

## Assessment of DOE O 414.1C Criterion 1 – Program

**Objective:** The Contractor’s QA Program Description documentation describes programs and processes that comprise the total scope of their QA management system. The organization and reporting chain are established and utilized to ensure clear lines of authority.

| Criteria   | Laboratory Documents and Records  | Observations |
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| <p><b>DOE O 414.1C Criterion 1 - Program</b></p> <p><b>a) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.</b></p> <p><b>b) Establish management processes, including planning, scheduling, and providing resources for work.</b></p> | <ol style="list-style-type: none"> <li>1. IQA1001, Integrated Quality Assurance</li> <li>2. IQA 1001 Overview Definition of IQA</li> <li>3. IQA 1001 Para 1.2.1.2</li> <li>4. IQA 1001 Overview, Principles of the Quality Program.</li> <li>5. IQA 1001 Title Page</li> <li>6. IQA1001 Para 5.2 Management Responsibilities, Para 5.4 Specific Provisions for Processes Not Already described.</li> <li>7. IQA1001 Chapter 9, Assessments</li> <li>8. Most departments in the division collect various performance measures including computer system uptime, service desk tickets resolved etc. These data are used to improve processes. See attached Pion_KaonClusterStatus.pdf. To improve performance, CD has initiated the ITSM process accepted throughout the industry. See attached the ITSM document for the Incident</li> </ol> |              |



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Documents and Records Reviewed:

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Persons Interviewed:

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**Supplemental Lines of Inquiry:**

1. Has a Quality Assurance Program (QAP) description document been developed by the contractor and approved by DOE?
2. Does the QAP describe the management processes that the contractor applies in the daily management of work? If not covered in the QAP, how does the contractor communicate management processes that ensure workers know what is expected from their performance of work?
3. Does the QAP include a description of the organization structure, functional responsibilities, levels of authority, and identify interfaces for those managing, performing and assessing work? If not covered in a QAP document, how is the information communicated to workers and do workers have a clear understanding of their roles and responsibilities?
4. Does the QAP clearly identify a senior level management commitment to quality and safety and that every component and employee of the organization is included in the scope of the quality management system? If not covered in the QAP, where and how does management communicate this commitment?
5. Did senior management approve the QAP? If not approved by senior management, does the approval authority have sufficient support from senior management to ensure quality and safety issues are not compromised should conflict develop between competing interests that could result in compromising quality/safety?

6. Does the QAP include a description of management processes to be applied for planning, scheduling and selection of resources to be allocated for work? If not described in the QAP, is this covered in other documents? Identify and review documents that communicate requirements for planning, scheduling and selection of resources for performing work.
7. Does the contractor's quality management program include a need for conducting self-assessments or management assessments, and independent assessments as defined in the DOE Order 414.1C? If not, what is management's position for not requiring the assessments? Do managers and workers clearly understand what is expected?
8. Does contractor senior management monitor performance trends for work that would indicate the effectiveness of quality management controls? Ask a senior manager to describe how he/she monitors performance and have him/her show you evidence of feedback that supports conclusions that are being drawn.
9. Does the management process encourage and include worker participation in identifying opportunities for quality/safety improvements? Ask workers if their expertise is sought on work processes to perform applicable work, and if not, what is their perception of the adequacy of the direction they are given?

## Assessment of DOE O 414.1C Criterion 2 – Personnel Training & Qualification

| <b>Objective:</b> The training and qualification program is defined and implemented to ensure that personnel are capable of performing their assigned work.  |   |              |
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| Criteria   | Laboratory Documents and Records  | Observations |
| <p><b>DOE O 414.1C Criterion 2 – Personnel Training and Qualification</b></p> <p><b>a) Train and qualify personnel to be capable of performing assigned work.</b></p> <p><b>b) Provide continuing training to personnel to maintain job proficiency.</b></p> | <ol style="list-style-type: none"> <li>1. Job description</li> <li>2. Job description, ITNA, Hazard analysis</li> <li>3. Excel 2007 Intro Class &amp; Evaluation</li> <li>4. Job description, ITNA</li> <li>5. Job description, ITNA, Attached list of Computer Training offered.</li> <li>6. Excel 2007 Intro Class &amp; Evaluation</li> <li>7. New Employee Orientation Training, Hazard analysis</li> <li>8. New Employee Orientation Training, All hands meetings (see <a href="http://www.usqcd.org/meetings/allHands2009/">http://www.usqcd.org/meetings/allHands2009/</a>), Computer Training offered during computer security days, TuneIT Up campaign</li> <li>9. Training procedures are up dated as needed. See CD-CAP #4.</li> <li>10. ITNA, TRAIN See 9.</li> </ol> |              |
| <p><b>Conclusions</b> – Provide an overall (on-balance) summary statement regarding the extent to which the Laboratory is satisfying the above objective and criteria.</p>   |   |              |

**Strengths –**

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**Weaknesses –**

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**Findings / Recommendations –**

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**Documents and Records Reviewed:**

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Persons Interviewed:

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**Supplemental Lines of Inquiry:**

1. Has the contractor established a process that ensures persons responsible for managing and performing activities possess the appropriate level of experience, knowledge, skills and abilities that are commensurate with their responsibilities? A review of worker skill requirements against the individual qualifications of assigned workers should be made to assess the adequacy of the contractors program.
2. Has the contractor established qualification requirements for workers? Documents that establish worker qualification requirements should be reviewed to establish the adequacy of the contractor's program. Documents include contracts, task description documents, training requirement documents and other means that the contractor has implemented and uses. The review should include how requirements are passed down to subcontractors and for persons who serve as Subject Matter Experts (SME).
3. Has the contractor made provisions and committed resources that facilitate the training needs and qualification of personnel? Are responsibilities and authority for persons who provide training clearly defined and understood and are they held accountable for carrying out their responsibilities? Does the contractor use indicators of training performance to assess improvements needed in training? Are training programs systematically evaluated and revised to maintain and improve required skills and knowledge?
4. Does management assure that persons selected for positions through transfer or hire have the necessary qualifications that are appropriate for performing assigned work? Select samples from the contractor's human resource files and track the contractor's activities that were followed in getting them prepared for their work assignments.
5. Are job/worker skills proficiency requirements defined and worker training needs developed based on defined requirements? Review documents that perform this function to establish if they are consistent with the need to ensure worker skill proficiency is properly established and workers possess the level of proficiency desired by management for performing work.
6. Does management solicit input from workers regarding the adequacy of training that is being provided? Is feedback from job performance used to help evaluate and refine training programs? Interviews of managers and workers should result in a consistent and compatible understanding of what is desired and whether results are adequately achieved.
7. Do training modules include consideration of safety, emergency plans, security and operations information that is necessary for personnel to adequately prepare for and perform assigned duties? Review contractor problem reports to determine if there are weaknesses in the contractor's program for preparing workers to perform assigned duties?

8. Does training modules include a message about the organization's mission, vision, goals and the importance of all workers and their contribution to the overall achievement? Is this communicated to all levels of workers within the contractor's organization? If not, are there problems that could be cited as potential weaknesses in this aspect of the contractor's program.
9. Does management assure that training plan content is current and reflects the latest information regarding the site, facility, and organization procedures and controls; technical and professional references; and past organization/industry experience and applicable lessons-learned? If not, what is the contractor's position for not ensuring training plan content is current?
10. Have training record needs been identified and are they maintained current? A review of a sample of training records should be performed to determine if they are up-to-date and that current training needs are being implemented in a pro-active manner.

## Assessment of DOE O 414.1C Criterion 3 – Quality Improvement

| <b>Objective:</b> Management establishes a culture for improving quality of products, processes, and services by establishing priorities, promulgating policy, promoting cultural aspects, allocating resources, communicating lessons learned, and resolving significant management issues and problems that can hinder the organization from achieving its quality objectives.   |   |              |
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| Criteria   | Laboratory Documents and Records  | Observations |
| <p><b>DOE O 414.1C Criterion 3 – Quality Improvement</b></p> <p>a) <b>Establish and implement processes to detect and prevent quality problems.</b></p> <p>b) <b>Identify, control, and correct items, services, and processes that do not meet established requirements.</b></p> <p>c) <b>Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.</b></p> <p>d) <b>Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.</b></p> <p><b>DOE O 226.1A Attach 1, App A</b></p> <p>3. <b><u>EVENT REPORTING.</u> Formal programs will be established and effectively implemented to identify issues and report, analyze, and address operational events, accidents, and injuries.</b></p> | <ol style="list-style-type: none"> <li>1. OQ-05-30-2009-5 Root Cause CAP. OQ-05-06-2009-4 Quality Training. IQA 1001 Chpt. 3. At CD, weekly Operations meeting with the Division head is the primary forum for these discussions. Meeting presentations are archived and action items are resolved. See cd-ops-meeting-minutes.pdf</li> <li>2. CAP. OQ-05-06-2009-4 Quality Training. IQA 1001 Chpt. 3, Para 5.2.2.</li> <li>3. Fermilab Compiled 2009 2<sup>nd</sup> Qtr Self Assessment form. Compiled Fermilab Assessment Schedule due 8/31/2009.</li> <li>4. Fermilab Assessment Manual 3902, OQ-05-04-2009-2 Assessments Policy CAP</li> <li>5. IQA1001 Para 3.3.2 Management Review</li> <li>6. IQA1001 Para 1.3 Graded Approach</li> <li>7. IQA1001 Para 3.1 Introduction</li> <li>8. IQA1001 Chpt 8 Inspection &amp;</li> </ol> |              |

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| <p>a. Reportable occurrences that meet occurrence reporting and processing system thresholds and associated corrective actions will be evaluated, documented, and reported as required by the DOE directive (M 231.1-1, Environment, Safety and Health Reporting Manual).</p> <p>b. For activities covered by the Price-Anderson Amendments Act, nuclear and worker safety and health issues (e.g., noncompliance) meeting DOE reporting thresholds should be self-reported through the DOE-wide Noncompliance Tracking System to mitigate the severity level of the violation and potential financial penalties.</p> <p>c. Trending analysis of events, accidents, and injuries is performed in accordance with structured/formal processes.</p> <p>4. <b>WORKER FEEDBACK.</b> In addition to structured assessments, DOE contractors will establish and implement processes to solicit feedback from workers and work activities. Common feedback mechanisms are described in site plans/program documents and include the following:</p> <p>a. employee concerns programs,</p> | <p>Acceptance Testing, Chpt 9 Assessments</p> <p>9. Fermilab Corrective &amp; Preventive Action Procedure 1004.1001</p> <p>10. IQA1001 Para 8.4.1 Control of Nonconforming Items</p> <p>11. OQ-05-30-2009-5 Root Cause CAP</p> <p>12. OQ-05-30-2009-3 Lessons Learned CAP</p> <p>13. CD Service Desk is another method of solving problems. See RQC3AServ.pdf for a sample screenshot.</p> <p><b>LOI DOE226.1A</b></p> <p><b>Contractor Event Reporting</b></p> <p>FESHM 3010 Significant &amp; Reportable Occurrences</p> <p>FESHM 3020 Incident Investigation &amp; Analysis</p> <p>FESHM 3030 Noncompliance Tracking System</p> <p>1a. Fermilab Integrated Contractor Assurance Program 3901 Chpt 6 Reporting</p> <p>1b. Fermilab Integrated Contractor Assurance Program 3901 Chpt 6 Reporting</p> <p>2a. CD management initiates various formal reviews for projects and processes to find out the root cause of a problem</p> |  |
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| <p>b. telephone or intranet “hotline” processes for reporting concerns or questions,</p> <p>c. pre-job briefs,</p> <p>d. job hazard walk-downs by workers prior to work,</p> <p>e. post-job reviews,</p> <p>f. employee suggestion forms,</p> <p>g. safety meetings,</p> <p>h. employee participation in committees and working groups,</p> <p>i. labor organization input.</p> <p><b>5. <u>ISSUES MANAGEMENT.</u></b><br/> <b>Contractors must ensure that a comprehensive, structured issues management system is in place. This system must provide for the timely and effective resolution of deficiencies, and be an integral part of effective contractor assurance system (see also DOE Order 414.1C, Criterion 3, “Quality Improvement”).</b></p> <p>a. <b>Program and performance deficiencies, regardless of their source, must be captured in a system or systems that provide for effective analysis, resolution, and tracking. Issues management must include structured processes for—</b></p> | <p>and mitigation methods.</p> <p>2b.</p> <p>3a. FESHM 3010 Significant &amp; Reportable Occurrences</p> <p>3b. Fermilab Emergency Response Plan</p> <p>3c.</p> <p>3d.</p> <p>3e.</p> <p>3f.</p> <p>3g.</p> <p>3h.</p> <p><b>Lessons Learned</b></p> <p>1a. Fermilab Integrated Contractor Assurance Program 3901 Chpt7. Lessons Learned. OQ-05-30-2009-3 Lessons Learned CAP.</p> <p>1b. Fermilab Integrated Contractor Assurance Program 3901 Chpt7. Lessons Learned. OQ-05-30-2009-3 Lessons Learned CAP.</p> <p>1c. Fermilab Integrated Contractor Assurance Program 3901 Chpt7. Lessons Learned. OQ-05-30-2009-3 Lessons Learned CAP.</p> <p>1d. Fermilab Integrated Contractor Assurance Program 3901 Chpt7. Lessons Learned. OQ-05-30-2009-3 Lessons Learned CAP.</p> |  |
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| <p><b>(1) determining the risk, significance, and priority of deficiencies;</b></p> <p><b>(2) evaluating the scope and extent of the condition or deficiency (e.g., applicability to other equipment, activities, facilities, or organizations);</b></p> <p><b>(3) determining event reportability under applicable requirements (e.g., Price-Anderson Amendments Act, Occurrence Reporting and Processing System, security incident reporting);</b></p> <p><b>(4) identifying root causes (applied to all items using a graded approach based on risk);</b></p> <p><b>(5) identifying and documenting suitable corrective actions and recurrence controls, based on analyses, to correct the conditions and prevent recurrence;</b></p> <p><b>(6) identifying individuals/organizations responsible for implementing corrective actions;</b></p> <p><b>(7) establishing appropriate milestones for completion of</b></p> | <p>1e. Fermilab Integrated Contractor Assurance Program 3901 Chpt7. Lessons Learned. OQ-05-30-2009-3 Lessons Learned CAP.</p> <p>1f. Fermilab Integrated Contractor Assurance Program 3901 Chpt7. Lessons Learned. OQ-05-30-2009-3 Lessons Learned CAP, ES&amp;H Section-Lessons Learned Website Page.</p> <p>2a.</p> <p>3a.</p> <p>3b.</p> <p>3c.</p> <p>3d.</p> <p>3e.</p> <p>3f.</p> <p>3g.</p> <p>3h.</p> <p>3i. Performance measures See attached for various performance measures for CMS: CMS Critical systems.pdf.</p> <p>3j.</p> <p>3k.</p> <p>3l.</p> <p>3m.</p> <p><b>Contractor Issues Mgmt.</b></p> <p>1a. Fermilab Integrated Contractor</p> |  |
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| <p><b>corrective actions, including consideration of significance and risk;</b></p> <p><b>(8) tracking progress toward milestones such that responsible individuals and managers can ensure timely completion of actions and resolution of issues;</b></p> <p><b>(9) verifying that corrective actions are complete;</b></p> <p><b>(10) validating that corrective actions are effectively implemented and accomplish their intended purposes, using a graded approach based on risk; and</b></p> <p><b>(11) ensuring that individuals and organizations are accountable for performing their assigned responsibilities.</b></p> <p><b>b. Issues management will provide a process for rapidly determining the impact of identified weaknesses and taking timely action to address conditions of immediate concern. For such conditions, interim corrective actions (e.g.,</b></p> | <p>Assurance Program 3901 Chpt 9 Issues Management</p> <p>1b. Fermilab Integrated Contractor Assurance Program 3901 Chpt 9 Issues Management</p> <p>1c. Fermilab Integrated Contractor Assurance Program 3901 Chpt 9 Issues Management</p> <p>2a.</p> <p>2b.</p> <p>3a.</p> <p>3b.</p> <p>3c.</p> <p>4a.</p> <p><b>Contractor Feedback</b></p> <p>1a. Fermilab Integrated Contractor Assurance Program 3901 Chpt. 8 Worker Feedback, FESHM 1060 Fermilab ES&amp;H Concerns Program</p> <p>1b. Fermilab Integrated Contractor Assurance Program 3901 Chpt. 8 Worker Feedback</p> <p>1c. Fermilab Integrated Contractor Assurance Program 3901 Chpt. 8 Worker Feedback, FESHM 2060 Work Planning &amp; Hazard Analysis, FESHM 7010 ES&amp;H Program for Construction, Fixed Price, FESHM 7011 ES&amp;H Program for Construction, Time &amp; Materials (other than fixed price), FESHM 7020, Subcontractor Safety, Other than</p> |  |
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| <p><b>stopping work, shutting down activities, or revising a procedure) are to be taken as soon as a condition is identified and without waiting until a formal report is issued.</b></p> <p><b>c. Processes for analyzing deficiencies, individually and collectively, must be established to enable the identification of programmatic or systemic issues. Process products will be used by management to monitor progress in addressing known systemic issues and to optimize the allocation of assessment resources.</b></p> <p><b>d. Sites must have effective processes for communicating issues up the management chain to senior management, using a graded approach that considers hazards and risks. The processes must provide sufficient technical basis to allow managers to make informed decisions and must include provisions for communicating and documenting dissenting opinions. Processes for resolving disputes about oversight findings and other significant issues must be</b></p> | <p>Construction.</p> <p>1d. Fermilab Integrated Contractor Assurance Program 3901 Chpt. 8 Worker Feedback</p> <p>2a.</p> <p>2b.</p> <p>3a.</p> <p>3b.</p> <p>3c.</p> <p>3d.</p> <p>3e.</p> <p>3f.</p> <p>3g.</p> <p>Director's Policy Manual (Applicable to many of the Criteria)</p> |  |
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implemented. The processes must include provisions for independent technical reviews of significant issues.

6. **LESSONS LEARNED.** Formal programs must be established to communicate lessons learned during work activities, process reviews, and event analyses to potential users and applied to future work activities. Contractors must identify, apply, and exchange lessons learned with the rest of the DOE complex. Contractors must review and apply lessons learned identified by other DOE organizations and external sources to prevent similar occurrences (see also DOE Order 414.1C, Criterion 3, “Quality Improvement”).
7. **PERFORMANCE MEASURES.** Contractors must identify, monitor, and analyze data measuring the performance of facilities, programs, and organizations. The data must be used to demonstrate performance improvement or deterioration relative to identified goals. Using a program to analyze and correlate data, contractors must suggest further improvements and identify good practices and lessons learned. To accomplish these objectives, contractors must establish

**programs that identify, gather, verify, analyze, trend, disseminate, and make use of performance indicators (see also DOE Order 414.1C, Criterion 3, “Quality Improvement”).**

**Performance indicator data must be considered in allocating resources, establishing goals, identifying performance trends, identifying potential problems, and applying lessons learned and good practices. Quantitative performance indicators/measures also may be considered in evaluating performance and establishing oversight priorities. However, quantitative performance measures provide only a partial indication of system effectiveness and must be considered in combination with other appraisal and operational awareness results.**

**Conclusions** – *Provide an overall (on-balance) summary statement regarding the extent to which the Laboratory is satisfying the above objective and criteria.*

**Strengths –**

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**Weaknesses –**

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**Findings / Recommendations –**

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Documents and Records Reviewed:

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Persons Interviewed:

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**Supplemental Lines of Inquiry:**

1. Does the contractor have in place a means for identification of quality problems? It is suggested the contractor's QAP be reviewed to see what has been defined. Next, ask various managers to describe the contractor's program for quality improvement. Finally, interviews with workers should be performed to establish their level of understanding of the contractor's quality improvement program.

2. Are contractor personnel at all levels committed to quality performance? Identify how commitment to quality performance is communicated and applied through reviews of work control procedures, and training module information. Interviews with workers enable gaining worker perception and understanding of commitments to quality performance.
3. Are quality audits and surveillances scheduled based on the importance of the activity, past performance, and suspected weak areas? Are they timed to identify problems early in a process? Interviews with the QA Manager and supervisors are sources of how audits and surveillances are scheduled and conducted. A representative sample of audits and surveillance reports should be reviewed and assessed regarding their adequacy for identifying precursors to problems.
4. Are the results of quality and surveillance audits documented and evaluated to allow early detection and correction of performance problems? Are quality problems being identified; evaluated and their causes and significance determined; and are management disposition actions effectively applied?
5. Does the contractor emphasize, at all work levels, the desired quality improvement approach is the "prevention" of problems?
6. When improvements are determined necessary, does management balance quality/safety requirements with mission priorities? If not, what seems to be the predominate tendency regarding management decisions?
7. Does contractor management encourage employee participation in planning, developing, exploring and implementing new ideas for improving quality in products, processes, and services?
8. Has the contractor established a program to analyze quality related information from various internal and external sources to identify improvement opportunities in the quality management system, processes, items, products, or services?
9. Has the contractor implemented a tracking system that enables effective follow-up on the adequacy of actions to improve quality?
10. Has the contractor established a program that ensures items, services, and processes that do not meet established requirements are identified, isolated and controlled to prevent their being applied during work processes? This should be explored with both management and workers to ensure a consistent understanding exist as to what is expected.
11. Does the contractor's corrective action program include the identification of "root-causes" to quality and safety problems to prevent recurrence? If not, ask the contractor's QA manager for an explanation of what is being done to ensure causes to problems are established and changes to management controls are effective in preventing their recurrence.
12. Has the contractor implemented a "Lessons-Learned" program that utilizes feedback from within and other related organizations to assist efforts in minimizing or preventing quality problems? If not, ask the contractor's QA manager for an explanation of what is being done to ensure causes to problems are established and changes to management are effective in preventing their recurrence.
13. Does the contractor track through resolution quality problems identified as Type "A" Accident events, Price-Anderson enforcement events, and Inspector General identified issues? If not, ask the contractor's QA manager for an explanation of what is being done to ensure causes to problems are established and changes to management are effective in preventing their recurrence.

**Supplemental Lines of Inquiry for DOE O 226.1A sections regarding Event reporting, Worker Feedback, Issues Management, Lessons Learned, and Performance Measures:**

## Contractor Event Reporting Lines of Inquiry

1. Oversight Program - Are the processes for event identification, reporting and investigation formal and documented and meet the requirements of DOE Directives?
  - a. Have appropriate, formal processes and procedures been established to detail the requirement for the identification, documentation, investigation, analysis, reporting, and management of issues for operational events (including non-reportable incidents), accidents, occupational injuries and illnesses, and quality assurance and nuclear safety issues?
  - b. Do processes require timely and appropriate identification, documentation, and local notification of operational events, incidents, accidents, occupational injuries and illnesses and nuclear safety issues?
2. Training & Qualification - Are personnel implementing event identification, reporting, and investigation processes adequately trained and qualified to perform assigned oversight activities (in accordance with DOE O 226.1A, DOE M 360.1-1B, and DOE M 426.1-1A)?
  - a. Has the contractor defined the requirements for experience, knowledge, skills and abilities for personnel implementing event identification, reporting, and investigation activities?
  - b. Has the contractor provided and ensured completion of appropriate training for personnel implementing event, accident, occupational injury and illness, and nuclear safety issue management activities?
3. Implementation of Program Responsibilities - Are event identification, reporting and investigation responsibilities appropriately validated, documented, communicated, classified, evaluated, tracked and resolved?
  - a. Is reporting of operational events, accidents, occupational injuries and illnesses, and nuclear safety issues conducted in accordance with applicable nuclear, security, environment, occupational safety and health, and quality assurance requirements, applicable DOE Directives, and contract terms and conditions?
  - b. Are immediate and compensatory measures to operational events, accidents, occupational injuries and illnesses and nuclear safety issues sufficiently defined and taken as part of line management initial response to operational events, in the development of follow-on corrective action plans?
  - c. Are operational events, accidents, occupational injuries and illnesses and nuclear safety issues promptly and rigorously reported to management, documented, and investigated in accordance with formal issues management processes that identify causes and recurrence controls, management and programmatic weaknesses, and the need to communicate lessons learned?
  - d. Are corrective and preventive actions resulting from investigation of events, accidents, and occupational injuries and illnesses formally managed to completion and effective in preventing recurrence?
  - e. Are events, accidents, occupational injuries and illnesses, and nuclear safety issues reported to SC and other regulatory entities in a timely and thorough manner as required by DOE Directives and regulations?
  - f. Are operations and engineering organizations, including support organizations, appropriately involved in the identification, assessment, and development of corrective action plans of reportable events, accidents, and occupational injuries and illnesses?
  - g. Are trending analyses of events (including non-reportable incidents), accidents, and occupational injuries and illnesses performed in accordance with structured/formal processes and applicable DOE Directives?

- h. Are the processes and performance of event, accident, occupational injury and illness, and nuclear safety issue management properly evaluated for effectiveness on an appropriate frequency?

### **Contractor Operating Experience/Lessons Learned Lines of Inquiry**

1. Oversight Program - Are the processes which constitute the operating experience/lessons learned program formal and documented and, when taken together, meet the requirements of DOE O 226.1A and DOE O 210.2?
  - a. Has the contractor established and implemented a formal program that screens lessons learned from external sources for local applicability and evaluates site conditions and processes to determine if actions are needed to apply applicable lessons learned and ensure that actions deemed necessary are implemented?
  - b. Has the contractor identified an institutional program coordinator and contacts/coordinators in line and support organizations?
  - c. Has the contractor established and implemented processes that identify, document, disseminate and apply lessons learned from investigations of incidents/accidents and occupational injuries, including near misses, and from work activities that warrant communication to other organizations?
  - d. Has the contractor established tools and services to encourage and facilitate the documentation and communication of lessons learned such as templates, guidance documents, and subject matter expert assistance?
  - e. Do work planning and training for design, construction, research, operations, and maintenance processes include triggers to prompt or record the research and application of potentially applicable lessons learned?
  - f. Has the contractor established tools that encourage and facilitate the research of lessons learned, such as a searchable database and links to external source sites?
2. Training & Qualification - Are personnel implementing operating experience/lessons learned processes adequately trained and qualified to perform assigned oversight activities (in accordance with DOE O 226.1A, DOE M 360.1-1B, and DOE M 426.1-1A)?
  - a. Has the contractor provided and ensured completion of appropriate training on the expectations, requirements, and processes for the development, identification, sharing, and application of lessons learned?
3. Implementation of Program Responsibilities - Are operating experience/lessons learned program responsibilities appropriately implemented?
  - a. Are appropriate sources of lessons learned being regularly and rigorously screened by the coordinator(s) and/or subject matter experts and line organizations for applicability and the need for action?
  - b. Have work planners, supervisors, managers, subject matter experts, and training staff subscribed to the DOE lessons learned database?
  - c. Are screening and technical review activities and results documented and tracked to demonstrate and manage program implementation?

- d. Is the disposition of process and performance deficiencies identified through lessons learned processes managed in accordance with the formal issues management and corrective action tracking system process(es)?
- e. Is lessons learned information readily available to potential users?
- f. Are innovative, successful practices shared as well as negative lessons learned?
- g. Are internally generated lessons learned evaluated for their potential value to other DOE facilities and shared with the DOE complex as appropriate?
- h. Are lessons from experiences within and outside the contractor organization effectively communicated and used in work planning and training?
- i. Do safety committees or other boards provide effective feedback, including reviewing performance, analyzing data for lessons learned, and assigning and formally tracking action items for improvement?
- j. Is contractor facility management collecting and disseminating to their staff both lessons learned and good practices from operational events related to their facilities and similar DOE facilities?
- k. Are internally identified lessons learned being reported to the DOE operating experience program for sharing with the DOE complex when appropriate?
- l. Have metrics to measure program performance, use, and effectiveness been established?
- m. Has the adequacy of the operating experience/lessons learned program been adequately assessed by the contractor on an appropriate frequency?

### **Contractor Issues Management Lines of Inquiry**

1. Oversight Program - Are the processes that constitute the Contractor issues management program formal and documented and meet the requirements of DOE O 226.1A?
  - a. Have comprehensive processes and procedures been established and implemented that provide for the consistent, timely, and effective collection, analysis, and resolution of process and performance deficiencies and other issues, regardless of their source? Are separate processes and tracking tools compatible and sufficiently integrated to facilitate consistent implementation, trending, and performance measurement?
  - b. Does the issues management program include processes (including the Occurrence Reporting and Processing System and Price-Anderson Amendments Act) and tools that address the following essential elements:
    - i. Determining risk, significance and priority?
    - ii. Evaluating the scope and extent of condition or deficiency?
    - iii. Determining and ensuring reportability in accordance with DOE or regulatory requirements?
    - iv. Analyzing for root and contributing causes using a graded approach?

- v. Development of effective corrective action plans that include recurrence controls that address identified root and contributing causes?
  - vi. Assigning and changing ownership of issues, action plan development, and corrective action implementation?
  - vii. Milestones for completion of corrective/preventive actions and requirements for revisions of milestone dates?
  - viii. Tracking of progress of actions?
  - ix. Verification that actions are complete?
  - x. Validation of the effectiveness of corrective/preventive actions using a graded approach?
  - xi. Ensuring that the status of issues management is communicated to management and individuals and organizations are held accountable for performing their assigned responsibilities for managing issues?
- c. Have formal policies and processes been established and communicated for rapidly determining if deficiencies or conditions pose immediate and/or significant risk of harm to workers, the public, or the environment and provide for interim actions such as stopping work, system shutdown, or other compensatory measures pending formal processing of the issue?
2. Training & Qualification - Are personnel implementing contractor issues management processes adequately trained and qualified to perform assigned oversight activities (in accordance with DOE O 226.1A, DOE M 360.1-1B, and DOE M 426.1-1A)?
- a. Has the contractor defined the requirements for experience, knowledge, skills and abilities for personnel implementing issues management activities?
  - b. Has the contractor provided and ensured completion of appropriate training for personnel implementing issues management activities?
3. Implementation of Program Responsibilities - Are contractor issues management program responsibilities appropriately implemented?
- a. Are issues (including lower level deficiencies) periodically formally analyzed collectively to identify adverse trends or areas of weakness that require corrective or preventive actions?
  - b. Are adverse trends and needed corrective actions formally documented and addressed using the formal issues management process?
  - c. Are the processes and performance for the issues management program properly evaluated for effectiveness on an appropriate frequency?
4. Program Effectiveness - Are the contractor issues management processes effective in ensuring that site operations are performed safely, securely, and in compliance with applicable requirements'?
- a. Are the above issues management program elements being effectively implemented?

### **Contractor Worker Feedback Lines of Inquiry**

1. Oversight Program - Are the processes which constitute the contractor worker feedback programs formal and documented and, when taken together, meet the requirements of DOE Directives?
  - a. Has an effective employee concerns program been established and implemented that encourages the reporting of employee concerns and provides thorough, documented investigations, with timely and effective corrective actions and recurrence controls that are tracked to completion?
  - b. Are confidentiality and anonymity protections and rights to appeal clearly communicated to employees and effectively implemented during the resolution of concerns?
  - c. Do site processes require/encourage formal reviews or documented feedback from performers and supervision after completion of maintenance, experimental activities, or operational evolutions?
  - d. Has an effective DPO process or program been established and implemented, in accordance with the Contractor Requirements Document associated with DOE M 442.1-1? Were DPOs appropriately supported?
2. Training & Qualification - Are personnel implementing Contractor Worker Feedback program processes adequately trained and qualified to perform assigned oversight activities (in accordance with DOE O 226.1A, DOE M 360.1-1B, and DOE M 426.1-1A)?
  - a. Has the contractor defined the requirements for experience, knowledge, skills and abilities for personnel implementing employee concerns and worker feedback activities?
  - b. Has the contractor provided and ensured completion of appropriate training for personnel implementing employee concerns, DPO, and worker feedback activities?
3. Implementation of Program Responsibilities - Are contractor employee concerns and worker feedback responsibilities appropriately implemented?
  - a. Are the mechanisms and processes for employees to (1) report and get resolution to safety concerns; and (2) report a DPO clearly communicated to employees through vehicles such as new employee and refresher training, posters, intranet sites?
  - b. Are worker feedback information, DPOs, and safety concerns expressed by employees and the activities and supporting information for disposition of feedback and concerns formally documented/logged?
  - c. Are investigations of employee concerns, DPOs, and feedback information thoroughly performed without conflict of interest and with the involvement of technical expertise as appropriate?
  - d. Is employee confidentiality maintained as requested and as detailed in program documents?
  - e. Are corrective/preventive actions taken as a result of investigating employee concerns, DPOs, and feedback processes appropriate and managed in a formal manner in accordance with contractor procedures?
  - f. Are the resolutions of employee concerns and DPOs communicated to concerned individuals with a solicitation of concurrence and identification of appeal mechanisms?
  - g. Are the processes and performance for the employee concerns, DPOs, and worker feedback programs formally and adequately evaluated for effectiveness on an appropriate frequency?



## Assessment of DOE O 414.1C Criterion 4 - Documents and Records

| <b>Objective:</b> The contractor's documents and records management system is effective in supplying documents for personnel to safely and correctly perform their assigned responsibilities, and records that provide evidence that work was correctly performed.                      |  |              |
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| Criteria  | Laboratory Documents and Records   | Observations |
| <p><b>DOE O 414.1C Criterion 4 - Documents and Records</b></p> <p><b>e) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.</b></p> <p><b>f) Specify, prepare, review, approve, and maintain records.</b></p> | <p>LOI:</p> <ol style="list-style-type: none"> <li>1. IQA 1001 Chapter 4 addresses Documents &amp; Records. Improvements to current practices are addressed in CAPS OQ-04/27/09-01, OQ-05/06/2009-6 &amp; OQ-06/09/2009-1. Business Services Section Records Management Policies &amp; Procedures. "Fnal gov records handbook" (see attached pdf file of the handbook published on the BSS website.)</li> <li>2. CD implemented a comprehensive instance of the open source Docdb tool. This instance is named as CD-DocDb and it is used for comprehensive document control for the division. This document database has public and private access control capabilities. It also allows for certificate based access control. See general information in attached file "DocDbinfo.pdf").</li> <li>3. CD policies and procedures, requirements and design documents are maintained in the</li> </ol> |              |

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|  | <p>CD-DocDB. CD facilities documents are maintained in this database as well. Upper management enforces the culture of using this repository as the official source of documents through regular meetings. To address the issue of administrative controls of the controlled documents, CD is working on implemented a corrective action plan documented in the CD-CAP #2 (attached, file "CD-04-14-2009-2 Rev 001 A1.pdf")</p> <ol style="list-style-type: none"><li>4. See 3</li><li>5. CD-DocDb also allows for categorization by topic areas, extensive version control and searchable reporting. See the list of topic areas attached. This system is also used to keep track of selective meeting minutes, conference and review documents.</li><li>6. Most of the CD records are maintained electronically. Paper records are maintained by the record owners. CD does not have a file plan yet. To mitigate this issue, the CD-CAP #1 (file "CD-04-14-2009-1 Rev 002 A2.pdf") was issued (attached). CD Records coordinator is working closely with the Laboratory Record</li></ol> |  |
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|  | <p>Manager. CD has various electronic databases to keep track of various records. Some examples include CD EquipDb to keep track of CD sensitive items and CD Misjob for equipment repairs in conjunction with the Laboratory's Sunflower System.</p> <ol style="list-style-type: none"><li>7. CD maintains a large datacenter that is continuously updated assuring that the data remains retrievable for adequate period of time.</li><li>8. CD is currently working on getting File Plans update see 6.</li><li>9. See 7.</li></ol> |  |
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**Conclusions** – *Provide an overall (on-balance) summary statement regarding the extent to which the Laboratory is satisfying the above objective and criteria.*

**Strengths** –

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| <ul style="list-style-type: none"><li>•</li></ul> <p><b>Weaknesses –</b></p> <ul style="list-style-type: none"><li>•</li><li>•</li><li>•</li><li>•</li></ul> |
| <p><b>Findings / Recommendations –</b></p> <ul style="list-style-type: none"><li>•</li><li>•</li><li>•</li></ul>   |

Documents and Records Reviewed:

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Persons Interviewed:

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**Supplemental Lines of Inquiry:**

1. Has the contractor fully implemented a comprehensive document and records control management system? Is there a document or set of documents applicable to the control of documents and records?

2. Are documents that control work processes, specify requirements, or establish designs prepared, reviewed, approved, issued, and revised in a controlled manner? Are these documents readily available to facility personnel having responsibilities for maintenance and operation of facility safety related and non-safety related systems?
3. Does the document control management system ensure that safety and quality management requirements are appropriately documented and communicated by ensuring workers have the proper documents for performing work? Does the document control management system support maintenance of facility configuration control through a process of controlled document reviews for proposed changes to the facility configuration?
4. Are facility documents maintained current to reflect the actual facility configuration and current design requirements? Maintained current implies that design requirements for facilities are correctly reflected in documents, and that facilities reflect design requirements as specified in approved design documents.
5. Have records requirements been defined and are persons who are responsible for implementing the requirements been trained on the requirements? How are records defined and who is responsible for identifying documents that become records? Is this process clearly defined and have persons performing documents/records management functions been fully trained on their functions?
6. Do records adequately support technical, regulatory and enforcement decisions and provide evidence that work was correctly performed?
7. Are there adequate means and controls for the development and preservation of records for all record forms being maintained (e.g., electronic, written, printed, microfilm, photographs, optical disks, etc.)?
8. Are there schedules for records retention and disposition and are they consistent with requirements of DOE O 200.1, *Information Management Program*, dated 9-3-96?
9. Is the hardware and software used to create and store records being maintained to enable records to be readily retrievable?

## Assessment of DOE O 414.1C Criterion 5 – Work Processes

| <b>Objective:</b> Work processes are carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and ES&H controls to achieve a planned end result.  |  |              |
|---|--|--------------|
| Criteria  | Laboratory Documents and Records   | Observations |
| <p><b>DOE O 414.1C Criterion 5 – Work Processes</b></p> <p><b>a) Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.</b></p> <p><b>b) Identify and control items to ensure their proper use.</b></p> <p><b>c) Maintain items to prevent their damage, loss, or deterioration.</b></p> <p><b>Calibrate and maintain equipment used for process monitoring or data collection.</b></p> | <p>1. Two CD work processes are discussed in this section; a) Computer security and b) Data center operation.</p> <p style="margin-left: 40px;">a. The Computer Security team creates and maintains policies and procedures as defined in the above documents. Director’s Policy #21 (<a href="http://www.fnal.gov/directorate/Policy_Manual.html#No_21">http://www.fnal.gov/directorate/Policy_Manual.html#No_21</a>, see attached) contains the description of user responsibilities for computing at Fermilab. Computer security life cycle policy is used to enforce managerial, operational and technical controls. There are several levels of management coordinators for computer security. Primary controls are managed by the Division/Center/Section General Computer Security Coordinator (GCSC). The Lab is required to have a formal Computer Security program as specified by the DOE Order 205.1a. Also, FISMA compliance is required by OMB as described in NIST 800.53. See CD ComputersecurityHomepage.pdf for a snapshot of the home page for the implementation of the computer security</p> <p style="margin-left: 40px;">b. Data center operation: Data center assets are managed using two different CD databases, namely EquipDb, and Misjob and the Laboratory wide Sunflower asset management system. CD sensitive assets, that is, expensive computer equipment, are tracked and</p> |              |

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|  | <p>maintained using these databases There are various operational software deployed to manage these data centers. See attached a snapshot of the performance metrics for the D0 servers.</p> <ol style="list-style-type: none"> <li>2. CD management holds weekly operations meetings where these issues are discussed. Any interested party can attend this meeting.</li> <li>3. See 2.</li> <li>4. IQA 1001 Para 5.2.2. All Personnel</li> <li>5. QA 1001 Para 5.3 Work Process Control. FESHM 2060 Work Planning &amp; Hazard Analysis</li> <li>6. See attached work instructions as described in 1       <ol style="list-style-type: none"> <li>7. Graded approach is implemented in CD using the strategic planning and tactical planning process.</li> </ol> </li> <li>8..See 4.</li> <li>9.. CD implements Sc/I procedure to isolate defective items.</li> <li>10: IQA 1001 Section 10 Suspect/Counterfeit Items. FESHM 3010 Significant and Reportable Occurrences.\</li> <li>11..See 2.</li> <li>12 Data products are the most important materials for CD. CD maintains various archival equipment including robots and tape/discs libraries which are routinely upgraded to prevent deterioration. Apart from the extensive online reports used to monitor the status, facilities managers perform routine daily walkthroughs to visually inspect the facilities</li> <li>13.. See controls defined by procurement.</li> <li>14.. An extensive methodology for monitoring the process of data collection, movement and archiving.</li> </ol> |  |
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**Conclusions** – Provide an overall (on-balance) summary statement regarding the extent to which the Laboratory is satisfying the above objective and criteria.

**Strengths –**

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**Weaknesses –**

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**Findings / Recommendations –**

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**Documents and Records Reviewed:**

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Persons Interviewed:

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**Supplemental Lines of Inquiry:**

1. Are contractor work control procedures and standards that are used by workers consistent with accepted technical standards, administrative controls, and hazard controls that have been adopted to meet regulatory requirements? The reviewer should select and review a representative sample of procedures to establish that the contractor's management processes do ensure compliance with regulatory requirements.
2. Has the contractor implemented a management process that results in line management and workers cooperatively reviewing work processes that can be improved? This may include feedback from prior work as well as supervisor-worker critiques that follow the implementation of completed work.
3. Does contractor management solicit and encourage input from workers regarding work processes? Worker attitude and moral can be an indicator of possible deficiencies in the management/worker relationship and its ability to generate a "team approach" to the performance of quality work. The reviewer should look at existing work control procedures being applied and solicit comments from workers regarding the clarity of what is expected as documented in the procedure, problems perceived by the workers, and their input as to their role, if any, in the actual planning for performing the work.
4. Does contractor management communicate an expectation of worker accountability for quality and safety in performance of work? Do workers understand management's expectations regarding their performance?
5. Does contractor management ensure the following information is communicated to workers prior to the beginning of work:
  - Customer and data requirements for the work and final product?
  - Hazards associated with the work to be performed?
  - Safety, administrative, technical, environmental, and quality controls to be applied during the work?
  - Technical standards to be applied?
  - Acceptance criteria applicable to the work?
  - Procedures to be applied for verification of completed work?

If elements of the above are missing, determine the worker's perception of what is expected and the basis for the perception.

6. Are work instructions or other means used to define the work processes documented and controlled? This concern focuses on the adequacy of the contractor's document control and work control practices for assuring workers have the correct documents to perform work.
7. Does the contractor follow a "graded approach" for the development of work instruction detail that is commensurate with the complexity and the importance of the work? This inquiry is getting at the contractor's methods for prioritizing work from a perspective of quality/safety, and the depth of detail regarding the controls to be applied.
8. Do workers indicate their complete understanding of controls that are applied to the work and are there provisions for them to document their understanding? The intent is to ensure that management communicates the level of importance expected for worker adherence to controls imposed on the worker, and that the worker clearly understands managements concern regarding their attention to the detail necessary to perform the work. This can be explored through reviews of documents provided by management and interviews of workers to assess the adequacy of their understanding of what is required. Confirmation of worker understanding should be weighed against management's expectations that are placed on workers. Interviews of both management and workers may be necessary to arrive at a conclusion of the adequacy of this process.
9. Has the contractor implemented controls that prevent workers from using incorrect or defective items? If not specifically defined, the reviewer should determine the contractor's process for ensuring workers do not access or use incorrect or defective items.
10. Does the contractor have a program for identifying and controlling suspect/counterfeit items?
11. Does the contractor have a program for controlling and maintaining items?
12. Are items and materials maintained and stored to prevent their damage, loss or deterioration?
13. Does the contractor's program for the control of items include supplier/manufacturer controls to ensure that suppliers use quality materials for the manufacture of items?
14. Does the contractor's materials control program ensure that equipment/tools used for process monitoring or data collection are calibrated, maintained, and properly secured?

## Assessment of DOE O 414.1C Criterion 6 – Design

| <b>Objective:</b> The contractor's design management process provides for the control of design functions and interfaces that enables producing quality design output products that effectively support facility maintenance and operation functions.   |  |              |
|---|--|--------------|
| Criteria  | Laboratory Documents and Records   | Observations |
| <p><b>DOE O 414.1C Criterion 6 - Design</b></p> <p><b>a) Design items and processes using sound engineering/scientific principles and appropriate standards.</b></p> <p><b>b) Incorporate applicable requirements and design bases in design work and design changes.</b></p> <p><b>c) Identify and control design interfaces.</b></p> <p><b>d) Verify/validate the adequacy of design products using individuals or groups other than those who performed the design work.</b></p> <p><b>e) Verify/validate work before approval and implementation of the design.</b></p> | <ol style="list-style-type: none"> <li>1. OQ-05-22-2009-2 Fermilab Design &amp; Engineering Process Manual CAP, OQ-05-30-2009-1 Fermilab Assessments Manual CAP</li> <li>2. OQ-05-22-2009-2 Fermilab Design &amp; Engineering Process Manual CAP, OQ-05-30-2009-1 Fermilab Assessments Manual CAP</li> <li>3. Ldap_authentication_design_note.pdf</li> <li>4. Yes. Reviewed internally or externally as appropriate.</li> <li>5. Yes</li> <li>6. Yes.</li> <li>7. CD is not involved in safety system design</li> <li>8. See above</li> <li>9. Yes.</li> <li>10. Only reputable off-the-shelf software is used for design.</li> <li>11. See the above design document</li> <li>12.</li> <li>13. Design documents follow the</li> </ol> |              |

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|  | <p>project specific management processes. These processes are determined using a graded approach.</p> <p>14. Done as needed using graded approach.</p> <p>15. OQ-05-22-2009-2 Fermilab Design &amp; Engineering Process Manual CAP, OQ-05-30-2009-1 Fermilab Assessments Manual CAP</p> <p>16. Most of the work done by CD is to support other projects or programs outside of CD jurisdiction. Verification methodologies follow rules established by those programs and projects.</p> <p>17. See above.</p> <p>18. OQ-05-22-2009-2 Fermilab Design &amp; Engineering Process Manual CAP, OQ-05-30-2009-1 Fermilab Assessments Manual CAP</p> <p>19.</p> |  |
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**Conclusions** – *Provide an overall (on-balance) summary statement regarding the extent to which the Laboratory is satisfying the above objective and criteria.*

**Strengths** –

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| <ul style="list-style-type: none"><li>•</li><li>•</li></ul> <p><b>Weaknesses –</b></p> <ul style="list-style-type: none"><li>•</li><li>•</li><li>•</li><li>•</li></ul> |
| <p><b>Findings / Recommendations –</b></p> <ul style="list-style-type: none"><li>•</li><li>•</li><li>•</li></ul>   |

Documents and Records Reviewed:

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Persons Interviewed:

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**Supplemental Lines of Inquiry:**

1. Has the contractor implemented a management process that enables the control of design inputs and outputs, design verification, design changes and configuration control? The contractor's design engineering management process controls should be reviewed to determine that design procedures are in place and are rigidly followed that control each design function.
2. Does the design process ensure that sound engineering/scientific principles and applicable standards are utilized to design items and processes? The contractor's management system defines requirements for persons authorized to perform design engineering functions and the persons performing design functions fully meet the contractor's qualification requirements.
3. Does design bases documents include all applicable requirements that are needed to develop detail design documents and for making changes to designs? This requirement is focused on design inputs. The contractor's design documentation should clearly establish what the requirements for each design are.
4. Are design interfaces, technical and administrative, clearly defined and controlled?
5. Are persons who are selected to perform design verification technically qualified to perform the work and are they independent of the design work they are assigned to verify?
6. Does the contractor verify design products before they are approved and issued for implementation?
7. Does the contractor use a "graded approach" in selecting the applicable design control requirements to be applied in developing designs?
8. Does the contractor's "graded approach," include a consideration of safety functions such as the safety class and its significance to safety for structures, systems, and components?
9. Does design output documentation provide acceptance, inspection, testing, and maintenance criteria for ensuring continuing reliability and performance of functional capability for items?
10. Does the contractor's design organization have a process for verification of the adequacy of software that is used for supporting the development of designs?
11. Do design records include documentation such as design inputs, calculations and analyses, engineering reports, design outputs, design changes, design verification documentation, and other supporting documentation that provides evidence that the design process was performed correctly?
12. Are contractual requirements and customer expectations reflected in design input documentation?
13. Do design output documents support other management processes such as dose and risk assessments, procurement, manufacturing, assembly, construction, testing, operation, inspection, maintenance, and decommissioning?
14. Are design output documents maintained current such that they reflect the actual installed status or "as built" configuration for structures, systems, and components?
15. Does the contractor's design verification program include a requirement for design reviews, alternative analyses, qualification testing, and peer reviews?
16. If the contractor allows interim (or partial) design verification to occur, is there a set of management controls that supports work such as procurement, manufacture, construction, or testing?

17. Does the contractor require design verification to be completed before reliance is placed on structures, systems, and components to perform their function?
18. Does the contractor's design process include a verification process for design changes that result from temporary modifications, or when installed designs do not reflect the design output documents for the item and is dispositioned "use-as-is?" If not, how are discrepancies in items dispositioned when accepted items differ from requirements provided in design output documents?
19. Has the contractor implemented special requirements for computer software that is used to originate or analyze design solutions that serve to mitigate potential accidents?

## Assessment of DOE O 414.1C Criterion 7 – Procurement

| <b>Objective:</b> The procurement process ensures that items and/or services provided by suppliers meet the requirements and expectations of end users.  |  |              |
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| Criteria   | Laboratory Documents and Records   | Observations |
| <p><b>DOE O 414.1C Criterion 7 - Procurement</b></p> <p><b>a) Procure items and services that meet established requirements and perform as specified.</b></p> <p><b>b) Evaluate and select prospective suppliers on the basis of specified criteria.</b></p> <p><b>c) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.</b></p> | <ol style="list-style-type: none"> <li>1. Procurement Policy &amp; Procedure Manual-All of it. FESHM Chapters 7010, 7011, and 7012. Fermilab Procurement terms and conditions; FL-1, FL-2. FL-3, FL-4, and FL-200.</li> <li>2. Fermilab Procurement terms and conditions FL-1 clauses 4, 5, and 6. FL-4 clauses 2, 7, and 16. Fermilab Procurement Policy and Procedure Manual Part III, and attachments section, Source Evaluation Board Procedure.</li> <li>3. BS-04/10/2009-07. Fermilab Procurement Manual CAP.</li> <li>4. IQA Chapter 10.</li> <li>5. The Laboratory's Procurement System is formally approved by DOE. Current approval runs through September 2011.</li> <li>6. Fermilab Procurement Policy and Procedure Manual-All of it. CD follows procurement policies and procedures. See attached PO# 581817 Rev 2.pdf.</li> </ol> |              |



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**Findings / Recommendations –**

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**Documents and Records Reviewed:**

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**Persons Interviewed:**

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**Supplemental Lines of Inquiry:**

1. Is the contractor's procurement management process commensurate with the importance for the end use of the purchased item or service? For example, are the procurement processes for safety-related structures, systems, and components graded based on their importance to safety and the protection of workers, public and environment?

2. Are procurement processes planned and controlled to ensure that procured items and services meet established requirements and perform as specified; that prospective suppliers are evaluated and selected on the basis of established criteria; and only approved suppliers are utilized that have established a track record of continuously providing acceptable items or services?
3. Does the procurement process ensure that suspect/counterfeit items are precluded from receipt? If not, does the contractor have a program for ensuring that items fully meet acceptance requirements at receipt?
4. Does the contractor have a process in place for identifying suspect/counterfeit items, and does the process ensure total exclusion of such items from accepted items?
5. Has the contractor's management controls for procurement been verified that they fully comply with DOE procurement and subcontracts through applicable DOE Orders, the Department of Energy Acquisition Regulation (DEAR) in 48 CFR subchapters A through H, and Federal Acquisition Regulation (FAR) in 48 CFR 970 et seq?
6. Does the existing procurement management system adequately meet end-user requirements and reflect requirements of the QA Rule and Order?
7. Does the procurement process demonstrate how the contractor's QA responsibilities are satisfied when subcontractors and suppliers perform work?
8. Is potential or prospective supplier capabilities reviewed and established early in the design and procurement phases?
9. Does the supplier qualification process include a review of the supplier's history for providing similar or identical services; an evaluation of certifications or registrations awarded by nationally accredited third parties; and an evaluation of qualitative and quantitative performance information provided by the supplier?
10. Does the contractor follow a process for the pre-qualification of prospective suppliers of structures, systems, and components? Does the contractor's requirement for prospective suppliers include having a quality assurance program and that it is verified to conform to contract requirements. Further, are prospective suppliers required to demonstrate their capability to meet performance and schedule requirements?
11. Does the contractor's review of suppliers include periodic follow-on reviews to verify and monitor that capabilities are continuing to be maintained and applied?
12. Do contractor's procurement documents specify critical or important acceptance parameters and "hold-points" for item inspection? Do they include verification that the supplier has provided specified documentation and that items were not damaged during shipment? Do they require verification or testing of items prior to or following shipment?
13. Does the contractor's acceptance program include provisions for supplier-generated documents be accepted through the procurement system and controlled by the end-user organization? Documents may include certificates of conformance, drawings, analyses, test reports, maintenance data, non-conformance documentation, approved changes, waivers, and accepted deviations.
14. Does the contractor's procurement program include the purchase of commercial-grade items that are intended for use in nuclear safety or high-risk activities? If so, was the procurement in accordance with documented processes that utilized recognized consensus standards?

15. Does the contractor engage in multi-site procurement practices? If so, have the sites agreed upon a set of requirements and responsibilities that govern quality requirements for procurements?

## Assessment of DOE O 414.1C Criterion 8 – Inspection & Acceptance Testing

| <b>Objective:</b> The contractor's inspection and test program requirements are effective in verifying that physical and functional aspects of items, services, and processes meet requirements and are fit for acceptance and use.   |   |              |
|---|---|--------------|
| Criteria  | Laboratory Documents and Records  | Observations |
| <p><b>DOE O 414.1C Criterion 8 – Inspection &amp; Acceptance Testing</b></p> <p><b>a) Inspect and test specified items, services, and processes using established acceptance and performance criteria.</b></p> <p><b>b) Calibrate and maintain equipment used for inspection and tests.</b></p> | <ol style="list-style-type: none"> <li>1. CD follows guidelines provided in the IQA document (see attached ESE IQA document ESE IQA policy V2.pdf)</li> <li>2. IQA1001, Para 8.5 Control of Measuring &amp; Test Eqpt. The CD sensitive equipment is maintained according to appropriate procedures. Equipment in the datacenter is tracked in the EquiDb database (see a screenshot Equipdb.pdf) Equipment repair records are maintained in the Misjob database (see attached a screenshot of Misjob.pdf). Calibration information is also maintained in this database.</li> <li>3. All personnel in charge of inspection and testing are fully qualified. Most of technicians have long professional experiences at Fermilab.</li> <li>4. CD staff members have the authority to report problems</li> <li>5. If the product is under warranty (most purchased products are), the unacceptable items are returned and replaced by suppliers (see attached the documentation of the LTO4 tape damage</li> </ol> |              |



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| <ul style="list-style-type: none"><li>•</li><li>•</li><li>•</li></ul>                                     |
| <b>Findings / Recommendations –</b> <ul style="list-style-type: none"><li>•</li><li>•</li><li>•</li></ul> |

Documents and Records Reviewed:

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Persons Interviewed:

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**Supplemental Lines of Inquiry:**

1. Has the contractor established acceptance and performance criteria for inspecting and testing specified items, services, and processes?
2. Does the contractor follow a defined program for calibrating and maintaining equipment used for inspections and tests?
3. Has the contractor specified technical qualification requirements for personnel selected to perform inspections and tests and are they empowered to access appropriate information and facilities to verify item acceptance?
4. Are inspection and test personnel independent of activities being inspected and tested and do they have the freedom to report results of the inspection/tests?

5. Are inspection/test results evaluated and verified by qualified personnel of the design organization to document that design requirements are satisfied?
6. Does planning for inspection/tests include identification of characteristics to be examined; qualification requirements for persons performing the examinations; descriptions of examination methods to be applied, including equipment and calibration requirements; acceptance and rejection criteria; environmental conditions for the examination; shelf-life and maintenance requirements, if any; required safety measures to be applied; and mandatory hold points, when applicable?
7. Does the contractor's inspection/tests acceptance program provide for identification and storage requirements for accepted items that ensures their correct application for the intended use?
8. In the event of changed item acceptance requirement parameters, are accepted items reviewed by persons knowledgeable of design requirements to determine if re-inspection and testing of item(s) is (are) necessary?
9. Is the contractor's Measuring and Test Equipment (M&TE) calibrated, maintained, and controlled using a documented process? Is the M&TE checked before each use to ensure it is of the proper type, range, accuracy, and precision, and is uniquely identified and traceable to its calibration data? Do contractor personnel work to procedures that establish requirements for testing, retesting, adjusting, and recalibrating M&TE? Are M&TE calibrated to traceable standards such as the National Institute of Standards and Technology or other nationally recognized standards when appropriate? Is M&TE use traceable to the accepted item?

## Assessment of DOE O 414.1C Criterion 9 – Management Assessment

| <b>Objective:</b> Managers periodically assess their functions to determine how well their organization is meeting both customer and management performance expectations and mission objectives, to identify strengths or opportunities for improving performance, and to correct identified problems.   |  |              |
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| Criteria   | Laboratory Documents and Records   | Observations |
| <p><b>DOE O 414.1C Criterion 9 – Management Assessment</b></p> <p><b>a) Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.</b></p> <p><b>DOE O 226.1A Attach 1, App A, Sect 2.a – Self-Assessment</b></p> <p><b>2. <u>ASSESSMENTS</u>. A rigorous and credible assessment program is the cornerstone of effective, efficient management of programs such as environment, safety, and health; safeguards and security; cyber security; and emergency management.</b></p> <p><b>Contractors will be responsible for developing, implementing, and performing comprehensive assessments of all facilities, systems, and organizational elements, including subcontractors, on a recurring basis. The scope and frequency of</b></p> | <p>1. Fermilab Assessment Manual 3902, OQ-05-04-2009-2 Assessments Policy CAP</p> <p>2. CD conducts self assessment at regular intervals. This year, three different self assessments were completed. See attached FY09 CD Hardware Mgmt Self Assessment.pdf</p> <p>3. CD staff members are aware of the importance of self-assessments and the upper management encourages thorough appraisals.</p> <p>4. See 3.</p> <p>5. Weekly CD operations meetings are the usual forum for identification and dissemination of short-term issues. Long-term issues are discussed in the management meetings.</p> <p>LOI DOE O226.1A</p> <p>1a. Fermilab Assessment Manual 3902, OQ-05-04-2009-2 Assessments Policy CAP</p> <p>1b. Fermilab Assessment Manual 3902, OQ-05-04-2009-2 Assessments Policy</p> |              |

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| <p><b>assessments must be specified in site plans and program documents (e.g., the quality assurance program) and must ensure that required assessments by applicable DOE directives are being performed; the effectiveness of safety management programs, including programs that are credited in the safety basis for nuclear facilities are being assessed adequately; deficiencies are being self-identified; and corrective actions are being taken in a timely and effective manner. External peers or subject matter experts may be utilized to support assessment activities.</b></p> <p><b>a. <u>Self-Assessment</u> is used to evaluate performance at all levels periodically and to determine the effectiveness of policies, requirements, and standards and the implementation status (see also DOE Order 414.1C, Criterion 9, “Management Assessment”).</b></p> <p><b>(1) Management self-assessments (also called management assessments) are performed by contractor management, and are developed (scope and review criteria) based on</b></p> | <p>CAP</p> <p>1c. As-Is Criteria &amp; Controls, Selected CRAD list.</p> <p>1d. OQ-05-30-2009-5 Root Cause CAP</p> <p>1e.</p> <p>1f. CD has established several performance indicators. CD data centers have interactive machine uptime and performance quality statistics. CD operates IT Service Desk to measure service tickets. The organization is working toward a comprehensive ITSM process to integrate process performance indicators. See attached Service_desk.pdf document</p> <p>1g. See f.</p> <p>1h. Done using meetings, reports etc. for now. However, CD is working on a comprehensive ITSM process deployment over the next few years. Extensive documents exist on the ITSM process.</p> <p>2a. Fermilab Assessment Manual 3902, OQ-05-04-2009-2 Assessments Policy CAP</p> <p>2b. ITNA</p> <p>3a. CD division head conducts various weekly meetings to assure that expectations are met.</p> <p>3b. Fermilab Assessment Manual 3902, OQ-05-04-2009-2 Assessments Policy</p> |  |
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| <p><b>the nature of the facility/activity being assessed and the hazards and risks to be controlled.</b></p> <p><b>(2) Self-assessments, which focus on hands-on work and the implementation of administrative processes, involve workers, supervisors, and managers to encourage identification and resolution of deficiencies at the lowest level practicable (e.g., workplace inspections and post-job reviews).</b></p> <p><b>(3) Support organizations will perform self-assessments of their performance and the adequacy of their processes.</b></p> <p><b>(4) Contractor, at all levels, will assess the implementation and adequacy of their processes, including analysis of the collective results of lower-level self-assessments.</b></p> <p><b>(5) Self-assessment results will be documented commensurate with the significance of and risks associated with activities being evaluated. Deficiencies will be</b></p> | <p>CAP</p> <p>3c. Fermilab Compiled 2009 2<sup>nd</sup> Qtr Self Assessment form. Compiled Fermilab Assessment Schedule due 8/31/2009.</p> <p>3d. Fermilab Compiled 2009 2<sup>nd</sup> Qtr Self Assessment form. Compiled Fermilab Assessment Schedule due 8/31/2009.</p> <p>3e. Fermilab Compiled 2009 2<sup>nd</sup> Qtr Self Assessment form. Compiled Fermilab Assessment Schedule due 8/31/2009.</p> |  |
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| <p><b>accurately described and documented for evaluation and correction using formal issues management processes.</b></p>  |  |  |
| <p><b>Conclusions</b> – <i>Provide an overall (on-balance) summary statement regarding the extent to which the Laboratory is satisfying the above objective and criteria.</i></p> <p><b>Strengths</b> –</p> <ul style="list-style-type: none"> <li>•</li> <li>•</li> </ul> <p><b>Weaknesses</b> –</p> <ul style="list-style-type: none"> <li>•</li> <li>•</li> </ul> |  |  |
| <p><b>Findings / Recommendations</b> –</p> <ul style="list-style-type: none"> <li>•</li> <li>•</li> </ul>  |  |  |

Documents and Records Reviewed:

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Persons Interviewed:

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### **Supplemental Lines of Inquiry:**

1. Has the contractor established a management assessment program?
2. Are management assessments performed to determine the effectiveness of management processes versus expectations for performance? Can managers identify examples of assessments and improvements that resulted?
3. Do contractor senior managers emphasize the importance of self-assessments and ensure that subordinate managers plan, schedule, conduct, evaluate and document results of self-assessments?
4. Do managers view their participation in the assessment process as being essential to ensure their gaining a first-hand understanding of how well their management systems are functioning?
5. Are managers aware of any problem(s) that may be hindering their organization from achieving their objectives; do they aggressively pursue corrective measures; and are personnel trained on changes that result from corrective actions?

### **Supplemental Lines of Inquiry for DOE O 226.1A section regarding Self-Assessments:**

1. Process - Are the processes for assessment and performance measurement formal and documented and, when taken together, meet the requirements of DOE O 226.1A and DOE O 414.1C?
  - a. Has the contractor established appropriate, formal processes and procedures for conducting self-assessments of all programs, processes, and performance of facilities, systems, and organizational elements?
  - b. Do these processes and procedures adequately detail the requirements for all types of assessment and performance measurement activities, such as management walkthroughs, surveillance and inspection activities, formal assessments and reviews, and post-job reviews?
  - c. Have guidance and support tools such as checklists, templates, and databases been provided?
  - d. Has the contractor established appropriate and formal processes and procedures for identifying, monitoring, analyzing data measuring the performance of facilities, programs, and organizations and for identifying and implementing needed actions and opportunities for performance improvement?
  - e. Do self-assessment processes encourage and facilitate the involvement of workers, supervisors, and managers to develop assessment skills and abilities?
  - f. Have adequate processes, procedures, and guidance been developed to ensure an effective performance indicator program?
  - g. Have the appropriate performance indicators and parameters been selected to effectively measure performance and identify adverse trends in a timely manner to ensure prompt mitigation and corrective actions?
  - h. Do assessment and performance measurement program procedures provide appropriate linkages to the issues management, corrective action, and reporting processes?

2. Training & Qualification - Are personnel implementing the assessment and performance measurement program processes adequately trained and qualified to perform assigned oversight activities?
  - a. Has the contractor defined the requirements for experience, knowledge, skills and abilities for personnel implementing assessment and performance measurement activities?
  - b. Has the contractor provided and ensured completion of appropriate training for personnel implementing assessment and performance measurement activities?
3. Implementation of Program Responsibilities - Are assessment and performance measurement program responsibilities appropriately implemented?
  - a. Does line management routinely monitor and observe the activities of their workforce to ensure activity, facility, and institutional requirements and management expectations are met?
  - b. Are formal, rigorous, effective self-assessments conducted at all levels and in all organizations to determine the adequacy of programs and performance and identify deficiencies needing correction and areas and means for performance improvement?
  - c. Are institutional programs periodically evaluated for adequacy, including assessment of implementation by line and support organizations?
  - d. Is the subject, scope, and frequency of self- assessments based on a formal analysis that addresses elements such as risk; regulatory or standards based requirements; type and complexity of work activities, facilities, and conditions; past performance; trend analyses; or management concerns?
  - e. Are planned assessments documented on an appropriate schedule that is maintained to reflect pertinent information and status (e.g., additions, completions, cancellations, and substitutions)?
  - f. Are assessment activities sufficiently performance-based, including an appropriate focus on observation of work, inspection of field conditions, review of evidence of compliant and effective performance, and effectiveness of corrective actions for previously identified deficient conditions?
  - g. Is the performance indicator program periodically reviewed to ensure the most appropriate sets of data and data analysis parameters are being employed?
  - h. Is performance data being sufficiently analyzed, with conclusions drawn and presented to management, and needed actions identified and taken?
  - i. Are the processes and performance of assessment and performance measurement programs evaluated for effectiveness on an appropriate frequency?

## Assessment of DOE O 414.1C Criterion 10 – Independent Assessment

| <b>Objective:</b> Contractor senior management has established a process to obtain an independent assessment of the organization's programs, projects, contractors, and suppliers.   |  |              |
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| Criteria   | Laboratory Documents and Records   | Observations |
| <p><b>DOE O 414.1C Criterion 10 – Independent Assessment</b></p> <p><b>a) Plan and conduct independent assessments to measure item and service quality and the adequacy of work performance and to promote improvement.</b></p> <p><b>b) Establish sufficient authority and freedom from line management for independent assessment teams.</b></p> <p><b>c) Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.</b></p> <p><b>DOE O 226.1A Attach 1, App A, Sect 2.b – Internal Independent Assessments</b></p> <p><b>2. ASSESSMENTS. A rigorous and credible assessment program is the cornerstone of effective, efficient management of programs such as environment, safety, and health; safeguards and security; cyber security; and emergency</b></p> | <ol style="list-style-type: none"> <li>1. Fermilab Assessment Manual 3902, OQ-05-04-2009-2 Assessments Policy CAP</li> <li>2. Fermilab Compiled 2009 2<sup>nd</sup> Qtr Self Assessment form. Compiled Fermilab Assessment Schedule due 8/31/2009.</li> <li>3. Fermilab Assessment Manual 3902, OQ-05-04-2009-2 Assessments Policy CAP</li> <li>4. ITNA</li> <li>5. Fermilab Assessment Manual 3902, OQ-05-04-2009-2 Assessments Policy CAP</li> <li>6. OQ-05-30-2009-5 Root Cause CAP</li> <li>7. Fermilab Assessment Manual 3902, OQ-05-04-2009-2 Assessments Policy CAP</li> <li>8. OQ-05-30-2009-3 Lessons Learned CAP</li> </ol> <p>LOI DOE O 226.1A</p> <p>1a. Fermilab Assessment Manual 3902, OQ-05-04-2009-2 Assessments Policy CAP</p> |              |

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| <p>management.</p> <p><b>Contractors will be responsible for developing, implementing, and performing comprehensive assessments of all facilities, systems, and organizational elements, including subcontractors, on a recurring basis. The scope and frequency of assessments must be specified in site plans and program documents (e.g., the quality assurance program) and must ensure that required assessments by applicable DOE directives are being performed; the effectiveness of safety management programs, including programs that are credited in the safety basis for nuclear facilities are being assessed adequately; deficiencies are being self-identified; and corrective actions are being taken in a timely and effective manner. External peers or subject matter experts may be utilized to support assessment activities.</b></p> <p><b>b. <u>Internal independent assessments</u> will be performed by contractor organizations or personnel that have authority and independence from line management, to support unbiased evaluations (see also DOE O 414.1C, Criterion 10,</b></p> | <p>1b. Fermilab Assessment Manual 3902, OQ-05-04-2009-2 Assessments Policy CAP</p> <p>1c. As-Is Criteria &amp; Controls, Selected CRAD list.</p> <p>1d. OQ-05-30-2009-5 Root Cause CAP</p> <p>1e. As a part of the Fermilab's independent assessment program, programs, CD undergoes various assessments on corresponding performance measures. A combined independent ISO 14001:2004 and OHSAS 18001:2007 is scheduled for CD during October 2009. See attached the last report for Fermilab. NSF ISO_OHSAS Combined Audit Report April 2009.pdf.</p> <p>1f. Yes. Corrective actions from actions from assessment reports are resolved. A review response report for the 2008 Annual Progress Review of the Lattice QCD Computing Facility project is available if needed.</p> <p>1g.</p> <p>2a. Fermilab Assessment Manual 3902, OQ-05-04-2009-2 Assessments Policy CAP</p> <p>2b. ITNA</p> <p>3b. Fermilab Assessment Manual 3902, OQ-05-04-2009-2 Assessments Policy CAP</p> <p>3c. Fermilab Compiled 2009 2<sup>nd</sup> Qtr Self</p> |  |
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| <p><b>“Independent Assessment”).</b></p> <p><b>(1) The assessments will be formally planned and scheduled based on the risk, hazards, and the complexity of the processes and activities to be evaluated.</b></p> <p><b>(2) Independent evaluators will be appropriately trained and qualified and have knowledge of the areas assessed.</b></p> <p><b>(3) Reviewers will be dedicated contractor staff, members of external organizations, or both.</b></p> <p><b>(4) Although independent assessments are applied to individual activities and processes, they will typically focus on entire facilities or projects, and programs and management processes that are used by multiple organizations.</b></p> <p><b>(5) Internal independent assessments will concentrate on performance and observation of work activities and the results of process implementation.</b></p> | <p>Assessment form. Compiled Fermilab Assessment Schedule due 8/31/2009.</p> <p>3d. Fermilab Compiled 2009 2<sup>nd</sup> Qtr Self Assessment form. Compiled Fermilab Assessment Schedule due 8/31/2009.</p> <p>3e. Fermilab Compiled 2009 2<sup>nd</sup> Qtr Self Assessment form. Compiled Fermilab Assessment Schedule due 8/31/2009.</p> <p>3f. Fermilab Compiled 2009 2<sup>nd</sup> Qtr Self Assessment form. Compiled Fermilab Assessment Schedule due 8/31/2009.</p> |  |
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**Conclusions** – *Provide an overall (on-balance) summary statement regarding the extent to which the Laboratory is satisfying the above objective and criteria.*

**Strengths** –

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**Weaknesses** –

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**Findings / Recommendations** –

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Documents and Records Reviewed:

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Persons Interviewed:

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### **Supplemental Lines of Inquiry:**

1. Has contractor senior management established a program of independent assessments for its organization's programs, projects, suppliers and subcontractors?
2. Do managers plan, schedule and conduct independent assessments to measure item and service quality and the adequacy of work performance to promote improvement?
3. Does the management structure ensure there is sufficient authority and freedom from line management to enable independent teams to effectively perform assessments?
4. Are persons who conduct independent assessments technically qualified and knowledgeable in the areas they are assigned to assess and have had no previous responsibility for the work being assessed? Are they also qualified and knowledgeable on how to plan and perform assessments?
5. Do independent assessments include an evaluation of the following:
  - Work performance and process effectiveness;
  - Quality of work products;
  - Compliance to established management system requirements;
  - Identification of abnormal performance and potential problems;
  - Opportunities for improvements; and
  - Documenting and reporting of assessment results?
6. Are results of independent assessments analyzed to determine if problems are global to establish the appropriate remedial management action to be initiated for correcting problems?
7. Are findings from assessments tracked to determine progress and effectiveness for correcting identified problems? Are results of the tracking activity communicated to senior management?
8. Does the contractor use a "Lessons Learned" reporting mechanism to enable other management groups to benefit from identified issues?

### **Supplemental Lines of Inquiry for DOE O 226.1A section regarding Internal Independent Assessments:**

1. Process - Are the processes for assessment and performance measurement formal and documented and, when taken together, meet the requirements of DOE O 226.1A and DOE O 414.1C?
  - a. Has the contractor established appropriate, formal processes and procedures for conducting internal independent assessments of all programs, processes, and performance of facilities, systems, and organizational elements, including subcontractors?

- b. Do these processes and procedures adequately detail the requirements for all types of assessment and performance measurement activities, such as surveillance and inspection activities, and formal assessments and reviews?
  - c. Have guidance and support tools such as checklists, templates, and databases been provided?
  - d. Has the contractor established appropriate and formal processes and procedures for identifying, monitoring, analyzing data measuring the performance of facilities, programs, and organizations and for identifying and implementing needed actions and opportunities for performance improvement?
  - e. Have adequate processes, procedures, and guidance been developed to ensure an effective performance indicator program?
  - f. Have the appropriate performance indicators and parameters been selected to effectively measure performance and identify adverse trends in a timely manner to ensure prompt mitigation and corrective actions?
  - g. Do assessment and performance measurement program procedures provide appropriate linkages to the issues management, corrective action, and reporting processes?
2. Training & Qualification - Are personnel implementing the assessment and performance measurement program processes adequately trained and qualified to perform assigned oversight activities?
- a. Has the contractor defined the requirements for experience, knowledge, skills and abilities for personnel implementing assessment and performance measurement activities?
  - b. Has the contractor provided and ensured completion of appropriate training for personnel implementing assessment and performance measurement activities?
3. Implementation of Program Responsibilities - Are assessment and performance measurement program responsibilities appropriately implemented?
- b. Are formal, rigorous, effective self-assessments conducted at all levels and in all organizations to determine the adequacy of programs and performance and identify deficiencies needing correction and areas and means for performance improvement?
  - c. Are institutional programs periodically evaluated for adequacy, including assessment of implementation by line and support organizations?
  - d. Are appropriate and effective independent assessments performed, including evaluations of assurance system effectiveness?
  - e. Is the subject, scope, and frequency of independent assessments based on a formal analysis that addresses elements such as risk; regulatory or standards based requirements; type and complexity of work activities, facilities, and conditions; past performance; trend analyses; or management concerns?
  - f. Are planned assessments documented on an appropriate schedule that is maintained to reflect pertinent information and status (e.g., additions, completions, cancellations, and substitutions)?
  - g. Have subcontractors implemented appropriate and effective self-assessment programs, and is the contractor's subcontractor oversight program effectively evaluating performance, providing feedback to subcontractors, and ensuring correction of process and performance deficiencies?

- h. Are assessment activities sufficiently performance-based, including an appropriate focus on observation of work, inspection of field conditions, review of evidence of compliant and effective performance, and effectiveness of corrective actions for previously identified deficient conditions?
- i. Is the performance indicator program periodically reviewed to ensure the most appropriate sets of data and data analysis parameters are being employed?
- j. Is performance data being sufficiently analyzed, with conclusions drawn and presented to management, and needed actions identified and taken?
- k. Are the processes and performance of assessment and performance measurement programs evaluated for effectiveness on an appropriate frequency?

## Assessment of DOE O 414.1C Requirements for Suspect/Counterfeit Items Prevention

| <b>Objective:</b> The Laboratory should have a formal system under Quality Assurance with adequate controls defined and implemented to identify and preclude Suspect/Counterfeit Items (S/CI) from being introduced into safety systems and applications that create potential hazards.  |   |              |
|--|---|--------------|
| Criteria   | Laboratory Documents and Records  | Observations |
| <p><b>DOE O 414.1C S/CI Requirements</b></p> <p><b>a) The Laboratory has a formal system of controls in place for assurance that all items procured meet the requirements for their intended use.</b></p> <p><b>b) The Laboratory has a system of mechanisms to continuously maintain current, accurate, updated information on SC/Is and associated suppliers using all available sources.</b></p> <p><b>c) The Laboratory has a training program with detailed records that ensures appropriate managers, supervisors, and workers are trained and informed on prevention, detection, and disposition of S/CIs.</b></p> <p><b>d) The Laboratory ensures that the standards and methods used for determining the acceptability of items are continuously reviewed, and based on consensus standards and/or commonly accepted industry practices</b></p> | <ol style="list-style-type: none"> <li>1. OQ-05-30-2009-6 S/CI Program Document CAP, 1006.1001 Draft Administrative Procedure for S/CI.</li> <li>2. OQ-05-30-2009-6 S/CI Program Document CAP, 1006.1001 Draft Administrative Procedure for S/CI.</li> <li>3. Personal ITNA</li> <li>4. Personal ITNA</li> <li>5. CD follows methodologies followed by the laboratory and implements the information provided during training.</li> <li>6. Not a CD responsibility</li> <li>7. CD follows rules established by procurement.</li> <li>8.</li> <li>9. S/CI link on OQBP Web page</li> <li>10. Alerts on file.</li> <li>11.</li> <li>12.</li> <li>13.</li> </ol> |              |

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| <p>consistent with applicable law.</p> <p>e) <b>The Laboratory has S/CI controls that include Engineering involvement in the procurement process, notably in the development of specifications during inspection and testing and when replacing, maintaining, or modifying equipment.</b></p> <p>f) <b>The Laboratory has procurement procedures that preclude the introduction of S/CIs by: (1), identifying technical and QA requirements; (2), accepting only those items that comply with procurement specifications; and (3), inspecting inventory and storage areas to identify, control, and disposition S/CIs.</b></p> <p>g) <b>The Laboratory has testing methods approved by Engineering for the testing of procured or in-place S/CIs.</b></p> <p>h) <b>The Laboratory has routine maintenance cycles or inspection activities for their safety as well as non-safety systems that shall include provisions for the identification of S/CIs.</b></p> <p>i) <b>The Laboratory has established policies and procedures for exchanging information on nonconforming products and</b></p> | <p>14.</p> <p>15.</p> <p>16. Not applicable to CD</p> <p>17.</p> <p>18. OQ-05-30-2009-6 S/CI Program Document CAP, 1006.1001 Draft Administrative Procedure for S/CI.</p> <p>19. Not a CD responsibility</p> <p>20. OQ-05-30-2009-6 S/CI Program Document CAP, 1006.1001 Draft Administrative Procedure for S/CI.</p> <p>21. Not a CD responsibility</p> <p>22. Not a CD responsibility</p> <p>23. I am not aware of one.</p> <p>24. CD reviews items associated with alerts. No SC/Is have been reported from CD</p> <p>25. I am not aware of any.</p> <p>26. Not a CD responsibility</p> <p>27. No</p> <p>28. No. Not a CD responsibility.</p> |  |
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| <p><b>materials among other agencies.</b></p> <p><b>j) The Laboratory has specific procedures for receiving and disseminating S/CI information through their respective Inspectors General or other appropriate officers.</b></p> <p><b>k) The Laboratory notifies their suppliers of nonconforming products in accordance with GIDEP procedures (in addition to the required actions specified in FAR Part 46.407).</b></p> |  |  |
| <p><b>Conclusions</b> – <i>Provide an overall (on-balance) summary statement regarding the extent to which the Laboratory is satisfying the above objective and criteria.</i></p>  |  |  |

**Strengths –**

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**Weaknesses –**

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**Findings / Recommendations –**

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**Documents and Records Reviewed:**

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**Persons Interviewed:**

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### Supplemental Lines of Inquiry:

1. Has the Laboratory implemented a system to assure the procurement of items designed to meet specified requirements for intended use? [DOE O 440.1A]
2. Has the Laboratory installed mechanisms to continuously maintain accurate, updated information on SC/Is and associated suppliers using all available sources? [DOE O 440.1A]
3. Has the Laboratory instituted a training program, with detailed records, for training and informing managers, supervisors, and workers on controls for prevention, detection, and disposition of S/CIs? [DOE O 440.1A]
4. Have all Laboratory personnel, employees and management associated with S/CIs, completed the prescribed S/CI training?
5. Have the standards and methods used for determining the acceptability of items been reviewed (based on consensus standards or accepted industry practices consistent with applicable law)? [DOE O 440.1A]
6. Do the S/CI controls include Engineering involvement in the procurement process (notably in the development of specifications during inspection and testing and when replacing, maintaining, or modifying equipment)? [DOE O 440.1A]
7. Do procurement procedures identify technical and QA requirements that prevent the introduction of S/CIs? [DOE O 440.1A]
8. Do procurement personnel review the DOE S/CI website to determine if a prospective supplier has been identified by the DOE as supplying S/CI?
9. Does the contractor's S/CI Coordinator keep the S/CIs Home Page updated with the latest S/CIs information? How often?
10. Does the contractor's S/CI Coordinator maintain a file of S/CIs alerts, occurrence reports, internal notifications, evaluations and investigations?
11. Do the procurement procedures accept only those items that comply with procurement specifications? [DOE O 440.1A]
12. Do procurement procedures identify means or methods for inspecting inventory and storage areas to identify, control, and disposition S/CIs? [DOE O 440.1A]
13. Are representative samples of procured materials being inspected before they are accepted (to verify conformance to specification and performance requirements)?
14. Are maintenance, inspection, test, and acceptance records traceable to the original Purchase Order (PO)?
15. Does the contractor have procedures on testing methods approved by Engineering for the testing of procured or in-place S/CIs? [DOE O 440.1A]
16. Do the managers (Project, Operation, Facility and Support Services) identify, establish and maintain current lists of safety systems, equipment, or facilities?
17. Are there routine maintenance cycles or inspection activities for safety as well as non-safety systems that include provisions for identifying S/CIs? [DOE O 440.1A]
18. Are S/CIs reported to GIDEP and the IG? [DOE O 231.1, DOE O 232.1A, DOE 2030.4B]

19. Are trend analyses being conducted, and Lessons Learned issued for improving all S/CI activities? [DOE O 440.1A]
20. Does management participate in the Government/Industry Data Exchange Program (GIDEP)? [OMB Policy Letter 91-3]
21. Are suppliers of nonconforming products or materials notified in accordance with GIDEP procedures? [OMB Policy Letter 91-3]
22. Are suppliers of nonconforming products and materials being notified according to GIDEP procedures (as well as to the actions specified in FAR Part 46.407)? [OMB Policy Letter 91-3]
23. Does the Laboratory conduct assessments for S/CI?
24. Have the corrective actions concerning S/CI found in previous assessments been implemented, and the findings closed?
25. Have the SCI reported as Occurrence Reports in previous assessments been closed and reported to ORPs?
26. Has an ALERT been sent out to other contractors and laboratories (procurers), and the IG been properly notified?
27. Have previously identified S/CI been verified as S/CI through further assessment?
28. Have previously identified products or materials labeled as S/CI been exonerated as being S/CI?