Annex I – JRP protocol

Version Date: 28 May 2024

23RPT02 ETraceAbs

Establishing European traceability for medical measuring devices through optical absorbance liquid filters

Start date: 01 June 2024

Duration: 36 months

Coordinator Farshid Manoocheri Aalto

<u>Glossary</u>

BIPM	International Bureau of Weights and Measures
CCPR	Consultative Committee for Photometry and Radiometry
CC0	Creative Commons Public Domain Dedication (public licenses)
CIML	The International Committee of Legal Metrology
CIPM MRA	CIPM (Comité international des poids et mesures) Mutual Recognition Arrangement
CMC	Calibration and Measurement Capability
CRM	Certified Reference material
DI	Designated Institute
DMP	Data Management Plan
EMN	European Metrology Network
EURAMET	European Association of National Metrology Institutes
FAIR	Findable; Accessible; Interoperable; Re-usable (data principles)
GPG	Good Practice Guide
IEC	International Electrotechnical Commission
ILV	International Lighting Vocabulary
JRP	Joint Research Project
KCDB	Key Comparison Database
KC	Key Comparison
LAF	Liquid Absorbance Filter
LF	Liquid Filter
MMD	Medical Measuring Device
NMI	National Metrology Institute
OIML	International Organisation of Legal Metrology
OALF	Optical Absorbance Liquid Filters
PT	Proficiency testing
RM	Reference material
RMO	Regional Metrology Organisation
SC	Stakeholders Committee
SI	International System of Units
TC-PR	Technical Committee for metrology in Photometry and Radiometry
SIM	The Inter-American Metrology System
UV	Ultraviolet (wavelengths)
VIS	Visible (wavelengths)
WP	Work Package

<u>Contents</u>

Section	,	
A1	Project data summary	
	Financial summary	
A3	Work packages summary	5
Section	B: Overview of the research	6
B1	Summary of the project	
B2	Excellence	8
	B2.a Overview of the objectives	
	B2.b List of deliverables	9
	B2.c Need for the project	
	B2.d Progress beyond the state of the art	
	B2.e Gender dimension	
	B2.f Open science	12
	B2.g Research data management and management of other research outputs	13
B3	Potential outcomes and impact from the project	
	B3.a Projected outcomes for industrial and other user communities	
	B3.b Projected outcomes for the metrological and scientific communities	
	B3.c Projected outcomes for relevant standards	
	B3.d Projected wider impact of the project	
	B3.e Summary of the project's impact pathway	
B4	The quality and efficiency of the implementation	
	B4.a Overview of the consortium	
	C: Detailed project plans by work package	
C1	WP1: Selection and characterisation of optical absorbance liquid filters as reference materials	
	C1.a Task 1.1: Selection of optical absorbance liquid filters as reference materials	
	C1.b Task 1.2: Optical characterisation of optical absorbance liquid filters	21
	C1.c Task 1.3: Characterisation of selected optical absorbance liquid filters for temperature	
	dependence, cycling, and UV exposure	22
C2	WP2: Establishing the degree of equivalence of optical absorbance measurements for optical	
	absorbance liquid filters	
	C2.a Task 2.1: Diagnostic measurement comparison	
	C2.b Task 2.2: Consolidation measurement comparison	
00	C2.c Task 2.3: Development of a strategy to transfer acquired skills to stakeholders	25
C3	WP3: Transfer of expertise within the consortium and a coordinated approach to establish	05
	measurement traceability to SI across Europe for optical absorbance liquid filters	
	C3.a Task 3.1: Take up of the capabilities, technology and measurement infrastructures	
C4	C3.b Task 3.2: Technical procedures and Good Practice Guide WP4: Creating impact	
64	C4.a Task 4.1: Dissemination and communication	
	C4.a Task 4.1. Dissemination and communication	
C5	WP5: Management and coordination	
00	C5.a Task 5.1: Project management	
	C5.b Task 5.2: Project meetings	
	C5.c Task 5.3: Project reporting	
C6	Gantt chart	
Section D1	0	
D1 D2	Scientific/technical risks	
D2 D3	Management risks Ethics	
Section	E: References	44

Section A: Key data

A1 Project data summary

Coordinator contact details:

Coordinator:	Farshid Manoocheri		
Address:	o University, Maarintie 8, 02150, Espoo FINLAND		
Phone:	+358505902483		
Email:	farshid.manoocheri@aalto.fi		

Participant details:

no.	Participant Type	Short Name	Organisation legal full name	Country
1	Internal Beneficiary	Aalto	Aalto-korkeakoulusäätiö sr	Finland
2	Internal Beneficiary	CMI	Cesky Metrologicky Institut	Czechia
3	Internal Beneficiary	GUM	Central Office of Measures	Poland
4	Internal Beneficiary	INRIM	Istituto Nazionale di Ricerca Metrologica	Italy
5	Internal Beneficiary	IPQ	Instituto Português da Qualidade, I.P.	Portugal
6	Internal Beneficiary	РТВ	Physikalisch-Technische Bundesanstalt	Germany
7	Internal Beneficiary	RISE	RISE Research Institutes of Sweden AB	Sweden
8	Internal Beneficiary	SMU	Slovenský Metrologický Ústav	Slovakia
9	Internal Beneficiary	TUBITAK	Turkiye Bilimsel ve Teknolojik Arastirma Kurumu	Türkiye
10	External Beneficiary	BIM	Bulgarian Institute of Metrology	Bulgaria
11	External Beneficiary	DMDM	Ministarstvo privrede - Direkcija za mere i dragocene metale	Serbia
12	External Beneficiary	INM	I.P. Institutul Național de Metrologie	Republic of Moldova
13	External Beneficiary	UMTS	State Enterprise "All-Ukrainian State Research and Production Center for Standardization, Metrology, Certification and Consumers Rights Protection" - SE "UKRMETRTESTSTANDART"	Ukraine
14	Associated Partner - linked to all Internal Beneficiaries	AGILENT UK	Agilent Technologies LDA UK Limited	United Kingdom

A2 Financial summary

	Internal Beneficiaries	External Beneficiaries	Unfunded Beneficiaries	Associated Partners	Total	Total Eligible
Labour (€)	392 600.00	60 700.00		6 400.00	459 700.00	453 300.00
Subcontracts (€)						
T&S (€)	73 500.00	24 200.00		1 600.00	99 300.00	97 700.00
Equipment (€)						
Other Goods, Works and Services (€)	49 500.00	17 200.00			66 700.00	66 700.00
Internally Invoiced Goods and Services (€)						
Financial Support to 3 rd parties (€)						
Indirect (€)	128 900.00	25 525.00		2 000.00	156 425.00	154 425.00
Total costs (€)	644 500.00	127 625.00		10 000.00	782 125.00	772 125.00
Total costs as % of total costs	82.4 %	16.3 %	0.0 %	1.3 %		
Total Eligible Costs (€)	644 500.00	127 625.00			772 125.00	772 125.00
EU contribution (€)	644 500.00	127 625.00			772 125.00	772 125.00
EU contribution as % of total EU contribution	83 %	17 %	0 %	0 %		
Months	77.9	34.7		1.0	113.6	113.6

A3 Work packages summary

WP No	Work Package Title	Active Participants (WP leader in bold)	Months	
WP1	Selection and characterisation of optical absorbance liquid filters as reference materials	SMU , Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, TUBITAK, BIM, DMDM, INM, UMTS, AGILENT UK	30.2	
WP2	Establishing the degree of equivalence of optical absorbance measurements for optical absorbance liquid filters	IPQ , Aalto, CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS	27.3	
WP3	Transfer of expertise within the consortium and a coordinated approach to establish measurement traceability to SI across Europe for optical absorbance liquid filters	INRIM, Aalto, CMI, GUM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS, AGILENT UK	25.9	
WP4	Creating impact	CMI , Aalto, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS, AGILENT UK	17.9	
WP5	Management and coordination	Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS, AGILENT UK	12.3	
Total months				

The information in tables A2 and A3 reflect the estimates of resources as of the start of project in June 2024. The tables will not necessarily be updated during the course of the project.

Section B: Overview of the research

B1 Summary of the project

<u>Overview</u>

All medical measuring devices (MMDs) need to be verified to comply with the EU's Medical Devices Regulation (2017/746) and standards. Many devices, such as those used in clinical diagnostics, use optical absorbance as the measurand. Optical absorbance liquid filters (OALF) are used to calibrate optical absorbance equipment, but there is currently a capability gap across NMIs and DIs in the manufacturing, characterisation, and use of such filters, which leads to a lack of traceability. This project aims to bridge this gap by supporting the development of measurement capabilities for optical absorbance of liquid filters in emerging NMIs and DIs, and to enable them to provide traceability of measurement results as well as OALF as reference materials to national and international stakeholders with the lowest possible measurement uncertainty. This will improve the accuracy of clinical measurements and treatment outcomes for patients.

Need

More accurate diagnostics are needed to improve clinical outcomes thereby decreasing mortality rates, reducing healthcare costs and improving quality of life of citizens. As well as improving healthcare systems, it is also important to ensure that public trust and confidence in European medical institutions is maintained.

Many MMDs (e.g., ultraviolet-visible (UV-VIS) spectrophotometers), measure optical absorbance in micro volumes. The devices must be calibrated for absorbance according to pharmaceutical quality standards (detailed in European Pharmacopeia), but some instruments should also be calibrated for absorbance at required specific wavelengths due to their construction. However, precise calibration methods of absorbance at required wavelengths are not usually possible using commercially available liquid and solid traceable standards. Therefore, criteria for appropriate materials as reference OALF are needed.

Accredited calibration laboratories, inspection bodies and MMD manufacturers need to deliver quality medical and metrology services, and as a result NMIs need to provide optical absorbance measurement results traceable to SI units. OALF, in addition to other reference materials for MMDs, can be used to achieve this but further work is needed. Specifically, organisations which perform calibration, verification, inspection, and conformity assessment of MMDs need the availability of national capabilities for traceable measurements of absorbance of OALF for the spectral range of 220 nm to 780 nm, and for the photometric range up to 3.000 absorbance to adequately assess and to ensure the reliability of the measurements of MMDs.

In addition, in order to ensure that the optical absorbance measurement results provided by NMIs and DIs to end users follow internationally accepted standards, measurement intercomparisons and skills testing need to be performed to establish equivalence across Europe. Most of the participant NMIs need this as formal evidence of the quality of their absorbance measurements for providing calibration services to testing laboratories, medical bodies, and inspection bodies in their countries.

The EU Regulation 2017/746 includes requirements for "Devices with a measuring function", but there is no clear division and description of the requirements. Concomitantly, according to the ISO 15189:2012 standard, all MMDs with high impact on measurement results must be calibrated. For spectrophotometers, general characteristics and methods of testing and verification are specified in OIML standard R135 however references are outdated, and it does not provide procedures that can be fully adopted for MMDs. Recommendations and a good practice guide are needed on the manufacture, characterisation, and use of OALF to revise these outdated OIML standards.

Objectives

The overall objective for this project is for emerging NMIs (BIM, CMI, DMDM, INM, INRIM, IPQ, TUBITAK and UMTS) to develop and for established NMIs/DIs (Aalto, GUM, RISE, and SMU) to upgrade their national metrological capacity in SI-traceable measurements of optical absorbance of liquid absorbance filters.

The specific objectives of the project are:

- 1. To determine a set of minimal criteria (physical and chemical properties) for optical absorbance liquid filters as reference materials, which will include a dilution series of optical absorbance liquid filters to be characterised and calibrated.
- 2. To develop traceable measurement capabilities of absorbance of optical absorbance liquid filters in emerging NMIs and DIs for the minimum spectral range from 220 nm to 780 nm, and absorbance range from 0.001 up to 3.000 (corresponding to a nominal internal transmittance of 99.77 % and 0.1 %, respectively), at atmospheric pressure, within the temperature interval from 15 °C to 40 °C and with a relative standard uncertainty of 0.3 % to 1.0 %.

- 3. To establish equivalence in the measurement of optical absorbance liquid filters across participating European NMIs according to capabilities developed in Objective 2.
- 4. To produce a good practice guide on the manufacture, characterisation, and use of optical absorbance liquid filters, which will be shared with EURAMET TC-PR along with a request for its consideration to be published as a EURAMET guide.
- 5. To facilitate the take up and long-term operation of the capabilities, technology and measurement infrastructure for optical absorbance measurements using optical absorbance liquid filters developed in the project, by the measurement supply chain (NMIs/DIs, calibration, and testing laboratories), standards developing organisations (OIML, EURAMET TC-PR), and end users (e.g., industry, instrument manufacturers, regulators). To include preparation of strategies and roadmaps for the future development of these capabilities by all participant NMIs.

Progress beyond the state of the art and results

Determination of minimal criteria for optical absorbance liquid filters as reference materials

Currently, precise calibration methods of MMDs for absorbance at required specific wavelengths are not possible using commercially available liquid and solid traceable standards and the calibrations are performed at approximate wavelengths and absorbance levels. The project will set criteria for appropriate materials as reference OALF and propose several types of OALF covering the optical absorbance from 0.001 to 3.000 in the spectral range from 220 nm to 780 nm according to available knowledge and review of the existing literature. The new reference and traceable OALF developed in the project will help to improve the limited range of commercially available standards.

Traceable measurement capabilities of absorbance of optical absorbance liquid filters in emerging NMIs and DIs

Almost all NMIs/DIs from Europe have recognised optical absorption measurement capabilities, but the problem is that not all of them have the necessary experience in the manufacturing, characterisation and use of OALF and the use of these liquid filters in ensuring traceability of MMDs. The project will establish traceable measurement capabilities in OALF by developing new measurement systems or by improving the existing facilities in emerging NMIs/DIs. This will allow the dissemination of optical absorbance via Certified Reference Materials (CRMs), targeting a low uncertainty of 0.010 at an absorbance level of 3.000 and at temperatures between 15 °C and 40 °C, to be used for the dissemination of the unit of optical absorbance to national healthcare services, medical laboratories, and testing laboratories.

Establishment of equivalence in the measurement of optical absorbance liquid filters

At present, most of the participant NMIs do not have formal evidence of the quality of their optical absorbance measurements of OALF and cannot provide calibration services to testing laboratories, medical bodies, and inspection bodies in their countries. The project will allow all participants to participate in measurement intercomparisons to validate their development efforts. The NMIs/DIs will be able to establish a complete national traceability chain at a level of uncertainty close to the expert institutes for the MMDs.

Good practice guide on the manufacture, characterisation and use of optical absorbance liquid filters

The instructions and guidance available from different standards developing organisations are not fully relevant to the sophistication and precision level of present instrumentation and lack details on technological progress of MMDs. With support of the EURAMET TC-PR, the project will develop a good practice guide on the manufacture, characterisation and use of OALF, and will request EURAMET to consider its publication as a EURAMET guide. Targeting the end-users, the good practice guide will include chapters for medical laboratories, manufacturers of MMDs, testing laboratories, inspection bodies and calibration laboratories concerning the correct selection and use of OALF nominated as CRMs.

Outcomes and impact

Outcomes for industrial and other user communities

The new measurement systems for the OALF and production of reference standards developed in the project will enable accredited bodies and calibration and measurement laboratories to implement a recognised traceability chain for OALF measurements which are used for calibration, inspection and verification of MMDs. This will lead to new national accreditation schemes.

The reference materials developed in the project will ensure that testing laboratories and medical laboratories can link the optical absorbance quantity for their MMDs (e.g., biochemical and immunological analysers) to SI units. This will enable them to ensure the reliability of their measurements.

To encourage the uptake of results, the project will organise at least two workshops for the end-user community (i.e. accredited laboratories, research centres, technical assessors for accreditation bodies, etc.) to disseminate best practices in ensuring metrological traceability for MMDs by using OALF.

Outcomes for the metrology and scientific communities

The development of capabilities for SI traceable measurements of optical absorbance using OALF developed in the project will enable emerging NMIs/DIs to establish a complete national traceability chain at a level of uncertainty close to the expert institutes for the MMDs, with the potential for recognition and demonstration of competence in accordance with CIPM MRA. This will address the lack of European Calibration and Measurement Capabilities (CMCs) in the BIPM database regarding optical absorbance measurements, as well the lack of CMCs for CRM for optical absorbance. The metrology and scientific communities will benefit from improved global equivalence and reduced uncertainty in key metrological areas such as spectral transmittance and absorbance.

Outcomes for relevant standards

The good practice guide on the manufacture, characterisation, and use of OALF with application for MMDs will contribute to the revision of outdated International Organisation of Legal Metrology (OIML) standards regarding the use of spectrophotometers for medical laboratories (OIML R 135). The good practice guide will also be submitted to EURAMET TC-PR for publication as a EURAMET guide.

The consortium will also share results of the project with other relevant standards bodies including CIE (TC2-98, related to the measurement of reflectance and transmittance), CCPR (whose activities concern measurement standards for photometric and radiometric quantities and development of absolute radiometry), and ISO (TC 172, optics and photonics).

Longer-term economic, social and environmental impacts

This project will support accredited bodies, national healthcare services and the research community through the implementation of recognised traceability chains for MMD measurement. This project will significantly advance the expertise on manufacturing, characterisation and use of OALF, in less experienced NMIs, for ensuring traceability of MMDs. This will lead to improved quality of diagnostics and cost efficiency in the healthcare system. The build-up of measuring capabilities will empower emerging NMIs/DIs to offer extended and improved calibration services and CRMs, fulfilling the needs of the national services and healthcare institutions. An important aspect is to provide the means for fulfilling the legal metrological aspects for MMDs. It has huge healthcare impact for the EU internal market and provides the basis for the implementation of necessary measures for public protection. The resultant impact of the project will lead to an increase in the protection of European citizens by increasing the confidence level in measurements of MMDs. Smart specialisation of European NMIs through realisation and implementation of an improved spectral transmittance-absorbance scale will provide better traceability to light based diagnostic instruments used at the point of care. Finally, the project will improve the capabilities of European NMI/DIs in the measurement of spectral absorbance of substances. This will have a positive impact on getting more accurate and reliable results from the tests performed for water quality monitoring and environmental protection.

B2 Excellence

B2.a Overview of the objectives

The overall objective of this project is for emerging NMIs (BIM, CMI, DMDM, INM, INRIM, IPQ, TUBITAK and UMTS) to develop and for established NMIs/DIs (Aalto, GUM, RISE and SMU) to upgrade their national metrological capacity in SI-traceable measurements of absorbance of optical absorbance liquid filters.

The specific objectives of the project are:

- 1. To determine a set of minimal criteria (physical and chemical properties) for optical absorbance liquid filters as reference materials, which will include a dilution series of optical absorbance liquid filters to be characterised and calibrated (WP1).
- 2. To develop traceable measurement capabilities of absorbance of optical absorbance liquid filters in emerging NMIs and DIs for the minimum spectral range from 220 nm to 780 nm, and absorbance range from 0.001 up to 3.000 (corresponding to a nominal internal transmittance of 99.77 % and 0.1 %, respectively), at atmospheric pressure, within the temperature interval from 15 °C to 40 °C and with a relative standard uncertainty of 0.3 % to 1.0 % (WP2 and WP3).

- 3. To establish equivalence in the measurement of optical absorbance liquid filters across participating European NMIs according to capabilities developed in Objective 2 (WP2).
- 4. To produce a good practice guide on the manufacture, characterisation, and use of optical absorbance liquid filters, which will be shared with EURAMET TC-PR along with a request for its consideration to be published as a EURAMET guide (WP3).
- 5. To facilitate the take up and long-term operation of the capabilities, technology and measurement infrastructure for optical absorbance measurements using optical absorbance liquid filters developed in the project, by the measurement supply chain (NMIs/Dis, calibration and testing laboratories), standards developing organisations (OIML, EURAMET TC-PR), and end users (e.g., industry, instrument manufacturers, regulators). To include preparation of strategies and roadmaps for the future development of these capabilities by all participant NMIs (WP2 and WP4).

Relevant objective (Activity delivering the deliverable)	ective number ctivity livering		Deliverable type	Participants (Lead in bold)	Delivery date
(A1.3.8) ch st lic (d m ar ab re va		Report on calibration, characterisation, and robustness studies for a series of absorbance liquids with different concentration (dilution) and suggestions for minimal criteria in terms of physical and chemical properties of optical absorbance liquid filters as reference materials relevant to various types of Medical Measuring Devices	Report	GUM, Aalto, CMI, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS, AGILENT UK	Feb 2026 (M21)
2, 5 (A3.1.10)	D2	Report on improved capability of participating NMIs and DIs for the calibration and characterisation of optical absorbance liquid filters, together with roadmaps and action plans for future capacity building	Report	INRIM, Aalto, CMI, GUM, IPQ, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS	May 2027 (M36)
2, 3 (A2.1.3)	D3	Report on the diagnostic absorbance comparison using optical absorbance liquid filters	Report	IPQ, Aalto, CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS	May 2026 (M24)
2, 3 (A2.2.4)	D4	Report on the intercomparison measurements on optical absorbance liquid filters with absorbance of up to 3.000 and a target relative standard uncertainty of 0.3 % to 1.0 %	Report	Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS	Apr 2027 (M35)
4 (A3.2.3)	A3.2.3) D5 Good practice guide on the manufacture, characterisation, and use of optical absorbance liquid filters with application for Medical Measuring Devices Good practice guide Aalto, BIM, DMDM GUM INM, INRIM, IPQ, PTB, R SMU, TUBIT UMTS,		Aalto, BIM, CMI, DMDM GUM, INM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, UMTS, AGILENT UK	May 2027 (M36)	

B2.b List of deliverables

2, 3, 5 (A2.3.2)	D6	Strategy to transfer the experience gained on sample preparation, calibration, and characterisation of optical absorbance liquid filters and measurement traceability to the stakeholders related to Medical Measuring Devices	Report	IPQ, Aalto, CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS	Apr 2027 (M35)
n/a	D7	Evidence of contributions to or influence on new or improved international guides, recommendations, and standards with a specific focus on the following guides and committees: OIML, EURAMET TC-PR	Reporting documents	Aalto , all participants	May 2027 (M36) + 60 days
		Examples of early uptake of project outputs by end-users.			
		Updated dissemination, communication and exploitation plan.			
n/a	D8	Delivery of all technical and financial reporting documents as required by EURAMET	Reporting documents	Aalto , all participants	May 2027 (M36) + 60 days

B2.c <u>Need for the project</u>

Many MMDs used in clinical diagnostics and in devices such as biochemical analysers and immunological analysers, are using optical absorbance as their basic measurement quantity. Absorbance measurements are also performed for quality verification and estimation of quantity values in immunological, most biochemical, and other parameters (characteristics) of biomaterials, which are used for evaluation of the human health and diagnostics of diseases. In classical metrology all devices that measure optical absorbance are calibrated/verified/inspected by using optical neutral glass filters which are themselves calibrated by using high performance spectrophotometers. As MMDs in many cases have flow cells, or automatic systems, or specific cuvettes where use of neutral glass filters is impossible, the need to develop such CRM of OALF is monumental and indisputable.

Many pharmaceutical and medical laboratories working on various devices from UV-VIS spectrophotometers to microplate readers and dedicated instruments measure absorbance in micro volume. Those instruments must be calibrated at least according to European Pharmacopeia, but some instruments should be calibrated for absorbance at required specific wavelengths due to their construction. However, precise calibration methods of absorbance at required wavelengths are not usually possible using commercially available liquid and solid traceable standards and the calibrations are performed at approximate wavelengths and absorbance levels. Therefore, criteria for appropriate materials as reference liquid absorbance filters are needed.

Due to the strong demands from accredited calibration laboratories, inspection bodies, analyser and MMD industries and medical laboratories for the international recognition of quality medical and metrology services, the NMIs need to provide optical absorbance measurement results traceable to SI units through OALF, in addition to other reference materials for MMDs. Also, many inspection bodies, such as the Moldovian SE CEMAC, which perform calibration/verification/inspection and conformity assessment of MMDs, are interested in the availability of national capabilities for traceable measurements of absorbance of OALF for the spectral range from 220 nm to 780 nm, for the photometric range from 0.001 up to 3.000 absorbance, in order to adequately assess and to ensure the reliability of their measurements of MMDs.

Cost-efficiency of European healthcare systems needs to be enhanced. One way to do this is to improve the quality of diagnostics. The necessity of taking under control the MMDs is regulated in the EU regulation (Regulation (EU) 2017/746) [1] which clearly states that all MMDs must be verified. Also based on ISO 15189:2012 [2] and ISO 13485:2016 [3] all MMDs with high impact on result must be calibrated. Due to these strong demands for the international recognition of quality medical and metrology services, the NMIs/DIs need to provide optical absorbance traceable to SI units through OALF.

The EU Regulation 2017/746 contains only general requirements for "Devices with a measuring function", but there is no clear division and description of the requirements, since the concept of "in vitro diagnostic medical devices" includes a huge number of different means, types of materials, and procedures that are used in medical laboratory diagnostics. In the case of spectrophotometers that are used as "in vitro diagnostic medical devices", the general characteristics and methods of testing and verification are specified in OIML R135 [4].

However, there are references to outdated documents and standards which have been revised or withdrawn. In addition, the standard R135 does not provide testing procedures that could entirely be adopted for MMDs. Therefore, contributions are needed in the form of recommendations and a Good Practice Guide to revise these outdated OIML standards regarding the use of spectrophotometers and devices for medical laboratories.

Improving healthcare systems and maintaining public confidence in medical institutions of European countries are long-term needs. Thus, updating procedures and development plans are needed to facilitate the take up and long-term operation of the capabilities, technology and measurement infrastructure developed in the project.

B2.d Progress beyond the state of the art

Determination of minimal criteria for optical absorbance liquid filters as reference materials

Current state of the art

Many pharmaceutical and medical laboratories working on various devices from UV-VIS spectrophotometers to microplate readers and dedicated instruments measure absorbance in micro volumes. Those instruments must be calibrated at least according to European Pharmacopeia, but some instruments should be calibrated for absorbance at required specific wavelengths due to their construction. However, precise calibration methods of absorbance at required wavelengths are not usually possible using commercially available liquid and solid traceable standards, and the calibrations are performed at approximate wavelengths and absorbance levels. In particular, medical devices such as microplate readers, nano-drop type UV-VIS and other types of medical analyser should be calibrated exactly at method measuring wavelength and absorbance range. New reference and traceable OALF will help to improve this limited range of commercially available standards.

Progress beyond the state of the art

The project will set criteria for appropriate materials as reference OALF and propose several types of OALF covering the optical absorbance from 0.001 to 3.000 in the spectral range from 220 nm to 780 nm according to available knowledge and review of the existing literature [5].

<u>Traceable measurement capabilities of absorbance of optical absorbance liquid filters in emerging NMIs and DIs</u>

Current state of the art

Almost all NMIs/DIs from Europe already have recognised optical absorbance measurement capabilities, but the problem is that not all of them have the necessary experience in the manufacturing, characterisation, and use of OALF, and the use of liquid filters in ensuring metrological traceability of MMDs. Being at the top of the traceability chain, poor knowledge of calibration/verification/inspection methods can jeopardise the accuracy and the precision of the traceability chain, which are required by the customers, such as accredited bodies, healthcare centres, hospitals, and medical testing laboratories.

Progress beyond the state of the art

The project will establish traceable measurement capabilities for OALF by developing new measurement systems or by improving the existing facilities in emerging NMIs/DIs. This will allow the dissemination of optical absorbance via CRMs, targeting a low uncertainty of 0.010 at an absorbance level of 3.000 and at temperatures between 15 °C and 40 °C, to be used for the dissemination of the unit of optical absorbance to national healthcare services, medical laboratories, testing laboratories. Emerging NMIs/DIs will be able to offer extended calibration services with a high level of accuracy and to produce and certify RMs with an uncertainty level sufficient to be used by accredited calibration laboratories and industrial companies.

Establishment of equivalence in the measurement of optical absorbance liquid filters

Current state of the art

At present most of the participant NMIs do not have formal evidence of the quality of their optical absorbance measurements of OALF, and cannot provide calibration services to testing laboratories, medical bodies, and inspection bodies in their countries.

Progress beyond the state of the art

The project will accommodate the establishment of the degree of equivalence of the optical absorbance measurements by means of comparisons amongst participating NMIs/DIs. This will be a prerequisite step to enable the recognition and demonstration of the competence of these NMIs/DIs' measurement capabilities in accordance with CIPM MRA, enhancing wider agreements negotiated for international trade and regulatory affairs.

Good practice guide on the manufacture, characterisation and use of optical absorbance liquid filters

Current state of the art

The instructions and guidance available from different standards developing organisations are not at the level of present instrumentation and lack details on technological progress of MMDs.

Progress beyond the state of the art

In this project a Good Practice Guide on the manufacture, characterisation, and use of OALF with application for modern MMDs will be developed. Strategies for the long-term operation of OALF measurements will be developed in the participating emerging countries to allow a target oriented and economic development of all planned services. This concerns services to accredited bodies and industry as well as research activities.

B2.e <u>Gender dimension</u>

The development of improved absorbance standards in the UV to NIR (Near Infra-red) wavelength range and exploitation of improved absorbance measurement capabilities of NMIs are expected to be gender neutral. The gender dimension is not relevant to the technical content of the project.

Even though the work in the project itself is not expected to have a gender dimension, the exploitation of improved traceability chain of spectrophotometry and health related diagnostics by optical methods may have a gender dimension. Females and males may perceive colours differently, which may be revealed by improved measurement standards. In addition, giving traceability to blood sample analysis may have a gender dimension as various diseases are gender influenced.

The project will target its dissemination and impact activities equally to all genders and will also communicate to stakeholders and end users in a manner that addresses all genders.

B2.f Open science

During the lifetime of this project, open science practices will be implemented as integral parts of the methodology. As stipulated in the Partnership Grant Agreement (Annex 5) and planned in the data management plan (DMP), the data and other research outputs generated in the project will be managed responsibly, in line with the FAIR principles. Open access will also be provided to scientific publications under the conditions set in the Grant Agreement (Annex 5).

In addition to the mandatory open science practices, the project will implement the following practices:

(i) Early and open sharing of research

Manuscripts of the project paper(s) will be submitted to a suitable open access platform to accelerate the dissemination of results ahead of publishing. Manuscripts will be posted by the project in widely known and accessible repositories such as Zenodo and Aalto University databases.

(ii) Measures to ensure reproducibility of research outputs

The project will provide information about the research outputs/tools/instruments needed to validate the conclusions of scientific publications or to validate/re-use research data. In addition, the project will provide digital or physical access to the results needed to validate the conclusions of scientific publications.

The project will ask its Stakeholder Committee to provide input and feedback on the project's work plan to support the robustness and reproducibility of its methods and research outputs. Including the wider community will provide the opportunity to identify methodological flaws or other inconsistencies in the project's research. Review and discussion of the methods and results will also make the work less exposed to errors and should enable it to benefit from stakeholder feedback and improvement.

All NMI/DI participants are either accredited to or work in compliance with ISO/IEC 17025 Testing and calibration laboratories. This enables the participants to demonstrate that they operate competently and generate valid results, thereby promoting confidence in their work.

Instruments developed or upgraded during the project will be validated through interlaboratory comparisons, where repeated measurements will be made on the same liquid absorbance filters and compared between participating institutes (WP2, WP3). To support quality assurance and quality control procedures, the participants will follow agreed measurement procedures. Variations between measurements will be determined and assessed, and uncertainty budgets will be produced.

(iii) Providing open access to research outputs

Research data generated in the project will be managed by following FAIR principles and open access to research data under the principle 'as open as possible, as closed as necessary', as per the Grant Agreement.

The project will disseminate its research output (including reports, good practice guides, tutorials, lectures, mathematical models, and datasets) in an open science manner, using open access repository such as Zenodo, Aalto University database or freely accessible part of the project's website. The disseminated data will be accompanied by all the required instructions for use and metadata.

Furthermore, the project will provide free links to the project's reports, resources, publications, data and outputs on the project's website and on the project's participants' websites to promote their availability to stakeholders. Awareness on the project will be raised by Stakeholder Committee members with links to the project's website.

(iv) Participation in open peer-review

Peer review is traditionally an anonymous process, however there are calls for an open peer-review process, where reviewers' comments and recommendations and authors' feedback are open for others to view. Open Research Europe (ORE) was recently set-up by the EC for use by their project's participants and is a no-fee, open access, peer-reviewed publishing venue for EU-funded research, thus the project will consider it as target journal for its publications.

(v) Involving all relevant knowledge actors including citizens, civil society, and end users in the co-creation of R&I agendas and contents

To support further discussions and dissemination the project will create forums and/or discussion groups, for example using ResearchGate and the project's website, where the exchange of information between stakeholders with the project participants can occur. In addition to this, the project's Stakeholder Committee will provide input and feedback to the project.

Close cooperation and research mobility between the project participants from universities and NMIs will also support the transfer of knowledge between these communities. Graduate students and young researchers will be invited to take part in the scientific work and to join the online stakeholder workshop to provide feedback.

B2.g Research data management and management of other research outputs

Types of data/research outputs:

Data will be from spectroradiometric absorbance measurements, calibrations of spectrophotometers and spectroradiometers, comparisons of optical absorbance of OALF, and validations of measurement facilities and procedures. Numerical data will be in CSV format and text description data will be in Markdown format. Research outputs will include a report of improved calibration and characterisation of OALF, a good practice guide, and comparison protocols. Their estimated overall size is 1 GB - 200 GB. Existing data will originate from: participants and the scientific literature. Project data will not be combined with existing data as it will only be used to validate the project's results.

Findability of data/research outputs:

Data/research outputs will be findable with a unique and persistent identifier (PID) e.g., DOI, GIT Commit/tag, Handle. The metadata will provide bibliographic information and information on funding and licensing terms. Where applicable, the metadata will include PIDs for authors (ORCID), organisations (ROR, ISNI), funders (ROR, GRID, FundRef), and related publications and research outputs (DOI, URN, ISBN, Handle). The data/research outputs will be deposited in trusted repositories (see https://www.re3data.org/). Protocols will be stored in e.g. https://www.protocols.io/.

Accessibility of data/research outputs:

All of the data needed to validate the results presented in scientific publications/research outputs will be made openly available by default unless there is a specific reason not to publish them. Other data/research outputs will be made available on a case-by-case basis if relevant for third parties. The coordinator, relevant participant(s) and the project management board will be responsible for IPR / access considerations. Open access will be decided on a case-by-case basis and agreed with the data/research output owners (where confidentiality is required for proprietary information). IPR considerations will be managed in line with the DMP, the Consortium Agreement, the Grant Agreement and the DCE plan. Open access will be granted as soon as is reasonably possible (i.e. there may be delays due to IPR considerations (e.g. whilst a patent application is pending)). The data/research outputs will remain accessible for the lifetime of the repository. Users will be required to acknowledge the project and the funding source, according to the latest CC BY license.

Interoperability of data/research outputs:

The datasets will use the trusted repository's basic metadata schema for administrative data, which is compliant with the recommended standards used by DataCite (<u>https://search.datacite.org/</u>), BASE search (<u>https://www.basesearch.net/</u>), OpenAIRE (<u>https://www.openaire.eu/search</u>). For individual datasets, the following discipline specific vocabularies, standards, formats, and methodologies will be used: e.g., ILV

(International Lighting Vocabulary), GUM (Guide to the Expression of Uncertainty in Measurement). The compatibility of the project specific vocabularies will be guaranteed through appropriate mappings (glossary, alignment tables, etc.) to more commonly used vocabularies. The generated vocabularies will be published. The project's datasets that will be deposited in the chosen trusted repository will include qualified references to other datasets from the same project and/or previous research.

Reusability of data/research outputs:

The data/research outputs will either be licensed under the latest available version of the CC BY license or a license with equivalent rights as set out in the Grant Agreement. Users will be required to acknowledge the consortium and the source of the data in any resulting publications. Alternatively, the Public Domain Dedication License (CC 0) will be used. README files will be provided together with the data/research outputs, in order to enable their analysis and re-use. Spectral absorbance of liquid absorbance filters' files can be validated for their structure by using the JSON schema in web-based tools. The PID of the JSON schema can be found in the file itself. The data are in a common format and can be read using widely available software (open source or commercial). Any data published in open access journals will be usable by third parties after the datasets have been deposited in a trusted repository. The data that does not relate to peer reviewed publications will be made available for re use on a case-by-case basis.

Curation and storage/preservation costs:

The estimated curation and storage/preservation costs for making the data and research outputs FAIR are $1500 \in (\text{personnel costs})$. These costs will be kept to a minimum by using i) suitable trusted repositories from the Registry of Research Data Repositories (https://www.re3data.org/) where no additional costs are associated with long-term preservation, and ii) by making only relevant data and outputs FAIR. The estimated curation and storage/preservation costs are included in the project's budget and will be claimed if compliant with the Grant Agreement's conditions.

Participant, person or team responsible for data management and quality assurance:

This consortium will not establish a Data Access Committee (DAC). The coordinator, with support from the participants, will have overall responsibility for the management of data/research outputs and quality assurance. The coordinator will be responsible for coordinating updates to the data management plan and for deciding on a case-by-case basis which data/research outputs will be kept and for how long. The participant(s) that produced the data will be responsible for organising backup and storage, archiving, and for depositing the data/research outputs within the chosen repositories.

B3 Potential outcomes and impact from the project

B3.a <u>Projected outcomes for industrial and other user communities</u>

The project will develop improved capability of participant NMIs for the calibration and characterisation of OALF. The early beneficiaries of this project's outputs will be the national accredited calibration and inspections bodies, and verification/calibration laboratories with availability of SI traceable measurements of spectral absorbance and accurately characterised/certified OALF. Additional beneficiaries will be testing laboratories, healthcare institutions and medical laboratories, that use CRM of OALF as a means to link the quantity for their MMDs (e.g., biochemical analysers, immunological analysers and others) to SI units. The use of OALF will also help manufacturers to control the metrological parameters of MMDs during production. Industrial manufacturers and users of photonic equipment will benefit from the developments, as the target is to develop technology that simplifies the traceability and enables instruments to be calibrated easily. These will lead to new national accreditation schemes which will benefit accredited bodies and calibration and measurement laboratories. Furthermore, at least two training courses or webinars will be organised by SMU with support of AGILENT UK, INM, PTB, and UMTS for the end-user community (i.e., accredited laboratories, research centres, technical assessors for accreditation bodies, etc.) to disseminate best practices in ensuring metrological traceability for MMDs by using OALF. In consultation with EURAMET TC-PR, the project consortium will develop a Good Practice Guide on the manufacture, characterisation, and use of OALF with application for MMDs which will benefit European producing industries of OALF and MMD users for preparation and use of samples for calibration of their devices.

B3.b Projected outcomes for the metrological and scientific communities

The early impact of this project on the metrological community is related to the opportunity to build capacity at NMIs/DIs (INM, UMTS, BIM, CMI, INRIM, DMDM, IPQ, TUBITAK) to establish/improve their capabilities in measurement methods related to OALF. At the end of this project these NMIs will be able to establish a

complete national traceability chain using the CRM of OALF for MMDs at a level needed by each participating country. Additionally, these NMIs will have the opportunity to establish their degree of equivalence for OALF measurements by means of participation in inter-laboratory comparisons, organised in the scope of this project, leading to their recognition and demonstration of competence in accordance with CIPM MRA. This will lead to a change in the current lack of European CMCs in the BIPM database regarding optical absorbance measurements, as well the lack of CMCs for CRM for optical absorbance. This build-up of measuring capabilities will empower the emerging NMIs to offer new/improved calibration services and CRMs, fulfilling the needs of the national healthcare institutions, medical laboratories, and inspection bodies.

The primary beneficiaries of the direct outputs of this project will be the metrological radiometry community, but the wider scientific community will also gain significant benefits from the methods, calibration facilities, measurement protocols and services developed. At the end of this project the scientific community will benefit from the enhancement in quality and equivalence of the optical absorbance measurements thanks to improved traceability chains. The knowledge transfer to this community will be made through the publication of project's results in at least 2 papers in peer-reviewed journals and by the presentation of at least 7 oral or poster presentations at international conferences. Moreover, the findings of the project will support research and innovation on determination of new materials' optical properties in the scientific community of the involved countries.

B3.c Projected outcomes for relevant standards

The participants will disseminate information on the project's progress and results to international and European standardisation bodies. The project's results will be presented to OIML, for the consideration of the project outputs in future revision of outdated documents such as OIML standards regarding the use of spectrophotometers for medical laboratories (OIML R 135).

The participants who are members of corresponding technical committees will inform them about the results of this project and will endeavour to ensure they are incorporated in any updates to the standards or guidelines (see table below). For example, the representatives on the corresponding committee or working group from the participants will jointly ask the chairperson to include a point in the agenda to briefly present the outputs of the project related to the working group activities and ask for comments from the other committee/working group members. Where appropriate a written report will be submitted for consideration by the committee or working group.

Standards Committee / Technical Committee / Working Group	Participants involved	Likely area of impact / activities undertaken by participants related to standard / committee	
CIE – Division 2 TC2-98	Aalto, INRIM, PTB, RISE	Aalto, INRIM, PTB and RISE are involved in technical committees which within CIE-Division 2. The project coordinator is a specially-invited-mem the most relevant committee TC2-98 which deals with measuremer reflectance and transmittance and will report the progress of the project t TC2-98. Aalto with support of INRIM, PTB and RISE will share the progres the project with TC2-98. Aalto will invite the chair of TC2-98 to particip the project stakeholder committee. This TC meets approximately ever months.	
CCPR WG-KC and Task Groups	Aalto, TUBITAK, CMI, SMU, INRIM	CCPR is the Consultative Committee for Photometry and Radiometry whose activities concern measurement standards for photometric and radiometric quantities, development of absolute radiometry, and advice to the CIPM on matters concerned with radiometry and photometry. Various working groups such as Working Group on Key Comparisons (WG-KC), Calibration and Measurement Capabilities (WG-CMC), and Strategic Planning (WG-SP) within CCPR will benefit from the output of the project. Meetings are held approximately every 12 months. Aalto, TUBITAK, CMI, SMU, and INRIM will regularly inform the CCPR on the project's progress and its outputs (papers, conference presentations, etc.) and seek to identify opportunities to incorporate project results into a new or updated standards.	

EURAMET TC-PR	Aalto, CMI, INRIM, IPQ, SMU	EURAMET TC-PR is the technical committee for Photometry and Radiometry. EURAMET TC-PR meets annually in January/February. Information about the overall objectives of the project will be given in 2025 by Aalto and INRIM. Presentation of the results of EMRP/EMPIR and Partnership projects has usually been on the agenda in the TC-PR meetings. SMU, IPQ, INRIM and CMI will report the progress of project on activities of WP1-WP4 at the annual EURAMET TC-PR meetings in 2025 to 2027. Aalto will share information on the development of the GPG in the meeting of 2027 and will seek feedback and support.
OIML TC 18/SC5	UMTS	TC 18 and TC 18/SC5 are Technical Committee and Subcommittee of the International Organization of Legal Metrology (OIML). One of the aims is development of "standards and related documents for use by legal metrology authorities and industry" in the field of production and operation of Medical measuring instruments (TC 18) and Measuring instruments for medical laboratories (TC 18/SC 5). UMTS will inform TC 18/SC5 about ongoing project activities. In the final part of the project, UMTS will present the results of research on the use of liquid absorbance filters for medical spectrophotometers and proposals for the revision of OIML R135 "Spectrophotometers for medical laboratories" in TC 18/SC 5. Meetings are held by decision of he International Committee of Legal Metrology (CIML).
ISO/TC 172	RISE	ISO/TC 172 on Optics and photonics deals with standardisation of terminology, requirements, interfaces and test methods in the field of optics and photonics. RISE will inform this TC on the project's progress and its outcomes regarding characterisation and traceable measurement of liquid filters. The group meets annually.
EURACHEM	UMTS, BIM	EURACHEM is a network of organisations in Europe having the objective of establishing a system for the international traceability of chemical measurements and the promotion of good quality practices. UMTS is a member of EURACHEM, and its representatives are in 3 working groups in the structure of EURACHEM. BIM is currently a member of EURACHEM and participates at General Assembly, which meets once per year. UMTS with support of BIM will inform the progress of the project and get feedback on needs regarding liquid absorbance filters.

B3.d Projected wider impact of the project

Economic impact:

The project will support accredited bodies, national healthcare services and the research community through the implementation of recognised traceability chains for MMD measurement. This will significantly advance the expertise on manufacturing, characterisation and use of OALF for ensuring traceability of MMDs. This in turn will improve the quality of diagnostics and have positive impacts on cost-efficiency of European healthcare systems. The work will provide opportunities for new calibration services to be developed, new and enhanced MMDs and the manufacture of a variety of new absorbance liquids and reference materials.

Environmental impact:

The project will improve the capabilities of European NMI/DIs in the measurement of spectral absorbance of substances. This will have positive impacts on obtaining more accurate and reliable results from the tests performed for water quality monitoring and environmental protection.

Social impact:

An important aspect from the results of the project is to provide the means for fulfilling the legal metrological aspects for MMDs. The resultant impact of the project will lead to an increase in the protection of European citizens by increasing the confidence level of measurement of MMDs. In turn this will improve health outcomes for patients through enhanced diagnostics and monitoring capability.

B3.e Summary of the project's impact pathway

SPECIFIC NEEDS EXPECTED RESULTS DCE MEASURES What are the specific needs that triggered What do you expect to generate by the end of What dissemination, communication and this project? the project? exploitation measures will you apply to the results? The necessity of taking under control of - Improved capability of participant NMIs the MMDs (In Vitro Diagnostic Medical for the calibration and characterisation of Dissemination: Available know-hows are Devices) is regulated in the EU regulation OALF (Expected result 1) distributed among participants via 5 online (Regulation (EU) 2017/746) which clearly and onsite training events and new - The degree of equivalence of states that all MMDs must be verified, adequate OALF will be disseminated absorbance measuring systems and the also based on ISO 15189:2012 which among participants. At least 2 quantity of absorbance of the project states that all MMDs with high impact on peer-reviewed joint publications will be participants is established by using OALF result must be calibrated. produced. 7 presentations in international particularly in the spectral range from conferences exploiting previously 220 nm to 780 nm and absorbance range Many MMDs used in clinical diagnostics, produced materials, including good devices such as biochemical analysers, from nominal 0.001 to 3.000 with an practice guidelines. immunological analysers, and others, are uncertainty of 0.3 % to 1.0 %. (Expected using optical absorbance as basic Communication: A Stakeholder result 2) measurement quantity. Not many Committee will be created. Project - A Good Practice Guide on the NMIs/DIs have the capability of the website will be created and updated; manufacture, characterisation, and use of required/requested optical absorbance publishable summary will be distributed to OALF with application for MMDs measurements traceable to SI units stakeholders. Promotion of specific (Expected result 3) through OALF. results to interest groups will be made in - Report of improved calibration and various national and international The need to determine a set of minimal characterisation of OALF, together with meetings. Flyers and posters will be criteria for OALF as reference materials roadmaps and action plans for future prepared and made available in the can pave the path to further manufacture capacity building (Expected result 4) project website and distributed via emails a variety of absorbance liquids. and letters. Videos will be produced - New OALF manufacturing addressing industry and the public. process/recipe (Expected result 5) Exploitation (see exploitation task for more details): Calibration services will be developed, and standard or certified reference materials will be provided by several participants. The expertise produced will be made available to accreditation organisations, inspection bodies, MMD users and to a larger community outside the consortium. TARGET GROUPS OUTCOMES IMPACTS Who will use or further up-take the results of What change do you expect to see after What are the expected wider scientific, the project? Who will benefit from the results successful dissemination and exploitation of economic and societal effects of the project of the project? contributing to the expected impacts outlined project results to the target group(s)? in the work programme and call scope? End users: Improved and extended knowledge and capabilities in OALF within the less Scientific: NMIs/DIs within the project consortium, experienced NMIs (INM, UMTS, DMDM, NIMs/DIs in other developing countries Improved global equivalence and reduced TUBITAK). (outside the project consortium), CCPR uncertainty in key metrological areas as Improved CMCs of spectral absorbance and regional metrology organisations CCPR-k6, spectral transmittance and such as EURAMET TC-PR, and SIM and transmittance. absorbance. (Inter-American Metrology System). New services for providing CRMs and Reduced capability gap between Accreditation organisation and European NMIs/DIs in the spectral their handling Inspection bodies e.g., ACCREDIA absorbance characterisation, calibration, Evolution and improvement of related (Italy), MOLDAC (Moldova), SE CEMAC and use of OALF standards (OIML R 135). (Moldova) Economic: Standardisation bodies: OIML, ISO Improved quality of diagnostics and cost Accredited calibration laboratories of efficiency in healthcare system via the highest level (ANALYSIS d.o.o advanced expertise on manufacturing, (Serbia), SE CEMAC (Moldova)) characterisation and using of OALF Reference material and instrumentation Societal: producers (CRM) Increase of the protection of the European The healthcare sectors having access to citizens by increasing of confidence level new CRMs and improved services from of measurement of medical measuring national NMIs/DIs devices. Smart specialisation of European NMIs through realisation and implementation of improved spectral transmittanceabsorbance scale will provide better traceability to light based diagnostic instruments used at the point of care.

B4 The quality and efficiency of the implementation

B4.a <u>Overview of the consortium</u>

The project consortium brings together a wide range of European NMIs and DIs and one industrial participant with dedicated expertise in the field of Photometry and Radiometry. The consortium comprises 9 internal beneficiaries, 4 external beneficiaries and 1 associated partner from 14 countries. The consortium participants have strong relationships with their industrial stakeholders and the end-user community, which ensures high impact of the project to many target user groups.

Aalto is the Metrology Research Institute of Aalto University that is the designated institute (DI) for maintaining and developing national standards of optical quantities in Finland. Aalto is involved in all work packages and will coordinate the project. Aalto contributes to the project with use of its high-accuracy equipment for measuring liquid absorbance filters and will benefit from and contribute to preparation of recommendations for proper use of liquid filters and best practice guide for absorbance measurements.

CMI is the NMI of Czechia, responsible for maintaining and developing National Standards. CMI's department of Radiometry and Photometry has excellent capabilities in scientific-technological field demonstrated by a number of facilities, published papers in indexed journals and presentations on international conferences. Within the project CMI will improve and validate its absorbance measurement capability in UV wavelength range. CMI is leading WP4 and contributes to activities in other work packages.

GUM is the NMI in Poland and is responsible for the maintenance and development of national and reference standards for photometry, radiometry, and spectrophotometry. To cope with increasing demands for metrological services at the highest level of accuracy, GUM is still increasing its knowledge, experience and expertise in order to improve its measurement methods, metrological infrastructure and competence of staff. GUM is going to contribute to all work packages.

INRIM is the National Metrology Institute of Italy which is responsible for maintaining and developing optical measurement standards. In the frame of this project INRIM intends to extend existing spectral transmittance measurement capabilities to the absorbance measurement of liquid filters. INRIM will benefit of know-how transfer from experienced participants, upgrading of the measurement set-up and validation of the new measurement capability. INRIM will lead WP3, and it will be involved in all work packages.

IPQ is the National Metrology Institute of Portugal; is responsible for the maintenance and development of national and reference standards for photometry, radiometry, spectrophotometry and refractometry of liquids. It has participated in European Research projects with expertise in photometry and spectrophotometry, in the visible spectral interval, thanks to a double beam double monochromator spectrophotometer. In addition to accepting the responsibility to lead the WP2 "Establishing the degree of equivalence of optical absorbance measurements for liquid absorbance filters", IPQ will participate in all work packages.

PTB is the National Metrology Institute of the Federal Republic of Germany, with scientific and technical service tasks. Division "Optics" supports industry, science and society by providing measurement services, research and development in the field of optical technology. The work group "Reflection and Transmission" of the Applied Radiometry Department develops accurate standards, high-accuracy methods and systems for spectral measurements of the transmission and reflection properties of substances and materials. PTB will contribute to all work packages.

RISE is the National Metrology Institute of Sweden. The Photometry and Radiometry Laboratory at RISE is responsible for maintaining the national reference standards for photometric and radiometric measurement quantities, e.g., transmittance, absorbance, and reflectance. The laboratory has expertise in optical measurements, calibrations, and research in the ultraviolet, visible, and infrared wavelength range. RISE has many years of experience in evaluations of optical properties of materials and surfaces and will contribute to all the work packages.

SMU is the National Metrology Institute of Slovakia. It is responsible for realisation, development and maintenance of all National Standards in Slovakia, including Photometric and Radiometric ones. SMU has good experiences with preparing and characterisation of wide range of certified reference materials, also of liquid filters. SMU offers its experiences and skills to lead WP1 and will participate in all work packages. SMU's expectations of the projects are focused on developing our existing methods, introduce new characterisation procedures and preparing new materials.

TUBITAK is Türkiye's scientific and technological research centre. The National Metrology Institute, UME, takes place under the TUBITAK. It is responsible for realisation, development, and maintenance of National Standards. With these infrastructures, the spectrophotometric properties (reflectance, transmittance, and

absorbance) of liquid and solid materials in the 220 nm – 2500 nm wavelength range can be investigated with high accuracy. Due to these experiences, TÜBİTAK will contribute to all the work packages.

BIM is the National Metrology Institute in Bulgaria and is responsible for the development and maintenance of national standards for Spectral transmittance, Spectral Reflectance, and other quantities of optical properties of materials. BIM will work on measurements of spectral absorbance of liquid filters in UV/VIS range. As a result of participation in this project it is expected to increase the expertise and technical potential and to develop new measurement services in the field of absorbance measurements and RM certification. BIM will be involved in all the work packages.

DMDM is the National Metrology Institute of the Republic of Serbia which is responsible for the development and maintenance of national standards. The motivation for participating in the project is the expansion of measurement capability in the UV range on the primary spectrophotometric system developed in their laboratory. DMDM will be involved in all work packages.

INM is the National Metrology Institute of the Republic of Moldova which is responsible for implementation of policies in the field of scientific and legal metrology at national level. INM has experience in optical absorbance measurements and facilities for spectral range from 220 nm up to 3300 nm, assured by spectrophotometer Lambda 950. INM needs to establish and develop metrological traceability at national level for medical measuring devices through OALF. INM will contribute to all of the work packages based on its knowledge in manipulation and preparation of Reference Materials.

UMTS is one of the four Designated Metrology Institutes of the Ministry of Economy of Ukraine. UMTS has a secondary standard of units of spectral transmission in the range from 200 nm to 2500 nm. The experience of the production and use of liquid filters for verification/calibration medical analysers and spectrophotometers is over 20 years. There is a full complex of equipment for the manufacture and research of the metrological characteristics of liquid filters. UMTS will be involved in all the work packages.

AGILENT UK is a leader in life sciences, diagnostics and applied chemical markets. Agilent will contribute to WP1 and WP3 by measuring temperature dependence of selected filters and giving guidance on spectrophotometric applications. AGILENT UK is an Associated Partner and is associated to all Internal Beneficiaries.

Section C: Detailed project plans by work package

C1 WP1: Selection and characterisation of optical absorbance liquid filters as reference materials

The aim of this work package is to determine a set of minimal criteria (physical and chemical properties) for OALF as reference materials, which will include a dilution series of absorbance liquids. This will be achieved by selecting, producing and characterising a variety of working and reference materials (RMs) of OALF. The characterised working and RMs will be used to investigate the conditions and instrument parameters that influence the optical absorbance measurements.

To achieve this, WP1 is divided into three tasks:

Task 1.1: will select, prepare and distribute suitable working and RMs of liquid filters to be used in diagnostic and consolidation comparisons in WP2, based on individual NMI activities.

Task 1.2: will characterise the selected OALF. The characterisation will include homogeneity, pH, temporal stability, and dependence of optical absorbance on measurement wavelength and bandwidth.

Task 1.3: will study temperature effects on OALF, in the temperature range between 15 °C and 40 °C, and UV radiation exposure effects at ambient pressure.

C1.a Task 1.1: Selection of optical absorbance liquid filters as reference materials

The aim of this task is to select, prepare and distribute suitable working and RMs of OALF to be used in diagnostic and consolidation comparisons that will be carried out in WP2. The reference materials will be defined by agreement within the consortium, choosing relevant OALF appropriate for the participant NMIs' and DIs' activities. Where possible, existing reference materials will be chosen. Additional OALF will be purchased by CMI, RISE, and TUBITAK to be distributed to the other participants where necessary for UV aging.

Activity number	Activity description	Participants (Lead in bold)
A1.1.1 M3	SMU with support of Aalto, UMTS and INM will set criteria for selecting appropriate materials for liquid filters and propose several types of OALF covering the optical absorbance from 0.001 to 3.000 in the spectral range from 220 nm to 780 nm according to available knowledge and review of the existing literature on their properties. The expected number of measuring wavelengths is up to 10.	SMU , Aalto, INM, UMTS
	Selection of the materials will include liquid filters based on aqueous acid solutions of inorganic salts (potassium bichromate, chromium perchlorate, nickel sulphate, cobalt sulphate, copper sulphate).	
A1.1.2 M8	SMU with contribution of INM, GUM and UMTS will prepare the liquids selected in A1.1.1, with different concentrations in bottles or ampules necessary for the robustness studies, in tasks 1.2 and 1.3 and for comparisons in A2.1.2 and A2.2.3. SMU will send a set of liquids to each of the following participants: Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, TUBITAK, BIM, DMDM, INM, UMTS and AGILENT UK, who will then prepare their own liquid filters.	SMU, INM, GUM, UMTS
	SMU will prepare an internal report on the selection and preparation of the OALF with input from A1.1.1 and share with the consortium.	
A1.1.3 M11	RISE, CMI and TUBITAK will select and manufacture/purchase two sets of samples of liquid filters (selected in A1.1.1) in sealed quartz cuvettes to be used in temperature cycling and UV aging studies in activities A1.3.5. to A1.3.7.	RISE, CMI, TUBITAK
A1.1.4 M13	GUM, INM, Aalto, PTB, SMU, UMTS and RISE will select and agree on the OALF to be used in the robustness studies of selected liquids (in Tasks 1.2.and 1.3). These will be a subset of those prepared in A1.1.2. At least 3 different liquids (different chemicals with 2-3 concentrations) with different optical absorbance levels from absorbance 1 to 3 will be selected for the robustness study. GUM will include the selected liquids in the "Report of the robustness studies" in A1.3.8.	GUM, INM, Aalto, PTB, SMU, UMTS, RISE

A1.1.5 M19	IPQ, with input from Aalto, CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS and AGILENT UK will select and agree on at least six OALF based on the results of A1.1.4, A1.2.10 and A1.3.7 and for comparison protocol in A2.2.2 and to be used in the comparison measurements planned in A2.1.2 and A2.2.3.	IPQ, Aalto, CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS, AGILENT UK
---------------	---	--

C1.b Task 1.2: Optical characterisation of optical absorbance liquid filters

The aim of this task is to characterise the OALF selected in A1.1.1 and prepared in A1.1.2 and A1.1.4. The characterisation will include homogeneity, pH, temporal stability, and dependence of optical absorbance on measurement wavelength and bandwidth.

Activity number	Activity description	Participants (Lead in bold)
A1.2.1 M8	INM with support of Aalto, PTB, SMU and UMTS will agree a plan and protocol for the measurements which will be done in A1.2.2 to A1.2.9. The protocol will include guidance on measurement conditions to be used, expected number and range of measurements and items such as which participants will undertake which measurements and how results should be recorded to enable consistent reporting.	INM, Aalto, PTB, SMU, UMTS
A1.2.2 M10	INM with support of Aalto, SMU and UMTS will perform preliminary measurements at wavelengths based on the protocol in A1.2.1 to provide measurement conditions such as absorbance interval, wavelength interval, and possible temperature effects on the absorbance of the selected liquid filters and their associated chemicals or "Blanks" selected in A1.1.1.	INM, Aalto, SMU, UMTS
A1.2.3 M11	TUBITAK with support of DMDM will perform measurement of homogeneity of a set of samples selected from A1.1.1 of OALF based on the protocol in A1.2.1 without moving the samples and with an uncertainty of 1 %.	TUBITAK , DMDM
A1.2.4 M13	According to the discussions and knowledge transferred in A3.1.1, UMTS, RISE and Aalto will measure selected liquid filters (LF) from A1.1.2 for certain measurement parameters of their systems such as linearity, wavelength, and stray light based on the protocol in A1.2.1. RISE with support of Aalto will perform test measurements to derive corrections for the influence of inter-reflections and optical properties of liquid filters such as index of refraction using the setup from A3.1.8.	UMTS , RISE, Aalto
A1.2.5 M14	UMTS will study the influence of pH on the spectral properties of LF based on the protocol in A1.2.1. All parameters will be indicated in the passport for LF. UMTS, RISE and Aalto will also make an uncertainty budget for their own measuring systems based on research. UMTS, RISE and Aalto will take measurements at agreed time intervals to determine the temporal stability of liquid filters.	UMTS, RISE, Aalto
A1.2.6 M17	Using the results from measurements in A1.2.2 to A1.2.5, UMTS will compile inputs for the "Report of characterisation of the liquids" (in A1.3.8) concerning determination of effects of measurement parameters and temporal stability of selected liquid filters.	UMTS
A1.2.7 M17	Aalto, GUM, SMU, TUBITAK, INRIM, DMDM and BIM will take part in determination of short time stability of the OALF and the measuring systems at room temperature (23 ± 1) °C and at the wavelengths that will be determined in activities A1.1.2 - A1.1.4 and according to protocol in A1.2.1. Aalto will compile inputs for the "Report of characterisation of the liquids" in A1.3.8	Aalto, GUM, SMU, TUBITAK, INRIM, DMDM, BIM
	concerning determination of short time stability of the selected liquid filters.	
A1.2.8 M17	GUM, Aalto, SMU, TUBITAK, DMDM and BIM will contribute (according to protocol in A1.2.1.) to determination of dependence of optical absorbance of selected liquid filters on the bandwidth of measurement system where possible (0.5 nm, 1.0 nm, 2.0 nm and 5.0 nm) at room temperature (23 ± 1) °C and at the wavelengths determined in activities A1.1.2 - A1.1.4.	GUM , Aalto, SMU, TUBITAK, DMDM, BIM
	GUM will compile inputs for the "Report of characterisation of the liquids" in A1.3.8 concerning determination of dependence of optical absorbance on the bandwidth of the selected liquid filters.	

A1.2.9 M13	SMU, BIM, GUM, PTB, RISE, INRIM and INM will take part in determination of spectral absorbance of selected liquid filters in the spectral range from 220 nm to 780 nm with an interval of 1 nm and bandwidth of 1 nm (according to protocol in A1.2.1). SMU will compile inputs for the "Report of characterisation of the liquids" in A1.3.8 concerning determination of spectral dependence of optical absorbance of the liquid filters.	SMU, BIM, GUM, PTB, RISE INRIM, INM
A1.2.10 M18	GUM with support from Aalto, CMI, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS and AGILENT UK will compile inputs from A1.2.6 to A1.2.9, for the "Report of characterisation of the liquids" in A1.3.8.	GUM, Aalto, CMI, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS, AGILENT UK

C1.c <u>Task 1.3: Characterisation of selected optical absorbance liquid filters for temperature</u> <u>dependence, cycling, and UV exposure</u>

The aim of this task is to study the temperature effects on OALF selected in A1.1.1, in the range of temperatures between 15 $^{\circ}$ C and 40 $^{\circ}$ C, and the effects of UV radiation exposure at ambient pressure.

Activity number	Activity description	Participants (Lead in bold)
A1.3.1 M9	TUBITAK with support of Aalto, AGILENT UK, CMI, GUM and RISE will agree a plan and protocol for the measurements which will be done in A1.3.2 to A1.3.7. The protocol will include guidance on measurement conditions to be used, expected number and range of measurements and items such as which participants will undertake which measurements and how results should be recorded to enable consistent reporting. Knowledge shared and developments in A3.1.2 will feed into this.	TUBITAK , Aalto, AGILENT UK, CMI, GUM, RISE
A1.3.2 M12	TUBITAK, AGILENT UK, GUM and Aalto will perform optical characterisations of selected liquid filters from A.1.1.2, according to the protocol in A1.3.1, in the temperature interval of 15 °C and 40 °C and estimate the uncertainty budget in absorbance measurements by considering the temperature effects.	TUBITAK , Aalto, AGILENT UK, GUM
A1.3.3 M14	RISE, Aalto, INRIM, GUM, TUBITAK and BIM will characterise at least three types of OALF from A1.1.2, according to the protocol in A1.3.1, with different concentration and absorbance levels of 0.5, 1.0, and 2.0 at relevant temperatures (20 °C, 23 °C, 25 °C and 37 °C) with an uncertainty of 1 °C, at three wavelengths of absorption peaks, with a relative uncertainty of less than 1 %.	RISE , Aalto, INRIM, GUM, TUBITAK, BIM
A1.3.4 M18	GUM, TUBITAK, INRIM, SMU, INM and BIM will investigate the robustness of selected OALF from A1.1.2, according to the protocol in A1.3.1, in terms of temperature effects on absorbance, at the ambient pressure and temporal stability at relevant wavelengths during month 12 and month 18. The measurement beam will be set to a bandwidth of 1 nm if possible.	GUM , TUBITAK, INRIM, SMU, INM, BIM
A1.3.5 M18	TUBITAK will measure the thermal aging of selected OALF from A1.1.3 and according to protocol agreed in A1.3.1. The measurements of absorbance are performed before and after the temperature cycling (8 °C to 40 °C to 8 °C) to determine thermal aging effects.	TUBITAK
A1.3.6 M17	CMI and RISE will provide traceable measurements of applied UV doses used in UV aging procedure to check the effect on the absorbance of selected filters from A 1.1.3.	CMI, RISE
A1.3.7 M18	CMI with support of RISE will study UV aging of 3 pieces of selected OALF from A1.1.3 at constant room temperature. The changes in spectral absorbance caused by UV aging will be studied.	CMI, RISE
	CMI will compile inputs for the "Report of characterisation of the liquids" in A1.3.8 concerning determination of UV aging of the liquid filters.	

A1.3.8 M21	GUM will compile inputs from A1.1.4, A1.2.10 and A1.3.7 with the help from Aalto, CMI, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS and AGILENT UK and circulate the report to consortium. Once the report has been agreed by the consortium, the coordinator on behalf of GUM, Aalto, CMI, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS and AGILENT UK will then submit it to EURAMET as D1 : <i>"Report on calibration, characterisation, and robustness studies for a series of absorbance liquids with different concentration (dilution) and suggestions for minimal criteria in terms of physical and chemical properties of optical absorbance liquid filters as reference materials relevant to various types of Medical Measuring Devices".</i>	GUM, Aalto, CMI, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS, AGILENT UK
A1.3.9 M35	Aalto with contribution from all participants will submit a paper in a peer-reviewed journal to disseminate the results of the characterisation and robustness of the liquid filters studied.	Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS, AGILENT UK

C2 WP2: Establishing the degree of equivalence of optical absorbance measurements for optical absorbance liquid filters

The aim of this work package is to establish the degree of equivalence of absorbance measuring systems and of the absorbance quantity by means of OALF in the 220 nm to 780 nm interval for absorbance values ranging from nominal 0.001 to 3.000.

This is achieved in several stages of knowledge sharing in WP3, measurement systems preparations in WP1, preliminary (diagnostic) comparison measurements in Task 2.1, and a blind (consolidation) intercomparison measurement with the objective of reaching a standard uncertainty of better than 1 % at absorbance level of 3.000 in Task 2.2. Finally, in Task 2.3 efforts will be given to developing a strategy and a road map to transfer the experience gained and measurement traceability to the stakeholders in close interactions with the activities of WP4, Creating Impact. In addition, an analysis of pilot comparisons such as COOMET.PR-730/UA/17 «Spectral regular transmittance in the ultraviolet range from 200 nm to 380 nm» for the selection of liquid filters for these comparisons within the framework of this project will be carried out.

These measurement comparisons and activities will be a necessary step for enabling the emerging NMIs/DIs to gain the needed recognition and demonstration of their competence in their measurement capabilities in accordance with CIPM MRA, enhancing wider agreements negotiated for international trade and regulatory affairs.

C2.a Task 2.1: Diagnostic measurement comparison

The aim of this task is to establish a baseline measurement comparison of participants' facilities for OALF and use the results to improve these infrastructures in preparation for a full intercomparison in Task 2.2. The work will involve all project participants in making preliminary measurement comparisons of absorbance to diagnose the faulty or incomplete aspects of the measuring systems, data analysis methods, etc. used by participating NMIs (CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS) / DIs (Aalto) for the measurements of OALF. IPQ with support of Aalto will set the necessary conditions for benchmark measurements, prepare protocols, organise measurements, and prepare measurement results and reports. Based on diagnostic comparison, the emerging NMIs (INM, UMTS, DMDM, TUBITAK) and other participants (Aalto, BIM, CMI, GUM, INRIM, IPQ, RISE) will improve their infrastructures to make them ready for the consolidation intercomparison planned in Task 2.2.

Activity number	Activity description	Participants (Lead in bold)
A2.1.1 M20	IPQ with support of Aalto will prepare a protocol detailing the samples and procedures for a diagnostic comparison measurement where the absorbance of the tested liquids will be determined and compared at 3 relevant temperatures such as 15 °C, 25 °C and 37 °C, at ambient pressure, using two types of liquids, each having 3 different concentrations selected in A1.1.5.	IPQ, Aalto

A2.1.2 M23	IPQ with support of Aalto will coordinate the measurement comparison outlined in A2.1.1. IPQ, Aalto, CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM and UMTS will undertake the measurements and present their results together with the uncertainty budget in an internal report.	IPQ, Aalto, CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS
A2.1.3 M24	IPQ with support of Aalto will prepare the "Report of diagnostic comparison" based on inputs from A2.1.2 with feedback from IPQ, Aalto, CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM and UMTS. Once the report has been agreed by the consortium, the coordinator on behalf of IPQ, Aalto, CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM and UMTS will then submit it to EURAMET as D3 : "Report on diagnostic absorbance comparison using optical absorbance liquid filters".	IPQ, Aalto, CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS
A2.1.4 M25	Based on diagnostic comparison report, the emerging NMIs (INM, UMTS, DMDM, TUBITAK) and other participants (Aalto, BIM, CMI, GUM, INRIM, IPQ, RISE) will provide and execute a plan for improvement of their infrastructures (measurement, data analysis, etc.) where possible to make them ready for the consolidation comparison in Task 2.2.	IPQ, Aalto, CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS

C2.b Task 2.2: Consolidation measurement comparison

The aim of this task is to perform a consolidation intercomparison to confirm the degree of equivalence of the NMIs' and DIs' (IPQ, Aalto, CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS) optical absorbance measurements, particularly by using OALF measured in A2.1.2.

Activity number	Activity description	Participants (Lead in bold)
A2.2.1 M12	UMTS, Aalto and IPQ will make an analysis of other piloted comparisons such as COOMET.PR-730/UA/17 «Spectral regular transmittance in the ultraviolet range from 200 nm to 380 nm» to compare the liquid filters used in those comparisons to learn best practice to feed into A2.2.2.	UMTS , Aalto, IPQ
A2.2.2 M26	Aalto with support of IPQ will prepare a protocol with the input and agreement of CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM and UMTS for a consolidation comparison at two temperatures (25 °C and 37 °C), at ambient pressure, using at least 6 OALF selected according to the conclusion of A1.1.5 and A2.1.4.	Aalto, IPQ, CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS
A2.2.3 M34	Aalto with support of IPQ will coordinate the consolidation comparison outlined in A2.2.2. Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM and UMTS will undertake the measurements and report the results together with the uncertainty budget in an internal report.	Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS
A2.2.4 M35	Aalto with support of IPQ will prepare the "Report of consolidation comparison" based on inputs from A2.2.3. Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM and UMTS will take active part in analysis of the results shown in the report and discuss to identify possible methodological, instrumental, and other errors. Once the report from the comparison has been agreed by the consortium, the coordinator on behalf of Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM and UMTS will then submit it to EURAMET as D4: "Report on the intercomparison measurements on optical absorbance liquid filters with absorbance of up to 3.000 and a target relative standard uncertainty of 0.3 % to 1.0 %".	Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS
A2.2.5 M36	Aalto with contribution of CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM and UMTS will submit a paper in a peer-reviewed journal, using material from A2.2.4, to disseminate the results of the consolidation intercomparison.	Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS

C2.c Task 2.3: Development of a strategy to transfer acquired skills to stakeholders

The aim of this task, based on the results of Task 2.2, is to develop a strategy for all participant NMIs to transfer the gained experience on sample preparation, calibration, and characterisation of OALF and measurement traceability to stakeholders related to medical measuring devices in their countries and Regional Metrology Organisations. Stakeholders would include accreditation organisations and MMD users.

Activity number	Activity description	Participants (Lead in bold)
A2.3.1 M34	INM with support from Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, and UMTS will arrange at least two events to initiate and follow-up discussions with stakeholders for planning on how to develop a strategy for NMIs and DIs to transfer the gained experience on sample preparation, calibration, and characterisation of OALF and measurement traceability to the stakeholders related to medical measuring devices in their countries and Regional Metrology Organisations. This will be initiated from the beginning of the project and will involve stakeholders such as accrediting organisations or laboratories in online/hybrid events. The first event will be organised by M18. INM will use contacts and input from Stakeholder Committee (A4.1.1).	INM, Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, UMTS
A2.3.2 M35	The NMIs/DIs (CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS) /(Aalto) will each prepare a report on a strategy/roadmap to transfer the gained experience on sample preparation, calibration, and characterisation of OALF and measurement traceability to the stakeholders related to medical measuring devices in their countries and Regional Metrology Organisations. IPQ will compile a summary report of the strategies of participants.	IPQ, Aalto, CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS
	Once the summary report has been agreed by the consortium, the coordinator on behalf IPQ, Aalto, CMI, GUM, INRIM, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS will then submit it to EURAMET as D6 : <i>"Strategy to transfer the experience gained on sample preparation, calibration, and characterisation of optical absorbance liquid filters and measurement traceability to the stakeholders related to Medical Measuring Devices".</i>	

C3 WP3: Transfer of expertise within the consortium and a coordinated approach to establish measurement traceability to SI across Europe for optical absorbance liquid filters

The aim of this work package is to build up at least one new accessory to the measurement facility at INRIM and upgrade traceable optical absorbance measurement capability of all participant NMIs and draft technical procedures and Good Practice Guide that can be used by medical laboratories, testing laboratories, inspection bodies and calibration laboratories. This work package is subdivided into two tasks: the first task (Task 3.1) is devoted to take up operation of the capabilities, technology and measurement infrastructure for optical absorbance measurements of liquid filters. The second task (Task 3.2) is devoted to collecting and sharing the knowledge of more experienced laboratories to develop a common background for preparation, characterisation, and measurement of liquid filters and to draft harmonised technical measurement procedures and technical guidelines.

C3.a Task 3.1: Take up of the capabilities, technology and measurement infrastructures

The aim of this task is to build up at least one new accessory to the measurement facility at INRIM and to build up or upgrade traceable measurement capability, technology, and measurement infrastructure for optical absorbance of liquid filters across the consortium. The participants involved in the activities of this task will prepare measurement systems to study temperature effects. The development of measurement capability of Aalto, CMI, INR, INRIM, RISE, TUBITAK and UMTS will include homogeneity, temporal stability, effect of interreflections and index of refraction, UV aging, and dependence of optical absorbance on measurement wavelength and bandwidth. This work will be undertaken in parallel with WP1.

Activity number	Activity description	Participants (Lead in bold)
A3.1.1 M12	SMU supported by AGILENT UK, INM, PTB and UMTS will coordinate two online workshops in the first year for project participants (in months 3 and 12) to transfer initial background knowledge for preparation, characterisation, management and measurement of liquid filters and to facilitate early communication and active involvement.	SMU , AGILENT UK, INM, PTB, UMTS
A3.1.2 M6	INRIM and INM will upgrade their measurement systems with new accessory for cuvette temperature control for optical characterisations of liquid filters and will receive training and support from Aalto and CMI in preparation for A1.2.7, A1.2.9, and A1.3.3 in the wavelength range of 220 nm to 780 nm for a measurement bandwidth of 1 nm. Aalto and CMI will arrange 2 online discussions and site visits at INM and INRIM to help improve their uncertainty budgets in absorbance measurements to less than 1 % at 3.000 absorbance.	INRIM, INM, Aalto, CMI
A3.1.3 M8	Aalto, INRIM, RISE, GUM, and BIM will prepare their measurement systems for optical characterisation of liquid filters in A1.3.2 and A1.3.3 in the temperature interval of 15 °C and 40 °C and estimate the uncertainty budget in absorbance measurements by considering the temperature effects on wavelengths of peaks of absorbance.	Aalto , INRIM, GUM, BIM, RISE
A3.1.4 M9	BIM and DMDM will receive on-site training and support; and IPQ an online training and support, from INM and PTB to upgrade their capability in making samples of OALF from solution concentrations corresponding to absorbance of 0.5 to 2.0 which is necessary for the activities A1.3.3 and A2.1.2.	BIM , DMDM, IPQ, INM, PTB
A3.1.5 M10	TUBITAK with contribution of DMDM will develop a power stabilized laser based set up for accurate measurement of homogeneity with uncertainty of 1 % of at least 4 samples of OALF in A1.2.3.	TUBITAK , DMDM
A3.1.6 M10	CMI with support of RISE will upgrade its absorbance measurements in the wavelength range of 220 nm to 350 nm and prepare the UV aging facility to be used for the UV aging of selected liquid filters in A1.3.6 and A1.3.7.	CMI, RISE
A3.1.7 M10	TUBITAK will prepare temperature cycling facility (8 °C to 40 °C to 8 °C) to be used for the thermal aging of liquid filters in A1.3.5.	TUBITAK
A3.1.8 M10	RISE with support of Aalto will prepare a measurement setup to investigate and to derive corrections for the influence of inter-reflections and optical properties of selected liquid filters such as index of refraction for the measurements in A1.2.4 with an uncertainty of 1 %.	RISE, Aalto
A3.1.9 M22	GUM will manage the on-site trainings which will be provided by Aalto, SMU, UMTS to other participants (in A3.1.1, A3.1.2, A3.1.4) in order to solve problems encountered from the results of the characterisation and intercomparison measurements.	GUM , Aalto, SMU, UMTS
	Main topics will be the practical aspects of measurements including practical training in measurements and individual discussions about the systems of less experienced institutes and possibilities of their further development. Representative measurements will be performed during these individual trainings on reference materials which will be prepared and characterised in WP1.	
A3.1.10 M36	All improvements collected in A3.1.1 to A3.1.8 will be presented and discussed at the mid-term JRP meeting (around M18). INRIM, INM, Aalto, CMI, GUM, IPQ, RISE, SMU, TUBITAK, BIM, DMDM and UMTS will provide a report of their improvements including upgraded facilities and staff training, together with roadmaps for future improvements required. INRIM and INM with the input of all participants will compile the reports and produce a summary report. Once the summary report has been agreed by the consortium, the	INRIM, Aalto, CMI, GUM, IPQ, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS
	coordinator on behalf of INRIM, Aalto, CMI, GUM, IPQ, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS will then submit it to EURAMET as D2 : "Report on improved capability of participating NMIs and DIs for the calibration and characterisation of optical absorbance liquid filters, together with roadmaps and action plans for future capacity building".	

C3.b Task 3.2: Technical procedures and Good Practice Guide

The aim of this task is to develop harmonised measurement procedures for optical absorbance of OALF with uncertainty budget, summary reports describing the activities performed by each participant, and to produce a Good Practice Guide that can be used in the quality systems of all NMIs/DIs. This will be done based on the knowledge of the experienced laboratories, such as SMU and UMTS for preparation of samples of OALF and

PTB and Aalto for absorbance measurement expertise, integrated with the knowledge gained from the characterisation activities on the OALF (WP1) and measurement intercomparisons (WP2).

Activity number	Activity description	Participants (Lead in bold)
A3.2.1 M24	INRIM with input from Aalto, CMI, GUM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS and AGILENT UK will develop a draft Good Practice Guide for the preparation and use of OALF ranging from 0.001 up to 3.000 for MMDs and for the characterisation and SI traceable measurement of OALF for NMIs and medical measuring device users. This will be based on the knowledge obtained from A1.3.8 and A3.1.9. EURAMET TC-PR will be asked for feedback on the guide.	INRIM, Aalto, CMI, GUM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS, AGILENT UK
	Targeting the end-users, the project consortium will include in the draft of the Good Practice Guide relevant chapters for medical laboratories, testing laboratories, inspection bodies and calibration laboratories concerning correct use of such OALF.	
A3.2.2 M27	Using the draft guideline from A3.2.1, Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM and UMTS will each prepare their own technical procedure for the measurements of optical absorbance of OALF, including sample preparation, the measurement procedures and the uncertainty budget. They will also formalise the acquired competencies according to their internal quality systems.	INRIM, Aalto, CMI, GUM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM,
	Each participant NMI will be responsible for the activity conducted in their own laboratory. INRIM will act as an advisor.	INM, UMTS
	Each participant NMI will produce "Measurement procedures including complete uncertainty budget".	
A3.2.3 M36	Aalto will review the draft guideline from A3.2.1 and the technical procedures from A3.2.2 and then will engage in discussions with TC-PR. Once the Good Practice Guide has been reviewed and agreed by the consortium, the coordinator on behalf of Aalto, BIM, CMI, DMDM GUM, INM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, UMTS, AGILENT UK will then submit it to EURAMET as deliverable D5 : <i>"Good Practice Guide on the manufacture, characterisation, and use of optical absorbance liquid filters with application for Medical Measuring Devices"</i> .	Aalto, BIM, CMI, DMDM GUM, INM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, UMTS, AGILENT UK

C4 WP4: Creating impact

C4.a Task 4.1: Dissemination and communication

The objective of this task is to disseminate the outputs of the project to the wider community. The primary beneficiaries of the direct outputs of this project will be the metrological radiometry community, but the wider scientific, medical, and industrial community will also gain significant benefits from the methods, calibration facilities, measurement protocols and services developed. Industrial manufacturers and users of photonic equipment will benefit from the developments, as the target is to develop technology that simplifies the traceability and enables instruments to be calibrated easily.

The dissemination of technical and scientific information will be achieved through formation of a stakeholder committee, establishing a public website, workshops for stakeholders, participation in conferences, the publication of papers in peer reviewed journals, conference proceedings, production of videos, and by proposing comparison protocols to technical committees.

Activity number	Activity description	Participants (Lead in bold)
A4.1.1 M36	Stakeholder Committee INM with support from Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, UMTS and AGILENT UK will create a Stakeholder Committee of at least 5 members by M03 including EURAMET TC-PR and SIM members, national accreditation bodies, national legal metrology agencies, liquid absorbance filter manufacturers and users from industry and medical laboratories. The aim of the stakeholder committee is to clarify the needs of the various end-users' communities and to give advice on the project progress. The interaction will be achieved with invitation by INM, Aalto and CMI to meetings, typically held in conjunction with the project meetings to foster the collaboration between	INM, Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, UMTS, AGILENT UK

	the NMIs and end-users' communities. Key stakeholders in the areas of legal metrology,	
	accreditation, standardisation, manufacturers of MMDs, and medical laboratories will be contacted regarding membership of the Stakeholder Committee.	
A4.1.2	Project website	CMI, all
M36	A project webpage will be created by CMI by M03 with public access and a part restricted for participants only. The open access area will be fed with project reports, papers published by the participants, project meetings, and other information considered relevant to be shared with the stakeholders. The part of the website with restricted access will be dedicated to exchange of information and reports throughout the project. It will also include a digital archive of all minutes of meetings, presentations, reports, and papers from the project.	participants
	The project website will clearly acknowledge, in a prominent position on the homepage (e.g., in the header, footer or centre and in a readable size), the Metrology Partnership. This will be done by including either i) the Partnership project website header/footer badge and acknowledgement text (this text can be anywhere on homepage) or ii) the Partnership acknowledgement badge.	
A4.1.3	Workshops	SMU,
M36	SMU supported by AGILENT UK, INM, PTB and UMTS will coordinate 2 online workshops to transfer fundamental background knowledge for preparation, characterisation, management and measurement of liquid filters for project participants, young researchers, and stakeholders:	AGILENT UK, INM, PTB, UMTS
	 Physical background Design of a measurement systems Practical aspects of measurements of optical absorbance of liquid filters Technical realisation of measurements of optical absorbance of liquid filters Measurement procedures Problems and malfunctions Uncertainty budget 	
A4.1.4	Repository	Aalto, all
M36	Aalto supported by all the other participants will establish a dedicated repository by M03 to collect useful background bibliography, relevant technical information from the characterisation of the liquid filters (WP1) and intercomparisons (WP2) (temperature dependence, homogeneity, etc.), and from manufacturers of MMD. The repository will be continuously updated by participants along the project duration.	participants
	This activity will support the Good Practice Guide preparation; it is not the project repository for activities/reports; it will collect selected information.	
A4.1.5	Publication in peer-reviewed journals	Aalto, all
M36	The participants will submit at least 2 papers to peer-reviewed journals during the project (all these peer-reviewed papers are identified in activities in the technical WPs) with the results of D1 to D4 . Target journals include Metrologia, Accreditation and Quality Assurance, Measurements, or any other similar in open access.	participants
	All participants will contribute to the elaboration of scientific "Papers".	
	The expectations are that at least 2 out the 2 publications will be the result of a collaborative effort from participants from different countries.	
	The authors of the peer reviewed papers will clearly acknowledge the financial support provided through the Partnership as required by EURAMET in accordance with Article 17, Article 18, and Annex 5 of the Grant Agreement with the following text:	
	"The project (23RPT02 ETraceAbs) has received funding from the European Partnership on Metrology, co-financed from the European Union's Horizon Europe Research and Innovation Programme and by the Participating States."	
	The authors will ensure that the following meta data is submitted and included for each paper:	
	Funder name: European Partnership on Metrology	
	• Funder ID: 10.13039/100019599	
	23RPT02 ETraceAbs	
	The participants will comply with open access requirements detailed in the Grant Agreement Section 17 by also depositing each paper in a suitable open access trusted repository.	

A4.1.6	Conference prese	entations		TUBITAK, All
M36		e following interna	east 7 oral or poster presentations with the results ational conferences.	participants
	CIE quadrennial s		ce in 2025	
	• CPEM 2024-2026			
	• CIM 2025			
	expected that all papers. The author	the conference ors of the confere	be identified during the lifetime of the project. It is presentations will result in published conference ence papers will clearly acknowledge the financial equired by EURAMET.	
	All participants will	contribute to the	elaboration of scientific papers.	
	TUBITAK will ensu international confe		hment of the target number of papers presented at	
A4.1.7	Videos			SMU, Aalto
M34	for measurements videos will be ava presentations. The	and b) giving pra ailable on the pr videos will clearl AMET for further	ce 2 videos on a) the preparation of reference OALF ictical hints on working with, and use of OALF. The oject website and used in scientific and popular y acknowledge the Metrology Partnership. The link promotion and considered for wider circulation such rtal.	
A4.1.8	Cooperation with	standardisation	bodies	Aalto, CMI,
M36			ject will be disseminated to a range of standards ck sought (see details below and in the table in	GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM,
	Standards Committee / Technical Committee / Working Group	Participants involved	Likely area of impact / activities undertaken by participants related to standard / committee	INM, UMTS
	CIE – Division 2 TC2-98	Aalto, INRIM, PTB, RISE	Aalto, INRIM, PTB and RISE are involved in technical committees which work within CIE- Division 2. The project coordinator is a specially-invited-member of the most relevant committee TC2-98 which deals with measurement of reflectance and transmittance and will report the progress of the project to CIE TC2-98. Aalto with support of INRIM, PTB and RISE will share the progress of the project with TC2-98. Aalto will invite the chair of TC2-98 to participate in the project stakeholder committee. This TC meets approximately every 12 months.	
	CCPR WG-KC and Task Groups	Aalto, TUBITAK, CMI, SMU, INRIM	CCPR is the Consultative Committee for Photometry and Radiometry whose activities concern measurement standards for photometric and radiometric quantities, development of absolute radiometry, and advice to the CIPM on matters concerned with radiometry and photometry. Various working groups such as Working Group on Key Comparisons (WG-KC), Calibration and Measurement Capabilities (WG-CMC), and Strategic Planning (WG-SP) within CCPR will benefit from the output of the project. Meetings are held approximately every 12 months. Aalto, TUBITAK, CMI, SMU, and INRIM will regularly inform the CCPR on the project's progress and its outputs (papers, conference presentations, etc.) and seek to identify	

				
			opportunities to incorporate project results into a new or updated standards.	
	EURAMET TC-PR	Aalto, CMI, INRIM, IPQ, SMU	EURAMET TC-PR is the technical committee for Photometry and Radiometry. EURAMET TC-PR meets annually in January/February. Information about the overall objectives of the project will be given in 2025 by Aalto and INRIM. Presentation of the results of EMRP/EMPIR and Partnership projects has usually been on the agenda in the TC-PR meetings. SMU, IPQ, INRIM and CMI will report the progress of project on activities of WP1- WP4 at the annual EURAMET TC-PR meetings in 2025 to 2027. Aalto will share information on the development of the GPG in the meeting of 2027 and will seek feedback and support.	
	OIML TC 18/SC5	UMTS	TC 18 and TC 18/SC5 are Technical Committee and Subcommittee of the International Organization of Legal Metrology (OIML). One of the aims is development of "standards and related documents for use by legal metrology authorities and industry" in the field of production and operation of Medical measuring instruments (TC 18) and Measuring instruments for medical laboratories (TC 18/SC5)". UMTS will inform TC 18/SC5 about ongoing project activities. In the final part of the project, UMTS will present the results of research on the use of liquid absorbance filters for medical spectrophotometers and proposals for the revision of OIML R 135 "Spectrophotometers for medical laboratories" in TC 18/SC5. Meetings are held by decision of The International Committee of Legal Metrology (CIML).	
	ISO/TC 172	RISE	ISO/TC 172 on Optics and photonics deals with standardisation of terminology, requirements, interfaces and test methods in the field of optics and photonics. RISE will inform this TC on the project's progress and its outcomes regarding characterisation and traceable measurement of liquid filters. The group meets annually.	
	EURACHEM	UMTS, BIM	EURACHEM is a network of organisations in Europe having the objective of establishing a system for the international traceability of chemical measurements and the promotion of good quality practices." UMTS is a member of EURACHEM and its representatives are in 3 working groups in the structure of EURACHEM. BIM is currently a member of EURACHEM and participates at General Assembly, which meets once per year. UMTS with support of BIM will inform the progress of the project and get feedback on needs regarding liquid absorbance filters.	
A4.1.9 M9	General commun		ster will be prepared by CMI addressing all relevant	CMI, all participants
	information about month 9. The text be available for do be used as a hand letters and emails	the project and t will be written for wnload on the pro out during project a (as a pdf-attac	the participants in the beginning of the project in r non-specialist audience. The flyer and poster will ject website for all participants. The flyer will mainly a presentations at conferences and will be added to chment) for communications with all non-project be used to present the general outline of the project.	

A4.1.10	European Metrology Networks (EMNs)	Aalto, INRIM,
M27	EMN TraceLabMed aims to promote a coordinated and service oriented European metrology infrastructure to enhance metrological traceability of in vitro diagnostics (IVDs). Aalto, INRIM and TUBITAK have already made initial contacts with EMN TraceLabMed and will aim to organise a workshop or round table discussion during 2024/2025 meetings of the EMN, and will seek feedback on alignment of project activities with stakeholders' needs, experiences, and progress in metrology-based data assessment.	TUBITAK

C4.b Task 4.2: Exploitation and uptake

Activity number	Activity description	Participants (Lead in bold)
A4.2.1 M36	A dissemination, communication and exploitation plan (DCE) will be created at the beginning of the project by INRIM, with support from all participants, and submitted to EURAMET at M6. It will be reviewed and updated at least at each project meeting.	INRIM , all participants
	The DCE plan will provide further details on the expected results identified in the activities below.	
	 Expected result 1 - Report of improved capability of participant NMIs for the calibration and characterisation of optical absorbance liquid filters. Expected result 2 - Established equivalence in measurement of optical absorbance liquid filters across participating European NMIs (Results of the intercomparison measurements on OALF with absorbance of up to 3.000 and achieving a relative standard uncertainty of 0.3 % to 1.0 %). Expected result 3 - Good Practice Guide on the manufacture, characterisation, and use of optical absorbance liquid filters with application for Medical Measuring Devices. Expected result 4 - Report of improved calibration and characterisation of optical absorbance liquid filters, together with roadmaps and action plans for future capacity building. Expected result 5 - New OALF manufacturing process/recipe 	
A4.2.2 M34	Expected result 1: Report of improved capability of participant NMIs for the calibration and characterisation of optical absorbance liquid filters (A3.1.10) The report will be used to highlight to end users (e.g. accredited bodies and calibration and measurement laboratories) the benefit that high quality characterisation and calibration services can bring. The report will be disseminated to end users via the stakeholder committee (A4.1.1). In addition, the report will be presented to end users at the online project workshops (A4.1.3) to encourage uptake.	INM, Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, UMTS
A4.2.3 M36	Expected result 2: Established equivalence in measurement of OALF across participating European NMIs (Results of the intercomparison measurements on OALF with absorbance of up to 3.000 and achieving a relative standard uncertainty of 0.3 % to 1.0 %) (A2.2.4) INM with participating NMIs/ DIs (Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, UMTS) will present the results of the intercomparison to TC-PR as evidence to initiate an update of CMCs for the quantity of spectral absorbance to BIPM's Key Comparison Data Base (KCDB) or in the NMI's scope of accreditation.	INM, Aalto, CMI, GUM, INRIM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, UMTS
A4.2.4 M36	Expected result 3: Good Practice Guide on the manufacture, characterisation, and use of optical absorbance liquid filters with application for Medical Measuring Devices (A3.2.3) The GPG will be used as a basis for recommendations for improving regulations and procedures in calibrating the MMDs. The guide will be disseminated to the end users (e.g., medical laboratories, testing laboratories, inspection bodies and calibration laboratories) via the stakeholder committee (A4.1.1). The guide will also be presented to end users at the project workshops (A4.1.3) to encourage uptake. In addition, the guide will be submitted to EURAMET TC-PR for consideration as a EURAMET Guide.	INRIM, Aalto, CMI, GUM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS
A4.2.5 M35	Expected result 4: Report of improved calibration and characterisation of optical absorbance liquid filters, together with roadmaps and action plans for future capacity building (A3.1.10). The report will be used by the participating NMIs/ DIs (Aalto, CMI, GUM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS) to develop better services for their end-users and customers. In addition, the report will be shared with other NMIs/DIs not involved in the consortium via TC-PR.	INRIM, Aalto, CMI, GUM, IPQ, PTB, RISE, SMU, TUBITAK, BIM, DMDM, INM, UMTS

A4.2.6 M28	Expected result 5: New OALF manufacturing process/recipe (A1.1.2) SMU and INM with support of UMTS, plans to use the recipe to develop a new range of CRM optical absorbance liquid filter products. These CRMs will not be made commercially available to MMD users until after the project has been completed. However, SMU, with support from INM and UMTS, will take steps to encourage the uptake within the project duration. The process/recipe will be published in peer review publications and will be disseminated to other NMIs via TC-PR.	SMU, INM, UMTS
A4.2.7 M16	INM with support from all participants will carry out a market analysis to identify potential fields of applications for the absorbance calibration services and other techniques and artefacts developed within this project. This is important for the uptake of the project results in other applications outside the traceability chain of NMIs.	INM , all participants
A4.2.8 M18	Aalto will select a suitable pre-existing online database of chemical properties and contribute to this database service by providing a list of OALF characterised from 220 nm to 800 nm agreed by all participants. This will be advertised on the list of Aalto's regular services and in oral scientific presentations, etc.	Aalto , all participants
A4.2.9 M20	PTB with support from all participants will carry out research to identify potential difficulties of use and measurements of selected OALFs in WP1 obtained from different suppliers. This will be used in workshops in A3.1.1 and highlighted in the project's webpage in A4.1.2.	PTB , all participants
A4.2.10 M18, M36	The consortium will identify measures that they will use to demonstrate that the project has narrowed the gap between the capabilities of their consortium and other NMIs/DIs in Europe. Summaries will be produced at months 18 and 36, demonstrating how the project helped emerging/smaller NMIs in the consortium to develop their capabilities closer to the wider European NMI/DI level. Where appropriate this improvement will be quantified. All participants will provide input to these summaries and the coordinator will provide	Aalto , all participants
	this information demonstrating the narrowing of the capability gap at the mid-term review and at the end of the project.	

All IP and potential licencing/exploitation will be handled in accordance with the Grant Agreement and the Consortium Agreement.

C5 WP5: Management and coordination

C5.a Task 5.1: Project management

Activity number	Activity description	Participants (Lead in bold)
A5.1.1 M36	The project will be managed by the coordinator from Aalto who will be supported by the project management board consisting of one representative from each participant including the leaders of each work package. The members of the project management board will guide the project in addressing all the administrative, contractual and financial matters, attend the project meetings, organise the progress meetings at their local institutes and call additional meetings if needed to ensure the overall project's success.	Aalto , all participants
A5.1.2 M36	The work package leaders will report on the on-going progress of the project to the coordinator by e-mail and telephone or online conferences.	Aalto , SMU, IPQ, INRIM, CMI
A5.1.3 M36	The coordinator, with support from the participants, will manage the project's risks to ensure timely and effective delivery of the scientific and technical objectives and deliverables.	Aalto , all participants
A5.1.4 M36	The consortium will ensure that any ethics issues identified are addressed.	Aalto , all participants

C5.b Task 5.2: Project meetings

Activity number	Activity description	Participants (Lead in bold)
A5.2.1 M1	The kick-off meeting involving all participants will be held within one month after the official start of the project at Aalto.	Aalto , all participants
A5.2.2 M36	There will be five formal project meetings. These meetings include the kick-off (M1), mid-term (M18) and final meeting (M36). In addition, two further meetings will be held around M9 and M27. The meetings will be held prior to reporting. The meetings will review the progress and will be used to ensure that the participants are clear as to their role for the next period. The location of the meetings will rotate among the participants. Where possible, meetings may be held as satellite meetings to important conferences or committee meetings.	Aalto , all participants
A5.2.3 M36	The stakeholders will be invited to the project meetings and related events to ensure intensive communication between them and the project consortium.	Aalto , all participants
A5.2.4 M36	Technical meetings of work package groups may be held whenever necessary and will be arranged on an ad-hoc basis.	Aalto , all participants

C5.c Task 5.3: Project reporting

Activity number	Activity description	Participants (Lead in bold)
A5.3.1 M1	One month after the start of the project a publishable summary will be produced and submitted to EURAMET.	Aalto , all participants
A5.3.2 M6	Six months after the start of the project a data management plan (DMP) and a dissemination, communication and exploitation (DCE) plan will be produced and submitted to EURAMET.	Aalto , all participants
A5.3.3 M36 +60 days	 Following Articles 19 and 21 and the data sheet of the grant agreement, information will be submitted to EURAMET, in accordance with the procedures issued by them to enable EURAMET to comply with its obligations to report on the programme to the European Commission. Progress reports will be submitted at months 9, 27 (February 2025, August 2026 + 45 days), 18, 36 (November 2025, May 2027 + 60 days). Outcomes and Impact reports and updated publishable summaries will be submitted at the same times. All participants will provide input to these reports and the coordinator will provide these to EURAMET. Where necessary, additional reports and / or information may be requested to enable EURAMET to comply with its obligations to the European Commission. 	Aalto , all participants
A5.3.4 M36 +60 days	Periodic Reports (including financial reports, updated data management plan, and updated dissemination, communication and exploitation plan) will be delivered at months 18 and 36 (November 2025, May 2027 + 60 days) in accordance with Articles 19 and 21 and the data sheet of the grant agreement. All participants will provide input to these reports and the coordinator will provide these to EURAMET.	Aalto , all participants
A5.3.5 M36 +60 days	Final Reports (including financial reports, updated data management plan, and updated dissemination, communication and exploitation plan) will be delivered at month 36 (May 2027 + 60 days) in accordance with Articles 19 and 21 and the data sheet of the grant agreement. All participants will provide input to these reports and the coordinator will provide these to EURAMET.	Aalto , all participants
A5.3.6 M22	Some projects will be subject to a midterm review in Spring 2026. Where projects are selected for a midterm review, reports (project self-assessment, updated publishable summary and presentation) will be delivered prior to the midterm reviews for Call 2023, following the schedule detailed by EURAMET for the specific review. All participants will provide input to these reporting documents and the coordinator will provide the documents to EURAMET.	Aalto , all participants

Formal reporting will be in line with EURAMET's requirements and will be submitted in accordance with the Reporting Guidelines.

C6 Gantt chart

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
Months	Jun-24	Jul-24	Aug-24	Sep-24	Oct-24	Nov-24	Dec-24	Jan-25	Feb-25	Mar-25	Apr-25	May-25	Jun-25	Jul-25	Aug-25	Sep-25	Oct-25	Nov-25	Dec-25	Jan-26	Feb-26	Mar-26	Apr-26	May-26	Jun-26	Jul-26	Aug-26	Sep-26	Oct-26	Nov-26	Dec-26	Jan-27	Feb-27	Mar-27	Apr-27	May-27
Activit																																				
	WP	P1																																		
	Tas	k 1.	1				_	_									_	_																		
1.1.1																																				
1.1.2																																				
1.1.3																																				
1.1.4																																				
1.1.5																																				
					Tas	k 1.	2																													
1.2.1																																				
1.2.2																																				
1.2.3																																				
1.2.4																																				
1.2.5																																				
1.2.6																																				
1.2.7																																				
1.2.8																																				
1.2.9																																				
1.2.10																																				
				Tas	k 1.	3																														
1.3.1																																				
1.3.2																																				
1.3.3																																				
1.3.4																																				
1.3.5																																				
1.3.6																																				
1.3.7																																				
1.3.8																					D1															
1.3.9																																				

0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
- 0	1	- 2	3	4	5	0	/	•	9	10	11	12	12	14	10	10	1/	10	13	20	21	22	25	24	25	20	21	20	25	30	51	52	33	54	33	30
Months	Jun-24	Jul-24	Aug-24	Sep-24	Oct-24	Nov-24	Dec-24	Jan-25	Feb-25	Mar-25	Apr-25	May-25	Jun-25	Jul-25	Aug-25	Sep-25	Oct-25	Nov-25	Dec-25	Jan-26	Feb-26	Mar-26	Apr-26	May-26	Jun-26	Jul-26	Aug-26	Sep-26	Oct-26	Nov-26	Dec-26	Jan-27	Feb-27	Mar-27	Apr-27	May-27
Activit	ies																																			
	WP	2																																		
																	Tas	k 2.	1														\square			
2.1.1																																		\square		
2.1.2																																				
2.1.3																								D3												
2.1.4																																				
									Tas	k2.:	2																									
2.2.1																																				
2.2.2																																				
2.2.3																																				
2.2.4																																			D4	
2.2.5																																				
	Tas	k 2.	3																																	
2.3.1																																				
2.3.2																																			D6	

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18		20			23	24	25	26	27	28	29	30	31	32	33	34	35	36
Months	Jun-24	Jul-24	Aug-24	Sep-24	Oct-24	Nov-24	Dec-24	Jan-25	Feb-25	Mar-25	Apr-25	May-25	Jun-25	Jul-25	Aug-25	Sep-25	Oct-25	Nov-25	Dec-25	Jan-26	Feb-26	Mar-26	Apr-26	May-26	Jun-26	Jul-26	Aug-26	Sep-26	Oct-26	Nov-26	Dec-26	Jan-27	Feb-27	Mar-27	Apr-27	May-27
Activit																																				
	WP	3																																		
	Tas	k 3.	1																																	
3.1.1																																				
3.1.2																																				
3.1.3																																				
3.1.4																																				
3.1.5																																				
3.1.6																																				
3.1.7																																				
3.1.8																																				
3.1.9																																				
3.1.10)																																			D2
	Tas	k 3.	2				-																													
3.2.1																																				
3.2.2																																				
3.2.3																																				D5

European Partnership on Metrology

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
Months	Jun-24	Jul-24	Aug-24	Sep-24	Oct-24	Nov-24	Dec-24	Jan-25	Feb-25	Mar-25	Apr-25	May-25	Jun-25	Jul-25	Aug-25	Sep-25	Oct-25	Nov-25	Dec-25	Jan-26	Feb-26	Mar-26	Apr-26	May-26	Jun-26	Jul-26	Aug-26	Sep-26	Oct-26	Nov-26	Dec-26	Jan-27	Feb-27	Mar-27	Apr-27	May-27
Activit																																		\square		\square
	WP	4																																		
	Tas	k 4.	4 4 4 4 4 4 4 4 4 4 4 4 4 4																																	
4.1.1																																				
4.1.2																																				
4.1.3																																				
4.1.4																																				
4.1.5																																				
4.1.6																																				
4.1.7																																				
4.1.8																																				
4.1.9																																				
4.1.10																																				
			Tas	k 4.	2																															
4.2.1																																				
4.2.2																																				
4.2.3																																				
4.2.4																																				
4.2.5																																				\square
4.2.6																																				Ш
4.2.7																																				\square
4.2.8																																				\square
4.2.9																																				
4.2.10																																				

European Partnership on Metrology

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
Months	Jun-24	Jul-24	Aug-24	Sep-24	Oct-24	Nov-24	Dec-24	Jan-25	Feb-25	Mar-25	Apr-25	May-25	Jun-25	Jul-25	Aug-25	Sep-25	Oct-25	Nov-25	Dec-25	Jan-26	Feb-26	Mar-26	Apr-26	May-26	Jun-26	Jul-26	Aug-26	Sep-26	Oct-26	Nov-26	Dec-26	Jan-27	Feb-27	Mar-27	Apr-27	May-27
Activi																																				
	WP 5																																			
	Tas	k 5.	1																																	
5.1.1																																				
5.1.2																																				
5.1.3																																				
5.1.4																																				
	Tas	k 5.	2																																	
5.2.1																																				
5.2.2																																				
5.2.3																																				
5.2.4																																				
	Tas	k 5.	3																																	
5.3.1																																				
5.3.2																																				
5.3.3																																				
5.3.4																																				
5.3.5																																				
5.3.6																																				

Section D: Risk and risk mitigation

Risk (description)	Likelihood, impact and	Mitigation	Contingency				
	severity of occurrence	i.e. what the consortium will do to decrease the likelihood of the risk occurring	i.e. what the consortium will do if despite the mitigation the risk still occurs				
Task 1.1 Preparation and distribution of suitable working and RMs of OALF are ceased due to organisational and other changes and restrictions	Likelihood after mitigation: Low Impact: Possible delay in the activities. Level of severity: Low	There is more than one participant that support and complement the task.	Other support participants will take over for the activities that are not possible by the lead participant.				
Task: 1.2, 1.3 Malfunction of existing equipment in one of the laboratories taking part in these activities	Likelihood after mitigation: Medium Impact: Possible delay in this activity. Level of severity: Low	The participants will ensure that the equipment remains under good quality control/user access control and is regularly maintained. This will reduce the risk of misuse and damage. The laboratory in question will try to find suitable new equipment, procure replacements or arrange for rapid repairs. It is also possible for one participant to lend its equipment to the other participant. In addition, there is more than one participant in most activities and if one is unable to participate, the others can still characterise the materials.	For the setups where it was not possible to replace a malfunctioning device / component and measurements could not take place, the measurement process will be explained theoretically, and the missing results will be replaced by previous data and discussed.				
Task 1.3: The low target uncertainties of the characterisation measurements in A1.3.3 cannot be achieved	Likelihood after mitigation: Medium Impact: Increased uncertainty in the reference estimates of the absorbance deviations. Level of severity: Low	The participants have undertaken characterisations in previous projects and are aware of the challenges and have made the preparations. The time schedule allows for the required flexibility to find alternative solutions. Consultation on facilities amongst participants to identify the reason and improve the facilities/measurement conditions.	Characterisations with higher, but confirmed, uncertainty will be used.				
Task 1.3: Malfunction of UV aging facility to be prepared at CMI in the activity A3.1.6	Likelihood after mitigation: Low Impact: Increased uncertainty in the reference estimates of the absorbance deviations. Level of severity: Low	The participants have developed a similar facility in previous internal projects and are aware of the challenges and have made the preparations for UV aging such as those available at Aalto.	In case of malfunction of the UV aging facility prepared in A3.1.6 a similar facility can be rented from one of the stakeholders.				
Task: 2.1, 2.2 The interlaboratory comparison is not completed within the scheduled time because the transfer of liquid standards to be measured are not available in time	Likelihood after mitigation: Low Impact: The analysis of results of interlaboratory comparisons will be delayed. Level of severity: High	The progress of the comparisons will be closely monitored. If delays are identified, the reasons for the delay will be discussed and appropriate rescheduling will be made if the problem cannot be resolved.	The interlaboratory comparison will be performed using a reduced number of transfer standards / artefacts.				

D1 Scientific/technical risks

Task 2.2: The low target uncertainties of the comparison measurements cannot be achieved by at least one participant	Likelihood after mitigation: Medium Impact: Evaluation of the results of the interlaboratory comparison or pilot study will not be possible within the project lifetime. Level of severity: High	Consultation on facilities amongst participants to identify the reason and improve the facilities/measurement conditions.	The interlaboratory comparison will be performed by a reduced number of transfer standards and participants.
Task 2.3 One or more of participants are unable to complete the A2.3.2 due to administrative or organisational reasons	Likelihood after mitigation: Low Impact: The activities are incomplete only for one or more participants. There will be no impact on activities of other participants. Impact of project will be limited in scope. Level of severity: Medium	The consortium will encourage the participants to take pre- emptive actions early in the timeline of the project to develop ideas for their roadmaps in line with strategies of their organisation. The activity leader and consortium will support participants to produce the material by, for example, providing templates and suggestions from their own roadmaps.	The consortium will take actions to include the missing activities in the strategy/roadmaps of a few other participants.
Task 3.1 The build up or upgrade traceable measurement facilities is not completed within the scheduled time	Likelihood after mitigation: Low Impact: Increased uncertainty in the reference estimates of the absorbance deviations and/or reduced range of temperature investigated. Level of severity: High	The participants have undertaken characterisations in previous projects and are aware of the challenges and have made the preparations. The time schedule allows for the required flexibility to find alternative solutions. Consultation on facilities amongst participants to identify the reason and improve the facilities/measurement conditions.	Characterisations with higher but confirmed uncertainty will be used. In case of malfunction of the temperature controller a similar facility can be rented from one of the stakeholders.
Task 3.2 The preparation of guidelines is not completed within the scheduled time	Likelihood after mitigation: Low Impact: Possible delay in this activity. Level of severity: Low	The progress of the guideline's preparation will be closely monitored. If delays are identified, the reasons for the delay will be discussed and appropriate rescheduling will be made.	The guidelines will be completed using a reduced set of information.

D2 Management risks

Risk (description)	Likelihood, impact and severity of occurrence	Mitigation i.e. what the consortium will do to decrease the likelihood of the risk occurring	Contingency i.e. what the consortium will do if despite the mitigation the risk still occurs
Key personnel are lost to the project	Likelihood after mitigation: Low Impact: The loss of key team members would create difficulties in delivering the project, or specific tasks or deliverables. Level of severity: Very low	None of the team members are planning to leave or retire within the project. The grouping of experts within the consortium should minimise the areas where knowledge is held by a single person. All the participants will identify backups for key workers wherever possible to reduce the overall risk to the project. Project plans will be shared within the consortium and results and methodology will be documented.	If a key member leaves the project, then the participant concerned will be responsible for appointing a replacement. Also, experts from another laboratory may be able to take over. However, this may still lead to a delay in delivery.

Inadequate communication between participants	Likelihood after mitigation: Low Impact: Duplication of work, or difficulties in agreeing suitable time schedules for training or work not undertaken due to a failure to communicate findings. Level of severity: Very low Likelihood after mitigation:	Due to the inherent structure of the project, i.e. with web based seminars and virtual meetings, information flow is expected to be good. If appropriate, additional virtual meetings will be held.	The project plan is relatively clear, i.e. the dates for the web based seminars, the trainings and the visits will take place. However, there might be delays in case of inadequate communication.				
technical activities and tasks are complex	Medium Impact: Tasks are delayed or are not possible to deliver. Level of severity: Low	leaders have been scheduled to ensure proper sharing of knowledge. The inter- dependencies between tasks will be considered at meetings to ensure that this is addressed properly in the planning of the work. The technical WPs will be closely managed by their WP leaders to ensure that they deliver their own outputs.	in time and thus a delay in the output of one deliverable does not necessarily cause an immediate delay in another.				
Problems dealing with Intellectual Property (IP) ownership and/or exploitation might occur and could be a source of potential conflict	Likelihood after mitigation: Low Impact: Disagreement between the participants could delay the project (in implementing the work and publishing results). Level of severity: Medium	All beneficiaries will sign the grant agreement and all participants will sign the consortium agreement, which includes IP clauses. IP will be handled accordingly.	Independent arbitrators will be used in the event of disagreement between participants.				
The onsite facilities of participants, and/or access to public/commercial services or sites is restricted for a period of time during the project due to an extraordinary event or situation that is beyond the participants' control e.g. COVID-19	Likelihood after mitigation: Low Impact: Activities and deliverables are delayed, or no longer able to be completed. Level of severity: Medium	In most cases, activities on the critical path have been scheduled to have some overlap in time and participant contributions and thus a delay in the activity one participant will not necessarily cause an immediate delay in another.	Where possible, work will be reassigned to an alternative participant, or rephased, therefore minimising delays and technical deviations that would have a negative impact on the project. If necessary, the consortium will contact EURAMET to discuss options according to the Grant Agreement.				
Organisation of workshops, training and joint demonstrator activities in a post- or trans-COVID world	Likelihood after mitigation: Medium. Impact: Failure to show the outputs at workshops or through joint demonstrator activities risks reducing the knowledge transfer and impact from the project. Level of severity: Medium	The training activities will be undertaken as remote training.	The interlaboratory training will be performed using a reduced number of people or days.				
Environmental and Health and Safety: Staff involved in the project do not follow the relevant H&S procedures in particular related to the use and disposal of liquid absorbance filters	Likelihood after mitigation: Low Impact: LAF are aqueous solutions of metal salts with low concentrations and don't contain hazardous bio-components. Level of severity: Low	Staff involved in the project take part in annual training and tests on H&S procedures in accordance with the internal procedures and quality systems. Using and disposing of liquid absorbance filters are described in the supporting documentation.	Personnel who already work with filters will receive additional training on this topic before starting research.				

D3 Ethics

The Partnership Ethics Review 2023 has given JRP 23RPT02 ETraceAbs "Ethics clearance".

Ethical integrity

The participants will ensure that all ethics issues related to activities in the project are addressed in compliance with ethical principles (including the highest standards of research integrity as set out in the ALLEA European Code of Conduct for Research Integrity <u>https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/european-code-of-conduct-for-research-integrity horizon en.pdf</u>), the applicable international and national law, and the provisions set out in the grant agreement. This includes the ethics issues identified in the ethics screening and the submitted documents, and any additional ethics issues that may emerge in the course of the project. In the case where any substantial new ethics issues arise, participants will inform the granting authority EURAMET e.V, and for each ethics issue applicable, participants will follow the guidance provided in the Horizon Europe 'How to complete your ethics self-assessment' guide'.

The consortium will ensure that appropriate procedures, policies and structures (<u>https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/guideline-for-promoting-research-integrity-in-research-performing-organisations horizon en.pdf</u>) are in place to foster responsible research practices, to prevent questionable research practices and research misconduct, and to handle allegations of breaches of the principles and standards in the Code of Conduct.

Data protection

By signing or acceding to this grant agreement and / or consortium agreement each participant asserts that the requirements of the General Data Protection Regulation (GDPR) 2016/679 which entered into force on 25 May 2018 will be met. Under the regulation, the data controllers and processors are fully accountable for the data processing operations. Any violation of the data subject rights may lead to sanctions as described in Chapter VIII, art.77-84 of the GDPR.

If personal data are transferred from the EU to a non-EU country or international organisation, such transfers will be in accordance with Chapter V of the GDPR 2016/679. If personal data are transferred from a non-EU country to the EU (or another third state), such transfers will comply with the laws of the country in which the data was collected.

Non-EU countries

The consortium will ensure that participants and collaborators, including those from non-EU countries, fully adhere to Horizon Europe ethics standards and guidelines, no matter where the research or activities are carried out and that research or activities performed outside the European Union are compatible with EU, national and international legislation and can be legally conducted in one of the EU Member States. If applicable, details on the material, samples and/or equipment which will be imported to/exported from EU must be provided and the adequate authorisations granted by the relevant authorities have been or will be obtained and kept on file by the consortium. The consortium will also, in the case of dual use applications, clarify whether any export licence is required for the transfer of knowledge, equipment or material.

Environmental and Health and Safety

The ethics screening identified that there are potential environmental and health and safety issues arising from this project, related to the handling of chemicals in the processes of manufacturing test samples.

By signing or acceding to this grant agreement and / or the consortium agreement each participant asserts that appropriate health and safety procedures conforming to relevant local and national guidelines and/or legislation, are followed by staff involved in this project. Any risks and precautions will be clearly stated and understood by all staff involved in the project, and the risks minimised where appropriate. For safety purposes, authorisations for the use of facilities and materials will be obtained, where appropriate, and kept on file by the consortium (e.g. approval of safe working practices in the laboratory, security classification of the laboratory). Where applicable, further information on the possible harm to the environment and environmental risks due to the research, and the precautions and measures taken to mitigate the risks will be kept on file by the consortium.

Section E: References

- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- [2] ISO 15189:2012, Medical laboratories Requirements for quality and competence with last revision and confirmation in 2012
- [3] ISO 13485:2016, Medical devices Quality management systems Requirements for regulatory purposes with last revision and confirmation in 2016
- [4] OIML R135 Spectrophotometers for medical laboratories, with last revision and confirmation in 2004
- [5] R.W. Burke, R. Mavrodineanu (1977) Standard Reference Materials: Certification and used of acidic potassium dichromate solutions as an ultraviolet absorbance standard – SRM 935, NBS Special publication 260-54, 157 pages