

<b>SUBJECT:</b>	Control of Documents & Records Procedure	<b>NUMBER:</b>	<b>10.003.000</b>
<b>RESPONSIBILITY:</b>	Quality Assurance Manager	<b>REVISION:</b>	000
<b>APPROVED BY:</b>	Head, Office of Quality and Best Practices	<b>EFFECTIVE:</b>	<b>10/23/07</b>

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## 1.0 Purpose

The purpose of this procedure is to describe the processes in place to implement control of documents and records in the quality system at Fermilab in compliance with DOE O 414.1C Contractor Requirements Document Section 3d Management/Criterion 4 – Documents and Records.

## 2.0 Applicability

This procedure applies to Fermilab Research Alliance, LLC (including all legal entities under its exclusive control) and all its employees, contractors, subcontractors, and Fermilab users.

## 3.0 Responsibility and Authority

The Director, Office of Quality and Best Practices (OQBP) authorizes this document by signature.

The owner of this document is the head of the Office of Quality and Best Practices (OQBP) who is the point of contact for the quality program. Revisions other than minor editorial changes must be reviewed by Quality Development Team representatives from each Division, and Section and the OQBP, and comments adjudicated prior to issue of the approved revision to the document.

Revisions which are other than minor, shall be denoted by a change in the integer portion of the revision number (example, Rev 001 becomes Rev 002), and shall be approved by the Head of OQBP. Minor editorial changes, those that do not add, diminish or otherwise change requirements must be approved by the EG&G Quality Manager at Fermilab. Minor changes shall be denoted by decimal values in the revision number (example, Rev 001 becomes Rev 001.01) and their approval shall be documented in the table of revisions only.

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## 4.0 Procedure

Fermilab documents that specify policies and other quality requirements, prescribe processes, and or establish design specifications must be controlled to ensure that the direction they provide is accurate, current, and approved by authorized individuals. Fermilab’s system for managing Laboratory-wide policies and procedures is described in this procedure in accordance with the Fermilab QA Plan [insert link here].

Heads of Divisions, and Sections must establish systems to control procedural requirements, design, and other quality management documents used solely within their division.

Where specific quality requirements are imposed by outside customers/sponsors, or are required for accelerator facilities, specific additional document control requirements may be included in a supplement.

Documents and records are required to effectively manage, perform, and assess work. Documents and records are also necessary to provide evidence of compliance with requirements. Documents and records shall include applicable requirements to indicate that work (including safety) has been properly specified and accomplished. Management shall identify any documents and records that must be developed and controlled. Management is responsible to provide the resources necessary to accomplish the document and record requirements.

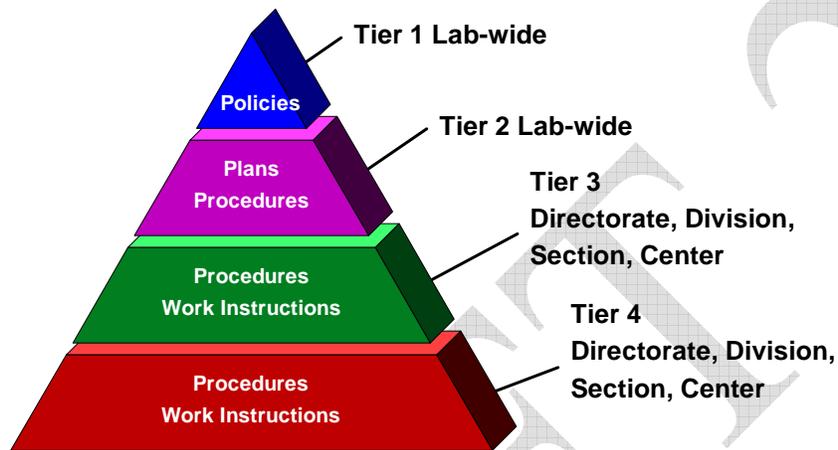
In accordance with DOE Order 200.1 Information Management Program and the Fermilab Directors Policy number 13, Document Control, ([Document Control](#)) all policies, program documents, program implementation plans, and procedures shall be controlled by the issuing organization and the issuing organization shall schedule reviews and updates for each document under its control.

A document control system shall be in place to control the preparation, review, approval, issue, control, and revision of documents. Documents are required by Fermilab’s organizations, projects, or programs to control policy and administrative and/or technical information. A document may describe work to be done, data to be used at different locations or by different people, or, in changing situations, data to be controlled from time to time for reference purposes. The document control system shall be established to supply the documents necessary for personnel to safely and correctly perform their assigned responsibilities, and to provide evidence of compliance with requirements. Document control systems ensure that the mechanisms developed to implement the safety management functions of DOE P 450.4 are properly prepared, controlled, and available for use.

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Structure

Figure 1 shows the three tier hierarchy of Fermilab documents. Forms and records may be found at any level in the hierarchy.



**Figure 1 Fermilab's Four Tier Document Hierarchy**

#### **4.1 Tier 1 Documents**

Tier 1 documents are laboratory-wide policies, reviewed and approved by the Laboratory Director. They represent the highest level Fermilab generated document, with an integer only format. For example, the quality policy number is number10.

#### **4.2 Tier 2 Documents**

Tier 2 documents are laboratory-wide governing documents, plans or procedures.

Governing documents or plans are numerically structured beginning with the policy number, then suffixed by a unique two digit identifier. For example, the QA Plan which specifies laboratory wide requirements for implementing the QA Policy is 10.01.

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Laboratory-wide Implementing procedures may implement a policy directly, or a governing document or plan above it. Their numbering begins with the policy number example, 10 and are suffixed by six digits broken into two groups of three. For example the graded approach procedure is 10.002.000 which implements requirements in the QA Plan, which in turn implements the QA Policy. They are approved by the appropriate authority appointed by the Laboratory Director for the program being implemented. For example, ES&H documents at this level are approved by the ES&H Director and QA documents at this level are approved by the Head of the Office of Quality and Best Practices. Forms implementing a procedure or work instruction inherit the numbering of the document they support and are suffixed in the format Form x. For example the graded approach procedure would be numbered as 10.002.000 Form 1.

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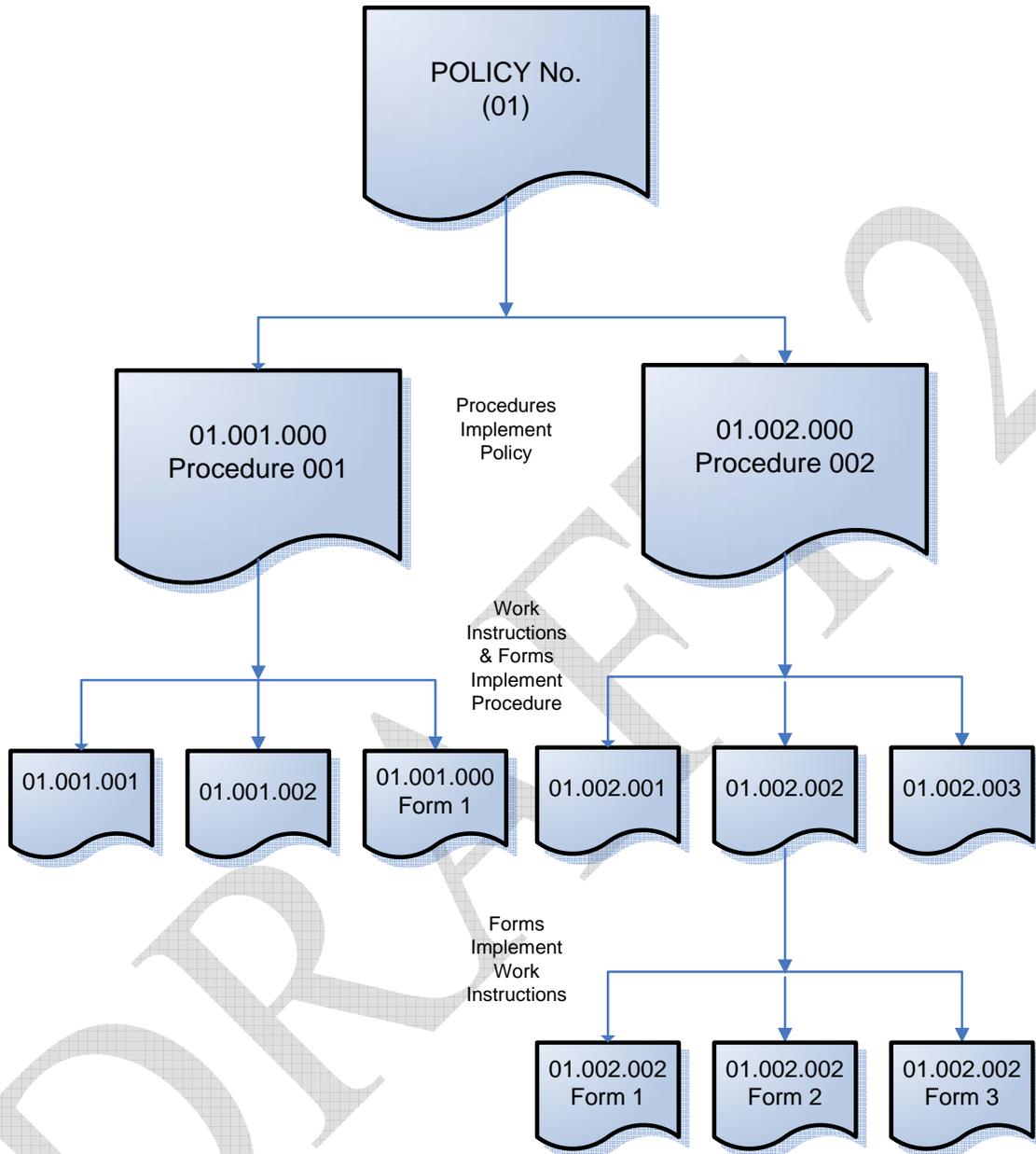


Figure 2 Overview of Fermilab's Document Hierarchy

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### 4.3 Tier 3 Documents

Tier 3 documents are requirements documents that apply within a directorate, division, section, center, organization, department, group or project. They include unique policies, procedures, methods, work instructions and other quality implementing procedures and forms. These documents may be approved by authorized persons at different levels in the organization to which they apply, depending on the scope of the document. For example, a division-wide policy or procedure will be approved by the head of that division, whereas a procedure specific to one organization within a division such as electrical engineering may be approved by the head of the electrical engineering organization. However changes affecting regulatory; statutory compliance may require higher levels of authorization. They inherit the number of the policy, governing document, plan or procedure they are implementing locally or for a specific project. Where such documents are traceable to laboratory-wide policies, governing documents, plans or procedures there numbering schemes shall inherit the laboratory-wide numbering scheme.

Work instructions or procedures are tier 3 documents that identify work processes having a significant impact on any of the following:

- Programs
- Financial Systems
- Potential impacts on environment, safety and health.

Work instructions and procedures are the responsibility of the issuing Directorate, Division, Section, Center, department, group or project line managers. Line management creates work procedures that will ensure quality, financial integrity, compliance, and safety.

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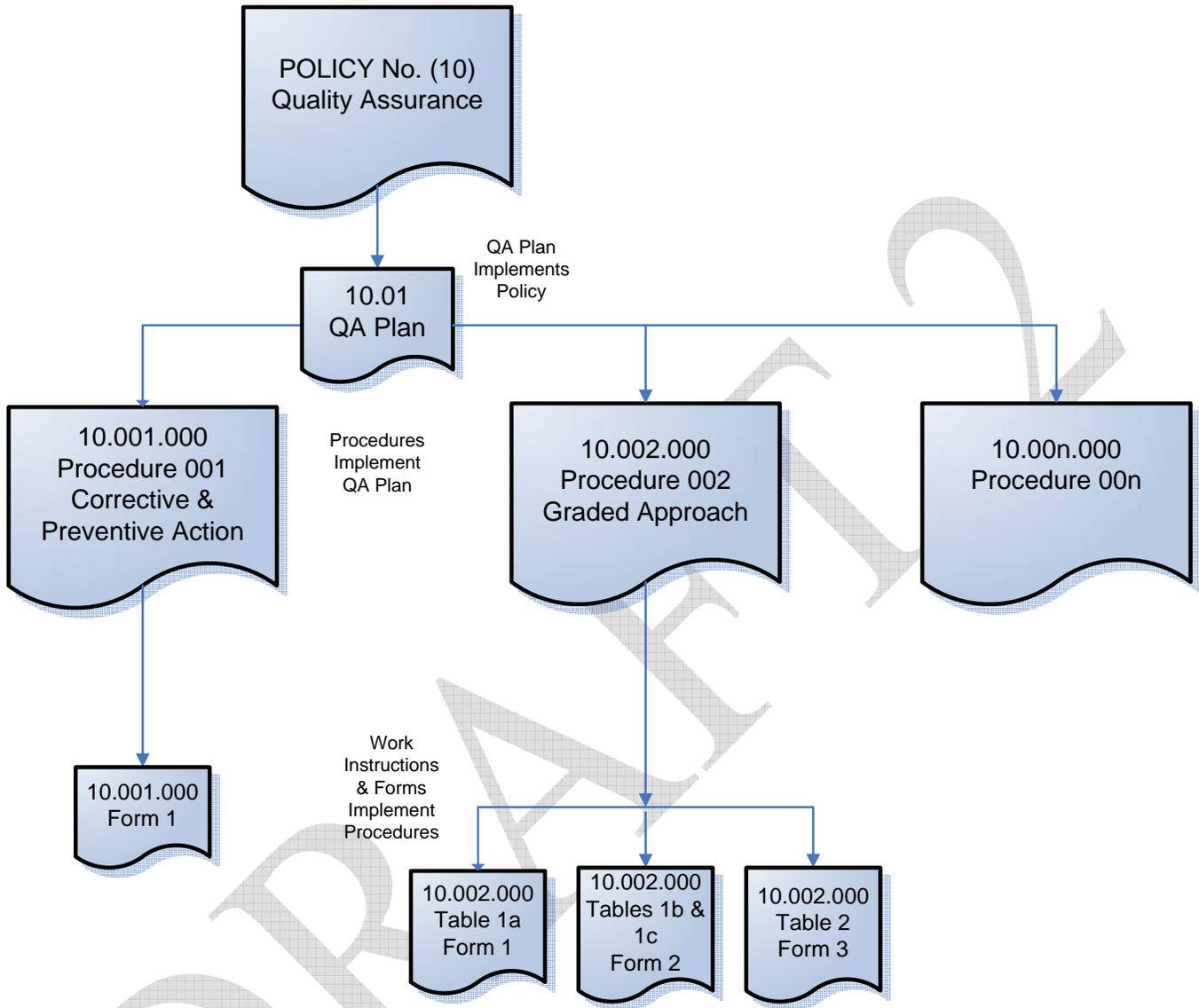
#### **4.4 Tier 4 Documents**

Tier 4 documents include permits, certifications and other approvals required by Tier 2 or Tier 3 requirements documents. These may be issued by the ES&H Section, one of the institutional safety officers, or Safety Council, or by outside agencies as required to ensure compliance with all Federal, State or local rules and regulations or voluntary consensus standards.

Figure 3 illustrates the document hierarchy for some specific quality system documents, including policy, quality assurance plan, and two procedures, with supplemental forms and tables.

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**Figure 3 Example of OQBP Document Hierarchy**

Legacy documents with may require deviations from the hierarchy described due to centralized Laboratory-wide controls. For example, Fermilab drawing numbers ([Drawing Numbers](#)) and publication numbers ([Obtain Doc Number](#)) both of which are assigned in a controlled manner to organizations by Technical Publications, a central department within Business Services Section (BSS).

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## 4.5 Document Process

The documentation process consists of the following fundamental steps.

- Establish the information necessary to construct the document (document, form, table, worksheet, drawing,)
- Establish the content and the method and form of storage.
- Determine who the owner, authorized approver (responsible), reviewers and users of the document will be
- Create a draft including the following information to control the document
  - Subject (or Document Title) – what it is / what it is about
  - Number - a unique number following a hierarchy of traceability described herein
  - Responsibility – identifies who owns the document
  - Revision - a unique revision number beginning with 000 for unpublished drafts, 001 for the first official approved publication, and then incrementing by 1 for each re-approval and re-issue, or by 0.01 for minor, editorial revisions
  - Reviewers – if in addition to the approver of the document
  - Approved by – identifies who is the authorized approver
  - Effective – identifies the date the procedure becomes effective, usually the date of approval
  - Review cycle, if not specified at a higher level (such as Tier 1 policy, plan or procedure) for a subordinate procedure
  - Additional controlling information or metadata as required (such as controlled points of issue, related documents, standards or other requirements addressed, distribution, responsibilities for management and personnel, etc.)

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- Distribute and peer review the document with authorized and qualified personnel. The extent and depth of peer review should be commensurate with the associated risk.
- Reconcile feedback, issues or comments raised by reviewers
- Distribute for re-review by the reviewers if necessary, depending on risk
- Complete final editorial changes including a Table of Contents the document is sufficiently long and/or complex
- Publish and distribute the final version – ensure prompt removal of prior, obsolete versions from official points of issue (ex: field manuals)
- Archive the document in such a way as to prevent changes, loss, deterioration or damage

The originating organization shall maintain a master list of all approved versions of a document.

## **4.6 Records**

### **4.6.1 Definition of a Record - 44 United States Code Section 3301**

"Records" includes all books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of data in them.

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NON-RECORDS

Library and museum material made or acquired and preserved solely for reference or exhibition purposes, extra copies of documents preserved only for convenience of reference, and stocks of publications and of processed documents are not included in this definition. They are non-records.

**4.6.2 Record Management**

In accordance with DOE O 414.1C Criterion 4, and DOE O 243.1 Records Management Program, records must be identified, prepared, reviewed, approved and maintained. A record contains information that is retained for its expected future value allowing DOE and Fermilab to retrieve them in order to make informed decisions. All Fermilab employees, users, and contractors must comply with the records management system in place at Fermilab.

A record contains information that is retained for its expected future value. Fermilab records support technical and regulatory decisions and provide evidence that work was correctly performed. Records may be in a variety of forms (e.g., electronic, written, or printed; microfilm; photographs; radiographs; or optical disks). Typical records include procedures, plans, and manuals; training and qualification results; acceptance test results; technical/ regulatory correspondence; environment, safety and health records; operational and financial records; design basis descriptions, design review results, design revisions, and configuration management data; and quality problem resolutions.

Fermilab records are managed centrally by the Records Management department ([Records Management](#)) of Business Services Section in accordance with DOE O 243.1, Records Management Program. DOE Order 243.1 states that contractors shall “maintain adequate and proper documentation”.

Fermilab policies and procedures for records management are maintained by Records Management and described in more detail in the Records Management Handbook ([Records Procedures](#)). The system includes provisions for specifying, preparing, reviewing, approving, disposing, and maintaining records and references applicable rules, regulations and directives governing how the laboratory is to manage records.

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Record protection, preservation, change, traceability, accountability, and retrievability are also specified. Fermilab's record retention is specified according to published DOE rules ([DOE Records Disposition](#))

Apart from the mandated Laboratory-wide records management program, the heads of each Division, Section and Center must ensure that sufficient records exist to reflect accurately the present and final status of completed work. Record storage area's should be appropriate to the risk, type, and level of records maintained.

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## 5.0 Responsibilities

The Fermilab Director

- Holds senior leaders accountable for implementation of, and compliance with, this procedure
- Provides financial support to senior leaders for pertinent activities
- Ensures the use of graded levels of documentation, recordkeeping, and assessment
- Approves the Quality Assurance Policy.

Division and Section Heads

- Comply with and champion this procedure for their areas of responsibility
- Provide the necessary resources as appropriate to the findings/issues using a graded approach.

Head of Business Services Section

- Provide the resources necessary to create and maintain a central Fermilab Document Control and Records Management system
- Appraise the QQBP of changes in regulations, DOE directives or other applicable sources with potential impacts to document and record procedures at Fermilab

The Office of Quality and Best Practices

- Specifies how Fermilab will control documents in the Quality System.
- Manages, and approves the Fermilab Control of Documents Procedure
- Provides periodic status reports to the Laboratory Director, responsible managers, and others as appropriate
- Provides support to responsible management in resolving document control issues

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## 6.0 References

6.1 DOE O 414.1C Quality Assurance – Contractor Requirements Document, Attachment 2  
Management/Criterion 4 – Documents and Records

## 7.0 Definitions

7.1 Graded Approach: The process of ensuring that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with: the relative importance to safety, safeguards, and security; the magnitude of any hazard involved; the life-cycle stage of a facility or item; the programmatic mission of a facility; the particular characteristics of a facility or item; the relative importance to radiological and non-radiological hazards; and any other relevant factors. (10CFR830)

Table of Revisions

Author	Description	Revision	Date
Jed Heyes	Draft	000	10/23/07