Validation

1. **Purpose**
   
   The purpose of this policy is to provide a documented, systematic and consistent approach to NOPSEMA’s regulation of validation processes.

   This Validation Policy supports and provides detail to the overarching Assessment Policy. This policy should therefore be read in conjunction with N-04000-PL0050.

2. **Scope**
   
   This policy applies to all scopes of validation and validation statements submitted to NOPSEMA under the Commonwealth Offshore Petroleum and Greenhouse Gas Storage (Safety) Regulations 2009 [OPGGS(S) Regulations] and the relevant State and Northern Territory equivalents, where powers have been conferred on NOPSEMA (currently only Victoria).

3. **Relevant legislation**
   
   The Commonwealth Offshore Petroleum and Greenhouse Gas (Safety) Regulations 2009 and, in particular, OPGGS(S) Regulations 2.24, 2.26, 2.30, 2.34 and 2.40 are relevant to validation.


   It should be noted that, dependant on the location of a facility, State or Territory legislation may apply which may or may not mirror the Commonwealth legislation. For simplicity this policy only makes explicit reference to the Commonwealth legislation; however, the policy will be applied equally, regardless of jurisdiction, in jurisdictions where the legislation confers powers on NOPSEMA.

4. **Validation Policy**
   
   For the sake of this policy NOPSEMA has defined the word Validation to mean:

   A process undertaken by an independent competent party, namely the Validator, to provide assurance to NOPSEMA that the design, construction and installation of safety-critical systems incorporate measures that will protect the health and safety of persons at or near the facility, and (in the case of a proposed facility) are consistent with the formal safety assessment for 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 agreed between NOPSEMA and the Operator.

   From NOPSEMA’s perspective validation deals with hardware, firmware and software whereas the safety case pertains to the facility and the activities conducted at the facility.

4.1 **When is validation required?**

   NOPSEMA shall request a validation in respect of all proposed facilities and all significant changes to a facility. Validation cannot be requested if a safety case revision is triggered for any other reason. For example, 5-year revisions of safety cases without significant change or modification do not require validation.
4.2 Agreeing the scope

Prior to NOPSEMA agreeing the scope of validation the following should be considered:

- It is expected that the scope of validation contains an overview of the proposed new facility or modification, and which particular stage in the life of the facility the scope relates to;
- It is expected that a systematic process is demonstrated for the selection of the safety critical systems to be validated, and these systems clearly identified in the scope (Note 1);
- For each safety-critical system included for validation the relevant code(s) or standard(s) should be identified;
- The agreed scope of validation should cover the design, construction and installation of any new, or modified, safety-critical equipment, including hardware, firmware and software systems;
- Demonstration of validator selection process, evidence of their independence and competence and that they will have free access to data;
- The scope of validation should contain provision for the validator to assess the appropriateness of the codes and standards identified to be met for each safety-critical system; and
- It is expected that a clearly defined deliverable is identified which states that the items being validated satisfy the requirements of Regulation 2.40.

When a scope of validation is agreed, NOPSEMA shall confirm in writing.

Note 1: NOPSEMA generally propose, as a minimum, that the operators use the safety-critical systems identified in the validation matrix (N-04200-FM0325), as the basis for the scope of validation.

NOPSEMA also encourages operators to use of a Proposed Scope of Validation Submission Cover Sheet (N-04200-FM0880) when making submissions of proposed scopes of validation.

4.3 Submission timing

An operator must not submit a safety case or revised safety case (where that revision relates to modification or decommissioning) for a facility unless the operator and NOPSEMA have agreed the scope of validation, except in the case of an ‘early engagement’ submission made under OPGGS(S) Regulation 2.24 (5). NOPSEMA may return safety cases to the operator, if submitted ahead of the agreement on the scope of validation.

4.4 Assessment of the documentation provided for a validation

The operator must assess whether the person(s) undertaking the validation (the Validators) meet the criteria specified in OPGGS(S) Regulation 2.40 (5) and the validation complies with OPGGS(S) Regulation 2.40. The operator must then provide sufficient documented information to provide a reasonable level of assurance to NOPSEMA that the above requirements have been met.

In considering the appropriateness of the Validator(s) in respect of competence, ability and access to data, NOPSEMA shall consider the documentation provided by the operator that addresses both the processes employed by the operator to establish the appropriateness of the Validator(s) and the output of these processes.

In terms of the validation deliverable, received as part of the safety case assessment process, NOPSEMA shall consider the extent to which the validation statement matches the agreed scope of validation and provides reasonable assurance that the measures will be incorporated to protect the health and safety of persons at the facility and, where applicable, such measures are consistent with the formal safety assessment for the facility.