DOE External Regulation Task Force

Implementation Plan

For External Regulation of

Non-Defense

Science Laboratories

July 1, 2002

TABLE OF CONTENTS

Executive Summary				
Ext	ternal Regulation Plan	3		
I.	Background	3		
	A. Congressional Request/DOE Action	3		
	B. Requirements in Congressional Request	3		
	C. Exclusions from Congressional Request	4		
	D. Assumptions in Congressional Request	4		
	E. Other Issues	4		
II.	Potential Benefits of Implementing External Regulation	4		
	A. Improved Safety Efficiency and Effectiveness	4		
	B. Laboratory Support	5		
	C. Increase in Public Trust	5		
	D. Consistent Regulatory Requirements	5		
	E. Consistency of Management Practices	5		
	F. Potential Cost Savings	5		
	G. International Experience	5		
	H. Increased Competition from M&O Contractors	6		
III.	Concerns Regarding Implementation of External Regulation	6		
	A. Funding and Cost Concerns	6		
	B. Price-Anderson Indemnification	7		
	C. Political Concerns	7		
	D. National Security/Operational Concerns	9		
IV.	DOE Responses to Specific Congressional Requests	9		
	A. Estimate of Additional NRC and OSHA Resources	9		
	B. DOE Reductions in Funding and Staffing	10		
	C. Identification of Facilities That Cannot Be Implemented In A			
	Timely Manner	11		
	D. Necessary Contract Changes	12		
	E. Changes In Statutory Language	12		
	F. Regulatory Actions	14		
V.	DOE Implementation Activities and Schedule	15		

TAB A – DOE External Regulation Transition Activity Timeline

EXECUTIVE SUMMARY

Conference Report 107-258, accompanying the Energy And Water Development Appropriations Act For Fiscal Year 2002, dated October 31, 2001, directed that the Department of Energy (DOE) prepare an implementation plan for transitioning to external regulation at the Department's non-defense science laboratories. The Department was to assume that the Nuclear Regulatory Commission (NRC) would assume regulatory responsibility for nuclear safety, and the Occupational Safety and Health Administration (OSHA) would assume regulatory responsibility for worker safety at the affected laboratories.

Although Congress requested this plan, DOE has been considering this issue for some time. The development of the required Plan has brought to light advantages that external regulation could bring to the Department and its facilities. It has also brought to light a number of operational and policy concerns that need careful assessment. If the Department had no regulation of its facilities whatsoever, the question would simply be which form of regulation would be best, and the development of the plan suggests that there is much in favor of external regulation. All other things being equal, external regulation might very well be the preferred course. However, that is not the world in which the Department finds itself, and things are not equal. The Department is already regulated, as a consequence of which the development of the plan has brought to the fore not only the advantages of external regulation, but the operational issues that the Department would have to deal with in making the transition to external regulation. The external regulation issue, in other words, is not just one issue, but two: which form of regulation is better, and do the challenges of transitioning to external regulation defeat the advantages of doing so? Developing the plan showed that it would be imprudent to move to wholesale external regulation of the Department's Science facilities without answers to some of these questions. If the Congress directs the Department to proceed to external regulation, we would recommend experimenting at two Science facilities and using that experiment to provide answers to the operational and policy questions that still exist before expanding to any further part of the Department's complex.

The basic steps that the Department proposes to take are as follows:

- 1. Make several key DOE policy decisions prior to studying the potential for transition of the labs to external regulation;
- 2. Study potential DOE corporate costs and benefits;
- 3. Report results of analysis to Congress, including detailed recommendations on how to proceed with external regulation;
- 4. Make go/no-go decisions based on studies and analyses;
- 5. If go, complete contractual, legislative and statutory changes necessary, and;
- 6. If go, identify funding and proceed.

In summary, it appears that external regulation may well be the direction that the Department should take.

EXTERNAL REGULATION PLAN

DOE has been considering the issue of external regulation for some time. The development of the required Plan has brought to light many advantages that external regulation could bring to the Department and its facilities. It has also brought to light a number of operational and policy concerns that need careful assessment. The external regulation issue, in other words, is not just one issue, but two: which form of regulation is better (internal vs. external), and do the challenges of transitioning to external regulation defeat the advantages of doing so? Developing the plan showed that it would be imprudent to move at once to external regulation of all of the Department's Science facilities without answers to these questions. If the Congress so directs the Department, we would recommend experimenting at two Science facilities and using that experiment to provide answers to the operational and policy questions that still exist before expanding to any further part of the Department's complex. The proposed course of action is outlined in Section VI.

I. Background

A. Congressional Request/DOE Action

This plan responds to Conference Report 107-258, which accompanied the Energy and Water Development Appropriations Act for Fiscal Year (FY) 2002, dated October 31, 2001. The conference report requested that the Department of Energy (DOE) prepare an implementation plan for the transition to external regulation of the Department's non-defense Science laboratories. The plan is the product of a DOE task force that included DOE representatives from the National Laboratories, Environmental Safety and Health (EH), Office of Science (SC), General Counsel (GC), Operations Offices, and the Office of Management, Budget and Evaluation/Chief Financial Officer (CFO). Representatives from NRC and OSHA served as consultants to the group.

B. Requirements in Congressional Request

The conference report requested that the implementation plan include:

- All details necessary to implement external regulation;
- An estimate of the additional resources needed by the NRC and OSHA;
- Corresponding reductions in funding and staffing at the Department;
- Identification of specific facilities or classes of facilities for which external regulation cannot be implemented in a timely manner (Fiscal Year 2004);
- Necessary changes to existing management and operating contracts, and,
- Changes in statutory language necessary to transition to external regulation.

The plan builds on previous studies and pilot programs and is based on input from the affected DOE laboratories, DOE staff, OSHA, NRC, and discussions with organizations under external regulation. The plan describes the issues that must be addressed in order to consider external regulation of nuclear and worker safety at the following 10 non-defense Science laboratories:

• Ames Laboratory (AMES);

- Argonne National Laboratory East (ANL);
- Brookhaven National Laboratory (BNL);
- Fermi National Accelerator Laboratory (Fermilab);
- Lawrence Berkeley National Laboratory (LBNL);
- Oak Ridge National Laboratory (ORNL);
- Pacific Northwest National Laboratory (PNNL);
- Princeton Plasma Physics Laboratory (PPPL);
- Stanford Linear Accelerator Center (SLAC); and,
- Thomas Jefferson National Accelerator Facility (TJNAF).

C. Exclusions from Congressional Request

The Report language specifically excludes the consideration of external regulation at nuclear weapons facilities, environmental remediation sites, and other Department laboratories, facilities and sites.

D. Assumptions in Congressional Request

The Report language also details specific assumptions that are to be made in considering external regulation. The Department is to assume that external regulation would take effect beginning in FY04. The report also assumes that NRC would have regulatory responsibility for nuclear safety and OSHA would have regulatory responsibility for worker safety and health.

E. Other Issues

The development of the plan identified several other issues that need to be considered. They include:

- The cost of modifying DOE facilities and procedures (particularly some of those facilities with a large number of buildings over 40 years old, such as BNL and ORNL) to current OSHA and NRC standards;
- Ensuring continuity of facility/mission operations, particularly in regard to National Security;
- Resolution of current DOE variances/exceptions and interpretations that provide for technical non-compliance that, under external regulation, may not be granted by NRC and/or OSHA; and,

II. Potential Benefits of Implementing External Regulation

A. Improved Safety Efficiency and Effectiveness

Because external regulation would impose clear and consistent safety standards and clear lines of accountability under an NRC license, which is issued directly to the contractor, external regulation may result in improved safety efficiency and effectiveness. At hearings in 1999, NRC stated that external oversight "provides an increased assurance of safety in the long run." OSHA stated that "it appears that there is room for improvement in safety and health at DOE sites." If these statements were correct, then it would be expected that external regulation might result in a reduction in lost work time from accidents and injuries.

B. Laboratory Support

The laboratories, in general, support external regulation under two conditions: #1 that they hold the license; and #2 that DOE substantially reduce its safety oversight. They believe it will relieve them of the burden of DOE regulation and, in some cases, dual regulation, and save money.

C. Increase In Public Trust

In the long run, though perhaps not in the shorter run, implementation of external regulation may increase public trust in DOE because an independent authority (OSHA/NRC) will be responsible for safety oversight. According to the National Academy of Public Administration report, <u>Ensuring</u> <u>Worker Safety and Health Across the DOE Complex</u>, there has been public distrust of DOE facilities because there has been no external, independently reporting oversight body in place. This distrust is exacerbated by the fact that the public is aware of the general mission of DOE facilities, but not substantially involved as stakeholders. Because of this lack of public participation or knowledge regarding the physical plant, and because, generally, the only safety information coming out of the plants is when there is a problem, public confidence may not be at the highest level. By bringing in an independent agency such as NRC or OSHA, and instituting some of their open processes, the public's perception may be that the labs are being placed on a level playing field with non-DOE laboratories. These changes could enhance DOE credibility with the Congress, the States and the general public.

D. Consistent Regulatory Requirements

Contractors working at DOE Science facilities would be working under the same regulatory requirements as at comparable civilian and other government facilities. This may reduce DOE's long-term training costs because its contractors would be trained to work at either DOE or commercial facilities.

E. Consistency of Management Practices

External regulation of DOE is consistent with current domestic and international safety management practices. Through predictable standards and enforcement, it provides the organizing force for ensuring that responsibility for safety is well focused within line management.

F. Potential Cost Savings

There are potential cost savings for the contractor running the sites, for DOE in oversight manpower and budget, and in contractual changes. For instance, it is possible that DOE might be able to reduce its headquarters functions for the development of regulatory requirements. These potential savings will be more fully understood and quantified after the studies detailed below have been completed.

G. International Experience

Belgium, England, France, and Switzerland have transitioned to external regulation and value its benefits. All of their research facilities, variations of government-owned and contractor-operated sites, have been licensed and inspected by independent regulators for some time. Foreign government funding agencies and laboratory contractors cite several benefits of external regulation, including:

• Increasing safety;

- Improving credibility with the public;
- Leveraging funds for infrastructure improvements;
- Establishing a more accessible source to share worker concerns; and,
- Fostering more efficient organizations.

H. Increased Competition from M&O Contractors

External regulation may increase contractor interest in seeking work at DOE sites. There has been concern that prospective contractors may not have submitted proposals to perform work at labs due to perceived difficulties with learning and complying with DOE self-regulation.

III. Concerns Regarding Implementation of External Regulation

Currently there are a number of questions and concerns that should be resolved before DOE can implement external regulation at all of its Science laboratories. First, there is no solid costing information on which to base an estimate of total costs or to support a cost benefit analysis. These costs may include, but are not limited to, transition costs; NRC, OSHA and DOE costs for personnel and legislative changes; costs of upgrading the sites to current NRC and OSHA standards; potential penalties and fines; and ongoing steady-state costs to the Department. The potential costs, both monetary and to mission completion should a site be shut down due to violations, must also be considered. Second, many policy decisions have yet to be made (detailed below), some of which may be dependent upon legislative and statutory changes. And finally, sources of funding to support not only the implementation, but also the studies and preparatory steps to implementation, must be identified. Ultimately, these decisions will substantially impact not only DOE, but NRC and OSHA cost and operational issues.

A. Funding and Cost Concerns

Costs alone should not drive the final decision, but it is certainly important to know what the costs are likely to be. There is a potential for significant near-term costs to determine what actions are necessary (and funded) in order to bring the laboratory facilities into compliance with applicable OSHA and NRC regulations (gap analysis) and then to bring labs into compliance prior to actual transition. Neither OSHA nor NRC will accept the responsibility of regulating DOE facilities until they are in compliance with applicable regulations. Recent input from the labs indicates that significant additional funding may be necessary to cover transition costs such as facility upgrades to meet OSHA and NRC compliance standards. The facility upgrades may be as simple as the safety standards for ladders (the Department has a number of ladders installed prior to the issuance of OSHA standards which have the width of the ladder and the distance between rungs which are not in conformance with current OSHA standards). While these are not inherently unsafe, they do fail to meet OSHA standards. The cost will also be influenced by other factors such as the preventative maintenance backlog, and new procedures/training at the labs.

1. NRC and OSHA Costs

A summary of NRC and OSHA costs is provided in section IV.A. The laboratory comments indicate their belief that OSHA/NRC estimated costs have been overstated. It is a given that OSHA and NRC will require funding in order to regulate these laboratories.

2. Departmental Personnel

There may actually be no long-term cost savings because EH and program offices may require additional full time equivalents (FTEs) due to interfaces with NRC/OSHA and activities required to respond to issues raised. Additionally, where DOE regulations are more stringent than OSHA, OSHA expects DOE to enforce the higher standard. This enforcement may not require additional personnel, but will certainly require some existing personnel.

3. Sources of Funding

A source of funding for the studies proposed has not been identified. It will be necessary to fund both OSHA and NRC for their assistance in any future studies (as early as FY03), as well as covering DOE internal and contractor costs.

4. Budgeting Process

In order to implement external regulation at any level in the DOE complex in FY04, we would have to determine our budget requirements, particularly those relating to modifying facilities to meet external regulatory requirements. We will make every effort to have validated cost data in time for the FY04 budget submission. DOE will continue to work, under existing funding levels, to upgrade facilities at the 10 laboratories between now and the date transition funding is specifically approved. It must again be stressed that neither NRC nor OSHA will undertake regulation of any DOE sites until they have been brought into full compliance with applicable standards.

5. Historical Cost Issues

Other DOE transitions to NRC have proven more difficult, expensive and time consuming than anticipated. The transfer of the Portsmouth and Paducah Gaseous Diffusion Plants to NRC and OSHA regulation highlights some of these concerns.

- The original cost estimate was \$60 million: Estimated total actual cost is \$336 million;
- 6,000 non-compliances were identified;
- Transition took four years; and,
- Certification/licensing took two years and 2,300 pages of documentation.

B. Price-Anderson Indemnification

DOE's policy regarding the continuation of indemnification under the Price-Anderson Act must be clarified. If indemnification cannot be continued under external regulation, the laboratories feel that they cannot make the transition to external regulation.

C. Political Concerns

1. Regulation of Accelerators

The states and/or OSHA currently regulate industry accelerators. NRC indicated they would seek legislation granting NRC regulatory responsibility for accelerators at the affected laboratories. A determination must be made to decide if NRC should be the single external regulator of DOE nuclear and radiological safety.

2. Role of States

State Plan states are those to whom authority has been given to regulate occupational safety and health in lieu of OSHA. It will have to be decided whether State plan states will be given the authority to regulate the working conditions at the DOE labs. If State plan states are given authority to regulate

occupational safety and health at SC laboratories, there must be a waiver of sovereign immunity. If there is a waiver of sovereign immunity, authority to regulate should be delegated to a level no lower than the state level.

3. Legislative Relief for OSHA/NEPA Issues

Because OSHA does not have the authority to regulate State agencies, they will need legislative relief in order to regulate state and local employees at DOE facilities. Each agency's National Environmental Policy Act (NEPA) obligations must be defined, including language stating that NRC licensing is not a major Federal action that would trigger NEPA.

4. Multiple Regulators

A major concern, particularly among the laboratories, is that external regulation, in some cases, could potentially lead to <u>more, rather than fewer</u>, regulators at a site. Dual regulation (both external and internal), or layered oversight, would result only in increased cost and inefficiency. As an example, there is a potential for dual regulation with EPA regarding the National Emissions Standards for Hazardous Air Pollutants (NESHAP).

5. OSHA Adoption of Stricter DOE Standards

OSHA wishes to ensure that external regulation does not result in reduced or less effective protections for employees at DOE laboratories. OSHA has identified a number of safety and health hazards for which DOE currently enforces more protective safety and health standards than OSHA. OSHA rulemaking would be needed to adopt those DOE regulations that are more stringent. Where OSHA does not choose to conduct rulemaking, they have stated that they will still expect <u>DOE</u> to continue current levels of protection above and beyond current OSHA standards.

6. NRC "Agreement States"

"Agreement States" are those states that have accepted authority (through agreement with NRC) to license radioactive materials within their state. At least one Agreement State, Illinois, has stated their position that they should be authorized to assume responsibility for nuclear safety at DOE's non-defense Science laboratories, as they are for other facilities.

7. Relationships Among NRC/OSHA/ Defense Nuclear Safety Facilities Board (DNFSB)

The relationships among NRC, OSHA, and the DNFSB will require definition. The DNFSB is an independent Federal agency established by Congress to provide safety oversight of the nuclear weapons complex operated by the Department of Energy. There are a few isolated facilities within the affected Science labs (notably at ORNL and PNNL) that fall under the purview of DNFSB where these relationships will require definition.

8. Interfaces with Non-Science DOE Programs at Multi-Program Labs

Interfaces between/among regulators and non-covered DOE programs at multi-program Science labs must be defined. Of particular concern are the potential effects upon National Nuclear Security Administration (NNSA) activities performed at externally-regulated Science laboratories.

D. National Security/Operational Concerns

Under external regulation there is a potential for facility/mission operations to be impacted. OSHA, in particular, has stated that, "Under external regulation OSHA would use its full range of enforcement and partnership tools in the DOE complex." This could prove detrimental to NNSA activities, as well as other national security work performed as "work for others."

1. Public Involvement in NRC Licensing Procedures

NRC licensing procedures include public hearings, with participation from interveners. NRC's submission stated that, "NRC intends to use its current approach to public participation, including efforts to improve communication with major stakeholders, in dealing with the licensing and inspection activities at the regulated DOE laboratories. NRC's public process is well established. Licensing meetings are open to public observation. Selected inspection and enforcement meetings are also open. Development of rules and guidance includes obtaining and resolving public comments. Licensing procedures may include hearings, with participation from interveners. Members of the public may petition NRC for rulemaking and enforcement action." NRC has also cautioned that their cost "…assumptions are based on no intervention in the hearing processes. With intervention, estimates would be increased about 50 percent." This increased scrutiny, and the ability of detractors to bring legal action, particularly during the licensing period may expose the Department to additional potential for lawsuits and mission delays.

2. Security

It is unclear what role NRC security may fulfill in this process. NRC security requirements, security support and infrastructure are, in many cases, not as robust as DOE programs. DOE does not want to reduce any security measures, particularly in the post 9-11 environment. There is a question regarding the role that the NRC will play with respect to Security plans. OSHA/NRC personnel security clearance issues must be resolved prior to beginning any studies involving classified facilities.

IV. DOE Responses to Specific Congressional Requirements

The following section is arranged according to the requirements given in the Conference report.

A. An estimate of the additional resources needed by the Nuclear Regulatory Commission and the Occupational Safety & Health Administration.

The information below is excerpted from input provided from OSHA and the NRC regarding their resource needs under DOE external regulation. Please note that these are estimates and may vary depending on decisions made, as discussed elsewhere in this plan.

NRC Resource Needs

NRC estimates are based on the assumption that the DOE laboratory facilities are in a generally safe condition and in compliance with DOE orders and regulations. It is assumed by the NRC that the DOE <u>contractor</u> will be the licensee. DOE has not yet made this decision. NRC will request funding through direct appropriations and recover the costs through existing regulatory required fees assessed to the DOE facility applicants/licensees.

The NRC identified the following transition and steady state full-time-equivalent (FTEs) employee and funding needs (including the costs of regulating accelerators):

Year		FTEs	\$ (in millions)
Transition	FY03	48	\$8.0
Transition	FY04	46	\$7.3
Steady State	FY05	24	\$4.8

OSHA Resource Needs

While OSHA has not actively sought additional responsibility for external regulation of DOE sites, OSHA has for several years undertaken a variety of cooperative projects and activities with DOE to test the feasibility of such an action. OSHA's approach is based on the premise that the laboratories would generally be treated like other similar workplaces that OSHA regulates. OSHA believes that the best organizational approach would be to establish a single OSHA area office dedicated exclusively to interventions at DOE sites, in lieu of having OSHA interventions conducted from existing local area offices. OSHA anticipates that it will require:

- \$2.1 million/year to undertake an intervention program, including the support of 19 FTEs;
- \$445,000 to establish an area office (a one-time cost); and,
- \$6.4 million spread over five years (\$1.5million/year) to promulgate revised ionizing radiation standards. In addition, and not included in this cost figure, OSHA may need to engage in rulemaking to address other regulatory gaps that now exist because DOE safety standards are, in some cases, stricter than those currently enforced by OSHA. OSHA wishes to provide workers with the needed protection that is afforded them under DOE. It is OSHA's opinion that if they are to enforce those stricter DOE standards, then they must be formally adopted as a national standard.

B. Corresponding reductions in funding and staffing at the Department

In an attempt to determine corresponding DOE reductions in funding and staffing, DOE considered the cost components and results of various pilots, the data in the DOE ES&H Management Plan Information System, deferred maintenance information, and other sources. This review revealed the following:

- There is no actual cost data that can be used to reliably forecast the cost of transition to external regulation;
- DOE EH staff will still be required to oversee activities not covered by NRC/OSHA, as well as to interface with the DNFSB, NRC and OSHA. The Office of Independent Oversight and Performance Assurance (OA), which has responsibility for independent oversight within DOE, will continue to fulfill that role.
- The potential for dual regulation will require DOE operational office staff to remain in place and expenses may not be reduced;
- The previous reports and studies did not include a complete analysis of the potential DOE costs; and,
- The effect on DOE resources cannot be analyzed with precision since DOE's role and responsibilities after transition have not been finalized. This also makes it difficult to specify a timeline for completion of transitioning to external regulation.

There are several factors that may influence DOE costs during and after the transition to external regulation including, but not limited to:

- Future Congressional and Departmental policy decisions and direction, and implementation timeframes;
- The definition of DOE's role and responsibilities after transition;
- DOE costs during the NRC licensing process;
- Budgetary constraints;
- Individual laboratory program readiness and physical conditions;
- Site-specific implementation; and,
- The readiness and actions of the external regulators. As noted previously, both NRC and OSHA have indicated that they will not accept regulatory responsibility for a DOE facility until the facility is brought into strict compliance with applicable NRC and OSHA requirements.

C. Identification of specific facilities or classes of facilities for which external regulation cannot be implemented in a timely manner (FY2004)

The implementation of external regulation is firmly dependent upon two major factors:

- The ability of the DOE Science labs to identify gaps between the current physical condition of their facilities and NRC and OSHA requirements; and,
- Sufficient funding to perform the actual work necessary to close those gaps so that NRC and OSHA may assume regulatory responsibilities when DOE facilities are in compliance with their requirements.

Each laboratory developed two timelines: one for NRC licensing and one for OSHA regulation. The starting point for both timelines is defined as the time DOE receives legislative direction and subsequently gives contractual direction to the contractor to start a transition to external regulation by NRC and/or OSHA.

All 10 laboratories estimated they could complete the transition to OSHA regulation within two years of legislative direction. Ames, BNL, Fermilab, LBNL, ORNL, PPPL and TJNAF would take the longest time. Eight laboratories estimated they could obtain the necessary NRC licenses within two years. Due to material holdings and/or operations at Brookhaven and Oak Ridge National Laboratories, the transition is estimated to require up to three and four years, respectively.

The estimate of implementation times provided by the laboratories was based on specific working assumptions regarding important issues identified in previous DOE studies and pilots. The primary assumptions used were:

- The contractor is the sole NRC licensee;
- Rulemaking is not anticipated;
- OSHA retains regulatory responsibility for worker exposures to radiation from machine sources (e.g., accelerators and x-ray machines); and,
- No additional DOE incremental funding is available.

Any change to these assumptions will negatively impact the schedule calculations.

D. Necessary changes to existing management and operating contracts

Modifications to standard clauses contained in SC laboratory M&O contracts would have to be considered following any legislative action requiring a transition to external regulation. Generally, the clauses set forth below are included in most of the laboratory contracts and will be likely candidates for modification. Potential modifications to clauses that may be unique to a particular M&O contract would also have to be considered on a case-by-case basis.

DEAR 970.5204-78, "Laws, Regulations and Directives." Under this clause, DOE may provide List A, Applicable Laws and Regulations, and must provide List B, Applicable DOE Directives, to the contractor. List A would have to be modified to include NRC, OSHA and State regulatory requirements. List B would have to be modified as many of the DOE ES&H orders would be deleted from the list.

DEAR 970.5204-2, "Integration of Environment, Safety and Health into Work Planning and Execution." Pursuant to this clause, DOE contractors are required to submit to DOE for approval an Integrated Safety Management System description, explaining how its management and budget systems are integrated into the safe performance of the work. Issues related to the transfer of this approval authority to the external regulator will need to be addressed.

<u>DEAR 970.2870, "Nuclear Hazards Indemnity."</u> The Price-Anderson Amendments Act mandates that DOE indemnify its contractors whenever contractual activities involve a risk to the public from special nuclear, source and byproduct materials or in the event of a precautionary evacuation. DOE provides this coverage through the use of the "Nuclear Hazards Indemnity" clause. Whether changes are needed to this clause will depend on any decisions made regarding indemnification under external regulation.

<u>DEAR 970.3102-21, "Regulatory Enforcement, Fines and Penalties."</u> Contracts would need to be modified to reflect changes in enforcement roles.

Additionally, how management fees are established and paid will have to be reconsidered, as will the allowability of costs for dealing with the NRC on operational matters, such as transfer of licenses or potential imposition of fines and penalties.

E. Changes in statutory language necessary to transition to external regulation

Potential legislative and statutory actions that must be addressed to implement external regulation include:

- Determining appropriate distribution of regulatory responsibilities among DOE, NRC, OSHA, EPA and state agencies (for example, whether NRC, OSHA or state agencies would regulate sources of ionizing radiation (such as accelerators) that NRC does not currently have authority to regulate)¹;
- Determining whether to waive sovereign immunity and, if so, the extent of any waiver needed to permit regulation of DOE facilities and activities by state agencies;

¹The determination on the appropriate distribution of regulatory responsibilities will affect the extent to which some of the following issues need to be considered.

- Determining whether to grant NRC statutory authority to regulate sources of ionizing radiation for which it currently does not have regulatory authority under the Atomic Energy Act (AEA);
- Determining whether NRC should regulate DOE facilities and activities through licensing or through other methods, such as the certification process used for gaseous diffusion plants or informal rulemaking to establish nuclear safety and radiological protection requirements for DOE facilities and activities;
- Determining whether to grant OSHA specific legislative authority to cover state or local government employees at DOE laboratories operated by state employees;
- Defining the extent to which DOE could continue to require contractors to meet worker safety requirements that are more stringent than OSHA requirements and clarifying whether the imposition of more stringent standards by DOE would preempt OSHA from exercising its jurisdiction for occupational safety and health of DOE contractors under section 4(b) (1) of the Occupational Safety and Health Act;
- Determining whether external regulation should be funded through direct appropriations to external regulators or through the payments of fees by DOE or DOE's contractors;
- Defining the relationship between an external regulator and DOE and DOE's contractor (for example, if NRC licenses a DOE facility, should the licensee be DOE, DOE's contractor, or both DOE and its contractor);
- Defining the role, if any, of external regulators in decisions by DOE to select, retain, terminate, change and otherwise manage its contractors;
- Determining whether DOE contractors at science laboratories should remain indemnified by DOE under the Price-Anderson Act or whether they should be treated the same as the operators of other laboratories licensed by NRC who are not covered by Price-Anderson indemnification;
- Determining whether DOE non-profit contractors at science laboratories should remain exempt from or subject to limited civil penalties, or whether they should be treated like non-profit operators of other laboratories licensed by NRC who are subject to civil penalties;
- Grant OSHA specific legislative authority to cover state or local government employees at DOE laboratories operated by state employees;
- Clarify that OSHA is not preempted from exercising its jurisdiction for occupational safety and health of DOE contractors under section 4(b) (1) of the Occupational Safety and Health Act;
- Determining whether DOE or the external regulator would be responsible for matters such as safeguards, security, material control and accountability, and access to classified information;
- Determining the extent, if any, to which an external regulator could direct DOE management decisions concerning matters such as scheduling and allocating resources for clean-up and decommissioning activities;
- Declaring whether the transition of DOE facilities to external regulation would or would not be considered a major Federal action within the context of the National Environmental Policy Act (NEPA);
- Defining the extent to which regulatory actions by external regulators would be subject to NEPA;
- Determining the extent, if any, to which an external regulator could regulate activities undertaken by a science laboratory for NNSA or otherwise in furtherance of a national security function;
- Determining the potential for dual regulation in areas such as Environmental Protection Agency National Emissions Standards for Hazardous Air Pollutants regulations;
- Determining whether NRC should be able to enter into a contract or other arrangement for research by a science laboratory that it regulates without giving rise to a conflict of interest; and,

• Determining the amount that needs to be appropriated to fund the modifications to DOE facilities to comply with the requirements of external regulators.

F. Regulatory actions to transition to external regulation

Although this section was not specifically required in the House Conference Report, DOE feels it essential that these issues be raised. Potential regulatory actions that must be addressed to move forward with external regulation of DOE's non-defense laboratories include:

- Addressing the need for new NRC regulations (i.e., 10 CFR Part 80) by determining whether the regulations in 10 CFR that apply to NRC-regulated facilities, for example, 10 CFR Parts 19 (Inspections & Investigations), 20 (Radiation Protection), 21 (Defects and Non-Compliance Reporting), 30 (By Product Material Licensing), 33 (Broad Scope Licenses for By Product Material), 35 (Medical Use of By Product Material), 40 (Source Material Licensing), 50 (Licensing of Production and Utilization Facilities) and 70 (Special Nuclear Material Licensing), adequately address the unique nature of DOE facilities;
- Addressing how OSHA's Multi-Employer Citation Policy will be applied to DOE and the contractor. In some labs where DOE retains the daily supervisory authority to demand process and procedural changes, this would mean that DOE would be deemed a controlling employer and thus held accountable as such. Contractors might be unwilling to be subject to the control and direction of both DOE and OSHA;
- Addressing how current DOE regulations, (e.g., 10 CFR 707 (Workplace Substance Abuse Programs), 708 (Contractor Employee Protection), 820 (Procedural Rules for DOE Nuclear Safety), 830 (Nuclear Safety Management), 835 (Occupational Radiation Protection), 850 (Beryllium) may need to be amended to accommodate external regulation;
- Approving alternate funding and schedule provisions for decommissioning of radiological facilities and the disposition of low-level waste;
- Requiring the U.S. Environmental Protection Agency to rescind the National Emissions Standards for Hazardous Air Pollutants requirements for DOE facilities, as it has for other NRC-regulated facilities. This avoids the potential for dual regulation, particularly as it relates to certain Clean Air Act provisions;
- Addressing the issue of "co-located" workers, and who constitutes "members of the public" at DOE sites. At some sites, workers regulated by DOE and workers regulated by NRC work side-by-side within the same building or on different parts of the site. Different regulatory standards might apply to workers in similar situations;
- Ensuring that external regulation does not result in reduced or less effective protections for employees at DOE laboratories. OSHA has identified a number of safety and health hazards for which DOE currently enforces more protective safety and health standards than OSHA. The most critical gap identified is in radiation protection. For OSHA to enforce these more protective standards, OSHA rulemaking (or statutory direction) would be needed;
- Identifying and addressing regulatory gaps in authorization or regulation between NRC, OSHA, and/or DOE regulations (e.g., Beryllium, accelerators); and,
- Updating regulations dealing with accelerators regulated by OSHA and developing a regulation for accelerators to be regulated by NRC.

Given these concerns, the Department would propose that we undertake an experiment in FY03 with two labs, on the basis of which we will have better information on which to plan the transition to external regulation.

V. DOE Implementation Activities and Schedule

A. Begin work on legislative and regulatory changes Start time: September 2002 Responsible Office: Office of General Counsel

The Office of General Counsel has already completed some of the foundation work, as described in the report. That work will now continue with a goal of implementing legislation.

B. DOE decisions on policy issues

Start time: Immediate – complete by September 2002 Responsible Office: Office of Science

There are specific, critical policy decisions that DOE management must make in order to move ahead with external regulation processes. These decisions include:

- Specification of license holder;
- Determination of DOE post transition owner/stewardship role; and,
- Funding determinations.

C. Conduct detailed cost and effort analyses at two sites

Start time: October 2002 and beyond Responsible Office: Office of Science

Proceed with a detailed analysis at two affected sites. DOE and its contractors must complete or simulate all of the steps leading up to licensing and transition in order to understand the magnitude of costs and effort that may be involved. This involves theoretical replacement of DOE orders with applicable and equivalent NRC nuclear safety and OSHA worker protection requirements. The laboratories would be required to determine all activities required to bring the physical plant into compliance; accomplish the applicable personnel training; and complete all of the efforts necessary to implement external regulation, including licensing and certification activities and all changes to operational procedures post-transition to external regulation. All costs (both generated and saved) resulting from transfer and steady state operations, both in terms of budget and personnel, will be documented in detail. The potential costs (monetary and mission completion) should a site be shut down due to violations must also be considered. Assuming appropriate budget is available, OSHA and NRC will work with the laboratories and with DOE to assist in these studies. It will be necessary for corporate DOE to determine the impact that these changes would have on its onsite, field and headquarters budget and staff. It is suggested that the first laboratories to institute these studies be Thomas Jefferson Accelerator Facility and Argonne National Laboratory East. It will be the responsibility of the Office of Science to ensure that these detailed cost studies are completed.

D. DOE review of changes to resources and governance (SO/OA/EH and SC) to support external regulation

Start time: October 2002 Responsible Office: Office of Science in conjunction with other affected offices

DOE must internally review the impacts and costs of external regulation to onsite federal personnel, Operations Office personnel, and DOE Headquarters staffing and responsibilities.

E. Begin comprehensive cost-benefit analysis using results of steps C and D

Start time: February 2003

Responsible Office: Office of Science

The results of the detailed studies and the review of DOE resources and governance will be combined with a determination of potential savings to the Department and incorporated into a comprehensive cost-benefit analysis of the entire project prior to the final decision regarding external regulation.

F. Begin compliance/transition work at first two labs

Start time: March 2003

Responsible Office: Office of Science

Both OSHA and NRC have stated that they will not assume regulatory responsibility for any site that has not been brought into physical compliance with applicable NRC or OSHA regulations. The initiation of this work is based on a completed analysis of the work required to bring the facility into compliance with NRC and OSHA regulations, and the presumption of sufficient funding being available.

G. Begin detailed analysis of 8 remaining labs

Start time: April 2003

Responsible Office: Office of Science

Proceed with a detailed analysis at the 8 remaining sites. The process used in the remaining laboratories should be identical to that used in step C for the first two laboratories.

H. Begin cost-benefit analysis for the remaining 8 labs

Start time: August 2003 Responsible Office: Office of Science

The results of the detailed studies will be combined with a determination of potential savings/costs to the Department and incorporated into a comprehensive cost-benefit analysis of the remaining 8 laboratories. These analyses will be done on a rolling basis as results from the detailed studies become available, but the first is expected to begin in August 2003.

I. Begin site compliance work at remaining 8 labs

Start time: November 2003 Responsible Office(s): Office of Science

Both OSHA and NRC have stated that they will not assume regulatory responsibility for any site that has not been brought into physical compliance with applicable NRC or OSHA regulations. The initiation of this work is based on a completed analysis of the work required to bring the facilities into compliance with NRC and OSHA regulations, and the presumption of sufficient funding being available.

J. Institute changes to Management and Operating contracts and begin training at external regulation sites

Start time: After legislation passes Responsible Office(s): DOE Field Offices/Contracting Personnel/Office of Science

Necessary contractual changes to the M&O contracts at each of the affected laboratories must be identified and put into place prior to the implementation of external regulation. This effort should include identification of the DOE corporate safety and health requirements that go above and beyond OSHA and NRC requirements and will have to be contractually enforced.

K. Transition to External Regulation

Start Date: After legislation passes – staggered. Some labs will require more time than others Responsible Office(s): Office of Science/laboratories/OSHA/NRC

The actual transition to external regulation will depend on the fulfillment of two requirements. One is that all legislative and statutory changes directing this transition must be in place. The other is that all sites must be fully OSHA and NRC compliant. The best approach will likely be one that sees the sites transition in a sequential manner, rather than concurrently with one another.

Please see Tab A for the DOE External Regulation Transition Activity Timeline.

DOE External Regulation Transition Activity Timeline *All dates are start dates*



* It is suggested that the first two sites to do this detailed analysis could be Thomas Jefferson National Accelerator Facility and Argonne National Laboratory East. Once sufficient cost information has been accumulated to allow a limited cost/benefit analysis, the Department will make a go/no go decision regarding initiation of studies of the remaining labs. If the decision is go, the detailed analysis of the remaining 8 laboratories will begin as soon as possible.

** These steps will be completed for each Laboratory as the data becomes available and/or analyses is completed. The intention is to move ahead sequentially as each Laboratory becomes ready.

Tab A