1. **Basic Information**
   1.1 CRIS Number: 2005/017-464.02.01
   1.2 Title: **Reinforcement of administrative capacity as regards measuring instruments**
   1.3 Sector: Internal Market
   1.4 Location: Slovak Republic

2. **Objectives**
   2.1 Overall Objective(s):

   Enforcement of the legislation in the field of measuring instruments (Old and New Approach as well as the national one). Free movement of goods having measuring function covered by other directives, or regulated in non-harmonized area without distortion caused by changing environment in their usage and operation.

   2.2 Project purpose:

   Implementation of the Directive 2004/22/EC and smooth transferring of the application of the former old approach regulations or the national one to the New Approach

   2.3 Justification

   Based on Comprehensive monitoring report on Slovakia’s preparations for membership (2003):

   „Chapter 1: Free movement of goods
   Slovakia is essentially meeting the requirements for membership as regards the horizontal and procedural measures necessary for the management of Community legislation in the new approach sectors, the new approach sectoral legislation, and in the area of public procurement. Once the remaining aspects of the new approach acquis are put in place, Slovakia should be in a position to implement this acquis from accession.“

   „Slovakia must pay particular attention to completing the screening of its national legislation in the light of the principle of free movement and to ensuring the implementation and enforcement of the principle of mutual recognition.“

3. **Description**

   3.1 Background and justification:

   According to the NPAA from 2000, EU directives in the field of legal metrology have been transposed into Slovak legislation by the Act 142/2000 Coll., on Metrology and its executive decrees. Act No. 142/2000 Coll. on Metrology which entered into force on 1 July 2000 has also incorporated the provisions relating to metrological control in accordance with European Communities requirements.

   Before the Slovak Republic’s accession to the European Union metrological control was carried out only in accordance with national requirements. Implementation of the optional old approach directives, their co-existence with the national law was new element in the Slovak legal system. The necessity of mutual recognition of measuring instrument being put on the Community market according the Member States national regulations co-existing with old approach optional directives is very demanding for the enforcement authority. Most of the meters being used in the delivery of water and energy (utility services) are to be covered by the Directive 2004/22/EC (MID), which means new legal changes and the transfer from old to new approach. The significance of the proper enforcement is even growing bearing in mind that the market in goods delivered via utility services is subject of on-
going privatization. The former state responsibility for proper amount and quality delivery of water, gas and electricity is transferred to the private owner. The level of consumer and health protection should be kept, but the knowledge of the enforcement of newly valid and co-existing provision is not sufficient enough to ensure it.

Optional old approach directives relating to individual types of legally controlled measuring instruments have been adopted as a whole, but in some cases national legislation (national requirements) exists in parallel, while the free movement of measuring instruments corresponding with EC directives is ensured. 18 directives concerning technical and metrological requirements and testing methods for individual types of legally controlled measuring instruments have been implemented in the form of executive decrees to the Act as well as the directive 80/181/EEC on units of measurement. Directive 71/316/EEC on measuring instruments and methods of metrological control has been transposed into provisions of the Act and the horizontal decree on measuring instruments and metrological control.

Eleven of the above mentioned directives are to be repealed by the Directive 2004/22/EC of the European Parliament and of the Council on measuring instruments, which will be applicable as from 30 October 2006. The measuring instruments that have been put on the market according to the previous legislation (either the old approach or the national one) shall be also further permitted for measurement tasks in operations for which legally controlled instruments are prescribed to be used. The placing on the market and putting into use of those measuring instruments, which satisfy the rules applicable before 30 October 2006 is to be allowed until the validity of their type approval expires and for those having undefined validity of type approval is to be allowed for a period of maximum 10 years. This means that on the market and in use there will be simultaneously 3 different kinds of measuring instruments used for the same or similar measurement tasks being prescribed by the wide scope of legislation:

1) Measuring instruments placed on the market and put into use according to the Directive 2004/22/EC
2) Measuring instruments placed on the market and put into use according to the whole set of old approach Directives
3) Measuring instruments placed on the market and put into use according to national legislation. Such instruments, coming from other Member States or EEA Countries, and being offered for performing of measurement tasks, which are prescribed by Slovak legislation in the field of public health, safety and order, protection of the environment and consumer, levying taxes and duties and of fair trading, have to be allowed for use without unnecessary burden via relying on the mutual recognition clause. At the same time, different surveillance authorities acting in the above mentioned fields have to check the appropriate level of public interest protection.

The proper implementation of the Directive 2004/22/EC goes beyond its transposition and proper functioning of notified bodies. Even more necessary is the awareness of the changes from the side of the manufactures of measuring instruments as well as utility service providers and those being responsible for the public procurement linked to these services. Networking of the enforcement administration including those who perform the surveillance under the existing Slovak legislation prescribing the use of measuring instruments is further preconditions for the proper enforcement. This should be supported via input of Slovak metrological institute and notified bodies whenever special technical expertise is necessary. The borderline between different the EU legislation in this field shall be duly reflected during proper implementation of the Directive 2004/22/EC.

Especially the knowledge of the borderlines between medical devices having measuring function and measurement instruments, between non-harmonized part of regulated area in the field closed to MID, machinery directive and all directives dealing with energy efficiency requirements show many vacancies. This should be removed by adoption of procedures used in the EU Member States. The necessity to solve the possible future non-compliance coming from another operational control in usage of metrological instrument would became urgent importance with the privatization on gas, electricity and water distribution with the aim to ensure fair competition with the transposition the new EU package law on public procurement.
The transfer of the pre-market controls to the control on the market will precise the division of responsibility among implementation infrastructure agencies and will contribute to the strengthening of administrative co-operation and information exchange inside Slovak Republic. The more detailed division of the scope of activities of all implementation infrastructure starts with the proper implementation based on analysis of prescribed usage of measuring instruments and the borderlines of regulations provided for it. Following the consultations with EU experts on the proposed changes in legislation and including, if necessary, also the surrounding legal framework. This will include the gathering experience and know-how to deal with borderlines between different acquis and the MID based on EU Member States practices. In the Slovak Republic there are also about 5 surveillance bodies acting in the field of legally prescribed usage of measuring instruments, i.e. environmental, road, energy efficiency, trade inspection etc.

The field of medical devices is developing very rapidly and methods of measurement are very individual and complex. Also providing for e.g. conformity assessment in machinery directive is in almost cases made by the self-declaration of conformity for the whole system. This has been used also for the assembly having integrated measuring instruments. The assessment of the borderline is very individual in the non-harmonized part of the regulated area; some integration of the regulatory practice is desirable for the free movement of goods within the internal market.

It is important to meet, to study and adopt methods, procedures and practice prevailing in EU Member States and to incorporate them into Slovak law and regulatory practice and establish the system of their enforcement. That will influence the competitiveness of Slovak enterprises on common European market, which is one of the EU membership criteria and contribute to the implementation of the mutual recognition clause. Transfer of experience of EU Member States experts is seen as the most efficient way to reach this aim.

The overall objective of the project - enforcement of the legislation in the field of measuring instruments (Old and New Approach) and solving of issues concerning placing on the market of products with measuring function covered also by other directives – is primarily aimed to ensure the consumer protection mainly in the transitional period after putting the MID Directive into force and to prevent to placing on the market of non-complying measuring instruments.

3.2 Linked activities:

There is a linkage to following projects:

The Phare project SR9907.01 Implementation of the Standards and Certification Act (with Phare budget 1,8 M€ and Co-financing 0,16 M€).

The aim of the twinning project (SR 99/IB/EC/01) with partners from Germany and Austria was development of a tool for quick transposition of the New Approach directives in the framework of the Act with the removal of mandatory standards and certification, which was achieved by the adoption of the Act on technical requirements on products and conformity assessment as well as for the proper institutional building including the metrology.

The aim of this project was also to continue effort made in the implementation of the 93/42/EEC Medical Devices Directive. The Act on Metrology determines instruments, which are subject to the state metrological control. However, the broad scope of surveillance upon medical devices with measuring function is not fully covered by this specific Act. The Act on Drugs and Medical Devices provides for clinical testing and pharmacovigilance.

The Phare project SR0004 Application of the Act on technical requirements for products and on conformity assessment and technical assistance in the process of adoption of the Acquis Communautaire in the area of free movement of goods (with Phare budget 1,0 M€ and Co-financing 0,469 M€).

The aim of the twinning project (SK 00/IB/EC/01) with Spain partner was to ensure the implementation of the Act and adoption of the executive Governmental Ordinances to the Act, each
transposing one New Approach directive as well as the full membership of Slovak Institute of Standardization in CEN and CENELEC one year before accession. The project focused also on the mutual recognition principle in the areas close to the New Approach Directives as a supporting tool for PECA conclusions.

The ongoing bilateral Project PSO Pre Accession Programme PPA 03/SK/9/2 with the Nederland Meetinstituut aims at strengthening of the Slovak infrastructure for conformity assessment necessary for implementation of the directive concerning measuring instruments including its marketing approach with all economical aspects and effective co-operation among conformity assessment bodies. They are mostly private or newly privatized and have to learn how to provide the comprehensive services to their clients in the most efficient way. According to the PSO Project this has to be achieved by the increasing capacity of SMU and other conformity assessment bodies to become a Notified Body for the MID-directive by the increased awareness and abilities of Slovak producers and importers to meet MID criteria and by increased ability of Slovak Office of Standards, Metrology and Testing (UNMS) to transpose the MID into the Slovak legislation.

The project proposed in this fiche goes further in the area of MID implementation. It is aimed also at its enforcement with all possible overlapping areas, including the alignment of metrological control to the EU Member States practice. There are currently more than 80 references to the Act on metrology No 142/2000 Coll. and more than 1000 to its predecessor, the Act No 505/1990 Coll. on Metrology in the Slovak legal system.

3.3 Results:

At the end of the project the co-operation network will be established, the Directive 2004/22/EC proper enforced and written Guidelines for Co-operation network for enforcement developed

This project shall be realized in the form of both Twinning light and Technical Assistance. Whole project consists of 5 activities. Twinning light consists of three activities, two of them referring to Metrology and the third one to the Establishment of Network for Administrative Cooperation: Technical Assistance comprises two activities. Outputs from the several activities are mutual linked. Following results are expected:

3.3.1 Guide on procedures of administration.

They are several activities further explained with specific results, which will contribute to the Guide. Measuring instruments of regulated area could be divided in two areas. There is the EU harmonized area and non – harmonized area with national regulations. Therefore further effort is needed to optimize national regulations according to the practice of the other Member States in order to remove barriers for free movement of goods within the single market and to prevent possible proceedings. Non-harmonized part of regulated area in the field of measuring instruments is analyzed and the solution for

- changes in the enforcement law, if necessary
- proper application of mutual recognition principle
- basic co-operation in handling the borderline with the harmonized area

is proposed. Guide for proceeding of all administration involved elaborated.

This part of the project is focused on the approach to the non-harmonized part of the regulated area in the field of measuring instruments in EU Member States and on designation of involved bodies. Amendment of the Act on Metrology in the Slovak Republic deals with this area and has introduced the changes to comply with certain issue of metrological control as well as mutual recognition on the horizontal level.

3.3.2 Determination of rules for right implementation and practical application of MID in relation with other New Approach Directives.
The metrological surveillance in connection to the legal metrology control shall be explained and some requirements in Slovak law linked to this area reviewed.

According to the presentation of the EU practice in this field the need for changes in the existing Slovak implementation will be assessed and if identified, also introduced. The project outputs will be in form of a legally optimized document for legal metrology in Slovak Republic, i.e. for regulated area. The importance will be attached to area of measurements, which are not included in Directive 2004/22/EC as well as the proper maintenance of transitional period stipulated in the Directive 2004/22/EC.

The concrete outputs will be connected to the review of legislation documents and to the implementation of changes:
1. legal regulations implementing old approach directive (18 directives)
2. legal regulation implementing New Approach directive (as yet the governmental ordinance NAWI)
3. governmental ordinance(s) for MID implementation

The main assets are expected in:
- proper implementation and practical application of MID (10 kinds of legally controlled measuring instruments – MI-001 – MI-010) in relation with other New Approach Directives
- identification of the borderline between metrological requirements given in Old and New Approach Directives related to metrology and requirements given in other New Approach Directives

The outputs will be utilized by UNMS as regulatory and designating authority when establishing a Notified Body(ies) with aim to have proper MID implementation also during the transitional period and with the aim to determine unified and transparent condition for all applicants.

3.3.3 Network for Administrative Co-operation and Market Surveillance to enforce the Directive 2004/22/EC.

The use of measuring instruments for providing the protection of justified interest is mentioned in the recital 3 of Directive 2004/22/EC. Protection of justified interest via usage of measuring instrument, it means to give legal request and enforceability of amounts or limits, which should be granted or not exceeded. To launch this goal – a significant part of Slovak legislation requests for correct and traceable measuring instruments and sustainability of their measurement characteristic with description of periods and the ways to check the metrological characteristics during operational phase of measuring instruments. According to the Treaty as well as the directive this has to occur without introducing unjustified barriers of trade.

Outputs 1, 2 and 3 shall together provide for implementation and enforcement of the Measuring Instruments Directive with establishment of cooperation among competent authorities for smooth management of 10-year transitional period with common application of the harmonized area (New full harmonized Approach and old approach with optional harmonization). All inspection authorities dealing with enforcement of legally controlled measuring instruments will use the outputs also

3.3.4 Reference Guideline (1st part) in the field of temperature recorders and thermometers covered by Directives 92/1/EEC and 92/2/EEC.

The first part of the Reference Guideline covering the experience and practical approach to the regulation and market surveillance in the field of temperature recorders and thermometers for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen and ice cream covered by Directives 92/1/EEC and 92/2/EEC and possible other EU directives is elaborated and 25 people of the implementation infrastructure trained.

3.3.5 Reference Guideline (2nd part) for the usage of WELMEC guides for temporary substitution of harmonized European standards and normative OIML documents.
The second part of the Reference Guideline covering the usage of WELMEC guides for temporary substitution of normative OIML documents and harmonized standards and usage of modules of conformity assessment and of MID manufacturers databases is elaborated and 25 people of the implementation infrastructure trained.

Outputs 4 and 5 shall together provide for better understanding of the incorporation of certain measuring instruments covered by MID into acquisition in harmonized area (with checking the proper reflection in the Slovak implementation) as well as for the identification of the possible gaps, their removal, proper implementation of all MID modules and usage of tools created on the European level (databases).

The outputs of both TWL and TA the project will be presented by means of professional actions, delivery of know how, consultations and seminars.

The Slovak Office of Standards, Metrology and Testing (UNMS) will coordinate the activities of the project.

### 3.4 Activities:

Where relevant the involvement of potential notified bodies and/or inspection bodies is expected (especially where training is envisaged, it shall be available to all the notified bodies in the same field).

**Twinning light (0.250 MEUR)**

To implement TWL activities following will be needed:

**Project leader** for Activity 3.4.1 – 3.4.3:

- Coordinating of EU Member States inputs.
- Selection of short-term experts for all three components.
- Analyzing the present state of the art and the SMU approach to the non-harmonized part of the regulated area in the field of measuring instruments.
- Participation in workshops/seminars.
- Co-ordination and elaboration of components start up report and final report of approximately 180 pages including also the proposed model of Co-operation of all parties involved.
- Experience at least 10 years in metrology issues
- Experience at least 8 years in non-harmonized part of regulated area
- Experience at least 5 years in implementation of New Approach Directives
- Experience at least 5 years in enforcement policy

70 man-days, speaking English and/or German

The activities of short-term experts:

Activities related to Result 3.3.1:

**Activity 3.4.1** Presentation of the MID transposition as well as experience and Approaches to Non-harmonized Part of Regulated Area in the Field of Measuring Instruments in different EU Member States

Activity 3.4.1.1 Assessment of the prepared MID transposition;
Activity 3.4.1.2 Assessment of the SMU, SMI and SLM approach to the non-harmonized part of the regulated area in the field of measuring instruments;
Activity 3.4.1.3 Elaboration of a short start up method of about 25 pages;
Activity 3.4.1.4 Analysis of the present state of the art in Slovakia, Comparison with best practices in EU Member States;
Activity 3.4.1.5 Participation in 2 different workshops/seminars with Presentation of the Approach to the Non-harmonized Part of Regulated Area in the Field of Measuring Instruments in EU Member States.
States including the implementation of mutual recognition and legally prescribed usage of measuring instruments with case studies, each for 20 participants, with translation into Slovak language;  
Activity 3.4.1.6 Elaboration of final report and its presentation to those who are participating in its relevant parts of approximately 50 pages.

Experience for performance of activity 3.4.1 should be  
at least 5 years in metrology issues  
at least 5 years in non-harmonized part of regulated area.  
For this activity is required:  
1 short term expert for 25 man-days or 2 short term experts for 25 man-days together, speaking English and/or German,

Activities related to Result 3.3.2:  
**Activity 3.4.2** Presentation of the Experience and Practical Approach to the Regulation and Surveillance in the Field of Medical Devices with Measuring Function as well as the borderline with another New Approach directives, i.e. EMC, GA, ATEX, Machinery, NAWI.  
Activity 3.4.2.1 Analysis of the present state of play in SR;  
Activity 3.4.2.2 Providing information on best (known) practices of EU Member States Activity 3.4.2.3 Participation in Workshop explaining the borderline, for 30 participants;  
Activity 3.4.2.4 Assessment of the SMU, SLM, and SUKL approach to the metrological service for medical devices with measuring function, assessment of the services which should be provided on the borderline with other New Approach directives, ATEX (94/9/ES) LVD, EMC, Machinery  
Activity 3.4.2.5 Elaboration and participation on relevant part of final report of approximately 50 pages.

Experience for performance of activity 3.4.2 should be  
at least 5 years in metrology issues  
at least 5 years also in implementation of New Approach Directives  
For this activity is required:  
1 short- term expert for 25 man-days, speaking English and/or German

Activities related to Result 3.3.3:  
**Activity 3.4.3** Establishment of Network for Administrative Co-operation and Market Surveillance to enforce the Directive 2004/22/EC and ensure the smooth implementation of the transitional period without distortion of the free movements of goods and with application of the mutual recognition clause.  
Activity 3.4.3.1 Analysis of the present state of play in SR;  
Activity 3.4.3.2 Providing information from the best (known) practices of EU Member States  
Activity 3.4.3.3 Identification of main parties involved in requiring the use of legally controlled measuring instruments;  
Activity 3.4.3.4 Participation in Workshop explaining the proposed model for Co-operation, for 40 participants;  
Activity 3.4.3.5 Study Visit for 8 Slovak experts in the EU Member State in which the envisaged Co-operation is well functioning;  
Activity 3.4.3.6 EU Member States legislation using the legally controlled measuring instruments in the field of MID Directive and the Slovak practice; Suggestion for improvement;  
Activity 3.4.3.7 Presentation of flowchart with a model for Co-operation of administrative and market surveillance authority. Preparation of the guide for the best practice co-operation  
Activity 3.4.3.8 Elaboration and participation on relevant part of final report of approximately 40 pages, including the model of Co-operation.

Experience for performance of activity 3.4.3 should be  
at least 5 years in metrology issues  
at least 5 years in non-metrological legislation using legally controlled measuring instruments  
at least 5 years in enforcement policy  
For this activity is required:  
2 short term expert for 15 days (30 man- days), speaking English and/or German
Technical Assistance (0.2 MEUR)

Activities related to Result 3.3.4:

Activity 3.4.4 Presentation of the Experience and Practical Approach to the Regulation and Surveillance in the Field of Temperature recorders and thermometers for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen and ice cream (covered by European Directives 92/1/EEC and 92/2/EEC) as well as the borderline with or references to other directives.
Activity 3.4.4.1 Analysis of the present stay of play in SR;
Activity 3.4.4.2 Providing information from the best (known) practices of EU Member States
Activity 3.4.4.3 Participation in Workshop explaining the borderline, for 20 participants;
Activity 3.4.4.4 Assessment of approach of the UNMS, SMU, TSU Piešťany and other potential notified bodies to the metrological services in the framework of the above-mentioned Directives;
Activity 3.4.4.5 Elaboration of the first part of the Reference guideline and its presentation in the workshop to all interested parties as well as the final report of approximately 15 pages;

Experience for performance of activity 3.4.4 should be
at least 5 years in metrology issues
at least 5 years in harmonized area of the acquis referring to the measuring instruments
For this activity is required:
1 short term expert for 10 man-days, speaking English and/or German

Activities related to Result 3.3.5:

Activity 3.4.5 Preparation and elaboration of guidance and explanatory documents which will serve as temporary documents substituting harmonized European standards and normative OIML documents respectively in the field of MID Annexes, usage of WELMEC guides and MID databases.
Activity 3.4.5.1 The first part of the activity 3.4.5 is focused on water meters (MI-001), measuring systems for the continuous and dynamic measurement of quantities of liquids other than water (MI-005), material measures (MI-008).
It comprises:
- Elaboration of analysis concerning content of these documents
- Identification of the requirements of EN standards and OIML documents.
- Elaboration of the documents
- Advice for the implementation practice in the form of consultation and trainings
- Practical exploitation – training of the staff.

Activity 3.4.5.2 The second part of the activity 3.4.5 is focused on the usage of the WELMEC guides for practical application in harmonized field. It comprises:
- Elaboration of analysis of WELMEC guides.
- Requirements for application.
- Practical exploitation – training of the staff.

Activity 3.4.5.3 The third part of the activity 3.4.5 is focused on Application of conformity assessment modules given in MID Directive by notified bodies. This part should be clear by all market surveillance authority. It comprises:
- Elaboration of analysis of particular modules.
- Elaboration of modules application.
- Practical exploitation – training of the staff of NB and Market surveillance.

Activity 3.4.5.4 The fourth part of the activity 3.4.5 is focused on: Assurance of harmonized interpretation of provisions of the MID Directive.
It comprises:
- Elaboration of analysis of particular parts of MID Directive.
- Explanation of understanding of particular provisions of MID Directive.
- Mutual consultations concerning ambiguously interpreted provisions.
- Elaboration of the harmonized interpretation.
Activity 3.4.5.5 The fifth part of the Activity 3.4.5 is focused on the elaboration of the part of the Reference guidelines which will cover the guidance for access to the relevant databases in the framework of MID Directive.

It comprises:
- Elaboration of analysis of relevant databases.
- Elaboration of the basis for guidance
- Practical exploitation – training of the staff.

Experience for performance of activity 3.4.5 should be:
- at least 5 years in metrology issues
- at least 5 years in the field of interpretation of conformity assessment modules
- at least 5 years in the field of harmonized interpretation of New Approach directives

For this activity is required:
- 5 short-term expert for 10 days (50 man-days), speaking English and/or German, each for part of the Activity 3.4.5 (could be also realized by 10 short term experts for 5 days)
- 1 medium short-term expert for 30 days, coordinating the outputs of activities 3.4.4 and 3.4.5 as well as elaboration of analysis and documents requested, speaking English and/or German

3.5. Lessons learned:

According to the Phare Twinning Project SR 99/IB/EC/01, Twinning Project SK00/IB/EC/01 evaluation, the lessons have been already learn from the first project, relatively good evaluated but there were a criticism concerning not enough clear stipulation of objectives and activities results. This did not occur in the Twinning Project SK00/IB/EC/01 with excellent evaluation. See Interim Evaluation of the European Union Pre-Accession Instrument PHARE – No. R/SK/INT/02.124. Both of the Twinning projects mentioned were some common elements. Among others they were aimed at the removal of mandatory certification, the acceptance of the appropriate role of harmonized standards as the tool of presumption of conformity, proper implementation of the new approach directives and their enforcement. With the implementation of each new approach directive the regulatory area non-harmonized so far was reviewed, including the borderlines between old and new system.

4. Institutional Framework

The Slovak Office of Standards, Metrology and Testing (UNMS) is a central body of state administration in the field of technical standardization, conformity assessment, metrology and quality assurance. As a central body of state administration UNMS reports directly to the Prime Minister. Although it is headed by a president and not by a minister, it has in effect the same executive responsibilities as a ministry within the domain of technical regulations for products. UNMS is responsible for the development of national policies and for drafting the national legislation (laws, ordinances, decrees) for standardization, metrology, and conformity assessment. That means that UNMS is among other things in charge of the implementation of the system of European product legislation (Old and New Approach) in the framework of Slovak membership in the European Union. The transposition of the MID into national legislation is the task of UNMS.

The transposition of the MID directive is in the sole responsibility of the UNMS. The UNMS will designate Notified Bodies for performing particular tasks arising from the directive in order to ensure its implementation and functioning of the whole infrastructure of system. Market surveillance in the frame of the MID will be preformed by the Slovak Metrology Inspectorate, the independent body of state administration, established by UNMS. Although UNMS is not responsible for market surveillance in the surrounding fields, it has the co-ordination task in the field of free movement of goods in non–harmonized area. Therefore UNMS will also in future coordinate cooperation of inspection bodies as regards measuring instruments.

The possible risk presents only the planned amendment of the Act on division of responsibility among ministries and central state administration bodies, which envisaged subordinating the UNMS under the
Ministry of Economy. This may probably cause certain changes in administrative management of the project.

Project management: The project will be coordinated by a Steering committee under the umbrella of UNMS consisting of other beneficiaries and contractors representative. Representative of the EC, ACU and CFCU may take part in meetings as observers

5. Detailed Budget

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<th>€M</th>
<th>Transition Facility support</th>
<th>Co-financing</th>
<th>Total cost (TF plus co-financing)</th>
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(*) contributions form National, Regional, Local, Municipal authorities, FIs loans to public entities, funds from public enterprises
(**) private funds, FIs loans to private entities

6. Implementation Arrangements

6.1 Implementing Agency

Ministry of Finance of the Slovak Republic
Central Financing and Contracting Unit
Mrs. Sylvia Czuczurova, PAO
Ph.: +421 2 5958 2546
Fax: +421 2 5958 2559
Štefanovičova 5
817 82 Bratislava, Slovak Republic

6.2 Twinning Light and Technical Assistance

Twinning Light
Beneficiaries:
Slovak Office of Standards, Metrology and Testing - UNMS, Slovak Metrology Inspectorate- SMI, Slovak Legal Metrology - SLM, Technical Testing Institute – TSU and other potential notified bodies, surveillance authorities in line ministries

Technical Assistance
Beneficiaries:
Slovak Office of Standards, Metrology and Testing - UNMS, Slovak Metrology Inspectorate - SMI, Slovak Legal Metrology - SLM, Technical Testing Institute – TSU and other potential notified bodies, surveillance authorities in line ministries
Contact person:  
Project leader for Slovakia (TWL and TA):  
Ivan Mikulecký  
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National Contact Point:  
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Tel.: +421-2-5729 5514  
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6.3. Non-standard aspects  
Non applicable

Contracts

Twinning light – 1 contract for 250 000EUR (including 10 000€ for the ex post audit). The amount for the twinning light contract does not contain expenses/ costs such as transport costs for staff from the beneficiary country to MS for the purpose of attending study visits which according to the Twinning Manual have to be borne by the beneficiary country.  
Technical assistance 1 contract for 200 000 EUR

7. Implementation Schedule

7.1 Start of tendering/call for proposals  
September 2005

7.2 Start of project activity  
January 2006

7.3 Project completion  
February 2007

8. Sustainability

All beneficiaries are either state authorities which are part of the regulatory or market surveillance implementation or enforcement infrastructure or in the case of notified bodies already well established on the market and providing their services for the EU market even before accession according to the PECA Agreement. The beneficiaries have foreseen staff and financial resources necessary to maintain the functioning of the project. SMU has been beneficiary under PHARE Twinning Project SR 99/IB/EC/01 and TSU under Twinning Project SR 99/IB/EC/01 and Twinning Project SK00/IB/EC/01, in both cases the results were positive and sustainability ensured – see Interim Evaluation No. R/SK/INT/02.124

9. Conditionality and sequencing

Conditionality:  
An adequate project management and co-ordination structure has to be established within the UNMS. The top management of the Office must approve it before the project implementation starts.

Involvement and co-operation with other state administration authorities has to be considered and participation of the line ministry ensured. It must be undertaken by the SPO before the project implementation starts. During the implementation stage must be participation of the ministries and
their agencies responsible for the enforcement of the regulation prescribing the usage of metrological instruments. The legal output should be flexible completed and managed according to the results of the borderline analysis as well as analysis to ensure free movement of goods.

Sequencing:
Sequencing is indicated by means of the division of each activity into subparagraphs

Milestones for project implementation
In both cases, TWL and TA the project starts with the analysis of present situation, and comparison with the practice in the EU Member States. This stage shall be accomplished till the end of 1st Quarter 2006

Recommendation for improvement shall be accomplished by the 2 Quarter 2006 and the delivery of report and guidelines and other documents as requested shall be accomplished by the 4th Quarter 2006
ANNEXES TO PROJECT FICHE

1. Logical framework matrix in standard format (compulsory)
2. Detailed implementation chart (compulsory)
3. Contracting and disbursement schedule by quarter for full duration of programme (including disbursement period) (compulsory)
4. List of relevant Laws and Regulations (optional)

The Act on Metrology (Act 142, 17 March 2000 and set of its executive decrees, the Act 264 of 7 September 1999 on “Technical Requirements for Products and on Conformity Assessment,

5. Institutional Framework
6. Abbreviations
## Transition Facility Logframe

### LOGFRAME PLANNING MATRIX FOR Project

<table>
<thead>
<tr>
<th>Programme name and number</th>
<th>Reinforcement of administrative capacity as regards measuring instruments</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005/017-464.02.01</td>
<td>Contracting period expires on 15 December 2007</td>
</tr>
<tr>
<td></td>
<td>Disbursement period expires on 15 December 2008</td>
</tr>
<tr>
<td></td>
<td>Total budget: €450 000</td>
</tr>
<tr>
<td></td>
<td>TF budget: €450 000</td>
</tr>
</tbody>
</table>

### Overall objective

Enforcement of the legislation in the field of measuring instruments (Old and New Approach as well as the national one). Free movements of goods having measuring function covered by another directives or regulated in non-harmonized area without distortion caused by changing environment in their usage and operation.

<table>
<thead>
<tr>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guide of the administrative co-operation is published. Authority in the fields using legally controlled measuring instruments identified and trained in the field of MID enforcement. Network of authorities prescribing the usage and periodical checking measuring instrument is established and in function.</td>
<td>Web side of the Slovak Office of Standards, Metrology and Testing, Participation list in seminars and workshop devoted to this purpose</td>
</tr>
</tbody>
</table>

### Project purpose

- Implementation of the Directive 2004/22/EC and smooth transferring of the application of the former old approach or national regulations to the New Approach

<table>
<thead>
<tr>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Governmental Ordinance transposing MID is published, changes in the borderlines legislation identified and implemented.</td>
<td>Transposition sheet in the Celex, Justified complains in SOLVIT do not occur Collection of Law</td>
</tr>
</tbody>
</table>

### Results

<table>
<thead>
<tr>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.3.1 Non-harmonized part of regulated area in the field of measuring instruments is analyzed and the solution are proposed. Guide for proceeding of all administration involved elaborated</td>
<td></td>
</tr>
<tr>
<td>Enforcement law is in place, proper application of mutual recognition principle in place, Guide on procedures of administration published</td>
<td></td>
</tr>
<tr>
<td>Guide on procedures of administration Collection of Law Web sides of relevant administration</td>
<td></td>
</tr>
<tr>
<td>3.3.2 Borderline is identified and reflected in Directive 2004/22/EC implementation as well as the acquis related to it (both old and New Approach directives, i.e. EMC, GA, ATEX, Machinery, NAWI)</td>
<td></td>
</tr>
<tr>
<td>Rules for right implementation and practical application of MID in relation with other New Approach directives are issued</td>
<td></td>
</tr>
<tr>
<td>Web side of the SOSMT (Guideline for right implementation and practical application of MID in relation with other New Approach Directives ) Presentation list of seminar devoted to the Guide for administrative Co-operation and Market surveillance with the case study showing how to handle transition period</td>
<td></td>
</tr>
<tr>
<td>3.3.3 Network for Administrative Co-operation and Market Surveillance to enforce the Directive 2004/22/EC is established and smooth implementation of the transitional period ensured</td>
<td></td>
</tr>
<tr>
<td>Guide for establishment of Network for Administrative Co-operation and Market Surveillance to enforce the Directive 2004/22/EC with the hints to the harmonized standards, OIML recommendation and example of mutual recognition principle during the transition period presented to all administrative concerned</td>
<td></td>
</tr>
<tr>
<td>The changes in the Act of division responsibilities transferring the public policy to the Ministry of Economy</td>
<td></td>
</tr>
<tr>
<td>3.3.4 First part of the Reference Guideline covering the experience and practical approach to the regulation and market surveillance in the field of temperature recorders and thermometers for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen and ice cream covered by European Directives 92/1/EEC and 92/2/EEC, and possible another EU directives is elaborated</td>
<td></td>
</tr>
<tr>
<td>Linkage to the usage of measurement instruments covered by MID indicated, proper enforcement checked and if necessary the changes in Slovak legislation proposed and implemented</td>
<td></td>
</tr>
<tr>
<td>Reference guideline – part 1, he UNMS homepage with Usage of measuring instruments in selected part of acquis</td>
<td></td>
</tr>
<tr>
<td>3.3.5 Second part of the Reference Guideline covering the usage of WELMEC guides as documents for</td>
<td></td>
</tr>
<tr>
<td>Collection of law</td>
<td></td>
</tr>
<tr>
<td>Activities</td>
<td>Means</td>
</tr>
<tr>
<td>------------</td>
<td>-------</td>
</tr>
<tr>
<td>3.4.1 Presentation of the experience and approaches to Non-harmonized Part of Regulated Area in the Field of Measuring Instruments in EU Member States</td>
<td>Via input of EU expert(s)</td>
</tr>
<tr>
<td>3.4.1.1 Assessment of the prepared MID transposition</td>
<td>Incorporation of the assessment result into the Draft of Governmental Ordinance</td>
</tr>
<tr>
<td>3.4.1.2 Assessment of the SMU, SMI and SLM approach to the non-harmonized part of the regulated area in the field of measuring instruments</td>
<td>Elaboration of methods for the implementation of mutual recognition clause</td>
</tr>
<tr>
<td>3.4.1.3 Elaboration the short draft method</td>
<td>Comparison the behavior of EU Member States with the Slovak practice by the EU expert</td>
</tr>
<tr>
<td>3.4.1.4 Analysis of the present state of the art in Slovakia, Comparison to the best practice in EU Member States</td>
<td>Workshops with the presentation of the results</td>
</tr>
<tr>
<td>3.4.1.5 Participation in 2 different workshops/seminars with presentation of the analysis and comparison results</td>
<td>Elaboration of final report</td>
</tr>
<tr>
<td>3.4.1.6 Elaboration and participation on relevant part of final report</td>
<td></td>
</tr>
<tr>
<td>3.4.2 Presentation of the Experience and Practical Approach to the Regulation and Surveillance in the Field of Medical Devices with measuring Function as well as the borderline with another New Approach directives, i.e. EMC, GA, ATEX, Machinery, NA WI</td>
<td></td>
</tr>
<tr>
<td>3.4.2.1 Analysis of the present state of play in SR</td>
<td></td>
</tr>
<tr>
<td>3.4.2.2 Providing information from the best (known) practices of EU Member States</td>
<td></td>
</tr>
<tr>
<td>3.4.2.3 Participation in Workshop explaining the borderline, for 30 participants</td>
<td>Via input of EU expert(s)</td>
</tr>
<tr>
<td>3.4.2.4 Assessment of the SMU, SLM, and SUKL approach to the metrological service for medical devices with measuring function, to the services which should be provided on the borderline with another New Approach directives, ATEX (94/9/ES) LVD, EMC</td>
<td>Workshop with the summary of the information and borderline analysis</td>
</tr>
<tr>
<td>3.4.2.5 Elaboration and participation on relevant part of final report</td>
<td>Internal consultation with the EU expert Elaboration final report of activity 3.4.2 with the recommendation</td>
</tr>
<tr>
<td>3.4.3 Establishment of Network for Administrative Co-operation and Market Surveillance to enforce the Directive 2004/22/EC and ensure the smooth implementation of the transitional period without distortion of the free movements of goods and with application of the mutual recognition clause</td>
<td>Via input of EU expert(s)</td>
</tr>
<tr>
<td>3.4.3.1 Analysis of the present state of play in SR</td>
<td>Analysis of the laws requesting for use of measuring instruments to protect justified interest Inspection (Surveillance) authority are identified and asked for participation Information on the practice in EU Member States is provided on the workshop with the proposed model of co-operation</td>
</tr>
<tr>
<td>3.4.3.2 Providing information from the best (known) practices of EU Member States</td>
<td></td>
</tr>
<tr>
<td>3.4.3.8 Elaboration and participation on relevant part of final report of approximately 40 pages, including the model of Co-operation</td>
<td>Draft Co-operation guide is discussed on the spot, i.e. in the EU Member State with appropriate co-operation in place</td>
</tr>
<tr>
<td>Technical Assistance: 3.4.4 Presentation of the Experience and Practical Approach to the Regulation and Surveillance in the Field of Temperature recorders and thermometers for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen and ice cream (covered by European Directives 92/1/EEC and 92/2/EEC) as well as the borderline with or references to another directives</td>
<td>Final draft of cooperation guide is adopted in the form of attachment to the final report</td>
</tr>
<tr>
<td>3.4.5 Preparation and elaboration of documents which will serve as temporary documents substituting harmonized European standards and normative OIML documents respectively in the field of MID Annexes, usage of WELMEC guides and MID databases, training</td>
<td>Final report</td>
</tr>
<tr>
<td></td>
<td>Analysis and Workshop</td>
</tr>
<tr>
<td></td>
<td>Analysis and 5 Seminars/Workshops</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Time Implementation Chart

Project number 2005/017-464.02.01

Project title: **Reinforcement of administrative capacity as regards measuring instruments**

<table>
<thead>
<tr>
<th></th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INSTITUTION BUILDING</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PROJECT ACTIVITY 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PROJECT ACTIVITY 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>PROJECT ACTIVITY 3</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>PROJECT ACTIVITY 4</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>PROJECT ACTIVITY 5</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
Annex 3

Cumulative Contracting and Disbursement Schedule

Project number 2005/017-464.02.01

Project title: **Reinforcement of administrative capacity as regards measuring instruments**

<table>
<thead>
<tr>
<th>EUR</th>
<th>2005</th>
<th></th>
<th>2006</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Contracted</td>
<td>450 000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disbursed</td>
<td>250 000</td>
<td>275 000</td>
<td>300 000</td>
<td>400 000</td>
</tr>
</tbody>
</table>
4. Institutional Framework

**Notified bodies**

1. **Slovak Institute of Metrology (SMU)** in Bratislava is the main research and scientific body of state metrology and has the function of a national metrology institute. SMU is responsible for developing and maintaining national measurement standards which represent the basis for traceability of measuring instruments and measurements in the field regulated by the Act on Metrology and also in the non-regulated field. It is the only organization in the field of metrology that is allowed by law to issue type approval certificates.

2. **Slovak Legal Metrology (SLM)** is the main executive body of state metrology. SLM has about 130 employees in 5 offices: the headquarter is located in Banská Bystrica and regional offices in Bratislava and Košice, as well as branches in Nitra and Žilina. The offices are to some degree specialized: e.g. Banská Bystrica can provide metrological services in the field of physical quantities and chemicals, including environmental measuring instruments and Bratislava which has the largest laboratory can provide metrological services concerning taximeters, water meters, heat meters, meters for liquids other than water, automatic weighing instruments, volumetric instruments, material measures of length, exhaust gas analyzers, breath analyzers, as well as dosimeters. The standards of SLM are traced to national standards via transfer of the units of measurements from national standards to working standards to be used for verification and calibration of measuring instruments in industry. SLM does the initial verifications and reverifications of measuring instruments in the fields of surface area, volume and flow, mass, pressure, mechanical material tests, temperature and heat, density, refractometry and chemical composition. It does not do verifications of electricity meters and gas meters, because the manufacturers of these instruments have been authorized to do it themselves.

3. **Technical Testing Institute Piešťany (TSU Piešťany)**, an independent notified body for conformity assessment (EU notified body No. 1299). It is accredited certification, inspection and testing body for machinery and construction products and consumer goods. It deals also with verification and calibration of measuring instruments (length, pressure, moment of force, electrical quantities and oscilloscopes, sound level meters and integrating sound level meters, band-pass filters, measuring microphones, acoustic calibrators, personal sound exposure meters, measuring devices for mechanical oscillation and measures of non-linear electrical signal distortion, quantity flow meters of cold and hot water and flow-meter parts of heat meters).

4. **Other potential notified bodies** – laboratories performing at present verification of legally controlled measuring instruments according to EU old approach directives and purely national requirements which might be able to satisfy MID requirements for notified body mainly for module F.

**Inspection bodies**

1. **Slovak Metrology Inspectorate (SMI)** performs state metrology supervision over the measuring instruments and measurements including pre-packages and market surveillance in the field of non-automatic weighing instruments.

2. **Slovak Institute for Drug Control (SUKL)** performs the registration of drugs and medical devices including those having measurement function. It is a state body subordinated by Ministry of health responsible also for the authorization of the clinical testing of drugs.

3. **Other inspection bodies** - Different state or private bodies performing the inspection under the special regulation requesting the use of legally controlled instruments (energy inspection, environmental inspection, safety of traffic on the road inspection, health inspection).
Current situation

The implementation infrastructure has to be strengthened to cope with 10 years transitional period and ensure the free movement of measuring instruments. This should be done by:

a) the transfer of common knowledge from Member State(s) having experience with the simultaneous application of the optional old approach directive, because with the Directive 2004/22/EC application on further rules will joint to the previous one,

b) establishment of co-ordination network among all parts of implementing infrastructure.

The implementation of the New Approach Directives in the Slovak Republic is based on a general framework law, the Act 264 of 7 September 1999 on “Technical Requirements for Products and on Conformity Assessment”, which covers all the horizontal or common aspects of the directives. The directives are issued as governmental ordinances (secondary legislation) under this law. The MID directive will be transposed as an ordinance related to this law.

The Act on “Technical Requirements for Products and on Conformity Assessment” gives to UNMS in paragraph 8 the authority of notification of “Authorized Bodies” (or Notified Bodies after Slovak Republic has become a Member State of the EU on 1st May 2004). This notification procedure is laid down in detail in paragraph 11 of the Law, as is the procedure for supervision of the authorised bodies on the proper implementation of their tasks, and the procedures for withdrawal of a given notification. The Department of Testing of UNMS is responsible for this activity. There are at the moment more than twenty authorized bodies notified for conformity assessment task under the New Approach directives.

The Act on “Technical Requirements for Products and on Conformity Assessment” delegates the market surveillance tasks to bodies of state administration which are mentioned in the specific regulations concerning products. This means that there are at the moment 12 state organizations belonging to 7 ministries handling with this task although the Slovak Trade Inspection plays the major role. The Law on Metrology (Act 142, 17 March 2000) contains the task of market surveillance for measuring instruments among other things to the Slovak Metrology Inspectorate, one of the subsidiaries of UNMS. When the MID will come into force the market surveillance for these instruments will also be a task of SMI.
Abbreviations:

UNMS – Slovak Office of Standards, Metrology and testing (SOSMT)
SMU - Slovak Institute of Metrology
SLM - Slovak Legal Metrology
TSU Piešťany - Technical Testing Institute Piešťany
SMII - Slovak Metrology Inspectorate
SUKL - Slovak Institute for Drug Control
NB – Notified Body
NPAA – National Programme for the Adoption of the Acquis
EMC – electromagnetic compatibility
GA – gas appliances
ATEX – Equipment for use in potentially Explosive Atmosphere
NAWI – Non-automatic weighing instruments
MID – Measuring Instruments Directive
PECA – Protocol to the Europe Agreement on Conformity Assessment and the Acceptance of Industrial Products
OIML – International Organization for Legal Metrology
CEN – European Committee for Standardization
CENELEC - European Committee for Electrotechnical Standardization
WELMEC – European Cooperation in Legal Metrology
PSO – Programme for Cooperation with Eastern Europe