GUIDE FOR MAJOR HAZARD FACILITIES

DEVELOPING A SAFETY CASE OUTLINE

MARCH 2012





Safe Work Australia is an Australian Government statutory agency established in 2009. Safe Work Australia consists of representatives of the Commonwealth, state and territory governments, the Australian Council of Trade Unions, the Australian Chamber of Commerce and Industry and the Australian Industry Group.

Safe Work Australia works with the Commonwealth, state and territory governments to improve work health and safety and workers' compensation arrangements. Safe Work Australia is a national policy body, not a regulator of work health and safety. The Commonwealth, states and territories have responsibility for regulating and enforcing work health and safety laws in their jurisdiction.

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Contact information Safe Work Australia Phone: +61 2 6121 5317 Email: info@safeworkaustralia.gov.au Website: www.safeworkaustralia.gov.au





















TABLE OF CONTENTS

1.	INTRODUCTION	2		
2.	STEPS IN PREPARING THE SAFETY CASE OUTLINE	3		
3.	SAFETY CASE OUTLINE FORMAT AND SUBMISSION	5		
4.	CONTENT OF THE SAFETY CASE OUTLINE	6		
4.1	General requirements - content and purpose	6		
4.2	A written plan for the preparation of the safety case	6		
4.3	A description of the methods to be used in preparing the safety case	6		
4.4	Details of the resources to be applied in preparing the safety case	8		
4.5	A description of consultation	9		
4.6	Other inclusions (regulation 552 (e) & (f))	9		
5.	CHECKLIST	10		
APPENDIX A - WHS REGULATIONS 11				
APPENDIX B - DEFINITIONS				
APPENDIX C - FURTHER INFORMATION 17				

A safety case outline is a plan for the preparation of a safety case for a major hazard facility (MHF). It is essentially a project plan for the preparation of the safety case. A well-developed safety case outline will help the MHF operator to plan for and produce a safety case that meets the requirements of Chapter 9 - *Major hazard facilities* of the Work Health and Safety (WHS) Regulations.

The safety case outline sets out information, including a timetable, to explain how the MHF operator will prepare a safety case that meets these requirements. It should provide a clear picture of what the operator will do, how and when.

The safety case outline may also be used by the regulator to plan its interactions (such as site visits or requests for further information).

The intended outcome is a safety case outline that meets regulatory requirements and will be used by the operator as a project plan for the preparation of an acceptable safety case delivered on time to the regulator.

The safety case itself is a written presentation of technical, management and operational information about the hazards and risks that may lead to a major incident at a MHF, and the control of these hazards and risks. In the safety case, the MHF operator provides justification for the measures the operator has taken to ensure the safe operation of the MHF. By focusing attention on major incident prevention, the safety case can improve safety at the MHF.

The safety case forms part of the MHF operator's application for a MHF licence. Details about the information required in a safety case are provided in the *Guide for Major Hazard Facilities: Preparation of a Safety Case*.

This Guide forms part of a set of guidance material for MHFs that includes information on:

- Notification and Determination
- Safety Assessment
- Safety Management Systems
- Preparation of a Safety Case
- Safety Case: Demonstrating the Adequacy of Safety Management and Control Measures
- Information, Training and Instruction for Workers and Other Persons at the Facility
- Providing Information to the Community
- Emergency Plans.

WHAT DO THE REGULATIONS REQUIRE?

The operator of a determined MHF must provide a safety case outline to the regulator within three months after the determination of the MHF. The WHS Regulations set out the matters that must be included in the safety case outline.

Further details of the WHS Regulations are set out in Appendix A.

Relevant definitions are set out in Appendix B.

The development of the safety case outline will generally require the MHF operator to:

- understand what processes and systems are required by Chapter 9 of the WHS Regulations
- understand the purpose of the safety case
- identify what information will be required to prepare the safety case
- identify any existing information that might be used to meet these requirements
- carry out a comparison or analysis which evaluates the existing information against the requirements and determine what extra information is required to prepare the safety case (gap analysis or similar)
- determine how to obtain the extra information
- plan to evaluate how well the MHF meets the requirements of Chapter 9 of the WHS Regulations, and how to establish what actions, systems or processes are required to meet any deficiencies
- write the safety case outline.

MHF operators should refer to the *Guide for Major Hazard Facilities: Preparation of a Safety Case* during the preparation of their safety case outline.

Figure 1 outlines the steps involved in developing a safety case outline.

WHO PREPARES THE SAFETY CASE OUTLINE?

The MHF operator may decide to engage a suitably qualified and experienced person from outside the MHF to assist with the preparation of the safety case outline. However, the regulator expects the operator to have ownership of the safety case outline and the safety case. This means that people who work at the facility must be involved in the development of these documents and understand the decisions made and the implications of these decisions (see Section 4.5 of this Guide). External assistance should normally be limited to assistance with documentation, specialist advice that is used by the operator in making decisions, and provision of modelling or technical data. The MHF operator should demonstrate in the safety case outline that there is an appropriate balance between resources and knowledge from the MHF and those drawn from people outside the MHF.

FIGURE 1: Flowchart for the development of a safety case outline

Establish the Context

- Information:
 - a) Existing information Collate relevant existing documents and information e.g. risk/safety related studies prepared for development approvals, compliance status with approval conditions.
 - b) Validity of existing hazard analyses, HAZOPs, fire safety studies, hazard audits and status of implementation of recommendations.
- Identify information needed and additional work to be done (gap analysis).
- Decide on tools and techniques to be used and resources required.
- Establish decision making criteria justify any adopted risk criteria (i.e.qualitative or quantitative). Compare with criteria adopted in similar situations.
- Ensure mechanism for clear, auditable documentation of the process and the results.

Safety Assessment

- Hazard identification identify all major incidents, major incident hazards and Schedule 15 chemicals
- Identify existing risk controls.
- Conduct risk assessment consequence estimation, likelihood estimation and risk analysis (include whole of site with existing risk controls in place).
- Risk evaluation against the adopted criteria.



A separate document is required for each MHF. It should clearly identify the MHF to which it applies. The information may be provided in paper or electronic form and sent to the regulator at the address given in the notice of determination of the MHF unless otherwise notified in writing by the regulator.

- To make the safety case outline easy to follow and refer to, the following is recommended:
- All information in the safety case outline and any supporting documents should be legible. In particular, font sizes should be large enough, and diagrams and plans should be at an appropriate scale and of high enough resolution for details to be readable.
- The safety case outline should be set out in a clear and logical manner with headings, section numbers and a table of contents.
- Site-specific or industry-specific terminology and abbreviations should be explained, preferably in a separate glossary.
- Each page should include in the header or footer sufficient information to identify the MHF to which it applies, preferably the company or other name, the suburb or town, and the facility identification number assigned by the regulator (if any).
- Each page should include in the header or footer sufficient information to identify the document of which it forms part, including the date, version number, section number and page number (in the form 'page X of Y').
- The cover page should list the name and address of the MHF, the facility identification number assigned by the regulator (if any), the name, title and contact details for the person the regulator should contact if details in the safety case outline require clarification, and the date of preparation and version number of the safety case outline.

4.1 General requirements - content and purpose

The safety case outline must clearly identify the main activities and timetable that the MHF operator will follow in order to prepare a satisfactory safety case by the due date, and the resources that will be used. The safety case outline is in effect a project plan for the preparation of the safety case. The descriptions of the activities as required below should be linked to a timetable similar to a Gantt chart.

The safety case outline provides assurance to the MHF operator, workers at the MHF and the regulator that the operator has adequately scoped and planned for the development of the safety case and will be approaching the development in a structured and systematic manner.

The regulator expects that MHF operators will monitor their progress against the timetable and allocate additional resources if required to meet the due date. The regulator may refer to the timeline in planning its interactions with the MHF.

The requirements for the safety case outline are set out in Regulation 552. The following sections of this guide provide guidance on how to meet these requirements.

4.2 A written plan for the preparation of the safety case

This section includes key steps and timelines, with reference being made to each element of the safety case.

The MHF operator will need to:

- identify what information is required to prepare the safety case, by reference to regulations 554 to 563, Schedules 16 to 18 of the Regulations and the Guide for Major Hazard Facilities: Preparation of a Safety Case
- identify existing information and documents that could be used in the preparation of the safety case. This may include:
 - risk assessments
 - development approvals for the current operations at the facility, modification approvals, environmental licences and other statutory approvals
 - safety documentation, studies or reports (the safety management system in particular)
 - status of compliance with hazard/safety-related conditions imposed by a development approval/consent
 - results of inspections, reviews and audits and the implementation plan for safetyrelated action items
 - maps, plans and process diagrams
 - inventories of materials
 - information about process and storage conditions
 - identification of critical controls and systems
 - incident investigations, reports and action plans
 - specifications for equipment and processes
- review existing information and documents to determine their validity. Aspects to consider may include:
 - the assumptions and data on which they were based

- appropriateness of the hazard and risk assessment techniques used
- changes that may have occurred since the document was prepared (for example, substances, processes and surroundings)
- applicability to both on-site and off-site risk and public health and safety
- suitability of acceptance criteria for risk
- changes in knowledge (for example, health effects of materials, new incidents)
- compile a gap analysis or similar to determine and document what additional work is needed, such as improvements or extensions to existing documents and new work that will be required to complete the safety case.

Note: MHF operators must consider both public health and safety and WHS when managing risks (identifying, assessing and controlling risks) under Regulations 34 and 35.

4.3 A description of the methods to be used in preparing the safety case

This section includes methods for ensuring that all the information contained in the safety case is accurate and up-to-date when the safety case is presented to the regulator.

Note: The emergency plan, SMS and safety assessment are all stand-alone documents that must also be prepared around the same time as the safety case. MHF operators will need to allow for the sharing of resources to develop these documents, or perhaps include them in the overall allocation of resources and time for preparation of the safety case.

This section should list the major tasks and activities identified in the gap analysis or similar process (above), and show the order and timetable for these tasks and activities and the links between them. The methodology and outcome of the gap analysis should be outlined and the proposed tasks and activities should be listed and briefly described. Where existing documents are to be used, they should be listed with a notation of any aspects that are known to require significant modifications.

Time may also be needed in the early stages for updating or revising existing documents and studies before proceeding to the next activity. For example, an existing risk assessment may have been limited to on-site risks only, or off-site risks only, as required by some other legislation. In this example, updating/revising the risk assessment in itself may not suffice - the updating/revision may have to start at the hazard identification. The safety case must address all major incidents that could occur and all major incident hazards, including both on- and off-site risks posed by the facility.

Time may also be needed for new studies that could be identified as a result of updating/ revising existing documents. For the example outlined in the paragraph above, existing control measures may be focused on the safety of the site personnel. An adequacy review that considers off-site risk could show the need for additional control measures, such as safe shutdown systems with a higher level of reliability. A new HAZOP and possibly Safety Integrity Level (SIL) analysis of the systems might then become necessary.

Time and resources should also be allowed for other activities involved in preparation of the safety case, such as writing, peer review, approval processes and quality assurance. This includes resources for preparing the descriptive and analytical aspects of the safety case, such as demonstration of acceptable level of risk and justification of the selection of methodologies and controls, as well as the simpler information (for example, information about the facility location).

Better resource allocation and timing are possible when interactions are understood. A flow chart similar to the example at Figure 1 may be an effective representation.

The regulator recognises that the timetable described in the safety case outline could change before or during the preparation of the safety case. The MHF operator should ensure that any changes do not adversely affect the quality or on-time completion of the safety case and should notify the regulator of significant changes.

The safety case outline should include details of the tasks assigned and the required timing, and list who is responsible for their completion. Information about staff expertise can be included here or cross-referenced to information referred to below.

The safety case outline should also describe the system to be used to ensure that the tasks and activities listed will be completed to the required standard and on time.

4.4 Details of the resources to be applied in preparing the safety case

The MHF operator should use this section to demonstrate that adequate resources will be made available to prepare the safety case. It should include the number of persons involved and their relevant knowledge and experience, the sources of technical information and information about any software used for risk evaluation.

The description of the resources must include the points below and any other relevant information. The regulator recognises that the resources described in the safety case outline could change before or during the preparation of the safety case. The operator should notify the regulator of significant departures from the submitted safety case outline and ensure that the quality of the safety case is maintained at an acceptable level.

THE PERSONS TO BE INVOLVED AND THEIR RELEVANT KNOWLEDGE AND EXPERIENCE

This section should describe who will be primarily responsible for, or have key involvement in, the tasks and activities, and their level of involvement. It should also describe the knowledge and skills they bring to the activities and tasks. Names and/or position descriptions may be used, along with a brief outline of relevant skills, knowledge and experience.

SOURCES OF TECHNICAL INFORMATION

This may include:

- process safety analyses
- audit reports (such as process safety audits, safety management system audits, risk management audits and compliance audits)
- hazard identification and risk assessments
- inspection reports
- plant and process modifications
- design specifications, plant specifications and limitations
- safety studies (such as fire safety, explosion safety, safety integrity level or reliability studies)
- emergency plans
- release modelling
- frequency data

- toxicity data
- reports and analyses of serious incidents and incidents including near misses at the facility or other facilities
- security breach reports
- off-site and on-site consequence modelling reports
- information published by regulators or industry groups
- relevant research, including published papers.

The safety case outline should include details of the information intended to be used. Where this information already exists, give details such as full titles, document owner, date, edition, version numbers or web address. The details should be sufficient to enable the regulator to readily identify the documents and obtain copies.

SOFTWARE DETAILS

Details of software and type of modelling done in any existing studies and the software to be used for any proposed consequence modelling or risk analysis and evaluation should be included. The selection of software should be justified.

4.5 A description of consultation

This section contains a description of the consultation with workers that occurred in the preparation of the safety case outline and will occur in the preparation of the safety case.

Sections 47 to 49 of the WHS Act require consultation with workers in various circumstances, including when preparing the safety case outline. They describe some important characteristics of consultation, including sharing information with workers and providing opportunities for them to express their views and for these views to be taken into account.

For further information on consultation, refer to the Code of Practice: Work Health and Safety Consultation, Cooperation and Coordination.

MHF operators may also describe in this section how they plan to liaise with parts of the community that may be affected by a major incident.

4.6 Other inclusions (Regulation 552 (e) & (f))

The following must also be included:

- a draft of the emergency plan prepared or to be prepared under Regulation 557
- a summary of any arrangements that are to be made in relation to the security of the major hazard facility.

Use this checklist to ensure the safety case outline has addressed the requirements

Requirement				
1	A written plan for the preparation of the safety case, including key steps and timelines, with reference being made to each element of the safety case. Typical elements are given in the Guide for Major Hazard Facilities: Preparation of a Safety Case.			
2	A description of the methods to be used in preparing the safety case, including methods for ensuring the accuracy of information in the safety case.			
3	Details of the resources that will be applied to the preparation of the safety case, including, but not limited to:			
	 the number of persons to be involved and their relevant knowledge and experience and sources of technical information 			
	 the software to be used for risk evaluation (if any), together with information to support the appropriateness of the software for the intended use. 			
4	A description of the consultation with workers that:			
	 occurred in the preparation of the safety case outline 			
	 will occur in the preparation of the safety case. 			
5	A draft of the emergency plan prepared or to be prepared.			
6	A summary of any arrangements that are to be made in relation to the security of the major hazard facility.			
7	A cover page listing the name and address of the MHF, the name, title and contact details for the person the MHF Team should contact if details in the safety case outline require clarification, and the date of preparation of the safety case outline.			

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 The operator must alter the outline as required. 		 The operator must alter the outline as required.

Regulation	Requirement
574	The operator must give the regulator a copy of a safety case outline that has been altered:
	 under this regulation
	 by the operator on the operator's initiative.
	 The safety case outline as altered becomes the safety case outline for the major hazard facility.

APPENDIX B — DEFINITIONS

Class has the same meaning as in the ADG Code.

Control measure, in relation to risk to health and safety, means a measure to eliminate or minimise the risk.

Determined major hazard facility means a facility that has been determined under regulation 541 or 542 to be a major hazard facility.

Facility means a workplace at which Schedule 15 chemicals are present or likely to be present.

Failure of a control measure means:

- if the risk control measure is a positive action or event: the non-occurrence or the defective occurrence of that action or event
- if the risk control consists of a limitation on an operational activity, process or procedure: the breach of that limitation.

HIPAPs are the Hazardous Industry Planning Advisory Papers published by the NSW Department of Planning & Infrastructure. See Appendix C of this guide for a list of HIPAPs.

Incident is any undesired event, including major incidents and near misses. The regulations do not use the term 'near miss' but incorporate the concept by reference to 'potential occurrence of major incidents'. See Regulations 558(2)(a) and 561(4)(b), which relate to the SMS and the safety case.

Major hazard facility (MHF) means a facility:

- at which Schedule 15 chemicals are present or likely to be present in a quantity that exceeds their threshold quantity
- that is determined by the regulator under Part 9.2 to be a major hazard facility.

Major hazard facility licence means a licence granted to a major hazard facility under Part 9.7 of the Regulations.

Major incident at a major hazard facility is an occurrence that:

- results from an uncontrolled event at the major hazard facility involving, or potentially involving, Schedule 15 chemicals
- exposes a person to a serious risk to health or safety emanating from an immediate or imminent exposure to the occurrence.

An occurrence includes any of the following

- escape, spillage or leakage
- implosion, explosion or fire.

Major incident hazard means a hazard that could cause, or contribute to causing, a major incident.

MIHAPs are the Major Industrial Hazards Planning Advisory Papers published by the NSW Department of Planning & Infrastructure. See Appendix C of this guide for a list of MIHAPs.

Modification

- A reference to a modification of a major hazard facility is a reference to a change or proposed change at the major hazard facility that has or would have the effect of:
 - creating a major incident hazard that has not previously been identified
 - significantly increasing the likelihood of a major incident occurring
 - in relation to a major incident that may occur, significantly increasing:
 - its magnitude

the severity of its health and safety consequences.

A **change or proposed change** at a major hazard facility means a change or proposed change of any kind, including:

- a change to any plant, structure, process, chemical or other substance used in a process, including the introduction of new plant, a new structure, a new process or a new chemical
- a change to the quantity of Schedule 15 chemicals present or likely to be present at the major hazard facility
- a change to the operation, or the nature of the operation, of the major hazard facility
- a change in the workers' safety role
- a change to the major hazard facility's safety management system
- an organisational change at the major hazard facility, including a change in its senior management.

Near miss is any accident that, but for mitigating effects, actions or systems, could have escalated into a major incident.

Operator

- in relation to a facility, means the person conducting the business or undertaking of operating the facility, who has:
 - management or control of the facility
 - the power to direct that the whole facility be shut down
- in relation to a proposed facility, means:
 - the operator of a proposed facility that is an existing workplace
 - the person who is to be the operator of a proposed facility that is being designed or constructed.

Pipe work means a pipe or assembly of pipes, pipe fittings, valves and pipe accessories used to convey a hazardous chemical.

Present or likely to be present is a reference to the quantity of hazardous chemicals that would meet the maximum capacity of the facility, including:

- the maximum capacity of process vessels and interconnecting pipe systems that contain the hazardous chemicals
- the maximum capacity of storage tanks and vessels used for the hazardous chemicals
- the maximum capacity of other storage areas at the facility that could contain the hazardous chemicals
- the maximum capacity of pipe work outside process areas to contain the hazardous chemicals
- the maximum quantity of hazardous chemicals that would, in the event of failure, escape into the facility from pipe work that is situated off the premises but is connected to the facility
- the maximum quantity of hazardous chemicals loaded into or onto, or unloaded from, vehicles, trailers, rolling stock and ships that are from time to time present at the facility in the course of the facility's operations.

Note: Schedule 15 chemicals present or likely to be present in the tailings dam of a

mine are not to be considered in determining whether a mine is a facility or a major hazard facility

Proposed facility means:

- an existing workplace that is to become a facility due to the introduction of Schedule 15 chemicals
- a facility that is being designed or constructed.

Proposed major hazard facility means:

- an existing facility or other workplace that is to become a major hazard facility due to the introduction of Schedule 15 chemicals or the addition of further Schedule 15 chemicals
- a major hazard facility that is being designed or constructed.

Risk assessment involves considering what could happen if someone is exposed to a hazard and the likelihood of it happening.

Risk control means taking action to eliminate health and safety risks so far as is reasonably practicable, and if that is not possible, minimising the risks so far as is reasonably practicable.

Risk management in this guide means the processes of:

- identification of major incidents and major incident hazards
- safety assessment, including:
 - risk analysis (likelihood and consequences)
 - risk evaluation against risk criteria
- risk control (risk treatment)
- review and revision of the:
 - safety assessment
 - emergency plan
 - safety management system

Safety assessment is the process by which the operator of a major hazard facility systematically and comprehensively investigates and analyses all aspects of risks to health and safety associated with all major incidents that could occur in the course of the operation of the major hazard facility.

The safety assessment is a significant body of work that is drawn upon to demonstrate adequate safety in the safety case.

Safety case is a written presentation of the technical, management and operational information covering the hazards and risks that may lead to a major incident at a major hazard facility and their control, and which provides justification for the measures taken to ensure the safe operation of the facility.

Safety management system as set out in the Regulations (558 and 568) and Schedule 17 means the comprehensive integrated system for managing all aspects of risk control in relation to the possible occurrence of major incidents at a major hazard facility and is used by the operator as the primary means of ensuring safe operation of the MHF.

Schedule 15 chemical means a hazardous chemical that:

■ is specified in Schedule 15, table 15.1 of the WHS Regulations

 belongs to a class, type or category of hazardous chemicals specified in Schedule 15, table 15.2 of the Regulations.

SIL means Safety Integrity Level.

Threshold quantity, in relation to a Schedule 15 chemical, means:

- the threshold quantity of a specific hazardous chemical as determined under clause 3 of Schedule 15
- the aggregate threshold quantity of 2 or more hazardous chemicals as determined under clause 4 of Schedule 15.

APPENDIX C — FURTHER INFORMATION

This section is not an exhaustive list of references but simply a list of additional information regarding safety cases for MHFs. Note that some of these references have been written specifically for different regulatory regimes, but have some similarities to the requirements under the WHS Regulations.

A guide to the control of major incident hazards regulations 1999

UK Health and Safety Executive ISBN 0 7176 1604 5 www.hse.gov.uk/comah/

A qualitative model to evaluate the risk potential of major hazardous industrial plants

Suarez A. and Kirchsteiger C. 1998

EUR 18128 EN

Guidance for major hazard facilities: J-safety report

Queensland Department of Justice and Attorney General November 2008

Guidance note: safety report content and level of detail

National Offshore Petroleum Safety Authority (NOPSA) Revision 1, June 2009

Guidance on the preparation of a safety report (Seveso II)

Joint Research Center European Commission ISBN 92 828 1451 3 http://mahbsrv.jrc.it/GuidanceDocs-SafetyReport.html

Guidelines for integrated risk assessment and management in large industrial areas

International Atomic Energy Agency, Vienna 1998

IAEA-TECDOC-994 www.iaea.org/index.html

Guidelines for quantitative risk assessment 'Purple Book'

TNO, The Hague First Edition, 1999

CPR 18E

Guidelines on a major incident prevention policy and safety management system, as required by council directive 96/82/EC (Seveso II)

European Commission, Italy 1998

EUR 18123

http://mahbsrv.jrc.it/GuidanceDocs-SafetyManagementSystems.html

Hazardous industry planning advisory papers (HIPAPs)

No.1 - Emergency Planning (HIPAP 1)

No.2 - Fire Safety Study Guidelines (HIPAP 2)

No.3 - Risk Assessment (HIPAP 3)

- No.4 Risk Criteria for Land Use Safety Planning (HIPAP 4)
- No.5 Hazard Audit Guidelines (HIPAP 5)
- No.6 Hazard Analysis (HIPAP 6)

No.7 - Construction Safety (HIPAP 7)

No.8 - HAZOP Guidelines (HIPAP 8)

No.9 - Safety Management (HIPAP 9)

NSW Department of Planning & Infrastructure www.planning.nsw.gov.au

Major hazard control: A practical manual

International Labour Organisation, Geneva 1993

Third impression (with corrections) ISBN: 92-2-106432-8

Major industrial hazards advisory papers (MIHAPs) (Drafts)

These documents provide relevant technical information but do not reflect legislative requirements in the WHS Regulations.

No. 1 - Safety Assurance

- No. 3 Hazard Identification, Risk Assessment and Risk Control
- No. 6 Training and Education
- No. 9 Incident Reporting and Investigation

NSW Department of Planning & Infrastructure www.planning.nsw.gov.au or www.workcover.nsw.gov.au

Manual for the classification and prioritisation of risks due to major incidents in process and related industries

Inter-Agency Programme on the Assessment and Management of Health and Environmental Risks from Energy and Other Complex Industrial Systems

International Atomic Energy Agency, Vienna December 1993 and December 1996 (Rev. 1)

IAEA-TECDOC-727 and IAEA-TECDOC-727 (Rev. 1)

Multi-level risk assessment

NSW Department of Planning & Infrastructure 2011 www.planning.nsw.gov.au

Preliminary environmental risk ranking

Hutchison R.B., Perera J., Witt H.H. 1996

ANSTO Safety and Reliability, Risk Engineering Seminar Munro Centre for Civil and Environmental Engineering, University of NSW

Preparing safety reports: Control of major incident hazards regulations 1999

UK Health and Safety Executive HSG190

ISBN 9780717616879

AS HB 167:2006 Security risk management

Standards Australia

AS/NZS ISO 31000:2009 Risk management - Principles and guidelines

Standards Australia



PROVIDING MAJOR HAZARD FACILITY OPERATORS WITH INFORMATION TO DEVELOP A SAFETY CASE OUTLINE FOR A MAJOR HAZARD FACILITY.