

Title: Harmonised framework to validate on-site test kits, portable devices, and continuous measuring devices for water quality monitoring

Abstract

On-site test kits, portable and continuous measuring devices are useful to improve water quality assessment under EU directives and for industrial processes thus contributing to water management improvement. Although these devices have clear advantages (e.g., fast response and real-time monitoring), they are perceived as less reliable than conventional methods. Their innovative nature and/or operation mode require specific validation strategies that differ significantly from conventional analytical methods. Therefore, there is a need of developing a harmonised framework to validate on-site test kits, portable and continuous measuring devices for water quality monitoring to support their acceptance, promote their use and make their application sustainable.

Keywords

On-site test kits, portable devices, continuous measuring devices, water quality monitoring, harmonised validation, interlaboratory comparison, measurement uncertainty, equivalence of results, test benches.

Background to the Metrological Challenges

Anthropogenic sources (urban, industrial and agricultural) as well as natural processes (precipitation inputs, erosion and chemical weathering) greatly influence the quality of surface and ground waters. A monitoring program providing a representative and reliable estimation of the quality of surface and ground waters is necessary to support decision making, whether to implement costly measures to achieve load reduction of targeted substances, e.g., those listed in the annexes to the Water Framework Directive (WFD) and the coming revision of the Urban Wastewater Treatment Directive (UWWTD). However, most water quality monitoring programs are based on spot samples collection at a stated frequency, followed by laboratory analysis, but fail to consider the temporal variability of water chemistry and pollution by inorganic and organic compounds as well as pathogens.

The European Common Implementation Strategy Guidance n°19 strongly supports the use of screening tools and methodologies to improve monitoring programs by providing a complimentary approach to reduce the cost of incorrect information with regards to ecological status of water bodies within the WFD. These screening tools should be at an affordable cost, reliable, and produce comparable data. They may include in situ biomonitoring, online monitoring systems, biological early warning systems, field test kits for specific pollutants, portable analytical assay equipment, sensors, direct toxicological assays, and passive samplers. However, there is an urgent need to establish criteria and procedures to assess the validity and the quality of data obtained using these tools, in order to make these tools fit for application within the legislative framework. Studies have shown that these tools are not so well accepted and not widely used because they are usually not validated. Often, they are perceived as less reliable than conventional methods, lacking information on how to use them and/or how to interpret results. In consequence, they are found not fit for purpose for reporting to regulation requirements.

A harmonised framework to validate these devices will improve their overall acceptance and promote their use more widely. The different measuring principles and continuous operation mode require developing specific performance assessment infrastructure demonstrating they are fit for the intended use during the product's life cycle and the most demanding operating conditions.

Various guidance documents or international standards have been identified, e.g., CEN/TS 16800: CEN/TS 16800:2020 "Guideline for the validation of physico-chemical analytical methods",

EN ISO 13843:2017 standard “Water quality - Requirements for establishing performance characteristics of quantitative microbiological methods” and OECD 34 “Guidance document on the validation and international acceptance of new or updated test methods for hazard assessment”. The EPA 821B guidance “Protocol for review and validation of alternate test procedures for regulated organic and inorganic analytes in wastewater under EPA’s alternate Test procedure program” is particularly well adapted to test kits for physico-chemical parameters and includes a dedicated Annex for parameters that are defined by their method (Annex H).

The assessment of performance of portable and continuous measuring devices is currently only addressed by EN 17075:2018 “Water quality — General requirements and performance test procedures for water monitoring equipment — Continuous Measuring devices”.

Several standards exist or are on-going to perform interlaboratory comparison including ISO/CD TS 7013 (Water quality — Guidance document on designing an interlaboratory trial for validation of analytical methods) for physico-chemical parameters, EN ISO 16140-2:2016 (Microbiology of the food chain — method validation — part 2: protocol for the validation of alternative (proprietary)) for microbiological test methods, and ISO/TS 5594:2022 (Soil and water quality — Guidance and requirements for designing an interlaboratory trial for validation of biotests) for bioassays and biotests.

When dealing with parameters defined by their method, both standard ISO/TS 16489:2006 “Water quality – Guidance for establishing the equivalency of results” and EN ISO 17994:2014 “Water quality — Requirements for the comparison of the relative recovery of microorganisms by two quantitative methods” give recommendation and requirements to address the demonstration of equivalence of results by two methods and can easily be applied to test kits. However, adaptation of these standards to include both portable and continuous measuring devices need to be investigated.

Nonetheless, these standards and guidance documents address mainly laboratory analytical methods and therefore there is a need of adapting these to on-site kits and portable devices as well as continuous measuring devices.

Objectives

Proposers should address the objectives stated below, which are based on the PRT submissions. Proposers may identify amendments to the objectives or choose to address a subset of them in order to maximise the overall impact, or address budgetary or scientific / technical constraints, but the reasons for this should be clearly stated in the protocol.

The JRP shall focus on metrology research necessary to support standardisation in the field of water metrology by developing a harmonised framework to validate on-site test kits, portable devices, and continuous measuring devices for water quality monitoring.

The specific objectives are

1. To assess the metrological performance and measurement uncertainty of on-site test kits, portable and continuous measuring devices, considering both manufacturers and end-user needs (e.g., using both standard solutions and real matrix samples).
2. To conduct an Interlaboratory Comparison in the field to assess interlaboratory metrological performances under real-world conditions.
3. To improve comparability to a reference method (standardised or recognised/accepted) by demonstrating the equivalence of results for parameters defined by their method.
4. To design and develop test benches for assessing performances of on-site test kits, portable devices and continuous measuring devices under laboratory and field conditions.
5. To collaborate with the technical committees CEN/TC 230 “Water analysis” and ISO/TC 147 “Water quality”, EMN PolMo, and the users of the standards they develop to ensure that the outputs of the project are aligned with their needs, including the provision of a technical report/protocols on the validation of on-site test kits, portable devices and continuous measuring devices for water quality monitoring as well as recommendations for incorporation of this information into future standards at the earliest opportunity.

The proposed research shall be justified by clear reference to the measurement needs within strategic documents published by the relevant Regulatory body or Standards Developing Organisation or by a letter signed by the convener of the respective TC/WG. EURAMET encourages proposals that include representatives from industry, regulators and standardisation bodies actively participating in the projects. The proposal must name a “Chief Stakeholder”, not a member of the consortium, but a representative of the user community that will benefit from the proposed work. The “Chief Stakeholder” should write a letter of support

explaining how their organisation will make use of the outcomes from the research, be consulted regularly by the consortium during the project to ensure that the planned outcomes are still relevant and be prepared to report to EURAMET on the benefits they have gained from the project.

Proposers should establish the current state of the art and explain how their proposed research goes beyond this.

EURAMET expects the average EU Contribution for the selected JRPs in this TP to be 1.0 M€ and has defined an upper limit of 1.3 M€ for this project.

EURAMET also expects the EU Contribution to the external funded beneficiaries to not exceed 30 % of the total EU Contribution across all selected projects in this TP.

Any industrial beneficiaries that will receive significant benefit from the results of the proposed project are expected to be beneficiaries without receiving funding or associated partners.

Potential Impact

Proposals must demonstrate adequate and appropriate participation/links to the 'end user' community, describing how the project partners will engage with relevant communities during the project to facilitate knowledge transfer and accelerate the uptake of project outputs. Evidence of support from the "end user" community (e.g., letters of support) is also encouraged.

You should detail how your JRP results are going to:

- Address the SRT objectives and deliver solutions to the documented needs,
- Feed into the development of urgent documentary standards through appropriate standards bodies,
- Facilitate improved industrial capability or improved quality of life for European citizens in terms of personal health, protection of the environment and the climate, or energy security,
- Transfer knowledge to the international standardisation sector.

You should detail other impacts of your proposed JRP as specified in the document "Guide 4: Writing Joint Research Projects (JRPs)"

You should also detail how your approach to realising the objectives will further the aim of the Partnership to develop a coherent approach at the European level in the field of metrology and include the best available contributions from across the metrology community. Specifically, the opportunities for:

- improvement of the efficiency of use of available resources to better meet metrological needs and to assure the traceability of national standards
- the metrology capacity of EURAMET Member States whose metrology programmes are at an early stage of development to be increased
- organisations other than NMIs and DIs to be involved in the work.

Timescale

The project should be of up to 3 years duration.