

January 9, 2009

MEMORANDUM TO: John A. Nakoski, Chief  
Quality and Vendor Branch 2  
Division of Construction Inspection  
& Operational Programs  
Office of New Reactors

FROM: Donna J. Sinks, Quality Operations Specialist **/RA/**  
Quality and Vendor Branch 2  
Division of Construction Inspection  
& Operational Programs  
Office of New Reactors

SUBJECT: SUMMARY OF THE FIRST NRC WORKSHOP ON VENDOR  
OVERSIGHT FOR NEW REACTOR CONSTRUCTION

On December 10-11, 2008, the U.S. Nuclear Regulatory Commission (NRC) sponsored a Category 3 public meeting at the Marriott Bethesda North Hotel and Conference Center, Bethesda, Maryland. This workshop focused on vendor oversight for new reactor construction. The workshop facilitated an open discussion and presented insights and lessons learned with the nuclear industry, such as those documented in NUREG-1055, "Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants." This workshop provided the nuclear industry the opportunity to understand the NRC's safety regulations and guidance, in addition to how the NRC monitors quality assurance programs and other areas vital to new reactor construction.

The 514 workshop attendees represented companies and organizations as follows: 162 vendors, 11 new plant applicants, 10 plant owners/operators, 8 reactor design companies, 11 construction companies, 7 U.S. government organizations, 2 foreign regulators, 6 nuclear fuel suppliers/processors/disposers, and 2 news organizations. A list of workshop attendees is included in Enclosure 1.

The two-day workshop was divided into main sessions on the first day and breakout sessions on the second day. The main sessions of the workshop were devoted to providing the NRC's and industry representatives' perspectives on vendor issues, implementation of 10 CFR Part 21, "Reporting of Defects and Noncompliance," and commercial-grade item (CGI) dedication issues. The breakout sessions expanded the discussions on Part 21 and CGI dedication. The list of speakers and panelists is provided in Enclosure 2. All presentations are available in the NRC's Agencywide Documents Access and Management System (ADAMS) as accession number ML083400234.

CONTACT: Donna J. Sinks, DCIP/CQVB  
301-415-6651

### Day 1 – Main Sessions

On the first day, Gary Holahan, NRC Deputy Director of the Office of New Reactors (NRO), welcomed the workshop attendees and delivered opening remarks for the workshop. He discussed the growing international scope of new reactor construction, the unwavering commitment to quality and safety that licensees and vendors must maintain, and the value of attendee feedback in measuring the effectiveness of the workshop. Next, Glenn Tracy, NRC Director of the Division of Construction Inspection and Operational Programs (DCIP), NRO, addressed the audience on the NRC's perspective of the vendor inspection program for new reactors. Lastly, Mark McBurnett, Vice President of Oversight and Regulatory Affairs at South Texas Project Nuclear Operating Co., spoke about the industry's perspective using South Texas Project experiences and lessons learned.

The first general session, entitled "Supplier Oversight Issues - Overview of NRC's Vendor Inspection Program," began with NRO's John A. Nakoski, Chief of the Quality and Vendor Branch 2 (CQVB), DCIP. Mr. Nakoski provided an overview of the NRC's vendor inspection program. Then, Juan Peralta, Chief of the Quality and Vendor Branch 1 (CQVP), DCIP/NRO, discussed the NRC's international vendor activities. Both summarized key findings from vendor inspections. This session continued with presentations by industry representatives that addressed key issues from vendor audits. Sherry Grier, Chair of the New Plant Development Committee/Nuclear Procurement Issues Committee (NUPIC) and Procurement Quality Manager for Duke Energy, provided her insights on NUPIC and supplier oversight issues. Rosalie Nava of Crane Nuclear, and Chair of the Nuclear Industry Assessment Committee (NIAC), gave an overview of that committee's activities.

The second general session, "Commercial Grade Dedication Requirements and Guidance," addressed the use of the dedication process for basic components. NRC speakers included Richard McIntyre, CQVB/DCIP; Milton Concepcion, CQVP/DCIP; and Paul Prescott, Quality and Vendor Branch (EQVB), Division of Engineering (DE), Office of Nuclear Reactor Regulation. Mr. McIntyre presented a historical perspective of commercial grade dedication, Mr. Concepcion presented information on the CGI dedication process, and Mr. Prescott discussed the NRC perspectives on dedication acceptance methods.

The NRC's Kerri Kavanagh, CQVP/DCIP, concluded the day during the last general session, "10 CFR Part 21 Requirements and Guidance." Ms. Kavanagh summarized the Part 21 process and provided examples of inadequate Part 21 implementation.

### Day 2 – Breakout Sessions

The agenda for December 11 included a set of three concurrent break-out sessions, with representatives from the NRC, industry, and vendors serving as speakers, facilitators, and panelists. Presentations were made by each panelist, followed by a question-and-answer session based upon verbal or written questions from the audience.

#### *Break-out Session 1 – "10 CFR Part 21 Evaluations"*

Kerri Kavanagh, Sr. Reactor Engineer, CQVP/DCIP, facilitated Break-out Session 1. In this session, four panelists provided perspectives from the NRC, industry, and vendors. Victor

Hall, Operations Engineer, EQVB/DE, emphasized the processes for identifying deviations and evaluating for defects. Mr. Hall explained that for vendors, Part 21 is the law, whereas 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," is only a legally binding regulation for licensees. The licensees then impose the requirements of Appendix B on vendors through purchase orders and contract documents. Definitions for pertinent terms, such as deviation, evaluation, and notification, were summarized. The need for interface between the corrective action program and Part 21 was emphasized because NRC inspections have resulted in numerous violations of Part 21. Examples of such violations are the lack of procedures to evaluate deviations, not meeting the time frames to inform customers of deviations when the vendor was not capable of performing evaluation, deviations that are not always evaluated, and deviations that did not include evaluation for safety hazard.

William Ware, Dedication Lab Supervisor, Southern Nuclear Operating Co., presented the industry's perspective on Part 21 evaluations. He discussed that the purpose of Part 21 is to notify the NRC of any defects in a basic component or failures to comply, and that it applies to anyone constructing, owning, operating, or supplying materials or services for a licensed facility or activity. The reporting regulations in 10 CFR Part 50 and 10 CFR Part 73, "Physical Protection of Plants and Materials," that satisfy the evaluation, notification, and reporting obligations of Part 21 were cited. The three conditions under which nuclear power plants perform reportability evaluations are: (1) failures to comply; (2) items received but not installed; and (3) if applicable, suppliers unable to make a reportability determination. Mr. Ware further emphasized that if a Part 50 licensee sells a basic component to another licensee, then that seller becomes a "Supplier" under Part 21. In this case, the supplier notification requirements would apply to the selling entity. A reporting timeline from discovery to written notification was included, and Mr. Ware described his company's steps of the reporting process. Sample checklists to aid the evaluator in determining potential defects and potential failure to comply were also included at the end of the presentation.

Gayle Elliott, Licensing Manager from Regulatory Affairs, and James Bartleman, Manager, Corrective Action Program, AREVA NP Inc., presented the final Part 21 presentation from the vendor's perspective. Ms. Elliott included a description of the applicability of Part 21 and definitions of deviation and defect, with an emphasis on the activities associated with new reactors designed and constructed under 10 CFR Part 52. Also discussed was how AREVA employs an integrated Part 21 reporting system with WebCAP, a web-based business process tool. She further presented a simplified reporting process flow chart under Part 21, revealing the integrated relationship between the corrective action program process and the Part 21 reporting process. Mr. Bartleman provided a sampling of screening questions for both new and operating plants. At AREVA, selected qualified personnel are assigned specific activities related to deviation and defect determinations.

### Break-out Session 2 – "Critical Characteristics"

Milton Concepcion, Electrical Engineer, CQVP/DCIP, served as the facilitator for Break-out Session 2. As in the previous break-out session, three panelists provided perspectives from the NRC, industry, and vendors. Paul Bell, NRC Quality Engineer, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Materials Safety and Safeguards, provided an overall summary of the CGI dedication process as an alternate means of satisfying the requirements of

Appendix B to 10 CFR Part 50 with regard to procurement and acceptance of CGIs and services for use as basic components. He emphasized that an acceptable dedication program includes: (1) a technical evaluation that identifies technical and quality requirements, and (2) documentation of the acceptance method(s) used. A summary of NRC Inspection Procedure 43004, "Inspection of Commercial-Grade Dedication Programs," was provided. The procedure contains a discussion of equivalency evaluations, like-for-like CGI evaluations, and seismic/environmental considerations. Mr. Bell emphasized that when determining critical characteristics, the important design, material, and performance characteristics should be considered. Additionally, other factors, such as item functionality, manufacturer's technical data, and special considerations for applications requiring environmental or seismic qualification, should be included in determining critical characteristics.

The industry representative, Bhavesh Patel, Supervisor - Procurement Engineering and Dedication, Progress Energy, then discussed the selection of critical characteristics. He discussed some factors that are required for achieving reasonable assurance of the adequacy of a CGI dedication program. These factors included: adequate sampling of items chosen for verification; proper selection of critical characteristics for verification; appropriate degree of verification for each critical characteristic; and reasonable assurance that the item received conforms to the procurement document and will perform its safety function. Mr. Patel noted that determination of critical characteristics can be conducted using original design information, based on the item's safety function and a failure mode and effects analysis (FMEA) if original design information is not available, or completed using a FMEA in conjunction with original design information. He indicated that FMEA is the recommended process for safety classification and selection of critical characteristics. A flow chart of the analysis process (e.g., safety functions, failure mechanisms) provided in his presentation showed how to reach conclusions/results (i.e., the item's safety function and functional safety classification, and critical characteristics). Definitions of failure mode and failure mechanism were provided. Mr. Patel also presented a comparison of the definitions of critical characteristics in Electric Power Research Institute (EPRI) documents and in Part 21 to show that they are consistent. He further identified examples of the different types of critical characteristics (physical, performance, product identification).

The third panelist for Session 2, Craig Irish, Vice President - Sales & Marketing, Nuclear Logistics Inc. (NLI), presented a vendor's perspective on critical characteristics. A summary entitled "Dedication 101" reminded the attendees that it is required that the dedication process be used in conjunction with an approved nuclear quality assurance program meeting the requirements of Appendix B to 10 CFR Part 50 and that the process meets the requirements of Part 21. He noted that NLI uses three methods of verification and acceptance: 1) special tests and inspections (at a minimum), 2) commercial surveys, and 3) source surveillances (used on more complex dedications in conjunction with #1 above). Mr. Irish gave examples of critical characteristics selected based on the safety function of the item and the selection of critical characteristics for a molded case circuit breaker. More complicated items, such as switchgear, need verification by more than one method, and complex items may require the verification and acceptance of critical characteristics during the design, manufacturing, and factory testing of the item. Mr. Irish completed his presentation with a summary of lessons learned from complex dedications.

*Break-out Session 3 – “Sampling Under a Commercial-Grade Dedication”*

Break-out Session 3 was led by facilitator Richard McIntyre, Sr. Reactor Engineer, CQVB/DCIP. The session opened with a presentation by Paul Prescott, Sr. Operations Engineer, EQVB/DE, on the NRC’s perspective with respect to the CGI dedication sampling process. Mr. Prescott described dedication as an acceptance process that provides reasonable assurance that a CGI will perform its intended safety function, when used as a basic component. He also discussed sampling as a way to verify critical characteristics on a representative number of CGIs versus 100% verification testing. The NRC endorsed industry guidance of EPRI NP-5652, “Guidelines for the Utilization of Commercial Grade Items in Nuclear Safety-Related Applications, (NCIG-07),” in NRC Generic Letter 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products;” however, neither document addressed use of sampling in detail. NRC guidance specific to sampling was provided to NRC inspectors in Inspection Procedure 38703, “Commercial Grade Dedication,” including issues such as control of sampling plans, lot traceability/homogeneity, adequate documented technical basis, complexity of items, and supplier controls. NRC Draft Regulatory Guide DG-1070, “Sampling Plans Used for Dedicating Simple Metallic CGIs for Use in Nuclear Power Plants,” was issued in 1997 but was never finalized. The Nuclear Energy Institute (NEI) and EPRI completed TR-017218-R1, “Guideline for Sampling in the Commercial-Grade Item Acceptance Process,” but there has been no official NRC response or endorsement. It was proposed in Mr. Prescott’s presentation that in the future the NRC and stakeholders (e.g., NEI, NUPIC) review the TR for possible endorsement and resolve issues.

Session 3 continued with Marc Tannenbaum, Project Manager, EPRI, who presented a flow chart of the dedication process to show how a CGI that undergoes the dedication process is ensured to be equivalent to an item purchased as a basic component. Mr. Tannenbaum also presented a simplified flow chart showing the use of sampling in the acceptance process - select item’s critical characteristics, select acceptance method(s), form lots to be sampled, select and implement sampling plans, and document and trend results. A unique sampling plan is developed for each critical characteristic and relies on a number of selection factors. Mr. Tannenbaum showed diagrams of potential selection factors for supplier/item-related and test/inspection-related sampling plans. EPRI suggests using a graded approach to selecting the appropriate sampling plan for nondestructive tests and inspections. In contrast, sampling plans for destructive tests and inspections may vary based upon production, single product manufacturer, and multiple product manufacturer traceability. Mr. Tannenbaum identified several factors to consider when normal, reduced, or tightened sampling plans are considered and concluded his remarks by summarizing the final steps of the dedication process, which include implementation of the sampling plans, evaluation of the results to determine acceptance, and documentation. He stressed the importance of adequate documentation to establish the bases for sampling and to document the technical justification for the adequacy determination.

The last panelist of Session 3 was John DeKleine, Quality Director, Enertech. He began his presentation with a description of the documents that provide the basis for Enertech’s sampling program. At Enertech, he indicated that an engineering evaluation is used to document the logic for selecting the sample, based on the confidence level of the lot homogeneity. He further discussed that lot confidence is established by evaluating the applicable selection plan factors (e.g., product supplier, testing/inspection) and the type of test (non-destructive or destructive).

Mr. DeKleine emphasized that a commercial-grade dedication survey is not an audit. A survey focuses on what the suppliers do to control a critical characteristic under consideration for EPRI Method 2 dedication and that it assures the identified controls are satisfactorily implemented. Furthermore, at Entertech if Engineering is not part of the survey team, it performs an evaluation of the survey results for acceptability. This reinforces the goal that the survey supports the Engineering Dedication Plan. He also stated that the components of a simplified supplier survey process are: developing a survey plan, obtaining engineering approval, developing a worksheet, performing the survey, completing checklist questions, and performing adequacy technical evaluations. Mr. DeKleine presented some lessons learned, which stressed documentation of justifications and rationale for selecting a sampling plan, training to industry guidelines and procedures, and linking of Method 2 surveys to the dedication plan critical characteristic.

### Summary and Conclusions

Several key messages were developed from the interactions during the two days of the workshop:

- A robust Part 21 program should be linked to, or integrated with, a corrective action program.
- Both Part 21 and Appendix B to 10 CFR Part 50 apply to the design, fabrication, procurement, and use of basic components.
- Basic components may be purchased from vendors that have documented Appendix B programs, or by procuring CGIs and then implementing the dedication process.
- Verification of acceptability of an item being dedicated in accordance with Part 21 should focus on the critical characteristics of the item being dedicated.
- The rationale for a selected sampling program for CGI dedication must be adequately documented.
- If the requirements in a purchase document are not fully understood by the vendor, they should be discussed with the customer, ideally before beginning work under the purchase document.

Over 240 question cards were submitted to the NRC, of which some of the questions were answered during the general sessions and the breakout sessions. Answers to the submitted questions will be posted on the NRC website at a later date.

In an effort to enhance the next vendor workshop, the NRC solicited suggestions from the attendees. NRC Public Meeting Feedback forms were distributed to attendees, and 25 forms were received by the NRC staff at the end of the workshop. Additional forms are expected to be received. By including notification in the workshop program flyer, the NRC also solicited suggestions for topics of discussion at the next NRC vendor workshop. These feedback forms

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will be used to improve future vendor workshops and to focus on the appropriate topics at the workshops.

In summary, the workshop provided the opportunity to communicate the lessons of the past, to fully understand the findings of the present, and to work toward an environment that promotes the assurance of quality during the nuclear renaissance.

Enclosures:

As stated

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In summary, the workshop provided the opportunity to communicate the lessons of the past, to fully understand the findings of the present, and to work toward an environment that promotes the assurance of quality during the nuclear renaissance.

Enclosures:  
As stated

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<b>OFFICE</b>	CQVB/DCIP/NRO	BC:CQVB/DCIP/NRO
<b>NAME</b>	DSinks	JANakoski
<b>DATE</b>	1/7/2009	1/9/2009

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<u>DISTRIBUTION:</u>	CQVB/RF	CQVP/RF	JANakoski	JPeralta	VHall
	GHolahan	MJohnson	KKavanagh	RMclntyre	PBell
	PPrescott	RRihm	ARivera-Varona	JTappert	GTracy
	MConcepcion	DSinks			

Bhavesh Patel, Supervisor  
 Procurement Engineering and Dedication  
 Progress Energy  
 5413 Shearon Harris Road, Z-17A  
 New Hill, NC 27562

Jim Bartleman, Manager  
 Corrective Action Program  
 AREVA NP Inc.  
 3315 Old Forest Road  
 Lynchburg VA 24504

Craig S. Irish  
 Vice President, Sales & Marketing  
 Nuclear Logistics, Inc.  
 27 Linwood Street  
 Chelmsford, MA 01824

James Fiscaro  
 Senior Project Manager  
 Nuclear Energy Institute  
 1776 I Street NW  
 Washington, DC 20006

Gayle Elliott  
 Licensing Manager from Regulatory Affairs  
 AREVA NP Inc.  
 3315 Old Forest Road  
 Lynchburg, VA 24501

John DeKleine  
 Quality Director  
 Enertech, Curtiss-Wright Flow Control Nuclear  
 2950 E. Birch Set  
 Brea, CA 92821

Marc H. Tannenbaum  
 Project Manager  
 Electric Power Research Institute  
 1300 WT Harris Blvd  
 Charlotte, NC 28262

Sherry Grier  
 Procurement Quality Manager  
 Duke Energy  
 13225 Hagers Ferry Road, MC MG02PQ  
 Huntersville, NC 28214

Mark McBurnett, Vice President  
 Oversight & Regulatory Affairs  
 South Texas Project Nuclear Operating Co.  
 4000 Ave. F, Suite A  
 Bay City, TX 77414

William Ware  
 Dedication Lab Supervisor  
 Southern Nuclear Operating Company  
 7388 North State Hwy. 95  
 Columbia, AL 36319

Rosalie Nava  
 Quality Assurance Manager  
 Crane Nuclear, Inc.  
 860 Remington Blvd.  
 Bolingbrook, IL 60440

1<sup>st</sup> NRC Workshop on Vendor Oversight for New Reactor Construction  
December 10 – 11, 2008

Attendee List

<u>Name</u>	<u>Affiliation</u>
Abens, Paul	Emerson Process Mgmt. - Fisher Controls
Abrams, Mark	ABS Consulting Inc.
Adams, Mike	GE Hitachi Nuclear Energy
Aiken, Donna M.	Westinghouse Electric Co.
Alexander, Greg	Monarch Electric Service Co.
Allen, Sarah	Babcock & Wilcox Co.
Alonso, Carmen	GE Hitachi Nuclear Energy
Amirmokri, Homi	U.S. Department of Energy
Amsden, Greg	ACS
Apostolescu, Victor	Velan Inc.
Arroyo, Damaris	U.S. NRC - Nuclear Material Safety & Safeguards
Ashcraft, Joseph M.	U.S. NRC - New Reactors
Ashkeboussi, Nima	U.S. NRC - New Reactors
Baird, Zeb	Hirschfeld Steel Group LP
Baker, Richard	Bechtel Power Corp.
Barker, Joe	Flowserve Corp.
Barnes, Orié	Transco Products Inc.
Barry, Robert D.	Flowserve Corp.
Bartholomees, G. Hugh	Automated Engineering Services
Bartleman, James	AREVA NP
Baumgartner, Terry	Tetra Tech, Inc.
Beane, Paul	United States Enrichment Corporation
Belanger, Linda	DRS Power & Control Technologies, Inc.
Bell, Archie C.	Nuclear Logistics, Inc.
Bell, Michael	Curtiss Wright Corporation - Trentec
Bell, Paul M.	U.S. NRC - Nuclear Material Safety & Safeguards
Bennett, Jeffry A.	Progress Energy Florida
Benzer, Julie	General Rubber Corporation
Berger, Carl	Energetics Inc.

Bhatia, Bhupendra	U.S. NRC - New Reactors
Blum, Buck	URS Corp., Washington Div.
Blystone, Dixon	Penn Iron Works, Inc.
Bobo, Barry	HSB CT
Bohnsack, Terrill	Sandmeyer Steel Co.
Bolt, Tracy	Nuclear Logistics, Inc.
Bondurant, Bill	United States Enrichment Corporation
Borisky, Dave	Kiewit Power Constructors Co.
Borland, Scott	Amidyne Group
Bowling, Diana	US Concrete On-Site, Inc.
Boyle, Patrick	U.S. NRC - New Reactors
Brand, Eric P.	Imaging and Sensing Technology
Breaux, Korby	Flexitallic
Brillon, Richard	Westinghouse Electric Co.
Brodeur, Richard I.	The Okonite Company
Bryan, William J.	ANSYS, Inc.
Bryant, Barry C.	Dominion
Buffie, Bruce R.	B&W Nuclear Operations Group
Bunch, Saralyn	U.S. Department of Energy
Burgess, Bruce	U.S. NRC - Region III
Burns, Edward M.	Pebble Bed Modular Reactor (Pty) Ltd.
Burroughs, Eleasah	U.S. NRC - New Reactors
Bywater, Russell	Mitsubishi Nuclear Energy Systems, Inc.
Calle, Joselito O.	U.S. NRC - Region II
Campbell, Richard E.	EnergySolutions
Campbell, Paul	American Tank and Fabricating Co.
Capallo, Mark	Energy & Process Corp.
Carpenter, Cynthia	U.S. NRC - Enforcement
Carver, Ronald	Luminant Power
Cash, Michael	U.S. NRC - Office of the Inspector General
Cavallo, Jon R.	Corrosion Control Consultants & Labs, Inc.
Chandler, Donald B.	MACTEC Engineering & Consulting, Inc.
Cheney, Valentina	U.S. NRC - Nuclear Material Safety & Safeguards
Cheok, Geraldine	National Institute of Standards & Technology

Chilek, Jake	Rotork Controls, Inc.
Chinworth, Michael W.	Japan Nuclear Energy Safety Org.
Ciminel, Robert J.	Institute of Nuclear Power Operations
Cleavenger, Sabrina	U.S. NRC - New Reactors
Coates, Robert	L-3 SPD Electrical Systems
Colleli, Cathy	U.S. NRC - Office of the Inspector General
Colón, Araceli T. Billoch	U.S. NRC - Nuclear Reactor Regulation
Concepcion, Milton	U.S. NRC - New Reactors
Conrad, Brooke	Westerman, Inc.
Conti, Kenneth	AREVA NP
Cooper, John	Entergy Nuclear
Cooper, Rebecca	Nuclear New Build Monitor
Corbitt, Greg	Bechtel Power Corp.
Coronato, Louis	CT&G
Corp, Kimberley	U.S. NRC - New Reactors
Corsetti, Lawrence	Westinghouse Electric Co. - Nuclear Fuels
Couchman, Paul E.	IST-Conax Nuclear
Craffey, Ryan	U.S. NRC - Nuclear Safety Prof. Devel. Program
Crane, Samantha	U.S. NRC - New Reactors
Crespo, Guillermo	U.S. NRC - Region II
Crisler, Windell	Shaw Nuclear Services
Cronin, Frank	ABS Consulting
Csogi, Ralph	GPI
Cunningham, Larry	General Cable Corp.
Cushing, Jack	U.S. NRC - Nuclear Reactor Regulation
Cwalina, Greg	U.S. NRC - Nuclear Reactor Regulation
D'Agostino, Bruce	Construction Management Assoc. of America
Daniluck, John S.	Bechtel Power Corp.
Dasgupta, Surath	WorleyParsons Resources & Energy
Dean, James M.	Consultant
Decker, Bob	Weldstar Company
DeKleine, John "Rusty"	Enertech, Curtiss-Wright Flow Control Nuclear
Del Campo, Frank	MPR Associates
DeLutis-Smith, Shea	Clark Construction Group, LLC

Deschaine, Wesley	U.S. NRC - New Reactors
Detandt, John M.	James C. White Company, Inc.
DeWalt, Kurt	Imaging and Sensing Technology
Diaz-Castillo, Yamir	U.S. NRC - New Reactors
Dietzel, Bill	Flowserve Corp. - Flow Solutions Div.
DiLorenzo, Richard	The Okonite Company
DiMauro, Steve	Tioga Pipe Supply Company, Inc.
Dlugolenski, Stanley	Westinghouse Electric Co.
Dlugos, David	Ashcroft Inc.
Dodds, Matt	Westerman, Inc.
Dubon, Jose R.	Dominion
Dumke, Robert	Alfa Laval
Dunkin, Bradley D.	Oregon Iron Works, Inc.
Dunn, Terrance E.	Science Applications International Corp.
Dunscorn, Mark	Schnabel Engineering
Durkin, Timothy	Energetics Inc.
Easterling, Rick	Kinectrics - USA
Ebner, Jerome M.	AREVA Federal Services LLC
Edwards, Denise	U.S. NRC - Nuclear Material Safety & Safeguards
Eklund, Mats	Alfa Laval Lund AB
Elliot, Gayle	AREVA NP
Erickson, John	Kiewit Engineering Co.
Evans, John P., Jr.	URS Corp., Washington Div.
Fahey, Mary Kay	U.S. NRC - Investigations
Fandetti, Robert	LISEGA Inc.
Faria, Carolyn	U.S. NRC - Enforcement
Farschon, Christopher	Corrosion Control Consultants & Labs, Inc.
Feliu, Luis	Bechtel Power Corp.
Ferdas, Marc S.	U.S. NRC – Office of Exec. Dir. for Ops.
Ferrar, Steve	Curtiss-Wright Flow Control
Fetherolf, Steve	United States Enrichment Corporation
Fisher, Kay	DIVESCO, Inc.
Fisicaro, James	Nuclear Energy Institute (NEI)
Fitzwilliam, Jim	Trust Manufacturing, LLC

Flynn, Stacey	Alfa Laval Inc.
Flynn, Terence J.	Chempump
Fort, Daniel	AREVA NP
Fox, Ron	AREVA
Fraser, Robert G.	Black & Veatch Corporation
Fritz, Larry A.	Westinghouse Electric Co.
Fuller, Brad	Commonwealth of Pennsylvania
Gagge, John	EnerSys
Gagnon, Jon	GE Hitachi Nuclear Energy
Galletti, Greg	U.S. NRC - New Reactors
Garrett, George	Fluor Nuclear Power
Gatromb, Steven	Valcor Engineering
Gauthier, Steven A.	Bechtel SAIC Co.
George, Buster	Mid-South Nuclear, Inc.
George, Robert	Ametek Solidstate Controls
Gibbs, Catina	U.S. NRC - Nuclear Material Safety & Safeguards
Giddens, John M., Jr.	Southern Nuclear Operating Co., Inc.
Giles, Julie	SCE&G
Gilman, Michael	Shaw Group
Gilmartin, Brian M.	DRS Power and Control Technologies, Inc.
Gilmartin, Gary	B&W Y-12
Godfrey, Dewey	USEC Inc.
Gokhale, Kishore	Bechtel Power Corp.
Gould, Ken	Namco Controls
Grant, Geoff	Shaw Nuclear Services
Grant, Jim	Duke Energy
Greer, George	Flowserve Corp.
Grier, Sherrie	Duke Energy
Grooms, Kerry	B&W Y-12
Guthreau, Lance	ASCO Valve
Habeeb, Maliha	United Controls International
Hale, Robert B.	United Controls International
Hall, Victor	U.S. NRC - Nuclear Reactor Regulation
Hall, William	Babcock & Wilcox Co.

Hammarstrom, Amy	General Rubber Corporation
Harmon, Dale	Westinghouse Electric Co.
Harris, Garry	HTS Enterprise
Harris, Rozell	Southern Nuclear Operating Co., Inc.
Harris, Steve	Rotork Controls Ltd.
Harwell, Shawn W.	U.S. NRC - Nuclear Reactor Regulation
Hasha, Brian	Flexitallic
Hay, Lane	Bechtel Power
Hayes, E. Patrick	URS Corp., Washington Div.
Heck, Kenneth	U.S. NRC - New Reactors
Henderson, Mike	Premier Technology, Inc.
Henley, J. Bruce	The Brock Group
Hennessey, Patrick	OneCIS Insurance Company
Herbster, Craig	GE Hitachi Nuclear Energy
Herrity, Thom	U.S. NRC - Nuclear Reactor Regulation
Hewitt, Marc	Westinghouse - PaR Nuclear
Hignite, David A.	Shaw Global Modular Solutions
Hinze, Larry	Fluor Nuclear Power
Hobbs, R. Scott	URS Corp., Washington Div.
Hodge, C. Vernon	U.S. NRC – Nuclear Reactor Regulation
Hodges, Don	Utility Resource Associates Corp.
Hoffman, Donald	Excel Services Corp.
Holahan, Gary	U.S. NRC - New Reactors
Holler, David	Mitsubishi Nuclear Energy Systems, Inc.
Horan, Thomas	Hilti, Inc.
Horner, Daniel	Platts
Howell, Chuck	AQA International
Hudson, Dean	Oregon Iron Works, Inc.
Hudson, Don	4g Technologies, LP
Hughes, Timothy	Imaging and Sensing Technology
Imbro, Gene	Consultant
Irish, Craig S.	Nuclear Logistics, Inc.
Ishibashi, Fumihiko	Toshiba Corp. - America Nuclear Energy
Jabbour, Dr. Kahtan	Jabbour & Associates

Jacobs, Frank	U.S. NRC - Nuclear Material Safety & Safeguards
Jacobson, Jeffrey	U.S. NRC - International Programs
Jankauskas, Thomas F.	RANOR, Inc.
Janosko, Gary	Public Service Electric & Gas Co.
Jasinski, Robert	U.S. NRC - New Reactors
Jefferson, Fred	Scientech
Jennings, Jason	U.S. NRC – New Reactors
Jimenez, José G.	U.S. NRC - New Reactors
Johnson, Michael	U.S. NRC - New Reactors
Johnston, Tim	Ralph A. Hiller Co.
Jolly, Rajwant	Bechtel Power Corp.
Kamenicky, Larry	Westinghouse Electric Co.
Karably, Lou	S&ME, Inc.
Kartachak, Thomas	Parsons
Kavanagh, Kerri	U.S. NRC - New Reactors
Kavchak, Marilyn	U.S. Department of Energy
Kawahara, Sharon	Control Components Inc.
Keba, Jim	Sandmeyer Steel Co.
Kehoe, David	Shaw AREVA MOX Serv. - Savannah R. Site
Keim, Andrea	U.S. NRC - New Reactors
Keiser, Deborah L.	Lehigh Testing Laboratories, Inc.
Keller, Timothy S.	NUCON International, Inc.
Kenney, George W.	Curtiss Wright Corporation - Trentec
Kim, Sangjin	DOOSAN Heavy Industries & Construction
Kirkpatrick, Brian	Metals USA
Kirkwood, Jon	Excel Services Corp.
Kirt, Wendy M.	Energy Steel & Supply Co.
Kiwak, Joseph M.	Nuclear Innovation North America
Hjelseth, Joel	Westinghouse Electric Co.
Klawonn, Daniel	LISEGA Inc.
Kleeh, Edmund A.	U.S. NRC - New Reactors
Klorczyk, Fred	CONAM/MISTRAS Services
Knox, Walter L.	Gerdau AmeriSteel
Koltay, Peter	U.S. NRC – Commissioner’s Office

Kondo, Koichi	Toshiba America Nuclear Energy Co.
Kopyscianski, Peter P.	URS Corp., Washington Div.
Kottenstette, Andy	MACTEC Engineering & Consulting, Inc.
Kotzalas, Margie	U.S. NRC - Nuclear Material Safety & Safeguards
Kovach, Paul E.	NUCON International, Inc.
Kozak, Thomas	U.S. NRC - Region III
Krause, Fred	Shaw Nuclear Services
Kuhn, George	Spectrum Technologies/Southern Testing Services
Kulp, David	DRS Technologies
Lane, Robert	Spectrum Technologies/Southern Testing Services
LaRoche, Wilfred C.	HSB CT
Larson, Jeff	Invensys Process Systems
Lashley, Michael	Structural Integrity Associates
Laubach, Rick	nexArc Inc.
Laura, Rich	U.S. NRC - New Reactors
Lawman, Woody	Limitorque - Div. of Flowserve
Lawrence, Edward	Chalmers & Kubeck, Inc.
Le, Toomy N.B.	Bechtel Power Corp.
Lee, James	Supplier Quality Services
Lee, Min	U.S. NRC - New Reactors
Leigh, Danny	Fluor Nuclear Power
Lemieux, John	Electroswitch Inc.
Leon, Jennifer C.	U.S. NRC - New Reactors
Lipscomb, George	U.S. NRC - New Reactors
Loflin, Leonard	Electric Power Research Institute
Long, Anthony	Swepeco Tube LLC
Loprete, Jeffrey	ASCO Valve
Lukes, Bob	U.S. NRC - New Reactors
Lund, Per-Olof	Sandvik Materials Technology
Lydy, Steven	Baker Concrete
Lynch, James	IST
MacCrae, Michael	USEC Inc.
Mahadeen, Ramsey	Atlas Industrial Manufacturing Co.
Mahadevan, Ravi	Valcor Engineering

Malave-Velez, Yanely	U.S. NRC - New Reactors
Mallet, Bruce	U.S. NRC - Office of Exec. Dir. for Ops.
Mallia, Joseph P.	ACS
Mallory, Barry	Colonial Machine Co.
Mallory, Karen	Colonial Machine Co.
Malloy, Terence	ABB Medium Voltage Service
Manna, Eileen	BASF
Manning, Ted	WorleyParsons
Maret, Daniel	Sequoia Consulting Group
Marshall, Robert M.	Bechtel National, Inc. - WTP Project
Martin, Richard	Homewood Products Corp.
Martinez-Navedo, Tania	U.S. NRC – New Reactors
Matula, Thomas	U.S. NRC - Nuclear Material Safety & Safeguards
Matyskiel, Richard F.	ASCO Valve
Mayhorn, Earl	AmerenUE Callaway Plant
McBurnett, Mark	South Texas Project Nuclear Operating Co.
McCann, Tom	Morris Material Handling
McCarthy, Adam	Cameron
McDonald, Robert	Westinghouse Nuclear
McFarland, Alice	BASF Construction Chemicals
McIntyre, Richard	U.S. NRC - New Reactors
McLaughlin, Bob	Babcock & Wilcox Nuclear Power Gen. Group
McLaughlin, Bryan	Entergy Services Inc.
McPartlin, Gary O.	Iron Mountain Inc.
McVicker, Chuck	Ventyx
Melvin, Deborah	CCI
Mendoza, Jonathan	National Technical Systems
Meyer, Steve	Ameren
Mikach, John	Homewood Products Corp.
Millar, Dana	Entergy Nuclear
Miner, Peter J.	USEC Inc.
Minick, Merle	OneCIS Insurance Company
Miotla, Sherri	U.S. NRC - Office of the Inspector General
Mohr, John	Mitsubishi Nuclear Energy Systems, Inc.

Montgomery, Shandeth	U.S. NRC - New Reactors
Moore, Al	Southern Nuclear Operating Co., Inc.
Moreau, Norman P.	Theseus Professional Services, LLC
Morgan, David	Premier Technology, Inc.
Morgan, Michael J.	U.S. NRC - New Reactors
Morgan, Mike	AREVA NP
Morris, Kevin	Transnuclear, Inc.
Mudge, Tom	URS Corp., Washington Div.
Muller, Charles	Teledyne Brown Engineering
Murray, Demetrius	U.S. NRC - New Reactors
Nagle, Meghan	U.S. NRC - Administration
Nakoski, John A.	U.S. NRC - New Reactors
Nava, Rosalie	Crane Nuclear, Inc.
Nehls, Charles	Unistrut Corp.
Newman, Larry	U.S. Department of Energy
Newton, John	Teledyne Brown Engineering
Niccolls, Mike	Wagstaff Applied Technologies
Nichols, Brian	Conval, Inc.
Nishiyama, Hideki	Toshiba Corp. - Nuclear Energy Systems/Services
Nyzio, Michelle L.	Lockheed Martin
O'Brien, Steven	AREVA - Canberra Dover
Oehlberg, Richard	Electric Power Research Institute
O'Farrell, Gerald	Precision Custom Components, LLC
Offner, Arnold	Phoenix Contact
Oglesby, John H., Jr.	U.S. NRC - Region IV
Olson, Don	Columbiana Hi Tech, LLC
Oravitz, James W.	Tennessee Valley Authority
Ortega-Luciano, Jonathan	U.S. NRC - New Reactors
Osmundsen, Tor	Westinghouse Electric Co.
Otake, Ikuo	Mitsubishi Heavy Industries, Ltd.
Otis, Robert	Shaw
Packard, Stephen L.	Westinghouse Electric Co.
Pang, Joseph	American Society of Mechanical Engineers
Panzella, Thomas	Curtiss-Wright Flow Control

Papai, John S.	Westinghouse Electric Co.
Pascarelli, Robert	U.S. NRC - New Reactors
Pasquale, Daniel	U.S. NRC - New Reactors
Patel, Bhavesh	Progress Energy
Patel, Nitin	U.S. NRC – Nuclear Reactor Regulation
Patel, Raju	U.S. NRC - New Reactors
Paton, Robert J.	Energy Steel & Supply Co.
Paul, Steve	Bechtel Power Corp.
Pearson, John B.	S&ME, Inc.
Pecoraro, Joseph	Parsons
Peebles, William	Flanders Corp./CSC
Peralta, Juan	U.S. NRC - New Reactors
Perry, Lynne	Teledyne Brown Engineering
Peszka, Frank	Laboratory Testing Inc.
Peters, Gary	Gerdau Ameristeel
Petrosino, Joseph J.	U.S. NRC - Nuclear Reactor Regulation
Pettis, Robert L.	U.S. NRC - Nuclear Reactor Regulation
Pindar, Francis X., Jr.	Burns and Roe Enterprises, Inc.
Pischke, Mike	Alfa Laval Inc.
Pitts, Alfred, Jr.	UniStar Nuclear Energy
Plante, Lisa	Westinghouse Electric Co.
Plechy, George J.	ASCO Valve
Podlaszewski, Ken	ANSYS, Inc.
Polito, Joe	Alfa Laval Inc.
Pollock, Henry	Progress Energy
Poston, Johnnie	Global Quality Assurance, Inc.
Powell, Gary	Techalloy Welding Products
Prato, Robert J.	U.S. NRC – New Reactors
Preis, Bernie L.	TriVis Inc.
Prescott, Paul	U.S. NRC - Nuclear Reactor Regulation
Pugh, Bill	Gerdau AmeriSteel
Rahn, David	U.S. NRC - Nuclear Material Safety & Safeguards
Rainey, Carl	Black & Veatch Corp.
Raleigh, Deann	Scientech

Rasmussen, Richard	U.S. NRC - Commissioner's Office
Ray, Sheila	U.S. NRC - Nuclear Reactor Regulation
Reber, Jan	EnerSys
Rengifo, Christian	Ux Consulting
Reynolds, Dean	Underwater Engineering Services, Inc.
Rezk, Tamer N.	Bechtel Power
Rhoads, Kerry	Dominion
Rihm, Roger	U.S. NRC - New Reactors
Rivera, Aida	U.S. NRC - New Reactors
Rivera, Eric	U.S. NRC - Office of the Inspector General
Rivera, Rodolfo	U.S. NRC - Office of the Inspector General
Rizzi, Frank	Westinghouse Electric Co.
Robinson, Joseph	NDE Professionals, Inc.
Roche, Thomas	ABS Consulting
Rogers, Bill	U.S. NRC - Nuclear Reactor Regulation
Rogers, John E.	Whiting Corporation
Romano, Victor H.	ABB Medium Voltage Service
Roquecruz, Carla P.	U.S. NRC - Nuclear Reactor Regulation
Rose, Dave	Flowserve Corp.
Ross, William	EnerSys
Routh, Stephen	Bechtel
Roy, Fredrick	Parker Hannifin, Instrumentation Products Div.
Rozek, Eric	Defense Nuclear Facilities Safety Board
Rund, Jonathan	Morgan, Lewis & Bockius
Ryan, Rebecca	U.S. NRC - Office of the Inspector General
Salih, Ahmad	Transnuclear, Inc.
Salvador, Stuart	The Paul Mueller Company
Sanchez, Luis	United Controls International
Saniuk, Michael P.	AREVA NP
Sarma, T.V.	Bechtel Power Corp.
Saucier, Mark E.	SSM Industries, Inc.
Schlaseman, Caroline S.	MPR Associates, Inc.
Schleger, Brian	Ralph A. Hiller Co.
Schultz, Peter	Canadian Nuclear Safety Commission

Schum, E. Reilly	Wyle Laboratories, Inc.
Schweers, Doug	Excel Services Corp.
Scott, Barry B.	URS Corp., Washington Div.
Scott, Terry	Kiewit Corporation
Senkowski, E. Bud	KTA-Tator, Inc.
Seol, Sangpill	DOOSAN Heavy Industries & Construction
Shannon, Mel	U.S. NRC - Region II
Shell, George	Shaw AREVA MOX Serv. - Savannah R. Site
Shepherd, Amanda	US Concrete On-Site, Inc.
Sheppard, Rodney P.	Sargent & Lundy
Shirani, Oscar	Shaw Group - MOX
Sinks, Donna J.	U.S. NRC - New Reactors
Sisk, Robert	Westinghouse
Sizemore, Robert A.	Flowserve Corp.
Smith, Clayton T.	Fluor Nuclear Power
Smith, Sean	Lockheed Martin NS&S
Smith, Steve	Shaw AREVA MOX Serv. - Savannah R. Site
Smithers, Ed	CONAM/MISTRAS Services
Soler, Mark	Holtec International
Soto, Soly I.	U.S. NRC - Nuclear Material Safety & Safeguards
Soukchareun, Phousone	Westinghouse - PaR Nuclear
Sowa, Nick	CONAM/MISTRAS Services
Sparks, Jon	Wagstaff Applied Technologies
Spradlin, Ted	Fluor Corp.
Sprowls, Gary	ANSYS, Inc.
St. Onge, Mark T.	Rockbestos Surprenant Table Corp.
Stankiewicz, Edward	Joseph Oat Corporation
Stanze, Dave	Emerson Process Mgmt. - Fisher Valve Div.
Steingass, Timothy	U.S. NRC - New Reactors
Stepantschenko, Paul	Engine Systems, Inc.
Stevens, Paul	Epsilon Systems Solutions, Inc.
Stevenson, Richard R.	Shaw Nuclear Services, Inc
Stimart, Darlene	Xcel Energy - Nuclear Dept.
Stoltz, Marlin, II	Transnuclear Inc.

Stouch, James, C.	Precision Custom Components, LLC
Strnisha, James	U.S. NRC - New Reactors
Sutherland, William	Transnuclear, Inc.
Tabatabai, Omid	U.S. NRC - New Reactors
Talbot, Francis	U.S. NRC - New Reactors
Tannenbaum, Marc	Electric Power Research Institute
Tapia, Joseph	Mitsubishi Nuclear Energy Systems, Inc.
Tappert, John	U.S. NRC - New Reactors
Taylor, Robert	Kiewit Building Group Corporate
Tercey, Joseph K.	Williams Plant Services, LLC
Thatcher, Dale	U.S. NRC - Nuclear Reactor Regulation
Thomas, Dennis	Curtiss Wright Flow Control Corp. - Target Rock
Thomas, Stephen	Siemens Water Technology Corp.
Tierney, Mark	Laboratory Testing, Inc.
Timmons, Kevin	PCI Energy Services, LLC
Torres, Alan	SCE&G
Tracy, Glenn M.	U.S. NRC - New Reactors
Tracy, John	TriVis Inc.
Traynor, John	UniStar Nuclear Energy
Trozzi, Arthur	Westinghouse Electric Co.
Truxall, Justin	American Tank and Fabricating Co.
Tyler, Charles D.	South Carolina Electric & Gas Company
Ulassin, Kyle	South Texas Project Nuclear Operating Co.
Urton, John	Flanders Corp.
Vander Zwaag, Craig	Mirion Technologies
VanRoo, James C.	Siemens Water Technologies
Varner, David	Progress Energy Florida
Vickery, Doug	DuBose National Energy Services
Vidal, Raul	URS Corp., Washington Div.
Vigne, David	National Inspection & Consultants, Inc.
Vinyard, Paul	Northrop Grumman - Newport News Industrial
Volkening, David	Luminant Power
Voyles, Gale S.F.	Fluor Enterprises
Walcheski, Bob	Underwater Engineering Services, Inc.

Ward, Leslie A.	Data Systems & Solutions, LLC
Ware, William	Southern Nuclear Operating Co., Inc.
Wasmundski, Dottie	Lehigh Testing Laboratories, Inc.
Waters, Waylon	Energy Steel & Supply Co.
Watson, Rick	Kiewit Power Constructors Co.
Watts, Dennis L.	AREVA NP Inc.
Watts, Paul D.	RANOR, Inc.
Webb, John	Weir Valves & Controls USA Inc.
Webb, Michael	U.S. NRC - New Reactors
Weber, Carl	U.S. NRC - New Reactors
Wedemeyer, Michael	Fisher Controls International LLC
Weiland, Noah	Homewood Products Corp.
Wesch, Suzi	Davis Calibration
Wheeler, Bruce P.	Tyco Valves & Controls
White, Darrell	U.S. NRC - Region II
Whitley, Rodney	MOX Services
Wild, Robert K.	U.S. NRC - Office of the Inspector General
Williams, Charles M.	Apantec, LLC
Williams, Kim	Teledyne Brown Engineering
Williams, Preston M.	South Texas Project Nuclear Operating Co.
Wilson, Christine	Babcock & Wilcox Canada
Wilson, Jerry N.	U.S. NRC - New Reactors
Wilson, Tim	U.S. NRC - Office of the Inspector General
Wisniewski, John	Louisiana Energy Services
Woelfel, Eugene	BVZ (Zachry Holdings Inc.)
Wong, Paul C.H.	Canadian Nuclear Safety Commission
Worthington, Jeffrey	U.S. Environmental Protection Agency
Wray, John	U.S. NRC - Enforcement
Wright, Douglas	Constellation Energy Nuclear Group
Wynne, Edward	Fluor Nuclear Power
Yamasaki, Takeshi	Nuclear & Industrial Safety Agency (NISA)
Yates, Douglas	Shaw AREVA MOX Serv. - Savannah R. Site
Yauch, Ronald	USEC Inc.
Yelamanchi, Ram	Bechtel Power Corp.

Yerokun, Jimi	U.S. NRC - New Reactors
Yockey, Ernest C.	International Quality Consultants, Inc.
Yohon, Bob	Rotork Controls, Inc.
Young, Kyle	SCE&G - V.C. Summer Nuclear Station
Youngblood, Thomas W.	Lockheed Martin Missiles & Fire Control
Yurich, Frank	American Crane & Equipment Corp.
Zeitler, Michael	U.S. NRC - Office of the Inspector General
Zinke, George	Entergy Nuclear

1<sup>st</sup> NRC Workshop on Vendor Oversight for New Reactor Construction  
December 10 – 11, 2008

List of Speakers and Panelists

<u>Speaker/Panelist</u>	<u>Affiliation</u>
Jim Bartleman	AREVA NP Inc.
Paul Bell	U. S. Nuclear Regulatory Commission
Milton Concepcion	U. S. Nuclear Regulatory Commission
John "Rusty" DeKleine	Enertech, Curtiss-Wright Flow Control Nuclear
Gayle Elliott	AREVA NP Inc.
James Fisicaro	Nuclear Energy Institute
Sherry Grier	Duke Energy
Victor Hall	U. S. Nuclear Regulatory Commission
Gary Holahan	U. S. Nuclear Regulatory Commission
Craig S. Irish	Nuclear Logistics, Inc.
Kerri Kavanagh	U. S. Nuclear Regulatory Commission
Mark McBurnett	South Texas Project Nuclear Operating Co.
Richard McIntyre	U. S. Nuclear Regulatory Commission
John Nakoski	U. S. Nuclear Regulatory Commission
Rosalie Nava	Crane Nuclear, Inc.
Bhavesh Patel	Progress Energy
Juan Peralta	U. S. Nuclear Regulatory Commission
Paul Prescott	U. S. Nuclear Regulatory Commission
Marc H. Tannenbaum	Electric Power Research Institute
Glenn Tracy	U. S. Nuclear Regulatory Commission
William Ware	Southern Nuclear Operating Company