

Chemical Security

Office of Nuclear Security and Incident Response U.S. Nuclear Regulatory Commission

March 2014

Topics

- Background
- Site Visits
- Results
- Discussion on Path Forward



Background

- DHS Appropriations Act for FY2007
- 6 CFR 27 Chemical Facility Anti-Terrorism Standards (CFATS)
- MOU with DHS
- SECY-11-0108
- SRM-SECY-11-0108



Site Visits

- Nuclear Fuel Services
- Oconee Nuclear Power Plant
- B&W Nuclear Operating Group
- GE Vallecitos
- Global Nuclear Fuels -Americas
- Westinghouse

- Brunswick Nuclear Power Plant
- U.S. Enrichment Corporation – American Centrifuge Plant
- Areva-Richland
- Honeywell
- Louisiana Enrichment Services



Results

- Reviewed type and amount of chemicals onsite and compared it to DHS' Chemicals of Interest (COI) list.
- Toured the site and observed physical security in place to protect chemicals.
- All sites had adequate security to protect chemicals from sabotage and theft and diversion.
- At this time, NRC staff believes that there are no security gaps that warrant Rulemaking/Orders.
- Internal processes should be developed so that the NRC is aware of any changes to the status of chemicals.



Discussion on Path Forward



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Transition to Next Presentation





Fuel Cycle Cyber Security

March 3, 2014 NEI / NRC Alignment Meeting

NRC Progress



- Reviewing voluntary proposal
- Continuing to develop draft Order
 - Further consideration of potential consequences has produced a facility type approach
 - Modifications made considering comments from July 2013 NEI letter
 - Working on details for alternatives to isolation

Path Forward



- Evaluate and discuss voluntary proposal
- Continue to develop draft Order
- Remain sensitive to lessons learned from reactor cyber-security rule implementation

Transition to Next Presentation





Cumulative Effects of Regulation

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Introduction

CATEGORY 2 MEETING

 The primary discussions are expected to be between the NRC and representatives of licensed fuel cycle facilities. Members of the public will be invited to participate in this meeting at designated points during the meeting.

REMINDER

- The information contained herein is for discussion purposes only and does not represent the final NRC position.
- We will not be discussing the merits of the regulatory activities during this meeting.

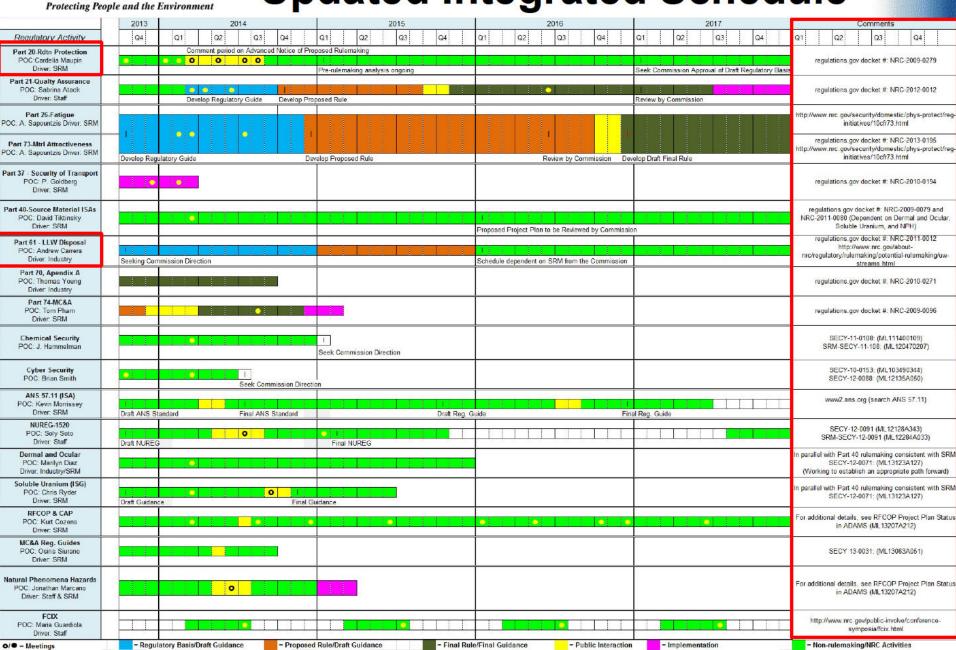


CER Agenda

- Review Updated Schedule
- Adjustments
- Relative Flexibility in Schedule
- Runner Up List
- New Regulatory Issues



Updated Integrated Schedule





Adjustments

- Examples of Improvements
 - Added Part 20 and 61
 - Focus on implementation (Pink)
 - Adjust meetings
- Challenges of Representing Implementation
 - Unavailable in the early stages of rulemaking
 - Guidance clarifies existing requirements
 - Improved by industry input
- Existing Schedule Vulnerabilities?



Updates to the Integrated Schedule

CER on the public website

<u>Home</u> > <u>Nuclear Materials</u> > <u>Fuel Cycle Facilities</u> > <u>Regulations, Guidance, and Communications</u> **http://www.nrc.gov/materials/fuel-cycle-fac/regs-guides-**

comm.html#cumeffects

- Supplement to the Integrated Schedule
 - Purpose
 - Bulleted summary
 - Related documents
- CER Meetings
 - Next meeting ???



Relative Flexibility

- Parallel development
- Safety/security Driven: Low flexibility
 - Example: Fukushima related activities
- Commission Driven: Limited flexibility
 - Milestones set by Commission
- Staff Driven Moderate to High flexibility
 - Milestones based on priorities/resources/feedback



Creating a Runner Up List

Considerations

- Lower priority
- Less intensive
- Longer term
- Broader effort

Items for Consideration

- Two Person Rule (Part 74)
- Part 95, INFOSEC
- Decommissioning Funding Rule
- Part 26 Fitness for Duty Programs
- Counterfeit (CFSI)
- EPA ANPR on a 40 CFR 190 rulemaking
- Etc.



New Regulatory Issues

- Important Criteria to Consider
 - Identify the problem and examples
 - Options for resolution
 - Identify implementation challenges
 - Seek stakeholder comments
- NRC Interested in Industry's Proposals

Supplement to Fuel Cycle Program Integrated Schedule Last Updated Friday, February 28, 2014

This supplement provides a public version of the purpose, brief overview, and background documentation available for the regulatory activities being tracked on the Fuel Cycle Cumulative Effects of Regulation Integrated Schedule. Links to the background documents have been included where possible.

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RULEMAKINGS

Part 20	"Standards for Protection Against Radiation"
Purpose:	Update the radiation protection standards to address improvements in the modeling of dose calculations.
Key Information	 The regulatory basis for the Part 20 rulemaking to update the radiation protection thresholds is under development. The Part 20 working group plans to publish several option papers to provide the public with an opportunity to provide early comment starting in March 2014. Once the regulatory basis has been completed by the staff, it will be provided to the Commission for a vote some time in 2015. Meetings Information System on Occupational Exposure ALARA Symposium – January 2014 Health Physics Society Midyear Topical Meeting – February 2014 NRC Regulatory Information Conference - March 2014 Conference of Radiation Control Program Directors Meeting Presentation – May 2014 Annual Health Physics Society Meeting – July 2014 Nuclear Energy Institute: Radiation Protection Forum Presentation – July 2014 Organization of Agreement States Meeting –August 2014
Related Information	 http://www.regulations.gov/#!docketDetail;D=NRC-2009-0279 http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/opt-revise.html SECY-08-0197 dated December 18, 2008 (ML083360555) SRM-SECY-08-0197 dated December 18, 2008 (ML090920103) SECY-12-0064 dated April 25, 2012 (ML121020108)
	SRM-SECY-12-0064 dated December 17, 2012 (ML12352A133)

Part 21	"Reporting Defects and Non-Compliance"
	Identify the information that must be provided to customers when a Part 21 report
Purpose:	is developed, define QA requirements described in procurement documents and
	specify the documentation of commercial-grade dedication activities.
Key	 Issue final regulatory basis in fall 2014
Information	Finalize proposed rule August 2015
IIIIOIIIIalioii	Expect to finish rulemaking in 2016
	 http://www.regulations.gov/#!docketDetail;D=NRC-2012-0012
	 http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/part-
Related	21-rulemaking.html
Information	 OIG-10-20 dated September 28, 2010 (<u>ML102710583</u>)
	 OIG-11-A-08 dated March 23, 2011 (<u>ML110820426</u>)
	 <u>SECY 2011-0135</u> dated September 29, 2011 (<u>ML112430138</u>)

Part 26	"Subpart I Managing Fatigue"
Purpose:	Rulemaking regarding applying fatigue to security personnel at material licensees.
Key Information	 Part 26 and 73 will be performed in parallel because they have similar stakeholders and both rules are security related The draft Regulatory Basis is expected to be developed by October 2014. Commissioner Assistant Note to Commission November 2014 Proposed rule to the Commission on May 2016 Draft regulatory Guides (multiple) to Commission by September 2016 Final rule to the Commission by November 2017 Final regulatory guide to the Commission by June 2018 Planning to request public comments on the regulatory basis via FRN and a public meeting in June 2014, around FCIX 2014. (same as Part 73)
Related Information	 http://www.nrc.gov/security/domestic/phys-protect/reg- initiatives/10cfr73.html Part 26: SRM-COMSECY-04-0037 (fatigue for officers at material licensees), dated September 1, 2004 (ML042450533)

Part 37	"Physical Protection of Category 1 and 2 Radioactive Material"
Purpose:	The objective of this final rule is to provide reasonable assurance of preventing the theft or diversion of category 1 and category 2 quantities of radioactive material.
Key Information	 Rulemaking to codify security orders (Increased Controls Order) Currently in the implementation stage Rule effective date: 3/19/2014
Related Information	 http://www.regulations.gov/#!docketDetail;D=NRC-2010-0194 http://www.nrc.gov/security/byproduct/10-cfr-part-37.html Final Rule *Update: Effective August 15, 2013 NUREG-2155 - "Implementation Guidance for 10 CFR Part 37, 'Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," dated February 2013 Non-technical Frequently Asked Questions Part 37 Implementation Questions and Answers

Part 40	"Domestic Licensing of Source Material"
Purpose:	Risk inform the regulatory requirements for certain Part 40 facilities by requiring an integrated safety analysis similar to Part 70, Subpart H. The requirements are proposed for facilities with significant quantities of uranium hexafluoride.
Key Information	 The Commission disapproved the rule and directed staff to develop regulatory guidance (e.g., chemical exposure hazards to be addressed in ISAs), determine the need for radiation performance requirements at source material facilities, and revise the regulatory analysis. The rule is linked to the development of guidance for Dermal and Ocular, Soluble Uranium, and Natural Phenomena Hazards.
Related Information	 http://www.regulations.gov/#!docketDetail;D=NRC-2009-0079 http://www.regulations.gov/#!docketDetail;D=NRC-2011-0080 SRM-M20070308B dated March 8, 2007 (ML070820023) Transcript of Commission Meeting dated March 8, 2007 (ML070720773) SRM-SECY-07-0146 dated October 10, 2007 (ML072830536) SRM-10-0128 dated November 30, 2010 Approval to publish proposed rule (ML103350037) SECY-12-0071 dated May 7, 2012 (ML12094A344) SRM-12-0071 dated May 3, 2013 (ML13123A127)

Part 61	"Disposal of Low Level Waste"
Purpose:	Rulemaking for a site-specific analysis or performance assessment for the disposal of depleted uranium (DU) and other long-lived isotopes in a near-surface disposal facility.
Key Information	 The Commission directed the NRC staff to modify the proposed regulatory basis which will be revised during the first half of 2014, prior to resubmittal to the Commission.
Related Information	 http://www.regulations.gov/#!docketDetail;D=NRC-2011-0012 http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/potential-part61-revision.html http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/uw-streams.html NUREG guidance document, "Guidance for Conducting Technical Analysis for 10 CFR Part 61" 2009 Technical Basis for Proposed Rule dated April 28, 2011 - ML111040419 Preliminary Proposed Rule Language dated May 2011 ML111150205 COMWDM-11-0002/COMGA-11-0002 - Revision to 10 CFR Part 6 dated November 03, 2011 (ML113070543) SRM-COMWDM-11-0002/COMGEA-11-0002 - Revision to 10 CFR Part 61 dated January 19, 2012 (ML120190360)

Part 70 A	Part 70 Appendix A "Reportable Safety Events"		
Purpose:	This rulemaking is related to NEI's petition requesting that the NRC amend its regulations to clarify safety event reporting requirements in Appendix A of Part 70.		
Key Information	 Rulemaking to revise the number of days that would be allowed for a licensee to submit the written report after discovery of the event and to remove redundant reporting requirements. This is a direct final rulemaking. 		
Related Information	 http://www.regulations.gov/#!docketDetail;D=NRC-2010-0271 Petition from NEI resolved in Federal Register volume 75 FR page 63725, dated October 18, 2010 		

Part 73	"Part 73-Material Attractiveness"
Purpose:	Update security regulations within Title 10 of the Code of Federal Regulations (10 CFR) Part 73, that considers material attractiveness.
Key Information	 Improve consistency and clarity; Make generically applicable security requirements similar to those imposed by security orders issued following the terrorist attacks of September 11, 2001. Consider risk insights from the National Laboratory, operational oversight and inspection activities, and international guidance; and (e.g., Material Attractiveness, Dose Limit Threshold, Sabotage, Safety-safeguards Interface). Use a risk-informed and performance-based structure.
Related Information	 http://www.nrc.gov/security/domestic/phys-protect/reg- initiatives/10cfr73.html SRM-SECY-09-0123 – Material Categorization and Future Fuel Cycle Facility Security-Related Rulemaking, dated July 8, 2010 (ML101890711)

Part 74	"Material Control & Accounting of Special Nuclear Material"
Purpose:	This rulemaking revises and consolidates the MC&A requirements in order to update, clarify and strengthen them
Key Information	 The comment period on draft rule and guidance was extended and now ends on March 10, 2014.
Related Information	 http://www.regulations.gov/#!docketDetail;D=NRC-2009-0096 OIG Report 03-A-15 dated February 6, 2013 (ML13037A476) SECY-08-0059 dated April 2008, (ML080580273) SRM-SECY-08-0059 dated February 2009, (ML090360473) SECY-11-0175 dated December 2011, (ML113400134) SRM-SECY-11-0175 dated April 12, 2012 (ML121030104) COMSECY-12-0026 dated November 2012, (ML12311A436) SRM-COMSEC-12-0026 dated May 2013, (ML13130A077)

Cyber Security		
Purpose:	Assure that NRC licensed Fuel Cycle Facilities provide reasonable assurance that digital assets associated with safety, security, emergency preparedness, and material control and accountability are adequately protected from cyber-attacks.	
Key Information	 Directed by management as part of process to evaluate this need for all types of non-power reactor licensees. Evaluating the need for establishing requirements for cyber security at fuel cycle facilities. The NRC staff will seek Commission direction. 	
Related Information	<u>SECY-12-0088</u> dated June 25, 2012 (<u>ML12135A050</u>)	

Chemical Security	
Purpose:	Assure that NRC licensed Fuel Cycle Facilities provide reasonable assurance that the physical security for chemicals of interest are equal to the Department of Homeland Security standards and adequately protect against sabotage, theft and diversion.
Key Information	 NSIR is scheduled to complete the final site visits in the first quarter of 2014. Provide the Commission with a summary of the responses with a Commissioner Assistant Note or Technical Assistant briefing summarizing the key issues, and a status of Department of Homeland Security's implementation of chemical security regulations. Hold a workshop with the licensees to identify what additional security measures, if any, should be incorporated into security plans (early to midsummer 2014). Provide the Commission with a notation vote paper that describes the staff's evaluation of those measures necessary to constitute an adequate chemical security framework at these facilities.
Related	<u>SECY-11-108</u> dated August 5, 2011 (<u>ML111460426</u>)
Information	 SRM-SECY-11-108 dated February 15, 2012 (<u>ML120470207</u>)

NON-RULEMAKINGS

ANS 57.11 "ISA Standard"	
Purpose:	ANS is developing an ISA standard that would provide clear guidelines for licensees to perform an ISA and improve the ability to identify those elements which serve as leading indicators of ISA quality.
Key Information	 Development of the standard could take up to 3 years to be finalized. The schedule has not been confirmed with ANS so the date for a public comment period has not been established.
Related Information	 www2.ans.org (search ANS 57.11) (http://www2.ans.org/standards/committees/nfsc/calendar/files/ans-57-11pins(2)-fornfscapproval.doc)

NUREG-1520 Revision 2, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility"	
Purpose:	Update the guidance for standard review plans for fuel cycle facilities.
Key Information	 NUREG-1520 is being revised and we anticipate that another revision will be needed after the ANS standard is issued. The revision will not address ISA related issues. A 90 day public comment period on the Draft NUREG will begin June 2014 and will be discussed at the 2014 FCIX.
Related	 SECY-12-0091 dated June 30, 2012 (<u>ML12128A343</u>)
Information	 SRM-SECY-12-0091 dated October 9, 2012 (<u>ML12284A033</u>)

Soluble Uranium and Dermal and Ocular	
Purpose:	Provide thresholds for soluble intake for workers and the most up to date standards for dermal and ocular exposure to an individual from licensed material or hazardous chemicals produced from licensed material.
Key Information	 NRC is working to create two Interim Staff Guidance documents one on acute uranium exposure standards and one on dermal/ocular exposures for compliance with 70.65(b)(7). The guidance documents must be completed to support the Part 40 rulemaking.
Related Information	 Acute Chemical Toxicity of Uranium With Application to 10 CFR 70.61 (NEI White Paper) (ML091490747) SRM-12-0071 dated May 3, 2013 (ML13123A127) – related to Part 40 rulemaking

Revised Fuel Cycle Oversight Process	
Purpose:	To develop the Revised Fuel Cycle Oversight Process (RFCOP) in accordance with Commission direction provided in SRM-SECY-11-0140.
Key Information	 A draft regulatory guide on the Corrective Actions Program (CAP) was published for a 30 day comment period in February of 2014. A public outreach meeting will be scheduled in early to mid-summer. Multiyear project; multiple public interactions, anticipate 3-4 outreach meetings per year.
Related	SECY-11-0140 dated October 2011 (ML111180705)
Information	 SRM-SECY-11-0140 dated January 5, 2012, (ML120050322)

Corrective Action Program (Part of RFCOP)	
Purpose:	Explain the proposed guidance (DG-3044) for fuel cycle licensees to receive the incentive contained in the NRC's Enforcement Policy related to the development of a corrective action program (CAP), including a brief history, status, and next steps.
Key Information	 The "CAP document" (i.e., Draft Regulatory Guide 3044) was published in February 2014 for public comment in the Federal Register. The guidance should improve stakeholder understanding of the CAP approval process. Possibly, solicit a letter from the Nuclear Energy Institute/industry with comments on DG-3044, including a discussion on any backfit concerns. Identify additional licensees interested in participating in the CAP approval process.
Related Info.	 The ADAMS accession number for DG-3044 is ML13219B204 The draft Regulatory Guide 3044 on CAP as published in the Federal Register, http://www.gpo.gov/fdsys/pkg/FR-2014-02-12/pdf/2014-03012.pdf SECY-11-0140 dated October 2011 (ML111180705) SRM-SECY-11-0140 dated January 5, 2012, (ML120050322)

Material Control and Accounting Regulatory Guides	
Purpose:	Effort to update the Regulatory Guides to be consistent with the 2006 agency expectation for regular revisions.
Key Information	 The purpose of this effort is to consolidate and eliminate outdated guidance as requested by the Chairman. 27 MC&A guidance documents are consolidated into 7 documents. Staff expect to complete the draft Regulatory Guides and technical basis for public comments by June 2014. None of the integrated Regulatory Guides are impacted by ongoing draft rulemaking of 10 CFR 74.
Related Information	SECY-13-0031 dated March 28, 2013 (<u>ML13063A051</u>)

Natural Phenomena Hazards	
Purpose:	Develop a generic communication to collect information to verify compliance with regulatory requirements and/or license conditions associated with the treatment of natural phenomena hazards in the facilities safety assessments.
Key Information	 The Generic Letter will serve as the basis to close Unresolved Items (URIs) from post-Fukushima Temporary Instruction 2600/15 regarding the natural phenomena events accident sequence and how licensees are in compliance with regulatory requirements. A supporting Interim Staff Guidance document may be developed to facilitate issue resolution and generic letter responses. The NRC staff will publish a generic letter and receive licensees response in 2015-2016.
Related Information	 Information Notice (IN) 2011-08, "Tohoku—Taiheiyou—Oki Earthquake Effects on Japanese Nuclear Power Plants—for Fuel Cycle Facilities," (ML110830824) Temporary Instruction (TI) 2600/015 "Evaluation of Licensee Strategies for the Prevention and/or Mitigation Of Emergencies at Fuel Facilities" on September 30, 2011 (ML12286A284) Nuclear Energy Industry (NEI) letter dated October 12, 2012, "Treatment of Natural Phenomena Hazards in the Integrated Safety Analysis," (ML12296A036)

Fuel Cycle Information Exchange	
Purpose:	The Fuel Cycle Information Exchange (FCIX) provides an opportunity for NRC staff, industry representatives, licensees, and other stakeholders to openly discuss regulatory issues of mutual interest, as they relate to key sectors of the nuclear fuel cycle.
Key	The FCIX is scheduled for June 10-11, 2014 at the US Nuclear Regulatory
Information	Commission headquarters.
Related	 Link to the NRC public website on the FCIX http://www.nrc.gov/public-
Information	involve/conference-symposia/fcix.html

Cumulative Impact: Relative Ranking of Regulatory Initiatives and Issue Resolution Principles

Janet Schlueter

Senior Director, Fuel and Materials Safety
March 5, 2014 - Atlanta



Issue Definition and Resolution

- Goal: Establish a timely process to:
 - Support transparent vetting of new generic regulatory issues, e.g., problem statement
 - Clarify and communicate regulatory concern and opportunities for industry input;
 - Establish and document clear expectations with regard to the rule, guidance and processes that apply;
 - Identify schedule and milestones in context of cumulative impacts initiative, i.e., relative rank



Issue Resolution Principles

- Transparency and Timeliness of Process
- Clear Communication
- Commitment by and Accountability of NRC and Industry
- Well-Documented Basis and Regulatory Analysis
- Risk-Informed and Performance-Based Approaches
- Implementable schedule and milestones



Principles (continued)

- Issue Resolution Process not intended to circumvent any formal regulatory process that exists today
- Recognize that the result of such a process may need to be further considered through formal rulemaking, guidance development or other regulatory processes or tools as reflected on the integrated schedule
- Iterative process, e.g., periodic review/update



Transition to Next Presentation



United States Nuclear Regulatory Commission

Protecting People and the Environment

Corrective Action Programs:

Draft Regulatory Guide 3044

S. Atack



Corrective Action Programs

- Important for licensees to self identify and correct issues
- Inherently tied to Safety Conscious Work Environment
- Enforcement Policy acknowledges licensee CAPs
 - January 2013 revision allows NRC disposition of SL IV violations as NCVs if certain criteria are met and licensee has "adequate" CAP
- NRC has prepared guidance for fuel facility CAPs
 - "Adequacy" entails having an acceptable and effective CAP
- CAP should evolve as licensees transition from construction to operations



CAP Guidance Status

- Draft NUREG-2154 (developed with NEI and industry input) issued for public comment – February 2013
- Public meeting April 2013
- ▶ NEI comment letter on draft NUREG April 2013
- NRC issued public comment resolution table for draft NUREG – June 2013, revised August 2013
- NRC staff withdrew draft NUREG July, 2013
- ▶ NRC issued response letter to NEI August, 2013



CAP Guidance Status

- Transition from draft NUREG-2154 to DG-3044
 - ▶ Elements of adequate CAP remain the same
 - policies, programs, and procedures
 - identification, reporting, and documentation of safety and security issues
 - significance classification and causal evaluation of safety and security issues
 - development and implementation of corrective actions
 - assessment of corrective action and program effectiveness
 - Format changes from staff guidance to licensee guidance
 - Licensee is able to commit to RG elements rather than submitting detailed license amendment request for NRC review and approval



CAP Guidance Status

- ▶ DG-3044 was issued for public comment on February 12, 2014, in the Federal Register.
 - Public comment period ends on March 14, 2014
 - Federal Register Notice:
 http://www.gpo.gov/fdsys/pkg/FR-2014-02-12/pdf/2014-03012.pdf
 - DG-3044: ML13219B204



Process for Use of DG-3044

Licensee commits to RG or alternate CAP described in a LAR*

Commitment to RG or alternate CAP is captured as a license condition

Once licensee has developed and implemented CAP policies and procedures to satisfy the RG commitments, licensee notifies the NRC that it is ready for inspection of its CAP program



Inspection of licensee CAP is performed to verify (1) adequacy of implementing policies and procedures and (2) effectiveness of CAP implementation

After successful completion of all elements above, NRC notifies licensee that it will begin to disposition SL IV violations as NCVs if criteria in Section 2.3.2 of the NRC Enforcement Policy are met

*LAR – license amendment request

Example: LES CAP Review and Inspection



Review

- LES requested use of NCVs for their facility by letter dated July 10, 2013 (ML13196A259)
- NRC issued RAIs on August 7, 2013 (ML13214A290)
- Revision 34d of the QAPD approved on January 31, 2014 (ML13301A706)

Inspection

- In-office: Nov. 12-15, 2013. Onsite Nov. 18-20, 2013
- Planning included review of previous construction inspection reports to credit past inspection activities
- Focused on operations

Example: LES CAP Review and Inspection



Conclusions

- CAP is acceptable
 - SER document approval of the written LES CAP
 - ► CAP is part of a license condition
- CAP is effective
 - Implementation of CAP is adequate for operations in areas of quality, safety, and security (MLI403IAI03 NRC inspection report)
 - Implementation of CAP is adequate for construction (MLI32I4AI4I NRC inspection report)



Next Steps

- NRC issuance of letter to LES: CAP adequate for NRC Enforcement Policy purposes
- NRC (RII and HQ) will incorporate lessons learned into draft CAP inspection procedure
- ▶ Address public comments on DG-3044, revise as appropriate
- DG-3044 presentations:
 - ▶ CRGR discuss any backfit concerns
 - ▶ ACRS as part of Revised Fuel Cycle Oversight Process
- Address CRGR and ACRS comments on DG-3044, revised as appropriate
- NRC review and final transmittal to the Federal Register for publication



Acronyms

ACRS – Advisory Committee on Reactor Safeguards

CAP – corrective action program

CRGR – Committee to Review Generic Requirements

DG – draft regulatory guide

HQ – Headquaters, NRC

LES – Louisiana Energy Services

NCV – non-cited violation

NEI – Nuclear Energy Institute

NRC – U.S. Nuclear Regulatory Commission

QAPD – Quality Assurance Program Description

RAI – request for additional information

RG – regulatory guide

RII – Region II, NRC

SER – safety evaluation report

Transition to Next Presentation



Acute Uranium Intakes for High and Intermediate Worker Exposure

Jim Hammelman NRC/NMSS/FCSS



Topics

- Issue
- History
- NEI White Paper
- Staff progress
- Next Steps



Issue

Industry proposed increasing acute uranium intakes associated with high and intermediate consequences to workers in ISAs



Revised Acute Uranium Intakes

History

- Fall 2007 First NEI-NRC meeting
- Summer 2008 draft NEI white paper
- Spring 2009 NRC comments on NEI paper
 - Major concern is inadequate discussion of uncertainties
 - Appears to lack the technical basis for substantial increases in uranium intake criteria
- Summer 2009 revised NEI white paper
- Summer 2012 noted ongoing review at FCIX
- 2013 conducted detailed review of technical literature



Overview of NEI White Paper

- Thorough review of available data and analysis including major UK and US efforts on effects of depleted uranium exposure
- Recommendations based on a 2008 Kathren and Burlkin paper that developed "provisional LD₅₀ [lethal dose]" of "at least 1 gram for inhalation intakes".
- Recommendation reflects scaling down from intake for "provisional LD_{50} " to smaller intakes that would result in the "life endangering" and "irreversible, serious" effects
- Recommendations
 - High consequences 500 mg soluble U
 - Intermediate consequences 100 mg soluble U



Staff Actions

- Reviewed NEI paper in detail
- Conducted an extensive review of the uranium toxicity literature to better understand the NEI paper in relation to other available information and analysis.



Staff Actions (cont)

- Detailed staff review identifies two approaches
 - Use the renal concentration-physiological effects relationship characterized by Renal Effects Groups developed by U.S. Army and endorsed by National Research Council
 - Scale down from "provisional LD50" intake estimate which was developed using old diabetes treatment information and biokinetic models for normal individual



Staff Actions (cont)

 Staff has greater confidence in intakes developed from the Renal Effects Groups developed by U.S. Army and reviewed and endorsed by National Research Council



Staff Actions (cont)

- The staff developed recommended values based on the Royal Society observations and the U.S. Army "Renal Effects Groups"
- Numerical values are
 - High consequences 400 mg soluble U
 - Intermediate consequences 150 -400 mg soluble U
- Numerical values are based on the assumption of soluble (Solubility class F).

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Next Steps

- Engage NEI as the staff prepares ISG
- Draft ISG for public comment (SRM 12-0071)
- Discuss draft ISG at 2014 FCIX
- Draft ISG timed to support Part 40 rule making effort (SRM 12-0071)

Transition to Next Presentation



Dermal Ocular Exposure

Jim Hammelman NRC/NMSS/FCSS



Topics

- Issue
- History
- Staff Observations
- Drivers
- Next Steps



Issue

- Issue is how to develop quantitative standards for credible High- and Intermediate-consequence events, including Dermal and Ocular exposures
- 10 CFR Part 70.61(b)(4) and (c)(4) require the Integrated Safety Analysis to consider acute chemical exposures, including Dermal and Ocular exposure pathways
- 10 CFR Part 70.65(b)(7) requires a description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or chemicals produced from licensed material, including Dermal and Ocular exposures

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History

- NRC and NEI have discussed compliance with Part 70, and the development of quantitative standards for Dermal and Ocular exposures, in multiple meetings and correspondence
- NEI-NRC letters
 - NEI letter September 8, 2008 (ML 083360632)
 - NRC letter November 10, 2008 (ML082900889)
 - NEI letter February 24, 2009 (ML090690732)
 - NRC letter June 12, 2009 (ML090920296)
 - NRC letter November 24, 2009 (ML093200082)
 - NRC letter August 16, 2010 (ML093440038)
- Last public meeting October 3, 2013



Staff Observations

- Recognize the difficulties of dermal and ocular exposure analysis
 - Dermal or ocular exposure may not be the dominant exposure pathway
 - No readily adoptable standards as there are for inhalation exposure
- Recognize that dermal and ocular exposure are generally not an issue at Fuel Cycle facilities
- "Standard" in place for Hydrogen Fluoride which is the more serious dermal or ocular exposure hazard

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Staff Observations (cont.)

Two technical challenges

 Identifying acceptable approaches for incorporating dermal and ocular exposure considerations into the ISA

 Identifying acceptable approached for developing dermal and ocular exposure standards, where appropriate

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Drivers

Dermal and ocular exposure analysis guidance required to

Support compliance with Part 70

Support Part 40 Rulemaking (SRM-12-0071)



Next Steps

- Option 1: NRC develops guidance and solicits industry and public comment after NRC position is developed, or
- Option 2: NRC and industry exchange ideas on the issues, then NRC develops guidance and solicits public comment
- Either option will employ an established guidance development process, seeking public comment prior to finalizing guidance

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Transition to Next Presentation



United States Nuclear Regulatory Commission

Protecting People and the Environment

Part 21 Site Visits and Status of 10 CFR Part 21 Rulemaking

March 6, 2014 – Atlanta, GA (REV. 2/19) Sabrina. Atack 8:00-9:30 a.m.



Outline

- Rulemaking Background
- Status and Schedule Overview

Observations from Site Visits

Revision I to Draft Regulatory Basis



Rulemaking Background

- Basis for changes to Part 21 and associated regulations
 - Many issues despite generic communications and outreach efforts
 - Recent audits by Office of the Inspector General reiterated issues
 - Opportunity to clarify expectations for non-reactor facilities
 - Timing will support new reactor construction
- SECY-11-0135 was issued on September 29, 2011, to inform Commission of staff's intent to pursue rulemaking
- Revision 0 of the Draft Regulatory Basis was issued in December 2012



Status and Schedule Overview





- September 2011 SECY-11-0135
- August 2011 First public meeting to discuss rulemaking
- December 2012 Rev.0 of Draft Regulatory Basis issued
- > April 2014 Draft Revision 1 of the Regulatory Basis
- Summer 2014 Public Meeting
- ➤ September 2014 Final Regulatory Basis
- September 2015 Issue Proposed Rule and

Guidance Documents

December 2016 - Issue Final Rule





Observations from Site Visits

▶ IROFS designations vary greatly by site

- ISA process allows variance in what items and activities are designated as IROFS
- Licensees may designate IROFS on a piece/part basis or more systematically

Procurement

- Lack of formal commercial grade dedication
- Strong reliance on functional testing
- Licensees implement graded process to identify and verify critical IROFS attributes as part of procurement and installation process



Observations from Site Visits

- Limited designation of basic components
- Variation in evaluation and reporting
- Operating Experience
 - Reviewed through:
 - Event reports
 - NEI call
 - Lack of formal program



Site Visit Insights

- Reasonable assurance of availability and reliability of IROFS without formal CGD process
 - Implementation of management measures provides reasonable assurance that the item will perform its intended functions
- Opportunity for improvement with respect to operating experience
- Difficult to reconcile Part 21 with the ISA rule
 - No conforming changes were made in 2000
 - ISA encourages risk management via use of administrative and hardware controls whereas Part 21 is focused on hardware

Draft Rev. 1 Regulatory Basis Considerations



- Continue with basic approach from Revision 0
 - Implementation period of 12 months following the effective date of the rule
- Focus on clarifying evaluating and reporting that is complementary to the ISA process
 - Clarify definitions in rule to ensure appropriate/desired scope of basic components for evaluating and reporting
 - Clarify substantial safety hazard through guidance
 - Provide guidance on use of a management measures program for achieving commercial grade dedication



Discussion and Conclusions

- Insights from site visits have informed staff's path forward
- Staff welcomes input on potential approaches
- Goal of issuing Revision 1 of Draft Regulatory Basis Spring 2014

Transition to Next Presentation



Implementation of Part 40 Rulemaking SRM for SECY-12-0071





Background

- In a SRM in 2007 (SECY-07-0146) staff proposed revising part 40 to integrate regulatory requirements from 10 CFR Part 70
- Commission approved development of proposed rulemaking
 - The proposed ISA rule for Part 40 would have added a new Subpart H to the regulations. The changes would require all facilities authorized to possess 2000 kgs. or more of uranium hexafluoride (UF6) to develop an integrated safety analysis
- Proposed rule was published in March 2010 and public comments were received
- SRM-10-0128, dated November 30, 2010 approved publication of the proposed rule
- SECY-12-0071, dated May 7, 2012, requested Commission approval to publish a final rule
- The Commission issued an SRM (SECY-12-0071) on May 3, 2013 disapproving the publication of the final rule and directed the staff to revise the rule and prepare additional guidance



Overview of SRM-12-0071 Tasks

- Develop the basis for Part 40 Performance Requirements
- Develop guidance related to chemical exposure hazards to be addressed in ISAs
- Develop criteria for determining adequacy of emergency plans for Part 40 facilities
- Develop guidance for existing facilities on Natural phenomena hazards
- Discuss how ISAs would be conducted without an ISA standard
- Prepare revised rule (either new proposed rule or final rule) with consideration to the Commission direction in SRM-SECY-11-0032 " Consideration of the Cumulative Effects of Regulation in the Rulemaking Process"



Goals for Meeting

- Feedback from industry regarding priority of Part 40 rulemaking
- Input on scope of guidance to be prepared in response to SRM

September 2011 Module 14 MFFF 71



Items to be Developed to Meet SRM Requirements

- Regulatory Guidance on Soluble Uranium intake, and dermal and ocular exposures (in concert with Part 70 guidance)
- Determine whether additional guidance is needed to provide additional criteria for determining the adequacy of emergency plans for Part 40 facilities
 - Engage stakeholders as part of NUREG-1520 revision



Items to be Developed to Meet SRM Requirements (cont.)

- Develop guidance for existing facilities on Natural phenomena hazards
 - □ NPH guidance will be developed to support post-Fukushima generic letter



Items to be Developed to Meet SRM Requirements (cont.)

- Develop the basis for Part 40 Performance Requirements
 - Staff will evaluate whether radiological related performance requirements taken from 10 CFR Part 70 are appropriate
 - Evaluation of types of source material that may be processed by Part 40 facilities and potential doses from releases
 - Will interact with the public and industry to obtain more information
 - May impact changes to the previous proposed Part 40 rule



Items to be Developed to Meet SRM Requirements (cont.)

- Discuss how ISAs would be conducted without an ISA standard
 - □ The Commission approved the staffs request to discontinue its development of interim staff guidance on ISA implementation issues and development of information on how the ISAs would be conducted without an ANS standard based on the timing for development of the standard



Discussion of Specific SRM tasks (continued)

- Prepare revised rule (either new proposed rule or final rule) with consideration to the Commission direction in SRM-SECY-11-0032 "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process"
 - Staff will determine whether rule needs to be issued as a final rule or a proposed rule based on outcome of guidance development and the need to change the language in the previous rulemaking effort
 - Development of regulatory analyses, rule basis, rule language, and revised NUREG-1962
 - Staff will interact with the public during the rulemaking process and will follow the CER process for rulemaking



Summary

- SRM-12-0071 disapproved the proposed rule and directed the staff to revise the rule and prepare additional guidance
- Staff is requesting stakeholder input on priority of rulemaking and the scope of guidance documents to be prepared
- Staff will determine whether to issue a new proposed rule or final rule after evaluating impacts on the rule language of newly developed guidance
- Rulemaking will follow CER process approved by the Commission

Transition to Next Presentation

Revised Fuel Cycle Oversight Process

Public Meeting to Discuss Initiatives Related to the Fuel Cycle Industry

March 6, 2014

Purpose

- Background RFCOP project
- Status RFCOP project
- Re-baseline efforts and considerations
- Seek stakeholder input on re-baseline effort

RFCOP - Background

- SECY-11-0140, Enhancements to the Fuel Cycle
 Oversight Process Commission approved January 2012
 - Phase I:
 - Activity I.A, Revised Enforcement Policy
 - Activity I.B, Enhanced Core Inspection Program
 - Activity I.C, Develop Effective CAP Guidance
 - Activity I.D, Develop CAP Inspection Procedure
 - Activity I.E, CAP Licensing Actions
 - Activity I.F, Determine Issue Characterization definition
 - Activity I.G Develop More-Than-Minor Non-Compliance Threshold

RFCOP - Background (Continued)

- Phase II:
 - Activity II, Cornerstones
 - Activity III, Qualitative Fuel Cycle Significance Determination Process (SDP)
 - Activity IV, Performance Assessment Process
 - Activity V, Supplemental Inspection Program
- Phase III:
 - Activity VI, Pilot Program
 - Activity VII, Quantitative Fuel Cycle Significance Determination Process
 - Activity VIII, Implementation of the Fuel Cycle Oversight Process

RFCOP Status

- Issued the revised Enforcement Policy
- Issued or about to issue 14 IPs and 1 IMC Appendix
- Issued a draft CAP RG for public comment
- Issued Inspection Report and Safety Evaluation Report (SER) on LES CAP
- Developed the More-Than-Minor non-compliance threshold definition (examples) and started the process to issue a revised IMC
- Obtained general agreement with industry that the performance deficiency definition is "non-compliance with requirements/regulation"
- Finalize the CAP IP considering lessons learned from the LES inspection and SER

Phase 1 essential completed by May 2014

Existing Plan & Schedule

- Details
 - Phase I
 - First two years planned in detail
 - Phase II and III
 - The plan provides only a high-level overview
- SRM did not make the RFCOP project a top priority
 - Lower than post-Fukushima response actions or Honeywell restart
 - RFCOP kept funding prioritization in mind
 - Cumulative effect of regulations is a consideration
 - NEI Letter (April 3, 2013)
 - Re-baseline of inspection program
 - Generic risk insights

Format - Redrafted Project Plan

- Same deliverables
- Planned format
 - Followed model successfully used to manage other large long-term projects
 - Overall project plan
 - Appendix for each deliverable
 - Uses table to define significant sub-deliverables and due dates
 - Table used to document sub deliverable status
 - Convenient to discuss progress with NRC management or stakeholders
 - Revised RFCOP Project Plan is a living document that will be regularly updated and periodically placed in ADAMS

Re-baseline Analysis

- Considered the following:
 - Additional interactions with ACRS and external stakeholders;
 - Incorporated the impact of sequestration and budget constraints;
 - Incorporated the impact of Fukushima actions and the Honeywell restart;
 - Incorporated the impact of staff resources (diverted to inspection transition plan) and
 - Cumulative Effects of Regulation (CER)

Re-Baseline Insights

- Some, but not all, SRM deliverables may need a reset date.
- All activities may not have been previously considered.
- Development of the cornerstone options should be worked in series not simultaneously.
- ACRS interactions need to be added to the schedule prior to submitting notation vote papers to the Commission.
- The Pilot program may involve all fuel facilities to facilitate a shorter test duration.

Published Schedule

Task Name	Original Schedule Finish Date	Status
SRM for SECY 11-0140 issued	01/05/12	Complete
PHASE I – Corrective Action Program, Issue Characterization, and Inspection Program Improvements		
Activity I.A, Revised Enforcement Policy	12/28/12	Complete
Activity I.B, Enhanced Core Inspection Program	06/20/14	May 2014
Activity I.C, Develop Effective CAP Guidance	07/31/13	May 2014
Activity I.D, Develop CAP Inspection Program	03/07/14	May 2014
Activity I.E, CAP Licensing Actions	09/30/14	Complete
Activity I.F, Determine Issue Characterization definition	03/29/13	Complete
Activity I.G Develop More-Than-Minor Threshold	06/26/14	May 2014
Phase II - RFCOP Framework Development		
Activity II, Cornerstones	06/19/15	Initiating
Activity III, Qualitative Fuel Cycle Significance Determination Process (SDP)	08/14/15	Future
Activity IV, Performance Assessment Process	04/15/16	Future
Activity V, Supplemental Inspection Program	04/15/16	Future
PHASE III – Pilot, Lessons Learned and Implementation		
Activity VI, Pilot Program	08/18/17	Future
Activity VII, Quantitative Fuel Cycle Significance Determination Process	06/16/17	Future
Activity VIII, Implement in of the Fuel Cycle Oversight Process	11/17/17	Future

SRM Submissions

Current SRM Actions for SECY-11-0140	SRM Due Date	Expected Change
PHASE I – Corrective Action Program, Issue Characterization, and Inspection Program Improvements		
Activity I.F, Determine Issue Characterization definition (CA Note performance deficiency)	06/23/16	No
Phase II - RFCOP Framework Development		
Activity II, Cornerstones (Notation Vote Paper on Cornerstones)	3/31/15	Yes
PHASE III – Pilot, Lessons Learned and Implementation		
Activity VI, Pilot Program (Notation Vote paper for permission to perform Pilot Program)	6/23/16	Yes
Activity VI, Pilot Program (Notation Vote paper for on the results of the pilot, including the proposed action matrix, any necessary changes to the revised FCOP, and the staff's recommendations for full implementation)	06/23/17	Yes
Activity VII, Quantitative Fuel Cycle Significance Determination Process (CA-Note for AO signature, the staff should develop and test the use of "focused PRA-like analyses," as recommended by the ACRS)	03/23/18	No

Near-term Actions

- Re-Establish RFCOP Steering Committee
- March 6 Public meeting on Revised Project Plan and Gantt Chart
- Revised Project Plan and Gantt Chart
- May 7 -Brief ACRS Subcommittee
- Submit Annual Update to Commission with Revised RFCOP Project Plan
- June 10-11 FCIX RFCOP presentation (possible)

Seeking Stakeholder Input

Questions

- What should be considered during the NRC re-baseline effort?
- Which draft deliverables would stakeholders request a public meeting?
 - What might the meeting format be for these discussions?
 - When in the process would stakeholders like to have public meetings on draft deliverables?
- What are licensees thoughts on the pilot program content and schedule?
- What are examples of the "generic risk insights," discussed in the NEI letter? (April 3, 2013)
- Other questions?

Questions?