATION OF SABS

The Director of Clinical Governance is responsible for monitoring the effectiveness of the SABS at the local level to ensure compliance with the CEC Quality Systems Assessment Program.

## 5 RELEVANT NSW HEALTH POLICY DIRECTIVES AND REFERENCES

### 5.1 Relevant NSW Health Policy Directives

NSW Health Policy Directive, Guidelines and Information Bulletin can be accessed at:  
<http://www.health.nsw.gov.au/policies/pages/default.aspx>

NSW Policies Directives	Document No.
Lookback Policy	PD2007_075
Open Disclosure Policy	PD2007_040
Patient Safety and Clinical Quality Program	PD2005_608
Patient Safety and Clinical Quality Program Implementation Plan	PD2005_609
Policy, Guideline and Information Bulletin Distribution System for NSW Health	PD2009_029
Complaint Management Policy	PD2006_073

### 5.2 References

Department of Health Safety Alert Broadcasting System (UK) available at  
<http://www.info.doh.gov.uk/sar/cmopatie.nsf/>

Medicines and Healthcare products Regulatory Agency (MHRA) available at  
<http://www.mhra.gov.uk>

US Food and Drug Administration FDA available at <http://www.fda.gov/cdrh/safety.html>

## 6 ATTACHMENTS

### 6.1 Safety Alert Template



# Safety Alert 00#/YY

**Title**

**(dd month year)**

**Distributed to:**

- Chief Executives
- Directors of Clinical Governance
- Xxxxx
- xxxxx

**Action required by:**

- Chief Executives
- Directors of Clinical Governance
- Xxxxx

**We recommend you also inform:**

- Xxxxxxxxxxxx
- Xxxxxxxxx
- Xxxxxx
- Xxxxxx

**Deadline for completion of action**

**(dd month year)**

**Expert Reference Group**

Content reviewed by:

- Xxxxxxxxxxxx
- Xxxxxxxxx
- Xxxxx
- Xxxxx

**Clinical Excellence Commission**

Tel. 02 9289 5500  
Fax. 02 9289 5599

Email:  
[quality@cec.health.nsw.gov.au](mailto:quality@cec.health.nsw.gov.au)

Internet Website:  
<http://www.health.nsw.gov.au/quality/sabs>

Intranet Website  
<http://internal.health.nsw.gov.au/quality/sabs/>

**Review date**

month year

**Heading**  
Para text text

1. step

**Heading**  
Para text text...

- bullet

- Actions required by Local Health Districts / Specialty Health Networks**
1. text text style step2
  2. text text

## 6.2 Safety Notice Template



# Safety Notice 00#/YY

### Title

(dd month year)

#### Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Xxxxx
- xxxxx

#### Action required by:

- Chief Executives
- Directors of Clinical Governance
- Xxxxx

#### We recommend you also inform:

- XXXXXXXXXXXX
- XXXXXXXXXXXX
- XXXXXX
- XXXXXX

#### Expert Reference Group

Content reviewed by:

- XXXXXXXXXXXX
- XXXXXXXX
- XXXXX
- XXXXX

#### Clinical Excellence Commission

Tel. 02 9269 5500  
Fax. 02 9269 5599

Email:  
[quality@cec.health.nsw.gov.au](mailto:quality@cec.health.nsw.gov.au)

Internet Website:  
<http://www.health.nsw.gov.au/quality/sabs>

Intranet Website  
<http://internal.health.nsw.gov.au/quality/sabs/>

#### Review date

month year

#### Heading

Para text text

1. step

#### Heading

Para text text...

- bullet

#### Suggested actions by Local Health Districts / Specialty Health Networks

1. Forward information to appropriate area for action.
2. Ensure a system is in place to document actions taken.

### 6.3 Safety Information Template



## Safety Information 00#/YY

**Title**

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**(dd month year)**

**Distributed to:**

- Chief Executives
- Directors of Clinical Governance
- Xxxxx
- Xxxxxx

**Expert Reference Group**

Content reviewed by:

- XXXXXXXXXXXX
- XXXXXXXX
- XXXXX
- XXXXXX

**Clinical Excellence Commission**

Tel. 02 9269 5500  
 Fax. 02 9269 5599

Email:  
[quality@cec.health.nsw.gov.au](mailto:quality@cec.health.nsw.gov.au)

Internet Website:  
<http://www.health.nsw.gov.au/quality/sabs>

Intranet Website  
<http://internal.health.nsw.gov.au/quality/sabs/>

**Review date**  
 month year

**Heading**

Paragraph

Paragraph

**Suggested actions by Local Health Districts / Specialty Health Networks**

1. Forward information to appropriate area for action.
2. Ensure a system is in place to document actions taken.