

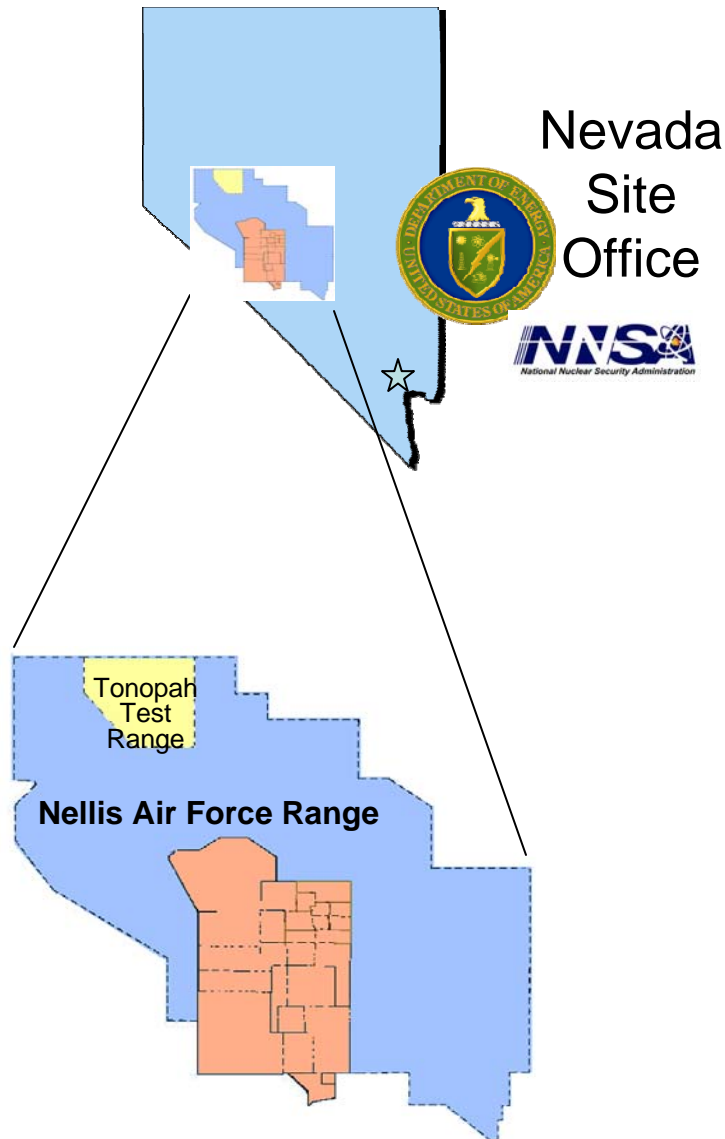
# Quality Grading

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Presentation made to the ASQ Section 0705

Michael Marelli

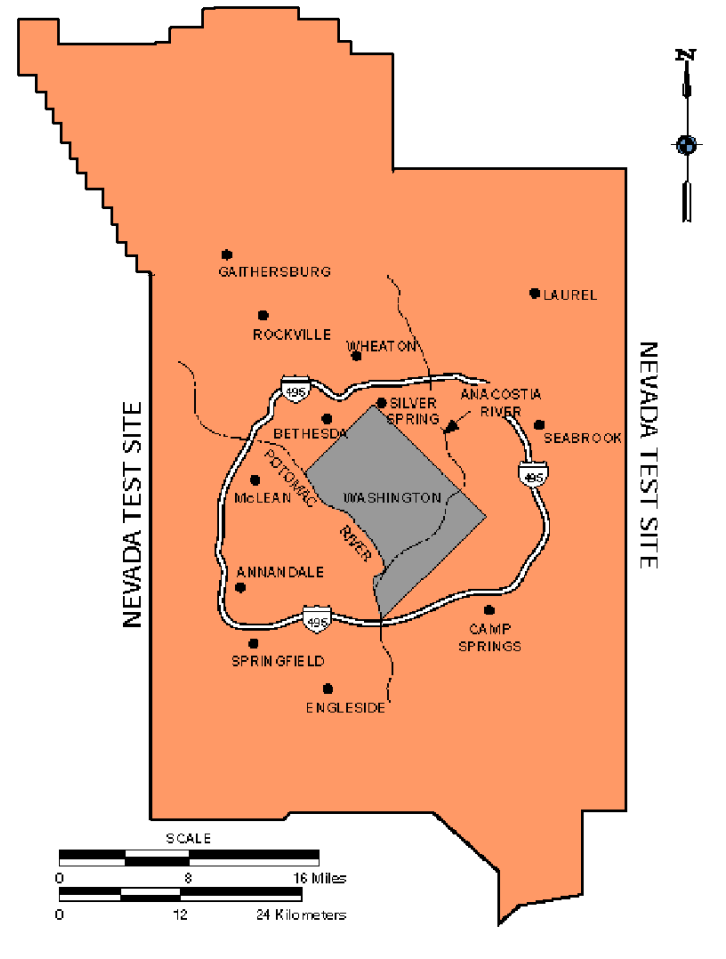
National Nuclear Security Administration, Nevada Site Office



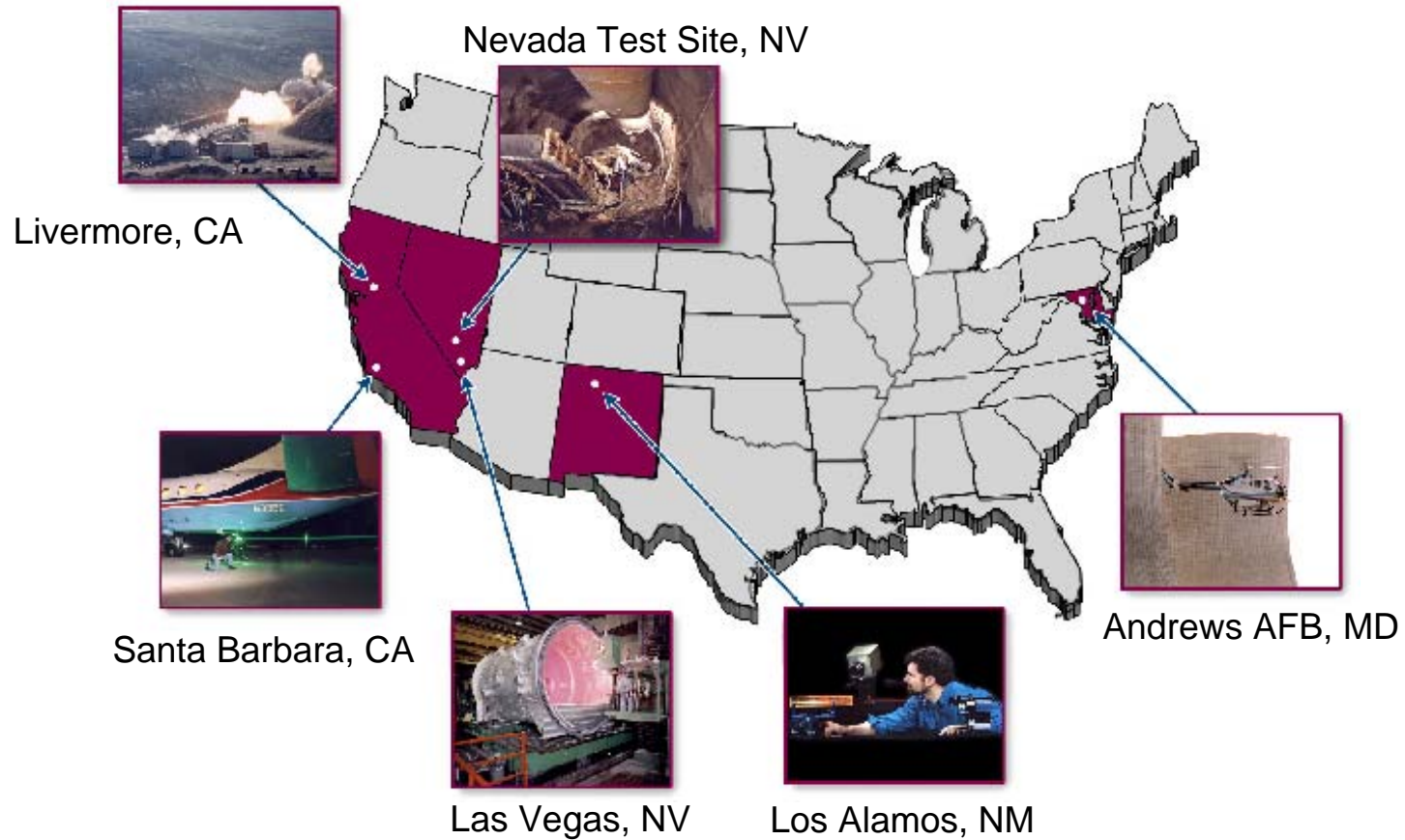
- **National Security**
  - Subcritical and Weapons Physics Experiments
  - Stockpile Stewardship
  - Emergency Management
  - Work For Others
- **Environmental Management**
  - Environmental Restoration
  - Groundwater Characterization
  - Low-level Radioactive Waste Management
- **Stewardship of the Nevada Test Site**

# The Nevada Test Site - a National Asset

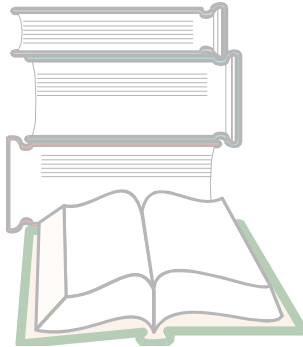
- 1,375 Square Miles
- Remote and Secure
- Housing and Feeding
- Emergency Services
- 1,436 Buildings - 2,900,000 Square Feet
- 700 Miles of Primary and Secondary Roads
- 2 Air Strips
- 5 Helicopter Pads
- 22 Water Wells
- 100+ Miles of Water Supply Line
- 138kV Loop (Main) to 8 Substations



# DOE/NV National Security Work Locations



# DOE/NNSA Hierarchical Regulatory Framework



- Code of Federal Regulations
- Department of Energy Orders and Manual
- National Consensus Standards
- Guides

# Nuclear Facility Regulatory Requirement

- **10 CFR 830.7 Graded approach.** Where appropriate, a contractor must use a graded approach to implement the requirements of this part [Part 830], document the basis of the graded approach used, and submit that documentation to DOE.

2. GENERAL QUALITY REQUIREMENTS.

- a. Quality Assurance Program Development and Implementation. A contractor must assign and identify a senior management position responsible for the development, implementation, assessment, and improvement of a QAP that does the following.
- (1) Implements QA criteria as defined in paragraph 3 of this CRD, S/CI prevention requirements as defined in paragraph 4, and safety software as defined in paragraph 5, using a graded approach and describing how the QA criteria and graded approach are applied. See paragraph 2 of this CRD for guidance on compliance.

# Nuclear Facility Consensus Standard - NQA-1 (2000), Foreword

“The extent to which this Standard should be applied will depend upon the specific type of nuclear facility, items, or services involved and the nature and scope and the relative importance of the activities being performed. The extent of application is to be determined by the organization imposing the Standard. For example, the organization may invoke all requirements, selected requirements, or requirements with appropriate changes.”

# DOE G 414.1-2A, Quality Assurance Management System Guide

“The purpose of grading is to select the controls and verifications to be applied to various items and activities consistent with their importance to safety, cost, schedule, and success of the program.”

# Relevant Factors

- the relative importance to safety, safeguards, and security;
- the magnitude of any hazard or risk involved;
- the life-cycle stage of a facility or activity;
- impact/consequences on the programmatic mission of a facility;
- the particular characteristics of a facility or activity;
- the nuclear safety classification or hazard category of the item or activity;
- adequacy of existing safety documentation;
- the relative importance of radiological and nonradiological hazards;
- complexity of products or services involved;
- performance history of a facility or activity; and
- any other relevant factors.

# DOE G 414.1-4, Safety Software Guide – Software Grading

## 2.2 GRADED APPLICATION

Proper implementation of DOE O 414.1C will be enhanced by grading safety software based on its application. Safety software grading levels should be described in terms of safety consequence and regulatory compliance. This Guide utilizes the grading levels and the software types (custom developed, configurable, acquired, utility calculations, and commercial design and analysis tools) to recommend how the SQA work activities are applied. The grading levels are defined as follows.

Level A, Level B, and Level C. Each level is defined by criteria relevant to the failure of the software to perform its intended safety function.

So How Does a Contractor Develop  
and Describe a Graded Approach?



# QAP Description

- The QAP must define the graded approach and describe how the QA criteria and graded approach are applied.
- The implementing mechanisms (procedures) implement the graded approach.

# A Former Nevada Site Office (NSO) Contractor's Approach

- Stoller-Navarro Joint Venture (SNJV) held a contract with NSO for environmental site characterization activities.
- Contract currently being re-bid.
- SNJV provided an excellent tool for communicating how they applied the graded approach.

QA Control Elements*				
Elements for Control	Documents Implementing a Graded Approach	Low Risks	Medium Risks	High Risks
1.0 Program	<ul style="list-style-type: none"> <li>•SNJV Project Execution Plan</li> <li>•SNJV Health and Safety Plan</li> </ul>	<ul style="list-style-type: none"> <li>•Management ensures policies, plans and procedures are in place for routine activities</li> <li>•Generic roles and responsibilities are identified</li> <li>•General Health and Safety requirements established for SNJV activities</li> </ul>	<ul style="list-style-type: none"> <li>•Projects are evaluated for the need for additional oversight</li> <li>•A site-specific Health and Safety Plan is developed</li> </ul>	<ul style="list-style-type: none"> <li>•Management ensures risks have been thoroughly evaluated</li> <li>•A site-specific Health and Safety Plan is developed with increased controls and restrictions.</li> <li>•Management ensures required hold points are identified</li> <li>•Management provides increased oversight</li> </ul>
2.0 Personnel Training & Qualification	<ul style="list-style-type: none"> <li>•Training Program subject area</li> <li>•R2A2 Document</li> </ul>	<ul style="list-style-type: none"> <li>•Basic indoctrination, orientation, and awareness training</li> </ul>	<ul style="list-style-type: none"> <li>•Required reading and quizzes, classroom, and perhaps on-the-job training</li> <li>•Prefield and regularly scheduled briefings</li> </ul>	<ul style="list-style-type: none"> <li>•On-the-job training [OJT], job performance measures, practicals to verify knowledge skills and performance</li> </ul>
3.0 Quality Improvement	<ul style="list-style-type: none"> <li>•Trending subject area</li> <li>•Deficient Conditions subject area</li> <li>•Event/Issue Management subject area</li> </ul>	<ul style="list-style-type: none"> <li>•Issues are identified and handled routinely in accordance with procedures</li> </ul>	<ul style="list-style-type: none"> <li>•Issues are formalized, raised to a higher level of management, tracked in the ACTS system, and evaluated for impact to the project</li> <li>•Issues are evaluated to determine if they are systemic</li> <li>•Lessons are identified and logged into a local database</li> </ul>	<ul style="list-style-type: none"> <li>•Events are investigated, a critique is held, cause analysis performed, and the issue analyzed for impact and applicability to the SNJV program as a whole.</li> <li>•Causes are evaluated and necessary controls developed to mitigate future events</li> <li>•A formal Lessons Learned is developed and distributed.</li> </ul>

**QA Control Elements\***

Elements for Control	Documents Implementing a Graded Approach	Low Risks	Medium Risks	High Risks
4.0 Documents and Records	<ul style="list-style-type: none"> <li>•Document Management subject area</li> <li>•Records Management subject area</li> </ul>	<ul style="list-style-type: none"> <li>•Documents are informal and uncontrolled (e.g., desktop instructions)</li> <li>•Records are not required</li> </ul>	<ul style="list-style-type: none"> <li>•Documents are prepared, reviewed, and approved according to procedures</li> <li>•Records are managed in accordance with approved procedures</li> </ul>	<ul style="list-style-type: none"> <li>•Documents are controlled</li> <li>•Records are documented and submitted on a regular basis to Central Files</li> </ul>
5.0 Work Processes	<ul style="list-style-type: none"> <li>•Data Quality Objectives Process subject area</li> <li>•Work Planning and Control Process subject area</li> <li>•Suspend Work/Stop Work subject area</li> <li>•Radiological Work: Preparing for Work subject area</li> <li>•Graded Approach to Radiological Controls procedure</li> <li>•Radiological Work: Performing Work subject area</li> <li>•Calibration and Maintenance of Measuring and Testing Equipment</li> </ul>	<ul style="list-style-type: none"> <li>•Project planning and activities are executed in a routine manner in accordance with SNJV procedures and plans</li> </ul>	<ul style="list-style-type: none"> <li>•Project planning and activities are evaluated by subject matter experts to determine which additional controls are required</li> </ul>	<ul style="list-style-type: none"> <li>•Project and planning documents contain job specific controls and procedures to mitigate hazards; any hold points are identified.</li> <li>•Assessment frequency is increased</li> </ul>
6.0 Design	<ul style="list-style-type: none"> <li>•SNJV does not conduct design work</li> </ul>	<ul style="list-style-type: none"> <li>•NA</li> </ul>	<ul style="list-style-type: none"> <li>•NA</li> </ul>	<ul style="list-style-type: none"> <li>•NA</li> </ul>

QA Control Elements*				
Elements for Control	Documents Implementing a Graded Approach	Low Risks	Medium Risks	High Risks
7.0 Procurement	<ul style="list-style-type: none"> <li>•Purchase of Materials and Services</li> <li>•Quality Assurance (QA)/Waste Management (WM) Requisition Review of Quality-Affecting Items/Services subject area</li> </ul>	<ul style="list-style-type: none"> <li>•Items are purchased using the standard procurement process</li> </ul>	<ul style="list-style-type: none"> <li>•Procurements for quality-affecting items are reviewed and approved by a QA representative</li> </ul>	<ul style="list-style-type: none"> <li>•Procurements for waste items are reviewed and approved by the Waste Certification Official</li> <li>•An engineer or subject matter expert reviews specialized procurements</li> </ul>
8.0 Inspection and Acceptance Testing	<ul style="list-style-type: none"> <li>•Receipt Inspection of Quality-Affecting Items and Hazardous Materials subject area</li> </ul>	<ul style="list-style-type: none"> <li>•Requires verification that the received item agrees with the procurement documentation (e.g., correct amount and type) and is not damaged</li> </ul>	<ul style="list-style-type: none"> <li>•Conducted in accordance with approved procedures and requires additional inspection or testing controls such as screening for S/CI</li> </ul>	<ul style="list-style-type: none"> <li>•Conducted with receipt inspection or acceptance testing plans and requires additional inspection or testing controls (e.g., involvement by engineers in item testing)</li> </ul>
9.0 Management Assessment	<ul style="list-style-type: none"> <li>•Management Assessments subject area</li> </ul>	<ul style="list-style-type: none"> <li>•Scheduled at the discretion of the responsible manager and can be in the form of a surveillance</li> </ul>	<ul style="list-style-type: none"> <li>•Scheduled and conducted in accordance with approved procedures and are formally planned, executed, and documented</li> </ul>	<ul style="list-style-type: none"> <li>•Scheduled with input from upper management and QA and can be supplemented by a team of subject matter experts</li> </ul>
10.0 Independent Assessment	<ul style="list-style-type: none"> <li>•Independent Quality Assessments subject area</li> </ul>	<ul style="list-style-type: none"> <li>•Often are unscheduled and are in the form of a surveillance</li> </ul>	<ul style="list-style-type: none"> <li>•Scheduled and conducted as determined by QA; conducted in accordance with approved procedures and are formally documented; conducted by persons not involved with the project being assessed</li> </ul>	<ul style="list-style-type: none"> <li>•Often scheduled before initiating work; scope is more comprehensive and reports are reviewed and approved by QA</li> </ul>

QA Control Elements*				
Elements for Control	Documents Implementing a Graded Approach	Low Risks	Medium Risks	High Risks
11.0 Suspect/Counterfeit Items	<ul style="list-style-type: none"> <li>•Suspect/Counterfeit Items (S/CI) subject area</li> </ul>	<ul style="list-style-type: none"> <li>•Standard procurement controls, including receipt inspection, as applicable to work scope</li> </ul>	<ul style="list-style-type: none"> <li>•Purchase orders and contracts include wording for S/CI screening and receipt inspection; items subject to S/CI are procured only from vendors on the Approved Vendor List</li> </ul>	<ul style="list-style-type: none"> <li>•Job-specific S/CI screening, identification, and procurement inspection plans are required; technical specifications and documentation requirements are also considered</li> </ul>
12.0 Software Quality Assurance (SQA)	<ul style="list-style-type: none"> <li>•Software Quality Assurance subject area</li> </ul>	<ul style="list-style-type: none"> <li>•None</li> </ul>	<ul style="list-style-type: none"> <li>•Software controls are in accordance with approved procedures and include a software inventory and classification</li> </ul>	<ul style="list-style-type: none"> <li>•Full life-cycle documentation is required including testing and validation plans which undergo review by QA</li> </ul>

\* Risks levels are cumulative (e.g., medium level risk includes low level controls plus medium level controls; high level risk includes low, medium and high level controls).

# Final Thoughts

- A table is an effective means of describing the graded approach
- Controls and Verifications should be specific and unambiguous
- Processes should be user-friendly