Supplementary files

Part I: English Version Questioner

Study Area Code: _____ Participant Code: _____

Structured self-administered questionnaire for Assessment to identify factors that affect medical laboratory accreditation implementation in selected public and private health facilities in Addis Ababa, Ethiopia

Part I Socio-Demographic Characteristics of the Respondent Dear participant, the following questions are targeted to differentiate your Socio-Demographic characteristics. Please circle the best proper choice of answer code.			
No	Questions	Coding Classification	Code
1	Gender	Male = 1	
		Female = 2	
2	Age in years	_____year	

4	Educational level	Diploma or below = 1 First Degree (BSC) = 2 Second Degree (MSc) = 3 Third Degree (PhD) = 4	
5	Monthly income	_____per month	
6	Work Experience/Service	_____year	

II. Knowledge Questions

Dear participants, the following questions are target to see your Knowledge towards Accreditation. Please circle the best choice of you answer code.

No	Questions	Coding Classification	Code
1	Have you been thought about Accreditation?	Yes = 1 No = 2	
2	Have you ever taken training related to ISO 15189?	Yes = 1 No = 2	
3	Do you have external consultants/mentors to assist with quality system implementation?	Yes = 1 No = 2	
4	Do you have information about Competency?	Yes = 1 No = 2	

III. Attitude Questions

Dear participants, the following questions are target to see your attitude towards accreditation. Please circle the best choice of you answer code.

No	Questions	Coding Classification	Code

1	accreditation is important for Medical laboratories?	Agree = 2 Disagree = 1	
2	ISO 15189 training is helpful for implementation of accreditation?	Agree = 2 Disagree = 1	
3	Do you believe your laboratory perform mplementation of LQMS?	Agree = 2 Disagree = 1	
4	Do you believe non-accredited laboratories affect satisfaction of their clients?	Agree = 2 Disagree = 1	

IV. IMPLEMENTATION OF ACCREDITATION

Dear participants, the following questions are target to see implementation of accreditation process. Please circle the best choice of you answer code.

No	Questions	Coding Classification	Code
1.	Do you have sufficient Resources human power, finance and inventory system?	Yes = 1 No = 2	
2.	Does the management support your laboratory?	Yes = 1 No = 2	
3.	Your equipment has full information?	Yes = 1 No = 2	
4.	Do you perform equipment calibration according to manufacturer instruction?	Yes = 1 No = 2	
5.	Do you have knowledge on availability accreditation body in Ethiopia?	Yes = 1 No = 2	
6.	Do you have a backup power supply?	Yes = 1 No = 2	
7.	Does Your laboratory participate on Proficiency Test?	Yes = 1 No = 2	
8.	Does the calibrated equipment/reagent traceability to IBM?	Yes = 1 No = 2	
9.	Staffs are motivating to implement ISO 15189?	Yes = 1 No = 2	
10.	Do you perform IQC for each test?	Yes = 1	

		No = 2	
11.	Do you perform method validation and verification?	Yes = 1 No = 2	
12.	Is your calibration reagents/equipment traceability maintained?	Yes = 1 No = 2	
13.	Do you participate EQA?	Yes = 1 No = 2	

V. Implementation as part of ISO 15189 accreditation		
(Key: Yes = Comply, No = not comply		
Its permanent facilities, or in associated or mobile facilities?	Yes=1 No =2	
Management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work?	Yes=1 No =2	
Does laboratory management have an effective means for communicating with staff	Yes=1 No =2	
Selecting and evaluating referral laboratories and consultants	Yes=1 No =2	

Does a list of selected and approved suppliers of equipment, reagents and consumablesexist ?	Yes=1 No =2	
Does the laboratory establish arrangements for advisory services	Yes=1 No =2	
Does the laboratory take corrective action to eliminate the cause(s) of nonconformities?	Yes=1 No =2	
Does the laboratory determine action to eliminate the causes of potential nonconformities in order to? prevent their occurrence?	Yes=1 No =2	
Does improvement activities directed at areas of highest priority based on risk assessments?	Yes=1 No =2	
Does the laboratory plan and implement the evaluation and internal audit processes?	Yes=1 No =2	
Does corrective action taken without undue delay to eliminate the causes of the detected nonconformities (see 4.10)?	Yes=1 No =2	
Does laboratory management review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care?	Yes=1 No =2	
Does the laboratory have job descriptions that describe responsibilities, authorities and tasks for all personnel?	Yes=1 No =2	

Does the laboratory provide training for all personnel on quality management system?	Yes=1 No =2	
Following appropriate training, does the laboratory assess the competence of each person to perform assigned managerial or technical tasks according to established criteria?	Yes=1 No =2	
Is a continuing education program available to personnel who participate in managerial and technical processes?	Yes=1 No =2	
Does the laboratory have space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients and visitors?	Yes=1 No =2	
Does the laboratory evaluate and determine the sufficiency and adequacy of the space allocated for the performance of the work?	Yes=1 No =2	
Does the laboratory and associated office facilities provide an environment suitable for the tasks to be undertaken, to ensure the following conditions are met:	Yes=1 No =2	
Safety facilities and devices are provided and their functioning regularly verified? EXAMPLE Operation of emergency release, intercom and alarm systems for cold rooms and walk-in freezers; accessibility of emergency showers and eyewash, etc.	Yes=1 No =2	
Are storage space and conditions provided that ensure the continuing integrity of sample materials, documents,	Yes=1	

equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results?	No =2	
Are clinical samples and materials used in examination processes stored in a manner to prevent cross contamination?	Yes=1 No =2	
Are storage and disposal facilities for dangerous materials appropriate to the hazards of the materials and as specified by applicable requirements?	Yes=1 No =2	
Are there adequate access to washrooms, to a supply of drinking water and to facilities for storage of personal protective equipment and clothing?	Yes=1 No =2	
Does the laboratory replace equipment as needed to ensure the quality of examination results?	Yes=1 No =2	
Is equipment operated at all times by trained and authorized personnel?	Yes=1 No =2	
Are current instructions on the use, safety and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer of the equipment, readily available?	Yes=1 No =2	
Does the laboratory have procedures for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration?	Yes=1 No =2	

Recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment?	Yes=1 No =2	
Do records maintained for each reagent and consumable that contributes to the performance of examinations?	Yes=1 No =2	
Does the independent verification by the laboratory confirm, through obtaining objective evidence (in the form of performance characteristics) that the performance claims for the examination procedure have been met?	Yes=1 No =2	
Does the laboratory validate examination procedures derived from non-standard/modified methods?	Yes=1 No =2	
Does the laboratory determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples?	Yes=1 No =2	
Does the laboratory use quality control materials that react to the examining system in a manner as close as possible to patient samples?	Yes=1 No =2	
Does the laboratory participate in an interlaboratory comparison program(s) (such as an external quality assessment program or proficiency testing program) appropriate to the examination and interpretations of examination results?	Yes=1 No =2	
Whenever an interlaboratory comparison is not available, does the laboratory develop other approaches and provide objective evidence for determining the acceptability of examination results?	Yes=1 No =2	

Does the laboratory ensure that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect patient care?	Yes=1 No =2	
Does the laboratory verify that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant?	Yes=1 No =2	
Does the laboratory have documented contingency plans to maintain services in the event of failure or downtime in information systems that affect the laboratory's ability to provide service?	Yes=1 No =2	

- If you have any additional factors that affects accreditation implementation?

Part II- English Version. In-depth interview /focus group discussion guide questions

FGD and In-Depth Interview Questionnaire for identifying factors affecting medical laboratory accreditation process in selected public and private health facilities in Addis Ababa, Ethiopia.

1. What do you know about accreditation?
2. How do you know about accreditation?
3. What is your attitude towards accreditation?
4. What is the benefit of practicing accreditation?
5. How can you prevent factors association with implementation of accreditation?
6. What action you think to be taken by the individual and government for implementation of accreditation?