

Rules for inspection according to the European Union Environmental Technology Verification (ETV) Pilot Programme

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CHAPTER 1: GENERAL

These Rules illustrate the procedure implemented by RINA for inspection activities in connection with the pilot programme for European Union Environmental Technology Verification (EU ETV), as well as the procedure which proposers are to follow to request the inspection.

The objective of EU ETV inspection is to provide developers, producers and investors access to independent performance validation of innovative environmental technology through scientifically recognised procedures.

In these Rules, the terms "inspection" and "EU ETV verification" are used as synonyms.

For any issues not covered by these Rules, reference is to be made to the "GENERAL CONTRACT CONDITIONS GOVERNING SYSTEM, PRODUCT AND PERSONNEL CERTIFICATION", which can be downloaded from the web site www.rina.org.

Access to EU ETV inspection is open to all proposers which make a formal request and does not depend on whether they belong to an association or group.

RINA will apply the fees established on the basis of its current tariffs for these inspection activities, and guarantees fairness and uniformity of application.

The terminology used in these Rules is the one contained in the standards and reference documents indicated in Chapter 4.

CHAPTER 2: AIM AND FIELD OF APPLICATION

These Rules establish the criteria and procedures to carry out inspection activities according to the EU ETV pilot programme and management of relations between RINA and applicant proposers.

EU ETV inspections concern innovative environmental technology and consist of an assessment of conformity in relation to the requirements applicable to the contract and to the reference standards and technical documents indicated in Chapter 4 below, by verifying that performance claims put forward by technology developers and manufacturers are complete, fair and based on reliable test results.

To access the EU ETV pilot programme, innovative environmental technology must meet the following criteria:

 To be an environmental technology which is innovative in terms of design, raw materials involved, production processes, use, recyclability or final disposal when compared with relevant alternatives;

- To have the potential to contribute to the efficient use of natural resources and a high level of environmental protection;
- To belong to one of the following technology areas:
 - water treatment and monitoring,
 - materials, waste and resources,
 - energy technologies; and
- To be ready for commercialisation or already commercially available.

CHAPTER 3: DEFINITIONS

The definitions of some terms used in these Rules are given below:

<u>Initial performance claim</u>: a set of technical specifications representative of the technical performance and potential environmental impacts of a technology under specified conditions of testing or use (operational parameters).

<u>Technical Manager</u>: the person who takes full responsibility for ensuring that the verification activities are performed in compliance with UNI CEI EN ISO/IEC 17020:2012.

<u>Proposer</u>: any legal entity or natural person established within the European Union or outside it who requests an inspection activity and on the basis of which the activity is performed. It can be the technology manufacturer or an authorised representative of the technology manufacturer. If the technologies manufacturers concerned agree, the proposer can be another stakeholder undertaking a specific verification programme involving several technologies (for example, as part of pre-procurement procedures).

General Verification Protocol (GVP): means the description of the principles and general procedure to be followed by the EU ETV pilot programme when verifying an innovative environmental technology.

<u>Specific Verification Protocol (SVP)</u>: means the protocol describing the specific verification of a technology as developed applying the principles and procedures of the GVP.

<u>Environmental technologies</u>: all technologies whose use is less environmentally harmful than relevant alternatives.

Innovative environmental technologies: environmental technologies presenting a novelty in terms of design, raw materials involved, production process, use, recyclability or final disposal, when compared with relevant alternatives.

CHAPTER 4 REFERENCE STANDARDS

- General Verification Protocol (GVP), available from the European Commission site
- ISO/IEC 17020 Conformity assessment

 Requirements for the operation of various types of bodies performing inspection
- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
- ACCREDIA RG-01-04 Regolamento per l'Accreditamento degli Organismi di Ispezione

CHAPTER 5 CARRYING OUT EU ETV VERIFICATION ACTIVITIES

5.1 APPLICATION FOR EU ETV VERIFICATION AND ELIGIBILITY CHECK

A proposer is to submit a request in writing for EU ETV verification: the request can also be made by e-mail, to the contact addresses available from the public site www.rina.org.

In order to perform the eligibility check of the technology, RINA sends the proposer a specially prepared form which the proposer is requested to fill in, sign and return to RINA.

On the basis of the information received, RINA makes a short, pre-verification ("Quick Scan") of some of the main characteristics of the technology to be verified in order to:

- Assess the suitability of the technology for inspection;
- Identify the relevant technology group; and
- Give a first indication of the complexity and cost of a full verification.

RINA informs the proposer about the eligibility of the technology, on whether to perform a full verification or not and provides a first indication of costs.

RINA considers a technology ineligible if: it does not fall within the scope of the EU ETV pilot programme; it is not ready to market; or if its performance and innovation levels are obviously too low and would harm the reputation of the EU ETV pilot programme.

Apart from these cases, the decision to proceed is up to the proposer, even when RINA does not recommend performing the verification.

5.2 VERIFICATION PROPOSAL

Following a positive reply from RINA on eligibility of the technology, a proposer who intends to

proceed with EU ETV inspection has to submit a proposal with all the information required.

In order to assist the proposer in preparing the proposal, RINA sends the proposer a specially prepared form ("Verification Proposal"). The proposer fills in and signs the Verification Proposal and returns it to RINA together with the requested documentation.

RINA examines the documentation submitted for compliance with the following:

- The relevant provisions of the GVP; and
- Where relevant, the specific guidance prepared by the ETV technical working groups (EU-TWGs);

and taking due account of:

- Appropriate technical standards or reference documents for the related technology group;
- The key environmental factors (in a lifecycle perspective) identified by the related technical working group;
- Protocols prepared for similar technologies in the EU ETV pilot programme;
- Where appropriate, the relevant part of protocols prepared in ETV programmes of third countries or in pilot or research projects; and
- Any recommendations from the advisory forum.

RINA may ask the proposer to revise or complete the Verification Proposal.

RINA prepares a quotation: it provides a detailed cost estimate on the basis of the expected workload for the service offered, together with a list of potential tests and analyses to be performed.

On receipt of acceptance of the quotation and of the signed order, following a preliminary review to check they are complete, RINA will inform the proposer that the order has been accepted.

On the basis of the contract and technical reference documents, RINA plans the inspection activities and defines the audit team, identifying qualified and independent verifiers to carry out the inspection.

The names of the verifiers who will be part of the audit team are communicated to the proposer who may ask, in writing, for them to be replaced, giving its reasons.

5.3 DEFINITION OF SPECIFIC VERIFICATION PROTOCOL

The proposer and the verification team are responsible for defining the SVP on the basis of the provisions of part B of the GVP and of any

relevant document provided in the EU ETV pilot programme through the technical working groups or steering group.

The proposer prepares a first draft of the SVP and submits the draft to the verification team.

The SVP is also examined by external, qualified and independent technical experts.

The names of the external technical experts are communicated to the proposer who may ask, in writing, for them to be replaced, giving its reasons.

In order to define the SVP, agreement has to be reached with the proposer on the performance parameters (i.e. the revised performance claim), on the type of tests, on data quality and on requirements on test data, measurement and calculation.

RINA requires the proposer's formal acceptance of the Final Revision of the SVP.

In the case of a disagreement between the Verification Body and proposer or another party in relation to the ETV pilot programme, the relevant technical working group may be asked by the Commission services, the Verification Body or the other party for an opinion. If the Verification Body decides not to follow the opinion of the technical working group, a detailed report justifying this decision should be addressed to the Commission services and to the accreditation body having accredited the Verification Body for the ETV pilot programme. The Commission services or the accreditation body (ACCREDIA) may decide appropriate measures on the basis of this report. In any case, RINA reserves the right to terminate the contract in the case of non-acceptance of the Statement of Verification by the proposer within 3 months from RINA approval, requiring payment for the activities carried out, according to the contractual agreement.

5.4 ASSESSMENT OF EXISTING DATA

The proposer provides the verification team with the available technical documentation on existing data, i.e. data obtained prior to approval of the SVP. The team assesses the acceptability of the data submitted in relation to the SVP and to the data quality required. If necessary, the verification team may ask the proposer for additional tests to conform to the SVP.

RINA carries out an initial assessment of the supporting evidence backing the performance claim given in the proposal, which also includes acceptability of the test data submitted and determines whether additional tests or measures are necessary to comply with the requirements of the verification under the EU ETV pilot programme, as indicated in the SVP.

RINA will decide on acceptance and/or the need for additional tests.

5.5 ASSESSMENT OF THE TEST BODY

In the cases required by the GVP, the verification team conducts an audit on the Test Body. In the case of an unfavorable outcome of the audit, the Proposer has three options:

- To require RINA to perform an additional audit before going ahead with the testing phase (this additional activity requires a new contractual agreement);
- To make use of a different Test Body (accredited under ISO 17025 for methods within the relevant area of analysis); and
- To make use of a different Test Body (not accredited under ISO 17025 for methods within the relevant area of analysis); also in this case an additional audit is necessary before going ahead with the testing phase (this additional activity requires a new contractual agreement).

5.6 TESTS AND TEST PLAN

If additional tests are necessary, the proposer has to designate one or more test bodies.

The proposer may perform the necessary tests inhouse. In this case, the test plans, all preparatory measures such as sampling and the tests themselves are prepared and implemented in agreement with and, if necessary, witnessed by an independent test body.

The Test Body or the proposer, in the case of tests carried out in-house, prepares the "Test Plan", performs the tests and drafts a "Test Report" on the basis of specially prepared forms provided by RINA based on the requirements of the Verification Protocol.

5.7 ASSESSMENT OF ALL DATA AND VERIFICATION

The final assessment of data starts when the performance data, including the test report data and acceptable data from the existing data prior to verification, are considered complete by RINA.

They also have to satisfy data quality requirements as provided in the SVP. The Verification Body undertakes a final assessment of these data, reviews the procedures followed during testing and determines if there is a pertinent and complete data set for verification and reporting.

5.7 DRAFTING THE VERIFICATION REPORT AND STATEMENT OF VERIFICATION

Following final assessment of the data, the verification team draws up a "Verification Report" which includes all relevant documents produced during verification such as the Quick Scan, Verification Proposal, SVP, Test Plan and Test Report.

The team also draws up a "Statement of Verification".

The Statement of Verification is a summary of the verification of about 4 pages and includes a summary description of the technology and purpose, the verified claim related to performance parameters, test design, operation conditions, test results and additional information.

The Verification Report and Statement of Verification are also reviewed by qualified and independent, external technical experts.

The names of the external technical experts are communicated to the proposer who may ask, in writing, for them to be replaced, giving its reasons.

Following possible revision and with the agreement of the proposer, the Statement of Verification approved by RINA is registered and published by the Commission services or by a body designated by the Commission services.

In the case of a disagreement between the Verification Body and proposer or another party in relation to the Statement of Verification, the relevant technical working group may be asked by the Commission services, the Verification Body or the other party for an opinion. If the Verification Body decides not to follow the opinion of the technical working group, a detailed report justifying this decision should be addressed to the Commission services and to the accreditation body having accredited the Verification Body for the ETV pilot programme. The Commission services or the accreditation body (ACCREDIA) may decide appropriate measures on the basis of this report. In any case, RINA reserves the right to terminate the contract in the case of nonacceptance of the Statement of Verification by the proposer within 3 months from RINA approval, requiring payment for the activities carried out. according to the contractual agreement.

CHAPTER 6 USE OF THE STATEMENT OF VERIFICATION AND ETV LOGO

The Statement of Verification may be used by the proposer in any dealings with other organisations, for marketing purposes and for official approval and may be included in the technical documentation of the verified technology. The proposer is to make the statement available in full

and is not to use parts of the statement for any purpose.

The proposer may quote the Statement of Verification as follows: the XX technology has been verified for the purpose PP in YY matrix by QQ verification body on DD.MM.YYYY. The Statement of Verification has been registered under number NN and is accessible at the following address: http://iet.jrc.ec.europa.eu/etv/or on the dedicated website designated by the Commission services.

The proposer is not to use the ETV logo alone, neither on products nor on published matter (printed, web or other) other than the Statement of Verification.

The proposer is obliged to report any information on changes in the technology to RINA with the data needed to evaluate whether the conditions for verification have changed.

If, after evaluation, RINA concludes that the conditions for verification have changed, the proposer is to start a new verification procedure for this technology or, alternatively, the Statement of Verification is to be withdrawn. The GVP may provide for a simplified procedure to be followed in the case of a new verification of a formerly verified technology. The Verification Report is considered proprietary to the proposer. However, for reasons of transparency, proposers are recommended to accept publication of the Report, hence enabling publication via the ETV – programme information channels. If the Verification Report is published, then the full report is to be published. Publication of parts of the Verification Report is acceptable only if the legitimate interests of the proposer in relation to the verified technology, in particular intellectual property, could suffer disproportionately great harm because of the full publication of the Report. In the case of publication of parts of the Verification Report, the verification body should check, before publication and at the cost of the proposer, that the parts to be published may not lead the reader to misinterpret the meaning or results of verification under ETV.

The Verification Report is to be accessible upon request by other verification bodies, by the Commission services, by national accreditation bodies and by members of technical working groups, under the same conditions of confidentiality applicable to the Verification Body. EU and national control authorities (including the EU Court of Auditors and Anti-Fraud Office) can request access under relevant procedures.

The Statement of Verification is published by the Commission services.

The Statement of Verification will be withdrawn by RINA if misused by the proposer. Misuse is defined as violation of the conditions of the EU ETV programme. In the case of withdrawal, the Statement of Verification and the Report or parts of the Report are to be removed from the web.

CHAPTER 7 CONFIDENTIALITY

RINA observes professional secrecy with regard to all information obtained in carrying out its tasks during the verification activities according to part B of the GVP, except in relation to the Commission, the European Court of Auditors, the competent authorities of the Member States in which its activities are carried out and Accreditation Bodies; proprietary rights are protected.

RINA guarantees the proposer that the activities of its subsidiaries or subcontractors do not affect confidentiality.

CHAPTER 8 IMPARTIALITY

RINA guarantees that it is not involved in activities which could be in conflict with its independence of judgement or integrity in relation to the verification activities for which it has been selected. This also applies to its top level management, to the personnel assigned to carry out the verification tasks as well as to consultancy services.

RINA guarantees the proposer that the activities of its subsidiaries or subcontractors do not affect the objectivity or impartiality of the verification activities; it guarantees that it carries out the verification activities with the highest degree of professional integrity and the requisite technical competency in the specific field and that it is free from all pressures and inducements, particularly financial, which could influence its judgement or the result of the verification activities, especially as regards people or groups of people with an interest in the results of the verifications.

CHAPTER 9 PROPOSER'S RESPONSIBILITIES

The proposer is responsible for reviewing and approving the plans and reports prior to their validation by RINA; for providing timely access to technology, accessories, manuals and training; for contracting and paying the test bodies for any services provided by analytical laboratories (for example, in the case of in-house testing); for compliance with the rules for use of the Statement of Verification.

If further tests are necessary after assessment of existing test data, the proposer can carry out the necessary tests in-house provided the testing plans and all preparatory measures, such as

sampling and the tests themselves, are prepared and implemented in agreement with RINA or with an independent test body which fulfils the requirements of part C of the GVP. The test report is to be drawn up by the proposer and approved by RINA or by the test body.

CHAPTER 10 RINA RESPONSIBILITIES

RINA guarantees that it is able to undertake all the tasks assigned to it in the technology groups for which it is accredited, whether or not these tasks are performed by it directly or on its behalf and under its responsibility.

RINA has in place a system of quality management and quality assurance documenting, coordinating and monitoring the measures taken to ensure that the verification activities are implemented in compliance with the requirements of the General Verification Protocol.

RINA is responsible for having at its disposal either personnel with technical knowledge and sufficient and appropriate experience to perform the verification tasks or, if the above personnel includes external experts, the necessary agreements or conventions ensuring availability of personnel concerned by ETV procedures.

Technical Rules
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