IDENTIFICATION OF ISO 15189 CLAUSES EXERCISE

Leading Bidder Laboratories (LBL) have been assessed by ACCREDITATION OFFICERS S.A and the team of assessors has made the following observations. Remember that the assessment comprises examining the laboratory's processes to ascertain whether they are capable of delivering (*inter alia*) requisition, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples along with subsequent validation, interpretation, reporting and advice (taking safety and ethics in medical laboratory work into account) to the level required to meet the needs of patients and all clinical personnel responsible for patient care. The Standard provides the particular requirements for quality (both technical and management) and competence, and provides a framework for the assessment.

Table below has 20 observations made by the assessors, and mainly deals with general requirements that are broadly in common with other ISO quality management system standards. You are required to identify the most appropriate clause of ISO 15189:2012 that relates to them.

No	Observation	Clause of 15189:2012
1	The laboratory has data available to support the use of Method LBL AF2/01. However there has been no formal review of the data for the derived examination procedure to demonstrate that the specific requirements for the intended use of the examination have been fulfilled.	
2	The equipment label on thermometer LBL-001 does not state the date of calibration, and no date of recalibration has been recorded.	
3	The laboratory has recently purchased a piece of equipment that uses the mutagen, ethidium bromide. There has been no evaluation by laboratory management into the impact of its use.	
4	The laboratory director, as the person with ultimate responsibility for the overall operation and administration of the laboratory, defined the intent of its quality management system in a quality policy.	
5	The quality manual does not define the roles and responsibilities of the laboratory director and quality manager.	
6	There are no criteria defined for the selection of suppliers of microbiological culture media.	
7	LBL had not estimated the uncertainty of measurement for either blood or urine creatinine test measurement procedures, and consequently did not have an uncertainty for the reported creatinine clearance value or its apparent change over time.	
8	LBL does not have a documented procedure covering the handling of patient complaints.	
9	The job description for the senior mycologist was not up to date.	
10	The laboratory accepted and tested a non-labelled sample not identified to the individual from which it was taken, without clear justification for doing so.	

11	The laboratory identified opportunities for improvement in its phlebotomy service, but did not address them as the area was not considered the highest priority based on risk assessments.	
12	Alterations to original observed data have been made that obliterate the original recorded values, and that do not record the date the change was made or who made it.	
13	Samples are stored in a fridge, which is maintained in an unlocked side room off the main hospital corridor that is used by patients.	
14	No maintenance records have been kept for three analyzers (LBL/MAIN/008, 010 and 011).	
15	Ten results reported over the last two months have fallen into a critical interval. There were no records maintained to show that a physician or other authorized health professional had been notified, or that any advice had been given to the requesting clinician although the agreement indicates this is required.	
16	The laboratory does not participate in EQA for Sodium examinations although several appropriate schemes are available.	
17	The laboratory has several major contracts with external agencies including pharmacy and insurance companies; however, records of reviews pertaining to these agreements and relevant discussions have not been maintained.	
18	The head of the serology department has selected and purchased POVA (micropipettes) in response to a manufacturer's seasonal discount offer. When asked, he stated that although the items do affect the quality of the laboratory's service, there is no documented procedure for selecting purchases and none is necessary.	
19	The laboratory does not have a procedure for identifying and managing nonconformities.	
20	The laboratory uses two referral laboratories; however, on assessing report AF/001 it was apparent that the result from the referral lab had not been reported to the clinician.	