

Validation

Document No: N-04200-GL0525 A52424

Date: 20/10/2021

1 Purpose

To provide guidance to both Industry and NOPSEMA assessors on the validation process as required by the Commonwealth Offshore Petroleum and Greenhouse Gas Storage (Safety) Regulations 2009 [OPGG(S)] and any relevant State or Northern Territory equivalents where powers have been conferred on NOPSEMA (currently only Victoria).

2 Scope

This guideline is applicable to:

- all proposed facilities, including facilities that are pipelines, located in Commonwealth and relevant State and Northern Territory designated coastal waters where powers have been conferred on NOPSEMA
- modification or decommissioning of existing facilities, including facilities that are pipelines, located in Commonwealth and relevant State and Northern Territory designated coastal waters where powers have been conferred on NOPSEMA, to which a significant change (e.g. modification or decommissioning) is proposed.

Note that validation of facilities that are pipelines located in State or Northern Territory designated coastal waters, other than Victorian designated coastal waters, is generally a matter for the relevant State or Northern Territory Authority.

In accordance with OPGGS(S) Regulation 2.40 (1), validation may be requested for:

- a proposed facility
- a proposed significant change to an existing facility.

It should be recognised that validation is linked to the safety case or revised safety case decision-making process in accordance with the following:

- For a proposed facility, i.e. a facility new to the regime, a safety case is required to be submitted to NOPSEMA, and prior to that submission, it is NOPSEMA policy to request a validation of the proposed facility. Acceptance of the safety case is then contingent on a satisfactory validation.
- For an existing facility, if an operator proposes to significantly change the facility (e.g. modify or decommission the facility), and where the safety case in force does not address that proposed modification or decommissioning, a safety case revision is required. Associated with that revision, and if NOPSEMA becomes aware of the proposed modification or decommissioning, it is NOPSEMA policy to request a validation of the significant change. If NOPSEMA does not become aware of the proposed modification or decommissioning, there is still a legal obligation on the operator to gain agreement on the scope of validation for the proposed modification or decommissioning prior to submission of the revised safety case. Where a validation has not previously been requested, NOPSEMA will formally

request a validation as part of the letter agreeing to the scope of validation. Acceptance of that revised safety case is then contingent on a satisfactory validation.

Validation is focused on safety-critical hardware, firmware and software, not processes and procedures.

3 Policy

Where the Regulations state that NOPSEMA may request a validation, it is NOPSEMA policy that validation will be requested. Refer to NOPSEMA Policy N-04200-PL0286 Validation.

4 Guidance

4.1 Introduction

The validation is required to be a statement in writing by an independent validator regarding the agreed matters (design, construction, installation) to the extent covered by the scope of validation developed by the operator and agreed by NOPSEMA.

Note that the validation relates to the facility (i.e. hardware, including process control hardware or its software equivalent) and not the activities undertaken at the facility or the procedures that manage those activities.

The validation must establish, to the level of assurance reasonably required by NOPSEMA, that:

- for a proposed facility, the facility incorporates measures that will protect the health and safety of people at the facility, and that those measures are consistent with the formal safety assessment (FSA) for the facility
- for a significant change to an existing facility, that after any proposed change or changes, the facility incorporates measures that will protect the health and safety of people at or near the facility.

4.2 Purpose

The purpose of this guidance is to assist operators to prepare a scope of validation for agreement by NOPSEMA, which will enable them to submit an appropriate validation statement that will demonstrate that appropriate measures have been taken to protect health and safety of persons, and where appropriate, will be consistent with the formal safety assessment for the facility.

4.3 Summary of legislative requirements

All references listed in this guidance are to Commonwealth Offshore Petroleum and Greenhouse Gas Storage (Safety) Regulations 2009 unless otherwise specified. Equivalent provisions exist in relevant State and Northern Territory legislation that is administered, under conferral of powers, by NOPSEMA.

OPGGS(S) Regulation	Requirements
<p>2.24 (4)</p>	<p>Safety case to be submitted to NOPSEMA</p> <p>The operator must not submit the safety case before the operator and NOPSEMA have agreed on the scope of the validation for the facility.</p> <hr/> <p>It is the operator who must arrange for agreement of the scope to be reached with NOPSEMA, and this must be done prior to submission of the safety case.</p> <p><i>Note: regulation 2.24(5) allows submission of a safety case prior to agreement of a scope of validation for a facility in certain limited circumstances.</i></p>
<p>2.26 (1)(d)</p>	<p>Acceptance or rejection of a safety case</p> <p>NOPSEMA must accept a safety case if, in a case in which NOPSEMA has requested a validation of the facility:</p> <ul style="list-style-type: none"> (i) the person, or each person, undertaking the validation meets the criteria specified in subregulation 2.40 (5); and (ii) the validation complies with regulation 2.40. <hr/> <p><i>One of the criteria for acceptance of a safety case is that the validator and the validation submission meet the requirements of the regulations.</i></p>
<p>2.30 (3)</p>	<p>Revision of a safety case because of a change of circumstances or operations</p> <p>If a circumstance mentioned in subregulation (1) or (2) is satisfied because the operator proposes to modify or decommission the facility, the operator must not submit the revised safety case before the operator and NOPSEMA have agreed on the scope of the validation of the proposal.</p> <hr/> <p><i>If a safety case revision is required due to a proposal to modify or decommission a facility, then agreement on the scope of validation must be reached prior to submission of the revised safety case.</i></p>
<p>2.34 (1)(d)</p>	<p>Acceptance or rejection of a revised safety case</p> <p>NOPSEMA must accept a revised safety case if in a case on which NOPSEMA has required a validation relating to a proposed modification:</p> <ul style="list-style-type: none"> (i) the person, or each person, undertaking the validation meets the criteria specified in subregulation 2.40 (5); and (ii) the validation complies with regulation 2.40. <hr/> <p><i>One of the criteria for acceptance of a revised safety case is that the validator and the validation submission meet the requirements of the regulations.</i></p>

OPGGS(S) Regulation	Requirements
2.40 (1)	<p>Validation of design, construction and installation, significant modification or decommissioning of a facility</p> <p>NOPSEMA may, by notice in writing, require the operator of a proposed facility, or an existing facility, to provide a validation:</p> <ul style="list-style-type: none"> (a) in respect of the proposed facility; or (b) in respect of a proposed significant change to an existing facility. <p><i>NOPSEMA may request, in writing, a validation.</i></p>
2.40 (2)	<p>Validation of design, construction and installation, significant modification or decommissioning of a facility</p> <p>A validation of a proposed facility is a statement in writing by an independent validator in respect of the design, construction and installation (including instrumentation, process layout and process control systems) of the facility, to the extent that these matters are covered by the scope of the validation agreed between NOPSEMA and the operator.</p> <p><i>Validation is a statement in writing by an independent validator. The validation must be consistent with the agreed scope.</i></p>
2.40 (3)	<p>Validation of design, construction and installation, significant modification or decommissioning of a facility</p> <p>A validation of a proposed significant change to an existing facility is a statement in writing by an independent validator in respect of the proposed change, to the extent required by the scope of the validation agreed between NOPSEMA and the operator.</p> <p><i>Validation is a statement in writing by an independent validator. The validation must be consistent with the agreed scope.</i></p>
2.40 (4)	<p>Validation of design, construction and installation, significant modification or decommissioning of a facility</p> <p>The validation must establish, to the level of assurance reasonably required by NOPSEMA:</p> <ul style="list-style-type: none"> (a) in the case of a proposed facility — that the design, construction and installation (including instrumentation, process layout and process control systems) of the facility incorporate measures that: <ul style="list-style-type: none"> (i) will protect the health and safety of persons at the facility; and (ii) are consistent with the formal safety assessment for the facility; and (b) in the case of an existing facility — that, after any proposed change or changes, the facility incorporate measures that will protect the health and safety of persons at the proposed facility.

OPGGS(S) Regulation	Requirements
	<i>The validation must provide assurance that the facility or the significant change, provides for the health and safety of people and, where relevant, is consistent with the FSA.</i>
2.40 (5)	<p>Validation of design, construction and installation, significant modification or decommissioning of a facility</p> <p>An operator who has provided material for a validation must satisfy NOPSEMA that each person who undertook the validation had the necessary competence, ability and access to data, in respect of each matter being validated, to arrive at an independent opinion on the matter.</p> <p><i>The operator must satisfy NOPSEMA as to the validators' independence, competence, ability and access to data.</i></p>

4.4 The validation process

Validation is primarily a process undertaken by an independent competent party, namely the Validator, to ensure that the design, construction and installation of safety-critical hardware, firmware and software (including instrumentation, process layout and process control systems) of the facility incorporate appropriate measures that will protect the health and safety of persons at the facility. It is an assurance activity that may be requested by NOPSEMA as per Regulation 2.40. Specifically, it is a statement in writing by the Validator in respect to the design, construction and installation (including instrumentation, process layout and process control systems) of a proposed facility, or significant change to an existing facility, to the extent required by the scope of validation developed by the operator and agreed by NOPSEMA.

Validation, as referred to in the legislation, should not be confused with verification. Verification generally requires someone to check that, for example, safety-critical equipment has been installed correctly and in-situ is fit for its function and use. The inclusion of elements of verification within a validation scope is potentially problematic, particularly for fixed facilities. For example, verification that a piece of safety-critical equipment is fit for its function and use often can only be conducted once the equipment has been installed. However, this equipment cannot be installed until a safety case, which provides for the installation of equipment, has been accepted by NOPSEMA, and any acceptance of a safety case related to such a proposed modification to a facility can only occur if the operator has provided a suitable validation statement as part of the safety case assessment process.

Consequently, verification is a separate and distinct process from validation and generally should be addressed within the safety case for the facility rather than coupled with validation.

Regulations on safety case contents requirements, such as Regulation 2.12, 2.14(2), 2.18 and 2.22(3), detail verification requirements that must be addressed in the safety case for a facility. Validation is a separate assurance process, provided for by the regulations and tied to safety case decision-making. It is essentially a three-step process as discussed below.

4.4.1 Requesting validation

NOPSEMA may, by notice in writing, require the operator of a proposed facility, or an existing facility, to provide a validation in respect of the proposed facility, or in respect of a proposed significant change to an existing facility [OPGG(S) Regulation 2.40(1)].

Operators should note that is NOPSEMA's policy to request a validation in respect of all proposed facilities and all significant changes to existing facilities resulting from a proposal to modify or decommission that facility. It is clear that for a proposed facility there must first be a registered operator before NOPSEMA is able to request a validation of that proposed facility. Operator nomination and registration is therefore the first step to be undertaken by the proponent.

Operators may choose to undertake third party validation of their proposed facility or proposed significant change to their existing facility, however under the Regulations, unless NOPSEMA formally requests a validation, they do not need to submit any validation material to NOPSEMA for consideration as part of the safety case assessment process [OPGG(S) Regulation 2.26(1)(d) and 2.34(1)(d)].

Notwithstanding the above, this does not excuse the operator from the requirement to gain the agreement of NOPSEMA on the scope of validation prior to submission of a safety case [OPGG(S) Regulation 2.24(4)] or revised safety case [OPGG(S) Regulation 2.30(3)]. Note: NOPSEMA may formalise the request for validation, in accordance with OPGGS(S) Regulation 2.40, as part of agreement of a scope of validation in accordance with OPGGS(S) Regulation 2.26(1)(d) or 2.34(1)(d).

4.4.2 Agreement of scope of validation

Once a validation has been formally requested, NOPSEMA and the operator are required to agree the scope of validation, prior to submission of the safety case or safety case revision [OPGG(S) Regulation 2.24(4)] or revised safety case [OPGG(S) Regulation 2.30(3)].

It should be noted that the regulations do not stipulate a time frame within which the proposed scope should be agreed, nor does it stipulate what actions should be undertaken should the operator and NOPSEMA not be able to reach agreement on the scope of validation. NOPSEMA expects an operator who has been requested to provide a scope of validation, to engage constructively with NOPSEMA in a timely manner in order to reach an agreement. For complex submissions, this may entail multiple meetings and discussions to resolve any differences in expectations. If agreement on a scope of validation submission is not reached, then the operator is unable to submit the safety case or safety case revision.

The proposed scope of validation needs to be commensurate with the activities and stages in the life of the facility described within the safety case for which acceptance is being sought. NOPSEMA encourages operators to submit the scope of validation document accompanied by a completed Proposed Scope of Validation Submission Cover Sheet, form N-04200-FM0880. For scope of validation submissions that are required by the regulations, the submission of form N-04200-FM0880 provides a check-list/prompt to the operator to ensure that they have addressed all of the required elements of a scope of validation, and also assists NOPSEMA in delivering a consistent and efficient validation scope of validation process. Completion and submission of form N-04200-FM0880 is not required for 'Nil' scopes of validation. However, the operator will generally need to provide justification for a 'Nil' scope of validation, particularly where their proposal is for modification or decommissioning.

While there is no formal provision for NOPSEMA to deal with the validator on agreement of the scope, NOPSEMA recognises the benefit of early discussion between operators and their preferred validators. It is often beneficial for operators to involve the validator early in the process, prior to seeking agreement from

NOPSEMA to the scope of validation, such that the operator can gain some level of assurance from the validator that the codes and standards selected for the proposed scope are likely to be appropriate to the items being validated. See Section 4.6 below for further discussion on scope of validation.

4.4.3 Submission of the validation

The validation must be complete and submitted to NOPSEMA along with information with respect to the validator, in order for an acceptance decision to be reached in relation to the safety case [OPGGS(S) Regulation 2.26(1)(d)] or revised safety case where NOPSEMA has requested a validation relating to the proposed modification [OPGGS(S) Regulation 2.34(1)(d)]. If, after completing its assessment of a safety case or revised safety case where a validation has been requested, NOPSEMA does not receive a validation complying with Regulation 2.40 in relation to the safety case or revised safety case assessment within 60 days from completion of its assessment, NOPSEMA will ordinarily reject the safety case.

An operator of a facility may only undertake activities in relation to that facility if there is a safety case in force for the facility that provides for those activities.

4.5 Timing

4.5.1 The timing of validation

For a proposed facility, i.e. a facility new to the regulatory regime, the following steps are offered as a guide to how validation fits into the requirements of other regulations:

1. Operator nomination and registration
2. NOPSEMA requests validation.
3. NOPSEMA / operator reach agreement on the scope of validation, i.e. what safety-critical elements of the facility are required to be validated and against which codes and standards (including validator confirmation of the appropriateness of those codes and standards). Consideration should be given to:
 - the timescale for when the validation of these elements is required in order to progress the safety case decision-making process
 - the nature and credit assigned, regarding validation, of any relevant marine certification
 - the form of the validation deliverable (e.g. statement, report or certificate).
4. It is also prudent at this stage to agree the actual validator(s) to address the requirements of OPGGS(S) Regulation 2.40 (5) with regard to competence and independence.
5. The scope of validation is agreed by NOPSEMA in writing.
6. The operator submits the safety case for the facility(s).
7. Safety case assessment/validation underway.
8. Validation delivered (within 60 days of completion of assessment of the safety case or revised safety case where validation is required).
9. Safety case decision-making.

4.5.2 The timing of validation

The requirement for validation clearly affects the timing of the submission of the validation and safety case documentation by the operator. For example, depending upon the nature of the facility, it may be necessary for the design and construction validation to be completed and submitted before the safety case for the installation stage in the life of the facility can be accepted. Likewise, it may be necessary for the

installation validation to be completed and submitted before the safety case for the operations stage in the life of the facility can be accepted.

For the purposes of the regulations, the validation submission may need to be provided in stages in order to permit safety case acceptance, however this depends on how an operator chooses to stage their submissions under the regulations. This should be clearly understood and agreed at the scope of validation agreement stage. In some circumstances, it may not be possible for an operator to submit documentation necessary for NOPSEMA to be satisfied about the validation in a timely fashion. This may potentially lead to delays in acceptance of the safety case, or if the operator cannot provide the validation statement within 60 days, unless otherwise agreed by NOPSEMA, the safety case will be rejected. In order to avoid unnecessary delays, NOPSEMA and the operator must be clear on what safety-critical elements of the facility need to be validated and when. This should be clearly reflected in the agreed scope of validation.

4.6 Scope of validation – General requirements

Once validation is requested, the operator should consider engaging with the validator to gain some assurance that the codes and standards selected as part of the proposed scope of validation are likely to be appropriate for the selected scope items. The operator should then submit a proposed scope of validation to NOPSEMA with a view to agreeing the scope. The scope of validation will generally vary depending on the particular circumstances and the stage in the life of the facility for which safety case acceptance is being sought, however any item which is intended to be employed as safety-critical equipment and will be installed on a facility during a particular stage in the life of a facility, even if it will not be employed as safety-critical equipment during that particular life stage, should be included in the scope of validation.

Operators should, as a minimum, consider use of the safety-critical systems identified in the validation matrix (N-04200-FM0325), as the basis for their proposed scope of validation. The operator should consider these elements and develop a scope tailored to the particular project or stage in the life of the facility noting that, as a general rule, anything that is intended to be installed which will subsequently be safety-critical needs to be included in the scope of validation. A number of factors should be considered by the operator in developing the proposed scope of validation, as discussed below.

The scope of the safety case, including the activities it covers and the equipment to be installed, determines which equipment must be validated before a safety case, for a particular stage in the life of the facility, can be accepted. The focus should be on equipment to be installed at that stage in the life of the facility, a failure of which, would pose a high risk to personnel (e.g. can result or contribute to an MAE), even if that equipment is not to be used during that particular stage in the life of the facility.

For a proposed facility, the selection of elements for validation should be based on the findings from the Hazard Identification and Risk Assessment processes undertaken as part of the Formal Safety Assessment (FSA) to identify Major Accident Events (MAE) and hence safety-critical elements of the facility that provide barriers to those identified MAEs. It is these safety-critical elements that should be subject to validation. However, for facilities which are likely to have safety cases for various stages in their life e.g. construction, installation, operation, etc. where safety-critical equipment is constructed and/or installed but is not going to be used for the particular stage in the life of the facility for which the safety case is submitted, it is important that these items are included in the proposed scope of validation. The reason this is important is that the requirement for validation is only triggered for new facilities, and for modification or decommissioning of existing facilities. Consequently, the transition into an operational stage in the life of a facility (including commissioning) does not, in itself, trigger the requirement for validation.

The Hazard Identification and Risk Assessment processes will ultimately form the basis of the FSA described in the safety case for the facility (see notes below on “Consistency with FSA”). For a validation of a proposed significant change to an existing facility, the elements selected to comprise the proposed scope of validation should be based on the following principles:

- Any previously validated elements of the existing facility affected by the significant change proposed should be reselected for validation.
- Any new equipment to be installed on the existing facility as part of the significant change that falls into the categories of equipment already subject to validation should be selected for validation.
- Any new equipment to be installed on the existing facility as part of the significant change that is identified by the risk assessment as being safety-critical should be selected for validation, including equipment installed for use during a subsequent stage in the life of the facility.

In developing the scope of validation, operators may consider that equipment that is located remote from, or that is inaccessible to people, is not considered to present a Major Accident Event risk, and hence the components of the facility at that location are not considered safety-critical (e.g. remote deepwater pipelines), and therefore may be excluded from a proposed scope of validation. NOPSEMA's expectation is that all hydrocarbon containing components of a pipeline should be included in such scopes of validation, therefore in these circumstances NOPSEMA will engage with the operator to ensure all hydrocarbon containing component parts of a pipeline facility are included in the scope of validation proposal, irrespective of the potential to impact people. Note that a pipeline facility is defined in subclause 4(8) of Schedule 3 to the OPGGSA 2006, and for subsea developments, may include the well and associated plant and equipment, and any pipe or systems of pipes through which hydrocarbon is conveyed from the well to the pipeline.

4.6.1 Scope of validation contents

It is beneficial if the scope of validation is not just a simple list of the identified safety-critical elements of the facility to be validated, but contains additional information on the following.

4.6.1.1 Overview of the proposed new facility or modification, and lifecycle

This should be a high-level review of the proposed new facility or modification, and need not be overly detailed.

Consideration should be given to including a drawing or pictorial representation as this can aid NOPSEMA's understanding of the proposal. While not necessary, some description of the reason for a modification can provide context to NOPSEMA.

4.6.1.2 Systematic process for the selection of the safety-critical validation items

Within the scope of validation, the process for selection of items for validation should be shown or described. It is the operator's decision whether to include with the scope of validation submission the full selection process, or to provide the description of the selection process along with the validation deliverable.

4.6.1.3 Relevant codes and standards identification

Relevant codes and standards should be identified for each safety-critical element. The link between the selected item and the code or standard to be applied should be clearly stated in the scope of validation. Codes and standards should be properly identified by their correct name, reference number, and if applicable, edition or revision. Where no edition or revision is stated it is generally assumed that the most

recent version of the code or standard will be used. However, to remove any ambiguity it is recommended that the version to be used is specified.

4.6.1.4 Relevant safety studies, analysis reports and safety documents

Where there are no applicable codes or standards identified for a safety-critical element, a link between the selected item and relevant safety studies, analysis reports and safety documents should be clearly stated in the scope of validation.

4.6.1.5 Validator selection process, independence and competence

The scope of validation should contain demonstration of the selection criteria for the validator, their competence in all aspects that are to be validated, and their independence.

4.6.1.6 Appropriateness of the codes and standards

The scope of validation should provide instruction to the validator to determine, as part of the validation process, that the code(s) and/or standard(s) selected are appropriate to the safety-critical system being validated.

4.6.1.7 Appropriateness of safety studies, analysis reports and safety documents

Where there are no applicable codes or standards identified, the scope of validation should provide instruction to the validator to determine, as part of the validation process, whether the safety studies, analysis reports and safety documents selected are appropriate to the safety-critical system being validated.

4.6.1.8 Clearly defined deliverable

The expectations for the validation deliverable should be captured when the scope of validation is agreed. If NOPSEMA and the operator are clear on what is expected by way of 'the validation', then the validation deliverable may be limited to a simple statement by an independent, competent validator to the effect that:

- for all safety-critical elements covered by the agreed scope of validation; the design, construction and installation codes and standards applied in relation to the facility are appropriate.
- if these codes and standards are used then the design, construction, and installation of the facility will incorporate measures that will protect the health and safety of persons at the facility and are consistent with the formal safety assessment for the facility, where appropriate.
- for any safety-critical elements covered by the agreed scope of validation where there are no applicable codes or standards identified, the relevant safety studies, analysis reports and safety documents applied in relation to a facility are appropriate and if these relevant safety studies, analysis reports and safety documents are used, then the design, construction, and installation of the facility will incorporate measures that will protect the health and safety of persons at the facility and are consistent with the formal safety assessment for the facility, where appropriate.

Alternatively, the validation deliverable may be in the form of a report or certificate for each of the elements identified by the scope of validation, see discussion in Section 4.8. Within the deliverable, the validator should record, as a minimum:

- if the safety-critical elements validated will be designed, constructed and installed as per the identified code or standard or, where relevant, as per the relevant safety studies, analysis reports and safety documents
- any omissions between the agreed scope and the deliverable

- any restrictions or reservations the validator has placed on the outcomes
- whether free access was given to all data requested in the course of the validation
- that the validation complies with Regulation 2.40 of the OPGGS(S) Regulations.

It should be noted that any restrictions or conditions placed on the outcomes of the validations might affect NOPSEMA's decision-making in relation to safety case acceptance. Section 4.8 discusses the different types of deliverable in more detail.

4.6.2 Lifecycle stages

As discussed above, the scope of validation must be aligned to the facility type and the stage in the life of the facility for which safety case acceptance is being sought. It should be noted that the Regulations state that a safety case is not required for construction or modification of a facility at a location that is not in Commonwealth waters, e.g. at a remote shipyard. In this instance, the types of safety cases submitted, and consequently, the related validation, would be affected. For example, consider validation for a Floating Production, Storage and Offloading (FPSO) project. An FPSO and related subsea equipment (including well(s)) may make up a facility. Typically, the component parts of the **facility** are constructed at remote locations outside Australian waters, and therefore a safety case for the construction stage in the life of the **facility** (i.e. the whole development) is not required. In order to operate in Australia, the facility would simply require a safety case for:

- the installation stage in the life of the facility, i.e. for the installation of these component parts at the location within Commonwealth waters where they are to be used
- a safety case for the operations stage in the life of the facility.

The operator of the FPSO facility is free to decide how many stages in the life of the facility a safety case provides for. An installation safety case for an FPSO would normally cover the installation of the riser and mooring system, flowlines, manifolds and other subsea equipment. If an operator chooses to submit several scopes of validation for agreement at the same time, they should ensure that it is clear which scopes of validation will relate to which safety case submissions.

4.6.3 No subsequent additions

The expectation is that there should be no iterations of the agreed scope of validation. Once the scope is agreed, it is preferable if there are no subsequent additions. If the selection of elements subject to validation is based on sound principles, then it is not envisaged that, on submission of the facility safety case, there would be major misalignment between the elements of the scope of validation agreed and the subsequent FSA, see discussion in Section 4.6.5.

It is however recognised that there may be circumstances where the design of a proposed facility is changed, or not adequately described by the operator, after agreement of the scope of validation. NOPSEMA therefore reserves the right to request changes to the scope of validation agreed, albeit only in exceptional circumstances. Therefore, if at any stage it becomes clear to NOPSEMA or the operator that an item, which is safety-critical, should have been included within the scope of validation proposed by the operator and agreed by NOPSEMA, NOPSEMA may take one of the following options:

- request a validation under regulation 2.40; or
- request further written information as part of the safety case assessment process such that an equivalent level of assurance, to that required by subregulation 2.40(4), is obtained; or

- reject the safety case for the facility for which activities associated with this safety-critical equipment are contemplated.

The approach taken will depend on the significance of the omitted scope item.

4.6.4 Appropriate standards

It should be noted that for those safety-critical elements of a facility, which are included in the agreed scope of validation, there should be a statement by the validator with respect to the appropriateness of the standards relevant to each of the elements. NOPSEMA should ensure that the operator is aware of this when agreeing the scope of validation.

4.6.5 Consistency with the FSA

For a proposed facility, the legislation requires that validation be consistent with the FSA for the facility. Operators typically conduct coarse HAZID workshops early in the design stage, and use output from these to identify safety-critical elements of the facility that will ultimately be subject to validation. This should result in safety-critical elements, i.e. those that form barriers to major accident events, being properly identified, included in the scope of validation and ultimately validated against appropriate standards.

4.6.6 Marine classification certificates

It is likely that some of the features of marine vessels, Floating Production, Storage and Offloading vessels (FPSOs), FSOs, accommodation barges, Mobile Offshore Drilling Units (MODUs), pipe lay barges, etc. that are facilities under the *Offshore Petroleum and Greenhouse Gas Storage Act 2006* (OPGGSA), would be subject to a form of validation by a reputable classification society at the time of design and construction, and subsequently on an ongoing basis, resulting in marine/class certificates being issued for the vessel.

If such a vessel is a proposed **facility** under Clause 4 of Schedule 3 to the Act, then the operator of such a facility may be requested to provide a validation, as mentioned earlier and as detailed in OPGGS(S) Regulation 2.40. The OPGGS(S) Regulations require NOPSEMA and the operator to agree the scope of validation for the facility, prior to submission of the safety case for the facility. As part of this agreement, NOPSEMA should ensure that the operator understands what is expected by way of the validation deliverable. In general terms, the validation must:

- address all elements of the agreed scope of validation
- be compliant with OPGGS(S) Regulation 2.40, and be supported by information with respect to the validator, in accordance with OPGGS(S) subregulation 2.40 (5).

The operator of a facility for which a validation is requested, and that is subject to marine classification, may claim that the class certification serves to address the validation requirement, (i.e. satisfy the requirements of OPGGS(S) subregulation 2.40 (2) or 2.40 (3) and (4)), for the facility, assuming that the validator meets the requirements of OPGGS(S) subregulation 2.40 (5). However, typically class certificates do not adequately address all of the safety-critical elements requiring validation and therefore often represent only part of the overall validation package.

In addition, compliance with OPGGS(S) subregulation 2.40 (5) must be separately established including competence, access to data, ability to form an independent opinion. Typically marine vessel classification societies include organisations such as Lloyds Register, DNV, ABS or BV and are members of the International Association of Classification Societies (www.iacs.org.uk).

It should be recognised that the class certification of a vessel may not apply to all elements of that vessel, but be limited to certain marine aspects. Alternatively, as is sometimes the case with MODUs, the class

certification may extend to include certain aspects of the drilling equipment. Further, it should be recognised that some class certification is against old or outdated codes that have since been replaced by newer codes or standards that provide for better safety outcomes.

When setting out to agree a scope of validation for facilities subject to marine classification, it is useful for NOPSEMA to be aware of the extent and type of marine classification certification that is applied. This discussion must occur at the scope of validation agreement stage and can only come from direct discussion with the operator. NOPSEMA inspectors should request the operators of such facilities to explain, clarify and provide documentary evidence as required, in order to determine the extent and appropriateness of the marine classification certification in the context of validation.

When agreeing the scope of validation for facilities subject to marine classification, the marine classification certification may be accepted as providing the reasonable level of assurance that those elements of the vessel to which they apply incorporate measures to protect the health and safety of the facility, as required by the Regulations. However, where outdated or otherwise inappropriate codes or standards are applied, NOPSEMA may not agree to the proposed scope of validation and may request that the facility is validated against newer more appropriate codes or standards.

For a proposed facility of this type, it may be preferable for the operator to engage an independent competent third party validator to consider all of the identified safety-critical elements of the facility, and to form a view on the likelihood that the proposed facility will be able to meet compliance with appropriate codes, standards and class rules. This is particularly pertinent to older vessels that are about to enter the regime for the first time and that may carry classification against older codes and standards. In this way, the validation deliverable may be restricted to a simple certificate or statement from an independent validator, rather than a collection of marine certificates, supported by validator statements with respect to the elements of the vessel identified in the scope that are not covered by marine certification.

In summary, in agreeing the scope of validation, the operator should discuss with NOPSEMA; the extent of the marine classification certificates, the appropriateness of those codes and standards, and the elements of the design, fabrication and construction of the vessel to which they apply.

4.6.7 Validation and saturation diving systems

Experience has shown that portable saturation diving systems have more hardware and equipment issues, from a safety viewpoint, than do permanently installed diving systems. Permanently installed diving systems are usually built to class society rules and maintained in class with a classification society. Portable systems are not commonly 'in class', whereas those installed permanently in Diving Support Vessels (DSVs) are usually in class with the same classification society as the vessel classifying society – though not necessarily so. Diving systems that are maintained in class have additional ongoing third party verification over and above what most diving companies and vessel companies provide for with portable diving systems; such as:

- class must be involved in the installation
- periodic surveys
- any changes must be agreed to by Class
- maintenance of comprehensive certification for all elements of the system.

As mentioned earlier, operators of proposed facilities planning to enter the regime will be subject to the validation requirements of the regulations, and the scope of validation must be agreed before submitting

the safety case for the facility. Where these proposed facilities have diving systems installed, the diving system should also be included in the scope of validation.

Where an operator proposes to install a saturation diving system on an existing facility then this modification constitutes a significant change (or modification) triggering a safety case revision, and hence will be subject to validation. Diving systems that are designed, built and maintained in class should be able to meet the requirements for validation. Diving systems that are not maintained in class with a classification society may require more extensive validation and will be considered on a case-by-case basis.

Operators intending to install diving systems on existing facilities should engage with NOPSEMA at the earliest opportunity to discuss the validation expectations.

4.6.8 Validation of well testing equipment

The proposed installation on a facility of well test equipment, generally including such items as process separators, surge tanks, steam generators, choke manifolds and high pressure piping, is deemed to constitute a *proposed modification* within the scope of OPGGS(S) subregulation 2.30 (1)(b)(ii) thereby triggering a requirement for a revision of the facility safety case.

Similarly, such a *proposed modification* is deemed to be within the definition of significant change stipulated within OPGGS(S) subregulation 2.40 (1)(b) thereby enabling NOPSEMA to require the operator to provide a validation in respect of the proposed significant change to the facility. As a matter of policy, NOPSEMA has determined that it shall request a validation in every such instance.

Example: Scope for well testing equipment on a MODU

The scope of validation is based on input from each phase of the well test package design. It includes input from risk assessments, formal safety assessments, design reviews and engineering interfaces for contractor equipment.

The Well Test Design Document is the principal document in which the (well test package) (temporary production Package) (Bleed of package) design is captured, and includes (but is not limited to) most of the scope items listed below:

- Modifications to the MODU structure (if any) from installing the well test package
- Fire and gas detection systems suitable for well testing operations
- Emergency shut down systems associated with the well test package
- Fire protection systems (both active and passive) required for well test operations (deluge, fire monitors, fire extinguishers, fire blankets and AR-AFFF trollies)
- Re-zoning of hazardous area classifications due to the placement of the well test package
- The validator will review the appropriateness of the hazardous areas classification/zoning
- Introduced or additional electrical equipment for hazardous areas (Ex - Explosion proof)
- Emergency communications system including radios, rig communications systems and the Public Announcement (PA) system
- Equipment specifications, specifically to verify design suitability, including manifolds, pipework, pressure vessels, steam exchangers & generators and electrical equipment
- The validator shall comment on the appropriateness of the codes and standards that are selected for design, construction and installation of the Safety Critical Equipment (SCE). This entails providing assurance that the SCE are being designed, constructed and installed to codes and/or standards that are the most appropriate to the intended service condition of the SCE.
- Review of design calibration settings for safety critical equipment (e.g. pressure vessels and pressure piping), including the proposed settings for all PSVs and PSH switches
- System throughput and back pressure calculations
- Relief line sizing calculations
- Relief line routing and relief exit points
- Layout plan of proposed equipment and location on the MODU
- Escape routes from the well test area to the temporary refuge and between the temporary refuge and muster stations
- Well test package maximum weights against the facility safe deck load limits. Deck load calculations
- Well test instrumentation, process layout and process control systems
- Design criteria
- Hazardous goods inventory and location including banded storage
- Chemical injection systems
- Noise and heat radiation calculations and management plans. The validator will assess the noise and heat calculations and ensure the cooling system proposed is adequate to achieve required cooling effect.

The design review shall evaluate the surface well test package and design processes against industry recognised codes and standards.

4.7 The validator

OPGGS(S) subregulation 2.40 (5) requires that the operator submits information on the validator in addition to the actual validation. An operator may choose to incorporate such material into the validation deliverable, however it should be recognised that it is beneficial to the operator for NOPSEMA to be assured of the validator's independence, competency and ability, and that he/she will have appropriate access to data, prior to the validation being delivered. This may therefore be included in the scope of validation and submitted to NOPSEMA for agreement.

Note that OPGGS(S) subregulation 2.40 (5) relates to a person who undertakes validation. This is taken to mean both the individual(s) and the validation organisation. The following subsections indicate the information which the operator may be expected to provide in order to satisfy subregulation 2.40 (5).

4.7.1 Competence and ability

The operator must satisfy NOPSEMA that each person who undertakes the validation is competent and able to do so. The operator may demonstrate this by:

- describing the process for the operators' selection of the validator(s).
- describing the operators competency criteria for validator(s).
- assessing the competency of the validator(s) against the above criteria.

4.7.2 Access to data

The validator should confirm in his report that he has had sufficient access to the necessary information to allow him to make his decision.

4.7.3 Independence

The validator must be sufficiently independent to form an impartial opinion on the matter. The operator may demonstrate this by providing:

- evidence of the validator being, or being employed by (in the case of an individual), an independent organisation which was not involved in the design, manufacture, construction or installation of the equipment being validated (e.g. validation certificate issued through Lloyd's or ABS); and
- evidence of the validator being, or being employed by (in the case of an individual), an organisation separate to the operator (e.g. a copy of the validation contract between the validator, or validator's organisation and the operator); or
- if the validator is directly employed by an organisation providing validation and design (or fabrication or installation) services:
 - documentary evidence that the company has not been involved in the design, fabrication or installation of the validated equipment.
 - a written statement from the validator confirming his independence (e.g. that he was not involved in the design, fabrication or testing of the validated equipment and that he was not under pecuniary or any other pressure to produce positive validation).

Note: a validator working for an operator or an organisation involved in the design, fabrication or installation of the validated equipment (even if the validator is working in a unit separate to the design, fabrication or installation division, department or branch etc.), is not considered sufficiently independent.

4.8 The validation deliverable

It could be envisaged that the validation may be delivered in two forms:

1. For proposed facilities, or for significant changes to existing facilities, with a clearly identified scope of validation, the validation deliverable may be in the form of a report containing a statement or set of statements, indicating that:
 - for the safety-critical elements of the facility selected for validation the design, construction and installation codes and standards applied in relation to a facility are appropriate.
 - that if these codes and standards are used, then the design, construction, and installation of the facility will incorporate measures that will protect the health and safety of persons at the facility and are consistent with the formal safety assessment for the facility, where appropriate.
 - where there are no identified applicable codes or standards for the safety critical elements of the facility selected for validation the relevant safety studies, analysis reports and safety documents applied in relation to a facility are appropriate and if these relevant safety studies, analysis reports and safety documents are used, then the design, construction, and installation of the facility will incorporate measures that will protect the health and safety of persons at the facility and are consistent with the formal safety assessment for the facility, where appropriate.
2. For more complex facilities a two tier validation approach may be used with the submission of a validation report containing:
 - a section with the specific items and areas being validated, and certification/validation reports issued, by discipline validators (e.g. pressure equipment validators)
 - another section with the lead validator's report providing an overall validation with respect to the agreed scope of validation (based on the certification and validation reports issued by the discipline validators) as per regulation 2.40.

Initial discussions with the operator and NOPSEMA may agree that only the lead validator's report needs to be submitted for review subject to the discipline validators' reports being available for review if requested. It is important to note that the validation delivered to NOPSEMA must satisfy the requirements of the legislation, i.e. OPGGS(S) subregulation 2.40 (2), 2.40 (3), and 2.40 (4).

No conditions: NOPSEMA, as a matter of policy (except for exceptional circumstances), does not grant conditional acceptances of safety cases. As a review of the validation is one of the factors to be considered in making a decision on safety case acceptance, it follows that any conditions in a validation submission would mean NOPSEMA would not be able to accept the safety case.

5 Other Matters

5.1 Validation of different facility types:

Type of facility	Activities considered	Safety Case	Validation and Other Issues
Large fixed platform	In-situ installation of jacket	Platform Installation Safety Case.	Validation of any safety-critical elements associated with MAEs identified for the installation of the jacket and for subsequent use of the jacket (i.e. structural integrity), e.g. Validation of pile driving, launching off a barge, etc.
	Installation of topsides, non-hydrocarbon commissioning	Platform installation Safety Case. Note may be same document as above or may be a formal revision to the above document.	Validation of any safety-critical elements associated with MAEs identified for the installation of topsides and for subsequent use of the topsides (i.e. process integrity), e.g. validation of lifting equipment, platform structure, process equipment, etc.
	Operations, including hydrocarbon commissioning	Platform Operations Safety Case. May be a revision to the above Installation Safety Case or a new Safety Case if the submission is to address all of the above activities i.e. multiple stages in the life of the facility.	<p>If this is a new safety case submission, validation of the design, construction and installation of the identified safety-critical elements of the facility is required to be complete.</p> <p>If this is a revised safety case just for the operations stage in the life of the facility, then validation should have been appropriately addressed during previous safety case submission(s).</p> <p>Separately, and as a content requirement of the safety case, the operator should describe how the operator ensures that safety-critical elements will be variously fit for purpose, or fit for its function and use, for the operations stage in the life of the facility.</p>

Type of facility	Activities considered	Safety Case	Validation and Other Issues
New FPSO facility (note facility extends to include subsea equipment)	Installation of subsea equipment, moorings risers, etc.	Installation Safety Case.	Validation of safety-critical elements relative to the installation stage in the life of the facility and for subsequent use of this equipment.
	Hook up of subsea equipment to floating buoy, arrival of FPSO and non-hydrocarbon commissioning	Installation Safety Case. Note may be same document as above or may be a formal revision to the above document.	Validation of the balance of the identified safety-critical elements.
	Hydrocarbon commissioning and operations	Operations Safety Case. Considered a formal revision to the above Installation Safety Case or a new Safety Case if the submission is to address all of the above activities i.e. multiple stages in the life of the facility.	<p>If this is a new safety case submission, validation of the design, construction and installation of the identified safety-critical elements of the facility is required to be complete.</p> <p>If this is a revised safety case just for the operations stage in the life of the facility, then validation should have been appropriately addressed during previous safety case submission(s).</p> <p>Separately, and as a content requirement of the safety case, the operator should describe how the operator ensures that safety-critical elements will be variously fit for purpose, or fit for its function and use, for the operations stage in the life of the facility.</p>
New MODU or existing MODU new to Australian waters	General drilling operations	Operations Safety Case.	<p>Validation of the design, construction and installation of the identified safety-critical elements of the facility is required to be complete.</p> <p>Separately, and as a content requirement of the safety case, the operator should describe how the operator ensures that safety-critical elements will be variously fit for purpose, or fit for its function and use,</p>

Type of facility	Activities considered	Safety Case	Validation and Other Issues
			<p>for the operations stage in the life of the facility.</p> <p>Marine certification may apply to some of the identified safety-critical elements of the facility.</p> <p>Validation of safety-critical elements of the facility that are not covered by Class certificates, and any modifications made in shipyard, need to be taken into consideration.</p>
Existing MODU working in Australian waters	Temporary, recurring, modifications - well testing	Formal revision to existing Operations Safety Case in force. Note installation of well test equipment is deemed a significant change to an existing facility, thereby triggering a revision.	<p>Validation of the design, construction and installation of the significant change (the well test equipment) is required to be complete.</p> <p>Separately, and as a content requirement of the safety case, the operator should describe how the operator ensures that safety-critical elements will be variously fit for purpose, or fit for its function and use, for the operations stage in the life of the facility.</p>
Marine vessel undertaking construction / installation activities	Installation of the component parts of a host facility, e.g. vessel installing subsea elements of an FPSO development.	Operations Safety Case.	<p>Validation of the design, construction and installation of the identified safety-critical elements of the facility is required to be complete.</p> <p>Separately, and as a content requirement of the safety case, the operator should describe how the operator ensures that safety-critical elements will be variously fit for purpose, or fit for its function and use, for the operations stage in the life of the facility.</p> <p>Marine certification may apply to some of the identified safety-critical elements of the facility.</p>
Pipelines in Commonwealth Waters	Design, construction (e.g. welding)	Construction and Installation Safety Case.	Validation of the design, construction and installation of the identified safety-critical elements of the facility is required to be

Type of facility	Activities considered	Safety Case	Validation and Other Issues
	and laying of the pipeline.		complete. That is, despite the fact that there may be few (if any) MAEs identified for the construction and installation stage in the life of a pipeline, the validation must address the safety-critical elements of the pipeline facility for the operations stage in the life of the pipeline. This is because Regulation 2.40(1) only allows NOPSEMA to require a facility operator to provide a validation in respect of a proposed facility or a proposed significant change to an existing facility (e.g. generally modification or decommissioning). Consequently, once a pipeline has been constructed and installed, there is generally no legal provision for NOPSEMA to request a validation of a proposed significant change.*

* Note: In this context, a proposed significant change to an existing facility is generally considered a modification or decommissioning. The only exception to this is in circumstances where a facility may have been designed to meet certain requirements, but at the point of initial safety case submission the operator did not contemplate the activity for which the facility was designed.

6 Critical success factors

- The success of this process depends on agreeing a scope of validation that is both effective and deliverable.
- The validation must be aligned with the scope of the safety case that is going to be submitted for assessment subsequent to the agreement.
- Early engagement with the operator, and the validator, is beneficial to ensure that what is delivered to NOPSEMA clearly satisfies the legislative requirements.
- There should be a clear view of what “treatment” is required for each element, such that an unconditional validation report can be provided in a reasonable time frame, and assurance about other matters that require verification are adequately covered in the safety case.