Graded Approach Procedure

Office of Quality and Best Practices
Fermi National Accelerator Laboratory
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1.0 PURPOSE

The purpose of the graded approach is to guide the selection of controls to be applied to activities which pose the greatest risk for significant negative impact on quality. This focuses management attention on activities which require the most control and oversight and reduces costs by minimizing the application of controls in areas of low risk.

2.0 SCOPE

The graded approach process is part of Fermilab's Integrated Quality Assurance program (IQA). Like Integrated Safety Management, Integrated Quality Assurance is based on the principle that the people best suited to understand risks are the ones who plan and perform the work. Like hazard analysis under ISM, the graded approach procedure is an evaluation of activities. It describes an incremental process which guides the user in determining the quality controls suitable for managing the activity.

3.0 APPLICABILITY

The application of this process depends on the mission of the organization performing the evaluation. It is intended to be implemented at all levels throughout the laboratory. For example, the Directorate will review the activities associated with the goals defined in the prime contract, while the Computing Division will review the activities associated with cyber-security.

The graded approach process is intended to:

- Identify activities which present significant quality risk,
- Determine the risks and necessary controls, and
- Document the determination

Laboratory-wide requirements described in the Fermilab Integrated Quality Management Program specify a minimum level of quality controls that all activities must satisfy. This prevents any activity from being "graded to zero".

4.0 RESPONSIBILITIES

LABORATORY DIRECTOR
Holds senior managers accountable for implementation of, and compliance with, this procedure, and ensures that adequate resources are provided.

DIRECTORATE
The Directorate is responsible for ensuring that the graded approach is applied to laboratory-wide activities.

OFFICE OF QUALITY AND BEST PRACTICES
The Head of the Office of Quality and Best Practices (OQBP) authorizes this document by signature. This document is reviewed every three years. OQBP also assures that Fermilab assessments review compliance with this procedure and the effectiveness of its implementation.

PROGRAMS, DIVISIONS, SECTIONS AND CENTERS
Associate laboratory directors and the heads of each program and division/section/center are responsible for applying the graded approach to activities under their control. They provide the necessary resources as appropriate to implement and maintain the graded approach process.

Division/section/center Quality Assurance Representatives (QARs) are responsible for coordinating and providing advice on implementation and maintenance of the graded approach to activities while avoiding any unnecessary duplication of documentation or effort.

PROCESS OWNERS
Owners of Fermilab processes (managers/supervisors/engineers/spokespersons) are responsible for ensuring that the graded approach procedure is applied to activities under their control.

5.0 PROCEDURE

The graded approach procedure allows managers to identify activities which present significant quality risk, determine the risks and necessary controls, and document the determination. Fermilab is developing an electronic, web based [Graded Approach Tool] which guides users through the correct steps and provides electronic documentation when applying this procedure to activities.

> NOTE: Some activities are unique to a division/section/center and will be evaluated and controlled by the responsible division/section/center. Other programmatic activities are cross-cutting across divisions/sections/centers. Where activities are cross-cutting it is the responsibility of the process owner to include the head of each affected division/section/center in the overall review and in selection of controls applied.

PROCEDURE STEPS

1. Activity Identification – identify those activities that present significant quality risk
2. Definition of the Steps of the Activity – understand the activity
3. Risk Evaluation and Control Choice – identify potential failures, develop controls to manage them
    1. Evaluate the current state of the activity and controls
    2. Describe the desired state of the activity and controls
4. Documentation of the Results of Steps B and C
5. Approval of the Results of the Graded Approach Process

5.1. ACTIVITY IDENTIFICATION

Using the following selection criteria identify those activities that present significant quality risk. Whenever an item or service is deliverable to an outside organization, the evaluation is performed from the client's point of view. Activities which meet any of these criteria are required to go through steps 1 to 5 of the graded approach process. Activities which do not satisfy the selection criteria, while omitting steps 1 to 5, must still conform to standard laboratory-wide quality controls as shown in Table 1.

- Major processes identified on lists of processes defined by each laboratory organization
- Reasonable likelihood of a 3 month delay (or 2 months for projects with duration less than 9 months) of the laboratory schedule
- Total project cost greater than $500K
- Reasonable likelihood of an occurrence, or repetitive occurrences, with cost impact greater than $100K
- Safety or environmental hazards, liabilities or risks greater than those generally accepted in an industrial environment
- Reasonable likelihood of a significant reduction in the public trust or scientific reputation
- Judgment of line management

5.2. DEFINITION OF THE STEPS OF THE ACTIVITY

- Consider goals of the activities, inputs, outputs, operating constraints, and interactions
- Consider using subject matter experts
- When an activity involves other organizations, consult with individuals from those organizations

5.3. RISK EVALUATION AND CONTROL CHOICE

This step provides process owners and QARs with methods for identifying potential failures, with an aim of applying the quality controls to manage the potential failures. As used herein risk refers to potential negative impact on expected outcomes such as cost, schedule, safety and reputation.

After activities have been identified and selection criteria applied, users open the web-based [Graded Approach tool], and are guided through each step of this procedure from A to E. By reinforcing the steps required throughout the process and the use of tables 1 and 2 in this procedure, the tool allows users to associate activities and risks directly with quality controls identified in the IQA.

Evaluate the Current State of the Activity and Controls
Determine the risks associated with the activity, which controls (including ES&H) are already in place, their adequacy and effectiveness for the specific risk being evaluated, and identify any remaining risk. A risk is not considered to be mitigated if the likelihood of a negative outcome, as identified in the selection criteria, is more frequent than once per year or the consequence of the occurrence is untenable (e.g., causes shutdown of major processes or experiments, impacts major programs at a value of over $XX (variable dollar amount depending on the program affected), harms the environment, approaches or exceeds operational limitations, etc.). This likelihood frequency does not supersede frequencies defined in other requirements documents (e.g. FESHM).

To assist in determining the remaining risk:

- For all risks evaluate the ways things can go wrong
- For project schedule delays consider using critical path analysis
- For operational delays consider performing a schedule contingency analysis
- For costs consider a detailed cost and contingency analysis

- Consider idea-generating tools such as failure modes and effects analysis, flowcharts, lists, cause and effect diagrams
- Consider available information such as published standards, data and/or methods; previous experience; previous risk analysis, and subject matter experts

Describe the Desired State of the Activity and Controls

- Considering the potential impacts and perceived likelihoods of the remaining risks identified above, choose one or more risk management strategies to address those risks (See Appendix 1):

Tolerate - accept the risk without additional controls
Terminate – eliminate the risk by modifying or not performing the activity
Treat - apply different and/or additional controls

When choosing a risk management strategy:

- Consider the expected lifetime of the activity
- Consider other activities that may be affected

- For those risks where the management strategy is to apply additional controls, or to modify / change the existing controls, develop them to mitigate the risk along with the means to monitor and determine their effectiveness. If the risk evaluation has not already done so, document and describe how the new / amended control is expected to reduce the impact and/or likelihood of negative outcomes to a level acceptable to management. For each risk, determine which QA criteria are applicable to that risk. For those applicable QA criteria, all topics listed in Table 2 relevant to the risk being treated must be addressed.

- It is expected that the QAR participates in the risk evaluation or reviews the output, and ensures that the QA controls identified in Table 1 and the areas which are required to be addressed in Table 2 are adequately addressed.

5.4. DOCUMENTING THE RESULTS OF THE GRADED APPROACH PROCESS

The purpose of documenting the results of the process is to communicate that risks have been adequately considered and addressed, and to share what has been learned with the laboratory.

The primary focus of the documentation should be on the controls which are currently not in place, while providing a minimal record of the identified risks, the existing controls and their adequacy of assuring quality.

Graded approach documentation ***is not*** required for activities which do not meet the selection criteria thresholds. However, when a process is reviewed and it is determined that it is not necessary to apply the graded approach a record of the review is kept.

Documentation ***is*** required for each activity which does meet any of the selection criteria thresholds. The results of the graded approach process are required to be documented electronically using the web-based [Graded Approach Tool] and made available to the laboratory.

These documents will be reviewed by the QAR team and OQBP to ensure consistency across the laboratory.

All activities evaluated using this procedure fall into one of the three following categories:

1. Activities with existing controls which adequately address the quality risks. Documentation for these activities provides a record of assurance.

2. Activities where mandatory baseline controls are not adequately implemented. Documentation for these activities provides a record of necessary actions to be taken.

3. Activities which require additional controls or modifications beyond the mandatory baseline controls to address the risks identified. Documentation of these activities provides a record of actions planned to mitigate remaining risks (not adequately addressed by existing controls).

5.5. APPROVAL OF THE RESULTS OF THE GRADED APPROACH PROCESS

The final choice of risk management strategies and controls must be reviewed and approved by line management and OQBP prior to implementation of the new / additional / changed controls. Upon approval the final results are subject to revision control.

6.0 RECORDS

Completed graded approach tool

7.0 REVIEW CYCLE

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

7.1. OWNER

OQBP QA Manager

7.2. REVIEWERS

OQBP Head
Division/section/center QARs

7.3. APPROVERS

OQBP Head

8.0 POLICY AND PROGRAM DOCUMENTS

Director's Policy 10 Quality Assurance
1001 Fermilab Integrated Quality Management Program
Fermilab Environment, Safety and Health Manual
3901 Fermilab Integrated Contractor Assurance Program
[Graded Approach Tool]

9.0 DEFINITIONS

Graded Approach – The identification of activities that present significant quality risk, defining those activities, evaluating risk and control choice, documenting and approving the application of the controls..

10.0 REFERENCES

N/A

11.0 TABLES

TABLE 1 - BASELINE REQUIREMENTS

Definition: Items with Formal Policy & Procedure, including the IQA, that apply to all activities.

QA Criteria	Baseline Requirements
Program	Laboratory Director's Policy #10
	Organization Chart
	Defined levels of responsibility
	Graded Approach Procedure
	FESHM
	[Integrated Contractor Assurance Program]
	Advisory Committees & Councils
	[Project Management Procedure]
	Applicable Laws & Regulations
Training & Qualification	Laboratory Director's Policy #19
	WDRS Policies & Procedures
	Qualification & Training
	Position/Job Description
	Institutional Training
	Site/Specific Training
	Training - FESHM 4010
	Work Planning and Hazard Analysis - FESHM 2060
	ES&H Program for Construction – Fixed Price - FESHM 7010
	Subcontractor Safety Other Than Construction- FESHM 7020
	ITNA
	Medical Fitness – FESHM 5310
	Employee / Subcontractor Orientation
	TRAIN
	Administrative Controls Prior to Required Training IQA 2.2
Quality Improvement	Significant & Reportable Occurrences - FESHM 3010
	ES&H Assurance Program - FESHM 1040
	Process Improvement
	[Project Management Procedure]
	[Management Review Procedure]
	[Corrective Action / Preventive Action]
	[Root Cause Procedure]

QA Criteria	Baseline Requirements
Documents & Records	Laboratory Director's Policy #1, 13
	Document Control
	Records Management Policies and Procedures
Work Processes	Laboratory Director's Policy #5, #18, #36
	Work Environment - IQA 5.4.5
	Material Control
	Property & Inventory Control Policy & Procedures
	Maintenance - IQA 5.4.2
	All Personnel Responsible for the Quality of Their Work - IQA 5.2.2
Design	Laboratory Director's Policy #8
	Work Smart Standards - FESHM 1070
	Fermilab Design & Engineering Manual [FDEPM]
Procurement	Laboratory Director's Policy #6
	Procurement Policies and Procedures Manual
	ES&H and National Environmental Policy Act (NEPA) - FESHM 5010
Inspection & Acceptance Testing	Significant & Reportable Occurrences - FESHM 3010
	Inspection & Acceptance Test [Corrective Action / Preventive Action] Control of Nonconforming Materials
Assessments	Laboratory Director's Policy #20
	ES&H Self Assessment Program - FESHM 1040.1
	[Fermilab Assessments Manual]
	[Corrective / Preventive Action]
S/CI	Laboratory Director's Policy #10
	Suspect/Counterfeit Items Program
	Significant & Reportable Occurrences - FESHM 3010
Scientific Research	[Director's Policy # on Research]
	[Quality Guidelines for Scientific Research]

TABLE 2 – TOPICS REQUIRED TO BE ADDRESSED FOR EACH RISK UNDER REVIEW BASED ON APPLICABILITY AND RELEVANCE PER SECTION C 2

QA Criteria	Required Topics to Address
Program	
Training & Qualification	Project, Task Specific Training IQA 2.1
	Documentation &/or Testing
	Continued Training IQA 2.3
Quality Improvement	Plan - Verifiable Quality Objectives
	Measure - Management Review, Documentation of Deficiencies & Opportunities for Improvement
	Analyze, Improve - Formal Corrective, Preventive Actions
	Report significant issues
Documents & Records	Control by Formal Versioning, Approval, Tracking Revision History
	Access control
Work Processes	Written Procedures
	Monitoring, Assessing Performance
	Formal Item Control
	Preventative & Predictive Maintenance
	Readiness Reviews
	Calibration of Process Equipment
Design	Iterative design
	Documented, Approved Requirements
	Establish Baseline
	Design Review
	Verification & Validation
	Change Control
	Documented Design Basis
	Configuration Management
Procurement	Supplier Performance
	Supplier Corrective Action
	Formal Vendor Qualification
	Acceptance Criteria
	Certification Requirements

QA Criteria	Required Topics to Address
Inspection & Acceptance Testing	Control of M&TE
	Documented Inspection & Acceptance Test Results
	Identify Item Inspection/Test Status
	Documented Inspection & Acceptance Plans
	Degree of Independence Required
	Considered During Design
Assessments	Div/Sec/Center Formal Assessment Plan
	Results Identify Deficiencies & Opportunities for Improvement
	Corrective, Preventive Actions Are Tracked to Closure
	Effectiveness of Corrective, Preventive Actions
	Qualifications of Assessors
S/CI	
Scientific Research	

APPENDIX 1 – RISK MANAGEMENT STRATEGIES

Risks are about events that, when triggered, cause problems. Usually once risks have been identified, they are evaluated as to their potential severity of impact and to the probability of occurrence. When these quantities are not simple to determine, it is important to make the best estimate possible. In ideal risk management, a prioritization process is followed whereby the risks with the greatest impact and the greatest probability of occurring are handled first, and risks with lower probability of occurrence and lower impact are handled in descending order. In practice the process can be very difficult, and balancing between risks with a high probability of occurrence but lower loss versus a risk with high loss but lower probability of occurrence can often be mishandled. The objective of risk management is to eliminate or reduce different risks related to a preselected domain to an acceptable level.

Tolerate:

Risk retention (or toleration) means accepting the possible consequences of not applying controls. This may be a viable strategy for small risks where the cost of mitigating the risk would be greater over time than the total losses sustained or where the likelihood of the negative outcome is considered sufficiently low. This may also apply to high risks where there is no feasible way of mitigation due to cost, technology or other consideration. Risks that are not terminated or treated are tolerated by default.

Terminate:

Risk avoidance (or termination) includes either eliminate the risk by modifying the activity or not performing an activity that could carry risk. An example would be not flying to avoid the risk of being in an airplane that is hijacked.

Treat:

Risk reduction (or treatment) involves methods that reduce the impact or likelihood of a negative outcome by applying additional controls. Examples include sprinklers or more expensive fire suppression systems designed to reduce the risk of loss in the event of a fire. Additional controls require a method to ensure that the chosen controls work as expected. Administrative checks, monitors or alarms may be used or, in the case of sprinklers, periodic functional tests may be required to ensure that they perform as expected.

Treatment options may include:

- Engineer a physical control or barrier
- Change the design of an activity, process or system to reduce dependence on human performance
- Add to an existing set of controls (An example might be adding a situation to an existing response plan)
- Change a procedure
- Use a new or different technology
- Add an administrative control (create a procedure, add an audit, etc.)
- Transfer the risk to another party (for example, outsource the activity to others)

Some ways of managing risk with high impact or high likelihood (or both) involve the concept of employing multiple barriers to provide defense in depth. Therefore more than one strategy and treatment may be utilized to provide sufficient assurance against the risk

APPENDIX 2 – FORM
Graded Approach Form

TABLE OF REVISIONS

Author(s)	Description	Revision	Date
QDT	Draft with Formatting Updated Tables B1.1	000	04/09/08
Jed Heyes	Changed numbering to new scheme	000 B2	05/08/08
Jed Heyes	Updates based on comments form OQBP review. Added standard QA document structure to document	000 B3	07/12/08
Jed Heyes	Final review	000 B4	07/23/08
Jed Heyes	Removed watermark, Formatted tables, & Replaced FIQMP with IQA	000 B5	10/01/08
Jed Heyes	Updated tables in appendix	000 B6	10/16/08
Jed Heyes	Added page numbers in footer	000 B7	10/21/08
Jed Heyes	Added requirements for research, Updated Policy # for S/CI	000 B8	10/22/08