

## **Overview of CONDUCT OF QUALITY ASSURANCE AUDITS (ORAUT-PROC-0080)**

The Oak Ridge Associated Universities Team (ORAUT), a contractor to the National Institute for Occupational Safety and Health (NIOSH), has a quality assurance (QA) system to oversee and maintain the overall quality of its work products and processes called the Quality Management System (QMS). The procedure being reviewed, *Conduct of Quality Assurance Audits*, (ORAUT-PROC-0080), provides ORAUT personnel with guidance and instruction to administer and conduct independent quality audits and assessments of its work. Included in the is procedure is guidance on planning, scheduling, and conduct of audits; development, review, and approval of QA Audit Reports; and the maintenance of audit records. It also describes the responsibilities and interactions of various ORAUT personnel as they implement the different steps of the procedure.

### **SUMMARY OF FINDINGS RESULTING FROM THE TECHNICAL REVIEW**

SC&A's review of the procedure produced two findings, both of which were in the form of suggestions on how the procedure could be improved in future revisions:

Finding #1: SC&A felt that this procedure inadequately describes how it fits into the overall ORAUT quality assurance program, with its several, inter-related procedures. Because of this, the reader sees only the one piece of the QA program discussed in the procedure and may not see how it relates to the other pieces.

Finding #2: SC&A felt that since the steps in the procedure were frequently difficult to follow, the reader would benefit from inclusion of a flowchart showing the work flow and decision points.

### **RESOLUTION OF FINDINGS**

NIOSH responded to the first finding by stating that this procedure is one of a number of "implementing procedures" under the project's Quality Management System, and by outlining the overall system and describing how the subject procedure fits into it. The response also noted that the overall Quality Management System and its several procedures are described in other documents, which are available for review. Finally, NIOSH concluded by stating that it would consider whether SC&A's comments would be included in future revisions of the procedure.

NIOSH responded to the second finding by acknowledging that inclusion of a flowchart would make it easier to understand the procedure and that it would consider including one in a future revision.

Both issues were resolved to the satisfaction of the Advisory Board.