Flexible scope for ISO15189 accreditation requires harmonization of scope specificity

Marc H. M. Thelen[1,2]

[1]Laboratory for Clinical Chemistry and Haematology, Amphia Hospital, Breda, the Netherlands; [2]SKML, Radboud University, Nijmegen, the Netherlands

Correspondence to: Marc H. M. Thelen. Laboratory for Clinical Chemistry and Haematology, Amphia Hospital, Breda, the Netherlands.
Email: mthelen@amphia.nl.

Abstract: ISO15189 has become the standard for quality management in laboratory medicine and its accreditation. To specify which activities are part of the accreditation a scope of accreditation is mandatory. A scope may be fixed with every individual activity listed or flexible with grouping of obviously coherent activities. Although European Accreditation (EA) promotes the flexible approach, in most countries the majority of the scopes is fixed. The European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) has published a guidance document to stimulate the use of a flexible scope. This guidance also advises to define the right degree of specificity of the scope based on a risk analysis performed in cooperation between national accreditation body and the scientific societies involved. The guidance was based on a successful, consensus based approach in the Netherlands where it led to the introduction of the definition of a source scope for every scientific society involved in laboratory medicine and adoption of the flexible scope by all laboratories that have made the transition for the former CCKL towards ISO15189 accreditation. So far, over 50% of all Dutch medical laboratories have made that transition and definition of scope has never been an issue in these transitions. Since the definition of the flexible source scope for each society in the Netherlands in 2014 there has been a trend to add specificity. Because adding specificity makes a particular working field more distinguishable from another, addition of specificity leads to a chain reaction of such additions in the source scope of societies. This might endanger the intentions of the flexible scope if increasing specificity would eventually would lead to an almost fixed scope. A harmonized approach in overlapping working areas of the different scientific societies is needed to find the optimal balance in scope granularity between specificity and flexibility.

Keywords: Flexible scope; ISO15189; laboratory accreditation; quality management system

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ISO15189 accreditation scope

Clinical laboratories around the world have built their quality management systems on different types of standards. Regional or national regulations and traditions resulted in systems based on either ISO15189, ISO9001 or ISO17025 or national standards as CLIA in the USA (1-5). Since the 2012 renewal of the ISO15189 standard with requirements for quality and competence in medical laboratories, this standard has started to gain impact as the standard for this field (5,6). Its impact not only grows by an increasing number of countries that switch from a different standard to ISO15189 accreditation, but also by the appreciation of accreditation that is expressed by national governments that make it mandatory, like in France or by health care insurance systems that make it mandatory for reimbursement. Even at the level of international legislation ISO15189 has acquired its position; the new IVD regulation of the European Union requires ISO15189 for the waiver of

CE labeled in house developed tests (7).

To communicate to its customers what particular tests and services are covered by its accreditation, laboratories are required to list the scope of their accreditation, which is published on the website of the particular accreditation body (NAB). The international laboratory accreditation cooperation (ILAC) has a policy on the formulation of scope (8). The European national accreditation bodies are united in European Accreditation (EA) and also have policies on scope that applies to all European ISO15189 accreditations. EA members have signed a multilateral agreement for the mutual recognition of their accreditations.

Fixed scope versus flexible scope

ILAC procedure G18 "Guideline for the Formulation of Scopes of Accreditation for Laboratories" (8) defines that a scope maybe fixed or flexible. In a fixed scope all individual analyses are mentioned including method and suitable sample types. In a flexible scope all these aspects may be less strictly defined. With a flexible scope it is allowed to perform additional activities under its current scope of accreditation after validation or verification in accordance with ISO15189 without evaluation by the accreditation body prior to operation of the activity. In all cases, however, the limits of the scope should be clear. In a scope description for a particular laboratory, fixed and flexible elements may be combined.

The ILAC G18 guideline states that in case of flexible scope the assessment process should focus on the appropriateness of the accreditation claim. This not only involves the description of the scope, but also processes like validation and verification of measurement procedures and competence of staff. In every assessment process the laboratory has to provide a listing of all activities with marking of all new activities since the prior audit. This allows the NAB to assess whether newly added listings are rightful part of the scope.

EA has two policies that are relevant to the topic of scope of accreditation. EA-4/17: EA position paper on the description of scopes of accreditation of medical laboratories (9) clearly promotes the use of the flexible scope and encourages NABs to promote its use. EA-2/15: EA requirements for the accreditation of flexible scopes (10), describes the specials points of attentions that are needed when assessing a laboratory with a flexible scope.

EFLM guidance

In 2015 the EFLM has published a guidance document that promotes the use of the flexible scope (11). It states that a flexible scope should be flexible enough to facilitate innovation, but also specific enough to clarify the definitions and limitations of a laboratories working field to both customers and assessors. The consensus paper describes a risk based approach for a process between scientific societies and NABs to define the proper degree of specificity. The approach was based on an experience form the Netherlands where laboratory accreditation then was in the transition from their national CCKL accreditation towards ISO15189-2012 accreditation. Since CCKL accreditation used a method of scoping that is considered not specific enough by EA and ILAC, there was a need for redefinition of the optimal granularity of scopes. Since the field was used to the advantages of flexibles scope, it was clear for all parties involved that the result had to be flexible. In their approach all parties decided to start the process with a risk analysis: what would go wrong if scope definition was too tight or too loose? A too lose definition may result in overestimation of an accreditation scope by customers or to selection of an assessor that lacks the competence to properly judge procedures during an assessment. A too tight definition of scope could hamper innovation or yield an enormous burden of between-assessment investigations for the addition of new methods to an existing scope. To mitigate these risks all scientific societies have described a so called "source scope" of all activities in their field (12). All scopes rely on description of unique combination of three elements: medical field, technical principle and sample type(s). Since "technical principle" is a looser concept than "technique" this allows for flexibility. The required unique combination with medical field ensures that only after competence has been established a technical principle may be applied to a different medical field, even if the particular medical field is already part of the scope. If, for example, a laboratory uses HPLC to determine catecholamines and gel-electrophoresis for hemoglobinopathies it cannot start to use HPLC for hemoglobinopathies within the scope of accreditation without requesting a change to the scope first.

The basis for these listed source scope items is the training syllabus for specialist in laboratory medicine of the particular field (13). When a laboratory applies for accreditation it selects those elements of the particular source scope that are necessary to cover all its activities.

The listing of all individual laboratory activities that is obligatory by rules in the application of accreditation now has to mention for every item in the listing to which element of the source scope it belongs. Flexible scoping is only allowed for those fields where a registered specialist in laboratory medicine of the particular field is responsible in the laboratory. In other cases, activities outside the "own" scientific discipline should be scoped fixed.

Experiences with the flexible scope

Since the introduction of the flexible scope in the Netherlands approximately 150 laboratories have been assessed by the Dutch accreditation body. All laboratories indeed make use of the proposed source scope and fixed elements are added if individual test outside the own scientific educational curriculum are performed. None of the laboratories reported complaints on the definition of scope to the NAB. In order to continuously monitor and evaluate all aspects of the transition from CCKL towards ISO15189 accreditation the Dutch NAB and all delegation of all scientific societies involved regularly meet. Part of the evaluation also is the definition of scope.

In 2016 the Dutch NAB has issued a policy on scopes that adds definition of scope for tests that are referred to an expert laboratory. That policy states that only if the referring laboratory adds interpretive comments to the results of the expert laboratory and has competence to do so, the referred activities may be part of the scope of accreditation.

Another part of the scope that is better defined now is point of care testing (POCT), for which ISO15189 accreditation also requires ISO22870 compliance. This has resulted in both a specific document on the assessment of POCT, and special attention for POCT in the definition of scope in previously mentioned policy on scopes. Apart from mentioning POCT according to ISO22870 as an element in the source scope of the particular field, the wording "+POCT" must be added to any source scope element where testing is also performed in a POCT setting.

Since its introduction in 2014 the source scopes of all the different fields of laboratory medicine were prone to advancing insight. All scopes have an appointed regent both with the NAB and with the particular scientific society. If a scientific society wishes to adapt their source scope this can be done by the regents. In this process, the role of the NAB regents is limited to check whether the change complies with the original principles, especially whether the particular element is indeed part of the educational curriculum of the society involved. As a result of several scope adaptions, a trend of increasing specification became noticeable and have led to an interesting discussion between the different societies and the Dutch NAB. In the description of the scope, some societies felt the need to increase granularity. The intention behind is to clarify content for customers of the laboratories, and may for that reason be appreciated. If, however, this involves a working area that is part of the curriculum of more societies, it could lead to under-appreciation of the source scope of the society that did not increase granularity since some particular specific items would seem to miss on that scope. The society for immunology for example, had specified "m-protein-analysis" to their scope. The particular working field is also part of the curriculum of the society for clinical chemistry and they did not yet specify m-protein-analysis, but rather considered that as an implicit part of their scope element serum protein analysis. Therefore, it could happen that an assessor that was familiar with both source scopes of immunology and clinical chemistry could think that a laboratory for clinical chemistry that performed m-protein-analysis could not do that under a scope element in the source scope for clinical chemistry and therefore had to add it as a fixed element from the immunology source scope to their laboratory scope. That would lead to the decision of the NAB to add an immunologist to the assessment team for the particular laboratory, resulting in an increased work load for audit teams and corresponding expenses for laboratories. To end this situation the society for clinical chemistry has decided to add the element 'm-protein-analysis' also to their source scope. Whether this is a good result, depends on the answer to the questions where this ends. Is this a justified correction of an immature system that needs ripening, or is this the beginning of the gradual deterioration from a truly flexible towards a fixed scope?

Harmonization of flexibility

In order to address the issue of shifting granularity and order to prevent that a scientific claim of scientific societies on scope element eventually would lead to the end of the flexible scope, the Dutch scientific societies have decided to find a harmonized viewpoint on the optimal granularity of scope elements that are part of the source scope of more than one society. As a start, societies are studying

how specific the technical principle and medical sub-field for molecular testing should be described. The original leading principles for granularity now can prove their use. The scope should be specific enough for a laboratory and its customers to determine whether a specific question can be addressed to the particular laboratory. For an assessor, it has to be specific enough to determine whether he or she has the expertise to rightfully assess the competence of the particular laboratory. If the scope becomes too specific however, the readability for lay users may be hampered and the specificity may object innovation when risk-free addition would need assessment by the NAB because of scope additions. Since all societies and the NB enjoy the advantages of the current flexibility all parties are deeply motivated to find a harmonized solution for the optimal granularity in specifying the source scopes.

Other countries that are in the process of adopting to a flexible scope for ISO15189 accreditation may accelerate their process by learning from these Dutch experiences.

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