



Procedure: Analyzing Requirements and Determining Significance Rating from Impact and Risk Analysis

1. Purpose:

This procedure in combination with the associated form 04.04.001.201 leads an analyst through the steps of interpreting, evaluating impact, and addressing a Laboratory policy or a Contract or regulatory requirement. The results of these steps can be quantified in terms of impact and implementing mechanisms ratings. These ratings can then be used to determine significance levels to set approval levels. A completed form can serve as record of completion of the analysis, and may be submitted as support for a record of decision (ROD) for the particular requirement being analyzed.

2. Applicability – Who this is for

This procedure encompasses requirements accepted or generated by the Laboratory, including newly accepted or generated requirements, requirements that are to be retired or are under consideration for retirement, and requirements that have been modified. Laboratory generated requirements usually are Laboratory or divisional policies. Persons analyzing requirements include Requirements Management Committee (RMC) members, members of other institutional committees (such as the Safety Advisory Committee), and Subject Matter Experts (SME), who in turn may draw on the assistance of others for inputs.

This procedure may be applied in the analysis of potential requirements (for example, those not yet accepted into DOE Contract 31), and its associated form (04.04.001.201) may be a helpful tool to assess impact of potential requirements.

2.1 Exceptions:

None

3. Prerequisites

Persons analyzing requirements or policies and their risk and impact on the Laboratory are expected to have a working knowledge of the LBNL Requirements Management Process (document number 04.04.001.003) and have expertise in their particular Policy Area with knowledge of the driving source requirements and knowledge of how the Laboratory operates.

4. 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. The contract includes applicable federal, state, and local

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Term	Definition
	regulations and requirements.
Deliverable	Any measurable, tangible, verifiable outcome, product, result, or item that must be produced to satisfy a requirement under the terms of an agreement, contract, or implementing mechanism. These include but are not limited to reports, plans, inventories, inspections, assessments, documents, procedures, programs, data, etc. A requirement specifies a deliverable, and therefore a deliverable is subject to requirements management practices.
Impact analysis	Detailed examination of the pros or cons that an action or requirement may have in light of its possible consequences (risks), or the extent and nature of change that it may cause.
Implementing mechanisms	A means to implement a policy or requirement, such as a document, training, program, communication or notification, role, and so forth.
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	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 more than one function, and a primary functional owner is therefore assigned. The wiki-RPM (PUB 201) has the most current policy area listing.
Record of Decision	Also known as ROD, a written record of a decision made regarding a requirement, policy, an institutional document, or regarding the implementation mechanisms or plan regarding a requirement, policy, or institutional document.
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: 10 CFR 851, Worker Safety and Health Program, LBNL Travel and Expense Policy, DOE Contract 31, Section (Clause) H.18, Application of DOE Contractor Requirements Documents

4.1 Acronyms

IA	Impact Analysis
RM	Requirements Management
RM PM	Requirements Management Program Manager
RMC	Requirements Management Committee
ROD	Record of Decision
SRD	Source Requirements Document
SME	Subject Matter Expert

5. 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
Requirements Management Committee (RMC)	<ul style="list-style-type: none"> • Provides centralized coordination and communications on Contract 31 requirements and related Lab policy matters. • Reviews and oversees disposition of Requirements Review Cases related to requirements, Laboratory policies, and on a case-by-case basis Laboratory implementing documents. • 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 work products (analyses, implementation plans, policies) by Working Groups (WG) and SMEs. • Reviews analyses and plans lead to practical (cost, breadth of impact, simplicity, etc.) implementation. • Reviews for evidence that risk analysis and problem solving techniques and best practices have been applied. • Advises responsible Sr. Line Manager on WG /SME work products. • Reviews communications plan to ensure effectiveness and thoroughness.
Requirements Management Program Manager (RM PM)	<ul style="list-style-type: none"> • Overall, manages the Laboratory's requirements management and institutional document management processes. Has author/review/recommendation responsibilities for quality and completeness of RM process and institutional document management process documentation. Oversees management of Laboratory's policy manual. Maintains the Requirements Management (RM) database. • For this process, coordinates inputs from RMC members, Working Groups, and the responsible Sr. Line Manager. Participates on the RMC to ensure quality, accuracy, efficiency and effectiveness of recommendations generated by the Working Groups, and guides resolution of issues or conflicts related to Laboratory policy or document matters at the lowest levels possible.
Sr. Line Manager	<ul style="list-style-type: none"> • 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 responsibility and authority to define and implement changes in policies, programs, procedures, etc. resulting from changes to Contract 31, UC requirements, and to applicable federal, state, local laws and regulations, as well as any direction provided by supplementary letters or memos from DOE or UCOP. • Has ownership and accountability for the technical content, accuracy and completeness of respective Function's documents. Approves institutional documents upon completion of required reviews. Ensures compliance with LBNL requirements and document management policies and procedures. • For this process, <ul style="list-style-type: none"> • Appoints WG members, SMEs, Document Authors. • Communicates to the RM PM and RMC objectives and general guidance

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Role	Responsibilities
	<p>on implementation for the requirement, policy or program under question.</p> <ul style="list-style-type: none"> Reviews and gives feedback on the analysis and recommendations by a Working Group and the RMC.
Subject Matter Expert (SME)	<ul style="list-style-type: none"> 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. Has ownership and accountability for the technical content, accuracy, and completeness of policy area documents. For this process, <ul style="list-style-type: none"> Leads Working Group in the identification and translation of requirements. Leads Working Group in the impact and risk analysis, and completion of recommendations (no further action, create an implementation plan, etc.) Communicates progress, actions and/or assignments to the RMC and respective Division Sr. Line Manager on regular basis. Drives for timely completion of case assignments.
Working Group (WG)	<ul style="list-style-type: none"> Under leadership of a SME/RMC member, performs detailed requirements analyses. Make recommendations in a timely fashion to the RMC, RM PM, Sr. Line Manager, and if applicable, the WG's sponsoring standing committee.

6. Procedure

Step	Role	Action	
1	RM PM/RMC/Sr. Line Mgr /SME	Determines need to analyze a requirement or policy	
2	Line Manager	Assigns Subject Matter Expert.	
3	RM PM	Logs info into database	
4	SME	Complete analysis of requirements per Guidelines (Appendix B), and assessment of risk and impact and determination of significance rating per instructions and forms (04.04.001.201 and 04.04.001.206)	
5	SME	Submits completed analysis and recommendations to RMC representative	
6	RMC rep/RM PM	Reviews PAM/WG analysis and recommendations	
7	RMC representative	If...	
		Then....	
		Analysis acceptable	Recommend approval by Sr. Line Manager(s). Go to Step 8
		Analysis is not acceptable	Return to Step 4 with guidance
8	Sr. Line Manager	Reviews and provides feedback	
9	RM PM	Updates database.	

7. References

7.1 Source Requirements Documents	
Requirement ID	Title
DOE Order 414.1D	Quality Assurance
PUB 3111	LBNL Operations and Quality Management Plan
04.03.001.000	LBNL Quality Assurance Policy
04.04.001.003	LBNL Requirements Management Process Description

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04.04.001.101-1.0

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The official or current version is located in the repository for Institutional Documents, accessible via OCA's website and/or the RPM. Printed or electronically transmitted copies are not official. Users are responsible for working with the latest approved revision.

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7.1 Source Requirements Documents	
04.04.001.000	<i>LBNL Requirements Management Policy</i>
04.03.001.001	<i>LBNL Risk Severity Guidelines (latest version)</i>
07.01.001.002	<i>ES&H Manual, Chapter 1, ES&H Requirements, Responsibilities, and Work Practices; Work Process A - Developing or Revising ES&H Policies and Programs</i>

7.2 Related Implementing Documents		
Document Number	Title	Type
04.04.001.201	<i>Analyzing Requirements</i>	Form
04.04.001.206	<i>Significance Rating</i>	Form
04.04.001.209	<i>ROD and Impact Analysis for C31 Changes</i>	Form

7.3 Other Documents (if any)	
Document Number	Title
PUB - 201	LBNL Requirements and Policy Manual (RPM)
04.04.001.300	<i>Processes during Pre-Adoption of LBNL Requirements</i>
04.04.001.301	<i>Procedure: Impact Analysis for Proposed Contract 31 Changes</i>

8. Contact

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

9. Revision history

Date	Revision	By whom	Revision Description	Section affected
12/1/10	0.0	L.Young	Initial	
2/9/11	0.1	L.Young	Organize into a procedure	All
3/2/11	0.2	L.Young	Add JC comments, expand, add copy form	All
9/28/11	0.3	L.Young	Update form to include B. Wells' inputs	
10/25/11	0.4	L.Young	Clean up process, definitions. Appendix A dollar amounts updated	All
12/12/11	0.5	L.Young	Prepare for signoff and pre-release to OCA web	
8/5/2014	1.0	L. Young	Review, align with current practice. Cross-ref to Lab Risk Severity Guidelines	Sections 5, 6, 7

APPENDIX A: Impacts and Risk Levels

[Note: Adopted from LBNL Risk Severity Guidelines 04.03.001.001. See latest version for most current dollar limits

Risk Value	Risk Level	Risk of Injury, Death or Environmental Impact	Property, Financial, Legal, Reputation, and Other Impacts	Requirements Compliance
3	High	<ul style="list-style-type: none"> Significantly impacts the safety of LBNL <ul style="list-style-type: none"> Injuries/illnesses involving permanent total disability, chronic or irreversible illness, or death Presents a significant hazard to the safety and health of workers, environment or public <ul style="list-style-type: none"> Exposures above regulatory limits Environmental release off site or above regulatory limits Requires immediate notification to external regulatory agencies 	<ul style="list-style-type: none"> Significantly impacts LBNL research activities and/or operations <ul style="list-style-type: none"> Extended facility shutdown or operational restrictions Significant loss or damage to property (physical or intellectual) <ul style="list-style-type: none"> Results in losses of \geq \$1M Results in excess cost due to inefficiencies \geq \$1M Significant potential for litigation or civil penalty Prevents UC from maintaining its contract with DOE to operate LBNL Results in considerable negative publicity or public opinion* 	<ul style="list-style-type: none"> Results in fines levied by external regulatory agencies Results in systemic noncompliance with regulations or contract requirements), and risks analyzed are deemed medium to high. Controls in place to keep risks minimal. Agreement by Lab Director.
2	Medium	<ul style="list-style-type: none"> Impacts the safety of LBNL <ul style="list-style-type: none"> Injury/illness resulting in hospitalization or temporary, reversible illnesses with a period of disability not in excess of 3 months Presents a hazard to the safety and health of workers, environment or public <ul style="list-style-type: none"> Exposures near regulatory limits Minor environmental release outside of building but on site Major release within building Requires notification to external regulatory agencies 	<ul style="list-style-type: none"> Impacts LBNL research activities and/or operations <ul style="list-style-type: none"> Short-term facility shutdown or operational restrictions Some loss or damage to property (physical or intellectual) <ul style="list-style-type: none"> Results in losses of \geq \$25K up to \$1M Results in excess cost due to inefficiencies of \geq\$100K up to \$1M Major potential for litigation or civil penalty Results in negative publicity or public opinion*. 	<ul style="list-style-type: none"> Results in systemic noncompliance with regulations or contract requirements, and risks analyzed and deemed low. Controls in place to keep risks minimal. Agreement by Sr. Management.
1	Low	<ul style="list-style-type: none"> Results in minor or negligible impact to the safety of LBNL <ul style="list-style-type: none"> Injury/illness not resulting in hospitalization Minor hazardous material release within building 	<ul style="list-style-type: none"> Results in minor or negligible impact to LBNL research activities and/or operations Little to no loss or damage to property (physical or intellectual) <ul style="list-style-type: none"> Results in losses of $<$ \$25K Results in excess cost due to inefficiencies of $<$ \$100K Little potential for litigation or civil penalty Little or no impact on perception of LBNL and UC* 	<ul style="list-style-type: none"> Results in compliance, or in a noncompliance with regulations or contract requirements with minor or negligible impact to LBNL

*For example, reputation, stakeholder/community confidence, or staff confidence.

APPENDIX B: Guidelines for Analyzing a Requirement

The following is to be used in conjunction with *Form: Analyzing Requirements and Determining Risks and Impacts*, document number 04.04.001.201; and with *Form: ROD and Impact Analysis for C31 Changes*, #04.04.001.209.

The main result of the analysis is a statement summarizing the requirement as it relates to Berkeley Lab.

Guideline 1: Examine what is being asked for.

- *Make sure it is applicable to Berkeley Lab!* If the requirement is a DOE Order, be sure to check the Applicability section to make sure the Order is applicable to LBNL. Then, focus on the Contractor Requirements Document (CRD), and not the main body of the Order.
- *Is this requirement mandatory?* Distinguish between “shall”, “must” vs “should”, “may”. Some aspects of the requirement may be mandatory, others may not be mandatory.
 - Comment: Complexity and cost of implementing mechanisms usually increase when the requirement (or aspects of the requirement) is mandatory. Over-compliance may result if “shall” is substituted for the stated “should”.
- Identify the conditions, constraints, etc. Must they all be met? Or only a subset?
- Be careful to interpret within full context of the subject matter of the source requirement document. A list of itemized paragraphs or sub-paragraphs may have a preamble that establishes the context of the particular list. For example, a preamble might say “the following are required...” or it could say, “the following are exceptions...” and these very different preambles will lead to very different interpretations of each of the paragraphs that follow.

Guideline 2: Extract and review “what” statements

- Look for what it is that is necessary and must be accomplished, produced or provided.
- Seek whether the requirement is attainable and verifiable. Specifically, will we be able to prove that we have met the requirement?
- Examples of “what”:
 - The contractor shall preserve the accident scene and assist the DOE Accident Investigation Team as required... (DOE O 225.1A, *Accident Investigations*)
 - Each facility/site must install a renewable energy project or show that renewable energy is not feasible... (DOE O 430.2B, *Departmental Energy and Utilities Management*)

Guideline 3: Determine whether there are specific deliverables

- Deliverables are work products or outputs resulting from addressing a requirement that are provided to the contracting agency as demonstration of compliance to the requirement. They offer the Lab’s proof that the requirement is being met.
- Note whether a system has to be established in order to meet the requirement and deliverable. For example, “the contractor shall track...” typically implies data collection, which in turn may mean development of a data collection and reporting tool. These would need to be considered in assessing the risks of implementation.
- Indicate what the specific deliverable is (program, report, document, data, etc.), frequency of delivery (once, annual, quarterly, etc.), by whom (which function(s)?), and so forth.
- Example:
 - The Contractor shall submit an update to its diversity Plan annually or with its annual fee proposal. (Contract31, Clause I.89, DEAR 970.5226-1 Diversity Plan (Dec 2000))

Guideline 4: Extract and review “how” statements (“how” the requirement is to be accomplished...usually non-binding)

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- Determine whether the requirement is directing how to achieve compliance or whether the Lab has options in how it ensures the requirement is met.
 - Comment: Considerations on how to accomplish the requirement drive the selection of implementation mechanisms and therefore determine costs, resources, and so forth.
- Be careful to distinguish the “what” from the “how”, which often include “should” wording. (Review Guideline #1 again!)
- Examples of “how”:
 - Implementation of System Engineer Program requirements should be tailored to facility hazards... (DOE O 420.1B, *Facility Safety*)
 - Electronic systems, such as instant messaging, that are not regularly backed up and controlled should not be used... (DOE O 243.1, *Records Management Program*)

Guideline 5: Examine and review “other” statements (usually goals, facts, or statements of compliance).

- In particular, look for and extract embedded references that fall under “what”, and may require compliance. These embedded references will need additional review.
- Statements that are goals or facts may not require action.
- Examples:
 - Compliance: The contractor must meet the requirements of 10 CFR Part 433... (embedded in DOE O 430.2B).
 - Goal: Projects must be in the forefront areas of science and technology... (DOE O 430.2B, *Departmental Energy and Utilities Management*)
 - Fact: STI is produced in various media - e.g., textual, audiovisual, multimedia, and digital - and is disseminated as technical reports; conference papers and presentations; journal articles; theses and dissertations; patents; scientific and technical software; *etc.* The majority of DOE-funded STI is publicly releasable, with a small percentage requiring restricted access. (DOE 241.1B, *Scientific and Technical Information Management*).