

**PROGRAM STATUS  
QUALITY ASSURANCE**

**April 30, 2008**

<b>DOE AND DOE CONTRACTORS</b> DOE Order 414.1C	<b>STATUS</b>
DOE and DOE contractors must develop and implement approved Quality Assurance Program (QAP) Plans using a graded approach.	<ul style="list-style-type: none"> <li>• Both the Site Office and the Contractors' QAP Plans have been developed, approved, and addresses the graded approach.</li> <li>• No formal implementation assessments of the programs have been conducted. Assessments will be factored into the Annual Assessment Plan.</li> </ul>
DOE field element QAP Plans must be approved by their respective Secretarial Officer. This responsibility cannot be delegated.	<ul style="list-style-type: none"> <li>• TJSO has an approved QAP Plan (approved April 18, 2008).</li> </ul>
Contractor QAP Plans are approved by the respective Secretarial Officer, or delegated to the field element manager (FEM).	<ul style="list-style-type: none"> <li>• The TJSO Manager approved the contractor's QAP Plan on April 5, 2007.</li> </ul>

<b>DOE FIELD ELEMENT MANAGERS (FEM)</b> DOE Order 414.1C	<b>STATUS</b>
Develop and implement approved QAP Plans.	<ul style="list-style-type: none"> <li>• Developed, but no formal implementation assessment has been conducted.</li> </ul>
Submit QAP Plans to the appropriate Secretarial Officers for review, resolution of differences of opinion, and approval.	<ul style="list-style-type: none"> <li>• TJSO has an approved QAP Plan, April 18, 2008.</li> </ul>
Identify the senior management position responsible for development and implementation of their QAP.	<ul style="list-style-type: none"> <li>• QA responsible positions have been identified in the QAP Plan.</li> </ul>
Perform independent assessment of their contractors' QAP.	<ul style="list-style-type: none"> <li>• No independent assessments of contractors' QAP have been performed; however, elements are evaluated through the course of operational awareness activities; i.e., weekly meetings between the TJSO point of contact and the Jefferson Science Associates Quality Assurance and Continuous Improvement Manager.</li> </ul>

Periodically perform and report management assessment result to their Secretarial Officer describing the effectiveness of field element and contractor QA implementation.	<ul style="list-style-type: none"> <li>Annual HSS's QA surveys on QA implementation have been completed and routed through the Office of Science (SC).</li> </ul>
Prepare and implement a Corrective Action Plan (CAP) to address all findings in the DOE Headquarters Corrective Action Management Plan (CAMP).	<ul style="list-style-type: none"> <li>No corrective actions requiring entry into the DOE Corrective Action Tracking System have been identified.</li> </ul>
Complete the CAP for items in the CAMP and conduct follow-up review on the effectiveness of the corrective actions.	<ul style="list-style-type: none"> <li>No corrective actions requiring entry into the DOE Corrective Action Tracking System have been identified.</li> </ul>

<b>QUALITY ASSURANCE PLANS</b> DOE Order 414.1C	<b>STATUS</b>
QAP Plans must identify a national or international consensus standard for implementation.	<ul style="list-style-type: none"> <li>The TJSO has identified ISO 9001-2000 as their Consensus Standard for implementing their QAP.</li> </ul>
Ten Quality Assurance Criteria that each QAP must address: <ol style="list-style-type: none"> <li>1. PROGRAM</li> <li>2. PERSONNEL TRAINING AND QUALIFICATION</li> <li>3. QUALITY IMPROVEMENT</li> <li>4. DOCUMENTS AND RECORDS</li> <li>5. WORK PROCESSES</li> <li>6. DESIGN</li> <li>7. PROCUREMENT</li> <li>8. INSPECTION AND ACCEPTANCE TESTING</li> <li>9. MANAGEMENT ASSESSMENT</li> <li>10. INDEPENDENT ASSESSMENT</li> </ol>	<ul style="list-style-type: none"> <li>The TJSO QAP Plan, dated November 2006 has been approved by the Office of Science HQ.</li> <li>The updated TJSO QAP has been approved.</li> </ul>
QAP Plans must address: Suspect Counterfeit Items Corrective Action Management Program Software Quality Requirements	<ul style="list-style-type: none"> <li>The TJSO QAP Plan, dated November 2006, has been approved by the Office of Science HQ.</li> <li>The TJSO QAP Plan is now in the process of being refined and should be completed by the end of April.</li> </ul>

## **ADDITIONAL RESOURCES**

- P.L. 106-65, *Department of Defense Authorization Act of 2000*
- DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide for Use with 10 CFR, Part 830, Subpart A, and DOE O 414.1A, Quality Assurance; DOE P 450.4, Safety Management System Policy; and DOE P 450.5, Line ES&H Oversight Policy*, dated 5-31-01
- DOE M 411.1-1C, *Safety Management Functions, Responsibilities, and Authorities Manual*, dated 12-31-03
- DOE G 414.1-3, *Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1B, Quality Assurance*, dated 11-03-04
- DOE G 414.1-2A, *Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A and DOE O 414.1C, Quality Assurance*, dated 6-17-05
- DOE G 414.1-4, *Safety Software Guide for use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*, dated 6-17-05
- TJSO SOPP-4.9, *ISM Program Description*, November 1, 2007

## **KEY DOCUMENTS**

- TJSO SOPP-4.6, Rev 0, *Quality Assurance Program*, November 2006
- TJSO SOPP-4.7, Rev 0, *Records Management Procedure*, June 20, 2007
- TJSO SOPP-4.2a, Rev 2, *Standard Operating Plans and Procedures (SOPP) System*, September 13, 2007
- TJSO SOPP-4.3a, Rev 3, *Self-Assessment Program*, January 10, 2008
- TJSO SOPP-4.5, Rev 2, *Operational Awareness Program*, March 12, 2008
- TJSO SOPP-2.6, *Quality Assurance Plan for NEPA (in progress)*

## **TJSO ASSESSMENTS**

- *Effectiveness of Feedback and Improvement Processes (Commitment 25)*, January 27, 2006
- *Effectiveness of Work Planning and Work Control (Commitment 23)*, February 6, 2006
- *ISMS Self Assessment*, April 11, 2007

## **AREAS OF CONCERN**

- Challenge of tailoring a consensus standard into our QAP that is commensurate with the risks associated with our site office activities.

### **CONTRACTOR ASSESSMENTS/OVERSIGHT**

- No independent assessments of contractor's QAP have been performed; however, elements are evaluated through the course of operational awareness activities.

### **PATH FORWARD**

- Utilize external resources to refine the TJSO QAP and related procedures to establish a routine schedule for self-assessment of the TJSO QAP and periodic assessments of the contractor's QAP.

**TJSO POINT OF CONTACT: Steve Neilson**