



Consultation Summary

Guidance Statement: Decision Making

formerly draft Guidance Statement: Regulatory Assessment Framework

Guidance Statement: Risk Assessments

formerly draft Guidance Statement: Environmental Risk Assessment Framework and draft Guidance Statement: Regulatory Controls

Document Version History

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Accessibility

This document is available in alternative formats and languages on request.

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1. Background

The Department of Environment Regulation (DER) is developing a robust suite of documents consistent with DER's regulatory principles (see *Guidance Statement: Regulatory Principles*) to guide the administration of its regulatory functions under Part V, Division 3 of the *Environmental Protection Act 1986* (EP Act). The draft *Guidance Statement: Regulatory Assessment Framework* (Draft GS: RAF), *Guidance Statement: Environmental Risk Assessment Framework* (Draft GS: ERAF) and *Guidance Statement: Regulatory Controls* (Draft GS: RC) for Part V, Division 3 of the EP Act were prepared as part of DER's hierarchy of instruments governing environmental regulation and apply to a range of DER's regulatory functions. This suite of documents, together form DER's Regulatory Framework.

DER released the three draft Guidance Statements for public comment on 4 December 2015 and consultation closed on 11 March 2016. In total, 23 submissions from external parties were received.

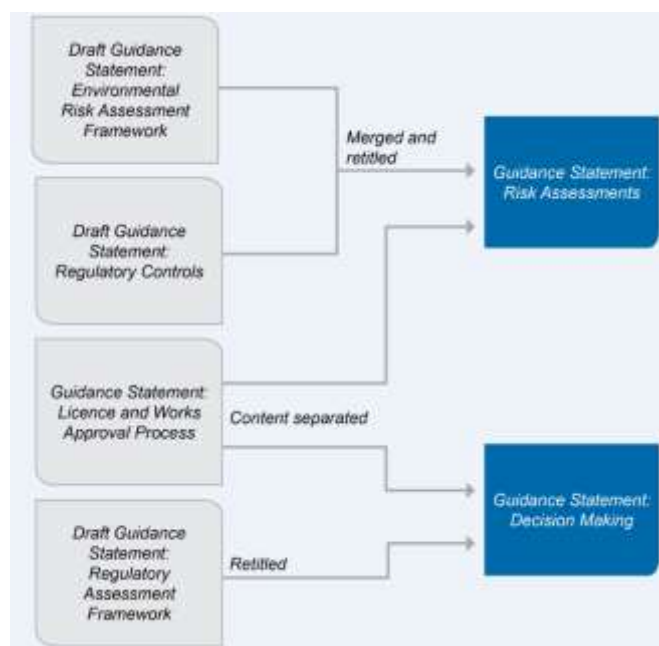
DER thanks all respondents and appreciates the time taken to provide comments on the draft Guidance Statements. DER has considered the issues raised in the submissions as well as learnings from pilot assessments trialling this approach. As a result, DER has finalised two Guidance Statements in place of the previous three draft Guidance Statements.

The *Guidance Statement: Environmental Risk Assessment Framework* has been merged with the *Guidance Statement: Regulatory Controls* and has been retitled as *Guidance Statement: Risk Assessments*. Combining these documents achieves better consistency with DER's regulatory principles and improves readability.

The draft *Guidance Statement: Regulatory Assessment Framework* has been renamed *Guidance Statement: Decision Making* to improve readability.

Guidance Statement: Decision Making and *Guidance Statement: Risk Assessments* now address the issues in *Guidance Statement: Licence and Works Approval Process* due to the similarity in subject matter. *Guidance Statement: Licence and Works Approval Process* has now been removed from DER's website.

The changes are summarised as follows:



This consultation summary report summarises the key issues from the submissions received on each of the three draft Guidance Statements and DER's responses to these issues.

2. Submissions

External submissions were received from the following parties:

	Submitting Party	Draft GS: RAF	Draft GS: ERAF	Draft GS: RC
1	Chamber of Commerce and Industry of Western Australia	•	•	•
2	City of Nedlands		•	•
3	Chamber of Minerals and Energy of Western Australia	•	•	•
4	C-Wise			•
5	Department of Parks and Wildlife	•	•	•
6	Fortescue Metals Group Ltd			•
7	Kwinana Industries Council	•	•	•
8	MBS Environmental	•	•	•
9	Roy Hill	•	•	•
10	Southern Ports Authority	•	•	•

	Submitting Party	Draft GS: RAF	Draft GS: ERAF	Draft GS: RC
11	Synergy	•	•	•
12	Water Corporation	•	•	•
13	Western Australian Local Government Association	•	•	•
14	Wesfarmers Chemicals, Energy & Fertilisers Limited	•	•	•
15	Waste Management Association of Australia	•	•	•
16	Clean Air Society of Australia and New Zealand		•	
17	Department of Health	•	•	
18	Fremantle Ports		•	
19	Kalgoorlie Consolidated Gold Mines	•	•	
20	Perth Energy		•	
21	Pilbara Ports Authority		•	
22	Office of the Environmental Protection Authority	•	•	•
23	Shire of Harvey	•	•	•

3. General

DER received a number of general submissions in relation to all three draft Guidance Statements. The issues raised can be grouped into the following categories:

- Inconsistencies between the documents;
- Insufficient linkages to other relevant DER guidance documents;
- Duplication with other State Government Agencies;
- Training, resources and DER staff;
- Application of DER's discretion;
- Consultation; and
- DER initiated review of premises.

These general comments are addressed below.

3.1 Inconsistencies between the documents

A number of comments were received on inconsistencies in terminology and linkages between the three draft Guidance Statements. A summary of the comments received is below.

3.1.1 Summary of comments received and DER response

Comment	DER response
New risk concepts are introduced in the Draft GS:RC that appear to contradict concepts presented in the Draft GS: ERAF. For example, Clause 1 introduces the terminology “emission risk” and “inherent risks of emissions types” in the context of the Regulatory Controls Matrix – it is not clear how these concepts relate to the concept of risk in the GS: ERAF.	Agreed. The concept of inherent risks has been removed. In order to improve readability and address concerns about the relationship and inconsistencies between the documents, these draft guidance statements have been combined.
Consistent terminology across all Guidance Statements is needed, specifically relating to how impacts on human health and amenity and impacts on the environment are described.	Noted. DER has reviewed its terminology and has amended the final Guidance Statements the subject of this Consultation Summary to ensure consistency of terms. All other Guidance Statements will be reviewed and amended for consistency of terminology.

3.1.2 DER position

In response to submissions, DER has merged Draft GS: ERAF and Draft GS: RC. DER considered this was necessary in order to improve readability and address concerns about the relationship, inconsistencies and linkages between the documents. DER has also shifted some of the tables from the appendices of Draft GS: ERAF into the content of the Guidance Statement itself. The Guidance Statements have also been re-ordered to support a more logical sequence.

The Guidance Statements also now include more consistent terminology to avoid confusion.

3.2 Insufficient linkages to other relevant DER guidance documents

The draft Guidance Statements have been released for consultation with a series of other Guidance Statements which all form core aspects of DER’s Regulatory Framework.

Comments were received that the three draft Guidance Statements did not explain clearly how other Guidance Statements would be referred to or the linkages between the documents. These comments are summarised below.

3.2.1 Summary of comments received and DER response

Comment	DER response
There needs to be a clearer explanation of how environmental siting and separation distances influence DER's assessment of prescribed premises.	Agreed. Environmental siting and separation distances in the context of DER's assessment of prescribed premises are more clearly referenced.
The flow chart in Appendix 1 of the Draft GS: ERAF should include stronger linkages to the relevant guidance documents and/or appendices that will inform the risk assessment process.	Agreed. This has been clarified and amended in the final <i>Guidance Statement: Decision Making</i> .

3.2.2 DER position

The flow chart has been updated in *Guidance Statement: Decision Making* to explain the linkage to other regulatory guidance statements and an overview of the process. Text describing linkages to other guidances has also been included in both Guidance Statements.

3.3 Duplication and other State Government Agencies

There were issues raised relating to when DER refers particular matters to other State Government agencies for advice, particularly the Department of Health (DoH). These comments are summarised below.

3.3.1 Summary of comments received and response

Comment	DER response
In Draft GS: RAF, the DoH is not listed as an agency to consult in relation to public health even though public health is referenced throughout the documents.	Agreed. DER has amended both final Guidance Statements to specifically reference that matters will be referred to DoH and that advice from other government agencies may be sought.

3.3.2 DER position

DER will work with, and seek advice from, other State Government agencies, such as the Office of the Environmental Protection Authority, the Department of Parks and Wildlife and the DoH, when required. *Guidance Statement: Decision Making* has been amended to include DoH as an interested party that may be notified on receipt of an application.

3.4 Training, resources and DER staff

A number of comments were received relating to the expertise and training of DER staff in applying the Guidance Statements. These comments are set out below:

3.4.1 Summary of comments received and DER response

Comment	DER response
...concern that DER may not have the required expertise to ensure consistent assessment of risk by Licensing Officers. To reduce this risk, it is recommended DER Licensing Officers are trained and supported on the implementation of the new environmental risk assessment process and ongoing monitoring undertaken to ensure a consistent approach to assessments.	Noted. Training and development of DER Licensing Officers remains a priority for DER for the implementation of the Regulatory Framework. DER will also conduct internal reviews to ensure a consistent approach to assessments is undertaken.
Guidance Statements must be used by the reviewing officers consistently. Historically industry has noticed that these have been used subjectively to varying degrees by individual officers.	Agreed. Training and development of staff is critical to ensuring consistent implementation of the Regulatory Framework.

3.4.2 DER position

No amendments to the Guidance Statement were made as a result of these comments.

3.5 Application of DER's discretion

A number of comments were received relating to the prescriptive or mandatory language contained within the Guidance Statements.

3.5.1 Summary of comments received and DER response

Comment	DER response
The language dealing with risk treatment appears overly prescriptive and should be avoided if possible. The use of "will be subject to control" should instead be replaced by "may be subject to control". This still allows DER the ability to implement control without appearing to mandate control. This is especially true to risks that are rated as moderate.	Agreed. The final Guidance Statements have been amended to allow greater scope for the exercise of DER's discretion. "Will" has been replaced with "may" in some cases.

Comment	DER response
... in a large number of areas of the guidance statements, statements are left open ended or in the absence of further clarification appear to be at DER's discretion. This is not a situation that is preferable due to the ambiguity and uncertainty that is introduced. This is especially of concern in light of the recent Supreme Court decision in relation to Roe 8.	<p>As set out above, DER has also received comments that some of the guidance statements have been too prescriptive, and stakeholders have requested that this prescription be reduced and greater discretion retained.</p> <p>DER has considered this issue generally and, consistent with a site-specific risk-based approach, considers that the discretion retained by DER is appropriate.</p> <p>With respect to the Supreme Court decision of <i>Save Beelihar Wetlands (Inc) & Anor v The Hon Albert Jacob MLA & Ors</i> (CIV 2445/2015), DER notes that the initial decision has been overturned on appeal. DER also notes that the main issues found in the initial decision relate to the application of policies in the decision making process, rather than the way in which the policies were drafted.</p>

3.5.2 DER position

DER has considered this issue generally and, consistent with a site-specific risk-based approach, considers that the discretion retained by DER is appropriate. DER accepts that a site-specific approach means that it is not possible to set out with complete prescription the approach taken for all premises in all situations. However, DER considers that the guidance provides sufficient information to stakeholders as to the approach taken by DER in its assessments.

3.6 Consultation

A number of comments were received relating to the number of Guidance Statements that have been released. These comments are summarised below.

3.6.1 Summary of comments received and DER response

Comment	DER response
A large number of guidance statements are being released for comment in a short period of time and without a clear understanding on how the overall process will work and the way the guidelines interact with each other. It is suggested that a review of the overall process be conducted once all guidelines are released to allow for fine tuning of the overall process.	<p>Noted. Amendments have been made to the final Guidance Statements to explain the linkages between them.</p> <p>In addition, some Guidance Statements have been merged to improve readability and enhance understanding of the overall process.</p>

3.6.2 DER position

DER will undertake further stakeholder briefings following the finalisation of the Consultation Summary – Guidance Statement: Regulatory Assessment Framework; Environmental Risk Assessment Framework; and Regulatory Controls (October 2016)

Guidance Statements to consider comments and suggestions. Stakeholders will also be afforded the opportunity to provide formal submissions on the regulatory framework as a whole, following implementation over the next 12 months.

3.7 DER initiated review of premises

A number of comments were received relating to a lack of understanding as to when and how DER could initiate a review of premises. These comments are summarised below.

3.7.1 Summary of comments received and DER response

Comment	DER response
The process appears to be instigated when the DER have some form of concern regarding the operation of a premises. However there is no real clarity on what level of risk to the environment would trigger the process. The guideline should make it clear to all that minor issues with low risk should not trigger an assessment and possible licence amendment.	<p>Noted. DER may seek to review premises at any time – and whilst the licence holder may consider the risk to be low, a review may be required to confirm this.</p> <p>DER has set out the circumstances it will have regard to in undertaking a review in <i>Guidance Statement: Risk Assessments</i>. These include incident or event reporting, information submitted in accordance with instruments, the period of review since the last review of a prescribed premises, any new relevant information, compliance inspections, complaints and enforcement.</p>

3.7.2 DER position

Amendments have been made to both Guidance Statements to provide more information and clarity on when DER may initiate a review.

4. Draft Guidance Statement: Regulatory Assessment Framework

The final Guidance Statement has been retitled to be “*Guidance Statement: Decision Making*” and also now includes the guidance from *Guidance Statement: Licence and Works Approval Process*.

DER received a number of specific submissions on the Draft GS: RAF (now *Guidance Statement: Decision Making*) and has grouped comments into the following categories:

- Transparency;
- Timeframes;
- Interested parties;
- Significant amendments; and
- Advertising.

4.1 Transparency

A number of comments were received on the transparency of DER's process, including procedural fairness related matters. These are summarised below.

4.1.1 Summary of comments received and DER response

Comment	DER response
The process...appears to abandon the former practice of application enquiries and scoping meetings for Works Approval or Licence Applications. To reduce the risk of assessment delays we suggest the process should still allow for some (more or less formal) means of obtaining advice from DER on whether a Works Approval or Licence is likely to be required, and the kind of information that is likely to be expected, before submitting an application sooner rather than later in the assessment process.	<p>Noted. Meetings will be available if requested. However, scoping meetings are not part of DER's formal assessment process.</p> <p>DER will be publishing fact sheets on categories of prescribed premises to provide consistent guidance on whether approvals are required.</p>
...concerns that interested parties' opinions can unduly influence quantitative analyses of risk unless there are specific means or controls within the Draft GS: RAF to provide a balanced assessment of all factors.	<p>Noted. DER undertakes risk assessments and applies regulatory controls that are proportionate to the level of risk (consequence and likelihood) that the activity poses to public health and the environment.</p> <p>DER's consideration of interested parties' comments will be documented in DER's decision making and the draft decision report and instrument will be provided to the applicant for comment.</p>
For procedural fairness and a streamlined administrative process, it would be advisable for the DER to notify the applicant of submissions received [from interested stakeholders] and to allow the applicant to respond. This would result in a more streamlined administrative process over a situation in which the applicant is only able to respond after the DER has developed a draft works approval or licence. It would also enable a process of direct stakeholder engagement by the applicant in which issues identified by other stakeholders can be addressed through negotiation prior to the finalisation of the instrument and in doing so reduce the prevalence of appeals.	DER notes that the draft decision report and instrument will be provided to the applicant for comment. During that time, the applicant may elect to respond to comments received by stakeholders, as set out in the decision report.

Comment	DER response
[These] sections ... are updated to ensure all decisions to decline or refuse environmental applications are reviewed by management.	DER notes that if there are concerns with decision making, applicants may either contact DER through info@der.wa.gov.au or submit an appeal to the Appeals Convenor. DER has updated its webpage to make this clearer for applicants, licence holders and works approval holders.
The Guidance Statement includes provision for notifying key interested parties involved in providing advice on the outcomes of relevant decisions.	Agreed. The final Guidance Statement has been amended to provide that DER will notify interested parties of the final decision and instrument.

4.1.2 DER position

The final Guidance Statement has been amended to make it clearer when an applicant will be provided with the draft decision report and instrument for comment. It has also been amended to provide that DER will notify interested parties of the final decision and instrument.

4.2 Timeframes

A number of comments were received stating that the Guidance Statement should make timeframes clearer. There were also comments on the nominal timeframe of 14 days for declining to deal. These are summarised below.

4.2.1 Summary of comments received and DER response

Comment	DER response
Timeframes (nominal or other) have not been provided for the General Process for Assessments (and in particular "Significant Amendments") and public advertisement of applications. The provision of timeframes, where possible, would be advantageous for planning purposes.	Agreed. Nominal timeframes for assessment will be included in an updated flow chart in the final Guidance Statement.
The Guidance Statement indicates that DER will decline to deal with applications where information requested for an assessment has not been submitted within 14 days. DER should allow that within those 14 days an alternative, appropriate, timeframe for submission can be negotiated.	Noted. The final Guidance Statement has been amended to allow for 21 days and to also enable this period to be extended with DER's agreement.

4.2.2 DER position

DER has amended the flow chart to include nominal timeframes and has amended the 14 day time period to 21 days. DER has also amended the final Guidance Statement to provide that time periods may be reasonably extended by DER on request by applicants.

4.3 Interested parties

A number of comments were received in respect of neighbours as interested parties. These are summarised below.

4.3.1 Summary of comments received and DER response

Comment	DER response
Include advising "neighbours". Applicants would like the opportunity to consult directly with neighbours before being approached "out of the blue" by DER.	Noted. In advising "other interested parties" this may include neighbours. DER considers that it is the applicant's responsibility to consult with neighbours prior to submitting an application and prior to DER advertising the application, where the applicant considers this appropriate to do so. Consultation can continue to occur after the application is advertised, however this should not delay the finalisation of the instrument.

4.3.2 DER position

The final Guidance Statement has not been amended to include neighbours as an interested party.

4.4 Significant amendments

DER will assess applicant amendments according to whether the amendment is minor or significant. A number of comments were received seeking clarification on when an amendment would be a significant amendment.

4.4.1 Summary of comments received and DER response

Comment	DER response
A definition of "significant amendment" has not been provided. This could result in subjectivity when determining the level of significance of a proposed amendment and uncertainty with regard to timeframes. It is suggested that clarity is provided with regard to DER's interpretation of a significant amendment.	Agreed. DER has amended the final Guidance Statement to clarify this and the term "major amendment" has been used consistent with DER's terminology for reporting purposes.

4.4.2 DER position

The final Guidance Statement has been amended to clarify when DER considers an amendment to be a "major amendment".

4.5 Advertising

A number of comments were received seeking clarification about application advertising which are summarised below.

4.5.1 Summary of comments received and DER response

Comment	DER response
Figure 1 indicates that applications for renewal, amendment, transfer or surrender of an existing works approval or licence will not require public advertisement. This is different from DER's current practice of advertising applications for licence renewals. Ceasing the practice of advertising licence renewal applications would incrementally streamline the process for renewing licences and would conform with the requirements of the EP Act which only requires that applications for new works approvals and licences be advertised. This is appropriate, as public consultation is most relevant in relation to new works approvals or licences.	<p>DER considers that in the interests of transparency and consultation, the following matters will be advertised –</p> <ul style="list-style-type: none"> • Applications for: <ul style="list-style-type: none"> ○ New works approval ○ New licence ○ Licence renewal ○ Works approval amendment (significant/major amendments only) ○ Licence amendment (only for significant amendments) • Decisions (grant/ refuse/ amend/ transfer/ surrender/ revoke): <ul style="list-style-type: none"> ○ New works approval ○ New licence ○ Licence renewal ○ Transfer ○ Surrender ○ Registration

4.5.2 DER position

DER has amended the final Guidance Statement to provide more clarity on what applications will be advertised.

5. Draft Guidance Statement: Environmental Risk Assessment Framework

This draft guidance statement has been merged with the draft *Guidance Statement: Regulatory Controls*. The final guidance statement has been retitled as *Guidance Statement: Risk Assessments*.

DER received a number of submissions on the Draft GS: ERAF and has grouped these comments into the following categories:

- Application and relevance of criteria;
- Applicant risk assessment;
- Risk ratings and controls;
- Unmitigated risk; and
- Ability of DER to undertake reviews of risk ratings.

5.1 Application and relevance of criteria

Appendix 5 of the Draft GS: ERAF contained Health and Ecosystem Criteria for Water, Land, and Air Quality. A large number of comments were received questioning the application of these criteria, summarised below.

5.1.1 Summary of comments received and DER response

Comment	DER response
The acceptability of the emissions should be assessed in the context of an appropriate criteria, the quality of the receiving environment (i.e. background levels), the emissions from the activity, and the emission reduction technology being proposed.	Agreed. A site-specific risk assessment will allow for a consideration of all relevant factors relating to the hazard, pathway, impact and controls. In establishing the context of the risk, DER will identify the location of the prescribed premises, give consideration to relevant topography and site features, identify relevant meteorological conditions, identify applicable standards and identify site and operator history.
Greater guidance is required with respect to the proxy health and ecosystem criteria. It is essential that the criteria are drawn from reputable sources and are set within a framework that clearly states how the criteria will be applied in practice to regulate industry, to ensure they are used in an appropriate and consistent manner.	Agreed. Having regard to a number of comments submitted during the consultation, the final Guidance Statement has been amended to delete the tables in Appendix 5 referencing specific criteria. The basis upon which consequence criteria have been determined will be expressly stated in DER's decision documentation. DER may have regard to published documents by Federal and State agencies, will undertake a site-specific assessment, and will also consider information provided by an applicant.
Table 4A does not provide context as to how the air quality criteria will be applied. Will it be at the premises boundary or the nearest sensitive receptor?	Noted. The final Guidance Statement has been amended to clarify that DER will apply consequence criteria at the receptor most affected by the emission (which may not always be the nearest receptor), having regard to the nature, value and sensitivity of the receptor.
How will the air quality criteria be applied in the event of process failures, emergency releases and extreme weather conditions?	Noted. Where premises may be subject to higher rates, or different types, of emissions from time to time (e.g. due to plant shut down for maintenance activities), DER will specifically include these emissions. DER will exclude rare or unforeseeable risk events and risk events which arise from an intervening cause. The general provisions of the EP Act apply to any such events.
The Draft GS ERAF does not provide information as to how proxy health and ecosystem criteria are intended to be applied. Further clarification is required	Agreed. As stated above, the proxy health and ecosystem criteria tables in Appendix 5 have been deleted from the final Guidance

Comment	DER response
<p>regarding:</p> <ul style="list-style-type: none"> Where the criteria will be applied Whether the criteria are intended to be compared to ambient monitoring data and/or air dispersion model predictions Whether the criteria will be applied within buffer zones or inside DER's recommended separation distances; and How the criteria will be applied in the event of process upsets and emergency releases. <p>DER should rectify this by conducting workshops with key stakeholders to determine the preferred approach.</p>	<p>Statement.</p> <p>DER will hold stakeholder workshops to explain the context and application of the Guidance Statements.</p>
<p>Presumably the draft values are not to apply within any area currently defined for management purposes in an Environmental Protection Policy (EPP) such as the Kwinana and Kalgoorlie EPP areas?</p>	<p>Correct. The final Guidance Statement has been amended to state that DER will apply consequence criteria in accordance with approved policies.</p>

5.1.2 DER position

DER has taken into account the large number of comments submitted relating to the tables in Appendix 5 referencing specific criteria. DER has decided to delete Appendix 5 and instead has included drafting to reflect the general approach outlined in the table above.

5.2 Applicant risk assessment and review

The Draft GS: ERAF did not clearly specify whether applicant developed baseline data, risk assessment and/or site-specific criteria could be provided to DER for consideration. A number of comments were received concerning this, and are summarised below.

5.2.1 Summary of comments received and DER response

Comment	DER response
<p>There will be circumstances where the use of applicant baseline data will allow for a more accurate risk assessment. It is recommended the Draft GS: ERAF is updated to allow the applicant to submit baseline data to inform the risk assessment.</p>	<p>Agreed. The final Guidance Statement has been amended to provide that DER will consider risk assessments and/or site-specific criteria developed by applicants. DER may apply consequence criteria with regard to baseline and reference data which are representative of the receiving environment. The basis upon which consequence criteria have been determined will be expressly stated in DER's decision report.</p>

Comment	DER response
The assessment must be based on the applicant's own risk assessment. DER does not have the expertise to do this, as DER's role is to validate.	Disagreed. DER's risk-based process is an assess-determine model under which DER assesses the risk and determines controls. As part of DER's assessment, any initial assessment of risk submitted by the applicant will be given due consideration.
It is suggested that risk assessment methods and results are made available to respective applicants.	Agreed. Risk assessments will be documented in DER's decision report. The draft decision report and draft instrument will be provided to an applicant in draft for comment prior to issue.

5.2.2 DER position

DER will consider baseline data, site-specific criteria and risk assessments developed by the applicant however will apply its risk assessment framework in accordance with the Guidance Statement. Risk assessments will be documented in DER's decision report and applicants afforded an opportunity to comment on draft decision reports and instruments.

5.3 Risk ratings and controls

The Draft GS: ERAF uses a Risk Assessment Matrix and Criteria to determine the risk of adverse impact to public health and the environment based on the evaluation of consequence and likelihood. A number of comments were received questioning the ratings and criteria of risk used throughout the risk assessment process.

5.3.1 Summary of comments received and DER response

Comment	DER response
The Draft GS: ERAF appears to be centred on not exceeding set criteria. Applicants may propose controls which achieve a "high" risk rating, which appears to be acceptable under the proposed risk assessment framework, without considering whether additional practicable controls could reduce the risk rating to moderate or low. There does not appear to be a requirement for occupiers to take all reasonable and practicable measures to minimise emissions.	Applicants for works approvals and licences under Part V, Division 3 of the EP Act are required to comply with the provisions of the EP Act. Consistent with DER's risk-based regulation regulatory principle, performance which is above acceptable levels for environmental risks will be achieved through a voluntary and incentive approach.
The consideration of site and operator history in "Establishing the Context" (Appendix 1) should also incorporate review of the performance of any improvements implemented by an applicant following a historical incident. Should it be shown the substantive improvements undertaken by the applicant have been effective, then the existence of a historical issue (i.e. past	Agreed. The final Guidance Statement has been amended to clarify when reviews of risk ratings will be undertaken.

Comment	DER response
breach or non-conformance) should not overly influence the risk analysis of a new, independent activity or lead to stricter limits on acceptability than would otherwise be the case.	
The term “insignificant” implies there has been some impact, but the impact is not significant. The definition should be changed to remove “no detectable impacts” and better describe what DER considers an “insignificant” consequence to public health.	Agreed. The consequence criteria have been significantly amended in the final Guidance Statement.
<p>The consequence table lists public health consequences that are vague and subject to being incorrectly interpreted.</p> <p>For example:</p> <ul style="list-style-type: none"> • What is meant by “large population” and “small population”? • “Health criteria significantly exceeded” is not a consequence <p>The term “significant” is subjective and potentially problematic – how is significance determined?</p>	Noted. In applying public health criteria, DER may also have regard to DoH's <i>Health Risk Assessment (Scoping) Guidelines – Public Health</i> and other relevant DoH publications. The consequence criteria have been significantly amended in the final Guidance Statement.
The significant high value or sensitive ecosystems referred to in the Severe, Major and Moderate categories (Appendix 2, Consequence table) are not defined. How is this determined, and at what stage in the assessment process?	Agreed. The consequence criteria have been significantly amended in the final Guidance Statement.
Examples could be provided on what a complete risk assessment would include.	Noted. Examples of the applied risk assessment process in pilot examples through decision reports will be set out on DER's webpage.
The risk based framework should include the concept of taking all reasonable and practicable measures to minimise emissions, such as the use of best available technology.	<p>Not agreed. The approach being applied is risk-based, that means regulation intends to prevent unacceptable risks to public health and the environment.</p> <p>With respect to minimising emissions and use of best available technology, the role of environmental performance beyond compliance is recognised in the <i>Guidance Statement: Regulatory Principles</i>.</p>

5.3.2 DER position

DER has significantly amended the consequence criteria to take into account the comments set out above and to simplify the approach.

5.4 Unmitigated risk

5.4.1 Summary of comments received and DER response

Comment	DER response
It is unclear whether the table in Appendix 3 is referring to unmitigated or mitigated risk. If the table relates to mitigated risk, this seems like an unjustifiable level of (mitigated) risk and would not be likely to be appropriate for developments posing risks to important conservation values. It is recommended that the risk ratings for events that are Likely + Major, Unlikely + Severe, Almost Certain + Moderate in Appendix 2 are amended to “Extreme” and the table in Appendix 3 is clearly explained as being based on unmitigated risk.	The table is referring to mitigated risk. The final Guidance Statement has been amended to clarify that in applying the risk criteria, DER will have regard to appropriate applicant controls.

5.4.2 DER position

DER has amended the final Guidance Statement to make it clearer that it will be assessing mitigated risk (to the extent of applicant proposed controls). Controls will be reviewed and considered in DER’s application of the risk criteria. The adequacy of controls and determination of what controls will form regulatory controls will be determined by DER.

5.5 Reviews of risk ratings

There were a number of comments requesting clarification of DER’s use of the word “monitoring and review” in the Guidance Statement, summarised below.

5.5.1 Summary of comments received and DER response

Comment	DER response
The imposition of monitoring requirements can have significant costs for holders of works approvals and licences. This should only be imposed where reasonably required. The Guidance Statement should be amended to state that “monitoring and review will be undertaken where <i>it is required</i> for the purposes of...”	Noted. The word “monitoring” relates to DER’s regulatory functions and not to industry monitoring requirements. To avoid confusion, the word “monitoring” has been removed and replaced with “review”.

5.5.2 DER position

DER has amended the Guidance Statement to provide further clarity around the review of a risk rating.

6. Draft Guidance Statement: Regulatory Controls

Draft GS: RC has been merged with Draft GS: ERAF. The final guidance statement has been retitled to be *Guidance Statement: Risk Assessments*.

In addition to the above general issues, DER received a number of specific submissions on the Draft GC: RC and has grouped comments into the following categories:

- Regulatory Controls;
- Infrastructure Requirements;
- Product Quality; and
- Emission Types and Limits.

6.1 Regulatory controls

A number of comments were received on the distinction between “primary” and “secondary” controls, and the application of different types of controls.

6.1.1 Example of comments received and DER response

Comment	DER response
The Regulatory Control Matrix is difficult to follow, particularly the distinction between “primary” and “secondary” controls, and the application of different types of controls.	Agreed. This was DER’s conceptualisation of controls, which DER acknowledges may be difficult for others to follow. The categories of primary and secondary controls have been removed and examples have been given of the types of controls that will apply.

6.1.2 DER position

The final Guidance Statement removes the categories of primary and secondary controls and makes it clear that the controls applied will be proportionate to the risk.

6.2 Infrastructure requirements

Infrastructure Requirements are a type of regulatory control used by DER, defined as:

“Where the design and construction of infrastructure or equipment to an engineering or construction standard is specified to prevent, control, abate or mitigate pollution or environmental harm.”

Comments were received relating to Infrastructure Requirements. These are summarised below.

6.2.1 Summary of comments received and DER response

Comment	DER response
DER may not have the expertise to be able to stipulate an engineering solution resulting in impractical design and excessive costs when there may be other ways to achieve the same environmental outcome.	Noted. DER will not specify solutions where it does not have expertise to do so. Where DER has proposed infrastructure requirements and the applicant considers there are alternatives to achieve the same outcome, DER will consider alternatives proposed, prior to making a final determination.
<p>Once a project is constructed and transitioning to a licence, the infrastructure has been built and siting of the infrastructure cannot be altered. The control types Siting of Infrastructure can therefore only apply to a works approval.</p> <p>Infrastructure Requirements may also not apply to licences, particularly if previously approved infrastructure has already been constructed.</p>	<p>Noted. While retrofitting infrastructure requirements may not always be practicable, in some cases this may be warranted to address unacceptable risks to public health or the environment. This will be assessed by DER on a case-by-case basis and will be proportionate to the level of risk.</p> <p>DER notes that the granting of approvals is made based on the information available at that time. New information and changes to the surrounding siting may result in unexpected impacts on receptors which will need to be addressed by the licence holder. Altering siting is not possible for the premises as a whole. However, where it may be reasonable to relocate specific infrastructure on the premises to mitigate the risk of emissions, then siting may be a relevant consideration even once premises are operational.</p>
The application of this control needs to be further considered and additional guidance provided. For instance, if DER specifies an emission reduction approach that doesn't achieve the necessary reductions despite best intentions, how will this be handled? In effect the applicant has wasted time and money and still not achieved the necessary outcome.	<p>Noted. The application of specified infrastructure requirements is determined on a case-by-case basis.</p> <p>DER will be progressing Environmental Standards to provide more certainty for specific industry groups for the types of infrastructure which would be acceptable.</p> <p>However, DER has considered the feedback from industry and has avoided being overly prescriptive as it seeks to avoid limiting innovation or placing unnecessary limitations upon industry. Further, and as outlined in the <i>Guidance Statement: Regulatory Principles</i>, DER has established that a preference for outcome based conditions wherever practical and reasonable will be made.</p>

6.2.2 DER position

Where DER has proposed infrastructure requirements and the applicant considers there are alternatives to achieve the same outcome, DER will consider alternative infrastructure requirements provided in response to a draft decision, prior to making a final determination.

The use of infrastructure requirements will take place on a case-by-case basis, proportionate to the level of risk.

DER has considered the comments received and has made an amendment to make it clearer that appropriate controls proposed by an applicant will be considered.

6.3 Product quality

A number of comments were received questioning the assignment of controls to an end product of prescribed premises.

6.3.1 Summary of comments received and DER response

Comment	DER response
Under DER's management of prescribed premises, the manufacturing process is what should be regulated, not the end product itself. No other category of prescribed premises has risks assigned to the end product that it produces. These end products are also not regulated under the manufacturing operations' prescribed premises licence. Risk relating to public health and amenity caused by potential pathogen transfer through contact with compost material under Category 67A in Table 1 should be removed.	<p>Noted. In accordance with DER's <i>Guidance Statement: Regulatory Principles</i>, in determining approvals, DER will assess whether the activities pose unacceptable risks to public health or the environment. Licensing and approval decisions will be proportionate to the level of risk posed to public health and the environment. High public health risks will be referred to the DoH.</p> <p>DER also notes that product testing at prescribed premises to address risks to public health are applied to other prescribed activities, such as asbestos testing for recycling facilities. DER remains of the view that product testing at premises on which organic material or waste is stored pending production to a commercial product is an applicable and appropriate regulatory control.</p>
Controls on product quality via a "specification on product" could serve to enhance the ability of operators to manage, under contractual arrangements, the dust and odour generating characteristics of products. Product quality will also influence the infrastructure requirements of the handling and storage of the product. For these reasons, product quality could be considered at a higher level of control.	Agreed. The final Guidance Statement has been amended to take this into account.

6.3.2 DER position

DER has considered the comments and notes that all regulation will be carried out proportionate to the level of risk. The final Guidance Statement has been amended to include specification on products accepted at prescribed premises as a potential regulatory control.

6.4 Emission types and limits

A number of comments were received relating to emission types and limits in the Regulatory Control Matrix. These are summarised below.

6.4.1 Summary of comments received and DER response

Comment	DER response
The Regulatory Control Matrix could assist the assessment process, on the understanding that the list is not considered authoritative or exhaustive. Some risks will not be significant for some sites, and other sites may present risks uncommon or insignificant for the same activity elsewhere.	<p>Noted. The emissions types which were listed in the Regulatory Control Matrix against prescribed premises categories represented typical and expected emissions. However, a site-specific assessment may identify other emissions or eliminate a listed emission if it is not relevant. The list of emissions was not intended to be exhaustive.</p> <p>The Regulatory Control Matrix has been deleted as a result of consideration of the comments received.</p>

6.4.1 DER position

DER confirms that the list of categories provided in the Regulatory Control Matrix was not exhaustive, and only represented typical and expected emissions. As a response to submissions, DER has deleted the Regulatory Control Matrix. Specific category information will be provided by DER in the form of fact sheets.