Discussion on the Problems and Countermeasures of Standard Method Management in Testing Laboratories

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Abstract. Adopting effective standards for testing is a prerequisite for ensuring the authenticity and reliability of testing data.In order to further improve the quality of laboratory work, after sorting out the problems found in the quality management work of the testing laboratory, we have identified the current problems in the testing laboratory, such as untimely updating of standards, non-standard use of standards, and lack of effective standard control and management. We have analyzed the reasons for the problems and proposed improvement measures for reference by the testing laboratory.

Keywords: Standard methods; Testing; Laboratory.

1. Introduction

Standards are the most fundamental basis for testing laboratories to carry out all testing work and ensure the credibility and reliability of testing data. Therefore, whether the testing laboratory effectively manages the standards directly determines the authenticity, credibility, and scientific of the testing reports issued by the laboratory to the outside world [1].

The following is a summary and analysis of the problems in the use and management of standards in the quality management work of testing laboratories. Some problems are individual among laboratories, while others are universal. The article proposes corresponding solutions, providing some reference for the effective management and continuous improvement of standards in the quality management work of testing laboratories.

2. Standard Daily Management

2.1 Standard novelty search

The novelty check of standards is a fundamental task of using standards for testing, but the phenomenon of using expired standards in testing laboratories often occurs. Some laboratories do not include the management of standard methods in their document control procedures, while others do not have detailed regulations on the procedure documents for standard method management. They do not clearly specify the responsible parties, methods, time, and related requirements for novelty retrieval of standard methods; Some laboratory testing personnel have a weak awareness of standard novelty, and there are omissions in personnel training and standard management, resulting in the fact that the new version of the standard has already been issued and the laboratory is still implementing the old standard for testing work.

The testing laboratory should clearly define the cycle of standard novelty check in the program documents, which should be conducted once a quarter or six months and set up a dedicated standard management position. The personnel in this position are responsible for the daily management of standards, such as borrowing, recycling, archiving, etc., and regularly organize comprehensive and systematic standard novelty check to ensure that the standard methods used in the testing report issued by the laboratory are the latest version, Thus improving the reliability and effectiveness of testing reports.At the same time, the formality of the standard source, such as the standard issuing laboratory or the standard information service platform[2], should also be specified to ensure the accuracy and timeliness of the Standard state. The laboratory shall keep and incorporate the results

of each novelty search into the management review. The content of each novelty search shall include the name of the standard, the standard code, the Standard state (current/expired/abolished), the date of this novelty search, the name of the novelty search personnel, the novelty search website used and other information.

2.2 Standard change handling

The laboratory has insufficient understanding of standard changes, and some believe that it is only a year change and does not require standard changes. Some laboratories are not clear about the concept of method confirmation and validation. Although so-called "changes" have been made, the effectiveness of standard method change validation is not sufficient. They simply fill out the record form of standard changes, fail to provide objective evidence, and have not conducted confirmatory tests to prove that the laboratory meets the specified requirements and the accuracy and reliability of the test results.

When there is a change in the standard, if there is no substantial change in the testing capability involved, the existing capacity of the laboratory can meet the requirements of the new standard, and the laboratory can handle the change filing through self-commitment; If there are substantial changes in the detection capability, such as changes in the operating procedures and technical parameters of the detection method, modifications to the detection environment, or the addition of new equipment and facilities, it is necessary to prove the ability to correctly apply the new standard through technical verification. The standard method verification should have relevant documents and implementation records, and the standard method change should be re verified.

Before introducing testing or calibration, the laboratory should verify its ability to correctly apply these standard methods. Verification not only requires identifying the corresponding personnel, facilities, environment, equipment, etc., but also proving the accuracy and reliability of the results through experiments, such as precision, linear range, detection limit, quantification limit and other method characteristic indicators. If necessary, inter laboratory comparisons should be conducted. If during the validation process, it is found that there are links that are not detailed in the standard method but affect the detection results, the detailed operating steps should be compiled into a work instruction book as a supplement to the standard method.

3. Use Of Standards

3.1 Verification of standards

Standard validation refers to the provision of objective evidence by the testing laboratory to prove that it can correctly apply the corresponding standards and meet the testing regulations and requirements [3].When formulating standard control procedures, the laboratory should ensure that suitable methods are used for all work in the testing, and complete the validation of the standard methods before using a standard for the first time or using a changed standard for testing. The verification content should cover the entire process of testing, such as whether the testing personnel operating standard methods have the corresponding technical capabilities, whether the transportation and storage of goods and materials meet the standard requirements, whether the performance of instruments and equipment meets the testing conditions, whether the environment of the site has an impact on the testing results, whether repeatability tests are carried out according to the standard requirements, and whether the testing results are repeatable and reliable [4].Only after all verification steps and results meet the testing requirements can the laboratory use this standard for testing. Finally, the laboratory should keep relevant records that can verify its technical ability to use the standard method correctly.

3.2 Standard deviation

Standard deviation refers to a certain deviation from the methods specified in the standard. Testing laboratories should establish procedures that allow deviations from testing methods, such as

documenting the implementation requirements for deviation applications, approvals, execution, results, and report descriptions. Some laboratories do not label the items involved in the deviation in the test report issued after it occurs, while others mistakenly believe that non-standard methods can be treated as method deviations.

The deviation from the standard shall not violate relevant laws and regulations or the laboratory's own quality policy and shall not affect the validity and accuracy of the test results. The detection after deviation should be controllable and traceable. It is worth noting that deviation is a short-term behavior that cannot be deviated for a long time. For the timing of deviation, deviation from the testing method should only occur when there are differences between objective conditions such as samples, resources, and experimental conditions and the requirements of the testing method. For example, if the sample properties do not meet the requirements of the testing method, there are differences between environmental facility conditions and the requirements of the testing method, and the testing steps and requirements of the testing method are different. If the objective conditions of the testing laboratory meet the specified requirements of the testing method, no deviation is allowed.

4. Controlled Standards

4.1 Standard control and management

Standards are the most fundamental external documents of testing laboratories, and there are no standard management and control procedures established in the laboratory's management system documents, some laboratories have too general and lack operability in the program files for standard management, without specifying the measures taken by the laboratory to control the standards, whether there is a unique identification, and without involving issues such as whether the novelty search channel is smooth.

The standard management control procedure should cover the entire process of document writing, review, confirmation, uniqueness identification, changes, deviations, and abolishment. The review of standard methods should include responsibilities, tracking methods, novelty frequency, and novelty time [5].Standard documents can usually be divided into paper versions and electronic versions. The laboratory should add unique identification to the paper version of the standard, including page number, total number of pages, revision status, etc., to truly achieve controllability and traceability for each standard document. Specialized authorized personnel should be assigned to manage electronic standards, and downloading and printing without authorization is prohibited. At the same time, the testing laboratory should ensure that controlled documents are notified or distributed to all departments or positions related to testing, such as work instructions, standards, testing methods, manuals, etc., which is conducive to timely learning by testing personnel.

4.2 Personnel Authorization

The testing laboratory should provide corresponding training, authorization, and ability confirmation for all operators in the testing positions according to their job requirements before taking up their positions with certificates [6]. However, in the on-site review, some testing personnel may not have the corresponding training records for the standard method without laboratory authorization before using it for testing. In this case, the relevant work of the testing personnel should be suspended, and they should be retrained and authorized before taking up their positions. Before using a standard method for testing activities for the first time, testing personnel should participate in training on the standard, such as lectures or practical training. Only after passing the assessment and being authorized by the laboratory management can they use the standard method for testing activities and issue testing reports.

Authorization and capability confirmation should be dated, as authorization is not a long-term or permanent authorization, but rather the ability of relevant personnel should be confirmed at any time as testing requires. If there are changes to the operating procedures in some standard methods,

the laboratory should conduct a new training and assessment for employees who use this standard. Only those who are competent can take up their positions to continuously ensure the technical capabilities of the testing laboratory.

5. Conclusion

As the technical basis for testing, standards play a supporting role in ensuring the fairness, accuracy, and scientific of testing work, improving product quality, and enhancing social recognition. Testing laboratories should continue to grasp the guiding role of standards in quality management in the future. On the one hand, they should further improve the construction of the standard management system, strengthen supervision, and ensure the effective operation and continuous improvement of the system; On the one hand, emphasis is placed on improving the standard awareness and sense of responsibility of management personnel, continuously innovating standard management methods, expanding standard management thinking, providing real and accurate data and results for society, and providing reliable and reliable technical support for the high-quality and efficient development of the national economy.

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