JETIR.ORG ISSN: 2349-5162 | ESTD Year : 2014 | Monthly Issue
JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)
An International Scholarly Open Access, Peer-reviewed, Refereed Journal

A REVIEW ANALYTICAL QUALITY CONTROL AND METHODOLOGY IN INTERNAL QUALITY CONTROL

Ms.Gayatri R. Amrutkar*, Mr.Viraj V. Naravane ,Ms. Smita S. Aher , Dr.Prashant R. Malpure, Dr. R. S. Bachhav

1.Student, Department of Quality Assurance Techniques, R. G. Sapkal college of Pharmacy,Anjaneri, Nashik-422213, Maharashtra, India.

2.Student ,Department of Quality Assurance Techniques, R. G. Sapkal college of Pharmacy,Anjaneri, Nashik-422213, Maharashtra, India.

3. Professor, Department of Pharmaceutical Chemistry, R. G. Sapkal College of Pharmacy, Anjaneri , Nashik-422213, Maharashtra, India.

4. Professor, Department of Pharmaceutics R. G. Sapkal College of Pharmacy, Anjaneri , Nashik-422213,Maharashtra, India.

5. Principal, Department of Pharmacology R. G. Sapkal College of Pharmacy, Anjaneri , Nashik-422213,Maharashtra, India.

Abstract:

Internal quality control (IQC) is an essential element of routine analysis to ensure that the uncertainty of results found during procedure validation is maintained over a long period of time. The primary method of IQC is to analyze the surrogate material along with the test materials in each run of the analysis, thus addressing the run-by-run accuracy (a subset of the "intermediate conditions") defined by VIM3. This "control material" must be as similar in composition as possible to the normal test materials, although there are always some differences. Results from the control material (control values) are plotted on a control chart and out-of-control results should be investigated and problems corrected. Considerable care is required in obtaining the correct parameter values for establishing statistical control limits, which can only be adequately estimated by routine use of the analytical procedure.

In contrast, target control limits must be established on a fitness for purpose basis and are necessarily broader than statistical control limits. Another type of internal quality control can be performed by analyzing duplicate test portions of some actual test samples. This provides a realistic variance, but only relates to repeatability accuracy. Another complication of duplication is that the accuracy of results typically varies with analyte concentration.

Keywords: Analysis quality control, Internal quality control, Quality management, Methodology Steps, Quantitative Analysis.

Introduction:

Analytical quality control, often abbreviated to AQC, refers to all processes and processes designed to ensure that laboratory analysis results are consistent, comparable, accurate, and within certain limits of accuracy. Components submitted to the analytical laboratory must be accurately described to avoid misinterpretation, assumptions or incorrect results. Quality and quantity data produced in the laboratory can be used to make decisions. In a chemical sense, quantitative analysis refers to the amount or concentration of an element or chemical compound in a matrix, which varies by element or compound. Fields such as industry, pharmaceuticals, and law enforcement may use AQC.[1][2]

The main method of IQC is to analyze the variable object next to the test material in all analysis conditions to determine the accuracy of the run to be performed (a small set of VIM3 is defined as "intermediate conditions"). This "regulatory meaning" should be similar to what is possible in the design of the test equipment, although there are always some differences. The results from the control items (control values) are shown in the control charts and the uncontrolled output should be investigated and resolved. Great care is required in determining the correct values for establishing statistical control limits, and this can only be adequately measured in the normal application of the analysis process. Conversely, targeted control limits should be placed above objective compliance and extend these statistical control limits. Another type of internal quality control can be achieved by analyzing duplicate test components of other actual test samples. This gives the true variance, but only relates to repeat accuracy. Another problem with repetition is that the accuracy of the results often varies depending on the focus of the analyst. [3]

Sampling is as important in analytical chemistry as it allows analytical chemists to have a useful sample size when the target population to be analyzed is large. A small sample size reduces uncertainty and the likelihood of error during the analysis process. Internal quality control (IQC) is an important element of standardized analysis that ensures that the uncertainty of the results obtained during process validation is maintained over a long period of time. [4]

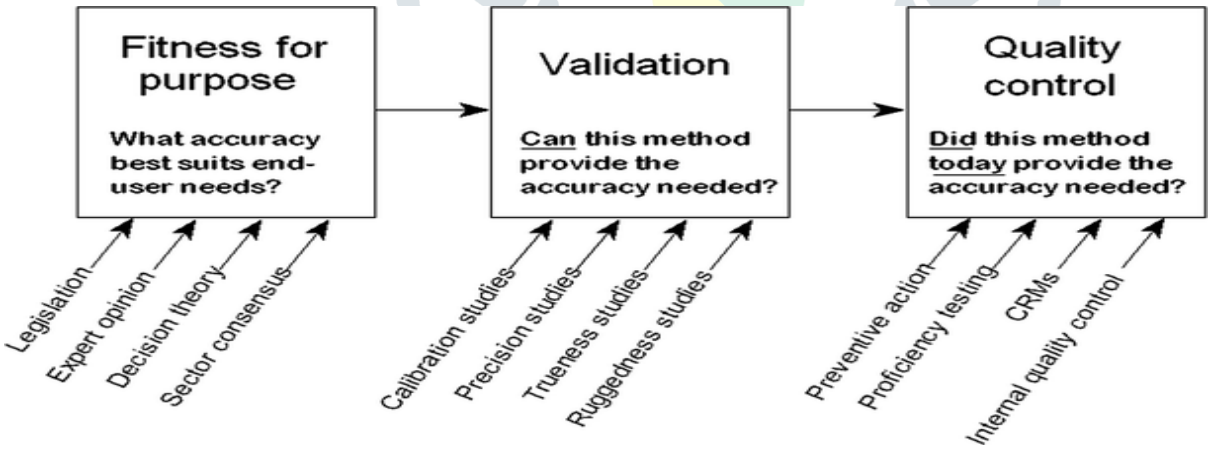


Figure-1: Methodology of internal quality control of chemical analysis

The results of analytical measurements can be associated with very serious consequences:

1. Health risk in relation to environmental or occupational exposure;

2. Fate of materials and products;

3. The result of research investigations;

4. The patient's state of health;

5. Confirmation of non-compliance with regulations;

6. Confirmation of the commission of a crime, etc.

Therefore, the results of the analyzes should be representative and the laboratory should be able to verify the correctness of the measurements with documented evidence. Each analysis can have significant consequences. Those responsible for running the laboratory may therefore have to testify about their findings in court proceedings. Decisions made based on inaccurate data are total mistakes. Analysts must be aware that their professional reputation and credibility may be at risk. They bear a serious responsibility both to the public and to the companies whose products they analyze. Their responsibilities include producing correct and timely analytical results and being fully accountable for the quality of their work. Although the above criteria seem obvious, the practice is often quite different. Many chemists seem reluctant to take a newly published method from the literature and use it to detect some contaminant after making minor modifications that allow them to publish a paper claiming to have a modified method X Y. It is not difficult to read the publications to recognize that many analytical chemists pay little attention to the reliability of the analytical results they produce.[5][6]

Meanwhile, the situation has not changed. A typical problem arises, for example, from the possibility of reducing the size of the test part due to the high sensitivity of the detection systems. Reproducibility is reported on the basis of yield tests, and the potentially significant effect of ground material inhomogeneity on the combined uncertainty and precision of results is very often ignored. The importance of this issue is underscored by special sessions held to discuss sample processing through international workshops, including the North American Chemical Residue Workshops (2014, 2016) and the European Pesticide Residue Workshop (2016).

As Horwitz pointed out, most analytical operations today are based on physical, not chemical, principles. We might think that the laws of physics would be harder to break than the laws of chemistry, but Murphy's Law "If anything can go wrong, it will" is paramount. Unfortunately, the consequences of an analytical error would only become apparent after the rejection of a test batch or interference with someone's property. We must find ways to apply strict quality control measures to detect errors in our measurements and eliminate them before they have serious consequences.[7]

Expanding national and international trade, the responsibility of national registration authorities to approve the use of various chemicals (e.g. drugs, pesticides, additives) and the constantly improving quality standards in every sector of society require reliable test methods, correct analytical data and complete reports reflecting all the results of comprehensive studies. The results should be acceptable to all parties involved.

Reliability means "the ability of an item to perform a required function under specified conditions for a specified period of time".

It is important to note that the variability observed in sampling is often greater than in analysis, although the latter option has historically been much more emphasized. Furthermore, it should always be accepted that the combined errors in sampling, sample processing and analysis will affect the accuracy and reliability of the results.

Without attempting to provide a complete historical background and describe current practices, the aim of this publication is to summarize the main activities undertaken to improve the quality of data and products. We also refer to earlier publications that provide relevant guidance. [8][9]

Role in quality management system

Process control is an essential element of a quality management system and refers to the control of activities used in sample handling and investigative processes to ensure accurate and reliable testing. Process control includes sample control, discussed in Chapter 5, and all quality control (QC) processes. QC monitors activities related to the investigative (analytical) phase of testing. The goal of QC is to detect, evaluate, and correct errors

caused by test system failure, environmental conditions, or operator performance before patient results are reported. [10][11]

What is Quality Control?

• QC is part of quality management aimed at meeting quality requirements (ISO 9000:2000 [3.2.10]). Simply put, it involves examining "control" materials of known substances along with patient samples to monitor the accuracy and precision of the entire analytical process.

• QC is required for accreditation purposes. In 1981, the World Health Organization (WHO) introduced the term "internal quality control" (IQC), which it defined as "a set of procedures for the continuous evaluation of laboratory work and emerging results".

• The terms QC and IQC are sometimes used interchangeably; cultural background and country may influence preferences for these conditions. In the past few years, "internal quality control" has become confusing in some quarters because of the different meanings that have been attached to the term. Some test kit manufacturers for qualitative tests have incorporated "built-in" controls into the kit design, which they sometimes refer to as internal controls.

• Other manufacturers include their own control materials in the kits they sell and refer to them as "internal controls", meaning that the materials are designed specifically for that manufacturer's kit. Finally, some people refer to any quality control materials that are used in conjunction with test runs as IQC, as stated in the 1981 WHO definition. [12]

Quality Control for varying methods

Quality control processes differ depending on whether laboratory tests use methods that provide quantitative, qualitative, or semi-quantitative results. These examinations differ in the following ways. A quantitative test measures the amount of analyte present in a sample, and the measurement must be accurate and precise. A measurement produces a numerical value as an endpoint expressed in a specific unit of measurement. For example, a blood glucose test result may be reported as 5 mg/dL. Qualitative tests are those that measure the presence or absence of a substance or evaluate cell characteristics such as morphology. The results are not expressed numerically, but qualitatively, e.g. "positive" or "negative"; "reactive" or "non-reactive"; "normal" or "abnormal"; and "growth" or "no growth". Examples of qualitative tests include microscopic examinations, serological procedures for the presence or absence of antigens and antibodies, and many microbiological procedures. Semi-quantitative examinations are similar to qualitative examinations in that the results are not expressed quantitatively. The difference is that the results of these tests are expressed as an estimate of how much of the substance being measured is present. Results can be expressed as "trace", "moderate" or "1+, 2+ or 3+". Examples are dipsticks for urine, tablet tests for ketones and some serological agglutination procedures. For other serological tests, the result is often expressed as a titer – again involving a number but providing an estimate rather than the exact amount present. Some microscopic examinations are considered semi-quantitative because the results are reported as estimates of the number of cells observed per low-power field or high-power field. For example, microscopic examination of urine may show 0–5 red blood cells in a single high-power field. Because quality control processes differ for these different types of examinations. [13][14]

Role in quality management system

Quality control (QC) is part of process control and is an essential element of a quality management system. It monitors the processes related to the test phase of testing and enables the detection of errors in the test system. These errors can be caused by test system failure, adverse environmental conditions, or operator performance. QC gives the laboratory confidence that test results are accurate and reliable before patient results are reported. This chapter explains how quality control methods are applied to quantitative laboratory testing.

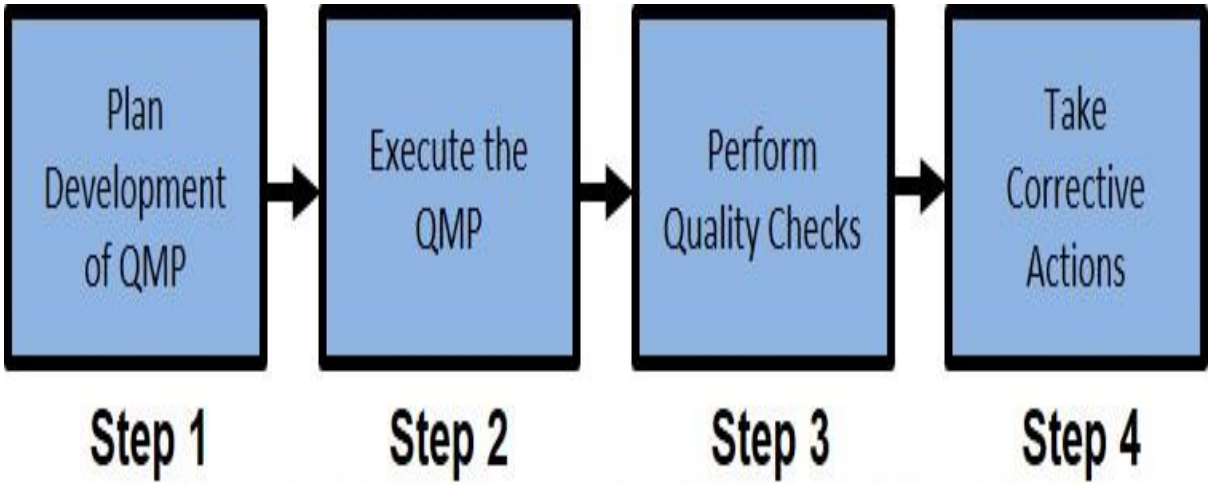


Figure-2: Quality Management Plan Methodology Steps

What is the Goal of the IQC?

The main objective of IQC is to ensure day-to-day consistency of an analytical process and thus help to determine whether patient results are reliable enough to be released. The required quality and assay performance varies between analytes as does the definition of a clinically significant error. [15]

Basic principles and terminology he main goal of the IQC is to compare process performance with expectations under sustainable performance.

 Stable performance starts by checking the controls over a period of time and then calculating the definition and standard deviation (SD or s). The estimates are then progressively based on the same controls and are compared to the true distribution, usually by sorting them into control charts with defined limits and also extracting some SD duplicates (usually 2 and/or 3).

 Unexpected values are identified to alert the analyst to possible changes in process performance. A control diagram is a graphical way of displaying control results.

 Control results are usually ordered by time or number of consecutive runs. Lines are usually drawn from one point to another to highlight any trends, formal shifts or informal outings.

 In healthcare laboratory applications where it is the practice to develop individual control rules, the control chart is often referred to as the Levey-Jennings chart, although the use of individual control values is reported by Henry and Segalove.10 the status of the control was decided. Analysis duration varies from system to system and laboratory to laboratory depending on the stability of the analytical system and its tendency to change, such as personnel, reagents, over-measurements or other factors that may present problems.

 Control limits drawn on a control chart providing graphical conditions for judging whether a measurement process is controlled or uncontrolled. These limits are usually calculated from the definition and standard deviations determined under stable operation.

 Regulatory law means the condition of a court decision, whether a review is ongoing or not. It is usually represented by an 8 with a symbol of the form AL, where A is the sum of the numbers or represents the number of control measures and L indicates the control limits.

 Therefore 13s means the control rule used with the Levey Jennings chart where the control limits are set as mean + 3s. Running is denied if one control measure exceeds any control limit.12s means a control rule where the control limits are set as mean + 2s. Shewhart is often considered.

Proposed guideline for the internal quality control of analytical result:

Analytical quality factors are related to quality definition, quality creation and quality control, and errors arise from external and internal sources as well as permanent and variable factors. In addition, the two main types of errors are classified as systematic and random errors. Internal quality control (IQC) systems can only operate on variable factors that are related to lot-to-lot variations (external factors) and laboratory performance (internal factors). When creating an adequate internal control system, we face several problems:

(i) Quality of control materials,
(ii) Types and frequency of possible errors,
(iii) Number and types of control materials,
(iv) Number of control replicates,
(v) Probability of error detection ,
(vi) False rejection probability,
(vii) Consequences of rejected signals,
(viii) Troubleshooting systems, and
(ix) Error prevention among many other conditions.

A Gaussian distribution of inspection results is assumed and statistical inspection rules are evaluated in terms of false rejection probability, Pfr, and error detection probability, Ped, for different rules. A combination of low Pfr and high Ped is obtained by combining the results of, for example, four measurements of the same control sample using the mean and range rules. Furthermore, it is not possible to establish a common control system that can be used for all quantities and analytical procedures; on the contrary, each procedure should have its own specific effective IQC system. [16]

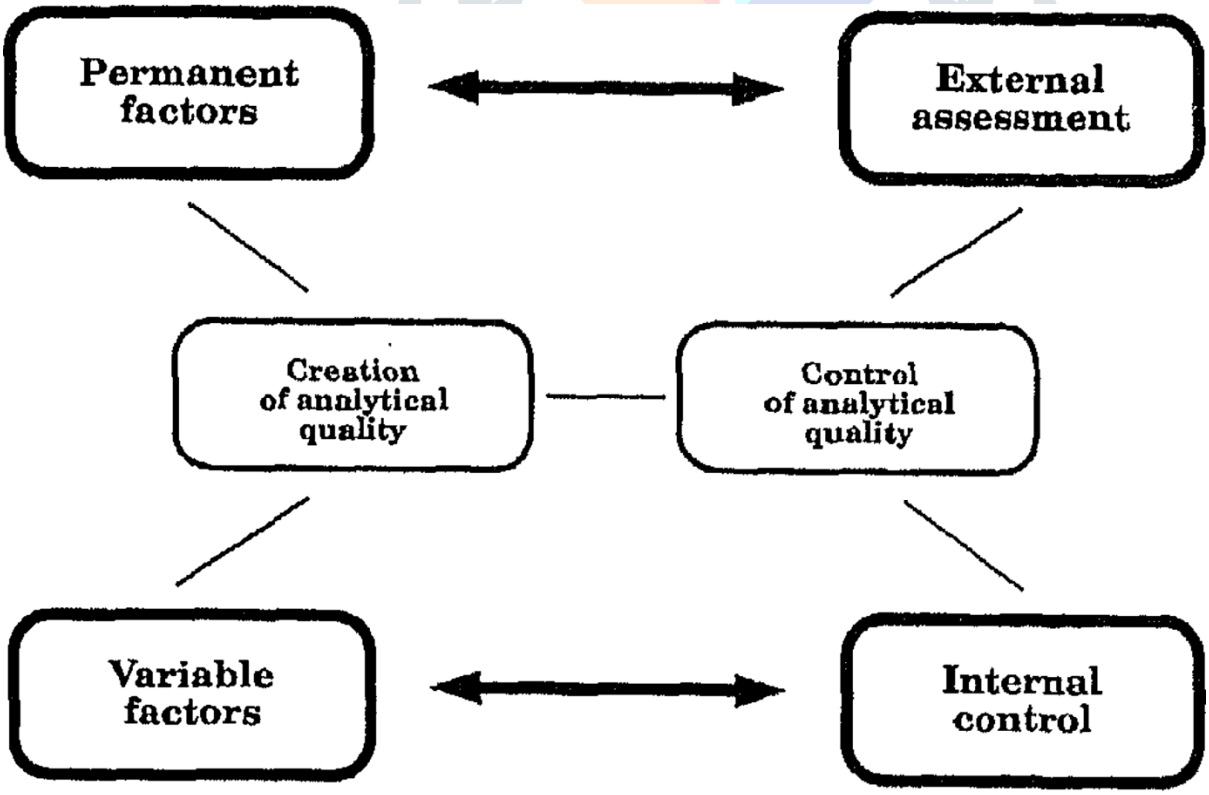


Figure-3: Proposed guideline for the internal quality control of analytical result

Analytical quality control materials should have the following features;

• have the same / similar matrix as the samples to be measured,

• Ease of use, as complex reintegration processes increase the risk of errors,

• It is stable for a long time,

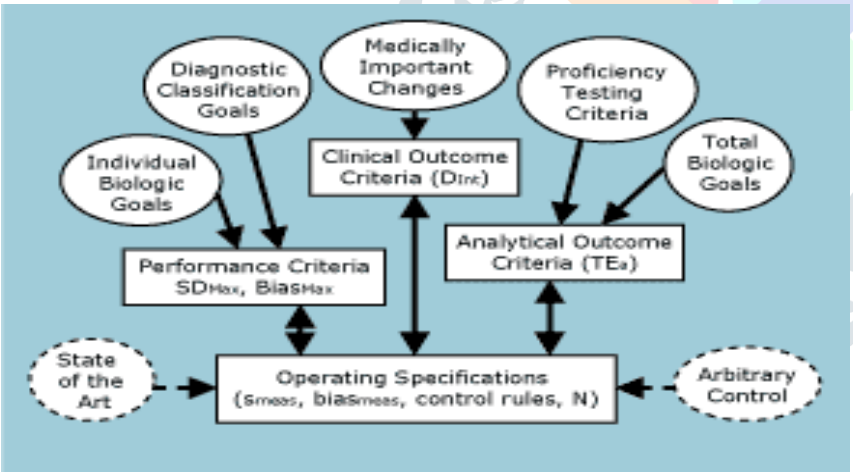
• Available in sufficient quantity,

• Keep the target values close to the samples.

Internal quality control (IQC) is an important element of standardized analysis that ensures that the uncertainty of the results obtained during process validation is maintained over a long period of time. The main IQC method is to analyze the surrogate material alongside the test material in all cases of analysis, thus focusing on the accuracy of the run (a subset of VIM3 defined as "intermediate conditions"). This "regulatory meaning" should be similar to what is possible in the design of the test equipment, although there are always some differences. The results from the control items (control values) are shown in the control chart and out-of-control outputs should be investigated and problems solved. Great care is required in finding the correct values for establishing statistical control limits, and this can only be adequately measured in the normal application of the analysis process.

The steps to plan the QC statistics process are presented as follows:

1] Explain the need for quality testing.
2] Determine the accuracy of the method and the bias.
3] Identify IQC candidate processes.
4] Guess IQC performance.
5] Set IQC performance standards.
6] Select the appropriate IQC process [17]



References:

1. Latimer, G. (Ed.) Official Methods of Analyses of AOAC International, 21st ed.; AOAC International: Rockville, Maryland, 2019; ISBN 0-935584-89-7.
2. Horwitz, W. History of the IUPAC/ISO/AOAC Harmonization Program. In Proceedings of the 4th International Symposium on the Harmonization of Quality Assurance Systems in Chemical Analysis, Geneva, Switzerland, 2–3 May 1991.
3. Lehotay, S.J.; Cook, J.M. Sampling and sample processing in pesticide residue analysis. J. Agric. Food Chem. 2015, 63, 4395–4404.
4. Vu-Duc, N.; Nguyen-Quang, T.; Le-Minh, T.; Nguyen-Thi, X.; Tran, T.M.; Vu, H.A.; Chu, D.B. Multi-residue pesticides analysis of vegetables in Vietnam by ultrahigh-performance liquid

chromatography in combination with high-resolution mass spectrometry (UPLC-Orbitrap MS). J. Anal. Methods Chem. 2019, 2019, 1–10.

5. Ambrus, Á; Szemánné-Dobrik, H.; Domák, Z.; Kerekes, K. Sources of random variation of pesticide residue analytical results. AOAC Internat. 2021, 104, 523.
6. Whitaker, T.B.; Wiser, E.H. Theoretical investigations into the accuracy of sampling shelled peanuts for aflatoxin. J. Am. Oil Chem. Soc. 1989, 46, 377–378
7. ISO 9000:2015; Quality Management Systems—Fundamentals and Vocabulary. Available online: www.iso.org/standard/45481.html.
8. Westgard JO, Barry PL, Hunt MR (1981) Clin Chem 27:493–501
9. Koch DD, Oryall JJ, Quam EF, Deldbruegge DH, Dowd DE, Barry PL, et al. Selection of medically useful quality-control procedures for individual tests done in a multitest analytical system. Clin Chem 1990; 36: 230-3.
10. Henry RJ, Segalove M. The running of standards in clinical chemistry and the use of the control chart. J Clin Pathol 1952; 5: 305-11.
11. Groth T, Falk H, Westgard JO. An interactive computer simulation program for the design statistical control procedures in clinical chemistry. Comput Programs Biomed 1981; 13: 73-86.
12. Analytical quality control (AQC) program to ensure the highest level of confidence in reported data Archived March 28, 2012, at the Wayback Machine
13. https://en.wikipedia.org/wiki/Analytical_quality_control.
14. Handbook For Analytical Quality Control In Water And Wastewater Laboratories Archived November 14, 2013, At The Wayback Machine.
15. Marquis P, Masseyeff R.;Evaluating an internal quality control procedure: application to multidimensional control;Ann Biol Clin (Paris). 2002 Sep-Oct; 60(5):607-16. French. PMID: 12368148.
16. Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. Clin Chem 1997; 43: 1348-51.
17. The National Institute of Standards and Technology is a physical sciences laboratory and non-regulatory agency of the United States Department of Commerce. https://nvlpubs.nist.gov/nistpubs/Legacy/IR/nbsir85-3105.pdf