

December 29, 1997

FOR: The Commissioners

FROM: L. Joseph Callan /s/ Executive Director for Operations

SUBJECT: STATUS REPORT OF THE NUCLEAR REGULATORY COMMISSION TASK FORCE ON OVERSIGHT OF THE DEPARTMENT OF ENERGY, IN RESPONSE TO COMSECY- 96-053 - DSI 2 (Report No. 2)

PURPOSE:

The purpose of this paper is to inform the Commission of the status of the work of the Nuclear Regulatory Commission Task Force formed to identify, in conjunction with the Department of Energy (DOE), the policy and regulatory issues needing analysis and resolution, before seeking NRC oversight responsibility for DOE nuclear facilities. This report covers the period September 13, 1997, to December 12, 1997.

SUMMARY:

This paper provides a status report on the work of the Task Force on Oversight of the Department of Energy (DOE) from September 13, 1997, to December 12, 1997. During this period, the major focus of Task Force activities was on: (a) finalizing the Memorandum of Understanding (MOU) between NRC and DOE; (b) developing the work plan, for the Lawrence Berkeley National Laboratory (LBNL) pilot project and a matrix of issues that relates MOU objectives to generic and site-specific areas of analysis; and (c) conducting an initial information-gathering visit to LBNL and completing Phase I of the Work Plan. In addition, the task Force held a public meeting on December 11, 1997, from 7 p.m. to 9 p.m., at the Federal Building in Oakland, California. During the Phase I visit, the NRC staff conducted an inspection of each major facility at LBNL. No safety issues requiring immediate corrective actions were identified.

CONTACTS: John H. Austin, NMSS/ERDF
(301) 415-7275
Patricia A. Rathbun, NMSS/ERDF
(301) 415-7178

BACKGROUND:

In SECY-97-206, dated September 12, 1997, the staff provided a status report to the Commission, regarding the work of the Task Force on oversight of DOE, up to that date.

DISCUSSION:**INTERAGENCY AGREEMENT FOR FISCAL YEAR 1997**

An Interagency Agreement for reimbursement of NRC's fiscal year (FY) 1997 costs associated with preparing the MOU and creating a pilot program plan was signed on September 25, 1997. Under the Interagency Agreement, NRC recovered approximately \$227,000 from DOE. Reimbursement under the Interagency Agreement is not applicable for FY 1998, since Congress appropriated funds directly to NRC, for NRC's activities associated with the pilot program.

STATUS OF PILOT PROGRAM

The MOU was signed by Chairman Jackson and transmitted to Secretary Peña on November 21, 1997 (Attachment 1) and focuses on a pilot program of simulated regulation. This document is available at <http://www.nrc.gov/NRC/NMSS/MOU.html>.

The overall objectives of the pilot program, as stated in the MOU, are to determine the desirability of NRC regulatory oversight of DOE nuclear facilities and to support a decision on whether to seek legislation to authorize NRC regulation of certain DOE nuclear facilities. Further, the pilot program is designed to test regulatory concepts at certain DOE nuclear facilities, through simulated regulation, by evaluating a facility and its standards, requirements, procedures, practices, and activities against the standards that NRC believes would be appropriate to ensure safety at that pilot facility.

In addition, there are eight specific objectives given in the MOU:

- Determine the value added by NRC regulatory oversight of activities at a pilot set of DOE nuclear facilities.
- Test regulatory approaches that could be used by NRC in overseeing activities at a pilot set of DOE nuclear facilities.
- Determine the status of a set of DOE pilot facilities, with respect to meeting existing NRC requirements, or acceptable alternatives, and identifying any significant safety issues.
- Determine the costs (to DOE and NRC) related to NRC regulation of the pilot facilities and other DOE facilities that might be in a similar class and condition.
- Evaluate alternative regulatory relationships between NRC, DOE, and DOE contractors at the pilot facilities. Identify DOE contract changes that would be needed to provide for NRC oversight of contractor operations.
- Identify issues and potential solutions associated with a transition to NRC oversight of DOE nuclear facilities.

- Identify legislative and regulatory changes necessary or appropriate to provide for NRC regulatory oversight of DOE nuclear facilities.
- Evaluate how stakeholders should be involved if the NRC assumes broad eternal regulatory authority over DOE nuclear facilities.

Implementation details for each pilot facility are being negotiated by DOE, NRC, and DOE contractors in individual work plans (see LBNL Phase I Work Plan in Attachment 2). Each plan will contain a consistent set of core questions and issues that needs to be addressed for all facilities, to make the broader decision on whether to seek regulatory jurisdiction over DOE nuclear activities. To accomplish this, and to ensure that the issues that the Commission requested the staff to examine are covered, the staff has developed the "Matrix of Issues To Be Considered," which is included as Appendix B in Attachment 2. This document was developed collaboratively by NRC, DOE, LBNL, and the State of California. It is designed to display the relationship between the objectives of the MOU and the issues identified by the Commission and others; to operationalize these issues and objectives; and to provide indicators that can be examined either on a generic or site-specific basis. The matrix is considered a "living document," in that additional concepts and/or indicators may be added as the LBNL pilot progresses, and as additional pilot sites are visited.

LBNL PILOT

The LBNL Pilot is currently underway and the staff has completed two site visits to LBNL. A familiarization visit took place on November 18-20, 1997, and was designed to finalize the Phase I Work Plan and prepare for the Phase I on-site visit, as well as arrange for the Stakeholder meeting held on December 11. During the familiarization visit, the staff received background briefings, became familiar with the facilities and regulatory bases for radiation safety, and made tours of the following facilities:

- Advanced Light Source;
- Biomedical Imaging;
- 88-inch Cyclotron;
- Hazardous Waste-Handling Facility;
- National Tritium Labeling Facility; and
- PIT Room Bldg. 70.

During the week of December 8 - 15, 1997, a team consisting of staff from NRC Headquarters as well as Regions I and IV began Phase I of the pilot of simulated regulation of the LBNL. The staff followed the LBNL Phase I Work Plan (Attachment 2) that had been agreed to by the NRC and DOE, and was prepared to implement the MOU, between the NRC and DOE dated November 21, 1997.

During this Phase I visit, NRC staff interacted with DOE, the State of California, the LBNL contractors, and the University of California (UC). This included inspections of each major facility identified at LBNL previously, as well as preliminary work on a mock NRC license application, to identify issues related to implementation of eternal regulation of DOE. The team's review included a review of the LBNL site organization, the management of the radiation safety program -- including the role of the radiation safety committee and radiation safety officer -- and the implementation of the radiation safety program. The team examined the training of facility users and radiation protection staff; the receipt, transfer, and inventory of radioactive materials; personnel radiation protection -- including personnel monitoring, radiation surveys, laboratory and survey instrumentation, and the as low as is reasonably achievable (ALARA) program, radioactive waste management, effluents and legacy issues; the implementation of radiation safety procedures and requirements; the transportation of radioactive materials; environmental monitoring; and emergency preparedness. No safety issues requiring immediate corrective actions were identified.

The team also met with DOE and LBNL staffs and discussed issues that might be affected by eternal regulation, such as the terms of the DOE/UC contract, the existing applicable Work Smart Standards, LBNL Integrated Safety Management Systems, DOE's oversight role and practices, and the baseline operational costs of radiation protection at LBNL.

NRC and the State of California Department of Health Services provided LBNL with relevant documents and guidance for the preparation of radioactive materials licenses. The State of California also provided documents and guidance pertaining to the registration of radiation generating machines.

At the conclusion of the week, the team met with DOE, LBNL, and the UC management and described its preliminary findings.

A public meeting was held on December 11, 1997, from 7 p.m. to 9 p.m., at the Federal Building in Oakland, California. Extensive efforts were made to notify members of the public about the meeting. Over 600 letters were sent to potential stakeholders, a Federal Register Notice and a Press Release were issued, and notices were placed in Laboratory publications.

Approximately 50 people attended: including members of local public interest groups; employees from LBNL, Lawrence Livermore National Laboratory, and Los Alamos National Laboratory; DOE and NRC employees at Walnut Creek, and members of the Pilot Team. No members of the media were present. Extensive background materials were made available, including the MOU and the Berkeley Pilot Project Work Plan. The meeting lasted two hours and included background material on the Pilot Project, from the DOE and Berkeley Lab perspective, from Dick Nolan, DOE Site Office -- and on the NRC perspective and Pilot Team activities, from John Austin, NRC Task Force. The meeting was conducted by a facilitator and a transcript was prepared by a court reporter. A summary of the meeting will be prepared for inclusion in the appendix to the final LBNL report.

The question and answer period took over an hour. Questions covered a broad range of subjects, including: NRC's mission and activities; the scope of the pilot program; the nature of materials to be covered by eternal regulation; the relationship between NRC, the State, and other Federal agencies -- including a waiver of sovereign immunity; the cost of NRC assuming regulatory authority instead of DOE self-regulation; the impact on DOE and NRC staffing; potential conflicts of interests; involvement of the public in the regulatory process; and the means of determining the value added by eternal regulation. Commenters were encouraged to review the Phase I Work Plan, particularly the list of issues in Appendix B, and to submit their questions and issues in writing on forms provided for that purpose. A deadline of January 5, 1998, was set for written comments on the Work Plan, so as to have

an impact on Phase II activities. Written comments on other aspects of eternal regulation of DOE facilities were requested by February 11, 1998.

The Phase II on-site visit is scheduled to begin on January 12, 1998, with an additional visit planned in February, if necessary. The final report for the LBNL pilot is expected in April 1998.

OAK RIDGE NATIONAL LABORATORY RADIOCHEMICAL ENGINEERING DEVELOPMENT CENTER PILOT

The Radiochemical Engineering Development Center (REDC) Pilot Project is scheduled to begin in January 1998. The staff currently plans to make the first site visit to the REDC facility on January 23, 1998, to familiarize team members with the activities of the site, and to begin to determine the regulatory bases for radiation safety. At this time, the team will begin discussions of the work plan, and will prepare for the Phase I on-site visit. It is currently anticipated that the Phase I on-site visit will take place during the week of February 13, 1998, and the Phase II on-site visit will take place during the week of March 20, 1998. However, REDC is currently in the process of implementing the Work Smart Standards as part of the Integrated Management System and it would prefer that Phase I not take place until around May. The staff will continue to negotiate with REDC to have Phase I occur as soon as meaningfully possible.

SAVANNAH RIVER SITE INDEPENDENT SPENT FUEL STORAGE INSTALLATION PILOT

DOE has recently proposed this site. The advantages of including the Savannah River Site/Independent Spent Fuel Storage Installation include:

- It is a new construction project that will have to be designed in accordance with NRC standards, consistent with the FY 1998 Energy and Water Development Appropriation Act Conference Report.
- It will permit us to test the flexibility of the NRC program in new situations (e.g., aluminum clad fuels).
- The facility will eventually be privatized.
- It is representative of a class of facilities.
- It is an environmental management facility.

In addition, it meets the criteria established for selection of pilot projects:

- It falls within the planned limit of three pilot facilities for FY 1998.
- It represents a facility that is similar to current NRC licensees.
- There is a strong possibility that the existing NRC regulatory program can be applied.
- It is anticipated to operate for a long period (e.g., 10 years or more).
- The facility is willing to participate.

STAKEHOLDERS

There are two areas pertaining to stakeholder involvement in the process of determining possible NRC regulation of DOE facilities. The first is stated in the MOU as Objective 8: "Evaluate how stakeholders should be involved if NRC assumes regulation of certain DOE facilities." A recommendation on this issue will depend on the regulatory approach chosen to implement eternal regulation and will be formulated in the context of the overall pilot program.

The second is to keep the stakeholders at each pilot facility informed of the pilot program and ensure that any relevant issues raised by the stakeholders are considered within the context of the pilot program. For example, a stakeholder plan for the LBNL was developed that included scheduling a public meeting in Oakland, California; making a significant effort to contact all interested members of the public through letters to known stakeholders, a notice in the Federal Register, and elsewhere, and Press Releases; inviting relevant concerns in writing from the public; and responding to those concerns in writing as an appendix to the final LBNL Report.

Members of the public were also asked to comment on how stakeholders should be involved if NRC assumes regulation of DOE facilities. Those comments will be considered as part of the final report, at the end of the two-year pilot program.

A similar stakeholder plan will be developed for each of the other pilot facilities, but the content may vary, depending on the type of current stakeholder involvement at the DOE facility.

CONFIRMATORY RESEARCH

In the Staff Requirements Memorandum dated March 28, 1997, regarding the Direction-Setting Issue 22 (Research), the Commission directed the staff to "Identify the impact on research needs of NRC Oversight of Department of Energy (DOE) nuclear facilities, and advise the Commission on the resource implications of those impacts." The subject has been incorporated into the "Matrix of Issues To Be Considered" in the Pilot Program. (See Issue Description for Objective 7 in the LBNL Work Plan, Attachment 2.) As the Task Force completes a pilot project, it will provide lessons learned to the Office of Nuclear Regulatory Research (RES). Assuming NRC is authorized to regulate non-defense program DOE facilities in FY 2001, RES, in coordination with NMSS, will conduct a scoping study to determine appropriate research based on the numbers, types, conditions and safety significance of facilities NRC could anticipate regulating and lessons learned from the pilot projects. The programs and resources identified in this study can provide a basis for requesting resources in the FY 2001 budget.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection.

The Office of the Chief Information Officer reviewed this Commission Paper for information technology and information management implications and has no objections.

The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

original /s/ by
Hugh L. Thompson, Jr. for
L. Joseph Callan
Executive Director for Operations

Attachments: 1. MOU signed by Chairman Jackson to Secretary Peña dtd 11/21/97
2. LBNL Phase I Work Plan

Version: November 20

PILOT PROGRAM ON ETERNAL REGULATION OF DOE FACILITIES BY THE NUCLEAR REGULATORY COMMISSION

**WORK PLAN
FOR
THE ERNEST O. LAWRENCE BERKELEY NATIONAL LABORATORY PILOT**

1 Cyclotron Road, Berkeley, California 94720

Approved: _____

Date: _____

Dr. Carl J. Paperiello, Director
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission

Date: _____

Dr. Martha A. Krebs, Director
Office of Energy Research
U.S. Department of Energy

Date: _____

John C. Tseng, Acting Director
Nuclear Material Stabilization Task Group
U.S. Department of Energy

Date: _____

Dr. James M. Turner, Manager
Oakland Operations Office
U.S. Department of Energy

Date: _____

Dr. Charles V. Shank, Director
Lawrence Berkeley National Laboratory

**WORK PLAN
FOR
THE ERNEST O. LAWRENCE BERKELEY NATIONAL LABORATORY PILOT PROJECT**

PART I - BACKGROUND INFORMATION

INTRODUCTION, PURPOSE AND RESPONSIBILITIES

This document sets forth the work plan for the simulated regulatory review activities of the Ernest O. Lawrence Berkeley National Laboratory (LBNL) Pilot, to be carried out by the Nuclear Regulatory Commission; the Department of Energy (DOE); the University of California (UC); the State of California Department of Health Services (DHS); and LBNL. The work plan contributes to the implementation of the Memorandum of Understanding (MOU), between NRC and DOE, dated November 21, 1997. The duration of the Pilot Program is five months from the date of signing of this work plan of simulated NRC oversight/regulation of radiation-related programs at the LBNL. The LBNL facility is located in Berkeley, California, and is managed and operated by the UC under contract DE-AC03-76SF00098, with DOE. Nothing in this work plan confers health and safety regulatory authority at the LBNL facility, where such authority is not already provided by law.

The DOE will remain the lead Federal Agency for emergency response to an event at the facility, in accordance with existing requirements and procedures. NRC will evaluate DOE and contractor response to any event that occurs during this pilot.

The term "simulated regulation" is defined in section III. of the MOU, between NRC and DOE, which states:

NRC will test regulatory concepts and evaluate a facility and its standards, requirements, procedures, practices, and activities against standards that NRC believes would be appropriate to ensure safety in view of the nature of the work and hazards at that pilot facility. Simulated regulation will involve interactions with DOE, DOE's contractors, and the NRC. Simulated regulation will include NRC inspections of each pilot facility to identify issues related to implementation. NRC's inspections will not result in enforcement actions to compel compliance with particular standards or requirements. However, significant inspection findings that impact health and safety will be transmitted promptly to the DOE organization for the pilot facility, for review and corrective actions, as appropriate.

The work plan for the LBNL Pilot was developed by NRC, DOE Headquarters, DOE Oakland Operations Office, LBNL, UC, and the State of California. Participants in the LBNL Workplan development are identified in Appendix A.

A team of NRC and DOE staff, led by two co-team leaders from NRC and DOE, is charged to perform this pilot program, as described in the MOU, and to prepare a final report. NRC will review the LBNL facility and program, applying the concept of simulated regulation. DOE will assess the benefits and cost impacts of eternal regulation. The DHS, UC, and LBNL are all participants in the pilot assessment of LBNL, but are not required to concur in the Federal reports.

OBJECTIVES

The purpose of the "Pilot Program on Eternal Regulation of DOE Nuclear Facilities by the NRC" is to obtain sufficient information to determine the desirability of NRC regulatory oversight of DOE nuclear facilities, and to support a decision on whether to seek legislation to authorize NRC regulation of DOE. Top-level objectives identified in the MOU are as follows:

1. Determine the value added by NRC regulatory oversight of activities at a pilot set of DOE nuclear facilities;
2. Test regulatory approaches that could be used by NRC in overseeing activities at a pilot set of DOE nuclear facilities;
3. Determine the status of a set of DOE pilot facilities, with respect to meeting existing NRC requirements, or acceptable alternatives, and identifying any significant safety issues;
4. Determine the costs (to DOE and NRC) related to NRC regulation of the pilot facilities and other DOE facilities that might be in a similar class and condition;
5. Evaluate alternative regulatory relationships among NRC, DOE, and DOE contractors at the pilot facilities. Identify DOE contract changes that would be needed to provide for NRC oversight of contractor operations;
6. Identify issues and potential solutions associated with a transition to NRC oversight of DOE nuclear facilities;
7. Identify legislative and regulatory changes necessary or appropriate to provide for NRC regulatory oversight of DOE nuclear facilities; and
8. Evaluate how stakeholders should be involved if NRC assumes broad eternal regulatory authority over DOE nuclear facilities.

The Lawrence Berkeley Pilot Program will be conducted in support of the joint NRC/DOE Pilot Program. Major objectives specific to the Lawrence Berkeley Pilot Program are as follows:

1. Evaluate the effect of eternal regulation on the effectiveness and efficiency of the LBNL radiation protection program;
2. Prepare mock license applications and mock registration applications for NRC and/or State of California regulation of radioactive materials, accelerators, and other radiation-generating machines;
3. Review the current LBNL radiation protection program and compare with NRC/State requirements, to identify gaps or inconsistencies;
4. Estimate the cost and level of effort necessary to transition LBNL to eternal regulation;
5. Evaluate possible division of regulatory responsibilities between the NRC and State of California, the effect on DOE oversight activities, and provide recommendations;
6. Review by NRC and State regulation coverage of all aspects of LBNL radiological operations, including accelerators, waste management, environmental monitoring, and decontamination and decommissioning;
7. Identify legislative and regulatory issues and potential solutions associated with a transition to NRC or State of California regulation of LBNL; and
8. Develop a stakeholder plan to involve the public in the pilot team process to ensure that relevant issues of public concern at LBNL are addressed.

In Appendix B, the "Matrix of Issues To Be Considered" provides elaboration of the top-level and site-specific objectives for the conduct of the pilot. The matrix will be modified to address additional issues as they arise.

SCOPE OF THE LBNL PILOT

The format for the pilot will be modeled after the pre-licensing visits employed by NRC in certain licensing situations. The team will use a risk-informed, performance-based approach to help focus the effort on those areas most important to safety. A major focus will be to identify those program elements that could be covered by existing NRC and State of California regulations and guidelines. In addition, the pilot will include a review of safety considerations that are not expressly addressed by regulations.

This review will include all uses of radiation-producing machines and radioactive materials, including waste management and environmental protection activities. In addition to review of records, the assessment methodology will be composed of five main elements:

- Examination of documents,
- Profile of site characteristics and facility inventories;
- Interviews with LBNL/DOE staff;
- Scope of procedures and training; and

- Assessment of radiation conditions at the facility, focusing on areas of major risk and effluent pathways.

DHS participation in the LBNL pilot permits an evaluation of the full range of options for eternal regulation of LBNL radiation protection. The State of California, an NRC Agreement State, currently regulates nearly all non-Federal activities, conducted in California, using radioactive material or radiation-generating machines.

The assessment will be performed using criteria appropriate for an NRC license of broad scope.

In addition, accelerators and other facilities with radiation-producing machines will be assessed with regard to the performance standards in 10 CFR Parts 20 and 36, as well as the radiation control regulations of the DHS.

PART II - SCHEDULE AND MAJOR ACTIVITIES

LBNL PILOT SCHEDULE

Nov 18-20	Pre-project Planning Meeting
Nov 21- Dec 7	Preparation for Phase I Review Effort
Dec 8-12	Phase I On-Site Review and stakeholder meeting
Dec 13-Jan 11	Documentation of Phase I Review, Review of Phase I, Preparation for Phase II
Jan 12-16	Phase II On-Site Review
Jan 17-Feb 1	Documentation of Phase II Review
Feb 2-6	Phase II On-Site Review (if necessary)
Feb 7- April	Preparation of Final Report/NUREG

PREPARATION

Before arriving at the LBNL site for the entrance briefing, the team will obtain and review facility background/history from appropriate sources, including DOE, LBNL, and the Internet.

This will include the contractual and regulatory basis for site activities, such as the U. S. Code of Federal Regulations (CFR) references, contract number DE-AC03-76SF00098, DOE Orders, relevant standards, and other information, as determined by the team. The site safety history will be examined, as well as other types of information that would shed light on the current safety culture and operating environment of the facility.

PHASE I PROGRAMMATIC REVIEW

The purpose of the Phase I Programmatic Review is to familiarize team members with the LBNL site and activities and provide an opportunity to conduct a programmatic evaluation. NRC, DOE, DHS, and LBNL will hold an entrance meeting at LBNL at the beginning of the Phase I on-site review.

Following the entrance meeting, the review team will spend approximately one week at the site, carrying out a preliminary assessment of the areas listed below. All aspects of the preliminary assessment will be coordinated through the Radiological Control Manager at LBNL.

- A. Site and Facility Organization, including scope of activities at each facility;
- B. Management of radiation safety program, including the role of the Radiation Safety Committee, the role of the Radiation Safety Officer, and implementation of audit programs;
- C. Review of the radiation safety program and its programmatic elements. This review will include:
 - Training of facility users and radiation protection staff;
 - Receipt, transfer, and inventory of radioactive materials;
 - Personnel radiation protection, including personnel monitoring, radiation surveys, laboratory and survey instrumentation, and as low as is reasonably achievable (ALARA)
 - Radioactive waste management, effluents, and legacy issues;
 - Implementation of radiation safety procedures and requirements;
 - Transportation of radioactive materials;
 - Environmental monitoring;
 - Emergency preparedness; and
 - Other radiation program areas as may be appropriate on the basis of on-site findings.

These programmatic elements are defined in more detail in Appendix C.

In addition to these preliminary assessments, the review team will tour major facilities and be briefed on the following topics:

1. Terms of the DOE/UC contract;
2. Existing applicable standards (Work-Smart Standards);
3. LBNL Integrated Safety Management Systems;
4. DOE's oversight role and practices, (e.g., performance assessment); and
5. Baseline operational costs of radiation protection at LBNL.

During the Phase I review, NRC and DHS will provide LBNL with relevant documents and guidance for the preparation of radioactive materials licenses. The DHS will also provide documents and guidance pertaining to the registration of radiation-generating machines.

At the conclusion of the week, the team will meet with DOE, LBNL, and UC management and describe its preliminary findings.

Subsequent to the on-site effort, NRC and DOE management will review the preliminary findings from Phase I and provide direction on the areas to be assessed during the net phase.

Phase I Completion Milestones

Completion of the following actions will be assessed in determining the success of Phase I:

- NRC and DHS delivering of license applications and guidance to LBNL staff (supporting LBNL objective #2);
- Carrying out briefings and tours of the LBNL facilities and programs, to familiarize the review team with the organization and operations (supporting LBNL objective #3);
- Defining similarities and differences between LBNL and other NRC and DHS licensees (supporting LBNL objective #5);
- Identifying LBNL personnel and organizations which are responsible for the various aspects of LBNL radiological operations, such as accelerator operations, waste management, personnel dosimetry, etc. (supporting LBNL objective #6);
- Soliciting input from local stakeholders early in the process (supporting LBNL objective #8); and
- NRC, DHS, DOE, and LBNL agreeing on the scope and schedule of the Phase II on-site review.

PHASE II ON-SITE REVIEW EFFORT

A focus of the Phase II On-Site Review Effort will be to prepare the mock license applications and mock registration applications for NRC and/or DHS regulation of radioactive materials, accelerators, and other radiation-generating machines. The focus also includes performing detailed reviews, beginning transition planning, identifying significant safety issues, and analyzing benefits and cost effects.

At the conclusion of the review, the team will meet with DOE, LBNL, and UC Management and describe its preliminary findings.

Phase II Completion Milestones

Completion of the following actions will be assessed in determining the success of Phase II:

- Estimating the value-added of NRC regulatory oversight of DOE nuclear facilities (supporting LBNL objective # 1);
- Preparing mock applications for NRC and DHS licenses (supporting LBNL objective #2);
- Comparing LBNL radiation protection program with NRC/DHS expectations for broad-scope license (supporting LBNL objective #3);
- Verifying that LBNL requirements are effectively implemented (supporting LBNL objective #3);
- Estimating cost and level of effort to bring LBNL into compliance with NRC/DHS requirements for broad-scope license. Estimating the funding needs for NRC and the cost impact on the DOE oversight program (supporting LBNL objective #4);
- Developing a draft conceptual model of appropriate roles, responsibilities, and authorities for eternal regulation of LBNL and identifying needed actions for transition planning (supporting LBNL objectives #5 and #6);
- Identifying necessary legislative and regulatory changes needed to implement the proposed regulatory framework for eternal regulation of this facility or class of facilities (supporting LBNL objective #7); and
- Developing a site-specific stakeholder involvement plan that satisfies NRC, DOE, and DHS protocols (supporting LBNL objective #8).

In addition to these specific tasks, the review team will evaluate the Appendix B "Matrix of Issues to be Considered" for any further issues that may be appropriate to address during the review.

PREPARATION OF FINAL REPORT/NUREG OF THE LBNL PILOT

DOE and NRC personnel will prepare and provide, to the Secretary and the Commission, a report, and, as appropriate, briefings on the LBNL Pilot, that address the objectives in Part I of this work plan. The report will examine the advantages and disadvantages of NRC regulation of the pilot facility, as well as other DOE facilities in a similar class of facility.

APPENDIX A

PARTICIPANTS IN LBNL WORKPLAN DEVELOPMENT

John Austin, NRC, HQ
Ed Bailey, State of California Department of Health Services
Ray Berube, DOE/Office of Environment, Safety and Health
Frank Costello, NRC, Region I
Sarah Eary, DOE/Oakland Operations Office
Bill Eisele, LANL, UCOP

Ken Groves, University of California Office of the President
 Robin Henderson, DOE/Office of General Counsel
 Steve Hsu, State of California Department of Health Services
 Jay Larson, DOE/Office of Energy Research
 David McGraw, LBNL
 Kris Morris, DOE/Office of Environmental Management
 Dick Nolan, DOE/Oakland Operations Office
 Dan Osburn, DOE/Oakland Operations Office
 Patricia Rathbun, NRC, HQ
 Mike Schoonover, LBNL
 Kathy Shingleton, LLNL, UCOP
 Beverly Stephens, DOE/Office of Environment, Safety and Health
 Roanne Summers, NRC, HQ
 Anne Troy, DOE/Office of General Counsel
 John Tseng, DOE/Office of Environmental Management
 Dave Wesley, State of California Department of Health Services
 Gary Zeman, LBNL

APPENDIX B

MATRIX OF ISSUES TO BE CONSIDERED

OBJECTIVES	ISSUES	ISSUE DESCRIPTION	ACTIONS & INDICATORS	POTENTIAL OUTCOMES
1. Determine the value added by NRC regulatory oversight.	Potential Benefits <i>(Generic/Site Specific)</i>	Will eternal regulation provide increased: <ul style="list-style-type: none"> discipline and accountability; credibility and openness; stability and predictability; efficiency and effectiveness of operations, greater assurance of safety? 	1.1 Identify savings associated with streamlined DOE framework 1.2 Determine efficiency of proposed requirement set 1.3 Estimate savings associated with using licensed/qualified subs 1.4 Estimate cost avoidance due to increased public trust and confidence 1.5 Evaluate level of participation by stakeholders	<ul style="list-style-type: none"> Seek transition of some or all DOE facilities to NRC regulation prior to completion of the NRC/DOE Pilot Program Seek transition of some of all DOE facilities after completion of the NRC/DOE Pilot Program Not seek transition of any DOE facilities upon completion of the NRC/DOE Pilot Program Cancel NRC/DOE Pilot Program and not seek transition of any DOE facilities.
<ul style="list-style-type: none"> Test regulatory approaches that could be used by NRC in overseeing activities (at a pilot set of DOE nuclear facilities). 	Regulatory Mechanism <i>(Generic/Site Specific)</i> Enforcement <i>(Generic)</i> NARM/Accelerators	What are the potential methods (e.g. licensing, certification) of regulating the identified DOE activities? How can risk-informed, performance based regulatory approaches be applied in the pilot program? How would a mock license (or other appropriate regulatory document) be prepared?	2.1 Evaluate the effect of NRC regulation on DOE contracts 2.2 Identify and address jurisdictional issues 2.3 Develop	<ul style="list-style-type: none"> Regulation through licensing Regulation through certification Regulation through registration Regulation through a

	<i>(Generic/Site Specific)</i>	<p>How will NRC regulation affect on-going DOE initiatives?</p> <p>By what means will the NRC regulatory framework be enforced; fines, compensatory measures - liability of Federal managers, shutdown, flexibility to allow balancing with national security requirements. How has DOE been enforcing? How does DOE translate requirements into contract terms and into implementation?</p> <p>To what extent does EPA have an enforcement program that is applicable to this pilot facility? How well does it work?</p> <p>What is the most appropriate division of regulatory responsibilities between the NRC, the</p>	options for enforcement mechanisms	Master DOE license
3. Determine status of DOE facilities with respect to meeting existing NRC requirements, or acceptable alternatives, and to identify any significant safety issues.	<p>Facility Identification</p> <p><i>(Generic/Site Specific)</i></p> <p>Identify significant safety issues</p> <p><i>(Site Specific)</i></p> <p>Maintain safety focus</p> <p><i>(Generic)</i></p>	<p>What are the DOE facilities and activities that would be subject to NRC regulation?</p> <p>What quantities of radionuclides does the pilot facility possess?</p> <p>Using the pre-licensing interaction model, determine the extent of significant departures from NRC requirements, DOE requirements, or any other applicable requirements?</p> <p>How will NRC maintain uniform standards, and avoid degradation of oversight of current NRC licensees?</p> <p>How will NRC maintain credibility and have an immediate positive effect?</p> <p>How is the facility implementing the Federal Policy for the protection of human subjects in the use of AEA facilities and materials and how is it implemented for classified research involving human subjects?</p>	<p>3.1 Evaluate the compatibility of NRC and DOE/contractor requirements</p> <p>3.2 Prepare options for resolution of conflicts between NRC/State and DOE/contractor requirements</p> <p>3.3 Document significant safety issues at DOE nuclear facilities</p>	<ul style="list-style-type: none"> List of DOE facilities and radionuclide quantities that would be subject to NRC/State regulation Requirements enforced at DOE sites are very similar to NRC/State requirements Requirements enforced at DOE sites are different from NRC/State requirements but can be resolved on a site by site basis Requirements enforced at DOE sites are different from NRC/State requirements and must be resolved between NRC and DOE
<ul style="list-style-type: none"> Determine the costs (to DOE and NRC) related to NRC regulation of the pilot facilities and other DOE facilities that might be in a similar class and condition. 	<p>Resources Needed FTE/Money</p> <p><i>(Generic/Site Specific)</i></p> <p>Funding Analysis</p> <p><i>(Generic/Site Specific)</i></p> <p>Funding How to Obtain</p> <p><i>(Generic/Site Specific)</i></p>	<p>What are the financial and personnel resource needs for eternal oversight for both the ramp-up phases and for the long term after transition to full eternal regulation is complete?</p> <p>What are the costs to DOE, NRC, the State and the pilot facility?</p> <p>What are the various methods of funding eternal oversight?</p>	<p>4.1 Estimate NRC costs for regulation of DOE facilities</p> <p>4.2 Estimate DOE costs associated with transition to NRC regulation (contractor and DOE Fed costs)</p> <p>4.3 Evaluate various mechanisms for funding NRC</p>	<ul style="list-style-type: none"> Funding of the regulator via direct appropriations Funding of the regulator via fees paid by the contractor or DOE Funding of the regulator via direct appropriations for transition phase and fees for the long term

			during transition and in the long term	
<ul style="list-style-type: none"> Evaluate alternative regulatory relationships between NRC, DOE, and DOE contractors at the pilot facilities. Identify contract changes that would be needed to provide for NRC oversight of contractor operations. 	<p>Other Federal Agencies (OSHA, EPA, etc.) <i>(Generic/Site Specific)</i></p> <p>Lead Agency Concept <i>(Generic)</i></p> <p>Role of Agreement States/ Consistency <i>(Generic/Site Specific)</i></p> <p>Regulated Entity <i>(Generic)</i></p> <p>Contract Changes <i>(Generic/Site Specific)</i></p>	<p>What relationships should the eternal regulator have with other regulators of DOE facilities? What MOUs or other arrangements are needed with such regulators and other oversight organizations such as OSHA, EPA, States, and the DNFSB?</p> <p>Should DOE's "lead agency" concept be put into practice and if so, how?</p> <p>What role will Agreement States have in the regulation of DOE nuclear facilities within their borders? If there are many State regulators, how will significant differences among their regulatory requirements be avoided?</p> <p>Who should be the regulated entity: DOE, the contractor, or both?</p> <p>What contract changes would be necessary to implement eternal regulation?</p>	<p>5.1 Evaluate advantages and disadvantages of DOE or contractor as regulated entity</p> <p>5.2 Identify potential regulatory overlaps and gaps</p> <p>5.3 Propose means to compensate for potential regulatory overlaps and gaps</p> <p>5.4 Identify mechanisms for translating current DOE Directives (Rules, Orders) to NRC/State regulatory requirements</p> <p>5.5 Determine is gross differences exist between regulations of various States, and evaluate the differences</p> <p>5.6 Identify contractual changes necessary to transition to external regulation</p>	<ul style="list-style-type: none"> DOE as regulated entity Contractor as regulated entity NRC as sole regulator NRC lead with State support State lead with NRC support State as sole regulator Alternative form of regulation
<ul style="list-style-type: none"> Identify issues and potential solutions associated with a transition to NRC oversight of DOE nuclear facilities. 	<p>Impact and Transition Schedule <i>(Generic/Site Specific)</i></p> <p>DOE Order System <i>(Generic)</i></p> <p>Security/Safeguards <i>(Generic/Site Specific)</i></p> <p>Decontamination and Decommissioning <i>(Generic/Site Specific)</i></p> <p>Inspector General</p>	<p>What is the potential schedule for transition of the identified facilities and activities to eternal oversight? How will the transition be made from the current DOE order system, implemented by contract clauses, to an eternal framework?</p> <p>What is the process to identify and reconcile differences between DOE and NRC requirements?</p> <p>Should DOE retain regulatory authority over security and safeguards and if so, for how long?</p> <p>What role should NRC or the Agreement States have in decontamination and decommissioning of DOE nuclear facilities?</p> <p>How will DOE facilities meet the NRC financial assurance requirements for decommissioning?</p>	<p>6.1 Determine the impact of transition schedule upon the cost of transition</p> <p>6.2 Propose a transition plan</p> <p>6.3 Propose a transition schedule</p> <p>6.4 Identify DOE requirements that will be replaced by eternal regulation</p> <p>6.5 Identify responsible</p>	<ul style="list-style-type: none"> No changes until legislation is final. Operate in transition period under DOE using new standards and requirements Dual/mixed standards and requirements Develop list of replaced requirements: Safety requirements (e.g. 10 CFR 835); management requirements (e.g. ORPS);

<p>Jurisdiction <i>(Generic)</i></p> <p>Conflict-of-Interest <i>(Generic)</i></p> <p>Price-Anderson <i>(Generic)</i></p> <p>Low-Level Waste <i>(Generic/Site Specific)</i></p> <p>Transportation <i>(Generic/Site Specific)</i></p> <p>Emergency Preparedness <i>(Site Specific)</i></p> <p>Defense-related Issues <i>(Generic)</i></p>	<p>How can dual jurisdiction of two Inspectors General be avoided?</p> <p>(170A): How would NRC regulation of DOE affect NRC's ability to fund activities at DOE laboratories to support regulation of commercial or DOE nuclear operations?</p>	<p>offices/officials in DOE for all requirements to be placed under eternal regulation</p> <p>6.6 Identify contract modifications suitable for implementation of eternal regulation</p> <p>6.7 Determine applicability of S&S at the Pilot facility</p> <p>6.8 Review and compare current NRC and DOE processes for D&D</p> <p>6.9 Identify facilities at Pilot site which are under D&D status</p> <p>6.10 Identify contract work the site is doing for the NRC or State.</p> <p>6.11 Define differences between PA coverage under Doe and NRC systems and impact on contractor</p> <p>6.12 Define differences</p>	<p>contract requirements (WSS; App. F, G)</p> <ul style="list-style-type: none"> • Involve all necessary parties in review of requirements • Obtain buy-in by both DOE and NRC on all altered requirements • No change to contract • Contract to require only that contractor be qualified by holding an NRC/State • • • • • • • • •
<p>NEPA Issues <i>(Generic)</i></p> <p>Information Technology <i>(Generic/Site Specific)</i></p>	<p>Under NEPA, which agency --DOE or the NRC --would prepare EISs and EAs?</p> <p>How compatible are the NRC's and DOE's information technologies and systems for records management, including established records retention periods for recordkeeping requirements imposed on the contractors. What impact would NRC regulation of DOE have on DOE's information collection activities under the "Paperwork Reduction Act?"</p>	<p>6.15 Identify mechanism for preparing/filing NEPA-required reports at the Pilot sites</p> <p>6.16 Identify information technology and systems used for records management and document transfer.</p> <p>6.17 Identify any information collections and document whether or not they have OMB approval.</p>	<ul style="list-style-type: none"> • Some impact of eternal regulation on DOE RAP team program • DOE takes lead for NEPA document preparation • Eternal regulator takes lead for NEPA document preparation • Develop a plan to link DOE/NRC/State information technology systems used for records management and document transfer

				<ul style="list-style-type: none"> Develop plan with milestones, schedule, and resource estimates to obtain OMB review and approval for any identified information collections without OMB approval
<ul style="list-style-type: none"> Identify legislative and regulatory changes necessary or appropriate to provide for NRC regulatory oversight of DOE nuclear facilities. 	<p>Appropriate Organizational Structure for NRC <i>(Generic)</i></p> <p>Legislative Language <i>(Generic)</i></p> <p>Regulations <i>(Generic/Site Specific)</i></p> <p>Regulatory Program <i>(Generic/Site Specific)</i></p>	<p>How should the NRC be organized to fulfill its new responsibilities? Should there be a separate NRC office for regulation of DOE, or for regulation of DOE defense facilities?</p> <p>Develop legislative language laying out scope and extent of NRC authority, relationship with other regulatory agencies, and consider the effect of existing statutes on NRC oversight of DOE facilities.</p> <p>What parts of 10 CFR would be applicable? To what extent should 10 CFR be amended?</p> <p>What confirmatory research is needed?</p> <p>How will the NRC training program need to be changed?</p>	<p>7.1 Determine need for onsite presence</p> <p>7.2 Define role of Agreement State</p> <p>7.3 Identify applicable sections of 10 CFR by mapping 10 CFR 1 - 100 into 10 CFR 800 series</p> <p>7.4 Perform scoping study to estimate programs and resources as needed</p> <p>7.5 To what extent will heavy elements and accelerators require training needs?</p>	<ul style="list-style-type: none"> NRC/State onsite presence is necessary NRC/State onsite presence is not necessary Agreement States closely involved in eternal regulation Agreement States somewhat involved in eternal regulation Agreement States not involved in eternal regulation Mapping 10 CFR 1 - 100 into 10 CFR 800 series is/is not feasible Identify gaps in coverage
<ul style="list-style-type: none"> Evaluate how stakeholders should be involved if the NRC assumes broad authority over DOE nuclear facilities. 	<p>Reg Relationships/ Stakeholder</p> <p>Involvement <i>(Generic)</i></p> <p>2.206/Citizen Suits <i>(Generic)</i></p> <p>Public Involvement <i>(Other than 2.206 petitions)</i></p> <p><i>(Generic)</i></p>	<p>How will the public, local government, and tribal governments be involved other than through 2.206 petitions or citizen's suits?</p> <p>Should legislation allow "citizen' suits" against the eternal regulator or DOE on facility safety questions, as the environmental statutes do on environmental questions?</p> <p>Are hearings needed? If so, what would be their nature and timing?</p>	<p>8.1 Identify local stakeholder issues</p> <p>8.2 Develop joint DOE/NRC process for dealing with local issues</p> <p>8.3 Develop joint DOE/NRC process for public affairs, and press coverage during and after Pilots</p>	<ul style="list-style-type: none"> Preparation of a plan to resolve discrepancies between NRC, DOE and State stakeholder involvement protocols

A. Site and Facility Organization, including Scope of Activities at Each Facility.

The assessment phase will focus on (1) organizational structure, reporting chains and lines of succession, (2) responsibilities, authorities and limits of key personnel, (3) availability of key personnel and (4) assignment and qualifications of personnel. The effectiveness of the organizations with respect to safety will be determined from a performance-based assessment in the other topic areas, particularly with regard to problem resolution effectiveness

B. Management of Radiation Safety Program, including Role of Radiation Safety Committee, the Role of the Radiation Safety Officer, and Implementation of Audit Programs.

The review will include an assessment of overall program awareness, management involvement and oversight, and the communications among Management, Radiation Safety Committee, Radiation Safety Officer, and Users. The independence and qualifications of review and audit organization personnel will be assessed to ensure acceptably diverse and experienced personnel in the technical and administrative topics. The controls (plans, procedures, checklists and supervisory or peer review) and frequency of reviews and audits of safety-related topics will be reviewed. The review and audit findings will be reviewed, and the management prioritization and resolution of review and audit findings will also be evaluated for timeliness and technical acceptability.

C. Training of Facility Users and Radiation Protection Staff

The review will include an assessment of the initial qualifications and training of facility and radiation protection staff, periodic re-training, and the training of ancillary staff.

D. Receipt, Transfer and Inventory of Radioactive Materials

The review will include an assessment of the procedures, including implementation, for ordering radioactive materials, receipt and surveys of incoming packages of radioactive materials, the distribution and transfer of radioactive materials at the site, and the inventory of radioactive materials.

E. Personnel Radiation Protection, including Personnel Monitoring, Radiation Surveys, Laboratory and Survey Instrumentation, ALARA, the Implementation of Radiation Safety Procedures and Requirements, the Security of Radioactive Materials, and Use of Safety Interlocks

The posting, control, and security of radiological control areas will be examined. This will include personnel training, personnel and facility radiological surveys and use of protective equipment, materials and clothing. An assessment of airborne, contamination, radiation fields and associated protective structures, interlocks, systems and components, and monitoring devices will also be made. Personnel exposure records will be examined to ensure accurate, timely monitoring. The principles of as low as reasonably achievable (ALARA) will also be assessed in the application of the various radiation protection features for the facility.

F. Radioactive Waste Management, including Effluents, Environmental Monitoring, and any Past Burials and Legacy Issues

This assessment will examine if gaseous, liquid and solid radiological releases are controlled in accordance with principles of ALARA and properly monitored and recorded. It will include evaluation of the as-built condition of the facility to ensure all release paths are taken into consideration. Monitoring instruments will be assessed as to operability, calibration, and maintenance. Environmental monitoring will be examined in this assessment. Radioactive waste disposal practices will be examined, including a review of any potential past burials of radioactive materials.

G. Transportation of Radioactive Materials

The review will include an assessment of the procedures, including implementation, for the preparation for shipment, packaging, labeling, placarding, surveys, and transportation of packages containing radioactive materials, both onsite and shipments away from the site.

H. Emergency Preparedness

The assessment will determine if the emergency preparedness program is maintained in a state of operational readiness. It will determine if personnel are trained to deal with emergency situations. It will also assess if the emergency implementing procedures are consistent with facility safety analyses and design. It will assess the extent to which key emergency response facilities, equipment, instrumentation and supplies are readily available and maintained. If off-site support is needed, the assessment will evaluate the extent to which off-site agencies are prepared to provide the needed assistance.

I. Environmental Monitoring

The review will determine the adequacy of environmental monitoring programs as discussed in site procedures and measure the effectiveness of implementation. The review will also seek to identify any incompatibilities between the site monitoring plans versus programs outlined by the NRC and State of California. The environmental monitoring assessment will include accuracy of dose modeling in addition to a review of source sampling and receptor surveillance for both normal and accident conditions.

J. Worker Protection from Prompt Radiation Hazards at Particle Accelerators

Practices associated with worker protection from the prompt radiation hazards of particle accelerators will be addressed. Practices will be evaluated with respect to LBNL procedures, however State of California regulations pertaining to these hazards and relevant NRC regulations will also be noted.

K. Naturally-Occurring and Accelerator-Produced Radioactive Materials (NARM)

A review of procedures addressing control of NARM will be conducted. The program elements used to control NARM at LBNL will be evaluated for compatibility with State of California regulations and NRC general radiation protection regulations in addition to assessing implementation of LBNL requirements.

L. Safeguards and Security

The effect of safeguard and security issues on effective external regulation of radiation protection will be evaluated.