POLICY ISSUE
INFORMATION

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FOR: The Commissioners

FROM: Luis A. Reyes
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SUBJECT: MULTINATIONAL DESIGN APPROVAL PROGRAM STAGE 1

PURPOSE:

This paper informs the Commission of activities and plans associated with Stage 1 of the Multinational Design Approval Program (MDAP).

SUMMARY:

Stage 1 of the MDAP is focused on new light water reactor designs where the vendor is seeking design certification in accordance with the Nuclear Regulatory Commission's (NRC's) regulations, and where the same or similar reactor design is being reviewed by the NRC's regulatory counterparts for licensing in other countries. In Stage 1, participating regulatory authorities will share results of their design review activities. Collaborative reviews and research of identified issues will also be considered, as applicable. In reviewing design certification applications filed with the NRC, the NRC will use its current design certification

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process, as specified in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, incorporating expertise of other national regulatory bodies into its reviews. Other governments participating in Stage 1 of the Multinational Design Approval Program (MDAP) will be free to utilize the NRC's outputs to support their own national licensing processes.

MDAP Stage 1 will first be applied to the AREVA NP, Inc. (AREVA), Evolutionary Power Reactor (EPR). The first EPR is currently under construction in Finland, with additional reactors planned for France and the U.S.

The NRC staff believes that a meaningful opportunity exists to leverage the technical work of its counterparts in the NRC's EPR design review, based on initial discussions with its counterparts and AREVA. MDAP Stage 1 should increase the focus on key safety issues, and efficiency and effectiveness of the EPR review. Additional coordination between NRC, its counterparts, and AREVA is needed to ensure the program implementation is properly planned with consideration of all stakeholder interests, including the public.

BACKGROUND:

The primary objective of the MDAP, as stated in Chairman Diaz's July 22, 2005, proposal to the Commission (COMNJD-05-0006, ADAMS Accession No. ML052150282), is to enhance protection of public health and safety and the environment for the beneficial civilian use of nuclear energy. The MDAP will increase and formalize the level of multinational cooperation in upcoming design certification reviews, building on prior experience where the NRC staff has held discussions and shared research information with its foreign counterparts. The Commission approved MDAP Stage 1 in a September 8, 2005, Staff Requirements Memorandum for COMNJD-05-0006 (ADAMS Accession No. ML052510752).

MDAP Stage 1 will leverage resources across national regulatory bodies in the design reviews of new near-term power reactors. Participation in Stage 1 of the MDAP will focus on new light water reactor designs for which a vendor is seeking a U.S. design certification and for which the same or similar reactor design is being reviewed by our foreign regulatory counterparts for licensing in their respective countries. In the U.S., the NRC will incorporate information from other national regulatory bodies into its technical reviews as part of the 10 CFR Part 52 design certification process.

MDAP Stages 2 and 3 will focus on efforts to more closely align differing national regulatory frameworks, eventually applying those frameworks to licensing of Generation IV reactors. These activities will be described in subsequent Commission papers.

The document summarizing Chairman Diaz's "U.S. Proposal for a Multinational Design Approval Program," dated March 28, 2008 (ADAMS Accession No. ML060900337) provides an overview of all three stages currently envisioned for the program.

DISCUSSION:

During MDAP Stage 1, the multinational technical exchange will be focused on technical areas where the knowledge transfer can occur considering national differences in codes, standards, and regulations. The actual review of the design certification application through rulemaking will remain the sole responsibility of the NRC, as will the site-specific reviews required as part of

the 10 CFR Part 52 process. Similarly, other nations will retain responsibility for licensing activities within their borders.

As stated above, MDAP Stage 1 is first being applied to regulatory reviews of the AREVA EPR reactor design. The EPR is a large pressurized water reactor of evolutionary design, with a design output of about 1,600 MWe. Design features include four divisions of 100-percent capacity active engineered safety features, a large dry containment, and a "core catcher" for containment and cooling of core debris for severe accidents that result in reactor vessel failure. The containment, two of the four engineered safety features divisions, the spent fuel pool, and the control room are surrounded by a shield building for additional protection against external hazards.

Application of MDAP Stage 1 to the regulatory design reviews of other reactor designs such as the Pebble Bed Modular Reactor (PBMR) will be considered on a case-by-case basis. The staff will inform the Commission of other opportunities to apply MDAP Stage 1 if and when they arise.

The first EPR is currently being built at the Olkiluoto site in Finland, with commercial operation projected for 2009. In France, it is expected that EPRs will be first built at the Flamanville site. AREVA has also submitted a bid for EPR construction in China.

AREVA informed the NRC of its intent to initiate pre-application discussions for the EPR in a December 2, 2004, letter (ADAMS Accession No. ML043410096). Additional information regarding AREVA's pre-application plans were provided in a February 8, 2005, letter (ADAMS Accession No. ML050420257). AREVA met with NRC staff on several occasions in 2005 and early 2006 to familiarize the NRC staff with the EPR and to determine the scope of topics to be addressed in the pre-application review. This initial planning phase was completed in early 2006.

In its letter to the NRC dated February 3, 2006 (ADAMS Accession No. ML060440560), AREVA described a proposal for detailed pre-application discussions. The NRC staff accepted this proposal in an April 7, 2006, letter (ADAMS Accession No. ML060900021), noting that NRC's planning will include consideration of cooperation with foreign counterparts via the MDAP.

Meetings between AREVA and the NRC staff on EPR technical topics began in April 2006 and will continue throughout the pre-application review. The staff expects the first EPR pre-application reports will be submitted by AREVA for staff review later this year. Pre-application topics will include NRC review of AREVA submittals addressing various technical topics, including quality assurance, safety analysis methodology, probabilistic risk assessment, severe accidents, instrumentation and controls, human factors, and physical security. AREVA has stated that it plans to apply for NRC certification of the EPR design in late 2007.

Stage 1 of the MDAP has begun with the NRC staff obtaining information on the breadth and depth of the EPR design reviews already completed and planned by the French and Finnish regulatory agencies. Insights from AREVA regarding the process being used to convert the European EPR design to U.S. design standards will also be used to inform decisions regarding the attainable level of cooperation and use of information.

Initial bilateral meetings were held in late January and early February 2006 between NRC staff and counterparts in Finland and France, STUK and ASN, respectively. The main objectives of the trip were to obtain insights regarding the Finnish and French licensing processes as applied to the EPR, including schedules and outputs, obtain preliminary information regarding the breadth and depth of French and Finnish regulatory design reviews of the EPR, provide an overview of the MDAP and the U.S. licensing process to the French and Finnish regulators, and to discuss logistical issues relative to the implementation of Stage 1 of the MDAP. STUK and ASN representatives both indicated willingness to cooperate in the EPR review. NRC's counterparts have also expressed interest in personnel exchanges to facilitate EPR cooperation. Based on preliminary information gathered during this trip, the NRC staff confirmed a meaningful opportunity exists to leverage the technical work of its counterparts in the NRC's EPR design review, increasing the focus on key safety issues, and efficiency and effectiveness of the review.

NRC staff representatives traveled to AREVA offices in Lynchburg, Virginia, on April 25, 2006, to discuss AREVA's process for converting the Olkiluoto 3 (OL3) EPR engineering design to U.S. codes, standards, and regulatory requirements. AREVA presently has about 200 engineers in the U.S. working on the design conversion. This conversion is intended to demonstrate explicit compliance with U.S. regulatory requirements. AREVA does not intend to demonstrate that evaluations conducted for other regulatory authorities are adequate to fulfill U.S. requirements.

AREVA intends to maintain a high degree of similarity between the EPR designs planned for deployment in Finland, France, the U.S., and other parts of the world. The basic plant configuration, such as four trains of engineered safety features and shielded containment, is the same for all EPRs. The designs are very similar at the level of detail described in design piping and instrumentation drawings.

Differences between the designs are found in other design parameters. For example, AREVA expects the U.S. EPR to be rated at 4,590 MWt vs. 4,300 MWt for OL3. There are differences in seismic design in all countries, with the U.S. design requirement being most severe in terms of ground acceleration. The electrical system design in the U.S. will be based on the 60 cycle/second grid, using 3 bus voltages, while European systems will be based on 50 cycles/second with 2 bus voltages. The different electrical systems lead to different specifications for motors and other components throughout the plant, along with different electrical distribution systems, resulting in somewhat greater space requirements for the U.S. design. The EPR at Olkiluoto will include an analog instrumentation and control system as a backup to the primary digital system, and a containment vent; these features are not included in the French or U.S. designs.

Based on its knowledge of the differences between the EPR designs, AREVA suggested that cooperation between regulators be focused on severe accident features, probabilistic risk assessment, and digital instrumentation and controls. AREVA indicated that OL3 is expected to have technical specifications similar to the U.S. EPR; therefore, cooperation on this topic may be possible, as well.

The ability to share information and review results between the NRC and its counterparts will depend on the similarity of the designs submitted to the respective regulatory bodies. As discussed above, at a coarse level of detail, the EPR being constructed in Finland is configured

the same as those planned for construction in France and the U.S. However, at finer levels of detail, the designs differ. The greater the design differences at a regulatory level of detail, the more difficult it will be to utilize work completed by a foreign counterpart in the NRC's review.

The ability to utilize a counterpart's regulatory products is also affected by differences in regulatory requirements. In some cases, such as loss-of-coolant accident analyses, the NRC's regulations prescribe evaluation methodology and give very explicit acceptance criteria. Other regulatory approaches address this topic in somewhat different ways. However, review of the technical reports from NRC's foreign counterparts will increase the staff's confidence in its safety conclusions when its evaluations against NRC regulations reach similar conclusions, even in cases where differences in regulatory requirements limit the direct use of information.

Additional factors affecting internal NRC work processes and interactions with counterparts include coordination of milestones between the NRC and its counterparts, public access to information, and processes for resolution of discrepancies in regulatory review results.

Effective multinational cooperation will require coordination of review project milestones and schedules between the NRC and its counterparts. That is, if the NRC intends to use information obtained from a counterpart in a safety review, that information needs to be completed in time for the NRC staff to evaluate it as part of the NRC's review. The schedules should reflect any discussions between NRC staff and counterparts which are necessary for the staff to thoroughly understand the information provided. Similarly, the NRC will need to fulfill any schedule agreements to provide information supporting a counterpart's regulatory activities. Failure to meet schedule milestones can delay completion of regulatory products. Planning for the EPR design certification review will identify topics where MDAP information will be used. During the certification review, the staff will monitor progress towards receipt of this information as part of its ongoing project management. Potential delays will be identified as soon as possible and compensatory measures taken to minimize effects on the overall project schedule.

MDAP Stage 1 planning will also need to address the handling of information shared between counterpart regulators. It is expected that information used to inform an NRC safety decision will be publicly available, except as provided by 10 CFR 2.390. This regulation allows the NRC to withhold information when it is submitted in confidence by a foreign source. However, if information provided by a counterpart is used to reach a safety conclusion, withholding that information from public disclosure reduces the ability of the public to understand the basis for the NRC's conclusion, and may be inconsistent with the agency's strategic goal for openness in its regulatory processes. Therefore, the NRC and its counterparts will need to agree upon processes for handling shared information, including public disclosure of that information, as appropriate.

Furthermore, to effectively use information provided by foreign counterparts, the staff may need to review information submitted by license applicants to other regulatory authorities to verify that the design being reviewed by the NRC staff is the same as that submitted for review and accepted by our counterpart. The NRC and its counterparts will need to agree upon processes for handling shared information, including public disclosure of that information, including additional stakeholders (i.e., license applicants) in these discussions, as appropriate.

MDAP working arrangements should also address protocol for resolution of safety issues identified during review of a counterpart's work product. Expectations for documentation and

tracking of any issues, notification of counterparts, and a resolution process will need to be established. While such problems are expected to be rare, it should be anticipated that some small number of issues might arise, given the large scope of a reactor design review. The nature of issues that can arise could range from discrepancies due to differences in regulatory requirements to previously undetected errors in an applicant submittal. Identification and resolution of these issues will contribute to a safer design and provide insight regarding differences in national regulatory schemes that may be useful for MDAP Stage 2.

As the NRC begins its EPR review efforts, the quantity and scope of EPR information available from our foreign counterparts is far greater than the NRC can provide in return. Therefore, the NRC's foreign counterparts have expressed interest in cooperation on topics outside the scope of the EPR design review as a means to ensure an equitable exchange of technical information. Proposals to share information on these topics will need to address issues described above, such as schedule coordination.

As part of planning for the EPR design certification review, the staff plans to develop an MDAP Stage 1 cooperation table that includes each technical review area, references to relevant regulator technical reviews (planned and completed), review schedules, and specific opportunities for technical cooperation. The staff is also considering conducting a trilateral meeting with Finnish and French counterparts to discuss this table and other MDAP Stage 1 logistics.

Initially, this planning will address cooperation during the EPR pre-application review. As cooperative topics are identified, the staff will also establish a process governing how work from foreign counterparts will be used in pre-application activities. Prior to utilizing the technical inputs obtained from the foreign regulators, the NRC staff will ensure the information being used is applicable to the EPR design to be submitted for NRC certification and relevant to NRC's regulatory requirements. The staff will revise the process as experience is gained from initial counterpart interactions during the EPR pre-application review to provide appropriate guidance for later cooperative efforts which will take place during the course of the design certification review starting in late 2007.

A preliminary list of planned MDAP Stage 1 milestones is provided in the enclosure.

COMMITMENTS:

Listed below are the staff's commitments from this paper:

1. The staff will inform the Commission of interest in application of MDAP Stage 1 to reactor designs other than the EPR if such opportunities arise.

2. The staff will inform the Commission if Finland or France request payment for their services.

CONCLUSION:

Through cooperation with the Agency's international counterparts, MDAP Stage 1 can improve the safety focus, and efficiency and effectiveness of the NRC's reviews of new reactor designs. NRC's international counterparts can receive similar benefits from cooperation with the NRC. Implementation of MDAP Stage 1 will require additional coordination with the NRC's

international counterparts and with reactor designers to ensure the interests of all stakeholders, including the public, are appropriately considered.

RESOURCES:

The FY 2006 enacted and FY 2007 President's Budget include a total of 2 full-time equivalent (FTE) for all aspects of MDAP, with 1 FTE in the Office of Nuclear Reactor Regulation (NRR) and 1 FTE in the Office of International Programs (OIP). The FY 2007 budget for implementation of MDAP Stage 1 for NRR is 0.5 FTE for project management and staff effort to coordinate with the NRC's counterparts and review foreign regulatory products. An additional 0.5 FTE was budgeted to cover NRR Stage 2 efforts. With respect to OIP resources, 1 FTE was budgeted for FY 2007 to cover Stage 1 and 2 activities.

For FY 2008, 1 FTE was requested to support NRR's efforts in managing MDAP including supporting the U.S. EPR design certification review which is expected to commence in December 2007. The assumption is that these resources will be split between Stage 1 and 2 activities. One FTE of OIP resources were also requested for FY 2008. The Stage 1 activities should result in improved focus and efficiency of the staff's review. The staff will consider the potential effects of MDAP Stage 1 as it develops the EPR review schedule and budget estimates.

COORDINATION:

This paper has been coordinated with the Office of International Programs and with the Office of the Chief Financial Officer. The Office of General Counsel has no legal objection to the contents of this paper.

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Enclosure:
MDAP Stage 1 Preliminary Milestones

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Enclosure:
MDAP Stage 1 Preliminary Milestones

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MDAP STAGE 1

PRELIMINARY MILESTONES

January 31 and February 4, 2006 (complete)	Conduct fact finding visit with Finnish and French regulators to discuss logistics and scope of EPR review
April 25, 2006 (complete)	Conduct fact finding visit to AREVA to discuss EPR design conversion process and design differences
June 15, 2006	U.S. - Finland bilateral meeting to discuss lessons learned from STUK review of the EPR, and MDAP Stage 1 course of action and working arrangements
Summer 2006	MDAP Stage 1 meeting to confirm working arrangements and establish MDAP Stage 1 technical topics for cooperation during EPR pre-application review
starting Fall 2006 (tentative)	NRC personnel travel to Finland or France for familiarization with counterparts' EPR review activities and to exchange regulatory outputs
End of 2006	Establish processes for incorporation of counterparts' review products in NRC EPR pre-application evaluations
2007	Incorporate MDAP Stage 1 planned information exchanges and lessons learned into planning for EPR design certification

Enclosure