

UT-BATTELLE, LLC  
OAK RIDGE NATIONAL LABORATORY  
QUALITY SERVICES DIVISION

FISCAL YEAR 2005  
QUALITY MANAGEMENT SYSTEM PLAN

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## **Fiscal Year 2005 Quality Management System Plan**

### **Section 1: High Level Expected Outcomes and Associated Measures**

The purpose of the Quality Management Plan (QMS) is to implement quality management principles and methodology throughout the various Laboratory management systems and associated processes.

Implementation of the QMS will enable the delivery of products and services that meet our customers' requirements and expectations, plan and perform Laboratory operations in a reliable and effective manner to protect the environment, safety and health of our staff and the public, and standardize and continuously improve in all aspects of Laboratory operations.

It is our goal to assist ORNL in understanding their quality management responsibilities so that we can work together to drive process improvement.

The outcomes we expect for QMS include:

- A management system that meets the core values and concepts of DOE, nationally, and internationally recognized quality management system standards.
- Effective and efficient tools and processes that enable line management to drive process improvement through the implementation of the QMS.
- A support organization that meets internal and external customer expectations through a talented, empowered, and motivated support staff.

### **Section 2: Situation Assessment**

In FY2004 one of the major initiatives was the achievement of the ISO 17025 certification for the Metrology operation. This was successfully achieved and has positioned the organization to expand the level of service to the laboratory and outside customers. Additional goals for 2005 in this area will be:

- The capabilities of the Metrology operation are not well known across the laboratory leading to additional expense and inconsistent quality standards.
- Implementation of the new Calibration subject area is incomplete.
- There exist duplicate and inconsistent calibration capabilities across the laboratory.
- Establishment of qualification expectations for Quality Managers and Quality Assurance Specialists was begun in FY2004 and will be a multiyear process.

Steps will include a skills inventory and the development of individual development plans.

In FY2004 emerging work for Office of Civilian Radiological Waste created a need to reestablish NQA-1 type quality plans in support of nuclear related science and technology projects. ORNL was successful in establishing the plans that were required for a successful proposal and the Laboratory has been added to the Qualified Vendor List. However, there are other emerging nuclear related work areas that will need NQA-1 plans and a lab wide template needs to be developed.

In FY 2004 a strategic realignment of the Safety Surveillance resources from Quality Services to the Welding Inspection (WI) and Fabrication Division (FD) was undertaken. The benefits of this move were:

- Allows the inspection activities to be integrated into the crafts scheduling activities reducing delay times and access issues.
- The realignment also begins a process of involving the inspectors more in the development of the work planning documents, establishment of operability specifications and ultimately less reliance on end of maintenance inspections to ensure quality.
- FY2005 activities will include the establishment of process specific self-assessments to provide assurance to the QSD and WI&FD managers that the change has not compromised the quality of the inspection activities or the conduct of the maintenance.

Internal assessments of the P-AAA program have identified specific vulnerabilities that will be addressed in FY2005. These issues involve leadership and program implementation concerns. Specific areas include trending and issues management, and extent of condition reviews will receive focus,

Need for the consistent integration of the quality assurance function, as described in the ORNL Quality Assurance Program Description, into the work planning processes and tools utilized throughout the Laboratory to enhance the success of activity outcomes and mitigate the risks associated with the conduct of a wide variety of work types.

### **Section 3: Objectives, Actions and Measures**

Based on our situation assessment and the stated strategic intents of the Level 1 ESH and Q plan's, we have established three objectives for QMS to be executed by the Quality Services Division.

## **Objective 1**

*Improve the alignment of the management system along the lines of DOE 10 CFR 830 Subpart A, ISO 9001, Baldrige quality standards, and other appropriate quality standards.*

### **Actions and Measures:**

- Conduct a performance assessment of the Quality Management System to determine proper alignment of the management system with national and international quality programs.
- Develop a centralized approach to the review of laboratory quality plans.
- Develop metrics to gauge the effectiveness of the supplier quality program and the impact of the integrated supplier information system.
- Extend the ISO 17025 certification process to additional QSD services as appropriate.
  - Evaluate additional facility needs for expansion or consolidation based on Metrology workloads developed in FY2005.
- Establish NQA-1 quality plan templates that will significantly improve the Laboratory's ability to quickly respond to emerging nuclear Science and Technology opportunities in the in this area.
  - Develop the skills set and planning infrastructure to flexibly respond to the wide range of quality requirements presented through the funding of diverse set of sponsors.
- Expand the knowledge, skills and abilities of the QSD Quality Manager's and Quality Assurance Specialist's in the NQA-1 area to support their various research customers.

## **Objective 2**

*Develop and implement effective processes and tools that enable line management to incorporate quality standards within their work processes to drive improvement.*

### **Action and Measures:**

- Improve alignment and efficiency of the ORNL calibration processes.
  - Conduct an assessment of the implementation of the Calibration Subject Area by the end of the second quarter and develop appropriate actions to mitigate any vulnerabilities.

- Evaluate a realignment of the various calibration capabilities to ensure consistent quality expectations and reduce redundant capabilities.
- Improve the trending and analysis of nonconformance reporting information to drive reduction in nonconformance rates. Nonconformance rates will be tracked.
- Improve the prevention, detection, and reporting of Suspect/Counterfeit items. Metrics will include identification rates and response times in providing information to internal and external customers.

### **Objective 3**

*Improve the competency and effectiveness of the QSD support services in providing leadership and guidance in the implementation of Quality Management System requirements.*

#### **Actions and Measures:**

- Obtain customer input to identify areas of improvement to ensure that the management system components, processes, and tools are efficient, effective, and value added to the support of research. This will be measured through customer survey and feedback.
- Improve the competency and effectiveness of the QSD support services through better communication, standardization of qualifications, skill enhancement, and redefinition of expectations to provide a consistent and valuable set of staff skills, resulting in superior delivery of service to customers. This will be measured through internal and external assessment activities demonstrating a reduction in the number of repeat findings.
- Plan for staff development through QSD succession plan and document in the Performance Assessment and Development System (PADS). The measurement for this will be the completion of the succession plan and PADs by February 2005.
- Promote diversity within the division as specified in the ORNL EEO/WFD Performance Measures.

#### **Section 4: Issues and Support Needs**

**This Plan assumes some work at risk and has no contingency or ability to withstand mid-year cuts.**

1. An FY2004 goal that will potentially impact FY2005 resources is the consolidation of laboratory space in the Intercomparison Studies section. In summary:
  - The installation of a laboratory hood in 5510A has been plagued by significant delays and cost overruns in FY2004. Discussions with F&O to resolve these delays and overruns have been unsuccessful.
2. Senior Management in FY2005 must address integration or alignment of the SNS Quality Program into the overall Laboratory program as SNS transitions from construction phase to operations.
3. Improvements to the Calibration Subject Area need to be fully implemented and supported by senior management in FY2005.
4. The effective implementation of the quality management system, the results of research and development activities, and the consistent satisfaction of sponsors would be enhanced through an increased level of quality assurance support.

**Section 5: IT Reporting**

IT Requirements Report

IT Requirement	Brief Description of IT Investment	Development/Modernization Enhancement			Steady State			Funding Source	
		FY2004	FY2005	FY2006	FY2004	FY2005	FY2006	Indirect Y/N	Direct Y/N
MetCal-MetTrack	Application used to develop, store, and execute software-based calibration procedures, archive calibration records, and perform automated calibration recalls.	Plan maintained with the software vendor to provide us with automatic upgrades for a fixed price of (\$1,700.)	\$1,700	\$1,700	\$50,000	\$52,500	\$55,000	Y	
ISP Database	Application used to track, trend, store and archive bioassay QC data.	\$10,000	\$5,000	\$5,000	\$30,000	\$30,000	\$30,000	Y	
Respirator database	Application used to track respirator and cartridge information and also parts inventories.	\$8,000	0	0	\$17,000	\$18,000	\$19,000	Y	
SAS	Statistical analysis software used for database management and statistical analysis	\$4,000	0	0	\$1,200	\$1,200	\$1,200	Y	

**Section 6: Budget Submissions**

Metrology – Maintain Internal Standard Instruments	\$280K
Metrology – Maintain Calibration Facility	\$ 80K
Metrology – Establish and Maintain ISO 17025	\$125K
Metrology – Program Management	\$315K
Metrology – Maintain Calibration Recall System	\$ 70K
Safety Surveillance Inspections – Facility	\$150K
Safety Surveillance Inspections – Operations	\$135K
Quality Management System Maintenance and Line Support	\$325K
Quality Management System – ORNL Costs of Battelle ISIS	\$ 20K
<u>Intercomparison Studies</u>	<u>\$105K</u>
Total	\$1,605K