QAM 12070: GRADED APPROACH PROCEDURE

Revision History

Author	Description of Change	Revision Date
Jemila Adetunji	Changes include: • a refinement of roles and responsibilities, and addition of 3.4 Fermilab Risk Officers; • clarification of definitions, program description, and procedure sections; • removal of approval requirement; • updates to references section.	January 2018
Kathy Zappia	Initial release of QAM chapter replaces OQBP Graded Approach Procedure 1002.1000 rev. 000.1 B10.	December 2013

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1.0 INTRODUCTION

The purpose of the graded approach is to guide the selection of the level of controls to be applied to activities which pose the greatest risk or significant negative impact on operations or laboratory reputation. 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 DEFINITIONS

Activities – This encompasses a wide range of work performed to meet the lab's mission, including but not limited to operations work, basic and applied research, software development, procurement, design, construction, modification, and decommissioning,

Grading -Selecting the controls and verifications to be applied to various items and activities consistent with their importance to safety, cost, schedule, and success of the program.

Risk - A fundamental consideration in determining the extent to which controls should be applied at the facility level.

3.0 RESPONSIBILITIES

3.1 Division/Section Heads and Project Managers (D/S/P)

D/S/P's are responsible for applying the graded approach to activities under their control. They provide the necessary resources to implement and maintain the graded approach process.

3.2 All Employees and Users

Process owners, managers, supervisors, scientists, and engineers are responsible for ensuring that the graded approach procedure is appropriately applied to their activities.

3.3 Quality Management System Owner

Ensures that this process is applied accordingly and this document maintained.

3.4 Fermilab Risk Officers

All Fermilab Risk Officers are responsible for ensuring that the graded approach procedure is applied to activities pertaining to the identification and management of risks in their areas.

4.0 PROGRAM DESCRIPTION

The graded approach process is part of Fermilab's Quality Assurance Program. The Program is based on the principle that the people best suited to identify, understand, and assess risks are the people who plan and perform the work. This chapter describes an incremental process which guides the user in determining the level of controls suitable for managing the risks posed by an activity.

The first step in the grading process is to identify the hazards, consequences, and probability of failures for the work being performed. The second step is to specify the requirements and controls to be applied. The third step is to determine the depth, extent, and degree of rigor necessary in the application of the requirements and controls. The final step is to communicate and implement the appropriate requirements

and controls. The necessary degree of rigor should be applied by means of documented work processes (procedures, instructions, specifications, and controls).

The application of this process depends on the mission of the organization performing the evaluation and is intended to be implemented at all levels. Each D/S/P has the freedom to tailor a grading scale that will fit their specific needs. Factors such as cost, schedule, environment, health, safety, quality, mission, public perception, and security shall be considered when grading quality requirements.

The graded approach process goals are to:

- Identify activities which present significant operational risks
- Determine the risk levels
- Determine the necessary controls and requirements to be applied
- Determine the depth, extent, and degree of rigor in the application of requirements
- Document and approve the determination

5.0 PROCEDURES

When using a graded approach, it should be noted that some activities identified are unique to D/S/P's and shall be evaluated by the responsible D/S/P, while other programmatic activities will cut across organizational lines. It is the responsibility of the process owner, in this case, to include the head (or designated representative) of each affected D/S/P in the review and selection of controls applied in cross-functional situations.

5.1 Identify Activity & Risk

Identify activities presenting a significant risk if proper controls are not in place. Examples include:

- Processes identified as critical
- Control failures that result in program downtime or a delay to the laboratory schedule
- Single point failures of equipment that may jeopardize project budgets or schedules
- Control failures that may compromise data quality or result in complete or partial loss of data
- Activities that can cause injuries, environmental hazards, liabilities, or risks greater than those generally accepted in a research environment
- Occurrences that could cause a significant reduction in the public trust or scientific reputation

NOTE: *Whenever an item or service is a deliverable to an outside organization, the evaluation shall be performed from the customer's point of view.*

5.2 Define Steps of Activity

Identify the activities that present a significant risk and all the steps involved in those activities that have been chosen. Ensure these activities are documented appropriately in accordance with Fermilab's Document Management & Control Policy. When understanding the chosen activities:

- Consider goals of the activities, inputs, outputs, operating constraints, and interactions.
- Consider utilizing subject matter experts.
- Consult with individuals from other organizations if an activity involves that organization.

5.3 Evaluate Current Risk

Evaluate the current state of the identified activity and controls that are already in place. Determine the known risks associated with each activity, adequacy and effectiveness of controls for each risk,

and identify any remaining risks. Factors such as cost, schedule, environment, health, safety, quality, mission, public perception, and security shall be considered when evaluating risks.

5.4 Assign Graded Risk Level

Risk Level for Activities

Assign a graded risk level to each activity based on the potential impact for the risks identified. Activities rated as higher risk/high impact will require a higher degree of control and risk management as opposed to activities rated as low risk/low impact. As stated above, factors such as cost, schedule, environment, health, quality, safety, mission, public perception, and security shall be considered when grading risk levels. Refer to QAM Chapter 12030 – iTrack Procedures and Risk Assignment.

Risk Level for Software Applications

In accordance to the QAM Chapter 12090, Software Quality Assurance Grading and Inventory Procedure, each D/S/P shall determine their own quality grade levels that best fit their needs for software applications they manage. For example, the Software Quality Assurance Program identifies 3 quality grade levels to grade software applications. Software is graded high, moderate, or low depending on the worst consequence if controls fail.

- High Risk – Consequences such as injury or death, environmental hazards, release of DOE sensitive information could occur.
- Moderate Risk – Consequences such as program downtime, or minor disruptions in laboratory operations could occur.
- Low Risk – Consequences such as reduction in data quality could occur.

Risk Level for Projects

Projects also identify risks associated with their Work Breakdown Structure and develop appropriate risk registers to apply to their tasks. In both cases, applications or operations graded as high risk would require more controls than those graded as low risk.

5.5 Select Risk Management Strategies & Identify Additional Controls

Select the risk management strategy that best fits the activity being evaluated and the grade level assigned to the activity.

Fermilab has several established methods to assist in determining appropriate controls and risk management strategies to implement. They include (but are not limited to) the following:

- Project risk plans for scientific research project teams – tools used include Primavera Risk Analysis and Risk Registers
- Risk plans used for ITIL (Information Technology Infrastructure Library) implementation and other Computing Sector projects
- Fermilab Engineering Manual – tools used include Risk Assessment Spreadsheet
- QAM Chapter 12030 used for risk management for ESH&Q – tools used include iTrack
- QAM Chapter 12003 – Software Quality Assurance Program
- FESHM Chapter 2060 - Work planning and hazard analysis
- Operational Readiness Clearances and Accelerator Readiness Reviews

Determine where controls are missing. Identify the controls that are necessary to close the gaps, and mitigate risk based on the quality level and risk management strategy selected. For example, the

Software Quality Assurance Program ensures proper controls are put in place depending on the quality grade level assigned to software applications. The output of this step shall be that adequate controls are chosen and risk management strategies identified to mitigate the risk of impact on quality regardless of the method or tools employed.

5.6 Documentation

The process for documenting the results from risk analysis should be defined by the Division, Section, Project, or Functional Area. Lessons learned (QAM 12010) should be shared with the laboratory, when appropriate.

6.0 REFERENCES

Fermilab Quality Assurance Program
QAM 12003: Software Quality Assurance Program
QAM 12010: Contractor Assurance/Lessons Learned Program and Procedures
QAM 12030: iTrack Procedures and Risk Assignment
QAM 12090: Software Quality Assurance Grading and Inventory Procedure
FESHM Chapter 2060 - Work planning and hazard analysis