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LABORATORY ACCREDITATION IN THE NEW MEMBER STATES

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ABSTRACT

The number of laboratories worldwide accredited according to ISO 17025 has steadily increased in the last ten years. These laboratories are from different institutions – universities, research institutes and routine laboratories – governmental agencies or private companies. The aim of this work is to highlight the present situation of testing and calibration laboratories in the new Member States of the EU – Bulgaria and Romania.

Data on accredited laboratories are taken from the Web sites of accreditation bodies signatories to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement – The Executive Agency Bulgarian Accreditation Service (BAS) and the Romanian Accreditation Association (RENAR). A distinction between laboratory types is made and a correlation between population, gross domestic product and total number of accredited laboratories is presented.

1. Introduction

Reliability and comparability of measurement results is only achieved if the highest demands are pursued towards the laboratories they are obtained in. This is only possible if the laboratories can demonstrate technical competence according to the requirements laid down in ISO/IEC 17025:2005 (E) [1]. Regulations in the field of laboratory accreditation do not differ between the laboratories seeking accreditation. Regardless of the number of methods or the number of parameters subject to accreditation, the laboratory should cover all the requirements of ISO/IEC 17025:2005. In this respect small and large private laboratories undergo the same

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assessment by the national accreditation bodies. On the other hand, the university laboratories and the laboratories of research institutes have somewhat different specific activities. They require flexibility of the decision making in the laboratory management. Such an experience in the European Union (EU) [2 – 4] and worldwide [5, 6] is of paramount importance when creating and accrediting such a laboratory. Introducing concepts and practices laid down in the quality management systems also benefits other activities – not only provision of tests or calibrations, but education and research [5, 6]. Furthermore, laboratories of such institutions might fulfill a demand that is unmet by commercial laboratories in the country, e.g. consultancy, expert reports or provision of solutions for specific tasks. In the new Member States, only a small fraction of the accredited laboratories are in universities and research institutes.

2. Discussion

The Treaty on the European Union states that any European country may apply for membership if it respects the democratic values of the EU and is committed to promoting them. The first step for the country is to meet the key criteria for accession, referred to as 'Copenhagen criteria'. The EU operates comprehensive approval procedures that ensure new members are admitted only when they can demonstrate they will be able to play their part fully as members.

Political and social changes in Bulgaria and Romania prior to their accession to the European Union in the last decade, necessitate new national regulatory requirements, especially in the field of environment preservation and public health.

The operational programmes are based on the goals and priorities of EU environmental policy and reflects the international environmental commitments that Bulgaria and Romania have undertaken, as well as both the commitments undertaken to the EU in the pre-accession period, and the specific national interests. Harmonization of some laws and national regulations, especially in the field of environment protection, has required that analyses related to environmental impact be carried out by accredited laboratories, e.g. analytical laboratories must be accredited in order to undertake analysis of drinking water and wastewater in Bulgaria [7 – 9]. This is the reason private and government laboratories to be recognized as routine laboratories.

Data of the World Bank for 2015 [12] indicates gross domestic product (GDP) just above 3 times higher for Romania compared with Bulgaria, which is consistent with the population difference of the two countries [13] (Tab. 1).

Table 1. Number of accredited testing, calibration and medical laboratories in the new Member States

Country	Number of accredited testing laboratories [10, 11]	Number of accredited calibration laboratories [10, 11]	Number of accredited medical laboratories [10, 11]	GDP for 2015 ($\times 10^6$ US\$) [12]	Population 2017 [13]
Bulgaria	273	23	4	50,199	7,045,259
Romania	514	38	914	177,954	19,237,513

But similarities stop here. The data from the Web sites of accreditation bodies signatories BAS [10] and RENAR [11] reveals that total number of testing laboratories in Romania is only 1.9 times higher. The difference in the number of calibration laboratories is somewhat the same – 1.7 times higher in Romania. For both Member States the number of the accredited laboratories in universities is relatively small – 6 and 5, respectively for Bulgaria and Romania (Tab. 2).

Table 2. Distribution of the accredited laboratories in the new Member States

Country	Number of accredited testing laboratories [7, 8]	Number of accredited calibration laboratories [7, 8]	Number of accredited medical laboratories [7, 8]
Bulgaria	273	23	4
University testing laboratories	6	1	2
Research and development laboratories	16	2	0
Private or governmental laboratories	241	20	2
Romania	514	38	914
University testing laboratories	5	0	0
Research and development laboratories	40	3	12
Private or governmental laboratories	469	35	902

Many of these laboratories have valid accreditation in more than just one field of testing, or comprise more than one laboratory. This is the case with the author's Laboratory for Water Analysis, which is a part of the University Construction Testing Laboratory along with the Laboratory for Construction Materials Testing and the Laboratory of Soil Mechanics and Foundation Engineering [14, 15]. One of the reasons for such a small percentage is that these laboratories are in fact research and development laboratories and provision of testing results and/or calibrations for customers is an additional service. On the other hand, the general perception is that the implementation of a quality management system is bureaucratic and expensive. The management boards rely on achieving credibility and national recognition through the scientific reputation of the universities or by the number and quality of publications. The same is valid for the calibration and medical laboratories – only one accredited calibration laboratory and two medical laboratories in Bulgarian universities and none in Romania.

The number of accredited research and development laboratories in Bulgaria and Romania is similar and relatively small compared to the total number of accredited laboratories – 6 and 8% respectively in the field of testing and 9 and 8% respectively in the field calibration. The results of this survey are consistent with published data in a recent paper by Grochau et al [16] in the Americas.

There are twelve accredited Romanian medical laboratories and none in Bulgaria. The finding is somewhat alarming and consistent with the total number of accredited medical

laboratories in both the member states – there are only four accredited medical laboratories in Bulgaria, compared with the staggering number of 914 medical laboratories in Romania. One of the reasons for such a huge number in Romania is that most of general practitioners own or have an accredited medical laboratory at their disposal. The regulations in Bulgaria do not require such things. Maybe it is time for the regulators to acquire the good practice and implement more strict control for the results obtained in the medical laboratories aiming at better diagnostics of illness and ultimately better public health.

3. Conclusion

Usually the academic staff is involved in all the activities of the testing and calibration laboratories, because of their experience and competence, which often exceeds the demands. This is mainly the reason why the experience of such laboratories is sought by industry, since these laboratories are fulfilling a demand that wasn't satisfied by commercial laboratories. In this respect the new Member States – Bulgaria, Romania and the recently associated Croatia (as of 1 July 2013) should encourage laboratory accreditation in universities, where the scientific potential is concentrated. The task can be achieved by introducing specific legislation requirements, e.g. analysis and product certification should only be by accredited laboratories; by funding (national and international) for university laboratories seeking accreditation; or by establishing inter- and intra-university frameworks. Only then, the university laboratories will stop pursuing accreditation mainly due to the request of external clients.

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АКРЕДИТИРАНЕ НА ЛАБОРАТОРИИ В НОВИТЕ СТРАНИ ЧЛЕНКИ

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***Ключови думи:** ISO/IEC 17025, лабораторно акредитиране, университетски лаборатории за изпитване, страни членки*

РЕЗЮМЕ

Броят на акредитираните лаборатории според ISO 17025 се е увеличил през последните десет години. Тези лаборатории са от различни институции – университети, научни институти и рутинни лаборатории от правителствени агенции и частния сектор. Целта на статията е да покаже текущото състояние на лабораториите за изпитване и калибриране в новите страни членки на ЕС – България и Румъния.

Данните за лабораториите са получени от акредитиращите агенции – Изпълнителна агенция Българска Служба по Акредитация (ИА БСА) и Румънската Асоциация по Акредитация (RENAR). Представени са разликите между видовете лаборатории и е направена корелация между населението, brutния вътрешен продукт и броя на акредитираните лаборатории.

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