Application of validation and verification according to EN ISO/IEC 17029 in the EU Legal Framework

	Question / issue	Answer / solution
	APPLICATION ➢ Is validation/verification the suitable conformity assessment activity? ➢ Is a validation/verification body the adequate provider of conformity assessment?	
1.	What is the **object** associated with the stated needs and expectations (specified requirements)?	If the “object” qualifies as **declared information** (claim, report, statement, declaration, project plan, consolidated data, or else) and the applicable requirements relate to the trustworthiness (plausibility, truthfulness, correctness) of this information, it can be a case for **validation/verification as conformity assessment** activity.
2.	What do **validation/verification as conformity assessment** activities provide?	Validation and verification as conformity assessment activities lead to a **statement of conformity**, which either confirms the declared information or which can attest that the given claim could not be confirmed to be plausible or true.
3.	Do validation/verification always result in a **formally attested statement**?	When fully completed, the **decision** on whether or not to confirm the assessed claim is always made. Depending on the applicable set of rules and procedure (the “programme”), the decision can be formally attested for the client on an issued validation/verification statement. When contributing to a different conformity assessment, e.g. product certification according to EN ISO/IEC 17065, the validation/verification statement can also serve as evidence and be issued for the certification body to be taken into account as evaluation result. This applies even though explicit reference to EN ISO/IEC 17029 is not yet included in the 2012 version of EN ISO/IEC 17065.
4.	Does the validation/verification statement have a **temporal validity**?	The statement issued by the validation/verification body does not have a period of validity. In that way it resembles an inspection report/certificate. The statement reflects only the **situation at the point in time** it is issued. It is not issued with a validity date at which the statement would expire.

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5.	Can a validation/verification **statement be withdrawn**?	The statement does **not have an expiry date**, and therefore there is generally no withdrawal or suspension of the statement. However, it might happen that **facts are discovered after the issuance** of the statement that require a revision of the statement and allow for considering withdrawal of the statement in this case.
6.	Do the **specified requirements** apply to declared information (a “claim”)?	The specified requirements shall be laid down in a programme. The requirements shall be applicable to the declared information and relate to its plausibility and truthfulness, respectively. If the assessable requirements **apply rather to a different object than the declared information** itself, this specified entity could be the “object” and a different conformity assessment activity could be more suitable than validation/verification.Examples: − To confirm the claim “This installation is safe!”, the tangible installation itself will have to be inspected according to EN ISO/IEC 17020. − To confirm the claim “This watch is watertight!”, the product itself will have to be tested and/or certified according to EN ISO/IEC 17025 and/or EN ISO/IEC 17065. − To confirm the claim “This workshop is competent in recycling batteries!”, the process or service of recycling will have to be audited and certified according to EN ISO/IEC 17065. − To confirm the claim “Our quality assurance is effective!”, the organisation’s management system will have to be audited and certified according to EN ISO/IEC 17021-1.

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	PROGRAMMES ➢ Description of the declared information to be validated/verified. ➢ Specification of the applicable requirements. ➢ Methodology for performing the validation/verification.	
7.	How can we trust a **verification of a claim** if the claim was also validated but the **result of the validation** was not reached as promised?	The claim that is validated and the claim that is verified are **not the same claim**. Therefore, there is no direct link between those two claims being separate objects of conformity assessment. There is no obligation within the standard to combine validation and verification.
8.	Which **rules and procedures** apply for validation/verification?	The set of applicable “rules, procedures and management” for carrying out validation/verification activities are specified in the so-called **programme**. Validation/verification bodies have to operate a programme, which provides the **specific details** and concrete application for the sector, technical area, legal framework or other defining conditions for the particular validation/verification process. Programmes can be operated at international, regional, national, sub-national or sector-specific level.
9.	What is a “validation/verification **programme**”?	A validation/verification programme (also called “scheme”) is the **collection of specifications**: 1. describing the **claims**, i.e. the “object of conformity assessment”; 2. identifying the applicable **requirements**; 3. providing the **methodology** for performing the validation/verification. A validation/verification programme further specifies the requirements according to the applicable standard (EN ISO/IEC 17029) and can add more or stricter requirements.

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10.	What is the **content** of a validation/verification programme?	A programme to be operated by validation/verification bodies according to EN ISO/IEC 17029 specifies at least: − the **scope** of validation/verification (i.e. the claim to be confirmed and its boundaries as well as reference to the requirements to which the claim is validated/verified), − **competence** criteria for the validation/verification team and body, − **process** steps for executing the validation/verification, − evidence gathering **activities**, − **reporting**. Further details to be given by the programme in addition to the specifications of EN ISO/IEC 17029 include: − the applicable **level of detail** where the standard provides only minimum requirements, − **specifics** where the standard provides only generic requirements, − **choice** of specifications where the standard only provides options, recommendations, or potential requirements. Annex A to EN ISO/IEC 17029 contains elements to be further specified by the programme.

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11.	What **examples** are there of validation/verification programmes?	The validation/verification of declared information plays a role as conformity assessment in the following applications as examples: − Reports on greenhouse gas emissions are verified for trade in the **EU Emission Trading System** (for reference see Directive 2003/87/EC, Regulation (EU) 2018/2067, EN ISO 14065, EN ISO 14064-3); also in the transport sector (for reference see Regulation (EU) 2015/757 for maritime transport and Regulation (EU) 2017/2392 for aviation). − Declared environmental information is validated and verified for assurance of carbon or water **footprints** (for reference see EN ISO 14065, EN ISO 14067, EN ISO 14046) either as final statements or as part of certification schemes, e.g. for products in accordance with EN ISO/IEC 17065. − Claims to adhere to the principle of “do not significantly harm” to the environment according to the Regulation (EU) 2020/852 are validated in Spain in order to apply for funds within the framework of the European Recovery and Resilience Facility. − Verification of reports by undertakings on their sustainability are expected in several legal acts of the EU Green Deal, e.g. the proposed EU Directive on corporate **sustainability reporting** or the proposed EU Regulation on taxonomy. − Validation and verification by bodies according to EN ISO/IEC 17029 can provide assurance within the context of **supply chains** with respect to social, environmental or other ethical claims and the corporate due diligence (for reference see the proposed EU Directive on corporate sustainability due diligence, ISO 22095 and ISO/TS 17033).
12.	**Who sets the rules** and procedures for validation/verification?	Programmes can be legal frameworks, a set of international, regional or national standards, global initiatives, sector applications as well as individual agreements with clients of the validation/verification body. **Programme owner** can be validation/verification bodies themselves, governmental authorities, trade associations, groups of validation bodies/verification bodies, external programme owners or others.

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13.	Can I use a **mark** on the product to show that the claim related to the product was verified?	The use of a mark is voluntary. The mark may only be used in relation to the claim, which has been validated/verified. The **mark shall not give the impression that the product is certified**.
14.	What are "**Agreed Upon Procedures**" (AUP)?	AUP are **verification activities** that result in evidence for confirmation of a claim, but do not complete the functions of conformity assessment, where the gathered evidence is subsequently reviewed for its suitability, adequacy, and effectiveness of evidence to support a decision whether or not conformity with the specified requirements has been demonstrated and therefore can be attested with a validation/verification statement. In that regard, **AUP are not conformity assessment**, hence assurance is not provided. However, the report of results can be valuable. Similarly, the engagement of testing laboratories (according to EN ISO/IEC 17025) or inspection bodies (according to EN ISO/IEC 17020) can be limited to the determination activity only, with reporting on the results but without decisive conclusion and on conformity of the tested or inspected item and the respective attestation.
15.	Can **Agreed Upon Procedures** (e.g. as referred to in ISO 14065) be used in validation/verification programmes, **compliant with EN ISO/IEC 17029**?	− If the **minimum requirements** for the validation/verification process according to EN ISO/IEC 17029 are fulfilled, a programme can make use of Agreed Upon Procedures (AUP) as part of the evidence gathering activities. In this case, the validation/verification body can take the AUP results into account as input to the review of evidence as being sufficient and appropriate for deciding on the conformity of the claim, hence the confirmation of the declared information.
	VALIDATION/VERIFICATION BODIES ➢ Characterisation of validation/verification bodies as "Tool" from the "CASCO Toolbox". ➢ Eligibility of validation/verification bodies as conformity assessment bodies for implementation of Community harmonisation legislation (notified bodies).	
16.	Are validation and verification bodies **conformity assessment bodies**?	Yes, EN ISO/IEC 17029 defines validation/verification bodies in line with the other standards in the CASCO toolbox, such as testing laboratories (EN ISO/IEC 17025), inspection bodies (EN ISO/IEC 17020), and certification bodies (EN ISO/IEC 17021-1, EN ISO/IEC 17024, EN ISO/IEC 17065).

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17.	Can validation/verification bodies be **accredited**?	Yes, EN ISO/IEC 17029 specifies the requirements for technical competence, impartiality, and consistent operation of validation/verification bodies and serves as basis for recognition, such as through accreditation.
18.	Do validation/verification bodies have to be **independent third-parties**?	No, as any conformity assessment body, validation/verification bodies have to act impartially (only perform validation/verification when they are free from bias or conflicts of interest). But validation/verification according to EN ISO/IEC 17029 can be performed by the entity declaring the information to be assessed (first-party), by an entity with user interest in the declared information (second-party), or as by an entity independent of the declaring entity or user interests (third-party). The requirements for bodies providing validation/verification as first-, second-, and third-party bodies are the same with only very few exemptions. The applicable programme, whether specified by a private programme owner or legally provided in the EU regulated framework, can require that validation/verification is provided as a third-party activity by independent bodies.
19.	Do conformity assessment bodies according to EN ISO/IEC 17029 have to be **competent for both, validation and verification**?	No, conformity assessment bodies according to EN ISO/IEC 17029 can be validation bodies only, verification bodies only, or provide both activities.

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