STATISTICAL ANALYSIS

ISO 17025: Practical Benefits of Implementing a Quality System

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As a laboratory certified to ISO 9001:2000 and accredited to ISO 17025, rtech laboratories has incorporated an overall system for technical and quality management, which results in benefits observed in daily laboratory practices. Technical requirements were updated to include the addition of formal personnel training plans and detailed records, method development and validation procedures, measurement of method uncertainty, and a defined equipment calibration and maintenance program. In addition, a stronger definition of the sample preparation process was documented to maintain consistency in sampling, and a more rigorous quality control monitoring program was implemented for chemistry and microbiology. Management quality improvements focused on document control to maintain consistent analytical processes, improved monitoring of supplier performance, a contract review process for documenting customer requirements, and a system for handling customer comments and complaints, with continuous improvement through corrective and preventive action procedures and audits. Quarterly management review of corrective actions, nonconforming testing, and proficiency testing aid in determining long-term trending. The practical benefits of these technical and management quality improvements are seen on a daily basis in the laboratory. Faster identification and resolution of issues regarding methods, personnel or equipment, improved customer satisfaction, meeting quality requirements of specialized customers, and overall increased laboratory business are all the result of implementing an effective quality system.

rtech laboratories began working toward ISO 9002:1994 in September 1995 and achieved certification in October 1996. The ISO 9002 quality system put essential pieces into place, including documentation of all analytical and administrative processes and control of equipment and calibration practices. Continuous improvement activities, such as corrective and preventive action, internal audits, management review, and customer surveys, were also initiated.

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After the final approval of the ISO 17025 standard (General Requirements for the Competence of Testing and Calibration Laboratories) by members of the International Standards Organization in December 1999 (*ISO 17025:1999*, 1st Ed., 1999, ISO, Geneva, Switzerland, pp 12–15), rtech further developed its quality system by adding components to achieve accreditation to ISO 17025. The additional components of the new standard specifically dealt with technical requirements for processes and analytical methods. rtech laboratories became accredited in March 2001.

rtech laboratories implemented ISO 9002 first because the ISO 17025 standard was not available. Currently, laboratories accredited to ISO 17025 maintain quality system parameters in line with ISO 9002. Maintaining dual accreditation or certification is not required, but may be beneficial. The benefits include more frequent audits by external auditors to keep the system sharp and the emphasis on customer requirements and satisfaction driven by the ISO 9000 standard series. rtech was accredited to ISO 17025 and certified to the new revision ISO 9001:2000 (*ISO 9001:2000*, ANSI/ISO/ASQ, December 13, 2000, American National Standards Institute, Washington, DC).

This article describes the process of implementing and maintaining a quality system, the process measurement capabilities of the system, continuous improvement, and overall practical benefits.

Implementation of the Quality System

Implementation began with documentation of all analytical, administrative, and quality processes to meet the requirements of the ISO 9002 standard. All personnel were trained on the ISO standard. The written methods were installed into a document control system. All equipment was identified and calibration requirements were determined. Once the processes were documented, the laboratory lived by the system. Records provided evidence of compliance, and internal audits were performed to identify issues and improve compliance. Documents were revised as needed to accurately describe processes.

Once there was adequate evidence of quality system compliance, an ISO 9002 registrar had to be chosen. Numerous registrar companies are accredited and controlled by a national accrediting body. In the United States this body is the Registration Accreditation Board (RAB). rtech laboratories chose Det Norske Veritas (DNV) as its registrar to certify that the quality system met the requirements of the ISO 9002 standard. Following certification, audits by the registrar take place every 6 months to maintain certified status.

Chemistry Method Approval Plan Tracking No: _____
Method Name: _____

Prepared by:_____ Date:_____

Method Status: ☐ New Method: Standard Reference (Sections 1 – 3)
☐ New Method: Non- standard (Sections 1, 2,4,5)
☐ Analytical Process change: Standard Reference (Sections 1 – 3)
☐ Analytical Process change: Non-standard (Sections 1, 2,4,5)
☐ Other: _____

1. Method reference.
2. Convert to document format. (Due:)
3. Verification Plan:
   Accuracy: (Due:)
   Precision: (Due:)
4. Feasibility Plan: (Due:)
5. Validation Plan:

   Precision: (Due:)
   Accuracy: (Due:)
   Detection Limits: (Due:)
   Limits of quantitation: (Due:)
   Linearity: (Due:)
   Range: (Due:)
   Other: (Due:)

Describe on-going method quality control:

Estimate the % waste composition and amount to be generated, if applicable:

Assign due dates for review meetings:

Method Approval Plan Acceptance:

Laboratory or Technical Operations Manager:_____ Date:_____

QA Manager:_____ Date:_____

Method Approval Data :

☐ Approved

☐ Rejected

Laboratory or Quality Manager:_____ Date:_____

Figure 1. Example method approval template.

The certification audit took place over 4 days. All elements of the ISO standard were covered. The auditor looked for evidence of compliance with the ISO standard and with internal documents. This evidence included records of analysis, customer contracts, equipment and calibration, training records, and interviews of personnel. Any nonconformances required a written corrective action to be submitted. The auditor would then review this at the next audit.

When the ISO 17025 system was implemented, an internal gap analysis of the current system against the ISO 17025 standard was performed. Results indicated that the ISO 9002 system fulfilled a majority of the management requirements; however, some additions were made. Small changes were made to the management review process. Clients needed to be informed in writing of the intent to subcontract analysis. Records needed to include enough information to allow analyses to be repeated under conditions as close as possible to the original. This included information on all equipment used, analysts, and temperatures.

More changes were needed to meet the 17025 technical requirements. The following were the largest issues:

(**a**) *Analytical method review*.—ISO 17025 requires the validation of all methods that are based on nonstandard references, are laboratory-developed, or are standard methods used outside of their scopes. Therefore, all analytical methods within the laboratory were reviewed against their references to meet theses criteria. Where necessary, methods were either changed to meet the references as written or were validated. Because rtech laboratories accredited all its analytical methods, the volume of work impacted the entire laboratory.

(**b**) *Sampling plan*.—ISO 17025 requires that a sampling plan be in place for the sampling of matrixes. In the food laboratory, a large number of matrixes are received. A plan for the sampling of a large variety of items was created. Examples include the following processes:

(*1*) *Unmixable (e.g., cheese block)*.—Use whole sample for products < 8 oz (ca 200 g). For >8 oz samples (>200 g), use the 3-point sampling plan. Sample from end, middle, and 1/4 of the way from end.

(*2*) *Combined food (e.g., lasagna entrée)*.—Use the 3-point sampling plan to obtain enough sample for the required sample size.

(*3*) *Meats*.—Use a 5-point sampling plan. Obtain one sample from each end (2 samples total), one sample from the middle, and one sample 1/4 of the way from each end (2 samples total).

(*4*) *Snacks*.—Shake bag to mix. Remove equal portions from each bag (up to 6 bags).

(**c**) *Quality control (QC) trending*.—A system was implemented to allow for entry of QC data on a networked Excel file. The data are entered by the analyst and are visible on a chart. The networked drive allows for viewing or entry access at all computer locations.

(**d**) *Method uncertainty*.—The standard requires the laboratory to have and apply a procedure for uncertainty. The established method uses historical QC data to estimate overall uncertainty of analyses wherever possible. The QC data col-

CA#

CORRECTIVE ACTION

Initiated By: _____ **Date:** _____

INITIATOR

1. Type of Issue (Circle):		2. Informer of Issue (Circle) :
a. Problem Data	g. Proficiency Testing	a. Customer
b. Client Information	h. Ineffective CA	b. Analyst
c. Equipment	i. Due Dates	c. Quality Assurance
d. Audit Nonconformance	j. Process	d. Supervisor/Manager
e. Customer complaint	k. Other	e. Auditor
f. Login		f. Customer Service

Description of Issue: (WO# **):**

Control of Nonconforming Testing: (Review associated data)

Nonconforming Data ?	Yes or No	Which data?:	
Raw Data Controlled?	N/A or Yes	Initials:	Date:
LIMS Data Controlled?	N/A or Yes	Initials:	Date:
Work Stopped?	Yes or No	Initials:	Date:
Customer Affected?	Yes or No	Customer Name:	
Customer Contacted?	Yes or No		
Work Resumed (If stopped)	Supervisor, Data Reviewer, Management Initials:		Date:

QA/MANAGEMENT

Assign a Responsible Person:	
Assign a due date:	

RESPONSIBLE PERSON

General Determinations and Root Cause:

RESPONSIBLE PERSON

Corrective Action :

Completion by Responsible Person:	Initials:	Date:
Approval by Management:	Initials:	Date:

QA

Action Appropriate? Yes or No	Systems Issues? Yes or No	Audit Needed? Yes or No
If audit needed, file a copy in the area audit follow-up file.		Date filed:
Check back Needed?	Yes or No	
Assign a Responsible Person:		
Assign a due date:		

Check back Plan:

CHECKBACK RESPONSIBLE PERSON

Checkback Results:

If additional action is necessary. Initiate a new corrective action:	CA#
Date:	Initials:

QA

Corrective Action Effective? Yes or No

Corrective Action Closed:	Initials:	Date:

Figure 2. Example corrective action form.

Table 1. Management review inputs

Management review inputs	
Quality assurance reports	Supervisory reports
Corrective/preventive action	Equipment
Proficiency testing	Staffing
Internal and external audits	Training
Quality control	Space
Equipment maintenance	Changes in volume or type of work
Nonconforming testing levels	Progress against goals
Purchasing information	Planning and progress of planning
Customer service information	Ability of system to meet goals
Customer complaints	
Customer surveys	
Ability to meet due dates	

lection system allows for access to current analytical data to review method uncertainty.

(**e**) *Method approval*.—Implementation of new methods or analytical changes to current methods needs to be a planned process. A template for method approval planning (Figure 1) was created that allows for options, including feasibility, verification of a standard method, or validation of a nonstandard or laboratory-developed method. The plans require approval before beginning work and approval of the data prior to placing the method into the system.

(**f**) *Reporting of results*.—ISO 17025 contains very specific requirements for reporting results. Changes were made to the laboratory information management system (LIMS) to comply. Final reports must include the following information:

(*1*) Approval signature

(*2*) Numbering (page *x* of *y*) and labeled with the work order number

(*3*) Analytical laboratory sampling plan

(*4*) References and uncertainty data (available upon request)

(*5*) Customer information

(*6*) Sample information. Samples unique identifier; sample description provided by the customer; date of receipt; temperature upon receipt, if applicable; condition of samples.

(*7*) Test information. Test description, results obtained, date tested, and units, if applicable; deviations to the test method; opinions and interpretations, if applicable; subcontracted results, if applicable.

As with the ISO 9002 implementation, the 17025 system changes were implemented. Internal audits were performed to check compliance and provide improvement, and then an accrediting body was chosen. Because the ISO 17025 standard is considered specialized for laboratories, a national organization does not control registrars or accrediting bodies. rtech therefore chose American Association of Laboratory Accreditation (A2LA) as the accrediting body because of its multilateral agreements with other countries, including Europe and Asia. These agreements are met and maintained by partners auditing each other, ensuring control of their processes. Other accrediting bodies that have been recognized by the National Cooperation of Laboratory Accreditation include the National Voluntary Laboratory Accreditation Program (NVLAP), American Industrial Hygiene Association (AIHA), and International Conference of Building Officials (ICBO). Audits to review the ISO 17025 system take place yearly to maintain accreditation for the first 2 years. In the third year, records are provided for review with an audit to follow the next year.

The 17025 accreditation audit was performed over a 4 day period. One day was spent on quality system documentation. Three days were spent on analytical evaluation. Any nonconformances required a written corrective action response.

Maintaining the Quality System for Continuous Improvement

The real benefits from operating a quality system begin after the certification process. Proper maintenance of the system is required to uncover issues and constantly improve. The maintenance of the system requires designated personnel to coordinate and monitor completion of required actions. Meticulous record keeping provides information on the adherence to system practices as well as the groundwork for process control measurement. Review of these measurements and responses to observed trends provide continuous improvement of the system. Elements requiring system maintenance and providing continuous improvement include:

Employee Training Plan Name: Start Date: Supervisor:

Employee Status: ❒ New Employee (Complete all sections of plan)
❒ Position change (Complete sections 2 – 5)
❒ Responsibility change (Complete sections 3 – 5)

System Training	Trainer	Expected Completion	Date complete
General Laboratory information	Supervisor	1 week from start	
Tour of facility (Parking, Bathrooms, First aid)	Supervisor	Day 1	
Introductions	Supervisor	Day 1	
Uniforms/Lab coats/Dress code	Supervisor	Day 1	
Personal Storage and Desk Area	Supervisor	Day 1	
Security access	Supervisor	Day 1	
Paid time off policy / Time cards / Pay schedule	Supervisor	Week 1	
Voice mail / Phone system / Phone Numbers	Supervisor	Week 1	
Color blindness testing	Supervisor	3 weeks from start	
Safety / ISO / LIMS training	Safety officer	3 weeks from start	
2) Required method training per position description See F/data/17025/spreadsheets/17025trngsum/Training Requirements	Supervisor	3 weeks from start	

3) General Training (Suggested)	Chem	Micro	Method #	Trainer	Expected Completion	Date complete
Automatic pipettes	Y	Y	05-4-GN011			
Balances	Y	Y	05-4-GN008			
Blenders	Y	Y				
Cleaning glassware	Y	Y	05-4-GN018			
Dilution schemes	Y	Y				
pH meters	Y	Y	05-4-GN021			
Reagent traceability	Y	Y	05-6-000			
Sample traceability	Y	Y	05-8-001			
Sample storage	Y	Y	05-8-000			
Centrifuges	Y	Y	05-4-GN009			
Pipette washing	Y		05-4-GN010			
Spectrophotometers	Y		05-4-GN015			
Autoclave	Y	Y	05-4-GN013			
Basic media preparation		Y	05-4-MC030			

4) Analysis or Process Method Training	Trainer	Demonstration of Proficiency	Expected Completion	Date complete

5) Training Plan Review

Expected Review Date	Actual Review Date	Supervisor Initials	Trainee Initials	Review Results

Training Plan Complete:

Supervisor: _____ **Trainee:** _____ **Date:** _____

Figure 3. Example training plan.

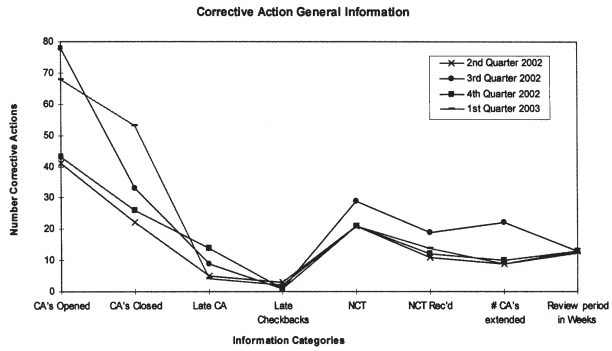

Figure 4. General information, including total number of corrective actions, number with late completion, and number of nonconforming test results.

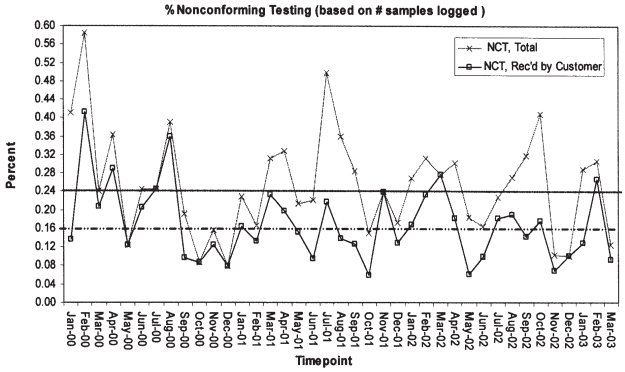

Figure 6. Percent of nonconforming testing results based on number of samples logged into the LIMS system.

(**a**) *Corrective and preventive action*.—Corrective action forms (Figure 2) are issued for audit nonconformances, problem data, customer complaints, and processes not followed as written. Preventive actions are initiated to investigate a potential quality or analytical issue or to improve a process. Corrective and preventive action spreadsheets are maintained to allow for enforcing timelines. The spreadsheets contain information on issue type, area, nonconforming results, and root cause.

When a corrective action is issued, the most important part of the process is root cause analysis. Whether the issue is analytical, process deviation, or quality system failure, the determination of cause is the most difficult. Sometimes the actual cause cannot be proven but only speculated by the process of elimination. The action taken must be appropriate to eliminate the cause. Once in place it is important to review the implementation to prove effectiveness. If ineffective, the process must start again.

(**b**) *Internal audits*.—Internal audits are performed on a predetermined schedule. The laboratory is split into 4 areas for auditing proposes: Chemistry, Microbiology, Quality Assurance, and Administration. Chemistry and Microbiology are audited separately every 6 months. The entire laboratory also undergoes a full system audit every 6 months.

Internal audits provide information on compliance to internal documented procedures and to adherence to standard requirements. They initiate change and improvement. As audits continue and the system matures, findings become more detailed.

The benefits include the changes made to increase compliance to documented processes by education of personnel or by changing the processes to make compliance easier. Also, analysts who participate in the audit improve their understanding of the quality system and the ISO standards. They also come away with a better understanding of the work their peers are performing in other areas.

(**c**) *Management review*.—The management review process is basically a meeting of management and supervisory personnel to discuss the state of the quality system. The specific inputs required for the meeting are listed in Table 1.

The review is conducted quarterly by the laboratory manager, technical operations manager, customer service manager, quality assurance manager, and supervisors. Minutes of the meeting are recorded. The required outputs of the meetings are decisions and actions related to improvement of the effectiveness of the quality system and all processes; improvement of product as related to customer requirements; and resource needs.

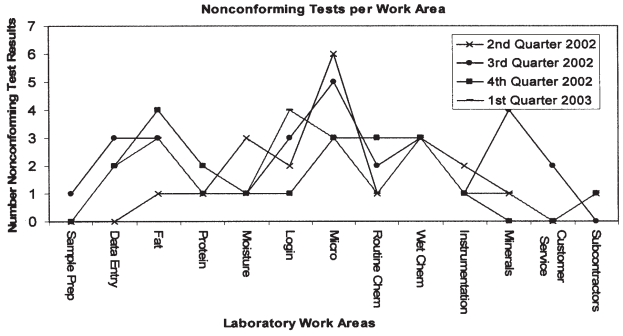

Figure 5. Nonconforming testing per laboratory work area.

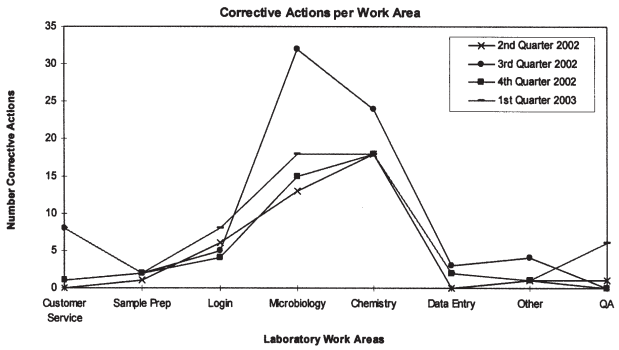

Figure 7. Number of corrective actions per work area of the laboratory.

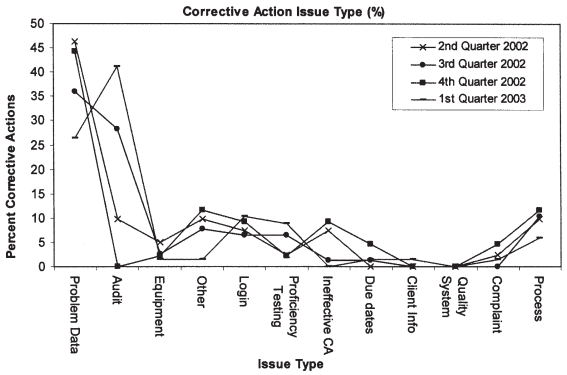

Figure 8. Percent issue type based on the total number of corrective actions.

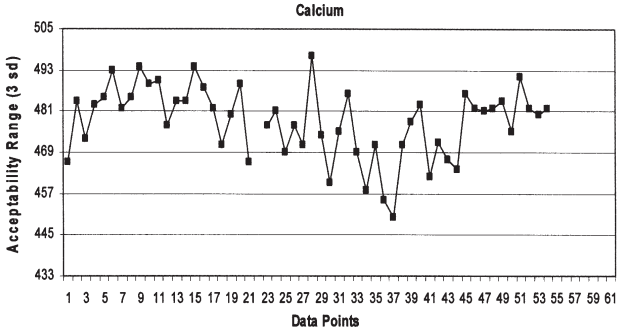

Figure 10. QC trending chart for calcium analysis by AA.

Management review is a very effective improvement tool. It allows a look at a broader picture of the quality system and associated trends. Improvements are noted that may otherwise be lost in day-to-day observations. Assigned actions are added to the weekly administrative meeting to facilitate completion before the next quarterly meeting.

(**d**) *Document review and revision*.—Analytical methods and other system documents are updated as changes occur. Maintaining the controlled document system requires laboratory management to approve change requests and revised documents and a coordinator to revise and distribute documents. All documents are also reviewed every 2 years against references and current practice. Reference documents must also be kept up-to-date and controlled.

(**e**) *Training*.—A training spreadsheet containing information on current training status of all personnel and all methods is maintained. Each person has a training file with records to demonstrate training history. The file contains a resumé to show that qualifications are met, a training plan (Figure 3), individual training records with demonstration of proficiency, document revision training records, and external training records.

(**f**) *Records*.—All records must be easily accessible. A system allows for archiving records with retrieval options.

(**g**) *QC*.—Analysts enter their daily QC information on a networked Excel drive. The quality assurance manager reviews the QC charts and data monthly and initiates corrective actions where appropriate. Ranges and values are changed as necessary. Method uncertainty and QC limits are reviewed based on these data and are changed as needed.

(**h**) *Proficiency testing*.—Proficiency testing is performed in all areas as available. The programs are coordinated by one individual. Duties include initiating programs annually; requesting analysis as samples are received; submitting results on time; reviewing collaborative results; issuing corrective action for unacceptable results; and communicating the results to the analysts.

(**i**) *Method approval*.—The method approval plans (Figure 1) are entered into a spreadsheet to track progress, completion, and final status.

(**j**) *Equipment calibration/maintenance*.—All equipment maintenance and calibration is on a reminder schedule. Monthly reminders are issued to analysts by quality assurance. Maintenance is performed and documented. Reminders are returned for next issue.

(**k**) *Purchasing and supplier performance*.—An approved supplier and subcontractor list is maintained. The suppliers are approved according to their performance on trial orders or their quality system information. If problems with a supplier occur, a form is submitted to identify the issue. If the issue results in nonconforming test results or delayed analysis, a corrective action is issued. Repeated or serious problems would result in the removal of the supplier from the approved list.

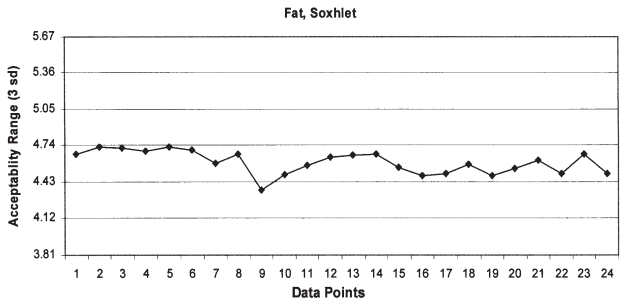

Figure 9. QC trending chart for Soxhlet fat analysis.

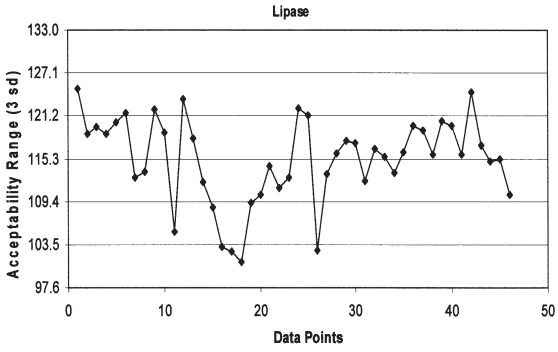

Figure 11. QC trending chart for lipase analysis.

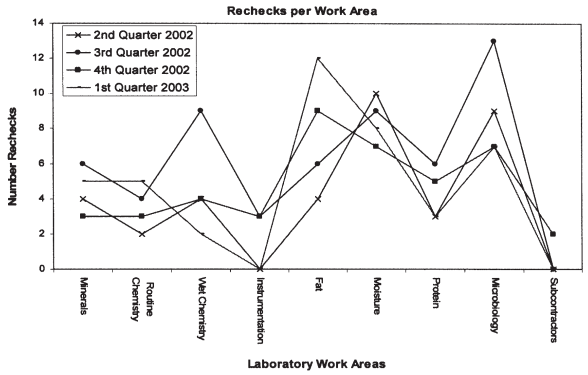

Figure 12. Trending of number of analytical rechecks per work area.

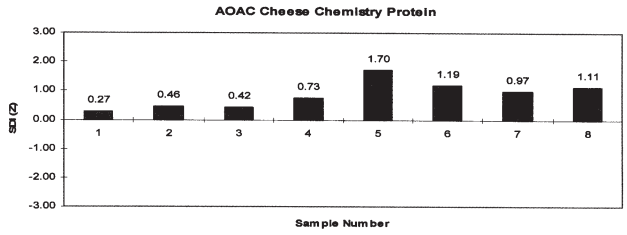

Figure 14. Proficiency testing for AOAC cheese chemistry protein analysis.

Process Measurement Capabilities

Processes can be measured through review of information presented in the corrective action spreadsheet, QC data, analytical rechecks, proficiency result trending, and purchasing information. All this information is presented at a quarterly management review meeting attended by management and supervisors.

(**a**) *Corrective action.*—The spreadsheet used to track corrective actions contains the following information: area, type of issue, investigator, description, and root cause. This information is reviewed quarterly by mangement for identification of trends. Figures 4–7 give examples of corrective action trending charts. Figure 4 shows trending of general information for corrective actions.

Reviewing the trend for the number of late corrective actions can be used to indicate the ability to move ahead on improvement activities. A significant increase here may show a lack of resources or commitment to quality system responsibilities.

Review of the trend for the number of corrective actions issued for nonconforming testing (NCT) is obviously important in maintaining quality results and customer satisfaction. The NCT is represented in 2 categories. The first is the total number NCT, which is any problem data produced, whether it is discovered in the data review processes or it passes through those stop gaps to the customer. The second, which is the more serious of the 2 categories, is the NCT received by the customer.

NCT is also reviewed weekly at the administration meeting for quick identification of trends. It is broken down further to review trends in work areas (Figure 5). Trends in particular areas may be indicators of systems, analytical, or training issues.

Figure 6 represents the percentage of NCT based on the number of samples logged into the system. This brings the total number of NCT into perspective in the broad system and provides a benchmark of performance. Note that the graph has a moving average line for both categories. Figure 7 is a trending chart of total number of corrective actions per work area. Trends here may be for audit, equipment, process, or data issues. Figure 8 provides trending on issue-type categories. Increasing trends in complaints and due dates are customer satisfaction issues. Proficiency testing increases are an analytical quality marker. Ineffective corrective action increases show problems with root cause analysis.

(**b**) *QC.*—The process measurement of daily QC data provides the best indicator of analytical performance. The charts are reviewed monthly for trends by quality assurance. Review comments and actions are noted. Analysts also observe trends by daily observation of charts when entering data, resulting in

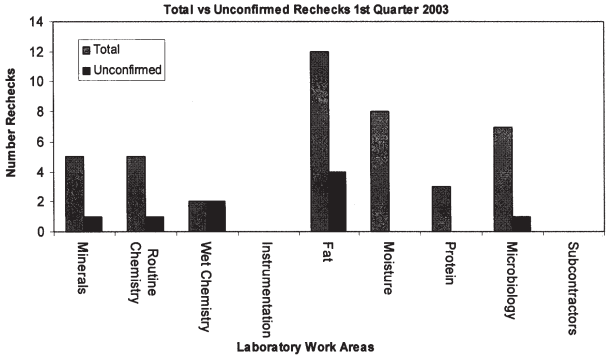

Figure 13. Trending of total number of analytical rechecks versus the number of unconfirmed rechecks.

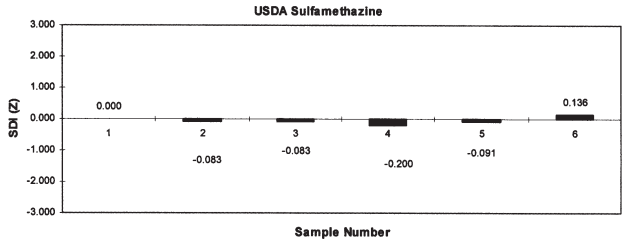

Figure 15. Proficiency testing for USDA sulfamethazine analysis.

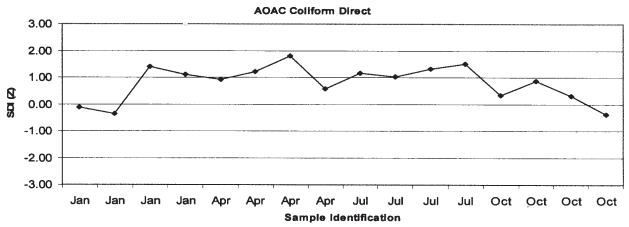

Figure 16. Proficiency testing for AOAC coliform direct analysis.

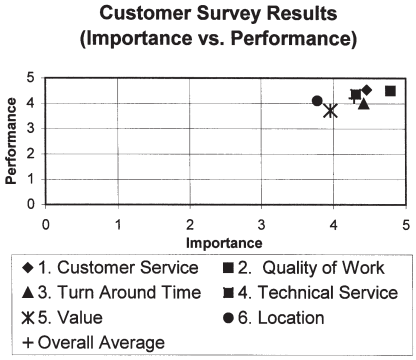

Figure 17. Survey results charted as importance to the customer and performance rating by the customer.

immediate resolution. Figures 9–11 show examples of QC trending charts. These charts are data points (traceable to dates on the Excel spreadsheet) plotted against acceptability ranges. Monthly reviews have shown longer-term trends and provided for analytical improvements.

(**c**) *Rechecks.*—All analytical results that are rechecked are carefully documented. Any rechecks that do not confirm require a corrective action. Recheck forms are reviewed quarterly for management review. Unconfirmed rechecks are also represented as nonconforming testing. Figures 12 and 13 show the trending of analytical rechecks. Figure 12 shows the total number of rechecks per work area. Increasing trends in total rechecks only may indicate a high level of rework that lessens efficiency. Figure 13 shows the quarterly number of confirmed versus unconfirmed rechecks per work area.

(**d**) *Proficiency results.*—Results obtained from proficiency testing programs are reviewed based on standard deviation index (sdi) or Z score. Any results >3 sdi, or 2 subsequent results >2 sdi, require corrective action. Results are charted as sdi and also reviewed for trends. Figures 14–16 show trending charts for proficiency testing. Trends here may show accuracy or precision issues. They may also be an indication of quality issues with the proficiency provider or show variation between different analytical methods.

(**e**) *Purchasing and supplier performance.*—Supplier and subcontractor performance is reviewed quarterly. The noted issues are reviewed against the total number of orders for that supplier. Action is required if 20% or more of the orders from a vendor had problems, or if management determines it necessary due to the severity of the problems.

(**f**) *Customer surveys.*—Internal and external customer surveys are performed annually. Figure 17 shows survey results charted as importance to the customer and rating of performance by the customer. The last survey had a 65% response rate. Results indicate that customers are satisfied with the services received. Individual open-ended comments are also reviewed. Action items are noted. Participants in the survey receive a written response.

Overall Benefits

Analysts in the laboratory recognize benefits from operating within a quality system. Controlled documented methods are the basis for training and a stable process. They appreciate the level of process control applied to the analysis and have channels to implement and complete needed changes. For example, when trends in QC for a visual endpoint titration method showed bias between analysts, an endpoint color template was created to standardize the process.

Because of corrective action trending and tracking, management within the laboratory identifies and resolves issues related to methods, personnel, and equipment more quickly. The method approval process provides a basis for decisions for analytical resources and new method implementation.

Customer survey results (Figure 14) show improved satisfaction as a result of the implemented quality system. Special customer requests are more easily met. Proficiency testing results are shared with customers by request. External audits may be performed by customers prior to testing. Overall, laboratory business has increased as demonstrated by increased revenue.

Summary

Implementation of ISO 17025 provides a system for continuous improvement of daily laboratory practices. Direct benefits include faster identification and resolution of issues, improved customer satisfaction, meeting of quality requirements of specialized customers, and an overall increase in laboratory business.