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EFCOG GRADED APPROACH BENCHMARKING



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OVERVIEW – GRADED APPROACH BENCHMARKING

- Why DOE contractors use a graded approach
- How a graded approach is used
- Benchmarking survey results
 - Why benchmark?
 - Survey conduct, who responded, federal customers for responding sites
 - What requirements drive the graded approach framework
 - Inputs for grading level selection
 - What processes/systems use a graded approach
 - Development and oversight of graded approach frameworks
 - Who selects grade level
 - Documenting and reviewing grade selection
- Examples from benchmark sites of graded approach framework, processes using graded approach, level drivers and controls

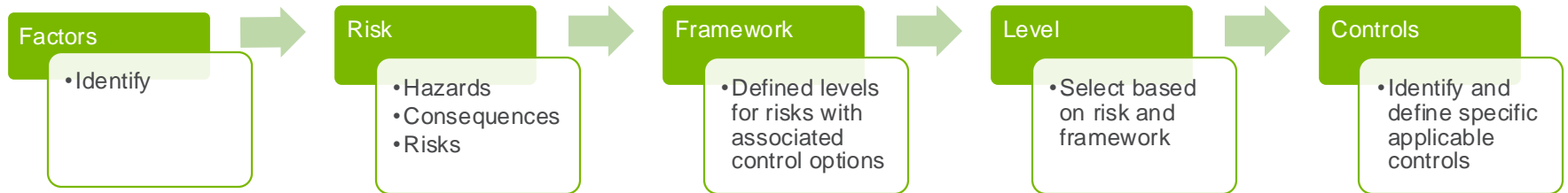
WHY A GRADED APPROACH

Effective and Efficient

- Stewardship of government (taxpayer) money
- Written into Prime Contracts (DOE O 414.1D Quality Assurance)
- Consensus standards suggest risk-based approach with commensurate controls

HOW A GRADED APPROACH IS USED

Graded approach application based on risk



WHY BENCHMARK NOW?

- DOE 414.1E Quality Assurance revision coming
- Understand what other sites do that works
- Input to improve graded approach

GRADED APPROACH SURVEY, BENCHMARKING

Benchmarking Survey to EFCOG

- Survey sent out 8/1/2024 to EFCOG Contractor Assurance and Quality Policy and Procedures task group mailing lists
- 13 responses from 11 sites:
 - Argonne National Lab (2)
 - Lawrence Livermore National Lab
 - Idaho National Lab
 - Portsmouth (2)
 - Fermilab
 - Sandia National Lab
 - Pacific Northwest National Lab
 - Oak Ridge National Lab
 - National Renewable Energy Lab
 - Hanford and Hanford WTP

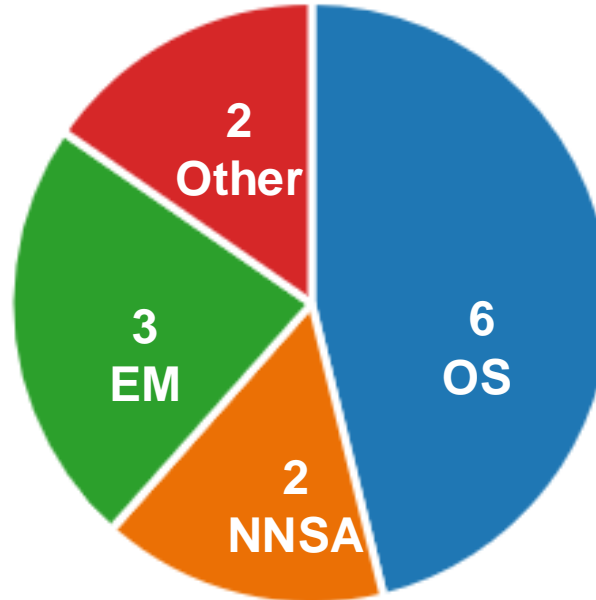
WHO – MAIN GOVERNMENT ORG FOR SITES

DOE Office of Science (OS)

DOE National Nuclear Security Administration (NNSA)

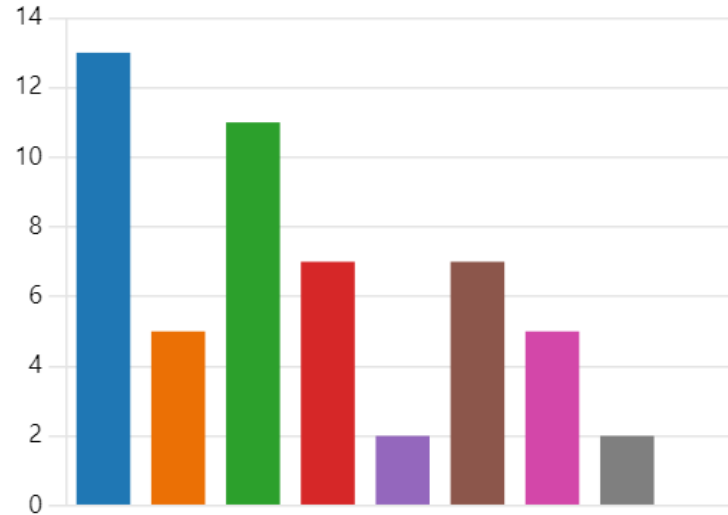
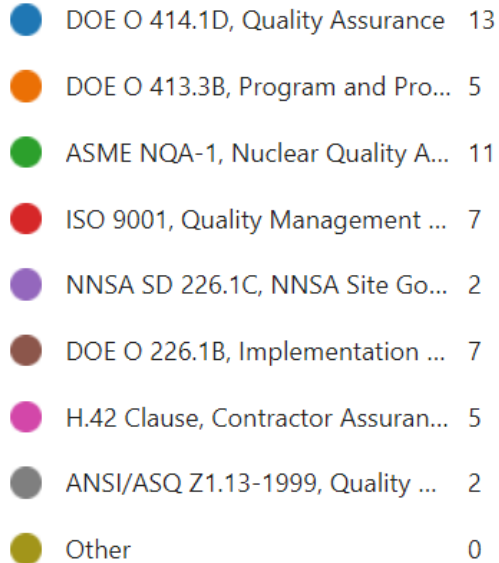
DOE Environmental Management (EM)

Other – DOE Energy Efficiency & Renewable Energy, Office of River Protection



REQUIREMENTS DRIVING GRADED APPROACH

Contractual, regulatory, standards

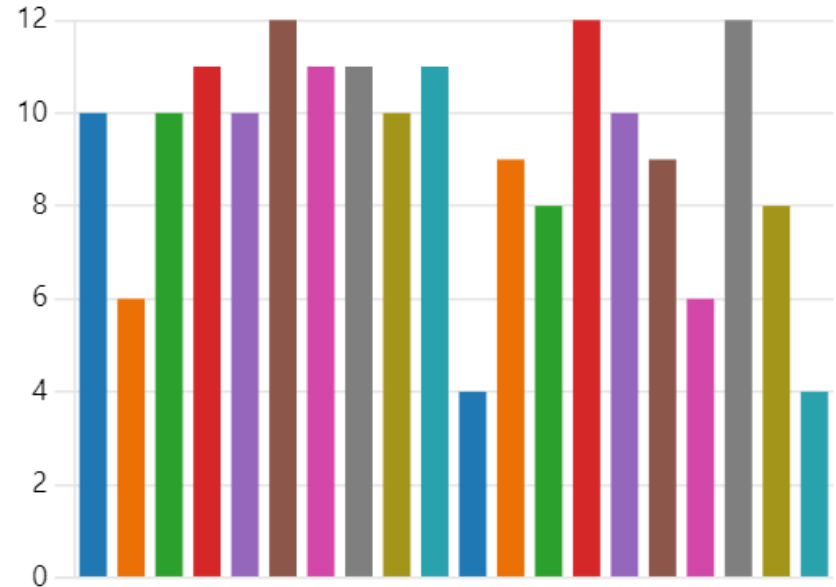


INPUTS TO GRADING SELECTION

Cited in DOE 414.1 QA (from 10 CFR 830.3, *Definitions*) :

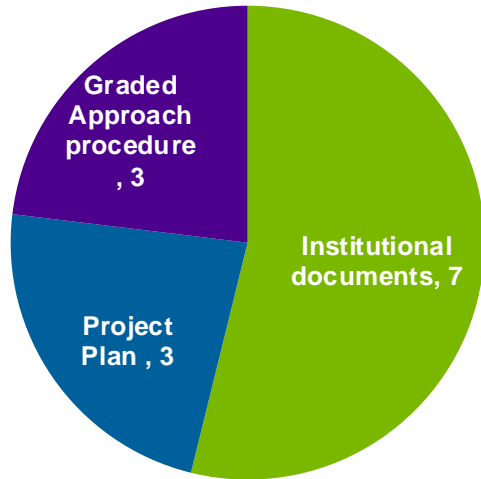
1. the relative importance to safety, safeguards, and security;
 2. the magnitude of any hazard involved;
 3. the life-cycle stage of a facility or item;
 4. the programmatic mission of a facility;
 5. the particular characteristics of a facility or item;
 6. the relative importance to radiological and nonradiological hazards; and any other relevant factors
- Consensus standards suggest risk-based approach with commensurate controls
 - Other contractual orders and standards may inform grading (NQA-1, 413.3)

WHICH PROCESS USE A GRADED APPROACH?

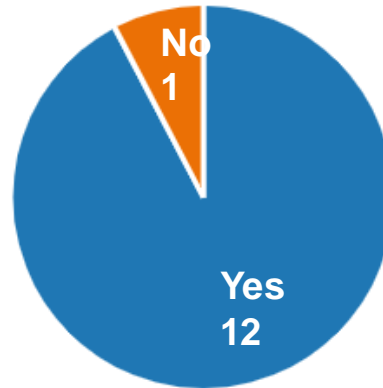


FRAMEWORK DEVELOPMENT & OVERSIGHT

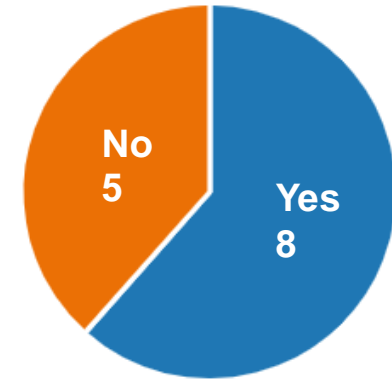
Frameworks are typically created by the Quality or Contractor Assurance organization, but may be at an institutional or project/process level



Where is Graded Approach Described?



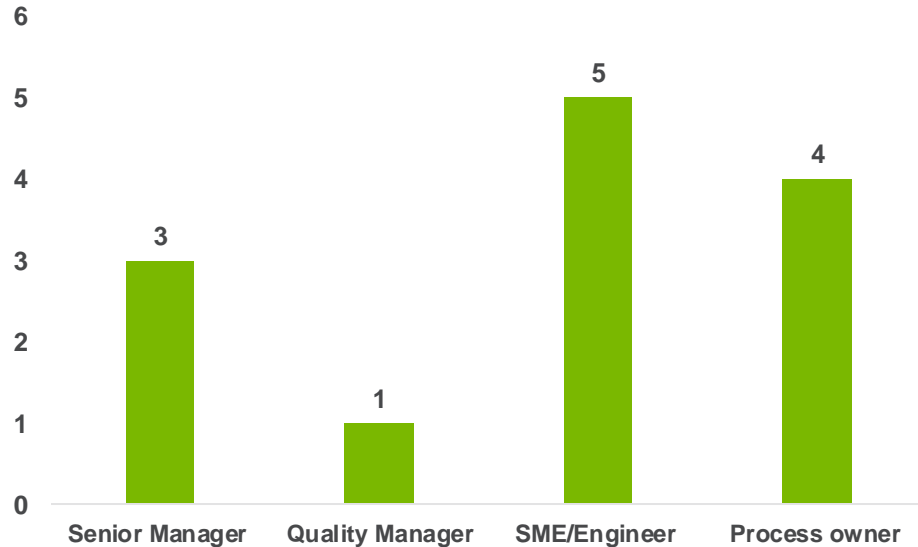
Is Graded Approach Reviewed by Federal Customer?



Is Graded Approach Approved by Federal Customer?

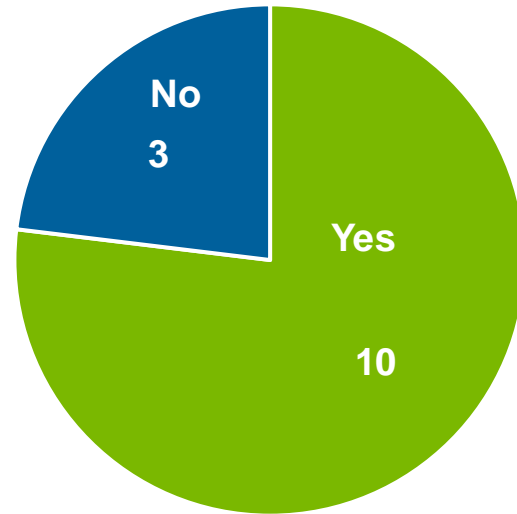
WHO DECIDES GRADING LEVEL?

- Role selecting the grade level to use –
 - Process users
 - Line managers
 - Subject matter experts



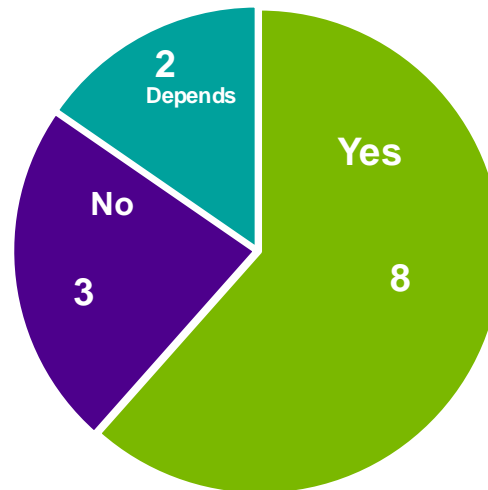
IS GRADING DECISION DOCUMENTED?

- On forms or in implementing software
- Within the work process



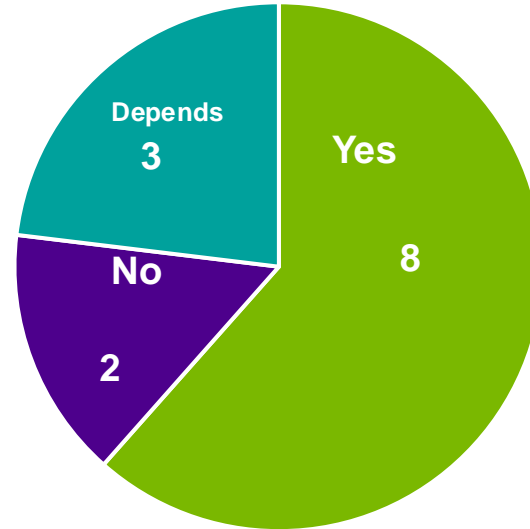
IS DOCUMENTED RATIONALE OR JUSTIFICATION FOR THE DECISION REQUIRED?

- Depends on the process and owner
- Whether justification is required may depend on the level selected

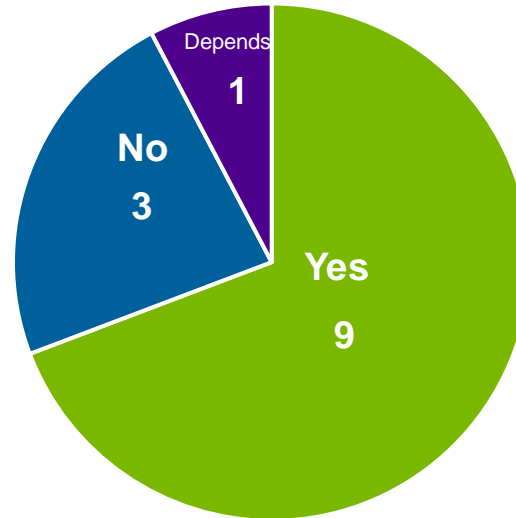


IS GRADING DECISION REVIEWED FOR CORRECTNESS OR CONSISTENCY?

- Variation in level of review
 - Initial review when procedure implemented
 - Assessment program
 - Procedure reviewed periodically
 - Corrective action review board
 - Specific grades
 - All for specific process
- Variation in who reviews
 - Line manager
 - Subject Matter Expert
 - Process Owner
 - Quality Assurance



MAINTAIN HEALTHY OR TARGETED DISTRIBUTION OF RIGOR ACROSS ALL GRADED LEVELS?



SUMMARY OF SURVEY RESULTS

- Graded approach frameworks, levels, selection criteria, and controls vary across the complex
- Graded approach level frameworks may be applicable site wide;
- Criteria to select levels and controls for each level may be determined at the process or project level
- Who selects the grade level varies across the complex
- Variation in grading decision reviews and who performs
- Variation of whether requirements are waived for less significant conditions/items
- Some sites have a targeted or expected distribution across grading levels and monitor actual vs targeted distribution.

HIGHLIGHTS FROM SITE DISCUSSIONS

- Argonne National Laboratory
- Fermi National Accelerator Laboratory
- Los Alamos National Laboratory
- Oak Ridge National Laboratory
- Sandia National Laboratory

GRADED APPROACH AT ARGONNE

- Inputs – 414.1, NQA-1, ISO9001
- Described in program and project plans, system descriptions, procedural documents
 - QAPP, SQAP, Project plans, Enterprise Risk description, Quality Manual
- Implemented in a wide variety of processes and work activities through process control documentation (policies, manuals, procedures, work control documents) and systems
 - Design, Procurement, Work planning, Performance assurance, Assessment manuals
 - Project management, Receipt inspection, Non-Conformance, S/CI procedures
 - Procurement, Issues management, Travel/expense, payroll, partner contract review, lab directed research review, publication review systems
- Evidence in records (system or documentary) of level selected and controls implemented
- Systems trigger reviews by SME's and/or managers as part of approval processes, depending on level

GRADED APPROACH AT ARGONNE (CONT.)

- Procurement: 4 quality levels -with controls in supplier management, contract documents, and inspections.
- Enterprise Risk: two-by-two matrix of risk level and adequacy of mitigation is used to determine allocation of resources for risk controls.
- Design: 4 levels of design process rigor, driving documentation, control activities, and who is involved
- Issues Management: 3 levels of Issue significance are identified + Opportunities for improvement - Level of analysis, actions, reviews
- Assessments - requirements, risks, or management needs or concerns.
- Work Planning and Control: Hazard and complexity drive selection of 4 types of work control documents, reviews, control sets and their verification, and inclusion in Management Awareness tool.

GRADED APPROACH AT FERMILAB

- Graded approach is risk based and described in the Quality Assurance Manual, QAM 12070
- Based on the principle that the people best suited to identify, understand, and assess risks are the people who plan and perform the work.
- Grading process is broken down as follows:
 1. Identify the hazards, consequences, and probability of failures for the work being performed.
 2. Specify the requirements and controls to be applied. Determine the depth, extent, and degree of rigor necessary in the application of the requirements and controls.
 3. 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).

GRADED APPROACH AT FERMILAB (CONT'D)

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
- Graded approach applied at the project level by each project owner

GRADED APPROACH AT FERMILAB (CONT'D)

- Graded approach for nonconformances based on severity level
 - Critical
 - High
 - Medium
 - Low
 - Minimal

GRADED APPROACH AT OAK RIDGE

- UT-Battelle applies the graded approach on the following processes:
 - Work control including research safety summaries for research activities
 - Work control including work packages or plans for operations, maintenance and service activities
 - Quality significance determination for procurement of items and services
 - Issues management significance determination
 - Assessments (independent, management, and activity)
 - Project-specific quality assurance plans and procedures for unique or singular customer requirements
 - Software Quality Assurance for **Safety Software Grading Levels**

GRADED APPROACH AT OAK RIDGE (CONT'D)

- Analysis and application of quality requirements using the graded approach is a process for ensuring that levels of pre-activity evaluation, application of management controls, extent of documentation, and actions necessary to comply with a requirement are appropriate, based on the following risk and hazard considerations:
 - Relative importance to safety, safeguards, security, environment, and missions
 - Type and consequence of any risk involved
 - Life-cycle stage of the facility, activity, or item (for example, age, status, and condition of the facility or process)
 - Programmatic mission of a facility or activity (complexity of products or service involved)
 - Any unique characteristics of the facility, activity, or item
 - Relative importance to radiological and non-radiological hazards

GRADED APPROACH AT OAK RIDGE (CONT'D)

The UT-Battelle QA plan provides an umbrella under ISO 9001-2015 for the entire laboratory, and also incorporates ASME NQA-1 and current Good Manufacturing Practices (cGMP). Project-specific QA Plans are customer-focused, with the flexibility to address the specific requirements of each customer and include the following:

- Graded Approach implemented at project level
- Communicated through Project QA Plans
- Evaluating need for site wide graded approach
- Line and program managers may develop and implement additional processes and controls as necessary to meet specific quality requirements.

GRADED APPROACH AT SANDIA

- General approach described in the QMS description
- Implementation is distributed across the lab rather than a centralized approach
- Graded approach implemented in functional area
- Each process has graded approach imbedded in it
- Details are contained in individual policies/procedures
- Verification and validation of grade choices found during assessments

GRADED APPROACH AT SANDIA (CONT'D)

- Processes using graded approach include:
 - Procurement
 - Environment, Safety & Health
 - Project management
 - Training
 - Hiring
 - Safety and Security

NEXT STEPS

- Reach out to additional sites?
- More in depth review of graded approach for specific processes/areas?

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