

# Laboratory Quality Management and In-House Reference Materials

By Deneen Rief and Paul Wehling

Analytical testing laboratories, like any type of complex system, exhibit an inherent variability that must be assessed and controlled in order to assure quality results. Historically, many types of systems have been used to deal with this variation, and improve the confidence in test results. Years ago, GLP's were introduced to control the technical aspects of laboratory quality. With the advent of Total Quality Management and the global acceptance of ISO 9000 quality systems, the same type of practices used to control quality in a manufacturing environment are now being used to manage laboratory variation. A Laboratory Quality Management (LQM) Program is a complete system designed to do just that – manage the technical and non-technical factors that affect laboratory variability.

The advantages of a Laboratory Quality Management program are many. An established LQM program will lead to reduced analytical variation, which means reduced product variation. A program will make your laboratory operations more efficient and in turn reduce processing and product costs. The primary advantage is to increase your confidence in analytical results.

## PARTS OF AN LQM PROGRAM

Most Laboratory Quality Management systems are based on international standards. ISO/IEC Standard 17025 outlines the requirements for a complete LQM program. In addition, the AOACI has published guidelines based on the ISO/IEC 17025 standard. The Association of Certified Independent Laboratories (ACIL) has established a proposal for qualifications of laboratory certification<sup>2</sup>. All of

these organizations agree that a good LQM program should contain the following:

- An LQM program consists of five key parts.
1. Quality Manual
  2. Staff and Training
  3. Methodology
  4. RM (in-house or recognized)
  5. Record Keeping

## Management Requirements:

There are many aspects to the quality system which control the management of information. The ISO/IEC 17025 Standard requires that the lab have written policies regarding organization, management review, document controls, contracts, purchasing, complaint handling, control of non-conforming test results, corrective action protocols, audits, and continual improvement.

## Technical Requirements

In addition to the requirements placed on the management of information, there are technical requirements that address the technical aspects of the laboratory. The standard requires that the lab have written policies covering the selection and training of lab personnel, environmental conditions of the lab, test methods and validation, equipment and instrumentation, measurement traceability, method verification, sampling, as well as sample handling protocols.

## QUALITY MANUAL

All of the policies mentioned above are contained in the Laboratory Quality Manual. This manual is a comprehensive collection of the laboratory's quality system. All accreditation bodies require some type of this manual to exist for each lab. In addition, sufficient control over the documents must be exercised so that obsolete versions are destroyed when they are replaced by newer ones.

## STAFF AND TRAINING

The basic philosophy of LQM regarding staff and training is that all personnel performing analytical procedures must be competent and trained by qualified trainers. This training must be documented. It is also recommended that the training be conducted by a single source for consistency and continuity.

## METHODOLOGY

Methodology has several requirements in an LQM program. The methods must be written in a format that is consistent throughout the laboratory. They can either be internally developed, or taken from international and national standards and technical organizations. All methods must be sufficiently validated, to ensure that they meet acceptable levels of precision and accuracy. Importation of recognized methods must be verified to demonstrate proper performance by the laboratory. Finally, the written methods must be accessible to all users.

## IN-HOUSE REFERENCE MATERIALS

Production of quality results is essential to all analytical laboratories, particularly in the food industry where consumers rely on accurate information from the nutrition label for making dietary choices. Assurance of the quality of these results is an ongoing effort that requires a

comprehensive quality program utilizing the best tools available. One is a program An In-House predetermined test every sample with a 1. determine



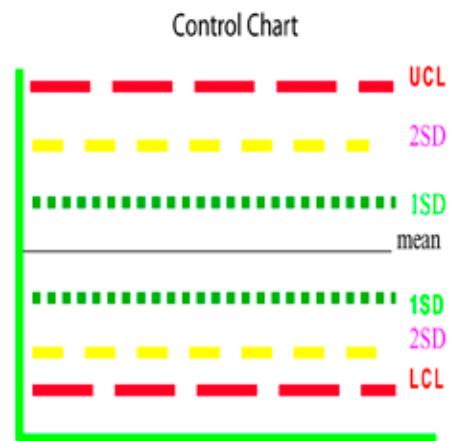
ul for this purpose materials, IHRMs. test matrix with a of interest that is ned. Analyzing a analyte: l for each run

2. increases understanding of the variation within an analytical method
3. builds confidence in the results

Of course, the laboratory must weigh the costs of the number of reruns for out-of-control situations versus the number of incorrect results being reported. Most laboratories choose in favor of extra reruns. With improved method control, the number of reruns will decrease over time.

## CHOOSING AN IHRM

Each method should have an associated IHRM that is chosen using the following criteria: The quality control material is representative of the matrices typically submitted to the laboratory and contains levels of an analyte comparable to the levels normally being tested. A sufficient quantity of control material must be generated, typically enough to analyze one sample per run for one year. In addition, the IHRM must be stable during storage, or have known storage characteristics, since it is often used over a one-year period of time.



## ESTABLISHING CONTROL LIMITS

When an IHRM is selected and meets the criteria above, it is analyzed at least twenty times over several weeks. These analyses should include different days, different

analysts, and different points within the analytical run. These data points are compiled and a standard deviation is calculated.

Control limits are then established using the following criteria:

- $UCL = \text{mean} + (3 \times SD)$
- $LCL = \text{mean} - (3 \times SD)$   
UCL = Upper Control Limit  
LCL = Lower Control Limit

Analyses are monitored on a Control Chart, which graphs IHRM results versus time. Results outside the control limits indicate that the method is not performing within specifications and all work must cease until the cause of the deviation is corrected. An out of control situation is defined as follows:

- Any point that falls outside the LCL or UCL
- 4 out of 5 consecutive points outside (+) 1SD or (-) 1SD
- 2 out of 3 consecutive points outside (+) 2SD or (-) 2SD
- 8 consecutive points all above or below the mean
- 8 consecutive points all increasing or decreasing
- non-random patterns observed

## RECORD KEEPING

There are several forms of documentation needed for an LQM program. Several logbooks including standard preparation logs, calibration logs, and analysis logs must be kept by the analyst and updated regularly. Training records must be documented as noted, and maintenance records of each piece of equipment should be kept in the laboratory. In addition, Corrective Action Protocol records should be used for each out-of-control situation on a control chart and each instrument issue. This will allow the analyst to identify root causes of problems and avoid recurrences.

## MONITORING THE PROGRAM

Each individual analyst is responsible for monitoring the control charts on a daily basis. In addition, a team of analysts should oversee the monitoring of the IHRM program. The goal of this team is to continuously monitor and improve the quality of the analytical methods. The IHRM program is an excellent tool to build confidence in your analytical testing procedures and thus in the quality of your product.

## COSTS vs. BENEFITS

The costs are few in comparison to the benefits of a Laboratory Quality Management Program. The costs include the initial preparation fee of establishing and implementing a program, analysis reruns, and a change in corporate mindset to “Do it right the first time”. The benefits are many:

1. Confidence in analysis
2. Confidence in analytical results
3. Increased customer satisfaction due to reduced product variation
4. Fewer hold orders due to analytical results
5. Improved recognition of instrument problems
6. Reduced costs due to reduced waste
7. Improved lab efficiency due to fewer rechecks and less time spent troubleshooting

## THE WAY OF THE FUTURE

As we know, the consumer is becoming more aware of product labels. The government is also putting more time and money into monitoring the quality of the food with frequent plant audits and the new Food Safety Initiative. Thus, the accuracy of analytical results is becoming more important. Each company is trying to cut costs and improve quality, so an extensive LQM program is extremely important.

A full LQM program is an essential part of analytical certification. In addition to an IHRM, other programs are available for use. The AACC and AOAC check sample program, use of certified reference materials, and collaborative efforts with other laboratories are all excellent tools for quality improvement.

## REFERENCES

1. Deneen Rief, John Szpylka, Ph.D., Jon DeVries, Ph.D. 1998 Assuring Quality Analytical Results Through the Use of In-House Reference Materials. *Poster given at the AOAC Annual meeting September, 1998.*

2. To view the ACIL/FLAWG proposal, visit: [www.aoac.org/techprog/chem.htm](http://www.aoac.org/techprog/chem.htm)

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