THE DIFFERENCE BETWEEN VERIFICATION, VALIDATION, REGULATORY COMPLIANCE AND CERTIFICATION

FOR SMEs CONSIDERING THE WATER TEST NETWORK

Interreg North-West Europe Water Test Network

European Regional Development Fund

There is often a degree of misunderstanding when it comes to product verification and what that actually means. As a business develops an idea or concept into a workable product there are a number of regulations, validations and compliance issues that need to be addressed if the business is to successfully gain market entry. For the purposes of this report it is critical to establish the definition of verification along with other terms that often get interchanged.

VERIFICATION

Verification is an activity that is technology specific and usually involves examination, inspection, testing and reviewing a product to establish that it meets the design specifications and/or is fit for the purpose for which it was designed.

VALIDATION

Validation is a sub-process of the verification or certification process. It involves testing a product to ensure that it meets a pre-determined specification. This normally requires demonstration that a product will perform to defined precision and accuracy targets. The requirements of the user may be slightly different to the design specification. For example, a top pan two decimal place balance may meet the design specification of being accurate to ±0.01g at 100g but may not meet the requirement of the user which specifies accuracy to ±0.0001g at 1g. In this instance the equipment can be verified as meeting the design specification but not validated for meeting the customer's needs.

REGULATORY COMPLIANCE

Regulatory Compliance is another aspect of product approval and is different to verification, certification and validation. Well designed and implemented regulation protects the interest of consumers and provides benefit. However, policy makers and regulators are constantly challenged on the appropriate level of regulation considered necessary; when it should be applied and how it is then enforced. In addition to this there is a constant political tension at play between reducing red-tape that encourages growth and risk taking, while at the same time, reducing risk to society in general. Performance characteristics of a product will always need to comply with the relevant regulations.
The relevant regulations can be found on the water test network webpage.

CERTIFICATION

The final category of approvals can be referred to as certification. Certification is applicable when there is a known standard or specification that is either nationally or internationally recognised. Unlike verification, certification includes ongoing surveillance of the manufacturing process and quality of product. Any deviation of improvement from the manufacturing process or specification may result in certification being withdrawn.

Table 1 highlights the key differences that need to be taken into account and illustrates verification and certification available for certain comparators.

TABLE 1

COMPARATOR	VERIFICATION	CERTIFICATION
Applicable International Standards	None are generally available	Covers existing standards and specifications
Laboratory standards used	ISO17025	ISO17025
Product testing protocol	ISO17020	ISO17065
Testing regime	Product specific design and only assesses the technology not the reliability of the manufacturing process	Testing done in controlled conditions and also looks at manufacturing repeatability
Design changes considered on the impact of the assessment	No	Yes
Surveillance after approved	No	Yes
Monitoring Data reliability	Low	High

When a product is innovative there is generally little supporting evidence that the technology works and confidence in the research data may be lower than that of tried and tested products. In addition to this there would be no international standard or specification for innovative products. There is no requirement within the verification to audit the manufacturing process or conduct ongoing surveillance once the product has been verified.

Any SME commercialising a product will need to make sure that they verify, validate and comply with the appropriate regulation. It is important that any SME considering entering into the water sector (or indeed other environmental sectors) understands the requirements of the regulating bodies and the customer requirements within that market.

ENVIRONMENTAL TECHNOLOGY VERIFICATION IN MORE DETAIL

Innovation is critical to addressing the environmental challenges faced within Europe and at a global level. Often innovation could make a significant change as a disruptive technology but in many cases never reach the markets. Environmental technology verification was developed to provide evidence that supports the claims of new technologies in a credible, scientific and quantifiable way.

Innovative environmental technologies provide technical solutions for specific environmental problems such as pollution control and climate change or they use natural resources in a more efficient manner when compared with the technologies that they are intended to replace. The ISO 14034 standard provides a process for verifying the performance of such technologies and charts a path for technology performance assessments where sustainability and innovation are inextricably linked. Use of the ISO 14034 standard helps build credibility, increasing market confidence that environmental technology performance claims are valid and supported by high quality, independent test data and expert opinion.

VERIFICATION WITH RESPECT TO ETV

Verification is a multi-stage process which is based on collaboration between the technology owner, the verification body and the testing laboratories. Agreement at each stage of the process is necessary to move on to the next and the technology owner has control over how they wish to proceed, normally this is informed by the analytical data used to substantiate the performance claims. The multiple stages of the process are shown in figure 1.

The first stage in the process is to sit down with the technology owner and define the performance claim. Once the claims are defined, a quick review of existing information and data that has been used to develop the claims will be completed. This is often known as a “quick scan”. A gap analysis is then conducted to identify any gaps in the quality and quantity of data

VERIFICATION WITH RESPECT TO ETV cont.

needed to verify the technology performance claims.
The gap analysis informs the verification plan and a further test data assessment is conducted. Some additional testing may need to be generated to provide enough analytical data that will support the performance claims. The Water Test Network provide the facilities and test laboratories to enable this to happen quickly.
Once the data is collected and analysed the performance of the system is verified and, assuming the data supports the claims, a verification report and certificate is produced. The certificate of verification will be recognised internationally meaning only one verification will be necessary to enter multiple international markets. If the issuing organisation is accredited as a certifying body (ISO 17020), accreditation can be claimed for issuing an ETV validation report/certificate for compliance ISO 14034 if the SMEs claims are verified. If the issuing body is not accredited as a certifying body, there must be no claim to accreditation on the report or certificate.
If the data does not support the claims then the claims, under certain circumstances, may be altered to reflect what the data tells us. Alternatively, the technology provider may choose to optimise the system more and repeat the verification process to ensure the original claims are verified.

BENEFITS OF VERIFICATION

The Water Test Network will enhance and support new product development and market entry through the application of verification as one of the tools for success. Through verification we will be able to help companies to demonstrate the value of their innovation compared to any existing best available technology and provide reassurance to investors that a new technology performs as well as or better than existing solutions. Environmental technology verification, when completed through the application of ISO14034:2015, will be recognised internationally so the verification certificates will allow or enable market entry beyond Europe.
Verification is often confused with certification or labelling. Normally certification is assessed against a pre-existing set of standards. Verification is flexible and not limited to comparison against technical specifications or standards. Each technology is assessed on its own merits with the test plan bespoke to that technology and designed on a case by case basis.

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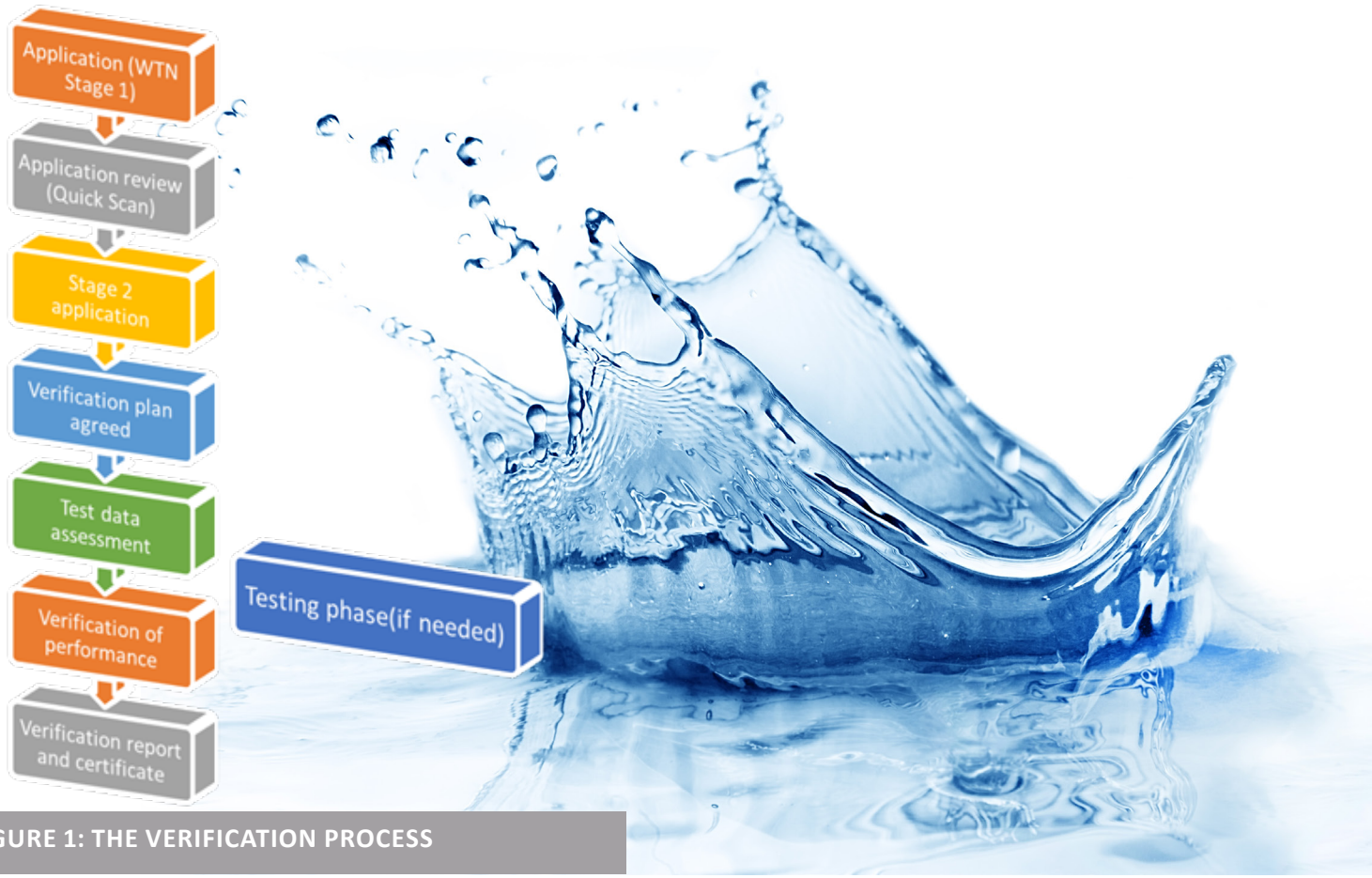

FIGURE 1: THE VERIFICATION PROCESS