

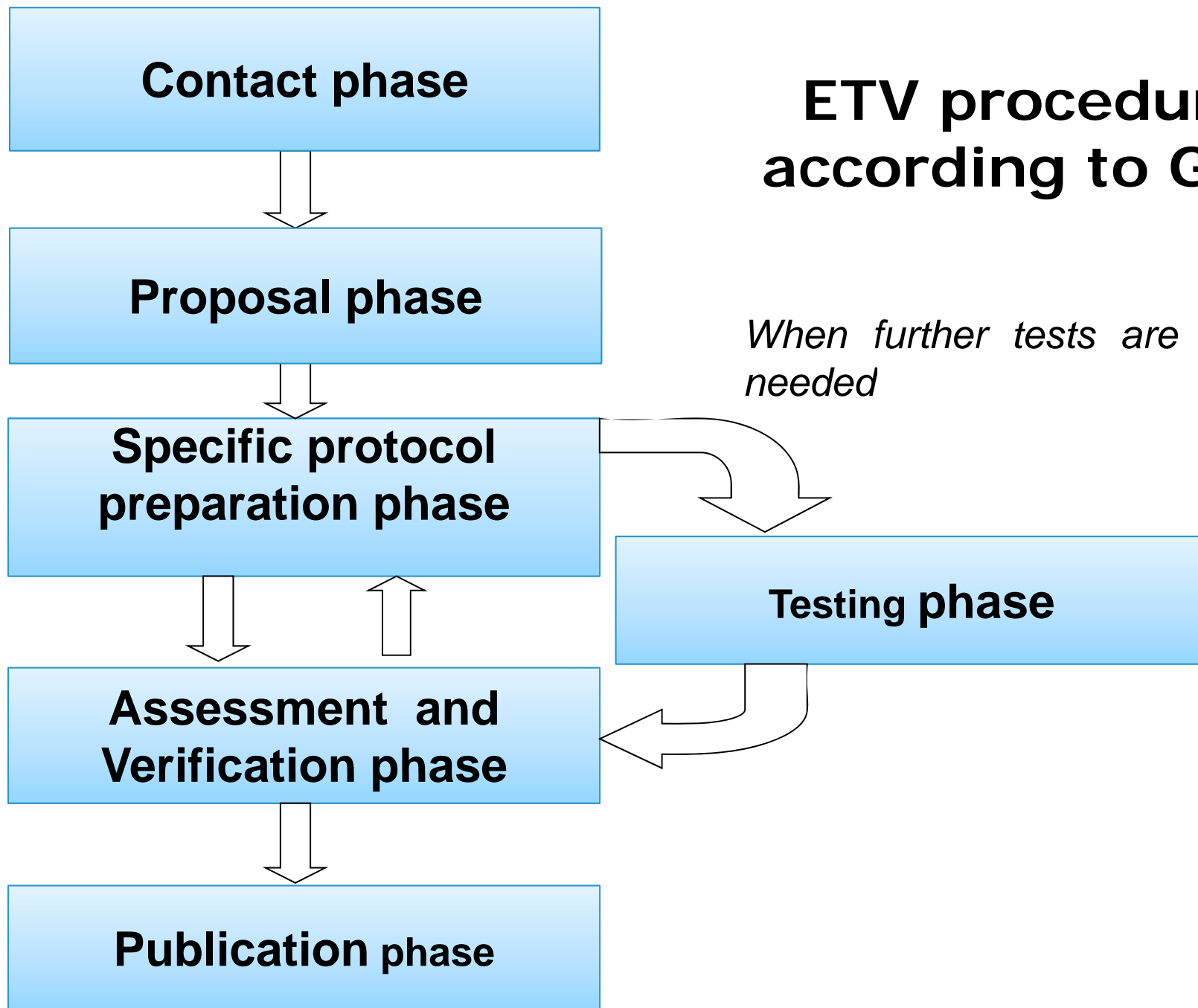
# **EU ETV pre-programme: Understanding the roles and responsibilities**

Uwe Fortkamp, 26<sup>th</sup> May 2011

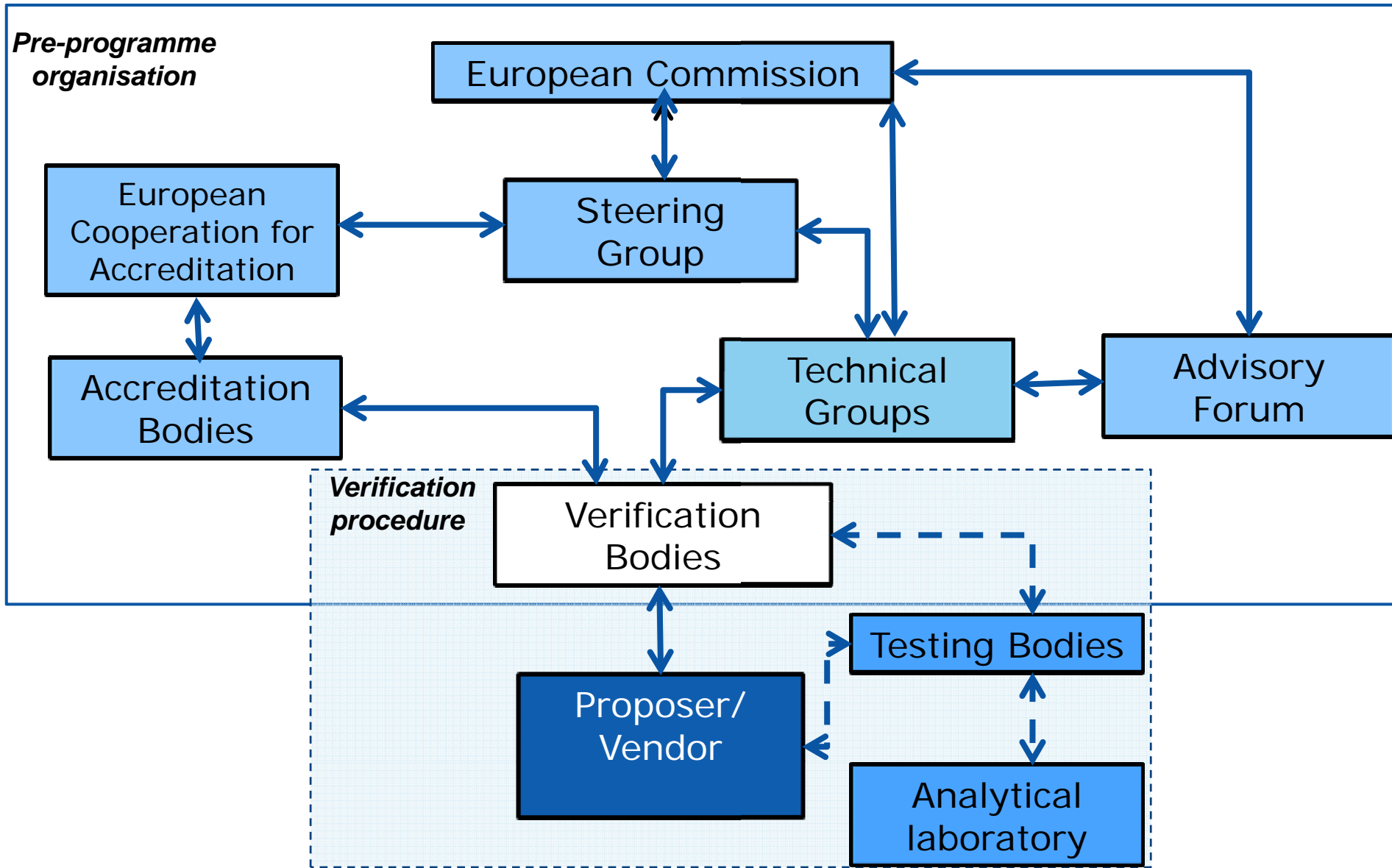
# This morning

- Introduction, this presentation
  - Based on the GVP (Generic Verification Protocol) Draft
  - The steps in the procedure (short)
  - Roles and responsibilities of different bodies (a bit more)
- Discussion
  - The different steps in Verification from a proposer or verification body perspective

# ETV procedure according to GVP



# Organisations in ETV pre-programme



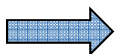
# European Commission Services

## Roles and Responsibilities

- ensure the **overall co-ordination** and supervision of the EU ETV pre-programme.
- In consultation with Steering Group, they define the **rules governing the ETV pre-programme**, including GVP and technology areas covered.
- Register and publish all **Statements of Verification**

## Chair(s)

- The European Commission services will convene and chair the Steering Group and the Advisory Forum.



# Steering group

**Assists Commission** in the implementation of the EU ETV pre-programme, **composed of representatives of the participating EU Member States**

Roles and Responsibilities, e.g.:

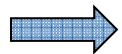
- Ensuring the due **recognition of Verification Bodies** in all ETV participating countries and the **acceptance of ETV 'Statements of Verification'** in all relevant markets.
- The **technology areas** to be covered by the EU ETV pre-programme
- **Advice on activities of technical groups**, in particular technical documents
- **Evaluation of the EU ETV pre-programme**



# European Coordination for accreditation

## Roles and Responsibilities

- To ensure EU wide recognition of the procedure for the accreditation of Verification

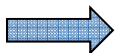


# Accreditation bodies

Established by law in each member state. Participation of national accreditation bodies coordinated by European cooperation for Accreditation.

## Roles and Responsibilities

- to ensure the **technical competence and capacity of Verification Bodies** to implement ETV procedures
- to ensure that an **adequate Quality Management System** is in place;
- to ensure the due recognition of Verification Bodies in the European Union, in order to **ensure the acceptance of ETV 'Statements of Verification'** in all relevant markets.



# Advisory Forum

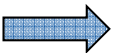
Technology purchasers and users, other stakeholders,  
justified interest

## Nomination

- The Commission services will convene the Advisory Forum, composed of stakeholders interested in the EU ETV pre-programme.

## Roles and Responsibilities

- **Advise on general issues** relevant for the implementation of EU ETV pre-programme.
- Thematic meetings or sub-groups of the Advisory Forum may be convened to advise on specific issues. In particular, sub-groups may give advice to the ETV Technical Groups on **needs of users, investors and regulators** in specific areas.



# Verification Bodies

## Nomination

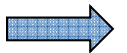
- Verification Bodies will be **accredited** by National Accreditation Bodies (for certain technology areas), with that considered nominated.

## Roles and Responsibilities

- Verification Bodies are responsible for **managing the EU ETV pre-programme** for certain groups of technologies This includes e.g.:
  - Implementation of the GVP
  - Assess and approve test methods and test data
  - Participation in the Technical Groups relevant for their technology area
  - Receipt and processing of Proposals for verification in their technology area,
  - Technical advice to proposers, e.g. definition of performance claim
  - ensure compliance with quality management requirements for test bodies

# Verification bodies

- Qualification, e.g.
  - Be accredited to comply with the requirements of **ISO 17020**. (inspection body) GVP part of the documentation describing the functions of the Verification Body
  - **independent**, e.g. not engaged in any activity that may conflict with their independence of judgment or integrity in relation to verification activities for which they are selected
  - Be **capable of carrying out all the tasks** assigned to it, itself or on its behalf
  - Have **Quality Management and Quality Assurance** to ensure that verification activities are implemented as in Part C of the GVP
  - Have **qualified personnel** according to GVP
  - **Professional secrecy** with regard to all information obtained
  - *etc.*



# Technical Groups

One per technology area or sub-area

Harmonise the implementation of ETV procedures by Verification Bodies in the different technology areas

Ensure the same level of quality of verification results, in particular Statements of Verification.

## Nomination

- The Technical Groups altogether shall include at least one **representative of each Verification Body** and a similar number of **other experts**, the list of which shall be adopted by the Commission after consultation of the Steering Group.

# Technical Groups

## Roles and Responsibilities

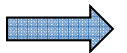
- Guidance on the **application of ETV procedures** in specific technology areas, including specific guidance documents where appropriate
- Screening of potential **environmental impacts** associated with the use of technologies, throughout the life cycle of related products
- **Detailing of technology areas** into technology groups and keeping list updated
- **Exchange of good practices** concerning the implementation of ETV, sharing of information on relevant market aspects for the technology area.
- **Inform and consult Steering Group**



# Proposer/Vendor

## Roles and Responsibilities

- The Proposer is supporting the technology verification, in particular through:
  - applying for verification
  - contracting with a Verification Body
  - liaising on plans and reports
  - making technology available
- The Proposer is responsible for:
  - reviewing plans and reports
  - providing timely access to technology, accessories, user manuals and training for the Verification Body
  - contracting and paying test bodies and for the services provided by Analytical Laboratories (in case of in-house testing);
  - comply with the rules for using the verification statement
- The Proposer may perform the necessary tests in-house.



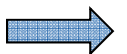
# Test Bodies

- Qualification

- Test Bodies shall fulfill the relevant requirements of the General Protocol of the EU ETV pre-programme as set out in Part C “Quality management of Test bodies”
- Staff of test body not the same and not dependent on staff for evaluation

- Nomination

- Test Bodies are **designated by the Proposer** to perform these tests, in consultation with the Verification Body. The Proposer is responsible for contracting with Test Bodies and for payment of the services provided by Test Bodies.



# Test Bodies

## Roles and Responsibilities

- Drafting the testing plans,
- Performing the tests, ensuring the level of quality required by the Verification Body;
- Ensuring quality of analysis used in the test and, when applicable, the compliance of analytical laboratories with the requirements of this GVP
- Drafting the report on the tests performed, for transmission to the Proposer and to the Verification Body.
- In case a proposer performs the necessary tests in-house, a test body might
  - draft the testing plans
  - review the testing plans elaborated by the proposer



# Analytical laboratories

Staff not the same as those responsible for evaluation in test body and not dependent on these

## Roles and Responsibilities

- **planning analysis and selecting analytical methods** in accordance with the requirements of the test body;
- **performing the analysis**, ensuring the level of analytical **quality** required by ISO 17025;
- **reporting** the analytical data to the test body in agreed format and with methods applied and obtained analytical uncertainty stated.

