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Flexible scopes of accreditation at the Conformity Assessment Body and Testing Laboratories

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Abstract:

An accreditation of testing laboratory as well as of the certifying body of products is always based on the fixed scope of accreditation which precisely and explicitly establishes the activity area of these units. As the time was passing, it was noticed that the fixed scope of accreditation is so restrictive that it limits an application of new methods, which could be added to the laboratory scope of accreditation and in the case if the certifying activity makes a product assessment, based on the latest editions of standards and legal regulations, impossible. In 2008, the above mentioned organizations, obtained a possibility to react to customers` needs through modifying or including additional activities to their scope of accreditation without a necessity of informing the supervisory body each time. This possibility resulted from the fact that competences of these organizations had been assessed by the supervisory bodies before. In both cases a possibility of applying the flexible scope of accreditation caused an increased responsibility of the organization due to a necessity of the system maintenance, which could control the changes. At present the flexible scope of accreditation is more and more commonly applied because it gives measurable benefits to all the accredited bodies – it enables a quick reaction to customers` expectations and it creates possibility of applying new methods. The article presents possibilities of applying flexibility in the accreditation of the laboratories and certifying bodies of products, based on the example of the KOMAG Institute.

Streszczenie:

Akredytacja laboratorium badawczego, jak również jednostki certyfikującej wyroby, zawsze oparta jest na stałym zakresie akredytacji, który precyzyjnie i jednoznaczne ustala obszar działania tych jednostek. Z upływem czasu zauważono, że stały zakres akredytacji jest na tyle restrykcyjny, że ogranicza nowe metody, które mogłyby zostać dodane do zakresu akredytacji laboratorium, a w przypadku działalności certyfikacyjnej uniemożliwia ocenę wyrobu w oparciu o najnowsze wydania norm lub przepisów prawa.
W 2008 roku umożliwiono wspomnianym jednostkom, reagowanie na potrzeby klientów poprzez modyfikowanie lub włączanie dodatkowych działań do swojego zakresu akredytacji bez konieczności każdorazowego informowania jednostki nadzorującej. Możliwość ta wynikała z faktu, że kompetencje tych jednostek zostały już wcześniej ocenione przez jednostki nadzorujące.
W obu przypadkach możliwość zastosowania elastycznego zakresu spowodowała większą odpowiedzialność jednostek z uwagi na konieczność utrzymania systemu, który mógł kontrolować zmiany. Obecnie elastyczny zakres akredytacji jest coraz powszechniej stosowany, gdyż przynosi wymierne korzyści wszystkim podmiotom akredytowanym - umożliwia szybką reakcję na oczekiwania klientów i stwarza możliwość zastosowania nowych metod. Artykuł przedstawia możliwości, zastosowania elastyczności w akredytacji laboratoriów oraz jednostek certyfikujących wyroby na przykładzie Instytutu KOMAG.

1. Introduction

An accreditation is a formal recognition of technical competences of organizations, being active in the conformity assessment scope, by the authorized domestic body and thus it is an impartial proof that they act according to the best practice.
According to the ISO/IEC 17000 Standard *"the accreditation it is third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks"* [1].

The accreditation is connected with a possibility of mutual recognition and comparison of the results of conducted tests and of conformity assessment on the international level through an implementation and application of international standards as well as guidelines.

In the European Union the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 [2], which aims at a regulation of legal frames for an accreditation process, was edited to guarantee an activity of all the organizations at the same level. The main objective of the Regulation is: to ensure the legal basis in relation to the accreditation and to ensure a uniform system of the market surveillance, i.e. a control of products introduced to the market, and in consequence – a uniform level of consumers` protection.

The mentioned Regulation strengthens the EU policy in the scope of accreditation through the following principles:

- each Member State shall appoint a single national accreditation body,
- national accreditation body has the appropriate financial and personnel resources for the proper performance of its tasks.

In Poland the accreditation process is voluntary and available to all the organizations and the body, authorized for conducting accreditation processes, is the Polish Centre for Accreditation (Polskie Centrum Akredytacji (PCA) [3].

The condition of granting an accreditation is a statement that the testing laboratory or conformity assessment body, applying for an accreditation, meets all the accreditation requirements, however the accreditation process itself consists in an assessment of a given organization both in terms of its competences in the technical scope as well as in the scope of the functioning management system.

The assessment effect includes an edition of the certificate together with the scope of accreditation by the authorized accreditation body**.** This certificate is an authorization within specific conformity assessment activities for which accreditation is sought or has been granted.

Each accreditation system is based on the fixed scope of accreditation, which enables an exact description of accredited activities and thus it introduces a certain restrictiveness in its management. This restrictiveness consists in a lack of possibility of an independent modification or addition of new areas of activity in which the organization wants to quote the granted accreditation [4].
Summing up, the scope of accreditation is a general description of technical competences, presented in a form of a specification of scopes of activity in connection with objects/ groups of objects.

In the case of conformity assessment body, the scope of activity included:

- name of product / product group,
- name of product certification schemes and/or acronym together with the edition identification,
- normative documents and/or legal requirements in relation to which the products are certified,
- the ICS identification for a product or a group of products.

In the case testing laboratories the scopes of accreditation consist of uniform thematic blocks (domains of tests-objects- technologies- methods) in which the following information is given [5]:

- testing area,
- product of materials - objects of tests / groups of objects / tested materials or products,
- test method (method, international standard, validated laboratory-developed methods),
- range of measurement,
- documented laboratory-developed methods and procedures and standard methods use.

The documents called in the scope of accreditation can be domestic, regional and international standards, Polish and European Union legal regulations, codes of conduct, generally available publications and author`s testing procedures or certification programmes.

At the moment of applying for an accreditation both the certifying body of products, as well as testing laboratories decide themselves about their scopes of accreditation, mainly taking into account such factors as:

- a customer`s interest in an assessment of products,
- personnel's competences,
- a knowledge of testing methods,
- technical possibilities.

In the case of the fixed scope it is not possible to extend it quickly, introducing new or modified methods, even if the laboratory competences in a realization and validation of similar methods have already been assessed by the accreditation body. Indeed, the application for an extension of the scope of accreditation can be submitted any time, however the time – consumption of the whole process may in reality make a quick reaction to the customer`s expectations impossible.

Therefore at the moment of establishing and approving the scope of accreditation, organizations take into consideration real possibilities and in general they do not apply for accreditation "for the future".

Such a situation caused an elaboration of the flexible scope of accreditation.

The scope of accreditation for testing laboratories can inhibit, in certain cases, their quick response to customers` needs, if the scope is too rigid with regard to the modification of test methods and the introduction of new ones using the same measurement principles. Document EA-2-05 published by the European Cooperation for Accreditation describes possibilities to allow flexibility in accredited laboratories [6].

Since then initially only in the environment of testing laboratories two terms have been used:

- **fixed scope of accreditation** - which means that the laboratory cannot modify the methods included in its scope. An introduction of modified methods to the scope of accreditation can take place no sooner than after an independent assessment conducted by the authorized accreditation body
- **flexible scope of accreditation** - which allows testing laboratory to make changes in methodology and other parameters which fall within the competence of the laboratory as confirmed by the accreditation body. The condition, enabling to change the scope for flexible one, is a positive assessment of laboratory competences, not only in the scope of conducting tests but also managing the activities within the framework of the flexible scope.

2. Management system features for laboratories seeking flexible scope on the example of the KOMAG`s Testing Laboratories

The most essential element, enabling an activity of accredited testing laboratory in the flexible scope, is an adaptation of the laboratory management system to the new requirements.

The management system based on the EN ISO/IEC 17025 standard should in particular regulate such issues as [7]:

- principles of cooperation with a customer, a review form of enquiries, offers and contracts, (contract review process confirms and informs the customer/enquirer that a request is within the limits of its flexible scope),
- the responsibilities for the management of the flexible scope and for each set of activities,
- a description of technical activities in the field of:
  - personel,
  - testing methods and their validation,
  - measuring instrumentation,
  - management.

The element, distinguishing the laboratories having the flexible scope of accreditation, includes an obligation of elaborating and continuous up-dating of the *List of accredited activities conducted under*

their flexible scope. This List should contain information as a minimum to that detailed in section 7.8.3 a-h of the ISO/IEC 17011:2017 [4].

The laboratory itself manages the List. The purpose of the List is to provide up-to-date transparency of the application of the flexible scope and shall be made publicly available.

Up–dating of the „List" results exactly from the management of activities within the framework of the flexible scope and may occur only and exclusively after an appropriate execution of all the planned stages of technical activities.

The testing laboratory which has the flexible scope in its accredited technical domain or area has a possibility [8, 9]:

- to use up-dated, standards methods,
- to adopt successive revisions of standard methods, provided that they are based on previously demonstrated technical competence,
- to apply modified methods of its own,
- to implement new methods of its own and standard methods.

A determination of flexible scope in tests can occur in relation to:

- samples, objects of tests, materials or products tested,
- tested features, properly measured along with range of measurement,
- a realization of testing procedures, standard specification: identifying the procedure used in tests, measurement techniques used,
- associated testing and measurement uncertainties.

However, it should be highlighted clearly that the testing laboratory, having such a big authorized capacity to act, can introduce new measuring or testing techniques in the framework of flexible scope of accreditation only after an assessment of competence and technical possibilities conducted by the accreditation body.

Three accredited testing laboratories, functioning in the structure of the KOMAG Institute, act on the basis of flexible scopes [10]. The experience, gained from the ten-year period of the applying such scopes, is a proof that such a system is efficient and useful.

These laboratories can decide themselves about an implementation of an additional testing method or about its modification within the limits determined by the scope and after having fulfilled all the requirements described in the management system.

In the KOMAG`s testing laboratories their own methodologies and procedures, which guarantee a proper management of flexible scope, were elaborated and implemented. These methodologies have, among others the following objectives:

- a use of the agreement survey procedure, taking into consideration an aspect of applying the accredited flexible scope,
- regular contacts with a customer and conveying information connected with the flexible scope,
- an assessment of technical and competence abilities of the laboratory for a realization of testing service,
- a continuous up-date of the "List" after a proper execution of appropriate technical activities and an introduction of the documents describing the modified or new testing methods,
- conducting analyses and undertaking corrective measures in the cases when in the result of a validation process it will be stated that the laboratory is not capable of issuing competent reports.

Each new need in the scope of realizing a testing service is analyzed from the point of view of technical and formal possibilities.

The laboratory assesses if it has possibilities of realizing a determined testing service in the framework of the fixed or flexible scope.

In the case of tests from the flexible scope there is a necessity of a verification of the suggested method and the laboratory conducts a risk analysis connected with an application of a new or modified testing method.

The hazards which may occur during an introduction of new methods are analyzed. They can include:

- the case, when the laboratory states that is not capable (due to any reasons) of realizing tests correctly and rejects a new method as impossible for a correct realization,

– the situation when the laboratory is not capable of realizing tests within the period required by the customer due to different factors e.g. a long – lasting validation process of the method, a necessity of purchasing new measuring instrumentation, a necessity of conducting additional consultations and trainings etc.

After having conducted a risk analysis, the laboratory undertakes activities connected directly with an elaboration of a new methodology or a modification of the existing one and then it approves of it and implements a new testing procedure. The laboratory also conducts a validation of the method or its verification, if it is a standard method.

After having up-dated and approved of the List extended by the new testing method, the laboratory can quote the accreditation in reports on the tests conducted according the new or modified method, a general procedure is shown in Fig.1.

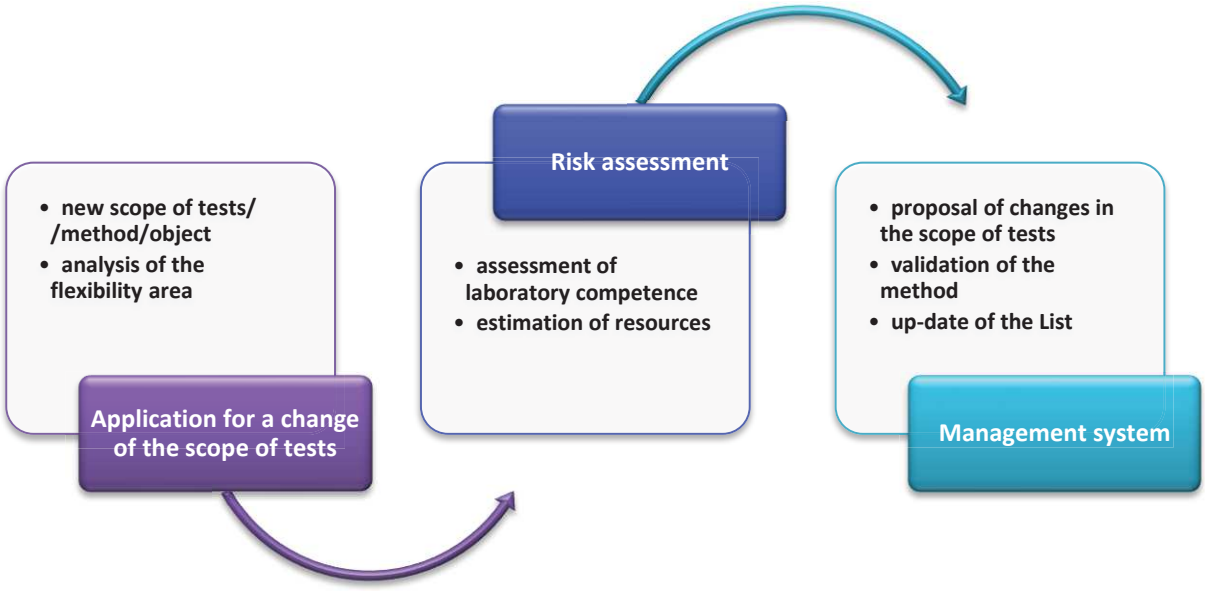

Fig 1. General scheme of a procedure for an introduction of a new method to the List

The implemented author`s methodology of conduct at the KOMAG testing laboratories guarantees a repeatability of procedures and ensures the proper management of the flexible scope.

In the decision for an accredited body there is a description of the scope of accreditation, i.e. what the body is competent to perform within its accreditation.

The design and details in the description of the scope are adapted to the respective conformity assessment area. A scope that includes flexible accreditation may be described in the accreditation decision with fewer details.

Experience of three KOMAG laboratories indicates that the expression flexible scope varies greatly from sector to sector. The following examples are proof of this [10].

The laboratory may have fixed five types of flexibility for certain test areas and may have fixed accreditation or two types of flexibility for certain test areas. Footnotes or other signs indicate the degree of flexibility for each part of the scope.

Example 1 - Laboratory of Material Engineering and Environment (AB 910)

Flexible scope		
Consumer products, products for contact with food, toys and articles for children, materials which may have contact with children, polymer and rubber products and raw materials for their production [1)]	Tests for safety Contents of bisphenol A –BPA [3)] Method of gas chromatography with tandem spectrometry of masses (GC-MS/MS)	Testing procedures [5)] Legal regulation [5)]
Limits of flexibility 1) An addition of the object to be tested in the framework of the group of objects 3) A change of measuring scope of the testing method 5) An application of up-dated and an implementation of a new method described in; standards/ procedures elaborated by the laboratory /legal regulations		

Example 2 – Laboratory of Tests (AB 039)

Flexible scope		
Products and construction components Components of machines and equipment	Linear and angular geometric dimensions Direct measurements [2)3)] Static strength Direct and indirect measurements [2)3)] Load - bearing capacity Direct measurements [2)3)]	PN-G-15050 [5)] PN-G-15533 [5)] DIN-5685-1 [5)] DIN 20637 [5)]
Limits of flexibility 2) An addition of the feature under testing within the framework of the object/group of objects to be tested and methods (testing technology) 3) A change of measurement scope of the testing method 5) An application of up-dated methods described in: standards/ procedures elaborated by the laboratory /legal regulations		

Example 3 - Laboratory of Applied Tests (AB 665)

Flexible scope		
Electric equipment (including devices designed for operation in space where gas explosion hazard occurs, of strengthened construction "p", *"pD"*, "e", "n", "m" and electric outfit [1)]	Electric, physical, mechanical strength, climatic properties and functional tests - direct and indirect measurements [2)3)]	PN-EN 60079-0 [5)] PN-EN 60079-2 [5)] PN-EN 60079-7 [5)] PN-EN 60079-15 [5)] PN-EN 60079-18 [5)] PN-EN 60204-1 [5)] PN-EN 61241-4 [5)]
Limits of flexibility 1) An addition of the object to be tested in the framework of the group of objects 2) An addition of the feature to be tested in the framework of the object/group of objects subject to tests and method (testing technology) 3) A change of measurement scope of the testing method 5) An application of up-dated methods described in: standards/ procedures elaborated by the laboratory /legal regulations		

In all the cases, the laboratory has to keep an updated list of accredited test methods including newly modified, introduced or developed methods available for the accreditation body. In all the cases, the scope of accreditation, i.e. the list of test methods, the range of products and measured parameters allow the laboratory and accreditation body to identify the limits of flexibility [11,12].

3. Management system for Conformity Assessment Body and Conformity Assessment Bodies using flexible scopes

In 2019 the up-dated document EA Requirements for the Accreditation of Flexible Scopes was published. It extended a possibility of using flexible scope also in relations to the activity of products' conformity assessment bodies [13].

The flexible scope in the products' conformity assessment body may concern:

- provisions of normative documents related to products,
- certification programmes of products.

A conformity assessment body of products, accredited in the flexible scope in the determined limits, has a possibility of:

- applying up-dated normative requirements and provisions concerning products,
- applying up-dated certification programmes including their following versions, if their use is not regulated by a different owner of the programme.

In the case of the conformity assessment body, having the accreditation for the notification purposes in the flexible scope, it has a possibility of using, in the determined scope of accreditation, the following documents:

- current editions of normative documents indicated in the scope of accreditation, in relation to which assessment processes are carried out,
- relevant normative documents (not indicated in the scope of accreditation) and their current edition appropriate for demonstrating conformity with the requirements of the legal regulations to be applied.

The implemented author`s proceeding methodology at the KOMAG`s Conformity Assessment Body is based on the management system acc. to the EN ISO/IEC 17065 Standard, due to which a repeatability of procedures is guaranteed and an appropriate management of the flexible scope is ensured [14,15,16].

According to the implemented methodology within the framework of the management system, an introduction of changes on the List is preceded by:

- checking of changes introduced in the normative document or in a new edition included in the scope of accreditation and a verification of testing possibilities in reference to these changes,
- a verification of possibilities to conduct a product assessment in reference to normative documents (not indicated in the scope of accreditation) relevant for demonstrating conformity with the requirements of the legal regulation to be applied and a verification of testing possibilities.

The following examples are proofs of flexible scope in two areas [15].

Example 1 - Accredited Body Certifying Products (AC 023)

Product/Product Group	Certification Scheme	Standard/normative document	ICS
Safety of machinery	PC-DBA/01 PC-DBA/02 PC-DBA/04	PN-EN ISO 13849-1 PN-EN 60204-1 PN-EN IEC 60204-11 PN-EN 62061 PN-G-50000	13.110
Limits of flexibility - an application of up-dated normative requirements and provisions concerning products			

Example 2 - Notified Body No 1456

Directive No. 2006/42/WE			
Product(s)	Conformity assessment procedure/module	Reference to national law	Reference to European law
12. Machinery for underground working of the following types: 12.1. locomotives and brake-vans; 12.2. hydraulic-powered roof supports.	EC type-examination	Annex 6, p. 2 [1)]	Annex. IX [2)]
Limits of flexibility - an application of relevant normative documents, appropriate for a demonstration of conformity with the requirements of legal regulations to be applied 1) Rozporządzenie Ministra Gospodarki z dnia 21 października 2008 r. w sprawie zasadniczych wymagań dla maszyn Dz.U. 2008 nr 199 poz. 1228 (order of Minister of Economy from 21st October 2008 on basic requirements for machines, Official Gazette 2008, No 199, Item1228) 2) Directive 2006/42/EC OF the European Parliament and of the council of 17 May 2006 on machinery			

4. Conclusions

Modern market gives testing laboratories and accredited bodies certifying products new challenges. A necessity of a fast reaction to customers` needs, resulting, inter alia, from changing legal regulations as well as from the technical progress, are the basic reasons of introducing innovative solutions by these entities.

Flexible scope of accreditation yields benefits to all the accreditation stakeholders, but on the other hand, introduces more requiring interpretations of relevant standard clauses and includes the bounds of the scope which are defined in a more distinct way [17, 18].

At present all the national accreditation bodies create a possibility of accrediting flexible scopes.

There is no doubt about the fact that the flexible scope is a reflection of laboratory competence for a realization of accredited tests not only in technical areas but also a laboratory ability for managing the process connected with having the flexible scope and its engagement in offering accredited tests within the framework of this scope.

At the market there are laboratories in operation, which conduct standard tests often within the framework of multi-year contracts and the form of the fixed scope of accreditation is completely sufficient for them.

In other cases a flexible form of the scope is a necessity, enabling testing laboratories to fulfil the requirements which change continuously.

In turn, in the case of the Conformity Assessment Body a possibility of applying the flexible scope facilitates an activity of following - up continuously changing normative requirements, being the basis of conducted assessments by such a body.

However, there is still a need of gathering experience, resulting from use of flexible scope of accreditation, because it is a new tool which requires an assessment of its efficiency.

It is clear that an accreditation should be based on the flexible scope if an entity wants to follow - up a modern development and serve customers` needs in determined areas.

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