

May 26, 2015

MEMORANDUM TO: Kerri A. Kavanagh, Chief
Quality Assurance Vendor Inspection Branch
Division of Construction Inspection
& Operational Programs
Office of New Reactors

FROM: Ashley Thomas, General Engineer */RA/*
Quality Assurance Vendor Inspection Branch
Division of Construction Inspection
& Operational Programs
Office of New Reactors

SUBJECT: SUMMARY OF APRIL 28, 2015, CATEGORY 3 PUBLIC
MEETING TO DISCUSS REVISION 1 OF THE DRAFT
REGULATORY BASIS TO CLARIFY THE REQUIREMENTS OF
TITLE 10 OF THE CODE OF FEDERAL REGULATIONS, PART 21

On April 28, 2015, the U.S. Nuclear Regulatory Commission (NRC) staff hosted a Category 3 public meeting at NRC Headquarters, in Rockville, Maryland. The purpose of the meeting was to discuss Revision 1 of the draft regulatory basis to clarify Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance" (Part 21) (Agencywide Documents Access and Management System (ADAMS) Accession Number ML14135A207). The goal of the proposed rulemaking described in the draft regulatory basis is to simplify and clarify the rule language in Part 21, provide consolidated regulatory guidance on compliance with Part 21, and enhance regulatory stability and predictability for the entities to which Part 21 applies. The meeting notice is documented in ADAMS under Accession Number ML15105A288.

DISCUSSION

Lisa Clark, Senior Attorney with the Office of General Counsel, facilitated the meeting on the NRC's behalf. Jermaine Heath, Reactor Operations Engineer with the Quality Assurance Vendor Inspection Branch (QVIB) in the Office of New Reactors (NRO), led the discussions pertaining to operating reactor facilities. Sabrina Attack, Fuel Cycle Operations Team Leader with the Programmatic Oversight and Regional Support Branch in the Office of Nuclear Material Safety and Safeguards, led the discussion pertaining to fuel cycle stakeholders. Victoria Huckabay, Reactor Operations Engineer with QVIB in NRO, and Paul Prescott, Senior Reactor Operations Engineer with QVIB in NRO, also participated on the panel for the NRC.

CONTACT: Jermaine Heath, NRO/DCIP
301-415-6066

The staff began the meeting by discussing the history of Part 21 and the need for rulemaking. The staff provided an update on the current status of the Part 21 rulemaking effort and discussed the proposed timeline for the remaining phases.

The NRC staff presented the Revision 1 of the draft regulatory basis which details the staff's position on proposing rulemaking intended to clarify the requirements associated with dedication of commercial grade items and the reporting of defects and noncompliance for all activities within the scope of 10 CFR Part 21. Specifically, the staff discussed Chapters 2, 3, and 4, which describe the proposed changes in the areas of evaluation and reporting, commercial grade dedication, and administrative changes, respectively.

The staff also discussed the status of the regulatory guidance, including draft guide (DG)-1291, "Evaluating Deviations and Reporting Defects and Noncompliance," and DG-1292, "Sampling and Dedication of Commercial Grade Items," which are being reviewed in concert with the rulemaking proposal. Several members of the public provided comments regarding the effectiveness of issuing guidance to address the ambiguity of the current Part 21 regulations, as opposed to rulemaking. Audience participants also expressed concern regarding several changes proposed by the staff that, in their opinion, expand the scope or intent of the current Part 21 regulations. Additionally, audience participants expressed concern regarding the timeline in which the Nuclear Energy Institute (NEI) 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance," Revision 0 (ADAMS Accession Number ML14245A416) and Electric Power Research Institute (EPRI) 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications, Revision 1 to EPRI NP-5652 and TR-102260" (ADAMS Accession No. ML14265A198) guidance documents would be endorsed for use by the NRC.

Following the meeting, the staff determined that industry guidance contained in EPRI 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications, Revision 1 to EPRI NP-5652 and TR-102260," dated September 2014 (ADAMS Accession No. ML14265A198) is consistent with current regulations on commercial grade dedication. The staff agreed to pursue the review of the EPRI guidance for endorsement through regulatory guide, DG-1292, "Dedication of Commercial Grade Items", outside of the Rulemaking process."

Evaluation and Reporting, Chapter 2 of the Draft Regulatory Basis

The staff provided their position on the time period for discovery and discussed the proposed revision to the definition of discovery. Audience participants asked several questions and provided feedback on the interpretation of the draft regulatory basis. Of note, comments were received to add a definition for "failure to comply" to the rule. Several members of the public expressed their opinion that clarification of the definition of "discovery" could be achieved through NEI guidance.

The staff also provided their position on the definition of "defect" and the proposed changes to simplify the definition. The staff also discussed the proposal to add a definition of "delivery" to the Part 21 regulations, to clearly define the transfer of ownership and reporting responsibilities. The audience participants provided several comments on the clarification of "defect" and "delivery" and how the proposed rule could be misinterpreted.

Additionally, the staff discussed the proposed changes to the Part 21 regulations with regard to the use of licensee event reports to satisfy Part 21 reporting requirements. The staff clarified that there are no proposed changes to the requirements of 10 CFR 50.72 or 50.73, nor are there any proposed changes to the NRC guidance on how to meet 10 CFR 50.72 or 50.73.

Finally, the staff discussed the division of Part 21 and 10 CFR 50.55(e) requirements and the staff's proposal to remove the requirement of reporting a significant quality assurance program breakdown. Following the meeting, and after further consideration, the NRC staff decided that it would propose to retain the regulatory language that requires the reporting of a significant quality assurance program breakdown.

Commercial Grade Dedication, Chapter 3 of the Draft Regulatory Basis

The staff discussed the proposed changes to create a new section, 21.71, for describing the requirements for dedication, and the proposed revised definition of dedication. The staff also provided clarification as to who can perform dedication. The staff received several comments from members of the public objecting the staff's proposal to remove verbiage from the regulation stating suppliers are exempt from the provisions of 21.71 to the extent that they supply commercial grade items.

The staff discussed the proposed changes to revise the definitions of commercial grade item and basic component for reactor facilities. Audience participants asked several clarifying questions as well as provided feedback regarding the proposed definition of commercial grade item.

The Office of Nuclear Material Safety and Safeguards (NMSS) staff discussed their proposal to prepare guidance related to commercial grade dedication as it applies to fuel cycle facilities. Audience participants expressed concern regarding potential missed opportunities for information to be shared with the NRC under the proposed infrastructure for evaluating and reporting.

Further, NMSS staff discussed the proposed changes to clarify the definition of basic component for fuel cycle facilities. Questions were raised by members of the public regarding linking performance requirements to a substantial safety hazard. The staff also received questions regarding classifying items relied on for safety as basic components.

NMSS staff also discussed their position on the implementation of management programs to satisfy the requirements for commercial grade dedication for fuel cycle facilities. The staff also discussed the proposed changes to the regulations that aim to acknowledge that facilities that are subject to Appendix B as part of their licensing basis have different expectations than those that are not subject to Appendix B. Additionally, the staff discussed the proposed guidance to describe the quality assurance controls that should be applied to dedication for nonreactor facilities. The staff received several questions and comments regarding the intent of the proposed changes.

Administrative Changes, Chapter 4 of the Regulatory Basis

The staff discussed the proposed administrative changes. There were no questions or comments from members of the public regarding the administrative changes.

A list of meeting attendees is enclosed. Please direct any inquiries to Jermaine Heath at Jermaine.Heath@nrc.gov, or (301) 415-6066.

Enclosure:
List of Attendees

Cc w/encl: See next page

Administrative Changes, Chapter 4 of the Regulatory Basis

The staff discussed the proposed administrative changes. There were no questions or comments from members of the public regarding the administrative changes.

A list of meeting attendees is enclosed. Please direct any inquiries to Jermaine Heath at Jermaine.Heath@nrc.gov, or (301) 415-6066.

Enclosure:
List of Attendees

Cc w/encl: See next page

ADAMS Accession No.: ML15139A513

NRO-002

OFFICE	NRO/DCIP/QVIB	NRO/DCIP/QVIB	NRO/DCIP/QVIB
NAME	JHeath	AThomas	KKavanagh
DATE	5/22/2015	5/26/2015	5/26/2015

OFFICIAL RECORD COPY

LIST OF ATTENDEES
U.S. Nuclear Regulatory Commission
Public Meeting to Discuss Revision 1 of The Draft Regulatory Basis To Clarify The
Requirements Of Title 10 Of The Code Of Federal Regulation, Part 21
Tuesday, April 28, 2015
9:00 a.m. – 5:00 p.m.

NRC

<u>Name</u>	<u>Office</u>
Thomas Matula	NRO
George Tartal	NRO
Andrea Keim	NRO
Ashley Thomas	NRO
Andrea Valentin	NRO
Aixa Belen	NRO
Antoinette Sakadales	NRO

STAKEHOLDERS

<u>Name</u>	<u>Organization</u>
Patrice Campbell	GEH
Steve Schilthelm	B&W
Michael Dunkelberger	MPR
Jana Bergman	CW/Sciencetech
Jim Gresham	Westinghouse
Tom Loomis	Exelon
Marc Nichol	NEI
Robert Thevret	Westinghouse
Doug Weaver	Westinghouse
Bill Horin	Winston & Strawn
Steve Toelle	Centrus Energy Corp.
Jim Rowlands	Precision Custom Components
Nima Ashkebouse	NEI
Kati Austgen	NEI
Doug Yates	Mox Services
Gayle Elliott	Areva INC.
William Ware	Southern Nuclear
Frederick Willis	Southern Nuclear
Findlay Salter	SCE&G
Curtis Castell	CB&I

VIA TELECONFERENCE

<u>Name</u>	<u>Organization</u>
Sidney Bernsen	Independent Consultant
Thomas Biagi	Parker Hannifin
Alan Blamey	Region 2 Division of Fuel Facility inspection
Kevin Bonser	General Atomics
David Breeding	Not obtained
William Bryan	Ansys Inc
Barry Bryant	Dominion
Robert Burg	Engineering Planning & Managing
Larry Carson	C&D Technologies
Stephen Casadevall	ASCO Valve
Ann Cottingham	Nuclear Energy Institute
Steven DiMauro	C&D Technologies
Paul Duke	PSEG
Paul Garcia	Ariba Inc
Dewey Godfrey	Centrus Energy Corp
Leslie Gray	Erin Engineering
Brenda Griego	ALion Science & Technology
Stanley Griffin	GE Hitachi Nuclear Energy
Michele Gutman	Westinghouse Electric Co
Bryan Hall	NSL Analytical
Jessica Hanek	Sargent Lundy LLC
Joshua Hart	Stevenson & Associates
Ken Heffner	Certrec
Kerri Kavanagh	NRC
Al Lafleur	NextEra Energy
Michael Leahy	Exelon
Daniel Lewton	Westinghouse Electric Co
Robert Link	Areva Richland Facility
Russell Lion	L&S Machine Co
Jon Lubahn	Consumers Energy
Robert Marshall	NuScale Power
Herbert Mayes	Southern Company
Adam McCartney	Cameron
Zina McDowell Heath	AECOM
Scott Murray	Global Nuclear Fuels
Michelle Nyzio	Lockheed Martin
Patrick Olson	Twin City Fan Companies
Nancy Parr	Westinghouse
Peggy Rescheske	Southern California Edison Company
William Rogers	Lockheed Martin
John Rogge	NRC Region 1 Div of Reactor Safety
Nick Serafin	Consumers Energy Laboratory Services
Marcy Shope	Nuclear Field Services Inc
John Simmons	Luminant Power
Carlos Sisco	Winston and Strawn LLP
Charles Slama	Urenco USA
Timothy Snoke	General Atomics

Glenn Strausser
William Stuckey
Maryann Swiergol
Joseph Tapia

USEC
AECOM
Hamill Manufacturing Company
Mitsubishi Nuclear Energy Systems