STANDARD SUMMARY PROJECT FICHE

Project Number 2003.004-341.03.02

1. Basic Information

Objective 3 - Education, Training and Research

1.1 CRIS Number 2003.004-341.03.02

1.2 Title Developing reliable infrastructure in the fields of measurements in chemistry in Lithuania according to the best EU practices

1.3 Sector Internal Market

1.4 Location State metrology service under the Ministry of Environment, Algirdo str. 31, 2006 Vilnius, Lithuania

2. Objectives

2.1 Overall objectives:

The overall objective of this **1.85 MEUR** Project, of which **0.3 MEUR** is provided from national co-financing is to align traceability, tractability, quality and fitness of chemical analytical measurements (metrology in chemistry) in Lithuania with the relevant *Acquis* requirements and corresponding best EU practices.

2.2 Project purposes

- Completion of the process of legal approximation by preparation of secondary legislation and enforcement guidelines covering Sectoral Approach Directives (i.e. 80/181/EEC on units of measurement, 98/83/EC on drinking water etc.) as regards metrology in chemistry
- Developed and implemented national strategy in metrology in chemistry field and calibration infrastructure established
- Strengthened co-operation between public and private sector actors and research institutes.

2.3 Accession Partnership and NPAA priority

The Accession Partnership 2001 defines the need for the following action: *reinforce the State Metrology Service and improve operational capacities and know-how of the accredited calibration laboratories; strengthen co-operation between the institutions involved in market surveillance activities.*

The NPAA refers to the following priorities in metrology field:

3.1-S18 *Strengthen State metrology service: develop and maintain state measurement standards, ensure calibration of measuring instruments, ensure implementation of pre-package control directives and regular monitoring of notified bodies.*

3.1-D9 *Develop new and update the already existing general verification methods of measuring instruments.*

Referring to the said above, the period between 2001-2004 is devoted to the modernization of the country's metrology infrastructure and harmonization of it with the EU requirements, which includes development of calibration and measurement capabilities of laboratories, professional development of specialists, establishment of regular (inter) national interlaboratory comparisons scheme, as the main tool to demonstrate competence of laboratories engaged in measurements in chemistry (environmental protection, health protection, law enforcement fields).

3. Description

3.1 Background and justification

Around 40% of the European Union directives are related to measurements by establishing essential requirements for measuring instruments or various materials in practically every sector (ref.: 98/79/EC on In Vitro Diagnostics and Medical Devices, 98/83/EC on Drinking Water), reference methods on measurement of quantities of harmful substances as well as on measurement of useful substances contents (e.g. sugar in sugar beets, dryness of grains etc.). As a number of laws and legal acts are already existing in Lithuania, just a few are mentioned: the Law on Metrology came into force in 1996. Requirements of the EU directive 80/181/EEC on units of measurement were transposed into national legislation in 2001, the Law on Drinking Water was passed in 2001 as well.

The European Commission positively evaluated the progress Lithuania made in the area of free movement of goods in the Regular Report 2001. Nevertheless, the Commission noted *in order to ensure full alignment, however and more effective enforcement of the acquis, these efforts need to continue.*

Regarding metrology field, the Commission particularly emphasized that some progress has been made in improving calibration equipment and in strengthening operational capacities and know-how. Furthermore, it stressed that *much more progress is needed to improve the administrative and operational capacities of the accredited calibration laboratories*.

Relevant Directives of the European Union in chemistry field provide general requirements related to the application of the principles of good laboratory practice and the verification of their applications for tests. These requirements are explained in the relevant European standards for calibration and testing laboratories and they cover all aspects of the activities of laboratories, including relevant activities for administrative and operational capacities and know how. The number of laboratories performing measurements in chemistry field in Lithuania is as high as 200. Just a handful (in total 8) has recently participated in international interlaboratory comparisons. The results achieved show the need for immediate action – according to criteria set out by an accreditation body only 30% of the results are acceptable (within target range).

Furthermore, comparing field of metrology in chemistry to other fields of metrology, i.e. mass, length, electricity etc. measurements, there are only two accredited laboratories (1% of all laboratories), though Law on Conformity Assessment requires that calibrations would be performed only by accredited laboratories.

Implementation of the measurements in chemistry information system is a prerequisite not only of the measurement quality management, but also for involvement of the civil society into

the regulation and quality evaluation process. Number of NGO's, such as Association EURACHEM-Lithuania, Technical Committees on standardization relevant to chemical measurements, Associations on laboratory medicine etc. were involved in evaluation of the present state of metrology in chemistry in Lithuania. The report was approved by the Institute of Reference Materials and Methods of the Joint Research Centre of the European Commission.

Referring to the concern that a lot of funds will be spent on technical equipment and hardware, it should be noted that metrology in chemistry field covers extremely wide range of applications – health protection, environment protection, drugs, forensics, food and veterinary etc. by measurement of single elements like heavy metals in water to various salts in soil which itself is a very complex mixture to big molecules consisting of thousands of elements in biochemistry and the range is constantly increasing. Secondly, the initial investments in this field have already been made from national funds and nearly 700,000 EUR has been invested both in equipment (the most expensive piece of equipment was worth 400,000 EUR) and improvement of the laboratory environment. It should also be noted that the equipment supplied is of the EU origin. Thirdly, this equipment does not cover all the ranges of measurements except elemental analysis, therefore, accessories and some additional equipment has to be supplied to increase the range and quality of measurements. Finally, the list of equipment has already been revised taking into account equipment for chemical measurements that will be supplied to Lithuania through on-going Phare projects.

As the EC and EC Delegation officers during discussion expressed a concern on a possibly insufficient amount of money for Twinning part, the number of man/months for medium and short term experts was increased and the total budget of the project was increased as well.

3.2 Linked activities

Regarding links to earlier projects, there was no training nor supply of equipment for the needs of development of infrastructure in metrology in chemistry field in Lithuania, except for the solely indication that field of chemistry should be explored done by the experts from the Netherlands in Phare LI9615 project in metrology field.

The proposed project is linked to the PHARE project LT 01.06.01 "Strengthening of Institutional Capacity to implement EU requirements on chemicals and genetically modified organisms management, IPPC and climate change" through development of traceable calibration services, traceability of measurements from SI units of measurement to end-users seen as an essential requirement.

Institute for Reference Materials and Measurements (IRMM) of the Joint Research Centre of European Commission supported participation of Lithuanian laboratories of chemical analysis at International Measurement Evaluation Programme IMEP rounds IMEP-16 (lead in vine, five laboratories) and IMEP-12 (trace elements in water, three laboratories). Status Report in the field of metrology in chemistry has been prepared under supervision of IRMM.

Within Phare project LIT 9615 "Support to the establishment of a national metrology system in conformity with EC requirements" a gaps and needs analysis was performed, but not particular support for metrology in chemistry was given.

Within the Phare LI 9701.01.04 "Standards Translation/Information Facilities" certain measuring equipment in electricity, temperature, length, volume and mass fields was supplied. No support for metrology in chemistry.

Within the Phare LI 0003-01 "Strengthening administrative and technical capacities to promote the free movement of goods", measuring equipment for establishment of national standards in flowrate, voltage, resistance and extension of capabilities of national standards of temperature and time/frequency is going to be supplied. The supply of equipment for the development of the Conformity Assessment infrastructure in the field of chemical measurements is partly linked to the necessary development of metrology in chemistry infrastructure, through the activities foreseen in the present project Fiche that would create an added value and provide sustainability to the previous and future projects in the field concerned.

3.3 Results

- National strategy and plans on metrology in chemistry developed and adopted.
- Process of legal approximation completed – secondary legislation developed and adopted.
- Traceability of measurements in certain ranges in chemistry ensured.
- Supported and facilitated application of quality systems in laboratories.
- Recommendations and plans for an improved organisation of State metrology service as a national metrology institute including staffing, equipment, and funding.
- Analysis of the need of certified reference materials and plans for their production in Lithuania prepared.
- Feasibility study on the computer/information/training system for analytical measurements and analytical laboratories performed,
- Computer/information systems for analytical measurements and training designed.
- Staff of laboratories trained (approximately 100 persons in Lithuania and 12 in Western European laboratories).
- Training programmes for university students (approximately for 100 students) prepared, training performed, information disseminated
- Necessary measurement equipment supplied, installed and operational.

3.4 Activities

The Project will be implemented through one Twinning Arrangement, one Service contract and one Supply contract.

3.4.1 Twinning:

Guaranteed results/expected outputs

- State metrology service reinforced in chemical measurements field.
- Strategy plan on development of metrology in chemistry prepared and adopted.
- Secondary legislation acts prepared or revised.
- Principles of good laboratory practice, ISO/IEC 17025 in the sectors implemented and calibration laboratories ready to be accredited.
- Analysis of training and education systems, development of training schemes and provision of training for the staff of relevant laboratories, control bodies and other related institutions, including industry and enforcement agencies.
- Primary measurement method of the amount of substance developed and validated.

- Traceability and tractability of measurements in chemistry down to industry ensured.
- Proficiency testing schemes and interlaboratory comparisons plans established and operational.
- Detailed technical specifications for the Supply component prepared.

Scope of the twinning (tasks of the PAA)

- A 2-year PAA, providing general management and institutional support in the area of ionising radiation, plus responsibility for overall management of the Project. The expert will be located at the State metrology service. PAA and short and medium term experts will contribute on the following matters on the following items in particular:
  - Development and revision of a comprehensive, coherent national strategy for the metrology in chemistry
  - Establishment criteria for evaluation of proficiency testing schemes
  - Establishment of stricter codes of ethics in evaluation of quality and fitness for purpose of analytical measurements, and the elaboration of an action plan for the enhancement of public awareness of such codes
  - Establishment of support mechanisms for the stimulation and promotion of traceability of analytical measurements
  - Support implementation of the detailed medium-term plan for strengthening Metrology in Chemistry approach, and infrastructure, adequate to provide valid measurements.
  - Development and implementation of a training programme, with a particular focus on the training of the future trainers, as well as analysts, inspectors and auditors, and the training of professional and social partners, especially in fields of health and environment protection, safety at work, food, veterinary and agriculture, forensic and trade, ensuring close relations with European partners.
  - Development of training systems, preparation, translation and provision of documentation.
  - Preparation and implementation of permanent interlaboratory comparisons system in Lithuania.

Profile of PAA

PAA should have the optimal combination of the following requirements:

Fluent written and spoken English, sound knowledge and experience in chemistry, previous experience working in similar institutions and/or projects. Experience of technical assessor for accreditation bodies would be an advantage.

PAA should be a good communicator and motivator, patient, and good organiser.
PAA will be supported by a team of short and medium term experts.

Short and medium term experts team - metrology in chemistry

Short and medium term experts' team operating within the metrology in chemistry area will provide expertise for a total of 12 man/months. The following activities are foreseen:

- Investigation of the existing legislation on metrology to produce a set of proposals to make necessary amendments or development of new legislation
- Proposals on adoption of the national legislation to correspond with the obligations under of community legislation
- Following the identified training needs, and development and delivery of new training programs to staff of State metrology service and related calibration laboratories, universities, covering but not limited to uncertainty calculation, selection and use of certified reference materials, application of quality systems, organisation of PT schemes and interlaboratory comparisons, validation of measurement procedures.
- Evaluation of existing capabilities of calibration laboratories in the relevant fields
- Up-grading of primary and reference methods used in laboratories
- Up-grading of laboratories
- Preparation of detailed technical specification for equipment
- System of training and examinations for personnel of calibration and measurement laboratories on chemistry introduced.

3.4.2 Services

State metrology service will require technical support for the development and implementation of local software systems on the (assessment of) capabilities of the chemical laboratories and for the training of the staff of analytical laboratories, including requirements of GLP (Good laboratory practice), GALP (Good analytical laboratory practice) etc., and calculation of uncertainties of measurements.

3.4.3 Supply

Based on the technical specifications prepared by the Twinning part of the project, equipment for chemistry and computerised information exchange system will be procured. Preliminary equipment list is provided in the Annex 4.

3.5 Lessons learned

Comparing the previous Phare projects in metrology field (respectively, LI 9615 and LI9701), during which certain measuring equipment and training were supplied, it was noticed that training in EU laboratories followed by the supply of the equipment allowed the laboratories to achieve accreditation of their services in a much shorter period, while supply of equipment followed by training was less effective. This may be explained by the fact that training was performed in the existing laboratories, having experienced personnel, necessary environment conditions, equipment and procedures and a very specific know-how, which can not be transferred to a reasonable extent to the local laboratory personnel in laboratories in development process. Therefore, the development and start of introduction of training programmes foreseen in the Twinning part of the project is scheduled in the early stage of the project's implementation. Furthermore, most of the study visits to the respective EU laboratories will be performed before the supply of equipment is completed.

4 Institutional Framework

State metrology service (VMT) under the Ministry of Environment is authorised by the Government of Lithuania to carry out metrology policy, ensure uniformity of measurements, to carry out other scientific, legal and administrative activities. It is also a founder of 5 State Companies – Metrology Centres performing calibration and verification of measuring instruments with a personnel amounting to three hundred people. Furthermore, it supervises

activities of 3 national standards laboratories (Lithuanian Energy Institute, Semiconductor Physics Institute and SC Vilnius metrology centre). As well, it supervises activities of the laboratories, authorised to perform verification of measuring instruments (presently 26 authorised laboratories).
A number of institutions and economic operators (Association of Manufacturers, Association of Calibration Laboratories, Research Institutes etc.) are contributing directly to VMT or through Lithuanian metrology council, where various ministries, research institutes, public and private bodies are represented.

To facilitate smooth running of the project the Steering Committee chaired by the Director of State Metrology Service will be set up. It will involve representatives of interested bodies (mostly out of the listed above).

5 Detailed Budget (in M€)

Project Components	**Investment Support**	**Institution Building**	**Total Phare (=I+IB)**	**National Cofinancing**	**IFI**	**TOTAL**
Twinning		0.70	0.70			0.7
Supplies	0.6		0.60	0.2		0.80
TA	0.25		0.25	0.1		0.35
TOTAL	**0.85**	**0.70**	**1.55**	**0.3**		**1.85**

The Phare amount is binding as a maximum amount available for the project. The ratio between the Phare and national co-finance amounts is also binding and has to be applied to the final contract price.
The national co-financing commitment is a tax-excluded net amount.

6. Implementation Arrangements

6.1 Implementing Agency

PAO: **Zilvinas Pajarskas**, Director of the CFCU

Address: J. Tumo Vaizganto 8A/2
2600 Vilnius
Lithuania

Telephone: + 370 5 212 66 21
Fax: + 370 5 212 53 35
E-mail: info@cfcu.lt

6.2 Twinning

The beneficiary institution is State Metrology Service and the following person is the responsible officer for the Project and the main contact point for the various aspects of the twinning: Osvaldas Staugaitis, tel. +370 5 213 33 49, fax +370 5 216 34 69, e-mail: os@lvmt.lt

6.3 Non-standard aspects

The Practical Guide for the Implementation of Phare, Ispa & Sapard and the Twinning Manual will be strictly followed.

6.4 Contracts

There will be three components in this project:

1. Value of Twinning Covenant 0.7 MEUR.

2. Value of Supply component: 0.8 MEUR, of which 0.2 MEUR is national co-financing.

3. Value of Service component is 0.35 MEUR, of which 0.1 MEUR is national co-financing.

Supply contract will be divided into three lots at least. Final decision will be taken after the needs assessment.

7. Implementation Schedule

Component	Start of Tendering	Start of Project Activity	Project Completion
Twinning	2Q/03	4Q/03	3Q/05
Supply	4Q/03	2Q/04	3Q/04
TA	4Q/03	2Q/04	2Q/05

8. Equal Opportunity

The institution involved in the project execution will observe equal opportunity of men and women in its recruitment and human resources development. The beneficiary will also ensure equal access of men and women to the project activities and results.

9. Environment

The investment components of this Project all relate to Institution Building activities.

10. Rates of Return

The investment components of this Project all relate to Institution Building activities.

11. Investment Criteria

The investment components of this Project all relate to Institution Building activities.

12. Conditionality and sequencing

This project is conditional on

- National Co-financing being available.

ANNEXES TO PROJECT FICHE

1. **Logical framework matrix in standard format**

2. **Detailed implementation chart**

3. **Contracting and disbursement schedule**

4. **Reference to Feasibility / pre-feasibility studies**

LOGFRAME PLANNING MATRIX FOR Project		Programme name and number	LI 2002-X-XX
Developing reliable infrastructure in the fields of measurements in chemistry in Lithuania according to the best EU practices		Contracting period expires 2Q/2005	Disbursement period expires 2Q/2006
		Total budget : 1.85 MEUR	Phare budget :1.55 MEUR
Overall objective	**Objectively verifiable indicators**	**Sources of Verification**	
Traceability, tractability, quality and fitness of chemical analytical and ionising radiation measurements in Lithuania aligned with the relevant Acquis requirements and corresponds best EU practices	Acquis requirements in the relevant fields met by accession. Min. 5 laboratories dealing with chemical measurements accredited (presently two). Min. 5 laboratories giving acceptable measureme quality results (validated through inter-comparisons IMEP, PT) (presently one) Number of acceptable measurement results in the laboratories will increase by 70%	EU Commission's reports Assessment reports of the IME programme European and national proficiency testing schemes Conference reports	
Project purpose	**Objectively verifiable indicators**	**Sources of Verification**	**Assumptions**
• Completion of the process of legal approximation by preparation of secondary legislation and enforcement guidelines covering Sectoral Approach as regards metrology in chemistry. • Developed and implemented national strategies in metrology in chemistry and calibration infrastructure. • Strengthened co-operation between public and private sector actors and research institutes.	• Gaps in legislation eliminated by accession. • 2 reference chemical analysis laboratories approved by the Government by the end of this project.	• Official newspaper of Lithuania • Project reports • Progress report to join EUROMET	Political support from the Government continued.
Results	**Objectively verifiable indicators**	**Sources of Verification**	**Assumptions**
• National strategies and plans on metrology in chemistry developed and adopted. • Process of legal approximation completed – secondary legislation developed and adopted. • Traceability and tractability of measurements in chemistry ensured. • Supported and facilitated application of quality systems in laboratories. • Recommendations and plans for an improved organisation of State metrology service as a national metrology institute including staffing, equipment, and funding. • Computer/information system for analytical measurements designed.	• National strategies and plans developed by 2005. • Necessary legislation adopted and implemented by accession. • 100 people of laboratories' personnel trained locally by 2005. • Courses on metrology in chemistry introduced at min. 2 universities by 2005.	• Project progress report • Reports on the results of interlaboratory comparisons • Official newspaper of Lithuania • Equipment supply documentation	Necessary legal acts adopted by the relevant institutions

• Staff of laboratories trained. • Necessary equipment purchased, installed and operational.	• 100 students trained. • 12 persons trained in the European Union laboratories and other institutions by the end of the project. • 2 interlaboratory comparisons in food and environment sectors run. • 10 seminars run and certificates to participants issued. • Equipment installed in several laboratories and operational.		
Activities	**Means**		**Assumptions**
• Development and revision of a comprehensive and coherent national strategy plan for metrology in chemistry. • Revision of the existing legislation and proposals for the new one. • Strengthening the State Metrology Service. • Evaluation of existing measurement capabilities of primary and reference laboratories. • Up-grading of primary and reference methods and of laboratories, including implementation of quality systems. • Preparation of detailed technical specifications for the equipment to be supplied • Support implementation of the detailed medium-term plan for strengthening metrology in chemistry. • Training needs analysis, development and implementation of training program. • Computer/information system for analytical measurements in the related fields designed and developed. • Preparation and implementation of permanent interlaboratory comparisons system in Lithuania.	PAA (24 m/m) and a pool of short and medium term experts (12 m/m) TA component One supply tender		Successful start and smooth implementation of the project.
			Preconditions • Co-financing available

Annex 2

Detailed Implementation Chart for the Project

Year	2003												2004												2005											
Month	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Twinning																																				
Supply																																				
TA																																				

design

tendering

implementation

Cumulative Contracting and Disbursement Schedule for the Project – Phare Contribution (€ Million)

	2003				2004				2005			
	31/03	**30/06**	**30/09**	**31/12**	**31/03**	**30/06**	**30/09**	**31/12**	**31/03**	**30/06**	**30/09**	**31/12**
Contracting												
• Twinning				0.7		0.7						
• TA						0.25						
• Supplies						0.6						
Total contracting (cumulative)				**0.70**	**0.70**	**1.55**						
Disbursement												
• Twinning				0.26	0.315	0.37	0.425	0.48	0.535	0.59	0.645	0.70
• TA						0.20	0.20	0.20	0.20	0.25	0.25	0.25
• Supplies						0.36	0.36	0.60	0.60	0.60	0.60	0.60
Total disbursement (cumulative)				**0.26**	**0.315**	**0.93**	**0.985**	**1.28**	**1.335**	**1.44**	**1.495**	**1.55**

Annex 4

Reference to Feasibility/Pre-feasibility studies

In the field of chemistry, development and implementation of the primary and reference measurements and traceable measurement standards, as the main direction in assurance traceability of the chemical measurements, is identified in the European Commission documents on Metrology in Chemistry, Report EUR 18405 EN and 19074 EN, and activities proceeding the Metrology in Chemistry, Status Report Lithuania.

During development of the list of the equipment the assumptions were made on the following needs: compatibility for analysis of hard samples by laser atomisation, for analysis of organics containing samples, for small samples, need of implementation of reference measurements in molecular chemical analysis by means of liquid chromatography, and need on strengthening of measurement capabilities in reference mass spectrometry laboratory.

INDICATIVE LIST AND BUDGET BREAKDOWN OF EQUIPMENT

No	Title of Activity	Indicative Budget (kEUR)
1	Organic 'High resolution mass spectrometer" HRMS	300
2	HPLC liquid chromatograph with mass detector and associated equipment	200
2	Laser head to ICP MS "Element-2" with associated equipment	170
3	Strengthening and updating of reference mass spectrometry laboratory (Organic and small sample introduction system to ICP MS, fume cupboard, water distiller, ultrasonic wash tank, reference pipettors, pressure vessels HF 50, electronic balances, sample mill, detectors, compatibles etc.)	80
4	Provision of certified reference materials to enable interlaboratory comparisons, validation of measurement procedures in selected laboratories	20
	Total	**770**

Improvement relating to computer information exchange system		
No	**Title of Activity**	**Indicative Budget (kEUR)**
1	Computers and servers	**30**