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Incompatibilities analysis in the accredited laboratory

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ABSTRACT

Purpose of the presented paper aimed at motivating the necessity of the accreditation of research and standardising laboratories as factors deciding about the competitive advantage of those organisations on the European Union market.
Design/methodology/approach used for the research has covered the analyses of results of internal and external audits conducted in one of Polish accredited laboratories and estimation of the incompatibilities occurred.
Findings of the carried out research are as follows: number and character of incompatibilities, which are exposed during internal and external audits, reflect size of organisation, where the management system is implemented, phase of implementation as well as the time of functioning.
Practical implications refers to any organisation which has quality management system implemented as well as to any accredited laboratory using internal audits as an element of continuous improvement and treating incompatibilities not as something disqualifying the investigated area, but as an supporting element.
Originality/value of the presented paper belongs to the methodology comprising the usage of internal audits' results - proved incompatibilities - as a tool for obtaining and assuring the confidence in the management system.
Keywords: Accreditation body; Accredited laboratory; Standardising laboratory; Incompatibilities analyses

1. Introduction

One of the factors deciding about the competitive advantage of the research laboratories on the market is the quality of the delivered services, which influences directly on the success of these organisations [1-4].

Qualitative demands, sharply rising competition as well as the increase of the expectations concerning the technical competences make the laboratories search the different solutions in the range of the improvement of management, they contribute significantly to seek for the new ways of confirming the abilities in the range of provided services, as well [5-8].

Even the laboratories with the long-lasting experience, face a necessity of submitting objective evidence of their competences as well as confirming the reliability of carried on research [9-11].

One of the ways to fulfil the mentioned demands is the laboratory accreditation together with the simultaneous implementation of the quality management system according to PN-EN ISO/IEC 17025:2005 standard guidelines [12].

First of all, the accreditation formally confirms the competences of the particular laboratory, improves the management system, and as the following - raises the efficiency and effectiveness of its functioning.

Obtaining the accreditation is connected also with the possibility of mutual recognition and comparison of the research results, even on

international level, by the elaborated standards as well as the guidelines concerning the activity of the other research laboratories.

2. Laboratory research and research laboratories

In the time of globalisation and the free flow of goods and services in the European Union the research laboratories look for the chances for entering, both Polish and Union market, in two areas related to [13]:

- the procedure of launching the goods on the Union market,
- national regulations (issued decrees and acts).

The voluntary area is connected with the system of the compatibility estimation, which has to guarantee the admitting to trading on the homogenous market of the European Union exclusively for the goods fulfilling the demands of the European Union directives, particularly directives of so-called "new approach" [13-16].

Fulfillment of these conditions aims at the elimination of the threat caused by goods posing a risk to life and the health of the consumers, as well as to the natural environment and next - creation of the conditions to the reliable estimation of the goods and the processes of their manufacturing by the qualified organisations, and as the result - the liquidation of the technical barriers in international trade [13-16].

System of the compatibility estimation consists of [13-16]:

- horizontal acts,
- national decree transposing the European Union,
- own national decree.

The system finds the secure in the Act on the system of the compatibility estimation. According to the Act, each manufacturer before launching the good on the market is obliged to conduct the estimation of the products' compatibility [13-16].

As the first step, every manufacturer has to determine which of the Polish legal documents implementing directives are connected with the particular good and to adjust to the requirements and procedures stated in the act. Manufacturer is also bound to carry the analyses of the threats posing a risk by the good to eliminate or reduce it [13-16].

The majority of the directives require from the manufacturer the declaration of conformity, in which he confirms that the good is consistent with principle requirements. Performance of all the demands referring to the article and all the procedures of the conformity estimation allow the manufacturer to mark the product CE (fr. Conformité Européenne) [13-16].

The inseparable element of such estimation is the necessity of carrying out the research of the goods either independently or by the third side, it means - by the accredited laboratory [16].

The obligatory area concerns the national acts and decrees, which impose in determined cases the obligation of submitting the results of research from the accredited laboratories.

Such provisions are the part of the following [17-21]:

- Act on building articles,
- Act on atomic low,
- Regulation of the Economy and Labor Ministry on the criteria and procedures permitting for the storage of the waste products on the damp dedicated for the particular waste,
- Regulation of the Economy Labor and Social Policy Ministry on the requirements determining issuing of the authorisation for legalising of the newly-defined kinds of the measuring equipment,
- Regulation of the Health Care Ministry on the researches and the measurement of the health harmful factors in the work place, where the mood, kind and the frequency of execution the tests and measurements of the health harmful factors in the work place is defined.

Units functioning in the area of the laboratory services can be classified accordingly to the following criterions (Fig.1) [22]:

- organisational and legal status,
- status of services,
- legal status of research results,
- subject of research.

Each laboratory can fulfill more then one criterion simultaneously [22].

The basic document, in which one presents the classification of laboratories accordingly to the legal status of research results, is the Act on the system of the compatibility estimation which distinguishes laboratories [22,16]:

- accredited
  - recognised by accreditation body as having the proprietary competences of certificating unit, inspection unit as well as laboratory conducting determined activities,
- authorised
  - classified by minister or the manager of central administration, adequate to the object of the compatibility estimation, as unit or laboratory announced to the notification process,
- notificated
  - authorised, announced to the European Commission and European Unions Member States as adequate to pass the procedure of the compatibility estimation.

General classification of the research laboratories due to the range of research has been made by Polish Accreditation Centre (table 1) [23].

3. Accreditation and accreditation bodies

Accreditation according to the terminological standard PN-EN ISO/IEC17000:2006 is „third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessments task" [24].

According to the Act on the system of the compatibility estimation „accreditation has to be understood as the recognition by the accreditation body of the competences of certificating unit, inspection unit as well as laboratory carrying out particular activities" [16,24].

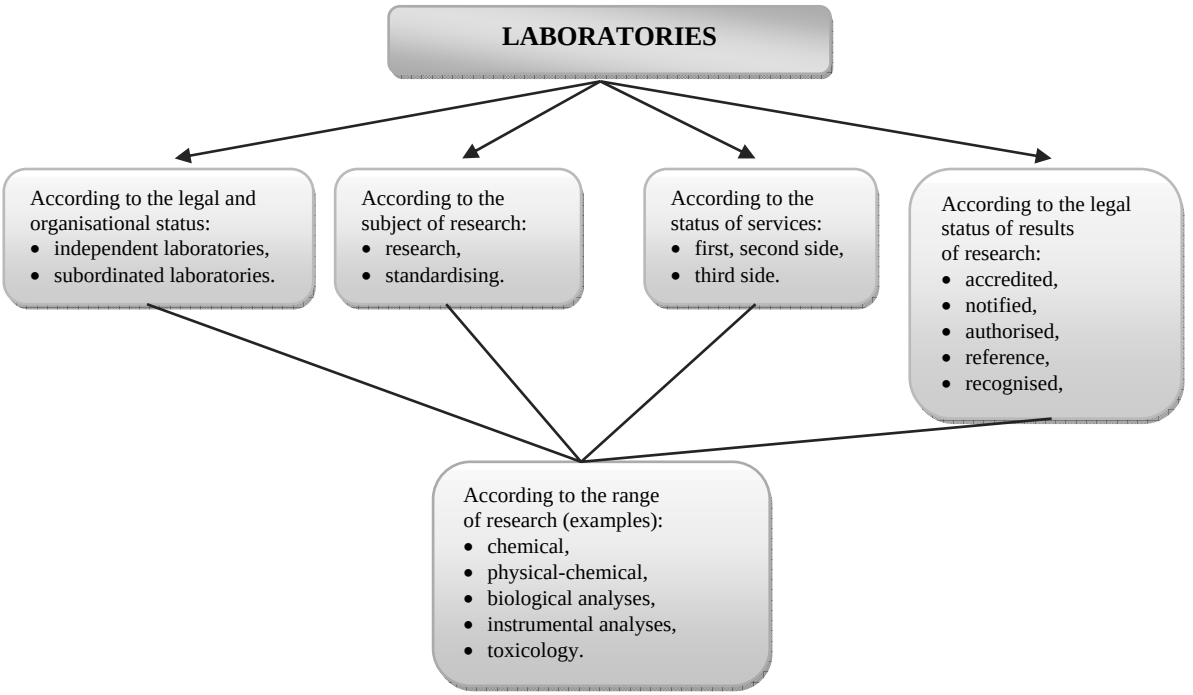

Fig.1. Scheme of laboratories classification [22]

Table 1.
General classification of the research laboratories in accordance with range of the conducted research [23]

RESEARCH LABORATORIES		
acoustics	sampling	geotechnics
ballistics	electromagnetic field	diagnostic microbiology
exploitation safety	ion radiation	resistance to mechanical and climatic threats
biology	radiation	fire resistance
legal expert opinion	general environment	optoelectronics
exploitation	physical and mechanical properties	organoleptics
electronics	chemistry	work environment
electrics	medical diagnostics	non-destructive testing
electromagnetic compatibility	doping	IT technologies
corrosion	vibration	physical properties
materials science	photometry	physical and chemical properties
mechanics	functionality	geometrical dimensions
microbiology	geology	

According to the Act on the system of the compatibility estimation „accreditation has to be understood as the recognition by the accreditation body of the competences of certificating unit, inspection unit as well as laboratory carrying out particular activities" [16,24].

According to the PN-EN ISO/IEC 17000:2006 standard „accreditation body is an authoritative body that performs accreditation; the authority of an accreditation body is generally derived from government". Accrediting body should act according to the demands of EN ISO/IEC 17011:2004 standard (in Poland PN-EN ISO/IEC17011: 2005 (U)) [24,25].

Accreditation bodies form a union both in regional and international organisations, for which the vital aim is [13-15]:

- creation and maintenance of the uniform system of accreditation being the base for elimination of the technical barriers in trade,

- recognition of certificates and reports issued by the accredited units and laboratories,
- supporting the implementation of international standards in the range of accreditation,
- building the confidence in the frames of multi-lateral agreements.

International organisation comprises accreditation bodies in the range of [13,26]:
- units certifying quality management systems,
- units certifying environmental management systems,
- units certifying goods

is IAF Multilateral Recognition Arrangement.

ILAC Mutual Recognition Arrangement includes accreditation bodies in the range of [13,26]:
- research laboratories,
- standardising laboratories.

EA MLA (European Cooperation for Accreditation Multilateral Agreement) organisation is an institution, which gathers European accreditation bodies having the right to accredit in all areas connected with compatibility estimation and including:
- standardising,
- research,
- monitoring,
- certifying of quality management systems,
- certifying of goods,
- certifying of persons,
- certifying of environmental management systems (EMS) and EMAS.

EA is a regional group represented in the international organisations, just like IAF and ILAC, and it's a signatory of agreement on mutual admission IAF MLA/ILAC MRA. Exemplary chosen accreditation bodis gathered in the frames of EA has been shown on Fig. 2 [26].

4. Accredidation demand for research laboratories

Polish Centre of Accreditation defined the accreditation demands for the research laboratories in the following documents [12,23]:
- PN-EN ISO/IEC 17025:2005. The general demands concerning the abilities of the research and standardising laboratories,

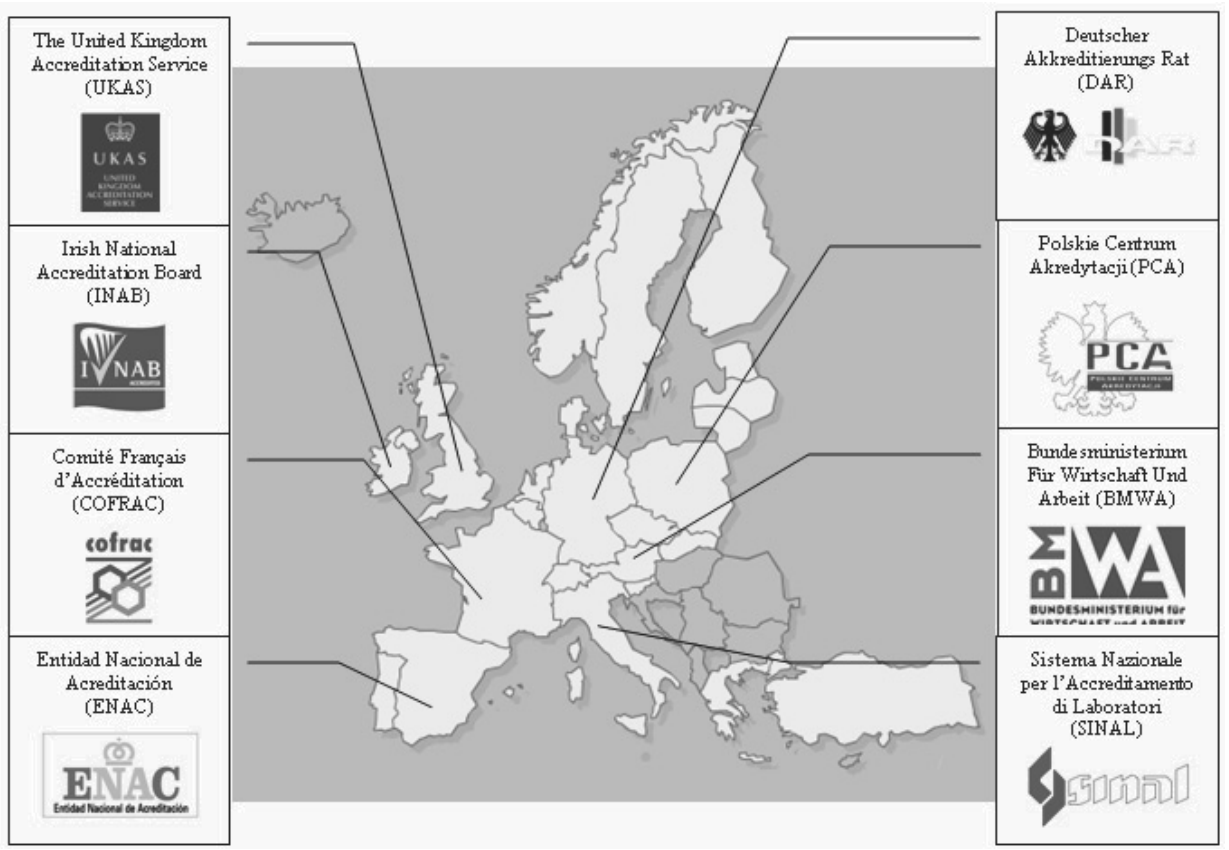

Fig. 2. Chosen accreditation bodies in the European Union [26]

- DA-01. The description of the accreditation system,
- DA-05. PCA policy on taking advantage of the proficiency research / comparisons among laboratories in the processes of accreditation and laboratories supervision,
- DA-06. PCA policy concerning the assurance of measuring cohesion,
- DAB-06. Obligatory participation in the research of proficiency,
- DAB-07. The accreditation of research laboratories. Detailed demands,
- PN-ISO 10012-1:1998/Ap1:2001. The demands concerning the assurance of the measuring equipment. Quality System of confirming the metrological measuring equipment compatibility.

The most important document being a base for the estimation of laboratory is PN-EN ISO/IEC 17025:2005 standard and its main aim is to standardise the requirements concerning each laboratory applying for the accreditation and proving that [12]:

- employs the quality system,
- is competent,
- obtains the credible results of the carried out research.

Fulfilling the requirements stated in the above-mentioned standard is strong base to obtain the certificate of accreditation.

PN-EN ISO/IEC 17025:2005 standard is being accepted as a universal document, due to the basic requirements which should be fulfilled by any laboratory regardless of [12]:

- kind and character of services,
- methods of research and standardising,
- organisational structure,
- size of laboratory.

Another advantage of PN-EN ISO/IEC 17025:2005 standard is similarity to the structure and requirements of PN-EN ISO 9001:2001 standard, that's why point 1.6 includes the statement: "If research and standardising laboratories fulfill the requirements of PN-EN ISO/IEC 17025:2005 standard then research are made in the management system being also compatible with the rules of ISO 9001 standard". The statement is so important because possessing by the laboratory the certificate of conformity with PN-EN ISO 9001:2001 standard is not equivalent with having the accreditation certificate and it doesn't confirm the competences of laboratory [12,27].

The main advantage of PN-EN ISO/IEC 17025:2005 standard is its readability and clearly specified requirements classified into two groups - requirements connected with management system and technical requirements [12].

5. Own research

The research has been conducted in one of the Polish accredited research laboratories. The Laboratory is a part of research and development unit and therefore - the national unit having legal personality, classified to the sector of public finances and having organisational status.

Algorithm of accreditation in the Laboratory has been shown on Fig. 3.

Fig. 3. Diagram of accreditation in the Laboratory

The system implemented in the laboratory demands supervision, monitoring, verifying as well as continuous improvement according to the basic requirements of: PN-EN ISO 9001:2001 standard, PN-EN ISO/IEC17025:2005 standard as well as accreditation demands of the Polish Accreditation Centre.

Their realisation is done by:

- planning the qualitative aims,
- estimation of the goods and processes,
- internal audits,
- corrective and preventive actions.

One of the basic tools applied for system estimation in the Laboratory is internal audit. The main aim of each audit is to answer the three basic questions:

- do the accepted by the organisation settlements concerning quality permit in fact to attain the intended aim?
- are the accepted settlements in fact realised?
- are the attained results of activities in agreement with planned settlements?

From the moment of implementation of the quality management system, the analysed Laboratory has been the subject

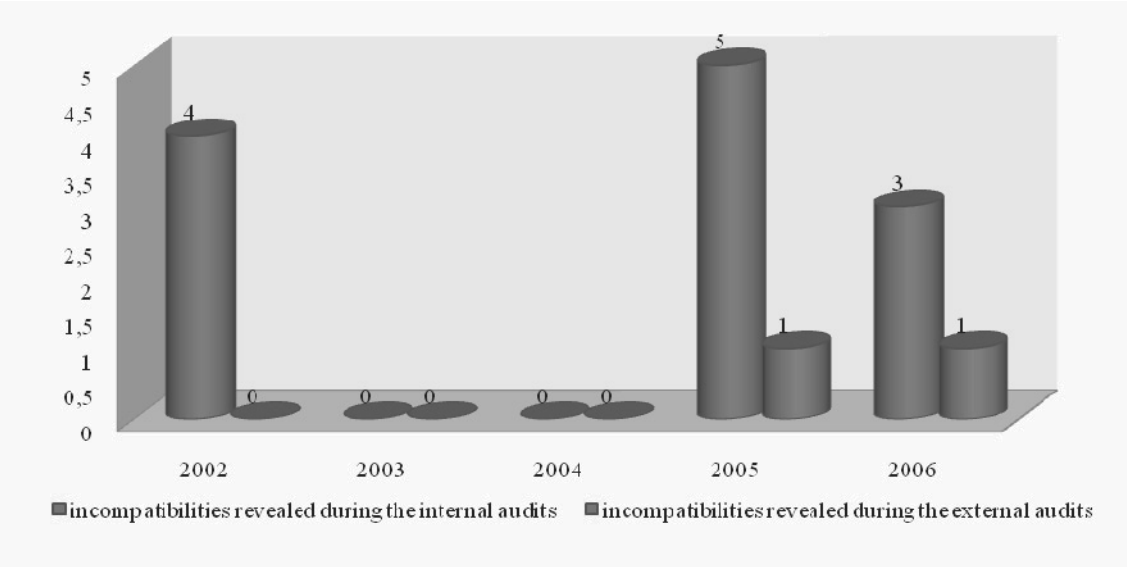

Fig. 4. The compilation of the number of incompatibilities that have been proved in the Laboratory during internal and external audits

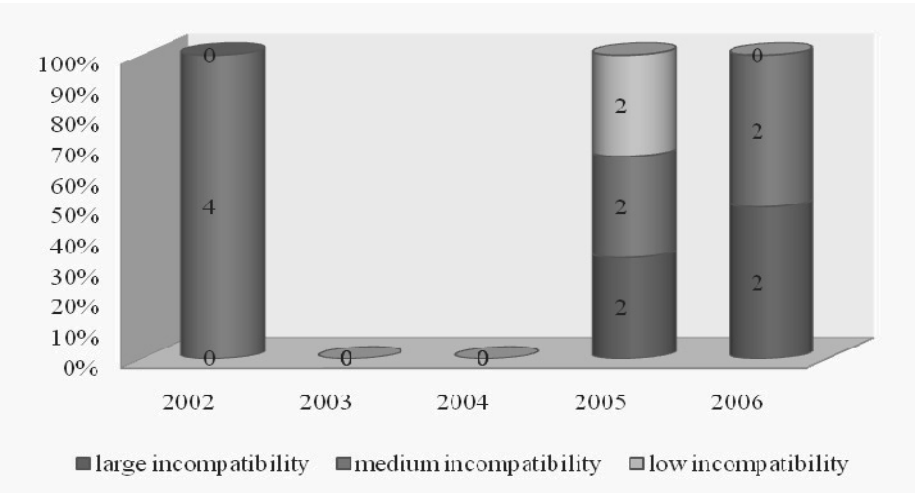

Fig. 5. The character of incompatibilities that have been proved in the Laboratory

of audit research. During the 6 years the Laboratory has passed 11 audits.

The number of incompatibilities proved in the Laboratory within the time of 6 years is presented on Fig. 4.

Great differentiation in the number of incompatibilities one can interpret as follows:

- during the first year of the system functioning in the Laboratory the proved incompatibilities have been connected with the lack of experienced staff in the scope of documents management and apparatus,
- in the years 2003 and 2004 in the Laboratory no incompatibilities have been proved, what can point out the correct implementation of the system as well as the improvement in the range of supervision over the documents and apparatus,

in the years 2005 and 2006, the incompatibilities have been proved again, what can be connected with the implementation of the next system in the Laboratory as well as requesting the accreditation in the Polish Accreditation Center. During the mentioned period of time, the first internal audits have been passed proving singular incompatibilities.

The most often proved incompatibilities concerned the control of documents and recordings as well as the control measuring and research equipment, which is the most common type of incompatibilities in every organisation.

However, the status of each incompatibility depended on its influence on the systems functioning as well as on the quality of the carried out research.

The character of the incompatibilities as well as areas, in which these have been identified, are presented on the drawings 5 and 6.

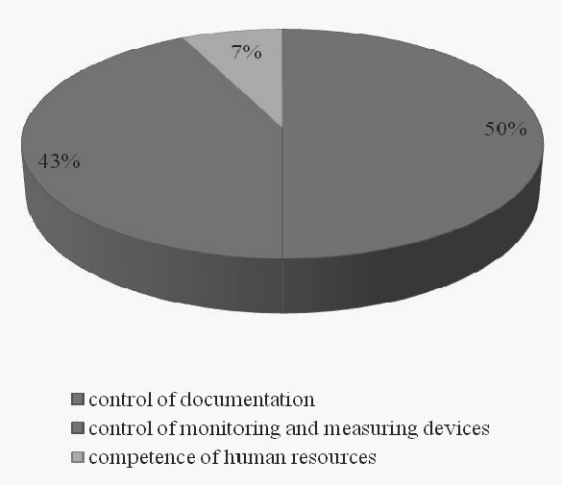

Fig. 6. Areas, in which particular incompatibilities have been identified

6. Conclusions

Implementation of the system based on PN-EN ISO/IEC 17025:2005 standard is a ground for laboratory accreditation, what guarantees its participation in the European conformity estimation system. Main aspects deciding about undertaking of the decision on laboratory accreditation are in Poland connected with Act on the system of compatibility estimation.

System implemented and functioning in the laboratory needs to be supervised, monitored and continuously improved; these are main requirements of the standard PN-EN ISO 9001:2001 and PN-EN ISO/IEC 17025:2005 as well as accreditation requirements of Polish Accreditation Center. One of the forms of their realisation, used in the analysed Laboratory, is internal audit.

In the Laboratory audits are perceived as positive actions and, when become exposed, are not treated as something disqualifying the investigated area, but as a supporting element, it means - a tool for obtaining and assuring the confidence in the management system.

Number and character of incompatibilities revealed during internal and external audits have reflected size of the organisation, where the management system had been implemented, phase of implementation as well as time of functioning. Incompatibilities reflected in the Laboratory have confirmed such an expanded structure of the organisation, the part of which the Laboratory is. Incompatibilities connected with control of monitoring and measuring devices and control of documentation have been the most often ones to occur.

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