

SEE QI project 6: Capacity building for harmonization of accreditation activities with the European rules in selected areas

[Regional Consultancy Fund for Quality Infrastructure \(QI\) in South East Europe \(SEE\)](#)

Main result: WB6 region implements, on market demand, the accreditation schemes (policies, requirements, procedures) in compliance with the practices of the national accreditation bodies being members of EA.

Duration: April 2020 – September 2021



Coordination:

Ms Jasna Stojanovic (ATS, Serbia), Mr Dejan Stojkovski (IARNM, North Macedonia)

External experts and facilitators:

Technical Experts from DAkkS, ACCREDIA, ESYD, ATS
Dr. Rozsa Ring, PTB consultant (backstopping, moderation and reporting)

Background

This regional project started with a preparatory meeting in February 2020 in Tirana, Albania, when the accreditation bodies (ABs) of the beneficiary countries agreed upon the scope of the projects, identified their joint priorities and appointed their contact persons. Then based on the technical support requested by the beneficiaries the PTB consultant elaborated a Work Plan including 3 main topics with several activities, such as

- 1 Exchange of experience (5 activities)
- 2 Developing new accreditation schemes and extending existing accreditation schemes (6 activities)
- 3 Accreditation in selected regulated areas (4 activities).



Project identification and planning, Tirana 02/2020

At the time the project was designed in Tirana in 02/2020, the consequences of the upcoming COVID-19 pandemic could not yet be anticipated. Therefore, in the course of project implementation all activities had to be implemented virtually as video-conferences, which was at this time an innovative approach for the project management and all partners involved.

Exclusively virtual project implementation

In the “Exchange of experience” area all 5 activities plus one additional activity have been successfully completed with the involvement of 4 experts from DAkKS, 3 experts from ESYD and 1 expert from ATS. There were 4 workshops on competence of accreditation personnel, on implementation of remote assessment and on specific issues of laboratories; and there were 2 trainings on statement of conformity and decision rules and on measurement uncertainty in sampling.

In the “Developing new accreditation schemes and extending existing accreditation schemes” area 4 of the 6 activities have been successfully completed and in addition, as an outcome of a training, a Guideline was published for accreditation bodies and laboratories with issues to consider when accrediting medical laboratories for the scope of COVID-19 molecular tests. There were 4 trainings with involvement of 2 experts from ESYD and 1 expert from ACCREDIA on accreditation of medical laboratories for POCT, accreditation of certification bodies for ISO 13485 and on identification of SARS-CoV-2 virus.

In the “Accreditation in selected regulated areas” area 1 activity was successfully completed with the involvement of 2 experts from Germany. There was a training on accreditation and notification in the field of CPR.

The **capacity development activities** in detail were as follows:

Time	Area	Topic
02/2020	Exchange of experience	ISO 17011(2017) requirements / Planning Workshop
07/2020	Exchange of experience	Remote assessments
11/2020	New scheme	Accreditation of medical laboratories for POCT
11/2020	Exchange of experience	Accreditation of CABs for sampling as standalone activity / Accreditation of laboratories for opinions and interpretation / Accreditation of CABs for statement of conformity
12/2020	Exchange of experience	ISO 17011(2017): Establishment competence criteria for each accreditation scheme / Effective evaluation methods to demonstrate competence of accreditation body personnel
01/2021	Exchange of experience	Remote assessments - follow up
02/2021	New scheme	SARS-CoV-2 identification (for ABs)
02/2021	New scheme	SARS-CoV-2 identification (for medical laboratories)
03/2021	Exchange of experience	Decision rules and statement of conformity
03/2021	Exchange of experience	Sampling – with a focus on measurement uncertainty
09/2021	New scheme	Accreditation of medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
09/2021	Regulated area	Accreditation and notification related to Construction Products Regulation (CPR)

In summary, almost 70% of the planned activities have been completed in the last 1,5 years. 2 additional new activities have been taken on board as a result of and in response to the upcoming COVID-19 pandemic. 12 foreign experts (6 from Germany, 4 from Greece, 1 from Italy and 1 from Serbia) shared their knowledge and experiences with the beneficiary countries.

All events were moderated by Rózsa Ring (PTB consultant), who also compiled a summary report of each activity. Although Serbia was withdrawn from a major part of the project, the countries showed a big interest:

Country	Number of activities participated	Number of total participants*
Albania	11	100
Bosnia-Herzegovina	10	32
Montenegro	8	33
North Macedonia	11	101
Serbia	5	44
Kosovo	10	23
Total	11	333

* Several persons attended in more events

Impact

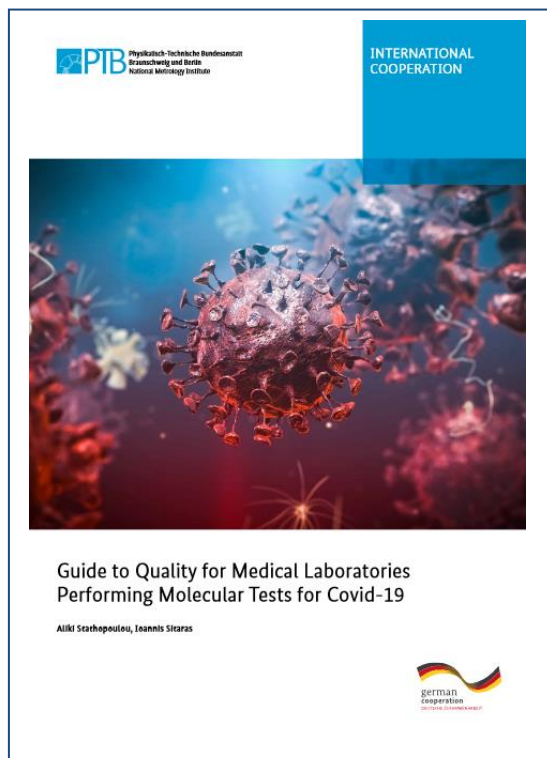
On 18 November 2021 the contact persons from WB6 ABs came together for a last final wrap-up meeting with the PTB project management and the PTB consultant (accreditation expert). Objective of the meeting was – amongst others – to receive feedback from the ABs, in how far the implemented trainings have contributed to concrete changes or innovations in the ABs practice and documented processes. The following impacts have been reported by WB6 ABs:

- Definition and application of competence criteria for assessors in different accreditation schemes (and a better understanding of the requirements of ISO 17011:2017 in general) has resulted in a better preparedness and reduction of observations and non-conformities in EA peer evaluations
- Resulting from the exchange of experience workshop on implementation of risk-based approach in line with ISO 17011:2017, ABs have updated their Risk register with identification and treatment of new risks
- WB6 ABs have started to conduct remote evaluations in order to respond to the new situation arising from the COVID-19 pandemic
- WB6 ABs have increased their assessment capacities for medical laboratories (SARS-CoV-2 identification) and testing laboratories (sampling, decision rules, opinions and interpretation....)
- Benefiting from the hands-on training and published Guideline on accreditation of medical laboratories for molecular test of Covid-19, ATCG of Montenegro has accredited the first medical laboratory according to ISO 15189 performing *In vitro medical testing: Sampling for SARS-CoV-2 laboratory diagnostics, Real-time PCR detection of corona virus SARS-CoV-2*.
- The guideline on accreditation of medical laboratories for molecular test of Covid-19 has been published by ABs and is used also by regulators as best practice in this field

Resulting from the exclusively virtual implementation of the project activities, a significantly higher number of participants could attend the virtual formats. External stakeholders like technical assessors, technical experts and personnel of CABs could also attend the virtual formats, whilst previously the limited seats in physical regional meetings were reserved to the classical target group of employees of the ABs. Regional on-site formats would have provided only 132 (based on 2 project-financed participants/AB in each regional meeting) compared to the above observed 333 attendees the chance to benefit from the regional training or exchange of experience formats. Additionally, in classical on-site capacity development formats, about the same time that was dedicated to attend the event had to be spent in travel time for the transportation to and from the meeting venue. Therefore, an enormous amount of effective working time has been made available for other purpose, by not travelling to on-site meetings.

Project Outputs

Guide to Quality for Medical Laboratories Performing Molecular Tests for Covid-19:



<https://see.ptb.de/see-qi-projects/harmonization-of-accreditation-with-european-rules/>