QUALITY ASSURANCE PROGRAM
GRADED APPROACH APPLICATION GUIDE

This Quality Assurance Program Graded Approach Application Guide is designed to assist personnel in the proper determination of graded approach principles to Laboratory activities.

1.0 APPROVAL RECORD

- Reviewed by: Training & Documents, Quality Assurance Coordinator (Molly Granseth)
- Approved by: Quality Assurance Manager & ESH&A Manager (Sean Whalen)
- Approved by: Deputy Director (Tom Lograsso)

The official approval record for this document is maintained by Training & Documents.

2.0 REVISION/REVIEW INFORMATION

The Quality Assurance Graded Approach Application Guide will be revised and updated during the specified Quality Assurance program revision schedule. The revision description for this document is available from and maintained by the author.

3.0 INTRODUCTION

The Quality Assurance Program Plan [10200.026] describes how Ames Laboratory provides reasonable assurance of adequate protection from adverse consequences for workers, the public, and the environment, taking into account the work to be performed and the associated hazards, as required by 10 CFR 830, Subpart A.

10 CFR 830.7 requires that, where appropriate, a graded approach must be used to implement quality assurance requirements. This document provides guidance to personnel applying graded approach principles to work and operational activities based on hazard and risk assessments.

The following references were used in the development of this guidance document:

- Quality Assurance Program Guide – DOE G 414.1-2B 5/8/2013
- Management and Independent Assessments Guide – DOE G 414.1-1C 3/27/2014

4.0 GRADED APPROACH APPLICATION

4.1 Concept

The graded approach concept refers to the process of ensuring the level of analysis, documentation, and actions taken to comply with a requirement are commensurate with characteristics related to an activity. The graded approach evaluates the probability of event occurrence associated with an activity or process, and the potential impacts of the event. Based on G 414.1-2B, factors to consider, but not limited to, include:

- The relative importance to safety, safeguards and security;
- The magnitude of hazard or risk involved;
- The life cycle stage of a facility or activity;
- The impact/consequences on the programmatic mission of a facility;
- The relative importance of radiological and non-radiological hazards; and

- The particular characteristics of a facility and other relevant factors.

A graded approach does not allow internal or external requirements to be ignored or waived. It is intended to allow the degree of controls, verification, and documentation to be varied in meeting requirements based on Ames Laboratory considerations, customer needs, and associated programmatic considerations.

4.2 Applying the Graded Approach

Graded approach application estimates risk based on levels of impact and probability of occurrence associated with activities or processes. Calculating risk is contingent on multiple factors including, but not limited to, those listed in Section 4.3. The purpose of the graded approach is to apply a suitable level of control and/or resource allocation to ensure an appropriate safety or business outcome. Efforts must be commensurate with outcomes to provide efficient utilization of resources.

When applying the graded approach consider the factors listed above and the impacts the activity might have on staff safety and well-being, Laboratory mission, facilities and equipment, and potential public perception. Qualitatively estimate whether the potential impact and probability would be low, moderate, or elevated, and which methods should be employed to most efficiently minimize risk and meet quality assurance requirements. Appendix A contains research and equipment purchasing examples. The Quality Assurance Program Graded Approach Application Assessment Form (10200.215) is available to assist with the grading process.

There are multiple potential risk outcomes when evaluating activities. While the procedure is designed to be qualitative, the outcome can be expressed with the following expressions:

Probability x Impact = Risk

- Low x Low = Low
- Low x Moderate = Moderate
- Low x Elevated = Elevated

- Moderate x Low = Moderate
- Moderate x Moderate = Moderate
- Moderate x Elevated = Elevated

- Elevated x Low = Elevated
- Elevated x Moderate = Elevated
- Elevated x Elevated = Elevated

Table 1: Graphical representation of the Ames Laboratory graded approach

Risk Assessment Matrix			
Impact of Risk (Consequence) — Elevated	Elevated	Elevated	Elevated
Impact of Risk (Consequence) — Moderate	Moderate	Moderate	Elevated
Impact of Risk (Consequence) — Low	Low	Moderate	Elevated
Seriousness of Risk = Probability x Impact	Low	Moderate	Elevated
	Probability of Risk		

The graded approach concept can be applied to all work and business practices at Ames Laboratory, from simple processes such as glassware rinsing with hazardous solvents or purchasing a #2 pencil, to complex research activities such as ball milling or purchasing complex laboratory equipment.

Risk is inherent to all activities and cannot be completely eliminated. Due to the lower-risk nature of Ames Laboratory activities and research relative to other DOE laboratories, a qualitative approach may be used when evaluating activities and grading approaches to risk management.

Ames Laboratory does not have a nuclear reactor, a linear accelerator or a plasma generator. Radiation producing devices are limited to twelve interlocked laser systems and twenty-two interlocked X-Ray systems. Limited amounts of radiological materials are used in research activities; storage is maintained on-site in a secure vault.

Reagent chemicals are used in limited quantities in laboratory settings and generally pose a moderate to low hazard. Some chemicals, however, such as pyrophoric liquids and solids, peroxide formers, and hydrogen fluoride, can pose an elevated hazard, even in small quantities. Nitrogen and helium are used in larger volumes for research applications. Maintenance chemicals include oil, limited volumes of paints and solvents, and materials for water treatment.

Ames Laboratory does not conduct classified research and does not store classified documents on site.

4.3 Graded Approach to Risk and Hazard Assessment

Risk is evaluated on the impacts to people, the environment, equipment, activity, or Laboratory/DOE mission. The impacts listed for the following categories are not intended to be complete, but are provided as examples of what should be considered during evaluation.

Probability is the potential for a failure, upset condition, or event to occur which causes an impact.

- Low Probability - occurrence is unlikely (< 5%)
- Moderate Probability - occurrence is somewhat likely (5 – 50%)
- Elevated Probability - occurrence is probable (> 50%)

Impacts are negative consequences ranging from minor injury to loss of data to a full scale disaster. Many of the terms used to grade impacts are not specifically defined; this allows flexibility during evaluation and a conservative approach when warranted.

Note: Percentages are provided only as a guide. Event history, equipment failure factors, human performance considerations, and multiple other factors may increase or decrease probability. Each activity or process must be thoroughly evaluated.

4.3.1 Relative importance to safety, safeguards and security

Note: Life safety is of primary importance when assessing risk and hazard. If the activity is likely to cause a fatal or life-altering injury or illness in the event of an accident, or if multiple persons could be involved, the risk is always elevated.

Low Risk

Probability - occurrence is unlikely

Impacts

- Minimal potential impact to personnel safety such as injuries only requiring minor first aid

- Equipment calibration has minimal impacts to life safety
- Security breach would have minimal impact on low-value items or data

Moderate Risk
Probability - occurrence is somewhat likely

Impacts

- Impact to personnel safety such as medical treatment beyond first aid
- Equipment calibration could impact life safety
- Security breach would have significant impact on medium-value items or data.

Elevated Risk
Probability - occurrence is probable

Impacts

- Significant impacts to personnel safety such as death, permanent hearing damage, permanent loss of physical function, permanent loss of limb or mobility, or could impact more than two persons
- Equipment calibration is directly related to life safety
- Security breach would have extreme impact on high-value items or data

4.3.2 Magnitude of hazard or risk involved
Note: If an event could potentially release legacy radiological, chemical (such as beryllium), or asbestos contamination, then the risk is moderate or elevated.

Low Risk
Probability - occurrence is unlikely

Impacts

- Minimal impact to a localized area of the Laboratory such as a single lab or workspace causing only minor disruption to activities
- Minimal impact to low-value equipment; value is not simply cost-based, but can extend to how critical the equipment is to activity/mission completion

Moderate Risk
Probability - occurrence is somewhat likely

Impacts

- Significant impact to a localized area or one or two pieces of high-value equipment causing activity suspension for an extended period
- Moderate impact to a larger area such as a suite of rooms, floor or building wing, or to multiple pieces of medium-value equipment causing activity suspension for an extended period

Elevated Risk
Probability - occurrence is probable

Impacts

- Impact to a large area of the Laboratory such as a floor or multiple floors
- Potential release of chemicals beyond the building envelope
- Loss of a single piece of high-value equipment
- Loss of several pieces of low to moderate value equipment

4.3.3 Life cycle stage of a facility or activity

Note: If failure of equipment could have an immediate impact on life-safety, such as air monitoring sensors, fire/heat/smoke detectors, safety interlocks, etc. then the risk is moderate or elevated.

Low Risk

Probability - occurrence is unlikely

Impacts

- Equipment and/or facility is new, has completed burn-in, and is still under warranty
- Failure of equipment will create minimal impact

Moderate Risk

Probability - occurrence is somewhat likely

Impacts

- Equipment and/or facility is mature and operating correctly
- Plans for replacement/upgrade should be in place
- Failure of equipment will have significant impact

Elevated Risk

Probability - occurrence is probable

Impacts

- Equipment and/or facility is reaching end-of-life
- Failure of equipment will have extreme impact

4.3.4 Impact/consequences on the programmatic mission of a facility

Note: Mission impact includes loss/damage to facilities or infrastructure, loss of critical personnel, or loss/reductions in funding. Impacts to Iowa State University or the City of Ames should also be considered.

Low Risk

Probability - occurrence is unlikely

Impacts

- Minimal impact to a limited area of the Laboratory mission
- Equipment calibration has minimal effects on research or operations

Moderate Risk

Probability - occurrence is somewhat likely

Impacts

- Significant impact to a limited area of the Laboratory mission, or moderate impact to a broad area of Laboratory mission

- Equipment calibration could have moderate effects on research or operations

Elevated Risk
Probability - occurrence is probable

Impacts

- Extreme impact to a limited area of the Laboratory mission, or minimal/moderate impact to a broad area of Laboratory mission
- Equipment calibration could have severe impacts to research or operations

4.3.5 The relative risk of radiological and non-radiological hazards
Note: If an event could potentially release legacy radiological, chemical (such as beryllium), or asbestos contamination, then the risk is moderate or elevated.

Low Risk
Probability - occurrence is unlikely

Impacts

- Minimal potential impact to personnel safety such as injuries only requiring minor first aid
- Minimal impact to a localized area of the Laboratory such as a single lab or workspace causing only minor disruption to activities
- Minimal impact to low-value equipment; value is not simply cost-based, but can extend to how critical the equipment is to activity/mission completion

Moderate Risk
Probability - occurrence is somewhat likely

Impacts

- Impact to personnel safety such as medical treatment beyond first aid
- Significant impact to a localized area or one or two pieces of high-value equipment causing activity suspension for an extended period
- Moderate impact to a larger area such as a suite of rooms, floor or building wing, or to multiple pieces of medium-value equipment causing activity suspension for an extended period

Elevated Risk
Probability - occurrence is probable

Impacts

- Significant impact to personnel safety such as death, permanent hearing damage, permanent loss of physical function, permanent loss of limb or mobility, or impact to more than two persons
- Impact to a large area of the Laboratory such as a floor or multiple floors
- Potential release of chemicals beyond the building envelope

4.3.6 Risk as applied to particular facility characteristics, and other relevant factors

Note: Ames Laboratory has several unique characteristics which must be considered when determining risk. Consider the following potential impacts when evaluating risks associated with research and operational activities. Apply the appropriate probability and impact profile

4.3.6.1 *Federal facility*

Ames Laboratory is a federal facility, but maintains an open campus and an unarmed watch force. The Laboratory follows the federal budget cycle and relies on Congressional oversight for allocations.

Probability - occurrence varies

Impacts

- Federal facilities may be subject to targeted acts of terrorism, violence, or protests.
- Government shut-downs due to congressional action may result in loss of funding, employee furloughs, or temporary facility closure.

4.3.6.2 *Collocated on ISU campus*

Ames Laboratory shares physical space with Iowa State University. The facility is open to foot traffic during normal business hours.

Probability - occurrence varies

Impacts

- The site is not as secure as other federal laboratories, which could lead to theft, vandalism, or sabotage.

4.3.6.3 *Sensitive Instrument Facility (SIF) located off-site*

The SIF is a federal facility located on ISU property approximately three miles northwest of campus. The SIF is open for research 24/7/365, but has tighter access controls than buildings located on campus.

Probability - occurrence varies

Impacts

- Ames Laboratory and ISU users must travel between campus and the SIF in personal and university vehicles.
- Ames Laboratory personnel deliver materials to the site.
- The guard force does not tour or inspect the SIF.
- Response time by Ames Laboratory emergency team members will be extended.

4.3.6.4 *Receives utilities from off-site*

Ames Laboratory receives power, water, and natural gas from the City of Ames or Iowa State University. The Laboratory has limited emergency power generation.

Probability - occurrence varies

Impacts

- Disruption of utilities could affect Laboratory capabilities and require the suspension of research and operational activities

4.3.6.5 Receives police and fire services from off-site

Ames Laboratory relies on Iowa State University and the City of Ames for police protection, the City of Ames for fire and emergency response, and Mary Greeley Hospital for medical response.

Probability - occurrence varies

Impacts

- Response times and capabilities could be impacted during large sporting events and/or emergencies such as floods, severe weather, student violence, or terrorism.

4.3.6.6 Shared faculty, staff, and students

Iowa State University and Ames Laboratory share faculty, staff, and students.

Probability - occurrence varies

Impacts

- ISU staff may be subject to different requirements based on office and/or laboratory location or funding source.
- Training courses may differ between Ames Laboratory and ISU, fostering confusion and incomplete understanding of roles and responsibilities.
- Students may not understand differing expectations between ISU and DOE programs.

4.3.6.7 Shared research space

Iowa State University and Ames Laboratory share research space through lease agreements.

Probability - occurrence varies

Impacts

- Work planning requirements may differ based on laboratory location and/or funding source.
- Researchers may be subject to oversight by AMES and ISU.
- University personnel may not be familiar with DOE requirements.

4.3.6.8 Legacy contamination

Due to historical research activities, Ames Laboratory has extensive, low-level radiological and metals contamination in non-occupied spaces such as pipe chases, service tunnels, and interstitial spaces. The Laboratory has been surveyed, but disturbance or work in contaminated areas must be controlled.

Probability - occurrence varies

Impacts

- Certain work activities must be performed by in-house personnel or authorized contractors.
- Uncontrolled construction and maintenance activities could lead to localized or wide-spread contamination.
- Personnel could be contaminated or exposed to serious radiological or chemical hazards.
- Portions of laboratories or buildings could be shut down for extended periods.

4.3.6.9 Weather

Flooding

Ames Laboratory is located in the Central Plains and is above the designated flood zone. However, the City of Ames and ISU have been impacted by sever flooding, and will likely experience flooding in the future. Flooding may impact Ames Laboratory activities due to road closures, facility closures, loss of community power and potable water, etc. Community impacts must be considered when evaluating the risk to Ames Laboratory activities.

Severe Weather

Primary severe weather related risks include snow and ice storms, severe thunderstorms, and tornados.

Seismic Activity

There is minimal risk of severe seismic activity, though the mid-west has experienced a recent increase in moderate temblors. No physical impacts have been noted in Ames or at Ames Laboratory.

Probability - occurrence varies; severe weather probability is high over the long term, but impact severity is highly variable

Impacts

- Minor to serious personnel injuries due to slips on snow and ice
- Inability of key personal to come to work
- Power outages due to storms could impact sensitive equipment

4.3.6.10 Public Perception

Public perception can be critical in the positive acceptance of DOE and Laboratory activities.

Probability - occurrence varies

Impacts

- Negative perception can lead to protests, loss of research opportunities, and loss of funding.

4.3.6.11 Loss of Funding

Funding sources to research and operational activities may be lost or reduced for a variety of factors.

Probability - occurrence varies

Impacts

- Shut down or reduction of activities may lead to disposal or mothballing of equipment, chemicals, or space.

4.3.6.12 Loss of Critical Personnel

Personnel critical to research or operational activities may be lost through attrition, injury, or death.

Probability - occurrence varies

Impacts

- Loss of critical knowledge or ability to effectively perform functions
- Discontinuation of research projects

Appendix A

Developing Risk Management Practices Based On Graded Approach

Example 1

Applying the graded approach, what is the relative hazard of the task, and which methods should be employed to control risk as much as possible?

Task: An Ames Laboratory researcher wants to use acetone for rinsing glassware. Approximately 25 ml of acetone will be used per rinse event. Glassware rinsing occurs on the benchtop near the sink into a 4 l waste bottle.

Hazards: Acetone is highly flammable and moderately toxic.

Controls: Small volumes are used at any one time. Laboratory room ventilation is on and adequate. Users wear PPE including safety glasses, chemical gloves, flame resistant lab coat, and closed toed shoes. The laboratory SOP clearly defines the procedure, the user has been trained, and the work process has been observed by an experienced person.

Risk: The risk associated with this specific task is **LOW**.

- *Relative importance to safety, safeguards and security – Low*
    - There is a low probability of fire and employee exposure due to adequate room ventilation and small volume of usage.
- *Magnitude of hazard or risk involved - Low*
    - The impact would be small and localized due to the room ventilation and low volume.
- *Life cycle stage of a facility or activity – N/A*
- *Impact/consequences on the programmatic mission of a facility - Low*
    - An event would have a small and localized impact due to the room ventilation and low volume.
- *The relative importance of radiological and non-radiological hazards - Low*
    - There is a low probability of fire and employee exposure due to adequate room ventilation and small volume of usage.
- *Particular facility characteristics and other relevant factors – N/A*

Graded Approach:
Normal laboratory controls are adequate for this procedure. However, the process could be further improved by rinsing glassware in a fume hood or substituting a less hazardous material.

Now consider how the risk might change if modifications occurred to the process, facility, personnel, etc. Would the impact and risk be elevated if larger volumes of acetone were used, if the waste bottle broke or spilled, or the room ventilation was off-line? What if the user was inexperienced or untrained, would there be a higher probability of occurrence?

Example 2

Applying the graded approach, what is the relative hazard of the task, and which methods should be employed to control risk as much as possible?

Task: An Ames Laboratory researcher wants to purchase a large and expensive piece of laboratory equipment to categorize and synthesize materials.

Hazards: The equipment value (~$555,000) represents a significant expense. The equipment will use moderate volumes of chemicals. The equipment is vital, but not critical, to the Laboratory mission.

Controls: Contract terms and conditions must specify that the equipment meet applicable conformance standards, and that installation of equipment includes a certificate of calibration. A list of potential chemical wastes and volumes should be provided to ESH&A for review. The purchase of supplemental insurance should also be considered.

Risk: The risk associated with this specific task is **Moderate**.

- *Relative importance to safety, safeguards and security – Low*
    - The volume and type of chemicals (limited amounts of flammable polar and non-polar solvents) is within the normal laboratory envelope
- *Magnitude of hazard or risk involved – Moderate*
    - The dollar value of the equipment presents a moderate risk in the event of loss, damage, or manufacturer error.
- *Life cycle stage of a facility or activity – Low*
    - The equipment is new, and highly technical
- *Impact/consequences on the programmatic mission of a facility – Low*
    - The equipment is vital to Laboratory mission and the specific research activity. However, failure to procure the equipment, or subsequent failure of the equipment, will only have short-term negative consequences.
- *The relative importance of radiological and non-radiological hazards – Low*
    - There is no radiological component. Only limited amounts of chemical are being used.
- *Particular facility characteristics and other relevant factors – Low*
    - N/A

Graded Approach:
Procurement procedures and existing terms and conditions are adequate to ensure that low and moderate risks are evaluated and addressed.

Now consider how the risk might change if the dollar value of the equipment doubled, tripled, or was increased ten-fold? What if receipt of a multimillion dollar research grant critical to Laboratory mission hinged on proper receipt and installation of this equipment?