

## EFLM Position Paper

Marc H.M. Thelen\*, Florent J.L.A. Vanstapel, Christos Kroupis, Ines Vukasovic, Guillaume Boursier, Edward Barrett, Francisco Bernabeu Andreu, Pika Meško Brguljan, Duilio Brugnoli, Maria Lohmander, Ludek Sprongl, Tatjana Vodnik, Irina Ghita, Michel Vaubourdolle and Willem Huisman, on behalf of the Working Group Accreditation ISO/CEN standards (WG-A/ISO) of the EFLM

# Flexible scope for ISO 15189 accreditation: a guidance prepared by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group Accreditation and ISO/CEN standards (WG-A/ISO)

DOI 10.1515/cclm-2015-0257

Received March 13, 2015; accepted May 4, 2015; previously published online June 6, 2015

**Abstract:** The recent revision of ISO15189 has further strengthened its position as the standard for accreditation for medical laboratories. Both for laboratories and their customers it is important that the scope of such accreditation is clear. Therefore the European co-operation for accreditation (EA) demands that the national bodies responsible for accreditation describe the scope of every laboratory accreditation in a way that leaves no room for doubt about the range of competence of the particular laboratories. According to EA recommendations scopes may be fixed, mentioning every single test that is part of

the accreditation, or flexible, mentioning all combinations of medical field, examination type and materials for which the laboratory is competent. Up to now national accreditation bodies perpetuate use of fixed scopes, partly by inertia, partly out of fear that a too flexible scope may lead to over-valuation of the competence of laboratories, most countries only use fixed scopes. The EA however promotes use of flexible scopes, since this allows for more readily innovation, which contributes to quality in laboratory medicine. In this position paper, the Working Group Accreditation and ISO/CEN Standards belonging to the Quality and Regulation Committee of the EFLM recommends using an approach that has led to successful introduction of the flexible scope for ISO15189 accreditation as intended in EA-4/17 in The Netherlands. The approach is

**\*Corresponding author: Marc H.M. Thelen**, Laboratory for Clinical Chemistry and Haematology, Amphia ziekenhuis, PO Box 90158, 4800 RK Breda, The Netherlands, E-mail: mthelen@amphia.nl

**Florent J.L.A. Vanstapel:** Laboratory Medicine, Department of Public Health, Biomedical Sciences Group, University Hospital Leuven, Belgium, KU Leuven, Leuven, Belgium

**Christos Kroupis:** Department of Clinical Biochemistry, Attikon University General Hospital, University of Athens Medical School, Athens, Greece

**Ines Vukasovic:** University Department of Chemistry, Sestre Milosrdnice University Hospital Center, Zagreb, Croatia

**Guillaume Boursier:** Department of Clinical Biochemistry, University Hospital of Montpellier, Montpellier, France

**Edward Barrett:** Consultant Clinical Biochemist, Limerick, Ireland

**Francisco Bernabeu Andreu:** Clinical Analytical Service, H.U. Principe de Asturias, Alcalá de Henares, Spain

**Pika Meško Brguljan:** Department of Clinical Chemistry, University Clinic for Respiratory and allergic Diseases Golnik, Golnik, Slovenia

**Duilio Brugnoli:** Clinical Chemistry Laboratory, Spedali Civili, Brescia, Italy

**Maria Lohmander:** SIS, Swedish Standards Institute, NU Hospital Care, Northern Elfsborg Hospital, Västmanland County, Sweden

**Ludek Sprongl:** Central Laboratory, Sumperk Hospital a.s., Sumperk, Czech Republic

**Tatjana Vodnik:** Center for Medical Biochemistry, Clinical Center of Serbia, Belgrade, Serbia

**Irina Ghita:** Synevo Central Lab Clinical trials, Ifov County, Chiajna, Romania

**Michel Vaubourdolle:** Laboratory for Medical Biology and Pathology, University Hospitals, Paris, France

**Willem Huisman:** Consultant European Specialist in Clinical Chemistry and Laboratory Medicine, The Hague, The Netherlands

risk-based, discipline and competence-based, and focuses on defining a uniform terminology transferable across the borders of scientific disciplines, laboratories and countries.

**Keywords:** flexible scope; ISO15189; laboratory accreditation; quality management system.

## Introduction

Since its introduction in 2003 ISO 15189 [1] has become the most important standard for accreditation of medical laboratories [2]. In some countries more general standards, such as ISO9001 [3] for quality systems or ISO17025 [4] for testing laboratories, are still used. In the US, medical laboratories are accredited for moderate or high-complexity laboratory testing by approved [5] organizations according to Clinical Laboratory Improvement Amendments (CLIA) rules [5]. The introduction of the latest third revision of ISO15189 in 2012, however, has given a new worldwide impulse to the use of this standard that has been particularly developed for the medical laboratories. The growing global recognition of ISO15189 also appears from the fact that some governments make it mandatory for medical laboratories or else insurance organizations (either public or private) demand it for reimbursement. In France, for instance, all medical laboratories must be accredited by Comité français d'accréditation (Cofrac) by 2020, a process that started in 2010. In Belgium it is mandatory for certain disciplines.

When a laboratory is accredited it has to be clear for all parties which particular services are part of that accreditation and which are not. This is defined as the scope of accreditation. According to regulations of the International Laboratory accreditation Cooperation (ILAC) and the European Co-operation for Accreditation (EA), laboratories must explicitly state on their reports which services are not under the scope of accreditation. Purpose of these regulations is clearly to prevent over-estimation of the accreditation of a laboratory by its customers. In accord with the multi-lateral agreement for recognition of accreditation between ILAC and EA member states, the national accreditation bodies (NAB) which are responsible for accreditation in their countries, must publish the scope of accreditation of every laboratory on their website. This allows the customers of the particular laboratories to check whether the service they seek is performed under accreditation or not.

## Definition of scope

The scope of accreditation describes for which laboratory services the accreditation is granted. According to ILAC and EA regulations, the description of the scope may be either fixed or flexible. A fixed scope states every single test or service in every medical field in every type material. A flexible scope does not mention individual tests or services, but coherent groups of services within a medical field and with identical technical principle with provision of all applicable materials (or products or matrices such as serum, plasma, blood cultures etc).

## Motivation for guidance

The European organization for accreditation EA has issued two relevant papers on scopes:

1. EA-2/15: EA requirements for the accreditation of flexible scopes [6].
2. EA-4/17: EA position paper on the description of scopes of accreditation of medical laboratories [7].

The EA describes that the scope can be either fixed or flexible and that “a flexible scope is preferred” [7]. EA encourages its member NABs to “provide this (flexible) service to their costumers” [6].

Although EA documents encourage flexible scopes and although laboratories as well as national societies for the different forms of laboratory medicine agree that flexible scopes are necessary for innovation, still in most countries accreditation is mostly under fixed scope (although they might refer to this as flexible). Although formally working with a fixed scope for some disciplines the scope may already have been defined in flexible terms, i.e., complete blood count (CBC) or identification and resistance testing of pathogens in feces. The reason for that seems that the NABs in spite of available EA guidance documents feel insecure about the border between flexible and too liberate.

## EA regulations on scopes

Apart from the definitions on fixed and flexible scopes, the above mentioned EA documents on scopes contain some important regulations and suggestions that are important for our view on defining scopes:

- Laboratories should thrive for a scope that covers all services within each medical field of their service.

- For each medical field mentioned in the scope, the laboratory should be able to demonstrate its competence in all pre-examination, examination and post examination aspects as well as interpretation and patient/physician consultation.
- The scope should be described by the medical field, the examination type and the description of the materials associated with the service.
- Services that are not part of the scope must be specifically reported as “performed not under accreditation”.

The EA encourages that NABs consult the national scientific societies to formulate flexible scopes [7].

## Choosing between fixed and flexible

To make a balanced choice between fixed or flexible it may be best to start with the purpose of the scope.

### Purpose of scope

The primary purpose of a scope of accreditation is for the customer of the laboratory service to be able to determine which services are provided under accreditation. For the customer, this translates into trust in the competence of the particular laboratory. For the customer the scope needs to be specific enough to establish in a smart manner whether the service sought is under accreditation. However, the customer might not be interested to check accreditation status of every single test in a group of associated tests that are reasonably associated with each other. A definition based on medical fields also guarantees that consultative services are provided for the whole field.

For NABs it is essential to have a clear view of all laboratory activities in order to allocate assessors with the right expertise when performing an assessment of the laboratory service of that particular laboratory, and for the assessors to have a clear view of what can be expected. This comprises a secondary reason for a clear scope.

In the light of the purpose, one can argue in favor of a flexible scope, but there also may be risks associated with the use of a flexible scope. When implementing a flexible scope, these risks must be mitigated.

## Reasons for a flexible scope

- A fixed scope puts an extra burden on intermittent innovation, as laboratories have to report every

change to their list of services to the NAB, and the NAB has to weigh the need for extra audits.

- A flexible scope gives a better more readable insight into service levels that can be expected for customers of a laboratory.

## Risk of flexible scopes

- When scopes are formulated too non-specific it can become unclear for the user of a laboratory service whether a particular service is either part or not of the scope of a particular laboratory.
- When scopes are formulated too non-specific, laboratories might provide services for which accreditation is suggested, but that are in fact outside its scope, without specifically mentioning this.
- NABs might select and send assessors with incomplete competence for all tests for which a laboratory seeks accreditation when the scope is formulated too non-specific.

## Mitigating the risk of flexible scopes

- We propose that the scope exists in two layers: a general flexible format that is submitted to and published by the NAB together with issuing the certificates, and a detailed listing of examinations that is maintained by the accredited laboratory, intermittently communicated to the NAB and that is the subject of regular audits at a predetermined frequency.
- The general scope is then based on medical disciplines, and general test principles (we will expand on this further on in the paper at the hand of the Dutch example).
- The detailed listing is a list of all examinations with sufficient detail for the user of the results to define a test result unambiguously. The NAB will use this listing to check whether it does not contain any examinations that are not covered by the flexible listing. Thus a detailed table has to be available and kept up-to-date defining the measurand in terms of analyte (e.g., sodium), sample type (e.g., whole heparinized blood), analytical matrix (e.g., plasma), analytical principle (direct potentiometry per kg solvent water, or indirect potentiometry per L volume).

- In the period between audits the laboratory shall report all changes in tests and diagnostic services that are provided by the laboratory to the NAB. This gives the NAB the opportunity to detect tests or services are performed that should be reported as outside the scope of accreditation.
- For accreditation, a laboratory is obliged to verify or validate all new or modified services according to ISO15189 (Section 5.5.1) [1]. This means that no services can be added to the scope without prior documented verification or validation and appropriate and successful IQC and EQC. As the laboratory process of validation is evaluated in every NAB audit, the risk of improper introduction of new tests is limited.
- The laboratory has to apply its standard procedures to the entire scope of activities in each of the accredited medical disciplines. If the laboratory chooses to report results as not under accreditation, than this must be unambiguously recognizable in all forms of reporting (either electronic or hard-copy, either cumulative or sample- or prescription-based reporting). Thus the NAB shall also audit the fraction of tests not under accreditation.

## The Dutch approach towards flexible scopes: flexible, but not bendable

In the Netherlands traditionally medical laboratories are accredited to the CCKL guidelines for laboratory medicine. The first edition of this CCKL guideline dates from 1994 and was one of the predecessors of ISO 15189. Along with the preparation of the introduction of ISO15189 (2012) the Dutch scientific societies of the different fields worked together with Raad voor Accreditatie (RVA), the Dutch NAB to formulate a transition roadmap from CCKL towards ISO15189 accreditation. Along with the scientific societies for clinical chemistry, which includes hematology in The Netherlands (NVKC), medical microbiology (NVMM), immunology (NVVI), hospital pharmacy (NVZA), pathology (NVVP) and clinical genetic laboratory diagnostics (VGKL) also were involved: the Dutch society of laboratory technicians (NVMM), the Dutch federation of oral anticoagulant therapy (FNT), and the most important Dutch organizer for external quality assessment (SKML). As scopes in CCKL are, extremely flexible, and are not in concordance with EA-4/17, the scopes needed to be redefined for ISO15189 accreditation since concordance with

EA 4-17 is essential for the NABs for their ISO 17011 accreditation as NAB.

Due to their history in extremely flexible CCKL scopes, The Netherlands seem to be the only country where flexible scopes for ISO15189 accreditation require more specificity, rather than loosening of current scopes. For that reason, the flexible scope definition for the transition from CCKL towards ISO15189 accreditation in The Netherlands holds a unique opportunity to introduce the flexible scope approach as originally intended and may be of value for other countries with no experience in flexible scopes.

At the beginning of the process, the main goals in the definition of scopes were different between the scientific societies and the NABs, and still needed to be made compatible with each other.

First it was established which criteria were important for all parties.

Important to the NAB were:

- Scopes must be specific enough to assure that services outside of the scope, cannot have the suggestion of being part of the scope.
- Scopes must be specific enough to determine the needed qualifications for an assessor to assess all possible tests/services that might be part of such scope. This is to prevent that an assessor could feel incompetent to assess the service, once at site during an audit.

It has to be clear within what limits innovation of new tests or services is allowed without the need for first establishing the competence of the laboratory on that particular combination of medical and technical field.

Important to the scientific societies were:

- Scopes must be flexible enough to allow innovation within a field that is already part of the scope without asking for scope extension.
- Scopes must be specific enough to distinguish between laboratories with different service level.

Both NAB and scientific societies immediately agreed that laboratories should not be allowed seeking accreditation for only a part of their service range. In other words; the accreditation scope of a laboratory should cover its complete service. This might not be easily achievable in countries where laboratory accreditation is at its beginning, but since in the Netherlands most medical laboratories already have a tradition in CCKL accreditation for their complete service array, this condition would add achievable customer protection against accreditation over-appreciation.

For both parties it was clear that services that are not part of the current scope of accreditation need prior

notification to the NAB that then decides what inspection is required in order to broaden the scope to the new service. The discussion was about how to define what new services can be self-declared as part of the current scope, and what not. The scope needs to be flexible, without becoming bendable.

The EA-4/17 classification of medical field and type of examination may be used to specify scopes that accommodate the demands of both NAB and scientific societies, but needed extension to a more specific level. For instance, the medical field of hematology may be subdivided into hemocytometry, coagulation and transfusion medicine. When such more narrow medical fields are used in combination with technical field, then unique combinations of medical and technical field arise that meet the demands of both parties. For instance, for the field of coagulation, the technical fields of plasma coagulation, thrombocyte coagulation and qualitative DNA investigations can divide the field of coagulation in way that surely can determine whether an assessor can feel confident to assess, and is specific enough to prevent suggestion of scope for tests being clearly outside of it. For the scientific societies it is important that laboratories can have innovation within each of these combinations of medical and technical field without requesting change of scope at the NAB. As ISO15189 demand documented verification or validation of all new or modified services, a flexible scope does not endanger the quality of the provided services.

As all unique combinations of medical and technical field define the scope, new combinations have to be reported to the NAB, even when both the medical field and the technical field already exist in other combinations. For instance, when a laboratory already has endocrinology and LC-MS/MS as combination in its scope and also hemoglobinopathy research with HPLC, but not with LC-MS/MS, this laboratory cannot add hemoglobinopathy with LC-MS/MS to its scope without prior notification to the NAB.

Working out this concept of unique combinations of medical subfield and technical field.

The level of detail in technical field was decided to be at the level of technical principle, not at the level of individual techniques. For instance automated immunoassays are considered as one technical principle. No difference is made between the different signal molecules that can be used to label antibodies or the detection techniques for those labels.

In the summer of 2013, all scientific societies active in medical laboratory services presented their translation of these principles to the RVA, the Dutch NAB as well as to each other.

Major findings of this inventory were:

- Most societies have come up with combinations of medical fields and technical principles that were comparable in their degree of specificity.
- Discussion between societies and NAB yielded quick consensus about the required level of specificity. With the different proposals on the table, discussion could be more practical and that facilitated the speed of the consensus process.
- Those societies that had formulated scopes that were more or less precise than the others, were able to rewrite their proposals to the agreed level of specificity within a very short time frame.
- Societies and NAB agreed that the established consensus outcome did both meet the EA-4/17 criteria and was practical enough for innovative medical laboratories.
- Societies and NAB decided to start using the newly defined scopes from 2014. The scopes as proposed and defined by the scientific societies function as “source scopes” since they contain all possible scope elements of the particular laboratory field. Individual laboratories can indicate whether they seek accreditation for a particular scope element.
- Where source scopes between societies had overlap discussion about mutual competence were decided by the question whether the particular scope element is in the training syllabus of the particular discipline or not. For countries with equivalence of standards the EC4 training syllabus for clinical chemistry and laboratory medicine may be used for the same purpose [8].
- It was agreed that flexible scoping is only possible for those source scopes and its elements that are covered by a staff laboratory member of the particular scientific society.
- When a laboratory seeks accreditation for an element that is not part of the flexible source scope of a discipline that is represented in the staff of the laboratory, then these elements can either be presented as fixed scope, or they have to be performed under responsibility of a special member of staff of the particular scientific society.

As an example a part of the source scope for clinical chemistry and hematology that is covered by the training syllabus of the Dutch society for clinical chemistry is depicted in Table 1 which is equivalent to that of the EC4 [8]. The complete source scope of all Dutch medical laboratory disciplines is continuously updated at the website of the RVA [9].



**Table 1:** English translation of part of the Dutch source scope for clinical chemistry as part of the Dutch transition plan from CCKL towards ISO15189 as agreed by the RVA and Dutch scientific associations for disciplines active in laboratory medicine.

Medical field	Request type, medical subfield	Technical principle	Accreditation requested	Material/product
Clinical chemistry and hematology	Preanalysis	Phlebotomy (extra-mural)	Yes/no	Blood
		Phlebotomy (intra-mural)	Yes/no	Blood
Clinical chemistry and hematology	Clinical chemistry, general	Sample preparation: reception, registration, processing, preparation for analysis (for instance: centrifugation), postanalytical result processing, process monitoring turnaround time surveillance.	Yes/no	All body fluids, blood cells, other cells, punctuates, bone marrow
		Routine analysis of electrolytes, enzymes, metabolites, blood gasses and related tests by with standard chemical tests such as spectrophotometry, nephelometry, turbidimetry, ion-selective electrodes	Yes/no	All body fluids
		Immunoassays	Yes/no	All body fluids
		Physical chemical analyses, such as viscosity	Yes/no	All body fluids
		Immunochemistry/protein chemistry	Yes/no	All body fluids
		Nucleic acid diagnostics such as PCR and sequencing	Yes/no	Blood cells, plasma, other cells
		Chromatography including HPLC, UPLC, GC	Yes/no	All body fluids
		(Tandem) Mass-spectrometry	Yes/no	All body fluids
		Atomic absorbance spectrometry	Yes/no	All body fluids
		Microscopy on cells, cyclinders, chrystals	Yes/no	All body fluids
		Metals and trace elements	Yes/no	Blood
		Kidney stone analysis	Yes/no	Kidney stone
Clinical chemistry and hematology	Clinical chemistry, fertility	Function tests (such as OGTT, sugar absorbance tests, hydrogen breath test)	Yes/no	All body fluids, expiration air
		Sperm analysis incl morphology en motility	Yes/no	Sperm
		Sperm analysis after vasectomy	Yes/no	Sperm
Clinical chemistry and hematology	Clinical chemistry, endocrinology	Sperm preparation for IUI according to the guideline of the NVCK/KLEM	Yes/no	Sperm
		Specific sample preparation such as organic extraction or equilibrium dialysis	Yes/no	All body fluids
		Nucleic acid diagnostics such as PCR and sequencing	Yes/no	Blood cells, other cells
		Immunoassays	Yes/no	All body fluids
		Chromatography including HPLC, UPLC, GC	Yes/no	All body fluids
		(Tandem) Mass-Spectrometry	Yes/no	All body fluids
Clinical chemistry and hematology	Clinical chemistry, metabolic inborn errors	Function tests (such as (O)GTT, synacthen test)	Yes/no	All body fluids, expiration air
		Specific sample preparation such as organic extraction or equilibrium dialysis	Yes/no	All body fluids
		Immunoassays	Yes/no	All body fluids
		Chromatography including HPLC, UPLC, GC	Yes/no	All body fluids
		(Tandem) Mass-Spectrometry	Yes/no	All body fluids
		Nucleic acid diagnostics such as PCR and sequencing	Yes/no	Blood cells, other cells
Clinical chemistry and hematology	Chemical analysis of metabolites	Chemical analysis of metabolites	Yes/no	All body fluids
		Enzyme diagnostics	Yes/no	Blood cells, other cells

Table 1 (continued)

Medical field	Request type, medical subfield	Technical principle	Accreditation requested	Material/product
Clinical chemistry and hematology	Clinical chemistry, immunology	Immunoassays Immunofluorescence Immunochemistry Immunoflowcytometry	Yes/no Yes/no Yes/no Yes/no	All body fluids All body fluids All body fluids Blood cells
Clinical chemistry and hematology	Clinical chemistry, neonatal screening	Specific sample preparation such as organic extraction or equilibrium dialysis Immunoassays Chromatography including HPLC, UPLC, GC (Tandem) Mass-Spectrometry Nucleic acid diagnostics such as PCR and sequencing	Yes/no Yes/no Yes/no Yes/no Yes/no	All body fluids Blood (spot) Blood Blood Blood cells, other cells
Clinical chemistry and hematology	Clinical chemistry, prenatal screening	Immunoassays	Yes/no	Blood, serum, plasma
Clinical chemistry and hematology	Clinical chemistry, point of care	POCT according to ISO 22870*	Yes/no	All body fluids

\*all POCT tests must also be part of scope for non-POCT analysis.

## Lessons for other countries from the Dutch approach

The Dutch approach has showed that a practical approach based on the right intentions can yield a scope description that meets the criteria of EA-4/17 and the needs of laboratory professionals. The most important lessons are:

- Start with the formulation of the risks that should be mitigated by the outcome;
- Scopes must be specific enough to be sure that tests that are provided, but are not part of the scope, cannot have the suggestion of being part of the scope;
- Scopes must be specific enough to determine the needed qualifications for an assessor to assess all possible tests that might be part of such scope. This is to prevent that an assessor could not have the appropriate expertise;
- Scopes must be flexible enough to allow innovation within a field that is already part of the scope without asking for scope extension;
- Scopes must be specific enough to distinguish between laboratories with different service level;
- Laboratories must seek accreditation for a scopes that cover all of its services.
- The consensus process is fast and practical. Instead of bilateral “negotiations” between the NAB and the individual societies, it can be decided that the “raw” proposal of the scientific societies of all medical laboratory medicine disciplines is shared with both each other and the NAB. This will lead to mutual inspiration and allows testing of different approaches to the mutually agreed criteria. This can lead to a quick consensus on the optimal level of specificity.

## EFLM recommendation

The Working Group A/ISO of the EFLM recommends that other countries follow the above mentioned risk-based approach to EA-4/17 on flexible scopes in an open dialogue between the NAB and the scientific societies of all medical laboratory disciplines along with all other parties involved. For laboratories, medical field or countries that have no or limited track record in accreditation, it may be necessary to make a gradual transition towards flexible scopes. Flexible scopes may be the privilege of those laboratories that have already demonstrated within a fixed scope that they have a validation/verification procedure that justifies the trust that comes with a flexible scope.

The risk-based approach is in line with the preventive action approach in ISO15189. Like all people, healthcare workers, including laboratory staff, do not like regulations without appreciating their purpose, but all do like to prevent risk. When quality regulations are based on an analysis to prevent risk, these regulations are much better accepted as they appeal to the intrinsic drive for doing the right things, the right way.

**Acknowledgments:** The authors acknowledge Dr. Yvette Kluiters of the laboratory for clinical chemistry and hematology of the Elizabeth Hospital in Tilburg, The Netherlands for her contributions in the formulation of the Dutch flexible scope for clinical chemistry.

**Author contributions:** All the authors have accepted responsibility for the entire content of this submitted manuscript and approved submission.

**Financial support:** None declared.

**Employment or leadership:** None declared.

**Honorarium:** None declared.

**Competing interests:** The funding organization(s) played no role in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the report for publication.

## References

1. ISO 15189-2012, Medical laboratories – Requirements for quality and competence.
2. Huisman W. European medical laboratory accreditation. Present situation and steps to harmonisation. *Clin Chem Lab Med* 2012;50:1147–52.
3. ISO9001-2008 Quality management systems – Requirements.
4. ISO/IEC 17025-2005, General requirements for the competence of testing and calibration laboratories.
5. List of approved accreditation organizations under the clinical laboratory improvement amendments (CLIA). Available from: <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOList.pdf>. Accessed on March 12, 2015.
6. EA-2/15. EA requirements for the accreditation of flexible scopes.
7. EA-4/17 EA position paper on the description of scopes of accreditation of medical laboratories.
8. Wieringa G, Zerah S, Jansen R, Simundic AM, Queralto J, Solnica B, et al. European Communities Confederation of Clinical Chemistry, The EC4 European syllabus for post-graduate training in clinical chemistry and laboratory medicine: version 4, 2012. *Clin Chem Lab Med* 2012;50:1317–28.
9. Raad voor Accreditatie RV. Medical laboratories source scopes [Dutch]. Available from: <https://www.rva.nl/en/document/download/F004-3>. Accessed on March 12, 2015.