

Course Number and Title Revision to LMS-PROC-125, Applying the Graded Approach to Quality	Date 01/27/2015
Terminal Objective <i>(Describes the expected outcomes of this training)</i> To establish an understanding of the revision to LMS-PROC-125, the background behind the changes to eliminate the confusion associated with this long standing procedure.	
Enabling Objectives <i>(Breaks the terminal objective into individual knowledge, skills or attitudes participants will be able to demonstrate at the end of the course)</i> The training establishes the requirements for each Division to Grade their activities, including the documentation of this determination (ANL-743 Form).	
Instructional Materials <i>(e.g. Handouts, audio-visual, actual machinery needed for the course, etc.)</i> See attached PowerPoint Presentation titled "Revision to LMS-PROC-125, Applying the Graded Approach to Quality".	
Lesson Content <i>(Enter here or attach)</i> See attached PowerPoint Presentation titled "Revision to LMS-PROC-125, Applying the Graded Approach to Quality".	

Revision to LMS-PROC-125, Applying the Graded Approach to Quality

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Quality Assurance & Control Program Manager

Background of the revision

- The current revision of LMS-PROC-125 (Revision 2) is an attempt to use a Risk Based approach to apply a graded level of Quality Assurance. The true application of the Graded Approach to Quality involves the incorporation of Work Planning and Control, Radiation Control Measures, Worker Safety and Health Protections, etc.
- LMS-PROC-125 simply establishes “how much Quality Assurance” we are applying to these activities. This involves the following:
 - Level of Quality Assurance related to supplier selection and qualification
 - Calibration of associated Measuring and Test Equipment
 - Control of associated Computer Software (i.e. application of DOE Order O414.1D Software Controls, related to Nuclear Facilities and activities in support of these facilities).
- This revision is necessary to clarify that the Graded Approach to Quality goes beyond procurement. This procedure establishes the Graded Approach for all activities at Argonne.



Background of the revision

- Currently, LMS-PROC-125 implements the following Criteria of 10 CFR 830 and the DOE Order (O414.1D).
 - 10 CFR 830.7
 - DOE Order O414.1D
 - Criteria 1 – Program
 - Criteria 6 – Design
 - Criteria 7 – Procurement
- LMS-PROC-125 is specifically cited in Appendix 1 of the Quality Assurance Program Plan.
- LMS-PROC-125 is referenced in the following Lab Documents
 - LMS-PROC-3, Control of Nonconforming Material
 - LMS-PROC-30, Engineering Services
 - LMS-PROC-48, Requesting Supplier Evaluation
 - LMS-PROC-49, Receipt Inspection
 - LMS-PROC-50, Control and Calibration of Measuring and Test Equipment
 - LMS-PROC-51, Inspection and Acceptance
 - LMS-PROC-114, Safety Software Quality Assurance
 - LMS-PROC-116, Commercial Grade Dedication
 - NWM-PP-521, Safety Management Program Descriptions
 - NWM-PP-524, Safety Software Quality Assurance Plan
 - LCF-PROC-1, Local Work Planning and Control Procedure [left off]



Background of the revision

- LMS-PROC-125 is referenced in the following Lab Documents - Continued
 - NWM-PP-522, Nuclear Maintenance Management Program
 - NWM-PP-523, NWM Quality Assurance Plan
 - EDG-QAP, QUALITY ASSURANCE PLAN FOR EXTERNAL DOSIMETRY
 - IG-QAP-001, QAP for the ESQ Radiological Safety Instrumentation Group
 - RSO-IG-004, Process for Receipt Inspection of Equipment
 - NWM-CM-305, NWM Master Equipment List Development and Maintenance
 - HOIST-1.1.4, Equipment Procurement Process
 - WM-QA-702, Waste Management Procurement Control
 - CONFIG-6, Configuration Management Process for Hazardous Category Nuclear Facilities Section 6, Assessments
 - ESQ-QA-4.1, Performing Supplier Evaluation
 - ESQ-QA-7.2, Supplier Audits
 - Integrated Safety Management System Description Document
 - WMO-QA-2, Quality Assurance Plan for the Waste Management Department
 - NWM-349, System Design Description: AGHCF Main Exhaust System
 - NWM-376, Nuclear Maintenance Management Program Crosswalk
 - ID-QAP-001, Internal Dosimetry Quality Assurance Plan
 - CYBER-3, Cyber Security Program Plan
 - Argonne Project Management Manual, Appendix D, ES&H Quality Management Guide
 - CONFIG-1, Configuration Management Process for Hazardous Category Nuclear Facilities Section 1, Management
 - NWM-252, Argonne National Laboratory Quality Assurance Program Description for Type B Fissile Material Packaging
 - NWM-TSD-101, Transportation Safety Document



Background of the revision

- As seen by the list of documents that reference LMS-PROC-125, the Graded Approach is much larger than simply Procurement.
- Here is the start of the confusion related to the applicability of LMS-PROC-125. This is what the current revision states in the Purpose

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Applying the Graded Approach for Quality
Laboratory-Wide Argonne Procedure LMS-PROC-125, Rev. 2
Effective Date: 12/13/2012

1 Purpose

Establish the process for applying a graded approach to select an appropriate level of rigor, based on relevant risk and mission, **when purchasing items and/or services.**



Background of the revision

- However, when reading the procedure steps the following is indicated:

3.2 Step-by-Step Procedure

The steps below are mandatory unless noted otherwise.

Step	Job Role	Action
1	Originator	<p>1.1 Characterize the item or activity as a structures, systems, components (SSC), facility, process, or service.</p> <p>1.2 Assign a quality level of A, B, C, or D (see Exhibit Section E.2, Assignment of Quality Levels).</p> <ul style="list-style-type: none">Identify the specific requirements and controls to be graded.Determine the depth, extent, and degree of rigor necessary in the application of the requirements assigned to a quality level before the work begins.Determine use of items being procured to apply quality level. <p>Note: Form ANL-742, Checklist for Classification of Quality Levels, is available as an optional tool to assist with this step.</p> <p>1.4 Complete form ANL-743, Classification of Quality Level. Documentation is not required for QL-D items unless downgrading an item or activity from a higher quality level.</p> <p>1.5 Forward completed form ANL-743 to division quality assurance representative (QAR) for review and concurrence.</p>

Background of the revision

- Moving forward the following changes have been made:
 - The purpose has been revised to simply state the following:

1 Purpose

Establish the process for applying a graded approach to quality assurance for Laboratory activities.

- Two Exclusions have been added:

1. At the request of NWM, relief was given to NWM from the use of LMS-PROC-125 for grading of items identified in the NWM Master Equipment List (controlled by NWM-CM-305).

Note: This will require revision of NWM QAPP and Procedures that still reference the use of LMS-PROC-125 for the Graded Approach.

2. Suppliers working under the Argonne Quality Program (staff augmentation) are exempt from the graded approach. The activities being performed by these suppliers will be controlled by the Work Planning and Control and Argonne Quality Program.
- Section 3.2.1 has been changed to “Characterization of a System, Structure, Component, Facility, Process or Service.”
 - Section 3.2.2 has been added and is identified as “Characterization of a Procurement related to a System, Structure, Component, Facility, Process or Service.”
 - This will allow a single ANL-743 form to be completed to characterize activities performed within a department or division, eliminating the need to endlessly complete ANL-743 forms with each procurement requisition.
 - ANL-742 form was deleted since it added no value to the process and wasn’t being used.



Background of the revision

- In reality, the Graded Approach to Quality is a component of the Integrated Safety Management process which is implemented by Work Planning and Control. The Graded Approach simply establishes how much quality is being applied to activities associated with those activities identified in Table E-2 (i.e. for Quality Level A, we develop and implement controls specified in ASME NQA-1-2008; for Quality Level B and C we incorporate a graded approach to Quality, as determined by the risk of the activity).
- The revision to LMS-PROC-125 will remove the confusion related to the completion of the ANL-743 and the definition of the Graded Approach across the Laboratory. In the end, once the characterizations are completed, it will remove the duplicative efforts in relation to the completion of the ANL-743 Form.



Revised section of Table E-2 to align with Work Planning and Control activities

- The much maligned Table in E-2 was completely revised to align with activities ongoing at the Laboratory to aid in the determination of Quality Levels.

Table E-2 Criteria to Aid in the Determination of Quality Levels

Activities	ESH/Q RISK LEVEL			
	Grading Level			
	A	B	C	D
Design Activity	Design of very high consequence system, structure, component, facility, or process	Design of a high consequence system, structure, component, facility or process	Design of a moderate consequence system, structure, component, facility or process	Standard commercial design activities for a minimal consequence structure, component, facility or process
Radiological Work	Activities in a very high consequence facility that could result in a significant off-site dose in excess of 5 REM	Activities in a high consequence facility that could result in significant localized dose in excess of 1 REM	Activities moderate consequence facility (in controlled areas) that require development and implementation of a radioactive work permit	Not applicable for radiological work
Electrical Work	Work on energized systems greater than 50 Volts in a facility or activity that poses a very high consequence	Work on energized systems greater than 50 Volts facility or activity that poses a high consequence	Work on energized systems greater than 50 Volts in a facility or activity that poses a moderate consequence	Trouble shooting circuits less than 50 Volts in a facility or activity that poses a minimal consequence
Stored Energy	Work on equipment or processes that require LOTO without disassembly in a facility or activity of very high consequence	Work on equipment or processes that require LOTO without disassembly in a facility or activity of high consequence	Work on equipment or processes requiring LOTO without disassembly in a facility or activity of moderate consequence	Inconsequential stored energy
Confined Space	Work in a very high consequence facility or activity requiring a confined space permit	Work in a high consequence facility or activity requiring a confined space permit	Work in a moderate consequence facility or activity requiring a confined space permit	Work in a minimal consequence facility or activity involving a non-permit confined space, when the task will not affect classification of the space



Going forward

- In the very near future (planning for Spring of 2015), the ANL-743 Form will be converted to Xink eliminating the requirement for QARs to maintain copies of these documents. This will also allow an expedited method for routing and approving these forms.
- Currently, there is a significant backlog of forms undergoing conversion to Xink. Once this backlog decreases, the conversion of ANL-743 will be accomplished and LMS-PROC-125 will be revised accordingly.
- ESQ-QA staff will provide assistance with the completion of ANL-743 Forms. Help can be solicited either through a telephone request, or sending an email to the ESQ-QA Staff.
 - To help facilitate the request for ESQ-QA assistance, the ESQ-QA Webpage has been updated with e-mail links that allow the requester to solicit help directly from ESQ-QA.



ESQ Quality Assurance Webpage

- The ESQ QA Webpage has been revised to include a section where requests for help can be sent directly to ESQ-QA.

Quality Assurance

The Quality Assurance (QA) department provides oversight of Argonne's quality management system (QMS) and supports the programmatic development, management, advisory services, and support of quality-related processes and systems.

See the links below for more detailed information about this service:

- ▶ [Conduct of Operations Program](#)
- ▶ [Suspect/Counterfeit Items Program](#)

Details | **Related Links**

Request help or information:

- ▶ [Training requests](#) (in-person quality assurance training)
- ▶ [Graded approach](#)
 - ▶ [Completing Classification of Quality Levels \(ANL-743\)](#)
 - ▶ [Questions regarding the graded approach \(LMS-PROC-125: Applying the Graded Approach for Quality\)](#)
- ▶ [Software grading and determination](#)
 - ▶ [Completing Safety Software Quality Assurance Identification \(ANL-887\)](#)
- ▶ [Source verification requests](#)
- ▶ [Adding a new supplier](#)
 - ▶ [Completing Candidate Supplier Evaluation \(ANL-731\)](#)

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Quality Assurance Representatives

A service of Environment, Safety, & Quality Assurance

As outlined in the Argonne Quality Assurance Program Plan, the QMS defines the requisite criteria and

New Links



Questions?

