



Commission for Energy Regulation

An Coimisiún um Rialáil Fuinnimh

## **ALARP Demonstration Guidance Document**

### **Consultation Response Paper**

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## Related Documents

[CER/12/062](#) Decision on the High Level Design of the Petroleum Safety Framework.

[CER/12/181](#) Draft ALARP Demonstration Guidance - Consultation Paper

[CER/13/071](#) Safety Case Guidelines

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# 1 Introduction

## 1.1 Background

The *Electricity Regulation Act 1999*, as amended *inter alia* by the *Petroleum (Exploration and Extraction) Safety Act 2010* (the ‘Act’) gives the Commission for Energy Regulation (CER) responsibility for the safety regulation of petroleum exploration and extraction activities in Ireland. The Act specifically includes a requirement for the CER to “establish and implement a risk-based petroleum safety framework” (collectively referred to in this document as the ‘Framework’). The Framework can be understood as the entire system that the CER uses to regulate the safety of petroleum activities<sup>1</sup>, and in particular designated petroleum activities<sup>2</sup>, carried out by petroleum undertakings<sup>3</sup>.

In June 2012, the CER published the *Decision Paper on the High Level Design of the Petroleum Safety Framework* (the ‘[High Level Design](#)’<sup>4</sup>). The [High Level Design](#) frames the key policy aspects and principles of the Framework which are subsequently reflected in the guidance, regulations and written regulatory documents and procedures that form the Framework.

## 1.2 Consultation on the Draft ALARP Demonstration Guidance Document

In November 2012 the CER published for consultation a *Draft ALARP Demonstration Guidance Document* (the Consultation Paper) which expanded on the high level requirements set out in the [High Level Design](#) and provided further detail of the CER’s expectations with respect to ALARP demonstrations under the Framework. The CER specifically invited comments on detailed aspects in the ALARP demonstration including:

- 1) Proposals for Risk Tolerability Limits;
- 2) Criteria for the Implied Cost of Averting a Fatality; and
- 3) The Gross Disproportion Factor.

The CER received submissions from the following 13 respondents:

- Commission for Irish Lights (CIL)<sup>5</sup>;
- ERM<sup>6</sup>;
- Geraldine Ring<sup>7</sup>;
- the Health and Safety Authority (HSA)<sup>8</sup>;
- Jerriann Sullivan<sup>9</sup>;
- the National Standards Authority of Ireland (NSAI)<sup>10</sup>;
- Peter Crossan<sup>11</sup>;

<sup>1</sup> As defined in Section 13A(2) of the Act.

<sup>2</sup> A designated petroleum activity is a petroleum activity designated as such by the CER by regulation pursuant to Section 13D of the Act.

<sup>3</sup> As defined in Section 13A(1) of the Act.

<sup>4</sup> See *Decision Paper on the High Level of the Petroleum Safety Framework* (CER/12062).

<sup>5</sup> CER/13/077.

<sup>6</sup> CER/13/079.

<sup>7</sup> CER/13/049.

<sup>8</sup> CER/13/078.

<sup>9</sup> CER/13/051.

<sup>10</sup> CER/13/076.

<sup>11</sup> CER/13/047.

- PSE Kinsale Ltd.<sup>12</sup>;
- Rahima Sayer<sup>13</sup>;
- Sarah Akamine<sup>14</sup>;
- Shell E&P Ireland Ltd (SEPIL)<sup>15</sup>;
- Sian Cowman<sup>16</sup>; and
- Talamh<sup>17</sup>.

Three respondents (ERM, PSE Kinsale Ltd and SEPIL) also requested to meet the CER to discuss their respective submissions. The minutes of those meetings<sup>18</sup> and respondent submissions are published alongside this Response Paper on the CER website.

The CER also received a submission from Keane Offshore Integrity Limited (KOIL) on KOIL's current role in offshore oil and gas activities in Ireland. The submission was issued for information by KOIL and did not raise any points on the ALARP Demonstration Guidance Document. As such it does not feature in this Response Paper, although it is published alongside the other responses received<sup>19</sup>. All responses should be read alongside this paper.

### **1.3 The Scope of the Consultation Response Paper**

This Response Paper sets out the CER's response to comments made in respect of the Consultation Paper, noting, when appropriate, where the ALARP Demonstration Guidance Document has been amended from that outlined in the Consultation Paper in light of comments received. This Response Paper should be read in conjunction with the *ALARP Demonstration Guidance Document*.

### **1.4 The Structure of this Response Paper**

This Response Paper is divided into three further sections:

- **General Points Raised by Respondents (Section 2)**  
This section addresses general points raised by respondents to the *Draft ALARP Demonstration Guidance Document*.
- **Specific Points Regarding the Draft Guidelines (Section 3)**  
This section addresses specific issues raised by respondents to sections of the *Draft ALARP Demonstration Guidance Document*. This section is in the format of a table.
- **Clarifications to the High Level Design (Section 4)**  
This section summarises the clarifications to be made to the High Level Design to ensure consistency with the *ALARP Demonstration Guidance Document*.

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<sup>12</sup> CER/13/045.

<sup>13</sup> CER/13/050.

<sup>14</sup> CER/13/048.

<sup>15</sup> CER/13/044.

<sup>16</sup> CER/13/052.

<sup>17</sup> CER/13/057.

<sup>18</sup> See CER/13/082, CER/13/084 and CER/13/083 respectively.

<sup>19</sup> CER/13/046.

## 2 General Points Raised by Respondents

### 2.1 Points made by a Number of Respondees

There were six responses that raised general points on the *Draft ALARP Demonstration Guidance Document* that did not refer to the specific sections. The CER has considered each of these responses, and has sought to summarise the issues raised. A number of responses can be grouped, at a high level, as follows:

- Hydraulic Fracturing;
- Risk Tolerability Criteria;
- Health Impact Assessments;
- Prescriptive Guidance; and
- Cumulative Risks.

The following paragraphs set out CER's response to each of the high level issues listed above. The table in section 2.2 sets out responses to other issues, which do not relate to specific sections of the Consultation Paper.

The CER has sought to summarise and respond to comments made in good faith. The full text of the comments are published alongside this Response Paper.

#### 2.1.1 Hydraulic Fracturing

##### 2.1.1.1 Points Made by Respondents

Several respondents were concerned that the *ALARP Demonstration Guidance Document* did not specifically address the risks involved in hydraulic fracturing (fracking), or stated that fracking could never be safely carried out, and that the precautionary principle should apply to it.

##### 2.1.1.2 CER's Response

Hydraulic fracturing is a designated petroleum activity and therefore requires a safety case to be approved by the CER before the activity can be carried on by a petroleum undertaking. The safety case must show that the risk of the activity is not intolerable and that risk reduction measures have been implemented such that the risk is ALARP. The methods described in section 4.5 in the *ALARP Demonstration Guidance Document* may be used to do this, but importantly the method must lead to a result that provides sufficient certainty. If none of the methods can provide sufficient certainty, recourse must be made to the precautionary principle. The precautionary principle does not necessarily mean that an operation cannot go ahead, but may mean that it is restricted in some way, or additional safety measures put in place, which, after a period of good operational performance may no longer be required.

The ALARP demonstration process is a robust one that can be applied to all petroleum activities and is in line with international practice. The CER believes that suitable guidance has been provided on when the precautionary principle is likely to be invoked. Due to

inherent uncertainty associated with the use of the precautionary principle, it is not appropriate to provide specific examples of where it should be applied.

## **2.1.2 Risk Tolerability Criteria**

### *2.1.2.1 Points Made by Respondents*

A respondent commented that the risk tolerability criteria are expressed only in terms of fatalities and do not explicitly include injuries. A respondent commented on the use of a cost per fatality criterion within the ALARP demonstration.

### *2.1.2.2 CER's Response*

All risks must be reduced to ALARP under the Framework. For Major Accident Hazards the CER is concerned with the risk of serious harm to health, not just fatality. However, there is no international precedence for risk assessment criteria for serious harm to health not least due to the inherent difficulties with comparing one type of harm with another, which is an issue that does not arise when fatalities are considered. In practice an approach in which conservative criteria are used to determine whether fatalities occur is usually applied in risk assessments and this is included in the *ALARP Demonstration Guidance Document*.

In relation to the respondent comment on the use of a cost per fatality criterion within the ALARP demonstration, the criterion given in the *ALARP Demonstration Guidance Document* is the Implied Cost of an *Averted Fatality*. This factor is required as part of a Cost Benefit Analysis, which may be used to justify not implementing a further risk reduction measure. It is one factor that contributes to whether a risk reduction measure may be deemed reasonably practicable to implement or not. It is not relevant to the argument as to whether the sum of the risk reduction measures implemented reduces the risk to a level that is ALARP as each risk reduction measure must be considered in turn.

## **2.1.3 Health Impact Assessment**

### *2.1.3.1 Points Made by Respondents*

Several respondents stated that a health impact assessment be required as part in the ALARP demonstration.

### *2.1.3.2 CER's Response*

A Health Impact Assessment (HIA) is a decision making tool which requires consideration of all aspects which might impact health, including, for instance, education and economic considerations. Hence, the scope of an HIA exceeds that which is required under the Framework and it would not therefore be appropriate to mandate its application by petroleum undertakings as part of the ALARP Demonstration. That being said, the *Safety Case Guidelines* do not preclude a HIA being made, and many of the elements which comprise a HIA are relevant to the safety risk assessment that is required by the Framework. It is for the petroleum undertaking to make a robust ALARP Demonstration. This requires an assessment of all risks to safety, including long term health issues, arising from all their operations.

## **2.1.4 Prescriptive Guidance**

### *2.1.4.1 Points Made by Respondents*

Several respondents commented that the level of prescription in the guidance should be increased.

### *2.1.4.2 CER's Response*

The CER has considered specific comments made in respect of levels of prescription, and in each case, has determined that that level of prescription suggested is not appropriate. As a general comment, the CER notes that the Act requires the CER to establish and implement a risk-based petroleum safety framework where petroleum undertakings will maintain risks at a level that is ALARP. The adoption of the ALARP principle infers a goal setting approach to safety. Rather than requiring petroleum undertakings to routinely comply with prescriptive requirements, the ALARP principle requires them to understand and manage the risks presented by their particular operations. Although this does not preclude the application of prescriptive requirements (and indeed the Safety Case Guideline do require a certain level of prescription), it does favour placing the responsibility of demonstrating that risks are reduced to a level that is ALARP firmly with the petroleum undertaking, rather than simply complying with a checklist of prescriptive requirements.

## **2.1.5 Cumulative Risk**

### *2.1.5.1 Points Made by Respondents*

A respondent commented that the total risk associated with all petroleum infrastructure within the industry must be assessed on a cumulative basis, and that the activities undertaken in the course of exploration and recovery should be described as part in the ALARP demonstration including a full listing of all chemicals to be used.

### *2.1.5.2 CER's Response*

In any instance where a person is exposed to the risk from more than one Major Accident Hazard source, the risk from each source will need to be evaluated. In most cases if the sources are at discrete, well-separated locations onshore, it would not be possible for a person to be affected from more than one source. However, exceptions may arise in the case of developments with, for example, unusually high concentrations of hydrogen sulphide, or if there was the possibility of a number of wells affecting groundwater should a failure occur and this was assessed to be a hazard. In this case, the cumulative risk from all major hazard sources must be calculated. It should be noted that the Safety Case Guidelines require petroleum undertaking to list all hazardous substances and their inventory to be included within the safety case.

## **2.2 Points made by Individual Respondees**

The table on the following page sets out CER response to other issues which do not relate to specific sections of the Consultation Paper.

Respondent	Section	Comment	CER Response	Guidance Update?
Sian Cowman	General	...it is impossible to regulate a destructive process such as hydraulic fracturing of shale gas safely.	See section 2.1.1.	No
Jerrieann Sullivan	General	A 'public consultation' has not been conducted by the CER in relation to the matters raised in document. Through what media are the public expected to become informed about the existence of this consultation? I only heard about this consultation by word of mouth from concerned residents facing the prospect of petroleum industry coming to their local area. The public, and indeed communities who stand to be affected by petroleum industry activities have no way of finding out about this consultation. Were radio, television and newspaper advertisements created and publicised in order to communicate the important of the issues being decided upon in this document? If not, why not? What provisions were taken to ensure that people likely to be affected by future petroleum activities were aware of this consultation and able to participate in it? What provisions were taken to ensure that people with low literacy, people without internet access, and people without financial resources had opportunities to hear about the existence of and participate in this consultation. On what grounds can the CER process be considered to be 'public consultation'? How does the CER 'consultation' process meet the requirements of the Aarhus convention? Can you point to any evidence to	The CER is satisfied that it has conducted an appropriate public consultation on the ALARP Demonstration Guidance Document. It should be noted that this public consultation has taken place in the context of a wider public consultation on the High Level Design of the Petroleum Safety Framework (the 'High Level Design') which took place in 2011 and 2012. As part of that consultation, which set out amongst other things the high level policy requirements and principles of ALARP Demonstration, the CER published both an initial consultation paper and a draft decision paper on the High Level Design for consultation. Notice of these papers was published in national and relevant local newspapers. At that time respondents were encouraged to join the CER mailing list to be notified of future consultation papers as part of the detailed design phase of the Petroleum Safety Framework (of which the ALARP Demonstration Guidance Document is one such document). The high level policy requirements and principles of ALARP Demonstration which were the subject of the public consultation process for the High Level Design are now contained in the	No

Respondent	Section	Comment	CER Response	Guidance Update?
		show that this 'consultation process' is anything more than a pretence of compliance with requirements for public consultation being carried out without any intention by civil servants to take the public opinion on board?	<p>ALARP Demonstration Guidance Document. The CER published the ALARP Demonstration Guidance Document on its website, circulated a notification to its Safety List mailing list and formally notified a number of statutory agencies.</p> <p>The CER has considered all comments made in the context of this and all other consultations and in line with the Aarhus Convention the CER has taken due account of these comments. A detailed response to each comment made on the Consultation Paper, together with changes made where appropriate to Decision Documents is set out in this paper. CER has today, in accordance with the Aarhus Convention, published its ultimate decision in relation to the ALARP Demonstration Guidance document, along with the reasons and considerations on which its decision is based.</p>	
Jerrieann Sullivan	General	Has the preparation of the ALARP Demonstration Guidance Document fully considered the specific circumstances of hydraulic fracturing or fracking in the unconventional extraction of shale gas in Ireland? If not, why not	See section 2.1.1.	No
Jerrieann Sullivan	General	Why does the document presume that there is a tolerable risk level for petroleum activities? Given that the WHO calculates that 300,000 people already lose their lives due to anthropogenic	The Act requires petroleum undertakings to reduce any risk to safety to a level that is as low as is reasonably practicable (ALARP). Implicit within the	No

Respondent	Section	Comment	CER Response	Guidance Update?
		climate change each year, on what ethical or other basis is it presumed that there the extraction of further petroleum resources is tolerable? How are risks to life and to health in communities in Ireland and globally due to climate change assessed in this instance?	ALARP principle is that whilst risks cannot be always reduced to zero, it should be possible to reduce them to a level that is ALARP, where they are tolerable to society and to demonstrate that this has been achieved. As set out in the High Level Design, it is appropriate for the ALARP Demonstration Guidance document to provide guidance risk on the risk levels for intolerable, tolerable if ALARP and broadly acceptable regions.  The issues of climate change are not considered within the Framework	
Jerrieann Sullivan	General	How are health impacts of petroleum activities such as fracking handled in the proposed ALARP Demonstration guidance? On what basis can a health impact experienced by a personal be objectively defined and assigned an industry cost?	See section 2.1.3.	No
Jerrieann Sullivan	General	What ethical principles underpin the guidance document? In particular what values and ethical principles have been used to determine what is a grossly disproportionate cost to industry for avoiding risk to a human life?	The principles underpinning the Framework are set out in section 4 of the High Level Design as follows:  <i>The CER's <b>strategic vision</b> for the Framework is:  A safe petroleum exploration and extraction industry in Ireland.</i>  <i>The CER's <b>mission</b> under the Framework is to:  Independently regulate petroleum exploration and extraction activities to protect life.</i>	No

Respondent	Section	Comment	CER Response	Guidance Update?
			<p><i>The CER will accomplish this mission through carrying out the following <b>roles</b>:</i></p> <ol style="list-style-type: none"> <li><i>1) foster and encourage safety in petroleum exploration and extraction activities;</i></li> <li><i>2) actively monitor &amp; enforce compliance of petroleum undertakings with their obligations under the Act;</i></li> <li><i>3) promote a regulatory framework that encourages continuous improvement of safety;</i></li> <li><i>4) work with other authorities to achieve our vision; and</i></li> <li><i>5) provide safety information to the public.</i></li> </ol> <p><i>The <b>regulatory goals</b> for the Framework are:</i></p> <ol style="list-style-type: none"> <li><i>1) that petroleum undertakings reduce risks to safety to a level that is As Low as is Reasonably Practicable (ALARP);</i></li> <li><i>2) that petroleum undertakings achieve safety performance commensurate with the best internationally; and</i></li> <li><i>3) to engender confidence that the regulatory framework is protecting the public</i></li> </ol>	
Jerrieann Sullivan	General	If the document is to apply to the fracking industry in Ireland will ALARP Demonstration include a full listing of all chemicals to be used and require industry and regulators to take account of the total risk associated with the multiple wells and gas	See section 2.1.5.	No

Respondent	Section	Comment	CER Response	Guidance Update?
		pipelines		
Jerrieann Sullivan	General	<p>How will the total risk that persons are exposed to as a result of fracking and other petroleum industry activities, the level of hazard identified by the cumulative risk factors associated with the industry be known and assessed over time?</p> <p>How, when and by whom will Health Impact Assessments be conducted? How long will health impacts be monitored for? How will health monitoring and health protection of the public be enforced by the regulator? How it is proposed to quantify and assign 'proportionate' costs for avoiding the risks of subjective experienced harm to a persons health, wellbeing and quality of life by petroleum industry activities?</p>	<p>This process is set out in detail in the ALARP Demonstration Guidance Document – in particular section 4 of that document.</p> <p>See section 2.1.5.</p>	No
Jerrieann Sullivan	General	<p>The paper identifies the first stage in hazard management as the comprehensive identification of hazards. In the case of hydraulic fracturing this is a relatively young industry and applied in the Irish context, there is no understanding of the likely hazards and no detailed analysis of appropriate codes and standards to safely manage this activity. In the absence of adequate information how can hazards be comprehensively indentified</p>	See section 2.1.1.	No
Jerrieann Sullivan	General	<p>How does the CER define good practice? How does the document take account of the influence of</p>	See section 4.3 of the ALARP Demonstration	

Respondent	Section	Comment	CER Response	Guidance Update?
		political and economic factors which influence what is considered good practice at any given time by regulators and by industry? How does the document take account of changes to good practice over time? Good practice evolves as knowledge and experience increases over time. How does the CER propose to define and justify what exactly 'good practice' is for hydraulic fracturing in Ireland? What principles, evidence, expertise would be used to justify a definition of good practice?	Guidance Document	
Jerriann Sullivan	General	How would the proposed guidance ensure the evaluation of the entire cumulative risk that the public are exposed to from petroleum activities, considering risk to ground water, air emissions, explosive hazard and the interaction between these petroleum industry impacts and impacts of other industries in Ireland which are not under the remit of the CER?	The CER cannot consider matters which are outset of its legislative remit.	
Geraldine Ring	General	I would like to express my deep concern that the ALARP Demonstration Guidance Document under the Petroleum Safety Framework is not designed to address the serious risks posed by onshore unconventional gas extraction through high volume slickwater horizontal fracturing (HVVF) or fracking for short	See section 2.1.1.	No
Geraldine Ring	General	...the ALARP guidance discusses "risk tolerability limits" in terms of fatalities. Is one to draw the conclusion that only fatality risks are to be	See section 2.1.2.	No

Respondent	Section	Comment	CER Response	Guidance Update?
		controlled by the CER?		
Geraldine Ring	General	...I find it appalling that the Irish government or the CER would consider that the very serious health risks posed by shale gas extraction could be in any way acceptable, and in particular that the issue of ALARP would be determined on a cost per fatality basis.	See section 2.1.2.	No
Geraldine Ring	General	...I believe that the precautionary principle should be applied and that the CER should never grant a safety permit for shale gas extraction in Ireland.	See section 2.1.1.	No
Geraldine Ring	General	I call for CER not to approve any permits for the shale gas industry to operate in Ireland.	See section 2.1.1.	No
Peter Crossan	General	...the Demonstration Guidance Document for ALARP must identify the clear risks associated with hydraulic fracturing. It must put forward prescriptive requirements that the undertakings must adhere to. Among these should be the requirement for a Health Impact Assessment to be taken in conjunction with a multi-disciplined team for assessment of risks to the local environment.	See section 2.1.3 and 2.1.4.	No
Peter Crossan	General	In the case of fracking, as yet no accepted international standard for good practice exists and therefore an ALARP Assessment must be	The CER agrees with this comment – the risk from all hazards and activities must be shown to be	No

Respondent	Section	Comment	CER Response	Guidance Update?
		undertaken for the totality of the activities associated with its working development.	ALARP.	
Peter Crossan	General	To assess Tolerability the evaluation needs to encompass the entire risk that persons are exposed to.	The CER agrees with this comment – guidance has been clarified to state this.	Yes
Peter Crossan	General	Where there is reason to believe that serious danger could exist, but the scientific evidence is insufficient, inconclusive or uncertain regarding the risk to public health and safety then the precautionary principle must apply.	The CER agrees with this statement.	No
Rahima Sayer	General	It is my belief that the Precautionary Principle must apply and the regulations of ALARP cannot be satisfied against the background of international concern, without a multi disciplinary approach and proper scientific assessment. A Health Impact Assessment of the process must form part of the Safety Case. [...] This must be clearly identified in the guidelines and made an absolute requirement for the evaluation of the Safety Case.	See section 2.1.1 and 2.1.3.	No
Rahima Sayer	General	The total risk associated with the multiple wells and gas pipelines associated with this industry must be assessed on a cumulative basis to include hazard identification. The processes to be undertaken by the industry in the course of exploration and	See section 2.1.5.	No

Respondent	Section	Comment	CER Response	Guidance Update?
		recovery should be described as part in the ALARP Demonstration including a full listing of all chemicals to be used.		
Sarah Akamine	General	I am concerned that the ALARP Demonstration Guidance Document under the Petroleum Safety Framework is not designed to adequately address the serious risks posed by onshore unconventional gas extraction, notably in the case of hydraulic fracturing.	See section 2.1.1.	No
Sarah Akamine	General	It is my view that the risks posed by this gas extraction are such that they cannot be adequately addressed to protect the health of local residents, and that such gas extraction should under no circumstances be permitted in Ireland.	See section 2.1.1.	No
Sarah Akamine	General	...the ALARP guidance discusses “risk tolerability limits” in terms of fatalities. Is one to draw the conclusion that only fatality risks are to be controlled by the CER? If so, this is a critical failing of the proposed regulatory system.	See section 2.1.2.	No
Sarah Akamine	General	In my view, the ALARP guidance must:  1. Define risk tolerability limits in a way that includes all known health impacts (not just fatalities) associated with hydraulic fracturing...	1. See section 2.1.2.  2. It is for the petroleum undertaking to identify all risks and demonstrate to the CER that they have done this. This cannot be done by the CER or its	No

Respondent	Section	Comment	CER Response	Guidance Update?
		<p>2. Identify all of the risks for which petroleum undertakings will be required to demonstrate ALARP.</p> <p>3. Require that the cumulative health and safety risks posed by all of the onshore gas installations and all associated preparatory, extraction, transport activities are taken into account in evaluating the risks to be managed and the tolerability levels</p> <p>Include the risks that will continue to be posed by gas extraction activities even after wells have been decommissioned...</p> <p>4. Require that a Health Impact Assessment, including baseline data collection and the evaluation of the cumulative risks associated with each installation in the context of other activities in the local area, be included in the evaluation and identification of safety risks.</p>	<p>guidance as it does not have full knowledge of the petroleum undertaking's operations.</p> <p>3. See section 2.1.5.</p> <p>Beyond this time the wells are not designated and do not fall under the Framework. Wells must be abandoned such that they present no realistic risk.</p> <p>4. See section 2.1.3</p>	
Sarah Akamine	General	Consider the impact on human health of contaminated food, as well as the risks to animal (livestock) of living in proximity to gas installations.	5. The Framework is concerned with safety to persons. The Act does not confer on CER a regulatory remit on wider environmental issues. However in certain circumstances there may be an overlap between "safety matters" and "environmental matters" and in such cases the CER will be concerned with those safety matters.	No

Respondent	Section	Comment	CER Response	Guidance Update?
		<p>6. Particular attention must be paid to the toxic chemicals that are used and released by hydraulic fracturing...</p> <p>7. The precautionary principle must be applied, not only by petroleum undertakings that apply for safety permits, but also by the CER that is in a position to either grant or refuse to grant such permits.</p>	<p>6. In the safety case, the petroleum undertaking must identify all hazardous inventories.</p> <p>7. See section 2.1.1.</p>	
Sarah Akamine	General	There need to be prescribed limits placed on this activity [...] I take the liberty of proposing a few below...	The Framework is a goal-setting framework, with the goal being that risk is ALARP. In the <i>Safety Case Guidelines</i> , the CER has identified some areas of prescription, where it is useful to ensure a common standard and this can be done unambiguously and without adversely affected safety. With, for example, the hazards of hydraulic fracturing varying from well to well, it is not appropriate to define separation distances as there is always the possibility that any sensibly defined distance is not large enough if, for example, there are significant H <sub>2</sub> S hazards. Certified welders would be expected to be used to construct a pipeline as this is Good Practice.	No

## 3 Responses with Reference to the Draft Guidance

### 3.1 *Summary of Responses and Issues Raised*

Of the 13 responses received to the *Draft ALARP Demonstration Guidance Document*, seven made comments on specific sections. The specific responses are tabulated below and ordered by section number. If the same comment has been made by different respondents, these are grouped together. The *Guidance Update* column denotes where the *ALARP Demonstration Guidance* has been updated following the response. Where it clarifies the CER's response, the updated text is provided.

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIIL & NSAI	List of Defined Terms in this Paper Individual Risk	The definition should be amended to: 'The risk of fatality to an individual per year.'	While this interpretation is correct for comparisons with the Risk Tolerability Criteria, it may not be in other circumstances. Therefore, the definition has been removed and clarity provided in section 5.2 in the <i>ALARP Demonstration Guidance Document</i> on the units for the individual risk criteria.	Yes
SEPIIL	List of Defined Terms in this Paper Major Accident	Further definition of this term is requested to support consistent classification of major accident hazards. We expect that there will be further clarity regarding the reporting of major accidents in the Petroleum Incident Regulations and in the Petroleum Incident Notification and Investigation Procedures. These regulations should align with Schedule 8 in the Control of Major Accident Hazards regulations (which are part of the HSA's remit).	The definition of major accident provides the CER's view (after previous consultations) of those hazards that the safety case should concentrate on (in addition to coverage of the General Duty).  The Petroleum Incident Regulations and the Petroleum Incident Notification and Investigation Procedures will be developed later in 2013 and the comments will be considered as part of the consultation process on those papers.	No
SEPIIL & NSAI	List of Defined Terms in this Paper Societal Risk	This definition should be amended to: 'The risk to members of society, i.e. the public, that are affected by the hazard.' This definition would then align with Section 5.3 (in particular, with the last sentence in that section, i.e. that the societal risk tolerability levels only apply to members of the public and the workforce should not be included in this assessment).	In order to avoid any confusion with the concept of societal risk used in section 5 in the <i>ALARP Demonstration Guidance Document</i> , this simple definition has been removed.	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL	1.2	We welcome the statement that ‘It is for the petroleum undertaking to decide how best to demonstrate that the risks from their activities are ALARP through its safety case.’ We would propose that a combination of the approaches listed in 4.5.1 may be appropriate to demonstrate that risks are managed to ALARP levels for Major Accident Hazards.	A number of approaches are available, but these approaches should not need to be combined for consideration of a particular risk reduction measure. If an approach is used to justify not installing a measure, then the approach needs to provide sufficient confidence in the result. For the reasons outlined in section 4.5.6.4 in the <i>ALARP Demonstration Guidance Document</i> , a combination of approaches to make a discrete decision is unlikely to be needed. In considering a large number of risk reduction measures, it is likely that a number of approaches will be used.	No
SEPIL	2	Last paragraph (First sentence): The word ‘reduction’ should be added at the end of the sentence, i.e. “grossly disproportionate to the risk” should read “grossly disproportionate to the risk reduction” (as stated elsewhere in the document).	Agreed. The text will be changed	Yes
SEPIL & NSAI	3.1	Third and sixth paragraphs: The third paragraph states that ‘The safety case must contain the petroleum undertaking’s ALARP demonstration that all risks, including non-Major Accident Hazards are reduced to a level that is ALARP.’ We would propose that, for risks in the broadly tolerable region, adherence to codes, standards and Good Practice would be sufficient to demonstrate ALARP and that any further reasonably practicable measures may be considered. This would	Section 4.4.3 in the <i>ALARP Demonstration Guidance Document</i> outlines the approach required for broadly tolerable risks, which aligns with this comment and UK practice.  For risks under the Broadly Tolerable Limit, further risk reduction measures must be considered. However, as Good Practice must have been followed and the risk level is low, there are unlikely	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
		<p>broadly align with the approach of the UK HSE as illustrated in our previous submission<sup>20</sup> and shown in Figure 1 in Appendix 1 (at the end of this tabulation). It is also described in the book “Reducing Risks, Protecting People”<sup>21</sup> in paragraph 123.</p> <p>If, for broadly tolerable risks, the CER maintains the requirement (in addition to the application of Good Practice) to identify and implement any further reasonably practicable measures then clarity would need to be provided regarding what will satisfy the CER in terms of a demonstration of ALARP for such risks.</p>	<p>to be many possible further risk reduction measures. The guidance contains the following: <i>Due to the relatively low risk associated with broadly tolerable risks, it is unlikely that the more complex assessment techniques outlined below will be required to determine whether a risk reduction measure should be implemented or not.</i></p> <p>To provide further clarity, Figure 2 will be updated to specifically mention broadly acceptable risks.</p>	
Peter Crossan	4	<p>While at section 4 of the CER’s consultation document, it outlines its expectations including hazard identification and processes to be described; it does not clearly outline what is required to provide sufficient evidence that risks associated with this process can be addressed or will be properly evaluated.</p>	<p>The <i>Safety Case Guidelines</i> identify the information from the <i>ALARP Demonstration Guidance Document</i> that needs to be documented.</p>	No

<sup>20</sup> SEPIL submission to the CER regarding CER/11/137 – Consultation Paper on the High Level Design of the Petroleum Safety Framework (Our Ref: COR-01-SH-GE-1674, dated 26<sup>th</sup> September 2011)

<sup>21</sup> Reducing Risks, Protecting People, HSE’s Decision Making Process (2001) <http://www.hse.gov.uk/risk/theory/r2p2.pdf>

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL	4.1	<p>In the third point it should be noted that risk tolerability criteria generally relate to the overall total risk, and so it is generally not appropriate to use such criteria when considering whether the risks associated with a single hazard are tolerable/ALARP, which seems to be what is suggested here.</p> <p>Clarification is required as the key issue for ALARP demonstration in connection with individual hazards is identifying and assessing all practical means of reducing the risks associated with the hazard.</p> <p>Overall the document seems to stress risk quantification as the principal means of demonstrating ALARP (eg. see in 4.4.2 and 4.5 as well). Could CER provide more guidance on of the application of QRA as part of ALARP demonstration? [The UK HSE view is closer to 'QRA and CBA should be used cautiously in support of qualitative or engineering arguments, including use of Good Practice' (as indicated in HSE Offshore Information Sheet No. 2/2006)].</p>	<p>The risk tolerability criteria apply to the total risk and in order to evaluate the total risk, the risk from each major accident hazard needs to be evaluated. QRA needs to be used to undertake this assessment, although the level of detail may vary from hazard to hazard depending on the complexity of the hazard and the risk contribution that it gives, but the method must be such that there is sufficient certainty in the result. The text in the third bullet has been updated to clarify this.</p> <p>To determine if a risk reduction measure needs to be implemented in order for the risk to be considered ALARP, any of the methods described in section 4.5 in the <i>ALARP Demonstration Guidance Document</i> can be used as long as the method leads to a result that is provides sufficient certainty.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIIL & NSAI	4.1	<p>This section should recognise a role for relevant Good Practice, Engineering Judgement, Qualitative and Semi-Quantitative approaches in the ALARP assessment of Major Accident Hazards. We would propose that Figure 3 in the UK HSE 'Guidance on Risk Assessment for Offshore Installations'<sup>22</sup> should be incorporated into the CER's flowchart (Figure 2). This would ensure that risk reduction measures that qualitatively give a high benefit and do not require significant effort (but which may be difficult to quantify) are implemented.</p>	<p>Within point (iv), the petroleum undertaking has to justify any identified risk reduction measures that are not implemented. This can be by Engineering Judgement, Qualitative Semi-Quantitative, or Quantitative method as long as the method is sufficiently robust to justify the conclusion. Currently this step is contained in one box within Figure 2 in the <i>ALARP Demonstration Guidance Document</i> but at the level of the information provided in the flowchart, it is not appropriate to expand the detail shown.</p> <p>In addition, it is noted that risk assessment is not the same as ALARP assessment and so it is not wholly appropriate to incorporate the UK HSE's figure into the CER figure.</p>	No

<sup>22</sup> <http://www.hse.gov.uk/offshore/sheet32006.pdf>

Respondent	Section	Comment	CER Response	Guidance Update?
SEFIL	4.1 3i, 5 (including Figure 2)	<p>We recognise that there may be a role for quantitative risk assessment in order to make a comparison with risk tolerability criteria; however, we disagree that all Major Accident Hazards require quantitative evaluation of the risk and we re-iterate the above point regarding the important role for all of the approaches listed in 4.5.1 (excluding, in general, the precautionary principle) in the ALARP assessment of Major Accidents Hazards. This should be reflected in Figure 2 in this section. It is our view that qualitative and semi-qualitative assessment and evaluation of the risk provides a valid demonstration that risk is managed to ALARP levels for well understood hazardous events. The UK HSE's Reducing Risks, Protecting People book states "The new version emphasises the role of risk assessment, both quantitative and qualitative, in the decision-making process and expands on the role of Good Practice in determining the control measures that must be put in place for addressing hazards."</p>	<p>Quantitative risk assessment is required to make a comparison with risk criteria and therefore all Major Accident Hazards must be quantitatively evaluated in order to determine the risk. However, the nature of the assessment may vary according to the risk. A well understood risk, or a risk that contributes a small part to the overall risk may only need a high level assessment in order to provide an accurate enough value to allow comparison with the tolerability criteria.</p> <p>Any of the techniques outlined in section 4.5 in the <i>ALARP Demonstration Guidance Document</i> can be used to determine whether a particular risk reduction measures needs to be implemented for the risk to be ALARP.</p> <p>To assist the explanation, Figure 2 in the <i>ALARP Demonstration Guidance Document</i> will be clarified by changing the question "Is the Hazard a Major Accident Hazard" to "Are there Major Accident Hazards" since the intention of the flowchart is to apply to the sum of all hazards rather than each hazard individually.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL	4.2.2	<p>First paragraph, second sentence: Insert the word 'may', i.e. "As illustrated in the diagram below, these hazards <i>may</i> have a low frequency, but high consequence, making them more difficult to manage, which is why they are a particular focus of the Framework and ALARP assessment."</p> <p>See also our comment regarding List of Defined Terms in this Paper, Major accident.</p>	<p>All Major Accident Hazards would have low frequencies so use of "may" is not appropriate. Major hazard with high frequencies are removed early in the design process.</p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
ERM	4.2.3	<p>It is helpful to ensure that there is some structure to the review and selection of risk reduction measures. This may be in the form of a workshop which, for risks in the intolerable or 'ALARP' regions, works through a set of guidewords (eg inherent safety, prevention etc) and lists potential measures. These may then be sifted by identifying a coarse 'cost' and 'effectiveness' band, carrying forward those which are clearly worth implementing and rejecting those clearly not worth implementing. The remainder would then be subject to further scrutiny.</p> <p>This demonstrates that a process has been undertaken, rather than it just being one person's opinion on potential measures.</p>	<p>Broadly speaking, the approach suggested is in line with the <i>ALARP Demonstration Guidance Document</i> as long as the coarse screening gives the petroleum undertaking sufficient confidence when excluding a particular risk reduction measure. Section 4.5.2.1 in the <i>ALARP Demonstration Guidance Document</i> has been added on the use of risk ranking techniques as part in the ALARP demonstration. Broadly speaking the ranking process needs to follow the same guidance as for the assessment of an individual measure.</p> <p>Whatever approach is applied, it must provide for a comprehensive list of potential risk reduction measures and allows for a decision to be made on any measures that are discarded.</p> <p>Any ALARP decision must be made with sufficient certainty, which is unlikely to be gained from one person's opinion.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	4.3.2	<p>It may be reasonably practicable to make changes to meet a new code or standard, but it has to be acceptable by the Regulator that it may not be. Some guidance on what level of assessment the CER would expect in relation to changes in codes or standards would be helpful as generally 'engineering judgement' would be expected to be sufficient in such cases.</p> <p>Can CER confirm this provision will not be applied retrospectively to existing facilities?</p>	<p>The guidance asks for an assessment to be carried out to determine whether it is reasonably practicable to makes changes to meet safety critical deficiencies between an old and updated code. Engineering judgement may be appropriate in some cases, but not necessarily all. The petroleum undertaking must use an assessment technique that gives them sufficient confidence in the result.</p> <p>The guidance has been updated to change 'safety implication' to 'safety critical deficiency' (see section 4.3.2 in the <i>ALARP Demonstration Guidance Document</i>).</p> <p>This process needs to be applied to existing facilities.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL & NSAI	4.3.2	Point 2 c: Installations are designed and built to hundreds of codes which are 'current' at that time. It would be impractical and extremely onerous if petroleum undertakings were required to check for modifications in each updated code and then carry out an assessment whether it is reasonably practicable to make the changes to meet the new code(s). We would propose that if a safety-related deficiency is identified in a code then an assessment should be carried out to see whether it is reasonably practicable to make changes which address the code deficiency.	<p>The <i>ALARP Demonstration Guidance Document</i> section 4.3.2 will be updated to require consideration of safety critical deficiencies between current and old codes when considering whether Good Practice has been achieved.</p> <p>The <i>Safety Case Guidelines</i> will also be updated to require a summary of the petroleum undertaking's processes to achieve this.</p>	Yes
Kinsale	4.4.1	Where ' <i>public risk</i> ' is referred to it would be worth noting that the concept does not apply to offshore activities, where all involved people are workers.	<p>In this context, the public excludes workers and so the societal risk limit does not apply offshore.</p> <p>The text has been updated to remove reference to 'public risk', which is not used elsewhere in the document and to clarify the meaning.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL	4.4.1	<p>First paragraph: We agree that quantitative risk assessment may be useful to allow comparison with risk tolerability criteria. However, we would propose adding the text ‘which could impact the public’ to the first sentence, i.e. ‘The risks from all Major Accident Hazards <i>which could impact the public</i> must be evaluated using quantitative risk assessment to allow explicit comparison with the Risk Tolerability Limits.’</p> <p>Third paragraph: For risks in the ‘tolerable if ALARP’ region, as stated elsewhere in this document, a combination of relevant Good Practice, engineering judgement, qualitative, semi-quantitative and quantitative risk assessments may be part in the ALARP demonstration process (see Figure 1 in Appendix 1).</p>	<p>The quantitative individual risk limits also apply to workers.</p> <p>See comment above on the use of the word ‘combination’.</p>	No
Kinsale	4.4.2	<p>In this section the second paragraph that references to risks not being evaluated with ‘<i>sufficient certainty</i>’ leading to the need for ‘<i>recourse to the precautionary principle</i>’ refers to section 4.6, when section 4.5.7 covers the precautionary principle (on which see comments below).</p>	<p>This has been changed to refer to the correct section.</p>	Yes
Kinsale	4.4.3	<p>The meaning of the last paragraph reference to ‘<i>the assessment for Major Accident Hazards</i>’ is not clear. A cross-reference would be helpful.</p>	<p>This section has now moved to 4.5.2.2 and updated such that the identified text does not appear.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIIL & NSAI	4.4.3	<p>It is our view that relevant Good Practice, codes and standards should be sufficient to demonstrate that broadly tolerable risks are ALARP and that petroleum undertakings may consider any further reasonably practicable measures. We agree that low cost risk reduction measures which provide a clear risk reduction should be implemented and that techniques such as engineering judgement and qualitative risk assessment are appropriate to assess broadly tolerable risks and determine appropriate risk reduction measures. If an assessment of gross disproportion is required then we would only support a qualitative assessment of the risk reduction and effort.</p> <p>Regarding the last paragraph, engineering judgement and qualitative risk assessments may be sufficient when no Good Practice is available.</p>	<p>If an assessment of gross disproportion is required to show that a risk reduction measure is not required when the risk is broadly tolerable, the method used to justify that needs to be robust enough to provide sufficient confidence in the result. Any of the methods outlined in Section 4.5 in the <i>ALARP Demonstration Guidance Document</i> may be used to do this, though it is more likely that the less sophisticated techniques are appropriate.</p> <p>The CER agree that if no Good Practice is available, then the suitability of a risk reduction measure could be judged by any of the means identified in section 4.5 in the <i>ALARP Demonstration Guidance Document</i> as long as the approach gave sufficient confidence in the result.</p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	4.5	As all of the activities that will require a safety case will require a quantitative risk assessment it would be worth stating early in the section that this would be expected to be the tool used for any quantification as part of an ALARP demonstration. The last paragraph of 4.5.5.1 content covers this.	<p>Quantification is required of all hazards to determine the risk and compare with the tolerability criteria. However, assessments of risk reduction measures to determine whether they need to be implemented for the risk to be ALARP can follow any of the methods in section 4.5 in the <i>ALARP Demonstration Guidance Document</i>.</p> <p>The text from the last paragraph of section 4.5.5.1 in the <i>ALARP Demonstration Guidance Document</i> has been moved to the start of this section and an additional section called <i>Assessing Risk Reduction Measures</i> (section 4.5.5.2) added.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL	4.5.3.1	<p>As outlined in our previous submission, qualitative risk assessment involves identifying hazards, assessing the risks and identifying measures which could reduce the risks, without the use of elaborate numerical models. For each potential event that may go wrong, the risk is assessed using a matrix to enable the potential likelihood and consequence severity to be judged and, from this, the risk is classed as 'high', 'medium' or 'low'. (Please note that the risk referred to here is unmitigated risk). The objectives of a qualitative risk assessment are to ensure that all of the risks are known and assessed, are effectively managed and that suitable and sufficient control measures are in place such that the risks are reduced to ALARP levels. It is our view that advanced qualitative risk assessment techniques such as bow-tie analysis<sup>23</sup> are key to an ALARP demonstration regarding Major Accident Hazards as they provide a clear illustration of the barriers that are in place to manage the risks (see Figure 3 in Appendix 1 for a bow tie extract of the left hand side of one onshore pipeline threat). As stated in a book on Risk Management<sup>24</sup> "A good ALARP demonstration should be a broad decision-making process in which all relevant parties are invited to participate actively: management, employee representatives, safety representatives, discipline experts." The use of workshops is an integral part of bow tie development so that all hazards are identified and that sufficient controls are in place to manage the risks to ALARP levels, i.e. the question 'what more/else can we do?' is a key part of these bow tie workshops.</p>	<p>The CER expect that a robust process such as a multi-disciplinary workshop is used to identify hazards and risk reduction measures. The 2<sup>nd</sup> paragraph of section 4.2.1 in the <i>ALARP Demonstration Guidance</i> expands on this. These are positives and negatives in the use of bow-ties; positives including the visualisation aspect, but this also being a negative as a properly constructed bow-tie where barriers are themselves subject to threats becomes difficult to visualise due to its size. The technique allows the requirements of section 4.2 in the <i>ALARP Demonstration Guidance Document</i> to be achieved, but does not provide sufficient information for decisions made under section 4.5 other than engineering judgement.</p> <p>The CER also note that qualitative cost benefit analysis has to be undertaken with care as comparing the cost (in €) of a risk reduction measure to a qualitative risk reduction (e.g. low) cannot be done without further guidance on what low means unless the cost of the measure is, by engineering judgement, far in excess of the risk benefit gained.</p> <p>The requirement for workshops is given in Section 4.2.1 of the guidance.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL	4.5.3.2	<p>It is our view that qualitative analysis is a valid and useful screening tool, to identify those risk reduction measures which obviously should be implemented or can be rejected on ALARP grounds, before moving on to more detailed, semi-quantitative and quantitative cost benefit analysis for the less obvious, grey-area type measures, if appropriate and required. This point was part of our previous submission<sup>20</sup> and is illustrated in Figure 4 in Appendix 1. This qualitative screening would also help to ensure that low cost measures that provide a clear risk reduction, but may be difficult to quantify, are implemented.</p>	<p>Such a screening method carried out correctly would not be inconsistent with the <i>ALARP Demonstration Guidance Document</i> and a specific section has been added on the ranking of risk reduction measures. This ranking and any decisions made from it must use a method that provides sufficient certainty. However, as stated at the end of section 4.5.4.1, qualitative assessment is not appropriate for many engineering issues.</p> <p>If a risk reduction measure clearly provides a benefit at low cost, nothing in the <i>ALARP Demonstration Guidance Document</i> requires detailed analysis to reach this conclusion. In general, the CER do not need justification of why a petroleum undertaking has opted for the safer of two options. It is only when the one that provides less risk reduction is implemented that this must be justified.</p>	Yes

<sup>23</sup> A bow-tie diagram is a means of representing the causes and consequences of a hazardous occurrence, together with the elements in place to prevent or mitigate the event.

<sup>24</sup> Risk Management: With Applications from the Offshore Petroleum Industry (2007) by Terje Aven and Jan Erik Vinnem (Springer). ISBN: 978-1-84628-652-0.

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL	4.5.4	It is our understanding that Risk Assessment Matrices used by petroleum undertakings which contain a frequency axis which includes bands such as 'has occurred more than once per year in the industry' and 'has happened more than once per year at the location' etc. and a consequence axis which includes bands such as 'minor injury', 'major injury' etc. would be an acceptable Semi-Quantitative Risk Analysis technique.	<p>Confirmed. This is the case:</p> <p><i>Possible ways to quantify the bands for the frequency side of the risk assessment include bands for events likely to occur:</i></p> <ul style="list-style-type: none"> <li>• <i>Every N years, where N varies between the bands;</i></li> <li>• <i>Once in the site's lifetime; or</i></li> <li>• <i>Once each year in the worldwide oil and gas industry.</i></li> </ul> <p><i>Whatever bandings are chosen they must be well-defined and not open to interpretation by the persons undertaking the risk assessment.</i></p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
SEFIL	4.5.5	<p>The topics ‘Quantitative Risk Analysis’ and ‘Cost Benefit Analysis’ should be in separate sections. While QRA may be useful to allow a comparison with risk tolerability criteria, it is likely that in many cases it will not be possible to quantify a risk reduction measure. As stated in the Reducing Risks, Protecting People book “CBA aims to express all relevant costs and benefits in a common currency, usually money. This in principle requires the explicit valuation of the benefit of reducing the risk. However, such a valuation may not always be possible or practicable – in these circumstances we rely on qualitative estimates. And, in any case, we apply common sense when reviewing the results.” Therefore, we believe that it would be better to have a separate section on Cost Benefit Analysis which also describes the important role for qualitative estimation of the benefit of the risk reduction measure and the cost/effort of implementing that measure in demonstrating gross disproportion.</p> <p>We re-iterate that there is a key role for a qualitative assessment of the risk reduction and effort to allow a qualitative demonstration of ALARP. We note that NOPSEMA states in their ALARP guidance<sup>25</sup>: “The operator may be able to rank available control measure options according to their benefits and costs in qualitative or quantitative terms. This will enable the operator to show that the appropriate balance has been achieved, where further steps to reduce risk would incur unreasonably high cost with little gain.”</p> <p>First sentence: This is unclear.</p>	<p>QRA is required to compare the risk to the tolerability criteria.</p> <p>The combination of QRA and CBA is one of the options available to justify why a particular risk reduction measure has been chosen.</p> <p>If the risk reduction gained from a particular measure cannot be evaluated and that measure is not implemented (the case where it is implemented is inherently safer and so will not come under scrutiny and the risk reduction from such a measure does not need to be calculated, or reported), one of the methods needs to provide a robust demonstration that non-implementation is justified. If no such argument is possible, the precautionary principle applies.</p> <p>Regarding the ranking of risk reduction measures, this does not in itself justify whether an ALARP situation has been reached. If they are ranked by effectiveness (with respect to cost and risk benefit), the petroleum undertaking still needs to undertake analysis (by one of the methods outlined in section 4.5 in the <i>ALARP Demonstration Guidance Document</i>) to robustly determine where the cut-off is between those measures that need to be implemented and those measures that do not. A specific section (section 4.5.1.1) on ranking of risk reduction measures has been added to the document.</p> <p>The first sentence of 4.5.5 (now 4.5.6) has been clarified.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
ERM	4.5.5.2	Great care must be exercised with CBA. It is often used as a means of justifying not doing something. Any CBA should certainly be scrutinised by taking a step back and asking the question as to whether the measure under consideration should really be implemented. Use of GDFs will go some way to ensuring that measures are not rejected by narrow margins, but it is important to be sceptical about the application of CBA.	The CER agree that any assessment technique should be used with care. Section 4.5.7.5 in the ALARP Demonstration Guidance Document covers the avoidance of reverse ALARP.	No

<sup>25</sup> NOPSEMA ALARP Guidance Note N-04300-GN0166 Rev 3 Dec 2011 (<http://www.nopsema.gov.au/assets/document/N-04300-GN0166-ALARP.pdf>)

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL	4.5.5.2	<p>First paragraph: Cost benefit analysis may not always involve a 'numerical assessment' as this may not always be possible and therefore it would be necessary to rely on qualitative estimates. As stated above, we believe that there is an important role for qualitative estimation of the benefit of the risk reduction measure and the cost/effort of implementing that measure in demonstrating gross disproportion.</p> <p>Third paragraph: We note that the CER refers to a Defined ICAF value of at least €2,400,000. Appendix B provides a value from the National Roads Authority which is based on the public. It is our view that, in order to account for workforce members, a different value should be used, or it should be accounted for by using a lower gross disproportion factor. See also our comments in relation to Appendices B and C.</p> <p>Third paragraph: Replace 'Appendix I' with 'Appendix B'</p>	<p>In regard to qualitative cost benefit analysis, see final paragraph of response to 4.5.3.1 above.</p> <p>Comments on the gross disproportion factor are covered in section 3.3 below.</p> <p>Appendix numbering changes accepted.</p>	Yes
Kinsale	4.5.6.1	<p>Wording should be amended to "...consequences that at least cover the worst credible case....."</p>	<p>The text has been amended as suggested as any risk assessment is not expected to include consequences that are not credible.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
NSAI	4.5.6.1	<p>Being a conservative assessment, this approach will be more likely to lead to the conclusion that a risk reduction measure should not be implemented.</p> <p>This appears to be counter intuitive – surely the assessment would lead to a risk measure should be implemented.</p>	This was a typographical error that has now been corrected.	Yes
SEPIL	4.5.6.2	Is there a proposed calculation method for lost/deferred production?	The petroleum undertaking's calculation method will be assessed by the CER, but the CER will not predefine a method for this. In this context the second paragraph of this section is highlighted with respect to non-implementation of risk reduction measures being dependent on the additional cost of lost or deferred production.	No

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	4.5.6.2	<p>The last paragraph <i>'if shortly after a design is frozen or constructed ... a risk reduction measure is identified ... the measure should be implemented as soon as practicable...'</i> is a concern as it is written and may cause problems. Clarification on how this might be applied is suggested - justifying that a measure is one that <i>'normally would have been implemented'</i> will also pose a challenge.</p> <p>[Note that in the minuted consultation meeting with Kinsale Energy, Kinsale explained that the issue with the above text was the element that states <i>as soon as practicable.</i>]</p>	<p>The judgement of what may normally have been implemented will be undertaken by subject experts at the CER in the same way as the CER would judge whether, for example, a petroleum undertaking's procedure meets the standard that would normally be expected. In cases where a risk reduction measure has mistakenly been not implemented during a design, the risk reduction measure cost is high because substantial redesign is needed whereas if it had been considered earlier in the design process the cost would have been lower and hence the risk reduction measure implemented. This section of the guidance seeks to avoid this situation where an error may lead to the non-implementation of a risk reduction measure.</p> <p>The text <i>as soon as practicable</i> has been removed as it is judged to be unnecessary as there this applies to the implementation of any risk reduction measure.</p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	4.5.6.4	This section seems to be superfluous as it is clear that, where an assessment of risk reduction is useful in an ALARP demonstration, the results from the most sophisticated approach (quantitative risk assessment) would be used. The lower level approaches are more generally used in a screening manner to decide on the hazards that need to be assessed using quantitative risk assessment.	The CER is aware of situations where this balance has been incorrectly made and so the guidance is useful.	No
SEPIL	4.5.6.4	In contrast to the statement here, it should be noted that there may also be examples when the use of qualitative estimation would conclude that a risk reduction measure is required, whereas a quantitative estimation may conclude that it would not be required (due to the conservative nature of qualitative assessment and the difficulty with quantifying some risk reduction measures).	It is possible for a petroleum undertaking to use one technique that would justify implementation of a risk reduction measure while use of a more sophisticated method would show that it was not required. This would be conservative and inherently safer.	No
Kinsale	4.5.6.5	In the section on 'Reverse ALARP' we believe that it should be pointed out that there may well be an argument that to reinstall or repair a risk reduction measure that was originally installed is not necessary. Such as when, for example, the operating conditions have changed such that the measure would no longer have the same risk reduction benefit.	The following text has been added to the paragraph: <i>This does not prevent a suitably justified decision not to re-instate a risk reduction measure if the original reason for having the risk reduction measure has changed due to, for example, a hazard having been eliminated.</i>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	4.5.7	This precautionary principle coverage is broadly consistent with UK HSE Guidance, but HSE add that 'invocation of the precautionary principle is extremely unlikely to be appropriate offshore', which we believe should be stated in the CER Guidelines. This is because the hazards and consequences of oil and gas operations are well understood. It would perhaps be helpful to include examples of the sort of uncertainty that would require the application of the precautionary principle.	<p>The CER believe that suitable guidance has been provided on when the precautionary principle is likely to be invoked.</p> <p>Due to inherent uncertainty associated with the use of the precautionary principle, it is not appropriate to provide examples of its application.</p>	No
SEPIL & NSAI	4.5.7	Second paragraph: There needs to be clarity on when the precautionary principle will, and will not, be applied, e.g. what is 'a high degree of uncertainty'?	This will need to be considered on a case by case basis. However a high degree of uncertainty would indicate that reasonable changes in input parameters to the risk calculation lead to different results.	No
Kinsale	5.2	It should be made clear what the precise definition of individual risk as quoted in Table 1 is, ie. the risk of death per year for the defined individual.	This is fatalities per year and the guidance has been updated to reflect this.	Yes
HSA	5.2	Paragraph 5.2 on Page 26 refers to taking account 'of the occupancy level'. Given the context, it would be clearer to replace this with 'the likelihood of a person being present'	This change has been made.	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
Talamh	5.2	<p>The Upper Tolerability Limit for Individual Risk to a member of the public is given as 10 to the power of minus 4, or one fatality a year per 10,000 of population. If the population of Ireland is taken as, say, 4 million, this effectively means the CER expects that 400 members of the public could be killed in petroleum related accidents without any question of the level of danger in the industry.</p> <p>From the recorded debates it is clear that the understanding of the Oireachtas in creating the Petroleum (Exploration and Extraction) Safety Act, 2010 was to ensure that the petroleum industry was safe for the public.</p> <p>The CER's position, however, is that they find it acceptable for the public to tolerate petroleum activities with a potential danger 100 times greater than what would be tolerated in everyday life.</p> <p>It is impossible to accept that the legislators intended this to be the outcome of making the petroleum industry safe for the public!</p>	<p>This analysis ignores the societal risk criteria. It is recognised that if a large number of people are exposed to an acceptable individual risk, this may not be an acceptable situation. For this reason, societal risk criteria are in place. For the whole population of Ireland to be at risk from a petroleum incident, as suggested, is not credible and, in this unlikely scenario, the societal risk criteria would not be met.</p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIIL & NSAI	Appendix B	<p>Equation: Replace 'Reduction in fatality risks' with 'Reduction in number of fatalities'</p> <p>The Defined ICAF proposed by the CER appears to be similar to the UK HSE's Value of Preventing a Fatality (VPF). The proposed Defined ICAF value is acceptable for the public if the intention is that the cut off value at which gross disproportion is judged to occur is when a 'Net cost of (risk reduction) measure' <math>\geq</math> Defined ICAF x GDF x Reduction in number of fatalities (where GDF is Gross Disproportion Factor)</p> <p>The proposed figure is for members of the public so it is important that the Gross Disproportion Factor differentiates between the public and the workforce.</p> <p>Please see also the comments regarding Appendix C and section 4.5.5.2.</p>	<p>In the equation, the term has been changed to <i>Reduction in Potential Loss of Life</i> and further explanation added.</p> <p>The ICAF concept is the same as VPF.</p> <p>Comment in regard to the gross disproportion factor is given in section 3.3 below.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	Appendix D	<p>We believe that the Individual Risk content is generally reasonable, although note that the HSE individual risk criteria used for land use planning are based on the risk of receiving a dangerous dose or worse (i.e. a lesser level of harm than fatality), largely because it is considered appropriate to adopt a more cautious approach for the purposes of land use planning, where it is still possible to advise against people being exposed to the risk.</p> <p>On societal risk, see the comments on 5.3 above.</p>	<p>That is correct. The UK HSE individual risk criteria currently used for land use planning are based on the risk of receiving a dangerous dose or worse. However, the individual risk limits used in Ireland by the HSA for land use planning advice are based on risk of fatality.</p>	No
SEPIL & NSAI	Appendix D	<p>Please see the comments regarding section 5.3.</p> <p>Last paragraph: Insufficient justification is provided for the lower figure selected for the petroleum industry compared to other hazardous industries. We do not agree that choosing a lower figure has an impact on continual improvement. Implementing a continual improvement is a lot more complex than setting a tighter target.</p>	<p>The last paragraph has been replaced with a clearer explanation of the process that was followed in selecting the CER criteria for the tolerability of societal risk (to the public only).</p> <p>See responses to section 5.3 below.</p>	Yes

## 3.2 Responses on the Risk Limits

### 3.2.1 Points Made by Respondents

Respondent	Section	Comment
Kinsale	5.3	<p>The FN tolerability limit lines shown in Figure 6 are an order of magnitude below the criteria referred to by the UK HSE in their SPC39<sup>26</sup>. The justification given on page 34 is that Ireland can use criteria which are an order of magnitude lower because the criteria do not apply to workers, and they are aiming for continual improvement. It is not clear how this reasoning is arrived at and further (numerical) explanation would be appropriate. It is also noted that these proposed levels would be inconsistent with currently applied HSA risk assessment criteria under COMAH legislation.</p> <p>Furthermore, we believe that care needs to be taken with the interpretation of such FN criteria. In the past, the UK HSE has described them as “Comparison Lines” rather than as strict criteria, implying that just because an FN curve crosses a line, it does not necessarily mean that the societal risk is, for example, intolerable.</p>
SEPIL & NSAI	5.3	<p>The societal risk limits proposed by the CER are not aligned with the HSA’s limits. It is of critical importance that consistent societal risk limits are applied in Ireland by regulatory authorities to provide confidence to the public. Furthermore, the limits proposed by the CER differ from those of the UK HSE.</p>

<sup>26</sup> <http://www.hse.gov.uk/foi/internalops/hidcircs/permissioning/spcperm39.htm>

### 3.2.2 CER's Response

To provide further clarity, the justification for the risk criteria has been updated in the ALARP Demonstration Guidance Document. The FN criteria were specified following a process involving a review of international societal risk criteria<sup>27</sup> and an extensive comparison exercise to test the application of the proposed criteria to relevant real examples of oil and gas installations, in the UK and other countries. A number of options were considered and a sense check was also applied by comparing with estimated worldwide historical experience. As a result of this review, the proposed FN criteria were considered appropriate and achievable for petroleum undertakings in Ireland within the regulatory remit of the CER; noting that the criteria apply to the public only and not to on-site workers (an important distinction that has a strong influence on the acceptability of the FN results, at lower values of N).

Regarding interpretation, instances where any part of the FN curve representing the societal risk to the public from a petroleum undertaking crosses the criterion for Intolerable Risk will be considered on a case-by-case basis. The CER would expect the FN results to lie wholly within the criterion envelope for Intolerable Risk in all but exceptional circumstances, but recognise the possibility that such exceptional circumstances may arise.

This apparent difference with the HSA Land Use Planning Guidelines is identified in the *Draft ALARP Demonstration Guidance Document*, but it should be recognised that the CER and HSA criteria serve different purposes. The HSA criteria are applied as part of a screening approach for proposed developments in the vicinity of all top tier COMAH sites (not only petroleum infrastructure), and determine the advice given by the HSA in individual cases. The role of the HSA in land use planning is to advise planning authorities on proposed developments and takes the form of "advises against" or "does not advise against".

The CER on the other hand is an approving authority and, based on the safety case and ALARP demonstration submitted, will determine whether or not a petroleum undertaking should be granted a permit. The proposed societal risk criteria provide guidance on what CER considers to be an appropriate limit in relation to petroleum infrastructure (section 5.1 in the *ALARP Demonstration Guidance Document*) that should be achievable for new petroleum infrastructure installations built in Ireland in all but exceptional circumstances. The CER recognises that exceptions could arise where justified by other benefits (e.g. over-riding national interest) and that the limits will be reviewed and, if necessary, may be revised in future in the light of experience (Section 1.2 in the *ALARP Demonstration Guidance Document*).

In the case of a proposed new petroleum infrastructure installation, the situation may arise where planning permission is granted to the proposed development before it is built, but more onerous societal risk limits would then be applied by CER. The CER will review the Design Safety Case at an early stage in the development process and, in the event that the

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<sup>27</sup> See in particular *Guidelines for Developing Quantitative Safety Risk Criteria*, Center for Chemical Process Safety, Wiley 2009.

CER risk limits are not met, the Design Safety Case would be refused. Petroleum undertakings should be aware of this at the planning stage (the sequence of permits with different authorities will be laid out in the CER's *Permissioning Map*) and by meeting the CER societal risk limits would be expected to meet the HSA land use planning societal risk criteria. Typically, at the early planning stages, a risk assessment would be based on preliminary design details and will tend to be cautious in its assumptions.

It is noted that the situation may also arise whereby proposed new residential (for example) developments apply for planning permission, which would result in an increase in the societal risk calculated from an installation, unconnected with any changes in the installation or its operation. In these situations, it would be expected that the affected petroleum undertaking would interact with the planning process to highlight such issues. In practice, such situations are expected to be rare.

A range of societal risk criteria are used in different countries worldwide. The limits proposed by the CER differ from those of the UK HSE, but are similar to those in use in other countries.

Note that an important difference between the CER risk limits and some other societal risk criteria in use is that the CER limits for societal risk apply only to members of the public and does not include workers. The risk to individual workers is controlled through the individual risk limits applied by CER.

### 3.3 Responses on the Gross Disproportion Factor

#### 3.3.1 Points Made by Respondents

Respondent	Section	Comment
Kinsale & NSAI	4.5.5.3	The suggestion that a Gross Disproportion Factor ' <i>of at least ten is advised</i> ' is difficult to justify and goes beyond what the HSE require in the UK. See Appendix C comments. Distinction should be made between workers and the general public
SEPIL	4.5.5.3	In section 4.5.1, in relation to demonstrating what is 'reasonably practicable,' the CER states that 'the approach to be used will vary according to the hazard, risks and risk reduction measure being considered.' It is surprising then, in this section, that the CER proposes to use a Gross Disproportion Factor (GDF) of at least 10 (rather than providing a range of numbers proportional to the risk level). It would seem appropriate that the gross disproportion requirement should be greater the closer the risk is to the tolerability threshold. We are of the opinion that the CER has not provided sufficient justification for choosing 10 as a minimum value and we would welcome the CER's estimate and justification for an appropriate upper bound, maximum value for the disproportion factor. It is also important that the CER differentiates between the public and the workforce in terms of GDF as the workforce receives a benefit and the CER is proposing to use a Defined ICAF which is based on the public. (Please see our comments regarding Appendix C and the comment regarding 4.5.5.2 also).  Second sentence: Replace 'Appendix II' with 'Appendix C'
Kinsale	Appendix C	As stated, the advice that a Gross Disproportion Factor (GDF) of at least 10 should be used is more conservative than the UK HSE advice of a factor between 2 and 10 (see SPC 39). The justification given is that the QRA results are bound to be uncertain. Given that the same comment could be made in the UK regime, we believe this approach to be overly conservative, provided that the QRA has adopted a cautious best estimate approach.
SEPIL	Appendix	It is our view that the Gross Disproportion Factor should be aligned with the range that is used by the UK HSE <sup>28</sup> , i.e.

<sup>28</sup> See <http://www.hse.gov.uk/risk/theory/alarpcba.htm>

Respondent	Section	Comment
	C	<p>from 2-10, where it states that “Rules of thumb adopted by Directorates/Divisions; Nuclear Safety Directorate takes as its starting point the HSE submission to the 1987 Sizewell B Inquiry that a factor of up to 3 (i.e., costs three times larger than benefits) would apply for risks to workers; for low risks to members of the public a factor of 2, for high risks a factor of 10; Hazardous Installations Directorate uses similar rules of thumb;”</p> <p>We believe that the CER’s proposal of a figure of at least 10 for the Gross Disproportion Factor (GDF) is not justified. It is the maximum value used by the UK HSE. The CER should provide justification for using a GDF greater than 10. The CER should also specify and justify an appropriate upper bound, maximum value for the disproportion factor. The approach where the level of risk is reflected by a variation in the GDF between 2 and 10 seems more appropriate. Furthermore, the GDF does not make any differentiation between the public and the workforce. This does not seem correct as the workforce receives a benefit for the risk to which they are exposed and therefore the GDF should be lower for workforce members.</p> <p>Please see also the comments regarding Appendix B and section 4.5.5.2.</p>
	HSA	<p>Also we note that the final paragraph of Appendix C, suggests a disproportion factor of 10 should be used in all cases. This would be contrary to our own approach, which follows that of the UK HSE, where a lower figure of 2 is used close to the ‘broadly tolerable’ boundary and the higher figure of 10 is used close to the ‘intolerable’ boundary; with judgement required (the operator would have to justify the figure chosen) in between.</p>

### 3.3.2 CER's Response

In considering the above responses, the CER is changing the requirement for the Gross Disproportion Factor such that it must be at least 2, with the CER requiring a robust justification if the factor used is less than 10.

For petroleum undertakings, the number of persons that may be exposed to any hazard is likely to be very low, far lower than say for the effects of a nuclear incident where a low risk may affect a very large number of people. Original work on the Gross Disproportion Factor in the UK was in relation to the nuclear industry and because of the large numbers of people involved, even a low individual risk may have led to a significant potential loss of life and therefore significant spend even with a relatively low disproportion factor. The CER wish to avoid a low disproportion factor being used to justify the non-implementation of a relatively low cost measure that has some risk benefit, but only to a small number of people whose individual risk is low. Therefore, a robust justification of a Gross Disproportion Factor below 10 is required.

## 4 Clarifications to the High Level Design

The consultation process for the *ALARP Demonstration Guidance Document* has resulted in some clarifications to the high level description of the ALARP process that was given in the [High Level Design](#). These clarifications are summarised below and will be incorporated into an updated version of the High Level Design once all the regulations, written regulatory documents and procedures which comprise the Framework have been completed. This is expected to occur in November 2013.

Section	Change and Rationale
5.1, Page 21	<p>From the bulleted list of approaches to demonstrate ALARP, the consideration of procedures, codes and standards has been removed as this is considered to be part of the requirement to meet Good Practice.</p> <p>[Also applies to the executive summary]</p>
5.1, Page 21	<p>It will be clarified that the mix of approaches usually required in an ALARP demonstration applies to the ALARP demonstration for a number of hazards, or risk reduction measures. For consideration of a single risk reduction measure, the decision on whether to implement the measure must be based on a single approach that gives sufficient certainty that the right decision has been made.</p> <p>[Also applies to the executive summary]</p>