

QUALITY ASSURANCE OF ECOSYSTEM HEALTH ASSESSMENT METHODS: THE BACTERIAL LUMINESCENCE ASSAY AS AN EXAMPLE.

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INTRODUCTION

Before a newly investigated and developed analytical method can be used routinely, the quality of the results obtained must be assessed and demonstrated, otherwise its use will have restricted value until standardization, traceability and transportability of the results will be verified.

There are international standards describing procedures to be followed when standardizing an analytical method. Published standards provide guidance on development and operation of proficiency testing schemes for analytical laboratories, especially in the last phases of method development.

Quality Control and Quality Assurance

Quality Control is the set of working procedures and operations undertaken to ensure that the data is produced with known limits of accuracy and precision.

Quality Assurance includes much more than the technical operations relating to controlling quality. Quality Assurance is the management system by which the laboratory ensures the quality of the results presented to any client requiring or using the data obtained (private customers, regulatory agencies, accreditation bodies...)

Quality Assurance is, therefore, an important part of laboratory management. A Quality Management System can be developed following international standards, with different objectives. The main goal of a Quality Management System in analytical laboratories would be not only to be able to ensure the quality of data generated, in respect to the analytical measurements performed, but also to be able to produce documented evidence to demonstrate objectively that all possible measures have been taken to prevent errors and to secure that quality of data is continuously achieved throughout all operations performed leading to the result given to a customer.

Validation of Analytical methods

An analytical method designed to produce data relating to a particular characteristic intended to be measured, must be “validated”, that is, ensure in documented form, its adequacy for the intended measurement, accuracy, precision, ruggedness, etc,

All analytical methods intended to routine testing of any large number of samples, should be subjected to a validation study, with the exception of Official methods (Standard Methods, Pharmacopoeia methods for drugs, official methods required by any administration, etc...).

Moreover, prior to analytical method validation, related equipment should be qualified and personnel should be trained and qualified for each specific particular method. Personnel competence and capabilities related to any analytical method performed in the laboratory

should be documented. (ISO, 1999)

Certification

Certification is the process that allows establishing that any product, service or activity complies with the requirements established in a documented standard

ISO Certification of the quality system means that the system complies with the requirements described in ISO standard ISO 9001, after the certification audit performed by a Certification Body. This is a voluntary action taken by the company management.

Accreditation

Accreditation is the acknowledgement of the technical competence of an organization to Perform a specific task (certification, testing or calibration, inspection or audit).

In other words, accreditation is the process by which a laboratory is recognized as having the technical competence to perform a particular test. For a testing laboratory, accreditation is the official acknowledgment of its technical capability and competence to perform certain assays.

ISO International Standard ISO 17025 describes the minimum requirements to be followed by a laboratory wishing to be accredited to perform a certain type of assays. Each accreditation correspond to a specific test performed in the laboratory, a specific analytical technique, or assays performed on a specific matrix, or a specified type of samples. (ISO, 1999)

LABORATORY COMPARISON STUDIES

Participation in laboratory comparison programs offers laboratories an opportunity for independent evaluation, verification and demonstration of the quality of the results obtained. Most of these programs have in common the comparison of the results presented by two or more laboratories performing the same assay, although laboratory comparison studies can have a number of different purposes (ISO, 1997 a, b)

Interlaboratory comparison studies may be used, for example, to:

- determine the performance of individual laboratories for specific tests or measurements
- monitor laboratories continuing performance
- identify internal problems in laboratories and initiate remedial actions
- determine the comparability or effectiveness of new measurement tests or methods
- monitor effectiveness of existing methods
- identify interlaboratory differences
- identify the performance characteristics of a method
- assign values to reference materials and assess their suitability
- provide additional confidence to laboratory clients

Accreditation bodies often use interlaboratory comparison exercises to evaluate the performance of accredited laboratories, and often accept interlaboratory comparison exercises carried out by independent organizations.

THE LUMINESCENT BACTERIA TOXICITY ASSAY

Designed and commercialised in the beginning of the 1980s, the main application of this toxicity bioassay has been the evaluation of the contamination capability of wastewater effluents. This assay was first commercialised as the Microtox® Test, and associated to this name, although today there are other commercial names using luminescent bacteria as the assay organisms for aquatic toxicity monitoring

The luminescent bacteria assay has been also used for other applications, related to prediction, monitoring and control of the quality of aquatic ecosystem. The assay has been used, for instance, in the fields of:

- toxicity screening of potential aquatic contaminants
- quantitative structure – toxicity relationships studies
- studies related to the effect of chemical and physical interferences on the aquatic toxicity of known contaminants
- study of toxic antagonistic and synergistic effects of mixtures of contaminants
- effect of temperature and pH on the known toxic effect of chemical contaminants
- identification of toxicity sources in aquatic ecosystems
- monitoring the quality of aquatic ecosystems

The luminescent bacteria toxicity assay has been adopted in Spanish and other environmental regulations, to monitor and control wastewater industrial effluents. (BOE, 1988,1989; DOGC 1985, 1990)

LUMINESCENT BACTERIA ASSAY INTERLABORATORY COMPARISON STUDIES

To verify the capability of the luminescent bacteria toxicity assay in the determination and monitoring of the toxicity of wastewater effluents, interlaboratory comparison exercises have been performed by the author during the last 10 years.

When using a particular bioassay to assess the environmental health of a particular ecosystem, it is obvious that the chosen toxicity assay, will respond differently and specifically to different chemical contaminants. The luminescent bacteria used as the test organism in this assay will respond differently to the toxic effect caused by different potential contaminants, and will have a distinct response depending on the mixture of potential contaminants present in the sample, including potential interferences between the chemical species that will form.

The initial purpose of these exercises was to evaluate the performance of the assay when contaminants of different chemical structure were present in the test sample. For instance, the behaviour of organic aquatic contaminants is different than the toxic interaction of inorganic pollutants with the test organisms. (Ribo, 1997)

The following table presents a summary of the results obtained in the 10 years of interlaboratory comparison studies performed using different samples and participating different laboratories.

INTERLABORATORY COMPARISON STUDIES

Summary of results

Study	Year	Number of samples	Number of Series	Number of Participants	CV%		Average
					5 min	15 min	CV%
1	1993	5	4	11	31,75	37,02	34.40
2	1994	5	4	19	27,34	27,09	27.22
3	1995	5	4	24	20,54	18,51	19.52
4	1996	5	4	21	25,82	26,07	25.95
5	1997	5	4	19	30,06	31,85	30.96
6	1998	5	4	22	23,11	25,51	24.31
7	1999	5	4	15	31,94	31,02	31.48
8	2000	5	6	25	21,67	21,54	21.62
9	2001	5	6	23	-	26,89	26.93
10	2002	6	6	22	-	26,01	26.01
AVERAGES					26,53	27,15	26,84

As a general conclusion, the overall coefficient of variation (CV) of this toxicity assay remains around 25%, when calculated as the percentage ratio between the average toxicity values over the standard deviation.

The data obtained has been very useful to the participating laboratories, to correct deviations, improve their analytical methods, improve and verify their internal quality control procedures, and keep up to date their accreditation before official bodies. Other studies have been performed using the data obtained, related to repeatability and reproducibility of the assay. (Ribo, et al, 2001)

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