

NRC AUTHORIZATION AND LEGISLATIVE PROPOSALS

HEARING BEFORE THE SUBCOMMITTEE ON ENERGY AND MINERAL RESOURCES OF THE COMMITTEE ON NATURAL RESOURCES HOUSE OF REPRESENTATIVES ONE HUNDRED THIRD CONGRESS

FIRST SESSION

ON

H.R. 2143

TO AUTHORIZE APPROPRIATIONS FOR THE NUCLEAR REGULATORY
COMMISSION FOR FISCAL YEARS 1994 AND 1995

H.R. 2170

TO AMEND THE ENERGY REORGANIZATION ACT OF 1974 AND THE
ATOMIC ENERGY ACT OF 1954 TO ENHANCE THE SAFETY AND SECUR-
ITY OF NUCLEAR POWER FACILITIES, AND FOR OTHER PURPOSES

HEARING HELD IN WASHINGTON, DC
MAY 27, 1993

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MAY 27, 1993

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**H.R. 2143 TO AUTHORIZE APPROPRIATIONS
FOR THE NUCLEAR REGULATORY COMMISSION
FOR FISCAL YEARS 1994 AND 1995**

**H.R. 2170 TO AMEND THE ENERGY REORGANIZATION
ACT OF 1974 AND THE ATOMIC ENERGY ACT OF 1954 TO
ENHANCE THE SAFETY AND SECURITY OF NUCLEAR
POWER FACILITIES, AND FOR OTHER PURPOSES**

THURSDAY, MAY 27, 1993

**HOUSE OF REPRESENTATIVES,
COMMITTEE ON NATURAL RESOURCES,
SUBCOMMITTEE ON ENERGY AND MINERAL RESOURCES,
Washington, DC.**

The subcommittee met at 10:40 a.m., in room 1324, Longworth House Office Building, Hon. Richard H. Lehman (chairman of the subcommittee) presiding.

OPENING STATEMENT OF CHAIRMAN LEHMAN

Mr. LEHMAN. Good morning. The Subcommittee on Energy and Mineral Resources is meeting today for a hearing on two bills dealing with the Nuclear Regulatory Commission, which I have introduced at the Commission's request.

At the outset, I would like to welcome the commissioners of the NRC to their first appearance before this Committee in the 103rd Congress. And I would also like to note that the NRC Inspector General, David Williams, is present and has submitted a separate written statement that we will make part of the official record of this hearing.

The first bill before us today is H.R. 2143, which would authorize appropriations for the NRC for fiscal years 1994 and 1995. For various reasons, having to do with past policy differences between the House and Senate, there has not been an NRC authorization passed since 1984.

We have conferred with Senator Lieberman over in the lower chamber [laughter] and have agreed that we want to get into the habit of exercising this authority again.

While this bill probably cannot be enacted in time to govern fiscal 1994 appropriations, as a two-year authorization we hope that it will govern fiscal 1995 appropriations.

The bill would authorize appropriations to the NRC of \$542.9 million for fiscal year 1994 and \$546.8 million for fiscal year 1995. The 1994 figure represents only a one point four percent increase over the Commission's 1993 appropriation. The 1995 figure is only seven tenths of a percent higher than that for 1994.

For the NRC Inspector General, this bill authorizes four point eight million for fiscal year 1994 and five million for 1995. These are four point seven and four point two percent annual increases, respectively.

Pursuant to the Budget Reconciliation Act of 1990, the Commission is required to recover 100 percent of its fiscal budgets for 1991 through 1995 from three sources. Fees for services, annual charges on licensees, and payments from the Nuclear Waste Fund. Thus, the Commission's activities are not funded from general revenues.

Nonetheless, the Commission has taken to heart the directive to reduce government costs, and has requested increases that are well below the rate of inflation. Indeed, the request for fiscal 1994 represents a fifty percent reduction in total—fifty-person—don't panic—reduction in total NRC staffing.

The Budget Reconciliation Act of 1993, which is before the House today, would extend the NRC's one hundred percent user fee requirement to fiscal 1998. This requirement has not been without some controversy and I will get into questions regarding that later.

[Text of the bill, H.R. 2143, follows:]

103D CONGRESS
1ST SESSION

H. R. 2143

To authorize appropriations for the Nuclear Regulatory Commission for fiscal years 1994 and 1995.

IN THE HOUSE OF REPRESENTATIVES

MAY 18, 1993

Mr. LEHMAN (by request) introduced the following bill; which was referred to the Committee on Natural Resources

A BILL

To authorize appropriations for the Nuclear Regulatory Commission for fiscal years 1994 and 1995.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Nuclear Regulatory
5 Commission Authorization Act for Fiscal Years 1994 and
6 1995".

7 **SEC. 2. AUTHORIZATION OF APPROPRIATIONS FOR FISCAL**
8 **YEARS 1994 AND 1995.**

9 (a) IN GENERAL.—There are authorized to be appro-
10 priated to the Nuclear Regulatory Commission, in accord-

1 ance with section 261 of the Atomic Energy Act of 1954
2 (42 U.S.C. 2017) and section 305 of the Energy Reorga-
3 nization Act of 1974 (42 U.S.C. 5875), the following
4 amounts:

5 (1) FISCAL YEAR 1994.—\$542,900,000 for fiscal
6 year 1994, to remain available until expended, of
7 which \$22,000,000 is authorized from the Nuclear
8 Waste Fund.

9 (2) FISCAL YEAR 1995.—\$546,800,000 for fiscal
10 year 1995, to remain available until expended, of
11 which \$22,000,000 is authorized from the Nuclear
12 Waste Fund.

13 (b) OFFICE OF INSPECTOR GENERAL.—There are
14 authorized to be appropriated to the Nuclear Regulatory
15 Commission's Office of Inspector General, in accordance
16 with the provisions of section 1105(a)(25) of title 31,
17 United States Code, the following amounts:

18 (1) FISCAL YEAR 1994.—\$4,800,000 for fiscal
19 year 1994, to remain available until expended.

20 (2) FISCAL YEAR 1995.—\$5,000,000 for fiscal
21 year 1995, to remain available until expended.

22 **SEC. 3. ALLOCATION OF AMOUNTS AUTHORIZED.**

23 (a) IN GENERAL.—The amounts authorized to be ap-
24 propriated under section 2(a) for fiscal years 1994 and
25 1995 shall be allocated as follows:

1 (1) REACTOR SAFETY AND SAFEGUARDS REGU-
2 LATION.—Not more than \$163,807,000 for fiscal
3 year 1994, and not more than \$168,005,000 for fis-
4 cal year 1995, may be used for “Reactor Safety and
5 Safeguards Regulation”.

6 (2) REACTOR SAFETY RESEARCH.—Not more
7 than \$99,969,000 for fiscal year 1994, and not more
8 than \$98,339,000 for fiscal year 1995, may be used
9 for “Reactor Safety Research”.

10 (3) NUCLEAR MATERIAL AND LOW-LEVEL
11 WASTE SAFETY AND SAFEGUARDS REGULATION.—
12 Not more than \$61,880,000 for fiscal year 1994,
13 and not more than \$63,025,000 for fiscal year 1995,
14 may be used for “Nuclear Material and Low-Level
15 Waste Safety and Safeguards Regulation”.

16 (4) HIGH-LEVEL NUCLEAR WASTE REGULA-
17 TION.—Not more than \$22,000,000 for fiscal year
18 1994 from the Nuclear Waste Fund, and not more
19 than \$22,000,000 for fiscal year 1995 from the Nu-
20 clear Waste Fund, may be used for “High-Level Nu-
21 clear Waste Regulation”.

22 (5) REACTOR SPECIAL AND INDEPENDENT RE-
23 VIEWS, INVESTIGATIONS, AND ENFORCEMENT.—Not
24 more than \$31,000,000 for fiscal year 1994, and not
25 more than \$31,369,000 for fiscal year 1995, may be

1 used for "Reactor Special and Independent Reviews,
2 Investigations, and Enforcement".

3 (6) NUCLEAR SAFETY MANAGEMENT AND SUP-
4 PORT.—Not more than \$164,244,000 for fiscal year
5 1994, and not more than \$164,062,000 for fiscal
6 year 1995, may be used for "Nuclear Safety Man-
7 agement and Support".

8 (b) LIMITATIONS.—The Nuclear Regulatory Commis-
9 sion may not use more than 1 percent of the amounts allo-
10 cated under subsection (a) to exercise its authority under
11 section 31 a. of the Atomic Energy Act of 1954 (42 U.S.C.
12 2051(a)) to enter into grants and cooperative agreements
13 with organizations such as universities, State and local
14 governments, and not-for-profit institutions. Grants made
15 by the Commission shall be made in accordance with chap-
16 ter 63 of title 31, United States Code, and other applicable
17 law.

18 (c) REALLOCATION.—

19 (1) IN GENERAL.—Except as provided in para-
20 graphs (2) and (3), any amount allocated for a fiscal
21 year pursuant to any paragraph of subsection (a) for
22 purposes of the program referred to in any such
23 paragraph may be reallocated by the Nuclear Regu-
24 latory Commission for use in a program referred to

1 in any other paragraph of such subsection, or for
2 use in any other activity within a program.

3 (2) LIMITATION.—The amount available from
4 appropriations in any fiscal year for use in any pro-
5 gram or activity specified in subsection (a) may not,
6 as a result of reallocations made under paragraph
7 (1), be increased or reduced by more than \$500,000,
8 unless the Nuclear Regulatory Commission submits
9 advance notification of such reallocation to the Com-
10 mittee on Energy and Commerce and the Committee
11 on Natural Resources of the House of Representa-
12 tives and the Committee on Environment and Public
13 Works of the Senate. Such notification shall contain
14 a full and complete statement of the reallocation to
15 be made and the facts and circumstances relied upon
16 in support of such reallocation.

17 (3) NUCLEAR WASTE FUND.—Funds authorized
18 to be appropriated from the Nuclear Waste Fund
19 may be used only for the high-level nuclear waste ac-
20 tivities of the Nuclear Regulatory Commission and
21 may not be reprogrammed for other Commission ac-
22 tivities.

23 **SEC. 4. RETENTION OF CERTAIN FUNDS.**

24 Money received by the Nuclear Regulatory Commis-
25 sion for the cooperative nuclear safety research program,

1 services rendered to foreign governments and international
2 organizations, and the material and information access au-
3 thorization programs (including criminal history checks
4 under section 149 of the Atomic Energy Act of 1954 (42
5 U.S.C. 2169)) may be retained and used, subject to appro-
6 priations, for salaries and expenses associated with such
7 activities, notwithstanding the provisions of section 3302
8 of title 31, United States Code, and shall remain available
9 until expended.

10 **SEC. 5. TRANSFER OF CERTAIN FUNDS.**

11 From amounts appropriated to the Nuclear Regu-
12 latory Commission pursuant to section 2(a), except for ap-
13 propriations from the Nuclear Waste Fund, the Commis-
14 sion may transfer amounts to its Office of Inspector Gen-
15 eral, except that the total amount so transferred during
16 any fiscal year may not exceed 5 percent of the amount
17 authorized under section 2(b) for such fiscal year.

18 **SEC. 6. LIMITATION ON SPENDING AUTHORITY.**

19 Notwithstanding any other provision of this Act, no
20 authority to make payments under this Act shall be effec-
21 tive except to such extent or in such amounts as are pro-
22 vided in advance in appropriation Acts.

○

Mr. LEHMAN. The second bill we're going to consider today, H.R. 2170, is a package of amendments to the Energy Reorganization Act and Atomic Energy Act that has been proposed for several years by the Commission. These amendments generally plug holes in various aspects of the Commission's enforcement authority over licensees as well as contractors and suppliers to licensees and others whose actions might pose threats to nuclear safety.

The NRC legislative package deals with notification requirements on licensees, civil monetary penalties, elimination of a congressional reporting requirement for the Advisory Committee on Reactor Safeguards, carrying of firearms by licensee employees, unauthorized introduction of dangerous weapons at regulated facilities, sabotage during facility construction, and administrative search warrants.

I will leave it to Chairman Selin to describe these amendments more fully in the Commission's testimony.

[Text of the bill, H.R. 2170, follows:]

103D CONGRESS
1ST SESSION

H. R. 2170

To amend the Energy Reorganization Act of 1974 and the Atomic Energy Act of 1954 to enhance the safety and security of nuclear power facilities, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 1993

Mr. LEHMAN (by request) introduced the following bill; which was referred jointly to the Committees on Energy and Commerce, Natural Resources, and the Judiciary

A BILL

To amend the Energy Reorganization Act of 1974 and the Atomic Energy Act of 1954 to enhance the safety and security of nuclear power facilities, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Omnibus Nuclear
5 Power Safety and Security Enhancement Act of 1993".

6 **SEC. 2. NOTIFICATION REQUIREMENTS.**

7 Section 206 of the Energy Reorganization Act of
8 1974 (42 U.S.C. 5846) is amended to read as follows:

1 "NONCOMPLIANCE

2 "SEC. 206. (a) Any person constructing, owning, op-
3 erating, or supplying a component of any facility or activ-
4 ity which is licensed or otherwise regulated by the Com-
5 mission pursuant to the Atomic Energy Act of 1954 (in-
6 cluding any facility leased by the United States Enrich-
7 ment Corporation), or pursuant to this Act, who obtains
8 information reasonably indicating that such facility or ac-
9 tivity or basic component supplied to such facility or
10 activity—

11 "(1) contains a defect; or

12 "(2) fails to comply with the Atomic Energy
13 Act of 1954 or any applicable rule, regulation, order,
14 or license of the Commission;

15 shall immediately notify the Commission of such defect or
16 failure to comply if such defect or failure to comply could
17 create a substantial safety hazard as defined by the regu-
18 lations promulgated by the Commission, unless such per-
19 son has actual knowledge that the Commission has been
20 informed in writing of such defect or failure to comply.

21 "(b) The Commission may issue such regulations and
22 orders as it deems necessary to ensure compliance with
23 this section, including regulations and orders requiring
24 any person subject to this section to devise and implement
25 procedures to identify, evaluate, and report defects and

1 failures to comply subject to the notification requirements
2 of subsection (a).

3 “(c)(1) Except as provided in paragraph (2), any per-
4 son who fails to provide a notification required by sub-
5 section (a), or who violates any regulation or order issued
6 under subsection (b), shall be subject to a civil penalty
7 in the same manner and amount as provided for violations
8 subject to a civil penalty under section 234 of the Atomic
9 Energy Act of 1954 (42 U.S.C. 2282).

10 “(2) An individual who is subject to the requirements
11 of this section solely because of employment by a person
12 subject to those requirements shall only be assessed a civil
13 penalty for failure to provide notice pursuant to subsection
14 (a) if such individual has actual knowledge of the report-
15 ing requirement imposed by subsection (a) and of a defect
16 as provided in subsection (a)(1) or of a failure of compli-
17 ance as provided in subsection (a)(2).

18 “(d) The requirements of this section shall be pre-
19 eminently posted on the business premises of any person
20 who is required to notify the Commission of a defect or
21 failure to comply under subsection (a).

22 “(e) The Commission may conduct such reasonable
23 inspections, investigations, and other enforcement activi-
24 ties as it deems necessary to ensure compliance with the

4.

1 provisions of this section and with any regulations and or-
2 ders issued thereunder.

3 “(f) For purposes of this section, the term ‘person’
4 has the same meaning as in section 11 s. of the Atomic
5 Energy Act of 1954 (42 U.S.C. 2014(s)), except that—

6 “(1) it also includes the Department of Energy
7 with respect to facilities of the Department regu-
8 lated by the Commission and with respect to any
9 item provided by the Department as a component to
10 a licensee; and

11 “(2) it does not include an individual unless he
12 or she is—

13 “(A) a sole proprietor or partner of a busi-
14 ness that constructs, owns, operates, or supplies
15 a component covered by subsection (a) of this
16 section; or

17 “(B) a director or responsible officer em-
18 ployed by a person subject to that subsection.

19 “(g) This section shall apply to the United States En-
20 richment Corporation and facilities leased by the Corpora-
21 tion, and to its directors and officers, to the same extent
22 as any other person subject to this section.”.

1 **SEC. 3. CIVIL MONETARY PENALTIES FOR VIOLATIONS OF**
2 **RULES, REGULATIONS, ORDERS, OR LICENS-**
3 **ING REQUIREMENTS.**

4 (a) IN GENERAL.—Section 234 a. of the Atomic En-
5 ergy Act of 1954 (42 U.S.C. 2282(a)) is amended to read
6 as follows:

7 “a. Any person who—

8 “(1) violates—

9 “(A) any licensing provision of section 53,
10 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109,
11 or any rule, regulation, or order issued there-
12 under;

13 “(B) the certification provisions of section
14 1701, or any rule or regulation issued there-
15 under;

16 “(C) any term, condition, or limitation of
17 any license or certification issued under any
18 section referred to in subparagraph (A) or (B);
19 or

20 “(D) any rule, regulation, or order issued
21 under subsection b., i., or o. of section 161; or

22 “(2) commits any violation for which a license
23 may be revoked under section 186;

24 shall be subject to a civil penalty, to be imposed by the
25 Commission, of not to exceed \$100,000 for each such vio-
26 lation. If any violation is a continuing one, each day of

1 such violation shall constitute a separate violation for the
2 purpose of computing the applicable civil penalty. The
3 Commission shall have the power to compromise, mitigate,
4 or remit such penalties.”.

5 (b) CONFORMING AMENDMENTS.—

6 (1) The heading of section 234 of the Atomic
7 Energy Act of 1954 (42 U.S.C. 2282) is amended
8 to read as follows:

9 “SEC. 234. CIVIL MONETARY PENALTIES FOR VIO-
10 LATIONS OF RULES, REGULATIONS, ORDERS, OR LICENS-
11 ING REQUIREMENTS.—”.

12 (2) The table of contents of the Atomic Energy
13 Act of 1954 (42 U.S.C. 2011 prec.) is amended by
14 striking the item relating to section 234 and insert-
15 ing the following:

“Sec. 234. Civil monetary penalties for violations of rules, regulations, orders,
or licensing requirements.”.

16 **SEC. 4. ADVISORY COMMITTEE ON REACTOR SAFEGUARDS.**

17 Section 29 of the Atomic Energy Act of 1954 (42
18 U.S.C. 2039) is amended by striking the last 2 sentences.

19 **SEC. 5. CARRYING OF FIREARMS BY LICENSEE EMPLOY-**
20 **EES.**

21 Section 161 k. of the Atomic Energy Act of 1954 (42
22 U.S.C. 2201(k)) is amended—

1 (1) in the 1st complete sentence, by inserting
2 "and licensees (including employees of contractors of
3 licensees)" after "(at any tier)";

4 (2) in the 1st complete sentence, by striking
5 "owned by or contracted to the United States or
6 being transported to or from such facilities" and in-
7 serting the following: "owned by or contracted to the
8 United States or licensed by the Commission, or
9 being transported to or from such facilities,";

10 (3) in the 4th complete sentence, by inserting
11 "or a licensee of the Commission" after "or a con-
12 tractor of the Department of Energy or Nuclear
13 Regulatory Commission"; and

14 (4) in the last sentence, by inserting "and the
15 Commission" after "The Secretary".

16 **SEC. 6. UNAUTHORIZED INTRODUCTION OF DANGEROUS**
17 **WEAPONS.**

18 Section 229 a. of the Atomic Energy Act of 1954 (42
19 U.S.C. 2278a(a)) is amended by inserting after "custody
20 of the Commission" the following: "or subject to its licens-
21 ing authority under this Act or any other Act".

1 **SEC. 7. SABOTAGE OF PRODUCTION, UTILIZATION, OR**
2 **WASTE STORAGE FACILITIES UNDER CON-**
3 **STRUCTION.**

4 Section 236 a. of the Atomic Energy Act of 1954 (42
5 U.S.C. 2284(a)) is amended to read as follows:

6 "a. Any person who intentionally and willfully de-
7 stroys or causes physical damage to, or who intentionally
8 and willfully attempts to destroy or cause physical damage
9 to—

10 "(1) any production facility or utilization facil-
11 ity licensed under this Act;

12 "(2) any nuclear waste storage facility licensed
13 under this Act;

14 "(3) any production, utilization, or waste stor-
15 age facility subject to licensing under this Act dur-
16 ing its construction where the destruction or damage
17 caused or attempted to be caused could affect public
18 health and safety during the operation of the facil-
19 ity;

20 "(4) any nuclear fuel for a utilization facility li-
21 censed under this Act, or any spent nuclear fuel
22 from such a facility; or

23 "(5) any uranium enrichment facility regulated
24 by the Nuclear Regulatory Commission;

25 shall be fined not more than \$10,000 or imprisoned for
26 not more than 10 years, or both."

1 **SEC. 8. ADMINISTRATIVE SEARCH WARRANTS.**

2 Section 161 c. of the Atomic Energy Act of 1954 (42
3 U.S.C. 2201(c)) is amended to read as follows:

4 "c. (1) Make such studies and investigations,
5 obtain such information, and hold such meetings or
6 hearings as the Commission may deem necessary or
7 proper to assist it in exercising any authority pro-
8 vided in this Act, or in the administration or en-
9 forcement of this Act, or any regulations or orders
10 issued thereunder. For such purposes the Commis-
11 sion is authorized—

12 "(A) to administer oaths and affirmations;

13 "(B) by subpoena, to require any person to
14 appear and testify or appear and produce docu-
15 ments, or both, at any designated place;

16 "(C) to conduct searches without a war-
17 rant of the premises of applicants, licensees,
18 and other persons subject to section 206 of the
19 Energy Reorganization Act of 1974 (42 U.S.C.
20 5846); and

21 "(D) by judicially approved, administrative
22 search warrant, to enter at reasonable times
23 premises under the control of any person not
24 covered by subparagraph (C) who is subject to
25 the Commission's jurisdiction.

1 “(2) Before a warrant is issued pursuant to
2 paragraph (1)(D), the Commission shall establish
3 that it has a reasonable suspicion that a violation of
4 a Federal statute or a Commission regulatory re-
5 quirement has been or will be committed. A search
6 pursuant to such a warrant shall be effected only for
7 purposes directly related to the basis for the war-
8 rant, and each such search shall be commenced and
9 completed with reasonable promptness.

10 “(3) Witnesses subpoenaed pursuant to para-
11 graph (1)(B) shall be paid the same fees and mile-
12 age as are paid witnesses in the district courts of the
13 United States.”.

○

Mr. LEHMAN. At this time, I would like to recognize for opening remarks the ranking member of the Subcommittee, the gentlewoman from Nevada, Mrs. Vucanovich.

STATEMENT OF HON. BARBARA F. VUCANOVICH

Mrs. VUCANOVICH. Thank you very much, Mr. Chairman. I thank you for holding this hearing.

In general, I have no problem with the legislative package. In fact, I am encouraged by the provision which would increase and expand the application of civil penalties for violations of the NRC requirements. I believe the Commission should remain ever vigilant and aggressive in the prosecution of violations of its rules and regulations.

I am concerned, however, about the provision which would allow the NRC to use administrative search warrants in lieu of criminal search warrants in some cases. This is language which should be examined carefully.

There are also a number of troubling programmatic issues that the NRC is dealing with which I know are of interest to members of the Committee, and I look forward to hearing about them, particularly steam generator issues and Thermo-Lag.

Of particular interest and concern to me this morning, Mr. Chairman, is the NRC's reaction to the release yesterday of a GAO report which concludes what we in Nevada have known for some time that the DOE has been pursuing an unrealistic deadline in their activities at Yucca Mountain and compromising scientific study in the process.

Now the GAO says that due to scientific uncertainties, technical activities to characterize the site may take as long as thirteen years longer than expected. The GAO also concludes that there simply is no way that a MRS will be ready by 1998. But perhaps most important, Mr. Chairman, the GAO calls for an independent review of the program. Legislation I introduced a few weeks ago also calls for an independent review.

In light of GAO's findings, I look forward to hearing from Chairman Selin about what the pace of NRC activities at Yucca Mountain will be in the future and how that might affect the NRC budget this year and next.

With that, I would be very happy to listen to the witnesses. Thank you, Mr. Chairman.

Mr. LEHMAN. Thank you very much.

I would like to recognize at this time the Chairman of the Energy and Power Committee of the Energy and Commerce Committee, Phil Sharp.

STATEMENT OF HON. PHILIP R. SHARP

Mr. SHARP. I appreciate that, Mr. Chairman. I am delighted to be here and regret I am not going to be able to stay.

I don't have any direct comments relative to actual reauthorization of the Commission. I would just express a concern, which we will be discussing here and in other forums around the country, I am sure, about what is going to happen in terms of plant life extension in two respects.

One is, what, if anything, the NRC will do on its own in the absence of applications to extend, since we have had a change in the status, as I understand it, of I believe two utilities that originally were going to extend.

And, secondly, related to that is whether we are running into public utility commissions around the country who are unwilling to pass through safety investments that the NRC believes are essential to safe operation. Whether that is becoming a practical inhibition to dealing with electric—the electric utility system and nuclear power and generation by nuclear. I simply don't know.

Mr. Chairman, I am just going to kind of leave those questions hanging.

I compliment you on your work. Today is sort of a higher priority, I think, for most people since this is when we are going to actually vote on the biggest deficit reduction package in the history of the country. And if we can get a majority of people to do that, and some of us believe it is imperative that we get that job done.

Thank you.

Mr. LEHMAN. Thank you very much.

I recognize the gentleman from Wyoming, Mr. Thomas.

STATEMENT OF HON. CRAIG THOMAS

Mr. THOMAS. Thank you. Some of us are not quite that dedicated to that proposition.

Mr. SHARP. At least one of us here this morning. [Laughter.]

Mr. THOMAS. At any rate, thank you very much for having the hearing and thank all of you for the tough job you're doing; I know it is a hard one. And it is a little like political things, whatever you do is wrong according to somebody.

I am a supporter of nuclear power. And I have always hoped that we would be able to move forward, particularly in the generation of electricity. It seems to me to make sense.

But we are not. And I suppose one of the general topics that I would like you to address a little bit is, if that is the case, if we are not having applications for licensing and so on, is there a reason for your activity to be less involved and less expensive than it has been in the past? I suppose that involves things like consolidation and this and that. But I think those are things that we do need to talk about.

I do have some concerns that I suppose are relatively minor in terms of the finances, but are very major. And I am talking about the charges that are levied against highway construction companies and well loggers and others. Last year a Wyoming contractor was billed at the rate of \$2,400 an hour for an NRC person to inspect soil density gauges, \$2,500 in material costs, even though the previous year it was \$1,400; \$380 I'm told to process a change of address in NRC records.

Now, it is important, the notion of fees. But, clearly, these are fees in a sort of peripheral area that are particularly expensive. And I would be interested to hear some comments on that.

We are pleased that you're here. And I am anxious to hear the testimony.

Thank you, sir.

Mr. LEHMAN. Thank you very much.

And once again, I want to welcome each of the commissioners here. We certainly appreciate your taking the time to be with us this morning and we understand the Chairman will do the talking.

So, Chairman Selin, we recognize you. Without objection, we will put your full statement and any other materials you have for submission in the record. You may proceed.

STATEMENT OF HON. IVAN SELIN, CHAIRMAN, NUCLEAR REGULATORY COMMISSION

Mr. SELIN. Thank you, Mr. Chairman. And thank you for your warm opening remarks.

I will try to answer, in my opening remarks, each of the points that have been raised, even though they are not in the prepared testimony.

We are very pleased to be with you to discuss the two bills, 2143 and 2170. We particularly appreciate your interest and support for these bills. We look forward to working with you as they progress through the Congress. We, too, look forward to the possibility of having authorization bills as well as appropriations, since they set out so much of our objectives and our goals and the guidance that we get from the Congress.

Before discussing the details of our budget, I would like to provide a light overall perspective on our principal programs and explain how we use our resources to fulfill our statutory mission.

About fifty-five percent of our budget request is directed toward the conduct of our regulatory program for nuclear reactors. We have a chart up here, and all you really have to see is that the big numbers are bad and small numbers are good. And these three general measures of performance have been going down over time.

In other words, performance of the overall set of nuclear reactors in the United States has been improving steadily at least over the last ten years. In fact, we are now to the point where the better performers appear to have reached plateaus where current performance levels are close to reasonable expectations. But the poorer reactors lag significantly behind the better ones in performance.

We've come to the conclusion that perhaps the most fruitful way for us to further reduce overall reactor risk is to concentrate our efforts on the poorer performers to bring them up to the level already reached by the better performers. This is a very important observation. And clearly a judgment on who are the better performers and who are not the better performers is a critical judgment.

The principal basis for judging licensee performance is what we call the Systematic Assessment of Licensee Performance, or SALP, program. The principal purpose of this integrated SALP review is to direct both NRC resources and licensee resources precisely to those areas that could most sharply affect safety and that need improvement.

The NRC's reactor oversight includes reactor inspections, particularly with the assignment of at least two resident inspectors to each reactor site. In an effort to improve the inspection process, we are modifying the SALP program and the reactor inspection program to focus even more on safety-significant performance. We will place more emphasis on SALP results in moving NRC inspection

resources from the better performers to make sure that we focus on the poorer performers.

Safety will be ensured while costs to the better performing plants will be reduced, which we think will provide additional incentives for plants to improve their performance.

Before I move to some of the newer topics, I perhaps might address several of the issues that were raised by members of the Committee.

As far as the Thermo-Lag issue is concerned, we have a thorough program in place to make sure that every plant in the country that relies on passive barriers rather than separation of the redundant safety systems will do a self-assessment, and this self-assessment will be inspected by our people before they go forward.

Thermo-Lag, quite frankly, is just the shorthand. We are concerned about all safety barriers, whether they are Thermo-Lag or some other factors. In fact, there is some information to suggest the problem may not be limited to Thermo-Lag.

As I went into some detail before Chairman Dingell's committee, there are a lot of things to be done. We are quite confident that the interim steps to protect the safety in the plants are quite strong. And it will take probably two years before every one of the plants is up to a satisfactory material condition.

We are not worried about the health and safety in the interim, given the fire watches and other interim measures that are being taken. These are expensive, they require constant vigilance, they are not very good in the long run, and the sooner the plants get away from these interim measures and the sooner they get to a satisfactory physical condition, the happier we all will be.

As far as steam generators are concerned, there's a very interesting problem here. The original—first of all, fifty percent of the pressure vessel boundary, in other words, the boundary that keeps the high-pressure steam in the primary system, which comes in contact with the radio-active fuel, the boundary which contains this high-pressure steam, fifty percent of that boundary occurs within the steam generator.

So leaks from the primary system to the secondary system in steam generators in pressurized water reactors are of very serious concern to us, to the licensees, to the general public, and, of course, to your Committee.

The original concern when the reactors were first put out was that there would be overall corrosion to—I should describe what a steam generator is.

What you have is a circuit that passes water over—water under very, very high pressure, over the reactor fuel, carries away the heat from the fuel, and it goes through a set of tubes. There could be fifteen hundred tubes in a steam generator. And that pressure is kept so high that the water doesn't boil. And then a second water circuit passes in an outside tube.

So you have inside the tube in which the primary water is flowing and then outside the tube in which the secondary water is flowing that is turned to steam by the transfer of heat over this pressure boundary. And that heated water, the steam, goes and it turns the turbine and it does the useful work.

In a pressurized water reactor, there can be two, three, or four steam generators. And the integrity of the inner tube, the tube that contains the pressurized water in the primary system, is absolutely critical to the safety of the system.

We have rules that allow a certain number of these tubes to be plugged in case of leakages. They tend to be ten percent or so of the tubes, and no more than that may be set.

The original concern was that the primary water tube would eventually corrode, the wall would become thin, and there would be a risk that, in case of an accident where the steam in the secondary escaped, and therefore where the back pressure went down, that tube would burst and there would be a loss of primary water, which is very bad, because then there wouldn't be water to cool the reactor. And the original tests that were set up were set up to look for a thinning of the walls.

Well, it turns out that, because of a lot of improvements in chemistry and management, that that's not such a serious concern. The serious concern these days is that there will not be general thinning of the walls but small cracks in the wall which, in the case of loss of pressure from the outside tube, could themselves leak.

The techniques that we had for measuring the integrity of the steam generator don't apply to small cracks. They really apply to general thinning. So we've had to come up with some new techniques. And the whole discussion has been what is a safe surrogate for this new kind of concern, rather than the original concern.

And we think that we have a pretty good story on this. But there is some technical—some range of technical opinions as to how to measure for very small, very deep cracks, and how dangerous they are.

In short, that's the steam generator issue.

As far as Congressman Sharp's question about public utility commissions, we don't have any example of a public utility commission refusing to put into the base improvements that we've ordered plants to do from a safety point of view. But, on a broader question, there is a serious concern that many observers of the industry have that investments in maintaining and operating nuclear power plants are examined on too short a payback period, and that therefore these investments are discouraged.

A particular example is the San Onofre plant in California, where our people required a number of major changes, over \$100 million of capital investment, to be put into that plant that was to continue to operate. And the California Public Utility Commission and the utility came to an agreement that rather than make these investments, they would close the plant. That's a legitimate commercial consideration, but it was driven by safety considerations.

Now, turning to the next question that was raised, namely the renewal of operating licenses, older American nuclear power plants in many cases are facing expiration of their original forty-year operating licenses. The operating license of the first plant that might seek license renewal expires in 2006, and a ten- to fifteen-year lead time is necessary for licensees to plan for license renewal or for alternative new capacity. So this is a timely question now.

As Congressman Sharp pointed out, the two—the original idea was that two specific plants would come in with applications and that these applications would be a good test of the process. But that turned out not to be so.

Both plants have withdrawn their applications for reasons that, in most cases, have little to do with the license renewal and are tied very much to plant-specific purposes.

So, instead, the plant, the staff, and industry have been looking for a more generic approach to license renewal. And in fact the NRC staff has developed a process for implementing the license renewal rule, which focuses on the effective management of those ageing effects which impact on safety during the twenty years, from forty to sixty years.

The specifics of this process represent an approach to implementation not expressly addressed at the time that the rule was promulgated. The Commission has made available to the public several papers detailing the staff's approach and our decision on whether and how best to implement the new approach or the variation of the new approach is imminent.

As far as the longer term question comes, the question that was raised by Mrs. Vucanovich about—and Mr. Thomas both, about what is the future of the industry and what should we be doing there. For the longer term the NRC has established a process to review future nuclear reactor designs which make it possible to resolve safety and environmental issues before rather than after the start of nuclear power plant construction.

The key to the process is the safety certification of standardized designs well before a utility develops a construction plan. We have four applications in hand. The first two, which represent pretty straightforward extensions of current technology are well along. We expect that it is possible that safety evaluations will be done by the summer of 1994 through the staff. The next two, which are more advanced designed—they involve different approaches to safety systems—will probably take a year longer to go forward.

To answer Congressman Thomas' question, we believe that these processes are extremely important, not only for the future of nuclear power in the United States, but really for the future of nuclear power around the world. The safety evaluations are oriented toward deployment in the United States. Many other countries, and many other utilities depend on them as well.

As Chairman Lehman pointed out, we have been able to accommodate the work that's going on in this area by making other reductions in our current budget and having a small decrease in real cost to our budget while taking on this additional work.

Switching to nuclear material, about fifteen percent of our budget request is devoted to ensuring the safe disposal of nuclear waste and the safe use and transport of nuclear materials. We are asking for a small increase in this program, entirely to deal with the additional responsibilities that the Energy Policy Act gave us last year, namely for the certification of the safety of the two enrichment plants that will transfer on July 1 to the United States Enrichment Corporation.

As far as nuclear waste is concerned, there has been a lot of attention paid not only to high-level waste, as Mrs. Vucanovich has

brought in, but to low-level waste. This is a fairly complicated system, since the main responsibility falls upon the states. We do have a responsibility both for encouraging the states to go forward and for taking a look at our regulations to make it clear what it will take to satisfy us that state compact sites are satisfactory.

There has been good news and bad news in the last year. Clearly the states are not making the schedules that were called for in the Low-Level Waste Policy Act and in the amendments act. On the other hand, there are three states, three compacts, that are operating now. The Northwest and Rocky Mountain Compact seems to be fairly stable. The trend toward lower waste volume has continued to the point where current disposal requirements are only about half of what they were ten years ago.

To summarize a very complicated situation, there are three potential sites and important decision points, and I think this next year we will see whether they go forward or whether there are really serious problems in the program.

In my statement, I discuss at some length the discussion of the medical use of byproduct material. I won't go into that great depth right now except to point out that we do pose an issue, which is a prime issue for any kind of an authorization bill, and that is, what's the proper authority for the NRC in regulating the medical uses? We have a rather extensive program. Some weaknesses have been found, but basically it's a sound program. But it only covers about twenty-five percent of the therapeutic uses of radiation to fight cancer.

So a fair question in our mind has been whether continuation of the existing scheme is the best way to use limited resources to achieve the goal of protection of the public. And we have given some thought to alternatives.

Among the options that we are looking at are, first, to maintain the current program. The second, to pull back NRC's regulatory involvement to concentrate on approval of the devices, but leaving to the states the job to regulate the medical use of the devices. The third option is similar to the second, except that we would also continue to write standards and guidelines for the use of the devices, but still leave the states the licensing and inspection process.

And the fourth would go the other way, which would be to do something like what we do today, but not just to limit the byproduct resources to byproduct materials, but to extend our regulation to cover all sources of radiation for therapy, which means in particular, linear accelerators as well. These new options would all require legislation.

We plan to provide Congress with an interim report on our effort to come to grips with this issue by August 6 of this year.

Turning to management and support, about 30 percent of our budget request is for day-to-day management of the agency and the normal housekeeping costs associated with keeping the agency doors open. Even in this area, we have assumed significant new responsibilities in the past several years: the establishment of an Inspector General, our increased international activities, collection of license fees at a hundred percent reimbursement, implementation of the Chief Financial Officer's Act, and our internal project of consolidating our headquarters facilities.

There are some very interesting things going on in the international area. I won't take the time to go over too much of them, except to point out we are playing an active role in the U.S. government's attempts to support nuclear safety initiatives in the former Soviet Union and in eastern Europe. And as far as the more growing areas, we have twenty-seven technical exchange agreements. We are very deeply involved in setting up or helping the countries set up regulatory regimes in east Asia in particular, and these are areas that are actively in the nuclear generating business and expanding their activities. These agreements help foreign nuclear regulatory organizations to create a regulatory environment similar to what we have here in the United States.

I might digress a minute to talk to Congressman Thomas' question about fees. We are, in fact, required to collect a hundred percent of our expenses through fees, either fixed fees or variable fees, license fees and service fees, except for that which comes from the nuclear—the high-level waste fund.

We don't really think that this is completely fair. There are activities that we carry out on behalf of the federal government that we believe ought to be covered by appropriations without reimbursement. The process was set up in the Energy Policy Act of 1992 for us to go out for comments to ask specific and general questions to get all this information, and then to come back and propose legislation.

I would like to point out that, first of all, it's not our decision whether we be a hundred percent fee-reimbursed or not. That is clearly a question of overall policy.

But from a management point of view, we see a number of advantages in being in the hundred percent fee-reimbursement area. It really does sharpen our attention to what we do and whether we do it efficiently. When we see high prices or activities which, on the face of them, don't seem to warrant these prices, we make sure that we go back and pay attention to reducing not only our costs, but our actual efforts in these areas.

Furthermore, it's hard to say I welcome the increased attention that we get from yourselves and all your constituents, but I do think it leads to good government. So we are generally quite happy with the fee reimbursement system, and we are going through the process calling for it.

On the specific questions that you raised, Mr. Thomas, the change of address is not correctly described. When somebody moves their—where they keep their nuclear materials, the dangerous nuclear materials, from one facility to another facility, we have to go out and inspect the second facility to make sure it is an appropriate place to move these materials. So it is not just changing the paper.

If they change from, say, a P.O. box to a street address, we don't charge for that. But if they move from one physical facility to another facility, that involves an inspection, et cetera. And I think we can handle your other questions in some detail at the appropriate point.

I would like to stress the openness of our NRC process. I think most of you are quite familiar with the changes we made in the last several years, so I won't spend too much time with that. And

then I would like to move to the legislative proposals, Mr. Chairman.

As I said before, we are most appreciative of your interest in the legislation's recommendations. I discuss in detail in the statements and you precisely summarized them in your opening statement.

Rather than going through each of them, perhaps I might talk about the one amendment that we've asked for which deals with the so-called administrative search warrant. First of all, the search warrants would have to be obtained as any other search warrant would have to be obtained, with a judge's consent. We are not asking for the authority that the Commission itself could just issue search warrants.

We would use these in situations where we have reason to believe that a licensee or nonlicensee might have counterfeit parts or records to show that what they said they had done they had not done, either records or evidence that might be destroyed by taking the time to go to court to get a subpoena, which is an open process where they can contest the subpoena, et cetera.

The staff tells us that two to three times a year, we would have used this process if we had it.

There is no other way to—unless statute permits you specifically to ask for an administrative or civil search warrant, the courts will not normally grant a search warrant. They will tell you, go get a subpoena; if the Congress wants you to have a search warrant, the Congress would have given you that authority. And criminal search warrants are really not a substitute for this.

In many cases we don't suspect or we can't meet the burden of proof for a criminal investigation. And, in any event, the process for getting a criminal subpoena is too complicated. You have to go to the US attorney, he doesn't know the Atomic Energy Act, he's got a lot of other things to do that are more pressing. It just doesn't really work.

So I think that this particular piece, in my opinion, is the highest priority of the process. It's a very limited authority that we're asking for, and we think it is quite a well justified one.

As far as the budget goes, you quite accurately and, I think generously, described our modest financial goals and recognized the responsible resource management that we've taken into steps. In fact, well before submitting our request to OMB, we undertook an aggressive, thorough review of our programs that led to a streamlined budget request to OMB and a streamlined budget request to the Congress.

We are budgeting increased resources to keep pace with industry activities associated with such items as reactor license renewal, and the safety reviews associated with certifying new power reactor designs.

In short, we have tried to keep a step ahead of events. By so doing, we think we've been able to undertake additional responsibilities and invest in those programs which affect the future while slightly reducing our budget in real terms. We will continue to do all this in a transparent manner that facilitates public understanding of our regulatory process.

I might point out that it's not easy to reduce fifty positions a year, in other words, a total of one hundred fifty positions over

three years from an organization of roughly three thousand positions. That creates pain and problems, for instance, for a number of your constituents. It creates pain for many parts of what we are doing. But it is an across-the-board attempt to be more efficient and more frugal, not picking out a couple of activities for unreasonable attention.

Mr. Chairman, members of the Subcommittee, this concludes our statement. My fellow commissioners and I will be pleased to answer any questions that you and the Subcommittee may have.

Thank you, sir.

[Prepared statement of Mr. Selin and attachments follow:]

STATEMENT SUBMITTED BY

UNITED STATES NUCLEAR REGULATORY COMMISSION

TO THE

SUBCOMMITTEE ON ENERGY AND MINERAL RESOURCES

COMMITTEE ON NATURAL RESOURCES

UNITED STATES HOUSE OF REPRESENTATIVES

CONCERNING

THE NUCLEAR REGULATORY COMMISSION AUTHORIZATION

FOR FISCAL YEARS 1994-1995

AND

LEGISLATIVE PROPOSALS

PRESENTED BY

IVAN SELIN

CHAIRMAN

SUBMITTED: May 27, 1993

FISCAL YEARS 1994-1995 AUTHORIZATION TESTIMONY

Mr. Chairman and members of the Subcommittee, we are pleased to appear before you to discuss H. R. 2143, the Nuclear Regulatory Commission's (NRC) authorization for fiscal years 1994 and 1995, and H. R. 2170, the Omnibus Nuclear Power Safety and Security Enhancement Act of 1993. We appreciate your interest and support for these bills, and look forward to working with you as they progress through Congress. Accompanying me today are Commissioners Rogers, Curtiss, Remick, and de Planque, the NRC's Executive Director for Operations and Chief Financial Officer, the General Counsel, and the Inspector General.

The NRC is responsible for ensuring that civilian uses of nuclear materials in the United States -- in the operations of commercial nuclear power plants, and in medical, academic, and industrial applications -- are carried out in a way which will adequately protect the public health and safety, the environment, and the national security. In implementing regulations we work to prevent unnecessary road blocks for the industry we regulate while ensuring that our responsibility to public health and safety is not compromised.

Before discussing the details of our budget we would like to provide an overall perspective on the NRC's principal programs and explain how we are using our resources to fulfill our statutory mission.

NUCLEAR REACTORS

Approximately 55 percent of the NRC's budget request is directed to the conduct of our regulatory program for commercial nuclear reactors. The major part of these resources is directed to overseeing and improving the overall safety performance of operating reactors and conducting the research necessary to support such regulatory activities. Our reactor program also includes resources to extend the license terms for operating reactors and to certify new light water reactor designs.

Maintaining Safety at Licensed Facilities

The 109 reactors that are licensed to operate in the U.S. generate approximately 21 percent of the Nation's electricity. Over the past several years the operational safety performance of U.S. nuclear power plants has continued to improve. This is demonstrated by the key operational safety indicators monitored by the NRC, which include forced outage rates, automatic scrams while critical, and significant events. These performance indicators are depicted in the first three charts in the appendix to our testimony. In general, the better performers appear to have reached plateaus where current performance levels are close to reasonable expectations, while the poorer reactors lag behind in performance. It now appears that the most fruitful way for us to reduce overall reactor risk is to concentrate our efforts on

the poorer performers, to bring them up to the level already reached by the better performers.

Although performance is improving, we must remain vigilant to ensure that existing nuclear power reactors and other licensed facilities continue to be operated safely. A principal source of information by which licensee performance is judged is the Systematic Assessment of Licensee Performance, or SALP program. Under this program the performance of each nuclear power licensee is evaluated through the periodic (usually every 18 months), comprehensive examination of available data, including inspection reports, special reviews, and licensing information. The purpose of the integrated SALP review is to direct both NRC and licensee attention precisely toward those areas that most affect safety and that need improvement.

The NRC's reactor oversight includes reactor inspections, particularly with the assignment of at least two resident inspectors to each reactor site. In an effort to improve the inspection process we are modifying the SALP program and the reactor inspection program to focus even more on safety significant performance. We will place more emphasis on SALP results in shifting a fraction of the NRC inspection resources away from the better performers to focus on the poorer performers. Safety will be ensured while costs to the better performing plants will be reduced, providing additional incentives for plants to improve their performance.

Another key NRC responsibility is to ensure that each nuclear reactor is staffed with trained and qualified reactor operators. Toward this end the NRC licenses all personnel authorized to operate reactors and requires requalification examinations to verify their continued proficiency.

The NRC also establishes physical protection requirements at commercial nuclear reactors. The objective of our physical protection requirements is to protect the public from sabotage-induced releases of radioactive material off the site. To establish a standard for protection requirements the NRC created a design basis threat against which to protect -- a hypothetical threat combining intelligence, technical studies on vulnerability, and costs to counter -- in an attempt to set prudent but reasonable standards for security at the plants.

The Commission believes that this is an appropriate time to reevaluate the design basis threat for radiological sabotage. The present threat statement does not address the use of a vehicle nor the use of a vehicle bomb against a nuclear reactor. To support this reevaluation the staff has formulated an action plan and has made it available to the public. Phase I of the plan consists of a reconnaissance -- a bringing up-to-date of earlier work and a review of recent developments. These findings

will be presented to the Commission on June 4, 1993; we then expect to make an initial determination of depth and direction for next steps. Depending on the results of the first phase, there may be a second phase entailing a more profound review and analysis of the changes in the nuclear industry, the use of a vehicle, and the countermeasures available to individual plants against vehicles. Or the Commission might decide to take action without further study.

Additionally with regard to safety at licensed facilities, the Commission appreciates the importance played by safety allegations. For instance, the recent NRC Inspector General report on Thermo-Lag fire barriers highlighted the importance of allegations in identifying safety-significant issues. The Commission is currently awaiting the results of the IG's report assessing NRC's overall program for handling safety allegations. After the Commission has had a chance to review the IG's report we will consider the appropriate next steps to ensure that individuals with safety concerns feel comfortable bringing these concerns to the NRC.

Research

The NRC's nuclear safety research program will continue to provide the independent expertise and technical information needed to support our regulatory activities, and to develop the regulations and guidelines necessary to implement Commission policy. It is essential to maintain an adequate research base if the safe use of nuclear power is to be continued; within the Federal government this responsibility falls almost entirely on the NRC. Nevertheless, as reactor issues are resolved and reactor design test programs are completed, we are able to realize some reductions in the research program.

Maintenance at Operating Facilities

Because the Commission believes that improved maintenance programs will result in enhanced plant safety, we require licensees to monitor the effectiveness of maintenance activities for safety-significant plant equipment. The requirement is expressed in a performance-based rule which allows licensees the flexibility to utilize their existing programs to the greatest extent possible. We plan to evaluate the effectiveness of maintenance programs by comparing system performance against licensee established goals instead of concentrating on the maintenance process. Most importantly, NRC is taking steps to build on these maintenance initiatives to support the license renewal process, as described below.

Renewing Operating Licenses

The older nuclear power plants operating in this country are facing expiration of their original 40-year operating licenses -- the operating license of the first plant expected to seek license renewal expires in 2004 -- and a 10- to 15-year lead time is necessary for licensees to plan for license renewal or alternative new capacity. One of the key issues for industry is knowing the NRC's requirements for license renewal up front in order for them to make reasonable determinations regarding the pursuit of license renewal versus some other means of replacement power.

The issuance of the NRC's rule on license renewal in December 1991 marked the completion of five years of intensive work on this very important regulatory issue. The rule establishes the procedures that a utility must follow in submitting an application, defines the requirements for license renewal, and identifies the information that must be submitted as part of an application as well as the requirements for implementing license renewal programs.

The NRC staff has developed a process for implementing the license renewal rule which focuses on the effective management of aging effects on the performance or condition of important plant structures and components during the renewal term. The specifics of this process represent an approach to implementation not expressly addressed at the time of rule promulgation. The Commission has made available to the public several papers detailing the staff's proposed implementation approach. Our decision on whether and how best to implement the new approach is imminent.

Outside the license renewal rule implementation, the NRC is continuing on its path to review license renewal applications. The Department of Energy originally funded lead plant applications for two nuclear facilities. Both lead plants have either cancelled or deferred their license renewal efforts for plant-specific reasons. As a result the industry is taking a different approach to license renewal -- one that is more generic and less dependent on particular plants. We find this approach to be promising from a regulatory perspective since it may permit generic resolution of issues affecting several plants, thereby reducing the number of significant plant-specific issues to be resolved early in the process.

The Babcock and Wilcox (B&W) Owners Group has started discussions with NRC on a license renewal program for B&W-designed facilities; during the past few months they have submitted several technical documents to us for review. Submission of a license renewal application from a member plant in FY 1997 is one of the objectives of the B&W program.

Additionally, the other owners' groups have indicated that they are considering a similar program. Baltimore Gas and Electric (BG&E) has also submitted their methodology for implementation of the license renewal rule to the NRC for review.

Reforming the Licensing Process

The NRC established a process to review future nuclear reactor designs which makes it possible to resolve safety and environmental issues before, rather than after, the start of nuclear power plant construction. The Energy Policy Act of 1992 codified this process, which provides for standard design certifications and combines the construction permit and the operating license for nuclear power reactors. The NRC's rule provides for a degree of predictability in the regulatory process; the standardization of facilities should enhance plant safety. The rule's primary objectives are: (1) to encourage standardization of future nuclear plants by the use of certified designs, and (2) to permit early and definitive resolution of siting and design safety issues prior to commencement of construction by use of combined construction permits and operating licenses. A combined license would be issued only after pertinent issues, including development of emergency plans, are resolved.

The rule has been structured to provide for public participation in the rulemaking on certified designs and in formal adjudicatory hearings on the combined construction permit and operating license at an early point in the process, before construction begins. A more limited opportunity for post-construction hearings prior to plant operation is also provided if an appropriate showing can be made that the plant has not been constructed in conformance with its acceptance criteria and there are specific operational consequences of nonconformance that would be contrary to assuring adequate protection of the public health and safety.

Certifying Standard Designs

The NRC has received four design certification applications under this new process. The first two applications are for evolutionary versions of existing light water reactor designs. The NRC staff has completed draft safety evaluation reports on both of these evolutionary designs. Although these draft reports include a number of open issues which we and the vendors are working to resolve, almost all the open issues deal with acceptance criteria, not with specific design problems. The other two applications are for novel light water reactor designs which employ passive safety features and modular construction; an initial review of each has begun.

The proposed budget continues to provide adequate resources to develop the independent information and analyses necessary to support our safety decisions on these new and unique designs.

NUCLEAR MATERIALS

Approximately 15 percent of our budget request is devoted to ensuring the safe disposal of nuclear waste and the safe use and transport of nuclear materials. The requested increase in this program is primarily to implement NRC's new responsibilities for certifying the gaseous diffusion uranium enrichment plants to be operated by the United States Enrichment Corporation.

Overseeing Uranium Enrichment

The Energy Policy Act of 1992 places significant new responsibilities on the NRC in the area of uranium enrichment. The Act establishes the United States Enrichment Corporation (USEC) and requires the NRC to certify radiological health and safety protection and adequate safeguards for the two gaseous diffusion uranium enrichment facilities which the Corporation will lease from the Department of Energy (DOE). The Act requires the NRC to develop standards for governing these facilities, to establish a certification process for the Corporation to comply with the standards, to consult with the Environmental Protection Agency (EPA), and to report at least annually to Congress on the status of health, safety, and environmental conditions of the facilities.

We anticipate that DOE will retain regulatory oversight for the facilities until our regulatory standards are in place. We have provided resources to develop standards and to prepare for the transition, but there are no resources to inspect or monitor the facilities in our FY 1994 budget request. We have devoted substantial resources to this project since enactment of the Energy Policy Act of 1992. Beginning July 1, 1993 we will begin charging the USEC fees to recover costs that we incur.

Managing Nuclear Waste

Our responsibilities for the safe transportation, storage, and disposal of nuclear waste were expanded significantly in the 1980's. The NRC became responsible for licensing a high-level waste geologic repository and spent fuel storage casks, and for providing the complete regulatory framework that will assist the states to develop and implement plans for the disposal of low-level radioactive waste.

During the past year the Department of Energy has taken some encouraging new approaches to high-level waste management. The DOE recently announced a strategy to address options for spent fuel receipt beginning in 1998. This new strategy includes the

use of multiple purpose casks for both transportation and interim storage of spent fuel at Federal sites. We have begun consulting with the DOE on the design requirements for such a cask and will review the design when submitted by the DOE for certification.

Our high-level waste efforts continue to keep pace with DOE's program as they proceed with surface-based testing and initiation of underground exploration at the Yucca Mountain site. The number of NRC reviews has increased recently in response to DOE activities.

With regard to low-level waste, one of the nation's commercial low-level waste disposal sites ceased disposal operations at the end of 1992, another has restricted access to the Northwest and Rocky Mountain compacts, and the third site is scheduled to close to out-of-compact disposal by July 1, 1994. State legislation, state budget constraints, litigation, and public concern have contributed to delays in establishing new low-level waste disposal sites. However, we do not believe these problems are insurmountable. Progress has been made by states over the last year both in siting and in issue resolution. At the same time, the trend toward lower waste volume has continued to the point where current disposal requirements are only about half of what they were a few years ago.

Decommissioning of Sites

We must be able to ensure that once an operating facility completes its useful life, the site is properly cleaned up. Thus, decommissioning and decontamination are an integral part of the NRC licensing process. We have developed a Site Decommissioning Management Program, creating an enforceable regulatory framework that includes cleanup standards and deadlines to ensure the timely cleanup of NRC regulated sites before licenses are terminated and the sites released for unrestricted use. The Site Decommissioning Management Plan has allowed the NRC to increase its oversight of approximately 45 previously contaminated sites to ensure satisfactory cleanup of low-level waste. Remedial action at two additional sites has been completed recently, allowing these sites to be removed from the Site Decommissioning Management Plan. Substantial cleanup progress has been made at five other sites. I believe we have been effective in communicating to licensees and the public NRC's expectations for timely and effective remediation of these sites.

We are also conducting an enhanced participatory rulemaking to establish standards for residual radioactivity for decommissioned sites. This rulemaking includes workshops around the country in which industry and grass roots environmental groups have come to the same table to discuss the difficult issues associated with these standards. EPA is participating in this effort. We are hopeful that it will result in the generic

standards needed to plan and implement future cleanup and decommissioning efforts in a more efficient manner.

Overseeing the Safe Use of Nuclear Materials

The NRC continues to be responsible for ensuring that civilian uses of nuclear materials in the United States are carried out in a way which will adequately protect the public health and safety, the environment, and the national security. The NRC licensees include existing nuclear power reactor operators and others who are primarily users of nuclear materials and fuel cycle facilities.

The NRC regulates a wide variety of nuclear materials licensees across the United States. There are about 22,000 licensed medical, academic, and industrial users of nuclear materials subject to regulation. Of these, approximately 7,000 are licensed directly by the NRC; the other 15,000 are regulated by the 29 states that participate in the NRC Agreement States Program. Nuclear materials are used in large industrial operations such as the manufacture of reactor fuel, in the production of radiopharmaceuticals, in fabrication of consumer products such as smoke detectors, and in operations using small and large quantities of radioisotopes in over seven million medical diagnosis and treatment procedures annually. Given the large and varied use of nuclear materials throughout this country, the overall safety record has been very good. However, we have found some weaknesses.

For example, one of the most important uses of byproduct material is for medical diagnosis and therapy. The last several years have seen increased Commission attention directed at the medical use program. Our regulatory program is directed towards assuring, in addition to worker and public safety, that the patient receives the dose of radiation or radioactive material that is prescribed by the physician. Occurrences of misadministrations -- primarily cases in which radiotherapy as delivered is different from that which is prescribed -- are not common, but are cause for concern about the effectiveness of the program.

In September 1992, staff presented to the Commission a management plan for the medical use program. Additionally, we plan to conduct two audits: an internal audit to determine how well we are implementing existing programs; and an independent audit to assess the adequacy and appropriateness of the current regulatory framework for medical use of byproduct material. We are also examining the relationship between the Agreement State programs and the NRC-operated program.

We would like to note that the NRC's jurisdiction covers only approximately 25 percent of the radiation therapy

treatments. The remainder, which involve identical radiation from different types of sources, are covered under a range of state regulatory programs. It is fair to ask if continuation of the existing scheme is the best way to use limited resources to achieve the goal of protection of the public. So we have been giving some thought to ways to address these issues. Among the options that come to mind and that appear to warrant evaluation -- although this may not be an exhaustive list -- are (1) maintaining the current program, (2) limiting NRC's regulatory involvement to approval for use of sealed sources and devices containing byproduct material with all the states then regulating their medical use, (3) NRC's continuing to write standards and guidelines with all of the states assuming responsibility for licensing, inspection and enforcement, or (4) extension of NRC regulation to all radiation sources used for therapy, not just byproduct material. The last three options would require legislation.

These and other approaches require careful evaluation, and coordination before the Commission would be in a position to make a decision on this matter, including any eventual recommendation to Congress for possible revision to our statutory authority. We plan to provide the Congress with an interim report on our efforts to come to grips with these issues by August 6, 1993.

The NRC has also undertaken new initiatives in the regulation of major materials licensees and fuel cycle facilities. Last year, NRC's Materials Regulatory Review Task Force reported its findings and recommendations concerning deficiencies and needed improvements in the licensing and regulation of major materials licensees. The NRC is now responding to those recommendations by developing a better regulatory framework for licensing and inspection, and by designating project inspectors for major materials licensees. The NRC has also conducted a regulatory impact survey for fuel cycle and major materials licensees to determine the impact of NRC activities on these licensees, in order not to impose unnecessary burdens inadvertently.

MANAGEMENT AND SUPPORT

Approximately 30 percent of our budget request is for the day-to-day management of the agency and the normal "housekeeping" costs associated with keeping the agency doors open. However, even in this administrative arena, we have assumed significant new responsibilities in the past few years which are putting greater pressures on our available resources. These include establishment of an Inspector General for NRC, increased participation in international nuclear activities, collection of significant additional license fees, implementation of the Chief Financial Officers Act, and consolidation of our headquarters employees.

International Activities

The NRC participates in a number of international nuclear safety and safeguards activities both on a bilateral basis and through multilateral organizations like the International Atomic Energy Agency and the OECD Nuclear Energy Agency. We believe that our cooperative efforts in sharing safety information and operational experience serve to make commercial nuclear power safer throughout the world and enables the NRC to benefit from the advances in and experience of nuclear programs in other countries.

Most notable this year are the expanded safety activities with the Republics of the former Soviet Union (FSU) and the countries of Eastern Europe stemming from the diplomatic initiatives at the Munich Summit and in Lisbon. The aid package offered at the Vancouver Summit also includes additional funding for safety assistance to Russian reactors.

In addition to nuclear power plant safety, health and environmental challenges are other potential targets for future aid of the FSU. The NRC is playing a role in the development of a much needed integrated plan for overall assistance.

We are now witnessing the growth of commercial nuclear power in Asian nations such as Japan, Taiwan, and South Korea, where U.S. vendors are actively competing for reactor sales, and the beginning of a new program in Indonesia. The NRC has technical information exchange agreements with 27 different countries; most recently we have concluded an agreement with Indonesia and renewed ones with China and Greece. These agreements provide a framework for bilateral cooperation on nuclear safety, safeguards, waste management and environmental protection; they help to open up communication channels with foreign nuclear regulatory organizations so that they have the means to create a regulatory environment similar to what we have here in the United States.

License Fees

The NRC is required by the Omnibus Budget Reconciliation Act (OBRA) of 1990 to collect approximately 100 percent of its annual budget from fees. That represents a substantial increase in fees from the previous requirements to collect 45 percent of our annual budget. To be fair and equitable, the NRC implemented the Act by assessing fees to essentially all of its applicants and licensees. As you may expect, the NRC has received severe criticism and complaints from licensees because of the increase in fees caused by the requirement to recover 100 percent of the budget. We believe there is basis for their complaints where they are being charged for services that do not directly benefit them. For example, the NRC is engaged in a number of

international activities, such as assistance to international organizations or countries which support U.S. interests. However, the costs of these activities must be recovered through fees assessed to NRC licensees.

We are addressing these and other concerns in response to the Energy Policy Act of 1992 requirement for the NRC to review its policy of assessing annual fees under OBRA-90, solicit public comments on the need to change such policy, and recommend to the Congress such changes in existing law as NRC finds are needed to prevent the placement of an unfair burden on certain licensees. After evaluation of the comments, we will submit a report to Congress, including recommendations for any statutory changes that are needed. I would note, however, that preliminary indications are that to eliminate some of the concerns will require legislation.

OPENNESS OF NRC'S PROCESSES

A primary NRC responsibility is to ensure integrity, candor, and openness in all our activities. Ensuring openness and candor in our processes cannot be accomplished by public statements alone; it must be incorporated in how the NRC does business at every level. We feel that the NRC has made great strides in keeping the public informed about what we are doing and why, and about successes and shortcomings. We have solicited the participation of the public and have benefitted from their contributions. As indicated earlier, the NRC currently has an enhanced participatory rulemaking effort under way to establish radiological criteria for decommissioning materials sites. We are opening some enforcement conferences to the public, we conduct open meetings to discuss each licensee's performance assessment, and the Regional Administrators now hold quarterly briefings for the public and the media.

LEGISLATIVE PROPOSALS

The Commission is most appreciative of the Subcommittee's interest in our seven legislative recommendations which were introduced by Congressman Lehman as H.R. 2170. Our testimony will discuss the main aspects of each of the NRC legislative proposals. Six of the proposals would amend provisions of the Atomic Energy Act; the remaining proposal would amend section 206 of the Energy Reorganization Act of 1974.

1. Enhancing Security at Nuclear Facilities

Ensuring the security of nuclear facilities is one of our important regulatory responsibilities. Three of the proposed amendments to the Atomic Energy Act seek to enhance our ability to deter theft of nuclear materials and sabotage of nuclear facilities.

The first proposal would make unauthorized introduction of weapons, explosives, or other dangerous instruments at NRC-licensed facilities a Federal crime. There have been an increasing number of reported incidents where persons without authorization have brought firearms into protected areas of NRC-regulated sites. While the motivations behind these actions appear to have been unrelated to the nature of the facility, these occurrences have highlighted the fact that there is no Federal law that imposes criminal sanctions against a person responsible for bringing a weapon to a nuclear facility.

Enactment of this provision would promote the national policy of maintaining comparable safeguards for similar nuclear materials at DOE-owned and NRC-licensed facilities. Unauthorized introduction of weapons or other dangerous instruments at nuclear facilities owned by the Department of Energy is a crime under the Atomic Energy Act.

The second proposal to enhance nuclear facilities' security would make sabotage of a nuclear facility during its construction a Federal crime if the action could jeopardize public health and safety during the facility's operation. Sabotage during the later stages of construction could go undetected because the inspections that would have discovered the sabotage may already have occurred. Here, also, there are no applicable criminal sanctions under Federal law.

Finally, we propose an amendment to the Atomic Energy Act to authorize guards at NRC-licensed facilities to carry firearms. Most importantly, the effect of this amendment would be to substitute Federal standards for state standards in determining the appropriateness of guards at these facility using deadly force to prevent theft of nuclear materials capable of being used for nuclear explosives. Currently, state law governs the use of deadly force by guards at NRC-licensed facilities, and it varies significantly; in many jurisdictions, the use of firearms in these circumstances could result in state criminal prosecution.

While this amendment was first proposed because of the need to protect against theft of strategic special nuclear materials, it would apply to any circumstance where successful completion of the crime would present an immediate and direct threat to the health and safety of the public. Recent events have convinced us that there is a broader need for this authority at NRC-licensed facilities. In addition, enactment of this provision would promote the national policy of maintaining comparable safeguards for similar nuclear materials and facilities in the public and private sectors. Guards at DOE facilities already possess this authority.

2. Enhancement of NRC's Investigation and Enforcement Authority

Three of the proposed amendments would enhance NRC's effectiveness in enforcing the statutory provisions that fall under our authority.

We are proposing to amend an Energy Reorganization Act provision that requires the NRC to be notified of defects or regulatory violations at nuclear power plants and other NRC-regulated activities, where such defects could create a substantial safety hazard. This notification requirement is now applicable only to individual officers or directors of the business that is involved. Failure to provide proper notice can result in a civil penalty being imposed on such individuals, but it is unclear whether the business entity itself can be penalized, or whether a non-licensee is even covered by the rule.

We believe that the business entity should be held responsible, and that it should be accountable whether or not it is an NRC licensee. This view is in accord with the general approach to regulation under the Atomic Energy Act and, experience tells us, would be more effective in deterring future violations of the rule.

In recent years it has become increasingly apparent that civil monetary penalties should reach all persons who violate NRC requirements, regardless of their status as licensees or non-licensees. For that reason we are also proposing to amend the Atomic Energy Act to make clear that the Commission has the authority to impose civil monetary penalties upon all persons subject to its authority who violate a Commission rule, regulation, or order issued under section 161 b., 161 i, or 161 o of the Act. Express authority for imposition of criminal penalties for most such violations is already provided by the Act.

We also propose an amendment to the Atomic Energy Act to permit the NRC to obtain a judicially-approved, administrative search warrant to inspect the premises of a non-licensee that is not part of the regulated nuclear industry. The warrant would allow the NRC to inspect a firm's premises without prior notice, if the NRC reasonably believes that action by that firm may be responsible for a violation that could potentially affect the public health and safety. Requiring use of the subpoena process, as is now the case, poses a high risk of destruction of evidence since notice and an opportunity to contest must be given. The administrative search warrant authority is needed to ensure that suppliers of NRC-licensees will not be able to deny agency investigators access to important information.

3. Elimination of ACRS Report

NRC's Advisory Committee on Reactor Safeguards is currently required to prepare an annual report to Congress on nuclear safety research. The preparation of the report has not proved to be an effective use of the time of ACRS members and the Commission's limited resources, so we are proposing to eliminate that requirement. Reports on significant nuclear safety research would continue to be provided to our congressional oversight committees under our general statutory responsibility to keep them informed.

FISCAL YEARS 1994-1995 AUTHORIZATION

Our fiscal year 1994 budget request is \$547.7 million, an increase of \$7.7 million above fiscal year 1993--less than a 2% increase. Our fiscal year 1995 budget estimate is \$551.8 million, less than a 1% increase above our request for fiscal year 1994.

Well before submitting our request to OMB we undertook an aggressive, thorough review of our programs. This review resulted in a streamlined budget request at less than the rate of inflation even as we undertake new responsibilities. We are budgeting increased resources to keep pace with industry activities associated with reactor license renewal and the safety reviews and inspections associated with issuing new power reactor licenses, and within our management and support program we have requested funds to strengthen our financial management systems, where recent IG reports have indicated the need for improvement.

In addition there are programmatic increases needed to fund some of our new responsibilities for regulating the United States Enrichment Corporation's facilities, as required by the Energy Policy Act. However, we found that by following the policy I discussed earlier, we could make offsetting reductions in current operations and in reactor research without compromising our safety responsibilities. This budget request complies with the Administration's Executive Orders and cost-cutting initiatives.

The NRC continues its efforts to identify better ways to accomplish our mission. These efforts will allow us to respond to future needs while minimizing the growth in resource requirements. For example, the Commission has determined that changes in workload will allow for the closing of the Uranium Recovery Field Office in Denver, Colorado. The work which is currently performed in that office is expected to decrease and the remainder will be carried out by personnel in our Dallas, Texas, regional office as well as staff in headquarters. This action will result in savings to the agency while continuing the

appropriate level of effort in this area. Also, we currently have under review the possible consolidation of our Western and South West regions. The review has been undertaken in recognition of the changing workload as the number of reactors and licensees have declined in the West. These reviews help to ensure the best application of available resources and will help us in our effort to meet the Administration's goals for continued resource reductions.

CONCLUSION

In conclusion I would like to reiterate that the NRC is committed to meeting its responsibilities for the safety of today's operating reactors and other NRC licensed activities. We have tried to stay a step ahead of events; by so doing we have been able to undertake additional responsibilities and invest in those programs which affect the future -- streamlining the regulatory process, renewing reactor licenses, certifying standard reactor designs, and managing waste disposal -- while slightly reducing our budget in real terms. We will continue to do all of this in a transparent manner that facilitates public understanding of our regulatory process.

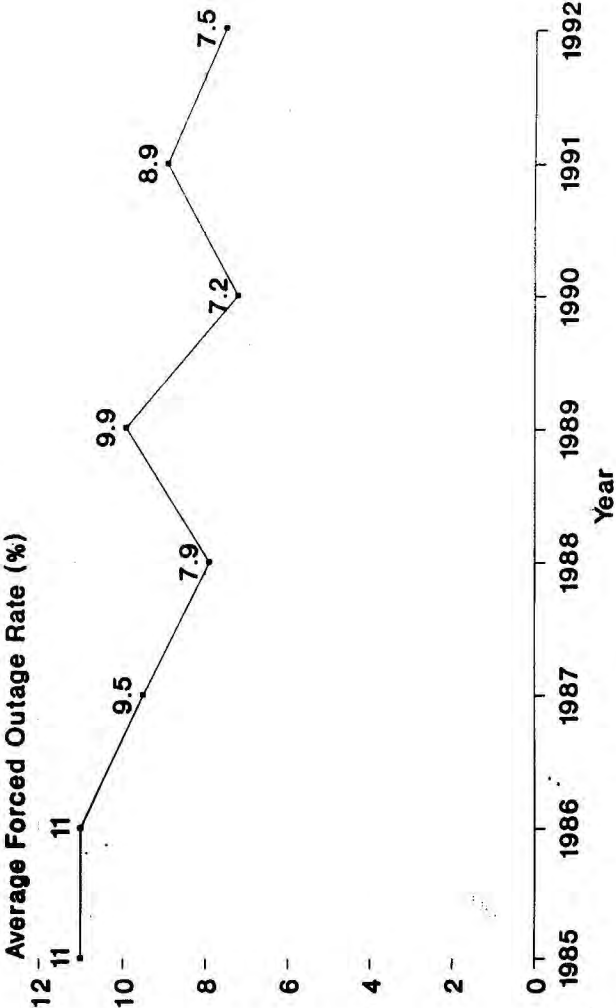
The details of our budget request for fiscal year 1994 and budget estimate for fiscal year 1995 have been provided to your Subcommittee. The request and estimate are included as an appendix to this testimony, and are summarized in two charts: Chart 4 summarizes our budget in terms of NRC's principal program objectives and illustrates changes to our program requirements; and Chart 5 depicts a gross allocation of resources to our two principal programs.

In the Commission's view this program is necessary to ensure effective regulation of an industry which touches virtually every facet of American life.

Mr. Chairman, this concludes our prepared statement. My fellow Commissioners and I will be pleased to answer any questions that you and the Subcommittee may have.

A P P E N D I X

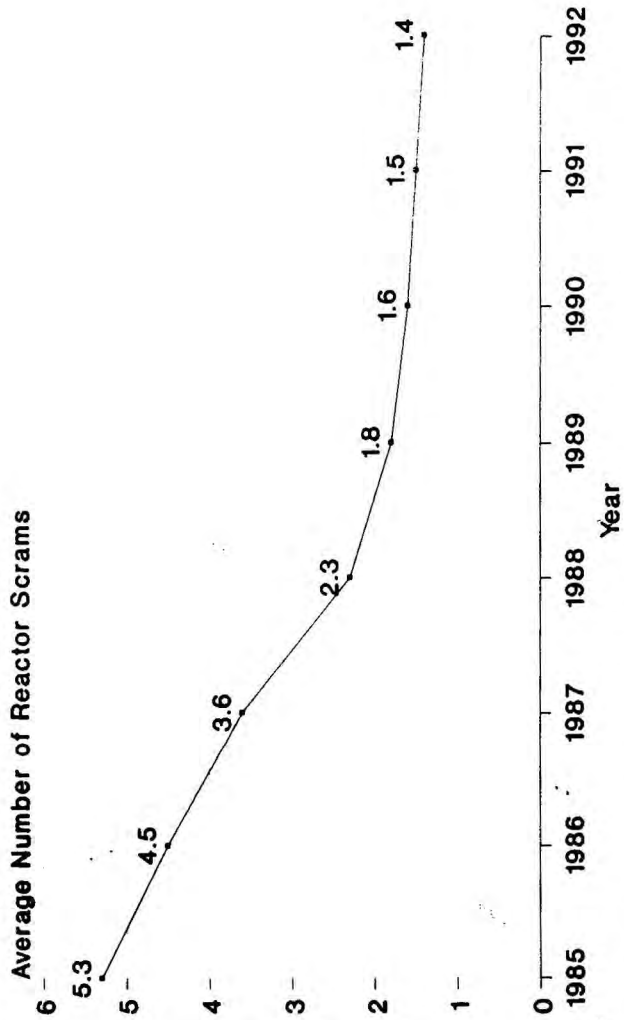
Forced Outage Rate
Annual Industry Averages
1985 - 1992



Note: Excludes plants in extended shutdown.

Chart 1

Automatic Scrams While Critical Annual Industry Averages 1985 - 1992

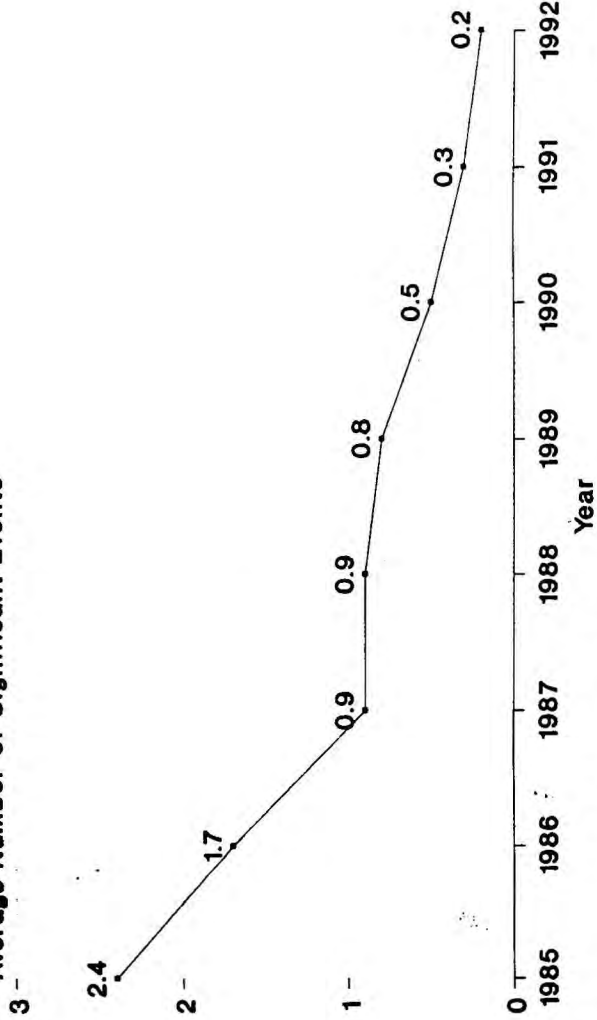


Note: Excludes plants in extended shutdown.

Chart 2

Significant Events Annual Industry Averages 1985 - 1992

Average Number of Significant Events



Note: Excludes plants in extended shutdown.

Chart 3

U.S. NUCLEAR REGULATORY COMMISSION
BUDGET SUMMARY
(Dollars in Millions)

	FY 1993 Base	FY 1994 Budget Current Services	Program Requirements	Net Budget	FY 1995 Budget Estimate
REACTOR REGULATORY PROGRAMS					
Reactor Safety and Safeguards Regulation	\$163.0	\$5.1	-\$4.3	\$163.8	\$168.0
Reactor Safety Research	100.6	2.7	-3.3	100.0	98.3
Reactor Special and Independent Reviews, Investigations, and Enforcement	31.0	.9	-.9	31.0	31.4
Subtotal	\$294.6	\$8.7	-\$8.5	\$294.8	\$297.7
NUCLEAR MATERIALS REGULATORY PROGRAMS					
Nuclear Material and Low Level Waste Safety and Safeguards Regulation	\$57.6	\$1.9	\$2.4	\$61.9	\$63.0
High-Level Nuclear Waste Regulation	21.1	.5	.4	22.0	22.0
Subtotal	\$78.7	\$2.4	\$2.8	\$83.9	\$85.0
MANAGEMENT AND SUPPORT					
Nuclear Safety Management and Support	\$162.1	\$9.7	-\$7.6	\$164.2	\$164.1
Inspector General	4.6	-.1	-.1	4.8	5.0
Subtotal	\$166.7	\$9.8	-\$7.5	\$169.0	\$169.1
TOTAL	\$540.0	\$20.9	-\$13.2	\$547.7	\$551.8

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Chart 4

U.S. NUCLEAR REGULATORY COMMISSION
BUDGET SUMMARY
(Dollars in Millions)

	<u>FY 1994 Budget</u>		<u>FY 1995 Budget Estimate</u>	
	<u>Amount</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>
REACTOR BUDGET				
Reactor Regulatory Programs	\$294.8	54	\$297.7	54
Management and Support*	<u>131.6</u>	<u>24</u>	<u>131.5</u>	<u>24</u>
Subtotal	\$426.4	78	\$429.2	78
NUCLEAR MATERIALS BUDGET				
Nuclear Materials Regulatory Programs	\$83.9	15	\$85.0	15
Management and Support*	<u>37.4</u>	<u>7</u>	<u>37.6</u>	<u>7</u>
Subtotal	\$121.3	22	\$122.6	22
TOTAL	<u>\$547.7</u>	<u>100</u>	<u>\$551.8</u>	<u>100</u>

*Assigned portion

Mr. LEHMAN. Thank you very much for your statement. Let me just say that there is a vote right now and Mr. Thomas and I think we will go make that vote. We will be back in ten minutes and then we will proceed with the questions at that point.

So we will recess for ten minutes.

Thank you.

[Whereupon, a brief recess was taken.]

Mr. LEHMAN. The hearing will resume.

Mrs. Vucanovich will be back shortly, but I think I will proceed nonetheless with some questions that I have.

First, just let me express my intention to cooperate as fully as possible with you, and I certainly appreciate the cooperation I and my staff have received thus far. We certainly have every intention of moving forward with the legislation in that spirit.

I do want to get into a couple things here, some of which were brought out in the chairman's opening remarks. And you did dwell at length on the issue of the search warrants that are in 2170. And I think having the search warrants in this bill, by the way, does necessitate a referral to the Judiciary Committee. So it is going to come under very careful scrutiny. And any time we do something like this, it raises a lot of red flags and draws attention.

And I wrote down your words, Mr. Chairman. You said this was a high priority, but you also felt it would be a very limited process, used only in certain circumstances. And you even quantified that, the number of circumstances you think it might have been used in the last year.

And I guess what you're saying, you're saying that the reason for this is because the existing process takes too long, it has too much opportunity in the process to undo it, I guess, or for it not to be effective.

And for the record, I think I'd like for you to elaborate on that a little more for us.

Mr. SELIN. Yes, sir.

First of all, I would just like to stress a couple of points. We're talking about judicially approved search warrants. We need to, in each case, appear before a judge to get the search warrant. We would have to justify the requested action and look only for material directly related to the basis for the search warrant.

There are precedents for this case. There are other federal agencies that have statutory search warrant authority. The Department of Transportation and the Food and Drug Administration. The FDA, I think, is a pretty good analogy to this situation.

We are talking about—there are two alternatives available to us today. We can go for a civil subpoena or we can go to a U.S. attorney to ask for a criminal search warrant.

As a practical matter, you can not get a civil search warrant, even going through the Department of Justice, because the courts will not grant a civil search warrant unless it is specifically authorized by statute. They say, use a subpoena; do not use a search warrant.

The problem with a subpoena, to summarize, Mr. Chairman, is not only that it is public but that it takes a long time and therefore whatever it is we hope to find on the search warrant could easily be destroyed or moved to some other place and not be available.

The problems with the criminal approach are, basically, two. First, of course, the burden of proof is much higher in a criminal case. We are looking for health and safety violations, not necessarily criminal violations. But the practical problem is that we have to go to a U.S. attorney. The U.S. attorney has to satisfy himself that this is a reasonable situation. U.S. attorneys don't know the Atomic Energy Act, they have many other priorities. Even if we pass that burden, then the documents must be served by a U.S. marshal, which is a further delay and a further scheduling problem.

And it is just not worth doing. I mean, we have found that it's just not practical to use the Department of Justice criminal process. So we are really hamstrung in these few cases.

Mr. LEHMAN. That logic in a way could be extended to all uses of search warrants. And I just wonder what the specific need is for it here.

In other words, I think the case you're going to have to make is the harm being done poses a potential threat to the public such that you need this additional strength in the warrant process.

Mr. SELIN. I think that's correct. We agree that that's the point that is involved.

In almost every case, we are interested in going to manufacturers of safety-related equipment. We are concerned that they are substituting non-safety related equipment or do not do the internal quality control that they have told us that they do. These are clearly health and safety issues that we have in mind.

There may be—in one case, there were gauges for water levels in reactors. We had heard rumors—we had heard allegations that the test results that we were getting were just the successes and that there were failures. And by the time we were able to get access to the manufacturer's records, they were not there. Now, maybe there were no failures or maybe the records were destroyed, but we just couldn't get at these.

We have had a major problem with counterfeit parts. The Department of Justice was just successful about a month ago in winning a conviction against a manufacturer of counterfeit parts. These are parts that attest to have a reliability consistent with what we require, that the industry requires for power reactors. But, in fact, they were just the everyday parts.

And I am sure you have a hardware store that sells only things that work, but a lot of us have had experience with the kind of things you get on a commercial level in terms of just nuts, bolts, fasteners, gauges, et cetera, which are not adequate to the nuclear power area.

We think the standard of reliability that we require is called for and do not feel that we can completely assure the quality of the parts without, in the very odd case, being able to go in and get the records or the—or get access to the manufacturing equipment or the rejects that have come along the way.

Mr. LEHMAN. Another controversy that stems from the hundred percent recovery requirement concerns the necessity for the Commission to charge its licensees the cost of activities that—activities that are not, I guess, directly attributable to the licensees.

Mr. SELIN. Yes, sir.

Mr. LEHMAN. Those include international nuclear safety support, like the former Soviet Union, support for agreement states that have taken over certain NRC material regulation responsibilities, such as licensing medical users and low-level waste repositories.

I realize that you are reassessing your fee structure now. I am wondering if you can tell us anything about how you foresee this problem being resolved.

Mr. SELIN. Yes, sir.

I think the two examples you brought up are actually quite different. In the first category, I would put those international activities that we do which are not part of our research program—in other words, we do some international research, because it's just cheaper to do the work in Japan than the United States. That clearly benefits our licensees. We put that aside.

We talk about assistance as not reimbursed by AID. We're talking about \$8 million a year of international programs, \$5 million direct, \$3 million in overhead that goes with that. That's a nontrivial amount of money. It's about one and a half percent of our annual budget.

Other activities that fall in that category are services we provide to federal agencies which are not reimbursable. For instance, we have been providing quite a bit of preparation to prepare for the United States Enrichment Corporation that's been done for the Department of Energy that's not reimbursable. Things like that are—you could question whether that's of general interest to the industry or whether that should be outside the base.

We're probably talking about roughly three percent or so of our expenditures that could be questioned.

My own personal view, since that's what I read you last, it's not fair that this be put in the base. The federal government has a very strong incentive not to make a lot of exceptions for user fees, and that has to be weighed by somebody else. But from our point of view, we don't think it's fair to ask the licensees to pay this. Also, having a hundred percent reimbursable puts us on our best behavior, and that's good. But if we weren't able to provide assistance to the executive branch's work with the former Soviet Union because of this, that would not be good.

As far as the agreement states go, that's clearly arguable, but it's a different kind of a situation, because the Congress clearly intended that the agreement—that states have the authority to carry out a lot of this activity, the materials activity, at the state level to integrate it with their other health programs and their other radiation control programs that we don't regulate. They have the benefit of our general advice and our technical assistance. They do get—they do not pay for the oversight that we provide for them. And that is true.

On the other hand, that was clearly intended as an inducement for the states to do this and to offset the costs that they have which we would otherwise have to bear if we had to do the inspections ourselves.

The total amount of money that we're talking about is not a share of the materials program. I think the total amount of money we're talking about is the actual cost of our state regulatory program, which is less than \$2 million, I mean the part that we would

look into, say, this program would not exist were it not for the agreement state program.

You could argue that that's also something that's done on the federal basis. I think that's part of the general health and safety of the materials business.

Mr. LEHMAN. Well, if we reduced the recovery requirement to, say, ninety or ninety-five percent to cover activities that are in the national interest but not attributable to the licensees, do you have any suggestions about how we make up the difference?

Mr. SELIN. It would have to be done out of appropriated funds. Actually, as a matter of fact, you would—the way our budget works, of course, is we don't work on a bottom line. The Congress appropriates our money and then we collect reimbursements and send them to the Treasury at the end of the year. So as a technical matter, you would continue to appropriate money to us but you would change our legislation to either not require a hundred percent reimbursement or to allow us certain accounts that did not have to be reimbursed.

And from an appropriations point of view, technically you would see no difference. On the other hand, the 302(b) allocations that are given to the Appropriations subcommittees would have to be changed to reflect that the reimbursement would be, say, ninety-five percent instead of one hundred percent.

If in fact, at the end of the year, we fail to collect a hundred percent, we don't have to give that money back up; we're supposed to try to collect a hundred percent, but we don't have a profit and loss—

Mr. LEHMAN. We would have to make up the difference in the budget. That's the bottom line.

Mr. SELIN. Yes, sir. It would be a loss of revenue equivalent to, say, five percent of \$500 million, say a \$20 million or \$25 million loss of revenue.

Mr. LEHMAN. Also, I would like to hear your response to some of the complaints we get from some of the small nuclear materials users like the medical community that the fees you assess are too high and don't reflect the service being performed for the fee.

Mr. SELIN. Well, the problem is the fees do reflect the service being performed. But you can argue that the service isn't worth that much money, we shouldn't be spending that much money for it.

Our accounting—let's start with the accounting.

The IG has talked about it. He said, our accounting is not set up for a fee-billing agency. I was the chairman of a consulting company for eighteen years; I am personally quite aware of what kind of accounting you need if you're going to require reimbursement for your services. We don't have the proper overhead pools. Everything is either overhead or direct, we don't have the more detailed overhead pools of, say, people who are in a materials area can't be charged to a single licensee but they shouldn't be charged to reactor people or vice versa.

So we have to fix that and we are in the process of fixing that. But all that will do is move some costs from one licensee to another licensee. The great value of the fee system is we take a look and we see how much we are charging these people. Where we see fees

that seem out of Kilter, intuitively we go in and we polish the process and say, do we really need to spend that much time in regulating certain of these licensees. And on the materials side, we've found a lot of small cases where we don't.

Just as an example, on the reactor side, we have a provision called 50.59. It says a reactor licensee can make changes of a certain kind, provided he's willing to defend those in inspection. He makes the changes, he claims there's no safety impact, and we do an inspection when we do the inspection. And if he's right, he's made the change.

We don't have that provision on the materials side. We probably should. We should allow a licensee to change the name of his radiation safety officer without getting a license amendment. And when we audit that person, if that person is not qualified, he will be fined, rather than have to make an amendment in advance.

There are a lot of these small changes that we're starting to make that without the inducement of license fee, we did not make.

On the other hand, we do have limitations for small businesses. If you're small enough, you can pay a \$400 annual fee. The next level is \$1,800. In some of the examples that Congressman Thomas set forward—we don't audit your books. This is a self-assessment. You have to attest to us that you have—you're a small business. And then once in five years or once in ten years we take a look at the books to see if it's true. But if the licensee does not come forward, he does not get the small fee.

And in a couple of cases that Congressman Thomas sent over, we sent people notice saying that they were eligible for the small fee and they never applied for it. They get a lot of mail and I'm sure they missed it, but there's not much more we can do except drop the fees, reduce our actual efforts, and then continue to communicate to make sure that people take advantage of the breaks that are available to them.

Mr. LEHMAN. Thank you. Let me move to another issue.

A good deal of 2170 is dedicated to physical safety at the plants and responding to the potential for terrorist activity. There has been a lot of concern recently. As you know, Chairman Markey, Chairman Sharp, and I signed a letter expressing some of our concern in the need to take some action for physical protection of the facilities following the incident at Three Mile Island and the bombing of the New York Trade Center.

And I guess I'll pose the question this way. Why hasn't the Commission moved more aggressively to secure the perimeters of our facilities, and why haven't we gone forward with the construction, for instance, of antitruck barriers to prevent a bombing incident from devastating a facility?

Mr. SELIN. I happen to think we are moving very aggressively. Now, the last time I appeared before Congressman Markey, he pointed out that you can either have reenactment or reconciliation, those are the only two choices in human relationships. And I would prefer reconciliation to reenactment. I would hope not to have to ask the question about why we didn't do something two or three years ago. I could defend it, but I don't think that's particularly useful.

But since the truck bombing and the entrance at TMI, we are moving as quickly as our regulations permit us to move. We do not believe, and I do not believe, that there is an imminent threat to health and safety. There is no intelligence, there is no reason to believe that you absolutely have to do this tomorrow, et cetera.

We believe that an improvement in health and safety is justifiable according to our so-called "backfit" rule, which is where you have to do a cost/benefit analysis and come forward and say we think that this is called for. Now the staff hasn't reported to the Commission. We're moving as fast as we can to do the work, to do the analysis, to get the data together, and to justify it.

But it would not be surprising if the conclusion is that something should be done to strengthen the perimeters. But not as a question of urgent health and safety, more as a question of good management based on a cost/benefit analysis.

Our regulations, and I believe common sense, require that, like anything else, to be put in a notice, to be published for comment, analysis has to be reviewed by people who are effected, et cetera. We are well on the way to a very fast-moving step. Now, staff may decide to do that, they may say further study is required, but we are on a schedule that will allow resolution of this issue according to our rules of openness and public comment and justification of steps that require increased spending on the part of the licensees that's quite consistent.

If I might just say one other thing? One of the arguments that's been raised is if you can put a barrier around a plant for a half a million dollars or a million dollars, why don't you do it? I think that's a very good argument. If the answer were, it's going to cost fifty or a hundred million dollars, I would feel differently, and that's *prima facie* proof that the price matters.

In other words, it's not a question of imminent health and safety. It is a cost/benefit analysis. And so we have to do the cost/benefit analysis. We can't just arbitrarily order people to do things because our judgment is that a little money is worthwhile and a lot is not.

So we are following the rules and we are doing it as aggressively as I believe we are permitted to do so.

Mr. LEHMAN. Thank you.

Mr. Allard?

Mr. ALLARD. Thank you, Mr. Chairman.

I am sorry I missed some of the earlier part of your testimony.

I guess I share some of the Chairman's concerns about your ability to go in and do a search and whether you should have those extended powers or not. Can you share with this Committee an example, maybe a hypothetical example, of where you would feel it would be necessary to use those powers?

Mr. SELIN. I could do a little more than that, sir. First of all, I would like to stress that the power we are asking for is the authority to ask a judge for a search warrant. It is not to issue one ourselves or to go in ourselves. And I can give you a couple of examples in the past.

In one case, we wanted to inspect the premises of a company making cement and grout used in nuclear power plants, because we had received allegations—and, as you all know, allegations are a terribly important source of safety information. We had received al-

legations that the product was substandard and the company falsely certified it as meeting industry standards.

When our inspectors arrived, the company challenged our authority to inspect. They wouldn't let us on the grounds. So we had to go back and get a criminal search warrant. But it took so long and they had so much notice, by the time we got in there we found nothing.

Now, maybe there was nothing to be found, but it took so many months that there was plenty of time to destroy any records that were available.

A second example is a company that was suspected of falsifying material test reports on such things as stainless steel bar stock and plates supplied to licensee vendors. We were denied access to inspect. Our inspectors show up. They're not licensees, the people are not licensees, they're vendors to licensees. They wouldn't let us look at their records.

So our office of general counsel discussed things with their attorneys, an agreement was reached, and we got access, but it took us over a week to get this access. And when we got there, we found nothing. Maybe there was nothing there, but a week was plenty of time to destroy the records.

We have about two or three cases a year in which we have reason to suspect there is something there that we don't get to. In other words, we have reason to suspect, we're denied access on a friendly basis, we eventually get in, but it takes weeks or months to get in, and we find nothing.

Mr. ALLARD. I have a couple of questions, since Congressman Vucanovich isn't here, that I would like to ask on her behalf.

One of them is, what steps if any does the NRC plan to take regarding the GAO's conclusion that characterization activities at Yucca could take up to 13 years longer to complete than expected.

Mr. SELIN. You have to understand—or I have to put on the record, to be more precise—what our responsibilities are. Our responsibilities are to respond to the Department of Energy program, not to independently set schedules or any other items. We've done two things. One is we've done a high-level review in 1989 in which we came up with two major concerns and I forget the exact number, but about two hundred minor concerns.

The Department of Energy has answered the two major concerns that we have and they've fully resolved a third of the minor concerns, and they continue with the other pieces.

Now, as far as scheduling goes, we could look around as well as anybody else and see that they're not going to make the schedules that were originally set up. We haven't seen the GAO report, but we have taken this into account.

We considerably cut back on our program to develop a so-called licensing support system, which is an extremely ambitious system to put onto computer records all documents that will eventually have to be used in a licensing agreement. We have cut way back on the pace of that. We have cut way back on the pace of some other activities.

Our objective is not to be on the critical path, and we will not be on the critical path on any of these points. We try not to be too

far ahead, really from the point of view of economy rather than anything else.

But if your question or Mrs. Vucanovich's question suggests what actions are we taking to rectify the situation in the GAO report, that's not our job, it's not our responsibility, and we're not taking any such actions.

Mr. ALLARD. Have you looked at—so you have not seen the GAO report?

Mr. SELIN. We have not seen it, no, sir.

Mr. ALLARD. Why haven't you seen it?

Mr. SELIN. I think they probably send it to the Department of Energy before they send it to us.

Mr. ALLARD. But you're aware that it exists?

Mr. SELIN. We've seen pieces of it. There were early findings. We have had interviews with the GAO people. We're generally aware of what's in the report.

I've forgotten the precise title, but the Department of Energy has its own review group that looks at the high-level waste program, who have made many of the same findings. They have briefed us at an official Commission meeting. We're generally apprised of the progress.

We have a couple of people who are resident inspectors who are on the site at Yucca Mountain, so we are generally apprised of their progress. It's just that specific document we have not seen.

Mr. ALLARD. Would you, for this Committee, review that GAO report and submit some written comments in regard to that report?

Mr. SELIN. We will be glad to do so, but we will do so within our charter, and I hope you won't be disappointed, because our charter is very limited on—

Mr. ALLARD. Well, if you will explain that to Congressman Vucanovich, I think that would help.

But if you would look at the GAO report and then put some written comments in your response, I'd appreciate that.

Mr. SELIN. Yes, sir.

Mr. ALLARD. The other question is, given that DOE has admitted in budget briefings that they will not be able to meet the 2001 date for filing a high-level waste repository license with the NRC, what type of delay would this represent for the NRC in processing the application? And then, the second part of the question, would a delay in the submittal affect staffing and those type of administrative procedures?

Mr. SELIN. To answer both your questions, we've already taken into account what we think is the most reasonable estimates of DOE's schedule. We have very good day-to-day working relationships with the staff. We know what they're doing and our budget already takes into account—it's not so much—I can't say it's built on 2005 instead of 2001. We look at their short term activities, we see what they're doing, and we make sure we have adequate staff to support in the proper regulatory sense their activities. So our budget is already built on their day-to-day schedules.

There is another area I should go into. It's not a budget area, but it's a question of confidence. The Commission made a finding called a High Level Waste Confidence Finding renewed two years ago that said that the complex of activities that deal with spent fuel

in the United States are adequate to give us confidence that nuclear power plants can continue to operate and can continue to generate additional spent fuel.

So from that point of view, we also very closely monitor the activities at Yucca Mountain, progress or lack of it toward monitored retrievable storage facility, and the short term storage on the power plants themselves. We are very comfortable that technologies are available to give very high confidence in storage of spent nuclear fuel for a very long time. The dry fuel storage seems to be good for as long as we can see, fifty years to one hundred years. We've used the phrase "a hundred years."

So at the same time as we work with the Department of Energy on what they're doing on Yucca Mountain, we continuously and continually upgrade our estimates of the overall safety of the handling of the fuel in the storage area and whether progress is being made in better storage techniques to accommodate the apparent slip in the availability of Yucca Mountain. We are comfortable that such progress is, in fact, being made.

Mr. ALLARD. To change directions completely, and this is my own question now, in hearing your response to the first question that I asked, the thought crossed me that probably OSHA inspects these facilities too, do they not?

[Pause.]

Mr. SELIN. Oh, I'm sorry, you're back to the business with search warrants?

Mr. ALLARD. Yes.

Mr. SELIN. Oh, okay. Let's start over again. Yes, sir. I was completely prepared to answer the wrong question, and it won't be the first time, either.

Mr. ALLARD. In regard to the search warrants, the first question that I talked about, OSHA also inspects these facilities, don't they?

Mr. SELIN. Sometimes.

Mr. ALLARD. Have you looked at what they are inspecting and what you are inspecting? There could be a duplication. You could be asking one thing and they could be asking another—

Mr. SELIN. No, sir, first of all I'm talking about people who are not our licensees in general. We're talking about suppliers to the nuclear industry, not licensees.

Mr. ALLARD. Okay.

Mr. SELIN. As a practical matter—

Mr. ALLARD. But you want permission to go in?

Mr. SELIN. Yes, sir.

Mr. ALLARD. Have you ever worked with the OSHA?

Mr. SELIN. It's not—we're not looking at the health and safety practices of these manufacturers for their own employees; we're looking to see if the equipment, the goods that they produce, have been certified for use primarily in nuclear reactors under the extreme conditions of heat and temperature in nuclear reactors, and that these will be safe. There's no overlap at these facilities.

There is overlap in our inspections of our own licensed facilities. When we do an inspection, say, of a fuel fabrication plant, we look at all federal rules. We look at environmental questions, we look at occupational health and safety questions, we look at radioactive safety questions.

So in those areas, there is need to coordinate, which we do. There is need to reduce overlap.

But those aren't the places that we need a search warrant.

I couldn't flat out say that we would never use or administer a search warrant at a licensee, but that's not the place we care about. We care about people who are supplying goods to the licensees; not the licensees themselves. And if there were concerns in this area, we would be—in fact, I will now make a commitment that we would not even ask for such a search warrant until we had issued regulations subject to public comment on how they would be used and how they would not be used.

Mr. ALLARD. Well, I just think that generally we have a problem with anybody in business, just generally speaking, with duplication. You have one agency that comes in—particularly if you get a highly regulated industry—where one agency comes in and makes one standard and another agency comes in and they don't talk to one another, they don't know what each other's doing, and the guy's in a situation he can't comply with.

Mr. SELIN. Yes, sir.

Let me just assure you that there is zero possibility of overlap in this situation. There is only one place, and that's not where we propose to use these search warrants, and that would be for somebody who is producing material for, say, a medical licensee who would have to worry about us and the Food and Drug Administration. And that's maybe one tenth of one percent of what we do. And we could set in our regulations situations such that that just wouldn't happen. The FDA has sufficient authority to do these things themselves.

We care about providers to the nuclear power reactor industry of safety-related equipment and supplies.

Mr. ALLARD. Thank you, Mr. Chairman. I don't have any other questions, and I yield back the balance of my time.

Mr. LEHMAN. Thank you.

Mrs. Vucanovich, do you have any additional questions?

Mrs. VUCANOVICH. Thank you, Mr. Chairman. I apologize to the Chairman for not being here for all of your testimony. I'd like to simply submit some questions for the record, and appreciate all of you being here.

Thank you, Mr. Chairman.

Mr. LEHMAN. Thank you. And, without objection, we will allow any members to submit questions and ask you to respond to those promptly.

[EDITOR'S NOTE.—See appendix.]

Mr. LEHMAN. Let me just briefly touch on one other item, and I will submit more questions to you on this.

But I just wanted to touch on the contract management issue that was brought up in your IG's report that criticized your contracts with the Department of Energy. And I guess my question is, is there something inherent in the way these things operate that makes them cost so much money?

And then, also, I note that the GAO attributed a lot of the problems at the labs to cost plus overhead contracts. And I wanted to know if that's typical of the way the NRC contracts deal with the labs.

Mr. SELIN. Yes, sir.

First, let me deal with the IG finding, which is much more limited. Then I will try to go to what I believe is your real concern, which is in fact our real concern.

The IG criticizes us not for spending too much or too little money on our DOE contracts, but they criticize us for not properly making sure that the bills that were paid were for the amounts that were authorized along the way. There was no question that they did the work that we're paying them for.

But what happens is we have a technical person who approves at the end of each month, looks at the DOE financial ledgers, looks at their time cards, says, yes, we did ask for and we did get thirty-eight hours of work at \$96 an hour. Then at the end when the bill comes in we were not going back and looking at these justifications to see if the amount of work that was justified added up to the amount of work that was done.

We did monitor the contracts, but we didn't close the loop at the end. As the IG himself said, and I quote from page four of his report—you'll have to trust me it's the right paragraph, because it's a good quote, "NRC management took prompt and decisive actions to correct these deficiencies." And, in fact, we have.

But this doesn't really go back to what I think is troubling you, and which is troubling us, which is the overall costs of these services.

About a year ago, Commissioner Remick and I went down to OMB—I guess it was about a year and a half ago. And we expressed to OMB, to the parts of OMB that dealt with the Department of Energy laboratories, our concerns that as their weapon business went down that their overhead would go up and that we would end up swallowing more of the overhead for the same amount of work, because we would be a larger proportion of the total work done in these laboratories.

After, we found out that OMB had no idea of what was happening on this situation and if we wanted to worry about this, we had to worry about it ourselves. So we set up an internal procedure between our Office of Research and our comptroller to compare the costs that were being charged over time from the laboratories and from laboratory to laboratory.

We didn't find much bothersome over time. In fact, the rates were not going up very fast. But we did find enormous differences from laboratory to laboratory for what looked to us like comparable work. And what we have tried to do—we're not as good at this as we should be, but we've tried to put work where we have some choices to the laboratories that seem to be giving us fairer prices.

But to us, even when we accounted for the way that one laboratory will include secretarial support or material support and another one will not in the hourly rate, we saw then and we still see large differences without, in our opinion, justification for the quality of work or anything else from one laboratory to another. And we have tried to adjust our work to get more economical prices.

But we are a very small part of their business and we don't think if we're their only market that they're going to fix that problem at the laboratories.

Beyond that, you get into the internal management of laboratories, and I can't answer that, what goes on inside.

Mr. LEHMAN. Thank you very much.

I would certainly allow any other members of the Commission, if they want to add anything at this point, to feel free to do so. We don't want you to just feel like potted plants there.

Mr. SELIN. If you ever have to chair a Commission meeting, sir, you would know you don't have to worry about the reticence of the Commission members. [Laughter.]

Mr. LEHMAN. Very good.

Well, thank you very much. We appreciate your testimony, your extensive response to questions, and we look forward to working together in the near future here.

Thank you.

Mr. SELIN. Thank you for your support, Mr. Chairman.

Mr. LEHMAN. The hearing's adjourned.

[Whereupon, at 12:05 p.m., the hearing was adjourned.]

APPENDIX

MAY 27, 1993

ADDITIONAL MATERIAL SUBMITTED FOR THE HEARING RECORD

GEORGE MILLER, CALIFORNIA, CHAIRMAN
PHILIP R. SHAFER, INDIANA
EDWARD J. MARKEY, MASSACHUSETTS
ALBERT J. CLARKE, PENNSYLVANIA
RICK JOE MANULL, WEST VIRGINIA
BRUCE F. VENTO, MINNESOTA
PAT WILLIAMS, MONTANA
RON W. LUGO, VIRGIN ISLANDS
ALAN GLADSTONE, CONNECTICUT
RICHARD H. LEHMAN, CALIFORNIA
BILL RICHARDSON, NEW MEXICO
PETER A. DENTZIO, OREGON
SEN. JIM FALCONE, ARIZONA
CARLOS ROMERO-SANCHEZ, PUERTO RICO
LARRY LAROCK, IDAHO
SEN. JAMES CRISWELL, KANSAS
CALVIN H. BOOLEY, CALIFORNIA
CARLOS ROMERO-SANCHEZ, PUERTO RICO
KARAH ENGLISH, ARIZONA
KIMBERLY SHEPHERD, UTAH
NATHAN ORAL, GEORGIA
SAMUEL D. KIRCHNER, NEW YORK
ROBERT A. UNDERWOOD, GUAM
HOWARD L. BERMAN, CALIFORNIA
LARRY EVANS, KANSAS
PATRY F. MINE, KANSAS
THOMAS J. BARTON, KENTUCKY
THOMAS H. BANNEY, WISCONSIN

U.S. House of Representatives
Committee on
Natural Resources
Washington, DC 20515-6201

DON YOUNG, ALASKA
RANKING REPUBLICAN MEMBER
JAMES V. HANSEN, UTAH
BARBARA F. VUCANOVICH, ARIZONA
ELTON GALLEGOS, CALIFORNIA
ROBERT F. SMITH, OREGON
CHAD THOMAS, WYOMING
JOHN J. DUNCAN, JR., TENNESSEE
JOHN HEFLY, COLORADO
JOHN T. BOGUTTLE, CALIFORNIA
WALTER ALLARD, COLORADO
RICHARD H. BAKER, LOUISIANA
KEN CALVERT, CALIFORNIA
SCOTT LANSING, COLORADO
RICHARD W. FORD, CALIFORNIA
LUT RICEY, ARIZONA

JOHN LAWRENCE
STAFF DIRECTOR
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SERIALS COUNSEL
DANIEL VIAL RICH
REPUBLICAN STAFF DIRECTOR

June 2, 1993

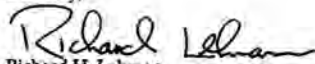
Hon. Ivan Selin, Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Chairman Selin:

Thank you for your very helpful testimony before the Subcommittee last week on H.R. 2143 and H.R. 2170. I am optimistic that we will be able to move these bills this year.

To help us compile a more complete record on the issues in the hearing, I would appreciate receiving your responses to the enclosed written questions from Rep. Vucanovich and me no later than June 28.

Sincerely,



Richard H. Lehman
Chairman
Subcommittee on Energy and
Mineral Resources

enclosures: Questions from Rep. Vucanovich
Questions from Chairman Lehman

Post-Hearing Questions for NRC from Chairman Lehman

1. In response to a question concerning the Commission's research contracts with DOE labs, Chairman Selin stated that the NRC had noted that there were large differences in charges for the same work among the various labs, and that the Commission was controlling costs in part by favoring the less costly labs. Please provide some detail on these cost differences among the labs, including a few specific examples describing the requested work with the bids that were offered by the labs.
2. The IG reports that closing out contracts and performing required evaluations at the conclusion of contracted work is a big problem for the Commission. Please explain why that is the case.
3. The IG notes that NRC management has taken decisive actions to correct contracting abuses with the DOE labs. Please briefly characterize the kinds of actions that have been taken.
4. One of the major preoccupations of the Commission during the past two years has been the issue of Thermo-Lag fire barrier material, which is used in most nuclear plants to protect safety-related electrical cable from fires. The Commission has declared Thermo-Lag to be non-functional. In recent testimony before Congressman Dingell's Oversight and Investigations Subcommittee, you admitted that the Thermo-Lag episode has been a significant regulatory failure for the agency. Resolution of the Thermo-Lag problem was highly dependent on an industry effort to conduct generic testing of the material. It has recently been reported that the collective industry effort has been hindered by legal concerns stemming from a grand jury criminal investigation concerning Thermo-Lag, and that widespread industry requests for exemptions from requirements of the fire protection rule could be in the wings. Do you anticipate that wholesale exemption requests or generic relaxation of the fire protection rule will be the primary means of resolution of this issue? Please explain.
6. You testified before Chairman Dingell that the Commission would be conducting a review to assess the generic regulatory implications of the Commission's failure to adequately comprehend the dimensions of the

Thermo-Lag problem. Do you have any results of that review that you can report at this time? Please explain.

7. There is apparently no statutory precedent for the term "administrative search warrant." Is there some reason why the Commission prefers that term to "administrative inspection warrant," for which there is statutory precedent?
8. In explaining your need for the administrative search warrant at hearing, you described an example involving a cement grout producer in which the Commission first tried to inspect the premises of the firm and was denied access, then sought and obtained a criminal search warrant. Possibly because of the prior notice involved, nothing was found when the warrant was executed. Is it not correct that if you had obtained the criminal warrant before attempting the search, there would have been no prior notice?
9. You objected to the amount of time required to convince a U.S. Attorney to seek a criminal search warrant from a judge. How much time transpired between the Commission's initial request and the issuance of a warrant in the previous example?
10. For any other instances in which the Commission has successfully obtained criminal search warrants in the past ten years, please provide the time that elapsed between the initial request and the issuance of the warrant.
11. Please also list any instances in the past ten years in which the Commission requested a criminal search warrant and it was denied, either by the U.S. Attorney in refusing to seek it, or by a judge.
12. Delays in the opening of new repositories for low-level radioactive waste, together with reduced access to existing facilities, is resulting in a large increase in the need for onsite storage, both at reactors and at materials licensees. Does extended onsite storage present any safety problems at either type of facility? Please explain.

13. One of several issues that currently embroils the potential Ward Valley low-level waste site in California is the type of hearing to hold. If California were not an agreement state and the site were being licensed by the NRC, would the Commission hold a formal adjudicatory hearing on the application?
14. Your testimony states that the NRC staff has developed a process for implementing the license renewal rule that represents an approach not addressed at the time the rule was promulgated in 1991. Is this process consistent with the rule? Please explain. If not, do you plan to formally amend the rule?

**QUESTIONS FOR NRC CHAIRMAN IVAN SELIN
FROM REP. VUCANOVICH**

-- Given that DOE has admitted in budget briefings that they will not be able to meet the 2001 date for filing a high level waste repository license with the NRC, what type of delay would this represent for the NRC in processing the application ? Would a delay in the submittal affect staffing, etc. ?

-- Last year, Admiral Watkins in a letter to Sen. Johnston proposed the possibility of phased licensing at yucca mountain. Mrs. O'Leary initially appears open to the idea. Does the NRC support the concept of phased licensing ? Why or why not ?

-- What has been the nature of your interaction with DOE on the issue of phased licensing ?

-- If an MRS was sited at a federal facility, as was proposed by Admiral Watkins last year, what would that entail for the NRC. For example, would you have to license it ?

-- Would a federal facility that would be the site of an MRS be held to federal environmental standards for which it is not currently required to meet ?

-- The Nuclear Waste Technical Review Board has called on DOE to establish a more flexible schedule for activities at Yucca Mountain. Have the NRC and DOE had any discussion about adjustments in the program in light of that recommendation in March of this year ?

-- What do your current activities at the Yucca Mountain site consist of ?



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 6, 1993

The Honorable Richard H. Lehman, Chairman
Subcommittee on Energy and Mineral Resources
Committee on Natural Resources
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

I am responding to your letter of June 2, 1993 concerning the May 27, 1993 hearing on H.R. 2143, the Nuclear Regulatory Commission Authorization Act for fiscal year 1994 and 1995 and H.R. 2170, The Omnibus Nuclear Power Safety and Security Enhancement Act of 1993. The responses to the questions forwarded by your letter are enclosed.

If I can be of further assistance, please let me know.

Sincerely,

A handwritten signature in cursive script, appearing to read "Dennis K. Rathbun", with a small flourish at the end.

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure(s):
As stated

cc: Rep. Barbara Vucanovich

QUESTION 1.

In response to a question concerning the Commission's research contracts with DOE labs, Chairman Selin stated that the NRC had noted that there were large differences in charges for the same work among the various labs, and that the Commission was controlling costs in part by favoring the less costly labs. Please provide some detail on these cost differences among the labs, including a few specific examples describing the requested work with the bids that were offered by the labs.

ANSWER.

To better understand cost variances among the laboratories, the NRC staff reviewed a small sample of projects from throughout the Agency for each DOE National Laboratory. The cost proposal information from that sample was used to determine the average FTE cost charged by the laboratories for NRC work for the period FY 1988 - 1992. Attachment 1 shows the results of this review.

Our findings revealed that generally costs charged to the Agency for laboratory work have risen each fiscal year for all laboratories. The costs for FY 1992 ranged from \$129,000 for Agency work performed by Idaho National Engineering Laboratory (INEL) to \$218,000 for work conducted by Lawrence Livermore National Laboratory (LLNL). Cost variances are attributable to a number of factors, e.g., laboratory direct and indirect rates, nature of the work placed at the various laboratories, skill mix of labor required to perform the work, as well as location of work performance.

The comparison of laboratory costs without respect to the nature of the work performed does not, however, provide a complete story. Accordingly, we recently analyzed the relative cost of doing business with the laboratories using projects with similar work efforts. Four sets of research projects were used for this analysis and the results/conclusions are shown in Attachment 2.

In most instances, the decision to place work at a particular laboratory is based upon a number of considerations, such as: expertise in a particular technical area; availability of staff to complete the work in the required time frame; unique facilities or equipment; and quality and timeliness of previous related work performed by the laboratory. In addition to these factors, the NRC Executive Director for Operations has instructed the staff to use the results of the review of cost variances among the laboratories to make informed judgements as to the most economical alternative in placing work to accomplish Agency requirements.

In some instances, when more than one laboratory has comparable capability to perform Agency work, the NRC has competed projects among the various laboratories. Attachment 3 contains the results of two such projects.

AGENCY-WIDE LABORATORY COSTS BY FISCAL YEAR

Attachment 1

*	FY88 **		FY89		FY90		FY91		FY92	
	AVG. FTE	AVG. PROJ COST	AVG. FTE	AVG. PROJ COST	AVG. FTE	AVG. PROJ COST	AVG. FTE	AVG. PROJ COST	AVG. FTE	AVG. PROJ COST
ANL	124	245	136	180	142	243	157	174	193	228
BNL	151	405	161	392	173	171	176	243	184	299
INEL	113	359	125	518	126	497	123	503	129	473
ORNL	130	277	141	295	153	272	154	313	178	349
LANL	N/A ***		115	560	140	332	164	175	178	311
LLNL	139	306	150	294	164	382	219	433	218	424
SNL	138	456	150	453	144	500	167	253	177	367
PNL	168	560	160	502	148	344	174	474	181	232

* ANL = Argonne National Laboratory
 BNL = Brookhaven National Laboratory
 INEL = Idaho National Engineering Laboratory
 ORNL = Oak Ridge National Laboratory
 LANL = Los Alamos National Laboratory
 LLNL = Lawrence Livermore National Laboratory
 SNL = Sandia National Laboratory
 PNL = Pacific Northwest Laboratory

** Average Project FTE and Project Cost in thousands of dollars.

*** N/A = Not applicable. The projects reviewed were not active in Fiscal Year 1988.

Cost Comparison (differences) Among DOE National Laboratories ^(1,2,3)

DOE LAB/PROJECT ⁽¹⁾	Average Cost Per Scientific/Technical Person Per Year ⁽¹⁾		(A) + (B) Staff year costs
Set 1. Nuclear Plant Aging	Direct Salaries (A)	Indirect Labor Cost + Other Direct Costs + G&A (Averaged per scientific/technical person) (B)	
PNL EIN: B2911	\$ 74K/person year	\$ 124K/person year	\$ 198K
- Diesel Generators			
- Service Water Systems			
- Snubbers			
- Chillers etc.			
BNL EIN: A3270	\$ 100K/person year	\$ 104K/person year	\$ 204K
- Motors			
- Chargers/Inverters			
- Control Rod Drives			
- LP-RHR Systems etc.			
ORNL EIN: B0828	\$ 112K/person year	\$ 108K/person year	\$ 220K
- Pumps			
- Valves MOV, CV, SOV, AOV			
- MSIV, PORV/BV			
- Aux. Feed System etc.			
INEL EIN: A6389	\$ 53K/person year	\$ 101K/person year	\$ 154K
- Residual Life Evaluation			
- HPCI			
- Electrical Systems			
- Aging-Risk Studies etc.			

Conclusion: The aging research computation clearly shows that INEL is the low cost performer for this set of work. The differences in cost between the other three laboratories (PNL, BNL, and ORNL) are smaller and less significant. Factors such as level of skill applied to the job and the effectiveness of laboratory project management from one task to another can affect cost performance and could change the cost relationships among the three laboratories for new tasks.

⁽¹⁾ All cost information derived from FY 1983 submittals of NRC Form 189.

⁽²⁾ The work done at all the Labs were comparable and the products were all acceptable.

⁽³⁾ Each Lab employed staff for this work exhibiting a slightly different mix of experience and grade.

⁽⁴⁾ Scientists, Engineers, and Technicians. (Most of this work was analytical - few technicians utilized).

⁽⁵⁾ Each Lab had shown particular knowledge and expertise in the specific areas under study.

Cost Comparison (differences) Among DOE National Laboratories ^{(1), (2), (3)}

DOE LAB/PROJECT ⁽⁴⁾	Average Cost Per Scientific/Technical Person Per Year ⁽⁴⁾			(A) + (B) Staff Year Costs
	Direct Salaries (A)	Indirect Labor Cost + Other Direct Costs + G&A (Averaged per scientific/technical person) (B)		
Set 2. Thermal Hydraulic Codes				
INEL J-6000	\$ 53K/person year	\$117K/person year		\$170K
BNL L-2187	\$ 80K/person year	\$157/person year		\$237K
Set 3. Severe Accident Analyses				
BNL A-3281	\$ 80K/person year	\$150K/person year		\$230K
ORNL J-6014	\$131K/person year ^a	\$111K/person year		\$242K
SNL A-1339	\$155K/person year ^a	\$ 45K/person year		\$200K

Conclusion:

Set 2. The comparison on thermal hydraulic code work shows that INEL cost was significantly less than the BNL cost.

Set 3. The comparison on severe accident analysis shows that SNL was somewhat less (about 15%) than the average of BNL and ORNL.

⁽¹⁾ All cost information derived from FY 1993 submittals of NRC Form 189.

⁽²⁾ The work done at all the labs were comparable and the products were all acceptable.

⁽³⁾ Each Lab employed staff for this work exhibiting a slightly different mix of experience and grade.

⁽⁴⁾ Scientists, Engineers, and Technicians. (Most of this work was analytical - few technicians utilized).

⁽⁵⁾ Each lab had shown particular knowledge and expertise in the specific areas under study.

⁽⁶⁾ Includes other indirect costs (fringe, matls, ADP support, travel)

Cost Comparison (differences) Among DOE National Laboratories^{1,2}

DOE LAB/PROJECT	Average Cost Per Scientific/Technical Person Per Year			
	Proposed Cost	Actual Cost ³	Effort Staff/Year	Staff Year Costs
<u>Set 4. PRA Australia</u>				
BNL L-1680	\$288K	\$270	1.28	\$211K
SNL L-1679	\$335K	\$215	1.10	\$195K

Conclusion: The significant point in this comparison is that the BNL's proposed cost was closer to its actual cost than were SNL's. The fact that is not shown in the figures is that extraordinary NRC project management efforts caused SNL's actual cost to come in substantially under the proposed cost. The cost of NRC project management is not included in the above figures.

¹ Both labs did acceptable and similar work, but not identical PRA's (e.g., PWR vs. BWR).
² Primary selection criterion was not cost, but technical capability and availability.
³ Work was required to be completed at the same fixed end date, but SNL started later than BNL.

Results of Two Projects Competed Among DOE National Laboratories

o Project title: Fuel Cycle Licensing Review Assistance

Project objective:

Conduct safety and environmental reviews of applications for licenses for the construction, operation and decommissioning of fuel cycle facilities.

Technical review results:

Laboratory proposals were evaluated against the following technical evaluation factors: laboratory experience in performing related work, qualifications of personnel identified to perform this work and the management system employed to oversee the effort.

<u>Laboratory</u> Average	Technical <u>Score</u>
Project	
<u>FTE Cost</u>	
Argonne National Laboratory (ANL) \$142,000	69
Idaho National Engineering Laboratory (INEL) \$193,000	60
Los Alamos National Laboratory (LANL) \$196,000	58
Lawrence Livermore National Laboratory (LLNL) \$215,000	66
Pacific Northwest Laboratory (PNL) \$170,000	- 88

Award:

Work was placed with PNL which received the highest technical score that reflected a high caliber of technical personnel, and extensive experience in fuel cycle related projects.

The low cost laboratory (ANL) was not recommended for award since it did not demonstrate adequate experience in the fuel cycle area and did not offer personnel with adequate experience to successfully complete the effort.

- o Project title: Survey and Evaluation of Aging Risk Assessment Methods and Applications

Project objective: Incorporate aging risk into a PRA.

Technical review results:

Los Alamos National Laboratory (LANL), Lawrence Livermore National Laboratory (LLNL) and Idaho National Engineering Laboratory (INEL) submitted proposals for the project. The technical review panel evaluated the proposals in terms of understanding project requirements, technical competence of proposed personnel and experience of laboratory in the technical area required to complete the project.

Project	<u>Laboratory</u>	Technical
	Average	Rank
<u>FTE Cost</u>		
	LANL	1
\$228,000	INEL	2
\$240,000	LLNL	3
\$204,000		

Award:

The technical review panel awarded the project to LANL since it proposed an outstanding project team and demonstrated an experience level necessary to successfully complete the effort. While LANL's cost was higher than LLNL, the technical evaluators concluded that LANL's technical superiority was worth the extra cost.

QUESTION 2.

The IG reports that closing out contracts and performing required evaluations at the conclusion of contracted work is a big problem for the Commission. Please explain why that is the case.

ANSWER.

There are two issues raised in this question. The first pertains to closeout of commercial contracts and the second to preparing final evaluations of DOE laboratory performance upon completion of projects.

With respect to commercial contracts, the NRC has made considerable progress in reducing the backlog of close-out actions. Prior to the issuance of the IG's June 1992 report, the contracting staff focused its efforts on negotiating new awards and administering active contracts. Since that time, however, NRC has placed greater emphasis on its close-out activity. A new contract for close-out assistance was awarded and includes rigorous performance standards and incentives. A senior level contracting staff member was assigned to monitor close-out progress. Revised close-out procedures were issued, incorporating appropriate streamlining measures which have helped expedite the close-out process. These actions have resulted in a reduction of approximately 400 contracts from the backlog of 829 discussed in the IG's report. We expect to close another 400 contracts by July 31, 1994.

Regarding the evaluation of DOE laboratory performance, the IG correctly noted that final written evaluations of laboratory performance were not prepared when projects were completed. To assure that final performance evaluations are now being prepared, the NRC management directive dealing with placement and monitoring work at the DOE laboratories has been modified to provide more definitive guidance on this requirement and NRC management and individual project managers have been made fully aware of the need for these evaluations. Finally, before projects can be closed out the final written evaluation must be prepared. It must be noted, however, that the NRC has been continually evaluating laboratory performance during the course of the project through the review of monthly progress reports from the laboratories, telephone contact, meetings and site visits with DOE laboratory personnel. The lack of final written evaluations in no way impacted NRC's oversight and management during the course of the work.

QUESTION 3.

The IG notes that NRC management has taken decisive actions to correct contracting problem with the DOE labs. Please briefly characterize the kinds of actions that have been taken.

ANSWER.

Actions to address the weaknesses found in the IG reports began with the NRC's Chief Financial Officer meeting with the management and key support staff members in each NRC office. At these meetings, the significance and the importance of sound financial and program management was stressed. Since then, the following specific actions have been taken:

- o To strengthen contract management over its DOE laboratory agreements, the NRC has drafted Management Directive 11.7 entitled, "NRC Procedures and Management Controls for Placement and Monitoring of Work With the Department of Energy," now under review and scheduled for issuance by the end of this fiscal year. The Directive will ensure that laboratory agreements are negotiated and managed consistent with sound business practices and contracting principles and will ensure uniform application of an agency-wide standard of contract management for projects placed with DOE.

The agency initiated a 6-month pilot program in the Office of Nuclear Regulatory Research to implement the draft directive. Results of the pilot program will be used to strengthen the Directive prior to issuance.

- o To remedy weaknesses found by the NRC IG in the agency's management of DOE acquired property under laboratory agreements, the NRC is reviewing its property management procedures and will strengthen existing policy as necessary. Correspondence will be sent to the staff and DOE underscoring the need to follow existing policy to ensure proper management oversight for property acquired with agency funds under laboratory agreements.
- o Action to close out all DOE laboratory research projects that have been completed is in progress. First priority was given to deobligating funds for projects with unpaid balances. In pursuing the closeout of projects completed years ago, we are using an abbreviated closeout procedure appropriate to the age of the project. We plan to close these projects by early next year.
- o An automated system for the tracking and updating of the status of all projects is under development. This system is also intended to provide an automated capability for procurement planning, budget execution, and financial management. Our target schedule is to have the high-priority components of the system in place by the end of FY 1993.
- o The Office of Research has developed and presented a one-day, hands-on project management course to virtually all of its project managers. These project managers have also attended the NRC project management course entitled "Acquisition for Project Managers." Also, by the end of FY 1993, all Research managers who have not already done so, will attend one or more project management training courses. Additionally, the

Office of Research is taking action to ensure that all project managers attend both project management courses.

- o To improve the DOE voucher review process, new procedures were established in the Office of Research to track, review and approve vouchers within a 20-day period. Also, a follow-up system was established in the Office of the Controller which alerts management when required reviews are not completed in a timely manner.
- o A verification review of over 9,500 DOE billings representing \$210 million in payments to DOE laboratories was performed to determine the reasonableness of the amounts billed. This review revealed that less than 0.08% of the \$210 million involved were questionable payments. Of the \$210 million of vouchers reviewed, we found no instance of illegal payments or any evidence of waste, fraud, or abuse.
- o To ensure that project files are properly maintained, the Office of Research has issued a directive which requires project managers and management to certify annually that project files are complete. A random sample of the active project files is then selected for a confirmation review by an independent party.

QUESTION 4.

One of the major preoccupations of the Commission during the past two years has been the issue of Thermo-Lag fire barrier material, which is used in most nuclear plants to protect safety-related electrical cable from fires. The Commission has declared Thermo-Lag to be non-functional. In recent testimony before the Subcommittee, you admitted that the Thermo-Lag episode has been a significant regulatory failure for the agency. Resolution of the Thermo-Lag problem was highly dependent on an industry effort to conduct generic testing of the material. It has recently been reported that the collective industry effort has been hindered by legal concerns stemming from a grand jury criminal investigation concerning Thermo-Lag, and that widespread industry requests for exemptions from requirements of the fire protection rule could be in the wings. Do you anticipate that wholesale exemption requests or generic relaxation of the fire protection rule will be the primary means of resolution of this issue? Please explain.

ANSWER.

The NRC does not anticipate wholesale fire barrier exemption requests from the industry and has expressed its intention to deny these requests should they be submitted. In addition, the staff has planned no generic relaxation or modification of the fire protection rule in order to resolve current fire barrier issues.

Members of the NRC staff met with NUMARC representatives on June 3, 1993, to discuss the scope and schedule of the industry test program. NUMARC representatives assured the NRC staff that the industry was moving forward with the testing program and that it did not advocate wholesale exemption requests as a means of addressing the technical issues. NUMARC representatives acknowledged that the grand jury investigation had caused individual utilities to withdraw their direct participation in the fire barrier test program, but alternatives, such as the use of independent contract personnel, had been developed to allow the timely continuation of the test program. Following completion of the NUMARC test program, each licensee will be required to assess its plant-specific Thermo-Lag barrier installations against the NUMARC test results. The staff expects that the licensees will need to upgrade certain fire barrier configurations to meet the NRC's fire protection requirements and may need to make repairs to correct fire endurance and ampacity derating deficiencies. The staff also expects that some licensees will need to conduct additional tests to qualify plant-specific fire barrier designs and configurations that were not modeled by the NUMARC program. The NRC staff expects each licensee to comply with the NRC fire protection requirements and the commitments in their licensing bases. The staff is currently in the process of issuing a supplement to Generic Letter (GL) 86-10, "Implementation of Fire Protection Requirements," of April 24, 1986. The GL supplement is a continuation of the clarification and guidance process and builds on the fire barrier testing acceptance criteria established in GL 86-10. The GL supplement will include additional guidance on the specific application of raceway fire barrier enclosures. The NRC's fundamental regulatory requirement to provide 1- or 3-hour fire barriers to separate redundant safe shutdown functions within the same fire area will not be modified by this GL supplement.

Independent of the present fire barrier issue, however, the NRC is reviewing the portions of all NRC regulations believed to be marginal to safety and cumbersome to implement and fulfill. Appendix R of 10 CFR Part 50 is among the rules which have been proposed for modification. The staff is considering replacing the currently prescriptive Appendix R with performance-based requirements which will allow the use of PRA technology and risk significance of fire sequences to determine fire protection features.

QUESTION 6.

You testified before Chairman Dingell that the Commission would be conducting a review to assess the generic implications of the Commission's failure to adequately comprehend the dimensions of the Thermo-Lag problem. Do you have any results of that review that you can report at this time? Please explain.

ANSWER.

No. A reassessment of the NRR reactor fire protection program was performed in response to the programmatic concerns raised during the review of Thermo-Lag fire barriers. The results of the reassessment were provided in the Report on the Reassessment of the NRC Fire Protection Program (February 27, 1993). The staff incorporated the recommendations of this report in two action plans which are currently undergoing management review. The Fire Protection Task Action Plan includes the application of lessons learned to other NRC programs. This comprehensive review will be conducted over the next 2 years, and preliminary results are not yet available.

QUESTION 7: There is apparently no statutory precedent for the term "administrative search warrant." Is there some reason why the Commission prefers that term to "administrative inspection warrant," for which there is statutory precedent?

ANSWER:

While there may be no statutory precedent for use of the term "administrative search warrant," the courts have used the term and the meaning appears to be well understood. See, for example, Martin v. International Matex Tank Terminals--Bayonne, 928 F.2d 614 (3rd Cir. 1991). We prefer this term to the term "administrative inspection warrant" because it is unclear whether the courts will find an inspection warrant to have the same reach as a search warrant, particularly in the area of seizure of defective components. A court challenge to a search conducted under an inspection warrant could result in an interpretation that limits the efficacy of the warrant.

QUESTION 8: In explaining your need for the administrative search warrant at hearing, you described an example involving a cement grout producer in which the Commission first tried to inspect the premises of the firm and was denied access, then sought and obtained a criminal search warrant. Possibly because of the prior notice involved, nothing was found when the warrant was executed. Is it not correct that if you had obtained the criminal warrant before attempting the search, there would have been no prior notice?

ANSWER:

Prior notice is not required in use of a criminal search warrant. However, use of a criminal search warrant means having to meet the rigorous standards of probable cause associated with criminal warrants. We are primarily interested in use of search warrants for civil purposes, where there is normally a lower threshold. Criminal search warrants also subject us to other constraints. Not only must we go to a U.S. Attorney for assistance in obtaining such a warrant, but a criminal search warrant must be served by a U.S. Marshal. This means additional coordination with a party outside of the NRC, and meeting scheduling and other requisites that may not be appropriate to NRC requirements.

QUESTION 9: You objected to the amount of time required to convince a U.S. Attorney to seek a criminal search warrant from a judge. How much time transpired between the Commission's initial request and the issuance of a warrant in the previous example?

ANSWER:

Our records do not indicate the exact date of the first contact with the U.S. Attorney's office, but the best recollection is that telephone contact was first made on August 24, 1992. Our records show that on August 26, 1992, NRC staff flew to Bridgeport, Connecticut, where the cognizant U.S. Attorney's office is located, to explain the safety significance of the issue involved and the possible NRC violations, and to assist in preparing the search warrant affidavit. The Judge signed the warrant on August 28, 1992. The warrant was served by the U.S. Marshal on September 1, 1992.

QUESTION 10: For any other instances in which the Commission has successfully obtained criminal search warrants in the past ten years, please provide the time that elapsed between the initial request and the issuance of the warrant.

ANSWER:

Our search of cases in which the Commission has successfully obtained criminal search warrants in the past ten years has identified 13 cases, in addition to the one discussed in our answer to question 9. In these 13 cases, elapsed time between NRC staff's initial contact with an Assistant U.S. Attorney (AUSA) and issuance of the search warrant was as follows:

- In a case opened in 1985, elapsed time between NRC staff's initial contact with an AUSA and issuance of the warrant was 6 days. The warrant was executed one day after issuance.
- In four cases opened in 1988 in which the search warrants were applied for and executed simultaneously, elapsed time between NRC staff's initial contact with an AUSA and issuance of the warrants was 10 days. The search warrants were executed four days later.
- In a case opened in 1988, elapsed time between NRC staff's initial contact with an AUSA and issuance of the warrant was 5 days. The search warrant was executed on the day the warrant was issued.
- In six cases opened between 1988 and 1991 in which the search warrants were applied for and executed simultaneously, elapsed time between NRC staff's initial contact with an AUSA and issuance of the warrants was 21 days. The search warrants were executed one day after issuance.
- In a case opened in 1991, elapsed time between NRC staff's initial contact with an AUSA and issuance of the warrant was 23 days. The search warrant was executed the day the warrant was issued.

Note that the data provided above do not reflect time consumed by preliminary, informal contacts with the Department of Justice (DOJ) to discuss the need for the warrant, having the NRC Office of the General Counsel put together a criminal search warrant package, and delivering the package to DOJ. The time required for these activities is often substantially longer than the time it takes to get the warrant once the AUSA contact is formally initiated.

The historical data shed some light on the Commission's decision to submit the administrative search warrant proposal to the Congress, but the information provided does not tell the whole story behind the Commission's decision. Not all violations of the laws that fall under the Commission's responsibility are subject to criminal penalties. Even when they are, the Commission may not be able to meet the high standards of probable cause associated with issuance of a criminal warrant. Further, the Commission believes that in many instances civil proceedings are a more appropriate and effective way of handling violations, particularly with respect to routine citations.

QUESTION 11: Please also list any instances in the past ten years in which the Commission requested a criminal search warrant and it was denied, either by the U.S. Attorney in refusing to seek it, or by a judge.

ANSWER:

We have no record of any instances in the past ten years in which a U.S. Attorney refused to seek a criminal search warrant requested by the Commission, or in which a judge refused to issue the warrant. This does not mean, however, that a preliminary, informal discussion between NRC staff and the U.S. Attorney's office may not have resulted in an NRC staff decision not to pursue the request.

QUESTION 12: Delays in the opening of new repositories for low-level radioactive waste, together with reduced access to existing facilities, is resulting in a large increase in the need for onsite storage, both at reactors and at materials licensees. Does extended onsite storage present any safety problems at either type of facility? Please explain.

ANSWER.

While public health and safety can be adequately protected if LLW is stored at either reactor or material licensees' sites, the Commission remains concerned about potential health and safety concerns associated with the increased reliance upon on-site storage of low-level waste. However, the public health and safety will be enhanced by disposal, as opposed to long-term, indefinite storage. There are several concerns relating to storage at both reactor and materials licensees' sites that make disposal the preferable waste management option.

The first concern with storage is waste container degradation and the consequences of this degradation. Stored waste packages need to maintain sufficient integrity to prevent dispersal of the waste during storage, transport, and handling, up to and including emplacement for disposal. Because of the variability of certain storage environments, waste packages may suffer degradation over an extended storage period.

A second concern regarding storage of LLW is increased radiation exposure. Onsite storage of LLW is not expected to result in any radiation exposure to the general public. However, storage could increase radiation doses to workers performing radiation surveys and inspections of LLW in storage and from the additional handling required for repackaging and unloading the waste from storage for disposal.

Another concern is the risk of releases in the event of an accident. Although NRC has not conducted a quantitative analysis of accident and release scenarios for a failed storage facility, NRC believes that the risk of releases as a result of an event or accident at numerous LLW storage sites around the country is higher than the risk of release from a limited number of disposal sites designed to meet the siting and design requirements in 10 CFR Part 61 or compatible Agreement State regulations.

Finally, some materials licensees may need to request amendments to their license to possess greater quantities of licensed material to accommodate increased onsite storage of LLW. Further changes to the license may be required depending on other restrictions in the license. For those cases where a license determines a license amendment is necessary, NRC issued guidance in February 1990 to identify information needed to support the licensee's amendment request for extended storage of LLW.

QUESTION 13:

One of several issues that currently embroils the potential Ward Valley low-level waste site in California is the type of hearing to hold. If California were not an agreement state and the site were being licensed by the NRC, would the Commission hold a formal adjudicatory hearing on the application?

ANSWER:

Under current NRC regulations, in those circumstances in which the NRC would be responsible for licensing a low-level waste disposal facility in a non-Agreement State, the Commission would be obliged, under its current regulations, to provide an opportunity to request an formal adjudicatory hearing in accordance with the provisions of 10 CFR Part 2, Subpart G. The regulations of the NRC in 10 CFR 2.105 require that a Notice of Proposed Action be issued for any license to be issued pursuant to 10 CFR Part 61. The Notice of Proposed Action provides that a hearing may be requested by the applicant for the license or by a person whose interest may be affected. The criteria for admission of a person as a party are those in 10 CFR Part 2, Subpart G. Thus, a hearing would be held only if a person were able to demonstrate standing as a part and had presented at least one good contention for resolution. See CFR 2.714. Absent a hearing request would be held; there is no requirement for a mandatory hearing on a Part 61 license.

QUESTION 14.

Your testimony states that the NRC staff has developed a process for implementing the license renewal rule that represents an approach not addressed at the time the rule was promulgated in 1991. Is this process consistent with the rule? Please explain. If not, do you plan to formally amend the rule?

ANSWER.

The staff has developed an approach for implementing the license renewal rule which can be adopted within the framework of the current rule, but for which rule changes may be appropriate to address potential inconsistencies with certain rule language and with language in the statement of consideration for the current rule. The staff's recommended approach was addressed in SECY-93-049. In SECY-93-113, the staff clarified this approach and included additional proposals that stipulate less stringent age-related degradation management program requirements for structures and components which are not of fundamental safety importance. Although the staff initially concluded that such structures and components need not be subject to the program change and reporting requirements contained in Section 54.33(d) and 53.37(c) of the current rule, the NRC Office of the General Counsel has indicated that this is not correct.

The Commission has directed the staff to convene a public workshop to discuss recommendations provided by the staff. This will include proposals resulting from experience, by practical application, with the staff approach and proposals for possible amendment to Part 54. The staff has been directed to submit to the Commission for its consideration, a summary of the results from the workshop and a draft proposed rulemaking.

The Commission is currently considering the staff's proposals for implementing the rule. Rulemaking could be initiated to modify the license renewal rule.

QUESTION 15.

Given that DOE has admitted in budget briefings that they will not be able to meet the 2001 date for filing a high level waste repository license application with the NRC, what type of delay would this represent for the NRC in processing the application? Would a delay in the submittal affect staffing, etc.?

ANSWER.

NRC does not believe a delay in DOE's submittal of an application would significantly affect the time that NRC will need to review it. Therefore, if DOE were to delay its license application, the only slip would be a corresponding delay in the completion of the NRC review.

It is unclear what effect a delay in the DOE submittal would have on NRC staffing. In order to assess the impact on NRC staffing of a delay in the DOE submittal, NRC would need to know the length of the delay and understand how the delay would affect the current ongoing DOE program.

QUESTION 16.

Last year, Admiral Watkins in a letter to Senator Johnston proposed the possibility of phased licensing at Yucca Mountain. Mrs. O'Leary initially appears open to the idea. Does the NRC support the concept of phased licensing? Why or why not?

ANSWER.

Until the elements of the Department of Energy's (DOE's) phased licensing approach are more clearly defined, NRC is unable to evaluate the concept fully. However, under 10 CFR Part 60, one form of phased licensing for a high-level waste repository is permitted. Once construction of the surface facilities and those subsurface facilities necessary for initial operation have been substantially completed, DOE could obtain a license to commence emplacement of small quantities of waste. From a regulatory perspective, phased licensing of the repository might be beneficial. The experience gained during the period when a relatively small quantity of waste was in place could enhance the effectiveness of the performance confirmation program and allow, if necessary, for less complex retrieval operations should it be determined that such operations were needed.

It should be noted, however, that in order to obtain construction authorization, DOE must first demonstrate that there is reasonable assurance that the types and amounts of radioactive materials intended to be disposed of in the entire facility could be disposed of safely.

QUESTION 17. What has been the nature of your interaction with DOE on the issue of phased licensing?

ANSWER.

The Department of Energy has most recently discussed the issue of phased licensing at a meeting with the Commission in June 1992. There have been no other interactions on phased licensing. DOE indicated generally that some form of phased licensing was under consideration. Detailed information on the technical or regulatory aspects of this approach were not provided to the NRC.

QUESTION 18.

If an MRS was sited at a federal facility, as was proposed by Admiral Watkins last year, what would that entail for the NRC. For example, would you have to license it?

ANSWER.

Yes, the Energy Reorganization Act of 1974 (42 U.S.C. 5842(3)) gives the NRC licensing and related regulatory authority for DOE "[f]acilities used primarily for the receipt and storage of high-level radioactive wastes resulting from activities licensed under such [Atomic Energy] Act."

QUESTION 19.

Would a federal facility that would be the site of an MRS be held to federal environmental standards for which it is not currently required to meet?

ANSWER.

NRC review of a license application for construction and operation of an MRS would be conducted against pertinent NRC regulations which include the requirement to prepare an environmental impact statement (EIS). An EIS must give due consideration to compliance with environmental quality standards and requirements which have been imposed by Federal, State, regional, and local agencies having responsibility for environmental protection. DOE has not yet identified any Federal facility as a potential site of an MRS; therefore, NRC is not in a position to identify whether a particular Federal facility or the activities of DOE otherwise qualify for exemptions from federal environmental standards.

QUESTION 20.

The Nuclear Waste Technical Review Board has called on DOE to establish a more flexible schedule for activities at Yucca Mountain. Have the NRC and DOE had any discussion about adjustments in the program in light of that recommendation in March of this year?

ANSWER.

The Nuclear Regulatory Commission has not had any discussions with the Department of Energy about adjustments in the program in light of the Nuclear Waste Technical Review Board's recommendation.

QUESTION 21. What do your current activities at the Yucca Mountain site consist of?

ANSWER.

Current Nuclear Regulatory Commission activities at the Yucca Mountain site involve the presence of an office in Las Vegas which is supported by two On-Site Licensing Representatives and an office at the U.S. Department of Energy (DOE) Field Operations Center located on the Nevada Test Site which is available for staff use during site visits. Through this presence, the NRC staff maintains cognizance of work being done at the site, and also has ready access to ongoing DOE field activities.

As part of its normal review practice, the NRC participates in site visits to Yucca Mountain to better understand and evaluate ongoing site characterization and Exploratory Studies Facility work. In addition, some DOE quality assurance audits that are observed by the NRC staff cover site activities. Representatives from the State of Nevada and affected units of local government are invited to attend.

In addition to evaluating ongoing work at the site, NRC conducts reviews directly related to DOE site activities. These include DOE documents such as the Site Characterization Plan semi-annual progress reports, Topical Reports, the Early Site Suitability Evaluation, Study Plans, and other reports prepared by DOE in support of its site characterization.

STATEMENT SUBMITTED BY
THE OFFICE OF THE INSPECTOR GENERAL
UNITED STATES NUCLEAR REGULATORY COMMISSION
TO THE
SUBCOMMITTEE ON ENERGY AND MINERAL RESOURCES
COMMITTEE ON NATURAL RESOURCES
UNITED STATES HOUSE OF REPRESENTATIVES

CONCERNING
THE FISCAL YEAR 1994-1995 BUDGETS
FOR
THE OFFICE OF THE INSPECTOR GENERAL

MAY 27, 1993

Good morning Mr. Chairman and members of the subcommittee. I am pleased to present my fiscal year (FY) 1994 budget request and my FY 1995 budget estimates for the Office of the Inspector General (OIG) of the U.S. Nuclear Regulatory Commission (NRC). The NRC is a regulatory agency, whose mission is to ensure that civilian uses of nuclear materials in the United States are carried out in a way that adequately protects public health and safety, the environment, and our national security.

My office was established in accordance with the Inspector General Act Amendments of 1988. Our mission is to prevent and detect fraud, waste, and abuse in the NRC's programs and operations, and to identify ways to improve their economy and efficiency. We are also charged with the responsibility of ensuring that the NRC employs sound financial management practices, as required by the Chief Financial Officers Act of 1990. During this past year, both the audit and investigative programs have continued to produce results consistent with these important legislative mandates.

Our program findings this year have suggested the presence of agency-wide problems in the area of financial management and concerns with certain regulatory programs. For example, audit findings revealed that the agency paid for substantial contract services without the required approvals and verification of invoices. In addition, over \$8 million was unnecessarily "tied up" as contract obligations that could have been used for other program initiatives. To its credit, the NRC has performed a substantial body of work in response to these findings. In safety-related areas, an investigation revealed that the agency relied on unverified nuclear industry test results when it accepted the use of the fire-barrier material known as Thermo-Lag. This material is now used in about 80% of our nation's nuclear power plants. In 1992, the NRC informed the industry that Thermo-Lag should be treated as inoperable.

During FY 1994 and FY 1995, we will continue to assist the NRC by reviewing programs and operations and will work with them to resolve these and other financial and management deficiencies. To accomplish this in FY 1994, I am requesting \$4.8 million and 42 FTEs. This represents about a \$200,000 increase over last year and an increase of one FTE. The estimated requirements for FY 1995 are \$5.0 million and 43 FTEs, which represents an increase of \$200,000 and 1 FTE.

The additional FTE in FY 1994 will be used to support my office with independent legal counsel. The Inspector General Act provides us with the authority to hire the necessary employees for carrying out the functions, powers, and duties of my office. The OIG must be an objective and independent unit in order to effectively evaluate the agency. This position is particularly important due to the nature and complexity of our existing investigative case work. Independent legal counsel is necessary to ensure that no conflict of interest arises between the agency and the OIG and to allow the OIG to properly fulfill its statutory duties and responsibilities.

Senator Glenn and other members of Congress have made it unquestionably clear that the

Inspector General Act of 1978, as amended, provides an Inspector General with the authority to employ such officers and employees as may be necessary for carrying out the functions, powers, and duties of an OIG. I believe that to properly carry out my statutory responsibilities, it is necessary for me to employ an independent counsel. I am, therefore, requesting one FTE for an attorney/advisor position.

Now, I would like to highlight some of our audit and investigative activities performed over the past year.

During 1992, several OIG audits and internal NRC studies found serious breakdowns in NRC's internal management controls. When these breakdowns occur, senior managers lack adequate assurance that activities under their purview are operating efficiently, effectively, and economically as required by directives. Furthermore, because internal controls are designed to protect the Government's resources, breakdowns can lead to fraud, waste, and abuse.

To achieve the necessary safeguards, the Federal Managers' Financial Integrity Act (FMFIA) and the Chief Financial Officers Act require Federal managers to establish and maintain effective systems of internal management and system controls. These requirements are augmented by Office of Management and Budget and agency directives. Simply defined, internal management controls are measures to safeguard resources, ensure compliance with applicable laws, and promote efficient and economical operations. These controls apply to virtually all agency programs and activities, as well as to NRC's accounting and financial management systems.

In a recently issued summary analysis, we reported that breakdowns in management controls exist and are a common problem found in many of our recent audits. In three areas--computer security, payments made to privately operated national laboratories, and the agency's general financial ledger--our audits found deficiencies serious enough to warrant reporting as material weaknesses in the agency's annual FMFIA report to the President and Congress. As a result, we concluded that the Chief Financial Officer should consider additional actions to ensure that management controls are viewed as an important responsibility for senior managers rather than as a tertiary, low priority task.

A March 1993 audit report disclosed problems concerning the placement of work at the Department of Energy's (DOE) national laboratories by NRC's Office of Nuclear Regulatory Research. Through an interagency memorandum of understanding, the NRC initiates major contracts with DOE for research projects. Our audit report included the following findings: NRC contracts with DOE for laboratory services were not closed out upon completion; NRC managers could not adequately account for NRC-funded property and equipment at the laboratories; funds from prior fiscal years were improperly transferred from project to project by NRC managers without the required approval of the Office of the Controller; and final DOE laboratory performance on projects was not evaluated as required. Additionally, management tools for tracking project status were lacking. For example, NRC could not

determine the completion status for 1,400 projects begun since 1975.

We made specific recommendations that collectively were designed to strengthen NRC's management of work placed at DOE laboratories to ensure that NRC's limited resources were adequately protected.

In August 1992, audit findings disclosed that NRC made payments to DOE laboratories since 1986 without reviewing or approving the associated invoices and verifying the accuracy of the payments. Such review and approval is required by the General Accounting Office, the Treasury Department, and NRC guidance. This failure to follow statutory and prescribed agency policies and procedures left NRC vulnerable to fraud, waste, and abuse. NRC management took prompt and decisive actions to correct these deficiencies.

Furthermore, the backlog of contract closeouts had increased despite earlier reports identifying the scope of the problem. In a June 1992 audit, we reported that NRC's inventory of completed, but not yet closed, contracts increased from 591 in May 1986 to 829 as of October 1991.

My office estimated that more than \$8 million was unnecessarily tied up by the contract closeout failure and could be made available for other NRC programs. In following our recommendations, NRC has de-obligated over \$6 million to date and has made significant progress toward reducing the backlog.

In our investigative program, we are continuing to experience an increased level of activity. During FY 1992, we received 296 allegations of wrongdoing, which resulted in 93 cases being opened for investigation. Also in FY 1992, my investigative staff closed 90 cases. We project, based on the number of allegations received during the first 3 months of this fiscal year, that the FY 1993 case load will be even larger. These statistics demonstrate an increase in program activity for the third consecutive year since the inception of my office in 1989.

One of the more significant issues over the past year was an allegation that Thermo-Lag, the fire barrier material used in most nuclear plants to protect safety and emergency shutdown electrical circuits from fire, is inadequate. This allegation resulted in an inspection to address the adequacy of NRC staffs' performance related to the acceptance and review of Thermo-Lag. In addition, the investigative staff, in coordination with the NRC's Office of Investigations, initiated a related investigation to determine if there was any criminal activity by NRC or licensee employees in connection with the testing of this material.

While the investigation is still ongoing, the inspection has been completed and it was determined that the NRC staff did not conduct an adequate review of fire endurance concerning the ability of the fire barrier material. Had the staff conducted a thorough review of test reports submitted by industry or verified test procedures and results, a number of problems with the test program and the material would have been discovered.

Another important case involved allegations by a former officer of a consulting services firm, which also handles radioactive material, that safety concerns brought to NRC attention were not properly addressed. The OIG's investigation disclosed that while NRC conducted an inspection based on the issues raised, the allegations were not fully and adequately examined. During the course of this investigation, a second inspection was conducted by NRC staff and seven regulatory violations were uncovered.

A highly significant aspect of this case is that the licensee employee who brought the safety concerns to NRC's attention was fired by the company. The firing was allegedly in retaliation for the employee raising his concerns with management prior to advising the NRC. This matter is being examined, along with other instances involving the firing of employees who raised safety concerns to their employers or to NRC management. Our purpose is to determine the adequacy of policies and procedures in place to protect the identity of whistleblowers and the adequacy of sanctions imposed against companies who engage in reprisals.

The OIG's investigative office continues to review allegations and initiate investigations involving medical uses of nuclear materials. In addition to the many cases of this nature that have already been addressed, we recently opened a number of inspections and investigations pursuant to our participation with an NRC Incident Investigation Team (IIT). The IIT was formed to investigate whether a misadministration of a radioactive pharmaceutical for treatment of a cancer patient contributed to her death. This office is attempting to determine if the licensee in this case had been adequately inspected by the NRC. This case also addressed a specific allegation involving a personal relationship between the licensee and an NRC employee involved in the licensing process.

In addition to investigations where public health and safety issues were of paramount importance, my office investigated a number of allegations involving personal relationships between NRC employees and NRC contractors. Many of these cases contained potential criminal aspects in that gratuities were received or administrative aspects in that there was a personal relationship between a person in a position to affect the contract and the contractor. This area will continue to be monitored very closely not only in response to specific allegations of wrongdoing, but also from a programmatic viewpoint. These are issues of constant concern on the part of senior management within the agency. We will continue to closely examine all allegations with serious consideration regarding the integrity of regulations.

Finally, from a financial standpoint, in FY 1992 our investigators continued to be alert for cases appropriate for application of the Program Fraud Civil Remedies Act. In the near future, the largest dollar volume case investigated by my office to date under this statute will be adjudicated.

This concludes my report to you on the activities of the past year and the current status of our operation. My office continues to enjoy a positive relationship with NRC management

and we appreciate their ongoing support and cooperation. The agency complies fully with our investigative and audit inquiries, and NRC management has consistently accepted and implemented our recommendations to improve agency operations.

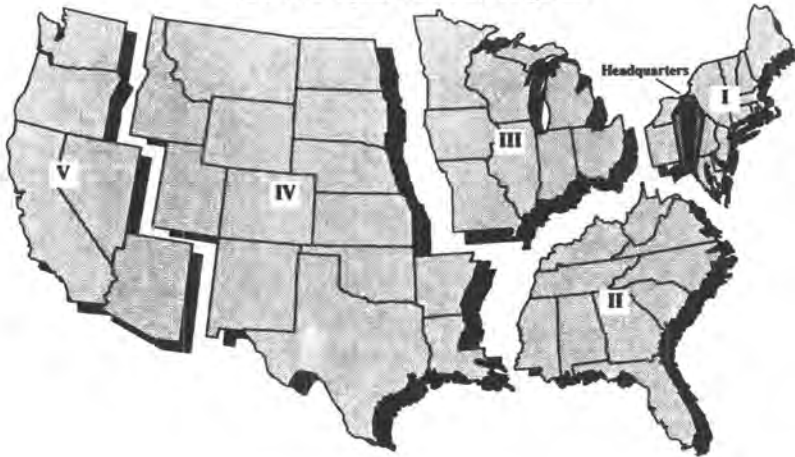
The challenge of providing assurance to the NRC on these vital, complex programs is great. We look forward to assisting the agency in continuing to improve the economy and efficiency of its programs and operations. Thank you for the opportunity to discuss our programs.

ASSISTANT INSPECTOR GENERAL FOR AUDITS

ANNUAL AUDIT PLAN

STRATEGY AND FY 1993 WORK PLANNED

NRC Headquarters and Regions



OFFICE OF THE INSPECTOR GENERAL
U.S. NUCLEAR REGULATORY COMMISSION

ANNUAL AUDIT PLAN
STRATEGY AND FY 1993 WORK PLANNED

OFFICE OF THE INSPECTOR GENERAL
U.S. NUCLEAR REGULATORY COMMISSION

FOREWORD

The Office of the Inspector General (OIG) is pleased to present its fiscal year 1993 Audit Plan. The plan provides our overall audit strategy and summaries of the specific audits planned for this year.

The U.S. Nuclear Regulatory Commission (NRC) is responsible for protecting the public health and safety during civilian uses of nuclear materials. This plan reflects the results of our strategic planning process aimed at concentrating our audit efforts in areas key to the primary mission of the NRC. As part of this process, we obtained input from the nuclear industry, special interest groups, including Public Citizen and the American College of Nuclear Medicine, the Congress, the General Accounting Office, the Office of Management and Budget, and senior-level NRC managers, including the Commissioners. We also considered such factors as NRC programs' dollar value, vulnerability to fraud and waste, and prior audit coverage. This process enables us to maximize the use of our audit resources.

Rather than set aside time to respond to unexpected high priority issues that inevitably arise, we have programmed all of our direct audit resources and will defer lower priority audits as necessary. This approach ensures that we only use our limited resources on high priority audits.

David C. Williams
David C. Williams
Inspector General

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APPENDIX II - AUDITS PLANNED FOR FISCAL YEAR 1993

BACKGROUND

The U.S. Nuclear Regulatory Commission's (NRC's) Office of the Inspector General (OIG) was established April 15, 1989 pursuant to Inspector General Act Amendments contained in Public Law 95-452. Simply stated, the OIG's mission is to prevent and detect fraud, waste, and mismanagement in NRC programs.

Accordingly, the OIG is committed to ensuring the integrity of NRC programs and operations. Audit planning is a critical aspect of accomplishing this commitment. Without such planning, the OIG cannot be assured that audit resources are used effectively and that Commission programs subject to the most risk receive appropriate audit coverage.

The Annual Audit Plan is the OIG's formal plan of action for managing the auditing workload and audit resources for fiscal year (FY) 1993. The plan reflects the interest and concerns of the nuclear industry, the Congress, the President's Council on Integrity and Efficiency (PCIE), the General Accounting Office (GAO), the Office of Management and Budget (OMB), and NRC senior managers, including the Commissioners.

Pursuant to OMB Circular A-73 guidance, we plan our audit coverage using factors such as:

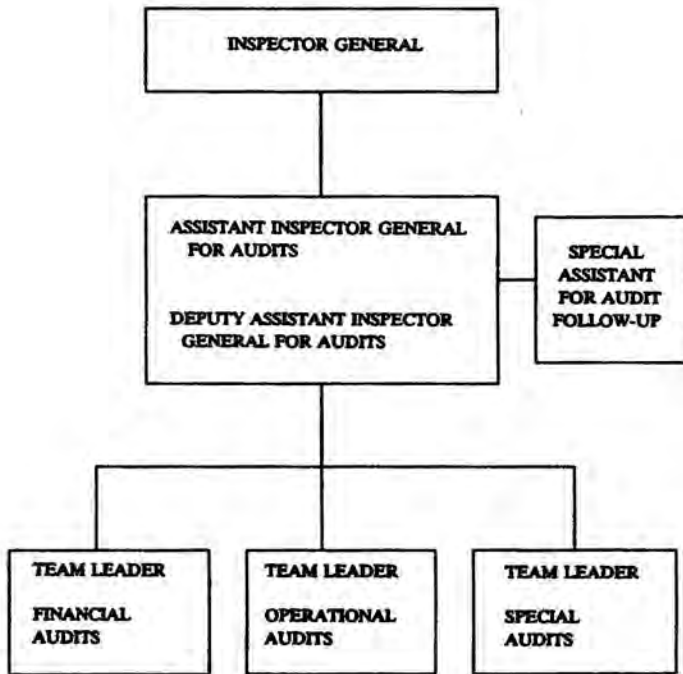
- o current and potential dollar impact;
- o adequacy of internal control systems as indicated by risk assessments and reviews required by OMB Circular A-123;
- o management needs;
- o prior audit experience;
- o availability of audit resources; and
- o audit risk.

The OIG performs the following types of audits:

Performance - These audits are conducted on selected NRC administrative and program operations to evaluate the effectiveness and efficiency with which managerial responsibilities are carried out. They focus on whether management controls, practices, processes, and procedures are adequate and effective. Performance audits also include reviews of selected programs and activities to evaluate their overall effectiveness in achieving anticipated results.

Financial - These audits include financial statement audits required by the Chief Financial Officers Act and financial related audits. These latter audits include reviews of such items as internal control systems, transaction processing, financial systems, and contracts.

Our audit mission is carried out by three staff groups to facilitate coverage of NRC's programs and activities. The organization chart for the OIG's audit function is as follows:

AUDIT STAFF ORGANIZATION

THE AUDIT PROCESS

The audit process represents the steps taken by OIG to conduct audits. This process involves several steps, ranging from notification of the office to be audited to making audit follow-up. The underlying goal of the audit process is to maintain an open channel of communication between the auditors and management officials to ensure that audit findings are accurate and fairly presented in the audit report. The key elements in the audit process are as follows:

Audit notification - formal notification to the office informing auditee of our intent to begin an audit.

Entrance conference - a meeting to advise agency officials of the purpose, objectives and scope of the audit, and the general methodology to be followed.

Survey - exploratory work conducted before the detailed examination to gather data for identifying audit objectives, documenting internal control systems, becoming familiar with the activities to be audited, and identifying areas of concern to management.

Audit - comprehensive review of selected areas of a program, activity, or function using an audit program developed specifically to answer the audit objectives.

Exit conference - a meeting with the agency's principal officials to present and discuss the results of the audit. This meeting provides agency management the opportunity to confirm information, to ask questions, and to provide any necessary clarifying data.

Draft report - an official draft report provided to the agency to obtain written comments on the audit findings. The agency is normally given 30 days to respond to the draft.

Final audit report - the final report that contains the agency's official written response to the draft.

Audit follow-up and closure - the process that assures that recommendations made to management are acted upon.

STRATEGIC PLANNING

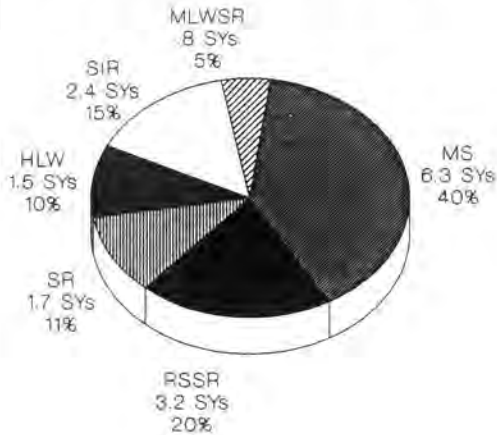
This year's plan re-emphasizes the strategic approach to planning we initiated last year. We plan to continue work in the same key programs that we identified last year. We believe this approach increases the effectiveness and usefulness of our work and also increases our audit coverage in major mission and program areas. During FY 1993, we have planned work in all six NRC mission areas. We also plan to increase our audit coverage of NRC contracts and in the audit follow-up area.

Descriptions of our audit strategies and a discussion of the areas we plan to pursue are provided as Appendix I. Appendix II provides a synopsis of the specific audits we plan to undertake.

ALLOCATION OF AUDIT RESOURCES

For FY 1993, the Assistant Inspector General for Audits has an authorized staff of 19. With this level of resources, we plan to make about 24 program/financial audits, 5 follow-up audits, and 5 contract audits. However, since 5 financial audits are required annually by either statute or agency regulations, we are effectively reducing the auditable universe of 213 activities, by only 19 audits per year. We have designated 83 of the 213 activities as critical and believe they should be audited at least once every 5 years, with the remaining 130 activities being audited much less frequently. At our current staffing levels and a constant audit rate, it would take us about 11 years to work through the entire audit universe. However, as a practical matter it will take considerably longer to cover the audit universe since we plan to audit those areas designated as critical more frequently. Our allocation of audit resources by NRC mission area is depicted in the following chart.

OIG FY 1993 AUDIT PLAN STAFFING BY NRC MISSION AREA



Legend

RSSR	-	reactor safety and safeguards regulations
MLWSR	-	material and low-level waste safety regulation
SIR	-	special and independent reviews
SR	-	safety research
HLW	-	high level waste
MS	-	management support
SY	-	staff years

NOTE: Percentages do not equal 100 percent due to rounding.

Our planned allocation of resources by audit category is as follows:

<u>Audit Category</u>	<u>Staff Years Allocated</u>
Performance Audits	9.1
Financial Audits	2.9 ¹
Contract Audits	2.4
Audit Follow-up	<u>1.5</u>
Total Direct Time	<u>15.9</u>

¹ These audits will be supplemented with contract audit support.

AUDIT STRATEGIES

NRC MANAGEMENT OF INSPECTION PROGRAMS

BACKGROUND

In carrying out regulatory oversight, reactor inspection and evaluation activities are among NRC's most important (and possibly most contentious) programs. The Reactor Inspection Program is primarily administered by NRC's Office of Nuclear Reactor Regulation (NRR) and is conducted by headquarters and regional inspectors. Regional inspections are conducted by both region-based and resident plant inspectors. Key reactor inspections include:

Core Inspections - inspections that provide minimal coverage at all plants through inspection of a cross-section of plant activities.

Mandatory Team Inspections - periodic inspections that address a specific area, such as licensee maintenance.

Regional Initiatives/Reactive Inspections - discretionary inspections selected by the Regional Administrator.

Special Team Inspections - 2-4 week long, technically oriented inspections of licensee operations.

Resident Inspections - on site NRC inspections made by resident inspectors who perform a variety of inspection activities and who regularly observe and verify licensee performance.

Vendor Inspections - reactive inspections to respond to vendor and license reports of defects in vendor-supplied products, materials, etc. to nuclear power plants.

Security and Safeguard Inspections - inspections to determine the operational effectiveness of power plant security.

NRR also administers the systematic assessment of licensee performance program (SALP), which provides an integrated assessment of a licensee's performance using data licensee event reports, inspection reports, etc. from the previous 12-18 months.

NRC's Office for Analysis and Evaluation of Operational Data (AEOD) also performs independent assessments of reactor operational performance through the following programs:

Diagnostic Evaluation Program - in-depth evaluations that supplement the SALP and the Performance Indicator Program.

Incident Investigation Program - includes region-directed Augmented Inspection Teams and headquarters-directed Incident Investigation Teams.

Performance Indicator Program - quarterly reports for each operating power plant showing trend data and historical comparisons based on various safety indicators.

In addition to reactor inspections, the Office of Nuclear Material Safety and Safeguards (NMSS) directs NRC inspections associated with licensee processing and handling of nuclear materials. Currently, NRC administers approximately 7,500 licenses for the possession and use of nuclear materials in medical and industrial applications and makes about 2,800 inspections annually. The inspections are normally performed by NRC regional office inspectors.

Not surprisingly, the magnitude of NRC's inspection activities and other assessments of licensee performance raise several questions regarding the overall effectiveness and achievement of agency objectives. For example, how are resources determined and allocated? Is the inspection process consistently implemented and reported? Are inspectors adequately trained? Is the Resident Inspector Program working effectively? In addition, a Regulatory Impact Survey produced a number of industry concerns about NRC's management of inspection program activities. For example, there were concerns with NRC's scheduling and control of on-site inspection activities.

especially team inspections. The survey also suggested that shortcomings existed in the training and qualifications of the professional inspection staff.

The balance of this paper lays out a conceptual framework for OIG undertaking a long-term effort to assess NRC's inspection and evaluation programs. Although we expect that our follow-on audits will focus on power reactors, the results of our survey also indicated a need to cover NRC's inspection programs covering material licensees.

AUDIT OBJECTIVE: Our overall long-term objective is to evaluate the effectiveness of NRC's management of its various safety inspection programs. This will include assessments of both the reactor and material inspection programs. We also intend to assess the extent that AEOD's independent assessments and trend analyses are used and to determine whether there is excessive duplication between AEOD's assessments and NRR's inspection programs. We intend to use a three-prong approach to make this assessment. First, we will assess how inspections are planned; second, we will evaluate how inspections are executed; and third, we will determine how inspection data is reported and used.

STRATEGY: Last year, we made a survey audit of NRC's inspection program to identify issues that warranted review and to help us appropriately assign work priorities, thereby making the most effective use of our resources. This work proved very worthwhile and during the next two years we will undertake a series of reviews that will concentrate on crosscutting issues (discussed below) but with a central theme, NRC management of inspection programs.

By analyzing crosscutting issues, such as resource allocation, training, consistency, etc., we can identify areas that affect all or most inspection programs, thus maximizing our audit effort. At the completion of a series of individual audits of these issues, we will prepare a consolidated report summarizing our overall observations on NRC's management of its inspection program oversight.

PLANNING ISSUES

- Resource Allocation. We will assess how NRR and NMSS inspection resources are determined and allocated between headquarters and the regions. We will also assess how AEOD determines its staffing requirements, especially for diagnostic evaluations.
- Training Requirements. Our audit objective will be to determine how inspector training needs are identified and met.
- Scheduling of Inspections. We will determine and assess how NRR and NMSS inspections and AEOD evaluations are scheduled.

EXECUTION ISSUES

- Program Consistency. Our audit objective will be to determine whether the approach used in performing inspections is consistent between inspection teams and between regions. We will also determine the degree to which diagnostic and trend data prepared by AEOD is used in performing inspections. In addition, we will assess the degree to which inspection and diagnostic data and evaluation and trend data is used for making SALPs. This would include determining how consistently such data are used in developing SALP ratings for licensees.
- Inspection Effectiveness. We will assess NRC's efforts to satisfy itself that NRR and NMSS inspection and AEOD evaluation programs are achieving stated goals. This would include assessing whether excessive duplication exists and the degree to which inspector utilize AEOD data, such as diagnostic evaluations and incident report data, during their inspections.
- Program Philosophy. We will identify the underlying philosophy of compliance versus performance-type inspections.

REPORTING ISSUES

- o Preparation of Data. We will determine how inspection data is recorded and reported. In this regard, we will assess the degree to which NRR and NMSS use trend analyses and other evaluation data prepared by AEOD.
- o Review Process. We will assess the process used to review inspection and evaluation report data, with particular emphasis on the safeguards to ensure the integrity of the information. We will evaluate how NRC management validates and reports inspection results, especially on inspections performed by resident inspectors.

INFORMATION RESOURCE MANAGEMENT

BACKGROUND

NRC management and its technical and administrative staffs depend heavily on information obtained from a vast number of automated information systems maintained within the agency. Many of these systems provide ready access to essential information on safety issues, operator licensing, reactor inspections, daily plant status, emergency response, risk assessment, and allegation management. The information obtained from these systems is integrated into NRC's decision-making process related to its licensing and regulatory functions and overall mission of protecting the public health and safety. Consequently, the integrity of the data that goes into these systems is vitally important.

The Office of Information Resources Management (IRM) is responsible for NRC's information resources management program. The program provides for centralized information resources in the areas of computer, telecommunications, and information support services. It also provides the essential services and technical means for the agency staff to receive, store, retrieve, manipulate, process, and transmit information in support of the agency's mission. Although the majority of the systems are managed by IRM, others are apparently developed, operated, and maintained by user offices.

NRC currently has about 220 operational systems and at least 10 other systems are being developed. These range from the comprehensive, agency-wide systems to the smaller, single-user systems. NRC expends over \$40 million a year on its information resources management function and the maintenance of the various systems.

Over the years, Federal agencies have received Congressional and General Accounting Office (GAO) criticism for not having a meaningful, strategic planning process for developing and acquiring computer systems. Interestingly, NRC's Five-Year Plan points out that "the present agency manpower and project tracking systems do not provide the planning, scheduling, or resource allocation functions needed to effectively manage the agency's staff resources. Since they evolved in a piecemeal fashion over a

number of years, the systems do not work together efficiently and seamlessly...."

The balance of this paper establishes OIG's conceptual framework for its long-term evaluation of NRC's information resources management, the need for the various systems maintained within the agency, and the integrity of the information that goes into the systems.

AUDIT OBJECTIVE: Our overall long-term objective is to determine the effectiveness of NRC's management of its automated information systems. Through a series of audits, we will determine (1) whether NRC systems are effectively and economically meeting users needs and (2) whether the information in the system databases is reliable and adequate to support management decisions that flow from it.

STRATEGY: During FY 1992 we made a survey audit of NRC's Information Resource Management Program to identify areas for more detailed review. We also hired a contractor to assist us. As spelled out in Appendix II, during FY 1993 we will continue work in the IRM area by doing several interrelated reviews with each successive review bringing us closer to our overall evaluation of this area. We will complete our assessment with a consolidated report, in FY 1994, summarizing our findings and conclusions on NRC's management of its automated information systems.

PLANNING ISSUES

- o Strategic Plan. We will determine whether NRC has a strategic plan for meeting its information needs and evaluate the adequacy of the plan. We will assess whether the systems under development fall within NRC's overall strategic plan.

EXECUTION ISSUES

- o Need for Systems. We will assess the need for and use of the systems maintained within NRC. This will include an assessment of duplicative databases and services from the systems.

Appendix I

- Integrity of Information. We will evaluate the quality controls over the data entry process and the databases and assess the accuracy of the data in the systems. We will also examine the extent to which NRC management relies on the information in this decision-making process whether and the information used is adequate to support such decisions.
- External Impact. Our objective will be to assess the extent to which external data is used to update the systems, how that data is used, and the reliability of that data.

REPORTING ISSUES

- Preparation of Data. We will determine what reports are prepared from the information contained in the systems and the use made of these reports. We will assess the appropriateness of the report format, contents, and timeliness.
- Distribution Process. We will review the distribution of information obtained from the systems. This will include an assessment of the timeliness of the distribution process.

NRC MANAGEMENT OF RESEARCH

BACKGROUND

Legislative Authorization

Under Section 205 of the Energy Reorganization Act (Public Law 95-209), the Director, Office of Nuclear Regulatory Research (RES), performs functions delegated by the Commission, including (1) developing recommendations for research deemed necessary for performance by the Commission of its licensing and related regulatory functions, and (2) engaging in or contracting for research that the Commission deems necessary for the performance of its licensing and related regulatory functions.

The Office of Nuclear Regulatory Research (1) plans, recommends, and implements programs for nuclear regulatory research, standards development, and resolution of generic safety issues for nuclear power plants and other facilities regulated by the NRC; (2) develops and promulgates technical regulations; and (3) coordinates research activities within and outside the agency, including appointment of staff to committees and conferences.

Goals and Objectives

The research program has three major goals and objectives, namely:

- o (1) Provide independent expertise and technical information for NRC's regulatory judgments, (2) anticipate potential safety problems, and (3) develop regulations and guides to implement Commission policy or requirements.

Structure of the Research Program

The research program is structured into four mission areas, each having multi-program elements. The four mission areas are (1) reactor licensing support, (2) materials licensing support, (3) reactor regulation support, and (4) high-level waste disposal.

The Nuclear Safety Research Review Committee (NSRRC) was established in 1988 on the recommendation of the National Research Council. NSRRC provides advice to the Director, RES, regarding the direction of NRC's nuclear safety research programs. The NSRRC consists of 13 members including a member from RES who acts as the Designated Federal Official. The Department of Energy (DOE) national laboratories and private institutions.

NRC Research Budget Breakdown

The fiscal year 1993 budget estimate of \$127 million for nuclear regulatory research is estimated to be –

- Fifteen percent or \$19 million for NRC salaries and expenses; 85 percent or \$108 million for contractor-related funding. Of the \$108 million for contract funding, approximately 70 percent or \$76 million will be spent in the national laboratories.

AUDIT OBJECTIVE: Our overall long-term objective will be to evaluate the effectiveness of NRC's management of its research program and to determine whether NRC is doing the research it should be doing. This will include assessments of identifying research needs and the application of research results. According to NRC's research philosophy, the primary benefits of research should be improved regulations through better definition and refinement of safety margins, anticipation of operational problems, and tools to deal with safety issues as they arise.

STRATEGY: During the past year, we made a survey audit of NRC's research program to determine (1) how the research program is formulated, (2) how funds are budgeted for projects, (3) the basis for selecting contractors, and (4) the benefits obtained from the work performed. During FY 1993, we plan to continue work in the research area by reviewing issues related to plant life extension and license renewal.

PLANNING ISSUES

We will review how the agency identifies and assigns priorities to research needs. We will also assess how research projects are used to: (1) support

regulatory decisions; (2) anticipate future problems having a safety significance; and (3) support the development of regulations.

EXECUTION ISSUES

Our objective will be to review how NRC manages projects in terms of costs, age, and priority. Of concern will be projects of long duration and large dollar costs. In addition, projects in which priorities have changed will be reviewed.

REPORTING ISSUES

We will review research projects that have been concluded and determine if they are being used to meet one or more of the research goals and objectives. Of concern in this area will be the effectiveness of project management to ensure that the project meets the intended purpose.

NRC'S FINANCIAL MANAGEMENT ACTIVITIES

BACKGROUND

As a result of the Chief Financial Officers (CFO) Act and the advent of the requirement to collect 100 percent of NRC's budget, NRC must exercise tighter financial management controls than ever before. Responsibility for the implementation of the requirements of the Act at NRC rests with the Executive Director for Operations, who was appointed NRC's CFO.

One of the key provisions of the CFO Act is the requirement for the agency to produce yearly financial statements, which would be subject to audit. To produce financial statements that have accurate information, the CFO must ensure that there are proper internal controls in place and the accounting systems are operating in accordance with GAO's principles and standards.

Another area upon which the CFO should focus attention is the controls exercised over contracting for goods and services, with the commercial sector and with the Department of Energy's (DOE's) national laboratories. The main feature of the controls should be to ensure that NRC's procurement activities conform to good business practices and comply with applicable rules and regulations.

Key areas where we need to focus our work include the following:

Budget formulation - the agency's process for deciding what resources are required and how they will be used.

Budget execution - the agency's ability to determine how it actually spends the monies received.

Financial statements preparation - the agency's process used to capture accounting data and ensure its accuracy for the task of producing required statements.

Federal Managers' Financial Integrity Act - assessment of the adequacy of the agency's system of internal (management) controls.

License Fee Management Program - method and timeliness of assessing and collecting for services rendered to licensees.

Accounting and finance - accounts for the daily spending activities for the agency.

Contract administration - procedures used by the agency to administer contracts once they have been awarded.

Contract operations - processes used by the Division of Contracts and Property Management to award contracts.

Contract audits - ensure that contractors are only charging expenses to a contract that are provided for in the contract terms and governing regulations.

Program support functions - methods used by the program offices to account for funds used to contract with the national laboratories.

NRC must be able to properly account for the expenditure of monies from its FY 1993 budget of over \$500 million. In addition, there is a need to ensure the timely collection of license fees since NRC is now required to collect approximately 100 percent of its budget from its licensees.

AUDIT OBJECTIVE: Our overall objective over the next few years will be to establish a frame of reference regarding how effectively the agency's internal control systems are functioning. This will provide us with a basis for our attestation of the financial statements produced by the agency. We also intend to examine the procedures used by the agency in planning its contractual work to ensure that appropriate procedures are followed when awarding task orders to the national laboratories.

STRATEGY: At the culmination of a series of audits in the areas that impact on the financial and resource management of the agency, we plan to prepare a summary report addressing systemic problems that are common within the

areas reviewed. We will also use the results of our audit work as input in our annual requirement to report on NRC's implementation of the Federal Manager's Financial Integrity Act.

PLANNING ISSUES

- Areas of Vulnerability. We will assess the adequacy of the agency's internal control procedures, focusing on the implementation of the recommendations from the external audit firm's review to ensure that the agency will be able to produce accurate accounting information.
- Accuracy of Accounting Information. We will perform audit work that will provide us with a basis for rendering an opinion on the financial statements and providing feedback on performance measurements for programs that began in the budget formulation period through the execution cycle.
- Program Needs Versus Financial Management. We plan to assess how the agency balances its dual mission of protecting the public health and safety with the need for sound fiscal management.

EXECUTION ISSUES

- Accomplishment of Goals. We will monitor the effort of the agency's external audit firm, perform our own audit effort, and work with our own external audit contractor. We will assess whether deficiencies exist in NRC's internal controls or financial management systems that need to be corrected to achieve compliance with CFO Act requirements.

REPORTING ISSUES

- Reporting of Results. We will determine whether the NRC has developed effective plans to ensure that fiscal results are timely and accurately reported.

AUDIT FOLLOW-UP

BACKGROUND

Audit follow-up is an integral part of good management and is the responsibility of both agency management officials and the auditors. Corrective action taken by management on resolved findings and recommendations is essential to improving the effectiveness and efficiency of Government operations. The Office of Management and Budget Circular A-50, revised, requires each agency to establish systems to assure the prompt and proper resolution and implementation of audit recommendations. The systems are to provide for a complete record of action taken on both monetary and non-monetary findings and recommendations.

NRC Bulletin 1201-4 establishes the procedures for follow-up on audit recommendations. This bulletin provides that NRC management has full responsibility for implementing corrective action for audit recommendations. NRC's Follow-up Official, among other things, monitors the follow-up system and ensures that management officials implement corrective action agreed to by management and OIG.

Audit reports may contain recommendations for management action whose status at report issuance is either:

Closed - indicating that corrective action was completed before the final report was issued—the ideal outcome of an audit report;

Resolved - indicating that the auditors and cognizant management officials have reached agreement on the corrective actions needed, but those actions have not yet been completed;

Unresolved - indicating that management and the auditors have yet to reach agreement on actions needed to correct a deficiency, or whether management will sustain a recovery or concur in any savings reported by the auditors.

OMB Circular A-50 also requires that audit recommendations be resolved within six months of issuance. Open audit recommendations are tracked by OIG and cognizant management officials through NRC's Audit Follow-up Program. It is expected that the NRC audit follow-up official regularly reports the status of OIG recommendations and the actions being taken by management to implement them.

Although all recommendations are tracked, those with monetary implications require more rigorous follow-up in accordance with the 1988 amendments to the Inspector General Act. Auditors are required to clearly identify savings resulting from audit recommendations in draft reports and to specifically request management's concurrence in the savings calculations in responding to the draft report. Any monetary recommendation for which concurrence has not been obtained upon report issuance must be considered unresolved until the auditors and management can agree upon a savings figure.

OBJECTIVE

Our objective is to ensure that NRC has developed and implemented an adequate audit follow-up system to ensure timely action on agreed-to corrective actions. In addition, we will determine whether implementation of the recommendations satisfactorily resolved the condition reported.

STRATEGY

OIG will accomplish its objective by reviewing the agency's follow-up system and following up on prior audit recommendations during subsequent audits in the same area. During FY 1993, we plan to evaluate the agency audit follow-up system and followup on recommendations made in four prior audits. The details are spelled out in Appendix II.

APPENDIX II

AUDITS PLANNED FOR FISCAL YEAR 1993

RELIABILITY OF DATA IN NRC'S SAFETY RELATED SYSTEMS

PLANNED LOCATIONS

NRC Headquarters and Regional Offices

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

NRC management and its technical staff depend heavily on information obtained from a number of automated information systems maintained within the agency. Many of these systems provide ready access to essential information on safety issues, operator licensing, reactor inspections and other key topics. The information obtained from these systems is integrated into NRC's decision-making process related to its licensing and regulatory functions.

AUDIT OBJECTIVES AND SCOPE

OIG plans to build on information obtained during a survey of the agency regarding user satisfaction of safety related systems. This review will target selected systems for more detailed examination to determine the extent to which the databases are duplicative and whether the data in the systems is reliable.

ESTIMATED RESOURCE REQUIREMENTS

This review will require 1,600 staff hours of effort.

NRC'S REACTOR VESSEL CAPSULE SURVEILLANCE PROGRAM

PLANNED LOCATION

NRC Headquarters

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

When the nuclear industry was first launched, NRC required reactor vessel manufacturers and utilities to retain extensive samples of the weld and base metal material used to construct each reactor vessel. NRC also required that a portion of these "capsules" be placed in the reactor to be irradiated throughout the life of the vessel, and the remainder retained by the utility as a control group. Utilities are required to periodically remove the capsules and test them to determine whether the vessel still meets NRC's embrittlement criteria. This testing is NRC's control to ensure the vessel is able to withstand a pressurized thermal shock accident. NRC's Office of Nuclear Regulatory Research (RES) is responsible for monitoring and assessing the results of utilities' capsule tests. Also, we recently learned that the Electric Power Research Institute, the research arm of the utility industry, just initiated an effort to compile a data base of capsule test results.

These capsules are critical to assessing the condition of the reactor vessel; however, questions have been raised regarding how closely RES is monitoring these tests. For example, during the Yankee Rowe license renewal process, it was learned that several years ago NRC waived the requirement for the utility to retain the vessel weld samples; therefore, neither the utility nor NRC had a basis for assessing the condition of the vessel. This was one of the key factors that led the utility to terminate operation of the plant. In addition, preliminary information indicates that (1) NRC may have granted similar waivers to other utilities, and/or (2) some utilities' capsule surveillance

programs may not be current. Consequently, significant questions exist regarding the adequacy of RES's reactor vessel capsule monitoring program.

AUDIT OBJECTIVES AND SCOPE

The objective of this audit is to determine whether RES's reactor vessel capsule surveillance program is current and provides a basis for NRC to assess the condition of the reactors it regulates. We will determine (1) how many, if any, program waivers NRC has issued, (2) how many utilities currently meet NRC monitoring requirements, (3) whether any utilities are approaching their pressurized thermal shock screening criteria, and (4) what regulatory action NRC is planning for the utilities whose capsule surveillance programs are not current. We will also determine the extent that the industry has conducted research on reactor vessels and how it was used by NRC and whether it duplicated NRC's research efforts. Initially, we will rely on information available at RES headquarters; if necessary, we may supplement this information with test data from national laboratories and/or other commercial test facilities.

ESTIMATED RESOURCE SURVEILLANCE

This audit will require 1,280 staff hours of effort.

NRC TECHNICAL TRAINING CENTER OPERATIONS

PLANNED LOCATIONS

Technical Training Center, Chattanooga, TN; Region II and NRC Headquarters

TYPE OF AUDIT

Performance (Priority II)

BACKGROUND

The Technical Training Center (TTC) provides for the technical training of NRC technical staff including resident inspectors, region- and Headquarters-based inspectors, reactor operator license examiners, operations center duty officers, licensing project managers, and technical reviewers. Training is provided on a space available basis for other Federal, state, and foreign government employees. Courses are offered in reactor technology system design and operation and in materials and fuel cycle safety, reactor health physics, and inspection and examination techniques.

The TTC maintains a 2-year integrated schedule of courses that supports long-range planning by agency managers and is flexible enough to respond to changing needs and priorities within the agency. Based on projected training needs, approximately 155 reactor technology course-weeks and 115 specialized technical training course-weeks will be scheduled each year during FY 1992-1996.

The TTC has a projected budget of \$3.7 million for program support and \$.8 million for administrative support and a staff of 34 employees for FY 1993. The resources allocated for administrative support for the TTC provide for rental of space; telecommunications service and equipment; and supplies, equipment, and materials to support the technical training of NRC personnel; spare parts and consumable materials for NRC-controlled simulators; and the development and maintenance of training aids.

AUDIT OBJECTIVES AND SCOPE

The overall objective will be to assess the effectiveness of TTC's operations. We would need to perform a limited survey of the TTC's operations to determine the specific objectives and scope of the review. The survey will cover such things as the interactions between Region II and TTC and AEOD and TTC; TTC's processes and procedures for managing course curriculums and schedules; the technical staff's evaluation of the courses and the curriculums; and other TTC activities.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require 1,600 staff hours of effort.

**REVIEW OF NRC PREPARATIONS FOR REVIEWING REACTOR
LICENSE RENEWAL APPLICATIONS**

PLANNED LOCATIONS

NRC Headquarters and Selected Regional Offices

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

This activity consists of safety and environmental reviews of applications for the renewal of existing reactor licenses for a period of up to 20 years beyond the 40-year term of their operating licenses. Approximately 75 percent of all operating reactors are expected to request license extension.

NRC efforts will be focused on administrative and regulatory issues which will establish the framework for evaluating utility license renewal requests. The NRC will develop and implement regulatory review guidance and technical acceptance criteria for the treatment and resolution of license renewal procedural and technical review issues identified in the license renewal rule or during the NRC review of renewal applications.

AUDIT OBJECTIVES AND SCOPE

This audit will assess the extent to which the agency is adequately preparing for the renewal of license applications. We are aware of concerns at the Commission level about whether the agency will be able to handle the electronic transfers of information, including drawings and other graphics. We will also assess NRC's efforts to establish a process for reviewing license renewal applications. This will include whether all necessary changes have been made to the standard review plan and whether regulatory guides and technical acceptance criteria have been established. The review will be

preceded by a limited survey during which time the specific objectives and scope will be established.

ESTIMATED RESOURCE REQUIREMENTS

This review will require 1,600 staff hours to complete.

**JUSTIFICATION TO OPERATE THE CENTER FOR
NUCLEAR WASTE REGULATORY ANALYSIS**

PLANNED LOCATIONS

NRC Headquarters and San Antonio, Texas

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

The Center for Nuclear Waste Regulatory Analysis (CNWRA) was established in FY 1988 to "provide sustained high-quality technical assistance and research free from conflict of interest" for NRC's portion of the high-level nuclear waste (HLW) program. The center is predicated on starting construction for the repository exploratory shaft in 1992. According to NRC's October 1991 Five-Year Plan, the agency recently renegotiated the new contract and plans to expend about \$69 million on this effort between FY 1992 and FY 1996.

Although the Federally Funded Research and Development Centers (FFRDCs) contracts are intended to be long-term in nature, the Office of Federal Management Policy requires that agencies conduct analyses prior to renewing FFRDCs to determine whether the unique FFRDC relationship is still needed. The analyses should address whether the marketplace has changed to the point where competition should be sought. They should also evaluate past performance and any future changes to the FFRDC's mission.

AUDIT OBJECTIVES AND SCOPE

The national program to resolve the HLW issue has been plagued by protracted delays. The purpose of this audit is to evaluate NRC's 1992 requesting sole source renegotiation justifications for CNWRA. The audit will

evaluate the nature and adequacy of the justification. In addition, we will assess (1) whether it may be premature for NRC to fund the CNWRA at this level and/or at this time, (2) how effective and what contributions CNWRA has made in resolving HLW issues, and (3) whether it may be more cost-effective to distribute CNWRA funding among other NRC programs. Work will be conducted at NRC headquarters and CNWRA in Texas.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require 1,280 staff hours of effort.

LICENSING SUPPORT SYSTEM PROGRAM

PLANNED LOCATION

NRC Headquarters

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

The Licensing Support System (LSS) Program was established to ensure effective and efficient discharge of NRC's responsibilities under 10 CFR Part 2, Subpart J, for loading and subsequent use of the LSS prior to and during NRC's high-level waste (HLW) licensing proceeding. The LSS is an electronic information management system that will contain the relevant licensing documents of DOE, NRC and other parties to the Commission's HLW repository licensing proceeding. The Office of the LSS Administrator monitors the LSS activities of the NRC, DOE, and other LSS participants to assure that their activities fully support the timely and proper functioning of the system. The status of the LSS is uncertain due to significant schedule delays of DOE's repository license application.

AUDIT OBJECTIVES AND SCOPE

The Objective of this review will be to assess whether (1) the LSS program is managed effectively and (2) the LSS staff is being efficiently used considering the delays in the license application.

ESTIMATED RESOURCE REQUIREMENTS

This review will require 1,280 staff hours of effort.

REACTOR INSPECTION PROGRAM MANAGEMENT

PLANNED LOCATIONS

NRC Headquarters and Regional offices.

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

NRC's inspection program requires that each reactor site receive a specified level of inspection effort. Although specific inspection procedures are prescribed in NRC's Inspection Manual, some reactor sites are to receive more inspection attention than others. The amount of inspection effort is to be derived from the Systematic Assessment of Licensee Performance (SALP) evaluation that NRC prepares for each licensee. As a result, a specific inspection plan is tailored for each site.

AUDIT OBJECTIVES AND SCOPE

The purpose of this review will be to determine how NRR management oversees completion of inspection requirements for each site, and how regional management assures the site-specific inspection plans are accomplished. We intend to visit all regional offices to gain an Agency-wide perspective of this matter. This audit would include an examination of the utility of the Master Inspection Planning System.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require approximately 1,400 staff hours of effort.

NRC'S ETHICS PROGRAM

PLANNED LOCATIONS

NRC Headquarters

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

The 1988 Office of Government Ethics (OGE) reauthorization legislation, Public Law 100-958, requires that executive agencies submit an annual report to OGE concerning certain aspects of their ethics program. The Office of the General Counsel (OGC) is responsible for the Agency's program. William Parler, General Counsel, is the Designated Agency Ethics Official (DAEO). In response to a recent OGE questionnaire, the DAEO ranked the top four elements of NRC's ethics program from the most difficult to administer to the least. In order of difficulty they are: (1) Understanding standards of conduct; (2) Oversight of financial disclosure process; (3) Advising department employees on post-employment issues; and (4) Employee awareness of ethics. Since its inception in April 1989, OIG has not conducted an audit of the Agency's ethics program to ensure that it is complying with the requirements of the Act.

AUDIT OBJECTIVES AND SCOPE

The purpose of our audit will be to review the legislative requirements of the Act and the Agency's ethics program to identify areas that may warrant a detailed audit.

ESTIMATED RESOURCE REQUIREMENTS

This survey will require about 1,280 staff hours of effort.

INSPECTION REPORT CONCURRENCE PROCESS

PLANNED LOCATIONS

NRC Headquarters and Regional offices.

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

We will review the process by which regional management approves inspection reports. When management disagrees with an inspector's findings, the inspector may file a Differing Professional View (DPV) or Differing Professional Opinion (DPO), as appropriate. The DPV is the less formal of the two processes.

The subject is a sensitive issue because NRC has previously received negative publicity and Congressional scrutiny because it failed properly consider an inspector's dissatisfaction with management's changes to an inspection report.

AUDIT OBJECTIVES AND SCOPE

This review will examine the procedures for requesting an inspector's concurrence on an inspection report, and the extent to which the regions properly use the DPO/DPV processes.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require approximately 960 staff hours of effort.

COMMITTEE TO REVIEW GENERIC REQUIREMENTS (CRGR)

PLANNED LOCATIONS

NRC Headquarters.

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

The CRGR is chartered to "eliminate unnecessary demands on licensees by ensuring that the need for a new requirement can be demonstrated by those proposing it....Through its review the CRGR seeks assurance that the proposed requirement: (1) is necessary for the public health and safety, (2) is likely to result in net safety improvement, and (3) is likely to have an impact on the public industry and government, which is consistent with and justified by the urgency of the need or safety improvement to be realized."

Because the CRGR is tasked to evaluate generic requirement and their impact outside the NRC, a review of its effectiveness in meeting its mission is appropriate. The nuclear industry has complained that NRC does not effectively consider the impact of generic requirements on its licensees.

AUDIT OBJECTIVES AND SCOPE

This review will determine (1) how the NRC staff channels generic requirements through the CRGR, (2) how the CRGR meets the requirements of its charter by making the three determinations stated above and, (3) the timeliness of the CRGR's determinations. We will not evaluate the technical adequacy of the CRGR's determinations.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require approximately 640 staff hours of effort.

VENDOR INSPECTION PROGRAM

PLANNED LOCATIONS

NRC Headquarters, Regional offices, nuclear plant sites, vendor offices.

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

NRC's Vendor Inspection Branch (VIB), centralized at NRC Headquarters, inspects certain vendors that supply approved products, equipments and materials that have safety-related applications in nuclear power plants. The vendors inspected are those that have an approved quality assurance program that conforms to the requirements of 10 CFR Appendix B. VIB also inspects utilities procurement programs to assure compliance with NRC's regulations.

Nuclear utilities can purchase safety-related products or services from "Appendix B" vendors or "commercial-grade" suppliers. Commercial grade suppliers are those that do not have an approved Appendix B program. Utilities may purchase safety-related products and services from these vendors if the utilities assure by a "dedication process" that the products or services are suitable for safety-related use.

Because utilities are increasing the level of purchases from commercial-grade suppliers, NRC is considering whether inspections of these vendors would be appropriate.

AUDIT OBJECTIVES AND SCOPE

The objective of this review will be to assess how VIB manages and controls this inspection program; the impact of VIB's inspections on utilities.

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procurement programs and vendor operations, and; whether NRC should initiate inspections of commercial grade vendors.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require approximately 1,400 staff hours of effort.

FINANCIAL ASSURANCES OF MATERIALS LICENSES

PLANNED LOCATIONS

NRC Headquarters and Regional Offices

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

In June 1988 NRC published regulations setting technical and financial criteria for decommissioning licensed nuclear facilities. Current licenses were to submit a "certification of financial assurance for decommissioning" or a "decommissioning funding plan" by July 27, 1990. For non-government materials licenses, NRC requires financial assurance ranging from \$75,000 to more than \$750,000. Financial assurance may be provided by several methods, including: 1) prepayment; 2) a surety, insurance, or other guarantee method; or 3) an external sinking fund with annual deposits. NMSS officials have said this rule has probably had as great an impact on material licensee financial and operating status as the recent 100% fee recovery rule.

AUDIT OBJECTIVES AND SCOPE

Our objectives are to determine 1) the adequacy of NRC's criteria for evaluating a licensee's decommissioning plan acceptability, 2) how NRC verifies a licensee meets its initial and continuing commitments detailed in the plan, 3) the number of licenses late in compliance with the rule and how NRC plans to bring them into compliance, and 4) licensees have purposefully violated the intent of rule and put the public at risk.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require approximately 1,280 staff hours of effort.

TECHNICAL SPECIFICATION IMPROVEMENT PROGRAM

PLANNED LOCATIONS

NRC Headquarters and selected Regions

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

The Technical Specifications Improvement Program was initiated by a 1987 proposed policy statement which was, in turn, based on a 1983 task group study which identified several broad weaknesses in technical specifications (NUREG-1024). The staff recently completed the resolution of public comments on the draft improved standard technical specifications (STS). Volunteering lead plants will begin conversions to the improved STS in early FY 1993.

AUDIT OBJECTIVES AND SCOPE

The objectives of this audit are to determine whether (1) the improved STS has adequately addressed the original weaknesses and (2) voluntary implementation will effectively resolve those weaknesses.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require 960 hours.

CONTRACT AUDITS

PLANNED LOCATIONS

NRC Headquarters and Contractor Facilities

TYPE OF AUDIT

Contract (Priority I)

BACKGROUND

With the addition of two contract auditors in the audit staff, OIG now has the capability to perform contract audits. NRC spends approximately \$100 million contracting with commercial vendors yearly for such things as technical assistance and research. There is a need for NRC to assure itself that the contractors are charging what is allowed by the terms of the contracts.

AUDIT OBJECTIVES AND SCOPE

We plan to conduct five incurred cost audits during the coming fiscal year to determine if the selected contractors are charging NRC in accordance with the terms and conditions of the contract and the Federal Acquisition Regulation.

ESTIMATED RESOURCE REQUIREMENTS

The audits will require a total of about 1,680 staff hours of effort.

NRC'S IMPREST FUND

PLANNED LOCATIONS

NRC Headquarters and Regional Offices

TYPE OF AUDIT

Financial (Priority II)

BACKGROUND

This review is performed annually in accordance with NRC Manual Chapter Appendix 1101, Part IV, Section A, which requires that "unannounced audits of each imprest fund be made by the Office of the Inspector General as frequently as deemed necessary, but at least annually." There are six imprest funds in NRC, one at Headquarters and one in each of the regional offices. There is approximately \$350,000 (cumulative) in the imprest funds. Also, NRC uses traveler's checks for travel advances and has a third party payment system for travel claims between \$100 and \$1,000.

AUDIT OBJECTIVES AND SCOPE

During the review, we will count the funds at all locations to ensure they are properly accounted for. We will also examine the disbursement procedures used by the cashiers to determine if they are effective in accounting for and protecting the funds. In addition, we plan to assess the impact that traveler's checks and third-party checks have on the level of the imprest fund at each location.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require about 400 staff hours of effort.

**COMPLIANCE WITH THE FEDERAL MANAGERS'
FINANCIAL INTEGRITY ACT (FMFIA)**

PLANNED LOCATION

NRC Headquarters

TYPE OF AUDIT

Financial (Priority I)

BACKGROUND

The Office of Management and Budget (OMB) Circular A-123 requires NRC to perform annual reviews and evaluations of internal controls in highly vulnerable components (that is, programs, functions, and organizations). The purpose of the reviews is to identify internal control weaknesses that require corrective actions. The results of the reviews are reported to the President and the Congress annually. During the annual reviews, NRC must (1) revise component risk ratings; (2) perform internal control reviews as required, several alternative internal control reviews, and functional reviews; (3) report all material weaknesses found during reviews; and (4) develop corrective action plans and implement the corrective actions effectively.

The Executive Director for Operations has overall responsibility for implementing FMFIA and Circular A-123 within NRC. The Office of the Controller is responsible for providing oversight and guidance to NRC offices concerning the review, evaluation, and implementation of effective internal controls. The Office of the Controller is also responsible for managing, directing, and evaluating NRC's reporting under FMFIA and Circular A-123.

AUDIT OBJECTIVES AND SCOPE

The objective of our audit will be to determine NRC's compliance with guidelines for implementing the Federal Managers' Financial Integrity Act. Specifically, the Office of the Inspector General (OIG) will evaluate actions taken in accordance with Office of Management and Budget and NRC instructions and guidelines for (1) correcting internal control weaknesses from prior FMFIA reports and General Accounting Office and OIG audit reports, (2) assigning risk ratings and conducting internal control reviews and alternative internal control reviews, and (3) documenting corrective actions for identified internal control weaknesses. In addition, the OIG will review office assurance statements when issued to ensure that all significant internal control weaknesses identified by current year evaluations were reported to senior management.

We will review a sample of risk ratings and control reviews to determine compliance with established criteria, including the documentation of required testing. We will review NRC offices' corrective action plans and documentation supporting the plans' implementation for completeness, effectiveness, and timeliness.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require about 500 staff hours of effort.

**LIMITATION ON USE OF APPROPRIATED FUNDS TO INFLUENCE
FEDERAL CONTRACTING AND FINANCIAL TRANSACTIONS**

PLANNED LOCATION

NRC Headquarters

TYPE OF AUDIT

Financial (Priority I)

BACKGROUND

On October 23, 1989, the President signed into law the Department of the Interior and Related Agencies Appropriation Act (P.L. 101-121) for fiscal year 1990. The act amended Title 31, United States Code, by adding Section 1352, entitled "Limitation on Use of Appropriated Funds to Influence Certain Federal Contracting and Financial Transactions."

The Inspector General is required to prepare and submit to Congress each year an evaluation of the NRC's compliance with and the effectiveness of the requirements of the act. This evaluation may include any recommended changes that may be necessary to strengthen or improve the requirements. The annual report is required to be submitted at the same time NRC submits its annual budget justifications to Congress. The annual report shall include the following:

- (1) All alleged violations relating to the NRC's covered Federal actions during the year covered by the report, (2) the actions taken by the Chairman in the year covered by the report with respect to those alleged violations and alleged violations in previous years, and (3) the amounts of civil penalties imposed by the NRC in the year covered by the report.

Any person who makes an expenditure prohibited herein shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such expenditure.

AUDIT OBJECTIVE AND SCOPE

The objective will be to evaluate the NRC's compliance with the requirements of the act. The audit will review, on a sample basis, recipient certification and disclosure forms for contracts, grants, cooperative agreements, and Federal loans or loan guarantees that were authorized during the current fiscal year.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require about 250 staff hours of effort.

INFORMATION ON CONSULTING SERVICES

PLANNED LOCATION

NRC Headquarters

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

The United States Code (31 U.S.C. 1114) requires that:

...(a) The head of each agency shall include in the budget justification for the agency submitted each year to the Committee on Appropriations of both Houses of Congress: (1) amounts requested for consulting services; (2) the appropriation accounts from which the amounts are to be paid; and (3) a description of the need for the consulting services, including a list of the major programs requiring the services.

(b) The Inspector General or comparable official of each agency shall submit to Congress each year, with the budget justification for the agency, an evaluation of the progress of the agency in establishing effective management controls and improving the accuracy and completeness of the information provided to the Federal Procurement Data System on contracts for consulting services.

AUDIT OBJECTIVE AND SCOPE

The objective will be to evaluate the (1) adequacy of NRC's system of management controls and (2) progress on improving the accuracy and

completeness of the information provided to the Federal Procurement Data System on the NRC's contracts for consulting services.

We plan to follow up on a January 28, 1992, OIG audit report, "Review of Contracting for Consultants," to determine if the recommendations contained in that report have been implemented.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require about 300 staff hours of effort.

AUDIT OF NRC FINANCIAL STATEMENTS

PLANNED LOCATION

NRC Headquarters

TYPE OF AUDIT

Financial (Priority I)

BACKGROUND

On November 15, 1990, the President signed into law the Chief Financial Officers (CFO) Act. The Act, in essence, called for agencies to prepare auditable financial statements at the end of fiscal year 1991 unless a waiver was granted by the Office of Management and Budget (OMB). The Office of the Inspector General (OIG) is required to audit the financial statements or seek audit from an independent external audit firm. Further guidance on producing statements is to be provided by OMB.

AUDIT OBJECTIVES AND SCOPE

In 1992 and beyond, OIG plans to ensure that the NRC financial statements are audited in accordance with applicable auditing standards, either by the OIG performing the audits, contracting with external audits firms, or a combination of both.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require about 2,000 staff hours of OIG effort plus the use of a CPA firm to assist in the audit of the financial statements.

NRC'S BUDGET FORMULATION

PLANNED LOCATIONS

NRC Headquarters and Regions

TYPE OF AUDIT

Financial (Priority I)

BACKGROUND

A budget is a statement of future plans. It serves as control against which performance can be measured.

Annually, NRC is required to prepare budget estimates and submit them to the Office of Personnel Management and Congress for approval. The Division of Budget and Analysis within the Office of Controller is responsible for issuing guidelines to NRC program, support, and regional offices, receiving input from the offices, and preparing the final budget.

AUDIT OBJECTIVES AND SCOPE

To determine that a sound budgetary system is operating for planning and cost control purposes; to determine if estimated costs are developed on a basis consistent with management's latest, most probable plans; and to determine if significant changes in plans and circumstances are reflected promptly thorough controlled and documented revisions.

Review the accuracy of budget preparation, test budget assumptions, and assess the reasonableness of explanations used by NRC budget officers to develop the most recent budget.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require about 1,400 hours of audit effort.

PROPOSAL EVALUATIONS - NON COMPETITIVE PROCUREMENTS

PLANNED LOCATIONS

TBD

TYPE OF AUDIT

Financial (Priority II)

BACKGROUND

In some procurement actions, the opportunity for competition either does not exist or is impractical to generate. In these instances, it is necessary that NRC procure non competitive work. Non competitive procurement is defined as a procurement action for new work for which only one source is solicited.

AUDIT OBJECTIVES AND SCOPE

To determine whether proposed costs are reasonable, allocable, and in accordance with Requests for Proposal (RFP) provisions and the Federal Acquisition Regulation, giving special attention to pricing methods used since comparison is not available as a means of determining the reasonableness of proposed costs.

Scope depends on individual contract types, amounts, DCAA cognizance, and procurement schedules.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require about 1,000 staff hours of effort (5 proposals x 4 weeks per proposal).

FOLLOW-UP REVIEW OF NRC'S DEBT COLLECTION PROCESS

PLANNED LOCATIONS

NRC Headquarters

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

Under the authority of the Debt Collection Act of 1982, OMB Circular A-129 prescribes policies for collecting Federal loans and other receivables. The circular sets standards for extending credit, collecting delinquent receivables, and writing off uncollectible accounts.

The audit was conducted to determine the effectiveness of NRC's compliance with the provisions of the Act and OMB Circular. We found that NRC did not bill about \$7,200 in interest and other late charges based on a sampling of delinquent account receivables. The report made two recommendations to improve the Agency's debt collection process.

AUDIT OBJECTIVES AND SCOPE

Our followup audit will review the status of the staff's actions taken to implement the recommendations.

ESTIMATED OBJECTIVES AND SCOPE

Our followup audit will review the status of the staff's actions taken to implement the recommendations.

ESTIMATED RESOURCE REQUIREMENT

This audit will require about 500 staff hours of effort.

**FOLLOW-UP REVIEW OF THE PROCUREMENT PRACTICES OF THE
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS (ACRS)**

PLANNED LOCATIONS

NRC Headquarters

TYPE OF AUDIT

Performance (Priority II)

BACKGROUND

We conducted an audit of the procurement practices of the ACRS at the request of the Commission to determine whether ACRS officials were complying with federal procurement regulations. ACRS procurement activity consists primarily of obtaining consulting services to support its mission. We issued a report of our findings in September 1991. Of particular concern, the report noted that ACRS had not fully complied with NRC procedures for obtaining services from DOE. In addition, the report noted that NRC's guidance for compensating DOE for services provided to ACRS was unclear. The report made four recommendations.

AUDIT OBJECTIVES AND SCOPE

Our followup audit will review the status of the actions taken to implement the recommendations. One of the recommendations concerns the need to petition the Comptroller General for a decision on the legality of compensation payments made to DOE for advisory committee members.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require about 400 staff hours of effort.

FOLLOW-UP REVIEW OF PART 170 LICENSE FEE PROCESSING

PLANNED LOCATIONS

NRC Headquarters

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

NRC collects fees for services provided to its licensees pursuant to Title V of the Independent Offices Appropriations Act of 1952. 10 CFR Part 170 covers the fees authorized by the Act. Part 170 fees are charged for services such as review of applications for new licenses and the inspection of licensee operations by NRC. On November 5, 1990, PL 101-508 was enacted authorizing NRC to collect approximately 100 percent of its budget through fees beginning in FY 1991 through FY 1995. Approximately \$80 million will be collected in FY 1991 and will increase to about \$100 million in FY 1992.

OIG reviewed NRC's Part 170 license fee processing to determine the adequacy of its billing procedures and related internal controls. The July 3, 1991 report made three recommendations to improve NRC's billing procedures and strengthen its internal controls.

AUDIT OBJECTIVES AND SCOPE

Our followup audit will review the status of the staff's actions taken to implement the recommendations.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require about 600 staff hours of effort.

NRC'S AUDIT FOLLOWUP SYSTEM

PLANNED LOCATION

NRC Headquarters

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

The Office of Management and Budget Circular A-50, "provides the policies and procedures for use by executive agencies when considering reports issued by the Inspectors General...." The circular specified the role of the agency's designated audit followup officials and the role of the Inspectors General. Each agency is required by Circular A-50 to "establish systems to assure the prompt and proper... implementation of audit recommendations." There is to be a complete record of action taken on both monetary and non-monetary findings and recommendations. NRC Manual Chapter Bulletin 1201-4, "Procedures for Follow-up of Audit Recommendation," represents NRC's internal guidance for implementing Circular A-50.

AUDIT OBJECTIVES AND SCOPE

Our overall objective will be to assess the adequacy of NRC's followup system in ensuring that corrective action has been completed as agreed to in the response to IG and other Federal agency audit reports. We will also follow up on selective recommendations from prior audit reports to test whether implementation of recommendations has in fact taken place.

ESTIMATED RESOURCE REQUIREMENTS

This work will require about 600 staff hours of effort.

**FOLLOW-UP REVIEW OF THE ATOMIC SAFETY
AND LICENSING BOARD PANEL**

PLANNED LOCATIONS

NRC Headquarters

TYPE OF AUDIT

Performance (Priority I)

BACKGROUND

The Atomic Safety and Licensing Board Panel (ASLBP) is the office that performs the hearing function for the Commission. The ASLBP was created by the Commission in 1962 under the authority of Section 191 of the Atomic Energy Act of 1954, as amended. NRC's hearings are generally conducted before a three member Board which is drawn from the Panel of members of the ASLBP. Hearings conducted by the ASLBP are the Commission's principal public forum in which individuals and organizations can voice their interests in a licensing, enforcement, or other matter, and have those interests adjudicated by an independent Board.

The OIG audit report found that the ASLBP was going through a transition period with a change in the types of cases conducted. As a result, it was difficult to project the workload and resource requirements necessary to carry out the mission of the ASLBP. The report made seven recommendations to improve and strengthen their management controls.

AUDIT OBJECTIVES AND SCOPE

We plan to review the status of the staff's action regarding the implementation of the recommendations and to determine whether the actions taken meet the intent of the report findings. Our audit will encompass the effectiveness of the Agency's Followup System and the responsiveness of the ASLBP.

ESTIMATED RESOURCE REQUIREMENTS

This audit will require about 450 staff hours of effort.

ACNP

American
College of
Nuclear
Physicians

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SNM

The Society
of Nuclear
Medicine

STATEMENT OF
THE SOCIETY OF NUCLEAR MEDICINE
and
THE AMERICAN COLLEGE OF NUCLEAR PHYSICIANS
concerning
H.R. 2143
submitted to the
U.S. HOUSE OF REPRESENTATIVES
ENERGY AND MINERAL RESOURCES SUBCOMMITTEE
of the
HOUSE NATURAL RESOURCES COMMITTEE
June 10, 1993

For More Information Contact:
Kristen D.W. Morris
Director of Government Relations
(202) 429-5120

On behalf of the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM), this written testimony is presented to the House Natural Resources Committee, Energy and Mineral Resources Subcommittee regarding H.R. 2143. This bill would authorize appropriations for the Nuclear Regulatory Commission for fiscal years 1994 and 1995.

Together the ACNP and SNM represent approximately 15,000 nuclear medicine physicians, scientists, and technologists. Attached is a description of nuclear medicine for your reference (attachment A). It is critical that access to nuclear medicine services be protected, since, in many cases it is the most accurate technology which can correctly diagnose a number of diseases and provide guidance with regard to treatment protocols. Furthermore, nuclear medicine provides non-invasive diagnostic and therapeutic services at a cost much lower than other options.

ACNP and SNM's objective throughout this statement is to offer our professional opinion and focus attention, on the unnecessary and duplicative aspects of Nuclear Regulatory Commission (NRC) regulation of nuclear medicine. However, there is a practical incentive for concern as well. Since NRC became funded from 100 percent user fees, costs have skyrocketed, due to regulations with little demonstrated benefit. New health care reimbursement systems, now generally based on capitations, mean that any additional regulatory compliance costs cannot be recovered by the provider and may not be passed on to the patient.

NRC conducted an evaluation of the medical section in 1985. At that time, the NRC estimated that by 1987, NRC regulations would cost the medical community approximately \$92 million. States regulate two thirds of all medical licensees under an NRC agreement so this figure is much larger on a national scale. Combine this estimate with costs associated with new regulations and one can come close to identifying a \$1 billion burden on society as a result of NRC regulation. While some of this regulation is important to ensure public health and safety, ACNP and SNM would argue that much is unnecessary and counterproductive.

ACNP/SNM
Page 2

A petition to the NRC regarding user fees is currently under consideration. On October 13, 1992, the NRC published a request for comment on the ACNP/SNM petition for rulemaking on the revised fee schedule. We are convinced that the current fee inequities unfairly burden medical licensees and threaten the continuation of many nuclear medicine practices, as indicated by the cancellation of approximately 400 medical licenses since the fee schedule was implemented. ACNP and SNM's primary interest is to obtain an exemption for medical licensees based on the fact that NRC has already exempted non-profit educational institutions based on their limited ability to pass on regulatory costs to their clients.

NRC received 96 comments on the petition; 79 supportive and 17 against. Generally, those favoring the proposal including the American College of Radiology, the Department of Veterans Affairs, the American Hospital Association, and the Small Business Administration - Office of Chief Counsel for Advocacy, pointed out the unique health services provided by nuclear medicine and the difficulty in passing on license fee costs to patients. A decision by the NRC on the ACNP/SNM petition is expected sometime in 1993.

However, even if our petition is favorably resolved, that does not justify the unbridled regulatory actions of the NRC. We have attached two letters from the Office of Management and Budget which severely criticizes NRC's Medical Quality Management Rule (attachments B and C). The following is a quote from a June 26, 1992 letter, signed by James B. MacRae, Jr. Acting Administrator and Deputy Administrator, Office of Information and Regulatory Affairs, OMB;

"To the extent that the NRC imposes costs on the regulated community to conduct programs that are not cost-effective, it will divert resources from programs that are cost-effective and, as such, would result in greater improvements in public health and safety. Thus, the NRC should review its actions in the context of this larger framework of the costs and risk management needs of the health care system as a whole.

ACNP/SNM
Page 3

"For the reasons set forth above, OMB believes that the reporting and record keeping requirements in this ICR [information collection request] have little if any practical utility. Therefore, the significant burdens imposed on the regulated community are unreasonable and I am disapproving this ICR under the authority of the PRA [paper reduction act]."

Since NRC is an independent agency, it completely ignored OMB. Please do not let this go unaddressed!

In April, the OMB reviewed NRC regulations under 10 CFR Part 35 Medical Use of Byproduct Material (attachment D). Comments signed by the Presidents of ACNP and SNM illustrated that NRC regulations cost an estimated \$212 million per year. Therefore, almost one fifth of the \$1 billion results from the regulation of medicine and not radiation safety. This represents \$21.20 per procedure allocated to just NRC regulation of medicine. The regulation reviewed on June 26, 1992 is perhaps the most duplicative and uneconomical regulation imposed by the NRC on the medical community to date, and accounts for an estimate \$5.80 per procedure alone.

In summary, the nuclear medicine community strongly urges Congress to review the medical application's program budget in great detail. Since the NRC's budget does not impact the deficit as it is funded through user fees, we fear that it does not receive the in-depth scrutiny as do other programs funded from general revenue funds. If the American health care system is required to bear the burden of user fees and compliance costs, it must be for regulation with merit and benefits to the public health and safety as a whole. Assertions of such benefit by NRC need to be documented by independent studies. The use of NRC staff as consultants to evaluate such programs and design new ones does not satisfy the criteria of impartiality or meet standards for outside review.

Thank you for this opportunity to highlight our concerns. If you have any questions please feel free to contact Kristen Morris, Director of Government Relations, at (202) 429-5120.



ATTACHMENT A

AMERICAN COLLEGE OF NUCLEAR PHYSICIANS
PROFESSIONAL AND PUBLIC INFORMATION PROGRAM

NUCLEAR MEDICINE: THE PHYSIOLOGIC SPECIALTY

Nuclear medicine began with the development of biologically radioactive materials approximately 50 years ago. Since then, nuclear medicine has evolved into its present state as a major medical specialty for both diagnosis and therapy.

MEDICAL IMAGING - The imaging section of nuclear medicine - the most visible to the public - utilizes radiopharmaceuticals (radioactive drugs that have no effect on the patient in general) to localize in various organ systems. By mimicking physiologic systems, organs such as the heart, bones, brain, lung, liver, gallbladder, and kidneys, can be "fooled" into concentrating the radiopharmaceutical. The addition of standard pharmaceuticals to alter physiology may enhance the diagnostic information obtained from a nuclear medicine procedure.

The distribution of the radiopharmaceutical is sensed by a camera-like detector which feeds the information to a computer. The computer displays a digital image of the specific organ, showing any abnormalities. Since detailed knowledge exists of the behavior of radioactive drugs in the normal, the abnormal states can be easily detected and quantified.

Radiation doses from nuclear medicine procedures are, in general, comparable or less than those of diagnostic radiology. Today, nuclear medicine covers the broad span of the medical specialties ranging from pediatrics to cardiovascular disease to dementia. There are nearly 100 different nuclear medicine imaging examinations available at the present time.

IN VITRO - The in vitro - or laboratory - practice of nuclear medicine are of key importance in measuring small concentrations of drugs and naturally occurring substances, such as chemotherapeutic agents and tumor-associated antigens.

THERAPY - The therapeutic aspects of nuclear medicine, present since its inception, are of increasing importance today. Certain diseases are only curable by use of a radiopharmaceutical. The growing ability to target a malignant disease with a combination of immunologic and radioactive materials holds a tremendous promise for an expanded therapeutic role in nuclear medicine.

There are currently 3500 hospital-based nuclear medicine departments in the United States. Of the 100 million nuclear medicine procedures performed each year, approximately 12 million are imaging examinations. Each hospital patient is likely to have at least one or more nuclear medicine examination during his/her hospital stay, because of the important role nuclear medicine is playing in diagnosis, maintenance, and therapy of the patient.



AMERICAN COLLEGE OF NUCLEAR PHYSICIANS
PROFESSIONAL AND PUBLIC INFORMATION PROGRAM

ATTACHMENT A

WHY DO PHYSICIANS ORDER NUCLEAR MEDICINE STUDIES?

A PARTIAL LIST OF REASONS

NEUROLOGIC APPLICATIONS

diagnose stroke
diagnose Alzheimer's Disease
demonstrate changes in AIDS dementia
evaluate patients for carotid surgery
localize seizure foci
evaluate post concussion syndrome
diagnose multi-infarct dementia

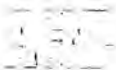
ORTHOPEDIC APPLICATIONS

quantify osteoporosis
localize sites for biopsy in tumor patients
measure extent of certain tumors
identify occult bone trauma (sports injuries)
diagnose osteomyelitis
identify bone infarcts in sickle cell disease
evaluate arthritic changes and extent

RENAL APPLICATIONS

detect renal obstruction
diagnose renovascular hypertension
measure differential renal function
separate mechanical from physiological obstruction
detect renal transplant rejection

(over)



ONCOLOGIC APPLICATIONS

tumor localization
tumor staging
identify metastatic sites in skeleton
judge response to therapy of skeletal metastases
evaluate levels of amputation in primary bone tumors

PULMONARY APPLICATIONS

detect pulmonary complications of AIDS
diagnose pulmonary emboli
quantify lung ventilation and perfusion
detect lung transplant rejection
detect inhalation injury in burn patients

CARDIAC APPLICATIONS

diagnose coronary artery disease
measure the effectiveness of bypass surgery
measure effectiveness of therapy for heart failure
detect heart transplant rejection
select patients for bypass or angioplasty
identify patient at high risk of coronary complications going to surgery
for other reasons
identify right heart failure
measure chemotherapy cardiac toxicity
evaluate valvular heart disease
identify patients with false positive EKGs
identify left to right shunts and quantify them
diagnose, size and localize acute heart attacks and before enzyme changes

OTHER APPLICATIONS

diagnose and treat hyperthyroidism (Grave's Disease)
detect acute cholecystitis
detect acute gastrointestinal bleeding
detect testicular torsion
detect occult infections
diagnose and treat blood cell disorders



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ATTACHMENT B

JAN 24 1992

Mr. James Taylor
Executive Director for Operations
Nuclear Regulatory Commission
Washington DC 20555

Dear Mr. Taylor:

On December 24, 1991, the Nuclear Regulatory Commission (NRC) resubmitted to the Office of Management and Budget (OMB) an information collection request (ICR) entitled "The Medical Use of Byproduct Material" for review under the Paperwork Reduction Act (PRA). This ICR would establish as a part of its quality management (QM) programs several additional recordkeeping and reporting requirements for practitioners of nuclear medicine and several types of therapy which use byproduct material. I am concerned with the NRC's failure to demonstrate clearly the practical utility of these requirements and to provide estimates of their burden as required by the PRA.

NRC reports that the purpose of this ICR is to require practitioners of nuclear medicine to maintain records and submit certain data to the NRC as part of its QM programs. These programs are designed to assure that radiopharmaceuticals are administered as prescribed by the authorized user physician, and that procedures are carried out as prescribed by authorized physicians. The NRC has not, however, clearly demonstrated that there is currently a significant problem requiring such a quality management program. Given the already high cost of medical care, it is important that the Federal government avoid further burdens for the health care sector, unless these additional requirements have practical utility and are likely to yield significant benefits. The NRC has not made this demonstration.

While OMB initially approved the QM requirements at proposal, OMB staff have reexamined these requirements in response to public comments that were received when the final package was submitted to OMB for review. OMB has received written comments from the Society of Nuclear Medicine/American College of Nuclear Physicians, and copies of letters concerning the final rule, and the pilot study from the Small Business Administration and the University of California at Los Angeles. Following these initial contacts, OMB staff discussed these requirements extensively with other members of the regulated community. These include representatives of three agreement states (New York, California, and Louisiana), several physicians who practice nuclear medicine, representatives of three other professional organizations (American College of Radiology, Joint Commission on the

Accreditation of Health Care Organizations, and the American Medical Association), members of the NRC's Advisory Committee on the Medical Use of Isotopes, and the staff of the Food and Drug Administration. OMB has also received numerous written comments from physicians and health care facilities in recent weeks. While the concerns outlined below are based on our own evaluation, we believe they also reflect the concerns of many of these individuals and organizations.

Practical Utility

The current rate of misadministration of radiopharmaceuticals is already quite low.¹ There appears to be widespread agreement on this point among almost everyone familiar with the issue. This is likely a result of several factors. Most practitioners already implement quality management programs on a voluntary basis; many as part of an accreditation or certification process sponsored by a professional association. There are important reasons for practitioners to do so. First, practitioners need to take every care that their procedures are done correctly to avoid malpractice suits. In addition, since records of their mistakes are available to the general public, such care is important to maintain their professional reputation. Finally, practitioners in the field are acutely aware of the public's general concerns about radiation, and take special care to ensure that mistakes do not occur to maintain the credibility of their specialty.

The care with which these procedures are conducted is reflected in the low rate of error for these procedures. Misadministrations or abnormal occurrences occur about one in every 3,300 procedures. The NRC's records indicate that there were 200 patients who received misadministrations between 1980 and 1990 in 89 recordable events. (When adjusted to account for misadministrations in agreement states, one can assume that there were perhaps 600 patients affected during this time period nationwide.) Assuming 600 errors between 1980 and 1990, this would indicate an overall error rate of approximately 0.03% for nuclear medicine, teletherapy and brachytherapy. Extrapolating from error rates in 1989 and 1990, one could roughly estimate that errors occur in 0.04% of all teletherapy procedures, in 0.02% of all brachytherapy procedures and in 0.03% of all nuclear medicine procedures.

¹The NRC estimates that there were approximately 600 misadministrations between 1980 and 1990, during approximately 1,980,000 procedures. Most misadministrations have no significant health effects; there have been only a relatively small number of incidents in which misadministrations or abnormal occurrences have clearly contributed to death or serious, permanent, or debilitating injury.

These are especially low misadministration rates when compared with rates of error in the administration of other drugs. A recent journal article reported that overall, medication errors occur in 13% to 18% of all hospital administered doses.² Among the errors found were the administration of the wrong dose, the wrong drug, or unordered drugs, administration to the wrong patient, at the wrong time, or by the wrong route. A published study of errors in the intensive care unit of one hospital indicated a medication error rate of 2.2%.³ Finally, a third study of medication errors in two children's hospitals found medication error rates of 0.49% and 0.45%.⁴ The error rate in nuclear medicine and therapies, then, are ten to one thousand times lower than the error rate for other drugs.

Given the already low rate of misadministrations and abnormal occurrences, the NRC has failed to demonstrate how these reporting requirements are likely to further decrease these rates, and thus have any practical utility. The NRC states that most medical facilities already have quality management programs in place which are similar to, the equivalent of, or even more stringent than the program mandated by the NRC. The occurrence of misadministrations at these facilities in the past demonstrates that despite good procedures, human fallibility will always result in some errors. Furthermore, there is significant concern within the medical community that any steps which must be taken which are not directly related to the delivery of safe and accurately administered procedures might be distracting and lead to other mistakes.

Burden of the ICR

The NRC claims that these QM requirements will impose only 6,490 hours of burden on the regulated community. A review of the record suggests, however, that physicians trying to comply with this rule will probably bear a significant recordkeeping and reporting burden.⁵ Physicians will need to design and implement

²"What We Know About Medication Errors: A Literature Review," Journal of Nursing Quality Assurance, November 1988, page 1).

³"Medication Administration Errors in an Adult Intensive Care Unit," Heart & Lung, July 1987, page 450.

⁴"Medication Error Prevention by Clinical Pharmacists in Two Children's Hospitals", Pediatrics, May 1987, page 718.

⁵Part of the problem in calculating our own estimate of the burden is the disagreement between the NRC and the regulated community as to what is required by these regulations. Since

a quality assurance program and recordkeeping system to satisfy the NRC's requirements, even though most physicians already have QM programs designed and monitored by professional associations.

In addition, it is likely that the development of a complete quality management program would take longer than the 40 hours indicated in the ICR's supporting statement. This is based on discussions with several physicians who practice in these fields, and their estimates of how long it took them to develop their programs, and OMB's own review of the regulatory guide for the rule. Furthermore, this estimate does not appear to include the time necessary for those who already have quality management programs to review carefully their programs to determine whether or not they meet the NRC's criteria.

The NRC supporting statement does not include the burden for the development of diagnostic clinical procedure manuals described in 10 CFR 35.2. Although there is no clear requirement to develop such manuals, the NRC later defined "prescribed dosage" as "an activity as documented: 1) In a written directive; or 2) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures." NRC's reference to the manual has been interpreted by many physicians as meaning that the NRC requires such manuals.

The NRC supporting statement also claims that there is no burden associated with maintenance of records concerning administered doses or dosages because these records are already kept as required by 10 CFR 35.53. But, the current requirements are not the same as the new requirements. The current regulations require that facilities keep records of doses that have been administered. However, they do not appear to require the maintenance of records, in an auditable form, of the prescription that led to the dose. To maintain these records in a fashion that would be easily auditable, physicians will probably have to keep a duplicate set of files.

The NRC also states that there is no burden associated with changes to a quality management program, since these changes are

there is no agreement between the regulated community and the NRC on what is required, it is not possible for OMB to independently develop our own estimate of the burden contained in this ICR.

Physicians generally keep these records in each patient's individual files; however, upon being inspected, he/she would have to remove these documents from each patient file for the inspector and then replace them once the inspection was complete. Therefore, the best way to meet this requirement is to keep duplicate records.

voluntary. However, the implementing regulations for the PRA clearly state that voluntary reporting requirements are covered under the scope of the PRA (see 5 CFR 1320.7(c)), and must therefore be included in the burden calculations. Furthermore, although these steps may be viewed as voluntary, to the extent that physicians feel they need to modify their programs consistent with good practice, they will make these changes.

OMB believes that most facilities will implement other recordkeeping procedures as part of their programs. The NRC program, as outlined in the rule and the regulatory guide, is ambiguous in some instances and very specific in others.⁷ The NRC's failure to specify what records must be maintained as part of a QM program does not mean that practitioners will not have to keep records. In fact, given the uncertainty within the regulated community as to what constitutes compliance with these requirements, it is likely that people will keep extensive records to ensure that they can produce any records that NRC inspectors request to see.

Finally, based on discussions which OMB has had with several physicians, the periodic reviews described in Section 6 of the Regulatory Guidance documents are likely to impose a significant burden on practitioners without having any real practical utility. Since the overwhelming majority of licensees have no misadministration in any given year, the requirement to engage in a lengthy review of their procedures to ensure that they are doing everything possible to reduce misadministration to zero, appears to have little if any value. Although it might make sense for those facilities that experienced misadministrations to review their procedures, this requirement is imposed on a significantly larger population with no apparent benefit.

Conclusion

I am concerned that the new reporting and recordkeeping requirements have little, if any, practical utility. I do not believe, based on the supporting documents provided by the NRC,

⁷For instance, the ambiguity as to whether or not clinical procedure manuals are required will probably result in physicians taking the time to develop them whether or not the NRC intended to require them. On the other hand, the guidelines require that before any procedure the licensee should verify the patient's identity by asking the patient their name and then confirmed by cross-referencing information in the patient record including at least one of the following: birth date, social security number, address, signature, or identification card. This is an extremely specific requirement which would better be left to the licensee's discretion.

that these requirements will reduce the number of misadministrations or abnormal events. I am also concerned that the NRC and the regulated community have widely different estimates for the burden of meeting these requirements. Nonetheless, these requirements will clearly impose a burden on the regulated community, without any clear benefits. I encourage the NRC to once again review the concerns we have outlined above with members of the regulated community so that they may come to some understanding of exactly what burdens are imposed by this program on the regulated community, and what purpose they will serve. Since there is a significant discrepancy between what the NRC believes is the burden imposed by this program, and the burden which the regulated community feels they will be required to shoulder, we feel that such a meeting would be useful. Once both sides can agree on the requirements of this program both the NRC and OMB would be in a much better position to evaluate whether or not the burden imposed by these requirements would be justified by its practical utility.

Sincerely,

Original Signed by
James B. MacRae, Jr.

James B. MacRae, Jr.
Acting Administrator
and Deputy Administrator
Office of Information
and Regulatory Affairs

cc: Hugh L. Thompson, Jr.
Ivan Selin, Chairman
Kenneth C. Rogers, Commissioner
James R. Curtiss, Commissioner
Forrest J. Remick, Commissioner
E. Gail de Planque, Commissioner

ATTACHMENT B



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555
January 24, 1992

Mr. James B. MacRae, Jr.
Acting Administrator and
Deputy Administrator
Office of Information and
Regulatory Affairs
Office of Management and Budget
1725 - 17th Street, NW
Washington, DC 20503

Dear Mr. MacRae:

Despite considerable efforts by both of our staffs to settle the differences of opinion concerning the proposed information collection requirements associated with the final rule amending Part 35, a satisfactory resolution has not been reached. Because the January 27, 1992 implementation date is imminent, the NRC must decide on the enforceability of the information collection requirements.

Based on your conversation with members of my staff on January 23, we expect to receive a letter from OMB elaborating OMB's remaining concerns. We note that NRC submitted a revised package dated September 11, 1991 for the revised information collection requirements in the final rule. The latter reduced the burden from 65,000 hours to 8,900 hours annually. In view of the fact that we have not been advised of an OMB disapproval within 90 days of our submittal, NRC's legal counsel has concluded that we can proceed with full implementation of the amendment. Indeed, given the reduced information collection requirements in the final rule, it seems to us that OMB review of the final rule was not needed, and that the final rule can become effective on the basis of OMB's March 30, 1990 appraisal of the proposed rule. But we nevertheless can proceed with continued interaction with OMB to resolve your concerns on the collections of information associated with amended Part 35.

This experience emphasizes the importance of good timely communication between our agencies and I thank you for your personal efforts in this matter.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

JAN 26 1992

Mr. James Taylor
Executive Director for Operations
Nuclear Regulatory Commission
Washington DC 20555

Dear Mr. Taylor:

On December 24, 1991, the Nuclear Regulatory Commission (NRC) submitted to the Office of Management and Budget (OMB) an information collection request (ICR) for review under the Paperwork Reduction Act (PRA). This ICR would authorize the NRC to require that medical practitioners engaged in therapies using radioactive material maintain records as evidence of a quality management program, submit copies of quality management programs to the NRC, and report to the NRC when misadministrations occur.

In a letter dated January 24, 1992, OMB asked NRC to address numerous issues that arose during our review of the ICR. OMB was concerned that the burden imposed on the regulated community by these reporting and recordkeeping requirements was not justified by the limited practical utility of the requirements.

The NRC responded to OMB in a letter dated March 23, 1992, stating that the NRC had already discussed with the regulated community the issues raised by OMB, and had incorporated their suggestions into the final rule to the extent that it was appropriate. The NRC reiterated its position that these requirements are necessary in order to protect the health and safety of the public.

After further review of the ICR's supporting statement, the NRC's letter of March 23 and its attachments, and other materials which OMB has received during its review, I have concluded that the limited practical utility of the requirements imposed on the regulated community do not justify their burden. I am therefore disapproving this ICR. In order to approve the ICR, OMB would have had to determine that the practical utility derived from the requirements in the ICR outweighed the burdens imposed by those requirements. In this instance, we could not make that finding.

Practical Utility of the Information Collection Request

OMB strongly supports the NRC's goal of taking measures to protect human health and the environment, as directed by the Atomic Energy Act. However, OMB believes that the reporting and

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recordkeeping requirements contained in this ICR would not contribute to that goal.

The practical utility of the reporting and recordkeeping requirements in this ICR may be measured by the degree to which they assist in any action which further protects human health and the environment. Therefore, in order to determine whether or not they have any practical utility, it is necessary to determine the degree to which they contribute to the NRC's ability to provide additional protection of public health above the current level of protection.

Currently, most facilities implement quality management (QM) programs to meet standards established by professional accreditation organizations. In fact, according to the NRC, 90% of all covered facilities already have a program that is equivalent to the requirements in this ICR and the associated rule. Notwithstanding these programs, however, misadministrations do still occur. The ICR and the associated rule is premised on the belief that mandating these programs for all covered facilities would further misadministrations, and in so doing provide additional protection for public health.

The information that the NRC has provided to OMB with the ICR does not support these assumptions. First, it is far from evident that the ICR will actually reduce misadministrations. The NRC has not presented OMB with any evidence that errors reported to the NRC tended to occur at the 10% of facilities without QM programs and would have been prevented had such programs been in place. Moreover, when compared to the error rates in other medical specialties, the error rates in the use of byproduct materials appear to be extremely low. In our letter of January 24, 1992, we cited several journal articles which identified error rates in the administration of medications in hospitals which were several orders of magnitude higher than the error rates cited by the NRC.¹ In addition to those studies, a Harvard University study of adverse events and negligence in hospitals which was recently completed strongly supports our earlier conclusion.² Given that the level of errors in

¹In the January 24, 1992 letter from James B. MacRae, Jr. of OMB to James Taylor of the NRC, OMB cited several journal articles which estimated medication error rates in hospitals of between 0.5% and 18%.

²According to the results of that study there were 2.672 million patients released from New York State hospitals in 1984. Of those patients, almost 99,000 (3.7% of all discharges) suffered adverse events (the study defined an "adverse event" as "an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization,

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procedures using byproduct materials is already extremely low (particularly when compared to other medical procedures) and is in fact approaching the limits of human error, it appears to be unlikely that the NRC program would significantly increase the public's overall health and safety by reducing the incidence of misadministrations.³

The NRC states that since the rate of misadministration rose significantly from 1989 to 1990, it is possible to reduce the rate of misadministrations from their most recent level. Even if the NRC is correct that the increase from 1989 to 1990 means that it is possible to further reduce misadministrations, the NRC has not shown that this ICR is likely to yield such reductions. The NRC has not presented any evidence that the rise in misadministrations between 1989 and 1990 was the result of any specific type of failure that the requirements in this ICR would address. Second, even if the ICR would significantly reduce misadministrations (which is unlikely for the above reasons), the additional protection afforded to public health and environment would be marginal. The NRC cites statistics which indicate that there are approximately 60 misadministrations of byproduct materials each year, representing approximately 0.03% of 200,000 covered procedures. Of the 60 annual misadministrations, few appear to have resulted in permanent injury.⁴ In fact, a

produced a disability at the time of discharge, or both") during their hospitalization; over 27,000 (27.6% of all adverse events) were due to negligence (the study defined "negligence" as "care that fell below the standard expected of physicians in their community"). Of those patients who suffered adverse events, approximately 13,450 (13.5% of all adverse events) died as a result of the adverse event. Of the adverse events which resulted in the death of a patient, approximately 6,900 (51% of adverse events which resulted in death) resulted from negligence. (New England Journal of Medicine. Incidence of Adverse Effects and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I. February 7, 1991. Vol 324 No 6 page 370 - 376.)

³On page 21 of a brief filed on March 6, 1992 with the U.S. Court of Appeals for the D.C. Circuit by the NRC in the case American College of Nuclear Physicians and Society of Nuclear Medicine v. United States Nuclear Regulatory Commission and United States of America (Civil No. 91-1431) the NRC conceded that "it cannot be said with certainty that the QM rule will reduce misadministrations."

⁴When discussing the need for this program, the NRC most frequently cites the 1975 Riverside incident in which several patients were overexposed due to the incorrect calibration of a cobalt 60 machine, and some of the patients may have died as a

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substantial percentage of the misadministrations probably resulted in no permanent adverse effects to the patient.⁵ In sum, the information that the NRC has provided to OMB, and the other information that OMB has received, does not support a conclusion that the reporting and recordkeeping requirements in the rule will contribute to the achievement of the goal of reducing misadministrations, and thereby providing additional protection to public health. Accordingly, these requirements have little if any practical utility.

Burden Imposed on Medical Practitioners

OMB is unable to determine with confidence the magnitude of the burden imposed on the regulated community by these recordkeeping and reporting requirements. According to NRC estimates, the final rule would impose an annual burden of almost

result of that mistake. However, the NRC subsequently promulgated rules in 1979 that require frequent calibration of equipment by qualified experts. Since the NRC has already taken steps to reduce the frequency of this type of error, it is unclear how the proposed measures would yield any further reduction in such risks. Although the NRC asserted that there were one or two other misadministrations which resulted in significant injury or death, the NRC never provided to OMB any background about other misadministrations.

*The NRC does not distinguish between that various levels of injury which patients have suffered as a result of misadministrations, simply stating that any exposure to radiation greater than a certain percentage above the prescribed level is assumed to be harmful. However, there are various level of injury which one could sustain from a misadministration, some more serious than others. A Harvard University study (see footnote 2) on the rate of abnormal events in hospitals, injuries were categorized as (1) Minimal impairment, recovery 1 month or less, (2) Moderate impairment, recovery 1 to 6 months, (3) Moderate impairment, recovery 6 months or more, (4) Permanent impairment, less than 50%, (5) Permanent impairment, greater than 50%, (6) Death, or (7) Could not reasonably judge impairment. The NRC made no attempt to categorize the adverse effects caused by byproduct misadministrations by level of severity or any other measure. OMB staff did review the misadministrations listed in the Federal Register notice at 56 FR 34104 with Dr. Terrence Bevin, President of the American College of Nuclear Physicians. He estimated, based on the limited data, that as few as 4 of the 66 misadministration might have resulted in any significant adverse effect.

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20,000 hours on the regulated community.⁶ According to the professional association the burden could easily reach 200,000 hours -- a factor of ten times larger than estimated by the NRC.⁷

The NRC has a clear conception of what is required by the ICR, and has calculated the burden based on how long it believes that it would take someone with an equally clear understanding of the ICR to meet its requirements. The professional associations, however, do not share this conception of the ICR.⁸ Instead they face substantial uncertainty about what the NRC expects the regulated community to do, and what each individual NRC inspector expects to find when inspecting a regulated party. Given this uncertainty, the regulated individuals and facilities are likely to be overly cautious -- and assume a greater paperwork burden -- because they cannot continue to operate without an NRC license.⁹

OMB suggested in January that the NRC and the regulated community meet to clarify the requirements of this ICR.¹⁰ OMB felt that such large discrepancies in burden hour estimate could only be explained if the regulated community interpreted the ICR as imposing requirements which the NRC never intended to impose. However, since the NRC's chose not to meet with the professional

⁶March 23, 1992 letter from James Taylor to James B. MacRae, Jr., enclosure 3.

⁷November 5, 1992 letter from Kristen Morris to Ronald Minsk.

⁸During separate discussions between OMB and the NRC and between OMB and the professional associations, OMB realized that the NRC and the Professional Associations do not even agree on what reporting and recordkeeping requirements the regulated community will have to comply with under the final rule and the ICR submitted to OMB for review. If the two parties cannot even agree on what is required by the rule and the ICR, then they certainly will not be able to agree on the burden they impose on the regulated community. This led OMB to suggest that the NRC meet with representatives of the regulated community.

⁹In addition to the paperwork burden borne by the regulated community in meeting the rule's requirements, they will also bear the costs of NRC's administration of this rule through fees imposed on the reporting community when NRC conducts its inspections. See 10 CFR 170 and 10 CFR 171 and 56 FR 31472, at which the NRC revised its fee schedule for licenses and inspections to recover approximately 100% of its costs as required by the Omnibus Budget Reconciliation Act of 1990.

¹⁰January 24, 1992 letter from James B. MacRae, Jr. to James Taylor, page 6.

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associations, there is no additional information that would allow us to improve our estimates." Accordingly, OMB can only conclude that the ICR's true burden hours lies somewhere between the NRC's and the professional association's estimates.

As explained above, the available evidence indicates that the reporting and recordkeeping requirements will have little if any practical utility furthering the goal of reducing injuries from misadministrations. Therefore, any significant burden is unreasonable, whether that burden amounts to 20,000 hours (as the NRC estimates) or 200,000 hours (as the professional association estimates). Thus, I conclude that this information collection request is not "necessary for the proper performance of the functions of the agency" and that the information collection will not "have practical utility for the agency." 44. U.S.C. 3504(c)(2), 3508; see 5 C.F.R. 1320.4(b), (c).

Conclusion

Currently, there is a growing concern about the ever increasing costs of medical care. Doctors can always run more tests, perform more procedures, take additional steps, and even perform more paperwork in an effort to reduce health risks. However, it is generally recognized that there are diminishing returns -- and that the medical community cannot conduct every test or take every possible precaution to prevent an adverse effect. As part of controlling the costs of medical care, society expects that the medical community will only incur those costs which have a reasonable likelihood of benefiting their patients.

In this regard, the relevant question is not whether the ICR would be more cost-effective than the other steps that the NRC could take to reduce the risks associated with the medical use of byproduct materials. The relevant question is whether the ICR is cost-effective in an absolute sense -- rather than relative -- sense. While this program may be more cost-effective than any other step the NRC could take, the program is not cost-effective in an absolute sense, because the practical utility (if any) that the program will yield does not justify the significant burden the program will impose. To the extent that the NRC imposes costs on the regulated community to conduct programs that are not cost-effective, it will divert resources from programs that are cost-effective and, as such, would result in greater improvements in public health and safety. Thus, the NRC should review its actions in the context of this larger framework of the costs and risk management needs of the health care system as a whole.

¹¹March 23, 1992 letter from James Taylor to James B. MacRae, Jr., page 2.

ATTACHMENT C

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For the reasons set forth above, OMB believes that the reporting and recordkeeping requirements in this ICR have little if any practical utility. Therefore, the significant burdens imposed on the regulated community are unreasonable and I am disapproving this ICR under the authority of the PRA.

Sincerely,
Original Signed by
James B. MacRae, Jr.
James B. MacRae, Jr.
Acting Administrator
and Deputy Administrator
Office of Information
and Regulatory Affairs

ACNP

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American
College of
Nuclear
Physicians**SNM**The Society
of Nuclear
Medicine

ATTACHMENT D

March 8, 1993

Ronald Minsk
Office of Information and Regulatory Affairs
NEOB-3019
Office of Management and Budget
Washington, DC 20503RE: Comments on the Nuclear Regulatory Commission Request for OMB review of
10 CFR Part 35 Medical Use of Byproduct Material.

Dear Mr. Minsk:

These comments are submitted on behalf of the over 14,000 physicians, scientists, and technologists of the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM), in response to the notice of 58 Fed Reg 366. In this time of health care reform it is imperative that costs, both direct and indirectly necessary to provide nuclear medicine services are identified. NRC regulation continues to be the most resource intensive practice expense. For this reason, we believe that the request for Office of Management and Budget Review regarding the collection of information by the Nuclear Regulatory Commission (NRC) under the provisions of the Paperwork Reduction Act (44 U.S.C. 35) deserves scrutiny. Our concerns with the request for OMB review mainly consist of a significant underestimation of time and cost to comply with the regulations as stated in 10 CFR 35. These errors are listed as follows:

Section 35.60(b)

This section requires that the licensee label each syringe or radiation shield as to its contents. The NRC contends that approximately 2,600,000¹ syringes or shields must be labeled annually using approximately 0.00416² hours each. The actual number of nuclear medicine imaging procedures performed per year is closer to 10,000,000³ studies. The great

¹ This value is taken from the NRC Request for OMB Review, Page 16, next to 35.60 (b).

² Ibid, Page 16.

³ A value obtained from a marketing research consulting firm that was once hired by the SNM. Values have ranged from 8 to 12 million. These are in vivo procedures.

discrepancy between these values arises from the fact that the NRC value only represents those institutions that are not covered by agreement state regulations. Since many items require that the agreement states impose regulations that are compatible with those of the NRC to be in compliance, the regulation is passed on to indirect users as well. So while only 2,600,000 responses are directly due to this NRC regulation, close to an additional three times that number are indirectly required due to the compatibility issue. As the number of agreement states rise, this ratio will become even larger, giving the appearance that there is less regulation by the NRC, when in fact it is either the same or increasing.

The value of 0.00416 hours corresponds to slightly less than fifteen seconds. This value is obviously in error in that it takes significantly longer to type or print out a label, check for its legibility, peel it from its protective backing, and affix it to the syringe or shield. Performing this activity in such a short period of time would lead to an increase in mislabeling and subsequent misadministrations. A more accurate estimate of the required time to perform this correctly would be at least five times the value listed in the request for OMB review. Observing an experienced technologist in one of our computerized radiopharmacies, the time spent in record keeping was 75 seconds per dose. Using the above values, the total annual licensee burden would be 208,333 hours at a minimum rather than the 10,816 hours as submitted by the NRC.

Using the NRC estimated cost of \$123.00⁴ per hour (including salaries and overhead), the annual cost to comply with this regulation alone is approximately \$25,625,000 rather than the NRC submitted cost of \$1,330,368, a difference of \$24,294,632.

Section 35.61(b)

This section requires that the vials that radiopharmaceuticals are drawn from also be labeled. Again since this is required for NRC compatibility, this regulation must be adhered to whether the licensee is under state or NRC supervision. We can apply the same correction factor as used above for radiopharmaceutical doses and state that approximately 2,310,000⁵ vials or radiopharmaceuticals require labeling. Using 75 seconds as the time required to create a label by an experienced technologist in a computerized radiopharmacy, the time necessary for compliance is approximately 48,125 hours. At a cost of \$123.00 per

⁴ OMB request for review, pg. 16

⁵ This value is generated by using the NRC values of total number of doses (2,600,000 syringes that need labeling) and their total number of vials that need labeling (600,000). This means that there are approximately 4.33 patient doses drawn per vial. Using the value obtained from the SNM approximation of the total number of patient doses (10,000,000) we can calculate that there are approximately 2,309,468 vials (10,000,000/4.33) that are used by agreement and NRC states together.

hour this amounts to \$5,919,375.00 which is again significantly higher than the NRC estimate of \$307,008*, a difference of \$5,612,367.

Section 35.22(a)(4) and (5)

This section requires that a radiation safety committee exist and consist of at least three members. Additionally, there must be at least one authorized user of each type of use permitted by the license present. The committee must also meet at least quarterly. The average radiation safety meeting is approximately an hour in length. Thus, there is a minimum of 12 hours per year per licensee. This too, is required by the state for compatibility with NRC regulations so that users in agreement states, as well as those directly regulated by the NRC, are affected by this rule. Given that there are approximately 1,900 NRC supervised licensees and 4,000 agreement state licensees (Total 5,900), this places a total burden of at least 70,800 hours upon the regulated community at a cost of approximately \$8,708,400. This value is higher than the \$1,476,000 as stated by the NRC in the record keeping requirements of the request for OMB review.

Section 35.32

This section contains the requirements for a quality management (QM) program. This recent addition to 10 CFR 35 is duplicative in nature since a quality management program is already required by the Joint Commission on Accreditation of Health Care Organizations (JCAHO). Not only does the JCAHO require a quality management program, it requires a quality improvement program. Therefore, this section is not only duplicative, but it falls short of the requirements made by another organization whose sole function is to ensure the proper health care of patients.

The vague wording of the regulation makes it essential that the QM program contain much more detailed information and documentation than even these professional organizations require.

The JCAHO consists of health care specialists who understand the aspects of quality management and improvement. These trained professionals are well aware of the pitfalls of the practice of medicine and know how to expose potential problems. The NRC cannot hope to attain their level of expertise in the inspection of quality management programs simply by creating broad regulations to that effect.

Physicians who desire an even greater level of quality assurance use the practice certification program of the American College of Nuclear Physicians. This program is significantly more detailed and thorough than either the NRC or JCAHO programs.

* This value is taken from the NRC Request for OMB review, Page 20, line 2

This section carries a significant economic impact on medical care. Even assuming that currently existing quality management and quality improvement mechanisms can be modified to fit the broad requirements of the NRC regulations, it would require a minimum of two people, one week to update the procedure manuals at a cost of 60 hours for the first year. Using the NRC rate of \$123.00 per hour including salaries and overhead, this amounts to \$9,840 per institution. This amounts to a staggering \$58,056,000 for the first year just to comply with a single aspect of the QM regulation. The procedure manual will need yearly revisions to ensure that it is complete. To comply with the record maintenance and audit as well as revising and updating procedures will take two people approximately three days to revise and update at a cost of 48 hours and 5,904 per institution. Nationwide this has an impact of \$34,833,600 per year. This expense offers no additional safety to the public since more effective safety and quality assurance mechanisms are already in existence.

Section 35.70 (a); 35.70 (b) is documentation portion

This section requires that "a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered." Although this rule may appear reasonable, we feel it is not, because technologists and physicians monitor areas in which they have worked, generally just before leaving the area, if there is any chance of a spill. The individual handling the radioactive material knows just where to monitor, and doesn't waste time monitoring areas where spills would not have occurred. Monitoring at the end of the day is redundant and not justifiable from a health physics point of view.

Let us imagine a situation in which a spill is "missed" and never found. As Tc-99m is used in 80% of diagnostic procedures at least, and the highest doses used are Tc-99m (1 to 30 mCi doses), let us assume a 1 mCi drop is inadvertently spilled, not noticed, and stays there irradiating whomever comes by. Let us assume that a technologist is exposed to this spot for 3 hrs. per day at an average distance of 1 meter until total decay of the spill. This would result in a total dose of 86 microrem effective dose equivalent. As everyone receives about 1000 microrem a day from background, and 2000 - 2500 microrem a day in high background areas, this is not significant.

It takes about 1/2 hour to perform a complete survey and document it on average. Assuming an average of 6 surveys per week per licensee, and 5900 licensees, this comes to (3 hrs/wk) (52 weeks/yr.) (5900) = 920,400 hours/year. At a cost of \$123/hr, that comes to \$113,209,200/year, not even counting the User Fees we have to pay the NRC to check for 312 entries per licensee. Let us say it takes 1/2 hour to check 312 entries. That is 5900 (0.5) (\$123) = \$362,850. The total cost for no significant decrease in radiation risk, is therefore \$113,572,050. The NRC document to OMB stated the cost of complying with the paperwork portion of this requirement is listed as only \$18,696,000, a difference of 94,876,050.

ATTACHMENT D

The total cost for the above five regulations only, is approximately \$212,000,000, illustrating an NRC underestimate of \$141,000,000. This represents \$21.20 of added charge to every patient's bill simply for the purpose of compliance with NRC and agreement state rules. The QM rule alone represents \$5.80 of this added charge with no demonstrated benefit to the general public.

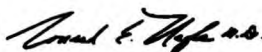
Conclusion:

In summary, there are many areas of the request for OMB review that are incorrect or misleading. Uniformly, all errors are one of underestimation of time, effort, and cost needed for compliance. The impact of level one compliance through agreement states on the regulated community is concealed in the request. The only possible explanation for this blatant oversight is to seemingly minimize the amount of regulation that is already in force.

The most recently added sections include regulations that are duplicative and add no significant benefit to the patient care or safety of the general public. The quality practice of medicine area is clearly outside the expertise of the NRC. ACNP/SNM feels that the regulations in place already are adequate and that additional regulations will only additionally burden the health care system with no additional safety benefits.

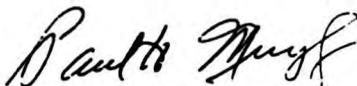
In this era of spiraling health care costs, it is imperative that rampant regulation without a demonstrated benefit be discouraged. Many of the aspects of 10 CFR 35 simply add to the regulatory burden without a demonstrated improvement in the protection of the public health and safety. It is time for the Office of Management and Budget to reassess completely the impact of 10 CFR 35 on the regulated medical community.

ACNP and SNM appreciate the opportunity to provide comments on the Request for OMB Review of 10 CFR 35. If you have any questions regarding our comments, please contact Kristen Morris, Director of Government Relations, in our Washington Office at (202) 429-5120.



Conrad E. Nagle, M.D.
President
American College of Nuclear Physicians

Sincerely



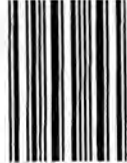
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Society of Nuclear Medicine

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