Equipment Qualification

Ernst Halder, Eurachem-CH

e.halder@rhone.ch

Eurachem

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SCS
Swiss Chemical Society

Division of Analytical Sciences

Introduction

In the early 1980s, instrument requirements appeared in various documents on analytical laboratories. These were rather vague. With clarity, only calibration was required.
For many laboratories, simply getting things right is no longer enough; they must also provide documented evidence to demonstrate the integrity of their data and the value validity of their results. Many laboratories achieve this through formal quality systems, generally implemented in accordance with one or more of the three main internationally recognised quality standards: the ISO 9000 series of standards [1], Good Laboratory Practice (GLP) [2,3] and ISO Guide 25 [4] However, these standards are intentionally very broad so that they are as widely applicable as possible. They contain general requirements, such as that instruments must be fit for purpose, properly maintained and calibrated to national or international standards, but they are not specific about what is actually required or how it should be achieved. It is also unclear where and when a formal proficiency test is appropriate and how it should be documented.

First steps

At the beginning of any instrument history is acquisition. The Analytical Methods Committee of the Royal Society of Chemistry first commented on this in a 1984 publication [5]. It included recommendations on the steps required for the successful evaluation, purchase, installation and reliable operation of analytical equipment. The series was continued until 2018 [6].

First set of rules for EQ

Against this background, the Government Chemist's Laboratory (LGC) has established an Instrumentation Working Group under the auspices of Eurachem-UK with the support of the DTI VAM Initiative [7]. The working group has brought together a broad cross-section of instrument manufacturers, representatives of accreditation bodies and regulatory authorities, and users of analytical instruments.
The publications [8,9] introduce the concept of Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ).

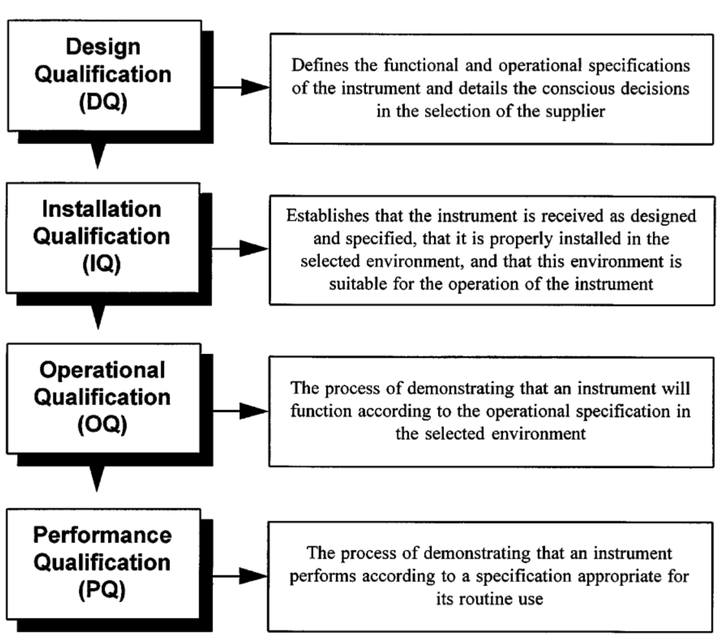
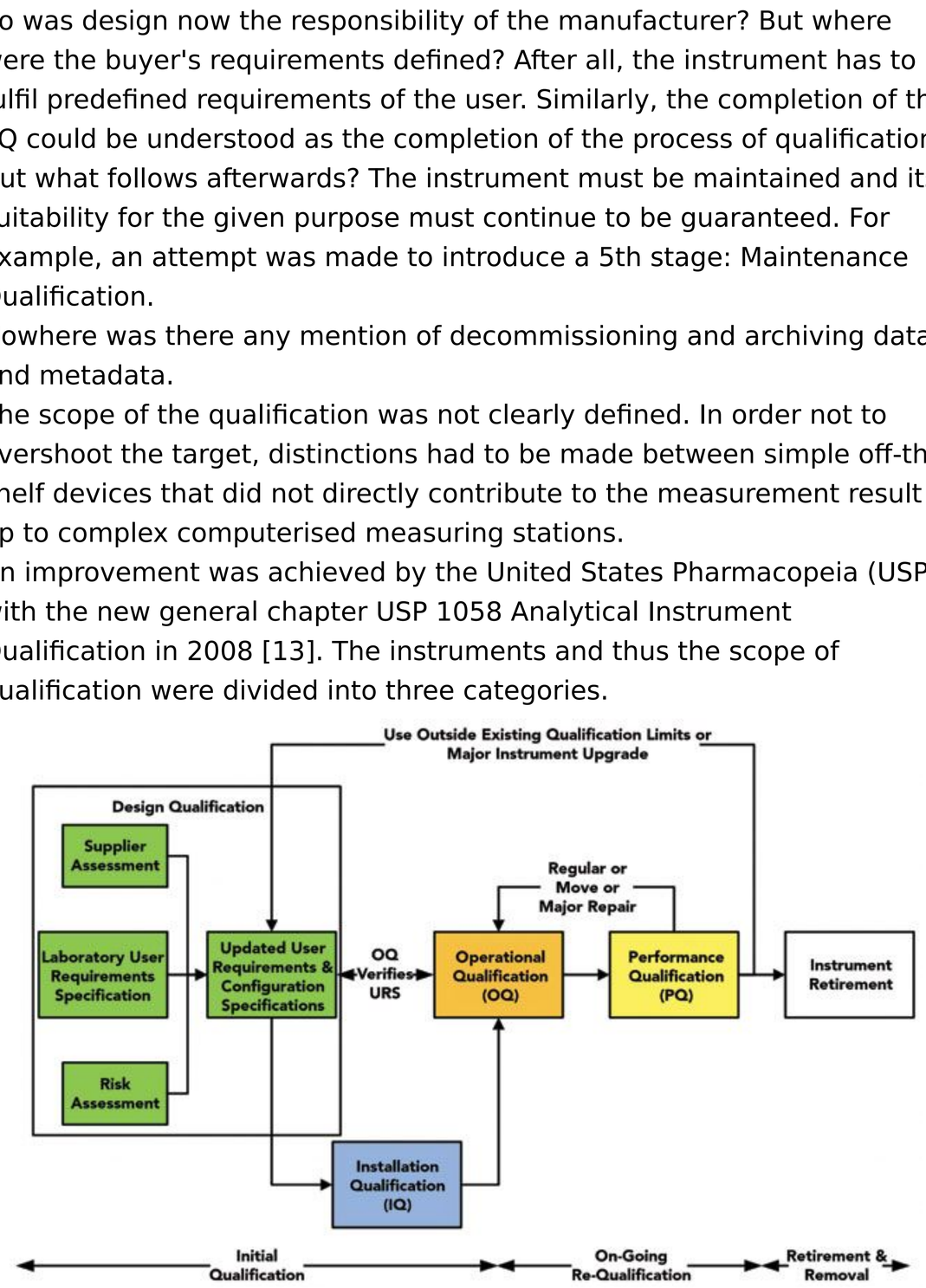


Fig. 1 The equipment qualification process

This concept was quickly adopted and consistently implemented in the pharmaceutical world. In the following four years, elaborated examples of HPLC [10] and UV/VIS instruments [11] were published from the VAM programme.
It was even adopted beyond the analytical laboratory as a general concept for all equipment [12]. In the ISO standards world, the concept received little attention.

Open questions and development

The concept remained stable for a very long time. However, some ambiguities soon became apparent. The first step, the DQ, raised questions. Design was understood in ISO 9001 as a development phase. So was design now the responsibility of the manufacturer? But where were the buyer's requirements defined? After all, the instrument has to fulfil predefined requirements of the user. Similarly, the completion of the PQ could be understood as the completion of the process of qualification. But what follows afterwards? The instrument must be maintained and its suitability for the given purpose must continue to be guaranteed. For example, an attempt was made to introduce a 5th stage: Maintenance Qualification.
Nowhere was there any mention of decommissioning and archiving data and metadata.
The scope of the qualification was not clearly defined. In order not to overshoot the target, distinctions had to be made between simple off-the-shelf devices that did not directly contribute to the measurement result up to complex computerised measuring stations.
An improvement was achieved by the United States Pharmacopeia (USP) with the new general chapter USP 1058 Analytical Instrument Qualification in 2008 [13]. The instruments and thus the scope of qualification were divided into three categories.



The new version of the general chapter USP 1058 Analytical Instrument Qualification in 2017 brought great progress with far-reaching changes. For a better understanding of the DQ phase, the User Requirements Specification (URS) was introduced. Great emphasis is placed on the role of software. The life of an instrument is understood as a process. It starts with the thoughts of acquisition and ends with the decommissioning of the instrument [14].

[1] Quality Systems – Model for quality assurance in design, development, production, installation and servicin"; EN ISO 9001 : 1994
[2] Good Laboratory Practice – The United Kingdom Compliance Programme; UK Department of Health 1989
[3] Good Laboratory Practice for Nonclinical Laboratory Studies; Food and Drug Administration (FDA); 21 CFR Ch.1 Part 58
[4] General requirements for the competence of calibration and testing laboratories; ISO/IEC Guide 25, 3rd Ed., 1990.
[5] Evaluation of analytical instrumentation.Part I. Atomic absorption Spectrophotometers, Primarily for use with Flames, Anal. Proc., 1984, 21, 45.
[6] Evaluation of analytical instrumentation. Part XXVII: a guide to good practice in the purchase of analytical instrumentation, Anal. Methods, 2018, 10, 3303
[7] Department of Trade and Industry (DTI) program Valid Analytical Measurement (VAM)
[8] M. Freeman, M. Leng, D. Morrison and R. P. Munden, Position Paper on the Qualification of Analytical Equipment, Pharmaceutical Technology Europe, November 1995
[9] P. Bedson, M. Sargent, The development and application of guidance on equipment qualification of analytical instruments, Accred Qual Assur (1996) 1 : 265–274
[10] Guidance on Equipment Qualification of Analytical Instruments: High Performance Liquid Chromatography (HPLC), June 1998, LGC/VAM/1998/026.2
[11] Guidance on Equipment Qualification of Analytical Instruments: UV-Visible Spectro(photo)meters (UV-Vis) Version 1.0 - September 2000 LGC/VAM/2000/079
[12] Pharmaceutical Inspection Co-Operation Scheme PE 009-16 (Annexes) 1 February 2022, Annex 15 Qualification and validation
[13] USP 1058 Analytical Instrument Qualification
[14] R.D. McDowall, How Can USP <1058> Help Data Integrity?, LCGC North America 2019 37, 312-316