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NRC Strategic Direction and Issues Affecting Agreement States

by

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Organization of Agreement States and the NRC

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INTRODUCTION

Good morning, ladies and gentlemen. I am delighted at this opportunity to address you at your Annual All-Agreement States Meeting, and to share my views on some of the issues you will be addressing over the next three days.

Before I begin discussing technical issues, I would like to recognize a few individuals who have been instrumental in making the Agreement State program such a success. First, I would like to recognize the current Chairman of the Organization of Agreement States, Mr. Robert Quillin of the State of Colorado. Mr. Quillin has been a very effective Chairman of the Organization, and we at the Nuclear Regulatory Commission (NRC) greatly appreciate his efforts in sponsoring and planning this Annual Meeting. Second, I would like to thank Mr. Edgar Bailey, head of the California Agreement State program, and his staff, for so graciously hosting this year's Annual Meeting.

Finally, I would like to recognize Mr. Roland Fletcher of the State of Maryland, who will be the new Chairman of the Organization of Agreement States beginning in January 1998. I look forward to working with Mr. Fletcher in the coming year.

As you know, the Commission has a strong and active interest in

the Agreement State program. I was pleased to sign an Agreement on March 10, 1997 with the Commonwealth of Massachusetts, making Massachusetts the 30th Agreement State. The Commonwealth now has regulatory authority over more than 400 licensees. I welcome Massachusetts to the Agreement State program.

I would like to begin today with a brief discussion of NRC strategic planning, and an overview of how the Agreement State program fits within the NRC strategic direction. I will then discuss two recent Commission decisions regarding radiological criteria for decommissioning and KI stockpiling, and several issues of current Commission focus, both internal and external, including: (1) the reauthorization of CERCLA; (2) the revision of 10 CFR Part 35; (3) options for disposition of surplus weapons-grade plutonium; and (4) external regulation, by the NRC, of DOE nuclear facilities.

NRC Strategic Planning

As many of you are aware, shortly after I took over as Chairman of the NRC, I initiated an agency-wide Strategic Assessment and Rebaselining effort, a project that basically consists of four phases. The first phase, which was completed in April 1996, consisted of a detailed introspective look at "what we do and why we do it." That is, finding the match-up between NRC foundational documents--such as the Atomic Energy Act and the Energy Reorganization Act--and the methods that we use to implement those directives, down to the level of specific activities.

The second phase was the development of overall direction-setting policy issues (known as DSIs), and the publication of issue papers, including preliminary Commission views, for each one. An important aspect of this phase was allowing stakeholders and members of the public to review the information and comment on the issues before the Commission made its final decisions. The Agreement States had a significant role in this part of the process. In addition to providing substantial written comments, Agreement States also participated in the three stakeholder conferences that were held to give the public an opportunity for oral comment and face-to-face interactions with agency representatives. These exchanges were extremely valuable in gaining a better understanding of each other’s perspectives and concerns. This phase was completed in August 1996.

Phase 3 involved the development of a Strategic Plan, which sets the long-term direction and goals for the agency, incorporates the DSI policy decisions, and is linked with the agency budget process. The Strategic Plan is dynamic in the sense that it is updated as the mission of the agency changes; in keeping with the Government Performance and Results Act (GPRA), the Strategic Plan is reviewed annually and updated every 3 years. Phase 3 was completed just last month with the submission of the NRC

Strategic Plan to Vice President Gore and to the Congress.

The fourth and final phase, which is already underway, involves the implementation of the Strategic Plan and the DSI decisions. At this stage, the Strategic Planning and Rebaselining moves from a "special, one-time effort" to a way of conducting business. This phase will involve developing a Performance Plan, integration of the Strategic Plan and the Performance Plan with the budget process, and performance monitoring. This is being done through the implementation, beginning this fall, of a new program and budget planning process, undergirded by the agency Strategic and Performance Plans. This will involve the development of operating plans by the different units of NRC, as well as systematic in-process program reviews and budget audits.

Agreement State Program Overview

As most of you are aware, DSI 4 focused on Agreement State issues. Through the decision on that DSI, as well as through other mechanisms, the Commission has provided the NRC staff with Agreement State program direction, and has required that the staff submit any policy-related issues to the Commission for approval. During the past few years, the Commission has approved a number of significant changes and initiatives that recognize the maturity of Agreement State programs, and that acknowledge the collective national efforts among Agreement States and the NRC to regulate the use of nuclear materials. These program revisions include:

- Use of the IMPEP program to evaluate both NRC regional programs and Agreement State programs, using teams comprised of both NRC and Agreement State staff;

- Publication of the final Statement of Principles and Policy for Agreement State Programs and the Final Policy Statement on Adequacy and Compatibility of Agreement State Programs;

- Use of joint NRC and Agreement State Working Groups on projects such as the revision to Part 35, and the control and accountability of devices;

- Agreement State review of draft NRC rulemaking plans that can affect the Agreement States before Commission approval; and

- Development and use of the Nuclear Materials Events Database.

Clearly, the Agreement States' contributions to the formulation of these program revisions have led--and will continue to lead--to their successful implementation.

On behalf of the Commission, I want to express appreciation for

those important contributions made by the Agreement States. While future changes to the Agreement State program may not be as rapid or as frequent as during the past few years, continuing modifications will be necessary to further improve the program and to address the evolving technical, societal, political, and economic environments in which we live and work. I now would like to address two issues on which the Commission has recently issued decisions.

Final Rule on Radiological Criteria for Decommissioning

On July 21, 1997, the Commission issued an amendment to its regulations (62FR39058) to establish acceptable radiation levels at the point when a nuclear facility is permanently shut down, the license terminated, and the site released for other uses. Under this regulation, commonly referred to as the License Termination Rule, a site can be released for either (1) unrestricted use, in which case it could be used for any purpose; or (2) restricted use, in which it could not be used for certain purposes, such as residential housing.

To be specific, a site may be released for unrestricted use if the radiation dose to an individual from residual on-site contamination will be as far below 25 millirem per year as is reasonably achievable. Alternatively, a site may be released for restricted use provided that the dose from on-site residual contamination is as low as is reasonably achievable and that legally enforceable institutional controls (such as deed restrictions) will ensure that the resulting dose to an individual does not exceed 25 millirem per year. In addition, if a site is released for restricted use, the licensee must provide financial arrangements to allow an independent third party to assume and carry out responsibilities for any necessary control and maintenance of the site.

Provisions are also included in the regulation that would limit the radiation dose to an individual in the unlikely event that institutional controls fail. An additional provision in the regulation for restricted use requires the licensee to seek advice--from individuals and institutions in the community who may be affected by the decommissioning--on whether the provisions for institutional controls proposed by the licensee (1) will provide reasonable assurance that the radiation dose from contamination remaining on site will not exceed 25 millirem per year, (2) will be enforceable, and (3) will not impose undue burdens on the local community or other affected parties.

I also should mention, for completeness, that, because the Commission was concerned about certain sites presenting unique decommissioning problems, the Commission included other provisions in the License Termination Rule that would allow, in very rare instances, for a site to be decommissioned under alternate criteria. The Commission would review proposals to use

these alternate criteria, and the ALARA principle--maintaining doses "as low as reasonably achievable"--would still be applied. The Commission expects the alternate criteria to be used only rarely.

The Commission believes that these new standards ensure protection of public health and safety and the environment. In addition, the regulations are consistent with the relevant recommendations of both national and international bodies tasked with developing radiation protection guidance. The new regulations also consider risk, cost-benefit, and socio-economic standards, and provide the needed flexibility to accommodate site-specific conditions.

Potassium Iodide (KI) Stockpiling

In 1995, the White House issued Presidential Decision Directive 39, entitled, "U.S. Policy on Counter-Terrorism." It directed Federal agencies to take a number of measures to reduce vulnerability to the potential terrorist use of nuclear, biological, and chemical weapons.

An interagency group, which was chaired by the Federal Emergency Management Agency (FEMA) and included NRC representatives, presented a report to the President that was approved for distribution in May of this year. The report recommended that the Federal government purchase and stockpile chemical nerve gas antidotes, vaccines for anthrax, antibiotics, potassium iodide and other medicines for use by the general public in the event of a terrorist attack. The Federal government is planning to put into place three national stockpiles of medical supplies that include potassium iodide. Additionally, there will be 26 Metropolitan Strike Teams, each with the option to have a full set of medical supplies that will include potassium iodide.

Currently, there are four locations nationwide with medical stockpiles including potassium iodide. Thus, the size and number of locations of Federal stockpiles of potassium iodide are expected to increase. Potassium iodide from these resources could be used as a protective measure for the general public in the event of a nuclear accident at a commercial nuclear power plant.

In June 1997, the Commission modified its position regarding the use of potassium iodide (KI) as a protective measure. The principal aspects of the revised policy are: (1) the recognition of availability of KI nationally as a part of the Federal stockpiles of medicinal supplies for nuclear, biological, and chemical threats; and (2) the Commission endorsement of the Federal Radiological Preparedness Coordinating Committee (FRPCC) recommendations to continue the present policy of stockpiling KI for emergency workers and institutionalized persons, and to leave to the States the decision to use KI for the general public.

This policy recognizes the central role of States in protecting public health and safety.

Under the revised position, potassium iodide will be available to any State for any type of radiological emergency at any time. If a State wishes to have its source of potassium iodide close at hand for use in a possible nuclear reactor accident, the Federal government will fund the purchase if requested. The interested State and/or local government will be responsible for maintenance, distribution, and any subsequent costs. NRC licensees will, as part of their emergency response planning, discuss this matter with the State and local government representatives who make decisions on protective measures for potential emergencies.

The best technical information indicates that prompt evacuation and in-place sheltering of the general public are the preferred protective actions for severe accidents at nuclear facilities. The pre-distribution and use of KI can be a useful supplement to enhance the effectiveness of evacuation or in-place sheltering. However, the State (or in some cases, the local government) is ultimately responsible for the protection of its citizens. Therefore, the decision for local stockpiling and use of potassium iodide as a protective measure for the general public is left to the discretion of State or local governments. Currently three States, Tennessee, Alabama, and Maine include in their emergency planning the use of potassium iodide as a protective measure for the general public.

When finalized by the FRPCC, the proposed new Federal policy will be published in the Federal Register. The NRC is working with FEMA to prepare the final policy statement and to develop implementation details. I expect this effort to be completed in the near future.

CERCLA Reauthorization

The next several areas of discussion are issues on which Commission action is currently underway or which have recently become areas of Commission focus. The first such issue is the Congressional action currently under way to reauthorize the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA). CERCLA reauthorization legislation is of great importance to the Commission because of its potential applicability to the cleanup of residual radioactivity resulting from material under NRC jurisdiction. The Commission is concerned with the CERCLA reauthorization because it may make statutory-specific residual risk standards applicable to the cleanup of radioactive material, without designating an NRC role in selecting or applying those cleanup standards. Given the NRC expertise in regulating commercial uses of radioactive material, the Commission believes that such an omission would be inappropriate. More importantly, statutory standards may differ

from the cleanup standards that were properly established in NRC rulemaking and require different cleanup actions than what the NRC and the Agreement States find to be necessary.

The Commission has submitted draft legislative language that would resolve many of these concerns. In brief, the Commission has requested that any CERCLA reauthorization would provide that any remedial or cleanup action, when applied to source, byproduct, or special nuclear material falling under NRC or Agreement State jurisdiction, will be considered protective of public health and safety, and the environment if it complies with applicable NRC or Agreement State regulations. That is, a remedial action that complies with Commission or Agreement State regulations would automatically satisfy CERCLA requirements for remediation and control.

The Commission is fully aware that the reauthorization of CERCLA could have a significant impact on the NRC Agreement State Program. If the ability of an Agreement State to require cleanup at sites containing radioactive material is made subject to a determination by EPA, this has the potential for creating duplicative requirements and findings and significant coordination problems between the NRC and the EPA, and could raise questions regarding the continuing viability of the Agreement State Program and the authority of Agreement States over Atomic Energy Act material and sites under their jurisdiction. The Commission intends to continue pursuing this issue with the Congress.

Part 35 Revision

The revision of the NRC medical regulatory program is a planned activity designed to focus on developing specific improvements in the regulations governing the medical use of byproduct material. During the past 4 years, the NRC has examined in detail the issues surrounding its medical use program. This process started with the 1993 internal senior management review; continued with the 1996 independent external review by the National Academy of Sciences, Institute of Medicine; and culminated in decisions on this issue as part of the NRC Strategic Assessment and Rebaselining discussed earlier. In particular, medical oversight was addressed in DSI 7, "Materials/Medical Oversight." The Commission's decision on DSI 7 reaffirmed NRC's medical regulatory role. In a subsequent Staff Requirements Memorandum, the Commission directed the staff to submit a plan for revising Part 35, associated guidance documents, and, as necessary, the Commission's 1979 Medical Policy Statement.

Under the program approved by the Commission, the staff is considering how Part 35 can be restructured into a risk-informed, more performance-based regulation--that is, how to focus regulatory oversight on those activities that pose the highest

risk, and how to impose less prescriptive requirements in these areas, that are commensurate with the risk. Additional staff efforts include addressing how best to capture not only safety-significant events, but also precursor events; evaluating the Quality Management Program provisions to focus on requirements essential for patient safety; and considering the viability of using or referencing available industry guidance and standards.

Representatives of the Organization of Agreement States and the Conference of Radiation Control Program Directors have been involved since the early stages through participation in the NRC Part 35 working group and steering group. Two States, Alabama and Ohio, each have had a representative actively participating in the working group, and a State of Georgia management representative is participating in the steering group. These groups have identified five major regulatory issues, developed alternatives for each issue, and identified pros and cons for each alternative. These issues include: (1) the Quality Management Program; (2) Radiation Safety Committee; (3) Training and Experience; (4) Patient Notification; and (5) the Threshold for Reportable Event. In addition, the groups have identified alternative recommendations for revision of the 1979 Medical Policy Statement.

These issues were the focus of last month's meeting between the NRC and the Advisory Committee on the Medical Use of Isotopes (ACMUI). They also will serve as the basis for discussions at two upcoming public meetings, to be held in Philadelphia on October 28 - 30 and in Chicago on November 12 - 14, to solicit early comment on the Part 35 revision. The NRC also has met with a number of medical professional organizations and more meetings are scheduled. I would also note for your information that a "Mini-Workshop" on this topic is scheduled at this meeting on Saturday morning.

The working group and steering group will be developing the proposed rule and associated guidance, and expect to complete these efforts by May 1998. The NRC plans to conduct two additional public meetings in the summer of 1998 during the public comment period for the proposed rule. NRC has established a web site via NRC’s technical conference forum to facilitate public input on an ongoing basis. The Commission has directed the staff to complete the rulemaking process by June 30, 1999.

Plutonium Storage and Disposition

In January of this year (1997), the U.S. Department of Energy (DOE) issued its Record of Decision for the Storage and Disposition of Weapons-Usable Fissile Materials. In its Record of Decision, DOE stated that it has decided to implement a program for the safe and secure storage of weapons-usable fissile material (plutonium and highly enriched uranium), and announced a

strategy for the disposition of surplus weapons-usable plutonium. DOE plans to pursue a dual-track approach for plutonium disposition, which would include: (1) immobilizing surplus plutonium with high-level radioactive waste in a glass or ceramic material, for direct disposal in a geologic repository; and (2) burning some of the surplus plutonium as mixed oxide (MOX) fuel in existing domestic commercial reactors before its disposal as spent reactor fuel in a geologic repository.

The NRC has a direct interest in this program, because it impacts at least three major areas that the NRC regulates--commercial nuclear power reactors, fuel cycle facilities, and the high-level radioactive waste geologic repository. The NRC has been actively evaluating the proposed plutonium disposition alternatives since the DOE Record of Decision was issued. Shortly after issuing its Record of Decision, the DOE briefed the full Commission on its plans for plutonium disposition. In February and March of this year, the NRC sponsored two technical seminars, both open to the public, in which representatives of the nuclear industry, including several foreign representatives, made presentations on the fabrication of MOX fuel and its use in commercial reactors.

In July of this year, the DOE issued a program acquisition strategy for selecting private sector organizations to assist in implementing the MOX fuel alternative for disposing of surplus weapons-grade plutonium. The MOX fuel fabrication services detailed in the proposed strategy include: designing, constructing or modifying, licensing, and operating a fuel fabrication facility; supplying commercial nuclear fuel for reactors; and ultimately, decontaminating and decommissioning the fabrication facility. The proposal would involve a one-time use of MOX fuel to dispose of existing weapons-grade plutonium, but would not include reprocessing. In addition, the MOX fuel fabrication facility would cease operation and be decommissioned after completing its mission of weapons-grade plutonium disposition.

Successful implementation of this approach also would require the full spectrum of irradiation services needed to burn MOX fuel at commercial NRC-licensed reactor facilities. This would include designing and engineering the necessary reactor and facility modifications; obtaining Federal, State and local environmental permits; performing core design and fuel design services; irradiating the fuel; and storing the irradiated fuel until it can be ultimately disposed of in a geologic repository. The DOE acquisition strategy also states that the U.S. would pursue the use of Canadian CANDU reactors, if international agreements are reached among the Russian Federation, Canada, and the United States for implementing disposition of U.S. and Russian plutonium.

Certain technical, financial, and political questions, related to the MOX fuel initiative and to plutonium disposition in general,

remain unanswered. In the U.S., industry representatives have expressed reservations about the size and duration of the investment necessary for commercial nuclear power companies to invest in the MOX fuel program--based on the financial vulnerability that could exist if unforeseen national or international events later prompted DOE to cancel the MOX program. And certain U.S. public interest groups have asked that the Federal government set minimum standards of safety or performance for commercial utilities to be selected to participate in the MOX program.

On August 28, 1997, at the Argonne National Laboratory near Chicago, DOE officials met with nuclear utility representatives and others to focus on these and other issues. And on September 17, DOE briefed the Commission on the overall DOE strategy for plutonium disposition, including its acquisition strategy for MOX fuel fabrication and irradiation services, and its plans for negotiating a binding agreement with the Russians.

The Commission recognizes fully the importance of this program--both to the U.S. and to nations around the world--as well as the need to carry out successfully the broader goals and objectives of weapons-usable fissile material storage and disposition. The Commission will continue to monitor the evolving DOE strategies for plutonium storage and disposition to ensure that the NRC is prepared to perform its emerging regulatory role in a manner that ensures the protection of public health and safety and that avoids unnecessary delays or costs.

External Regulation of DOE

By longstanding tradition and statutory direction, a primary mission of the U.S. Department of Energy (DOE) has been nuclear weapons production, as well as the development of commercial and naval nuclear reactors, and the conduct of energy-related research. With the end of the Cold War, certain elements of the DOE mission have shifted. The fundamental mission elements of the department have remained the same, but approximately half of the DOE nuclear budget is now devoted to three activities: materials management, decommissioning and cleanup, and waste management. Through decommissioning, DOE expects to decrease the number of its existing nuclear facilities from 600 to 200 over the next 10 years.

The self-regulation, by DOE or its predecessors, of all aspects of safety at its nuclear facilities, with the primary exception of environmental protection, has existed since the enactment of the original Atomic Energy Act in 1946. In 1994, legislation was introduced in the U.S. House of Representatives that would have subjected new DOE facilities to immediate external regulation, and would have created a stakeholder group to study external regulation of existing facilities. As an alternative to that

approach, the Secretary of Energy created, in January 1995, the Advisory Committee on External Regulation of DOE Nuclear Safety. The Advisory Committee was charged with providing advice and recommendations on whether (and how) new and existing DOE facilities and operations might be externally regulated to ensure nuclear safety.

In its December 1995 report, "Improving Regulation of Safety at DOE Nuclear Facilities," the Advisory Committee recommended that essentially all aspects of safety at DOE nuclear facilities should be externally regulated. The Secretary of Energy accepted and endorsed the Advisory Committee report, and created the DOE Working Group on External Regulation (Working Group) to provide recommendations on implementation of the Advisory Committee report. The December 1996 recommendations of the Working Group were: (1) that the NRC should be the external nuclear safety regulator, and (2) that the transition to external regulation should proceed in phases.

In September 1996, as part of the Strategic Assessment and Rebaselining effort, the NRC published DSI 2, which addressed options for the NRC position on regulating DOE facilities. In March 1997, after considering public comments and the December 1996 DOE decision, the Commission endorsed having the NRC assume nuclear safety regulatory oversight of certain DOE nuclear facilities, contingent on the NRC being given adequate resources (financial and human) to take on this new responsibility, and a clear delineation of the authority the NRC will exercise over the facilities. In addition, the Commission directed the NRC staff to convene a high-level NRC Task Force to identify, in conjunction with DOE, the policy and regulatory issues needing analysis and resolution. In a June 1997 meeting, Secretary of Energy Federico Peña and I agreed on a pilot program as a basis to explore pursuit of NRC regulation of DOE nuclear facilities.

At present, the NRC and DOE are preparing a Memorandum of Understanding (MOU) to establish the framework for a pilot program that could, if successful, lead to a joint recommendation by DOE and the NRC to the U.S. Congress that the NRC be given statutory authority to regulate nuclear safety at DOE nuclear facilities. The pilot program is intended to "simulate NRC regulation" of a selected set of DOE nuclear facilities, over a 2-year period, in order to help both agencies gain experience related to NRC regulation of DOE facilities. This also will provide an opportunity to develop actual data on the costs and benefits of external regulation. "Simulated regulation," as defined for the purposes of this pilot program, means that the NRC will test regulatory concepts, performing the facility oversight functions that it believes would be appropriate to ensure safety, evaluating the facility and its standards, requirements, procedures, practices, and activities against NRC standards. Two pilot facilities have been chosen: Lawrence Berkeley Laboratory and the Radiochemical Engineering Development

Center at Oak Ridge National Laboratory. After six to ten pilots have been conducted, the NRC and DOE will determine whether to seek legislation to give the NRC statutory authority to regulate individual DOE facilities or classes of facilities.

Issues to be addressed include (1) the form of the regulatory process (licensing, certification, consultation, or other processes), (2) who is to be regulated (DOE or its contractors), (3) the safety criteria, (4) the role of stakeholders, including the Agreement States, (5) safeguards and security, and (6) how best to transition into the external regulation framework, including the development of any necessary clarifying and/or enabling legislation. As we proceed, our primary goal is to remain rigorous in ensuring public and environmental protection on a cost-justified basis, and to ensure that whatever steps we take toward phased-in DOE oversight do not compromise our ability to ensure adequate protection of public health and safety within the scope of our current mission.

CONCLUSION

In closing, I would like to reiterate my appreciation for the important contributions that Agreement States have made and continue to make to these NRC program revisions, and to the NRC strategic direction as a whole. The past few years have brought dramatic changes to the Federal government in terms of the focus on identifying goals and measuring results, as well as cost-consciousness. As a result, it has become imperative--at the NRC and elsewhere--that we are able to articulate a detailed strategy of operation, the nexus between that strategy and our authorized functions, and the justification for the resources needed to accomplish that strategy.

While this emphasis certainly changes the way we do business, in the end I believe it will make us both more efficient and more effective as regulators. In reviewing with you a series of issues on which the Commission has been focusing, I hope that I have given you a greater appreciation for this perspective. I also hope that you will continue to work closely with the NRC so that we can continue to pursue this strategic vision in a responsible and effective manner.

Thank you for your attention. I would be happy to entertain questions at this time.