Guideline for Standards Development

1. Principle

Requirement revisions are to be implemented every 3 years. Generally, minor revisions (restricted to modification of errors in existing requirements or scores with no newly formed or revoked requirement number) are carried out annually, and major revisions (with addition of new requirements, revocation of existing items or relocation of requirements) are conducted triennially.

2. Annual Schedule

Item	Content	Schedule
- Requirement analysis	- Statistics of score per requirement	All-year
- Collecting opinions on the requirements	- Collecting opinions of institutes - Collecting opinions of inspectors - Collecting opinions on requirements	All-year
- Requirement revision meeting	- Review of requirements - Review of opinions on requirements - Discussions on revisions	Monthly
- 1st requirement revision workshop	- Review of opinions and analysis of requirements - Suggestions for requirement revision	**March-April**
- 2nd requirement revision workshop	- Review of revision proposals	**May**
- 3rd requirement revision workshop	- Finalization of requirement revision proposal and composition of the revised proof	**June**
- Collecting opinion on requirement revision proposal	- Collecting opinions of experts and Korean Society for Laboratory Medicine - Collecting feedback from Inspectors and Institutions inspected	**July-August**
- Review of the feedback on the proposed standard revision	- Review of the feedback - Making decision whether to accept the feedback	**September**
- Composition of the revised requirement	- Composition of the revised edition - Review by the Laboratory Medicine Foundation Operating Committee - Approval by the Foundation Board of	**September** **October** **November**

	Directors	
- Publication of the revised requirement - Guidance and education of the revision	- Dispatch revision and official document informing the revised content of inspection - Laboratory Accreditation Program Guide Workshop (3 times)	**November~ January next year**

3. Organization of the Requirements

The accreditation requirements are divided into 14 fields and each field is organized as the인증 following table shows. However, the fields of Clinical Chemistry and Urinalysis and Microscopy are separated but accounted as one field when appointing the scores.

No.	Field	**Organization**		
1	Laboratory Management	Scope of Inspection	External Quality Control Internal Quality Control Pre-analytical and Post-analytical Evaluation General Equipment and Instrument Test Performance and Instrument Operation Personnel Facilities and Environment	Laboratory Information System, Safety
2	Comprehensive Interpretation	Provided service		
3	Point-of-Care Testing	Provided service		Safety
4	Referral Medical Laboratory			
5	Diagnostic Hematology			
6	Clinical Chemistry			
7	Urinalysis and Microscopy			
8	Clinical Microbiology			Safety
9	Transfusion Medicine	Provided service		Safety
10	Diagnostic Immunology			
11	Flow Cytometry			
12	Histocompatibility Testing	Provided service		
13	Cytogenetic Testing	Provided service		

14	Molecular Diagnostic Testing			Safety

4. The first-level heading for the requirements are composed in the following manner.

Field code no.	**Field name(2009~2015)**	**Field code no.**	**Field name(2009~2015)**
01	Laboratory Medicine		
07	Comprehensive Interpretation		
08	Point-of-Care Testing		
09	Referral Medical Laboratory		
10	Diagnostic Hematology	40	Transfusion Medicine[General]
21	Clinical Chemistry	43	Transfusion Medicine[Hospital Blood Bank]
23	Urinalysis and Microscopy	46	Transfusion Medicine[Blood Supplying Center]
30	Diagnostic Microscopy[General]	50	Diagnostic Immunology
31	Diagnostic Microscopy [General Bacteria]	60	Flow Cytometry
32	Diagnostic Microscopy [Acid Fast Bacteria]	70	Histocompatibility Testing
33	Diagnostic Microscopy [Fungi]	80	Cytogenetic Testing
34	Diagnostic Microscopy [Parasites]	90	Molecular Diagnostic Test
35	Diagnostic Microscopy [Viruses]		
36	Diagnostic Microscopy [Fecal Occult Blood]		

5. Each requirement is constituted in the following manner.

- Question
- Text
- Yes/No/Not applicable
- Each requirement is marked with scores given for each requirement according to the content of evaluation in the following manner:

Yes: full score

Yes, but incomplete: Partial score is given based on the content of the text.

No: 0 point

Not applicable: The Requirement is not scored, and the item is not included in the total scoring.

6. Requirement development process

- The requirements are based on the following data.
  - ■ Related domestic laws
  - ■ Foreign and domestic regulations and guidelines
  - ■ Regulations and guidelines of related organizations
  - ■ Expert citations
  - ■ Expert opinion
  - ■ Other related opinion
    - The developed requirements go through the process of opinion collection and inspection in the following manner.
  - ■ Collection of expert opinion
  - ■ Guidance and collection of opinion involving the inspectors and the institute under inspection
  - ■ Review by the Operating Committee
  - ■ Approval by the Board of Directors

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7. Feedback on the requirements

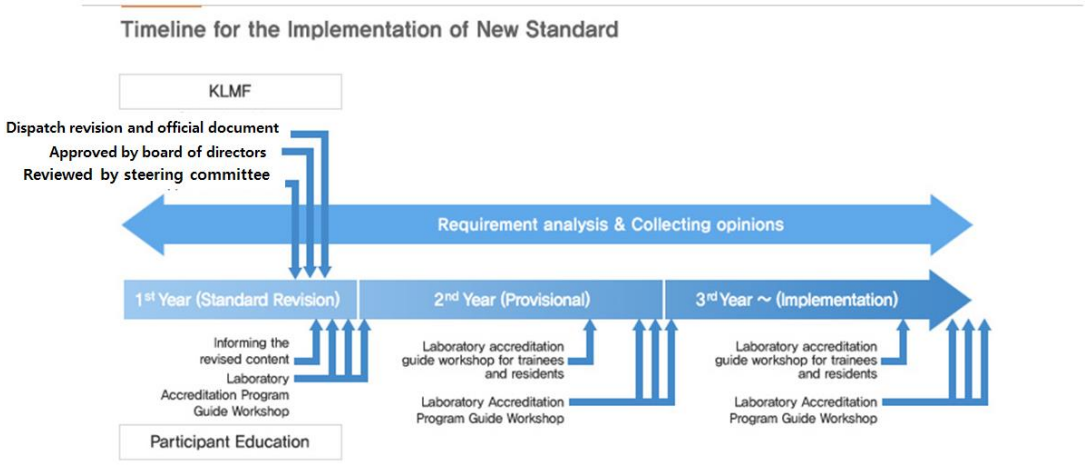
- During the inspection, the inspectors and the institute under inspection write down their opinion on the requirement and submit it to the foundation.
- Statistics of the score per requirement is calculated every year.
- At the 1st requirement revision workshop held every year on March, the feedbacks from the stakeholders are discussed to decide whether the requirement will be revised.

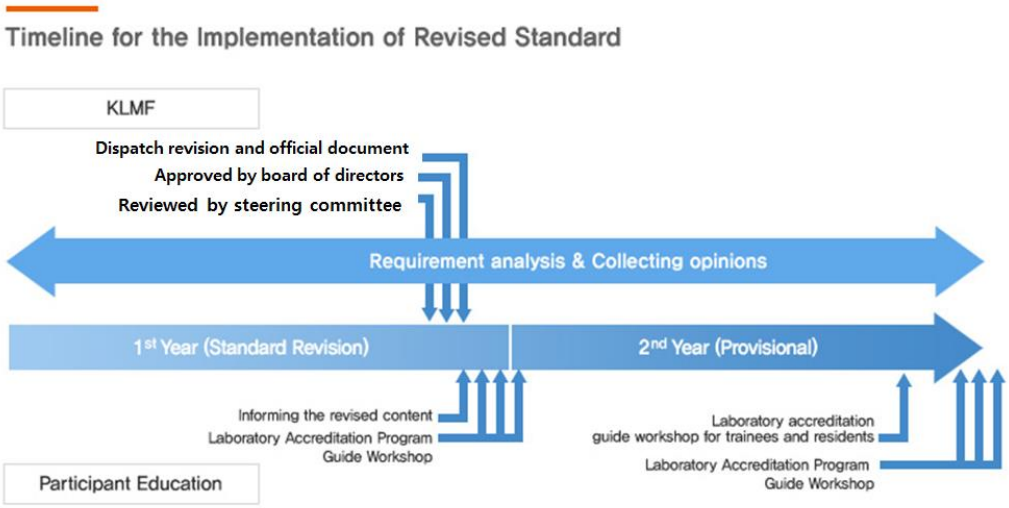
8. Newly established requirements

The newly established requirements are operated as 'recommended' for one year after its development, and then the score is given on the basis of the current state of implementation.

9. The plan for implementation

- The new and revised standard must be approved by the board of directors and the inspectors or surveyors and the users should be notified and provided sufficient time to get fully trained and understand each requirement.





- Notification Method
  - Official letter of standard revision notification
  - Issuance and distribution of examination checklists
  - Publish the revised checklist on the LMF homepage at http://lmf.or.kr.

- Training or Education Method
  - Laboratory accreditation guidance workshop
  - Surveyor or inspector workshop
  - Resident or trainee workshop
  - Post workshop materials on the LMF homepage
- Feedback
  - Checklist Q&A on LMF homepage
  - Survey : from attendees of the laboratory accreditation guidance workshop (will start in December 2017)

10. Requirement revision team

- The requirement revision team consists of one person per each field.
- The requirement revision team develops and revises the requirements.

11. Operation of the requirement revision team

The requirement revision team holds meetings and conducts work concerning the revision of the requirements.

At least 3 workshops are held for the revision of requirements and the work on requirement revision is carried out every year.

The revision team gives guidance on the revision for the revised requirements.