Quality management system for application of the analytical quality assurance cycle in a research project

2016 J. Phys.: Conf. Ser. 733 012046

(http://iopscience.iop.org/1742-6596/733/1/012046)

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Abstract. The lack of quality assurance and quality control in academic activities have been recognized by the inability to demonstrate reproducibility. This paper aim to apply a quality tool called Analytical Quality Assurance Cycle on a specific research project, supported by a Verification Programme of equipment and an adapted Quality Management System based on international standards, to provide traceability to the data generated.

1. Introduction

The Research and Development (R&D) Laboratories have great importance in the construction of pure or applied know-how. In Brazil, the majority of these kind of laboratories are in public universities. These laboratories generate data that could interest Academia or enterprises however, the problem arises when these data could not be reproducible and historically, the preoccupation with the quality assurance in these institutions is negligible [1].

To assure quality, the R&D laboratory could seek the formal accreditation of a quality management system (QMS) fulfilling the requirements of ISO/IEC 17025 or Good Laboratories Practices (GLP). It will discover that accreditation is not expensive but the maintenance of the QMS, it is.

For R&D laboratories that could perform tests and calibrations is technically easy to develop a QMS and extend it to the other activities (research and teaching). It is possible by the profit achieved with the tests or calibrations. However, there is an infinity of other kind of research projects that do not support parallel activities.

Another option is the development of a QMS without formal accreditation although based on the principles of international standards. The Eurachem Guide was developed to give guidance to make this possible [2]. Unfortunately, this guide was too much prolix.

Olivares and Lopes created a quality tool more concise and simple: the Analytical Quality Assurance Cycle (AQAC). It is based in the three most important technical requirements of ISO/IEC 17025:2005 standard: 5.4.5 Validation of Methods; 5.4.6 Estimation of uncertainty of measurement and 5.9 Assuring the quality of test and calibration results, resulting in three major concepts: I) Validation; II) Uncertainty and III) Quality Control. Two important details link those major concepts: the use of calibrated equipment and the use of certified standards (and certified reference materials). It is impossible to apply the AQAC without these items because there isn't traceability to the chain of verification of the conformity [3].

Nonetheless, it is necessary to make some adaptations in the AQAC because it is focused in the metrological traceability but there are the necessity to provide traceability of the information (reports, documents, records). Regarding these points, this paper aim to apply the Analytical Quality Assurance

Cycle in a specific research project to provide metrological traceability and the development of a QMS in the Research in Quality Assurance for Laboratories (RQA Lab), situated in São Carlos.

2. Methodology

2.1. The Analytical Method

The method developed was based on Stir Bar Sorptive Extraction (SBSE), but improved by cooling the sorptive phase then it had been called Refrigerated Sorptive Extraction (RSE) for extraction of polyaromatic hydrocarbons (PAHs) and alkylphenols (n-octylphenol and n-nonylphenol), in surface water. After the sample preparation, the chromatographic analysis was processed in a GC/FID.

2.2. Analytical Quality Assurance Cycle

The use of calibrated equipment and certified standards is very important and it is a key point to implement AQAC. However, the funding was end for the RQA lab and it was impossible to implement a calibration programme and the acquisition of certified reference standards. The solution was implement a verification programme for balances, based on Euramet Guidelines [4] and micropipettes based on ISO 8655-2 and 8655-6 [5,6] and the estimation of the uncertainty of the standard solution used in fortified blanks to did the Validation and Quality Control.

The Validation was performed contemplating: selectivity (matrix effect), linearity, precision, robustness and limits of detection. The estimation of uncertainty was processed using the guide Eurachem [7]. Quality Control was performed following the principles of control charts [8].

2.3. Quality Management System

The QMS developed was based on ISO/IEC 17025:2005 and Good Laboratory Practices. The Chemistry bachelor's program (IQSC-USP) have in its grade, the discipline "NBR ISO/IEC 17025 System" given by the professor Igor Renato Bertoni Olivares. The Standard Operational Procedures (SOPs) created by the students are harnessed and applied in the QMS.

3. Results and Discussion

Observing the figure 1, perhaps the common sense shows that the order to create the system was: i) QMS; ii) Verification Programme; iii) AQAC. Nonetheless, it was by the application of the AQAC that the necessity of the adaptations was noted.

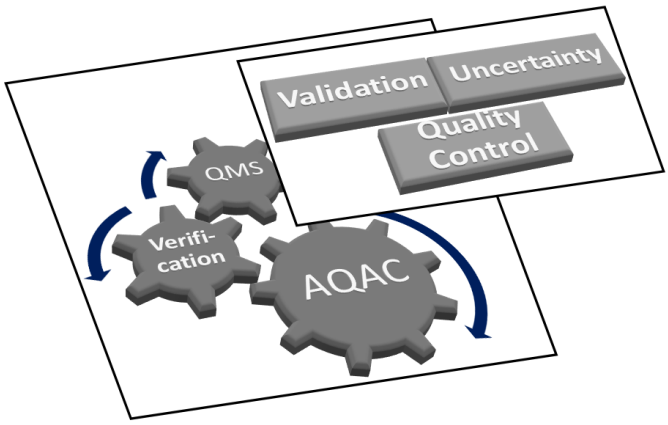

Figure 1: Schematic representation of the quality system idealized for the RQA Lab. In the first plan, the three major concepts: Validation, Uncertainty and Quality Control. In the second plan, the Quality Management System and the Verification Programme. The gearing represent that anything works solely.

The intermediate verification of balances is used to "know and control the drift of the balances in the period of two calibrations" and it could be performed by three tests: i) "repeatability test"; ii) "Test for errors of indication" and iii) "Eccentricity test" [4]. The verification of repeatability aim to know if the response of the balance changes with the weighing routine. However, in the Verification Programme,

the verification of repeatability was used to generate an uncertainty (standard deviation) for the balance, similarly for the micropipettes.

The metrological traceability was guaranteed by verification of the equipment using standard weights calibrated by laboratories accredited in ISO/IEC 17025. The uncertainty of the verification was used to estimation of the analytical uncertainty (see figure 2).

Is the uncertainty of the verification overrated or underestimated concerning the uncertainty of a calibration? It could be both: for micropipettes, probably, the uncertainty of the verification is bigger than the calibration because in the first one, the variability probably is less controlled. For balances, the uncertainty of the verification could be smaller than the calibration because in the verification some uncertainty sources are suppressed.

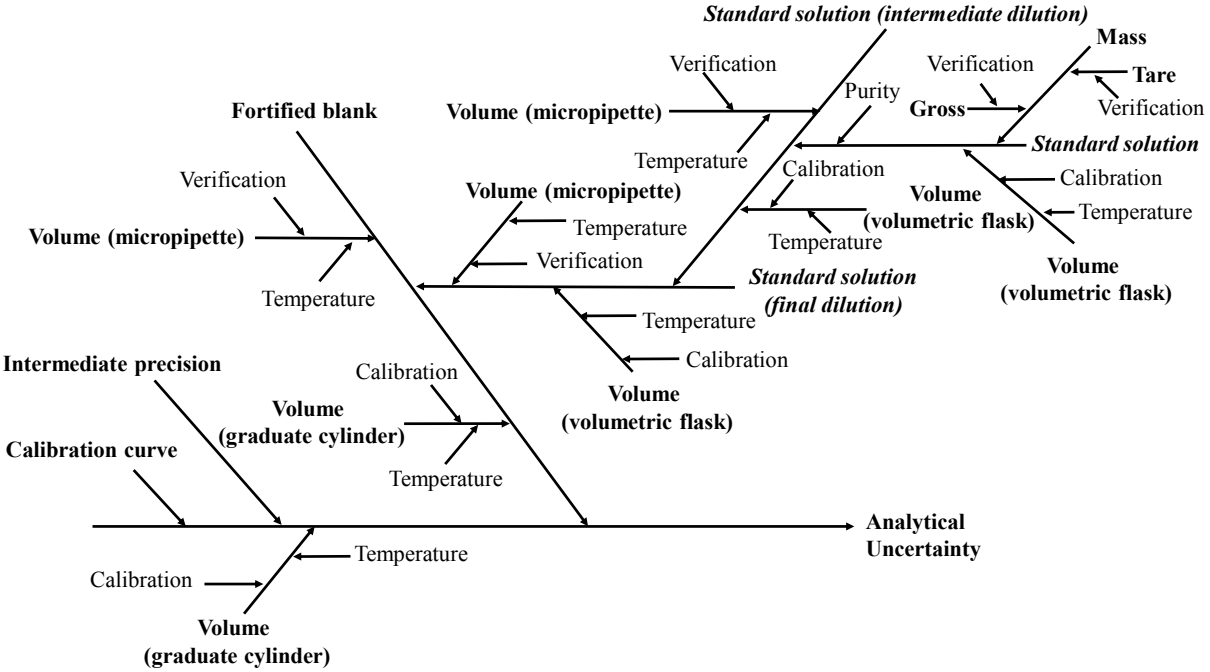

Figure 2: The Ishikawa diagram for analytical uncertainty. In the fortified blank, arise the uncertainty source of the dilutions of standard solution

Despite the doubts concerning the estimation of the uncertainty by the verification of equipment, the analytical uncertainty had as the major uncertainty sources, the precision of the measurement and the calibration curve. Both of them were performed using fortified blanks to obtain similar conditions to the sample analysis preventing that in the major sources there was an underestimate of uncertainty [9].

After the implementation of the Verification Programme, the Analytical Quality Assurance Cycle could be implemented. Although, there was the necessity to control documents and data. The Quality Management System was implemented using requirements of ISO/IEC 17025 and GLP. SOPs created by students in the audit simulation of the discipline “NBR ISO/IEC 17025 System” are adapted to be used in the laboratory. “Control of documents and records”, “Corrective and Preventive Actions”, “Personnel”, “Accommodation and environmental conditions”, “Measurement traceability” and “Reports” are examples of SOPs harnessed.

Moreover, the Coordination of Post-graduate Programme of the Institute of Chemistry of São Carlos showed the initiative to standardize the lab book for all students. The main motivation is to decide for the authors of patents in case of litigation, however it meet the GLP requirement that it should have a book for the research test. Moreover, these lab books could be the gateway to quality assurance for others research projects in the future.

4. Conclusion

The application of the analytical quality assurance cycle in a research project, supported by a quality management system with verification programme, could assure quality to the data generated, even that the lab operates without resources.

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