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# A Reference Guide for Learning from Incidents in Radiation Treatment

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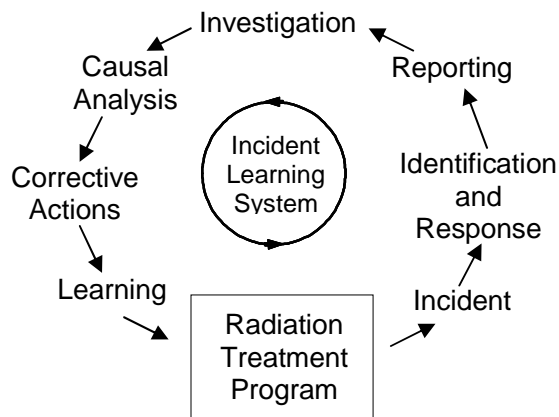
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**For more information contact:  
Health Technology Assessment Unit  
Alberta Heritage Foundation  
for Medical Research**

Suite 1500  
10104 - 103 Avenue  
Edmonton, Alberta  
Canada T5J 4A7

Tel: 780 423-5727  
Fax: 780 429-3509

# A Reference Guide for Learning from Incidents in Radiation Treatment



**David L. Cooke, Meina Dubetz,  
Rahim Heshmati, Sandra Iftody,  
Erin McKimmon, Jodi Powers,  
Robert C. Lee, Peter B. Dunscombe**



**HTA Initiative #22  
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*Prepared by:  
David L, Cooke, Meina Dubetz, Rahim  
Heshmati, Sandra Iftody, Erin McKimmon,  
Jodi Powers, Robert C. Lee, Peter B.  
Dunscombe*

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Additional information and comments  
relative to the initiative report are  
welcome and should be sent to:

Director, Health Technology Assessment  
Alberta Heritage Foundation for  
Medical Research  
1500, 10104 - 103 Avenue NW  
Edmonton, Alberta, Canada T5J 4A7

Tel: 780-423-5727  
Fax: 780-429-3509

[www.ahfmr.ab.ca](http://www.ahfmr.ab.ca)

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- Dr. Michael Herman, Mayo Clinic, Rochester, MN

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This reference guide for learning from incidents was developed by the RT Quality Assurance Committee at the Tom Baker Cancer Centre. Its development was facilitated by David L. Cooke, HQCA Research Fellow in Patient Safety, as part of a research program in patient safety and risk management directed by Robert C. Lee and Peter B. Dunscombe of the University of Calgary.

## PREFACE

The Alberta Heritage Foundation for Medical Research (AHRMR) health technology assessment initiative series provides policy and decision makers with the best information available on how to redesign their healthcare structures and processes to effectively improve the outcomes of their delivery systems. The safety of healthcare delivery systems and the safety of patients are very important outcomes.

When patients enter the health care system they expect to receive treatment and care that will lead to improvement in their condition. While they might be uncertain as to the probability of success of whatever medical procedure they are undertaking, they have high expectations for the quality of care that they will receive. They do not expect their condition to deteriorate as a result of adverse events in the medical treatment process. Indeed, “the primary objective of Canadian health care policy is to *protect*, promote and restore the physical and mental well-being of residents of Canada...” (Emphasis added).<sup>1</sup>

Part of our responsibilities as health care professionals is to recognize that incidents are normal and *will* occur in complex medical systems, and that some of these incidents may directly, or through interaction with latent unsafe conditions, cause an adverse event that harms the patient. Recognition that errors lead to incidents and that incidents lead to adverse events is the first step along the process of building fault-tolerance and robustness into the health care system. The second step is to have in place a *management system* to identify and respond to incidents in a way that supports organizational learning.

We present a model process that will assist health care organizations in developing and implementing a formal management system for learning from incidents. Developed specifically for the Radiation Treatment (RT) Program at the Tom Baker Cancer Centre, a major cancer treatment centre in Calgary, Alberta, Canada, the incident learning system described in this reference guide is built on sound safety management principles. It will contribute to the Alberta Cancer Board’s development of organization wide patient safety programs. It can easily be adapted for use at other health care institutions.

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## GLOSSARY

**Adverse event:** An incident that occurs during the process of providing health care and results in sub-optimal clinical outcome including unintended injury or complication leading to disability, death or prolonged hospital stay for the patient.

**Basic causes:** The underlying systemic causes of an incident which, when identified, permit meaningful management control.

**Domain:** A logical grouping of work processes within a clinical treatment process. For example, we have defined five domains within the radiation treatment process.

**Dose variation (or dose error):** Prescribed dose differed from administered dose

**Error:** A failure to complete a planned action as it was intended or a situation in which an incorrect plan is used in an attempt to achieve a given aim.

**Incident:** An unwanted or unexpected change from a normal system behavior, which causes or has a potential to cause an adverse effect to persons or equipment.

**Infrastructure incident:** A type of clinical incident that results from errors during design, manufacture, setup, commissioning, maintenance, upgrade or repair of equipment.

**Misadministration:** An incident in which a deviation from a prescription exceeds a defined tolerance.

**Potential incident (“near miss” or “close call”):** An incident that causes no harm but signals a potential weakness in the health care system. A potential incident can be classified as a potential serious incident or a potential major incident depending on its potential for harm to persons or equipment.

**Originator:** The person who discovers the incident

**Process incident:** A type of clinical incident that results from errors during the execution of a standard operating procedure.

**Protraction:** The act of prolonging something, e.g., extending the treatment time over a period of time.

**Random error:** Uncertainty or the limit of precision. For example, the random error associated with patient set-up on a machine is not really an error in the sense of a mistake but rather is variation associated with the limit of precision when repeating a process many times.

**Safety implications:** A hazard to the individual committing a security breach (e.g. entry into a hazardous area) and/or staff or patients, the community or the environment.

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***Security breach:*** Trespassing, weapons possession, break and enter, violation of security procedures, compromise of information or communication systems, disorderly conduct.

***Sporadic incident:*** An incident that occurs in a purely random fashion. In RT, an example of a sporadic incident would be omitting a prescribed wedge filter for a patient during one session of treatment delivery

***Systematic incident:*** An incident that will occur predictably under similar circumstances. It has the potential to affect multiple fractions in one patient or multiple patients until discovered and fixed. In RT, an example of a systematic incident would be the input of incorrect basic data in treatment planning system.

***Volume variation or volume error:*** Target volume differed from administered volume.



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## INTRODUCTION

### Background

The influential Institute of Medicine (IOM) report *To Err is Human: Building a Safer Health System*<sup>2</sup> brought adverse events (AEs) and the need for improvements in patient safety to the forefront of health research and practice in North America. The Canadian adverse events study<sup>3</sup> demonstrated the need for similar patient safety improvements in Canadian health care. The IOM report recommended a four-tiered approach to improve patient safety. One of these tiers is “Identifying and learning from errors by developing a nationwide public mandatory reporting system and by encouraging health care organizations and practitioners to develop and participate in voluntary reporting systems.”

In a later report<sup>4</sup> the IOM stated “*It is imperative that all health care providers develop comprehensive patient safety systems that promote learning. Learning systems relentlessly redesign care processes in pursuit of ‘best in class.’*” The incident learning system described in this reference guide is intended to do just that. In the spirit of *To Err is Human*, it recognizes that errors are normal and puts the emphasis of incident investigation on causal analysis and corrective actions to improve care process performance.

Similarly, the authors of the Canadian adverse events study concluded that “*Efforts to make patient care safer will require leadership to encourage the reporting of AEs, continued monitoring of the incidence of these events, the judicious application of new technologies and improved communication and coordination among caregivers.*”<sup>5</sup> The incident learning system described here contains a comprehensive process for ensuring communication of incident learning and coordination of corrective actions. Our approach can be used in conjunction with other risk management tools such as failure mode and effects analysis<sup>6,7</sup> and probabilistic risk assessment.<sup>8</sup>

In September 2004, the Quality Assurance Committee (QAC) for the Radiation Treatment (RT) Program at Tom Baker Cancer Centre (TBCC), a major cancer treatment centre in Alberta, Canada, began work on redesigning its incident reporting system.<sup>A</sup> The goal of this initiative is to improve safety and reduce the risk of critical incidents by learning from the more frequent lower severity incidents and near-misses that inevitably occur in a complex health-care delivery system like radiation treatment. The approach taken in designing the new system is to build on the existing system by learning from the health care literature<sup>9</sup> and from best practices in other industries.<sup>B</sup>

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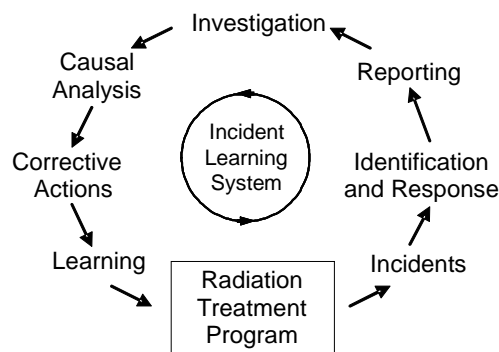
<sup>A</sup> The QAC team has also developed and implemented a survey process for tracking staff attitudes and awareness of patient safety and incident learning

<sup>B</sup> We are indebted to NOVA Chemicals Corporation ([www.novachem.com](http://www.novachem.com)), a major Canadian chemical company, for sharing information on their incident learning process

## Incident Learning System Design

The theory of incident learning is that safety in a complex operation over a period of time is a function of the number of incidents identified, the number of identified incidents reported, the quality of investigation and analysis of reported incidents, the effectiveness of corrective actions resulting from these analyses, and the amount of organizational learning that accumulates.<sup>10</sup> Although this theory seems reasonable, and is somewhat supported by anecdotal evidence, it has not been supported by empirical research. Our research program aims to gather evidence to support, refute or further evolve this theory and the assumptions upon which it is based.

The schematic diagram shown below (Figure 1) outlines the components of the incident learning system, designed as a continuous feedback loop into improvement of the TBCC Radiation Treatment Program. This guide is organized in sections corresponding to each step of the incident learning system, in sequence.



**Figure 1: The Incident Learning System**

Although this guide is written specifically for use in the Radiation Treatment Program at Tom Baker Cancer Centre, it is intended to be adaptable and generalizable to other programs of cancer treatment and to other treatment programs at other health care institutions. The tables and forms should be interpreted as examples that can be modified and adapted to the requirements of other health care delivery processes as required.

Bird and Germain<sup>11</sup> showed that for every incident involving loss of life or disabling injuries, there are hundreds of potential incidents (near-misses) and minor incidents. Their research led them to propose the 1:10:30:600 ratios shown in the “incident triangle” diagram (Figure 2). The validity of this incident triangle has been confirmed by the incident reporting experience at NOVA Chemicals Corporation over the period 1999 to 2004.<sup>C</sup> If the theory described in the previous section is correct, then safety will

<sup>C</sup> Personal communications between David L. Cooke and Eric Hiddema, Systems & Projects Manager, Responsible Care Shared Services, NOVA Chemicals Corporation

depend in part on our ability to learn from potential incidents (near misses) and minor incidents so as to take corrective measures that might prevent a future, more serious, incident from occurring. By focusing improvement efforts on the base of the incident triangle, we will increase the overall safety of treatment and care processes.



**Figure 2: The Incident Triangle**

One of the challenges of designing an effective incident learning system is to develop a classification process for different types of incidents that will reflect the intent of the “incident triangle” approach. Our classification tables will be presented in later sections of this guide.

## Process Measurement

To measure the effectiveness of the incident learning system we will use the ratio of the number of potential and minor incidents to the number of serious, major and critical incidents as a performance measure. We expect the overall total number of incidents reported to increase, so the larger the ratio, the better the reporting performance. In setting the performance target for this ratio, management should be guided by the incident triangle. The ratio =  $600 / (30 + 10 + 1) = 14.6$ , so we should expect this ratio to be greater than 10 and likely greater than 15.

$\frac{\text{Potential Incidents + Minor Incidents}}{\text{Serious Incidents + Major Incidents + Critical Incidents}} > \text{Target (e.g. 10)}$
--

So how many RT incidents would we expect to be reported in a centre such as the TBCC?

A study of radiation therapy misadministrations reported to the US Nuclear Regulatory Commission in 1992 estimated that the rate of reported misadministrations was 4.2 misadministrations per 100,000 procedures.<sup>12</sup> Their count of procedures included all

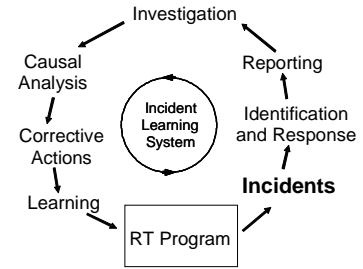
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brachytherapy procedures, teletherapy treatments, and radiopharmaceutical therapy procedures. Their definition of a reportable misadministration event would correspond to a critical incident in our system (see Table 3 on page 9). Thus, if there were 50,000 procedures per year carried out at TBCC, and if the US experience is directly transferable, we would expect up to two critical incidents, 20 major incidents, 60 serious incidents and 1200 incidents/potential incidents to be reported in the clinical treatment process each year. Even though this estimate might be on the high side, we should expect to see at least a tenfold increase in the number of incidents reported because of increased awareness and participation in an effective incident learning system (previously, about 50 -100 RT incidents were reported in a year at TBCC).

It is important to understand that incidents occur whether we report them or not. Thus we should not be upset if more incidents are reported. Though this may seem counter-intuitive, more incidents *reported* provide more opportunities to learn and improve.

## INCIDENTS

An incident is defined as an unwanted or unexpected change from a normal system behavior, which causes, or has a potential to cause, an adverse effect to persons or equipment.



All incidents must be reported. This is how we learn and improve the effectiveness of our systems and processes. It is the policy of most modern health care systems, including the TBCC and the Alberta Cancer Board, to foster an environment of continuous improvement in which incident reporting and learning can take place without blame or disciplinary action.

Incidents are to be reported in writing to a supervisor. The Appendix to this reference guide has samples of forms that may be used for reporting and investigating incidents. There is one easy-to-use form for reporting an incident and one in-depth form for the investigation.

The investigation process is designed to provide an explanation of which specific basic causes were identified, and yield recommendations that specifically address and ensure resolution to each cause. Individuals responsible for following up in each recommendation and target dates for completion will be identified.

Even with increased awareness, it is unlikely that all incidents will be identified. For example, incidents in radiation treatment may be difficult to identify if the causal events are not detected at time of occurrence or during subsequent chart review. It is likely that some incidents involving misadministration of radiation may not be classifiable, and indeed may not be discoverable, until the effects are manifested months or years later. Even then, careful investigation will be required because the toxicity effects may be the result of patient sensitivity to radiation rather than of misadministration.<sup>13</sup> Models may be useful to help identify unexpected deviations from normal toxicity effects.<sup>14</sup>

## IDENTIFICATION AND RESPONSE

### Identification of an incident

The first step is identifying the incident. It is usually not difficult to identify incidents that cause adverse events.

However, it may be difficult to identify those incidents with *potential* to cause adverse events. It is important to identify and report these potential incidents, sometimes called “near-misses” or “close calls,” because we can learn from them and take action to prevent actual incidents from occurring in the future. To illustrate the potential difficulty in identifying an incident, consider the following clinical examples:

- a) Failure to include the intended wedge factor (a factor which accounts for the attenuation of the wedge) in an RT planning calculation. As a result, the wrong dose is administered to patient.
- b) Failure to include the intended wedge factor in an RT planning calculation. Quality control procedures in treatment planning detect the failure and the calculations are corrected.
- c) Failure to include the intended wedge factor in an RT planning calculation. The failure is detected by quality checks during patient set up for treatment. The calculations are re-done and the correct dose is administered to the patient.

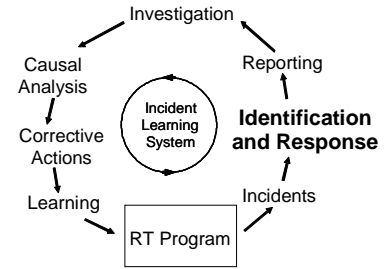
Which of these examples are incidents?

Example a) is an incident because the wrong dose is administered. The cause and severity of the incident may not be known until the investigation has been completed.

Example b) is not an incident. Even though a failure occurred, it was caught by normal quality control procedures within the domain that the failure occurred. Errors are normal and failures will occur, but we expect our quality control measures to detect and correct them before any harm is done.

Example c) is a potential incident and should be reported. Quality control procedures within the domain that the failure occurred did not detect the failure, which was detected at a later stage in the treatment process.

The important lesson from these examples is to understand the need for a sound organizational definition of what constitutes an incident. Tucker<sup>15</sup> has shown that “operational failures” occur at a rate that is much higher than any organization could process through a formal incident learning system. Other research shows that many adverse events that were detected through independent patient chart review were not detected by the organization’s incident reporting system.<sup>16</sup> Thus, while we do not want to overwhelm the incident learning system with trivial operational failures such as time wasted searching for an empty laundry hamper, it is important to identify and report





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minor incidents and potential incidents that are *deviations* from normal behavior and which *could* have the potential for harm.

While example b) suggests that failures routinely caught by the QC procedures in the domain in which they occurred would not be considered incidents, it is important to identify as incidents those failures that are not routine or which occur because of a deficient QC procedure.

If in doubt about whether or not an event constitutes an incident, discuss the matter with your supervisor.

### **Immediate Response**

The individual identifying the incident must take immediate action:

- To address any injury (e.g. provide/seek first aid for minor injury)
- To remove hazard (e.g. notify housekeeping of wet floor)
- Complete the Incident Report and submit it to your supervisor.

## REPORTING

### Incident report

The individual identifying the incident completes the INCIDENT REPORT - ORIGINATOR page of the Incident Report (see sample on page 29 of the Appendix), and returns the report to their supervisor.

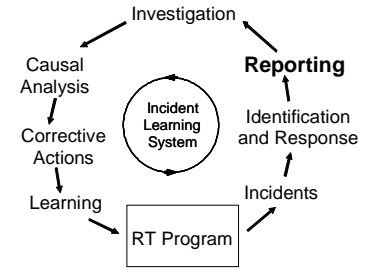


Table 1 should be referenced when completing the WHO section of the Incident Report.

**Table 1: Persons Involved in an Incident**

WHO	Details
Patient* (In-patient/Out-patient)	Any person scheduled for an appointment or treatment on the day in question
Public/Visitor	Any person not scheduled for an appointment or treatment on the day in question; And not onsite for work/research duties
Staff/Employee	Any employee or staff member of the Alberta Cancer Board, Calgary Health Region, or the University of Calgary who is required to regularly perform duties at the Tom Baker Cancer Centre site.
Visiting worker/Student (Affiliate)	Any person temporarily onsite for work/research duties. This would include individuals carrying out short term contract work.
Not applicable	No person affected (i.e. equipment)

\* For Patient - an oncologist signature is required in all patient incidents excluding potential incidents (i.e. "near-misses")

Table 2 identifies the TYPE of incident according to the process or system that failed. This should be referenced when completing the WHAT section of the Incident Report.

**Table 2: Type of incident by process or system that failed**

Incident Type	Process or System that Failed
Clinical*	Patient safety, treatment-related processes
Occupational	Staff, student, and visiting worker safety
Operational	Operational and technical systems related to machines, equipment, facilities, operational capability, procedures, patient flow, staff scheduling, etc.
Environmental	Processes preventing environmental exposure to radiation, drugs or chemicals
Security/Other	Personal and public security, information security, system integrity, physical asset security, public image, etc.

\* Clinical incidents can include, for example, radiation misadministrations, adverse drug reactions, diagnostic test problems, surgical site infections, etc.

The physical location of the incident should be referenced when completing the WHERE section of the Incident Report. The *work process/area* of the incident is intended

to provide further detail of the incident location. These are examples of responses to this section: Unit 1, office, patient waiting area and washroom.

Examples of forms that may need to be completed in addition to the incident report are:

- Provincial cancer board or regional health authority reporting requirements
- Worker's Compensation Board reporting requirements
- Any other forms appropriate to the jurisdiction and type of incident

The supervisor completes the next page of the incident report, INCIDENT REPORT – SUPERVISOR (see sample on page 30 of the Appendix). In doing so, the charts in Tables 3-7 should be referenced when assigning the severity classification. Upon completion of the report, the supervisor notifies the individuals indicated for the particular TYPE and SEVERITY of incident.

There are three levels of classification for potential incidents (“near-misses”). Most potential incidents will be classified as minor incidents because no harm is done. If a potential incident could have been a higher severity had it not been for chance, then it should be classified as a potential serious incident or a potential major incident depending on the assessment of potential impact. No distinction is made between potential major incidents and potential critical incidents because it can be difficult to assess the risk of actual impact beyond it being potential major.

Table 3 provides a guideline for classifying the severity of clinical incidents occurring in radiation treatment. Given the time delay before late effects of radiation become apparent, the supervisor may wish to assign both a severity level and a *probability* that any expected side effects will occur, and may make appropriate comments in the section “Additional information needed.”

**Table 3: Clinical incident severity**

Incident Severity	Examples: Clinical Incident	Individuals to be notified
Critical Incident	Radiation dose or medication error causing death or disability. Dose variation from prescribed total dose of >20%. Completely incorrect volume.	<i>Immediately notify:</i> Senior Management, Manager, Supervisor, Physician
Major Incident	Dose variation from prescribed total dose of 10 – 20%. Radiation dose or medication error causing side effects requiring major treatment and intervention or hospitalization. Set up variation that will/could impact on normal tissue effects (e.g. Heart, lung, eyes, kidney etc.).	<i>Immediately notify:</i> Senior Management, Manager, Supervisor, Physician
Potential Major Incident	A near miss that could have been a major incident.	Manager, Supervisor

**Table 3: Clinical incident severity (cont'd)**

Incident Severity	Examples: Clinical Incident	Individuals to be notified
Serious Incident	Dose variation from prescribed total dose of 5 - <10%. Radiation dose or medication error causing side effects requiring minor treatment or ongoing monitoring and assessment. Set up variation > 1cm – no critical structures included.	Within 24hrs notify: Manager, Supervisor, Physician
Potential Serious Incident	A near miss that could have been a serious incident.	Supervisor
Minor Incident	Dose variation from prescribed total dose of <5%. Near miss or unsafe condition which could potentially cause a treatment error.* Patient complaint.*	Supervisor, Physician*

\* Physician should only be notified if there is **actual** patient impact

In the preceding table, and in the tables that follow, the various levels of supervisory positions listed under “Individuals to be notified” may be interpreted as follows:

**Supervisor:** First level of management. Health care professionals such as nurses, radiation therapists, and dosimetrists usually report to this position.

**Manager:** Second level of management, to whom supervisors report. The position may be a department head or a program leader.

**Senior Management:** Third level of management, to whom managers report. The position may be a facility director or a vice president.

Table 4 provides a guideline for classifying the severity of incidents involving occupational injuries or illnesses. Occupational incidents involving accidental exposure to radiation or chemicals may also be classified as environmental incidents.

**Table 4: Occupational incident severity**

Incident Severity	Examples: Occupational Incident	Individuals to be notified
Critical Incident	Death, life-threatening injury or illness, or permanent disability.	<i>Immediately notify:</i> Senior Management, Manager, Supervisor, OH&S
Major Incident	Injury or illness causing lost work days. Broken limbs or burns.	<i>Immediately notify:</i> Senior Management, Manager, Supervisor, OH&S
Potential Major Incident	A near miss that could have been a major incident.	Manager, Supervisor, OH&S
Serious Incident	Injury or illness requiring medical treatment (not first aid).	<i>Within 24hrs notify:</i> Manager, Supervisor, OH&S

**Table 4: Occupational incident severity (cont'd)**

Incident Severity	Examples: Occupational Incident	Individuals to be notified
Potential Serious Incident	A near miss that could have been a serious incident.	Supervisor, OH&S
Minor Incident	Injury or illness requiring first aid A near miss or unsafe condition. Examples: entanglement, pinching, falling objects, broken glass	Supervisor, Occupational Health & Safety (OH&S)

Table 5 provides a guideline for classifying the severity of incidents involving failure of equipment or operational systems. The dollar values are purely arbitrary and should be selected to align with the maintenance and capital budget signing authorities of the organization. Final classification of incident severity may not be possible until all cost impacts become known.

**Table 5: Operational incident severity**

Incident Severity	Examples: Operational Incident	Individuals to be notified
Critical Incident	Equipment failure and/or damage not considered normal wear and tear costing more than \$50,000. Operations down-time of over a week of treatment time.	<i>Immediately notify:</i> Senior Management, Manager, Supervisor, Physician
Major Incident	Equipment failure and/or damage not considered normal wear and tear costing \$10,000 to \$50,000. Company Service Rep call-out. Operations down-time of 1 day to 1 week of treatment time.	<i>Immediately notify:</i> Senior Management, Manager, Supervisor, Physician
Potential Major Incident	A near miss that could have been a major incident.	Manager, Supervisor
Serious Incident	Equipment failure and/or damage not considered normal wear and tear costing \$500 to \$10,000. Operations down-time of 0.5-1 day of treatment time.	<i>Within 24hrs notify:</i> Manager, Supervisor, Physician
Potential Serious Incident	A near miss that could have been a serious incident.	Supervisor
Minor Incident	Equipment failure and/or damage not considered normal wear and tear less than \$500. Repaired by on-site technical support staff. Operations down-time of up to ½ day of treatment time. A near miss or unsafe condition. Service or operations-related complaint.	Supervisor

Table 6 provides a guideline for classifying the severity of incidents involving loss of containment or potential loss of containment of radiation or chemicals. A concurrent occupational incident may occur if a loss of containment leads to accidental exposure to staff or visiting workers.

**Table 6: Environmental incident severity**

Incident Severity	Examples: Environmental Incident	Individuals to be notified
Critical Incident	<p><b>Radiation -</b></p> <ul style="list-style-type: none"> <li>• Source lost/stolen &gt; 37 MBq (1 Ci).</li> <li>• System failure resulting in exposure to public or to other non-monitored individuals.</li> <li>• CNSC dose limit exceeded and there is a reasonable probability of medical effects (see Appendix, Table 12).</li> </ul> <p><b>Chemical -</b></p> <ul style="list-style-type: none"> <li>• Chemotherapy spill resulting in death, life-threatening injury or illness, or permanent disability.</li> </ul>	<p><i>Immediately notify:</i> Provincial/Federal authorities, Public Relations, Senior Management, Manager, Supervisor, Radiation Safety Officer (RSO)<sup>1</sup>, Radiation Safety Committee<sup>1</sup>, Physician<sup>2</sup>, OH&amp;S<sup>2</sup></p>
Major Incident	<p><b>Radiation -</b></p> <ul style="list-style-type: none"> <li>• Source lost/stolen ≤ 37 MBq (1 Ci).</li> <li>• Contamination discovered and requires investigation into biological uptake.</li> <li>• Certificate/ licence found to be expired.</li> <li>• CNSC dose limit exceeded (see Appendix, Table 12).</li> </ul> <p><b>Chemical -</b></p> <ul style="list-style-type: none"> <li>• Chemotherapy spill resulting in illness or reactions causing lost days or ongoing treatments.</li> </ul>	<p><i>Immediately notify:</i> Provincial/Federal authorities, Senior Management, Manager, Supervisor, Radiation Safety Officer (RSO)<sup>1</sup>, Radiation Safety Committee<sup>1</sup>, Physician<sup>2</sup>, OH&amp;S<sup>2</sup></p>
Potential Major Incident	A near miss that could have been a major incident.	Manager, Supervisor, Radiation Safety Officer (RSO) <sup>1</sup> , Radiation Safety Committee <sup>1</sup> , OH&S <sup>2</sup>

**Table 6: Environmental incident severity (cont'd)**

Incident Severity	Examples: Environmental Incident	Individuals to be notified
Serious Incident	<p><b>Radiation -</b></p> <ul style="list-style-type: none"> <li>• Source found to be leaking.</li> <li>• Contamination discovered in excess of exemption limits.</li> <li>• Projection of quarterly results suggests CNSC dose limit will be exceeded (see Appendix, Table 12).</li> </ul> <p><b>Chemical -</b></p> <ul style="list-style-type: none"> <li>• Chemotherapy spill resulting in an on going assessment of those in contact with chemotherapy agent.</li> </ul>	<p><i>Within 24hrs notify:</i></p> <p>Manager, Supervisor, Radiation Safety Officer (RSO)<sup>1</sup>, Radiation Safety Committee<sup>1</sup>, Physician<sup>2</sup>, OH&amp;S<sup>2</sup></p>
Potential Serious Incident	A near miss that could have been a serious incident.	Supervisor, Radiation Safety Officer (RSO) <sup>1</sup> , OH&S <sup>2</sup>
Minor Incident	<p><b>Radiation -</b></p> <ul style="list-style-type: none"> <li>• Source accessed by non-authorized individual.</li> <li>• Access to secure area found left unsecured.</li> <li>• ALARA dose limit exceeded (see Appendix, Table 13).</li> <li>• Contamination discovered.</li> <li>• Deadline for leak test/ ACR submission/ survey meter calibration passed.</li> <li>• Emergency equipment found to be missing or inadequate.</li> <li>• Staff member found to be working in area without receiving necessary safety training.</li> <li>• Radiation procedures not followed (possible upgrade to greater severity depending on the omission).</li> </ul> <p><b>Chemical -</b></p> <ul style="list-style-type: none"> <li>• Equipment failure with IV pumps or tubing that may have resulted in chemotherapy spill.</li> <li>• Complaint concerning the safe handling or storage of chemicals or radiation sources.</li> </ul>	Supervisor, Radiation Safety Officer (RSO) <sup>1</sup> , Physician <sup>2</sup> , OH&S <sup>2</sup>

<sup>1</sup> For radiation incidents only<sup>2</sup> For chemical incidents only

Table 7 provides a guideline for classifying the severity of incidents involving security or other incidents not captured in Tables 3-6.

**Table 7: Security/other incident severity**

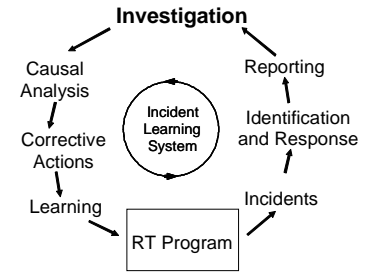
Incident Severity	Examples: Security Incident	Individuals to be notified
Critical Incident	<p>Events that result in a formal investigation by a regulatory body or public agency.</p> <p>Theft, vandalism and/or fraud costing more than \$50,000.</p> <p>Events resulting in police involvement (e.g. workplace violence, bomb threat, extortion, blackmail, etc).</p> <p>Security breach* with safety implications and damage.</p> <p>Media coverage that immediately creates a negative public image.</p>	<i>Immediately notify.</i> Senior Management, Manager, Supervisor, Security
Major Incident	<p>Theft, vandalism and/or fraud costing \$10,000 to \$50,000.</p> <p>Security breach* with safety implications but no damage.</p> <p>Workplace violence.</p> <p>Media coverage with potential to create a negative public image.</p>	<i>Immediately notify.</i> Senior Management, Manager, Supervisor, Security
Potential Major Incident	A near miss that could have been a major incident.	Manager, Supervisor, Security
Serious Incident	<p>Verified community complaint with security implications.</p> <p>Theft, vandalism and/or fraud costing \$500 to \$10,000.</p> <p>Security breach* with damage but no safety implications.</p> <p>Threatened workplace violence.</p>	<i>Within 24hrs notify.</i> Manager, Supervisor, Security
Potential Serious Incident	A near miss that could have been a serious incident.	Supervisor, Security
Minor Incident	<p>Community complaint.</p> <p>Theft, vandalism and/or fraud costing less than \$500.</p> <p>Security breach* with no safety or damage implications.</p> <p>A near miss or unsafe condition.</p>	Supervisor, Security

\* Security Breach: For a complete definition, see the Glossary



## INVESTIGATION

Membership of the investigation team and the timeline for completing the investigation report depend on the type and severity of the incident as defined in Table 8.



**Table 8: Composition of the incident investigation team**

	Minor	Serious	Major	Critical
Clinical	Individuals involved Supervisor	All the previous and <ul style="list-style-type: none"> <li>• Other domain<sup>1</sup> members involved in patient's care</li> </ul>	All the previous and <ul style="list-style-type: none"> <li>• Other domain<sup>1</sup> members</li> <li>• Manager</li> </ul>	All the previous and <ul style="list-style-type: none"> <li>• Supervisors of other domains<sup>1</sup></li> </ul>
Occupational	Individuals involved Supervisor	All the previous and <ul style="list-style-type: none"> <li>• OH&amp;S</li> <li>• QAC member</li> </ul>	All the previous and <ul style="list-style-type: none"> <li>• Manager</li> </ul>	All the previous
Operational	<ul style="list-style-type: none"> <li>• Individuals involved</li> <li>• Technical Supervisor</li> </ul>	All the previous and <ul style="list-style-type: none"> <li>• Unit supervisor</li> <li>• RT supervisor</li> <li>• QAC member</li> </ul>	All the previous and <ul style="list-style-type: none"> <li>• Manager</li> </ul>	All the previous
Environmental (non-radiation)	Individuals involved Supervisor	All the previous and <ul style="list-style-type: none"> <li>• OH&amp;S</li> <li>• QAC member</li> </ul>	All the previous and <ul style="list-style-type: none"> <li>• Manager</li> </ul>	All the previous
Environmental (radiation)	Site RSO	<ul style="list-style-type: none"> <li>• Provincial RSO</li> </ul>		
Security/Other	Individuals involved Supervisor Security	All the previous and <ul style="list-style-type: none"> <li>• QAC member</li> </ul>	All the previous and <ul style="list-style-type: none"> <li>• Manager</li> </ul>	All the previous
Reporting Timeline	Minor	Serious	Major	Critical
Initial Investigation	Within 10 working days	Within 10 working days	By next business day	Immediately
Updated Report	With reasonable change <sup>2</sup>	With reasonable change <sup>2</sup>	With reasonable change <sup>2</sup>	With reasonable change <sup>2</sup>
Final Report	When event is concluded	When event is concluded	When event is concluded	When event is concluded

<sup>1</sup> See Incident Domain section overleaf and the Glossary for a definition of "domain"

<sup>2</sup> As determined by the investigation team if and when new information becomes available

The first two pages of the investigation report are for extracting information from which causes can be identified and recommendations can be made (see example in Appendix,

pages 31-32). Note that many sections of the report form cannot be filled out until the data has been gathered and/or judgments made during the course of the investigation.

Each incident should be assessed in terms of its impact and its characteristics (domain and type). Impact has been divided into sections for patients, persons, resources, and operations.

### Incident Domain

The following chart and the process map shown overleaf should be referenced when assigning the process DOMAIN to the incident.

**Table 9: Examples of work processes in each domain**

Domain	Details of work process (examples)
Assessment	Histology and Physical Examination Diagnostic Imaging and biochemical tests Pathology reviews
Prescription	Dose, fractionation Target/Treatment volume localization
Preparation	Dose distribution computation Simulation Treatment aid preparation and verification Data Entry
Treatment	Equipment set-up Patient set-up Adjuvant treatment coordination Treatment of acute side effects of radiation therapy
Follow up	Clinical examination of patient response Treatment of chronic side effects of radiation therapy

The domain for non-clinical incidents will be defined by the work area in which the incident occurred.

### Radiation Treatment Process Map

This map (Figure 3) shows the progress of a patient through the five domains (Assessment, Prescription, Preparation, Treatment, and Follow Up) associated with Radiation Treatment. An incident is assigned to the domain in which it originated and not to the domain in which it is discovered.

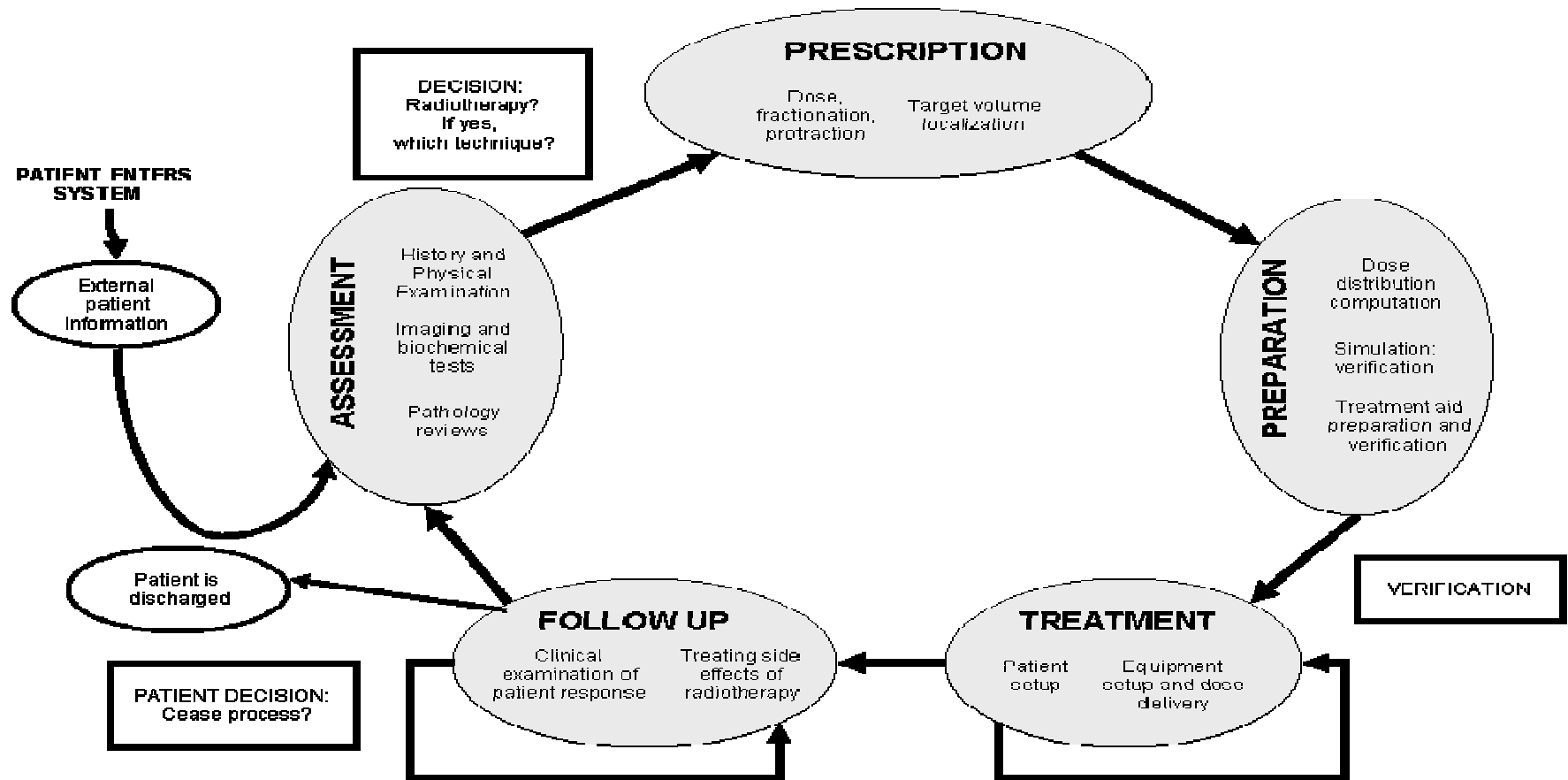


Figure 3: RT Process Map

## Incident Type – Clinical Incidents

Within each domain, we classify clinical incidents based on their type as described below:<sup>17</sup>

1. *Prescription elements*: Incidents are classified as dose incidents (administered dose differed from prescribed dose) or volume incidents (irradiated volume differed from prescribed volume). Dose and volume are 4-dimensional concepts which are applied to the organs at risk as well as the target containing the tumor. Note that a volume incident always implies an incorrect dose to some volume. In other areas of medical care, the *prescription elements* will clearly differ, e.g. prescription elements in systemic therapy would include drug types and doses.
2. *Source*: Incidents are categorized as either process or infrastructure incidents. Process incidents may occur during the execution of a standard operating procedure in one of the five domains. For each step in a procedure, errors may occur during transcription, selection and/or interpretation of input parameters, execution of the step or the transfer of output parameters to charts, and other patient data management systems. A characteristic of a “process” in our definition is that the activity is directed towards an identifiable patient. Infrastructure incidents result from errors during design, manufacture, commissioning, maintenance, upgrade or repair of equipment. Infrastructure also encompasses data books and clinical protocols for dosimetry and other calculations. A characteristic of “infrastructure” is that it is established for multiple patients. Clearly the establishment of infrastructure for a treatment facility involves processes. However, for the purposes of keeping the incident classification as general as possible the processes followed to establish the infrastructure are at a deeper level and are not specifically addressed at this level of classification.
3. *Occurrence*: We do not consider random errors caused by normal variation or the limit of precision to be incidents. However, when the outcome of an event is outside this tolerance envelope, it may be reported as an incident. We define two types of such incidents: systematic incidents and sporadic incidents. A systematic incident is one that will occur predictably under similar circumstances. It has the potential to affect multiple fractions for one patient or multiple patients until discovered and fixed. Common examples of systematic incidents are those caused by equipment calibration errors or by consistently erroneous behavior of individuals due to poor training, inexperience or a sub-standard work process. A systematic incident could also occur because the requisite knowledge was not available to the organization and therefore not included in the training program or in the design of the work process. A sporadic incident results from an error that would not be considered “normal variation” but which occurs in a purely random fashion despite having

suitable infrastructure, well-designed work processes and adequate quality control procedures.

In RT, an example of a sporadic incident would be omitting a wedge for a patient during one fraction of treatment delivery. Occasional transcription errors would also fall into this category. The impact of a sporadic incident depends upon the domain in which the incident occurs. A sporadic incident at preparation will affect a whole course of RT whereas a sporadic incident at treatment will not. Sporadic incidents should be monitored carefully as repetition of similar incidents may suggest that the incidents are in fact systematic but the underlying systemic cause has not yet been identified and corrected. The table below provides further examples of systematic and sporadic incidents.

**Table 10: Examples of systematic and sporadic incidents in different domains**

Domain	Systematic incident	Sporadic incident
Prescription	Error in the medical basis for dose prescription.	Error in calculating dose per fraction from total dose and number of fractions.
	Dose prescription offered in rad/minute, even though source output was measured and reported in roentgen/minute.	Transcription error while recording prescription onto patient chart.
Preparation	Input of incorrect basic data in treatment planning system	Failure to include intended wedge factor in treatment planning calculation.
	Application of wedge factor twice during dose calculation due to unfamiliarity with computer program.	Error in recording treatment field positions on patient chart.
Treatment	Error in calibration of machine output.	Omission of wedge during one fraction of treatment delivery.
	Electrical fault resulting in incorrect analog display of electron energy.	Incorrect positioning of gantry angle during a treatment session.

It should be clear from the examples in Table 10 that a sporadic incident early in the process may lead to a systematic incident for a given patient. For example, a sporadic incident in calibration of machine output will affect all patients until found and corrected. A sporadic event in patient prescription or preparation may yield a systematic variation for a given patient throughout treatment.

### Incident Type – Other Incidents

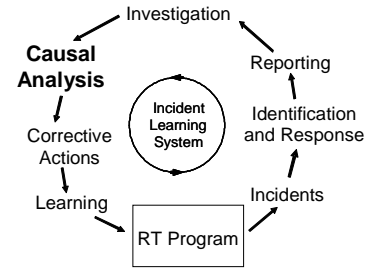
Other incidents are classified according to the characteristics of the incident. Most categories, such as *injury/illness*, are self explanatory but some may require further explanation:

- *Hazardous conditions*: conditions that could lead to an actual incident if not addressed. These could include a defective work process as well as actual physical conditions.

- *Patient flow or work flow disruption:* applies to incidents causing delays or interruptions to work processes or to normal operation of facilities or equipment.
- *Quality control failure or omission:* can be used to characterize incidents that occurred despite existing quality controls. If checked, this may suggest some corrective actions to improve quality control procedures.
- *Other:* We cannot anticipate all types of incidents that may occur. Please try to characterize each incident as best you can.

## CAUSAL ANALYSIS

Causal analysis is documented in the left hand column on the third page of the investigation report (see sample in Appendix C on page 31).



One of the purposes of an incident investigation is to analyze the facts surrounding the incident in order to determine the *basic causes* of the incident. There are often several causes of an incident, and the investigation team should seek to understand the *causal structure* that links one or more basic causes to the various immediate causes of the incident. Incidents are seldom the result of a single cause.

For example, the immediate causes of a fire are a source of ignition and a source of flammable material. These can often be easily identified by an investigation team. However, the basic causes of a fire may not be so easy to find as they would lie buried in the job factors, personal factors or systemic/management factors of the organization.

The technique for determining basic causes is sometimes called “root cause analysis” or the “Why - Why” Procedure.<sup>18</sup> The process is similar to that for developing cause-and-effect diagrams used in quality management<sup>19</sup> and starts with the effect (incident) and works backwards by asking “why?” at each node to determine the cause. The technique is illustrated in the example below:

Effects		Causes	
Injury	Caused by (why?)	Fall	
Fall	Caused by (why?)	Wheelchair fell backwards	
Wheelchair fell backwards	Caused by (why?)	No attendant	Opening door

Effects		Causes	
Opening door	Caused by (why?)	Hard to open	
Hard to open	Caused by (why?)	Springs on door	
Springs on door	Caused by (why?)	Springs too heavy for disabled person	
Springs too heavy for disabled person	Caused by (why?)	<b>Inadequate Design Specifications</b>	

Effects		Causes	
No attendant	Caused by (why?)	Nurse called away	
Nurse called away	Caused by (why?)	Inadequate Staffing	
Inadequate Staffing	Caused by (why?)	<b>Inadequate Work Planning</b>	

The basic causes of loss were documented by Bird and Germain<sup>20</sup> and a simplified and updated version of their classification system is shown in the table overleaf.

The following table should be referenced when identifying the basic cause or causes involved:

**Table 11: Basic cause(s)<sup>D</sup>**

<b>Job Factors</b>		
1. Standards/Procedures/Practices 1.1 Not developed 1.2 Inadequate standard/ procedure/practice 1.3 Standard/procedure/ practice not followed 1.4 Inadequate communication of procedure 1.5 Inadequate assessment of risk 1.6 Not implemented	2. Materials/Tools/Equipment 2.1 Availability 2.2 Defective 2.3 Inadequate maintenance 2.4 Inspection 2.5 Used incorrectly 2.6 Inadequate assessment of material/tools/ equipment for task	3. Design 3.1 Inadequate hazard assessment 3.2 Inadequate design specification 3.3 Design process not followed 3.4 Inadequate assessment of ergonomic impact 3.5 Inadequate assessment of operational capabilities 3.6 Inadequate programming
<b>Systemic/Management Factors</b>		
4. Planning 4.1 Inadequate work planning 4.2 Inadequate management of change 4.3 Conflicting priorities/ planning/ programming 4.4 Inadequate assessment of needs & risks 4.5 Inadequate documentation 4.6 Personnel availability	5. Communication 5.1 Unclear roles, responsibilities, and accountabilities 5.2 Lack of communications 5.3 Inadequate direction/ information 5.4 Misunderstood communications	6. Knowledge/Skill 6.1 Inadequate training/orientation 6.2 Training needs not identified 6.3 Lack of coaching 6.4 Failure to recognize hazard 6.5 Inadequate assessment of needs and risks
<b>Personal Factors</b>	<b>Natural Factors</b>	
7. Capabilities 7.1 Physical capabilities (height, strength, weight, etc.) 7.2 Sensory deficiencies (sight, sound, sense of smell, balance, etc.) 7.3 Substance sensitivities/ allergies	8. Judgment 8.1 Failure to address recognized hazard 8.2 Conflicting demands/ priorities 8.3 Emotional stress 8.4 Fatigue 8.5 Criminal intent 8.6 Extreme judgment demands 8.7 Substance abuse	9. Natural Factors 9.1 Fires 9.2 Flood 9.3 Earthquake 9.4 Extreme weather 9.5 Other

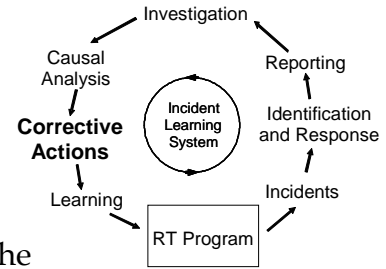
<sup>D</sup> Source: NOVA Chemicals Corporation, used with permission



## CORRECTIVE ACTIONS

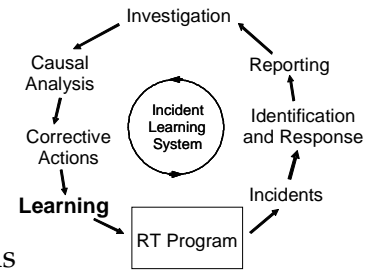
Corrective actions are documented in the right hand column on the third page of the investigation report (see sample in Appendix on page 33). The individuals to whom the corrective actions are assigned for follow up are identified on the fourth page of the investigation report (see sample on page 34).

Once the corrective actions have been identified, the individuals responsible for the follow-up will complete the “Corrective Actions Follow-up Report” (see sample on page 35). A separate follow-up report should be completed for each corrective action.



## LEARNING

The goal of organizational learning is to build a safety culture so that an individual does not have to experience an incident themselves to learn from it. Organizational learning is difficult: organizations tend to forget the lessons of the past, so that similar incidents will occur again in the future. For example, there are many reports of incidents of inadvertent intrathecal administration of vincristine, a chemotherapy drug. In protocols for the treatment of acute lymphoblastic leukemia, intravenous vincristine is often scheduled at the same time as intrathecal methotrexate or cytarabine. A possible error is the intrathecal administration of vincristine, which is a catastrophe.<sup>21</sup> The risk of this incident can be eliminated by preparing vincristine for intravenous bolus administration in a small-volume intravenous bag, as opposed to a syringe. This lesson has been learned by the majority of hospitals in Australia.<sup>22</sup> However, until this lesson has been learned by all hospitals in all countries, vincristine misadministration incidents will continue to occur.



To promote organizational learning, the following measures will be taken:

1. When the corrective actions resulting from an incident investigation have been implemented, the supervisor responsible for the incident will review the effectiveness of the actions taken and prepare a communication describing the lessons learned from the incident.
2. The lessons learned will be communicated to the individuals involved in the incident and in its investigation. This action formally “closes” the incident.
3. The supervisor will also communicate the lessons learned to a wider audience depending on the value of the lessons learned and the severity of the incident. The audience might include departmental staff meetings, leadership team meetings, facility-wide incident review meetings, or leadership of similar organizations in other jurisdictions or geographies. For example, the learning from an incident in the Radiation Treatment Program at the Tom Baker Cancer Centre in Calgary might be communicated to the leaders of such programs in all cancer centres in Alberta or to all cancer centres nationwide.
4. The Quality Assurance Committee will review the lessons learned from all incidents on a periodic basis, not less frequently than annually. The purpose of this review is to identify any system-wide improvements that may not have been identified because the incidents were previously investigated and considered in isolation. The results of this review will be communicated to all staff.

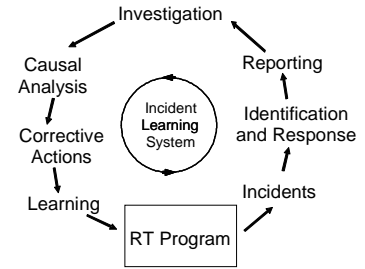
To keep the memory of incidents alive, it is recommended that lessons learned in previous years be periodically reviewed by investigation teams in the context of more recent incidents.

The individual/individuals to whom the communications were assigned to complete the “Learning Follow-Up Report” (see sample on page 36) are responsible for communicating the lessons learned from the incident. In doing so, the following chart should be referenced to ensure the *minimum* communications requirements are met. Potential Serious and Potential Major Incidents are to be communicated in the same manner as Serious and Major Incidents.

**Table 12: Minimum communications for incident learning**

Incident Severity	Minimum communication:
Critical Incident	All the previous and <ul style="list-style-type: none"> <li>• Email notice to Senior Management and Patient Safety Officer</li> <li>• Discussion at Board/Directors’ meeting</li> </ul>
Major Incident	All the previous and <ul style="list-style-type: none"> <li>• Email notice to program affected</li> <li>• Discussion at special meeting</li> <li>• In-service as required</li> </ul>
Serious Incident	All the previous and <ul style="list-style-type: none"> <li>• Email notice to department affected</li> <li>• Place on Intranet notice board</li> <li>• Discussion at next routine department meeting</li> </ul>
Minor/ Potential Incident	Email notice to those in domain affected

## APPENDICES



## APPENDIX A: ENVIRONMENTAL INCIDENT (RADIATION) CNSC DOSE LIMITS

Table 12: Environmental incident (radiation) CNSC dose limits<sup>23</sup>

Person affected	Type of exposure	Dose Limits	Cumulative period
Nuclear Energy Worker (NEW) or Radiation Worker (RW)	Whole body	20 mSv	1 year
Nuclear Energy Worker (NEW) or Radiation Worker (RW)	Extremity/Skin	500 mSv	1 year
	Lens of eye	150 mSv	1 year
Pregnant NEW/RW	Whole body	4 mSv	Term of pregnancy
Any other non-patient	Whole body	1 mSv	1 year

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## APPENDIX B: ENVIRONMENTAL INCIDENT (RADIATION) ALARA DOSE LIMITS

Table 13: Environmental incident (radiation) ALARA dose limits<sup>24</sup>

Person affected	Type of exposure	Dose Limits	Cumulative period
Nuclear Energy Worker (NEW) or Radiation Worker (RW)	Whole body	1 mSv	1 year
Any other non-patient	Whole body	0.05 mSv	1 year

**APPENDIX C: EXAMPLE OF ONE COMPLETED SET OF FORMS FOR A  
CLINICAL INCIDENT**



**TOM BAKER CANCER CENTRE  
RADIATION THERAPY INCIDENT REPORT - ORIGINATOR**

Incident: an unwanted or unexpected change from a normal system behavior, which causes, or has the potential to cause, an adverse effect to persons or equipment.

**WHO**

Please indicate by checkmark *WHO* was potentially affected/actually affected by this incident.

- |                          |                                     |                         |
|--------------------------|-------------------------------------|-------------------------|
| Potentially affected     | Actually affected                   |                         |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | <b>*Patient</b>         |
| <input type="checkbox"/> | <input type="checkbox"/>            | Public                  |
| <input type="checkbox"/> | <input type="checkbox"/>            | Staff                   |
| <input type="checkbox"/> | <input type="checkbox"/>            | Visiting Worker/Student |
| <input type="checkbox"/> | <input type="checkbox"/>            | Not applicable          |

\*Patient Number: Z,0000000

\*Oncologist notified (for ACTUAL incidents only):

Name: Dr. R. Oncologist

Signature: R. Oncologist

Date: 2005/06/02 time: 11:30 am

**WHAT**

Please indicate *WHAT* system(s) were involved in this incident.

- Clinical
- Occupational
- Operational
- Environmental
- Security/Other: \_\_\_\_\_

**WHERE**

Please indicate *where* the incident occurred

Room number: \_\_\_\_\_

Work process/area: RT Unit #10

**WHEN**

Date incident occurred:

2005/05/06 time: 10:30 am

Date incident was discovered:

2005/06/02 time: 10:30 am

**Description of incident**

Please briefly summarize the incident:

First treatment: PA MLC visually checked against DDRs in room. PA field treated and EPI taken during treatment. EPI assessed immediately and it was recognized that a 1cm x 2cm area of MLC was missing.

What was your response?

PA MLC checked thoroughly - okay, thus PA field treated. Information taken to calc room upon completion of daily treatment to have MLC leaves adjusted

What other forms (if any) were filled out?

**Signature**

Name (print): J. Therapist

Signature: J. Therapist

Date: 2005/06/02 time: 11:00am

***Please submit immediately to your supervisor.***

*To be completed by supervisor*Received by: A. ManagerDate received: 2005/06/02 time: 11:45amReport Index: IRF0105

**TOM BAKER CANCER CENTRE**  
**RADIATION THERAPY INCIDENT REPORT - SUPERVISOR**

**Incident Severity****Initial severity classification**

Potential	Actual	Severity
	<input type="checkbox"/>	Critical
<input type="checkbox"/>	<input type="checkbox"/>	Major
<input type="checkbox"/>	<input type="checkbox"/>	Serious
	<input checked="" type="checkbox"/>	Minor

Additional information needed:

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**Details of initial response**

Radiation Oncologist notified and viewed EPI.  
Identified area of MLC variation is small and  
thus no dose correction necessary.

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**Individuals Notified**Name (Print): Dr. R. OncologistDate: 2005/06/02 time: 11:50Name (Print): P. DosimetristDate: 2005/06/02 time: 12:05

Name (Print): \_\_\_\_\_

Date: YYYY/MM/DD time: HH:MM

Name (Print): \_\_\_\_\_

Date: YYYY/MM/DD time: HH:MM

Name (Print): \_\_\_\_\_

Date: YYYY/MM/DD time: HH:MM

Name (Print): \_\_\_\_\_

Date: YYYY/MM/DD time: HH:MM**Signature**Name (print): A. ManagerSignature: A ManagerDate: 2005/06/02 time: 12:05pm

*Note: if you are not a member of the Quality Assurance Committee, please submit this form immediately to one of the following:*

	Phone	Pager
RT Safety Officer	12345	6789
Head, Medical Physics	12345	6789
Electronics Dept	12345	6789
Supervisor, Dosimetry	12345	6789
Supervisor, RT	12345	6789
Supervisor, Nursing	12345	6789



To be completed by Investigator

Received by: A.N. InvestigatorDate received: 2005/06/02 time: 15:00Report Index: IRF0105

TOM BAKER CANCER CENTRE

**RADIATION THERAPY INCIDENT REPORT - INVESTIGATION**

Incident: an unwanted or unexpected change from a normal system behavior, which causes, or has a potential to cause, an adverse effect to persons or equipment.

**Administrative information**

Persons interviewed:

Name	Date interviewed
Floor Therapist	2005/06/02
Calc room Therapist	2005/06/02
	YYYY/MM/DD
	YYYY/MM/DD
	YYYY/MM/DD

**Verification of preliminary report information**

Please indicate by either agreement or a revised response for each element of the incident report.

Info	Agreement	Revised Response
Warrants incident report	√	
Who	√	
What	√	
Where	√	
When	√	
Initial severity classification*	Minor	

\*If initial severity revised, list additional people notified:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Related documentation**

Additional reports attached:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Incident Impact (Complete all that apply)***Patients:*# patients affected: 1# fractions per patient affected: 1# fields per fraction affected: 1Deviation from prescribed dose: minimalDeviation from prescribed volume: minimal

Dosimetrist/medical physicist who analyzed incident:

Name: P. Dosimetrist Date: 2005/06/02Signature: P. Dosimetrist

Name: \_\_\_\_\_ Date: YYYY/MM/DD

Signature: \_\_\_\_\_

*Persons:*

- | Yes                      | No                                  |   |
|--------------------------|-------------------------------------|---|
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | First Aid required                      |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | Medical attention required              |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | Hospitalization required                |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | Ongoing treatment/therapy required      |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | (staff) days of work lost: _____        |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | (patient) days of treatment lost: _____ |

*Resources:*

Total overtime hours (TBCC staff): \_\_\_\_\_

Total hours (outside service): \_\_\_\_\_

Replacement/repair costs: \_\_\_\_\_

Total hours for incident analysis: \_\_\_\_\_

Additional costs: \_\_\_\_\_

*Operations:*

Number of treatment units affected: \_\_\_\_\_

Number of patients affected: \_\_\_\_\_

Fractions lost per patient: \_\_\_\_\_

Fractions delayed by &gt; 15 min.: \_\_\_\_\_

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**TOM BAKER CANCER CENTRE**  
**RADIATION THERAPY INCIDENT REPORT - INVESTIGATION**

Incident Characteristics (Complete all that apply)	Incident details
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Domain (Please consult reference guide):

Discovery: Treatment

Origin: Preparation

Type (Clinical)

*Prescription Element (check one or both):*

- Dose
- Volume

*Source (check one):*

- Process
- Infrastructure

*Occurrence (check one):*

- Sporadic
- Systematic

Type (Other)

*Check one and circle any options that apply:*

- Hazardous condition
- Injury/illness
- Patient flow or work flow disruption
- Quality control failure or omission
- Vehicle or transportation incident
- Property or equipment failure or damage
- Complaint
- Regulatory non-compliance
- Spill, release, odour or noise
- Theft/vandalism/fraud/security breach
- Other: \_\_\_\_\_

Please provide additional details revealed during the investigation:

- PA MLC check consisted only of a visual assessment in the room using the DRR prior to treatment.
- Before having MLC adjusted, treatment plan and treatment sheet were checked for documentation regarding change in MLC shape for PA field.
- Treatment planner consulted.
- MLC shape imported. When shape imported a second time all leaves were in the proper position.
- 2 MLC leaves in incorrect position variation of 1 cm each thus difficult to visualize in shaper or on the treatment unit.
- All information second checked in calc room.
- Machine running on time with full complement of staff.

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Has this incident happened previously?

No:   √  

Yes: \_\_\_\_\_ More than Once: \_\_\_\_\_



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**TOM BAKER CANCER CENTRE**  
**RADIATION THERAPY INCIDENT REPORT - INVESTIGATION**

**Corrective actions assigned to:**

Name: RTManagement Date: 2005/06/03Name: \_\_\_\_\_ Date: YYYY/MM/DDName: \_\_\_\_\_ Date: YYYY/MM/DDName: \_\_\_\_\_ Date: YYYY/MM/DD

**Learning actions assigned to:**

Name: RTManagement Date: 2005/06/03Name: \_\_\_\_\_ Date: YYYY/MM/DD

**Signatures of investigation team:**

Name: A.Manager Signature: Amanager Date: 2005/06/03Name: J.Therapist Signature: JTherapist Date: 2005/06/03Name: P.Dosimetrist Signature: PDosimetrist Date: 2005/06/03Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: YYYY/MM/DDName: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: YYYY/MM/DDName: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: YYYY/MM/DD

**Investigation team member responsible for documentation of this incident:**

Name: T. Member Date: 2005/06/03



To be completed by Implementer  
Received by: RT Management 2  
Date received: 2005/06/20 time: 09:30  
Report Index: IRF0105



TOM BAKER CANCER CENTRE  
LEARNING FOLLOW-UP REPORT

**Learning assigned to:**

Name: RT Management 2

Date: 2005/06/20

**Communications:**

Check the method of communication and *note date*:

- Email (attach copy)                      Date: YYYY/MM/DD
- Place on Intranet Notice Board        Date: YYYY/MM/DD
- Discussed at meeting (attach minutes):
  - Routine                                      Date: 2005/06/29
  - Special meeting called                      Date: YYYY/MM/DD
  - In-service                                      Date: YYYY/MM/DD

**Summary of the contents communicated:**

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Completion Date: 2005/06/29

Signature: RT Management 2

**Please submit to:** T. Member

## REFERENCES

1. Canada Health Act 1984, C. 6, S.3.
2. Institute of Medicine (IOM) report *To Err is Human: Building a Safer Health System*. National Academy Press 2000
3. Baker GR, Norton PG, Flingoff V, et al. The Canadian adverse events study: the incidence of adverse events among hospital patients in Canada. *Canadian Medical Association Journal* 2004;170(1):1678-86.
4. Institute of Medicine (IOM) report *Patient safety: achieving a new standard for care*. National Academy Press, 2004.
5. Baker GR, Norton PG, Flingoff V, et al. The Canadian adverse events study: the incidence of adverse events among hospital patients in Canada. *Canadian Medical Association Journal* 2004;170(1):1678-86.
6. Joint Commission Resources, 2005. *Failure Mode and Effects Analysis: Proactive Risk Reduction*. 2<sup>nd</sup> Edition, Oakbrook Terrace, IL.
7. Apkon M, Leonard J, Probst L, et al. Design of a safer approach to intravenous drug infusions: failure mode effects analysis. *Quality & Safety in Health Care* 2004;13:265-71.
8. Wreathall J, Nemeth D. Assessing risk: the role of probabilistic risk assessment (PRA) in patient safety improvement. *Quality & Safety in Health Care* 2004;13:206-12.
9. Simon A, Lee RC, Cooke DL, Lorenzetti D. Institutional medical incident tracking systems: a review. Alberta Heritage Foundation for Medical Research, 2005; Initiative Paper #17.
10. Cooke DL. *Learning from incidents*. In: Gonzalez JJ (ed) *From Modeling to Managing Security – A System Dynamics Approach*, pp. 75-108. Kristiansand, Norway: Norwegian Academic Press.
11. Bird FE, Germain GL. *Practical loss control leadership*, 1986. Institute Publishing, A Division of the International Loss Control Institute: Loganville, GA.
12. Ostrom LT, et al. Lessons learned from investigations of therapy misadministration events. *International Journal of Radiation Oncology Biology and Physics* 1996;34 (1):227-34.
13. Hall EJ. Do no harm – normal tissue effects. *Acta Oncology* 2001;40(8):913-6.
14. Jung H, Beck-Bornholdt HP, Svoboda V, et al. Quantification of late complications after radiation therapy. *Radiation Oncology* 2001;61(3):233-46.

15. Tucker AL. The impact of operational failures on hospital nurses and their patients. *Journal of Operations Management* 2004;22(2):151-69.
16. Cullen DJ, Bates DW, Small SD, et al. The incident reporting system does not detect adverse drug events: a problem for quality improvement. *The Joint Commission Journal on Quality Improvement* 1995;21(10):541-8.
17. Ekaette, Lee, Cooke, Kelly, Dunscombe. *Working paper: risk analysis in radiation therapy: the application of a new taxonomic structure*; 2005.
18. Joint Commission Resources 2003, *Root cause analysis in health care: tools and techniques*, 3<sup>rd</sup> edition. Oakbrook Terrace, IL.
19. Fitzsimmons JA, Fitzsimmons MJ. *Service Management*. 2004; 4<sup>th</sup> Edition. McGraw Hill/Irwin: NY
20. Bird FE, Germain GL. *Practical loss control leadership*. 1986; Institute Publishing, a Division of the International Loss Control Institute: Loganville, GA.
21. Womer RB, Tracy E, Soo-Hoo W, et al. Multidisciplinary systems approach to chemotherapy safety: rebuilding processes and holding the gains. *Journal of Clinical Oncology* 2002;20(24):4605-12.
22. Stefanou A, Dooley M. Simple method to eliminate the risk of inadvertent intrathecal vincristine administration. *Journal of Clinical Oncology* 2003;21(10):2044.
23. CNSC Regulations, Radiation Protection (13.1): 2000.
24. CNSC Regulatory Guide G-129, rev. 1, October 2004.