ORA-NTEU QMS Memorandum of Understanding

1. ORA will provide training to employees prior to, or in conjunction with, the implementation of its Quality Management System (QMS). A representative designated by NTEU will provide input concerning the QMS training. The QMS Program Manager will consider this input in determining the type, frequency, scope, and duration of the training. If additional training is designed at the local level, the local QMS representative will similarly seek input from the designated local union representative before developing and conducting the training. Employees will be provided the QMS training on duty time and the Employer will consider requests to change schedules necessary to accommodate the training.

2. ORA will request and consider the input of a designated NTEU representative before conducting a performance review of the QMS. The NTEU representative will be provided a copy of the summary reports related to a performance review.

3. ORA managers will analyze, resolve, and report problems identified by QMS activities through prescribed QMS procedures. Employees will not be held accountable for systems problems; deficiencies due to systems problems will not become part of an employee's performance or personnel records.

4. ORA will consider the input of the designated NTEU representative before determining the initial selection, training, and performance criteria for QMS auditors to be used in ORA audits and local internal audits. Selection of auditors for specific audits will be done by the appropriate ORA manager from the pool of qualified auditors. The NTEU Chapter President will be notified 14 calendar days in advance of any audit within the Chapter's jurisdiction. Such notice shall be given by facsimile or E-Mail.

5. Notification of NTEU regarding changes in ORA-wide QMS will be done in accord with Article 3 of the CBA. Notice regarding changes in local SOPs which are not national in scope and which impact the working conditions of employees will be served on the appropriate NTEU Chapter President in accord with Article 3 of the CBA.

6. This MOU will remain in effect for the duration of the general CBA between FDA and NTEU at which time it may be reopened at the request of either party.

Peter F. Gimbrere,
NTEU National Negotiator

DATE: 10-31-00

Patricia Maroney-Benassi,
QMS Program Manager

DATE: 10-25-00

Malcolm L. Frazier,
Director, Office of Resource Management, ORA

DATE: 10/25/00

ORA Quality Management System, continued

What's the same?

The changes due to the QMS do not affect the basic approach to quality management in ORA:

- ORA defines its work processes through standard operating procedures as expressed in statutes[1], national procedures[2], operating manuals[3], and local documented procedures.
- Employees follow work processes based on training and procedures.
- Managers or designated employees perform quality control (QC) through checks, reviews and approvals.
- Managers examine the effectiveness of QC activities by periodic internal quality assurance (QA) reviews of work products.

What's different?

The new QMS is a maturation of the current QC/QA model:

- The QMS applies to Headquarters' offices, which, based on their work patterns, have different levels of SOPs and QC than the Field offices.
- The QMS emphasizes a process oriented approach rather than product oriented reviews.
- Through a new "document change request" procedure, employees will have defined input into ORA national and local guidance documents.
- Publication of new guidance or procedures follows a defined process that includes assessment of training needs related to the new or changed procedure.
- ORA quality concerns and process deficiencies will be handled through defined nonconformance and corrective action procedures .
- Current regional audits will be replaced by ORA quality audits in a defined program.

Contact

For further information on the ORA QMS, contact

- Malcolm Frazier, Director, Office of Resource Management, HFC-10
- Patricia Maroney-Benassi, Ph.D., QMS Program Manager, HFC-240

[1] Examples are Good Guidance Practices and Freedom of Information Act as well as FDA regulations.
[2] Examples are Compliance Programs and Compliance Policy Guides.
[3] Examples are the existing Investigator's Operations Manual, Laboratory Procedures Manual, and Regulatory Procedures Manual.

Executive Summary

ORA Quality Management System, Status as of June 7, 2000

What is the QMS?

The ORA Quality Management System, or QMS, is a system-wide enhancement of ORA's current approach to managing quality. The QMS relies on clear, uniform, and accessible criteria for work processes, for quality control, and for feedback and system improvement. The QMS focuses on managers' responsibility to manage quality-related systems and is based on internationally accepted quality system standards.

Scope: The QMS applies to all ORA units in Field and Headquarters offices (except the Office of Criminal Investigations, which operates under a separate quality program).

Timeline: The QMS has been in various stages of development and implementation in ORA since 1997. The initial focus is on highly significant, mission-related work processes such as sample collection, sample analysis, and seizure actions.

Involvement: Several cross-functional, managerial and staff taskforces have contributed to the QMS development. A network of representatives is used for information sharing and an Intranet web site contains information on all development and implementation activities.

QMS principles, goals, and policy

At the onset of the project in 1997, ORA adopted a set of guiding principles to guide QMS development and implementation:

- *Demand compliance to an equivalent quality standard for ourselves as we expect of industry*
- *Keep the focus on systems, not on people*
- *Use a whole system approach for all ORA*
- *Quality can be managed*
- *Use a regulatory adaptation of internationally accepted quality elements*

In 1998, the ORA senior staff agreed upon a get of general goals for the QMS:

- *Increase management assurance of work quality*
- *Improve consistent and uniform application of ORA activities.*
- *Protect ORA knowledge base.*
- Improve work products and processes

In 1999, the ORA senior staff gave initial clearance to an ORA Quality Policy and initial objectives:

ORA managers and staff are committed to providing quality work through timely, effective, and efficient work processes, activities, and products. In supplying work products fit for their intended uses, we meet our obligations to our internal FDA customers, regulated industry, and the American public to fulfill ORA's role in the FDA mission.

To implement the Quality Policy, ORA will (1) establish an ORA Quality Management System and (2) focus on quality at all levels of management so all staff can provide quality work.
