

## Standard Summary Project Fiche

### 1. Basic Information

1.1 Désirée Number: BG 0201.12

**1.2 Title: Strengthening of the national conformity assessment system**

1.3 Sector: Internal market

1.4 Location: Bulgaria, Sofia

### 2. Objectives

2.1 Overall Objective(s):

- Increased exportability and competitiveness of Bulgarian industry
- Enforced New Approach Acquis and functioning infrastructure ensuring free movement of industrial goods

2.2 Project purpose:

The project purpose is to ensure the provision of adequate services to industry by conformity assessment bodies (CABs), standardisation and metrology institutes.

Specific purposes in the area of:

**Conformity Assessment** - Strengthening of the national system of CABs in the selected priority areas of New Approach Directives: LVD, Machinery, EMC, CPD, Pressure equipment, SPV, Gas appliances and Toys, ensuring that they are equipped and capable autonomously to carry out the relevant conformity assessment procedures.

**Standardisation** – CEN/CENELEC full membership criteria met. In particular, provision of effective information services adequate to the CEN/CENELEC practice, and facilitation of enforcement of the NA Directives through full transposition and application of harmonised standards.

**Metrology** – Provision of the necessary capacity to meet the requirements of priority industrial sectors as regards accuracy, reliability and traceability of measurements carried out.

2.3 Accession Partnership and NPAA priorities

#### **Reference to the Accession Partnership 2001:**

*Free movement of goods:*

- Modify the framework law on technical requirements implementing New and Global Approach principles to ensure it is in line with the *acquis*.
- Reinforce horizontal administrative infrastructure and separation of standardisation and certification functions. Implement New Approach directives on the basis of modified framework legislation and reinforcement of related administrative capacity (conformity assessment bodies and laboratories). Speed up the adoption of EN harmonised standards.

#### **NPAA**

The short-run activities will focus on the transposition of directives related to the national priorities in production and trade. After the adoption of the framework Law on Technical Requirements to Products, efforts will be focused on building the structures necessary for the

application of New Approach principles and the stimulation of private initiative for setting up testing, certification and inspection bodies. The priority objective is the implementation of the principles under the New Approach and the Global Approach.

- Progressive implementation of the product safety requirements with priority action in the sectors in which Bulgaria has competitive advantages;
- Building up a functioning conformity assessment and market surveillance system;
- Establishing of a national calibration system that will respond to the industry needs and the conformity assessment system;
- Establishing of the necessary infrastructure for carrying out of metrological control of the pre-packaged products and metrological surveillance;
- Fulfillment of the full membership requirements of the National Standardisation Body in CEN/CENELEC.

### 3. Description

#### 3.1 Background and justification:

According to the Regular Report 2001 “Bulgaria still needs to create an effective network of independent certifying bodies and laboratories. Special attention needs to be given to the development of a national conformity assessment system, and in particular to certification bodies which supply services under the conformity assessment procedures of the Global Approach. As regards standardisation, the adoption rate has increased by 40% although it still has not reached the level required for membership of CEN and CENELEC”.

Transposition of New Approach legislation (10 directives transposed by the end of 2001, the remaining directives are to be transposed in the course of 2002) creates the legal basis for the development of the relevant conformity assessment system offering services to manufactures. Transposition of the *acquis* and implementation infrastructure provides conditions for signing of PECA, which will guarantee free movement of industrial goods. Bulgarian industry now has to respond to identical requirements on the local market and for exporting to the EU. In the new situation the industry demand for certification and testing services is expected to increase rapidly stimulating development of certification bodies and test laboratories. At the present stage, Bulgarian enterprises cannot afford the whole amount of necessary investments in test equipment to cover relevant assessment procedures, which is aimed to be partially financed within this project in priority sectors for PECA negotiations. Due to the economic situation the bigger part of financing for standardisation and metrology activities are covered through the state budgeting.

The National Standardisation Body, which will be segregated from the State Agency for Standardisation and Metrology (SASM) and operate independently since 2002, must achieve the level of customer service adequate to the growing needs of the industry. To respond to that tendency a modern library and efficient print-on-demand service will be developed within this project. In order to achieve full membership in CEN and CENELEC it has to demonstrate ability to respond efficiently to the high volume of data and document communication within the European standardisation system. The EU and international standards organisations policy is the information (standards, catalogues and other documents) to be distributed electronically (CDs and Internet). Focusing on full membership in CEN and CENELEC, which is planned to be achieved by the year 2004, the Standardisation Body should give evidence of possession of required means, competence and expertise. Participation of qualified experts in CEN Technical Committees, elaborating harmonised standards mandated by EC, will be financed within this project.

In order to achieve confidence in calibration and testing results and recognition of certification and accreditation activities, it is necessary to demonstrate traceability of measurements towards national measurement standards and international recognition of these standards. Achievement of

full membership in EUROMET will prove compliance with metrological practice in EU and increase confidence in measurement activities in Bulgaria. It is planned to move national standard laboratories to new premises improving their environmental conditions and to purchase a number of measurement standards ensuring traceability of measurements in priority industrial needs. This will be implemented according to the long-term strategy for development of national measurement standards and the infrastructure of calibration laboratories, elaborated under Phare 2000 project. The range of investments for new equipment, covered by the State budget is planned to be supported through the Phare project.

In the process of preparation of this project fiche consultations have been carried out with representatives of industry (Bulgarian Chamber of Electrical Engineering and Bulgarian Branch Chamber of Machine Building), which indicated the specific needs of industry sectors they represented. During the project implementation they will actively participate and contribute to achievement of the project objectives. This will result in a fair assessment of the priorities of the related industry sectors and adequate response to their needs.

For more details on sectors – conformity assessment, standardisation and metrology, refer to ANNEX 8.

### 3.2 Linked activities:

Under the Phare Programme BG 9602 training of certification personnel on operation, auditing and certification of products, quality systems and personnel was carried out, awareness and willingness to develop appropriate conformity assessment structures were achieved. The project “Upgrading of Laboratories” has been successfully implemented: three laboratories - “Pressure”, “Electric energy and power” and “Time and frequency” at the National Centre of Metrology (NCM) were equipped, and the respective laboratory personnel underwent the proper training. Experts from SASM Directorate “Standardisation” were trained and IT equipment was purchased.

Under the bilateral programme of the Government of the Netherlands - PSO, a project “Implementing of the European model of conformity assessment in Bulgaria; strengthening of the institutional structure and the relations between the institutions” (PSO 99/BG/9/1) is financed. The project is implemented by Netherlands National Metrology Institute and RvA (Dutch Accreditation Council) and will be finalised with a joint accreditation of 4 testing laboratories.

The implementation of Phare 2000 Project “Establishing of a conformity assessment system” is to be launched at the beginning of 2002 and will emphasise on-the-job training and coaching in organisation and operational practice in conformity assessment activities related to accreditation, certification, and market surveillance. The CABs, which will participate in Phare 2000 project and intend to enlarge the scope of their activities, are in the list of potential beneficiaries for supply of testing equipment under Phare 2002.

This new project will be a logical extension of the previous projects and will lead to strengthening of the necessary conformity assessment system, metrology infrastructure and standardisation services. As a result the requirements for signing of PECA in priority sectors will be met.

### 3.3 Results:

The project, that consists of six sub-projects, foresees to produce the following results in the different areas:

#### **Sub-project 1: Technical Assistance for CABs**

- R1.1. Detailed technical specification of equipment for CABs based on technical and economical appraisal of the requirement specification developed;
- R1.2. Advisory support provided to CABs on specific technical and operational issues according to their scope of activities;
- R1.3. Conformity Assessment Bodies authorised and capable autonomously to implement entirely the conformity assessment procedures under the relevant NA directives: LVD, Machinery, EMC, CPD, Pressure equipment, SPV, Gas appliances and Toys.

#### **Sub-project 2: Supply of Equipment for CABs**

- R2. The necessary equipment for testing laboratories, covering the conformity assessment procedures, supplied and operational.

#### **Sub-project 3: Technical Assistance for Standardisation**

- R3.1 Strategic plan (including service concept) developed;
- R3.2. Detailed technical specification of equipment based on reviewed requirement specification developed;
- R3.3. Efficient information services to distribute (eg. print-on-demand principle), promote and to provide customers with adequate access to standards and related information (eg. on line bibliographical access, multi-access full texts database of Bulgarian standards);
- R3.4. Standardisation staff successfully trained in the development of customer services, promotion of standardisation (towards industry users) and participation in technical committees;
- R3.5. Procedure manual for operation of the information system of the National Standardisation Body elaborated;
- R3.6. CEN/CENELEC membership criteria met including active participation of Bulgarian experts in the work of CEN Technical Committees.

#### **Sub-project 4: Supply of Equipment for Standardisation**

- R4.1 State-of-the art information systems and IT equipment supplied and fully operational;
- R4.2. Adequate media equipment available for Technical Committees and to be also used for training purposes (eg. training of clients and personnel).

#### **Sub-project 5: Technical Assistance for Metrology**

- R5.1. NCM staff successfully trained on requirements for preparation of Terms of Reference (ToR) for construction plan for NCM laboratories
- R5.2. Assessed construction plan for NCM laboratories against the achievement of the necessary laboratory conditions and its compliance with the ToR;
- R5.3. Detailed technical specification based on reviewed requirement specification (ANNEX 7) elaborated;
- R5.4. EUROMET full membership acceptance criteria met:
  - NCM active participation in EUROMET projects on international comparisons in the fields of electric, physical and mechanical measurements;
  - Reach equivalence of measurement standards in order to ensure international recognition of measurement and calibration certificates issued by NCM;
  - NCM quality system in use and assessed by experts from national metrology institutes (NMIs) members of EUROMET.

## **Sub-project 6: Supply of Equipment for National Standard Laboratories**

R6.1. Seven (7) laboratories equipped and operational, traceability of measurement standards established and staff trained on equipment use and operation as well as on software application.

### **3.4 Activities:**

As follows a list of activities (more details about them are provided in ANNEX 8):

#### **Sub-project 1: Technical Assistance for CABs**

A1.1.1. Development of detailed technical specification of equipment for CABs based on reviewed requirement specification-ANNEX 5 (approximately 3 man months);

A1.2. Providing a pool of EU experts available on request over a period of one year for consultation on-site on operational and technical issues (approximately 6 man months);

A1.3. Training of staff on practical implementation of conformity assessment procedures (approximately 6 man months):

A1.3.1. Organisation of 4 sectoral workshops on conformity assessment matters;

A1.3.2. On-the-job training on conformity assessment procedures implementation;

A1.3.3. On-the-job training on testing methods in the equipped test laboratories.

#### **Sub-project 2: Supply of Equipment for CABs**

A2. Procurement of equipment for test laboratories of CABs according to the technical specifications prepared and its consecutive putting into operation.

#### **Sub-project 3: Technical Assistance for Standardisation**

A3.1. Elaboration of a strategic plan (including operational procedures if necessary) to develop and implement adequate information and customer services (approximately 2 man months);

A3.2. Elaboration of detailed technical specification based on the requirement specification - ANNEX 6 (approximately 1 man month);

A3.3 Development of application for printing/sales/distribution of standards, including Web-application for bibliographical database and Web-application for e-commerce (approximately 6 man months);

A3.4. Development of a bibliographical database and a full text database application under suitable dB engine (approximately 6 man months);

A3.5. Training of personnel on information, promotion and customer services (approximately 2 man months);

A3.6. Elaboration of a procedure manual for operation of the information system of the National Standardisation Body (approximately 4 man months);

A3.7. Participation of 10 Bulgarian experts in the work of CEN Technical Committees elaborating harmonised standards mandated by EC (approximately 1 man month);

A3.8. Evaluation of the compliance with CEN criteria and determination of possible shortcomings (approximately 1 man month).

#### **Sub-project 4: Supply of Equipment for Standardisation**

A4.1. Procurement of database, equipment for the library/information centre and software as well as its customisation;

A4.2. Procurement of media equipment (ANNEX 6).

#### **Sub-project 5: Technical Assistance for Metrology**

A5.1. EU experts train NCM staff in drafting the ToR and in assessing the construction plan for a national metrology complex (in particular to evaluate specific environmental conditions like

stability, low vibration and minimised magnetic and electromagnetic fields) - approximately 1 man month;

A5.2. Assessment of the construction plan for NCM laboratories against the achievement of the necessary laboratory conditions and its compliance with the ToR (approximately 0,5 man month);

A5.3 Elaboration of detailed technical specification based on reviewed requirement specification (ANNEX 7) and long-term strategy for development of national measurement standards and the infrastructure of calibration laboratories elaborated under Phare BG 0003.02.02 "Technical assistance for metrology" (approximately 1 man month);

A5.4. Organisation and participation in seven international comparisons (following EUROMET procedures) for NCM measurement standards in the following areas (approximately 5 man months):

- electric measurements;
- physical measurements;
- mechanical measurements.

A5.5 Peer-assessment of NCM quality system by experts from national metrology institutes (NMIs) members of EUROMET (approximately 2 man months).

#### **Sub-project 6: Supply of Equipment for National Standard Laboratories**

A6.1. Procurement of metrology equipment for seven (7) selected laboratories (ANNEX 7), including calibration traceable to internationally recognised measurement standards, putting into operation and training.

## **4. Institutional Framework**

The following is the institutional framework within which the project will have to operate:

#### **Sub-project 1: Technical Assistance for CABs and Sub-project 2: Supply of Equipment for CABs**

Following transposition of New and Global Approach, Bulgarian conformity assessment bodies are established on the basis of existing testing laboratories (some of them with more than 30 years experience), usually, in cooperation with quality systems certification bodies. Part of the CABs recently has changed or plans to change their status from state owned to private (registered according to the Trade Law).

Initial identification and pre-selection of the potential beneficiaries was carried out by SASM in cooperation with Bulgarian Chamber of Electrical Engineering, Bulgarian Branch Chamber of Machine Building, Ministry of Regional Development and Public Works (for the scope of CPD) and Bulgarian Accreditation Service. The pre-selection of CABs and required equipment specifications were elaborated in a way that ensures the ability of CABs to cover entirely the conformity assessment procedures under NA Directives in priority industrial sectors, also included in PECA negotiations (see item 2.2). The selection was done taking care about fair competition and trying to avoid unnecessary duplication of test equipment. There are several CABs in the field of LVD, CPD and Machinery Directive, which cover different product groups and do not overlap their scopes.

The selected CABs will be equipped and their staff trained in order to meet the European requirements for notified bodies.

#### **Sub-project 3: Technical Assistance for Standardisation and Sub-project 4: Supply of Equipment for Standardisation**

The beneficiary in the field of standardisation is the Standardisation Directorate within SASM. Standardisation Directorate carries out all activities related to the elaboration, approval,

publication and distribution of Bulgarian standards. The total number of staff is 64. According to the Law on National Standardisation SASM has been designated as the national standards body and balanced participation of all interested parties is ensured. At present, the Standardisation Directorate is hosting secretariat of 75 Technical Committees, which requires the provision of communication and meeting facilities for the work performed by the TCs working groups.

SASM represents Bulgaria in the European and international standards organisations - a full member of ISO and IEC and an affiliate member to the European organisations CEN and CENELEC.

The Law amending the Law on National Standardisation was adopted by the Parliament on 23 January 2002 (published in State Gazette issue 13/05.02.2002) and will enter into force as from 6<sup>th</sup> of April 2002. According to the provisions of this Law, the functions currently performed by the Standardisation Directorate are envisaged to be transferred to Bulgarian Institute for Standardisation (BIS). BIS will be established as a national standardisation body with the status of independent legal entity at the Council of Ministers.

After the establishment of BIS, "Exchange of Information on Standards" Department will be in charge of the project implementation.

#### **Sub-project 5: Technical Assistance for Metrology and Sub-project 6: Supply of Equipment for National Standard Laboratories**

The beneficiary in the field of metrology is the State Agency for Standardisation and Metrology, particularly Directorate General "National Centre of Metrology". The total number of staff of the National Centre of Metrology is 112. SASM was accepted as a corresponding member of EUROMET in 2000 and NCM already participates in 13 EUROMET projects.

The National Centre of Metrology establishes and develops the system of national measurement standards, ensures traceability of measurements and satisfies the main needs of calibrations for the industry and for the existing infrastructure of testing and calibration laboratories.

The National Centre of Metrology strives to prove its competence according to the EUROMET strategy for implementation of the Mutual Recognition Agreement on the measurement standards and certificates of calibration and measurement. Therefore, introduction of a quality system in compliance with the requirements of ISO/IEC 17 025 has been launched. The quality system will be assessed through peer-assessment in accordance with the EUROMET procedures.

In the last few years, some national measurement standards were renovated and new standards were purchased with State budget and European programme means. Considerable financial means are still necessary to satisfy the needs of traceability in the country and to establish conditions of international equivalence of most of the national measurement standards.

## 5. Detailed Budget

	Phare Support					
	Investment Support	Institution Building	Total Phare (=I+IB)	National Co-financing*	IFI*	TOTAL
Sub-project 1: TA for CABs		€200 000	€200 000			€200 000
Sub-project 2: Supply of Equipment for CABs	€3 060 000		€3 060 000	€1 020 000		€4 080 000
Sub-project 3: TA for Standardisation		€310 000	€310 000			€310 000
Sub-project 4: Supply of Equipment for Standardisation	€150 000		€150 000	€50 000		€200 000
Sub-project 5: Technical Assistance for Metrology		€130 000	€130 000			€130 000
Sub-project 6: Supply of Equipment for National Standard Laboratories	€1 050 000		€1 050 000	€350 000		€1 400 000
<b>Total</b>	<b>€4 260 000</b>	<b>€640 000</b>	<b>€4 900 000</b>	<b>€1 420 000</b>		<b>€6 320 000</b>

\* Should the total cost of works proposed exceed the estimate shown in the table above, the beneficiary institution will provide the necessary additional budget.

## 6. Implementation Arrangements

### 6.1 Implementing Agency

The implementing agency is the CFCU in close co-operation with the beneficiary State Agency for Standardisation and Metrology.

Contact details for all Components:

State Agency for Standardisation and Metrology

Mr. Ivelin Bourov, President

21, 6<sup>th</sup> September Street

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### 6.2 Twinning

*Not applicable*



### 6.3 Non-standard aspects

*Not applicable*

### 6.4 Contracts

The Programme is expected to be contracted under one service contracts for technical assistance for CABs, standardisation and metrology and three supply contracts for CABs, standardisation and metrology. Their estimated €values are as follows:

Contract 1:	€ 640.000
Lot 1. Technical Assistance for CABs	€ 200.000
Lot 2. Technical Assistance for Standardisation	€ 310.000
Lot 3. Technical Assistance for Metrology	€ 130.000
Contract 2: Supply of Equipment for CABs	€3.060.000
Contract 3: Supply of Equipment for Standardisation	€150.000
Contract 4: Supply of Equipment for National Standard Laboratories	€1.050.000
<b>Total</b>	<b>€4.900.000</b>

## 7. Implementation Schedule

### 7.1 Start of tendering

The TORs for all programme components and/or project specifications will be ready by November 2002.

### 7.2 Start of project activity

Expected date of commencement of first contract will be 1 April 2003.

### 7.3 Project Completion

Expected date of last payment under last contract will be 30 November 2006. The additional year for disbursement is justified by the complexity of the project with complex contracting and equipment supply in a specialised technical field.

## 8. Equal Opportunity

The management of the beneficiary institutions will ensure that men and women are equally represented in all training measures. For and during all training events, lists of participants will be established and kept with the project documentation. The issue of women's participation will have to be addressed in the progress reports.

## 9. Environment

*Not applicable*

## 10. Rates of return

*Not applicable*

## 11. Investment criteria

### 11.1 Catalytic effect:

The Phare investments under this project will contribute to the strengthening of the necessary conformity assessment system and its functioning at the required EU level.

At the present stage, investments in the national metrology and standardisation are supported mainly through the state budget (in addition two supply projects were implemented under Phare BG 9602) due to the fact that Bulgarian industry cannot make any significant contributions despite the urgent need of their services in order to increase its exportability and competitiveness.

CABs cannot afford the whole amount of necessary investments in test equipment to cover the relevant assessment procedures. In order to support the establishment of these bodies and the enforcement of the adopted *acquis* it is necessary investments to be made without delay.

The range of investments covered by the State budget is insufficient for achieving of the above-mentioned objectives and the Phare support will be crucial.

The lack of financial support will lead to a significant delay in the process of establishment of the necessary conformity assessment infrastructure in Bulgaria and will impede the free movement of goods.

#### 11.2 Co-financing:

In addition to the Phare funds the investment components of the project will receive co-financing from the State budget and from private sector to the total value of €1.420.000 (25% of the total investment budget).

#### 11.3 Additionality:

*Not applicable*

#### 11.4 Project readiness and Size:

As a logical continuation of the previous Phare programme BG 9602 and the current one BG0003.02 the investments under this project are based on the precise evaluation of the needs of standardisation and metrology. Assessments of the necessary metrological equipment and supplies for standardisation have been carried out with regard to the successful implementation of this project and the achievement of its objectives.

As a result of the consultations with representatives of Bulgarian Chamber of Electrical Engineering and Bulgarian Branch Chamber of Machine Building, a fair assessment of the priorities of the related industry sectors was carried out and a preliminary list of the potential beneficiaries was established. The final selection will be made in an impartial way, under clear and transparent criteria (eg. co-financing availability, sound business plan) by an independent committee established during a feasibility study. The feasibility study will consist of:

- Assessment of market projections in priority sectors;
- Developing a methodology to approve eligible CABs. The criteria will take into account business feasibility/relevance of the investment and financial sustainability of the beneficiary. An independent committee will assess the eligibility of CABs. The composition of the committee will be specified during the development of the technical specifications. The feasibility study should be completed before the commencement of the project.

#### 11.5 Sustainability:

The equipment to be purchased within the “CABs” sub-project will comply with EU norms and standards and will be designed for a useful life of at least 10 to 20 years. All equipment will be required to comply with the applicable European directives and to be compatible with the test equipment in use at other European conformity assessment bodies. Maintenance of the equipment, in particular the cost for spare parts and supplies will be borne by the budget of the respective CABs.

The investments within the “Standardisation” sub-project will be sustainable in the long term and will comply with EU norms and standards in the field of standardisation customer servicing. The maintenance of the equipment and information system will be borne by the budget of BIS.

The equipment to be purchased within the “Metrology” sub-project is, equivalent to previous metrology laboratory investments in Bulgaria and those in other national institutes, designed for a useful life of at least 10 to 20 years. It is expected to be in service at the time and past accession of Bulgaria to the EU.

All equipment will be required to comply with the applicable European directives and to be compatible with the standards in use at other European national standards institutes. Maintenance of the equipment, in particular the cost for spare parts and supplies will be borne by the budget of the SASM.

#### 11.6 Compliance with state aids provisions

Wide and equal opportunity for the potential beneficiaries (CABs) under this project will be provided. The final selection will be made during the preparation of the feasibility study.

The other beneficiaries of this project are the only national bodies in the respective fields - standardisation and metrology.

#### 11.7 Contribution to National Development Plan

*Not applicable*

### 12. Conditionality and sequencing

At the time of commencement of the project the following conditionalities will be achieved:

- The Law on Technical Requirements to Products amended in order to abolish the contradictions between the provisions of Chapter V of the present Law on Technical Requirements to Products and the New and Global Approach principles;
- The necessary legislation in the sectors covered by NA Directives to be adopted;
- CABs established and staff successfully trained (under Phare 2000 – sub-project BG 0003.02.01);
- The present Standardisation Directorate within SASM segregated from SASM and established as Bulgarian Institute for Standardisation;
- Working procedures, IT equipment and network fully operational in the national standardisation body;
- Determined priorities and a documented long-term strategy for development of national measurement standards (under Phare 2000 sub-project BG0003.02.02);
- Feasibility study on CABs eligibility to be completed before the commencement of the project.

Most important milestones of the sub-projects are as follows:

#### **Sub-project 1: Technical Assistance for CABs**

- M1.1. Development of technical specifications for CABs' equipment;
- M1.2. Expert facilities provided to respond to the specific needs of CABs;
- M1.3. Staff successfully trained and capable to perform autonomously conformity assessment procedures.

#### **Sub-project 2: Supply of Equipment for CABs**

- M2. Necessary equipment supplied and operational.

#### **Sub-project 3: Technical Assistance for Standardisation**

- M3.1. Business strategy and service concept developed;
- M3.2. Elaboration of precise Technical Specification of the equipment to be purchased;
- M3.3. Operational IT based service/distribution system;
- M3.4. Satisfactory level of customer service achieved;

M3.5. Procedure manual elaborated;  
M3.6. Bulgarian experts actively participate in CEN TCs work;  
M3.7. Membership in CEN/CENELEC.

#### **Sub-project 4: Supply of Equipment for Standardisation**

M4.1. State-of-the-art information system fully operational;  
M4.2. Media equipment in place.

#### **Sub-project 5: Technical Assistance for Metrology**

M5.1. NCM staff successfully trained on requirements for preparation of ToR for construction plan for NCM laboratories;  
M5.2. ToR for construction plan for NCM laboratories developed by the trained NCM staff;  
M5.3. ToR for the construction plan for NCM laboratories reviewed and assessed by EU experts from national metrological institutes (NMIs);  
M5.4. Construction plan for NCM laboratories assessed by EU experts against the achievement of the necessary laboratory conditions and its compliance with the ToR;  
M5.5. EUROMET full membership acceptance criteria met.

#### **Sub-project 6: Supply of Equipment for National Standard Laboratories**

M6.1. Technical Specification for supply of metrology equipment developed;  
M6.2. Seven (7) Laboratories equipped and traceability of measurement standards established.

### **ANNEXES TO PROJECT FICHE**

1. ANNEX 1: Logical framework matrix in standard format
2. ANNEX 2: Detailed implementation chart
3. ANNEX 3: Contracting and disbursement schedule by quarter for full duration of programme (including disbursement period)
4. ANNEX 4: List of relevant Laws and Regulations
5. ANNEX 5: Requirement specification for supply of equipment for CABs
6. ANNEX 6: Requirement specification for supply of equipment for standardisation
7. ANNEX 7: Requirement specification for supply of equipment for metrology
8. ANNEX 8: Overview of economic conditions, legal framework and perspectives in the field of standardisation, conformity assessment and metrology

# ANNEX 1

LOGFRAME PLANNING MATRIX FOR	Programme name and number	
<b>Project: Strengthening of the national conformity assessment system</b>	Contracting period expires: Nov 2004	Disbursement period expires: Nov 2006
	<b>Total budget: €6 320 000</b>	<b>Phare budget : €4 900 000</b>

Overall objective	Objectively verifiable indicators	Sources of Verification
<ul style="list-style-type: none"> <li>Increased exportability and competitiveness of Bulgarian industry;</li> <li>Enforced NA Acquis and functioning infrastructure ensuring free movement of industrial goods.</li> </ul>	<ul style="list-style-type: none"> <li>Increased number of products offered for export to EU in the field of NA Directives;</li> <li>Industrial products in compliance with the provisions of the applicable NA Directives placed on the market;</li> <li>Authorised CABs in all relevant areas;</li> <li>Satisfactory records from market surveillance authorities.</li> </ul>	<ul style="list-style-type: none"> <li>EC regular report;</li> <li>Manufacturers information;</li> <li>Sectoral Chambers;</li> <li>Authorisation records;</li> <li>Market surveillance reports.</li> </ul>

Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
<p>The project purpose is to ensure the provision of adequate services to industry by conformity assessment bodies (CABs), standardisation and metrology institutes.</p> <p>Specific purposes in the area of:</p> <p><b>Conformity Assessment</b> - Strengthening of the national system of CABs in the selected priority areas of New Approach Directives: LVD, Machinery, EMC, CPD, Pressure equipment, SPV, Gas appliances and Toys, ensuring that they are equipped and capable autonomously to carry out the relevant conformity assessment procedures.</p> <p><b>Standardisation</b> – CEN/CENELEC full membership criteria met. In particular provision of effective information services adequate to the CEN/CENELEC practice, and facilitation of enforcement of the NA Directives through full transposition and application of harmonised standards.</p>	<ul style="list-style-type: none"> <li>Number of certificates issued;</li> <li>Number of conformity reports.</li> <li>Positive assessment report by CEN&amp;CENELEC;</li> <li>Number of harmonised standards under relevant NA Directives.</li> </ul>	<ul style="list-style-type: none"> <li>Registry of the issued certificates and reports at CABs.</li> <li>CEN/CENELEC reports;</li> <li>Official Bulletin of SASM.</li> </ul>	<ul style="list-style-type: none"> <li>Economic development does not undergo significant changes that can jeopardise the projections for project implementation;</li> <li>Industry continues to recover and modernises production.</li> </ul>

<b>Metrology</b> – Provision of the necessary capacity to meet the requirements of priority industrial sectors as regards accuracy, reliability and traceability of measurements carried out.	<ul style="list-style-type: none"> <li>• Full membership in EUROMET</li> </ul>	<ul style="list-style-type: none"> <li>• EUROMET reports</li> </ul>	
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Results	Objectively verifiable indicators	Sources of Verification	Assumptions
<p>Sub-project 1: Technical Assistance for CABs</p> <p><b>R1.1. Detailed technical specification of equipment for CABs based on technical and economical appraisal of the requirement specification developed;</b></p> <p><b>R1.2. Advisory support provided to CABs on specific technical and operational issues according to their scope of activities;</b></p> <p><b>R1.3. Conformity Assessment Bodies authorised and capable autonomously to implement entirely the conformity assessment procedures under the relevant NA directives: LVD, Machinery, EMC, CPD, Pressure equipment, SPV, Gas appliances and Toys.</b></p>	<ul style="list-style-type: none"> <li>• Technical specification document;</li> <li>• Advisory records;</li> <li>• Official authorisation in the scope of NA Directives: LVD, Machinery, EMC, CPD, Pressure equipment, SPV, Gas appliances and Toys.</li> </ul>	<ul style="list-style-type: none"> <li>• SASM;</li> <li>• EC Delegation;</li> <li>• CFCU;</li> <li>• SASM;</li> <li>• SASM Official Bulletin – Registry of CABs.</li> </ul>	<ul style="list-style-type: none"> <li>• Investment climate continues to improve in the industrial areas selected under the project;</li> <li>• CABs pursuing accreditation;</li> <li>• Notifying authorities established and operating;</li> <li>• State budget secures adequate funds for ensuring the framing operational conditions.</li> </ul>

<p><b>Sub-project 2: Supply of Equipment for CABs</b></p> <p>R2. The necessary equipment for testing laboratories, covering the conformity assessment procedures, supplied and operational.</p>	<ul style="list-style-type: none"> <li>• Acceptance reports;</li> </ul>	<ul style="list-style-type: none"> <li>• SASM</li> <li>• CFCU</li> </ul>
<p><b>Sub-project 3: Technical Assistance for Standardisation</b></p> <p>R3.1 Strategic plan (including service concept) developed;</p> <p>R3.2. Detailed technical specification of equipment based on reviewed requirement specification developed;</p> <p>R3.3. Efficient information services to distribute (eg. Print-on-demand principle) promote and to provide customers with adequate access to standards and related information (eg. On line bibliographical access, multi-access full texts database of Bulgarian standards);</p> <p>R3.4. Standardisation staff successfully trained in the development of customer services, promotion of standardisation (towards industry users) and participation in technical committees;</p>	<ul style="list-style-type: none"> <li>• Strategy document adopted;</li> <li>• Technical specification documents;</li> <li>• Number of served clients;</li> <li>• Assessment of compliance with the conditions for CEN&amp;CENELEC membership;</li> <li>• Training records;</li> </ul>	<ul style="list-style-type: none"> <li>• BIS – project reports</li> <li>• BIS;</li> <li>• CFCU;</li> <li>• EC Delegation;</li> <li>• Report on the fulfillment of the criteria for CEN&amp;CENELEC membership.</li> <li>• Project documentation at beneficiary;</li> </ul>

<p>R3.5. Procedure manual for operation of the information system of the National Standardisation Body elaborated;</p> <p>R3.6. CEN/CENELEC membership criteria met including active participation of Bulgarian experts in the work of CEN Technical Committees.</p>	<ul style="list-style-type: none"> <li>• Manual adopted by Steering Committee;</li> <li>• Positive assessment report;</li> <li>• Satisfactory participation in CEN/CENELEC Technical Committees.</li> </ul>	<ul style="list-style-type: none"> <li>• Project reports;</li> <li>• CEN/CENELEC reports;</li> <li>• CEN/CENELEC Secretariat.</li> </ul>
<p><b>Sub-project 4: Supply of Equipment for Standardisation</b></p> <p>R4.1 State-of-the art information systems and IT equipment supplied and fully operational;</p> <p>R4.2. Adequate media equipment available for Technical Committees and to be used also for training purposes (eg. Training of clients and personnel).</p>	<ul style="list-style-type: none"> <li>• Acceptance reports;</li> <li>• Acceptance reports;</li> </ul>	<ul style="list-style-type: none"> <li>• BIS;</li> <li>• CFCU</li> <li>• BIS;</li> <li>• CFCU</li> </ul>
<p><b>Sub-project 5: Technical Assistance for Metrology</b></p> <p>R5.1. NCM staff successfully trained on requirements for preparation of Terms of Reference (ToR) for construction plan for NCM laboratories</p> <p>R5.2. Assessed construction plan for NCM laboratories against the achievement of the necessary laboratory conditions and its compliance with the ToR;</p> <p>R5.3. Detailed technical specification based on reviewed requirement specification (ANNEX 7) elaborated;</p>	<ul style="list-style-type: none"> <li>• Training records;</li> <li>• Validation report on the construction documentation;</li> <li>• Technical specification documents;</li> </ul>	<ul style="list-style-type: none"> <li>• Training reports and project documentation at beneficiary; CFCU; EC Delegation;</li> <li>• Project documentation at NCM, SASM;</li> <li>• NCM, SASM;</li> <li>• CFCU;</li> <li>• EC Delegation;</li> </ul>
<p>R5.4. EUROMET full membership acceptance criteria met:</p> <ul style="list-style-type: none"> <li>• NCM active participation in EUROMET projects on international comparisons in the fields of electric, physical and mechanical measurements;</li> <li>• Reach equivalence of measurement standards in order to ensure international recognition of measurement and calibration certificates issued by NCM;</li> <li>• NCM quality system in use and assessed by experts from national metrology institutes (NMIs) members of EUROMET.</li> </ul>	<ul style="list-style-type: none"> <li>• Positive assessment report;</li> </ul>	<ul style="list-style-type: none"> <li>• EUROMET report at SASM;</li> </ul>
<p><b>Sub-project 6: Supply of Equipment for National Standard Laboratories</b></p> <p>R6.1. Seven (7) laboratories equipped and operational, traceability of measurement standards established and staff trained on equipment use and operation as well as on software application.</p>	<ul style="list-style-type: none"> <li>• Positive peer assessment or accreditation</li> </ul>	<ul style="list-style-type: none"> <li>• NCM;</li> <li>• EUROMET;</li> <li>• BAS.</li> </ul>

Activities	Means	Assumptions
<p><b>Sub-project 1: Technical Assistance for CABs</b></p> <p>A1.1.1. Development of detailed technical specification of equipment for CABs based on reviewed requirement specification (ANNEX 5);</p> <p>A1.2. Providing a pool of EU experts available on request over a period of one year for consultation on-site on operational and technical issues;</p> <p>A1.5. Training of staff on practical implementation of conformity assessment procedures:</p> <p>A1.5.1. Organisation of 4 sectoral workshops on conformity assessment matters;</p> <p>A1.5.2. On-the-job training on conformity assessment procedures implementation;</p> <p>A1.5.3. On-the-job training on testing methods in the equipped test laboratories.</p>	<ul style="list-style-type: none"> <li>• Consultancy;</li> <li>• Training;</li> <li>• Workshops;</li> <li>• Documentation.</li> </ul>	<ul style="list-style-type: none"> <li>• Users of conformity assessment and standardisation co-operate effectively in the respective project activities;</li> <li>• CABs established and staff successfully trained (Phare 2000 BG0003.02.01);</li> <li>• Organisations identified as beneficiaries recruit and retain adequate staff;</li> <li>• Bulgarian Accreditation Service develops its capacity for MRA signing within EA.</li> </ul>
<p><b>Sub-project 2: Supply of Equipment for CABs</b></p> <p>A2. Procurement of equipment for test laboratories of CABs according to the technical specifications prepared and its consecutive putting into operation.</p>	<ul style="list-style-type: none"> <li>• Tender dossier;</li> <li>• Acceptance procedures.</li> </ul>	
<p><b>Sub-project 3: Technical Assistance for Standardisation</b></p> <p>A3.1. Elaboration of a strategic plan (including operational procedures if necessary) to develop and implement adequate information and customer services;</p> <p>A3.2. Elaboration of detailed technical specification based on the requirement specification (ANNEX 6);</p> <p>A3.3 Development of application for printing/sales/distribution of standards, including Web-application for bibliographical database and Web-application for e-commerce;</p> <p>A3.4. Development of a bibliographical database and a full text database application under suitable dB engine;</p> <p>A3.5. Training of personnel on information, promotion and customer services;</p> <p>A3.6. Elaboration of procedure manual for operation of the information system of the National Standardisation Body;</p> <p>A3.7. Participation of 10 Bulgarian experts in the work of CEN Technical Committees elaborating harmonised standards mandated by EC;</p> <p>A3.8. Evaluation of the compliance with CEN criteria and determination of possible shortcomings.</p>	<ul style="list-style-type: none"> <li>• Consultancy;</li> <li>• Training;</li> <li>• Documentation;</li> <li>• Development guidance documents.</li> <li>• Contribution and attendance to CEN TCs meetings;</li> <li>• Audits.</li> </ul>	






<p><b>Sub-project 4: Supply of Equipment for Standardisation</b></p> <p>A4.1. Procurement of database, equipment for the library/information centre and software as well as its customisation;  A4.2. Procurement of media equipment (ANNEX 6).</p>	<ul style="list-style-type: none"> <li>• Tender dossier;</li> <li>• Acceptance procedures.</li> </ul>	<ul style="list-style-type: none"> <li>• Projected structure fully materialised for all the investment part.</li> </ul>
<p><b>Sub-project 5: Technical Assistance for Metrology</b></p> <p>A5.1. EU experts train NCM staff in drafting the ToR and in assessing the construction plan for a national metrology complex (in particular to evaluate specific environmental conditions like stability, low vibration and minimised magnetic and electromagnetic fields);  A5.2. Assessment of the construction plan for NCM laboratories against the achievement of the necessary laboratory conditions and its compliance with the ToR;  A5.3 Elaboration of detailed technical specification based on reviewed requirement specification (ANNEX 7) and long-term strategy for development of national measurement standards and the infrastructure of calibration laboratories elaborated under Phare BG 0003.02.02 "Technical assistance for metrology";  A5.4. Organisation and participation in seven international comparisons (following EUROMET procedures) for NCM measurement standards in the following areas:</p> <ul style="list-style-type: none"> <li>• electric measurements;</li> <li>• physical measurements;</li> <li>• mechanical measurements.</li> </ul> <p>A5.5 Peer-assessment of NCM quality system by experts from national metrology institutes (NMIs) members of EUROMET.</p>	<ul style="list-style-type: none"> <li>• Training;</li> <li>• Consultancy;</li> <li>• Workshops;</li> <li>• Consultancy;</li> <li>• Design review</li> </ul>	<p><b>Preconditions</b></p> <ul style="list-style-type: none"> <li>• Legislation in place –adopted a Law amending the Law on Technical Requirements to Products and a new Law on Measurements;</li> <li>• Organisations identified as potential Conformity Assessment Bodies maintain their commitment to develop such activities;</li> <li>• Pre-selection of beneficiary CABs made and co-financing ensured;</li> <li>• Financial commitment of non-state beneficiaries on the national co-financing secured;</li> <li>• Standardisation procedures and IT equipment in place in the national standardisation body (Phare BG9602);</li> </ul> <p>The areas for which investments are being made are identified as priorities in the long-term strategy for development of national measurement standards (Phare 2000 BG0003.02.02).</p>
<p><b>Sub-project 6: Supply of Equipment for National Standard Laboratories</b></p> <p>A6.1. Procurement of metrology equipment for seven (7) selected laboratories (ANNEX 7), including calibration traceable to internationally recognised measurement standards, putting into operation and training.</p>	<ul style="list-style-type: none"> <li>• Tender dossier;</li> <li>• Acceptance procedures.</li> </ul>	

# ANNEX 2

## Detailed Implementation Chart for CABs

	2003												2004												2005					
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J
<b>Sub-project 1: Technical Assistance for CABs</b> (Contract 1 - Lot 1. Technical Assistance for CABs)																														
<b>A1.1</b> Development of detailed technical specification of equipment for CABs based on reviewed requirement specification																														
<b>A1.2</b> Providing a pool of EU experts available on request over a period of one year for consultation on-site on operational and technical issues																														
<b>A1.3</b> Training of staff on practical implementation of conformity assessment procedures:																														
<b>A1.3.1</b> Organisation of four sectoral workshops on conformity assessment matters																														
<b>A1.3.2</b> On-the-job training on conformity assessment procedures implementation																														
<b>A1.3.3</b> On-the-job training on testing methods in the equipped test laboratories																														
<b>Sub-project 2: Supply of Equipment for CABs</b> (Contract 2 - supply of equipment)																														
<b>A2</b> Supply of equipment for test laboratories of CABs according to the technical specifications prepared and its consecutive putting into operation																														

-  Tendering, contracting
-  Implementation and disbursement
-  Disbursement and completion

# ANNEX 2

## Detailed Implementation Chart for Standardisation

	2003												2004												2005					
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J
<b>Sub-project 3: Technical Assistance for Standardisation</b> (Contract 1: Lot 2. Technical Assistance for Standardisation)																														
<b>A3.1.</b> Elaboration of a strategic plan (including operational procedures if necessary) to develop and implement adequate information and customer services																														
<b>A3.2.</b> Elaboration of detailed technical specification based on the requirement specification																														
<b>A3.3.</b> Development of application for printing/sales/distribution of standards, including Web-application for bibliographical database and Web-application for e-commerce																														
<b>A3.4.</b> Development of a bibliographical database and a full text database application under suitable dB engine																														
<b>A3.5.</b> Training of personnel on information, promotion and customer services																														
<b>A3.6.</b> Elaboration of a procedure manual for operation of the information system of the National Standardisation Body																														
<b>A3.7.</b> Participation of 10 Bulgarian experts in the work of CEN Technical Committees elaborating harmonised standards mandated by EC																														
<b>A3.8.</b> Evaluation of the compliance with CEN criteria and determination of possible shortcomings																														
<b>Sub-project 4: Supply of Equipment for Standardisation</b> (Contract 3: Supply of Equipment for Standardisation)																														
<b>A4.1.</b> Procurement of database, equipment for the library/information centre and software as well as its customisation																														
<b>A4.2.</b> Procurement of media equipment																														



Tendering, contracting  
Implementation and disbursement  
Disbursement and completion

## Detailed Implementation Chart for Metrology

	2003												2004												2005					
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J
<b>Sub-project 5: Technical Assistance for Metrology</b> (Contract 1: Lot 3. Technical Assistance for Metrology)																														
<b>A5.1</b> EU experts train NCM staff in drafting the ToR and in assessing the construction plan for a national metrology complex (in particular to evaluate specific environmental conditions like stability, low vibration and minimised magnetic and electromagnetic fields)																														
<b>A5.2</b> Assessment of the construction plan for NCM laboratories against the achievement of the necessary laboratory conditions and its compliance with the ToR																														
<b>A5.3</b> Elaboration of detailed technical specification based on reviewed requirement specification (ANNEX 7) and long-term strategy for development of national measurement standards and the infrastructure of calibration laboratories elaborated under Phare BG 0003.02.02 "Technical assistance for metrology"																														
<b>A5.4</b> Organisation and participation in seven international comparisons (following EUROMET procedures) for NCM measurement standards in the following areas: <ul style="list-style-type: none"> <li>• electric measurements,</li> <li>• physical measurements,</li> <li>• mechanical measurements</li> </ul>																														
<b>A5.5</b> Peer-assessment of NCM quality system by experts from national metrology institutes (NMIs) members of EUROMET																														
<b>Sub-project 6: Supply of Equipment for National Standard Laboratories</b> (Contract 4: Supply of Equipment for National Standard Laboratories)																														
<b>A6.1</b> Procurement of metrology equipment for seven (7) selected laboratories (ANNEX 7), including calibration traceable to internationally recognised measurement standards, putting into operation and training																														


Tendering, contracting  
Implementation and disbursement  
Disbursement and completion

and Disbursement Schedule

d Investment Projects for the State Agency for Standardisation and Metrology of Bulgaria								
PLANNED								
uly–Sept.2003	Oct.-Dec.2003	Jan.–March 2004	April-June2004	July–Sept.2004	Oct.-Dec.2004	Jan.–March 2005	April-June 2005	TOTAL €
<b>640000</b>		<b>4260000</b>						<b>4900000</b>
200000								<b>200000</b>
310000								<b>310000</b>
130000								<b>130000</b>
		3060000						<b>3060000</b>
		150000						<b>150000</b>
		1050000						<b>1050000</b>
		<b>384000</b>			<b>3272000</b>		<b>1244000</b>	<b>4900000</b>
		120000			60000		20000	<b>200000</b>
		186000			93000		31000	<b>310000</b>
		78000			39000		13000	<b>130000</b>
					2000000		1060000	<b>3060000</b>
					135000		15000	<b>150000</b>
					945000		105000	<b>1050000</b>

## ANNEX 4

### **List of relevant Laws and Regulations**

- Law on Measurements, adopted 9 April 1998;
- Law on National Standardisation, adopted 4 June 1998;
- Law amending the Law on National Standardisation (State Gazette 13/05.02.2002);
- Law on Technical Requirements to Products, adopted on 1 October 1999; Amendment of the Law on Technical Requirements to Products in process;
- Decree 269/30.12.1999 of the Council of Minister for establishing of State Agency for Standardisation and Metrology;
- Ordinance on the essential requirements and conformity assessment of appliances burning gaseous fuels, transposing Directive 90/396/EEC (State Gazette 75/12.09.2000). The Ordinance entered into force on 13.06.2001;
- Ordinance on the essential requirements and conformity assessment of construction products, transposing Directive 89/106/??? (State Gazette 93/14.11.2000). The Ordinance will enter into force on 14.11.2001;
- Ordinance on the essential requirements and conformity assessment of electrical equipment designed for use within certain voltage limits, transposing Directive 73/23/EEC (State Gazette 62/13.07.2001). The Ordinance will enter into force on 14.01.2003;
- Ordinance on the essential requirements and conformity assessment for electromagnetic compatibility, transposing Directive 89/336/EEC (State Gazette 78/11.09.2001). The Ordinance will enter into force on 12.09.2002;
- Ordinance on the essential requirements and conformity assessment of equipment and protective systems intended for use in potentially explosive atmosphere, transposing Directive 94/9/EC (State Gazette 81/21.09.2001). The Ordinance will enter into force on 01.07.2003;
- Ordinance on the essential requirements and conformity assessment of simple pressure vessels, transposing Directive 87/404/EEC (State Gazette 85/2001) The Ordinance will enter into force on 03.10.2002;
- Ordinance on the essential requirements and conformity assessment of machinery, transposing Directive 98/37/EC(State Gazette 91/2001). The Ordinance entered into force on 27.10.2001. The transitional period expires on 27 April 2003;
- Ordinance on the essential requirements and conformity assessment of toys, transposing Directive 88/378/EEC (State Gazette 62/13.07.2001). The Ordinance will enter into force on 14.07.2002;
- Ordinance on the essential requirements and conformity assessment of lifts, transposing Directive 95/16/EC (State Gazette 94/2001). The Ordinance will enter into force on 03.08.2002;
- Ordinance on the essential requirements and conformity assessment of recreational craft, transposing Directive 94/25/EC (State Gazette 96/09.11.2001). The Ordinance will enter into force on 10.05.2003;
- Ordinance on the essential requirements and conformity assessment of explosives for civil uses, transposing Directive 93/15/EEC (State Gazette 26/12.03.2002). The Ordinance will enter into force on 31.12.2002;

### Requirement Specification of Testing Equipment for CABs

**1. Council Directive of 21 December 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to construction products (amended)**

Equipment shall include the following items (a more detailed list will be provided during the procurement phase):

Apparatus for abrasive testing, atomic absorption spectrometers, testing chamber , concrete mixers, dynamometers, analytical balances, flame photometers, humidity cabinets, infrared spectrometers, furnace, oscilloscope, reflection meter, strength testing equipment, system for modelling of dynamic loadings, transducers, universal mechanical testing machines, vacuum chambers, tanks, balances, shakers.

Total budget approximately EUR 1 300 000

**2. Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of Member States relating to electromagnetic compatibility (amended)**

Equipment shall include the following items (a more detailed list will be provided during the procurement phase):

Automatic antenna towers, GTM cell, oscilloscopes, calibration sets, turntable, equipment for electrostatic voltage checks, broad band antenna burst generators, reference transfer standards, frequency counters, digital multimeters, frequency generators, pulse generators, receivers and frequency analysers,.

Total budget approximately EUR 1 100 000

**3. Council Directive of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (amended)**

Equipment shall include the following items (a more detailed list will be provided during the procurement phase):

Convection cabinet, pulse generators, ionisation meters, pressure test apparatus, laser radiation testing equipment, UV radiation test instruments, conditioning chamber, high voltage power sources, infrared thermometers, tracking tester, test generators, oscilloscopes, winding testers, dynamometers.

Total budget approximately EUR 740 000

**4. Directive of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (amended)**

Equipment shall include the following items ( a more detailed list will be provided during the procurement phase):

Hardness testers, analogue recorders, dimensional control equipment, noise and vibration analysers, noise meters, ultrasonic test equipment, spectrometers, humidity meters, pressure and vacuum meters, X-ray testers, thermometers, dynamometers, environmental test chambers, dust test cabin.

Total budget approximately EUR 650 000

**5. Council directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to appliances burning gaseous fuels (amended)**

Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment

Council Directive of 25 June 1987 on the harmonisation of the laws of Member States relating to simple pressure vessels (amended)

Equipment shall include the following items (a more detailed list will be provided during the procurement phase):

Combustion waste products analyser, gas analysers, visual inspection systems, IT equipment, thermometers, infrared cameras, devices for chemical analysis, ultrasonic flaw detector, metallurgical microscopes, high pressure pumps, gas leakage tester.

Total budget available approximately EUR 200 000

**6. Council Directive of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys (amended)**

Equipment shall include the following items (a more detailed list will be provided during the procurement phase):

Atomic absorption spectrophotometer, testing chamber , dynamometers, humidity cabinets, flammability testing devices, reference materials, shaking machine.

Total budget approximately EUR 90 000

**TOTAL BUDGET: 4.080.000 EUR**



## Requirement Specification for supply of equipment and software for Standardization

No	Designation	Unit	Price per unit, EUR	Price, EUR
1.	Database server – processor 2x Intel Pentium Xeon, RAID-data file, 1x18 GB + 3x18 GB, RAM 1.5 GB, cache – 2 MB, CD-ROM, Back-up device 24 GB, 15” monitor, keyboard, mouse	1	7300	<b>7300</b>
	Firewall	1	1500	<b>1500</b>
2	Work Station – Intel Celeron 1 GHz 20 GB, 256 MB RAM, FDD – 3,5”, network card 10/100 Mb- RJ-45, CD-ROM 17” monitor, keyboard, mouse	Up to 33	1200	<b>39600</b>
3	Copy centers (including network, scanning, printing, copying, stapling, duplex)	2	11000	<b>22000</b>
4	Copy machine –	1	3000	<b>3000</b>
5	Printer – LJ, A4, Black & White, 600x600 dpi, speed 24 ppm, network ready	2	1700	<b>3400</b>
6	UPS – 3 kWA, 120 min – load; Input Volt 187-285 VAC 1 phase, Output – 220 VAC 1 phase	5	1000	<b>5000</b>
8	Multimedia system – resolution 800x1200 ANSI lumen	1	4500	<b>4500</b>
9	Screen – 180?180 cm	1	225	<b>225</b>
10	White magnetic board – 120x180 cm	1	225	<b>225</b>
12	Metal case for storage of magnetic computer data medium – fire-resistant, 60x45x40	1	680	<b>680</b>
	<i>Shelves for archive</i>	--	--	<b>10000</b>
	Notebook – Modem, Windows	1	1500	<b>1500</b>
	Network connection (upgrading)	0	2500	<b>2500</b>
	<b>Sub-TOTAL</b>			<b>101.430</b>

## Software

N?	Designation	Unit	Price per unit, EUR	Price, EUR
1.	Upgrade of programs for applications processing and control MS WinNT Cal 4.0 - 31 licences; MS WinNT Srv 4.0 - 5 licence, SCL Srv. 6.5 - 10 licences, Exchange Srv. 5.5 - 4 licence, Exchange CAL 5.5 - 31 licences; Proxy Srv 2.0 - 3 licences, Windows 98, Office 97	--	-	<b>798</b>
2.	Upgrade for database (SCL Srv. 6.5 up to MS SQL 2000 Server)	--	--	<b>300</b>
3.	Cyrillic Program	6	28	<b>16</b>
4.	Licenses for workplaces for office packages Comment: needs to be the same number as the workstations (see hardware)	33	500	<b>1650</b>
5.	Scanning program in DJVU format	1	2200	<b>220</b>
6.	Software for establishment of information system (i.e. documents management center for standards)	1	45000	<b>4800</b>
7.	Web Application	1	6700	<b>670</b>
8.	Customer Service / HelpDesk Application (CRM)	1	10000	<b>1000</b>
9.	Training			<b>400</b>
	<b>Sub TOTAL</b>			<b>9854</b>
	<b>TOTAL (equipment+ software)</b>			<b>199.78</b>

## ***Requirement Specification for supply of metrology equipment***

### **ELECTRICAL MEASUREMENTS**

The requested equipment will provide the traceability of measurement results in testing of electrotechnical products in order to prove their compliance with the essential requirements of 73/23/EEC Directive on Low Voltage Equipment and harmonised standards.

The Directorate General “National Center of Metrology” will provide the traceability of electric quantities in the country by calibration of measurement standards of laboratories of the state body for legal metrology and accredited laboratories by means of which the quality of produced electric energy and electrical appliances is directly ensured.

No	Designation	Unit	Price per unit, EUR	Price, EUR
	Electric Energy Measurements Laboratory			
1.	National (secondary level) standard for current and voltage ratios at industrial frequency Automatic current and voltage transformer test set Current power supply High voltage supply Standard current comparator Electronic high precision standard voltage divider Programmable electronic standard burden for current transformers Programmable electronic standard burden for voltage transformers Measurement software for current and voltage transformers PC Calibration certificate from NMI Training course	1		418 050
			44 130	44 130
			65 280	65 280
			95 200	95 200
			48 960	48 960
			65 960	65 960
			33000	33 000
			37 270	37 270
			20 000	20 000
			750	750
			2 500	2 500
			5 000	5 000
	Electromagnetic Measurements Laboratory			
1.	Secondary level voltage standard – Reference DC voltage divider		60 000	60 000
2.	Secondary level AC/DC voltage transfer standard		40 000	40 000
3.	National (secondary) level AC current standard – Thermoelectrical converters with current shunts		20 000	20 000
	TOTAL:			538 050
Note: All positions include calibration certificates and training				

## ACOUSTIC MEASUREMENTS

The requested equipment is intended for implementation of 89/392/EEC Directive on Safety of Machinery, 93/42/EEC Directive on Medical devices and 2000/14/?? Directive on Noise emissions from installations working outdoor as well as for achieving mutual recognition of results of measurements and tests of mechanical materials and products, and medical devices and accessories.

No	Designation	Unit	Price per unit, EUR	Price, EUR
I.	Secondary measurement standard for sound pressure in air	1		
I.1.	Multifunctional computer system - Microphone Version – portable with software for signal processing and metrology calibration	1		
I.2.	Reference standard microphones with calibration certificates and apparatus Microphone (EN61094-1) Microphone (EN61094-1) Standard microphones with automatic recognition (TEDS) Microphone Calibration apparatus (EN61094-1;2)	 1 1 2 2 1		
I.3.	Multifunctional acoustic calibrator (according EN 60942)	1		
I.4.	Audiometric Set Artificial Mastoid (EN 60373) Artificial Ear (EN 60126) Measuring Amplifier Microphones Calibration certificate Special measurement	 1 1 1 2 2 2		
I.5.	Necessary accessories Two-channel power supply unit for microphones Microphone preamplifier Microphone cables Adaptors	 1 4 4 2		
	TOTAL:			96 000
Note: All positions include calibration certificates and training				

## OPTICAL MEASUREMENTS

The requested equipment is intended for implementation of 93/42/EEC Directive on Medical Devices and for achieving mutual recognition of results of measurements and tests of medical devices and accessories. Traceability of measurement standards linked to the measurements for assessment of products of textile industry, chemical industry, food, wine and tobacco industries, pharmaceuticals industry and ecology will be provided.

No	Designation	Unit	Price per unit, EUR	Price, EUR
1.	Secondary standard for Transmittance, regular, spectral – UV-VIS-NIR Spectrophotometer		125 000	125 000
2.	Secondary standard for polarimetry – Polarimeter		25 000	25 000
3.	Secondary standard for radiance factor and color coordinates - Reference Spectrophotometer (Color Eye)		12 000	12 000
	<b>TOTAL:</b>			<b>162 000</b>
<b>Note:</b> All positions include calibration certificates and training				

## HARDNESS MEASUREMENTS

The requested equipment is intended for implementation of 89/392/EEC Directive on Safety of Machinery and 90/384/EEC Directive on Non-automatic weighing instruments as well as for achieving mutual recognition of the results of measurements and tests of mechanical materials and products.

No	Designation	Unit	Price per unit, EUR	Price, EUR
1.	Hardness standardized blocks (Super Rockwell)	3	770	770
2.	Hardness standardized blocks: HBS – 2,5/187,5 HBS – 10/3000(1000) Bal indenter HBW, 2,5 5 ? 10 mm	3	2 600	2 600
3.	Hardness standardized blocks : HR	3	770	770
4.	Hardness standardized blocks : HV	3	770	770
5.	Hardness Standard Machine Super Rockwell N and ? with three sets hardness standardized blocks	1	25 650	25 650
6.	Digital Precision Measuring Amplifier DMP 40	1	12 900	12 900
7.	Calibration System 3 in 1 (Type 2) with force transducers and torque transducers	1	208 140	208 140
8.	Software for measurement industry professionalse	1	5 130	5 130
9.	PC	1	750	750
	<b>TOTAL:</b>			<b>257 480</b>
<b>Note:</b> All positions include calibration certificates and training				

## IONIZING RADIATION

The measurements of quantities in the scope of ionizing radiation measurements are related to the following European directives:

Directive 92/29/Euroatom of 03.02.92 Standard document for monitoring of radioactive waste shipments

Council Directive 97/43/Euroatom of 30 June 1997 on health protection of individuals against ionizing radiation in relation to medical exposure and repealing Directive 84/466/Euroatom

Council Directive 96/29/Euroatom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and general public against the dangers arising from ionizing radiation

Council Regulation (EEC) No 737/90 on the conditions governing imports of agricultural products in third countries following the accident at the Chernobyl nuclear power stations.

No	Designation	Unit	Price per unit, EUR	Price, EUR
	<b>Photon Dosimetry Laboratory</b>			<b>213 000</b>
1.	<i>Reference gamma calibration bench (irradiator), full system control, for photon dosimetry with:</i>	<b>1</b>	200 000	200 000
	<i>reference line</i>	1	166 000	166 000
		3	2 000	6 000
	<i>set of cavity ionization chambers;</i>	3	1 000	3 000
	<i>measuring devices for ionization chambers current and voltage;</i>	3	5 000	15 000
	<i>reference radioactive sources;</i>	1	10 000	10 000
	<i>PC, specialized software for data acquisition and data processing</i>			
2.	Reference dosimeter with set of 3 ionization chambers	1	10 000	10 000
3.	Phantom for the calibration of personal dosimeters	1	3 000	3 000

	Radioactivity Measurements Laboratory	133 470		
1.	Reference radioactive sources for the calibration of surface contamination monitors – alpha emitters, Class 1 (ISO 8769)	10	700	7 000
2.	Reference radioactive sources for the calibration of surface contamination monitors – alpha emitters Class 2 (ISO 8769)	10	500	5 000
3.	Reference radioactive sources for the calibration of surface contamination monitors – beta emitters Class 1 (ISO 8769)	15	550	8 250
4.	Reference radioactive sources for the calibration of surface contamination monitors – beta emitters Class 2 (ISO 8769)	15	300	4 500
5.	Reference radioactive sources for gamma –spectrometry, type “Marinelli”	9	630	5 670
6.	Reference point radioactive sources for gamma-spectrometry	9	450	4 050
7.	Measuring system with gas-flow proportional detectors for alpha-emitters activity with computer, specialized software for data acquisition and data processing, full system control	1	12 000	12 000
8.	Measuring system with gas-flow proportional detectors for beta-emitters activity with computer , specialized software for data acquisition and data processing , full system control	1	12 000	12 000
9.	Reference combined monitor with alpha-, beta-, gamma-detectors	1	15 000	15 000
10.	Measuring system for radon activity with reference radioactive source , computer, specialized software for data acquisition and data processing, full system control	1	36 000	36 000
11.	Coincidence measuring system for the radionuclides decays in (α,β)-γ coincidence, computer, specialized software for data acquisition and data processing, full system control	1	24 000	24 000
	TOTAL:			346 470
Note: All positions include calibration certificates and training				

# OVERVIEW OF ECONOMIC CONDITIONS, LEGAL FRAMEWORK AND PERSPECTIVES IN THE FIELD OF STANDARDISATION, CONFORMITY ASSESSMENT AND METROLOGY

## EXECUTIVE SUMMARY

It is critical that resources allocated within the project focus on New Approach **sectors**, which represent a strategic industrial priority at national level.

An analysis of several macroeconomic variables (eg. trade flows, foreign direct investment, internal production) and an overview of the legal framework (legislation, market surveillance infrastructure) highlighted the following sector repartition:

- Group 1 - It consists of sectors with a developed industry active both in the Bulgarian market and in export to the EU (LVD, EMC, CPD, Machinery). Laboratories require assistance in terms of know how and equipment. In this case priority is given both by pressures from industry and market surveillance purposes.
- Group 2- Sectors where industry is not well developed, laboratories need assistance, however major driver is market surveillance activities (SPV; Gas Appliances, Toys).

In the field of **Standardisation** main challenges lie in achieving CEN/CENELEC full membership on one side, but also on the capacity to ensure participation of Bulgarian industry in standardisation activities.

Major efforts in CEN/CENELEC are related to the capacity to develop appropriate information services (IT and customer service), which will fasten their progress towards membership.

In the field of **Conformity Assessment** support is intended to reinforce the capacity of the bodies to meet industry requirements. For this reason it is recommended that laboratories will submit a detailed business plan. Only CABs complying to the evaluation criteria (to be defined during the feasibility study) and sector priority will be considered eligible for the investment.

In the area of **Metrology** the equipment needed and the TA reflects their need to become full EUROMET members. The assessment to be accomplished within the PHARE 2000 project on metrology will provide the strategic framework to plan the level of accuracy required to satisfy Bulgaria industrial needs.

## 1. MACROECONOMIC FACTORS

### 1.1 Trade comparative advantages

According to a recent paper on the impact on technical barriers to trade (CEPs/EU Commission, 2000), trade in industrial products between the EU and the CEECs (Central and Eastern European Countries) is now essentially free of tariff and non-tariff restrictions, the principal impact of accession to the EU on trade flows will be through access to the Single Market of the EU. A key element of this will be the removal of technical barriers to trade.



With regard to new approach sectors the picture varies across the CEECs. Most of the CEECs reveal a comparative advantage<sup>1</sup> in a limited number of new approach sectors but usually to a greater extent than in old approach sectors.

Bulgaria in particular show a comparative advantage in the following sectors covered by New Approach directives:

- Construction products directive-
  - Clay products for construction purposes, Cement, lime plaster), Semi finished wood products, Iron and Steel Industry, construction users/others
- Machinery directive
  - Machine tools for metal processing, Machines for iron and steel industry

**Table. Distribution of Sectoral Revealed Comparative Advantages by Approach to TBT (1998)**

	Products code	Ratio
Iron & steel industry (ECSC) construction uses/others	221 ND	7.210497
Clay prod. for construction purposes	241 ND	9.441408
Cement, lime, plaster	242 ND	8.86285
Boilers, reservoirs, tanks	315 ND	0.784964
machine tools working metal	322 ND	1.721731
Machines for iron & steel industry	325 ND	1.301781
Manuf; of electrical machinery	342 ND	0.578417
Manuf. of telecom equipment	344 ND	0.130049
Domestic type elect. Appl.	346 ND	0.37532
Manuf. Electrical lamps and others	347 ND	0.695364
Medical & surgical equipment	372 ND	0.028828
Toys and sports goods	494 ND	0.396639

Source CEPS (2000)

## 1.2 Internal Production

An analysis of the economic activities in Bulgaria shows the following repartition of the domestic production in the NA priority sectors.

**Table. Annual data of enterprises ('000 BNL at current prices)**

	NACE	Production	% over total production
<b>INDUSTRY - TOTAL</b>		<b>19702819</b>	<b>100%</b>
Manufacturing Of Machinery, Equipment And Household Appliances, Excluding Those Included In Other Branches	34	1062338	5.39%
Production Of Products From Non-Metal Mineral Raw Materials *	29	676492	3.43%
Manufacturing Of Electrical Machines And Apparatuses	36	399835	2.03%
Manufacturing Of Medical Equipment, Precision Devices And Instruments	38	74303	0.38%
Manufacturing Of Games And Toys	415	5898	0.03%

\*Includes construction products

Source: extract from the national classification of economic activities (NACE)- National Institute for statistics

<sup>1</sup> The comparative advantage is calculated with an index which take into account in the numerator the share of a particular sector in the country's exports to the EU, whilst the denominator shows the share on this product in total EU imports. A value of the index in excess of one is taken to reveal a comparative advantage in the production and export of that sector.

### 1.3 FDI –Foreign direct investment

An overview on the foreign direct investment in the sectors covered by the New Approach directives shows that both the construction sector, the electro-technical sector and to a minor extent also the gas appliances sector will be positively interested.

Public works types of investment are planned to take place in the next few years (eg.a new bridge over the Danube, the installation of a Gas Pipeline to transport gas from Russia). This shall stimulate the internal demand in the construction product and indirectly also the machinery sector where domestic industry is well developed. More difficult to estimate what will be the impact for the Gas appliance sector, where domestic industry is not yet organized. Apart few domestic companies the market is mainly served by foreign import.

Private investments are present and more are planned to take place in the electro-technical field. Several foreign companies are already present in the country (eg. SIEMES, ABB). Some green-field investments are also planned (eg. Hyundai Heavy Industries with a power transformation plant).

The table below indicates the amount of FDI in the selected NA sector. The data shows a positive growing trend since 1998.

**Table. FDI by Sector by years in USD (millions)**

Sector	1998	1999	2000
Mechanical Products	21.3	18.0	64.7
Electronics, computers and communication equipment	11.5	5.9	28.6
Construction	6.3	6.5	12.7
Electricity, Gas and Water	0.0	0.0	18.7

Source: Agency of Foreign Investment

### 1.4 Reference Sources:

- Interview with Ms Silvana Lubenova Ministry of Economy EU Integration Directorate
- [www.bfia.org](http://www.bfia.org) - Agency for foreign investments — information available in English and German
- [www.nsi.bg](http://www.nsi.bg) - National Institute for Statistics –information(National Classification of Economic Activities for 2001)
- CEPS/EU Commission (2000), Technical Barriers to Trade in the European Union: data, trends and implications for Accession Countries”, Paul Brenton, John Sheely and Marc Vancauteran.

## 2. LEGAL FRAMEWORK

Most of the ordinances are in course of transposition in the national legislation, by 2004 all most relevant NA directives will enter into force. Moreover PECA protocols will cover the following sectors:

Electrical safety	X
EMC	X
ATEX	X
Machinery	X
Lifts	X
PPE	X
R&TTE	
Gas Appliances	X
Simple Pressure Vessel	X
Pressure Equipment	
Medical devices	X
GMP for medicinal products	X
GLP for medicinal products	X
GLP for chemicals	
Cosmetics	
Construction products	
Hot water boilers	X
Refrigerators and freezers	
Explosives for civil use	
Measuring instruments	
Non automatic weighing instruments	
Prepackaging	
Toys	
Recreational craft	
Marine equipment	

It is recommended that the principle of separation of powers shall be put fully operational at the moment of implementation of the project. Ideally public authorities should retain solely legislation and enforcement (market surveillance) functions and ensure that the system of third party certification to regulatory requirements has sufficient technical competence and independence (accreditation).

Moreover, cooperation with other countries and/or Member States should be considered as a valid alternative in those areas where internal demand for testing and certification does not reach the necessary capacity. For this reason, any possible legal constraint shall be removed to ensure a better functioning of the system. Moreover, technical cooperation in the quality infrastructure areas is strongly encouraged by the European Commission. A PHARE networking project "Internal Market Quality Infrastructure" to encourage cooperation among candidate countries will soon be implemented for all candidate countries.

### 2.1 Market surveillance infrastructure

An important PHARE project is in course of implementation for the development of the market surveillance infrastructure in the country. The project aims to increase knowledge and awareness at the level of authorities, government services and economic operators. As for today, sectors with a higher propensity of readiness are gas appliances, construction products

and toys. EMC, LVD and Machinery sectors will follow. Expertise is generally available, however laboratories are not always equipped.

The current legal framework and the necessary development of the market surveillance infrastructure confirm the need to equip the laboratories in the priority-selected areas.

## **2.2 Reference Sources**

- Interview with the Pre-Accession Adviser for the Market Surveillance PHARE 2000 project
- Interview with European Commission (DG Enterprise, DG Enlargement, EU Delegation in Bulgaria)

## **3. STANDARDIZATION**

### **3.1. Background**

The Law on National Standardization was adopted by the Parliament of the Republic of Bulgaria on 4 June 1999 and entered into force on 18 September 1999. According to this law SASM, as a national standards body, is the only institution that has the exclusive right to distribute standards on the territory of the country. SASM performs this activity following the rules and practice acknowledged by the international and European standards organizations of which it is a member.

This Law established a legal basis for the transition from mandatory standardisation to voluntary standards. Since 17 September 2000 the use of standards in Bulgaria is voluntary. The Law regulates the main rules for the development of national standards by applying the principles of openness, transparency, consensus by all the interested parties and voluntary status.

The activities of SASM in the field of standardization are stipulated in the law: it draws up a standardization programme in accordance with the priorities for development of the national economy; issues and distributes Bulgarian standards and draft Bulgarian standards; issues an annual catalogue of Bulgarian standards; keeps a register of the technical committees; issues an official bulletin and organizes training of specialists in standardization.

SASM represents the Republic of Bulgaria in the European and international organizations for standardization. The Republic of Bulgarian is a full member of the international organizations for standardization ISO and IEC. SASM is an affiliate member to the European organizations CEN/CENELEC. Aiming at full membership in CEN and CENELEC, which is planned to be achieved by the year 2004, the standardization body should give evidence of possession of required means, competence and expertise.

In order to comply with the requirements of the European Commission for segregation of standardization, certification and market surveillance functions, a Law amending the Law on National Standardization was adopted by the Parliament at the end of January 2002, which will enter into force from 6<sup>th</sup> of April 2002. According to the provisions of this Law, the functions currently performed by the Standardization Directorate are envisaged to be transferred to Bulgarian Institute for Standardization (BIS). BIS will be established as a national standardization body with the status of independent legal entity at the Council of Ministers.

### **3.2 CEN CENELEC membership conditions and strategic development of the standardization body.**

The main challenges for the development of Standardization in Bulgaria, in the European scene, are two fold:

- Fulfillment of full membership requirements of CEN/CENELEC
- Commitment of the Bulgarian industry and CABs to the European Standardization approach

On one hand, some membership requirements have already been met (eg. conditions 1 to 4, and partially condition 8 and 9) but others still need further efforts, namely:

- participation in CEN/CENELEC work (condition 5)
- operational telecom and IT infrastructure (condition 6)
- the implementation of harmonized standards (condition 7)- in this respect 40 % of CEN standards and 30 % of CENELEC are being transposed.

On the other hand, it is critical to ensure that Bulgarian industry and CABs are:

- involved in the national/European/international Technical Committees
- understand the benefits and use of 'voluntary' European harmonized standards (standards have been mandatory for many years in Bulgaria)

Therefore the strategy objectives for the coming years (which implementation is to be supported by the current project) are the following:

- support the timely adoption of European standards, on a reliable and future-prove fashion, through the provision to the Standardization Directorate of relevant software applications and IT equipment
- promote the use and benefits of standards and gain the commitment of all stakeholders in the standards building process, by providing the standardization staff with the required skills (e.g. promotions, training, customer service, communication, team and consensus building), support applications and training materials and equipment.

Even though progress was made since last PRAQIII assessment reports. Some of the concerns were already identified back in 1999 (“...The low rate of adoption of EN indicates what is still left to be done...In order to raise the motivation of the experts in the country to join the national standardisation work and further on international and European work, more awareness seminars should be made in the country.”)

An additional concern is that the financial sustainability of the organization. So far, the body is financed for 80 % from the state budget. The revenue generated from the sale of standards is not enough to sustain the organization (at present time the sale of standards covers less than 10 % of total revenues). The development of training activities appears to be in line with the development of the organization from a state agency to an independent body.

The potential clients can be identified as:

- manufacturers;
- conformity assessment bodies;
- accreditation bodies;

- laboratories in a process of accreditation;
- government bodies/public authorities;
- certification bodies.

The training will be directed towards the above-mentioned potential clients with the objective of increasing their number. In the initial phase, after the project starts we envisage to conduct one seminar per month - with approximate number of participants 10 persons. This means 12 trainings per year with 120 participants.

#### CEN CENELEC conditions

1. Europe Agreement signed
2. Approximation of the national system with that of the EU:
  - *The specific legislative framework for voluntary standardization is in place and fully operational*
  - *technical pre-existing legislation which would permit the adoption (or keeping in place) of technical rules which would contradict the European standards, are removed as far as possible, or modified in such a way as to allow ENs to play the same role in the market as they play in the Internal Market.*
  - *there is full application of at least part of the Directive 83/189 concerning standardization activities*
3. the NSB is recognized as official standards body in his own country,
4. the NSB can cover national membership fees,
5. the NSB is able to deal efficiently with the work of CEN and CENELEC. In particular the NSB is able to convey a national point of view on technical matters as well as on formal issues (vote, enquiry,...).
6. the NBS are in possession of operational telecommunications and IT infrastructure,
7. 80 % of ENs are implemented as national standards
8. participation in the notification procedure of their national work,
9. evidence on copyright and exploitation rights given in documents.

Ref CEN/CENELEC membership conditions

### 3.3 Equipment

⇒ R4.1 State-of-the art information systems and IT equipment supplied and fully operational;

It is crucial for the beneficiary to set up enter in possession of operational telecommunications and IT infrastructure allowing it to respond efficiently within the CEN/CENELEC system.

Moreover, the future development of the standardization body will depend on its ability to involve industry and other potential users/customers of standards. It is therefore strategic for the standardization body to further develop its information services. The investment should therefore focus on the development of the necessary infrastructure to run a modern and efficient information system.

Procurement of computers is required in the following departments/sections of the standardization body:

- Electrical engineering standards department and Standards in Industry department (at present 16 PCs available - need to add 14 additional PCs). The 14 additional PCs required will serve to ensure the proper development of TCs activities.
- Standards library section, information service section (at present 4 PCs available; there is a need to add 5 additional PCs). The additional PCs will serve to ensure access to

standardization information to customers and to support the activities of the information services department.

- New directorate of International cooperation, new department of European standardization and new section “Data bases”. These departments/sections are not yet established, but they will enter into operation in the next few months (following the approval of the new Statutes of BIS by the government). Total requirements for the new departments are a total of 14 new PCs. The purchase of the PCs shall be put under conditionality that the departments/section come into existence before the beginning of the project.

#### **Bulgarian standardization institute perspectives**

In 2003 when the project will be launched the Law Amending the Law on National Standardisation will be already into force, and according to it, the present Standardisation Directorate within SASM will be established as Bulgarian Institute for Standardisation at the Council of Ministers. The number of personnel of the Bulgarian Institute for Standardisation is planned to be 80 servants (i.e. 16 more servants). Some additional functions will be assigned to the Bulgarian Institute for Standardisation:

- to issue an Official Bulletin;
- to carry out international and European integration activities;
- to arrange the meetings of the National consultative council for standardization

The structure of the Bulgarian Institute for Standardization will be modified - a new Directorate with administrative functions will be established. During the project implementation some changes in the structure and work organization are possible. The head office of the Bulgarian Institute for Standardization may be moved into a new building

Ref Interviews with Management staff of standardization department

For additional information about the existing equipment and functional destination of the PCs, please refer to the document “Functional information for standardization”, available from the Standardization Directorate of SASM

⇒ R4.2. Adequate media equipment available for Technical Committees and to be also used for training purposes (eg. training of clients and personnel).

Media equipment is also included in the investment list. This reflects the need to ensure a more efficient working environment for the TCs and training activities.

### **3.4 Sources used**

- Interviews with SASM-EU integration department

Ms Olga Manofova, Director

Ms Violina Panayotova,

Ms Ralitsa Assenova,

- Interviews with SASM Standardisation Directorate

Ms Zdravka Valeva, Director Standardisation Directorate

Ms Kristina Kantcheva, Chief of library section

Mr Ilcho Harizanov, expert Information services and technologies

- SASM-Internal document “CEN/CENELEC membership conditions”, CEN General Assembly, Bratislava 4 May 2001.
- SASM-Internal document “Functional information for standardization”
- SASM Internal document “Information system-functional characteristics”
- PRAQIII assessment reports

## **4. CONFORMITY ASSESSMENT**

### **4.1. Background**

Regarding the transposition of EU legislation it can be said that Bulgaria has made quite a good progress - a legislative base is already in place (10 New Approach directives transposed by the end of 2001, the remaining directives are to be implemented in the course of 2002). Despite this fact, it still needs to create an effective network of independent certifying bodies and laboratories. The need to establish and strengthen an effective system of conformity assessment bodies, and in particular certification bodies which supply services under the conformity assessment procedures of the Global Approach, was, on the one hand, pointed out from the European Commission and, on the other hand, realized and accepted by the government as well as the industry represented by the branch chambers.

As a result of this, three project proposals for financing under the Phare Programme 2002 for supporting the establishment of conformity assessment bodies were submitted to the Ministry of Economy - one from the State Agency for Standardisation and Metrology, and the other two from the Branch Chamber of Electrical Engineering and the Bulgarian Branch Chamber for Machine Building. Taking account of the fact that machine building and electrical engineering represent two of the priority sectors of Bulgarian industry, the Ministry of Economy decided that it would be relevant they to be included within the framework of the SASM project "Strengthening of the national conformity assessment system", which aims at strengthening of the conformity assessment bodies with activities in the priority industrial sectors covered by the NA Directives: LVD, Machinery, EMC, CPD, Pressure equipment, SPV, Gas appliances and Toys.

### **4.2. Conformity Assessment infrastructure**

Priority New Approach sectors were identified by SASM and the Ministry of Economy. In particular the following sectors were identified: Low Voltage Directive, Machinery, Electromagnetic Compatibility, Construction Products, Pressure Equipment, Simple Pressure Vessels, Gas Appliances and Toys.

Interviews with CABs highlighted the following sector priorities:

Group 1- Sector with a developed industry active both on the Bulgarian market and in export to the EU (LVD, EMC, CPD, Machinery)

Group 2- Sectors where industry is not developed but laboratories shall be set up to serve mainly for market surveillance purposes (SPV; Gas appliances, Pressure equipment, Toys)

#### Group 1

*-Electrotechnical field-* in this area industry is well developed and production is important both for the Bulgarian market and for export. The presence of foreign direct investment drives the



demand for the development of the sector and therefore also the demand for testing and certification.

Representatives from industry push for the concentration activities in one big centre for testing which could become a reference lab for the Balkan region. On the other hand there is also the propensity to think that small and flexible laboratories would be needed to serve the need of regions, especially in the low voltage field.

Market surveillance infrastructure will soon be ready to enforce post market control. Expertise is available but laboratories, except few fortunate cases, are not well equipped.

*Construction products* - in this area the large amount of public works planned in the near future push laboratories to invest in new equipment. Moreover, Bulgaria is located in an area frequently hit by earthquakes, which imposes strict control on the materials.

Even if the CPD directive doesn't fall under the PECA protocol, Bulgarian construction industry is well developed. Construction products serve the Bulgarian market and are also exported into the Union.

*Machinery* - there is long tradition of activities in these areas. Today producers in the machinery sectors are exporting about 50% of their products to the EU.

In the past this industry played an important central role among socialist countries (eg forklifts). Manufacturers are, however, still not fully aware of the new rules. Machines are often not in compliance with EU technical regulations.

## Group 2

*Toys* - toys manufacturers are based mainly outside the country. Bulgarian industry is not active in this specific sector. Demand for conformity assessment services will mainly come from companies outside Bulgarian willing to place toys on the market and from market surveillance authorities for post market control.

*Gas Appliances, Pressure equipment, Simple Pressure Vessels* - also in this sector, like in the case of toys, industry is not organized. Few companies operate in the field of Gas appliances, most of the products are imported from abroad. Again demand for testing is driven mainly from foreign companies importing products in Bulgaria and by market surveillance authorities.

## **4.3. Equipment**

R2. The necessary equipment for testing laboratories, covering the conformity assessment procedures, supplied and operational.

In order to identify the potential beneficiaries of the project - CABs, the State Agency for Standardisation and Metrology prepared and distributed a questionnaire which allows assessment to be made of their capacity for carrying out conformity assessment of products covered by the NA directives, as well as of their needs for supply of equipment which on the other hand, will enable consistent performance of conformity assessment procedures. This questionnaire was distributed to the following institutions: Bulgarian Accreditation Service, Bulgarian Branch Chamber for Machine Building and Bulgarian Branch Chamber for Electrical Engineering, Ministry of Regional Development and Public Works as well as to

CABs that participated in trainings under previous programmes (for instance, PRAQ ???, Phare BG 9602).

As a result of questionnaires distributed by SASM and the above-mentioned institutions, 34 questionnaires filled in by CABs and testing laboratories (some of them with more than 30 years experience) were received in the agency.

After an initial analysis of the questionnaires thus received, it was established that a large part of the CABs work in the scope of several directives and they even intend to extend their activities also for other directives, including such which have not been transposed into the Bulgarian legislation yet, or such that do not relate to the specified priority areas.

The pre-selection of CABs was carried out by SASM in cooperation with the Ministry of Regional Development and Public Works (for the scope of CPD) and was made in a way that ensures that the priority sectors of Bulgarian industry are adequately covered. Finally, 23 CABs and testing laboratories were selected - especially bodies which main activities and long experience relates particularly to these sectors. There are several CABs in the field of LVD, CPD and Machinery Directive, which cover different product groups and do not overlap their scopes.

In the process of preparation of the required equipment specifications the potential beneficiaries were requested to indicate conformity assessment modules covered and the harmonised standards against which they carry out tests using the equipment. Finally, the equipment specifications included in the project fiche (Annex 5) were elaborated in such a way that ensures the ability of CABs to cover entirely the conformity assessment procedures under NA directives in priority industrial sectors, which themselves are also included in PECA negotiations.

Final selection of the conformity assessment bodies, precise evaluation of their needs and the relevance of required equipment should be performed during a feasibility study. The introduction of a transparent and clear procedure of allocation of equipment is necessary in order to ensure an efficient use of the funds. Beneficiaries will have to present a detailed business plan and to show concrete means of co-financing. Only the bodies fulfilling these conditions shall be considered eligible for the financing scheme.

Interviews with potential private investors show that private co-financing of the laboratories shall not represent a major hinder. However during the procedural phase problems may arise regarding the date of disbursement of the 25 % co-financing. The feasibility study shall take into account when and how the private co financing shall be released in order to avoid delay in the delivery of the equipment.

Source

#### 4.4. Sector priorities

It is critical that resources allocated within the project focus on New Approach sectors, which represent a strategic industrial priority at national level. An analysis of several variables (eg. trade flows, foreign direct investment, market surveillance infrastructure, legal framework) and interviews with CABs and SASM management team created the basis for a sector prioritisation matrix.

The following table summarizes the sector priorities.

	Trade/ Comp. advantage	PECA	Market surveillance	Law entering into force	Priority
<i>ATEX</i>		X		07/03	
<i>LVD</i>	X	X	X	01/03	Group 1
<i>EMC</i>	X	X	X	09/02	Group 1
<i>Machinery</i>	X	X	X	04/02	Group 1
<i>Lifts</i>		X		08/02	
<i>PPE</i>		X			
<i>R&amp;TTE</i>				Na	
<i>Gas Appliances</i>		X	X	in force	Group 2
<i>Simple Pressure Vessels</i>		X		10/02	Group 2
<i>Pressure Equipment</i>				Na	Group 2
<i>Medical devices</i>		X		Na	
<i>GMP for medicinal products</i>		X		Na	
<i>GLP for medicinal products</i>		X		Na	
<i>GLP for chemicals</i>				Na	
<i>Cosmetics</i>				Na	
<i>Construction products</i>	X		X	in force	Group 1
<i>Hot water boilers</i>		X		Na	
<i>Refrigerators and freezers</i>				Na	
<i>Explosives for civil use</i>				Na	
<i>Measuring instruments</i>				Na	
<i>Non automatic weighing instruments</i>				Na	
<i>Prepackaging</i>				Na	
<i>Toys</i>		-	X	07/02	Group 2
<i>Recreational craft</i>				05/03	
<i>Marine equipment</i>				Na	

## 4.5 Reference Sources

### Meeting and interviews with laboratories representatives:

- Ms Sashka Kozhuharova, Manager test laboratory, EUROTTEST
- Mr Asparuh Milanov, Director on technical problems , ITEM engineering
- Ms Maya Topalova, Director SASM Testing and Certification Directorate
- Ms Rayna Zlatarova, SASM Testing and Certification Directorate
- Mr Lubomir Raykov, CER Operational Manager , Bureau Veritas /Tecnitas
- Mr Vassil Nikolov, Termola Ltd
- Mr Stefan Zaevisky, Kontrol 94
- Mr Rumen Guglev, NISI Sofia
- Ms Zorka Petrokova, CIZGTRC
- Mr Trayanka Lyubenova, Bulgarkontrola

### Interview with Sectoral Chambers of Commerce

- Mr Roumen Atanasov, Chairman of Bulgarian Chamber of Electrical Engineering
- Mr Iliya Keleshev, Chairman of Bulgarian Chamber of Machine building

### Interview with Private companies (potential investors for co-financing)

- Assen Hristov, CEO, Starcom (Construction products sector)
- Mr Miroslav Damianov, Director of Research and Development, REI Holding (electrotechnical sector)

### Meeting with Project team PHARE 2000 Certification/Accreditation

- Mr David Burns, team leader certification

## 5. Metrology

### 5.1. Background

During the last two years a priority in the activities of the National Center of Metrology (NCM) is to strengthen the scientific metrology in Bulgaria in order to reach equivalence of Bulgarian measurement standards as well as international recognition of measurement and calibration certificates issued by NCM.

In connection with this priority the following steps have been made:

- In October 1999 Mutual Recognition Arrangement (MRA) between national metrology institutes of the member-states of the Metre Convention was signed by the NCM director.
- In June 2000 the NCM management took a decision on quality system implementation according to the EUROMET guidelines.
- NCM has applied for EUROMET full membership after a decision of the Bulgarian government. In October 2000 NCM was accepted as a corresponding organisation of EUROMET (applicant-NMI) according to a decision of EUROMET General Assembly (former Executive Committee).
- At the beginning of 2001 tables of NCM on calibration and measurement capabilities were developed and sent to EUROMET Technical Committees.
- An application for participation of NCM laboratories in EUROMET projects for international comparisons according to EUROMET procedure has been submitted. The possibilities for such participation are limited by technical status of the national measurement standards and environmental conditions in the laboratories.
- An analysis of the status of national measurement standards has been undertaken.

As a result the attention was drawn to three weak points, which do not correspond to NCM goal to fulfill the requirements for full membership in EUROMET and of MRA as well as to ensure the necessary traceability in the country. The weak points are as follows:

- Need to build up a new metrology complex for national standard laboratories meeting modern environmental requirements;
- Need to bring up-to-date the national measurement standards and to extend NCM calibration and measurement capabilities in order to ensure traceability of measurements in the field of New Approach directives;
- Need to demonstrate the equivalence of Bulgarian measurement standards and compliance of the metrology practice of national standard laboratories through international comparisons.

## **5.2. Equipment**

⇒ R6.1. Seven (7) laboratories equipped and operational, traceability of measurement standards established and staff trained on equipment use and operation as well as on software application.

Renovation of measurement standards in the field of electrical, acoustic, hardness, optical, photon dosimetry and radioactivity measurements is aimed at ensuring sufficient uncertainties of measurement results and supporting implementation of the following New Approach Directives: 89/392/EEC, 90/384/EEC, 93/42/EEC, 89/392/EEC, 93/42/EEC, 2000/14/??, 73/23/EEC. It should be pointed out that in fact real needs exceed the project proposal.

The new equipment is intended to improve the Bulgarian standard laboratories presentation at an international level throughout EUROMET intercomparisons.

After consultation with EU metrology experts, the equipment is considered to be appropriate for the type of activities NCM should realize. However, the final assessment of the specifications shall be performed after the elaboration of the long term strategy for development of national measurement standards and the infrastructure of calibration laboratories (planned to be realized in the course of 2002 under the Phare 2000-BG 0003.02.02 "Technical Assistance for Metrology") which will provide conditions for accuracy and traceability of measurements.

## **5.3 Reference Sources**

### Interviews

- Mrs. Ani Todorova, Director General of Directorate General "National Center of Metrology"
- SASM International Cooperation and European Integration Directorate
- Interview with EU metrology expert