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1.0 Purpose

To provide guidelines for determining the Quality Assurance Classification Categories for AGS systems, subsystems, and assemblies.

2.0 Scope

The requirements of this document apply to all AGS construction, operations, and research activities. Tools and tooling are exempt from this requirement.

3.0 Policy

- 3.1 A graded approach to QA is employed to place the most emphasis upon and allocate proper resources to those items that may have the greatest effect upon AGS performance, personnel, equipment, environment, safety, cost, and schedule.
- 3.2 AGS QA Categories have been established to aid in the development and implementation of department and division quality assurance procedures and systems.
- 3.3 Responsibility lies with the cognizant Division Heads, or designee, to ensure that the appropriate QA Category is assigned to each system, subsystem, or assembly.
- 3.4 AGS systems, subsystems, and assemblies are to be classified into one of the following categories: A1 (Critical); A2 (Major); A3 (Minor); A4 (Other).

4.0 References

BNL Environment, Safety and Health Standard, Section 1.3.3, Safety Analysis Reports/Safety Assessment Documents.

5.0 Procedure

- 5.1 Systems/subsystems are classified by the Division Head in the development process.
 - 5.1.1 When a subsystem or assembly is to be procured as a deliverable end item, only the end item needs a QA Category assigned.
- 5.2 When an engineering drawing or specification is prepared, the cognizant engineer (CE) will determine which QA Category is applicable to the items defined by the drawing or specification. If a drawing or specification defines an assembly, the CE shall determine the applicable QA Category for each item within that assembly.
- 5.3 The QA Category designation shall be specified on procurement documentation, drawings and/or specification cover sheets.

- 5.4 The cognizant Division Head, or designee, shall review and approve the QA Category designation prior to the release of a new drawing or specification. The QA Category designation shall not be changed without the specific approval of the cognizant Division Head, or designee.
- 5.5 Guidance for assigning QA Classification Categories is given in Table 1. The criteria contained in Table 1 is a brief synopsis of the applicable requirements in the BNL Environment, Safety and Health Standard (ES&H), Section 1.3.3, Safety Analysis Reports/Safety Assessment Documents. For a more detailed description of category criteria reference the BNL ES&H manual and consult with the cognizant ES&H coordinator.
- 5.5.1 It must be recognized, that although an attempt has been made to quantify the effects of a failure on the AGS, engineering judgement and adequate margins of safety must be employed when selecting a QA Category.
- 5.5.2 The category selected should be based on the most severe effect of the failure.
- 5.5.3 Costs should include all expenses incurred as a result of the failure: replacement cost, cost of labor, downtime, cleaning (including decontamination), renovating, replacing, or rehabilitating structures, equipment, or property.
- 5.6 The CE should be aware that items requisitioned from BNL general stock (S&M) are automatically classified as AGS QA Category A4. If the CE determines that the QA Category A4 is inadequate, the CE must specify and implement additional testing and/or inspection of the general stock item prior to its use.
- 5.7 In order to further assist in properly classifying all systems, subsystems, assemblies, subassemblies and components, the following considerations should be used as guides:
- 5.7.1 Safety - A system, subsystem, assembly, or component which will be relied upon to mitigate the consequences of a major facility accident or significant radiological incident within the experimental area of the facility should be classified as critical (A1).

Engineered safety systems, subsystems, assemblies, or components designed to protect personnel from direct radiation, electrical, mechanical, chemical or cryogenic hazards (such as safety interlocks on doors), should generally be classified as critical (A1) in lieu of classifying the hazardous equipment itself.

For example, if a capacitor bank for a power supply system poses a significant electrical hazard to personnel, rather than classifying the capacitor bank as A1 from a safety viewpoint, the fence and gate interlock system preventing access to the capacitor bank during hazardous conditions should be classified A1.

From a safety viewpoint, the incorporation of component redundancy, or the

documentation showing that failures are "remote" or "extremely remote" (as defined in section 1.3.3, figure 1, of the ES&H manual), or showing that failures would result in a nonhazardous condition, could provide an acceptable basis for lowering the classification level.

- 5.7.2 Quantity, Cost or Schedule - When the cost of an item or quantity of items is high (i.e. exceeds \$10,000 for Category A4), or the lead time to purchase or produce the item or quantity of items is long, it may be necessary to upgrade the QA Category to protect against a potentially significant adverse cost or schedule impact.

For example, a single electronic component of a particular type may potentially have a minor impact upon system availability and reliability, but when a large quantity of that component is used in a system the potential impact upon availability and reliability may be major.

- 5.7.3 Table 2, Engineering Activity Guide By Classification Category, describes recommended activities for specific classifications. It is the responsibility of the CE/CS to decide which activities are applicable to their particular design/procurement.

Note: Item listed for Category A1 are mandatory.

- 5.7.5 Items which have not been assigned QA Classifications shall automatically be considered AGS Category A2 (Major) items, until a classification is assigned.

AGS QA Classification Category Criteria

	QA Category			
	A1 Critical ¹ (Hazard Severity Category I & II)	A2 Major (Hazard Severity Category III)	A3 Minor (Hazard Severity Category IV)	A4 Other (>Hazard Severity Category IV)
Program Impact				
Equipment Loss (\$)	>250K	>50K to 250K	10K to 50K	<\$10K
Program Downtime	>3 weeks	>4 days to 3 weeks	2 to 4 days	<2 days
Program Compromise	Total loss/severe reduction in data quality or equipment output, or repeat of test/insp. program required.	Major reduction in data quality or equipment output, or repeat of test/insp. program required.	Minor reduction in data quality or equipment output, or repeat of data point(s) required.	Negligible reduction in data quality or equipment output.
ES&H Impact¹				
Personal illness/injury	Death/severe injury or occupational illness.	Moderate injury or occupational illness resulting in >5 lost work days.	Minor injury or occupational illness resulting in 1 to 5 lost work days.	None
Radiation Release/Exposure	Reference Figure 1 in Section 1.3.3 of the ES&H Manual			No Release/Exposure
Non-Radioactive Release/Exposure	Reference Figure 1 in Section 1.3.3 of the ES&H Manual		No Release/Exposure	No Release/Exposure
Probability¹				
Probability of Occurrence	Reference Figure 1 in Section 1.3.3 of the ES&H Manual			

Table 1

¹The criteria contained in table 1 is a brief synopsis of the applicable requirements in the BNL Environment, Safety and Health Standard (ES&H), Section 1.3.3, Safety Analysis Reports/Safety Assessment Documents. For a more detailed description of category criteria reference the BNL ES&H manual and consult with the cognizant ES&H coordinator.

Recommended Engineering Activity Guide By Classification Category

Category				<u>ENGINEERING ACTIVITIES TO ENSURE QUALITY</u>
A1 ¹	A2	A3	A4	
X	X			Plan design effort (develop milestones) & define design criteria.
X	X	X		Determine appropriate codes, standards, and practices.
X	X	X		Prepare/distribute drawings and specifications.
X	X	X		Perform design reviews (as required).
X	X	X		Specify QA requirements in the purchasing documents. (When feasible, specify the requirements of BNL-QA-101).
X	X	X		Evaluate alternate proposals/exceptions from suppliers.
X	X			Evaluate QA program of potential suppliers.
X	X			Prepare/review operating procedures for check-out, start-up, and operations.
X	X			Prepare/review maintenance procedures for facilities and equipment.
X	X	X	X	Identify Age Sensitive Material (ASM). Items with limited calendar/operating life.
X	X			Prepare manufacturing procedures & travelers for complex items.
X	X			Assure special processes are performed & verified, by technically competent personnel, in accordance with written procedures.
X	X	X		Perform source, receiving, inprocess, and final inspect/test (as required) per documented instruction/procedure.
X	X	X		Identify, segregate, review (as required), and control nonconforming items and items awaiting inspection/test.
X	X	X	X	Inform Division of Contracts & Procurement of defective materials which are received.
X	X			Determine the cause of nonconformances and develop remedies to preclude the recurrence.
X	X			Indicate inspect/test status on the item or on documentation traceable to the item.
X	X			Perform trend analysis, when required.
X	X			Provide traceability to the items of lots inspected.
X	X	X		Identify equip. requiring calibration, establish calibration frequency and show calibration status on equipment.
X	X			Document requirements for handling, storage and shipping.
X	X	X		Prepare & maintain records of actions affecting quality ² .

Table 2

¹Activities listed for Category A1 systems, subsystems, and assemblies are mandatory. For all other Categories, listed activities should be considered by the CE/CS

²Quality Assurance Records include Inspection & Test Results (Internal & Vendor Items); Calibration Records; Material Certifications; Waivers/Deviations; and Nonconformance Reports.