



Commission for Energy Regulation

An Coimisiún um Rialáil Fuinnimh

Safety Case Guidelines

Consultation Response Paper

DOCUMENT TYPE:	Consultation Response Paper
REFERENCE:	CER/13/070
DATE PUBLISHED:	February 28 th 2013

*The Commission for Energy Regulation,
The Exchange,
Belgard Square North,
Tallaght,
Dublin 24.
www.cer.ie*

Related Documents

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

[CER/12/182](#) Draft Safety Case Guidelines – Consultation Paper

[CER/13/073](#) ALARP Demonstration Guidance Document

Table of Contents

1	Introduction	1
1.1	Background	1
1.2	Consultation on the Draft Safety Case Guidelines	1
1.3	The Scope of the Response Paper	2
1.4	The Structure of this Response Paper	3
2	General Points Raised by Respondents	4
2.1	Summary of Responses and Issues Raised	4
2.1.1	<i>Scope of the Safety Case Guidelines</i>	<i>4</i>
2.1.2	<i>Emergency Response</i>	<i>4</i>
2.1.3	<i>Hydraulic Fracturing</i>	<i>5</i>
2.1.4	<i>Health Impact Assessment</i>	<i>6</i>
2.1.5	<i>Prescriptive Guidance</i>	<i>6</i>
2.1.6	<i>Risk Assessment</i>	<i>6</i>
3	Responses with Reference to the Draft Guidance	8
3.1	Summary of Responses and Issues Raised	8
4	Clarifications to the High Level Design	65

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 activities¹, and in particular designated petroleum activities², carried out by petroleum undertakings³.

In June 2012, the CER published the *Decision Paper on the High Level Design of the Petroleum Safety Framework* (the ‘High Level Design’⁴). The High Level Design frames the key policy aspects and principles of the Framework to be reflected in the underlying guidance, regulations and written regulatory documents and procedures.

1.2 Consultation on the Draft Safety Case Guidelines

In November 2012 the CER published for consultation *Draft Safety Case Guidelines* (the ‘Draft Guidelines’) 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 safety cases under the Framework. The consultation enabled the general public, industry and other interested parties to comment on the Draft Guidelines. Interested parties were invited to comment on the Draft Guidelines by the submission of written responses. In accordance with Section 13L(2) of the Act, the Draft Guidelines were issued to the:

- Health and Safety Authority;
- National Standards Authority of Ireland;
- Environmental Protection Agency;
- Irish Aviation Authority; and the
- Minister for Transport, Tourism and Sport.

The CER received submissions from the following 13 respondents:

- Commissioners for Irish Lights (CIL)⁵;
- ERM⁶;
- the Health and Safety Authority (HSA)⁷;
- the Irish Offshore Operator Association (IOOA)⁸
- the National Standards Authority of Ireland (NSAI)⁹;

¹ As defined in Section 13A(2) of the Act.

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

³ As defined in Section 13A(1) of the Act.

⁴ See *Decision Paper on the High Level of the Petroleum Safety Framework* (CER/12/062).

⁵ CER/13/077.

⁶ CER/13/079.

⁷ CER/13/078.

⁸ CER/13/053.

- Peter Crossan¹⁰;
- PSE Kinsale Ltd.¹¹;
- Rahima Sayer¹²;
- the Radiological Protection Institute of Ireland¹³;
- Sarah Akamine¹⁴;
- Sian Cowman¹⁵;
- Shell E&P Ireland Ltd (SEPIL)¹⁶; and
- Talamh¹⁷.

Three respondents (ERM, PSE Kinsale Ltd and SEPIL) also requested to meet the CER to discuss their respective submissions. The minutes of those meetings¹⁸ 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 Safety Case Guidelines. As such it does not feature in this Response Paper, although it is published alongside the other responses received¹⁹. All responses should be read alongside this paper.

1.3 The Scope of the Response Paper

This Response Paper sets out the CER's response to comments made in respect of the Draft Guidelines, noting, when appropriate, where the CER policy has been amended from that outlined in the Draft Guidelines in light of comments received. This Response Paper should be read in conjunction with the *Safety Case Guidelines*, which are published with this Response Paper.

⁹ CER/13/073.

¹⁰ CER/13/060.

¹¹ CER/13/055.

¹² CER/13/061.

¹³ CER/13/056.

¹⁴ CER/13/059.

¹⁵ CER/13/062.

¹⁶ CER/13/063.

¹⁷ CER/13/057.

¹⁸ See CER/13/082, CER/13/084 and CER13/083 respectively. Respondent meeting minutes are available here: <http://www.cer.ie/en/petroleum-safety-meeting-minutes.aspx>

¹⁹ CER/13/058.

1.4 The Structure of this Response Paper

This Response Paper is divided into three further sections:

1. General Points Raised by Respondents (Section 2)

This section addresses the general points raised by respondents to the Draft Guidelines.

2. Specific Points Regarding the Draft Guidelines (Section 3)

This section addresses issues raised by respondents in respect of specific sections of the Draft Guidelines. This section is in the format of a table.

3. 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 *Safety Case Guidelines*.

2 General Points Raised by Respondents

2.1 Summary of Responses and Issues Raised

Four respondents raised a number of general points on the Draft Guidelines which did not relate to specific sections but were of general application. The CER has considered each of these responses, and has sought to summarise the high level issues raised. These general points can be grouped as follows:

- Scope of the *Safety Case Guidelines*;
- Emergency Response;
- Hydraulic Fracturing;
- Health Impact Assessment;
- Prescriptive Guidance; and
- Risk Assessment

The following paragraphs set out CER's response to each of the issues listed above. 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 Scope of the Safety Case Guidelines

2.1.1.1 Points Made by Respondents

One respondent commented that it was inappropriate to have the regulations for onshore and offshore activities included in the same guideline document.

2.1.1.2 CER's Response

The Framework developed pursuant to the Act applies in respect of all petroleum activities, whether onshore or offshore. Similarly, the *Safety Case Guidelines* provide guidance for the development of safety cases in respect of both onshore and offshore activities. While the *Safety Case Guidelines* outline what should be contained in a safety case however, they do not prescribe the manner in which risks to safety are to be managed. A petroleum undertaking is required by the Act to prepare a safety case that ensures and demonstrates that the risks associated with a certain petroleum activity are reduced to a level that is As Low as is Reasonably Practicable (ALARP). This necessarily requires that different risks will be managed differently. Nothing in the *Safety Case Guidelines* requires or assumes a similar treatment of different risks, only that the same key safety considerations are addressed in respect of all designated petroleum activities.

2.1.2 Emergency Response

2.1.2.1 Points Made by Respondents

One respondent commented that the emergency response section of the *Safety Case Guidelines* did not include local residents.

2.1.2.2 CER's Response

The Framework for Major Emergency Management is designed primarily to provide for the protection, support and welfare of the public in times of emergency²⁰. Section 4.7.2 of the *Safety Case Guidelines* requires that petroleum undertakings demonstrate compliance the Framework for Major Emergency Management.

2.1.3 Hydraulic Fracturing

2.1.3.1 Points Made by Respondents

Several of the respondents were concerned that the *Safety Case Guidelines* 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. Several respondents were also concerned about the use of chemicals.

2.1.3.2 CER's Response

The *Safety Case Guidelines* provide guidance as to the content of all safety cases prepared pursuant to the Framework. A petroleum undertaking is prohibited from carrying on a designated petroleum activity unless a safety case in respect of that activity has first been approved by the CER and a safety permit has been issued²¹.

In order for CER to approve a safety case, the safety case must show that the risk associated with a given petroleum activity is not intolerable and that risk reduction measures have been implemented such that the risk associated with that activity is reduced to a level that is ALARP. Where risk reduction methods, such as those described in section 4.5 in the *ALARP Demonstration Guidance Document* do not provide sufficient certainty as to the management of the risk associated with an activity, recourse must be made to the precautionary principle. It should be noted that the application of the precautionary principle does not necessitate that an operation cannot go ahead. It may, for example, mean that it is restricted in some way, or require that additional safety measures are put in place.

Hydraulic fracturing, where it is carried out pursuant to a petroleum authorisation, is a designated petroleum activity²². The ALARP Demonstration process will apply equally to it, as to all other petroleum activities.

The ALARP Demonstration process prescribed in the Framework is robust 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 examples of its application.

The *Safety Case Guidelines* provide for a listing of all hazardous substances and their inventory to be included within the safety case.

²⁰ *A Framework for Major Emergency Management*, available online at <http://www.mem.ie/memdocuments/a%20framework%20for%20major%20emergency%20management.pdf>

²¹ Section 13M(2).

²² Hydraulic fracturing falls within the definition of 'production' which is designated pursuant to Regulation 4 of the Designated Petroleum Activities Regulations to be published by the CER.

2.1.4 Health Impact Assessment

2.1.4.1 Points Made by Respondents

Several respondents stated that a health impact assessment be required as part of the ALARP Demonstration.

2.1.4.2 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.

2.1.5 Prescriptive Guidance

2.1.5.1 Points Made by Respondents

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

2.1.5.2 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 Guidelines* 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.

2.1.6 Risk Assessment

2.1.6.1 Points Made by Respondents

One respondent commented that for onshore unconventional hydrocarbon extraction, the QRA must include a full assessment of the health risks (short and long term) to residents in

the local area, and this assessment must take into account the cumulative risks posed by other petroleum infrastructures (well pads, compressor stations, pipelines, etc.) in the vicinity.

One respondent queried the meaning of inherent safety in the context of unconventional gas exploration.

2.1.6.2 CER's Response

Under the Framework, petroleum undertakings will be required to assess the risk to safety, including long term health issues, arising from all their operations, not just hydraulic fracturing operations. Hence under the Framework, all risks to health must be robustly assessed and be demonstrated to be ALARP.

An assessment of cumulative risks is inherent in the ALARP Demonstration Guidance and risk tolerability thresholds are applied to the total risks associated with a petroleum activity.

Inherent safety is the concept of improving safety by designing out hazards completely rather than accepting them and installing barriers to reduce the risk they pose.

3 Responses with Reference to the Draft Guidance

3.1 Summary of Responses and Issues Raised

Of the 13 responses received to the *Draft Guidelines*, nine 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 *Safety Case Guidelines* have been updated following the response. Where it clarifies the CER's response, the updated text is provided.

Respondent	Section	Comment	CER Response	Guidance Update?
Peter Crossan	General	...any risk assessment to include the risk to the human population of a region where fracking is intended to be permitted must require the CER to make prescriptive in its criteria for an ALARP Assessment ...	See section 2.1.5.	No
Rahima Sayer	General	Design of the Safety Case must incorporate proper scientific assessment and health impact assessments in order to protect human and animal health and the local environment.	See section 2.1.4.	No
Rahima Sayer	General	...what is required here is a dedicated and prescriptive model solely designed to address the implications of hydraulic fracturing including a descriptive risk assessment.	See section 2.1.3.	No
Sarah Akamine	General	...the regulations relating to offshore and onshore petroleum activities should not be covered by the same documents.	See section 2.1.1.	No
Sian Cowman	General	I understand that the framework does not include specific safety guidelines for onshore hydraulic fracturing of shale gas (or any other form of shale gas exploitation). Now, and in the eventuality that CER considers specific safety guidelines for hydraulic fracturing in the future, I have one important point to make - it is impossible to regulate a destructive process such as hydraulic	See section 2.1.3.	No

Respondent	Section	Comment	CER Response	Guidance Update?
		<p>fracturing of shale gas safely.</p> <p>Please see this report produced by the Economic and Scientific Policy Department of the European Union into the impacts of shale gas and shale oil extraction on the environment and human health</p>		
CIL	General	Where related to safety of navigation CIL are available to assist the CER in the production of these documents.	Noted.	No
ERM	General	The guidelines make no reference to major accidents to the environment. The recent Maitland report introduced the concept of an Environmental Assurance Plan which addresses environmental aspects of operations – presumably including major accidents. There is a large amount of overlap between the measures necessary to prevent major process safety accidents and major accidents which could affect the environment. Indeed many scenarios (including Macondo) have implications for people, asset and the environment. This overlap is recognised by the Seveso Directive, which requires duty holders to consider both accidents to people and the environment	The CER’s regulatory role under the Framework is <i>with respect to safety</i> . The Act does not confer on CER a regulatory remit on wider environmental issues. However in certain circumstances there may be overlap between “safety matters” and “environmental matters” and in such cases the CER will be concerned with such matters to the extent of any such overlap ²³ .	No

²³ For instance environmental damage to property arising from a designated petroleum activity *may* give rise to safety concerns which would need to be addressed within the risk assessment and safety management system proposed by the petroleum undertaking in its safety case.

Respondent	Section	Comment	CER Response	Guidance Update?
HSA	General	The Safety Case guidelines have a very strong emphasis on offshore installations and compliance with these Guidelines can only compliment the worker protection requirements in our Offshore Installations, Act 1997 and the Safety, Health and Welfare at Work (Extraction Industries) Regulations 1997 (Council Directives 92/91/EEC and 92/104/EEC).	Noted.	No
SEPIL	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 on the units for the individual risk criteria.	Yes
SEPIL	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.'	In order to avoid any confusion with the concept of societal risk used in section 5 in the <i>Safety Case Guidelines</i> , this simple definition has been removed.	Yes
SEPIL	List of Defined Terms in this Paper Major accident	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).	This will be considered as part of the consultation process on the Petroleum Incident Regulations	No

Respondent	Section	Comment	CER Response	Guidance Update?
CIL	1.1	Irish Lights accept that the Safety Case will contain information relating to the analysis of navigational hazards and the measures used in mitigating the risks. It is appropriate that the safety case is submitted to the CER and not directly to CIL from the petroleum undertaking. However it should be noted that if and when the safety case has been approved there should be clarity as to who applies for statutory sanction for the establishment/alteration/disestablishment of Aids to Navigation.	Noted. Responsibility for obtaining statutory sanctions will remain with the petroleum undertaking in all cases.	No
CIL	1.2.2.1	Similar to the requirements of CIL in the statutory sanctioning process, AtoNs shall not be established, altered or disestablished without the permission of CIL.	Agreed.	No
ERM	1.2.2.2	Does this mean that for an undertaking with combined operations the CER would issue more than one Permit, say one for well work and one for production? Could this create ambiguity over permitted activities should one aspect receive a permit and the other not? Would the safety case have to precisely delimit the scope of each activity, or would this be referred to in the Permit?	Production from a well would not be classed as a combined activity, but the petroleum undertaking would require two permits; one for the well work and one for the on-going production through the platform, pipeline and/or onshore terminal as relevant. The permit will precisely define what is permitted.	No

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL	1.2.2.2	We would propose that, where possible, a well test would be covered in the Well Safety Case. If it is an unplanned well test, would it require an additional approval (and if so, is it via a modification of the existing Well Safety Case)?	<p>Well testing may be included as a normal operation in the Well Safety Case. Well testing through an existing completion (i.e. where the hydrocarbon containment boundary is unchanged) is not a material change and so would not require resubmission of the Well Safety Case. Where a material change is required for a well test the Well Safety Case must be resubmitted.</p> <p>The well operations that a Non-production Installation can carry out should be described in the Non-production Safety Case in a manner such that they are independent of a particular well, and any pre-conditions for safe operations should be stated.</p>	No
CIL	1.2.2.3	CIL will have an interest in the arrangements for AtoN management and monitoring and will be available to provide general advice in this area.	Agreed.	No
SEPIL	1.4	We note that no timescales related to submission/review are provided. We understand from this section that the Safety Case Assessment Procedures (to be issued in May 2013) will set out the CER's assessment process, including timescales, for safety cases submitted by petroleum undertakings. However, it would be	<p>The timetable for submission/review will be outlined in the <i>Safety Case Assessment Procedures</i>.</p> <p>Section 13P of the Act sets out the statutory timescales for the CER in assessing safety cases.</p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
		helpful if the timescales for submissions could also be provided in the Safety Case Guidelines document.		
SEPIL	1.4	This states that 'In certain circumstances, these Guidelines require petroleum undertakings to demonstrate compliance with the requirements of relevant sections of the <i>Compliance Assurance Procedures</i> (in particular with respect to Verification).' We note however that, according to the CER's Project Implementation Timeline, the majority of these Compliance Assurance Procedures will not be finalised until November. Will there be a transition period thereafter to allow Petroleum Undertakings to perform a gap analysis versus the CER's requirements and allow sufficient time to close any gaps that may exist?	Further guidance on transition arrangements will be provided in due course.	No
Kinsale	2.1	We believe that it would be preferable that the CER makes it clear that one of the two options described as 'practical mechanisms....in submitting safety cases' must be followed so that only one copy of each safety case (given the number of different safety cases required for a typical operation) is prepared. Option (a) works very well in the UK regime.	Both of the options given involve a mechanism by which a single safety case can be submitted when a number of persons hold a petroleum authorisation. Multiple safety cases could be submitted by each petroleum undertaking, but this is not the CER's preference and is unlikely to be the preference of the petroleum undertakings involved. However the CER will not prescribe a single practicable mechanism, but will consider	No

Respondent	Section	Comment	CER Response	Guidance Update?
			each proposed approach on a case-by-case basis.	
SEPIL	2.1	We would support option (b) a single safety case signed by a disclosed agent for and on behalf of each individual person named on the associated petroleum authorisation.	Both of the options given involve a mechanism by which a single safety case can be submitted when a number of persons hold a petroleum authorisation. Multiple safety cases could be submitted by each petroleum undertaking, but this is not the CER's preference and is unlikely to be the preference of the petroleum undertakings involved. However the CER will not prescribe a single practicable mechanism, but will consider each proposed approach on a case-by-case basis.	No
CIL	2.2	It is important that the information provided is in the appropriate format, for instance when considering safety of navigation, up to date and appropriate scaled admiralty charts should be used. Positions should be given in Latitude and Longitude using WGS 84 datum. Sources for historical data should be recognised.	Agreed.	No
SEPIL	2.3	It is our understanding that, while the CER may review documents referenced in the Safety Case, those references will not be required to be made available to the public. In accordance with the Act	The 'public version' of the safety case may exclude contents that relate to matters of industrial, commercial or personnel confidentiality, public security or national defence. The precise scope will	No

Respondent	Section	Comment	CER Response	Guidance Update?
		<p>and with Section 10 it is the 'public version' of the approved Safety Case that is required to be made available to any member of the public who requests it.</p> <p>Will the CER be satisfied with the Well Examiner's review of detailed calculations/reference documents?</p>	<p>be included following a public consultation process to occur later in 2013.</p> <p>The safety case is expected to make reference to detailed calculations, assessments, procedures, or similar. All information referenced within a safety case must be retained by the petroleum undertaking and must be made available to the CER for review if required. This may be necessary during assessment of the safety case or during subsequent inspections.</p> <p>The guidance on well examination has not yet been prepared, but will be finalised by November 2013.</p>	
CIL	2.5	CIL would consider that any permanent or temporary changes that would have an effect on safe navigation should be reported to CIL.	Agreed.	No
ERM	2.5	A reduction in manpower should prompt a re-assessment of risk management, so should any case where there are significant/material changes in the roles and responsibilities of personnel or in the competencies required to operate the undertaking or any element of the technology relied upon.	Reduction in manpower may be needed for a number of reasons that are not safety critical. For example, if a construction campaign finishes, manpower may be significantly reduced without any impact on safety due to the decreased workload. The criteria of the minimum number of persons being reduced is an example of a material change. If a petroleum undertaking makes other	No

Respondent	Section	Comment	CER Response	Guidance Update?
			changes to the manpower number, competency requirements, or similar they should always consider whether this constitutes a material change.	
NSAI	2.5	<p>The responsibility for identifying "<i>material change</i>" lies with the undertaking. More clarity needed to identify changes that may have significant risk impact.</p> <p><i>Material</i> changes that are <i>may be</i> considered to be material include, but are not limited to:</p>	See comments below on material change.	No
SEPIL & NSAI	2.5	<p>"<i>adjacent the boundary</i>" does not address the risk. Change to</p> <p>Facility shall have a remotely operated fail-safe isolation valve located <i>suitably to ensure effective isolation of the facility.</i> adjacent to the boundary;</p>	See comments below on material change.	Yes
ERM	2.5	<p>Change text to:</p> <p>"If a new Safety Critical Element or safety critical activity is required or one is removed;"</p>	There are a very large number of safety critical tasks on an onshore, or offshore petroleum facilities and these will not need to be described in the safety case, though the process by which the risk from them is managed will need to be outlined within the SMS. Therefore, it is not expected that the addition, or alteration to a safety critical task would constitute a material change unless the total risk was to change substantially as a result of this change. Petroleum undertakings should consider whether such changes are a material change.	No

Respondent	Section	Comment	CER Response	Guidance Update?
NSAI	2.5	<p>Material changes to the approved production safety case will be captured in the production safety case without the requirement to resubmit the design safety case.</p> <p>There should be only one current safety case in use at any time for a given activity.</p>	See comments below on material change.	No
Kinsale	2.5	<p>There is a danger that this section could require resubmission of safety cases for relatively insignificant changes (e.g. increasing the 'number of stated personnel' by one or moving the boundary fence of an onshore facility by a metre or two), although most of the examples given are assessed to be appropriate.</p> <p>The UK HSE generally expect material change resubmissions of offshore safety cases for changes that have a significant effect, although they have required operators themselves to define what would constitute 'material' changes.</p> <p>The UK HSE has generally only required resubmission of COMAH reports if there are potentially "significant repercussions" (see www.hse.gov.uk/comah/report-review.pdf). The proposed CER wording should refer to a change having a 'significant effect', and include examples that give a clearer idea.</p> <p>In the event of a material change, the requirement for a Design Safety Case in advance of a revised Production Safety Case is exceedingly onerous by comparison with the UK North Sea as an example of a well-established safety case regime.</p>	<p>Increasing the maximum number of persons on an installation will have significant risk implications (e.g. it may mean that there is no longer a spare lifeboat) and so it is considered to be material. It is acknowledged that moving a boundary fence may or may not be material so this example has been removed. The bulleted list that is given contains examples of changes that are considered by the CER to be material.</p> <p>The Design Safety Case is required before a Production Safety Case update due to material change for the same reason that a Design Safety Case is required for a new build – to allow the CER to review the design at a points where changes can easily be made. The complexity of the Design Safety Case should reflect the complexity of the material change, which themselves can vary from a facility (offshore bridge linked platform, or extension of onshore terminal) to a more detailed change to a particular SCE. In the former case, it is clear why the Design Safety Case is required since the change is similar in scope to a new build, while in the latter the Design Safety Case potentially only needs to consider the SCE in question and its interactions with the installation.</p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL	2.5	Second paragraph: We agree with the statement that “it is the responsibility of the petroleum undertaking to form an appropriate judgement on whether a proposed alteration to an activity the subject of an approved safety case is material or not.”	Noted.	No
SEPIL	2.5	<p>Third paragraph, first sentence: The current definition of ‘material change’ is very broad and could necessitate frequent Safety Case re-submissions for changes which do not significantly impact the risk. It is our view that, in the context of the Petroleum Safety Framework, a change will be material if it has a significant impact on the risk or the major accident hazard profile.</p> <p>Third paragraph, third sentence: This sentence should be re-worded to ‘Changes that <i>may</i> be considered to be material include, but are not limited to:’ (as some of the changes listed, e.g. ‘if a boundary fence of an onshore Facility is moved,’ may not impact the risk/major accident hazard profile).</p>	<p>The text has been updated to clarify that it is material changes that affect the basis of the safety case that are of interest to the CER. The <i>Safety Case Guidelines</i> provide guidance only and it remains for the petroleum undertaking to determine whether a change is material or not. That being said, the bulleted list at section 2.5.1 of the Safety Case Guidelines represents the minimum requirements of CER in considering whether a change is in fact material.</p> <p>The title of this section has also been changed to <i>Update of an Approved Safety Case</i> for clarity.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL	2.5	Fourth paragraph, first sentence: We propose that this sentence should be re-worded to 'Material changes for wells <i>may</i> include changes to well use and changes to:'	The CER requires notification of the changes to wells that are listed, and the mechanism for this notification is the Well Safety Case.	
SEPIL	2.5	Third & fourth paragraphs: Drilling operations are carried out on a continuous basis and may require program alterations at short notice due to prevailing site conditions. These changes could add/change the status of a Safety Critical Element and require immediate implementation/approval (normally approved in real time by a well examiner). Clarification needs to be provided on how the CER will manage and support 24 hour well work as there may be a number of notification changes on a particular well activity when carrying out operations. We believe that at a minimum, a web-based, online facility with defined input entries and requirements should be made available to the petroleum undertakings so that changes/updates can be submitted and approved in real time and unnecessary delays in operations avoided. We re-iterate that a material change should be a change that has a significant impact on risk levels.	Comments on timescales are noted and will be considered the Safety Case Assessment Procedures.	No

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL		Sixth paragraph: We disagree with this paragraph. It is our view that after the Design Safety Case is approved it should be frozen. All further material changes should be captured in the Production Safety Case alone, i.e. only one safety case should be 'current' at any time. We propose that the Production Safety Case should supersede the Design Safety Case and capture any future design modifications. This updated Production Safety Case would then be submitted to the CER for approval. The requirement to submit both a Design and revised Production case would involve duplication and could lead to errors.	The Design Safety Case is not a 'live' document and its purpose is completed once the Production Safety Case has been accepted. If there is a material change, a new Design Safety Case is submitted that only needs to include reference to the change and can refer to the Production Safety Case. This has been clarified in the Safety Case Guidelines.	Yes
Kinsale	2.5.1	The described temporary material changes applicable to well operations, which will require submission of the Well SC to the CER for approval, seem to be a very onerous requirement – unless the approval process for such a resubmission is similar to that for a Well Notification.	A temporary material change to a Well Safety Case, which means adding a temporary addendum to the Well Safety Case, is anticipated to be a straightforward process analogous to a well notification in the UK.	No
NSAI	2.5.1	The examples given are routine activities and should not be included in discussion about " <i>temporary change</i> ". Temporary and foreseeable activities will be included in the production safety case or well	The activities described all require a change to the hydrocarbon containment envelope, or other SCEs and therefore are a material change. However, some of these activities are routine and so a short addendum to the safety case may be submitted in these cases. This addendum is a short document	No

Respondent	Section	Comment	CER Response	Guidance Update?
		<p>safety case as appropriate.</p> <p>The guidelines should make the point that the onus is on the operator to identify what types of changes are routine.</p>	<p>that is analogous to a UK well notification. An update to the safety case (by the addendum) is needed to ensure that a temporary material change is managed and the CER can regulate such changes.</p>	
ERM	2.5.1	<p>“Extra or altered plant or equipment needs to be described” should this not also specify new or changed working methods or tasks? Temporary, non-standard, or modified tasks can create opportunities for error, some of which could be safety critical.</p>	<p>This change is acknowledged by changing the third from last bullet to:</p> <p><i>Any additional or altered tasks, roles and responsibilities of the installation manager and offshore staff need to be described for normal operations and emergency response.</i></p>	Yes
SEPIL	2.5.1	<p>First paragraph, second bullet point: This statement is not clear.</p> <p>Fourth paragraph, first sentence: Regarding the term ‘barrier,’ it is our understanding it is another term for a safety critical element (as defined in the High Level Design).</p> <p>Fourth paragraph, list of bullet points: The examples given are routine activities and should not be included in a discussion about ‘temporary material changes’. Temporary and foreseeable activities will be included in the Well Safety Case or Production Safety Case as appropriate. The guidelines should make it clear that the onus is on</p>	<p>This paragraph has been removed.</p> <p>Barrier is another term for some Safety Critical Elements.</p> <p>The text of the fourth bullet in the example box has been clarified to read: <i>The safety case must show that the combined operation is suitably managed between the Non-production and Production Installations and that where the safety management systems interact, or overlap, it provides clarity with regard to the procedures that are in place and the roles of individuals. In particular, the procedures and processes for communications between the two parties should be</i></p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
		<p>the operator to identify routine changes.</p> <p>Example box, fourth bullet point: This statement is not clear.</p>	<p><i>highlighted. A bridging document must be referenced and summarised in the safety case.</i></p> <p>See also comment above regarding routine activities.</p>	
Sarah Akamine	3.1	<p>Here are just a very few obvious prescriptive requirements for onshore unconventional gas extraction that I think you should add under <i>Prevention</i> (this list is not exhaustive!):</p> <p>“Safety cases for onshore unconventional hydrocarbon extraction must describe how the following requirements are achieved:</p> <ul style="list-style-type: none"> • All ground and surface sources of drinking water must be protected from any contamination by: <ul style="list-style-type: none"> ➤ Methane ➤ NORMs (normally occurring radioactive materials) ➤ Heavy metals ➤ Salts ➤ Fracking chemicals ➤ • The health and safety of local residents must be protected by preventing: <ul style="list-style-type: none"> ➤ VOC and methane emissions ➤ Explosions ➤ Blow-outs ➤ Earthquakes” 	<p>The CER has considered each of the proposed prescriptive requirements in turn and for reasons set out in section 2.1.5 do not believe it is appropriate to include.</p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
CIL	3.1	CIL would note the possibility that some offshore structures may be sub surface and still present a danger to navigation and may need to appropriately marked. It should also be taken into account that pipelines and associated control structures will create hazards in terms of anchoring, particularly near the shore. Automatic Identification System (AIS) is in itself an AtoN and requires statutory sanction from CIL.	The text in the second bullet has been updated to refer to Installation rather than Facility	Yes
NSAI	3.1	<p>Address needs of Irish Coast Guard</p> <ul style="list-style-type: none"> Offshore helicopter landing areas must comply with the standards provided within the CAP 437 guidance <i>and be sufficient to accommodate the requirements of the Irish Coast Guard</i>; 	The text has been updated to state that offshore helicopter landing areas must comply with relevant national and international standards. The requirements of the Irish Coast Guard are specifically noted.	Yes
NSAI	3.1	<p>This is not applicable to subsea infrastructures.</p> <ul style="list-style-type: none"> All offshore <i>surface</i> petroleum infrastructure must have AIS complying with relevant national and international requirements <i>including AIS repeaters</i>. 	The text in the third bullet has been updated to refer to <i>surface</i> petroleum infrastructure.	Yes
Sarah Akamine	3.2	<p>I propose the following basic (minimal) control and detection measures for onshore unconventional hydrocarbon extraction:</p> <ul style="list-style-type: none"> Continuous monitoring of air quality and 	The CER has considered each of the proposed prescriptive requirements in turn and for reasons set out in section 2.1.5 do not believe it is	

Respondent	Section	Comment	CER Response	Guidance Update?
		<p>regular (monthly) sampling of ground water and surface water.</p> <ul style="list-style-type: none"> • Well pads shall be manned at all times. • Provisions shall be made for the safe and timely evacuation of local residents in case of a Major Accident. • Provisions shall be put in place for notifying local residents of any degradation in water or air quality due to the petroleum activity, or an accident. 	appropriate to include.	
RPII	3.2	Section 3.2 of the Safety Case requires the petroleum infrastructure to have suitable means in place to detect hazards and then achieve a safe condition. As it is likely that Class 7 radioactive materials could be brought on to a rig by external service companies, for example for the purposes of well logging, then these materials would probably come under this requirement.	Noted.	No
ERM	3.2	The safety case should consider any reliance on people to detect and control MAHs. For example, if detection and control involves responding to an alarm, what performance standards are specified for the competence, authority and capability of the operator to respond?	The safety case should identify any reliance on people to detect and control MAHs, though in most cases it is expected that automated systems are in place. In such a description realistic expectations of human performance must be considered. Performance standards that are analogous to those needed for SCEs are not required in the safety case, but a specific requirement for	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
			identifying and assessing emergency response measures dependent on human performance has been added to the emergency response section.	
NSAI & SEPIL	3.2	The annulus does not normally have a remotely operated isolation valve.	The prescriptive requirement for Wellhead/ Xmas tree valves has been removed given that meeting Good Practice will achieve the same aim of the proposed prescriptive requirement. In this circumstances, it not beneficial to include this specific prescriptive requirement (see section 6.3.6 of the High Level Design).	Yes
SEPIL	3.2	Fifth bullet point: This statement should be re-worded as follows: All pipelines that contain or may contain hydrocarbons crossing the boundary fence of an onshore Facility shall have a remotely operated fail-safe isolation valve located <i>suitably</i> , <i>to ensure effective isolation of the facility</i> .	Agreed; onshore valve needs to suitably located and the text has been updated to clarify this.	Yes
Sarah Akamine	3.3	...not a single one of the safety case requirements listed under this heading [Emergency Response] mentions local residents?	See section 2.1.2.	No

Respondent	Section	Comment	CER Response	Guidance Update?
ERM	3.3	Consider the reliability of any reliance on people for emergency response or mitigating action/intervention.	See response to ERM comment on section 3.2 above regarding the reliance on people during emergency response.	No
SEPIL	3.3	<p>This section specifies TEMPSC for at least the full POB. We propose that wording is added similar to the two paragraphs below from ISO 13702 to strengthen this statement, make it more encompassing for all types of installation and add a requirement to consider redundancy:</p> <p><i>'In many locations, the optimum approach to providing secondary means of evacuation will be totally enclosed motor-propelled survival craft (TEMPSC) in accordance with IMO and other acceptable standards. It is important that full consideration is given to the type and design of the TEMPSCs, their location, their ability to be safely launched and the conditions they will experience once launched (e.g. weather conditions, fires on the sea, smoke and radiation from topside fires).</i></p> <p><i>Where provided, the TEMPSC should be readily accessible from the main TR and have a total capacity of at least the maximum personnel on board. The EER analysis may identify the need for additional TEMPSC so that the minimum capacity can be successfully reached and used for evacuation considering all credible scenarios and conditions. Consideration should also be given to severe weather conditions in which the positions of certain TEMPSC may be particularly vulnerable and further redundancy may be required.'</i></p>	The suggested text is too detailed for inclusion in the <i>Safety Case Guidelines</i> . However, the text given may denote good practice in regard to the provision of TEMPSC. Petroleum undertakings always need to achieve Good Practice, or another measure that gives the same level of risk reduction.	No

Respondent	Section	Comment	CER Response	Guidance Update?
ERM	4.1	This should include a high-level definition of requirements to demonstrate performance standards for asset/equipment integrity management. Failures of inspection and maintenance of pipelines, vessels, rotating/mechanical equipment, electrical equipment and instrumentation can contribute to MAH risk. The Production safety case should demonstrate how the integrity of at least safety critical elements will be managed.	This is too detailed for this section of the safety case. Further sections go on to detail these types of requirements in the safety case.	No
Sarah Akamine	4.	This entire section seems to consider only the case of offshore activities, without taking the specific circumstances of onshore, densely spaced well pads in populated areas.	See section 2.1.6.	No
ERM	4.1	The safety case should include a demonstration that the proposed manning levels are sufficient to perform all safety critical roles. Insufficient manpower is the typical cause of maintenance backlog, which poses a significant process safety risk.	The appropriate level of manning is important to ensure on-going safe operation. However, determining that the manning level is suitable is best measured by indicators such as maintenance backlog, or ability to deal with change requests. Since these measures may change relatively quickly, the CER's approach is that they will be the subject of audit and inspection rather than outlined in the safety case.	No

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	4.1	<p>This seems to state that there will be a requirement for multiple Well Safety Cases and in the case of Kinsale Head, an offshore Production Safety Case and an onshore Production Safety Case. The section is probably in need of dividing into sub-sections to improve its clarity. In particular the requirements for Well Safety Cases need clarification – the content in relation to, for example, use of a BOP and the requirement to resubmit the Well SC is particularly confusing.</p> <p>More clarity in the last sub-section, about shared infrastructure and its implications would be useful, especially in relation to ‘adopting’ a safety case. Certainly there is a lot of potential for confusion with so many safety cases in operation.</p>	<p>The Safety Case Guidelines have been updated to provide that a Well Safety Case is not required for an existing production well, but that the well must be included in the Production Safety Case.</p> <p>A Well Safety Case is required for any well work, which includes any work that alters the pressure containment boundary, or is a material change to the well.</p> <p>During production, a BOP is not required on a well, but if well work activities are planned to be undertaken and are described in the Well Safety Case, the BOP arrangements (i.e. method of closure, redundancy etc) should be described in the Production Safety Case as the BOP is unlikely to be particular to a well, but could be used on multiple wells. Before the said work was undertaken on a well, the Well Safety case would have to be submitted. It would have to state that the BOP assembly was suitable.</p> <p>The text will be updated to make this point clearer.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
NSAI & SEPIL	4.1	<p>The 'onshore' Production Safety Case will be required to cover all petroleum infrastructure from and including the pipeline landing valve on the shore to the onshore facility (included associated pipelines).</p> <p>In the event that a safety report is required under Seveso requirements one report/safety case should suffice.</p>	<p>The Safety Case Guidelines provide the requirements for the content required for the safety case to be submitted to the CER. Within the CER-HSA MoU²⁴, there is a commitment to: ... <i>communicate on and cooperate on their review and assessment of the Authority's Pre-Operation Safety Report and the CER's requirement for a Safety Case for relevant undertakings.</i> This may extend to the safety document being submitted to both the CER and the HSA which satisfies both the HSA's and CER's requirements.</p>	No
RPII	4.2.3	<p>Section 4.2.3 the Safety Case requires the roles and identities of Third Party Organisations to be summarised. The RPII would suggest that both drilling and well service companies are covered under this Section which would included companies that are licenced by the RPII.</p> <p>Also included in this Section, are Third Party Companies whose co-operations may be required in a emergency situation. If an incident occurs on petroleum infrastructure involving a Class 7 material then the RPII, as the Regulatory Authority, may itself have a role under this Section.</p>	<p>Agreed. Drilling and well service companies are covered under this section.</p> <p>Noted. RPII may also have a role with respect to section 4.7 of the Guidelines.</p>	No

²⁴ See <http://www.cer.ie/en/petroleum-safety-reports-and-publications.aspx?article=8837a707-bc43-489c-9d05-19824b480a33>

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL	4.2.3	<p>First Paragraph: This list appears to be onerous and the benefit of providing these details is not clear regarding all of the organisations listed. In addition, integrity management, drilling and well services companies are likely to be numerous and changing frequently.</p> <p>Second and third paragraphs: we agree with the proposal regarding identification of third parties whose co-operation may be required in an emergency as this is clearly beneficial.</p>	<p>These organisations have safety critical roles and so should be included in the safety case. It is not obvious why, for example, the integrity management contractors/consultants would be changing so frequently as for this to become an onerous requirement.</p>	No
CIL	4.3.1	<p>For offshore facilities and pipelines the map in question should be an Admiralty large scale nautical chart of the area in question. Positions should be given in Latitude and Longitude using WGS 84 datum.</p>	<p>The text has been updated to reflect this comment: <i>Location and orientation of the Facility (for offshore installations this should be on an admiralty large scale nautical chart of the area in question with positions in latitude and longitude using WGS 84 datum);</i> <i>Location and purpose of any wells including identification of water depth for subsea wells;</i></p>	Yes
Sarah Akamine	4.3.3	<p>It should be explicitly stated that all chemicals and substances used in unconventional hydrocarbon extraction must be publicly disclosed.</p>	<p>See section 2.1.3.</p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale & NSAI	4.3.3	In relation to oil and gas operations, the specified required information will not be generally available for the main hazardous fluids.	The CER consider that the information is required, and is available to petroleum undertakings. The requirement is very similar to COMAH cases.	No
SEPIL	4.3.5	<p>First paragraph: It is our understanding that the CER's remit is public safety and therefore we question that the CER require information about workers. It would be very difficult to get an accurate figure for the location and numbers of members of the public and it is not clear that Petroleum Undertakings have the right to gather this type of information.</p> <p>The personnel on a rig / vessel can be affected on a subsea location due to the hazard of dropped objects from the installation – this is currently part of the HSA's remit and we would expect that that will continue to be the case, i.e. it will not be required to cover this in a Well Safety Case.</p> <p>Second paragraph: We would propose the following change: For onshore sites the location and numbers of the local population, <i>used in the risk assessment</i>, should be shown on a map.</p>	<p>The CER has responsibility for regulating the safety risks of petroleum activities. The petroleum undertaking must undertake risk assessments to ensure that the risks from all the hazards are reduced to ALARP. The risks from all MAHs must be evaluated using QRA to allow explicit comparison with the Risk Tolerability Limits. Numbers of people potentially at risk must therefore be known. this would also be part of the planning process and critical to the location of an onshore site.</p> <p>The fact that a hazard is regulated by the HSA does not mean that it is excluded from being regulated by the CER.</p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
ERM	4.3.6	Are maintenance activities covered elsewhere?	Maintenance activities are not required to be described in detail in the safety case in respect of the detailed workscope of the maintenance, or the detailed hazards involved with each different type of maintenance (though the safety case has to contain a hazard identification). Section 4.5.4 details the requirements for the description of the assurance activities that are undertaken on SCEs.	No
ERM	4.4.1	Add the following text... “to include the risk posed by unsafe acts by people due to error or deliberate violation of safe operating rules (hence it should be necessary to define performance standards for procedural control measures.”	Further guidance on hazard identification is given in section 4.4.6 and it is not considered appropriate to identify unsafe acts above other hazard causes in the guidance.	No
ERM	4.4.1	Suggest the following wording... “For a petroleum activity that has the potential to give rise to a Major Accident Hazard, a systematic assessment of the technical and human risk associated with each hazard including its likelihood and consequences and an assessment of whether the risk tolerability criteria are met.”	The suggested change does not clarify what is required. The risk is required to be evaluated regardless of what causes the hazard and subsequent risk.	No

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale & NSAI	4.4.1	<p>The first sub bullet is a little confusing, referring to hazards that have the 'potential to cause a Major Accident Hazard'. It would probably be better to refer to the 'potential to cause a Major Accident'. There seems to be some confusion throughout the document in the use of the term hazard. It might be simpler to define 'hazard' as anything that could potentially lead to a 'major accident'.</p> <p>[The minuted consultation meeting with Kinsale also shows concern of the underlined word all in the description of the hazards needing to be described as a list of all hazards would have to include a large number of non-major hazards]</p>	<p>The text has been changed to:</p> <p><i>Identify the hazards that persons are exposed to including all those that have the potential to cause a Major Accident</i></p> <p>The word <i>all</i> has been moved as there is no need to identify all occupational hazards in the safety case because it is not possible a priori to know what every occupational hazard that might occur (though the SMS must be designed such that its use ensures that all risks are reduced to a level that is ALARP). The majority of the safety case is concerned with MAHs and petroleum undertakings should ensure that all major hazards and their causes are identified.</p> <p>The term hazard cannot be defined as suggested as there are hazards that need to be considered under the General Duty that do not have the potential to be major accidents.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	4.4.1	In the third major bullet (and in Section 4.4.5.1), 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. Some clarification is required.	Agreed; this bullet has been changed to: <i>For a petroleum activity that has the potential to give rise to a Major Accident, a systematic quantitative assessment of the total risk from all hazards including their likelihood and consequences and an assessment of whether the risk tolerability criteria are met.</i>	Yes
SEPIL	4.4.1	<p>In some places, the document says explicitly, or implies that the risk associated with a single major hazard needs to be compared with the risk tolerability criteria. In other places, it says that the total, summed risk from all hazards needs to be compared against the criteria – this is what would normally be expected.</p> <p>For example, the third bullet in this section includes the statement that ‘a systematic assessment of the risk associated with each hazard..’ etc. This should state ‘a systematic assessment of the risk associated with <i>all</i> (major accident) hazards..’ etc.</p>	<p>The risks from all MAHs must be evaluated using QRA to allow explicit comparison with the Risk Tolerability Limits. The Risk Tolerability Limits apply to the totality of all risks. The total risk must be placed in the correct part of the ALARP diagram to enable the appropriate assessment. In addition, for public risk, all MAH sources must be included in the comparison with the Risk Tolerability Limits, which means that if two or more designated petroleum activities can affect the same public population, the total risk from these sources should be evaluated and compared against the Risk Tolerability Limits. For risk to workers, non-major hazards (e.g. occupational hazards) have to be included in addition to all MAHs sources.</p> <p>The change suggested is agreed with and the text has been clarified to confirm that the risk tolerability criteria apply to the total risk.</p> <p>It is also noted that each hazard must assessed to determine whether the residual risk is ALARP once the risk has been shown to be below the Upper Tolerability Limit.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
ERM	4.4.2	There should be a comprehensive assessment of people, plant and process hazards. This should be somewhat prescriptive about human error assessment, as otherwise experience shows that this will be omitted. Suggest that the wording of this paragraph is amended to reflect this aim.	The penultimate sentence has been changed to include the potential for human failure as well as equipment failure. The sentence has been changed to: <i>The assessment must cover all human factors, infrastructure, plant and equipment that could cause or contribute to an accident, including subsea systems, pipework, process plant and plant areas and utilities</i>	Yes
SEPIL	4.4.2	We would assume that for non Major Accident Hazards, a Hazards and Effects Register which identifies the hazards, threats, top event, consequences, assesses the risk using a risk assessment matrix and lists the controls that are in place would be sufficient.	For judging the acceptability of a risk once the total risk has been shown to be below the Upper Tolerability Limit, a number of methods are suggested as described in the <i>ALARP Demonstration Guidance Document</i> including risk matrices.	No
SEPIL	4.4.3	We welcome the clarity that will be provided when Appendix II is populated and the list of standards that represent good practice in Ireland is available.	Noted.	No
SEPIL	4.4.4	The following text should be added to the first sentence 'and impact the public' and "ALARP if tolerable" should read "tolerable if ALARP", i.e. For activities that have the potential to give rise to a Major Accident Hazard <i>and impact the public</i> , the Individual Risk and the Societal Risk arising must be compared to the risk tolerability criteria to determine whether the risk is intolerable, broadly tolerable, or <i>tolerable if ALARP</i> .	Societal Risk Limits only apply to the public, so this clarification is not required here. Individual Risk Limits need to be compared for the public and workers. Agreed; the text has been updated to: <i>tolerable if ALARP</i> .	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
Sarah Akamine	4.4.5	<p>For onshore unconventional hydrocarbon extraction, this quantitative risk assessment must include a full assessment of the health risks (short and long term) to residents in the local area, and this assessment must take into account the cumulative risks posed by other petroleum infrastructures (well pads, compressor stations, pipelines, etc.) in the vicinity. Keeping in mind that in the USA well pads are constructed at densities of up to 6 per km² (EU Parliament report <i>"Impacts of Shale Gas and Shale Oil Extraction on the Environment and on Human Health"</i> http://www.europarl.europa.eu/document/activities/cont/201107/20110715ATT24183/20110715ATT24183EN.pdf), the cumulative effects of such intensive and highly polluting industrial activity in populated areas is not negligible.</p>	See section 2.1.6.	No

Respondent	Section	Comment	CER Response	Guidance Update?
ERM	4.4.5.1	<p>A full QRA is not always necessary to demonstrate that risks are ALARP. Use of more qualitative tools such as bowties can provide a compelling case for safety without the need for excessive analysis. This is particularly the case for normally unattended installations where QRA can give misleading results. Some quantification is important, for judging acceptance, but this can be achieved by intelligent use of risk matrices and examination of safeguarding barriers using bowties. Often QRA can provide a 'number' without providing insight, unless it is applied by experienced practitioners rather than inexperienced analysts.</p>	<p>There is a need to ensure that the risk is below the Upper Tolerability Limit before it can be shown that the risk reduction measures reduce the risk to a level that is ALARP. For an Installation where the risk is likely to be low, this can be undertaken with conservative assumptions that maybe require less rigorous analysis as long as the result confidently shows that the risk is below the Upper Tolerability Limit. In a risk matrix it is only possible to evaluate a single hazard and different risks cannot be summed in such a matrix. Even for a simple installation such as a NUI there will be multiple hazards meaning that the risk matrix cannot be used.</p> <p>For judging the acceptability of a risk once the total risk has been shown to be below the Upper Tolerability Limit, a number of methods are suggested as described in the <i>ALARP Demonstration Guidance Document</i> including risk matrices.</p> <p>The CER agree that QRA, as with any other risk assessment technique, should only be applied by competent persons.</p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	4.4.5.1	See above. The normal quantitative risk assessment approach is to determine the overall risk levels, taking account of all hazards, and if it is above the broadly acceptable level then the various (dominant) contributors to the risk should be examined individually to determine whether the overall risks are ALARP.	The first sentence of section 4.4.5.1 in the <i>Safety Case Guidelines</i> has been updated to: <i>A quantitative risk assessment (QRA) is required in the safety case in order to determine the total risk, compare against tolerability criteria and identify what drives that risk so that the hazards can be managed.</i>	Yes
Kinsale	4.4.5.2	The 'Example' given is relatively prescriptive about the QRA approach, citing ' <i>for an offshore platform, use of around four release sizes</i> '. We are assuming that such examples are not a prescriptive part of the guidance and request that this should be clearly stated.	The following text has been added to section 1.3.2 in the <i>Safety Case Guidelines</i> : <i>The examples provided in the example boxes are illustrative only and are included to aid understanding and are not prescriptive nor exhaustive. They do however represent the CER's understanding in relation to subject matter of the example.</i>	Yes
ERM	4.4.6	Suggest the following change to wording... Identify potential human failures: consider what human failures may occur in carrying out safety critical activities (e.g. failures that increase the likelihood of a hazardous effect, or failures that could degrade the reliability of preventative barriers, or mitigating control measures).	Note that the text in this section has been moved to section 4.6.3.3 in the <i>Safety Case Guidelines</i> within the SMS as the expectation is that the SMS includes human factors considerations and for this some analysis needs to be undertaken. While a listing of safety critical tasks is not required due to the impossibility of defining such a list, this section of the SMS has been updated to reinforce that the SMS must ensure that all safety critical tasks that are undertaken have sufficient safeguards.	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
ERM	4.4.6	<p>Identify performance influencing factors...</p> <p>Workload assessment and manning levels are critical for managing maintenance backlog risk. This should be highlighted here.</p>	<p>Note that the text in this section has been moved to section 4.6.3.3 in the <i>Safety Case Guidelines</i> within the SMS as the expectation is that the SMS includes human factors considerations and for this some analysis needs to be undertaken.</p> <p>Inadequate manning would make a failure more likely in any task, not just maintenance. Inadequate manning will be included in the list of examples of Performance Influencing Factors.</p>	Yes
ERM	4.4.6	<p>Monitor and review...</p> <p>This should include assessment and monitoring of competencies, especially the validity of safety critical qualifications.</p>	<p>Note that the text in this section has been moved to section 4.6.3.3 in the <i>Safety Case Guidelines</i> within the SMS as the expectation is that the SMS includes human factors considerations and for this some analysis needs to be undertaken.</p> <p>Monitor and review of competencies is an important aspect of a safety management system and such details are required in section 4.6.5.2 (4th paragraph, 1st bullet) in the <i>Safety Case Guidelines</i>.</p>	No
Kinsale	4.4.6	<p>This section gives the impression that the safety case must demonstrate how human factors is integrated into the risk assessment process and outlines key principles to be addressed. Some clarification on what level of information is being</p>	<p>Note that the text in this section has been moved to section 4.6.3.3 in the <i>Safety Case Guidelines</i> within the SMS as the expectation is that the SMS includes human factors considerations and for this some analysis needs to be undertaken.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
		<p>looked for would be helpful.</p> <p>It would generally be expected that the SMS content in the case would be the place where this is addressed.</p>	<p>A summary of how human factors have been considered should be provided in the safety case, supported by a reference to other material if necessary. Section 2.2 in the <i>Safety Case Guidelines</i> outlines the level of information that is required.</p>	
ERM	4.4.7	<p>This section should include an additional subsection on Safety Critical Task Risk.</p> <p>Safety critical tasks are those in which failures of performance can increase the likelihood of creating major accident hazards. Typical errors lead to:</p> <ul style="list-style-type: none"> Breaking containment, Disabling safeguards, Changing integrity, Temporary modes/configurations, Introducing ignition/heat sources. <p>For the guidance document it would be sufficient to demand a demonstration that human error/failures on safety critical tasks cannot introduce major accident hazards.</p>	<p>The SMS needs to cover operations that are listed in the response and the overall aim of the SMS is to ensure that risks are ALARP. Therefore, no separate section is required to show that risks from tasks are reduced to a level that is ALARP.</p> <p>However, this is an important operational aspect and would be the subject of CER audit and inspection.</p>	No
Kinsale & NSAI	4.4.7	The second sentence statement about SCEs and ALARP (effectively stating - even if risks from	This statement refers to the possibility of defining good SCEs, but applying them to a bad design or	No

Respondent	Section	Comment	CER Response	Guidance Update?
		failure of each chosen SCE are ALARP overall risk may not be ALARP) appears to go beyond established practice.	operation. For example, all the SCEs on an onshore plant may meet Good Practice, e.g. good integrity management, gas detection etc, but the offices on the same site may be too close to the process area and thus the risk may not be reduced to a level that is ALARP.	
ERM	4.4.7.1	The choice of SCE must be transparent and traceable. Their role in preventing or mitigating major accidents should be readily understood by the Regulator and most importantly by the workforce. The use of bowtie diagrams in making this demonstration is extremely valuable. The graphical nature of this technique allows the reader to assess the importance of such measures and understand the implications, should the SCE fail to meet its performance standard. I would suggest that it would make sense to mandate the use of bowties or similar techniques in making the choice of SCE transparent. It must be noted however, that bowties are not in themselves a robust means of demonstrating the effectiveness of SCEs. This should be undertaken with appropriate techniques such as HAZOP, SIL, FMEA etc.	<p>Bowties show a list of control measures and can be used in the same way as a HAZID, or similar techniques to help to identify SCEs. Many other techniques are also available (e.g. QRA, SIL assessment, FMEA) and the CER does not wish to mandate any particular technique as different ones will be applicable in different circumstances.</p> <p>The petroleum undertaking should assure themselves that they have a robust method of identifying SCEs and that these SCEs can deliver the appropriate performance to manage risks ALARP.</p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	4.4.7.1 & 4.4.7.2	Again these suggest that the risk from each hazard must be demonstrated to be reduced to a level that is ALARP, something that is not required to be demonstrated in UK North Sea Safety Cases.	This is required in many other jurisdictions. The overall risk cannot be shown to be reduced to a level that is ALARP without considering the individual hazards.	No
SEPIL	4.4.7.1	Second paragraph: We would propose that this sentence is re-worded as follows: "In most cases, the assumptions made on the performance of the safety critical equipment in the semi-quantitative/quantitative risk assessments should be stated within the SCE performance standards."	The performance standards will need to justify the appropriate performance of the SCE and this may or may not be undertaken by semi-quantitative/quantitative risk assessments. In many cases Good Practice is sufficient, but if not, it is likely that semi-quantitative/ quantitative risk assessments will be required to determine required performance. A risk assessment can then use either performance standard, industry standard or actual data as long as its use is suitable and justified.	No
Sarah Akamine	4.4.7.2	Inherent safety", in the context of the safety regulations for onshore unconventional hydrocarbon extraction, refers to what, exactly?	See section 2.1.6.	No
Kinsale	4.4.8	'General duty' legal compliance might be expected to be addressed within the Safety Management System content of a safety case.	The Act requires the petroleum undertaking to control the risks from all hazards to a level that is ALARP. For this reason a specific section of the safety case is required to provide clarity. This section may cross-reference the SMS if required.	No

Respondent	Section	Comment	CER Response	Guidance Update?
ERM	4.5.1	Safety critical tasks should be introduced here too.	SCEs cover hardware controls, not tasks. While performance standards for hardware have been in place in other jurisdictions for many years, there is no framework for tasks and it is not clear what advantages such an approach would bring as a large proportion of a typical SMS is concerned with ensuring that tasks are safely managed (by the permit to work and other associated systems). The CER does not intend to ask for such an approach.	No
CIL	4.5.3	From CIL perspective performance standards will relate to the specifications as given in IALA Recommendations.	Noted.	No
ERM	4.5.3	The same Performance Standards scheme can be applied to human factors for safety critical tasks; particularly, functional, available, survivable and interaction, but maybe resilience would replace survivable.	See comment above on safety critical tasks.	No
Kinsale	4.5.3	The level of prescription in relation to reliability targets may be difficult for operators to comply with and goes further than is required in the UK North Sea regime for instance.	Reliability is a key requirement for any safety critical system as SCEs do not provided a safety benefit during times when they cannot operate. A summary should therefore be provided to demonstrate the process by which reliability targets are set and reliability is assured and verified.	No

Respondent	Section	Comment	CER Response	Guidance Update?
ERM	4.5.4	Here too assurance has been focused on SCEs. It should also focus on Safety Critical Task competencies.	See comment above on safety critical tasks.	No
SEPIL	4.5.5	<p>First paragraph, last sentence: We would propose replacing the term ‘fabrication’ with the more general ‘construction’ term as this would better align with the terminology in the PEES Act, i.e. To do this, verification needs to cover design, <i>construction</i>, commissioning and operations, including the associated assurance routines”</p> <p>Second paragraph, second sentence: We note that, according to the CER’s Project Implementation Timeline, the majority of these Compliance Assurance Procedures will not be finalised until November. Will there be a transition period thereafter to allow Petroleum Undertakings to perform a gap analysis versus the CER’s requirements and allow sufficient time to close any gaps that may exist?</p>	<p>Agreed; the text has been updated to refer to: <i>construction</i>.</p> <p>Transition arrangements will be agreed at a later date.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
ERM	4.6.3.3	This section could be expanded slightly to include a focus on safety leadership and safety culture. There are good practice elements that can provide measurable aspects of leadership and culture that can support the safety case demonstration. This may not be applicable to the design safety case, but would be relevant to the others.	Safety leadership and culture are important aspects of an SMS. The policy section of the SMS guidance (section 4.6.2 in the <i>Safety Case Guidelines</i>) has been updated to include the following requirement: <i>Show clear safety leadership and commitment to a good safety culture;</i>	Yes
SEPIL	4.6.3.5	Second paragraph – we understand from this statement that relevant Good Practice, management systems and procedures which include a robust permit to work system will form a key part of the ALARP demonstration for broadly tolerable risks.	Agreed. However, it is unlikely that any petroleum activities achieve a risk that is broadly acceptable for workers who need to use the permit to work system. Individual hazards may have risks that are lower than the broadly acceptable limit, but this is not directly relevant in an ALARP assessment except to say that ALARP for low risk, well-understood hazards, which characterises some occupational risks, is more likely to be demonstrated by adherence to Good Practice and the more simple assessment techniques. Guidance for acceptance of broadly acceptable risk is given in the <i>ALARP Demonstration Guidance Document</i> .	No
ERM	4.6.4.4	Suggest the following word changes... “The safety case should demonstrate how the petroleum undertaking ensures that any persons performing safety critical activities that can impact on safety are competent and have the necessary information and supervision when carrying out the activity and will describe the process for this in the safety case.”	The suggested change to the text makes the paragraph clearer, and is accepted.	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
CIL	4.6.5	In this case CIL is the third party. AtoN performance and availability records shall be produced quarterly. AtoNs shall be electronically or physically monitored during activation. For instance if an AtoN light ceases to function an alarm should inform the operator of that fact.	Noted.	No
SEPIL	4.6.4.7	Fourth bullet point: We would welcome further clarity regarding this point.	<p>This point covers the unavailability of an SCE for a period of time. The petroleum undertaking will have a management system that determines whether operations can continue without the SCE and the additional controls that need to be put in place to do this. The petroleum undertaking also needs to consider whether this constitutes a material change.</p> <p>To link this to the material change definition, the text has been changed to:</p> <p><i>Documented procedures to cover situations where the absence of the control (for example a Safety Critical Element) or the deviation from a stipulated operating criteria could lead to deviations from the Approved Safety Case if these changes become more significant and affect the basis of the safety case, the petroleum undertaking needs to consider the need for a material change, see section 2.4 for further guidance);</i></p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL	4.6.5.4	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.	Guidance will be provided in the <i>Petroleum Incident Notification and Investigation Procedures</i> .	No
NSAI	4.7.2	The safety case must demonstrate how the petroleum undertaking complies with the Framework for Major Emergency Management ²⁸ Is this appropriate for offshore installations.	The Framework for Major Emergency Management sets out arrangements which facilitate the principal response agencies/ principal emergency services (e.g. the Health Service and Irish Coastguard) in scaling-up the response required, and to work together in the management of large-scale incidents. Since Major Accidents offshore may require the involvement of the principal response agencies it is considered appropriate for the safety cases of offshore installations to demonstrate compliance with the framework.	No
Sarah Akamine	5I	..a Well Notification should be submitted (and published) for each onshore well.	Onshore Installations are subject to planning permission and so notification will be given by the planning authorities of any planned petroleum infrastructure.	No
Sarah Akamine	5	Safety Cases and Emergency Response procedures should take into account the existence or nonexistence of hospitals with 24-hour emergency facilities in the vicinity.	See section 2.1.2.	No

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	5.1	<p>The principle is very similar to that applied in the UK North Sea, but the requirements for Well Notifications are very onerous if the rationale for how multiple wells can be covered by the same well notification is taken literally. The last sentence of the first paragraph would be clearer if it was stated that it applied when a Well SC was not yet in place, although it is puzzling that the first required submission isn't the new Well SC, with the Well Notification to follow once the SC is approved.</p> <p>In a similar vein, at the bottom of page 40, the sentence <i>'Where a Well Notification is required it must be submitted before a Well Safety Case can be approved.'</i> is puzzling – as Well Notifications will still be required when a Well SC is in place and approved.</p>	<p>The Well Notification requirement has been removed from the <i>Safety Case Guidelines</i> in order to improve clarity. The purpose of the notification was to provide the CER with an early indication of upcoming petroleum activities in order to better facilitate future safety case assessment. This will be stated in an advisory and generic sense in the <i>Safety Case Assessment Procedures</i>.</p> <p>In addition, for any well intended to be operated in conjunction with a production facility (effectively all wells apart from exploration, or appraisal wells), the previous well notification requirements were also required in the Design Safety Case. The Design Safety Case requirements have been updated to explicitly include this detail rather than refer to the (now removed) Well Notification guidance.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
IOOA	5.1	<p>The concept of a Well Notification as detailed in Section 5 of the Guidelines is at variance with International best practice and its stated intent “to provide the CER with an early opportunity to assess whether the well work being proposed is in accordance with the Framework” is considered entirely unnecessary. The Guidelines state that prior to a Well Work Safety Permit being granted, a Well Safety Case must first be approved. IOOA sees no merit in adding another additional step to the Well Safety Case approval process and considers it an extra administrative burden with no additional value being provided. There is no similar stage in the Design, Production and Decommissioning Safety Cases and it is recommended that this step be removed from the Guidelines in order to create a streamlined process across all safety cases under the Petroleum Safety Framework.</p>	See previous comment on the removal of the requirement for Well Notifications.	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL	5.1	<p>The stated purpose of the well notification is “to provide the CER with an early opportunity to assess whether the well work being proposed is in accordance with the Framework”. It should be recognised that there is absolutely no value in the Well Notification other than it acting as an early notification process which will use up resources on what is essentially an unnecessary activity. In terms of process simplicity, it is recommended that this should all be covered by way of the Well Safety Case. Should there be a requirement for early submission of the Safety Case then this can be incorporated into a ‘submission timeline’ which has yet to be defined.</p> <p>We recommend that the implementation of the Safety Case Guidelines under the Petroleum Safety Framework fully replaces the existing well notification regime (of the Department of Communications, Energy and Natural Resources) and that this is made clear in the Guidelines.</p>	See previous comment on the removal of the requirement for Well Notifications.	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
NSAI	5	<p>This sections needs clarification. A flow diagram would help.</p> <p>What is the interaction between the Well notification process and the PAD approval process?</p>	See previous comment on the removal of the requirement for Well Notifications.	Yes
Kinsale	5.3	With a Well SC already in place, it should be stated that a Well Notification could cross-refer to this descriptive content in the related Well SC to avoid repetition of the required details.	See previous comment on the removal of the requirement for Well Notifications.	Yes
Kinsale	5.3.3	It would helpful if it was stated that the ' <i>workers associated with the well</i> ' will be covered in the related Production or Non-Production Safety Case, which is also where their risks are addressed.	See previous comment on the removal of the requirement for Well Notifications.	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	5.4	<p>For the reasons given above in 4.4.1, the requirement for an ALARP demonstration that specifically requires comparison of quantified risks with tolerability limits is very onerous. It would be anticipated that a Well work ALARP demonstration would be based on good practice and engineering judgement.</p>	<p>Although the requirement for a Well Notification has been removed, this response is also relevant to a Well Safety Case.</p> <p>There is a need to ensure that the risk is below the Upper Tolerability Limit before it can be shown that the risk reduction measures reduce the risk to a level that is ALARP. For a Facility where the risk is likely to be low, this can be undertaken with conservative assumptions that maybe require less rigorous analysis as long as the result confidently shows that the risk is below the Upper Tolerability Limit. For wells, the location of the well with respect to local populations (especially onshore) is of paramount importance.</p> <p>The risk assessment can refer to a risk assessment in a Production, or Design Safety Case.</p> <p>For judging the acceptability of a risk once the total risk has been shown to be below the Upper Tolerability Limit, a number of methods are suggested as described in the <i>ALARP Demonstration Guidance Document</i> including risk matrices.</p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
IOOA	6	<p>A clear timeline should be provided for submission of the Well Safety Case in order to facilitate well planning and resource allocation by the Petroleum Undertaking. In addition, there should be a clear and unambiguous understanding of the role of the CERs implementation of the safety case regime in relation to existing offshore well notification procedures as currently carried out by the DCENR. It is critical that unnecessary duplication is avoided in this area. IOOA therefore recommends that the implementation of the Safety Case Guidelines under the Petroleum Safety Framework fully replaces the existing well notification regime and that this is made clear in the Guidelines.</p>	<p>The <i>Safety Case Approval Procedures</i> will document the timeline.</p> <p>Transition arrangements will be agreed with the DCENR to ensure unnecessary duplication is avoided.</p>	No
IOOS	6	<p>Drilling operations are carried out on a continuous basis and may require program alterations at short notice due to prevailing site conditions. Clarification needs to be provided on how the CER will manage and support 24 hour coverage during well work as there may be a number of notification changes on a particular well activity when carrying out operations. No explanation is given in the Safety Case Guidance document as to how this will be managed. IOOA believe that at a minimum, a web-based, online facility with defined input entries and requirements should be made available to the Industry so that updates can be submitted and approved in real time and unnecessary delays in operations avoided.</p>	<p>Guidance will be provided in the <i>Safety Case Assessment Procedures</i> and comment has been noted.</p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	6.1	<p>Requirements for Well Safety Cases are very onerous if the rationale for how multiple wells can be covered by the same Well SC is taken literally. Wells can only be covered by a single Well SC if practically every detail of the wells is the same and certainly each different reservoir would imply a need for a different Well SC. The implication is that the Kinsale Head undertakings would require at least five Well Safety Cases.</p> <p>As in 5.1, improving the clarity of description of the requirements would be helpful. The first paragraph is especially confusing and would seem to be more applicable to Section 5.1 as it is about well work. Either here or in 5.1, clear statements of the approved document requirements needing to be in place for well work to be carried out either on a production installation or using a non-production installation would be a big help.</p> <p>In the third paragraph, the last sentence appears to suggest that a Well Safety Case is likely to need a temporary addendum dependent on the BOP equipment involved in the proposed well work – trying to minimise the number of document updates required for a new piece of work would be helpful. Covering this in the Well Notification might be the answer?</p>	<p>A number of elements of the guidance have been altered so that it is clear that a Well Safety Case is not required for a production well, but that the well must be included in the Production Safety Case.</p> <p>A Well Safety Case is required for any well work, which includes any work that alters the pressure containment boundary, or is a material change to the well.</p> <p>The first paragraph has been clarified.</p> <p>If well work is to be undertaken, a Well Safety Case should be submitted. The BOP will be described in the (Non)-Production Safety Case and its applicability for the well work in question described in the well safety case. The temporary addendum concept is not needed here due to the fact that a Well Safety Case is not required for a producing well.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL	6.1	<p>Drilling operations are carried out on a continuous basis and may require program alterations at short notice due to prevailing site conditions. The changes that need to be made could require immediate implementation or approval (normally approved in real time by a well examiner). Clarification needs to be provided on how the CER will manage and support 24 hour well work as there may be a number of notification changes on a particular well activity when carrying out operations. We believe that at a minimum, a web-based, online facility with defined input entries and requirements should be made available to petroleum undertakings so that changes/updates can be submitted and approved in real time and unnecessary delays in operations avoided. We re-iterate that a material change should be a change that has a significant impact on risk levels.</p>	<p>In the CER scheme, the well examiner is an ICB, who reviews whether the petroleum undertaking is following their processes for management of the well. Thus regulatory approval can never be given by a well examiner.</p> <p>Further information on assessment and submission procedures will be provided in the <i>Safety Case Assessment Procedures</i>.</p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
ERM	6.3	Plenty of work has been undertaken since Macondo to identify best practice for well operations. (eg Well Life Cycle Integrity Guidelines from Oil & Gas UK) It was clear from this incident that in the dynamic nature of a drilling campaign, deviations from best practice were justified (erroneously). The big question is how do you capture and prevent such deviations from best practice. The Regulator could maintain a set of accepted practices (perhaps in the form of bowtie diagrams) against which it would judge the acceptability of a proposed methodology, with the operator justifying any deviation.	The CER is not the custodian of Good Practice, but the well operations must be shown to meet good practice where this exists.	No
Kinsale	6.3.1	See comment in 5.3.1 above with reference to <i>'workers associated with the well'</i> .	The CER requires this information within the Safety Case. However cross referencing may be acceptable.	No
SEPIL & NSAI	6.3.3	Different wording should be considered for exploration activities as some of the required information may not be available at the exploration stage.	It is considered that this information will be available.	No
Kinsale	6.3.5.1	The described requirements do not mention the requirement for Well Notifications to carry out any well work.	See previous comment on the removal of the requirement for Well Notifications.	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	6.3.5.2	See earlier comment in relation to 2.5.1. The implication is a requirement for several different submissions and stages of approval that would seem to be un-necessarily cumbersome. Perhaps a clarification of exactly what the requirements are would help, i.e. the submissions and in which order.	It has been clarified that only a Well Safety Case (and Production or Non-production Safety Case) is required to gain a Well Work Permit.	Yes
Kinsale	6.4	Much as commented on above in 5.4, an ALARP Demonstration for a well or wells, the requirement for an ALARP demonstration that specifically requires comparison of quantified risks with tolerability limits is very onerous. It would be anticipated that a Well SC ALARP demonstration would be based on good practice and engineering judgement.	The methods used to demonstrate that the risk has been reduced to ALARP must provide certainty that the correct risk reduction measures have been implemented. The methods that may be used to do this are outlined in the <i>ALARP Demonstration Guidance Document</i> .	No
Kinsale	6.6	It would be hoped that this can make it clear that a Well SC would not need to describe the SMS that applies to the wells where they are connected to a Production installation but would only need to refer to the SMS that is described in the related Production Safety Case.	Agreed. The SMS is covered in the (Non)-Production Safety Case and so the text has been updated to: <i>This section is only required if a well is left plugged and not producing as the well would not be covered by the SMS of any associated Non-production Safety Case or Production Safety Case.</i>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	6.7	The requirements as described will result in a lot of duplication if they are to be included in each Well SC. The actual requirements will also need to be covered in both related Production and Non-Production safety cases.	<p>The following text has been added to the end of section 5.1 (was 6.1) in the <i>Safety Case Guidelines</i>:</p> <p><i>If the well activity is being undertaken on an existing well, or in a well that is intended to be joined to an existing production installation, then the Well Safety Case may refer to the associated Production Safety Case as relevant. However all aspects must be covered, so that, for example, if the possibility of a blow-out is greater during drilling and additional measures are required above those described in the Production Safety Case, these measures need to be described in the Well Safety Case.</i></p>	Yes
NSAI	7	No reference in this section to recognize safety cases from accepted safety cases from other jurisdictions for mobile drilling equipment.	The Safety Case Guidelines set out the CER's requirements for Non-production Safety Cases, and these are aligned where possible with international practice. It is recognised that mobile drilling equipment will likely have equivalent safety case in other jurisdictions, however this will not negate any of the CER's specific requirements.	No

Respondent	Section	Comment	CER Response	Guidance Update?
SEPIL	7	<p>This section should include a reference to recognise Safety Cases approved in other jurisdictions for mobile drilling equipment.</p> <p>For a rig/drilling vessel, is the submission of a Non Production Safety Case done by the rig vessel owner or by the Petroleum Undertaking who has contracted the rig/vessel?</p>	<p>See comment immediately above.</p> <p>The petroleum undertaking must submit the Non-production Safety Case.</p>	No
NSAI	7.3.4	<p>This requirement could be unrealistic for smaller operators.</p>	<p>The CER remains of the view that the requirements of this section remain appropriate for all petroleum undertakings</p>	No
SEPIL	7.5	<p>We understand that the term Safety Critical Element is defined as stated in the High Level Design, i.e. they 'may be understood to refer to such parts of an installation and its plant, including computer programmes, a purpose of which is to prevent or limit the effect of a major accident, or the failure of which could cause or contribute substantially to a major accident'</p>	<p>Agreed.</p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	8.1	<p>The concept of a 'material change' to a Design Safety Case is difficult to comprehend given the relatively high-level nature of content that would be expected in such a document. Some of the listed content requirements are also fairly onerous, although some at least are described as 'Examples'.</p>	<p>The Design Safety Case is required before a Production Safety Case update due to material change for the same reason that a Design Safety Case is required for a new build – to allow the CER to review the design at a point where changes can easily be made. The complexity of the Design Safety Case should reflect the complexity of the material change, which could vary from a very significant change (offshore bridge linked platform, or extension of onshore terminal) to a more detailed change to a particular SCE. In the former case, it is clear why the Design Safety Case is required since the change is similar in scope to a new build, while in the latter the Design Safety Case only needs to consider the SCE in question. Any material change to a Design Safety Case should be considered within this context and would be needed if, for example, an unmanned site became manned during the design process.</p> <p>It will also be clarified in the text that a Design Safety Case submitted for a material change to a Production Safety Case only needs to cover aspects that are relevant to the material change and can refer to the production safety case to avoid repetition.</p>	Yes

Respondent	Section	Comment	CER Response	Guidance Update?
NSAI	8.1	See comment on 2.5 4 th last para. Is the intent that the design safety case should remain a live document or can it be subsumed into the production safety case?	<p>The Design Safety Case will be superseded by, for example, a Production Safety Case.</p> <p>Note that a Design Safety Case will be required for material changes but this is envisaged to be a document commensurate in size to the complexity of the change being made.</p> <p>The text has been updated to make this clear.</p>	Yes
SEPIL	8.1	<p>First paragraph, footnote 31: we understand from this footnote that facilities such as Corrib will not be required to submit a Design Safety Case in the first instance.</p> <p>Fifth paragraph: It is our view that after the Design Safety Case is approved it should be frozen. All further material changes should be captured in the Production Safety Case alone, i.e. only one safety case should be 'current' at any time. We propose that the Production Safety Case should supersede the Design Safety Case and capture any future design modifications. This updated Production Safety Case would then be submitted to the CER for approval. The requirement to submit both a Design and revised Production case would involve duplication and could lead to errors.</p>	<p>Corrib will not require a Design Safety Case.</p> <p>Further guidance on transition arrangements will be provided in due course.</p> <p>It is important the CER has early sight of design changes that affect the overall risk of the Installation. As stated in the Safety Case Guidance the threshold for what constitutes a material change is higher for a Design Safety Case than a Production Safety Case and so this should not prove onerous. Cross-referencing will be permissible rather than duplication of information.</p> <p>The Design Safety Case becomes redundant once the subsequent Production Safety Case has been approved. For any further changes the Design Safety Case (if required) need only refer to the change and may cross reference the Production Safety Case.</p>	No

Respondent	Section	Comment	CER Response	Guidance Update?
ERM	8.3.6	This section should specify an early demonstration of the feasibility of the proposed operational concept, taking into consideration workload under a range of operating modes, manpower number, and any specialist demands for competencies.	The following text has been added to this section: <i>In addition, the Design safety Case must show how the proposed manning arrangements have been derived such as to provide an adequate level of manning for safe operations.</i>	Yes
Sarah Akamine	9	For unconventional onshore hydrocarbon extraction, even after wells are abandoned the risk of water pollution and methane migration (with the possibility of explosions) remains for years, even decades. There should be a requirement for continued monitoring and for a fund to be established by the petroleum undertaking before the commencement of petroleum activities that will be sufficient to cover all the long term pollution and safety risks associated with the site.	The proposal for a fund to be established by petroleum undertaking is an issue relating to the conditions of the petroleum authorisation itself rather than within the scope of the Framework.	No
ERM	9.3.6	During decommissioning, equipment and facilities are used in non-standard modes, which increase the likelihood of human error. There should be a reassessment of safety critical tasks to identify potential failure modes that could affect major accident risk.	Assessment of safety critical tasks is not required to be outlined in the safety case. However, the SMS will need to cover decommissioning activities as relevant.	No
Sarah Akamine	10	The "public version" of safety cases must include the full disclosure of all chemicals used.	See section 2.1.3.	No

Respondent	Section	Comment	CER Response	Guidance Update?
Kinsale	10	It is noted that there will be a future consultation on 'public versions' of Safety Cases – CER should note that this will bring about more documents for undertakings to control and manage.	This point has been noted.	No
SEPIL	10	See also our comment regarding section 2.3. In accordance with the Act, it is the 'public version' of the approved Safety Case that is required to be made available to any member of the public who requests it (and not the references contained therein).	The precise scope will be included following a public consultation process to occur in 2013.	No
NSAI	Appendix II	PEESTC will advise on suitable standards	Noted.	No

4 Clarifications to the High Level Design

The consultation process for the *Safety Case Guidelines* has resulted in some clarifications to the high level description of the safety case requirements 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 completed. This is expected to occur in November 2013.

Section	Change
Table 1, Page 26 6.3.1.1, Page 27 6.3.5, Page 31	The requirement for a Well Notification will be removed. The Design Safety Case requires some very similar information to the Well Notification.
6.3.1.2, Page 27	The requirement that wells should be included in the Production Safety Case will be clarified. Previously wells would have been described an in Well Safety Case, which was a document kept 'live' throughout the lifecycle of the well. However this made the Well Safety Case and changes to it very complicated. This has now been simplified, and the temporary material change concept changed to an addendum to the safety case.
6.1, Page 24 6.3.4, Page 31 6.3.4.1, Page 31	The scope of the Decommissioning Safety Case will be updated to the point where any apparatus designed to contain or convey petroleum that comprises or forms part of such petroleum infrastructure is free of hydrocarbon.