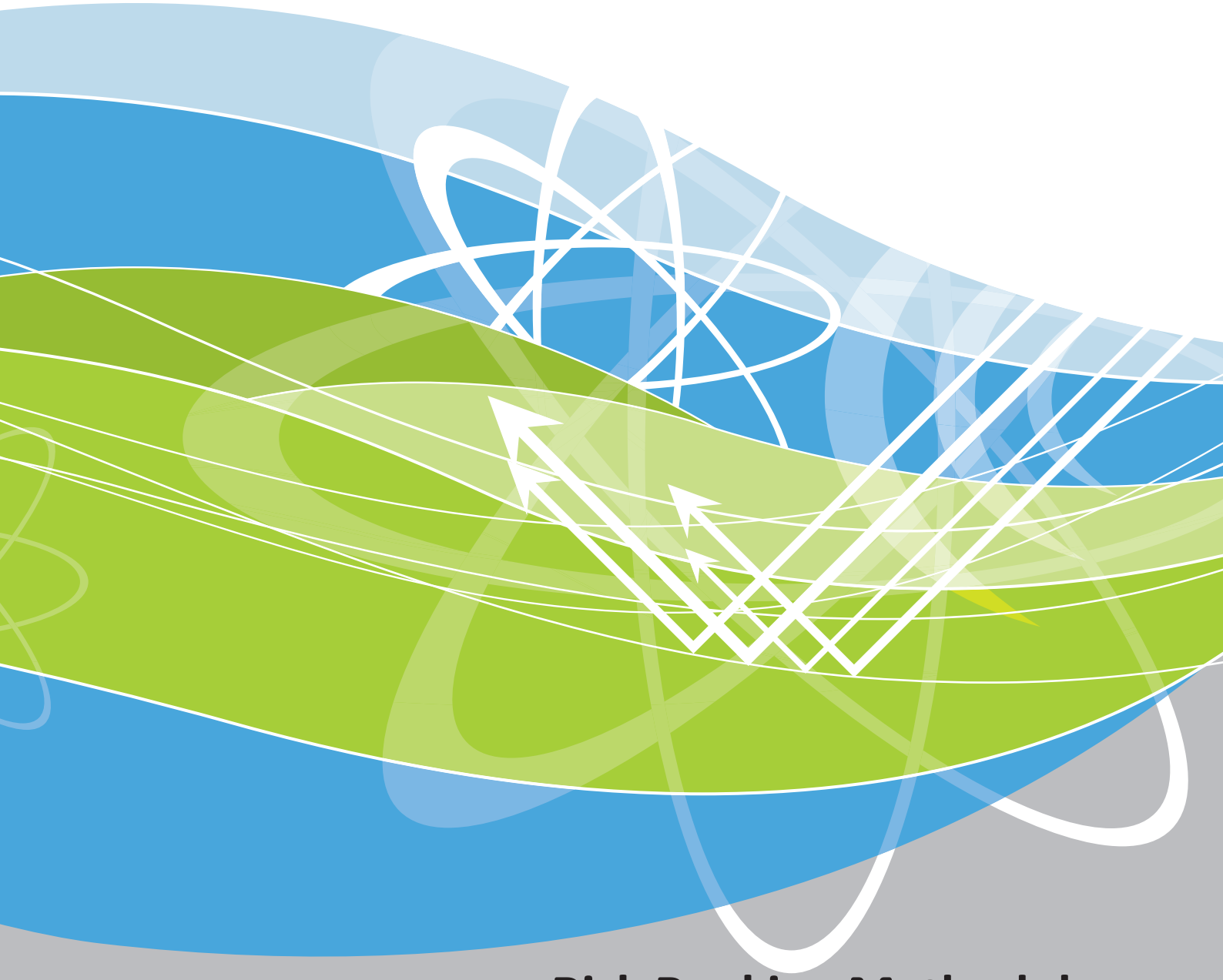
Australian Government
Australian Radiation Protection and Nuclear Safety Agency

ARPANSA

Protecting people and the environment from the harmful effects of radiation

GUIDE FOR REGULATORY OFFICERS



Risk Ranking Methodology

June 2013

Australian Government
Australian Radiation Protection and Nuclear Safety Agency

GUIDE FOR REGULATORY OFFICERS: Risk Ranking Methodology v3

REGULATORY SERVICES

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1. Objective

The objective of this document is to provide guidance on how the risk of a licence holder, subset of a licence holder or site can be assessed. It is meant as an aide to regulatory officers to promote consistent and transparent risk ranking of sources and facilities. The resulting risk will be a useful tool in planning inspections and directing regulatory effort, enabling resources to be allocated to areas of higher risk. Other factors such as geographic location, specific issues arising, timing of previous inspections etc are also taken into account when planning the inspection program. This document is not intended for use by the licence holders as they will have their own risk management strategies.

When implemented appropriately this guidance will ensure that:

- Licence holders are assessed in a consistent and transparent manner by different regulatory officers
- The regulatory officer is alerted if the risk of a licence holder changes. Changes can occur if through the acquisition or disposal of sources, through changes in controls or through changes in the level of regulatory oversight. Regulatory officers will be alerted if the risk increases but can also note and respond to the reasons for reductions in risk.
- Regulatory resources can be directed in an efficient and justifiable manner.

2. General Principles

The risk ranking methodology presented in this document can be used to assess the risk of a licence holder, subset of a licence holder or site. The methodology presented has evolved from previous guidance and utilises ways of assessing risk that are already in use within the Branch. The risk is based on hazard and control – these two parameters are considered suitable as they are straightforward to assess based on existing information available to the regulatory officer. Risk is often expressed in terms of likelihood (chance of something happening) and consequence (outcome of an event). In our circumstances hazard and control are more suited, as they are based on parameters already assessed or evaluated by regulatory staff. Hazard is a measure based on consequence and control is a qualitative measure of likelihood.

Hazard is a measure based on the consequence of potential harm to people and/or the environment. Guidance on how to evaluate the hazard is given in Section 4 for sources and in Section 6 for facilities. The hazard of a source is assigned a number between 1 and 3 and the hazard of a facility is assigned a number between 1 and 4.

> *NOTE: Even though a source and a facility might be given the same hazard level they cannot be compared as they are based on different factors. Facilities are inherently more hazardous than sources.*

Control is defined as the demonstrated ability to maintain safety of sources, facilities or part thereof. The control is assigned a number between 1 and 5. It is based initially on an evaluation of the licence application, and later by the licence holder's compliance history and assessments made of the licence

holder. Section 7 in this document gives guidance on how to evaluate the control of sources and facilities.

Risk is calculated by multiplying hazard with control. The risk of a source and a facility **cannot** be directly compared as the hazard levels are based on different consequences for a source and a facility, ie a low risk source does not have the same risk as a low risk facility.

For licence holders spread out over several sites with varying control and hazard between the sites, it is appropriate to assess the risk for each site separately. Facilities can be evaluated as a whole, or a subset of a facility can be evaluated. This will be appropriate for complex facilities where inspections target specific areas and the whole facility is generally not inspected at one given time.

3. Risk-ranking – Sources

The following matrix should be used to calculate the risk of sources. Guidance on how to evaluate the hazard is given in section 4 and guidance on how to evaluate control is given on in Section 7.

	Control				
Hazard	**Very high** **1**	**High** **2**	**Medium** **3**	**Limited** **4**	**Very limited** **5**
1	1	2	3	4	5
2	2	4	6	8	10
3	3	6	9	12	15

RISK - SOURCES

	1-2	Negligible risk
	3	Low risk
	4-6	Medium risk
	8-9	High risk
	10–15	Very high risk

4. Guidance on evaluating hazard of sources

Hazard Level	Description	Ionising radiation	Non-ionising radiation *(see table below for full list)*
Hazard Level 1	Dealings with controlled apparatus or materials where there is potential for accidental exposures which: (a) in the case of ionizing radiation, would be in the order of the annual public dose limit (1 mSv); or (b) in the case of non-ionizing radiation, would exceed exposure limits but would be unlikely to result in injury.	Group 1	Optical sources – low emission
Hazard Level 2	Dealings with controlled apparatus or materials where there is a potential for accidental exposures which: (a) in the case of ionizing radiation, are greater than the annual public dose limit (1 mSv) but are unlikely to result in acute injury; or (b) in the case of non-ionizing radiation, exceed exposure limits by a wide margin and could lead to injury.	Group 2	Certain UV sources (transilluminators, germicidal lamps) Class 3B lasers OFCS Hazard level 3B
Hazard Level 3	Dealings with controlled apparatus or materials where there is a potential for accidental exposures which: (a) in the case of ionizing radiation, could result in acute injury; or (b) in the case of non-ionizing radiation, could result in severe injury.	Group 3	Class 4 lasers OFCS Hazard level 4

Table 1 Hazard levels of sources

For ionising radiation the hazard level follows the Group, ie Group 1 has a hazard of 1, Group 2 has a hazard of 2 etc. In determining the activities (in Becquerels) of ionising sources within the above categories, the logic is based on escalating in 100x multiples of the exemption levels (EL) for activities of the sources. The ELs come from the International Atomic Energy Agency 'General Safety Requirements - Part 3 (Interim)' and are based on the effective dose expected to be incurred by any member of the public due to the exempted material being of the order of 10 microSv – a dose which is considered to be below regulatory concern.

- **Hazard Level 1** < about 100xEL ie < about 1mSv (annual limit for the public) from scenarios
- **Hazard Level 2** < about 100x100xEL ie < about 0.1 Sv from scenarios resulting in stochastic effects
- **Hazard Level 3** < about 100x100x100 EL ie < doses of the order of a Sv resulting in deterministic effects and life threatening injuries

Medical sources

ARPANSA regulates only a small number of medical sources; most fall under State or Territory jurisdictions. When assessing the hazard of medical sources, patient exposure should be considered. In some cases this can increase the hazard category of the source. For the purpose of risk ranking most medical sources are categorised according to which group they belong to (Group 1 has a hazard of 1 etc). However, fluoroscopy units for interventional radiology and CT scanners should be considered to be Hazard Level 3.

Guidance on evaluating hazard of NIR apparatus

In the table below guidance is given on how to rank the hazard of apparatus emitting non-ionising radiation. This guidance is generic and regulatory officers will have to exercise judgement when assessing individual items. No account of potential impacts on the environment has been taken, but these are generally low or non-existent when dealing with non-ionising radiation.

Controlled Apparatus	Hazard Level
Magnetic field non-destructive testing device	1-3*
Induction heater or furnace	1-3**
Industrial RF heater or welder	1-3**
RF plasma tube	1-3**
Microwave or RF diathermy equipment	1-3**
Industrial microwave or RF processing system	1-3**
Optical sources (UV, IR, Visible)	1-2
- Optical sources – low emission	1
- Transilluminators	2
- Germicidal lamps (not enclosed)	2
Class 3B laser product	2
Class 4 laser product	3
OFCS Hazard Level 3B	2
OFCS Hazard Level 4	3

Table 2 Hazard level of NIR apparatus

Notes:

*Fatal injuries may occur because of flying objects and disruption of pacemakers and other implants.

**Most standard RF equipment would normally have a hazard level of 1-2. A potential for large induced currents may result in severe injury (hazard level 3).

5. Risk-ranking – Facilities

The following matrix should be used to calculate the risk of facilities. Guidance on how to evaluate the hazard of a facility is given in section 6. Table 3 is used if a whole facility is being evaluated. For large facilities it is useful to evaluate the risk of a subset of the facility. This will enable inspections to target high-risk areas. In this case Table 4 is used to evaluate the hazard. Guidance on how to evaluate control is given in Section 7.

Control

Hazard	**Very high 1**	**High 2**	**Medium 3**	**Limited 4**	**Very limited 5**
1	1	2	3	4	5
2	2	4	6	8	10
3	3	6	9	12	15
4	4	8	12	16	20

RISK - FACILITIES

	1-2	Negligible risk
	3-4	Low risk
	5-9	Medium risk
	10-12	High risk
	15–20	Very high risk

6. Guidance on evaluating hazard of facilities

The table below should be used to categorise the hazard of a complete facility. The hazard of the facility is established according to the potential for significant consequences outside the facility or outside the site. The hazard categories F1, F2 and F3 are as defined in *REGULATORY GUIDE: Regulatory Assessment Principles for Controlled Facilities.*

Hazard category of facility	**Hazard level** *(to feed into the matrix on p.7)*
F3 – potential for significant consequences outside the site	4
F2 – potential for significant consequences on the site outside the facility, but not outside the site	3
F1 – no potential for significant consequences outside the facility	2

Table 3 Hazard level of facilities

Guidance on evaluating hazard of structures, systems and components (SSC) of a facility

To assess the hazard of part of a facility first determine whether it is a facility with hazard category F1, F2 or F3. Then use the table below to determine the nuclear and radiation safety implications of the particular SSC being assessed. The hazard will be based on the hazard category of the facility as a whole (F1, F2 and F3) and the safety implications of the specific SSC of a facility being assessed.

Safety implications of individual structures, systems and components (SSC)	**Corresponding hazard level for a F3 facility** *(to feed into the matrix on p.7)*	**Corresponding hazard level for a F2 facility** *(to feed into the matrix on p.7)*	**Corresponding hazard category for a F1 facility** *(to feed into the matrix on p.7)*
SSC that forms a primary means of ensuring radiation or nuclear safety	4	3	2
SSC that makes an important additional contribution to radiation or nuclear safety	3	2	1
Any other SSC that do not belong to the above two categories	1	*	*

Table 4 Hazard level of individual SSC of facilities for safety risk assessment

*Assume negligible risk for this individual system.

7. Guidance on evaluating level of control

Control is defined as the demonstrated ability to maintain safety of sources, facilities or part thereof.

There are five levels of control:

1. Very high
2. High
3. Medium
4. Limited
5. Very limited

The control of the licence holder is based initially on an evaluation of the licence application, and later by the licence holder's compliance history. This will include evaluation of a number of parameters and assessment of information available to ARPANSA. The assessment should take into account various sources of information which include the following:

1. Inspection findings and their conclusions + licence holder response
2. Information from quarterly reports
3. Other reports provided to ARPANSA (for example incident or accident reports)
4. Information presented to ARPANSA in various types of submissions
5. Information obtained in meetings with licence holders

Table 5 can be used as a guide to assist in determining the control for a licence holder, subset of a licence holder or site. The list is not exclusive and the parameters should not be considered as absolute criteria. Other factors considered to impact on the control should be considered if relevant. The highest number obtained when assessing the licence holder (or part thereof) against the criteria in the table should be used as the control. This number will feed into the risk ranking matrix (page 3 for sources and page 6 for facilities) to determine the risk. If the control of the licence holder/site/system is not known, use a default control of 4 (limited).

The assessor is referred to individual ARPANSA guidelines for details on assessment criteria e.g. *REGULATORY GUIDE: Regulatory Assessment Principles for Controlled Facilities*, *REGULATORY GUIDE: Plans and Arrangements for Managing Safety*, and *REGULATORY GUIDE: Holistic Safety Guidelines* for further guidance. Depending on the type of licence, the level of engineered safety provisions will vary in types and scope of operation. A graded approach should be applied. For example, a less sophisticated apparatus or facility will not require as comprehensive plans and arrangements as would a nuclear reactor.

Control	Inspections	Compliance with licence conditions having significant implications for safety	Compliance with licence conditions having no or minor implications for safety	Incidents/ Accidents[1]	Defence in Depth (DiD) (if relevant)	Plans and Arrangements[3]	Other holistic safety[2] aspects
1 Very high	An inspection or site visit has been conducted within the last year.	No non-compliances within the last year.	No non-compliances within the last year.	No incidents or accidents within the last year.	DiD well designed and well implemented, maintenance of all SSC of all levels is effective.	Detailed knowledge of plans and arrangements exists. They are well developed and are reviewed annually by the licence holder.	Detailed knowledge of holistic safety of the licence holder exists. It is assessed to be good.
2 High	An inspection or site visit has been conducted within the last 2 years.				DiD well designed and well implemented, maintenance of some systems of some levels of DiD has shortfalls with no consequences on prevention, control and mitigation of potential accidents.	General knowledge of plans and arrangements exists. They are well developed and are reviewed annually by the licence holder.	General knowledge of the holistic safety of the licence holder exists. It is assessed to be good.
3 Medium	An inspection or site visit has *not* been conducted within the last 2 years.		A non-compliance within the last year.		DiD is designed and implemented acceptably. Some SSC of DiD level 1, 2, 4 and 5 have minor insufficiencies which could impact on prevention of accidents and mitigation of their consequences.	Plans and arrangements fulfil minimum requirements. The most important documents are reviewed annually by the licence holder.	No indications that holistic safety is inadequate.
4 Limited		A non-compliance within the last year.	Several non-compliances within the last year.	One incident within the last year. Near-misses included.	DiD is designed and implemented acceptably. Some SSC of DiD level 3 – safety systems have minor insufficiencies which could impact on control of accidents. Some SSC of DiD level 1, 2, 4 and 5 have major insufficiencies which could impact on prevention of accidents and mitigation of their consequences.	Plans and arrangements do not fulfil minimum requirements.	Holistic safety is assessed to be inadequate.
5 Very limited		Several non-compliances within the last year.		One accident within the last year.	DiD designed and implemented acceptably; systems of multiple levels of DiD are poorly maintained or operated with potential major impact on DiD prevention, control and mitigation of accident situations.	Plans and arrangements are well below minimum requirements.	Holistic safety is assessed to be poor.

Table 5 Levels of control for sources and facilities

[1] Incidents are as defined in Schedule 13 of the NDRP and accidents defined in REGULATORY GUIDE: Reporting an Accident

[2] Refer to the Holistic Safety Guidelines for more detail.

[3] Refer to REGULATORY GUIDE: Regulatory Assessment Principles for Controlled Facilities, REGULATORY GUIDE: Plans and Arrangements for Managing Safety for more detail.

8. Flow Diagram for updating Licence Holder Risk Ranking