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Revision 1.0

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Next Review Date: 8/9/2017

Process Description: Managing Institutional Documents

1. Purpose

This document describes the process for managing institutional documents, which include policies and procedures, at Lawrence Berkeley National Laboratory (LBNL). It flows from the Laboratory's policy on document management, and provides a systematic approach to ensuring that LBNL staff has access to current, reliable, and concise information, so that work can be performed in a safe, efficient, and compliant manner.

2. Applicability

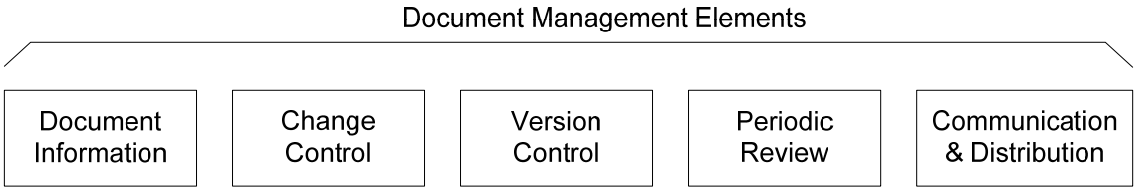
This process applies to people who write, review, approve, maintain, and store institutional documents, and to people who have responsibility for creating and managing business systems that support the maintenance, storage and retrieval of institutional documents.

2.1 Exceptions

This process does not apply to scientific or technical publications. See Scientific and Technical Publications Requirements in the LBNL Requirements and Policies Manual (RPM). .

3. Process Description

The process for document management is comprised of five main elements: document information, change control, version control, periodic review, and communication/distribution. This process, therefore, sets forth definitions and steps required to develop, organize, store, and retrieve institutional documents at LBNL.



3.1 Document Information

To enable control, certain information about the document is required. Such information includes standardization of document types, numbering and formats.

3.1.1 Document Types

Types of LBNL institutional documents for communicating requirement information are listed in Appendix A. The type is selected based on the kind of information being communicated.

3.1.2 Document Formats

Documents are developed using standard formats for each of the institutional document types. The list of templates for institutional documents can be found in Section 6.2. Sections common to all institutional documents should include: purpose or scope, persons affected or applicability, roles and responsibilities, source requirements references, implementing document references, contact information, revision history.

3.1.3 Document Numbering Convention

For institutional policies, document numbers are comprised of four fields separated by periods, and a version suffix separated by a hyphen: XX.YY.ZZZ.AAA-BB, where

XX is a two-digit number reflecting the Requirements and Policies Manual (RPM) Section
YY is a two-digit number reflecting the Policy Area
ZZZ is a three-digit number reflecting the policy number
AAA is a three-digit number reflecting the supporting or implementing document number.
BB is a two-digit number reflecting the revision number.

Institutional documents that are directly related to policies should carry a number that shows the policy root. Institutional documents already assigned LBNL Publication document numbers retain those numbers, and may be assigned a second number per the convention cited above for database tracking purposes.

3.1.3 Document Dating Conventions

The published version of every document carries three dates: the "effective date", the "publication date", and the "next review date". The "publication date" refers to the date on which the particular revision of a document is published, or made available, to end users. The "effective date" is often the same as the original publication date, unless the document has been significantly changed, in which case the effective date may be the same as a particular publication date. The "next review date" refers to the next time the document is to be formally review for possible revision (see Section 3.4 of this process document). A "last reviewed date" may be used instead of "next review". Additional dates (such as approval date) may be requested in templates and data forms for tracking and monitoring purposes, but are not generally published.

3.1.4 Revision History Convention

A revision history is required for each institutional document. A revision history table is one section of the document, and minimally includes a listing of the associated revisions, revision dates, who made the modification, and a brief summary of the changes made.

3.1.5 Record Tracking and Database

Document information is collected, and subsequently loaded into the institutional Requirements Management System (RMS) database. A comprehensive RMS database enables traceability between

contractual and other regulatory or standards requirements and the Lab policies and implementing documents. The database sorting and other manipulations may be based on a number of document information parameters, including the document numbers introduced in Section 3.1.2.

3.1.6 Record of Approvals

When required, approval signatures are to be collected on a single hardcopy page containing the specific institutional document's identifying information (document title, number, revision, issue date, as might be found in the header and footer). A copy of the page with original signatures may then be pasted into the softcopy master of the document, with a note stating the location of the filed original signed page.

E-mail with a clean chain of approving emails may be accepted for institutional documents. The e-mail with the chain of names and dates should be preserved in pdf form and added to the document's history repository (for example, in the RMS database).

On-line system approvals may also be accepted for institutional documents.

3.2 Change control

Change control helps to ensure that all documents are reviewed for technical accuracy and ease of use. Change control comprises all steps related to changing a document, including introduction of a new document or retirement of a document. Documents are tracked and monitored through development, review, approval, and distribution. This is detailed in *Developing, Reviewing, Approving Institutional Policy Documents* (document number 10.06.001.102) *and Developing, Reviewing, Approving Non-policy Institutional documents* (document number 10.06.001.101).

3.2.1 Change types

The type of change defines the level of review and approval. Table 1 describes the types of changes and the associated levels of review. For major changes, approvals may be further graded based on a significance rating, which is determined from an impact and risk analysis (see *Determining Significance Rating*, document number 04.04.001.206).

For those cases directly involving policy and/or interpretation of requirements, the Requirements Management Committee (RMC) per the *LBNL Requirements Management Process* (document number 04.04.001.003) reviews and logs the type of change.

Type of Change	Definition	Review/Approval authority
Major Change	Includes the addition of a new institutional document, the retirement of an obsolete document, or revision to an existing document that significantly changes its meaning, requirements, responsibilities or method of implementation, or is an extensive rewrite of an existing document. May have high impact on other institutional documents.	Varies depending on the type of document. See Appendix A.
Major Change/30 Day Notice [Specific to Lab HR policies]	Major change to HR policy that affects employment terms and conditions. - 30 day comment period starts with policy notice announced in Today at Berkeley Lab (TABL)	- Chief Operating Officer (or designee) - Chief HR Officer - Legal
Minor Change	A change that makes no substantial alteration in requirements or responsibilities, in the judgment of the Sr. Line Manager and/or Policy Area Manager.	Responsible RMC representative or Line manager
Editorial change	- Typos, format, grammar, - updating hyperlinks, doc number changes - Editing text to clarify or be consistent with existing requirements within the document and/or with other institutional documents	Inform Responsible RMC representative, or Line Manager, or SME

3.2.2 Comment resolution

Reviewer comments and associated dispositions should be formally recorded and reconciled. Often a Word version of the document with track changes and comments may serve as one forum for capturing comments. In those infrequent instances in which resolution is difficult, a Record of Decision form may be used to document the differences of opinion and the decision that is taken (and why.

3.3 Version control

Version control covers the distribution and availability of the right version of a document to users. This process element includes uploading and storing in a repository, versioning, retrieval, and archiving. See Procedure #10.06.001.103, *Storing, Retrieving, and Archiving Institutional Documents.*

In keeping with LBNL's *Quality Assurance Program Description*, PUB 3111, and its quality assurance (QA) policy, LBNL institutional documents are expected to be stored with controlled access so as to prevent unauthorized changes. Control practices are to be exercised to ensure that only the current and approved version of a document is available to users. Each page of printed or downloaded softcopy versions shall be marked with a statement such as "(date printed) *The official or current version is located in the on-line Requirements and Policy Manual (RPM)* (or *on-line* xxx *document*). *Printed or electronically transmitted copies are not official. Users are responsible for working with the latest approved revision.*"

Obsolete or superseded documents and forms must be marked and their access must be limited or removed to avoid inadvertent use by general users.

In keeping with LBNL archival requirements and QA recordkeeping policy, previous versions may need to be retained for legal and archival purpose, and therefore are to be suitably labeled, stored, and protected.

The Sr. Line Manager with the function's policy SME(s) has responsibility to identify the specific Policy Area documents that fall under LBNL archival requirements. These selected documents are to be treated per Procedure #10.06.001.103, *Storing, Retrieving, and Archiving Institutional Documents*. The RPM falls under LBNL archive requirements and a copy of record is created and filed every year. .

3.3.1 Repository for controlled documents

Copies of controlled active and retired versions of institutional documents must be stored in a repository so that hardcopy or electronic collections may be straightforwardly extracted for archival or storage purposes. The collection of controlled active versions represents the master set of all Laboratory institutional documents. Links cited in institutional documents and in websites that reference institutional documents should be to the documents in this master set in the repository[1]. A management system to control access to the repository is required, particularly for those documents that contain sensitive or confidential information. See Procedure #10.06.001.103, *Storing, Retrieving, and Archiving Institutional Documents.* The RPM itself resides in an application that includes version tracking, and hence in itself can satisfy the requirement for a controlled repository.

Note that potential technologies for repositories will change over time, and alternatives should be assessed every three years or so.

3.3.2 Web postings and web communication of information

On-line web-based communications are the most common method of enabling access to information contained within institutional documents. Web postings are considered "documents" (see Definitions, Section 5) and if any portions of the contents of such postings are considered institutional documents, then by Lab policy such web postings are subject to this document management process. Web postings, providing general users with access to policies and implementing documents, should link to the active master copies within the repository. Policy or requirements information for departmental, functional, and policy area web pages must be derived from the active master set. Web pages must not be used to introduce new or revised policy, but may cite or link to the appropriate page(s) of the Laboratory's policy manual. Policy or requirements information not drawn directly from the active master set is considered uncontrolled.

The responsible functional Sr. Line manager has responsibility for ensuring currency and accuracy of the web postings and pages. To help keep track of where policy or requirement information has been duplicated, web pages may be included in the reference listing of implementing documents.

3.4 Periodic Review

Institutional documents, after first publication, are to be reviewed periodically to ensure alignment with contract requirements, LBNL policies and implementing documents and practices. Such reviews should occur at a frequency of every three years, unless contractual or regulatory requirements or best practices specify a more frequent schedule. The review of an institutional document is initiated by a responsible SME,

[1] Linking directly to the controlled documents in the master set can minimize broken links or links to obsolete documents, or links to documents no longer accessible because the document has moved.

the RMC representative, and/or the Senior Line Manager, and has the main purpose of determining whether the document needs to be revised. If revision is required, then the steps of *Developing, Revising, and Approving Institutional Policy Documents* or *Developing, Revising, and Approving Non-policy Institutional Documents* must be followed. A next review date is then included in the document's metadata set, and is adjusted each time the document is revised.

3.5 Communication and Delivery

After publication of an approved document, persons impacted by the document must be notified in accordance with the implementation plan supporting the particular document. The primary communication mechanism for Lab-wide notification is *TABL* (*Today at Berkeley Laboratory*) and e-mail. Depending on the level of importance of the changes in policy or procedures as determined by risk analysis, notifications may be announced in all-hands forums at the Lab, Division and/or department levels. For those cases in which the impacted audience is smaller than the full Lab, notifications should be appropriately targeted. Notifications should include not only what the change (or new) policy or procedure is and where the document is located, but also additional details, such as training, required to implement the policy or procedure.

4. Roles and Responsibilities

The list below emphasizes the roles and responsibilities pertinent to only this procedure. For the most comprehensive and up-to-date version of Requirements Management roles and responsibilities, see *LBNL Requirements Management Governance*, document 04.04.001.002.

Role	Responsibilities
Document Author	• Recommended by the Sr. Line Manager, or Requirements Management Committee (RMC) member to prepare institutional documents. Usually is a SME. Appointed by Sr. Line Manager. Assignment is on a per case basis. • Ensures clarity, accuracy, usability, and conciseness of the document(s). • Provides technical expertise to support the interpretation and implementation of requirements. • Gathers information from other functional and/or policy areas that have knowledge or expertise relevant to the document. • At the direction of the RMC member or SME, prepares document for review and approval by others. Obtains approvals for the assigned document. • With the oversight of the RMC member and assistance of CSO editor prepares institutional documents for publication. Has responsibility for all technical content and the integrity of any links introduced.
Subject Matter Expert (SME)	• A Laboratory employee or consultant with specialized knowledge about a certain topic or field of interest. • Provides technical expertise to the RMC and/or Working Group as it relates to the interpretation and implementation of requirements, including the development and review of policies and implementing documents. • May be a Working Group member, may be an author or reviewer • (Lead or senior functional SME) Has ownership and accountability for the technical content, accuracy, and completeness of policies. o Leads in the identification and translation of requirements. Seeks and has the assistance of Working Groups (WG) and RMC member o Leads the development and/or revision of policy and implementing documents

Role	Responsibilities
	within area of responsibility in accordance with requirements. Seeks and has the assistance of WG and RMC member. o Coordinates document reviews, comment resolution, and implementation actions. ▪ May be delegated by Sr. Line Manager to approve certain institutional documents upon completion of required reviews. o Must be trained on LBNL RM and document management processes. • Communicates progress, actions and/or assignments to the RMC and respective Division Sr. Line Manager on regular basis.
Requirements Management Committee (RMC)	• Provides centralized coordination and communications on Contract 31 requirements and related Lab policy matters. • Applies the RM process in the review and disposition of Requirements Review Cases related to requirements, Laboratory policies, and on a case-by-case basis Laboratory implementing documents. Ensures that flow-down from requirement into implementing documents is addressed. • Reviews and recommends best qualified cross-functional team to address requirements analyses, implementation mechanisms and plans, policy and procedure documents. • Reviews and applies cross-functional knowledge and judgment on WG, SME work products (analyses, implementation plans, policies). • Advises responsible Sr. Line Manager on WG/ /SME work products. • Reviews communications plan to ensure effectiveness and thoroughness. • Reports to ALDO/COO. • Champions RM and institutional document management processes.
Requirements Management Program Manager (RM PM)	• Manages the Laboratory's requirements management and institutional document management processes. Is the main driver and champion of these processes. Has author/review/recommendation responsibilities for quality and completeness of RM process and institutional document management process documentation. • Serves as the Laboratory's contact point on requirements and institutional document management-related matters. • Coordinates inputs from the RMC members, the Working Groups, and the responsible Sr. Line Manager. Presents to RMC for discussion and resolution. • Oversees management of Laboratory's policy manual. • Maintains the Requirements Management (RM) database for tracking requirements, their associated policy areas (PA), owners, records of implementing mechanisms, and their flow down to implementing documents. Maintains accuracy and currency of the RM tracking system. Has review/approval responsibility for quality and completeness of requirement, policy, and document metadata.
Sr. Line Manager	• Has responsibility and accountability for managing Laboratory requirements that pertain to his/her area of responsibility, including identification of what the requirements are and implementing them through policies, programs, procedures, etc. • Has full responsibility and authority to make and enforce policies related to his/her respective area of expertise and responsibility • Ensures compliance with LBNL requirements and document management policies and procedures. • Has ownership and accountability for the technical content, accuracy and completeness of respective Function's documents. Approves institutional documents upon completion of required reviews..

Role	Responsibilities
	• Reviews and approves policy recommended by a Working Group and the RMC. • Has option to delegate approval authority to SME or RMC member.
Chief Operating Officer (COO)	• Has full responsibility and authority to make, implement, and enforce policies related to the Laboratory Operations. • Works with the RM PM and Sr. Line Managers to resolve difficult or complex policy matters, (for example, setting priorities or providing judgment on controversial policy or implementation, or allotting funds) that may arise in the process of review and translation of requirements or policy into implementation. • Reviews and approves policy and detailed implementation plans recommended by the Sr. Line Managers and the RMC. Reviews and approves institutional documents, as required. • Appoints RMC members and RMC chairperson.
Reviewers	• Review and provide comments and comment resolution concurrences on documents that directly affect operations. Reviewers may be other SMEs, members of Working Group(s), RMC members, affected users, members of Laboratory institutional committees, Laboratory managers, and so forth.
CSO (Creative Services Office) Editor	• Works closely with RM PM to maintain the Laboratory's Requirements and Policies Manual (RPM) • Works closely with the RMC members, RM PM, Document Author, and SMEs to develop and maintain Laboratory policy documents. • General duties include: rewriting, copy editing, proofing Laboratory policies ; verifying that referenced • URLs are correct and current; publishing approved Laboratory policies in the RPM.Updates as necessary user-accessible web features such as links, institutional glossary, search parameters, and so forth. • At the direction of the RM PM or Director of Office of Institutional Assuranec performs searches for past policies.
Functional Document Control Coordinator	• An optional resource hired by a Function to manage the Function's portfolio of institutional and functional documents per the Laboratory document management process and policy. • Works closely with Document Author, PAM, SMEs and WG to develop documents. • Manages Function's document database • Manages Function's repository of functional documents. Ensures uploading of final approved institutional documents into institutional document repository, and provides the RM PM with accurate and current institutional document metadata.

5. Definitions

Term	Definition
Contract 31	"Contract 31" is short for Contract No. DE-AC02-05CH11231 between the U. S. Department of Energy and the University of California describing the terms for management of LBNL. The Contract includes a statement of work (SOW) for the science missions and it details the requirements for managing the operations and business of LBNL.
Disposition	Actions taken regarding records no longer needed to conduct regular, current business.
Document	Written, visual, audio-video-recorded information stored in the form of hard copy, film,

	magnetic tape, electronic data, or in an on-line, web-based format
Document Information	Also referred to as document metadata, and includes (but not limited to) titles, document numbers, revision dates, and for traceability, the related source requirements and implementing documents' information.
Document Management	A business management process that ensures organization access to current, reliable, and concise information. Document management process includes document control, change control, configuration control, periodic review, and communication/distribution.
Functional area	A grouping of individuals on the basis of the function each performs in the organization (for example, human resources or IT). A Division, Department, or Office at the Laboratory. Functional areas may have oversight of one or more policy areas, or may share responsibility for a policy area with another function.
Institutional document	A publication authorized by Laboratory management that delineates laboratory-wide or multi-departmental policy, procedures, regulations, programs, plans, and so forth. Scientific and technical publications and reports are not included in this definition.
Laboratory Driving Requirement	Institutional documents that (1) are mandated by the contract, applicable regulations, or UC, and approved by at least Berkeley Lab senior management, and (2) drive institutional policies, processes, or other documents. These driving requirements do not include Laboratory policies, and are typically program or system descriptions.
Metadata	See Document Information
Policy	Statements or directives from the federal, state or local government; the University of California; or Berkeley Lab senior management that set a course of action, define acceptable conduct, or implement governing principles.
Policy Area (PA)	A grouping of related policies. Policy areas are organizationally neutral; that is, they do not reflect organizational structure. Though organizationally neutral, Policy Areas typically are assigned to an Operations function. Some policy areas may span across more than one function, and a primary functional owner is therefore assigned.
RM Database	A database tool for managing requirements and related information, including tracking requirements, their associated policy areas, owners, records of implementing mechanisms, and their flow down to implementing documents.
Record	All books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received that are preserved or appropriate for preservation that serves as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities.
Requirement	A specific obligation to perform an action mandated by LBNL senior management or the federal, state, or local government; or to comply with the Laboratory's contract with the Department of Energy; or to comply with agreements made between the Laboratory and its corporate manager, the University of California.
Requirements review case	An instance or a question related to a requirement that has been logged into the Requirements Management database for disposition by the RM Committee.
Significance Rating or Level	A value that reflects the significance of a new or revised institutional policy, program, process or other document. The value provides a means to grade (a) the approach for development (or revision) of the policy or program, (b) the amount of rigor associated with the various steps of the process, and/or (c) the level of approval authority for the policy or program.
Source requirements document	A high level document that establishes performance expectations as a result of a citable policy, directive, law, regulation, or contract. Examples: Clause H.18*, Application of DOE Contractor Requirements Documents;* 10 CFR 851, *Work Safety and Health Program*

Senior Line Manager	The highest level or most senior level of authority within a division or office. For example, the EHS Division Director or the Chief Human Resources Officer or Chief Financial Officer, or Public Affairs Department Head.
Revision	The act of altering or modifying a document.
Version	An altered or modified document, which is the result of revising.

5.1 Acronyms

ALDO/COO	Associate Laboratory Director of Operations/Chief Operating Officer
CSO	Creative Services Office
LM	Line Manager (Senior)
PA	Policy Area
RM	Requirements Management
RM PM	Requirements Management Program Manager
RMC	Requirements Management Committee
ROD	Record of Decision
RPM	Requirements and Policy Manual
SME	Subject Matter Expert
WG	Working Group

6. References

6. 1 Source Requirements Documents	
Requirement ID	**Title**
10 CFR 830	*Nuclear Safety Management*
DOE Order 414.1D	*Quality Assurance*
LBNL/PUB 3111	*LBNL Quality Assurance Program Description*
04.03.001.000	*RPM, Quality Assurance Policy*
10.06.001.000	*RPM, Document Management Policy*
04.04.001.000	*RPM, Requirements Management Policy*

6. 2 Related Implementing Documents	
Document Number	**Title**
04.04.001.003	*LBNL Requirements Management Process*
10.06.001.101	Procedure - *Developing, Reviewing, and Approving Non-Policy Institutional Documents*
10.06.001.102	Procedure - *Developing, Reviewing, and Approving Institutional Policy Documents*
10.06.001.103	Procedure –*Storing, Retrieving and Archiving Institutional Documents*
10.06.001.201	Form – *LBNL Procedure/Process Template and Information*
10.06.001.202	Form – *LBNL Policy Template and Information*
10.06.001.203	Form – *Policy Approval*
10.06.001.204	Form – *Non-Policy Document Approval*
04.04.001.206	Form – *Determining Significance Rating*
04.04.001.002	*LBNL Requirements Management Governance*

7. Contact

Email: requirementsmgmt@lbl.gov
Requirements Management Program Manager
LBNL Office of Contract Assurance

8. Revision history

Date	Revision	By whom	Revision Description	Section affected
11/24/10	0.0	L.Young	Initial	
1/31/11	0.1	L.Young	Align with RM governance	all
2/10/11	0.2	L.Young	Simplify numbering	3.1.3
3/11/11	0.3	L.Young	Align with existing Archive & Records Office practices	3.3
3/18/11	0.4	L.Young	Include M.Gravois inputs – change "Doc Control" & Config Control names	
4/13/11	0.5	LYoung	Clean up	all
10/21/11	0.6	L. Young	More clean up	Definitions, R&R
12/12/11	0.7	L.Young	Prepare for signature, pre-release to OCA web	
8/1/2014	1.0	L. Young	Align with current practice. Remove Policy Area Manager role; adjust roles, definitions.	all

Appendix A: LBNL Document Types and Graded Review and Approval

Document Category	Definition	Review[Note1]	Content Approval [Significance Rating][Note2]
Laboratory Mission	A public declaration of the mission and objectives of Lawrence Berkeley National Laboratory. Document Types: • Laboratory Mission	• Lab Director • Legal	Lab Director [A]
		RM PM reviews/approves for quality control	
Policy	Statements or directives from the federal, state, or local government; the University of California; or LBNL senior management that set a course of action, define acceptable conduct, or implement governing principles. Document Types: • Lab Policy	• COO • Sr. Line Manager • Legal • RMC	Lab Director [A, B] COO (or designee) [B, C] Legal [A, B, C]
		RM PM reviews/approves for metadata completeness & quality control	
Description Document	A document that describes overall purpose and/or attributes of a program, system, or process, and how the elements align. It may be used to provide context for multiple implementation documents, or to identify how requirements are satisfied in procedures, processes, or other implementing mechanisms. Document Types: • Program Description • System Description • Process Description • Plan Description (per DOE requirement)[Note4] Two review/approval levels: I. DOE/UCOP/Lab – (per DOE requirements) II. Lab initiated documents	Level I: • DOE Site Office • UCOP • Lab Director • COO • Sr. Line Manager Level II: • Sr. Line Manager (or designee) • RMC representative • Working Group	Level I: • DOE Site Office • UCOP • Lab Director or COO [A, B] • Sr. Line Manager [C, D, E] Level II: • Sr. Line Manager (or designee) [C, D], E
		RM PM reviews/approves for metadata completeness & quality control	
Implementing Document	A document that details the set of actions or steps that prescribe a method for performing a task or implementing a requirement. It specifies the how, who, and when for the performance of the task or requirement. Document Types: • Procedure • Form • Training • Charter • Roles, responsibilities, authority, accountability (R2A2)	• Sr. Line Manager (or designee) • SME • RMC representative • Working Group • User group • Lab standing committee	Sr. Line Manager (or designee) [C, D, E]

Note 1: Each document must be reviewed by at least 2 groups or persons who are not the Author.

Note 2: This column shows possible approvers. Approvals are graded and based on (a) type of change [Major, minor, editorial – see table in Section 3.2.1], and (b) if major, Significance Rating [A, B, C, D E- see Appendix B, extracted from document 04.04.001.206]. The assigned person may designate, preferably on a case-by-case basis, an alternate to review or approve.

Note 3: "Plan Description" refers to those few and select cases in which the DOE Contract requirement explicitly uses the "plan" rather than "program". Otherwise, the LBNL adopted definition for "plan" is an implementation document that describes execution details (budget, resources, tasks) of a program or project and covers a fixed time span.

Appendix B – Significance Rating – *See 04.04.001.206 for most current version of the template*

Instructions: For each line, select a value (1,2,3). Sum up each column, then sum the sums and divide by the number of lines. The resulting Impact Total and Implementing Total should be between 1 and 3 (inclusive). Definitions for low, medium, high for Impact are in Appendix A. Definitions for low to high for Implementing can be a bit more subjective. Note that the complexity/cost of Implementing Mechanisms is likely to scale with number of people impacted.

a		**Brief description of what is being analyzed:**			
		Value	**1**	**2**	**3**
b	**Impact**	# Policy Area(s)	☐ 1		☐ > 1
		# of people	☐ < 100	☐ 100 to 1000	☐ > 1000
	(see Table	Risk area (safety)	☐ Low	☐ Medium	☐ High
	for definitions)	Risk area (business)	☐ Low	☐ Medium	☐ High
		Risk area (compliance)	☐ Low	☐ Medium	☐ High
		Sums (# checks times Value):			
		Impact Total (sum total divided by 5)			
c	**Implementing Mechanisms**	Documents (number)	☐ Small (1-2)	☐ Medium (2-4)	☐ Large (>4)
		Documents (complexity)	☐ Easy (< 10 hr)	☐ Modest (<30 hr)	☐ Complex (>30 hr)
		Training	☐ Easy (dept)	☐ Modest	☐ Complex
		Resources, roles	☐ Small change	☐ Modest addition to existing	☐ Substantially different, new hires
		Property/equipment	☐ Small cost (< $10K)	☐ Modest cost (<$100K)	☐ High cost (>$100K)
		Communication	☐ Easy	☐ Modest	☐ Complex (pamphlets, multiple announcements over several months, etc.)
		Testing	☐ None	☐ Beta	☐ Alpha, Beta, Pilot
		Program	☐ No change	☐ Modest change	☐ Form new
		Sums (# checks times Value):			
		Implementing Total (sum total divided by 8)			
		Enter SIGNIFICANCE RATING *(use Figure 1 and Impact and Implementing Totals. Round up for fractions greater than or equal to 0.5. Round down for fractions less than 0.5)*			

Using the resulting Significance Rating, determine Approval Levels from Table 1 and Minimum Required Program Elements from Table 2.

FIGURE 1: Significance Rating

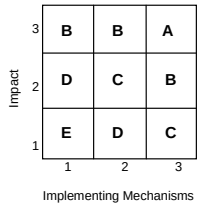


TABLE 1: Approvals:

Significance Rating	Approval
A	Lab Director (or designee)
B	COO (or designee)
C, D	Sr. Line Manager(s)
E	Sr. Line Manager (or designee)

TABLE 2: Minimum Required Program Elements

Significance Rating	Minimum Required Program Elements of a Management System
D, E	• Document gap analysis and comparison to current implementation methods • Select approach with input from users • Develop communications approach • Draft program/policy change for review • User review/input as needed
C	• Document gap analysis and comparison to current implementation methods • Benchmark (telephone calls and e-mails may suffice) • Select approach with input from users • Develop communications approach • Develop cost-benefit analysis • User/Lab Institutional Committee input* (consider an early committee briefing as appropriate) • Consider test period prior to full implementation (pilot testing) • Prepare implementation approach
A, B	• Document regulatory analysis and comparison to current implementation methods • Develop communications approach • Early briefing of Lab Institutional Committee* (for example, SAC) on new or changed requirement • Additional briefings to line management and users (as needed) • Benchmark (up to site visits) • User participation on development of approaches, evaluation of alternatives, and selection of final approach to implementation • Develop cost-benefit analysis • Develop detailed implementation approach • Run both an alpha test and beta test before implementation

*Lab Institutional Committee – for example, Laboratory Safety Advisory Committee (SAC)

Appendix C: Example of Document Tree/Taxonomy Hierarchy