

## Standard Summary Project Fiche – IPA centralised programmes

### Project Fiche: 11

#### **1. Basic information**

##### **Background:**

**1.1 CRIS Number: 2011/023-173**

**1.2 Title: Development of Quality Infrastructure (QI) and Metrology" (DQIM)**

**1.3 ELARG Statistical Code: 3.1**

**1.4 Location: Montenegro**

##### **Implementing arrangements:**

**1.5 Contracting Authority:** The Delegation of the European Union to Montenegro

**1.6 Implementing Agency:** The Delegation of the European Union to Montenegro

**1.7 Beneficiary (including details of project manager):**

##### **Component 1 (Technical Assistance):**

Ministry of Economy,  
Department for Quality Infrastructure (DQI),  
Mr Dragan Vukčević, Head of DQI,  
Rimski trg 46  
81000 Podgorica  
Montenegro  
E-mail: dragan.vukcevic@mek.gov.me  
Tel.: 020 247 119

##### **Component 2 (Supply):**

Ministry of Economy,  
Bureau of Metrology (BoM)  
Ms Vanja Asanović, Director of BoM  
Kralja Nikole 2  
81000 Podgorica  
Montenegro  
E-mail: vanja.asanovic@metrologija.gov.me  
Tel.: 020 601 360

##### **Financing**

**1.8 Overall cost: € 1.420.000**

**1.9 EU contribution: € 1.200.000**

**1.10 Final date for contracting:** Three years from the date of conclusion of the Financing Agreement

**1.11 Final date for execution of contracts:** Two years from the date of the final date for contracting

**1.12 Final date for disbursements:** One year from the Final date for execution of contracts

## 2. Overall Objective and Project Purpose

### 2.1 Overall Objective:

To facilitate trade and free movement of goods in compliance with the EU *acquis communautaire* in the field of Chapter 1 - Free movement of goods and the WTO requirements.

### 2.2 Project purposes:

To enhance the capacity of the Ministry of Economy and the Bureau of Metrology to meet the EU legislative, regulatory and technical requirements

### 2.3 Link with AP/NPAA / EP/ SAA

The 2010 Analytical Report of the European Commission on Montenegro highlighted the urgency and importance for Montenegro to accelerate the adoption and implementation of the *acquis* in the Free movement of goods agenda. The report *inter alia* says:

"Montenegro to implement the *acquis* will be central to its capacity to function successfully within the Union. In this respect, alignment with the *acquis* is a necessary but not sufficient condition to meet the obligations of EU membership."

Further the EC's 2010 Analytical Report on Montenegro also says:

#### "3.1. Chapter 1: Free movement of goods

The principle of free movement of goods means that products must be traded freely from one part of the Union to another. In a number of sectors this general principle is supplemented by a harmonised regulatory framework, following either the 'Old Approach' (laying down precise product specifications) or the 'New Approach' (setting general product requirements).

Transposition of harmonised European product legislation accounts for the bulk of the obligations under this chapter. Smooth implementation and proper enforcement of the *acquis* requires sufficient administrative capacity to notify restrictions on trade and to apply horizontal and procedural measures in areas such as standardisation, conformity assessment, accreditation, metrology and market surveillance.

The *Stabilisation and Association Agreement* creates a number of obligations in the field of free movement of goods, such as establishment of a free trade area. It also provides for gradual alignment to EU technical regulations and standards as well as metrology, accreditation and conformity assessment procedures."

In order to elaborate on the above, it should also be mentioned that the Article 77 of SAA on standardization, metrology, accreditation and conformity assessment commits Montenegro to the following:

#### "Standardisation, Metrology, Accreditation and Conformity Assessment

1. Montenegro shall take the necessary measures in order to gradually achieve conformity with Community technical regulations and European standardisation, metrology, accreditation and conformity assessment procedures.

2. To this end, the Parties shall seek to:

- (a) promote the use of Community technical regulations, European standards and conformity assessment procedures;
- (b) provide assistance to fostering the development of quality infrastructure: standardisation, metrology, accreditation and conformity assessment;
- (c) promote the participation of Montenegro in the work of organisations related to standards, conformity assessment, metrology and similar functions (e.g. CEN, CENELEC, ETSI, EA, WELMEC, EUROMET);
- (d) Where appropriate, conclude an Agreement on Conformity Assessment and Acceptance of Industrial Products once the legislative framework and the procedures of Montenegro is sufficiently aligned on that of the Community and appropriate expertise is available."

As part of its conclusions, the earlier quoted 2010 Analytical Report of the European Commission on Montenegro *inter alia* stated:

"... in the field of free movement of goods, Montenegro will need to enhance preparations and to make considerable and sustained efforts to align with the *acquis* and to implement it effectively in the medium term."

Proposal of National Program for Integration of Montenegro into the EU (NPI) for the period 2011-2015 includes the plan for approximation of technical regulations (EC directives) with most of this process being planned for the period 2011 - 2014. This proposed project is intended to assist with accelerating this process.

#### **2.4 Link with MIPD**

The Multi-annual Indicative Planning Document (MIPD 2011-2013) attributes great importance to the facilitation of the free movement of goods, and therefore to supporting the institutions involved in quality infrastructure (DQI and BoM in this particular case).

#### **2.5 Link with National Development Plan (where applicable)**

N/A

#### **2.6. Link with national/ sectoral investment plans (where applicable)**

N/A

### **3. Description of project**

#### **3.1 Background and justification:**

Montenegro has established the basic legislative framework and institutional

infrastructure for the development of quality infrastructure

In the period 2008-2010, the key laws on Metrology, Standardization, Accreditation General Product Safety, Law on Requirements for Products and Conformity Assessment of Products with the Prescribed Requirements, were adopted. They provide the basis for the development of the horizontal system ensuring that only a safe product can be placed on the market in Montenegro and that vertical legislation may not prescribe any measure which would represent a barrier. The legal documents define clearly the institutional competences and powers of the key quality infrastructure bodies - the Institute for Standardization of Montenegro (ISME), Bureau of Metrology (BoM) and the Accreditation Body of Montenegro (ATCG). However the legal framework is still not complete. A significant part of the old approach product legislation still needs to be transposed. 7 new approach directives are under a process of adoption, Amendments are envisaged for the Law on technical requirements in order to allow the transposition of the New Approach Directives. More modifications however will be required to achieve full harmonisation with "The New Legal Framework" (Decision 768/2008/EC, Regulation 765/2008/EC, Regulation 764/2008/EC). A new framework for monitoring the implementation of the commitments proceeding from TFEU Articles 34-36 is required to establish a legal basis for the preparation of annual state plans and reports on fulfilling these requirements.

Montenegro has established a coordination mechanism related to free movements of goods, which covers the responsible ministries for the relevant technical regulation transposing new approach and sectoral directives. The coordination role has been given to the Department for Quality infrastructure (DQI), which is part of the Ministry of Economy (MoE). DQI is the enquiry point according to directives 34/98 and 48/98 and the notification point according World Trade Organization (WTO) TBT. Despite this progress, the coordination needs to be significantly strengthened and the capacity of DQI has to be reinforced.

Along, the DQI must continue the transposition of the new approach directives and the establishment of enquiry point according to 98/34 Directive and WTO/TBS requirements. The coordination role and capacity of DQI needs to be strengthened in order to ensure the effective involvement of the key implementing bodies such as state inspectorates and Customs. Coordination with the conformity assessment bodies (CABs) and several responsible ministries has to be ensured as well. Further on, another need will be the establishment of an internal notification system between DQI and concerned organizations.

In the field of metrology, there are a number of needs as well. The Bureau of Metrology (BoM), as part of the Ministry of Economy, was established in 2006. The work in the field of scientific and legal metrology and precious metals is organized under BoM as an umbrella institution responsible for the entire metrology system at the highest level. Measuring instruments used for the purpose of trade in goods and services; protection of human and animal health, general security, property, environment and natural resources, safety at work, transport and protection from accidents; as well as checking the pre-packaged products and bottles as measuring containers, will be put to use in Montenegro only if compliant with the set metrological requirements and if those are verified and are labelled with the prescribed marking.

Calibration laboratories for mass, length, electrical quantities, time and frequency, volume and temperature are being developed within the Bureau of Metrology; these will establish, develop and maintain Montenegrin national measurement standards for the given unit.

### **3.2 Assessment of project impact, catalytic effect, sustainability and cross border impact (where applicable)**

#### Impact

The project is expected to have measurable and positive impacts in the medium and long-term.

As regards metrology a well-developed metrology system which provides necessary services without creating unnecessary technical barriers to trade is envisaged. This means improved Traceability improved through national calibration laboratories for mass, length, electric values, time and frequency, volume and temperature.

The Logframe in Annex 3 sets out specific benchmark indicators for ex-post assessment and validation of Impact. At a policy level, improved metrology standards are a fundamental requirement for the successful operation of the EU Single Market but also more globally to facilitate cross-border trade through common standards. As such the on-going reforms in metrology in Montenegro fit this rubric and the impact of EU intervention through this project will meet this goal by furthering Montenegro's convergence with EU standards.

The removal of technical barriers to trade is a precondition for the completion of the internal market. Since the adoption of the new approach in 1985, the harmonization of European industrial standards in several areas covered by European technical legislation has become an essential instrument in completing the single market. This approach was subsequently complemented by a coherent policy on certification and tests, setting out clear, consistent and transparent principles which apply to the product certification procedures to be used at Community level. The objective is to help establish a European policy on quality in cooperation with national and international standardization bodies to enable businesses to manufacture and sell their products throughout the EU and its Associated Countries with the aid of a system for the mutual recognition of trade marks and manufacturing processes.

Developing of the legal framework and administrative capacity required in Montenegro to meet the EU Commitments of the Government of Montenegro (GoM) in the area of Quality Infrastructure. Legislation, under the new approach, should be restricted to establishing the essential requirements that products must satisfy. These requirements fix the thresholds or levels of protection for the whole of the EC in the area of health and safety.

#### Catalytic effect

The project through improvements in the supply side of the economy is expected to have clear and tangible positive externalities. The evidence from earlier accession process is clear in terms of the net benefits for consumers and producers and the same is expected for the Montenegrin transition but will require continued commitment for effective enforcement and further on-going national and external intervention to lock-in the catalytic changes.

## Sustainability

Sustainability of EU intervention and support is guaranteed both in terms of policy commitment and allocation of national expenditure. Montenegro is a Candidate Country and committed to rapid convergence to the *acquis* generally and through measures to improve metrology and product conformity. As set out above, the intervention logic will continue to be valid and this will require further assistance calibrated upon the specific needs and gaps. The project outcomes will be sustainable in a more narrow sense through preconditions that require governmental commitments to ensure that EU-financed investment can be readily housed and operationalised and through commitment to finance all future maintenance costs.

## Cross-border impact

The Cross-border impact of the EU and GoM joint interventions is expected to be positive for the same economic reasons outlined above and the reduction of barriers to trade. The GoM is committed to fostering greater use of the sector's potential to foster regional integration processes and as recommended by the EU. This includes the implementation of regional trade agreements (CEFTA) and broader regional cooperation. The EU is already promoting the joint use of national structures that have been developed in a complementary way.

### **3.3 Results and measurable indicators:**

Result 1: Enhanced transposition of the *acquis* in the field of QI;

- 5 New Approach Directives (NAD) transposed and necessary secondary legislation changes mapped out by end of project (medical devices, medical devices in vitro, explosives, cosmetics and ATEX directive)
- 30 sectoral directives in area of pharmaceutical products transposed in national legislation
- Needs and gaps assessment undertaken for legislation in the field of free movement of goods

Result 2: Improved administrative capacity of DQI;

- Training Needs Assessment developed and training implemented in the first half of the project period
- At least 10 staff members trained and familiar with EU obligations for Montenegro by the end of the Project;
- Awareness raised among stakeholders (CABs, Manufacturers and other Governmental bodies) about the new tasks of the DQI in notification of technical regulations and in notification of conformity assessment bodies
- DQI trained in the directives 98/34/EC and 98/48/EC and procedures implemented
- WTO Enquiry Point for Technical Regulations established and functioning
- Full communication with TBT/WTO Secretariat established

Result 3: Improved capacity of the National Metrology Institution

- Three labs certified from National Accreditation body

- Positive opinion on traceability of chosen measurements standards (see in annex 4) received from NMI (National Metrology Institute) provided by a Member of EURAMET
- Three new laboratories fully equipped

### **3.4 Activities:**

#### Component 1: Harmonisation of the legislation with the Acquis

- 1.1 Assessment of the gaps in legislation in the field of free movement of goods and preparation of table of concordance
- 1.2 Preparation of a roadmap for transposition and implementation of technical legislation
- 1.3 Review and transposition of 5 New Approach Directives (medical devices, medical devices in vitro, explosives, cosmetics and ATEX directive)
- 1.4 Review and transposition of 30 sectoral directives in area of pharmaceutical products

#### Component 2: Improving the administrative capacity of the DQI;

- 2.1. Assessment of the Training Needs of the Ministry of Economy and the related bodies with view to the implementation of the new legislation;
- 2.2. Design and implementation of a training programme on Free movement of goods (at least 10 people trained and familiar with EU obligations for Montenegro);
- 2.3. Raising the awareness of the stakeholders (CABs, Manufacturers and other Governmental bodies) about the new tasks of the DQI in notification of technical regulations and in notification of conformity assessment Bodies
- 2.4. Training DQI in the requirements of EU directives 98/34/EC and 98/48/EC and assisting with designing and implementing the necessary procedures
- 2.5. Training DQI in the requirements of WTO TBT Agreement related to information and assisting with implementing the necessary procedures, including setting up the functioning WTO Enquiry Point for TR
- 2.6. Establishing full communication with TBT/WTO Secretariat

#### Component 3: Enhancing the capacity of the BoM

- 3.1. Preparation of three metrology labs for accreditation by the National Accreditation Body ;
- 3.2. Assisting the Bureau of Metrology for preparing for a peer assessment on traceability of chosen measurements standards (see in annex 4) from NMI (National Metrology Institute) by a Member of EURAMET
- 3.3. Supply of metrology equipment to BoM (The list of equipment is given in Annex 4.) in the priority field of Measurement Standards.

EU funding, through one service contract (1), will be provided for all activities under Component 1 and the activities 2.1-2.4 of Component 2. Activities 2.5. and 2.6 as described above will be funded by the national budget through a separate service contract. Component 3 will be implemented through 1 EU and 1 national supply contract. Both contracts are supply and the differentiation between the two will only depend on the costs and type of the required equipment.

### **3.5 Conditionality and sequencing:**

The project includes the following conditions:

- The Government of Montenegro provides the necessary funding for proper staffing of implementing bodies of Department of Quality Infrastructure and Bureau of Metrology, as well as other resources necessary to implement duties.
- Sufficient working space/equipment and other facilities are available before the project starts.
- Appointing the relevant staff by the beneficiaries to participate in capacity building activities, working groups, steering and coordination committees, as per work plan;
- The relevant national legal framework set up and enforced.
- The provision of co-financing of € 220 000 by the Government is assured.
- Endorsement by all key stakeholders of the Terms of Reference, specifications for the individual contracts to be engaged;
- Appointment of counterpart personnel by the beneficiary before the launch of the tender process;
- Allocation of working space and facilities by the beneficiary for technical assistance before the launch of the tender process;
- Strong commitment of the Government of Montenegro to meet the challenges of alignment with EU standards.

### **3.6 Linked activities**

IPA 2007 "Development of Quality Infrastructure in Montenegro" (DQIM) project, EuropeAid/126524/C/SER/ME, in implementation from 11.03.2010 to 11.11.2011.

One of the four Quality Infrastructure components of this project was devoted to providing technical assistance to the Ministry of Economy in the area of Quality Infrastructure, including Conformity Assessment and Technical Regulations (the latter mainly related to approximation of the European New Approach Directives, another component was devoted to the technical assistance in Metrology (BoM as beneficiary).



### 3.7 Lessons learned

Although some progress has been made through previous projects, a number of challenges remain:

- Legal Reform: Initial timelines for the adoption of legal instruments are not always respected, leading to delays in implementation and causing difficulties in project implementation. Agreed legal instruments are commonly subject to significant change prior to adoption. The project will pay particular attention to the assessment of this risk and undertake the necessary palliative measures in terms of adequate legislative committees and diverse stakeholders' inclusion in the form of working groups.
- Enforcement: In previous years, the main focus has been put on establishing the legal frameworks in the country. The capacity to enforce the law, however, has received insufficient attention. This project addresses this aspect, by proposing practical steps for raising the capacity to implement the new laws.

### 4. Indicative Budget (amounts in €)

Activities	TOTAL COST	SOURCES OF FUNDING									
		EU CONTRIBUTION				NATIONAL PUBLIC CONTRIBUTION					PRIVATE
		Total	% *	IB	INV	Total	% *	Central	Regional	IFIs	Total
Component 1 and 2											
contract 1 (IPA)	600.000	600.000	89.55	X							
contract 2 (NC)	70.000			X	70.000	10.45	70.000				
Component 3											
contract 3 (IPA)	600.000	600.000	80		X						
contract 4 (NC)	150.000				X	150.000	20	150.000			
<b>TOTAL</b>	<b>1.420.000</b>	<b>1.200.000</b>	<b>84.51</b>			<b>220.000</b>	<b>15.49</b>	<b>220.000</b>			

\* expressed in % of the Total Cost

[Contract 1 covers all activities under Component 1 and the activities 2.1-2.4 of Component 2.](#)  
[Contract 2 covers the activities 2.5. and 2.6 as described above. Contracts 3 and 4 cover all](#)

activities under Component 3. Both contracts are supply and the differentiation between the two will only depend on the costs and type of the required equipment.

## 5. Indicative Implementation Schedule (periods broken down per quarter)

<u>Contracts</u>	<u>Start of Tendering</u>	<u>Signature of contract</u>	<u>Project Completion</u>
<u>Contract 1 (EU service)</u>	<u>Q1 2012</u>	<u>Q3 2012</u>	<u>Q1 2015</u>
<u>Contract 3 (EU supply)</u>	<u>Q4 2012</u>	<u>Q1 2013</u>	<u>Q3 2013</u>
<u>Contract 2 (National service)</u>	<u>Q1 2012</u>	<u>Q2 2012</u>	<u>Q1 2015</u>
<u>Contract 4 (National supply)</u>	<u>Q3 2012</u>	<u>Q1 2013</u>	<u>Q2 2013</u>

## 6. Cross cutting issues (where applicable)

### **6.1 Equal Opportunity**

In general, gender needs will be considered as an analytical instrument, from programme design onwards. Quality infrastructure has overall implications in creating a level playing field for equal opportunity (gender, disability and old age).

At project level, it is of great importance that quality infrastructure officers are aware of equal opportunity issues, and that they also possess the required knowledge to do it correctly when designing standards. Equal opportunities will therefore be a part of the training to be delivered.

Likewise, the economic actors are in need of information and training on how and why equal opportunity issues will be implemented in quality infrastructure. Through the performance of training needs assessments, we will be able to ascertain the characteristics of gender equality amongst quality infrastructure officers.

### **6.2 Environment**

The training activities will include a specific component to address environmental issues through a) mainstreaming environmental issues within the beneficiary's mandate, b) assist the beneficiary to implement an 'internal environment assessment' to identify areas where it could improve its internal performance vis-à-vis environmental aspects.

### **6.3 Minorities**

In a multiethnic society, Montenegrin industrial standards cannot ignore the culture, history, language and religion of their national minorities and of the majority. The ability for minorities to access markets is essential for their future economic, social and political wellbeing. Access to standards in their own language is a further indicator of the level of minority rights protection in the country. The beneficiary will be assisted to implement an 'internal minority and vulnerable group assessment' to identify areas where it could improve its internal performance vis-à-vis minorities or other vulnerable groups.

## ANNEXES

- 1- Log frame in Standard Format
- 2- Amounts contracted and Disbursed per Quarter over the full duration of Programme
- 3 - Reference to laws, regulations and strategic documents:

Reference list of relevant laws and regulations

Reference to AP /NPAA / EP / SAA

Reference to MIPD

Reference to National Development Plan

Reference to national / sectoral investment plans

- 4- Details per EU funded contract (\*) where applicable:

For *TA contracts*: account of tasks expected from the contractor

For *twinning covenants*: account of tasks expected from the team leader, resident twinning advisor and short term experts

For *grants schemes*: account of components of the schemes

For *investment contracts*: reference list of feasibility study as well as technical specifications and cost price schedule + section to be filled in on investment criteria (\*\*)

For *works contracts*: reference list of feasibility study for the *constructing works* part of the contract as well as a section on investment criteria (\*\*); account of services to be carried out for the *service part* of the contract

(\*) non standard aspects (in case of derogation to PRAG) also to be specified

(\*\*) section on investment criteria (applicable to all infrastructure contracts and constructing works):

- Rate of return
- Co financing
- compliance with state aids provisions
- Ownership of assets (current and after project completion)

5. List of equipment that will be financed through Contract 2.1 - IPA

6. List of equipment that will be financed through Contract 2.2 - National contribution

## ANNEX 1: Logical framework matrix in standard format

<b>LOGFRAME PLANNING MATRIX FOR Project Fiche</b>	<b>Programme name and number:</b> Development of Quality Infrastructure (QI) and Metrology" (DQIM) project	
	<b>Contracting period expires:</b> Three years after conclusion of the Financial Agreement	<b>Disbursement period expires:</b> One year after the final date for the execution of contracts
	<b>Total budget : 1. 420. 000 EUR</b>	<b>IPA budget: 1. 200. 000 EUR</b>

<b>Overall objective:</b>	<b>Objectively verifiable indicators:</b>	<b>Sources of Verification:</b>	
To facilitate trade and free movement of goods in compliance with the EU <i>acquis communautaire</i> in the field of Chapter 1 - Free movement of goods and the WTO requirements.	Free movement of goods increased at least 2 % within next 5 years from the end of the project.	National statistics - MONSTAT	
<b>Project purpose:</b>	<b>Objectively verifiable indicators:</b>	<b>Sources of Verification:</b>	<b>Assumptions:</b>
To enhance the capacity of the Ministry of Economy and the Bureau of Metrology to meet the EU legislative, regulatory and technical requirements	<ul style="list-style-type: none"> <li>• At least 5 national calibration labs operational within 5 years of project-end.</li> <li>• At least 3 laboratories accredited by end of the project and at least another within 3 years of end of project. Quality management system fully implemented and application for</li> </ul>	<ul style="list-style-type: none"> <li>• Annual EC Progress Reports,</li> <li>• ex-post project or IPA evaluation report/s,</li> <li>• acceptance of quality management systems of BoM from EURAMET</li> </ul>	<p>Continuing political stability and commitment for enforcement of legislation .</p> <p>Stability of staff turnover levels.</p>

	<p>presentation submitted to EURAMET TC-Q within 5 years of project-end.</p> <ul style="list-style-type: none"> <li>• Level of harmonization of national technical legislation with EU acquis</li> <li>• Progress on TBT/WTO negotiation</li> </ul>	<ul style="list-style-type: none"> <li>• Annual report/s from BoM and/or Ministry of Economy</li> <li>• Register of technical regulations</li> <li>• NPAA</li> <li>• EC Regular reports</li> <li>• Government reports</li> </ul>	
<b>Results:</b>	<b>Objectively verifiable indicators:</b>	<b>Sources of Verification:</b>	<b>Assumptions:</b>
Result 1: Enhanced transposition of the <i>acquis</i> in the field of QI	<ul style="list-style-type: none"> <li>• 5 <i>New Approach</i> Directives (NAD) transposed and necessary secondary legislation changes mapped out by end of project (medical devices, medical devices in vitro, explosives, cosmetics and ATEX directive)</li> <li>• 30 sectoral directives in area of pharmaceutical products transposed in national legislation</li> <li>• Assessment of needs for new legislation and of gaps in existing legislation in the field of free movement of goods completed</li> <li>•</li> </ul>	<p>Official gazette</p> <p>Parliament database</p> <p>EC reports</p> <p>Project reports</p>	<p>Political commitment</p> <p>Preparedness of stakeholder and good cooperation</p> <p>Trained staff retained</p> <p>Availability of funds for equipment and implementation of testing and controls</p>
Result 2: Improved administrative capacity of DQI;	<ul style="list-style-type: none"> <li>• Training Needs Assessment developed and training implemented in the first half of the project period</li> <li>• At least 10 staff members trained and familiar with EU obligations for Montenegro by the end of the Project;</li> <li>• Awareness raised among stakeholders</li> </ul>	<p>Project reports</p> <p>Stakeholders feedback</p> <p>EC reports</p>	

	<p>(CABs, Manufacturers and other Governmental bodies) about the new tasks of the DQI in notification of technical regulations and in notification of conformity assessment bodies</p> <ul style="list-style-type: none"> <li>• DQI trained in the directives 98/34/EC and 98/48/EC and procedures implemented</li> <li>• WTO Enquiry Point for Technical Regulations established and functioning</li> </ul> <p>Full communication with TBT/WTO Secretariat established</p>	<p>WTO reports</p> <p>WTO secretariat reports</p>	
<p>Result 3: Improved capacity of the National Metrology Institution</p> <ul style="list-style-type: none"> <li>•</li> </ul>	<p>Three labs certified from National Accreditation body</p> <p>Positive opinion on traceability of chosen measurements standards (see in annex 4) received from NMI (National Metrology Institute) provided by a Member of EURAMET</p> <p>Three new laboratories fully equipped</p>	<p>Bureau of Metrology reports</p> <p>Accreditation certificates issued</p> <p>Opinion of the chosen NMI</p> <p>Accreditation certificates</p> <p>Bureau of Metrology reports</p>	<p>Continuous political support for adoption and enforcement t of legislation</p> <p>Staff and stakeholders motivation and cooperation</p>

Activities:	Means:	Costs:	Assumptions:
<p>Component 1: Harmonisation of the legislation with the Acquis</p> <ul style="list-style-type: none"> <li>• legislative gap assessment and preparation of table of concordance;</li> <li>• roadmap for transposition and implementation of technical legislation</li> <li>• transposition of 5 New Approach Directives</li> <li>• transposition of 30 sectoral directives in area of pharmaceutical products</li> </ul> <p><u>Component 2: Improving the administrative capacity of the DQI;</u></p> <ul style="list-style-type: none"> <li>• Training Needs Assessment</li> <li>• training programme on free movement of goods</li> <li>• Raising the awareness of the stakeholders (CABs, Manufacturers and other Governmental bodies) on notification</li> <li>• Training on EU directives 98/34/EC and 98/48/EC</li> <li>• Training on WTO TBT Agreement</li> <li>• Establishing full communication with TBT/WTO Secretariat</li> </ul> <p>Component 3: Enhancing the capacity of the BoM</p> <ul style="list-style-type: none"> <li>• Preparation of three metrology labs for accreditation by the National Accreditation Body ;</li> <li>• peer assessment on traceability of chosen measurements standards</li> <li>• Supply of metrology equipment to BoM</li> </ul>	<p>4 contracts – 2 service and 2 supply.</p> <p>EU funding – 1 service contract (600.000 EUR) and 1 supply contract (600.000 EUR)</p> <p>National funding – 1 service contract (70.000 EUR) and 1 supply contract (150.000 EUR)</p>	<p><b>1. 420. 000. EUR</b></p>	<p>Both beneficiaries commitment to cover future maintenance costs of funds to sustain the equipment</p> <p>Feasibility study inc. Technical specifications and cost price schedule prepared by signature of FM</p>



**ANNEX II: amounts (in €) Contracted and disbursed by quarter for the project**

Contracted	2012		2013				2014			
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Contract 1	600.000									
Contract 3			600.000							
<b>Cumulated</b>	<b>600.000</b>		<b>1.200.000</b>							
<b>Disbursed</b>										
Contract 1	120.000				210.000				210.000	
Contract 3			360.000	180.000		60.000				
<b>Cumulated</b>	<b>120.000</b>		<b>480.000</b>	<b>660.000</b>	<b>870.000</b>	<b>930.000</b>			<b>1.140.000</b>	

## **ANNEX 3: Reference to laws, regulations and strategic documents:**

### **Legislative documents**

- Regulation on the Amendments and Supplements to the Regulation on the Organization and the Method of Operation of the State Administration (Official Gazette of the Republic of Montenegro 60/06),
- Law on Metrology (Official Gazette of Montenegro 79/08),
- Regulation on the Organization and the Method of Operation of the State Administration (Official Gazette of Montenegro 7/11),
- Decree on legal units of measurement (Official Gazette of Montenegro 22/09);
- Rulebook on technical and metrological requirements and the procedure for authorization of persons for the preparation of water meters for verification (Official Gazette of Montenegro 44/09);
- Rulebook on technical and metrological requirements and the procedure for authorization of persons for the preparation of mass measuring instruments for verification (Official Gazette of Montenegro 65/09);
- Rulebook on technical and metrological requirements and the procedure for authorization of persons for the preparation of taximeters for verification (Official Gazette of Montenegro 74/09);
- Rulebook on the types, forms and the method of affixing marks that are used in the verification of measuring instruments, as well as a more detailed form and content of the certificate of the verification of measuring instrument and the certificate of the type approval of the measuring instrument (Official Gazette of Montenegro 80/09);
- Decree on legal measuring instruments that are mandatory subjected to verification and/or the type approval of the measuring instrument (Official Gazette of Montenegro 81/09);
- Rulebook on intervals for the reverification of legal measuring instruments (Official Gazette of Montenegro 86/09);
- Rulebook on the method of determining the compliance with the metrological requirements for legal measuring instruments (Official Gazette of Montenegro 04/10);
- Rulebook on metrological requirements for the basic clocks within telephone exchanges used for the calculation based on the call data records (Official Gazette of Montenegro 06/10);
- Rulebook on more detailed procedure and method of examination and approving the type of a measuring instrument (Official Gazette of Montenegro 10/10) ;
- Rulebook on technical and metrological requirements and the procedure for authorization of persons for the preparation of measuring systems for quantities of liquids other than water for verification (Official Gazette of Montenegro 15/10);
- Rulebook on technical and metrological requirements and the procedure for authorization of persons for the preparation of fuel dispensers and devices for liquefied petroleum gas for verification (Official Gazette of Montenegro 15/10).
- Law on Technical Requirement for Products and Assessment of Product Conformity against Set Standards (Official Gazette of Montenegro 14/08)
- Standardization Law (Official Gazette of Montenegro 13/08 )
- Accreditation Law (Official Gazette of Montenegro 54/2009) (Annex 14)
- Law on General Product Safety (Official Gazette of Montenegro 48/08)

**The Law on Technical Requirement for Products and Assessment of Product Conformity** against Set Standards (Official Gazette of Montenegro 14/08) stipulates an administrative structure for the adoption of technical regulations (line ministries adopt technical regulations within their respective sectors). This matter is further elaborated by secondary legislation:

- 1) Decree on the Notification Procedure in the Area of Technical Regulations, Standards and Procedures for Conformity Assessment (Official Gazette of Montenegro 55/08);
- 2) Decree on the Method for Preparation and Adoption of Technical Regulations and Technical Specifications and Register of Technical Regulations (Official Gazette of Montenegro 55/08);
- 3) Decree on the Method and Procedures for Assessment of Product Conformity against Set Requirements (Official Gazette of Montenegro 71/08);
- 4) Decree on the Conditions for the Application of Technical Regulations of Other States and Records of Foreign Conformity Certificates (Official Gazette of Montenegro 74/08).

**Stabilization and Association Agreement (SAA), Article 77 Standardisation, metrology, accreditation and conformity assessment** stipulates that

"Montenegro shall take the necessary measures in order to gradually achieve conformity with Community technical regulations and European standardisation, metrology, accreditation and conformity assessment procedures.

To this end, the Parties shall seek to:

- promote the use of Community technical regulations, European standards and conformity assessment procedures
- provide assistance to fostering the development of quality infrastructure: standardisation, metrology, accreditation and conformity assessment;
- promote the participation of Montenegro in the work of organisations related to standards, conformity assessment, metrology and similar functions (e.g. CEN, CENELEC, ETSI, EA, WELMEC, EUROMET etc).
- Where appropriate, conclude an Agreement on Conformity Assessment and Acceptance of Industrial Products once the legislative framework and the procedures of Montenegro is sufficiently aligned on that of the Community and appropriate expertise is available."

### **Institutional arrangements**

- **Department for Quality infrastructure at Ministry of Economy** employs 2 persons

**Bureau of Metrology (BoM)** employs 27 persons organised in 3 sectors (Regional and International Cooperation; Metrology Control, and Legal Affairs, Inspection Control and Administrative Procedures) and 1 Division for General Affairs. BoM's laboratory (mass, length, electrical quantities, temperature and pressure) facilities are being established. No Metrology Council to provide expert assistance in the field of metrology has been formed so far.

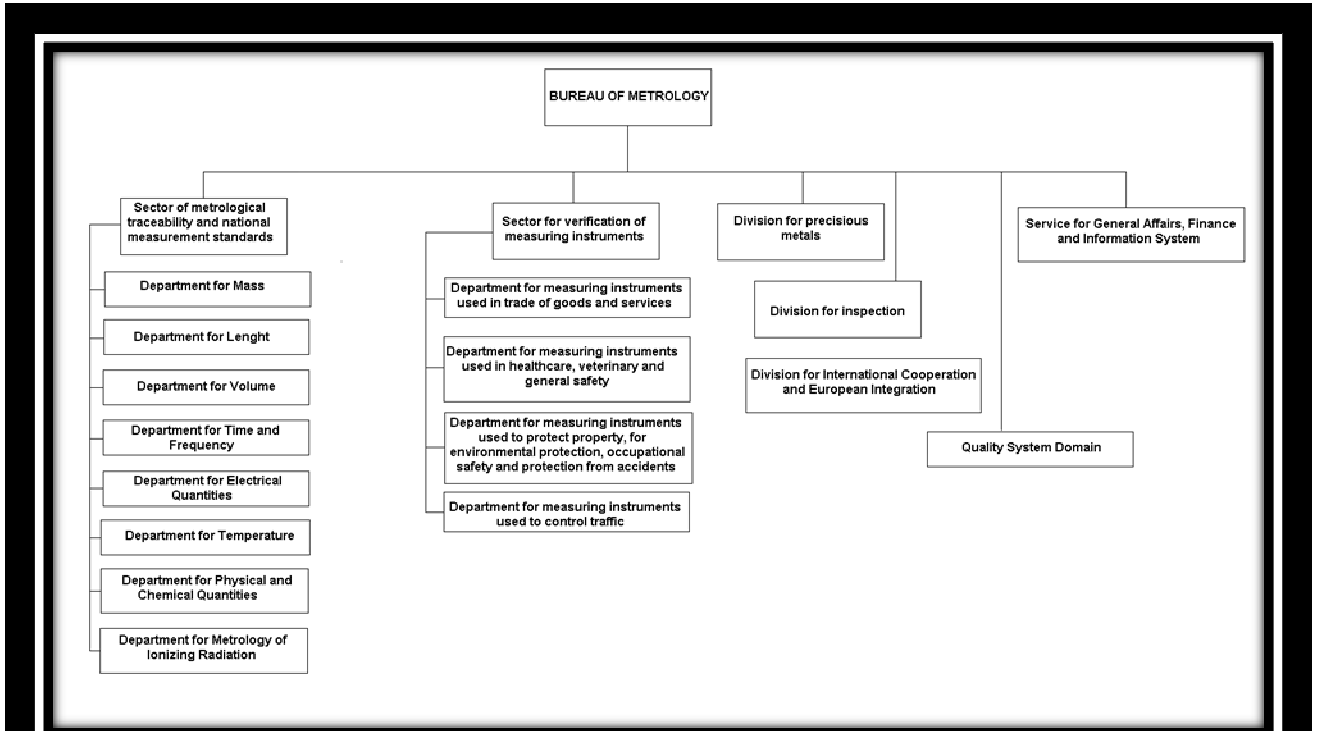


Figure 1: Organigramme at BoM

## **Annex 4: Details per EU funded contract**

### **Contract 1 Service contract - IPA**

Technical Assistance for the Contract 1.1 will consist of a long term service contract covering the transposition of EU Directives in Area of QI and capacity development for Department of QI. Technical assistance will be provided by a Contractor, selected through a restricted international procurement procedure.

The project team will consist of

Key Expert/Team Leader with 300 days (minimum)

Senior Non-Key Experts (short-term) 200 days.

Junior Non-Key Experts (short-term) 100 days.

The indicative duration of the project is 24 months.

The tasks of external consultant will contain the following but will not be restricted to:

- Review all areas in national technical legislation from the scope of QI
- Support the preparation of secondary legislation for transposition of the 5 NAD
- Support the preparation of sub laws for transposition of the 30 pharmaceutical directives
- Review internal mechanisms
- Deliver trainings for DQI staff

### **Contract 2 Service contract – National contribution**

National co-financing under Contract 1.2 will be used to purchase of IT equipment (computers, printers etc.), rent of the premises for seminars, rent of the office for EU experts, printing materials, etc.

**National contract will be awarded via national procurement procedures.**

### **Contract 3 Supply contract - IPA ( 0.6 mil €)**

**This contract will be consisted of purchase of equipment for the Bureau of Metrology**

List of equipment that will be financed through Contract 3 - IPA:

This list has own-estimates of costing but requires independent validation by the EC and we request that this is launched to re-calibrate both the list of supplies, the costs and technical specifications as per the EC's PCM Guidelines and requirement set out in the IPA Programming template for Annex 4.

1. MEASURING SYSTEM FOR CALIBRATION AND VERIFICATION OF MEASURING TAPES AND RULERS
2. DIGITAL HEIGHT GAUGE
3. UNIVERSAL STAND WITH MAGNETIC BASE
4. HIGH PRECISION INDUCTIVE PROBES
5. CALLIPER
6. PASSAMETER WITH DIAL INDICATOR
7. MEASURING STEEL TAPE 10 m
8. RULER 1 m

9. SYSTEM FOR MEASURING OF THE TRAVELLED DISTANCE OF TAXIMETER
10. STOPWATCH
11. COMBINE DEVICE FOR CHECKING DEPTH PROFILE OF TIRES AND TIRES PRESSURE
12. MEASURING STEEL TAPE 50 M

#### **MASS LABORATORY**

1. MANUAL MASS COMPARATOR
2. STANDARD WEIGHT
3. STANDARD WEIGHT
4. STANDARD WEIGHT
5. BASKET FOR F1 WEIGHTS 25 PIECES
6. 8 STANDARD WEIGHTS
7. MASS COMPARATOR
- 8.. HANDLE FOR LIFTING WEIGHTS

#### **VOLUME LABORATORY**

1. PIPETE CALIBRATION BALANCE 22 g
2. PIPETTE CALIBRATION BALANCE
3. INSTRUMENT FOR ENVIRONMENTAL DATA (AIR TEMPERATURE, HUMIDITY AND PRESSURE)
4. BALANCE WITH MAX CAPACITY 64100 g
5. BALANCE UP TO 600 KG
6. BALANCE UP TO 1100 KG

#### **PRESSURE LABORATORY**

1. PNEUMATIC DEAD WEIGHT TESTER
2. ACCESSORIES
3. ELECTRONIC DIFFERENTIAL PRESSURE GAUGE
4. ACCESSORY EQUIPMENT
5. INSTRUMENT FOR ENVIRONMENTAL DATA (AIR TEMPERATURE, HUMIDITY AND PRESSURE)

#### **LABORATORY FOR PRECIOUS METALS**

1. ANALITICAL BALANCE
2. ANALITICAL BALANCE
3. PRECISION BALANCE

#### **TEMPERATURE LABORATORY**

1. CALIBRATION FURNACE
2. SYSTEM FOR CALIBRATION OF TEMPERATURE AND HUMIDITY AIR SENZORS
3. PRECISION DIGITAL THERMOMETER WITH SCANNER
- 4.CALIBRATION SYSTEM FOR NON CONTACT AND CONTACT MEDICAL THERMOMETERS
- 5.REFERENCE DEW POINT METER
- 6.INSTRUMENT FOR ENVIRONMENTAL DATA (AIR TEMPERATURE, HUMIDITY AND PRESSURE)

## **Contract 4 Supply contract – National contribution( 0.15 mil €)**

**This contract will consist of purchase of equipment for the Bureau of Metrology**

**National contract will be awarded via national procurement procedures.**

The project implementation will be overseen by a Steering committee (SC) to be established during the inception phase. It will include representatives from the European Delegation to Montenegro, Beneficiaries, Ministry of Foreign Affairs and European Integration and Ministry of Finances, Ministry of Health. Representatives of the key data providers institutions and stakeholders (Agency for pharmaceutical products , CABs etc), may also be invited at the meetings of the SC in their consulting capacity.

The main functions of the SC are:

- To assess Project progress and guide it strategically;
- To assess the performance of the Consultant;
- To jointly discuss any critical points or bottlenecks for further activities;
- To propose and discuss remedy actions to be taken in order to tackle problems;
- To issue recommendations affecting timing, cost or contents;
- To comment and/or discuss the Consultant's reports

### **List of equipment that will be financed through Contract 4 - National contribution:**

1. X – RAY SPECTROFOTOMETER
  - for examination of peaces of precious metals with quantitative methodPRICE: 70 000.00 €
2. POTENCIOMETRIC TITRATOR
  - for examination of silver peacesPRICE: 16 500.00 €
3. FURNACE FOR CUPELLATION
  - for examination of peaces of precious metalsPRICE: 30 000.00 €
4. 2 FURNE CUPBOARDS  
PRICE: 5 000.00 €
5. MASS COMPARATOR  
Max  $\geq$  1 kg, d = 0.1 mg  
PRICE: 18 000.00 €
6. SOFTWARE FOR CALCULATION OF CONVENTIONAL MASS OF TESTING WEIGHTS COMPATIBLE WITH ALL TYPES OF COMPARATORS  
PRICE: 5 000.00 €
7. EQUIPMENT FOR CALIBRATION OF TEMPERATURE MEASURINF INSTRUMENTS OUTSIDE OF LABORATORY  
PRICE: 6 500.00 €