Discussion on Operation Management of Testing Laboratory

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Abstract. In order to continuously improve the level of testing through accredited laboratories, customer satisfaction is enhanced to continue to meet the requirements of the laboratory accreditation guidelines. From the aspects of people, machine, material, law, ring and test, the quality management experience generated in many years of work practice is summarized. First, we must start from three aspects of thinking, organization, and normative documents, and continue to strengthen the awareness of quality management; second, increase internal auditing efforts and pay close attention to the implementation of corrective measures; third, implement comprehensive supervision and promote the quality functions of various departments. The fourth is to implement the principle of full participation in quality management; the fifth is to give full play to the leadership role of “top management”. It provides a reference for the management system for continuous improvement of the accredited laboratory.

1. Personnel
For some special testing activities, the test results cannot be reproduced. When quality control is difficult, the laboratory should pay attention to the personnel's ability, training, supervision and technical communication with the peers. By increasing the training of existing personnel, timely training and assessment of inspectors, especially technical personnel, through training to broaden the horizon, understand the status quo, interoperability, clear the existing strength through assessment, determine development goals, and ensure Inspectors can update their ideas, master new methods, understand new technologies, and meet the needs of modern inspection management in a timely manner.

The problems in the personnel mainly include that some of the posts did not organize personnel training as required, and some new recruits were not assessed and authorized. RBT214-2017 stipulates that the laboratory shall document the capabilities required for each post affecting laboratory activities. As for the competency requirements, the laboratory shall determine the work undertaken by the personnel. The laboratory shall meet the requirements if the applicable laws, regulations, accreditation guidelines and their application instructions have specific requirements. Training requirements are clearly included in the general requirements of each position's capabilities and personnel.
laboratory shall formulate a training plan based on the needs analysis; the plan shall be reasonable, forward-looking, and uniform; clearly identify the positions, projects, time slots, implementing agencies, and training effectiveness evaluation methods that need to be trained; Training for potential risks in laboratories such as safety. The key to the effectiveness of the training is to see if it can meet the needs of current and future testing. Training is also one of the effective preventive measures. The laboratory shall evaluate and evaluate the technical capabilities of personnel. The methods may be qualification examination, on-site testing, questioning, comparison, and participation verification. The professional education of the inspectors and the applicability of the current positions, the satisfaction of professional technical skills and standards, The degree of understanding of job responsibilities and the degree of implementation of system documents. The management system is an important guarantee for the good operation of the laboratory. Following RB/T 214-2017 can help the laboratory to prove its operational capabilities and produce effective results. This paper sorts out and analyzes the non-conformities that appear in the operation of the management system in the past four years, finds the risk points, analyzes the causes and proposes countermeasures. The purpose is to improve the management by taking corrective and preventive measures in the future work.

2. Equipment
The testing laboratory must be inseparable from the equipment, and each instrument has its specific performance and usage. Sometimes the analyst does not understand the specific performance of the instrument. When testing, it often ignores the precision and accuracy of the instrument used, especially for some large-scale precision instruments. In addition, there are often some old instruments and equipment in the testing laboratory that cannot be eliminated, and they are not regularly repaired and maintained. The analysts still use these diseased instruments for testing and analysis, which will eventually lead to inaccurate test results.

Equipment is the material basis of inspection work, and its accuracy, reliability and management directly determine the accuracy of the test results. After continuous development and accumulation, our institute has been equipped with a large number of high-precision instruments and equipment. It is a very important job responsibility for inspectors to use and maintain these equipments. Next, sort out the problems in the use of the device. 1) The equipment is not properly equipped, and the range, accuracy or function does not meet the requirements of the standard. Before the equipment is purchased, it is necessary to carefully study the standards, understand the functions, range, accuracy and other requirements of the equipment, conduct sufficient and effective investigations, ensure that the technical indicators and functions of the equipment and equipment should meet the requirements, and the range should be related to the technical indicators of the measured parameters. Adapted. 2) The calibration of the equipment does not meet the requirements of traceability. The main performance is to verify some functions of the missing equipment during calibration. For example, the atomic absorption meter only verifies the flame furnace part, and does not trace the value of the graphite furnace part. Second, the calibration calibration value does not include the test point. For example, the calibration point of the mold incubator calibration certificate is 37 °C, but the standard requires the culture temperature to be 28 ± 1 °C; the glow wire tester only calibrates the temperature point of 600 °C, and does not cover the test requirement temperature of 960 °C. 3) The equipment does not confirm whether the calibration data meets the requirements of laboratory testing before it is put into use. Some instruments lack state identification. The accreditation assessment criteria stipulate that the inspection and testing organization shall confirm after the equipment is periodically verified or calibrated, and confirm that it meets the inspection and testing requirements before use. The contents of the verification or calibration shall be confirmed as follows: a) Whether the verification result is qualified and meets the requirements of the inspection and testing method; b) Whether the accuracy information of the equipment obtained by the calibration meets the requirements of the inspection and testing items and parameters, and whether Correct the information, whether the instrument meets the requirements of the inspection and testing method; c) Confirm the equipment status identification. 4)
During the period, the relevant equipment was not checked during the period. The guidelines stipulate that procedures should be established and maintained when period verification is required to maintain the credibility of equipment verification or calibration status. The period check is to check whether the equipment is stable between the two calibrations. The inspection and testing organization should judge whether the equipment needs to be checked during the period according to the stability and usage of the equipment. The judgment basis includes but not limited to: a) Equipment verification or calibration cycle; b) previous verification or calibration results; c) quality control results; d) equipment usage frequency; e) equipment maintenance; f) equipment operator and environmental changes; g) equipment usage range changes. Verification during equipment can reduce the risk caused by the inaccuracy of measurement equipment and reference standards, and effectively protect the interests of laboratories and customers. It is one of the effective preventive measures. In addition, when the instrument and equipment are corrected by the calibration information, the inspection and testing organization should promptly communicate to the relevant personnel and use it in the inspection and testing work. For standards, pay attention to their storage conditions and effective use dates.

3. Materials
The experimental materials used in the testing laboratory are generally divided into two types: the sample to be tested and the reagents and drugs used in the testing process. Under normal circumstances, the pre-treatment method of the sample to be tested, the environment to be placed after the treatment, whether the sample taken is representative, and the specification purity of the reagent used in the detection process will have an influence on the detection result.

In order to ensure the quality of purchased items and related services, the laboratory shall effectively control and manage the purchased items and related services. The purchase, acceptance, and storage of services, supplies, reagents, and consumables shall be controlled in accordance with the system to ensure the quality of inspection results. Procurement related services, including verification and calibration services, equipment purchase, design and construction of environmental facilities, transportation, installation and maintenance of equipment and facilities, waste disposal, etc. Suppliers and service providers of critical consumables, supplies, and services that affect the quality of inspections and inspections should be evaluated, and records of these evaluations and approved list of qualified suppliers and service providers should be maintained. Important consumables that affect the quality of inspection and testing, including medium for microbial detection, quality control strains, high-purity acid for inorganic analysis, chromatographic solvent for organic analysis, propane for power supply line cable without flame retardant test, etc. The varieties and acceptance criteria evaluated shall be accepted in batches after purchase and records shall be retained. The institutions that provide verification and calibration services should also be evaluated annually, including their qualification certificates, capability schedules, quality of service, and timeliness.

4. Method
Different detection projects have different methods. With the development of detection technology, more and more detection methods, and old detection methods are constantly being eliminated. Whether the analyst can choose the current effective detection method and master the various operation steps has a very important impact on obtaining accurate and credible test results.

Before using the standard method for the first time, it should be proven that these standard methods can be used correctly. If the standard method has changed, it should be reconfirmed and relevant supporting materials provided. When the laboratory is verified before the new test standard is put into use, it is first necessary to analyze and evaluate the text of the new test standard to assess whether the resource conditions of the personnel, equipment, methods, reagent materials and test environment possessed by the laboratory meet the test standards. When the evaluation result is that the above resource conditions can meet the requirements of the testing standards, it is also necessary to verify whether the laboratory has the technical ability to accurately execute the testing standard. For
chemical testing laboratories, it is necessary to pass technical tests to verify whether the testing technical indicators such as the standard curve, detection limit, recovery rate and precision of laboratory testers have met the requirements of the testing standards. When the test criteria for use are changed, the text of the new standard is first evaluated. If the evaluation finds that the new standard technical route has not changed, but only the standard name, year number or text format has changed, it can be directly used through technical review, put into use, and timely apply to the laboratory accreditation body and qualification accreditation authority. Standard changes. If the technical route found in the text evaluation is inconsistent with the technical route of the old standard, it is necessary to re-evaluate whether the resource conditions of the personnel, equipment, methods, reagent materials and testing environment possessed by the laboratory meet the requirements of the testing standards, and also Re-test the relevant technical parameters to confirm whether the laboratory has the technical ability to accurately execute the new test standard. If standards, specifications, and methods are not directly used by the operator, or their contents are not easy to understand, the regulations are not concise or lack sufficient information, or there are optional steps in the method, which may vary from person to person in the application of the method. When influencing the test data and the correctness of the results, work instructions (including additional details or supplementary documents) should be developed. During the on-site review, some inspectors were not standardized in the operation of certain experimental procedures because the standard regulations were not clear and no work instructions were prepared.

5. Facilities and environmental conditions
A specific test environment is required for the sample to be analyzed and tested. For example, the physical and chemical test items and the microbiological test are separated from each other and cannot be tested in the same environment. However, in the daily testing process, some inspectors save the map, often choose to conduct experiments, resulting in inaccurate test results.

In recent years, the expert group in the external review has submitted 19 non-conformities in terms of facilities and environmental conditions, and the problem has the highest frequency, including the following four cases. 1) The laboratory hardware does not meet the requirements of the testing standards or does not meet the requirements for safety protection and health protection. The accreditation assessment criteria stipulate that the inspection and testing institution shall have a workplace that meets the requirements for inspection and testing. The CNAS Accreditation Guidelines provide provisions for laboratory electrical safety, physical injury protection, and chemical injury protection in the application notes for each specialty. The facilities and environmental conditions of the laboratory must meet the requirements of the standard, and the accuracy of the test results should not be affected. At the same time, the safety and health of the testers should be protected. 2) When environmental conditions have an impact on the results, they are not monitored and recorded, such as the temperature and humidity of the constant temperature and humidity laboratory, the ambient temperature of precision measuring instruments (infrared spectrometer, tool microscope and three coordinate measuring instrument, etc.). The qualification assessment criteria stipulate that when the inspection and testing standards or technical specifications require environmental conditions or environmental conditions affect the inspection results, environmental conditions should be monitored, controlled and recorded. Therefore, when necessary, the laboratory should be equipped with environmental condition monitoring equipment and qualified. Monitor and record environmental conditions as relevant experiments are performed. 3) Hazardous waste disposal does not meet the requirements. CNAS-CL09 “Application Note for Accreditation Criteria in the Field of Microbial Testing” stipulates that laboratories should have facilities and systems for proper disposal of waste samples and hazardous wastes, paying attention to biosafety. CNAS-CL10 “Application Note for Accreditation Criteria in the Field of Chemical Testing” stipulates that laboratories should have measures and procedures for safe handling, disposal of toxic and hazardous substances and waste, and keep records of relevant treatment and disposal. The secondary biosafety laboratory should be equipped with a high pressure steam sterilizer, and waste samples and hazardous waste must be
autoclaved. The organic waste liquid and inorganic waste liquid produced by chemical detection shall be entrusted to a qualified disposal unit for proper disposal by toxic samples, and the relevant treatment records shall be retained. 4) Biosafety laboratories that perform microbiological testing do not use biosafety labels properly. The CNAS-CL09 “Guidelines for the Application of Accreditation Guidelines in the Field of Microbiological Testing” stipulates that work areas with aseptic (purification) requirements should be clearly identified and effectively controlled, monitored and recorded. The laboratory controls the personnel entering a specific area such as sterility or purification.

6. Test
Adopting reasonable and effective quality control measures can monitor the inspection work process, anticipate the signs of possible problems in the test or discover the existence of problems in time, so that the laboratory can take corrective measures or preventive measures in a targeted manner to avoid non-compliance with work. Guarantee the accuracy of the test results. The measures for quality control in laboratory testing can be divided into external control and internal control.

The main problem in our field is that the proficiency testing does not cover all the testing areas or sub-areas. The internal quality control project or frequency is not suitable for the testing work carried out, and the validity of the results cannot be completely monitored. Laboratory quality control refers to the control measures taken to control the error of the test results within the allowable limits. It includes two parts: internal quality control in the laboratory and external quality control in the laboratory. The quality control shall cover all types of inspection and testing items within the scope of qualification certification, and effectively monitor the stability and accuracy of the inspection results. The inspection and testing institution shall participate in the capability verification or inspection and testing agency comparison activities required by the qualification certification department. Our institute is a CNAS accredited laboratory. It must comply with CNAS's proficiency testing policy and meet the requirements of CNAS-AL07 “Capability Verification Field and Frequency Table”. For areas where proficiency testing is not available, internal quality control, quality control projects and The frequency should be compatible with the testing activities carried out by the laboratory. For the testing activities that are rarely carried out, quality control activities should be passed to ensure that the testing capability continues to meet the requirements. For data on quality control activities, laboratories analyze them to control and improve laboratory activities. When quality control data is not satisfactory, appropriate measures should be taken to prevent reporting of incorrect results.
Figure 1. Laboratory daily operation diagram

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