

**QA
3902.1004**

Fermilab Assessment Manual Chapter 4

Independent QA Assessments

**Office of Quality and Best Practices
Fermi National Accelerator Laboratory
Batavia, IL
April, 2012**

Approved By: _____



Jed Heyes

Head, Office of Quality and Best Practices

SUBJECT:	Fermilab Assessment Manual - Chapter 4 Independent QA Assessments	NUMBER:	3902.1004
RESPONSIBILITY:	Quality Assurance Manager	REVISION:	002
APPROVED BY:	Head, Office of Quality and Best Practices	EFFECTIVE:	4/6/2012

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1.0 Purpose

This procedure provides the instructions for the performance of Fermilab independent QA assessments.

2.0 Scope

The assessment program described in this manual applies to independent QA assessments led by the Office of Quality and Best Practices and to all Fermilab employees, subcontractors, and users participating in these assessments.

3.0 Responsibilities

3.1 Office of Quality and Best Practices (OQBP)

OQBP:

- Coordinates and/or performs all independent QA assessments at Fermilab
- Provides assessment training or verifies qualifications for those performing independent QA assessments

3.2 Heads of Divisions/Sections/Centers

D/S/C Heads are responsible for

- Providing the necessary resources to participate in independent QA assessments
- Implementing effective corrective actions in response to findings of noncompliance
- Tracking and reporting the status of Corrective Action Plans (CAPs)

3.3 Independent QA Assessment Team Leaders

Assessment team leaders are independent of the assessed organization and are responsible for:

- Planning, organizing, conducting and reporting the results of their assigned assessments
- Assigning prepared and qualified assessors to assessment activities
- Coordinating and directing assessment team activities during all phases of an assessment
- Participating in data gathering while conducting the assessments in the field
- Serving as the primary point of contact between the assessed organization and the assessment team
- Ensuring that CAPs are issued for noncompliance with requirements, that opportunities for improvement are reported as recommendations and that commendable practices are reported

3.4 Independent QA Assessment Team Members

Assessment team members are independent of the assessed organizations and may include personnel, subject matter experts or others from both within Fermilab and outside of Fermilab such as DOE or other organizations as needed to adequately perform the assessments. See section 4.5 for more detail on the use of subject matter experts (SMEs). Assessment team members are responsible for:

- Assisting the assessment team leader with planning assessments
- Gathering data while conducting assessments

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- Keeping the team leader and assessed organizations informed during the assessment
- Assisting the assessment team leader with reporting assessments and issuing CAPs

Team Leader and Team Member Qualification

Independent QA assessment teams are expected to be independent of the activities being assessed. However, due to limited resources or the specialized nature of activities being assessed it may be necessary to enlist SMEs from within an organization that is being assessed. Under these circumstances the SME will disclose any potential conflicts of interest which may arise and withdraw from some assessment activities if necessary.

Unless otherwise indicated, OQBP QA staff will lead all independent QA assessments. The Head of OQBP will ensure that the assessors assigned to lead independent QA assessments meet the following requirements:

- Auditor certification by ASQ, employer certification, or equivalent experience in management or planning, conducting and reporting assessments
- Audit training by ASQ, employer, or equivalent experience
- Required reading
 - Fermilab Integrated Quality Assurance, 1001
 - Fermilab Corrective & Preventive Action Procedure, 1004.1001
 - Fermilab Assessment Manual Chapter 4 Independent QA Assessment Procedure 3902.1004
 - Fermilab Quality Assurance (QA) Assessment FAQs
 - DOE O 414.1D, *Quality Assurance - CRD*
 - DOE G 414.1B, *Management & Independent Assessments Guide*
 - Quality Audits for Improved Performance* by Dennis R. Arter (3rd edition or later)
- Demonstrated participation under an OQBP assessment team leader
- Knowledgeable about the types of activities being assessed (may be satisfied by experience or obtained during assessment planning or both)

The Quality Manager or an assigned assessment team leader will ensure assessment team members performing independent QA assessments are familiar with but independent of the activities being assessed. The Quality Manager or an assigned assessment team leader will also ensure that team members receive appropriate direction when conducting assessments.

Independent QA assessment team members will include D/S/C Quality Assurance Representatives (QARs). QARs will not participate in independent QA assessments of the D/S/C to which they belong, but they will be kept informed of the status of independent assessments conducted in their D/S/C and may serve as the D/S/C escort. Subject matter experts may be consulted or participate on assessment teams when necessary.

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4.0 Procedure

Independent QA Assessments at Fermilab are assessments or surveillances (including verification and validation) sponsored or performed by OQBP and conducted by assessors independent of the assessed organizations.

To ensure the adequacy of the implementation of the quality management system, the Head of OQBP or the Fermilab QA Manager will schedule independent QA assessments. They ensure that assessments are conducted and reported as planned, and provide the personnel and resources needed to implement them. These assessments will include Quality Assurance and Contractor Assurance requirements. OQBP may periodically assess the degree to which management systems assessments sponsored or conducted by other management system owners are being followed as part of the requirements to implement Contractor Assurance.

Items considered when selecting areas to be assessed and in determining scope include:

- Importance and complexity of areas to be examined
- Previous assessment results
- Number and kinds of requirements which apply
- Assessment purpose and objectives
- Resources available to carry out assessment objectives
- Selection criteria such as those found in the Graded Approach Procedure 1002.1000
- Requests from D/S/Cs, the Assurance Council, DOE or senior management

The organizations to be assessed will be notified of scheduled assessments in advance of the planned start date, identifying the areas that will be reviewed and to request access to documents and areas to be assessed.

The independent assessment process flowchart is shown in Appendix 3 for QA assessments

4.1 Scheduling QA Assessments

The Quality Manager will develop and maintain a master list of all assessments to be performed on a recurring three year basis. The master list of assessments will be one of the sources used for scheduling annual QA independent assessments.

4.2 Planning QA Assessments

Planning of independent assessments will be a collaborative activity between staff in the organization to be assessed, the assigned assessment team leader and assessment team members.

The assessment team leader or an assigned team member will informally contact personnel in areas to be assessed to initiate a preliminary discussion of the assessment purpose, scope, and logistics.

The assessment team will identify QA and Contractor Assurance requirements to be assessed against. The assessment team will request copies of or access to all relevant controlling documents from the organization to be assessed and review these documents to determine if they implement the requirements to be verified, and to identify any additional requirements imposed by them. Lines of inquiry or checklists may be developed from these materials.

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An independent QA assessment plan will be developed and will include the information shown on the example of a completed plan form in Appendix 1. The assessment team and OQBP staff will review this plan. Others may be asked to review the plan as well.

The organizations to be assessed will be contacted formally, provided with a copy of the assessment plan, and notified of the resources, access, and support that will be needed. The assessed organization will arrange meeting rooms for the assessment team and make arrangements including logistics, points of contact and any special requirements or access approvals required such as protective devices, entry into restricted areas, training and so on.

4.3 Conducting QA Assessments

The assessment team leader will direct the activities of the assessment team members and will be the primary point of contact with the assessed organization's management during the assessment. The assessment team leader confirms that team members are prepared to perform their assigned activities.

The assessment team leader will conduct an opening meeting with the assessed organizations and assessment team members. Potential interviewees may also attend the opening meeting. During this meeting the assessment team leader will:

- Introduce the team members
- Summarize the assessment purpose, scope and the planned schedule
- Provide a copy of the schedule of activities
- Identify affected personnel and confirm that they can support the scheduled activities
- Confirm access to work areas and documents and the availability of meeting rooms for the assessment team
- Facilitate questions and answers

The assessment is conducted in accordance with the plan and schedule. Team members obtain and document the information needed to satisfy the purpose and scope of the assessment. Activities performed may include any of the following:

- Conduct interviews
- Examine documents and records to determine compliance
- Inspect facilities and observe work activities
- Examine work products
- Notify management of the responsible organization of potential noncompliance with requirements or opportunities for improvement

Documented information produced or obtained during this phase of the assessment may include:

- Process descriptions or flow charts
- Completed interview sheets and checklists
- Assessor notes
- Copies of documentation and records

The assessment team meets periodically to:

- Confirm team readiness
- Summarize progress and results
- Begin/continue the draft assessment report

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- Brief the assessed organization on progress, potential noncompliance with requirements or opportunities for improvement
- Respond to questions
- Allow the assessed organization to respond to issues or potential issues

4.4 Reporting QA Assessments

The assessment team leader conducts a closing meeting with the assessed organization and assessment team to:

- Inform them of the assessment results including any non-conformances or opportunities for improvement
- Allow the assessed organization to provide feedback on potential non-conformances and opportunities for improvement discussed
- Respond to questions

When preparing the report assessment team members review information obtained and draw conclusions about any non-conformance, opportunities for improvement or commendable practices observed. Observations will be examined to determine if collectively, they indicate more significant problems.

Problem areas identified during the assessment that are determined to be non-compliant with management system requirements or the organization's implementing requirements will be reported as findings, documented on Corrective Action Plans (CAPs), and processed in accordance with the Fermilab Corrective & Preventive Action Procedure, 1004.1001. Areas that are potentially non-compliant but are not within the agreed upon scope or are compliant but present opportunities for improvement, are reported as recommendations.

The assessment report will be documented. An example of a completed independent assessment report form is found in Appendix 2. The assessment report is submitted by the assessment team leader to the QA Manager for review and comments. When these reviews are completed and comments addressed, the report is submitted to the assessed organization and their QAR for review and comments. Upon reconciliation of comments, a final report is submitted by the assessment team leader to the assessed organization, and distributed to the QA Manager, their QAR, and other oversight organizations as necessary.

4.5 Corrective Action Follow-up

The D/S/C QAR will monitor corrective action progress for reported findings and notify the assigned assessment team leader of progress and when corrective actions are implemented and ready for verification.

5.0 Records

Independent assessment team leader qualification records, assessment plans, and assessment reports will be maintained in accordance with the Fermilab Records Management Program. CAPs will be maintained in accordance with the Fermilab Corrective and Preventative Action Procedure.

6.0 Review Cycle

This procedure shall be reviewed for accuracy and relevance on at least a three year cycle

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6.1 Document Owner
OQBP QA Manager

6.2 Reviewers
OQBP Staff
Division/Section/Center QARs

6.3 Approver
OQBP Head

7.0 Policy and Program Documents

1001 Integrated Quality Assurance (IQA) – Chapter 9 Assessments
3901 Fermilab Integrated Contractor Assurance Program (FICAP) – Chapter 4 Assessments
3902 Fermilab Assessment Manual – Chapter1 Program
3902.1004 Form 1 Fermilab Assessment Manual – Chapter 4 Independent Assessment Procedure Form1

8.0 References

DOE O 414.1D *Quality Assurance*
DOE G 414.1-1B, *Management and Independent Assessments Guide*
Clause H13 of the prime contract *Contractor Assurance System*

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Appendix 1 Fermilab Independent QA Assessment Plan Form Example

Fermilab Independent QA Assessment Plan	
Assessment Number & Title: 10-QA-005 XX Division - Function to assess	Version 1
Planned Dates of Assessment:	
<ul style="list-style-type: none"> • 04/30/12 – 05/04/12 - planning and desktop review of documentation • 05/07/12 – 05/11/12 - onsite activities (opening meeting, interviews, work process observations, closing meeting) • 05/18/12 - draft report • 05/25/12 - final report <p><i>Verification & validation of CAPs may be scheduled as appropriate.</i></p>	
Performing Organization: Office of Quality & Best Practices	
Assessed Organization(s): Departments AA and BB of Division XX	
Purpose: To assess the implementation and effectiveness of Integrated Quality Assurance (IQA) controls and any XX division controls applied to YY function(s) within the XX Division.	
Scope: The specific IQA criteria to be applied to this assessment are: <ul style="list-style-type: none"> • Documents & Records (IQA chapter four) • Work Processes (IQA chapter five) <p><i>Other IQA criteria, such as qualification & training and program while not specifically included in the scope, may sometimes be assessed within the context of the main IQA criteria.</i></p> <p>Other criteria for assessment:</p> <ul style="list-style-type: none"> • All Division XX policies, procedures, or work instructions related to the IQA criteria listed above. 	
Scope limitations:	
None	
Assessors' Names (Asterisk indicates Lead):	
<ul style="list-style-type: none"> • John Doe* (QAE) • Jane Doaks (QAR) 	
Reference Documents: Attachment 2 contains a list of Fermilab and XX Division policies, procedures, etc. related to functions being assessed. Additional documents may be added to this list as the assessment progresses.	

ATTACHMENT 1: Selected Criteria and Controls

<u>QA/CA Criteria</u>	<u>Controls</u>
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DOE O414.1D section X	1001 IQA Revision 2, Chapter X Control 2 Control 3
DOE O414.1D section Y	1001 IQA Revision 2, Chapter Y Control 2 Control 3

ATTACHMENT 2: Selected Fermilab and Division XX policies, procedures etc. related to the criteria that are within the scope of this assessment:

<u>D/S/C</u>	<u>Document</u>
Fermilab	Fermilab Procedure X, revision 1 Fermilab Procedure Y, revision 1
XX division	XX division Procedure for XXX, Revision 2, XX division Procedure for YYY, Revision 2,

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Appendix 2 Fermilab Independent QA Assessment Report Example

Fermilab Independent QA Assessment Report	
Assessment Number & Title: 12-QA-010 XX - function being assessed	Version: 1
Date(s) of Assessment: 05/07/12 – 05/11/12	
Performing Organization: Office of Quality & Best Practices	
Assessed Organization(s): XX Division including the following: <ul style="list-style-type: none"> • Headquarters (HQ) • Engineering department • Environment, Safety, and Health (ES&H) <p>According to division experts, the headquarters organization is responsible for setting the division's strategic direction and goals. Engineering department employees perform all aspects of product and service design and development. The ES&H department is responsible for division environmental, safety and health concerns.</p>	
Assessment Activities & Scope: <p>Implementation and effectiveness of controls for function being assessed described in IQA chapter Y and XX division requirements were examined via interview, observation, and document review.</p>	
Scope Limitations: <p>Functions AA and BB were considered out of scope and were not examined during the assessment.</p>	
Activities Reviewed Within this Assessment: <ul style="list-style-type: none"> • Work request processing • Job planning • Final acceptance • Work request close out. 	
Description of the Implementation & Effectiveness of Observed Activities: <p><u>Documents & Records</u></p> <p>The requirements of IQA Chapter four, Documents and Records, are met and are effectively implemented in Division XX. Work control documents are generated and maintained with revisions tracked, as seen in attachments File01 and File02. These documents show release dates, revision numbers and dates, and revision histories are used for document control. A records management file plan was presented indicating retention times for records identified, as required by the Fermilab Records Management Program (File03). Records exceeding this retention date are properly disposed of at the end of the prescribed retention period.</p>	

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Suspect/ Counterfeit Items (S/CI)

The requirements of IQA Chapter ten, Suspect/Counterfeit Items are met and are effectively implemented in Division XX. All persons interviewed have received the required S/CI training as indicated in the attached individual training history (File04).

Criteria: Work Processes

The requirements of IQA Chapter five, Work Processes, are not met and therefore are not effectively implemented in Division XX. There are no documented policies or procedures defining the Division XX work activities. Specific work processes are loosely defined and their performance is dependent on the experience and knowledge of Work Managers. These work processes are conducted according to the flow diagram included as attachment File05.

Conclusions:

Division XX operations function well due to the experience and knowledge of the personnel involved. Documented procedures would improve coordination of project management activities within Division XX. Some Work Manager administrative functions such as cost tracking are sometimes given lower priority than they should be.

Findings:

1. There are no documented policies or procedures defining the Division XX activities. The Integrated Quality Assurance manual (IQA), section 5.3, "Work Process Control" requires that "Line management is responsible for applying the graded approach to determine the appropriate level of work process controls, including which activities require written procedures and which procedures can be augmented through the appropriate personnel training and qualifications". Evidence for this finding includes:
 - a. Contradictory responsibilities for defining required training for specific tasks or verifying that required training is current
 - b. Inconsistent submission of HA documentation by different Fermilab D/S/C's
 - c. Practices vary between D/S/C's for Project Management

Observations and Recommendations:

1. **Observation:** There were two observations of project changes made after approval without required project change documents
Recommendation: A specific procedure for review and approval of project change documents should be implemented.
2. **Observation:** Test equipment calibration/maintenance procedures were in use by the Work Managers although specific calibration frequencies were not specified.
Recommendation: Department X should consider required calibration frequency requirements using a graded approach and revise calibration system procedures as needed.

Commendable Practices:

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1. Training and qualifying outside engineers collectively rather than on an ad hoc, as needed basis improves training efficiency and expands the number readily available to work at Fermilab.

Persons Interviewed:

- Assessed Person 1
- Assessed Person 2
- Assessed Person 3

Documents Reviewed:

- Department Procedure 1
- Department Procedure 2
- FESHM XXXX

Attachments:

- File01-workcontroldoc1
- File02-workcontroldoc2
- File03-fileplan
- File04-trainingrecords
- File05-processflow

Standards, Regulations, and Other Program Requirements Applied:

The specific criteria applied to this assessment were:

- 1001 Fermilab Integrated Quality Assurance (IQA)
 - Chapter four - Documents & Records
 - Chapter five - Work Processes
 - Chapter ten - Suspect/Counterfeit Items
- 1006 Suspect/Counterfeit Item (S/CI) Program
- 1006.1001 Controlling Suspect/Counterfeit Items Procedure

Corrective Action Plans Issued:

XX-20120526-01 - There are no documented policies or procedures defining the Division X activities.

Assessors' Names (asterisk indicates team leader):

- Assessment Team Member 1*
- Assessment Team Member 2

Submitted by: Assessment team leader

Date: 5/26/12

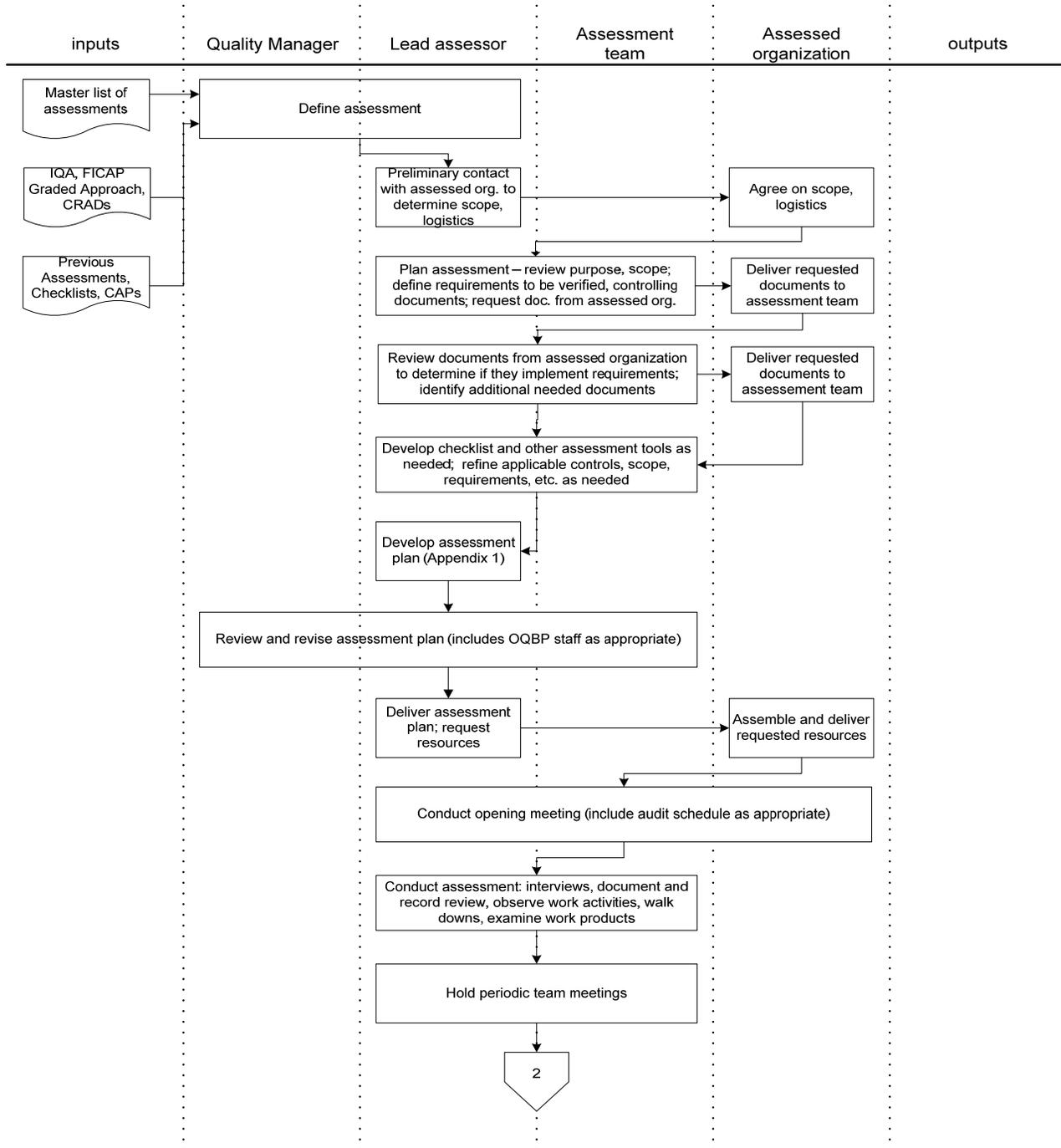
Distribution (Distribute to assessed organizations' management, OQBP head, and other interested parties):

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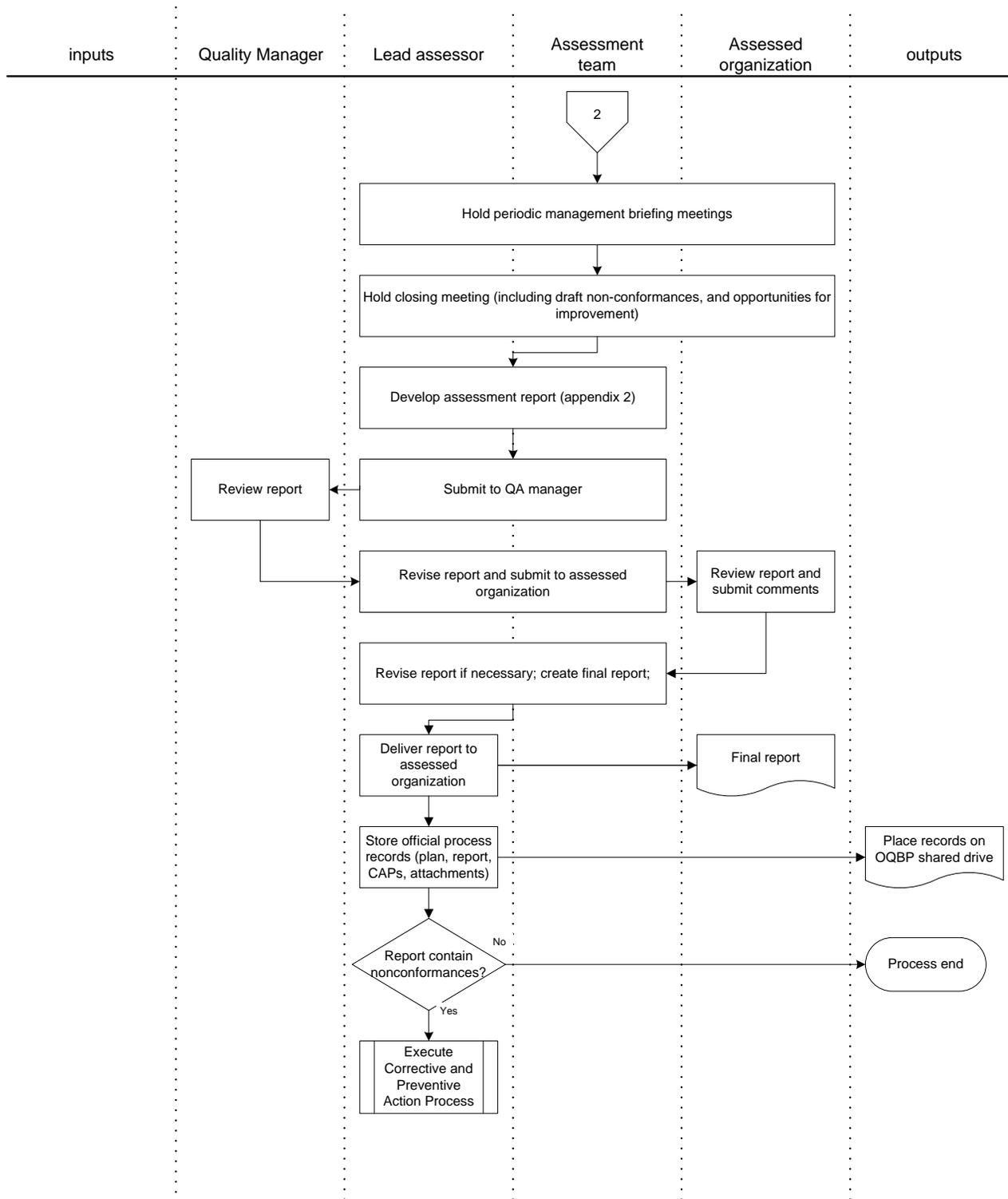
Division XX Division Head	OQBP Head
Division XX QAR	Assessment team member 1*
Department YY Department Head	Assessment team member 2
Department ZZ Department Head	

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Appendix 3 Fermilab Independent QA Assessment Process Flowchart



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TABLE OF REVISIONS

Author(s)	Description	Revision	Date
Larry Lamm	Initial draft based on input from Jeff Cotton, Jed Heyes & QAEs, updated based on some QAR feedback	000 A	06/26/09
Jed Heyes	Clarifications	000 A1	07/05/09
Jed Heyes	Updates based on feedback for September 2009 DOE QA assessment (removed minor/significant findings, defined findings, special assessments, Director's assessments & third party assessments) & Updated manual and forms from meetings with OQBP staff and for consistency, feedback received from QARs on this document and on the Management Assessment Procedure	000 A2 000 A3 000 A4 000 B 000 B1	09/22/09 11/08/09 11/12/09 12/21/09 12/30/09
Jed Heyes & Jeff Cotton	Minor grammatical updates & promoted	000 B2	01/02/10
Jed Heyes	Clarification on crediting other assessments as management or independent assessments and updates to, and reduction in the number of, tables with input from QAEs	000 B3	02/05/2010
Jed Heyes	C Records Management Policy & Procedures to Records Management Program to be consistent with IQA updates provided by Information Services in BSS.	000 B4	02/21/2010
Jed Heyes, John Martzel & Susan Rahimpour	Separated the manual into five chapters and reassigned document naming and number scheme. Clarified the various assessment types in relation to management & independent assessments. Introduction of the H13 clause. Separated management & independent assessment forms & examples from this appendix while retaining examples of completed forms in appropriate chapters. Removed non-essential forms. Improved format consistency and location of definitions.	000 C	04/26/2010
Jed Heyes	Updated for consistency with other chapters of the manual and from QAE review.	000 C1	05/04/2010
Jed Heyes	Minor clarifications to responsibilities, ensured consistency between text and flowchart; reduced scope of the procedure to the quality management system only.	001	10/7/2010
Jed Heyes	Inserted "QA" in header and appendices titles	001.1	10/8/2010
Jed Heyes	Updated the example plan and report in the procedure to reflect the new rev. 001.2 plan and report templates	001.2	12/10/2010

SUBJECT: Fermilab Assessment Manual - Chapter 4 Independent QA Assessments		NUMBER: 3902.1004	
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John Martzel, Jed Heyes	Integrated original Appendix 1 into section 3.4, clarified assessors independent of activities assessed versus organizations assessed and replaced reference to a training course with reference to assessment FAQs. Renumbered appendices 2-4 to 1-3. Minor updates including: section 4.4 paragraph 4 and Appendix 3, process flow chart, to reflect that the assessment report is reviewed by the QA Manager first, then by the assessed organization; Appendix 1, Assessment plan example, and Appendix 2, Assessment report example, to reflect the latest templates for each Changed references from DOE O 414.1C to 1D	002	04/06/2012