

# D05-02d6

## ASSESSMENT OF VALIDATION AND VERIFICATION BODIES

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## 1 PURPOSE

The purpose of this annex to D05-02 is to determine the scope and manner of assessment specific to assessing validation/verification bodies (V&V bodies) pursuant to SIST EN ISO/IEC 17029 and the accompanying validation/verification programmes.

To this end, the following concepts from SIST EN ISO/IEC 17029 shall be used:

**"claim"** – information declared by the client. The claim is the object of conformity assessment by validation and verification. The claim can represent a situation at a point in time or could cover a period of time. The claim can be provided in the form of a report, a statement, a declaration, a project plan, or consolidated data.

**"validation"** – confirmation of a claim, through the provision of objective evidence, that the requirements for a specific intended future use or application have been fulfilled. Objective evidence can come from real or simulated sources. Validation is applied to claims regarding an intended future use based on projected information (confirmation of plausibility).

**"verification"** – confirmation of a claim, through the provision of objective evidence, that specified requirements have been fulfilled. Verification is considered to be a process for evaluating a claim based on historical data and information to determine whether the claim is materially correct and conforms with specified requirements. Verification is applied to claims regarding events that have already occurred or results that have already been obtained (confirmation of truthfulness).

## 2 FOCUSES IN ASSESSING VALIDATION/VERIFICATION BODIES

The assessment of V&V bodies refers to the scope of accreditation in the fields defined in the application for accreditation or in the Annex to Accreditation Certificate.

The assessment shall include assessment of the head office of the V&V body and of the dislocated sites where the key activities take place, and witnessing of the performance of validation and verification when it is performed on the clients' premises.

### 2.1 Head office or dislocated sites

During assessment on the head office of the V&V body or its dislocated sites, the assessment team shall, in addition to general assessment techniques, primarily use the following techniques: review of records, review of system documents, and interviews with the V&V body's personnel. In particular, the assessors shall focus on the following:

- status of the V&V body, assurance of independence, identification of risk to impartiality, assessment of risk to impartiality, top management commitment to ensure impartiality;
- V&V body's organisational structure, committees;
- appropriate separation between functions of validation and verification, any consulting and other activities, when more than one such activity is performed by the same V&V body;
- insurance;
- knowledge and correct understanding of validation/verification programme/s;
- compliance of the quality management system with the requirements of the conformity assessment standard (SIST EN ISO/IEC 17029, Clause 11);

- appropriateness of the competence criteria (specific for each validation/verification programme) for the personnel involved in the validation/verification processes (for all functions, e.g. for: review of application, selection of personnel, planning, independent review of the decision process documentation, dealing with complaints/appeals);
- procedures for training/maintaining personnel's competence, monitoring their performance;
- selection of the validation/verification personnel;
- appropriateness of validation/verification procedures, validation/verification phases, planning;
- implementation of key activities at dislocated sites;
- effectiveness of the control system for sites where critical activities take place, if relevant;
- control and maintenance of records with the purpose of demonstrating effective carrying out of the validation/verification process. The validation/verification documentation shall include the following: application documents and evidence of application review; planning; sampling method; working materials from client's site visit, and other materials used in validation/verification; documentation supporting the conclusions of the validation/verification statement; and any report as evidence that the documentation of validation/verification has been reviewed by an independent reviewer; decision on validation/verification;
- review and preparation of validation/verification statement;
- proceeding in the case of discovering any facts after the issue of the validation/verification statement;
- making reference to validation/verification statement and use of marks;
- appropriateness of subcontractors, where relevant;
- accessibility of information, protection of confidentiality;
- making reference to accreditation;
- any other provisions of the validation/verification programme.

## **2.2 Assessment of environmental claim validation/verification bodies**

When assessing the conformity of environmental claims, the validation/verification bodies shall consider, in addition to the requirements of SIST EN ISO/IEC 17029, also the requirements of SIST EN ISO 14065, and the requirements specified in the defined programme. In the case of the EU ETS programme (see item 2.2.1), also the Commission Implementing Regulation (EU) 2018/2067 with amendments, and other relevant standards shall be taken into consideration, in addition to the above-mentioned standards.

In assessing an environmental information validation/verification body, the following shall be checked in addition to that stated under item 2.1 above:

- responsibility for its activities carried out within the framework of AUP ("agreed-upon procedures"), and for the reports on actual findings, issued as a result of using this procedure;
- fulfilment of ethical requirements for personnel (SIST EN ISO 14065, Clause 4);
- procedure for defining competence for each programme and sector;
- fulfilment of competence requirements by verifiers/validators, technical experts and reviewers (SIST EN ISO 14065, items 7.3.4 – 7.3.9);
- assurance of access to the relevant (internal/external) knowledge for consultation in relation with the programmes (SIST EN ISO 14065, Annexes D, E and F);
- manner and frequency of monitoring the personnel;

- subcontracting and description of the scope of subcontracted work;
- the validation/verification process, determining the scope of the business (e.g. verification, validation, AUP, or a combination thereof);
- planning and preparation of strategic analysis to define the scope of validation/verification; assessment of risk of noncompliance with the criteria; including information on the level of assurance and materiality;
- review of documentation by an independent person, the review contents;
- decision-making procedure, decision maker, decision on a claim or a report of actual findings (AUP);
- preparation and issue of validation/verification statement, the contents;
- availability of information on the process;
- rules on making reference to validation/verification, and use of marks;
- compliance with IAF MD 6.

### **2.2.1 EU ETS programme: Verification of greenhouse gas emission reports pursuant to Commission Implementing Regulation (EU) 2018/2067 with amendments**

To this end, the following definitions from Commission Implementing Regulation (EU) 2018/2067 shall apply:

"**verification**" means the activities carried out by a verifier to issue a verification report pursuant to Commission Implementing Regulation (EU) 2018/2067;

"**verifier**" means a legal person or another legal entity carrying out verification activities pursuant to Commission Implementing Regulation (EU) 2018/2067 and accredited by a national accreditation body pursuant to Regulation (EC) No 765/2008 and Commission Implementing Regulation (EU) 2018/2067, or a natural person otherwise authorised, without prejudice to Article 5(2) of Regulation (EC) No 765/2008;

"**EU ETS auditor**" means an individual member of a verification team responsible for conducting a verification of an operator's or aircraft operator's report other than the EU ETS lead auditor;

"**EU ETS lead auditor**" means an EU ETS auditor in charge of directing and supervising the verification team, who is responsible for performing and reporting on the verification of an operator's or aircraft operator's report;

"**technical expert**" means a person who provides detailed knowledge and expertise on a specific subject matter needed for the performance of verification activities for the purposes of Chapter III and for the performance of accreditation activities for the purposes of Chapter V of Commission Implementing Regulation (EU) 2018/2067;

"**operator's or aircraft operator's report**" means the annual emission report to be submitted by the operator or aircraft operator pursuant to Article 14(3) of Directive 2003/87/EC; the tonne-kilometre report to be submitted by the aircraft operator for the purposes of applying for the allocation of allowances pursuant to Articles 3e and 3f of that Directive; the baseline data report submitted by the operator pursuant to Article 4(2) of Delegated Regulation (EU) 2019/331; or the data report submitted by the operator pursuant to Article 5(2) of Regulation (EC) No 765/2008.

In assessing verifiers on greenhouse gas emission reports, the following shall be checked in addition to that stated under items 2.1 and 2.2 above:

- appropriateness of the competence criteria for EU ETS auditors, technical experts, independent reviewers (specific for the programme); normally, an interview shall also be conducted with the EU ETS auditor (Commission Implementing Regulation (EU) 2018/2067, Articles 36 – 40, EA-6/03 M, IAF MD 6);
- competence for verifying baseline data reports, new entrant data reports or activity level annual reports (Commission Implementing Regulation (EU) 2018/2067, Article 37, Commission Implementing Regulation (EU) 2020/2084);
- carrying out the verification procedure (pre-contractual obligations, determining the time (EA-6/03 M), strategic analysis, risk analysis, verification programme, preparation of internal documentation, verification reports ...);
- meeting the conditions for site visits not being carrying out;
- simplified installation verification;
- carrying out virtual site visits (Regulation (EU) 2020/2084) and its approval by the Competent Authority;
- review and preparation of verification statement, any facts discovered after the issue of the verification report and written statement (Commission Implementing Regulation (EU) 2018/2067, Article 27, ISO 14064-3, EA-6/03), baseline data reports, new entrant data reports, activity level annual reports;
- compliance with the requirements of EA-6/03 M, and other documents issued by EU, DG Clima;
- compliance with SIST EN ISO 14064-3, ISO 14066;
- rules for replacing lead auditors in aircraft operators;
- where relevant, a surveillance report of the performance of an accredited verifier carrying out verification in another Member State;
- conducting verifications abroad;
- implementation of key activities at dislocated sites;
- effectiveness of the control system for sites where critical activities take place, if relevant;
- cooperation with the Competent Authority (Ministry of Environment, Climate and Energy – MOPE).

### **3 SCOPE OF ASSESSMENT (WITH RESPECT TO THE FULL SCOPE OF ACCREDITATION)**

#### **3.1 Vertical audits**

As part of the initial assessment and reassessments in individual validation/verification programme of a V&V body, the assessors shall carry out altogether at least three vertical audits. In their selection, the cases of multi-site organisations and cases of validation/verification processes conducted abroad shall be taken into consideration.

At regular surveillance visits, at least one vertical audit per individual validation/verification programme shall be carried out to ensure that all accreditation fields are checked within one accreditation cycle. The vertical audits performed, including information on the field and programme, shall also be documented in the Witnessed and Vertical Audits Plan (OB05-66).

In the case of the **EU ETS programme**, one vertical audit shall be carried out, when possible (when the verifier has a client), in initial assessment for each activity group from the scope of accreditation (1-

12, 98, 99). At each surveillance, vertical audit shall be carried out for the activity group 1a or 1b, when these are within the scope of accreditation. In further 3 surveillances and reassessment, the performance of vertical audits shall be planned so that they are carried out for each activity group from the scope of accreditation within the framework of one accreditation cycle. Normally, cases of operators of installations that emit a large amount of emissions and complex emissions (including process emissions), shall be chosen. Correctness of calculation of the amount of total emissions based on original documents/data (cross-checking) should be verified in least one vertical audit as part of the initial assessment. Thereafter, such calculation shall be made at least once every two years. The procedure can be carried out in the case of vertical audit or in the case of a witnessed audit.

In selecting cases for vertical audits, the planned witnessing of performance of verifications shall also be considered to ensure equal representation of the accreditation activity in the sample being assessed.

When the verifier applies for an extension of the scope of accreditation to a new activity group, their competence shall be assessed, and a vertical audit shall be carried out on the scope of accreditation applied for.

### **3.2 Witnessing the performance of verification**

Assessing a V&V body while performing validation/verification means establishing whether the validation/verification processes are conducted pursuant to the rules, as recorded in the V&V body's management system and in the V&V programme, whether the validation/verification team members demonstrate proper knowledge and understanding of the validation/verification criteria and have the necessary skills and capabilities for carrying out validation/verification.

Within the scope of initial assessment and reassessment of the V&V body, the representative part of the validation/verification or at least one validation and one verification shall be witnessed, when this is carried out on the client's site within the framework of individual V&V programme. The witnessing and vertical audits plan shall be drawn up by the Sector Manager after initial assessment of the V&V body for the period of one accreditation cycle, and shall be revised, if necessary.

In the case of the **EU ETS programme**, at least one vertical audit shall be carried out, when possible, within initial assessment for the cluster (A-I) defined in the table below. When the verifier does not have a client for the specified cluster, SA shall make a decision as to whether or not to "conditionally" grant accreditation. "Conditional" grant of accreditation is only possible when the verifier informs SA early enough of its intended performance of verification for a "conditionally" granted scope of accreditation, so that SA can carry out the witness audit. In the case of finding any nonconformities during first witnessing for a cluster, SA may suspend or withdraw the accreditation. Should the verifier not be able to get a client to perform the activities for a "conditionally" granted scope till the end of accreditation cycle, the clients' accreditation for the particular part of scope shall be withdrawn.

For verifying baseline data reports, new entrant data reports, or activity level annual reports within the activity group No 98, the grant of accreditation will not be possible without witnessing the performance of verification.

Within the framework of reassessment, witnessing shall be carried out in at least one activity group. The number and the sector where the witnessing is to take place shall depend on the results of previous witnessing audits, on the complexity of the fields from the scope of accreditation, on the number of

operators and aircraft operators where the verifications are carried out, on the number of EU ETS auditors and EU ETS lead auditors and their experiences in verification.

In the case of extension to a new activity group within one cluster, a vertical audit shall be carried out for that activity group. In the case of extension of accreditation to a new cluster, however, witnessing shall be carried out. When this is not possible, SA shall decide whether or not to grant accreditation anyway, and the above rules shall apply in this situation.

Should the verifier no longer have a client for an activity group, SA shall suspend or withdraw accreditation for that activity, if it is no longer possible to demonstrate competence.

Cluster	Activity Group No.	Scopes of Accreditation / Subgroups
A	1a, 1b, 7	<ul style="list-style-type: none"> <li>- Combustion of fuels in installations, where only commercial standard fuels as defined in Commission Implementing Regulation (EU) 2018/2066 are used, or where natural gas is used in category A or B installations</li> <li>- Combustion of fuels in installations, without restrictions</li> <li>- Production of pulp from timber or other fibrous materials</li> <li>- Production of paper or cardboard</li> </ul>
B	6	<ul style="list-style-type: none"> <li>- Production of cement clinker</li> <li>- Production of lime or calcination of dolomite or magnesite</li> <li>- Manufacture of glass including glass fibre</li> <li>- Manufacture of ceramic products by firing</li> <li>- Manufacture of mineral wool insulation material</li> <li>- Drying or calcination of gypsum or production of plaster boards and other gypsum products</li> </ul>
C	2, 8	<ul style="list-style-type: none"> <li>- Refining of mineral oil</li> <li>- Production of carbon black</li> <li>- Production of ammonia</li> <li>- Production of bulk organic chemicals by cracking, reforming, partial or full oxidation or by similar processes</li> <li>- Production of hydrogen (H<sub>2</sub>) and synthesis gas by reforming or partial oxidation</li> <li>- Production of soda ash (Na<sub>2</sub>CO<sub>3</sub>) and sodium bicarbonate (NaHCO<sub>3</sub>)</li> </ul>
D	3, 4, 5	<ul style="list-style-type: none"> <li>- Production of coke</li> <li>- Metal ore (including sulphide ore) roasting or sintering, including pelletisation</li> <li>- Production of pig iron or steel (primary or secondary fusion) including continuous casting</li> <li>- Production or processing of ferrous metals (including ferro-alloys)</li> <li>- Production of secondary aluminium</li> <li>- Production or processing of non-ferrous metals, including production of alloys</li> <li>- Production of primary aluminium (CO<sub>2</sub> and PFC emissions)</li> </ul>
E	9	<ul style="list-style-type: none"> <li>- Production of nitric acid (CO<sub>2</sub> and N<sub>2</sub>O emissions)</li> <li>- Production of adipic acid (CO<sub>2</sub> and N<sub>2</sub>O emissions)</li> <li>- Production of glyoxal and glyoxylic acid (CO<sub>2</sub> and N<sub>2</sub>O emissions)</li> </ul>
F	10, 11	<ul style="list-style-type: none"> <li>- Capture of greenhouse gases from installations covered by Directive 2003/87/EC for the purpose of transport and geological storage in a storage site permitted under Directive 2009/31/EC</li> </ul>

Cluster	Activity Group No.	Scopes of Accreditation / Subgroups
		<ul style="list-style-type: none"> <li>- Transport of greenhouse gases by pipelines for geological storage in a storage site permitted under Directive 2009/31/EC</li> <li>- Geological storage of greenhouse gases in a storage site permitted under Directive 2009/31/EC</li> </ul>
G	12	- Aviation activities (emissions and tonne-kilometre data)
H	98	- Other activities pursuant to Article 10a of Directive 2003/87/EC
I	99	- Other activities, included by a Member State pursuant to Article 24 of Directive 2003/87/EC, to be specified in detail in the accreditation certificate

Before starting the witnessing of V&V, the V&V body shall submit a validation/verification programme with information on the validation/verification team members, verification/validation location and a validation/verification plan. The assessor shall assess the submitted documents and adjust the assessment accordingly.

In witnessing/assessing the validation/verification team's performance, the assessors shall carefully monitor the following:

- the work/cooperation of the members of the validation/verification team (including observers, interpreters, etc.), management of the team (control of changes to the plan);
- the manner of communicating with the client (initial meeting (its contents); closing meeting (its contents), and control of unpredictable situations);
- knowledge of the validation/verification programme and other relevant documents, validation/verification procedures and techniques (sample selection method, verification of data control, data tracing, etc);
- capability of acquiring material evidence (suitability of questions asked and focus on important requirements);
- the competences of the personnel performing validation/verification to analyse the correctness of data based on which the claim is prepared. Such person shall have the experience and knowledge (training) in the area of assessment/data control and of accounting principles;
- knowledge of international/national requirements for validation/verification according to the programme, and knowledge of the requirements for the competence of client's personnel;
- harmonisation of diverse opinions on findings, and recording of disagreements;
- reporting on findings (correct definition of a finding; nonconformities should not be reported as possibilities for improvement; the finding shall be related to the criterium and evidence);
- duration and appropriateness of the validation/verification programme (relevance of sites and coverage of the scope).

Within two weeks of the concluded validation/verification witnessed by the SA assessors, the V&V body shall submit to SA a validation/verification report, conclusions on the results of validation/verification, and a draft validation/verification statement for the witnessed case. The assessor team shall prepare a Report on the witnessed audit/verification (OB05-43), which shall include information on the assessment of the contents of a subsequently sent report.

During the witnessing of the validation/verification, the assessors shall assess the performance of the entire validation/verification team.



The assessors shall notify the members of the validation/verification team of the results of witnessing immediately after the witnessing, if possible.

#### **4 RECORDS**

Each assessor shall keep records on the conducted assessment on a checklist (OB05-77) in such a way that both the scope and method of assessment of individual elements of the system according to the requirements of the relevant standard, additional requirements, programmes and guidance for validation/verification bodies, as well as any general findings, special notes and reference to established nonconformities are evident. It is particularly important to specify the object of vertical audit (e.g. the validation/verification programme, the interlocutor, the reviewed records and the conclusions).

Technical assessors shall enter into the first table of the form the elements of the system they have assessed horizontally (assessing the adequacy and the effectiveness of system arrangements). These elements shall also be marked in the Horizontal Assessment table.

A mandatory annex to the technical assessor's checklist is the form OB05-43, Report on Witnessed Audit/Verification. The Report shall be prepared separately for each witnessed process.

The information on the Member States in which the verifier is performing verification/validation shall also be kept in V&V body's records.

Once the accreditation process is successfully completed, SA shall issue an Accreditation Certificate with an Annex covering the scope in which the requirements for accreditation were found to be met.

#### **5 SURVEILLANCE OF EU ETS VERIFIERS PERFORMING VERIFICATION ABROAD**

Pursuant to Article 50(5) of Commission Implementing Regulation (EU) 2018/2067, in the case of an accredited verifier performing verification of GHG emissions reports in another Member State, SA may request the national accreditation body of the Member State where the verification is performed to carry out surveillance activities on its behalf.

The procedure shall be carried out in accordance with the cross-border accreditation procedure.

#### **6 ASSESSMENT OF A VERIFIER – HOLDER OF ACCREDITATION CERTIFICATE ISSUED BY A FOREIGN ACCREDITATION BODY – WHEN PERFORMING VERIFICATION TO EU ETS IN SLOVENIA**

Pursuant to Article 50(5) of Commission Implementing Regulation (EU) 2018/2067, the national accreditation body of a Member State that has accredited a verifier may request SA to carry out surveillance activities of the verifier accredited in that Member State when it performs verifications in Slovenia. In that case SA shall agree with the accreditation body of the Member State on the method of surveillance, if any, and shall report its findings to the national accreditation body that has accredited the verifier (Commission Implementing Regulation (EU) 2018/2067, Article 74(1)).

The procedure shall be carried out in accordance with the cross-border accreditation procedure.



## **7 CHANGES WITH REGARD TO PREVIOUS REVISION**

The document has been completely revised; therefore, the changes are not marked. The scope of the document has been expanded to include the standard SIST EN ISO/IEC 17029. The provisions of the new editions of SIST EN ISO 14065 and SIST EN ISO 14064-3 have been included in the changes.

## **8 TRANSITORY PROVISIONS**

N/A

## **9 CONTROL OF THE DOCUMENT**

A valid document shall be located in i4 (SA Information System). A clean copy shall be published on SA website, and available in printed form at SA head office.

Individual copies may be controlled in physical form. The recipients or places of storage shall be shown in records on issuance of the document.

Other printouts and copies of the document shall have informative nature and shall not be considered as controlled copies. The validity of these documents should be checked in i4 or on the SA website.