

Quality Control Parameters for Custom Chemical Analysis via Emission Spectrometry in a Testing Laboratory as per ISO/IEC 17025

Sumaira Nosheen*, Shahzad Alam, M. Irfan, Farooq Iftikhar, Zaheer Abbass, Bilal Waseem, Badarudin Soomro, Salman Ahmad and Abdul Karim Aziz

Pakistan Institute of Technology for Minerals and Advanced Engineering Materials, PCSIR Labs Complex, Lahore Pakistan.

ARTICLE INFO

Article history:

Received: 30 July 2016;

Received in revised form:

12 December 2016;

Accepted: 21 December 2016;

Keywords

Chemical Analysis,
Emission Spectrometer,
ISO standard,
Quality Control,
Testing laboratory.

ABSTRACT

The process of quality assurance in a testing laboratory should reveal that the method and the analytical instrument give precise and accurate results, or whether aggravation occurs. The quality measures should comprise standard tests which give information on the characteristic performance of the method used by the laboratory. According to the literature, useful standard procedures contributing to the overall quality of analytical results are illustrated in relation with optical emission spectrometry. Parameters examined are general requirements for a complete quality system according to ISO/IEC 17025:2008 international standard including accuracy and precision. The performance of the whole system to measurement of samples of interest must be monitored with control charts. Data representing the routine performance of emission spectrometer systems and methods permit predicting long-term uncertainties and confidence intervals.

© 2016 Elixir all rights reserved.

Introduction

As a laboratory, which is ISO 9001 and 17025 accredited and have fully implemented quality system according to standard requirements, many practical benefits can be achieved in various areas. At present the requirement of quality control for a testing laboratory is necessary to ensure good comparability of data. Quality Control is defined as a set of activities or techniques whose purpose is to make sure that all quality requirements are met. In order to achieve this purpose, processes are monitored and performance problems are solved. A variety of texts exists such as Good Laboratory Practice and the quality assurance systems ISO 9001 and ISO 17025 [1-5]. However these international standards provide only general rules to install and maintain a quality system. It remains the responsibility of the laboratory to define appropriate procedures which assure that adequate quality is achieved, checking change in performance of method used [6-9]. Implementing an ISO/IEC 17025 laboratory management system is a means to ensuring efficiency and technical competency in calibration and testing laboratories. A laboratory that establishes a laboratory management system compliant with ISO/IEC 17025 joins the growing world partnership of accredited laboratories. An ISO/IEC 17025 accreditation certificate will show potential customers that your laboratory values quality and that you have taken steps to ensure that your calibration or testing results are accurate and reliable. ISO/IEC 17025 accreditation is available for both freestanding laboratories and for laboratories which are part of larger facilities. If you want to solidify your laboratory's stance as a serious competitor, it is imperative that your laboratory management system comply with ISO/IEC 17025. Accreditation is an objective way to assure your customers that you have demonstrated technical competence to provide reliable and accurate test or calibration results. Accreditation

is objective because an independent, third party accreditation body performs annual assessments to verify whether your system is meeting all of the requirements of ISO/IEC 17025. This independent evaluation is significant to the customer, because it is an unbiased guarantee that a laboratory is performing at its highest level. Another advantage of achieving ISO/IEC 17025 accreditation is that it will set a laboratory aside from your competitors. ISO/IEC 17025 is an ideal management system model for laboratories because it aims to control quality costs, get better measurement accuracy and guarantee consistency of results. It is also customer-driven. When implemented correctly, the elements of ISO/IEC 17025 work meticulously together to ensure that required quality levels are met and that customers' needs are satisfied. This can be a powerful strategic tool [10].

Implementation began with documentation of all analytical, administrative, and quality processes to meet the requirements of the ISO 17025 standard.

All personnel were trained on the ISO standard. The written methods were installed into a document control system. All equipment was identified and calibration requirements were determined. Once the processes were documented, the laboratory lived by the system. Records provided evidence of compliance, and internal audits were performed to identify issues and improve compliance. Documents were revised as needed to accurately describe processes.

I. Specific Requirements for a QC Laboratory

After the final endorsement of the ISO 17025 standard (General Requirements for the Competence of Testing and Calibration Laboratories) by members of the International Standards Organization in December 1999 (ISO 17025:1999, 1st Ed., 1999, ISO, Geneva, Switzerland, pp 12–15), the testing and calibration laboratories further developed its

Quality system by adding components to achieve accreditation to ISO 17025. The supplementary components of the new standard particularly deal with technical requirements for processes and analytical methods. The Emission Spectrometer Laboratory became accredited in 2008 [11].

II. Requirement for Operators

According to the standard ISO 17025, the laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff that is undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required. In some technical areas (e.g. non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, included in the standards for the specific technical field, or required by the customer [12].

III. Equipment Requirements

Some guidelines for the testing of metallic alloy samples are given in the Equipment Manual in detail [13]. Some ASTM methods are also followed strictly which are given in literature [13, 14, 15, 16, 17, 18, 19]. For testing a sample on Emission Spectrometer some parameters are defined listed in Table 1.

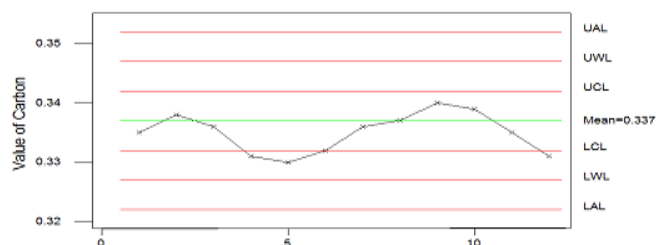
Table 1. Parameters of OES system affecting the analytical quality of results

No spark	Accumulation of dirt particles	Variation in results
White spark	Argon gas quality	Variation in results
Temperature	Stability	Precision/accuracy of measurements
Gas flow rate	Pressure & Purity	Precision/accuracy of results

The perception of quality is generally articulated in terms of accuracy, repeatability and reliability with long-term monitoring in regard with the chemical analysis of samples. The policy proposed in this paper is based on the use of CRM (certified reference materials) and calibration samples (SUS, setting up samples). Calibration samples (CRMs) allow control of the performance of the instrument. Control samples (CRMs, known as certified reference materials) are included in the analytical batch and treated in the same way as the unknown samples. The responses to specified compounds correspond to the actual analytical quality achieved. Control samples allow control of the presentation of the whole analytical procedure including the sample preparation step. These experiments represent a minimum number of control analyses and provide long-term results. However, control results must be fully documented, especially with control charts and stored for later inspection. The laboratory must demonstrate the validity of the method in all conditions.

In quality control charts, the changeable of concern is usually plotted on the y-axis versus number of results/sparks on x-axis. Every time, the new control values are collected as part of routine work and are added to the control charts for all parameters characterizing the operation of the spectrometric method. Based on the data collected during a certain period of time, acceptable performance limits can be established to ensure reliable results. Table 2 represents the quality control chart for only one parameter (carbon in low alloy steel)

Fig.1 Quality control chart of Carbon percentage in a Low Alloy Steel sample
(UAL: upper action limit, UWL: upper warning limit, UCL: upper control limits and vice versa)



IV. Quality Assurance

The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. Regular use of certified reference materials and/or internal quality control using secondary reference materials, participation in inter laboratory comparison or proficiency-testing programs. The selected methods should be appropriate for the type and volume of the work undertaken [20].

V. Maintaining the Quality system for Continuous Improvement

The real payback from operating a quality system begin after the certification process. Proper maintenance of the system is required to discover issues and continuously improve. The maintenance of the system requires elected personnel to coordinate and monitor completion of required actions. Scrupulous record keeping provides information on the devotion to system practices as well as the groundwork for process control measurement. Review of these measurements and responses to observed trends provide continuous improvement of the system [21].

VI. Conclusion

Quality assurance demonstrates how well is the method used during routine analysis. The function of the quality procedures must be then useful for laboratories in various fields. The quality control requires knowledge on the whole analytical process especially for methods which are used. The most important aspects for checking analytical error are through the definition of appropriate tests. The presented selection of test methods enables the analyst to get an overview of the most important performance characteristics of his method. After only a short testing time, it is possible to judge the functioning of the spectrometer parameters such as sensitivity of detection and precision and accuracy. Therefore, by analyzing control samples at regular time, the long-term reliability of the system is established and confidence in the results produced is generated. If the performance of the system is not suitable for the analysis, the acceptable operation conditions have to be restored before the analysis can be started or continued. However, to improve the quality of analytical procedures, introduction of better methods, equipment or improvement of personnel training are needed [22].

References

1. T. Engelhard, E. Feller, Z. Nizri, (2003), A Comparison of the Complimentary and Different Issues in ISO/IEC 17025 and OECD GLP, *Accred. Qual. Assur.* 8 (2003) 208.
2. H.W. Hembeck, GLP and other Quality Assurance Systems. A review, *Accred. Qual. Assur.* 7 (2002) 266.

3. NF EN ISO/CEI 17025, *Prescriptions generals concernant la competence des laboratoires d'etalonnages et essays*, AFNOR, Paris, 2005.
4. L.D. Eicher, The ISO 9000 family of International Standards, *Accred. Qual. Assur.* 2 (1997) 323.
5. F.J. Liorens-Montes, A. Ruiz-Moreno, Internationalization ISO 9001 implementation: An examination in laboratories involved in chemical measurement, *Accred. Qual. Assur.* 10 (2005) 304.
6. Ph. Quevauviller, *Quality Assurance for Environmental Monitoring*, VCH, Weinheim, 1995.
7. Ph. Quevauviller, W. Cofino, L. Cortez, *Trends Anal. Chem.* 17 (1998) 241.
8. J.W. Dolan, *LC-GC* 17 (2004) 328.
9. J. Ermer, H.J. Ploss, Validation in Pharmaceutical Analysis. *J.Pharm.Biomed.Anal.* 37 (2005) 859
10. Perry Johnson Laboratory Accreditation, Inc. 755 W. Big Beaver Rd., Suite 1325 Troy, MI 48084 U.S.A.
11. ISO 17025: Practical Benefits of Implementing a Quality System, *Journal of AOAC International VOL. 86, NO. 5, 2003*
12. ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
13. Optical Emission Spectrometer, METAL-LAB 75/80V, GNR. Srl, VIA SEMPIONE 187
14. <http://www.astm.org/Standards/E415.htm>
15. <http://www.astm.org/DATABASE.CART/HISTORICAL/E1086-08.htm>
16. <http://www.astm.org/Standards/E2209.htm>
17. <http://www.astm.org/Standards/E1999.htm>
18. <http://www.astm.org/Standards/E1251.htm>
19. <http://www.astm.org/Standards/E1806.htm>
20. ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
21. ISO 17025: Practical Benefits of Implementing a Quality System, *Journal of AOAC International Vol. 86, NO. 5, 2003*
22. P Masson, Quality control techniques for routine analysis with liquid chromatography in laboratories, *Journal of Chromatography A*, 1158 (2007) 168–173.