



Updates for the
EFCOG Quality Assurance Subgroup
from the
Office of Quality Assurance &
Nuclear Safety Management Programs

Christian Palay
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AU-30 Family Updates

Office of Nuclear Safety
(AU-30)

Garrett Smith (Director)

➤ Tom Hiltz

Nuclear Safety Basis & Facility Design
(AU-31)

Brian Dinunno (Director)

- Jim Bisker
- **Patrick Frias (NSR&D)**
- Caroline Garzon
- Pranab Guha
- Sharon Jasim-Hanif
- Sam Rosenbloom

Quality Assurance &
Nuclear Safety Management Programs
(AU-32)

Christian Palay (Director)

- Duli Agarwal
- Sonya Barnette
- Brendan Burns
- Jeff Feit
- James Heffner
- Kathy Knight
- James Shaw
- *SQA SME*



QA Policy Updates

- DOE-HDBK-1230-2019, *Commercial Grade Dedication Application Handbook*
- DOE Guide G 414.1-4A, *Software Quality Assurance Guide for Use with DOE O 414.1D, Quality Assurance*
- DOE-STD-3020-2015, *Specification for HEPA Filters Used by DOE Contractors*
- DOE-STD-3025-2007, *Quality Assurance Inspection and Testing of HEPA Filters*



Safety Software Central Registry Updates

- Implementing the corrective action plan from the AU-32 management assessment albeit slowly
- Prioritizing the candidate list of software
 - Existing software that needs to be updated
 - New software to be added to the registry



QA Policy Challenges

- Suspect Counterfeit Items
 - Reporting requirements
 - Organizational responsibilities
 - Outdated website
- Software Quality Assurance
 - Focus beyond nuclear safety
 - Emphasis on ASME NQA-1
- Graded Approach
 - No requirements beyond having one
 - Sole emphasis from 10 CFR 830



AU-32 Priorities

- Participating in the EFCOG Procurement Engineering Group
- Issuing the DOE Guide G 414.1-4A (Software QA Guide)
- Central Registry Corrective Action Plan
- DOE Order 414.1E, *Quality Assurance*



Office of Environment, Health, Safety and Security



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And Now This



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BACKUP SLIDES



Suspect Counterfeit Items

- DOE O 414.1D, section 1. c., requires the establishment additional process-specific quality requirements to be implemented under a Quality Assurance Program for the control of suspect/counterfeit items.
- DOE O 414.1D, Attachment 3, Section 2. b., requires the quality assurance program to identify the position responsible for S/CI activities and for serving as a point of contact with the Office of Health, Safety, and Security.
- DOE O 414.1D, Attachment 3, Section 4, requires that S/CIs must be reported in accordance with DOE O 232.2, Occurrence Reporting and Processing of Operations Information, dated 08-30-11 (or latest version).



Software Quality Assurance

- DOE O 414.1D requires that all software meet the applicable QA requirements in Attachment 2 using a graded approach
 - Section 4.a.(2) in the order for Departmental element and their associated field element(s)
 - Section 1.b in the Contractor Requirements Document for DOE Contractors
 - Both of the requirements are preceded by “Note”
- DOE O 414.1D applies to all work and part of the definition of work lists software development as either a defined task or activity



Software Quality Assurance

- There are 63 instances of the word “Software” in the QA order with 27 of those being for “Safety Software”
- Should the QA order be more clear defining the quality assurance requirements for all software activities and products?
- Is there too much emphasis on safety software for nuclear facilities?



Graded Approach

- DOE Order 414.1D requires using a graded approach to develop a QAP and implement the approved QAP
- The QAP must describe the graded approach used in the QAP
 - Section 4.a.(1) in the order for Departmental element and their associated field element(s)
 - Section 1.a in the Contractor Requirements Document for DOE Contractors



Graded Approach

- The QA order cites the definition of Graded Approach out of 10 CFR 830
- The QA Guide gives a better description of what is a graded approach
- The graded approach cannot be used to “grade quality assurance criterion to zero,” which has the effect of eliminating all verifications of the requirement (“to get out of work”).
- What it isn't:
 - One-size-fits-all
 - Minimum standard of quality



Other AU-32 Priorities

- Quality Assurance Program for Office of Nuclear Safety
- DOE Quality Assurance Community of Practice
 - DOE Software Quality Assurance Support Group
 - Central Registry Users & Developers Group