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Contents: Graded Approach for Quality Requirements

Effective Date: April 2000

Point of Contact: [Quality Program Office Manager](#)

Section	Overview of Content (see section for full process)
Introduction 1.Application of the Graded Approach 2.Determination of Applicable Quality-related Activities Definitions	<ul style="list-style-type: none"> • Consider all appropriate issues/risks. • Select the appropriate graded approach. • Select applicable quality-related activities. • Incorporate the graded approach.
<p>Exhibits</p> <p>Application of the Graded Approach Flowchart Quality Activity Guide</p>	
<p>Forms</p> <p>None</p>	

Training Requirements and Reporting Obligations

This subject area does not contain training requirements.

This subject area may or may not contain reporting obligations. See the subject area until obligations are listed here.

References

[Calibration](#) Subject Area

[Corrective and Preventive Action](#) Subject Area

[Engineering Design](#) Subject Area

[Inspections and Acceptance](#) Subject Area

[Integrated Assessment Program](#) Subject Area

[Internal Controlled Documents](#) Subject Area

[Nonconformances, Identifying and Reporting](#) Subject Area

[Records Management](#) Subject Area

[Training and Qualification](#) Subject Area

[Work Planning and Control for Experiments and Operations](#) Subject Area

Standards of Performance

All staff and guests shall comply with applicable Laboratory policies, standards, and procedures, unless a formal variance is obtained.

The Laboratory's policies, standards, and Laboratory-wide procedures and guidelines are based on an evaluation of external requirements documents and applicable non-government standards, e.g., orders, directives, and federal, state, and local laws.

All staff and users shall identify, evaluate, and control hazards in order to ensure that work is conducted safely and in a manner that protects the environment and the public.

All staff shall clearly and completely specify appropriate requirements for purchased goods and services consistent with project needs.

All scientific and professional staff shall identify and control items and material affecting scientific results.

Management System

This subject area belongs to the **Quality Management** management system.

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Subject Area: *Graded Approach for Quality Requirements*

Introduction: Graded Approach for Quality Requirements

Effective Date: April 2000

Point of Contact: [Quality Program Office Manager](#)

This subject area is applicable to all Brookhaven National Laboratory (BNL) activities and items involving construction, operations, maintenance, and research, including the procurement of equipment for these activities. It may also be used in the development of new subject areas so a unified graded approach to quality may be implemented throughout BNL Management Systems, as applicable.

A graded approach to quality is used to place the most emphasis on and allocate proper resources to those items and/or processes that may have the greatest effect upon personnel, environment, safety, health, cost, data, equipment, performance, and schedule. See the [Application of the Graded Approach Flowchart](#) for a description of this process. The graded approach is a process for determining that the appropriate level of analysis, management controls, documentation, and necessary actions are commensurate with an item's or activity's potential to

- ✦ Create an environmental, safety, or health hazard;
- ✦ Incur a monetary loss due to damage, or to repair/rework/scrap costs;
- ✦ Reduce the availability of a facility or equipment;
- ✦ Adversely affect the program objective or degrade data quality;
- ✦ Unfavorably impact the public's perception of the BNL/DOE mission.

This subject area provides a methodology for establishing a level of analysis, documentation, and actions commensurate with the programmatic and/or ES&H impact. The scope of the quality-related activities is a function of its risks and programmatic issues. Quality classification designations, A1 (Critical); A2 (Major); A3 (Minor); and A4 (Negligible), may be used to aid in selecting applicable quality-related activities, as appropriate.

The graded approach does not allow internal or external requirements to be ignored or waived, but allows the degree of controls, verification, and documentation to be varied in meeting requirements based on ES&H risks and programmatic issues.

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Subject Area: *Graded Approach for Quality Requirements*

1. Application of the Graded Approach

Effective Date: **April 2000**

Point of Contact: [Quality Program Office Manager](#)

Applicability

This information applies to BNL staff during the development and design stages of, and procurement for, a project, program, experiment, study, process, or system. It may also be used during the development of a new Subject Area where a graded approach to Quality is applicable.

Note: If an activity is addressed in the [Work Planning and Control for Experiments and Operations](#) Subject Area, further action regarding this subject area is not required.

Required Procedure

Note: When the design of a project/process/system is split between two Departments/Divisions (e.g., between a user Department/Division/Project and Plant Engineering), the responsibility for applying the graded approach resides with the Department/Division, who is ultimately responsible for the process, system, assembly, or item.

Differences between the user and support Department/Division/Project personnel regarding the graded approach are resolved, if necessary, by the Department/Division.

Step 1	If an existing Laboratory-level document (e.g., subject area, ES&H Standard) provides a graded approach, go to Section 2 Determination of Applicable Quality-related Activities . If not, then proceed to step 2 of this section.
Step 2	Using the criteria in Screening Guidelines for Work Planning & Control and Application of the Quality Graded Approach , in the Work Planning and Control for Experiments and Operations Subject Area, consider the following when reviewing for the application of a graded approach: <ul style="list-style-type: none"> • The graded approach (e.g., Quality Classification) should be based on the programmatic and/or ES&H impact.

	<ul style="list-style-type: none"> ○ The classification assigned to a subsystem or process may be more significant than the classification assigned to the overall system, process or experiment (i.e., System = A-3 and Subsystem = A-2). Similarly, the classification assigned to the lower levels may be more significant than the preceding level, (i.e., Assembly = A- 3 and Subassembly = A-2). ● Although an attempt has been made to quantify the adverse impacts, judgement and adequate margins of safety must be considered when selecting a classification. ● Costs should include all expenses, e.g., replacement cost, cost of labor, downtime, cleaning (including decontamination), renovating, replacing, or rehabilitating structures, equipment, or property.
Step 3	After considering all appropriate issues/risks, select the appropriate graded approach.

References

[Work Planning and Control for Experiments and Operations](#) Subject Area

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Subject Area: *Graded Approach for Quality Requirements*

2. Determination of Applicable Quality-related Activities

Effective Date: April 2000

Point of Contact: [Quality Program Office Manager](#)

Applicability

This information applies to BNL staff, who select Quality-related activities in an effort to mitigate ES&H and Programmatic risks.

Required Procedure

Note: Differences between user and support Department/Division/Project personnel regarding Quality activities are resolved, if necessary, by the Department/Division/Project Management.

Step 1	Check the exhibit Quality Activity Guide , which describes potential quality-related activities for specific mitigation of ES&H/programmatic issues, to ensure that current systems address all activities that apply. If applicable activities are addressed, further action regarding this section is not required.
Step 2	Using the exhibit Quality Activity Guide , select those quality-related activities that are applicable to the subject area, item, process, or experiment.
Step 3	Incorporate the graded approach and associated activities into the subject area, project, experiment, study, process, or system, as appropriate.

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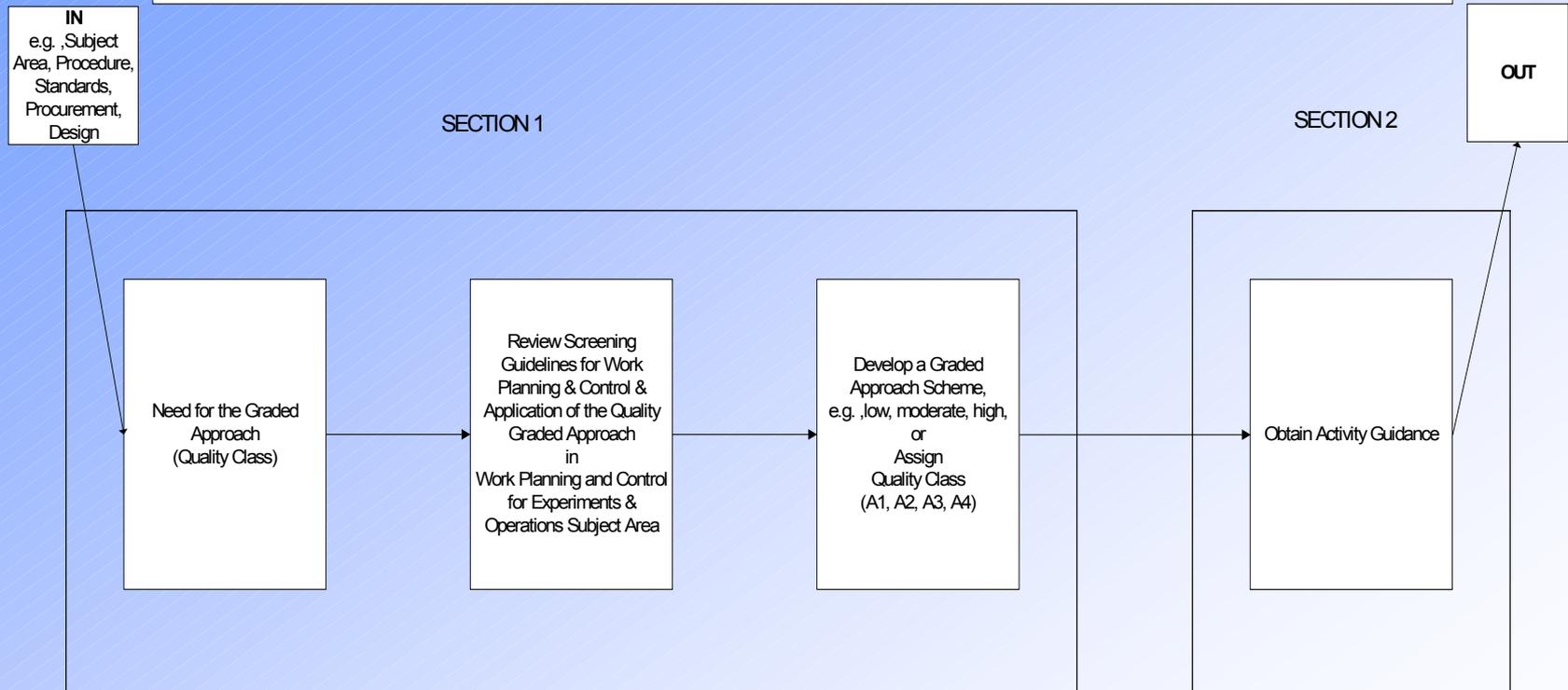
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Graded Approach

The Application of the Graded Approach (Quality Classification) and the Determination of Quality Related Activities





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Quality Activity Guide

Effective Date: **April 2000**Point of Contact: [Quality Program Office Manager](#)

Topic/Activity	References*
QA Program	
Develop Supplemental Quality Program where required by sponsor.	
Personnel Training and Qualifications	
Personnel Training (Select qualified personnel before work. Their training must be identified, completed, recorded, maintained, and reviewed before work).	Training and Qualifications Subject Area
Documents and Records	
Documents Identify documents considered necessary for meeting objectives, and for the safe conduct of operations of the facility/experiment, described processes, specify requirements, or established design.	Internal Controlled Documents Subject Area
Records Identify records documenting actions taken during an experiment/operation that have affected execution, milestones, or ESH&Q issues.	Records Management Subject Area
Work Process	
Prepare written instructions/standard operating procedures/technical-	Work Planning and Control for Experiments and

<p>operating procedures considered necessary for conducting the activity or experiment.</p>	<p>Operations Subject Area, Internal Controlled Documents Subject Area</p>
<p>Identify and control items that are considered necessary for meeting objectives and for safely conducting the activity or experiment to ensure their proper use.</p> <p>Identify and document special requirements for handling, cleaning, storage, and transport, as necessary.</p> <p>Maintain items to prevent their damage, loss, or deterioration.</p> <p>Identify, protect, and control material that has been identified as age-sensitive, and items subject to environmental deterioration.</p>	<p>Records Management Subject Area Work Planning and Control for Experiments and Operations Subject Area</p>
<p>Control of Measuring and Test Equipment Establish calibration procedures and frequency for equipment and devices considered necessary to meet the project's objectives and safe conduct of operations/experiments.</p>	<p>Calibration Subject Area</p>
<p>Computer Software Control, verify, and validate software critical to the project.</p>	<p>To be done</p>
<p>Control of Nonconforming Items Identify, control, and correct items, services, and processes that do not meet established requirements.</p>	<p>Nonconformances, Identifying and Reporting and Corrective and Preventive Action Subject Areas</p>
<p>Design</p>	
<p>Prepare drawings, specification, and other design documentation that are considered necessary to define the design parameter of the item/process.</p>	<p>Engineering Design Subject Area</p>
<p>Procurement</p>	
<p>Evaluate the capability of suppliers of critical, costly, or complex items.</p>	<p>Evaluation of Seller Quality Assurance (QA) Programs Subject Area</p>
<p>Inspect and/or test received items in</p>	

Inspect and/or test received items in accordance with specific requirements (internal and external).	Inspections and Acceptance Subject Area
Inspection and Acceptance Testing	
Conduct source, receiving, inprocess, and final inspection/testing of specified items, services, and processes using established acceptance and performance criteria.	Inspections and Acceptance Subject Area
Control of Measuring and Test Equipment Establish calibration procedures and frequency for equipment and devices considered necessary to meet the project's objectives and safe conduct of operations/experiments.	Calibration Subject Area
Independent Assessment	
Plan and conduct assessments to measure the adequacy of work performance and to promote improvement.	Integrated Assessment Program Subject Area

*Subject Areas and ES&H Standards are Laboratory-wide requirements.

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Definitions: Graded Approach for Quality Requirements

Effective Date: April 2000

Point of Contact: [Quality Program Office Manager](#)

Term	Definition
activity	A project, program, study, or experiment which can involve the construction or assembly, operation, monitoring, and maintenance of research apparatus and equipment. The activity may also be a combination of the two, i.e., designing and building the research apparatus and equipment, and then conducting research with it.
assembly	A number of subassemblies and/or components joined together to perform a specific function (i.e., pump, power supply, coil assembly, printed circuit board assembly).
component	One piece or two or more pieces joined together which are not normally subject to disassembly without destruction of designed use (i.e., gear, screw, cam, transistor, resistor, integrated circuit, epoxy, adhesive.).
experiment	Processes and preparations necessary to conduct non-routine tests or investigations of physical phenomena utilizing equipment, materials or energy.
graded approach	<p>A process for determining that the appropriate level of analysis, controls, documentation, and actions necessary are commensurate with an item's or activity's potential to</p> <ul style="list-style-type: none"> ≪ Create an environmental, safety, or health hazard; ≪ Incur a monetary loss due to damage, or to repair/rework/scrap costs; ≪ Reduce the availability of a facility or equipment; ≪ Adversely affect the program objective or degrade data quality; ≪ Unfavorably impact the public's perception of the BNL/DOE mission.
operations	Any activity involved with operating, monitoring, or maintaining a research facility, machine, or item of equipment.
process	Any activity that uses personnel, machine, and/or materials for the construction, fabrication, operation, or maintenance of research facilities, machines, or items of equipment.
project	A unique effort that supports a program mission with defined start

	<p>and end points, undertaken to create a product, facility, or system with interdependent activities planned to meet a common objective/mission.</p> <p>Projects include planning and execution of construction/renovation/modification/environmental restoration or decontamination and decommissioning efforts, and large capital equipment or technology development activities.</p> <p>Tasks that do not include the above elements, such as basic research, grants, and operations and maintenance of facilities, are not considered projects.</p>
quality activity guide	Describes potential quality-related activities for specific mitigation of ES&H/programmatic issues.
quality classification	An indicator using a weighted scale that is used once the ES&H and programmatic risks have been evaluated, e.g., A1 (Critical), A2 (Major), A3 (Minor), and A4 (Negligible).
research	The application of the scientific method, wherein phenomena are observed and correlated to controlled adjustments of input parameters, to an experimental or theoretical investigation whose outcome cannot be precisely predicted.
study	Careful investigation, examination, or analysis of a phenomenon, theory, or concept.
subassembly	Two or more components combined into a unit for convenience in assembling or servicing. (i.e., beam tube with vacuum flanges, magnet trim coils).
subsystem	A combination of assemblies, subassemblies, and components connected or associated together to perform an operational function (i.e., vacuum subsystem, cryogenic subsystem, magnet subsystem, tunnel).
system	A combination of subsystems, assemblies, subassemblies, and components joined together to form the finished product or prime level of assembly (i.e., accelerator, reactor, detector, building).

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Revision History: Graded Approach for Quality Requirements

Point of Contact: [Quality Program Office Manager](#)

Revision History of this Subject Area

Date	Description	Management System
April 2000	This subject area was developed by a team using the process for Standards-Based Management development. This is a new subject area.	Quality Management

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