# Reportable Events

Guidelines

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# Foreword

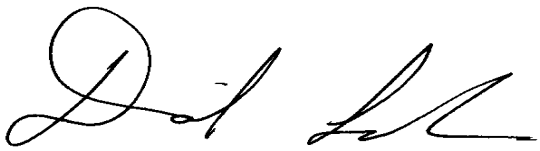
In a sector as large and complex as health, things will sometimes go wrong. The potential benefits of learning from our experiences are significant in terms of saved lives, harm prevented and resources freed up for the delivery of more and better care.

This document builds on the work that has been carried out to date by the Health Funding Authority and the Ministry of Health and provides guidance on processes and systems for organisational reporting, managing and investigation of incidents, accidents and hazards.

These guidelines will be useful for all organisations delivering health and disability services. Use of the guidelines should assist organisations to reduce the risk of harm to future consumers through improving the safety and the quality of services, and will set up systems for making sure that they learn from the event.

The cornerstone of the material set out in this document is the need to establish the underlying cause(s) of serious or sentinel events through root cause analysis. Unless the causes of reportable events are properly understood, lessons will not be learned and suitable improvements will not be made to secure a reduction in the risk of harm to future consumers.

I hope these guidelines will help to create an environment within health and disability services, both locally and nationally, that supports and encourages self-learning from analysing reportable events and promotes the redesign of systems as the main method for improving safety.



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# Introduction

There needs to be a fundamental rethinking of the way the health care sector approaches the challenge of learning from when things go wrong. Traditionally the sector has failed to learn the lessons from **reportable events** (as they will be called throughout these guidelines) and has an outmoded approach compared with other industries. The potential benefits of learning from our experiences are significant in terms of saved lives, harm prevented and resources freed up for the delivery of more and better care. This will require a concerted effort by health care professionals, organisations and regulators. Traditional boundaries and a culture of blame must be broken down. Most importantly, we must systematically design safety into the processes of care.

To improve this outmoded approach successfully and move towards an environment that supports and encourages self-learning, the following are essential:

- a standardised process for investigation, analysis and reporting
- a culture of learning – not one of blame
- a process for communicating the lessons learnt so others may benefit from this experience
- ensuring systems and practice change as a result of the lessons learnt.

Implementation of these guidelines will help to create an environment within health and disability services, both locally and nationally, that supports and encourages **self-learning** from analysing reportable events, and promotes the **redesign** of systems as the main method for improving safety. This requires supporting a **culture** where every health care worker takes personal responsibility for consumer safety, and where discovering and reporting problems, mistakes, and close calls is **rewarded**, not punished.

These guidelines replace the Health Funding Authority document *Reportable Events Guidelines*, published and distributed in February 2000. It is the culmination of two related projects:

- the Sentinel Events Working Party report to the Director-General of Health, titled *Toward Clinical Excellence: Learning from experience*
- the Sentinel Events Work Group, facilitated by Standards New Zealand, which developed and piloted the Sentinel Events Investigation, Analysis and Reporting Process.

This document updates the information from the *Reportable Events Guidelines* and includes new information on sentinel events reporting using root cause analysis methodology.

The guideline objectives are to:

- have a positive impact on improving care to consumers[1] and the working environment for employees
- focus attention on identifying and managing the underlying causes of serious undesirable events
- facilitate quality improvement and risk reduction
- ensure employees have the means to alert the organisation to problems that affect quality of service
- ensure the systems for identifying, reporting, and managing reportable events are robust and consistent with a quality improvement approach
- ensure the systems for identifying, reporting, and managing reportable events are appropriate to people's culture, values and behaviours
- ensure the systems and training for identifying, reporting, and managing reportable events are consistent with Māori values and beliefs and recognise Māori diversity
- reinforce line manager responsibility for managing events while maintaining organisational oversight of actions taken to improve quality and reduce risk
- ensure that the good practices operating in organisations are communicated to all providers
- provide a framework against which each provider can review and further improve its own reportable event system
- provide a baseline for best practice that can be revised and developed in the future.

## Reasons for reporting

Having a reporting system in place for incidents/accidents provides:

- an accountability mechanism
- evidence of a standardised sentinel event investigation, analysis and reporting system
- evidence of a systematic approach to the implementation of safety procedures
- an audit trail
- a record of risks, and information for the organisation's knowledge base.

## Key terms

Many, but not all, providers use the terms 'incident' and 'accident'. The following definitions indicate how these and other terms are used in the guidelines.

Incident: *an undesired event, which under slightly different circumstances could have resulted in harm to people, damage to property, or loss to process.*

[1] 'Consumers' is used to refer to clients, patients, and residents; ie, the receiver of services.

Accident: *an undesired event that results in harm to people, damage to property, or loss to process*.[2]

Sentinel event: *an undesired event that signals that something serious or 'sentinel' has occurred and warrants in-depth investigation*.[3]

It is recommended that the term 'adverse events' not be used because of its special meaning with regard to consumer injuries.

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2 FE Bird jr, GL Germain. *Practical Loss Control Leadership: The conservation of people, property, process and profits*. 2nd edition, Georgia: International Loss Control Institute, 1990.

3 See Appendix A: Event Categories.

# 1 Policy and Procedures

The organisation has one written policy requiring employees[4] to document events that the organisation defines as reportable events.[5]

1.1 The policy is brief, user friendly and refers employees to written procedures that describe how the policy is implemented.

1.2 The language used in the policy and procedures provides clear instructions to employees. Ambiguous language (for example, 'should' or 'may') is not used unless the intention is for individual interpretation.

1.3 The purpose of the reportable events policy is described in the policy.

1.4 The policy applies to all employees and services/departments of the organisation.

1.5 The policy is centralised: services/departments are not permitted to depart from the policy.

1.6 The scope of the policy specifically excludes events reported by consumers. Events reported by consumers are complaints or feedback and are managed according to the organisation's complaints policy.

1.7 The policy describes employees' responsibilities regarding reportable events as they relate to their position/designation. Employees' responsibilities are reinforced by specific mention in job descriptions.

1.8 The procedures recognise the 24-hours-a-day nature of event reporting and take into account the absence of personnel with designated responsibilities by defining the position that has responsibility in their absence.[6]

1.9 The policy requires that events affecting an individual consumer's care be documented in their clinical health record.

1.10 An example of the Reportable Event Form is attached to or referenced in the policy/ procedures.

1.11 There is a flow chart outlining the reportable events processes. The flow chart shows:

(a) the management processes for *managing each event* through to conclusion

(b) the management processes for *investigating the event* through to final actions (see sample flow charts Appendix A).

1.12 The following persons can complete event reports:

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[4] 'Employees' includes all persons acting as agents of the organisation and/or working on the organisation's premises (eg, students, volunteers, contractors).

[5] 'Reportable event' is the term that will be used throughout these guidelines.

[6] For example, a unit manager's responsibilities may be taken up by an after-hours co-ordinator at unit or facility level.

(a) the employee who first becomes aware of the event

(b) the employee most involved in the event

(c) the employee to whom an event is reported (if a form is not already completed).

1.13 Procedures allow extremely sensitive or complex events to be managed in accordance with other policies/procedures. These procedures are congruent with the reportable events policy but may require specific actions by appropriate employees/ managers.[7]

1.14 Employees are instructed to document events in an objective, factual and accurate manner.

1.15 The written policy, and implementation of procedures, must reinforce that event reporting is a quality improvement tool and is not to be used as a punitive tool by managers.

1.16 The policy (and supporting documentation including procedures) is reviewed at least every two years, at which time:

(a) any recommendations for improvement to the policy/procedures are documented

(b) an action plan for implementing the recommendations is written

(c) a methodology and criteria for evaluating the success of the implemented recommendations are formulated before the plan's implementation.

# 2 Definitions

The organisation has a definition of reportable events in the policy or procedures.[8]

2.1 The definition of reportable events is broad enough to require employees to report:

(a) events that have resulted in harm[9] to consumers, visitors and employees and that are discovered upon entry to the service, or occur during service provision

(b) serious harm suffered by employees, visitors or contractors as defined in the Health and Safety in Employment Act 1992

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7 For example, the occurrence of a sexual assault may be briefly recorded on the Reportable Event Form for the purposes of statistical data collection and reporting. However, the documentation relating to the management of the event may be kept separately from 'routine' events and managed according to the requirements of relevant internal policy and procedures and external entities; eg, the Police.

8 For example, 'incident and accident'.

9 Harm includes physical or emotional harm that is unrelated to the natural course of the consumer's illness or underlying condition. The harm may result from actions or omissions by employees.

(c) events that reflect an unsatisfactory situation in terms of the quality of clinical practice, quality of operational management, or quality of service delivery systems, and that require reporting to managers (this may include events related to the organisation's interface with other organisations, such as other service providers)

(d) events that have resulted in, or could have resulted in, loss or damage to property relating to consumers, visitors or employees or the organisation

(e) events that have resulted in, or could have resulted in, damage to the environment

(f) events that could have caused harm, serious harm, damage or loss if:

(i) the situation had not been rescued in time to prevent harm occurring

(ii) employees foresee that a recurrence of the event could result in harm.

2.2 Examples of the types of events to be reported are included in the policy/procedure.

2.3 The definition further categorises events as:

(a) reportable

(b) serious

(c) sentinel.

# 3 Hazards

The reportable events policy and procedures require that any hazards identified via event reporting be managed according to the organisation's hazard management policies.

# 4 The Reportable Event Form

The organisation dedicates one form to initial reporting of all events.[10]

4.1 Alternative methods of event notification, such as oral communication or letter, require subsequent completion of the dedicated form to promote development of a complete database for trend evaluation.

4.2 Sufficient instructions are accessible to the reporter to enable accurate completion of the form.

[10] The form may be in hard copy or electronic form. Additional supporting forms may be used as required; eg, blood/body fluid exposure form, medication error form, motor vehicle accident form.

4.3 The reporter is required to provide information to describe the event to managers. This includes providing:

(a) a description of the event and the condition of any injured person

(b) details of the immediate action(s) taken to minimise harm/loss and recover the situation

(c) identification details of the subject of the report,[11] including:

(i) *if a consumer,* their name, age, treating or admitting unit and contact details

(ii) *if an employee,* their name, designation and department

(iii) *if property, equipment, or environment*, identifying information, such as asset number, physical location, type of equipment and model number

(d) the names of all the people involved in the event, including witnesses,[12] to ensure they can be contacted later as required

(e) *if the event relates to a consumer*, information about whether they are aware of the event at the time the form is completed

(f) the safety barriers or control points that were breached that enabled the event to occur

(g) the date, time, and location of the event

(h) the date and time the form is completed

(i) the signature, printed name, and designation of the reporter

(j) space for people reviewing the event to sign the form.[13]

# 5 Notification of Individual Reportable Events

5.1 Serious and/or sentinel events are reported immediately by the reporter to the personnel designated by the organisation for the particular type of event.

5.2 Reportable events are notified to the following persons in the following order:

(a) the person responsible for the supervision or management of the unit/ department/service

(b) the person responsible for quality/risk/occupational health/safety management

(c) senior managers and appropriate others; for example, Director of Nursing, infection control.

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[11] 'Subject' is defined as the person/object that has, or could have suffered, loss; or caused, or could have caused, loss to a third party/object.

[12] From a workers' compensation perspective the listing of witnesses (staff and consumers) is crucial to facilitate quick and effective claims evaluation. From a consumer perspective, the listing of employees and consumers involved in an event aids effective management of any subsequent complaint, medical misadventure, claim or inquiry.

[13] For example, the immediate line manager, clinical nurse specialist, facilities manager. Alternatively, this may be provided on a separate form used for reviewing the event at the discretion of the organisation.

5.3 Timeframes for notification are designated in the procedures. Less serious events are notified within the following periods:

(a) unit manager: within eight hours and before the reporter finishes his/her day's work

(b) quality/risk/occupational health/safety management: within 24 hours

(c) senior managers: within 48 hours.

# 6 Information to Consumers

6.1 Consumers are informed if an event affects their care and treatment.

6.2 Consumers are advised of the actions employees will take to remedy any harm suffered by the consumer, or to prevent harm occurring to the consumer because of the event.

6.3 Where a consumer is unable to comprehend some/all of the information provided about the event, where practical, the consumer's representative is informed.

6.4 Consumers are advised if the circumstances of the reportable event require the organisation to report the event to an external authority;[14] for example, coroner, Police, National Radiation Laboratory, Ministry of Health.

6.5 Where a copy of the reportable event form *is* filed in the consumer's clinical health record,[15] *then* the consumer will also be:

(a) advised that a Reportable Event Form has been completed and why

(b) advised that a copy of the form has been filed in their clinical health record

(c) offered a copy of the Reportable Event Form at the time they are informed of the event's occurrence

(d) advised if an investigation into the event is occurring and when it will be completed

(e) advised of the outcome of any investigation in accordance with the disclosure requirements of the organisation's complaints management policy. This may or may not include providing the consumer with written information about the event and subsequent actions.[16]

6.6 If, as the result of an event, the consumer complains, their complaint is managed according to the organisation's complaints policy.

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[14] This does not apply to events where the reporting is for the gathering of statistical data, as consumers should already have been informed that this will or might occur.

[15] Organisations may or may not decide to include Reportable Event Forms in clinical records.

[16] This information will only be withheld from the consumer as per the Health Information Privacy Code if the consumer would be adversely affected by knowing the information. In this situation, the consumer's representative would be the appropriate person to be informed.

# 7 Investigation of Reported Events

7.1 Reported events are investigated to a depth that reflects:

(a) the seriousness of the potential risk of harm/loss or the actual harm/loss

(b) the likelihood of recurrence.

7.2 The investigation attempts to establish the course of events and possible causative/ contributory factors.

7.3 Investigation of events is the primary responsibility of line managers.

7.4 Investigations are conducted within the timeframes laid out in the policy.[17]

7.5 The line manager provides a documented report of the investigation (as required) to their immediate manager.

7.6 A process enables senior personnel with appropriate expertise and responsibility to review the investigations and actions taken by line managers to manage reportable events, and to intervene if required.[18]

7.7 There is a process that describes the managers/personnel who have authority to accept the findings of investigation reports. This process provides for the allocation of an appropriate manager to accept responsibility for the development and implementation of an action plan to remedy problems (where this is possible).

7.8 In addition to the routine reporting of reportable events in section 7, serious and/or sentinel events are reviewed in line with the methodology attached in Appendix C. This requires that:

(a) a review team is formed and approved

(b) a root cause analysis is undertaken

(c) root causes are identified

(d) a corrective action plan is developed

(e) a report that identifies residual risk and lessons learnt is completed

(f) an evaluation of the effectiveness of the actions is completed.

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[17] For example, investigations into serious events are commenced as soon as practical but within 24 hours of the event being reported. Non-serious event investigations are commenced as soon as practical, and within three days. Investigations are completed as soon as practical and if unable to be completed within 10 days notice is given to the designated senior manager and a timeframe for completion negotiated.

[18] In this context, senior personnel could include the quality manager, risk manager, health and safety manager, or directors of medicine/nursing. Each of these persons (including line managers) may involve other employees as necessary to fully manage the individual event and/or investigate for causative/ contributory factors.

# 8 Prevention of Event Recurrence

8.1 When root causes or contributory factors are identified they are documented and responsibility is allocated for developing an action plan to address them.

8.2 The recommended action plan includes:

(a) the name of the person responsible for developing and implementing the plan

(b) the actions required to develop and implement the plan (including referral to internal experts, advisors or managers)

(c) the timeline for implementing the recommended action plan (with milestones if appropriate)

(d) the methodology, criteria and date for measuring the effectiveness of the actions.

8.3 There are systems to ensure the recommended actions and solutions are communicated to employees so that:

(a) the proposed recommended actions are evaluated for their potential impact on other units or operational practices

(b) duplication of efforts to resolve closely related problems is prevented

(c) all of the expertise that needs to be involved in addressing the problem is obtained

(d) learning can occur.

8.4 Where a causative/contributory factor is identified, and its resolution requires organisation-wide changes, there is a process for referring it to the appropriate forum.[19]

# 9 Information to Employees

9.1 Employees are provided with feedback about reportable events. This will include:

(a) feedback to the reporting individual if possible and/or practical

(b) feedback to employees generally on the actions taken to address concerns raised through the reportable events system, such as via an employee newsletter or a quality improvement newsletter

(c) the effects of improvements; for example quality of outcome, time saved, harm prevented, or dollars saved.

[19] For example, quality improvement groups, patient care review groups, risk management committee, health and safety committee, infection control committee, pharmacy and therapeutics committee, medication management committee, theatre management group.

# 10 Reporting and Trends

10.1 Standard management reports are generated from completed Reported Event Forms and investigation reports.

10.2 The organisation's requirements for the reporting of a serious and/or sentinel event are met.

10.3 Information is presented graphically, wherever possible, for ease of communication.

10.4 Standard reports include:

(a) the number of events in each month and year of occurrence

(b) the number of events by type of event (these may include harm suffered by consumers, harm suffered by employees, damage to or loss of property, or medication errors)

(c) the number of serious events, including the following categories:

(i) events that caused major injury (defined as loss of function, either temporary or permanent) or death to consumers

(ii) consumers absent without the prior knowledge of the organisation

(iii) events that caused serious harm to employees, as defined in the Health and Safety in Employment Act 1992

(iv) events that caused serious property damage

(v) major security events causing harm or loss

(d) the number of events by causative/contributory factors[20]

(e) explanatory notes or cautions as to how the data should be interpreted.

10.5 At a minimum, standard reports are generated:

(a) monthly to unit managers, line managers, and staff personnel[21]

(b) quarterly to the chief executive

(c) six-monthly to the board.

10.6 Managers and staff personnel have the capacity to request additional reports to enable their analysis of specific quality and risk issues.

10.7 The employee responsible for managing event reporting has responsibility for identifying under-reporting from units or occupational groups, and developing strategies to encourage documentation of reportable events.

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[20] Causative/contributory factors could include: orientation/training, communication, consumer assessment process, physical environment, resources and/or staffing levels, equipment factors, storage/access, stress/ fatigue, information availability, competency/credentialing/professional conduct.

[21] For example, directors of medicine and nursing, quality/risk manager.

# 11 Reporting to External Agencies

11.1 Events that are reported by employees to external event reporting programmes (for example, AIMS programmes) are also reported to the organisation where the events meet the definition of reportable event specified by the organisation.

11.2 Events where employees, visitors or contractors suffer serious harm are reported to the Department of Labour as required by the Health and Safety in Employment Act 1992.[22]

11.3 Critical incidents occurring to consumers subject to the Mental Health (Compulsory Assessment, and Treatment) Act 1992 are reported to the Director of Mental Health (see Appendix D).[23]

11.4 Unintended adverse reactions occurring in association with the use of medicines are reported to the Centre for Adverse Reactions Monitoring (CARM) (see Appendix E).

11.5 Events related to the quality of medicines are first referred to that part of the organisation providing pharmaceutical services (eg, hospital pharmacy). Onward referral to Medsafe should be considered for serious issues. Contact the Compliance Team at Medsafe, Ministry of Health, tel: (04) 496 2176 or (04) 496 2000; fax: (04) 496 2229.

11.6 Events involving a medical device that has caused or could have caused an injury to the patient or the device user should be reported to the Compliance Team at Medsafe, Ministry of Health, tel: (04) 496 2176 or (04) 496 2000; fax: (04) 496 2229.

11.7 Events relating to the misadministration of radioactive materials are reported to the National Radiation Laboratory (see Appendix G), as required under Section 17.4 of NRL Code C-3 (1994).

11.8 Events involving the safety of electrical equipment are reported to the Energy Safety Service, Ministry of Consumer Affairs (see Appendix H).

11.9 Events involving fuel gas (mainly natural gas and LPG) are reported to the Energy Safety Service, Ministry of Consumer Affairs (see Appendix I).

11.10 Explosive events are reported to the Dangerous Goods Inspector or the equivalent.[24]

11.11 Each of these events is managed according to the organisation's usual reportable events policy and procedure *unless* specifically exempted in writing by the organisation in the reportable events policy and procedure.

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[22] As providers are familiar with this legislation, no further information is provided on health and safety reporting in these guidelines.

[23] There is no other *requirement* to report events to the Ministry of Health except under licensing. This requirement will be removed when the Health and Disability Service (Safety) Bill is passed. The reporting requirements under this Bill were not available at the time these guidelines were published.

[24] The requirements for reporting vary between territorial authorities. Contact your licensing territorial authority for their requirements.

# 12 Training

12.1 The training provided to employees emphasises the quality improvement focus of event reporting and discourages 'name, blame and shame' attitudes and behaviours.

12.2 Training of employees occurs during orientation and covers the event reporting policy and procedures.

12.3 Employees are regularly reminded of the need to report.

12.4 There are opportunities for retraining at least annually.

12.5 Employees with responsibility for investigating reportable events (and reviewing the results of investigations) receive training in event investigation within one month of appointment to the position.[25] This includes all line managers and senior staff personnel. Training includes simulation exercises.

# 13 Confidentiality, Retention, and Storage

13.1 There is a system to collate the documentation related to an event's management and investigation so that it can be stored centrally.

13.2 Completed Reportable Event Forms and documentation are stored securely under conditions that comply with the Privacy Act 1993 and Health Information Privacy Code 1994.

13.3 Original Reportable Event Forms and documentation relating to the management of the event are kept for at least 10 years after the occurrence of the event.

13.4 If Reportable Event Forms are filed in the consumer's clinical record, then all documentation relating to the event is kept until the consumer's record is destroyed, or until the record permanently leaves the control of the organisation (for example, is given to the consumer).

13.5 Archived computer data is retained according to the organisation's document retention policies.

# 14 System Assurance

14.1 There is an auditable trail of documentation for each reported event: from completion of the Reportable Event Form to outcome. Depending on the depth of the investigation, this could include the following process:

(a) completion of the Reportable Event Form

[25] The organisation implements a process to offer event investigation training to existing employees with investigation responsibilities.

(b) remedying the event at the time of discovery
(c) investigating the event
(d) identifying causative/contributory factors
(e) developing an action plan to address causative/contributory factors
(f) implementing the plan
(g) evaluating the plan
(h) informing managers (and, as necessary, the initial reporter) of the final outcome.

14.2 There is a system for conducting audits to evaluate compliance with the organisation's reportable event policy and procedures.

14.3 The reportable events system is evaluated at least three-yearly, and at any other time if a major change is made to:
(a) the reportable events management system
(b) the management structure of the organisation.

# Appendix A: Event Categories

## Reportable events

Reportable events include:

- events that have resulted in harm[26] to consumers, visitors, and employees that are discovered upon entry to the service, or occur during service provision
- serious harm suffered by employees/visitors/contractors as defined in the Health and Safety in Employment Act 1992
- events that reflect an unsatisfactory situation in terms of the quality of clinical practice, quality of operational management, or quality of service delivery systems, and that require reporting to managers. This may include events related to the organisation's interface with other organisations, such as other service providers
- events that have resulted in, or could have resulted in, loss or damage to property relating to consumers, visitors, employees or the organisation
- events that have resulted in, or could have resulted in, damage to the environment
- events that could have caused harm/serious harm/damage/loss if:
  (i) the situation had not been rescued in time to prevent harm occurring
  (ii) employees foresee that a recurrence of the event could result in harm.

## Serious events

The characteristics of a serious event include:

- a system failure resulting a reduction in the quality of service
- significant deviation from the organisation's usual process
- did not result in but has potential to result in significant harm
- an event that must be reported to regulatory bodies under statute
- an event that needs to be reported to the organisations insurance carrier
- the potential for adverse media attention.

A serious event is one that has the potential to result in death or major permanent loss of function, not related to the natural course of the consumer's illness or underlying condition.

Examples of serious events include those resulting from:

- missed or misdiagnosis
- incorrect or incorrectly performed procedure/medication
- contraction of notifiable blood-borne disease

[26] Harm includes physical or emotional harm that is unrelated to the natural course of the consumer's illness or underlying condition. The harm may result from actions or omissions by employees.

- harm resulting in admission to intensive care unit from ward or transfer to another provider
- employment of a person fraudulently posing as a registered health professional
- absence without leave of a client who may be seen as a danger to themselves or others
- serious harm involving staff
- failure in emergency management procedures resulting in a major disruption to patient care.

## Sentinel events

The characteristics of a sentinel event include:

- major system failure
- multiple teams, departments or services are involved
- the potential for serious adverse media attention
- the potential to seriously undermine public confidence
- when a group of consumers have potentially suffered harm.

Examples of sentinel events are:

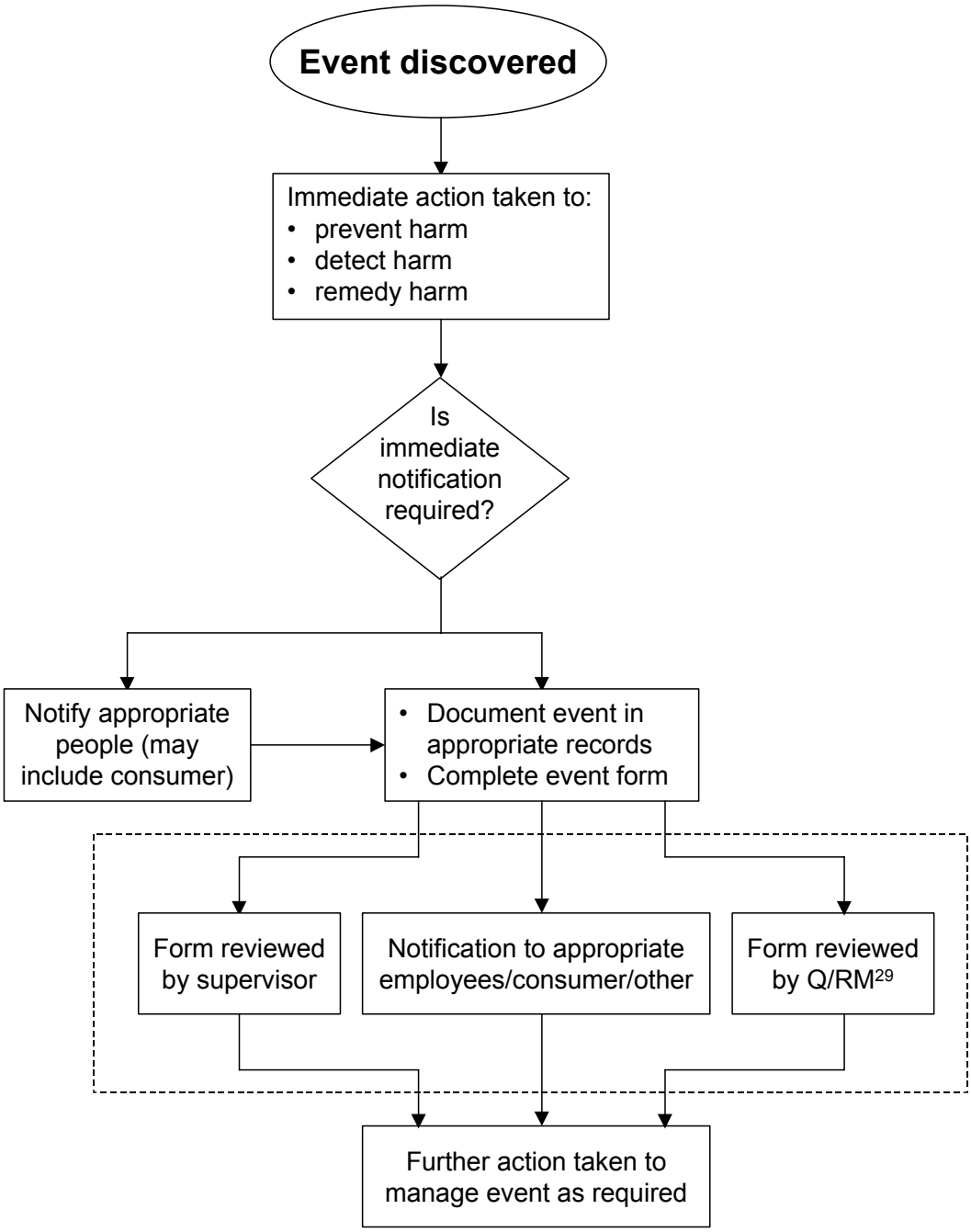
- an event which has resulted in an unanticipated death or major permanent loss of function[27] not related to the natural course of the consumer's illness/underlying condition[28]/pregnancy/childbirth;
- one of the following events (even if the outcome was not death or major permanent loss of function):
  - suicide of a consumer while in intensive psychiatric care
  - infant abduction or discharge to the wrong family
  - invasive procedure or intervention on the wrong patient or wrong body part
  - attempted or alleged sexual abuse or rape
  - errors of omission or commission that result in significant additional treatment or are life threatening, for example, medication errors, iatrogenic injury, recall of patients.

[27] This means sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or life-style change. When 'major permanent loss of function' cannot be immediately determined, applicability of this process is not established until either the patient is discharged with continued loss of function, or two weeks have elapsed with persistent major loss of functions, whichever occurs first.

[28] This means that death/loss of function occurs due to treatment, or lack of treatment, of the consumer's illness/condition.

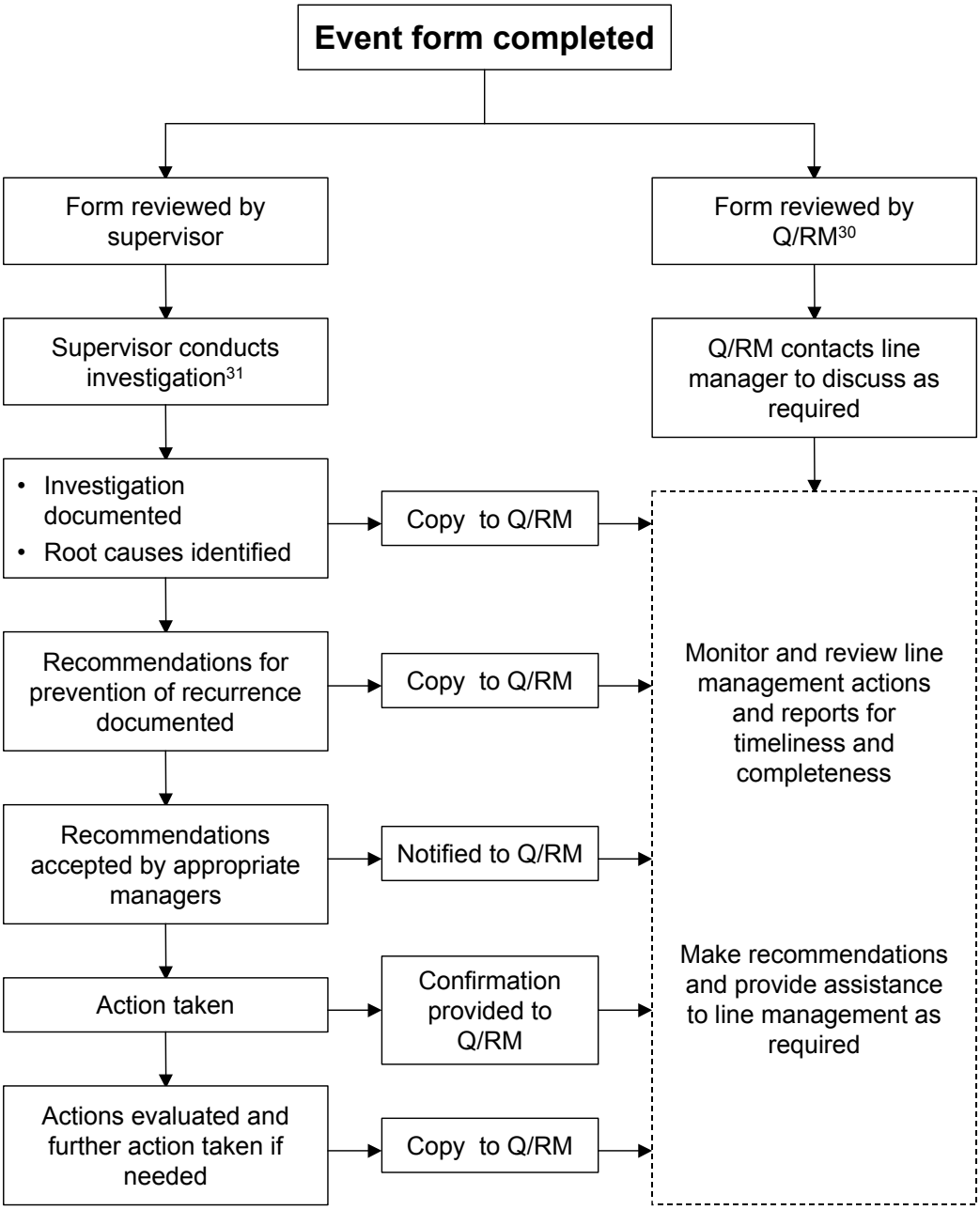
# Appendix B: Sample Reportable Event Flow Sheets

**Figure A1:** Management of events




[29] Q/RM – quality/risk management, or the equivalent function within the organisation.

**Figure A2:** Review and investigation of events




[30] Q/RM – quality/risk management, or the equivalent function within the organisation. Q/RM could refer the event to other expert personnel or committees as required, eg, health and safety, medicine management committee, facilities management.

[31] They may be assisted by appropriate persons, eg, infection control, security.

# Appendix C: Methodology for Investigating Reportable Events

When the very serious mistakes or errors (the '1 in a 1000' event which can be identified as a sentinel event) occur in organisations it is recommended that an investigation of the event be undertaken.

The following methodology has been adapted for the New Zealand health sector by a working group (P8152 – Sentinel Events) sponsored by the Ministry of Health and facilitated by Standards New Zealand. This methodology is outlined below and is available in a work book format from Standards New Zealand. Figure A3 at the end of this appendix illustrates the investigation and reporting process.

## Identification of a sentinel event

### *Determine the significance of the event and whether further investigation is needed*

Each organisation has a policy that clearly describes the circumstances that initiate a sentinel event investigation. The following actions are required.

- Identify that this is a sentinel event and that an investigation is required.
- Identify who is responsible for initiating the investigation (usually this will be a trained sentinel event investigation leader who has knowledge of the area affected by the sentinel event).
- Identify who should be notified that an investigation is required.
- Request approval for the investigation.
- Complete the appropriate form for the 'identification of a sentinel event'.

## Select the people for the investigation team

### *Bring together people who have an intimate knowledge of the 'normal process'*

Appropriate experts are essential for the sentinel event investigation. In some cases an existing group or team may be available to conduct the investigation, but in most cases a special team will need to be assembled to ensure all relevant parties are represented.

Ideally, the investigation team should consist of three or four people facilitated by the investigation leader. It is important to identify team members with multiple skills and the time to commit to the process. The range of expertise may include a combination of the following:

- knowledge of the affected system
- knowledge of the particular area affected

- senior responsibility for the affected area
- investigation experience
- knowledge of causal factors
- external expert view
- patient advocacy
- senior management experience.

Consider preparing terms of reference to assist the team to achieve its objectives.

## Plan the investigation

### *Collect facts, knowledge and physical items related to the event as soon as possible*

At this stage only a high-level collection of information is required. This will often be incomplete, and should focus on collecting knowledge, information or physical evidence that may be lost.

Excellent communication skills are required to facilitate this process in order to gain people's trust in the process and to collect *all* relevant information.

The purpose of collecting information at this stage is to:

- secure information to ensure it is available for use during the investigation
- describe the sentinel event, including the sequence of events leading up to the incident
- organise the information
- provide initial direction to the investigation team
- identify relevant policies and procedures
- identify what information is required to be collected about the event.

It is important to plan the investigation carefully at this stage to ensure that all data sources are identified. This may include collecting documentation, records and forms in relation to the event, including:

- statements and observations
- physical evidence and/or equipment contributing to the event
- information about relevant conditions affecting the event.

Information is best collected as soon as possible after the event has occurred. The use of a numbering or referencing system will assist in referring to and tracking information easily.

## Determine the sequence of events

### *Understand the event to ensure investigation accuracy*

The investigation team conducts a detailed investigation into the events contributing to the sentinel event to determine the sequence of events. Typically this is in much greater detail than the initial collection of information conducted by the investigation leader.

Numerous tools are available, and those selected are at the discretion of the investigation team. These include:

- *time person grids:* these allow you to follow the movements of people before, during and after the event
- *reverse chronological timeline:* this helps in working backwards from the event, to discover any parts of the process where problems may have occurred; the time person grids and reverse chronological timeline may be combined on one chart
- *flow charts:* these draw a picture of the movement of people, materials, documents or information within a process. In determining the sequence of events it may be useful to develop separate flow charts that illustrate (a) the sequence of events as documented in the policies and procedures; (b) the sequence of events that occurred during the sentinel event; and (c) an improved sequence of events.

The process for determining the sequence of events may flag 'issues' associated with, but not directly relevant to, the sentinel event investigation. It is useful to maintain a record of these in order to address them separately.

## Identify the event's causal factors

### *Identify factors that contributed to the event*

Having identified the sequence of events in detail, the investigation team should commence the identification of causal factors. This may include the following.

- *Brainstorming:* brainstorming to create a cause and effect diagram is often useful at this stage.
- *Cause and effect (fishbone) diagram:* the 'fishbone' diagram lists presumed causes on the ribs of the fishbone, grouped according to the major categories.
- *Active and latent failures:* according to this model, errors in a complex system can be divided into two classes: active failures and latent failures. Errors made by the operators performing the processes are active failures; for example, actions by a doctor, nurse or any other direct caregiver. Latent failures are attributed to people who influence the system; for example, housekeeping, maintenance, information systems and management.
- *Tier analysis chart:* this is a tool that assists the investigation team to identify basic system deficiencies by reviewing all the contributing factors, and amalgamating, combining or eliminating them to determine causal factors. Tier 0 consists of significant facts, including the direct cause of an event. Tiers 1 and 2 comprise contributing factors, which are added to the diagram in successive importance. Each tier builds on the data presented in the tier preceding it. Tier 3 identifies causal factors. Tier 4 determines the basic system deficiency or deficiencies that, if corrected, would prevent recurrence of the event.

## Select root cause(s)

### *Find correctable root cause(s) for the sentinel event*

Root causes are the most basic events or conditions that, if eliminated or identified, would reduce the possibility of the sentinel event and its consequences recurring. The analysis of the sentinel event's causal factors will determine the incident root cause or causes. It is essential that the investigation team is confident that they have adequately analysed the contributing factors to determine the actual root cause(s).

Root causes include:

- errors
- omissions
- slips
- system deficiencies
- inadequate competencies
- non-adherence to policies, procedures, protocols or work instructions
- poor communication or documentation
- inadequate facilities or equipment
- inadequate skill mix or availability of the health care team
- managerial inaction.

It is usual to identify more than one root cause, so the team will need to prioritise the solutions to each root cause. Having prioritised the solutions, corrective action should commence at the earliest opportunity.

Some solutions or actions will not eliminate all aspects of the root cause. This remaining level of risk, after treatment measures have been taken, is referred to as residual risk.

It is important to consider both the positive and negative impact of the proposed solutions on:

- interlinking processes within the whole system
- identical processes in different departments or services
- the effects on patients and staff who have infrequent but significant interaction with the process or service.

## Develop corrective action plan

### *Ensure recommended actions address root causes*

This key step in the sentinel event investigation process generates a measurable plan to address the root causes that either directly or indirectly contributed to the sentinel event.

An action plan should:

- list the root causes
- list the actions to address the root causes, as determined by the investigation team
- identify who is responsible for implementing the action(s)

- identify the timeframe for implementation
- identify any resource requirements
- evidence of completion (including measures for ongoing monitoring where required)
- formal sign-off of actions as they are completed
- identify the date to evaluate the effectiveness of the action plan.

## Report

### *Summarise the sentinel event investigation*

The purpose of the investigation team's report is to convey the results of the investigation in a manner that will help the reader understand what happened (the event description and chronology), why it happened (the causal factors and the root cause), and what can be done to prevent a recurrence (the proposed corrective actions).

All names should be excluded and, where necessary, assigned a number and role (for example, registrar 1, registrar 2).

The report should include the following components.

### Summary:

- statement of the event
- summary of root causes
- summary of actions.

### Introduction:

- a brief background description of the sentinel event and its results, and a statement regarding the team assigned to conduct the investigation
- descriptions of the scope of the investigation, its purpose, timeframe, methodologies employed in conducting the investigation and the findings.

### Analysis and findings:

- a factual description of the event, including chronology and responses to the event
- brief descriptions of and results from analyses that were conducted (for example, change analysis, events and causal factors analysis, and root cause analysis)
- include charts or diagrams in the appendix section of the report.

### Recommendations:

- root cause(s) identified and the rationale for selecting the root causes
- those not dealt with residual risk

- proposed and/or implemented corrective actions: *solutions* are to be correlated with root cause(s) to which they apply (who, what, when)
- rationale for choice of corrective action, including rejected corrective actions
- evaluation plans for evaluating the effectiveness of corrective actions, eliminating, minimising and isolating the root cause.

### Learning points:

- a specific listing of the learning points that need to be passed on to appropriate departments/staff, either through formal training or through some other means, such as individual feedback or required reading.

### Residual risk(s):

- where the RC is not addressed, or there is outstanding risk, the report should state the:
  - likelihood of recurrence
  - consequences of recurrence
  - control effectiveness if recommended actions are taken.

### Attachments:

- a listing of all attachments and references to this report; this may include, but is not limited to, flow charts, existing policy or new policies, and external standards.

## Implementation

#### *Ensure the corrective action plan is finalised and implemented*

A quality improvement approach is useful during the implementation stage. This may be achieved by the use of the PDCA (plan, do, check, act) cycle, IMPROVE (identification, map, problems, reasons, options, venture, evaluate/establish) or other continuous quality improvement methods. Implementation of the plan should follow the steps listed below.

1 Plan implementation of the corrective actions. Consideration should include:
- communicating the results
- investigating policies and procedures
- implementing training
- establishing plans for ongoing monitoring
- identifying other areas where the improvement could be implemented
- identifying barriers to change.

2 Pilot actions.

3 Test the effectiveness of the change.

4 Implement the recommended action.

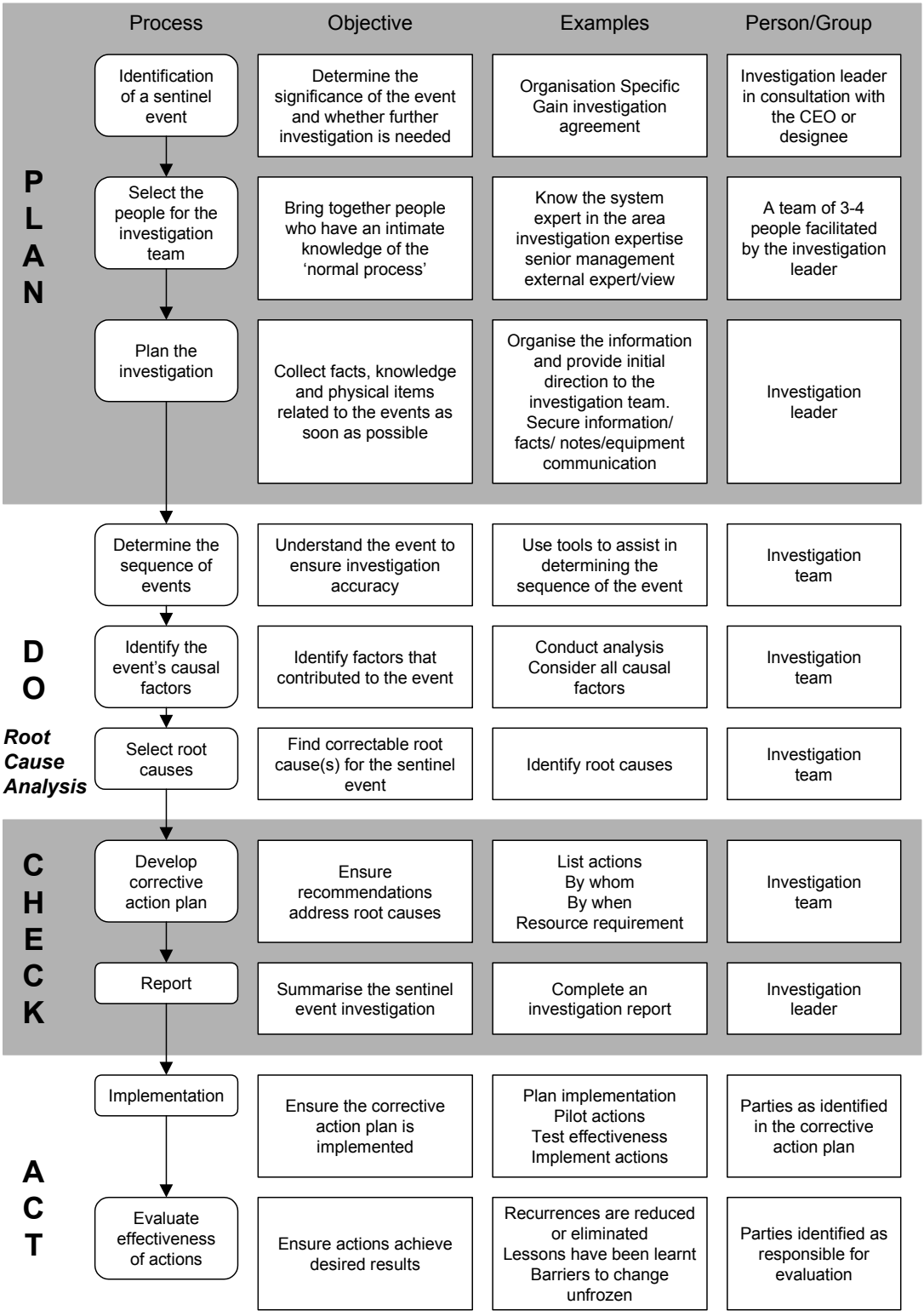
## Evaluate effectiveness of actions

### *Ensure actions achieve desired results*

At the evaluation date the changes/solutions specified within the action plan should be evaluated to ascertain the level of implementation and effectiveness. This is to ensure that:

- the root cause(s) have been addressed
- recurrences have been reduced or eliminated
- lessons have been learnt and communicated
- identified barriers to change have been unfrozen
- the loop is closed.

**Figure A3:** The investigation and reporting process



# Appendix D: Incidents related to Mental Health Consumers

Events that occur involving consumers subject to the Mental Health Act 1992 that require reporting to the Director of Mental Health, Ministry of Health, include, but are not limited to:

- all unexpected or sudden deaths
- all incidents involving serious harm to the person or others
- all serious injury involving violence to other patients or staff
- any other very serious incident.

# Appendix E: Reporting a Serious Event Associated with a Medicine

Unintended adverse events may occur in association with medicine use with appropriate prescribing and use of the medicine. They may also occur as a result of an error, including errors occurring because of inadequate labelling and lack of awareness of the adverse effects of the medicine.

These unintended adverse events, particularly those that are serious, or of clinical concern, are reported to the Centre for Adverse Reactions Monitoring (CARM) (Freepost 112002, CARM, PO Box 913, Dunedin, or fax (03) 4777150) using the following form. The form is also stapled into the centre of each issue of *Prescriber Update*, and can be downloaded from both the CARM and Medsafe web sites (www.otago.ac.nz/carm and www.medsafe.govt.nz).

More information about reporting adverse reactions to medicines can be found on the Medsafe web site at: www.medsafe.govt.nz/Profs/adverse.htm

**Form for Reporting Adverse Reactions to Medicines, Vaccines and Devices and all Clinical Events for IMMP**

CARM fax: 03 479 7150
CARM phone: 03 479 7247

PATIENT DETAILS

| Surname: | First Name(s): | NHI No: |
|---|---|---|
| | | Date of Birth: |
| Address: | | Sex: |
| | | Ethnicity: |

ALL MEDICINES IN USE – ASTERISK SUSPECT MEDICINE(S)
– Include OTCs and alternative medicines

| Medicine(s); Vaccine(s) + batch no | Daily Dose | Route | Date Started | Date Stopped | Reason for Use |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

DESCRIPTION OF ADVERSE REACTION OR INCIDENT

Date of Onset .....

Recovered ☐ Not yet recovered ☐ Unknown ☐ Fatal ☐ Date of Death: .....

Severe? Yes ☐ No ☐ Rechallenge? No ☐ Yes ☐ Result:.....

OTHER FACTORS – Please circle or specify as appropriate

Renal disease Hepatic disease Allergy Nutritional supp: Other medical conditions Chemical exposure

REPORTING DOCTOR/PHARMACIST/DENTIST/NURSE/OTHER

Name:

Address: Phone:

Signature: ..... Date: ..... / ..... / .....

DANGER/WARNING: ..... Input by: ..... Date: .....

# Appendix F: Reporting an Incident relating to a Medical Device

The aim of the scheme is to minimise adverse affects of incidents associated with a medical device and to improve the standard of medical devices. A medical device includes any material, instrument, machine, appliance, implant or component of these used in the delivery of health care other than a medicine. Medical instruments, catheters, drainage bags, drug infusion pumps and diagnostic equipment are all examples of medical devices.

Please use the attached form to report the problem. When a report is received, Medsafe contacts the distributor and works with them to resolve the problem. Medsafe and the Australian Therapeutic Goods Administration exchange information on any significant incident investigated.

Commonwealth Department of Health and Family Services

TGA THERAPEUTIC GOODS ADMINISTRATION

MINISTRY OF HEALTH
MANATU HAUORA

**The Australian and New Zealand Medical Device Incident Report Investigation Scheme**

**What is it?** The Scheme is a joint venture between the Australian Therapeutic Goods Administration and the New Zealand Ministry of Health intended to help maintain the standard of devices used in health care through voluntary co-operation between users, government and industry. It should be used in conjunction with local reporting channels. It provides an additional means by which unsafe products or procedures can be identified quickly so that appropriate action is taken.

Use this form to report any suspected problems with a therapeutic device which has or may present a health hazard. Reports originating in Australia should be sent to the Therapeutic Goods Administration and reports originating in New Zealand should be sent to the Ministry of Health.

**What should be reported?** 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 happens to your report?** The report will be investigated and discussed with the manufacturer/supplier. You may be contacted for further information. If appropriate both Agencies will assess the issue and it 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, efficiency or quality. 2. Therapeutic Device Alert – urgent information to inform those responsible for the device, or affected by the problem. 3. Report in a Therapeutic Device 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 Incident Report

Use this form to report any suspected problem with a therapeutic device which may create a health hazard. A therapeutic 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 diagnostic reagents.

**A. Product Identification** *(Provide all available details. Where * appears, delete whichever is not applicable)*

1. Product type/application (eg, urinary catheter)

2. Brand/trade * name and model number

3. Serial/batch/lot * number

4. Date of manufacture | Date of purchase | Date of expiry | * AUSTL or AUSTR No.

5. Manufacturer's name address and telephone

6. Supplier's name address and telephone

7. Has the manufacturer been informed of the problem? Yes ☐ No ☐

   If Yes, please supply the date and contact name

8. Is the product/packaging * available for inspection? Yes ☐ No ☐

***(please do not discard these items)***

**Important: Please fill in Sections B and C overleaf**

**B. Problem Description:**

1. Consequences and history of problem:
*(please Include history, circumstances, consequences and where relevant sketches or explanatory information)*

**C. Reporter Identification** Do you want your identity to remain confidential? Yes ☐ No ☐

1. Name
2. Position/ occupation
3. Dept or institution
4. Address
5. Telephone Facsimile

E-mail Office Use

Signature Date

**D. Submitting the Form**

**In Australia:**
Reply Paid 32
The Manager
Medical Device Incident Report Investigations
Therapeutic Goods Administration
PO Box 100 Wooden, ACT 2606
AUSTRALIA
**Fax Number: (02) 6232 8555,**
**E-mail: iris@health.gov.au**
**Urgent problems may be reported by telephone to our HOTLINE : 1800 809 361**

**In New Zealand:**
Compliance Team
Medsafe
Ministry of Health
PO Box 5013
Wellington
NEW ZEALAND
**Fax Number: (04) 496 2599,**
**E-mail: trevor_nisbet@moh.govt.nz**
**Urgent problems may be reported by telephone on (04) 496 2364**

This form is available on-line at www.health.gov.au/tga/froms.htm (TGA website) or www.medsafe.govt.nz (Medsafe website)

# Appendix G: Notification of Events to the National Radiation Laboratory

Notification of incidents during which a misadministration of radioactive materials occurs is required under Section 17.4 of RL Code C-3 (1994). Notification should be made by telephone call (tel: (03) 366 5059) in the first instance to the Director or the Manager, National Radiation Laboratory, Christchurch. After discussion, the type of information the NRL wants reported will be agreed. The NRL do not have an official form but each provider may devise their own as required. A form used by one provider is given for your information.

---

The Director or the Manager
National Radiation Laboratory
PO Box 25-099
**Christchurch**

Dear Sir or Madam:

As required under Section 17.4 of RL Code C-3 (1994), enclosed are details of an incident during which a misadministration of radioactive materials occurred.

| **Consumer Details:** | | |
|---|---|---|
| ID no.: | Sex: | Age: |
| Pregnant: | Lactating: | |
| **Incident Details:** | | |
| Date: | | |
| Examination: | | |
| Radionuclide: | Form: | |
| Activity prescribed: | Administered: | |
| Problem: | | |
| Consequence: | | |
| Signed: | Title: | |
| Dated: | | |
| Follow up: | | |
| Signed: | Title: | |
| Dated: | | |

# Appendix H: Electricity Act – Accident Reporting

The Electricity Act 1992 (section 16) requires that two types of events must be reported to the Secretary via the Energy Safety Service (ESS), Ministry of Consumer Affairs:

1 Any injury that results in serious injury or death of any person from an accident that:
- is caused wholly or partly by electricity; or
- involves or affects electricity; or
- involves or affects the use of electricity.

2 Every accident that consists of or includes an electrically initiated fire, where that fire results in:
- damage to any place; or
- damage to part of any place *and* renders it unusable for its intended purpose.

## Examples of electricity-related reportable events

The following examples describe the types of events to be reported:
- electrical shock or burns from electricity that involve direct or indirect contact
- short circuit or explosion causing burns
- accidents caused by the failure of an appliance to perform to its required standard
- any fire that is electrically initiated, ie, fires caused by electrical appliance or electrical installation.

## How to notify events

1 *Immediately* report the event's occurrence to the ESS on the 24-hour free phone: 0800 104 477.

2 *Within two weeks* of phone/fax notification, complete and submit an Electrical Accident Notification Report to the ESS. A copy of the accident form for reporting electrical events to the Secretary, can be found at www.ess.govt.nz.

## Other recommended actions

In addition to reporting to the ESS, it is *strongly recommended* that faults be reported to the equipment's manufacturer (or their agent) using the fault-logging forms provided by them for that purpose.

## Reporting to Department of Labour

Through a mutual understanding agreement, if the injury is reported to the Department of Labour then it is deemed to be reported to the ESS.

## For your information

Eventually, the ESS and the Department of Labour are intending to enable on-line reporting to both organisations using a common form. There is no similar memorandum of understanding between the Ministry of Consumer Affairs and the Ministry of Health.

# Appendix I: Gas Act – Accident Reporting

The Gas Act 1992 (section 17) requires that events relating to gas accidents must be reported to the Secretary via the Energy Safety Service (ESS), Ministry of Consumer Affairs. The detail of reporting is contained in Regulations 33(1) and 33(2).

Any accident that involves the production, supply, distribution, or use of gas and:

- that results in serious injury or death or any person; or
- significantly damages any property

must be reported.

Appropriate persons must notify accidents when they become aware of them. 'Appropriate persons' are defined as:

- gas distributors or gas retailers where the accident involves gas supplied by them
- registered gasfitters, craftsman gasfitters or registered gas inspectors within the meaning of the Plumbers, Gasfitters, and Drainlayers Act 1976 if they discover the accident
- persons working under an employer licence issued under the Plumbers, Gasfitters, and Drainlayers Act 1976 if they discover the accident.

In all other cases, the occupier of the place where the accident occurred must report the accident.

## How to notify events

- *Immediately* report the event's occurrence to the ESS on the 24-hour free phone 0800 104477.
- *Within seven days* of verbal notification, complete and submit either a:
  - gas appliance and installation incident or accident form; or a
  - gas distribution incident or accident form.

## The forms

The forms have fields for the information required by regulation 33 as well as for other information. The forms themselves are not prescribed by regulation. The fields on the forms relate to fields in an electronic database for the recording of accidents and incidents (near miss events). The ESS also maintains a database for equipment faults, which links to the accident/incident database.

The 0800 number listed at the top of the form for the notification of both gas- and electricity-related accidents links to a paging service, which operates 24 hours a day.

# Appendix J: Literature Review

| Article | Commentary |
|---|---|
| Battles JB, Kaplan HS, Van der Schaaf TW, et al. The attributes of medical event-reporting systems: experience with a prototype medical-event reporting system for transfusion medicine. *Archives of Pathol Lab Med* 122 (March 1998): 231–8. | Proposes a classification system for medical errors/events. |
| Beckmann U, West LF, Groombridge GJ, et al. The Australian incident monitoring study in intensive care: AIMS-ICU: the development and evaluation of an incident reporting system in intensive care. *Anaesth Intensive Care* 24 (1996): 314–19. | Describes the AIMS-ICU project and provides useful background information for ICUs that might want to know more about this programme, including its benefits and deficiencies. |
| Byrne AJ, Jones JG. Inaccurate reporting of simulated critical anaesthetic incidents. *British Journal of Anaesthesia* 78 (1997): 637–41. | The key finding was that while the 11 anaesthetists treated the 'patient' properly, only one anaesthetist correctly identified the problem. None accurately recorded the simulated events/time scale. The author observes that memories are stored as schemata, so that, with the highest integrity, we soon start reporting not what happened, but *what must have happened.* |
| Cullen D, Bates D, Small S, et al. The incident reporting system does not detect adverse drug events: a problem for quality improvement. *Journal on Quality Improvement* 21, 10 (1995): 541–8. | One of many available articles that identify under-reporting as a major issue for incident reporting systems. |
| ECRI. Rooting out hidden causes of adverse events. *The Risk Management Reporter*, June 1999. | A good overview of root cause analysis in health care, including the quote: 'everyone is willing to blame the system for problems until they realise you're talking about a system they are invested in and believe in.' |
| Lack A. Critical incidents. *Anaesthesia* 53, 10 (1998): 1035. | Describes a preventability scale for categorising incidents developed by the Royal College of Anaesthetists. |
| Leape L. Error in medicine. *Journal of the American Medical Association* 272, 23 (1994): 1851–7. | Gives an overview of problems affecting the effectiveness of incident reporting systems and error prevention strategies. The article discusses issues in the context of Reason's model of error causation. A useful article to make available to doctors. |
| Ray NK. 1995 from paper tigers to consumer-related quality assurance tools: reforming incident-reporting systems. *Mental Retardation* 33, 4 (1995): 239–47. | A good article about making incident-reporting systems consumer focused. |
| Sutton JC, Standen PJ, Wallace WA. Patient accidents in hospital: incidence, documentation and significance. *British Journal of CP* 48, 2 (1994): 63–6. | Ignore the final sentence of this article, which advocates abolition of incident reporting. Instead note that consumers' and nurses' perceptions of the types and causes of events differ widely. |

| | |
|---|---|
| Wilson D, McArtney RG, Newcombe RG. Medication errors in paediatric practice: insights from a continuous quality improvement approach. *European Journal of Pediatrics* 157 (1998): 769–74. | Identifies under-reporting when compared incidents to using trained observers recording incidents. The authors note that reporting of adverse incidents encourages multi-disciplinary co-operation, which is an integral part of the CQI process. |