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CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT OF 1979

GOVERNMENT

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CUMENTS

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HEARING

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BEFORE THE

SUBCOMMITTEE ON

HEALTH AND THE ENVIRONMENT

OF THE

COMMITTEE ON

INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

NINETY-SIXTH CONGRESS

SECOND SESSION

ON

H.R. 6057

(and all similar bills)

A BILL TO PROVIDE FOR THE PROTECTION OF THE PUBLIC
HEALTH AND SAFETY FROM UNNECESSARY EXPOSURE TO
RADIATION

SEPTEMBER 5, 1980

Serial No. 96-210



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CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT OF 1979

FRIDAY, SEPTEMBER 5, 1980

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2322, Rayburn House Office Building, Hon. Henry A. Waxman, chairman, presiding.

Mr. WAXMAN. The committee will come to order.

Today the Subcommittee on Health and the Environment is holding a hearing on the Consumer-Patient Radiation Health and Safety Act of 1979, H.R. 6057, and all similar and identical bills.

The recognition of the hazards posed by low-level radiation has increased dramatically in the last few years. The hearings held by Senator Kennedy and Congressman Eckhardt on fallout from the nuclear testing, those held by Senator Randolph and Congressman Eckhardt on exposure to X-rays, the incident at Three Mile Island, and the mammography study at NIH have served to heighten public awareness of this issue.

When what might be called the nuclear age began, most saw only the tremendous benefits of harnessing nuclear energy to serve man. Now we find that the legacy of that technological advancement may be the contamination of an entire planet.

Nuclear energy is not alone in this. We have often found technologic advances to be mixed blessings. Though powerplants and other types of technology should not necessarily be abandoned, I firmly believe that we must be completely committed to minimizing the public risk of radiation exposure from these and other sources.

This means that where it is within our power to reduce human exposure to radiation, we must exercise our responsibility to do so.

Radiation for diagnostic and treatment purposes is one area in which exposure is basically voluntary and controllable. The proponents of this legislation argue that a realistic first step would be to insure adequate training of those who participate in radiologic procedures.

The witnesses we will hear from today will hopefully educate us to the need for this bill, if any, and what other measures we, as guardians of the public health and safety, should consider.

I would like to now call on our colleague, the ranking Republican member of the subcommittee, Dr. Tim Lee Carter.

After him, I want to hear from the author of the legislation.

Mr. CARTER. Mr. Chairman, today we are considering the Consumer-Patient Radiation Health and Safety Act, H.R. 6057 and similar bills.

Recognition of the hazards posed by low-level radiation has increased dramatically in the past few years.

The hearings held last year by Senator Kennedy and Congressman Eckhardt on fallout from the nuclear testing, and those held by Congressman Paul Rogers of this subcommittee some 2 years ago, prove without question the dangers of radiation, particularly nuclear radiation, from our Government's atomic testing program.

As the distinguished chairman has said, this presents a danger to the entire world. If we follow the history of our nuclear testing in the West, in Nevada and Utah, we find that first, the tests were held above the ground and later, as the danger from these tests became apparent, they were held underground.

There were many cases of leukemia, lymphoma, and Hodgkins disease related to this nuclear fallout, and some of these cases—although it is not admitted by many—have been service connected because of the radiation which the men received at those sites.

I think as the distinguished chairman has said—we must be extremely careful in our use of X-rays. They certainly are extremely helpful as a diagnostic and therapeutic aid, yet no one knows the level at which mutations may occur which may indicate the start of the cancerous process.

So I think there is widespread agreement that exposure to X-rays should be held to a minimum, and utmost care should be taken in protecting the bodies of those are X-rayed. In many States, including Kentucky, much of this is being carried out at the present time, there are other States where regulation in this area is needed.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Dr. Carter.

We are pleased to recognize at this time our colleague, a member of this subcommittee, the distinguished Representative from Ohio who has taken the leadership in proposing this legislation and in asking us to move forward in this very important area.

Congressman Luken.

Mr. LUKEN. Thank you, Mr. Chairman. These are very busy days here on the Hill and I think the chairman should be congratulated for his diligence and unending patience in conducting hearings on many measures in these waning days of this session of Congress.

It is understandable that some of our colleagues who are intensely interested in this subject and in this legislation are unable to be here at this particular point in time.

Mr. Eckhardt, for example, who has been a leader in the railroad legislation which is unexpectedly on the floor of the Congress this morning, will be unable to be here right at the moment, but yet he is, as I understand it, a proponent of legislation of this kind.

I think he ranks as an expert in the Congress from his extensive experience in the oversight committee and the various other subcommittees of the Commerce Committee.

I have been honored to have introduced this legislation.

We have not made any great attempt to get a lot of cosponsors as yet, so I think the cosponsorship is rather limited for that reason,

out I think there would be many Members of the House who would be anxious to consider legislation of this kind.

It has already been described in general terms. The purpose is to reduce unnecessary patient exposure to radiation by requiring that operators of medical and dental X-ray equipment be properly trained and certified. That is the goal of the legislation.

It is important to note that while existing laws regulate the quality of X-ray equipment, the patient's health and safety is jeopardized when untrained personnel operate the machinery.

Today we are faced with increasing evidence of the link between radiation exposure and cancer and are compelled to seek ways to limit unnecessary exposure.

Despite these risks from overuse or misuse of X-rays, only 11 States have moved to place restrictions on who may operate radiation equipment.

The need to encourage States to develop credentialing programs is demonstrated by many disturbing facts.

Approximately 90 percent of the man-made radiation to which the general public is exposed, including radiation from nuclear power plants, is a result of medical and dental X-rays.

The Bureau of Radiologic Health estimates that 30 percent of the diagnostic X-rays may be unnecessary, a significant portion of which result from poor operator technique. That is what we are looking toward.

The June 1979 report of the Interagency Task Force on the Health Effects of Ionizing Radiation found that the improper use and maintenance of equipment may result in radiation exposures to patients that are unnecessarily high or that result in film unsuitable for diagnostic purposes.

The FDA's nationwide evaluation of X-ray trends program demonstrated that a patient undergoing the same X-ray examination may receive more than 100 times as much radiation in one hospital or clinic as in another.

I have offered these as facts. Of course, these hearings will be the proving grounds as to whether these are facts.

I think the subcommittee is certainly open. The purpose of the legislation is to examine these positions which I believe to be accurate, which many members of the subcommittee and the Congress who have testified believe to be accurate.

They would be the basis of a bill which seeks to assist the States in establishing accrediting and licensing programs while protecting the safety of the public which is now, unfortunately, being neglected.

Mr. Chairman, with that I think we can proceed with the hearing.

Thank you.

Mr. WAXMAN. Thank you very much for the statement.

Without objection the text of H.R. 6067 and agency reports thereon will be printed at this point in the record. Additional bills that will be considered in whole or in part during the hearing are as follows: H.R. 5934, introduced by Mr. Lent on November 16, 1979, and cosponsored on March 4, 1980, by Mr. Luken and Mr. Lundine, and May 22, 1980, by Mr. Lee and Mr. Mitchell of Maryland; and H.R. 6023, introduced by Mr. Lundine on December 4, 1979.

[Testimony resumes on p. 25.]

[The text of H.R. 6057 and agency reports thereon follow:]

[H.R. 6057, introduced by Mr. Luken on December 6, 1979,

Cosponsored on April 1, 1980, by:

Mr. Lent, Mr. Lundine, Mr. Scheuer, Mr. Ottinger, Mr. Corcoran, Mr. Glickman,
Mr. Corrada, Mr. Maguire, Mr. Mitchell of Maryland, Mr. Heftel, Mr. Grisham,
and Mr. Downey;

Cosponsored on July 2, 1980, by:

Mr. Lee.

are as follow:]

A BILL

To provide for the protection of the public health and safety
from unnecessary exposure to radiation.

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

3 SHORT TITLE

4 SEC. 101. This Act may be cited as the "Consumer-
5 Patient Radiation Health and Safety Act of 1979".

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PART I—GENERAL PROVISIONS

FINDINGS

SEC. 102. The Congress finds that—

(a) it is in the interest of public health and safety to minimize unnecessary consumer-patient exposure to potentially hazardous radiation;

(b) it is in the interest of public health and safety to assure efficacious radiologic procedures;

(c) it is in the interest of public health and safety to have a continuing supply of adequately educated and credentialed persons who administer radiologic procedures pursuant to accreditation and certification programs administered by State governments in accord-

1 ance with standards promulgated by the Federal Gov-
2 ernment;

3 (d) the protection of the public health and safety
4 from unnecessary consumer-patient exposure to poten-
5 tially hazardous radiation and assurance of efficacious
6 procedures is the joint responsibility of State and Fed-
7 eral governments; and

8 (e) persons who administer radiologic procedures,
9 including procedures at Federal facilities, should be re-
10 quired to demonstrate competence by reason of educa-
11 tion, experience, and examination.

12 STATEMENT OF PURPOSES

13 SEC. 103. The purposes of this Act are to—

14 (a) provide for the establishment and promulgation
15 of standards by the Federal Government for accredita-
16 tion of educational programs for persons who adminis-
17 ter radiologic procedures;

18 (b) provide for the promulgation of standards by
19 the Federal Government for certification of persons
20 who administer radiologic procedures to consumer-pa-
21 tients;

22 (c) insure that all activities conducted or funded
23 by Federal agencies are consistent with the purposes of
24 this Act; and

- 1 (d) encourage State administration of programs for
2 the accreditation of educational programs for persons
3 who administer radiologic procedures and for the certi-
4 fication of those persons.

5 DEFINITIONS

6 SEC. 104. Unless otherwise expressly provided, for the
7 purposes of this Act, the term—

8 (1) “radiation” means ionizing and nonionizing ra-
9 diation, in amounts beyond normal background levels,
10 from such sources as medical and dental radiologic pro-
11 cedures;

12 (2) “radiologic procedure” means any medical or
13 dental procedure intended for use in the diagnosis of
14 disease or other medical or dental conditions (including
15 diagnostic X-rays), or in the cure, mitigation, treat-
16 ment, or prevention of disease in humans which
17 achieves its intended purpose through the emission of
18 radiation;

19 (3) “medical practitioner” means any licensable
20 doctor of medicine, osteopathy, chiroprody, or chiro-
21 practic, who prescribes radiologic procedures to con-
22 sumer-patients;

23 (4) “dental practitioner” means any licensable
24 doctor of dentistry, who prescribes radiologic proce-
25 dures to consumer-patients;

1 (5) "persons who administer radiologic proce-
2 dures" means any person, other than a medical or den-
3 tal practitioner, who administers radiation to consumer-
4 patients and includes medical radiologic technologists
5 (including radiographers), dental auxiliaries (including
6 dental hygienists and assistants), radiation therapy
7 technologists, and nuclear medicine technologists;

8 (6) "Secretary" means the Secretary of Health,
9 Education, and Welfare; and

10 (7) "consumer-patient" means any person who is
11 subject to exposure to radiation from radiologic proce-
12 dures.

13 PART II—FEDERAL STANDARDS

14 RADIATION PROTECTION STANDARDS FOR ACCREDITATION

15 SEC. 121. (a) Within twelve months of enactment, the
16 Secretary shall by regulation promulgate radiation protection
17 standards for the accreditation of educational programs con-
18 ducted by institutions for persons who administer radiologic
19 procedures. Such standards shall distinguish between pro-
20 grams for the education of (1) medical radiologic technolo-
21 gists (including radiographers), (2) dental auxiliaries (includ-
22 ing dental hygienists and assistants), (3) radiation therapy
23 technologists, and (4) nuclear medicine technologists. Such
24 standards shall not be applicable to medical or dental practi-
25 tioners. Such standards shall include minimum accreditation

1 criteria for institutions in areas of administrative policies and
2 procedures, curricula, recordkeeping, faculty, administrative
3 support, and such other criteria as the Secretary shall deem
4 necessary for the adequate education of persons who adminis-
5 ter radiologic procedures.

6 (b) The Secretary shall review and, when appropriate,
7 revise the standards promulgated by him pursuant to this
8 section.

9 (c) Regulations under this section promulgating accredi-
10 tation standards shall include procedures whereby the Secre-
11 tary shall, upon application to him, evaluate and approve as
12 meeting the standards or disapprove existing activities for
13 accreditation of educational programs for any type of persons
14 who administer radiologic procedures as such activities are
15 conducted or planned to be conducted by any private, non-
16 profit, autonomous accrediting organization.

17 (d) The Secretary shall review, and when appropriate,
18 continue or withdraw his approval of any private, nonprofit,
19 autonomous accrediting organization where such approval
20 has been conferred under this section.

21 RADIATION PROTECTION STANDARDS FOR CERTIFICATION

22 SEC. 122. (a) Within twelve months of enactment, the
23 Secretary shall by regulation promulgate radiation protection
24 standards for the certification of persons who administer ra-
25 diologic procedures. Such standards shall distinguish between

1 certification of (1) medical radiologic technologists (including
2 radiographers), (2) dental auxiliaries (including dental hygien-
3 ists and assistants), (3) radiation therapy technologists (in-
4 cluding radiographers), and nuclear medicine technologists.
5 Such standards shall not apply to medical or dental practi-
6 tioners. Such standards shall include minimum certification
7 criteria for individuals in areas of accredited education, prac-
8 tical experience, successful examination, and such other cri-
9 teria as the Secretary shall deem necessary for the adequate
10 qualification of persons who administer radiologic procedures.

11 (b) The Secretary shall review and, when appropriate,
12 revise the standards promulgated by him pursuant to this
13 section.

14 (c) Regulations under this section promulgating certifi-
15 cation standards shall include procedures whereby the Secre-
16 tary shall, upon application to him, evaluate and approve as
17 meeting the standards or disapprove existing activities for
18 certification of any type of persons who administer radiologic
19 procedures as such activities are conducted or planned to be
20 conducted by any private, nonprofit, autonomous certifying
21 organization.

22 (d) The Secretary shall review and, when appropriate,
23 continue or withdraw his approval of any private, nonprofit,
24 autonomous certifying organizaton where such approval has
25 been conferred under this section.

1 PART III—FEDERAL ACTIVITIES AND GRANTS

2 FEDERAL AGENCY COMPLIANCE

3 SEC. 131. Each department, agency, and instrumentali-
4 ty of the executive branch of the Federal Government shall
5 comply with any minimum standards promulgated pursuant
6 to this Act.

7 FEDERAL ASSISTANCE PROGRAMS

8 SEC. 132. (a) In order to carry out the purposes of this
9 Act, three years after the date of its enactment each Federal
10 agency which is authorized to extend Federal grants, loans,
11 contracts, or other forms of financial assistance or reimburse-
12 ment for services or equipment used in whole or in part for
13 radiologic procedures shall provide such financial assistance
14 or reimbursement only in States that are administering ac-
15 creditation and certification programs at least as stringent as
16 Federal standards promulgated pursuant to part II.

17 (b) The Secretary may by regulation exempt any specif-
18 ic grant, loan, contract, or other form of financial assistance
19 or reimbursement from the requirements of this section if he
20 determines such exemption does not unreasonably risk public
21 health and safety.

22 STATE ASSISTANCE

23 SEC. 133. The Secretary shall provide the States such
24 advice and assistance as will foster adoption and administra-
25 tion of programs to achieve the purposes of this Act. Such

1 advice and assistance shall include, but shall not be limited
2 to, the preparation of a model law for consumer-patient radi-
3 ation safety. Such model law shall provide that—

4 (a) it shall be unlawful in the State for individuals
5 to expose consumer-patients to radiation from radio-
6 logic procedures unless they are persons who adminis-
7 ter radiologic procedures, other than medical or dental
8 practitioners, certified as meeting the criteria of section
9 122 of this Act as administered by the State or under
10 delegation of authority to an organization approved by
11 the Secretary pursuant to subsection (c) of that section;
12 and

13 (b) any educational requirements for certification
14 of persons who administer radiologic procedures, other
15 than medical or dental practitioners, shall be limited to
16 those received in educational programs meeting the cri-
17 teria of section 121 of this Act as administered by the
18 State or under delegation of authority to an organiza-
19 tion approved by the Secretary pursuant to subsection
20 (c) of that section.

21 GRANTS TO EDUCATIONAL INSTITUTIONS

22 SEC. 134. The Secretary may, under title VII of the
23 Public Health Service Act, make grants to institutions which
24 conduct educational programs, meeting criteria established
25 by section 121, to carry out the purposes of this Act.

1 GRANTS TO ACCREDITATION OR CERTIFICATION

2 SEC. 135. The Secretary may make grants to private,
3 nonprofit, autonomous organizations approved pursuant to
4 subsection (c) of section 121 or subsection (c) of section 122
5 in amounts up to 50 per centum of the costs of the planning,
6 development, institution, and operation of accreditation or
7 certification activities which the Secretary determines are
8 consistent with the purposes of this Act.

9 GRANTS TO STATES

10 SEC. 136. The Secretary may make grants to States in
11 amounts up to 50 per centum of the costs of the planning,
12 development, institution, and operation of accreditation or
13 certification activities which the Secretary determines are
14 consistent with the purposes of this Act. Such grants shall
15 provide for administering the accreditation of educational
16 programs (either by the State or under delegation of authori-
17 ty to an organization approved pursuant to subsection (c) of
18 section 121) or for administering the certification of individ-
19 uals (either by the State or under delegation of authority to
20 an organization approved pursuant to subsection (c) of section
21 122) where the radiation protection standards used are those
22 promulgated by the Secretary pursuant to part II.

1 PART IV—ADMINISTRATION

2 ADMINISTRATIVE PROCEDURES

3 SEC. 141. Standards prescribed under this Act shall be
4 promulgated by regulation in accordance with the procedures
5 set forth in section 553 of title 5, United States Code.

6 CONSULTATION

7 SEC. 142. In promulgation of radiation protection stand-
8 ards under this Act the Secretary shall consult with the En-
9 vironmental Protection Agency and with appropriate agen-
10 cies of the States.

11 PART V—APPROPRIATIONS

12 AUTHORIZATION OF APPROPRIATIONS

13 SEC. 151. There is authorized to be appropriated to the
14 Secretary such sums as necessary to carry out the purposes
15 of this Act.

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D. C. 20201

The Honorable Harley O. Staggers
Chairman, Committee on Interstate
and Foreign Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your request for reports on H.R. 5934, a bill "To provide for the protection of the public health (including consumer patients) from unnecessary exposure to radiation", and H.R. 6057, a bill "To provide for the protection of the public health and safety from unnecessary exposure to radiation."

In summary, we support the purposes of the bills: to assist in the development of State standards for licensure of radiologic technologists and accreditation of educational programs for radiological technologists. However, we oppose enactment of H.R. 5934 and H.R. 6057, because there is already sufficient authority for these activities under current law.

Part II of H.R. 5934 would require the Secretary of this Department, in consultation with other Federal agencies, to promulgate: (1) "Federal radiation guidance" with respect to consumer-patient radiation matters affecting public health; (2) "guidelines" regarding medical and dental radiation exposure of patients; and (3) "criteria and guidelines" for the application to consumer-patients of diagnostic x-rays, therapeutic radiation, and radiation in the treatment of disease. Part III of H.R. 5934 would require the Secretary to establish voluntary minimum standards for accreditation of radiological service educational institutions, and licensure of radiologic technologists. Part III would also authorize the Secretary to provide technical assistance to States to implement the voluntary standards, and to make grants to educational institutions, certification organizations, and State public health radiation programs which comply with the Act. Part IV would require the President, by Executive Order, to require each Federal agency authorized to extend any form of financial assistance or reimbursement to "effectuate the purposes" of the bill, including adoption of the minimum standards required to be promulgated.

Part II of H.R. 6057 would require the Secretary to promulgate Federal standards for accreditation of educational programs for persons who administer radiologic procedures, and for certification of persons who administer radiologic procedures to consumer-patients. Effective three years after enactment of H.R. 6057, part III of the bill would prohibit Federal financial assistance for services or equipment used for radiologic procedures in States that were not administering accreditation and certification programs at least as stringent as the Federal standards promulgated under Part II. Part III would also authorize the Secretary to make grants to educational institutions, nonprofit organizations, and States for accreditation, certification, and other activities consistent with the purposes of the bill and the radiation protection standards promulgated under Part II.

There is already sufficient authority under current law to carry out the activities provided for in H.R. 5934 and H.R. 6057. The Secretary has authority, under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act, to regulate radiation-emitting electronic products and medical devices. Pursuant to these authorities, the Department has been directing considerable resources to the education of both consumers and the medical profession in the safe and effective use of electronic products and medical devices, and to the development of voluntary standards for medical radiation personnel.

The issue of licensing of radiologic personnel was examined by the Interagency Task Force on the Health Effects of Ionizing Radiation, which was established in response to a May 1978 White House directive. The Task Force was chaired by HEW and included representatives from the Departments of Defense, Energy, and Labor, the Veterans' Administration, the Nuclear Regulatory Commission, and EPA. The final report of the Task Force, published in June 1979, recommended measures to be undertaken in cooperation with professional groups to improve the availability, training, and credentialing of personnel who administer radiation-related procedures.

In February 1979, concurrent with the issuance of preliminary findings by the Task Force, the Secretary directed the Food and Drug Administration (FDA) to "expand and expedite its current program for setting specific guidelines for the use of common x-ray procedures and specific guidelines for the education, certification, and testing of x-ray, nuclear medicine, and radiation therapy technicians." Pursuant to the Secretary's directive, the FDA on March 13, 1979, published in the Federal Register (44 FR 14637) a notice of intent to develop voluntary national standards for medical

radiation personnel. The activity, like the establishment of other guidance affecting radiation utilization such as gonad shielding and x-rays during pregnancy, will rely on extensive consultation and cooperative work with State radiation control agencies and professional organizations. To date FDA has received more than 600 responses to the notice of intent. A final analysis of these comments will be completed in the near future.

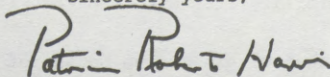
The Task Force Report also suggested creation of an inter-agency council on radiation protection to be chaired by EPA. On February 21, 1980, in response to this recommendation, the President established by Executive Order the Radiation Policy Council, to be chaired by EPA. The Council will advise on broad radiation policy, monitor implementation of Federal radiation protection policies by Federal agencies, resolve problems of jurisdiction among Federal agencies, recommend legislation, insure effective liaison with the States and Congress, and provide a forum for public comment.

We also oppose as unnecessary the provisions of these bills which would condition Federal financial assistance on compliance with the standards promulgated under the bills. Adoption of minimum standards on these radiation matters, where appropriate, can be accomplished administratively without legislative change.

For the foregoing reasons, we recommend that the bills not be favorably considered.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely yours,



Patricia Roberts Harris



GENERAL COUNSEL OF THE DEPARTMENT OF DEFENSE

WASHINGTON, D.C. 20301

18 July 1980

Honorable Harley O. Staggers
 Chairman, Committee on Interstate
 and Foreign Commerce
 House of Representatives
 Washington, D.C. 20515

Dear Mr. Chairman:

Reference is made to your request for the views of the Department of Defense on H.R. 6057, 96th Congress, a bill "To provide for the protection of the public health and safety from unnecessary exposure to radiation."

The bill provides for the establishment and promulgation of standards by the Federal Government for accreditation of educational programs for persons who administer radiologic procedures; provides for the promulgation of standards by the Federal Government for certification of persons who administer radiologic procedures to consumer-patients; insures that all activities conducted or funded by Federal agencies are consistent with the purposes of the bill; and encourages State administration of programs for the accreditation of educational programs for persons who administer radiologic procedures and for the certification of these persons. The bill proceeds on the assumption that safety responsibility lies with the Federal and State governments.

H.R. 6057 mandates that within twelve months of enactment, the Secretary of the Department of Health and Human Services issue radiation protection standards for the accreditation of educational programs for persons who will administer radiologic procedures. The standards shall not be applicable to medical or dental practitioners as defined in the bill. The Secretary of the Department of Health and Human Services shall also in the same time frame develop and issue radiation protection standards for the certification of persons who administer radiologic procedures. All Federal Government executive branch agencies must comply with the standards that are issued by the Secretary of the Department of Health and Human Services as a result of

this legislation. Three years after enactment, any Federal agency which extends financial assistance for equipment or services pertaining to radiologic procedures will provide assistance only in States that are administering accreditation and certification programs at least as stringent as the Federal standards promulgated by the Secretary of Health and Human Services. The Secretary of the Department of Health and Human Services may grant exemption to a specific grant, or other forms of financial assistance if it will not endanger unreasonably public health and safety. The Secretary of the Department of Health and Human Services shall provide help and guidance to the states to foster initiation and operation of programs to achieve the health and safety provisions of the bill. This assistance shall include the development of a model law for consumer-patient radiation safety. The Secretary of the Department of Health and Human Services under this legislation is authorized to make grants to institutions which conduct educational programs that meet the requirements of this bill, and make grants up to 50 percentum of the costs to organizations approved to operate accreditation or certification activities which are consistent with the purposes of this bill.

Since the standards requirements of the bill remain to be established by the Department of Health and Human Services, the Military Departments may be called upon to meet standards which are inconsistent with operational military requirements. Accordingly, we recommend that, if H.R. 6057 is favorably considered, a provision be made in the bill whereby the Secretary of Defense may waive the standards in the event of a national emergency or military necessity.

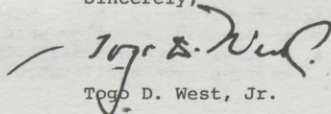
The Department of Defense supports the principles expressed in this legislation; however, we defer final comments on the merits of this legislative proposal to the Department of Health and Human Services.

Cost and Budget Data

Department of Defense costs or savings cannot be determined from the bill as drafted.

The Office of Management and Budget advises that, from the standpoint of the Administration's program, there is no objection to the presentation of this report for the consideration of the Committee.

Sincerely,



Togo D. West, Jr.



GENERAL COUNSEL OF THE DEPARTMENT OF DEFENSE

WASHINGTON, D.C. 20301

28 JUL 1980

Honorable Harley O. Staggers
 Chairman, Committee on Interstate
 and Foreign Commerce
 House of Representatives
 Washington, D.C. 20515

Dear Mr. Chairman:

Reference is made to your request for the views of the Department of Defense on H.R. 5934, 96th Congress, a bill "To provide for the protection of the public health (including consumer patients) from unnecessary exposure to radiation."

The bill proposes measures to protect the American public against needless overexposure to radiation in the health setting. The bill's provisions are based on the recommendations of several private and Federal committees and task forces which have addressed the subject of exposure to diagnostic and therapeutic radiation. The bill proceeds on the assumption that safety responsibility lies with the Federal and state governments.

H.R. 5934 would mandate credentialling and licensure of all providers, accreditation of provider training programs, a common Federal approach to radiation protection programs, standards and criteria applicable to all Federal agencies, and encouragement of state activity. The bill goes on to define the terms used in the text, assign responsibility, establish deadlines, establish program review and provide the funding of the program. The bill provides for consultation with and appropriate delegation of authority to private professional organizations.

The bill addresses a serious problem. The Department of Defense supports the principles expressed in this legislation; however, we defer comments on the merits of this legislative proposal to the Department of Health and Human Services.

Since the standards requirements of the bill are not spelled out, the Military Departments may be called upon to meet standards which are inconsistent with operational military requirements in times of national emergency or mobilization. Accordingly, we

recommend that, if H.R. 5934 is favorably considered, a provision be made in the bill whereby the Secretary of Defense may waive the standards if necessary to meet military requirements.

Recently, an Executive Order created a Radiation Policy Council. The bill's language should reflect and take into account the mission and functions of that new body.

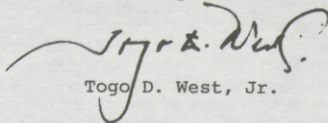
Cost and Budget Data

Department costs and savings cannot be determined from the bill as drafted.

Depending on the nature of the standards, this bill has the potential for imposing large and far-reaching delivery and educational costs upon the military medical departments, perhaps to the point of interfering with the delivery of medical radiological services.

The Office of Management and Budget advises that, from the standpoint of the Administration's program, there is no objection to the presentation of this report for the consideration of the Committee.

Sincerely,

A handwritten signature in dark ink, appearing to read "Togo D. West, Jr.", with a stylized, flowing script.

Togo D. West, Jr.



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

February 7, 1980

The Honorable Harley O. Staggers, Chairman
Committee on Interstate and Foreign Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This letter responds to your request for the Nuclear Regulatory Commission's views on H.R. 5934, the "Consumer-Patient Radiation Health and Safety Act of 1979." The NRC endorses the aim of this legislation to minimize exposure of consumer-patients to potentially hazardous radiation, but we believe the bill, as drafted, contains serious weaknesses.

For example, Section 102(e) states a finding that "the protection of public health and safety from unnecessary consumer-patient exposure to potentially hazardous radiation from all sources is the primary responsibility of State and local government...." We note that the Atomic Energy Act has vested in the Nuclear Regulatory Commission, rather than State or local governments, the primary responsibility for regulating the use of radioactive byproduct materials, which are a major source of radiation for medical purposes. In a recent policy statement the NRC stated its intention to "continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public." 44 Fed. Reg. 8242 (February 9, 1979). This regulatory position was not questioned by any of the commenters on the draft policy statement but rather was consistently recognized as a necessary role in the medical uses of radioisotopes. Consequently, we would not support legislation that does not recognize NRC's regulatory role in this regard.

As another significant alteration of present regulatory responsibilities, Section 121(d) of H.R. 5934 would transfer from the Environmental Protection Agency to the Secretary of Health, Education and Welfare the authority to develop Federal radiation guidance with respect to all radiation matters directly or indirectly affecting health, including formulation of environmental radiation standards. This transfer of authority is not limited to matters of consumer-patient radiation therapy hazards and goes well beyond the needs addressed by the bill. It would contradict recommendations for a reconstitution of a Federal Council on radiation similar to the previous Federal Radiation Council made in recent congressional evaluations and by the Federal Task Force on the Health Effects of Ionizing Radiation ("Libassi Report"). Such a change would fragment the Federal program to regulate the hazards of ionizing radiation.

Turning to matters of detail in H.R. 5934, we have the following comments:

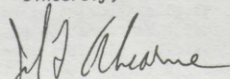
1. Section 131(a) requires the Secretary to promulgate voluntary minimum standards for the accreditation of educational institutions conducting education programs in radiologic services. Section 132(a) requires the Secretary to promulgate voluntary minimum standards for licensure of radiologic technologists. Section 141 makes compliance with all such standards mandatory on all Federal agencies. These standards are likely to substantially affect a large number of NRC licensees and many Federal agencies. Hence we believe it would be essential to include in any such bill a requirement that standards developed pursuant to Sections 131 or 132 shall be promulgated only after prior consultation and coordination with the Nuclear Regulatory Commission.
2. Section 104(5) defines "radiologic technologist," for purposes of the Act, as "any person, other than a medical or dental practitioner, who administers radiation to consumer-patients," and further enumerates several categories of radiologic technologists. Frequently in radiation therapy a radiation physicist acting on a prescription by a physician, directly supervises the administration of radiation to the patient by the radiation technologist, but does not himself administer it. Thus following the word "administers," the words "or directly supervises the administration of," should be inserted to provide for the qualification of such persons.
3. Section 121(b) enumerates categories of criteria and guidelines to be promulgated by the Secretary (HEW). Diagnostic nuclear medicine is not included. We believe that diagnostic nuclear medicine should be included under any such guidelines and that the categories in Section 121(b) should be changed to read as follows:
 - "(1) the application of diagnostic X-rays to consumer-patients;
 - "(2) the administration of radioactive drugs for diagnostic purposes to consumer-patients;
 - "(3) the therapeutic external application of beam radiation to consumer-patients for treatment of disease; and
 - "(4) the therapeutic internal application of radiation to consumer-patients for treatment of disease, such as therapeutic nuclear medicine applications."

Commissioners Gilinsky and Bradford have expressed the following separate views regarding H.R. 5934:

We endorse the objective of minimizing the exposure of consumer-patients to potentially hazardous radiation. While the Nuclear Regulatory Commission may be the appropriate agency to regulate the machinery and materials employed in nuclear medicine, it is not clear that it is the agency most competent to regulate the substance of the treatment or to license those administering such treatments. We endorse the comments made in the paragraphs numbered 1, 2, and 3, above.

For reasons discussed above and because of the many changes in detail which we believe are necessary before H.R. 5934 could be developed into a satisfactory piece of legislation, a majority of the Commission does not support the bill as currently drafted. Thank you for giving us the opportunity to comment.

Sincerely,



John F. Ahearne

Mr. WAXMAN. Later today we will hear from Congressman Lundine, one of the cosponsors of the Consumer-Patient Radiation Health and Safety Act, Congressman Eckhardt and Congressman Lent are unable to appear this morning but have asked that I enter their statements in the record.

Without objection, the Chair wishes to place in the record, as though read, the statements of Congressmen Bob Eckhardt of Texas, and Norman F. Lent of New York.

STATEMENT OF HON. BOB ECKHARDT, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. ECKHARDT. Mr. Chairman, members of the subcommittee, thank you for your invitation to appear before you today to present the findings of the Subcommittee on Oversight and Investigations in the area of unnecessary exposure to radiation from medical and dental X-rays and to comment on the proposed legislation which you are now considering. I must first say how important I believe it is that our oversight activities be coordinated with the legislative process within our committee. As that is the case today, so has it been in the past with our two subcommittees. After our oversight hearings into the dangers associated with certain infant formulas, legislation sponsored by two members of our subcommittee, Mr. Gore and Mr. Mottl, moved quickly through your subcommittee, the full Commerce Committee, and later through the House. I congratulate you, Mr. Chairman for the initiatives you have shown to make this possible. In the area we consider today, I commend the distinguished ranking minority member of our subcommittee, Mr. Lent, for sponsoring this legislation after thoughtfully considering the testimony which was presented at our oversight hearings last summer. I also commend Tom Luken of your health subcommittee and Stanley Lundine for their efforts.

As I mentioned, Mr. Chairman, the Subcommittee on Oversight and Investigations conducted hearings on the question of unnecessary exposure to radiation from medical and dental X-rays. We looked particularly at the issue of the qualifications and the education of those individuals who actually operate the X-ray machines. As you know, this is a technology which is capable of providing enormous benefits to mankind, particularly as a lifesaving tool in the diagnosis and treatment of disease, but, at the same time, possesses potential for serious harmful human health effects. Because medical and dental X-ray account for approximately 90 percent of our exposure to manmade sources of radiation we must take steps to insure that the device is used safely and only in the furtherance of good health.

Since its discovery some 84 years ago the use of X-rays in the healing arts has increased steadily over the years. The Food and Drug Administration found, and I am sure will describe to you in more detail, that in 1964, some 173 million radiologic examinations were performed of which 54 million were dental X-rays. By 1970, the total of X-ray exams performed had reached 212 million, a 23-percent increase. Assuming the same rate of increase we can expect nearly 300 million X-ray exams to be performed this year. Because of this increased emphasis on X-ray use in the healing arts, and in the light of our growing awareness of the dangers

associated with exposure to radiation, we must insure that exposure to X-ray radiation is limited to that which is medically necessary. The record is clear I believe that such is not the case today. Though there may be a difference of opinion as to the precise degree of unnecessary exposure to radiation from medical and dental X-ray, there is little disagreement that such overexposure exists.

Mr. Chairman, I commend our hearing record to you as you consider the various bills before you. Additionally, our subcommittee most recently issued a report on our investigation. It focuses primarily on the education and qualifications of X-ray operators and the impact of these factors on the unnecessary exposure to radiation.

In commenting on findings of that report, it is important that we not lose sight of the fact that an appropriately ordered and conducted diagnostic X-ray examination can be of substantial medical benefit to the patient and to society and such should not be discouraged. Our findings I believe, provide a foundation upon which your subcommittee can act legislatively:

One. Exposure to low level radiation from unnecessary or improperly performed medical and dental X-rays poses significant risk of adverse human health effects.

Two. Patients are exposed to excessive amounts of radiation from X-rays which are properly ordered but poorly performed by inadequately skilled or untrained operators.

Three. Minimum standards for licensure of radiologic personnel and for accreditation of educational programs would increase operator competence and decrease the likelihood of unnecessary radiation exposure.

Four. The Food and Drug Administration has been lax in exerting its current authority to encourage the establishment of such standards and lacks the statutory authority to require the establishment of minimum standards.

You will hear today that it is difficult to determine precisely the correlation between the poorly skilled or untrained X-ray operator and the unnecessary exposure to radiation. The president of the American Society of Radiologic Technologists, Daniel Donohue, testified before the subcommittee that, "The primary cause of overutilization or, if you will, exposure to unnecessary radiation of the public is caused by the fact that people operating equipment who have not been educated or trained in the proper use thereof." In describing a study that was conducted by the American College of Radiology, which significantly opposes the legislation which you are considering, Dr. Jerome Shapiro held that though they were unable to document that compulsory licensure had achieved significant changes in the level of practice, "we think credentialed people are certain to be superior." I believe that the only conclusion which we can reach is that the well educated, credentialed X-ray operator will reduce the amount of unnecessary exposure born by the consumer and that efforts should be made to require the credentialing of those operators and minimum standards for their education.

I believe the Food and Drug Administration and its Bureau of Radiological Health should be commended in several of their efforts to limit the amount of unnecessary radiation exposure. At the

same time, however, the FDA has not encouraged the adoption of X-ray operator standards as diligently as it might. Nearly 12 years have passed since enactment of the Radiation Control for Health and Safety Act which gave the Food and Drug administration authority to establish voluntary standards for the accreditation for educational programs and certification of persons who administer radiologic procedures. In the course of the subcommittee's hearings, there was virtual unanimity that the adoption of such standards by the States would have a positive impact upon improving the quality of X-ray examinations and consequently reducing X-ray exposure. Since in the past 12 years only 11 States have adopted licensing requirements for X-ray machine operators, the public will have to wait until the year 2025 until all States adopted certification and accreditation standards if the present pace is maintained. This is clearly unacceptable.

The principal recommendation which the subcommittee has adopted in its report—the one which I believe will correct this intolerable situation—is the enactment of Federal legislation to require States to establish standards for the accreditation of educational programs and, to train and certify individuals to perform radiologic procedures. Such legislation has passed the U.S. Senate on several occasions under the sponsorship of Senator Jennings Randolph, Democrat from West Virginia. Indeed, such legislation is again near passage in the Senate and is awaiting House action. I believe that such legislation is necessary and should be favorably acted upon by this subcommittee. I thank you once again for the opportunity to appear before you today.

STATEMENT OF HON. NORMAN F. LENT, A REPRESENTATIVE IN CONGRESS FROM NEW YORK

Mr. LENT. Thank you, Mr. Chairman. I want to thank you for giving me the opportunity to testify in support of this much-needed legislation, and commend you for holding these hearings even though it is late in a hectic session. I would also like to commend Chairman Eckhardt for his leadership in getting the Oversight Subcommittee involved in its indepth examination of the adverse health effects of low-level ionizing radiation. I am confident that much good will come from our work.

My interest in this area, of course, stems from my service on the oversight subcommittee. During the first session of the 96th Congress, I traveled with the subcommittee to Nevada and Utah, in order to take testimony directly from residents exposed to atomic bomb fallout during the weapons-testing programs of the 1950's and 1960's

It was during this initial phase of our radiation inquiry that I realized how insidious and dangerous radiation can be. We took extensive expert testimony both in the field and here in Washington—testimony which convinced me beyond any doubt of the link between exposure and subsequent carcinomas in medically significant numbers of victims. Our inquiry then turned to medical uses of radiation—the medical and dental X-ray.

Indepth studies, such as those by the HEW interagency task force and the General Accounting Office, have underscored the severity of this health hazard to the populace. I came away from

these hearings determined to do whatever I could to reduce unnecessary exposure. It became quickly apparent that the only way to reduce unnecessary exposure would be to concentrate on medical and dental X-rays.

A few facts will illustrate this point:

One. It is a scientific fact that 50 percent of exposure is from naturally occurring sources—rays from the Sun, radionuclides in everyday objects, such as granite or bricks, and so forth; and the rest is man made, and thus controllable to some extent.

Two. Of the 50 percent that is man made, 90 percent is from medical and dental X-rays, and thus controllable;

Three. Of an estimated 130,000 to 170,000 operators of X-ray equipment throughout the United States, only 90,000 have received formal training or have been certified as competent through State licensing or voluntary certification.

Four. Only about 11 States and Puerto Rico now have a formal licensing procedure. Fortunately, my State of New York is one of them.

Five. The information above must be viewed in light of the fact that there is no medically known safe level of exposure. Thus, exposure should be kept to the absolute minimum.

About this time last year I introduced H.R. 5924, a bill designed to encourage those States without a consumer-patient radiation policy to get one in place. Subsequently, I was asked by my colleague on the Commerce Committee, Mr. Tom Luken, to join with him on his bill, H.R. 6057.

Both bills are substantially similar, and provide generally:

(1) That the Secretary of Health and Human Services by regulation shall promulgate radiation protection standards for institutions training radiologic operators;

(2) That the Secretary shall by regulation promulgate certification standards for persons who administer radiologic procedures;

(3) That non-complying States, after 3 years, would lose Federal grants, loans, contracts or other financial assistance or reimbursement, for radiologic procedures; and

(4) That sufficient financial assistance be given to States to carry out the purposes of the Act.

Mr. Chairman, I believe this legislation to be timely, cost-effective and necessary to enable us to begin to get a handle on the cancer epidemic in this country. Moreover, similar legislation has just recently passed in the Senate.

Thank you.

Mr. WAXMAN. At this time I would like to ask our first witness to come forward, Dr. John Villforth of the Food and Drug Administration.

Dr. Villforth.

STATEMENT OF JOHN C. VILLFORTH, DIRECTOR, BUREAU OF RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY ROBERT C. ECCLESTON AND MARK BARNETT, BUREAU OF RADIOLOGICAL HEALTH

Mr. VILLFORTH. Thank you.

I am pleased to be before you to discuss the administration's position on H.R. 6057, H.R. 5934, and H.R. 6023, and to discuss their relationship to the Department of Health and Human Serv-

ices efforts to reduce medical and dental radiation exposure, and the administration's recent initiatives to curtail unnecessary diagnostic X-ray exposure.

With me are Mr. Mark Barnett and Mr. Robert Eccleston of the Bureau of Radiological Health staff. Both of these gentlemen have had experience in the area of working in the technologists' field and in the area of training and communication with the medical community and technologists.

The Department supports the purpose of the bills, to assist in the development of State standards for credentialing of radiologic technologists and accreditation of educational programs for radiological technologists and we are committed to carrying out programs to improve the performance of X-ray machine operators.

In addition, we fully support the goal of assuring optimum quality in all phases of health care and also endorse the objective of insuring that diagnostic X-rays are administered with the minimum amount of exposure by competent radiologic personnel.

Under existing authority, HHS produces and distributes educational materials for X-ray technologists, has developed a system through which radiologic personnel can assess their competence and strengthen their areas of weakness, assists States with licensure programs, and establishes quality assurance programs to help reduce patient exposure.

Under these three bills, the Secretary would be directed to promulgate standards for accreditation of educational programs conducted by institutions for persons who administer radiologic procedures and standards for credentialing of such persons.

These bills would also authorize a cutoff of Federal assistance programs in States that are not administering accreditation and certification programs at least as stringent as the Federal standards.

The Secretary would also be authorized to make grants to educational institutions, nonprofit organizations, and States which carry out accreditation and certification activities consistent with the purposes of the bill and the radiation protection standards. The Department opposes enactment of these bills primarily because they duplicate authority already vested in HHS under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. This authority is summarized in the appendix to my testimony. [See p. 32.]

The Department has implemented a combination of activities aimed at improving X-ray technologist performance. To upgrade the education of operators, both in the schools and in continuing, on-the-job training, and to insure that a proper emphasis is placed on radiation protection, the Department has actively collaborated with professional organizations in designing educational curricula.

The Department has also produced educational materials, such as a multimedia training package series showing X-ray technologists how to protect their patients and themselves from unnecessary radiation.

Nearly 5,000 of these training packages have been sold, and we estimate that about 30,000 persons view them annually.

To reach those operators who may not have access to formal educational programs, the Food and Drug Administration is work-

ing with the Health Resources Administration and the American Society of Radiologic Technologists to provide a system through which credentialed and noncredentialed radiologic personnel can assess their competence and strengthen their areas of weakness.

This system will be integrated into the ASRT's evidence of continuing education program, and efforts are underway to activate this system nationwide.

The Department has also assisted States with licensure programs in an attempt to assure that State requirements are consistent and uniform. Toward that end, HHS has proposed to develop, in cooperation with States and professional groups, recommendations on voluntary national standards for the qualifications of medical radiologic technologists.

We announced this endeavor in a March 1979 Federal Register notice of intent.

We have received over 600 responses from professional organizations, State agencies, and the public sector. We have analyzed these responses, and will publish the recommended standards in the near future.

Another effective means of reducing patient exposure is through quality assurance programs. Two examples of successful FDA efforts in this area are the BENT, breast exposure: nationwide trends, and DENT, dental exposure normalization technique, programs, which are aimed respectively at mammography and dental X-rays. Both of these programs enable States to identify quickly and inexpensively X-ray facilities where unusually high exposures are occurring. This is accomplished by mailing special cards containing radiation measurement devices to hospitals and clinics.

The instructions tell the technologist to expose the card as would normally be done in an actual X-ray procedure. The cards are mailed back to the State agency and read.

Followup visits by State personnel are made to facilities where high exposures are identified in order to pinpoint the problem and to suggest remedial action.

DENT, which is now used in 40 States and local agencies, has succeeded in reducing average dental X-ray exposures by 40 percent. Comparable reductions have been achieved among the 46 States now participating in BENT.

Most of the exposure reduction achieved by the DENT and BENT programs results from improving technologist performance, as opposed to improving equipment, irrespective of credentialing status.

Mandatory credentialing can assure that entry level X-ray equipment operators possess at least minimal competence. In addition, recent data seem to indicate that the kind of training and education which would be required by State licensure can improve technologist performance to some extent.

However, some studies point to two major problems which indicate that the proposed legislation may not be effective.

First, even with 24 months of education, many technologists perform well below their potential. Perhaps more important, factors such as work environment and supervision appear to affect technologist performance to a far greater degree than credentialing.

For example, data indicate that the most important determinant in the use of gonad shielding to protect patients may not be the credentialing or education of the operator, but whether or not radiology department supervisors insist that the shielding be used.

With this in mind, and because noncredentialed X-ray machine operators are today responsible for only about 10 percent of the population dose from diagnostic X-rays, we question whether a funding program that would award large sums of money to the States to institute mandatory credentialing programs will be the most effective way to improve the performance of X-ray machine operators.

We suggest that a more workable approach would be to conduct programs to improve the performance of all X-ray personnel and to strengthen entry level and continuing education of credentialed technologists who are now delivering 90 percent of the population dose.

On February 21, 1980, following a year-long interagency analysis of Federal ionizing radiation protection and research programs, the President issued an Executive order establishing the Radiation Policy Council.

The Council, chaired by the Administrator of EPA, is comprised of all agencies concerned with radiation control, and is responsible for advising the President on the formulation of broad radiation policies; monitoring implementation of Federal radiation protection strategies; resolving jurisdictional problems among Federal agencies; recommending needed legislation; insuring effective liaison with the States and the Congress, and providing a forum for public input.

A companion committee, the Interagency Radiation Research Committee, has also been created to address radiation research needs and to develop a comprehensive Federal research strategy.

One of the tasks that the council has been asked to consider is to implement a series of recommendations on diagnostic X-ray exposure reduction that were made by the Interagency Task Force on the Health Effects of Ionizing Radiation. These recommendations included the problem of training and credentialing of diagnostic X-ray personnel.

In summary, Mr. Chairman, there is unquestionably a need for assuring the competence of persons who administer radiation to patients, and HHS is working to reduce medical radiation exposure through programs that involve both credentialed and noncredentialed technologists.

The administration's opposition to these bills is based upon our belief that they duplicate existing authorities.

The administration believes that the Federal Government should continue to work with the private sector in devising viable and uniform standards for State licensure agencies and the medical professionals.

The legitimate role for the Government, we believe, is to provide leadership in the development of such standards by continuing cooperation with States and professional organizations.

This concludes my formal statement, Mr. Chairman. I would be glad to answer any questions you or members of the subcommittee may have.

[Testimony resumes on p. 38.]

[Attachment to Mr. Villforth's prepared statement follows:]

APPENDIX

GENERAL INFORMATION

The most significant exposure to man-made radiation occurs during the deliberate exposure of patients to radiation for medical diagnosis and therapy. Diagnostic uses of X rays and radiopharmaceuticals contribute 18 million person-rem each year to the U.S. population dose out of a total of about 50 million person-rem. Although most of these exposures are beneficial in that they allow health professionals to diagnose and treat injury and disease, some x-ray exposure is not medically necessary.

Approximately 130,000 medical x-ray machines are used to conduct about 186 million x-ray examinations annually, and 172,000 dental x-ray units are employed in 92 million dental x-ray examinations each year.

According to our estimate about 85,000 of the 130,000 to 170,000 persons now operating medical x-ray equipment are certified by either the American Registry of Radiologic Technologists (ARRT) or the American Registry of Clinical Radiography Technologist (ARCRT), or licensed by one of the eleven States and one territory (New York, New Jersey, California, Kentucky, West Virginia, Florida, Vermont, Arizona, Montana, Oregon, Hawaii, and Puerto Rico) administering such programs. This leaves approximately 45,000 to 85,000 non-credentialed individuals who perform x-ray examinations with training and job skills that can only be approximated.

Although the proportion of non-credentialed (medical) x-ray technologists actively employed is of concern, the figures alone may be misleading. Results of FDA-sponsored x-ray field surveys reveal that this segment of the workforce accounts only for about 15 percent of all x-ray examinations and about 10 percent of the population dose. In the dental x-ray area, about 200,000 dental hygienists and assistants

currently conduct x-ray examinations; about 145,000 of these (primarily dental assistants) are non-credentialed.

Besides diagnostic x-ray technologists, there are two medical specialty areas in which radiation is applied to humans: nuclear medicine and radiation therapy. Approximately 13,000 technologists work in the nuclear medicine field, of whom 6,500 are certified by the ARRT, the American Society of Clinical Pathologists (ASCP), or the Nuclear Medicine Technology Certification Board (NMTCB). We estimate that there are presently 2,000 radiation therapy technologists, 900 of whom are certified by the ARRT and 600 of whom are licensed by States.

Formal educational programs for medical x-ray technologists require 24 months of training and are located in hospitals as well as post-secondary academic institutions affiliated with clinical facilities. As of 1979, 817 educational programs enrolling 22,000 students were accredited by the Committee on Allied Health Education and Accreditation (CAHEA) in cooperation with the Joint Review Committee on Education in Radiologic Technology (JRCERT). There are about 135 educational programs for nuclear medicine technologists and about 100 educational programs for radiation therapy technologists.

HHS PROGRAMS

A promising area for reducing the number of medically unnecessary x-ray examinations is in the development and dissemination of x-ray referral criteria--indications for x-ray procedures based on patient history, signs, and symptoms. This guidance-setting activity represents one of the cornerstones of our efforts to assist clinicians in deciding when X rays are needed.

A major impetus in this area was the National Conference on Referral Criteria for X-ray Examinations, which was held in Washington, D.C., in October 1978 under the joint sponsorship of the Department and former Congressman Paul Rogers. The Conference, which brought together representatives of Government health agencies, medical specialties, third-party insurers, and the legal profession, provided an opportunity to discuss the reasons for unnecessary medical x-ray examinations, and to formulate a strategy by which Government and the private sector could jointly effect solutions.

In accordance with the Conference recommendation that the Federal Government assemble expert physician panels to develop x-ray referral criteria, HHS has formed three professional panels to examine routine chest x rays, x-ray pelvimetry, and voiding cystourethrography in children. Each of the panels has met at least once; the pelvimetry panel, comprised of representatives from the American College of Radiology and the American College of Obstetricians and Gynecologists, has developed a policy statement cautioning physicians against ordering pelvimetry because of a lack of demonstrated efficacy. The chest x-ray panel has developed draft statements on the use of three types of chest x-ray examinations.

In addition to the panels, the Agency has awarded five research grants to develop x-ray referral criteria. These studies are evaluating the clinical value of a number of x-ray examinations, including lumbar spine screening, dental panoramic, abdomen, upper GI series, and oral cholelscystography.

HHS is also augmenting physicians' training in such areas as the selection of patients for x-ray examinations, the physics of radiology, and good x-ray practices. This is being done through the Radiological Health Sciences Learning Laboratory, a program developed under HHS contract for training medical students, radiology residents, practitioners, and to some degree, radiologic technologists.

The program provides instruction in all three elements of x-ray usage: patient selection, conduct of the examination, and interpretation of the results. The Learning Laboratory is presently used in 80 percent of U.S. medical schools; we hope that within the next few years, every medical school will have incorporated this system into its overall medical education program. HHS will submit for the record a copy of some of the educational materials we developed for this program.

Because patients themselves sometimes request unnecessary x-ray examinations or resist appropriate procedures, the role of the patient should not be overlooked in seeking ways to reduce unnecessary exposure. Aware consumers can play an important role in helping to minimize exposure by requesting special shielding for the reproductive organs, alerting the physician about the possibility of pregnancy, or suggesting the use of previous x-rays to avoid a repeat examination. HHS has instituted a consumer-patient education program to relay basic messages and information about how consumers can avoid needless medical radiation exposure. We have, for example, distributed over 500,000 wallet-size, x-ray record cards which enable patients to keep track of their own examinations and to inform practitioners about previous exposures.

We have also collaborated with the American College of Obstetricians and Gynecologists in designing a poster for display in hospital radiology departments and in physicians' offices to remind women who suspect that they may be pregnant to alert the physician. Again, this material has received widespread dissemination. In April we began a major public education campaign involving consumer groups, hospitals, and medical organizations across the country regarding x-ray exposure and appropriate consumer safeguards. A copy of the materials we have prepared for use in this consumer program will be offered for the record.

CURRENT HHS AUTHORITY RELATING TO PROVISIONS OF H.R. 6057, H.R. 5934, and H.R. 6023

These bills direct the Secretary to promulgate standards for accreditation of educational programs conducted by institutions for persons who administer radiologic procedures and standards for credentialing of such persons. Recommendations on voluntary national standards for the qualifications of medical radiologic technologists are now being developed by HHS under authority, delegated to the Commissioner of FDA by the Secretary (21 CFR, Part 5, Subpart A), of section 356 of the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263d) and sections 301 and 311 of the Public Health Service Act (42 U.S.C. 241 and 243).

Section 356 of the Public Health Service Act provides for the establishment and conduct of programs designed to protect the public health and safety from electronic product radiation and authorizes making recommendations where appropriate. Section 301 and 311 provide

the broad responsibility to advise and promote cooperation between the States on matters relating to protecting the public against specified radiation hazards.

The bills authorize the Secretary to make grants to professional organizations, educational institutions, and States to carry out the purposes of the bills. Under section 796 of the Public Health Service Act, the Secretary has been directed to make grants to "eligible entities" (i.e., schools, States, and universities) for projects relating to training, credentialing, and continuing education of allied health personnel.

The Secretary has delegated to the Commissioner of FDA the authority to administer provisions of the Public Health Service Act (42 U.S.C. 263b-263n) which relate to electronic product radiation control, and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, et seq.) to assure the safe and effective use of medical devices, including medical devices that emit radiation.

The FDA also has authority to regulate the manufacture and distribution of radiopharmaceuticals and medical devices containing radioactive materials. It shares part of this authority with the Nuclear Regulatory Commission (NRC), which has similar powers when the drugs or devices contain material governed by the Atomic Energy Act.

The FDA's Bureau of Radiological Health sets basic performance standards for x-ray machines and other electronic products that emit radiation. The Bureau also issues voluntary recommendations for use of x-ray equipment and other radiation devices, conducts educational programs for professionals and consumers, and assists the States with their activities in this area.

Mr. WAXMAN. Thank you very much for your statement.

Why are the national standards being developed for technologists voluntary rather than mandatory?

Mr. VILLFORTH. Is your question why the present standards are voluntary?

Mr. WAXMAN. Why are they voluntary and not mandatory?

Mr. VILLFORTH. We feel that we should go the voluntary route because the nature of the problem is, as I said in my testimony, that only about 10 percent of the dose comes from noncredentialed individuals. Now we feel that producing a mandatory program and all the attendant costs would be diverting resources from the other elements that we feel should be addressed in order to get on with the job of radiation protection for the patient in the medical environment.

Mr. WAXMAN. Does Health and Human Services have the authority to mandate national standards for accreditation and educational programs now?

Mr. VILLFORTH. We feel that under the medical science amendments to the Federal Food, Drug, and Cosmetic Act, we have the authority to require standards for the performance of users of any medical device.

Under the restricted device provision of the medical device amendments, we could mandate that certain devices be declared as restricted devices and that certain types of training and preceptorship be required before anyone could use those devices.

Therefore, the Department feels it has the authority by these provisions of the Federal Food, Drug, and Cosmetic Act to do this. We have not done that.

Mr. LUKEN. Would the gentleman yield?

Mr. WAXMAN. I am going to yield to the gentleman for his question period now.

Mr. LUKEN. I just have a question or two I would like to get in.

I have an appointment with the Secretary of HUD at 11 o'clock. I wonder if I could ask these questions?

I am just intrigued by the position that you take here on page 4 of your statement. Before I get to that, I believe your assertion is that only 10 percent of the population's radiation dose is given by noncredentialed operators, is that right?

Mr. VILLFORTH. That is correct.

Mr. LUKEN. Does this include that given by noncredentialed dental assistants?

Mr. VILLFORTH. No, this is medical only.

Mr. LUKEN. Therefore, the failure to include about 145,000 of the 200,000 dental hygienists and assistants that conduct X-ray examinations seriously undermines the study?

Mr. VILLFORTH. I do not think so because the doses we are talking about in these cases are the significant bone marrow doses. This is where our analysis was directed, to determine the dose—

Mr. LUKEN. The dental doses aren't significant?

Mr. VILLFORTH. No, sir. We recognize they are important and need attention. In terms of priority, their contribution to the total population, both medical and dental X-ray dose, particularly, the dental bone marrow dose, which is an indication of its potential

contribution to somatic effects, leukemias, cancers, is relatively small and should not change the figures that significantly.

Mr. LUKEN. We will consider that as we go ahead with the hearing.

Now you concede that mandatory credentialing can insure that entry level X-ray equipment operators possess at least minimal competence?

Mr. VILLFORTH. Yes.

Mr. LUKEN. Yet you oppose it on the basis of budgetary reasons?

Mr. VILLFORTH. We are saying several things.

One, although the knowledge may be there through the entry level, the knowledge provided through, say a 24-month formal program, from our observations of the performance of those people who have gone through those programs and have been credentialed or licensed in those States which license, does not indicate that they are operating at the level that we think is appropriate for the training that they received.

Mr. LUKEN. You are saying 24 months of education didn't do any good?

Mr. VILLFORTH. We are saying 24 months of education did do some good, but not what we would expect, not as effective as we would expect.

Mr. LUKEN. That is an interesting test that you are giving. What you would expect is rather subjective. It did do some good? There was an improvement in the level of operation, caliber of operation of all these technologists, isn't that right?

Mr. VILLFORTH. We have no indication to know what the level of performance was before the 24 months.

Mr. LUKEN. Why did you bring it up? If it doesn't prove anything? If you didn't know what it was before, how do you know what the improvement is? What kind of study is that?

Mr. VILLFORTH. We can only look at those who have not had—

Mr. LUKEN. Isn't this a comparative you are coming up with? Your words are "below their potential." Aren't we talking about a comparison of where they started from and where they were after 24 months?

Mr. VILLFORTH. We are—

Mr. LUKEN. Are we or aren't we?

Mr. VILLFORTH. We are looking at the comparison between those who were credentialed and those who were not credentialed. The supposition had been that those who were not credentialed did not have adequate training. Our experience from the survey that we conducted shows that many of the noncredentialed technologists did have formal training, so it is very difficult for us to look at those who had no training whatsoever and compare them to the fully credentialed operators.

There are noncredentialed operators and credentialed operators. The noncredentialed consist of many people who are trained, who have had formal training.

Mr. LUKEN. It seems you are just discrediting your study.

The argument that you seem to be making here is there are other important factors such as work environment and supervision which appear to affect technologists' performance to a far greater

degree than credentialing; that is not really a substitute for their education, is it?

That is just another factor in the degree of improvement of their performance? These are other factors. They are not substitutes, are they?

Mr. VILLFORTH. No. That is correct. They are not substitutes for education.

Mr. LUKEN. That seems to be your argument as I see it. Also, you say that the data indicate that the most important determinant in the use of gonad shielding may not be credentialing or education of the operator, but whether or not radiology department supervisors insist that shields be used.

Again, of course, supervision is going to be important in reference to technologists, but I just fail to see the logic that that will be a substitute for improvement of the intrinsic capabilities in performance of the technologists themselves.

I just fail to see the logic.

Mr. VILLFORTH. Perhaps if I were to describe some of the results of the survey that we did, which we refer to as a front end analysis, which was a survey of the performance of operators, an attempt to look at a variety of operators in private practice, hospitals, clinics, both credentialed and noncredentialed.

We looked at 1,599 different technologists and determined several things. What their knowledge level was; how well they performed in certain tasks.

What we found was that those operators who had been trained and who had been credentialed did not perform significantly differently from those operators who were noncredentialed, and that both operators performed much less effectively of radiation protection than we felt was acceptable.

We attribute this to a large extent to the environment, the supervision, because in those situations where there was discipline in the environment, and a requirement for certain procedures—whether or not the technologists were credentialed—they performed better than in those departments or those institutions where there was not this supervision.

Mr. LUKEN. It seems to me that this argument is sort of like the argument that we shouldn't improve our educational facilities because most education is absorbed at home. That seems to be the kind of argument you are giving, that there are other factors other than the education of the technologists, which influence the level of their performance.

Incidentally, I believe the bill also sets up standards which would affect your testimony.

Mr. Chairman, I am sure we have to go.

Thank you very much. I will be back after my meeting. That will be about 11:30 I guess.

Mr. WAXMAN. How many States have taken action on their own in this area, of one sort or another?

Mr. VILLFORTH. We have 11 States which are now licensing, including Puerto Rico. They now have licensing provisions for technologists, technicians, operators.

Mr. WAXMAN. So only 11 States set up some minimum requirement for licensure?

What do the other States do?

Mr. VILLFORTH. There are six other States that have enabling legislation that are moving in that direction.

The remaining States do not have enabling legislation and apparently have not considered it.

Mr. WAXMAN. What qualifications are there for people who take X-rays?

Mr. VILLFORTH. There are no qualifications imposed by the States in those remaining States, or certainly by the Federal Government. There are some expected requirements through those hospitals that seek to have their facilities accredited by the American Hospital Association's Joint Commission on Accreditation of Hospitals.

Mr. WAXMAN. That would be in a hospital setting only?

Mr. VILLFORTH. In the hospital environment, yes.

Mr. WAXMAN. Otherwise, I assume we would expect that the malpractice that would be visited upon the physicians and dentists—

Mr. VILLFORTH. That is the intent.

Mr. WAXMAN. However, aren't we talking about a situation here where malpractice is so hard to prove and the impact of radiation could be 15, 20 years after the incidence of the exposure, so that malpractice really isn't a viable deterrent?

Mr. VILLFORTH. I suspect that is true if one is looking at the end point of radiation exposure as a criteria for the qualifications of the technologists. But, if the technologist X-rays the wrong portion of the anatomy or makes a bad film in which the diagnosis cannot be made or is incorrectly made because of the poor quality of the film, that type of malpractice, directed at the failure to provide information for the physician to get a good diagnostic image, is an immediate effect as opposed to the damage from radiation, which, as you point out quite correctly, will be 10, 20, 30 years.

Mr. WAXMAN. Unlike surgical removal of the wrong limb, most likely a patient wouldn't know that the wrong part of the body was X-rayed?

Mr. VILLFORTH. That is correct. Well, I cannot answer that.

I am sure the patient may know when it is an obvious fracture, or it may be a situation where the patient could be comatose in an emergency situation, that the wrong part of the body could be X-rayed and the wrong diagnosis made.

Mr. WAXMAN. So it is your view, or at least the administration's position, that it isn't so much the training that is crucial here, but the supervision of the people doing the X-raying?

Mr. VILLFORTH. That is one element.

I do not want to leave the impression that training is not important. Training is important. As we emphasized in our testimony, the Department believes in training and has worked with the professional organizations to develop training packages to assist in that training, both for those who are in school and those who are in continuing education.

We do believe that training is important. We are concerned that the emphasis of a mandatory credentialing program, to bring half of those operators who are not now licensed or credentialed up to some state of credentialing based on radiation protection as the end point is misleading. Although half of the operators in this

country operating X-ray machines are not credentialed, or not licensed, one must look at the fact that many of those people have had formal training; maybe not the full 24 months, but that it does not mean that they have walked in off the street.

We use that term quite often in these remaining States that have no program—you can walk in off the street and operate an X-ray machine. That is a true statement, but the point is that most of the situations where we have observed from our studies with the States, such as the nationwide evaluation of X-ray trend data, this and front end analysis that I described before, in fact, illustrate that in those facilities that have high workloads, the people are licensed or registered by professional organizations.

That makes sense from the standpoint of efficiency, wasted film, lost silver, threats of malpractice. They need qualified people operating in those departments.

Those departments are the departments that produce the high workload as opposed to the private practitioner.

Second, the diagnostic procedures done in these high workload departments, of big hospitals are the sophisticated procedures which result in higher doses to the bone marrow or to the critical organs of the body.

I use the bone marrow as an index.

In fact, then, if you look at what the real environment is of people who are delivering radiation, the dose contributed by those who are uncredentialed amounts to about 10 percent of the doses of those that are credentialed.

If we are trying, therefore, to institute a program to get everybody—including the 50 percent of people noncredentialed—up to a credentialing level, we are only going to affect 10 percent of the dose that has been delivered.

That is the concern of the Department.

Mr. WAXMAN. How much money are we going to have to spend to do that, to have an impact on that 10 percent?

Mr. VILLFORTH. Well, we have some figures that would give you some illustration of what the annual costs are through fees in some of the States. For example, our information for the State of Kentucky, Dr. Carter's State, is that their fees amount to something like \$20,000 a year in that State. But those fees in that State only bring in 38 percent of the cost of that program. So the cost of that program is essentially two-thirds higher than that.

In Arizona, the cost is \$47,000. In California the cost is \$217,000. That is about 52 percent of the actual—excuse me, that is fees brought into the State. \$217,000. That is about 52 percent of the roughly \$400,000 estimated cost to the State to run that program.

Oregon costs about \$40,000. In New York, the fees amount to \$75,000 to underwrite a program that costs about \$150,000.

I have not gone through and estimated if one were to use this for all 50 States what this cost might be, but we perhaps could get estimates from this and predict the cost. It is not an inexpensive program.

Mr. WAXMAN. Thank you very much.

Dr. Carter.

Mr. CARTER. Thank you, Mr. Chairman.

I know that approximately 12 States and a territory already require certification of radiologic technologists, is that correct?

Mr. VILLFORTH. I believe it is 11 States, including Puerto Rico.

Mr. CARTER. You would rather have a voluntary effort on the part of the States, is that correct?

Mr. VILLFORTH. Yes, sir.

Mr. CARTER. What methods of protecting those who give X-rays as well as those who receive them do you recommend?

Mr. VILLFORTH. Do I understand your question, sir, as you are asking for protection of the technologists themselves, the occupational exposure of the technologists?

Mr. CARTER. As well as the patient, yes, sir.

Mr. VILLFORTH. Well, the occupational provisions in most hospitals and private clinics come under the provisions of the Occupational Safety and Health Administration, or in those facilities where there are nuclear medicine departments they may come under the general provisions of the Nuclear Regulatory Commission.

We have not instituted any specifics in regard to protecting the technologists.

Mr. CARTER. The States have though, however?

Mr. VILLFORTH. The States have, under the suggested State regulations.

Mr. CARTER. Well, for many years, radiologists have used lead-lined gloves and lead-covered aprons in their X-ray rooms. Also the X-ray room is usually lead lined.

Mr. VILLFORTH. Yes, sir.

Mr. CARTER. In most cases. In the dental field, do you feel that our dentists are not trained well enough to use X-ray machines?

Mr. VILLFORTH. I think there is a lot of room for improvement in the dental field, particularly for dentists.

In several weeks I will be addressing the American Dental Association on two papers on radiation protection. I hope that I will be able to convince them of the need to improve the radiation protection philosophy in the dental environment.

I am concerned about that.

Mr. CARTER. Actually when you go to a dentist today and have X-rays, isn't it a fact that he usually covers your body with a lead-lined apron?

Mr. VILLFORTH. I do not know how usual that is. There are certainly many, many dentists that do that, yes, sir.

Mr. CARTER. Yes, sir. I have been to the dentist three or four times recently. On each occasion when I had my teeth X-rayed, that was done. What other types of protective devices does a dentist have?

Mr. VILLFORTH. You mean what type—

Mr. CARTER. The cone, for instance, on the dental X-ray machine, how is it constructed?

Mr. VILLFORTH. Most of the cones—

Mr. CARTER. It is a cone, is it not? It is constructed so that X-rays will be concentrated in one area and not spread, is that not correct?

Mr. VILLFORTH. That is generally correct, yes, sir. Not all of the machines have the cones, but generally they do.

Mr. CARTER. Well, I have never seen one that didn't. Maybe some of them don't.

How can we tell when a patient has been exposed to too much radiation in a year? How can we tell when they are approaching an unsafe level, since any level might be unsafe?

Mr. VILLFORTH. In terms of the technologists, technicians, or physicians and dentists, by the use of a personnel monitoring device which most States require, these are things called film badges or thermo luminescent dosimeters.

We generally call them personnel monitoring devices.

Mr. CARTER. These badges are sent in at regular periods?

Mr. VILLFORTH. Yes, sir.

Mr. CARTER. Do they measure the amount of radiation which has accumulated?

Mr. VILLFORTH. Yes, sir.

Mr. CARTER. I think that using some of these principles of patient protection, and protection of the technologist—if we can obtain the cooperation of the States—we could do a great deal to protect our patients throughout the country.

I believe that most technologists, most physicians, and most radiologists are cognizant of dangers, although some are adamant in refusing to admit there is a danger.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Dr. Carter.

Dr. Villforth, thank you very much for your testimony.

I would like to call Dr. William E. Brown from the American Dental Association, accompanied by Jocelyn Roman, American Dental Hygienists Association, and Miss Janelle Butler, president, American Dental Assistants Association, accompanied by Michael Lemov, counsel, Leighton, Conklin, Lemov & Jacobs.

First I would like to turn to a previous witness on our agenda. That is our colleague, Mr. Lundine, who is with us now. We would like to hear from you before we get into this panel because I know you have other committee meetings going on at the same time.

STATEMENT OF HON. STANLEY LUNDINE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. LUNDINE. Thank you very much.

If I can find one seat here, I will be brief.

Thank you, Mr. Chairman. I thank the indulgence of the panel as well. I have a prepared statement which I would like to ask be included in the record in its entirety. [See p. 46.]

Mr. WAXMAN. Without objection.

Mr. LUNDINE. Mr. Chairman, I really appreciate the consideration you are giving to what I think is a very important topic requiring some congressional review. That, of course, is the question of standards for the licensure of radiologic technologists.

I, along with our colleagues, Representative Lent of New York and Mr. Luken of Ohio, have introduced legislation to provide for voluntary standards for licensure of nonphysicians and dentists who are operating X-ray equipment on patients.

Between 130,000 and 170,000 men and women operate the Nation's 250,000 pieces of medical and dental X-ray equipment, but it is estimated that only about 80,000 of those roughly 150,000—or

about half of them—have shown their competency through voluntary certification or State licensing examinations.

Only nine States and Puerto Rico have licensing of X-ray technicians, and only California requires that all persons who administer X-rays pass a competency examination.

My home State of New York was the first in the Nation to pass a licensing requirement for those medical persons operating radiation equipment, yet there is no corresponding legislation in our State to provide the same requirement for dental practitioners.

I think that you will receive much more expert testimony than mine, but the support for increasing the standards and taking very careful assessment of the possibility of both improper techniques and excessive use of X-rays has come from associations normally, we in Congress might expect to be opposed to these kinds of standards being set by the Federal Government.

Recently the Pennsylvania Blue Cross did a study that revealed between one-half and three-fourths of all X-ray films they reviewed were technically unsatisfactory and had to be retaken. This is a waste. It is also, more importantly, a concern to many of us that patients and even technicians are thus being subject to unnecessary radiation exposure by poor technique or not using protective devices.

I am pleased that this committee is giving some consideration to these issues today, by looking at the bills introduced by Representatives Lent, Luken, and myself.

As you know, similar legislation providing for national standards has previously been considered favorably in the Senate several Congress in a row, and I'm glad to see the House begin the same.

I have talked to a lot of doctors specializing in the field, radiology, and to radiologic technologists, and health educators, regarding the impact of establishing a national criteria for X-ray training.

I am utterly convinced that this is one area where regulation which we often condemn could actually result in cost savings by eliminating unneeded or duplicative procedures that are now often required, due to operator error. We could see some improvement and some lessening of public concern over radiation exposure by taking this step.

I therefore strongly urge this subcommittee to begin action in the House to protect the health of our Nation's citizens and that of future generations by establishing this kind of a standard.

I thank you very much again for your attention to this matter, entire as well as your willingness to listen to me briefly.

[Mr. Lundine's prepared statement follows:]

HONORABLE STANLEY N. LUNDINE
TESTIMONY ON RADIATION SAFETY LEGISLATION
Health Subcommittee of the
Interstate and Foreign Commerce Committee
Friday, Sept. 5, 1980

Mr. Chairman:

Medical and dental uses of ionizing radiation represent a significant and growing source of radiation exposure for the U.S. population. Between 1964 and 1970, the annual number of x-ray exams increased 24%, from 173 million to 212 million per year. Today 240 million x-rays are ordered annually by medical and dental practitioners. This represents 90% of the man-made radiation, including radiation from nuclear power plants, to which the general public is exposed.

A gradual movement has begun in the medical profession to reduce the number of x-rays given to the patient, such as eliminating routine x-rays upon admission to a medical facility. This action will clearly help decrease rising medical costs, and will also reduce the potential risk a patient faces from exposure during an x-ray exam. The federal government is also stepping up its inspection of x-ray equipment to ensure it does not leak or overexpose the patient or operator. While these efforts are commendable and must continue, a large link has been left out of this chain: there has not been a corresponding effort to ensure that those persons operating the x-ray equipment know how to use it properly or even know the safety procedures involved.

I am here today to discuss the need for forging this link to complete our health safety chain. I, along with Representative Lent and Representative Luken, have introduced legislation in the House of Representatives to provide voluntary standards, needed standards, for the licensure of radiologic technologists.

Between 130,000 and 170,000 men and women operate the nation's 250,000 pieces of medical and dental x-ray equipment, but it is estimated that only 80,000 have shown their competency through voluntary certification or state licensing examinations. Only 9 states and Puerto Rico require the licensing of some x-ray technicians, and only California requires that all persons who administer x-rays, pass a state competency examination. My home state of New York was the first state in the nation to pass a licensing requirement for those medical persons operating radiation equipment, yet there is no corresponding legislation in the state to provide the same requirement for dental practitioners.

While there is much scientific controversy surrounding the health effects of low-level ionizing radiation on the human body, we can all agree that the benefits of a properly administered x-ray far outweigh the risks. No one, however, benefits if the film has to be reshot because of flawed operator technique. Adequate training of x-ray equipment users will not decrease the number of x-rays ordered by physicians or dentists, but it will significantly decrease the overexposure to the patient caused by high radiographic exposures or retakes.

In testimony before the Senate Committee on Labor and Human Resources, the American Dental Association expressed their support for dental assistant training in x-ray techniques. The ADA further stated they were more than satisfied that graduates of their courses were giving quality services, but they could not provide such assurances concerning the knowledge and skill of dental assistants who are not graduates of accredited dental assisting programs.

4) The American Dental Assistant Association estimates that an x-ray is taken during two-thirds of the visits a person makes to a dentist each year. Further

questioning during the Senate hearing brought out the statement that approximately three-fourths of all dental offices had dental assistants administering the x-rays, and by no means were all of these assistants trained or certified to prove their competency. A recent Pennsylvania Blue Cross study revealed that between one-half and three-fourths of the dental x-ray film they reviewed was technically unsatisfactory, and since a treatment could not be prescribed by using those films, they had to be retaken. Furthermore, a survey by the American Dental Association demonstrated that only one out of every four dental offices uses protective devices to shield patients and technicians from unnecessary radiation exposure. These devices include lead apron drapes for the patient, and wall structures to prevent radiation leaking from the exam room to other parts of the office. These safety techniques can be quickly learned, and mistakes prevented, if the technician receives some education and certification.

Mr. Chairman, as I stated previously, legislation has been introduced which would rectify this oversight. After introducing my own bill on licensing standards for operators of x-ray equipment, H.R. 6023, I joined with my colleague Mr. Luken on H.R. 6057, which provides similar national standards for x-ray operators. These bills call for the Department of Health and Human Services to develop standards for accrediting radiologic technology education programs and to develop minimal standards for certifying radiologic technologists. Minimum uniform standards for accreditation can be most effectively drawn by HHS with valuable cooperation of the professional associations which are testifying here today: the AMA, the ADA, and the ADAA to name a few. Voluntary certification and accreditation programs already exist in a few states, and these

could serve as models for these federal efforts to develop guidelines. It is a commonsense approach to a problem of increasing public concern.

Further, since HHS expects to complete by December 1980 its voluntary national standard for the qualification of medical radiologic technologists, these standards clearly could be a basis for the standards suggested in these bills. The federal government would not incur additional costs by taking this step.

The costs associated with quality health care are rising each year, and it is essential that cost containment be kept in mind when considering any new legislation. The area of radiologic technology is no different. The total cost of diagnostic x-rays is approximately \$6.3 billion per year. An average family of four pays about \$100 per year from medical and dental x-rays, either directly or through insurance premiums. John Villforth, director of the Bureau of Radiologic Health at the Food and Drug Administration testified before the Commerce Oversight Subcommittee last year that as many as 30% of the x-rays taken annually are unnecessary. Thus, if they could be eliminated, a \$2 billion savings per year would result.

I have spoken to many doctors, radiologic technologists and health educators regarding the impact of establishing a national criteria for x-ray training. The overwhelming response is one of extreme concern over the health hazards that exist from untrained operators, and a desire to see some form of national standard enacted. We cannot deal with public concern over radiation exposure until we take this step. I strongly urge this subcommittee to start this action in the House, to protect the health of our nation's citizens and that of future generations.

I thank you for the opportunity to be here today.

Mr. WAXMAN. Thank you very much for your statement. I want to commend you on that statement and for the leadership you have given to this issue.

While the Senate has dealt with this specific proposal a number of times, this is the first time the House has held hearings on the matter.

Due to the leadership that you and Congressman Luken and Congressman Lent are giving to this, we wanted to have this hearing so we could see whether this is the kind of approach we ought to be taking to correct a very serious problem that may have an impact on health and that really can't be measured until many years have gone by from the time that people are exposed.

Thank you very much for your statement.

Dr. Carter.

Mr. CARTER. You mentioned duplicative X-rays and the need to control them. How would you control duplication?

Mr. LUNDINE. Particularly in the dental profession there seems to be a correlation between the number of untrained operators and the percentage of inadequate tests. I think the Pennsylvania Blue Cross study indicated that where you have people doing the procedures that are not well trained, quite often they have to take a second or third X-ray simply because the first one was not adequate. By having higher standards, I think we would find that we would lessen the duplication.

Mr. CARTER. My experience not shown much duplication. I have been to the dentist several times recently. I must say that on all occasions, he used the utmost care. Of course, I noticed the protection of the lead apron which he gave me. I believe dentists generally know quite well what they are doing. I hope their helpers do. That is the point, I believe, of your legislation, to see that the ones who assist the dentists are capable of doing this without injuring the patient.

Mr. LUNDINE. Yes, sir.

Mr. CARTER. Thank you.

Mr. WAXMAN. Thank you, Dr. Carter.

Mr. Lundine, thank you for being with us.

Dr. Brown, welcome.

STATEMENTS OF DR. WILLIAM E. BROWN, CHAIRMAN, COUNCIL ON DENTAL EDUCATION, AND COMMISSION ON DENTAL ACCREDITATION, AMERICAN DENTAL ASSOCIATION, ALSO ON BEHALF OF AMERICAN ASSOCIATION OF DENTAL SCHOOLS, AND AMERICAN DENTAL HYGIENISTS' ASSOCIATION, ACCOMPANIED BY DR. MARIO SANTANGELO, ASSISTANT SECRETARY (ADA); JOCELYN D. ROMAN, CHAIRMAN, COUNCIL ON CONSUMER AND GOVERNMENT RELATIONS, AMERICAN DENTAL HYGIENISTS' ASSOCIATION; JANELLE BUTLER, PRESIDENT, AMERICAN DENTAL ASSISTANTS ASSOCIATION, ACCOMPANIED BY MICHAEL R. LEMOV, COUNSEL

Dr. BROWN. Mr. Chairman, I am Dr. William Brown. I am dean of the University of Oklahoma College of Dentistry and I currently serve as chairman of the Council on Dental Education, and the Commission on Dental Accreditation of the American Dental Association.

I am appearing on behalf of the American Dental Association, but am also authorized to speak on behalf of the American Association of Dental Schools and the American Dental Hygienists Association.

With me are Dr. Mario Santangelo on my far left, assistant secretary of the Council on Dental Education and the Commission on Dental Accreditation, and on my near left Mrs. Jocelyn Roman, executive director of the Fones School of Dental Hygiene at the University of Bridgeport, and also the chair of the ADHA Council on Consumer and Government Relations.

With your permission, she will make a very brief statement when I am finished.

All aspects of the dental profession share the concern of the Congress and the public over the unnecessary use of ionizing radiation. The official American Dental Association policy on this matter states, and I quote, "Use professional judgment to determine the frequency and extent of each radiographic examination; determine the minimum number of film exposures that will produce the desired diagnostic information."

Dental radiographs—and Dr. Carter, I am sure you know this—are used only for diagnosis and not for therapy and are indispensable for diagnostic and treatment planning purposes.

This distinguishes dental radiography from medical radiography, the latter dealing with therapeutic radiography in addition to the diagnostic.

Dental radiographs are very small generally and only about $2\frac{3}{4}$ inches of skin surface are exposed to the X-ray beam when a standard film is exposed.

The time required to expose dental radiographs is very small. For example, for a single periapical radiograph with a kilovoltage of roughly 65, milliamperage of about 10, source-to-film distance of 16 inches, the time of exposure is 1 second. This is in relation to the earlier discussion this morning concerning the equivalent whole body bone marrow exposure. Background radiation contributes about 126 millirems per year to the average individual.

In a series of radiographs, 20 films produce roughly 15.4 millirems to the entire bone marrow of the patient, so you can relate that to background radiation. I think it is also fair to say, and we know the sensitivity of the issue, that there are no data to demonstrate that there is a damage from dental radiographs, except perhaps for the earlier days when some of the operators, in fact, held films in their patients' mouth. My father was one of those, and he did get in trouble, but it took 20 years.

During the past two decades, remarkable progress has been made to reduce exposure to ionizing radiation through dental radiographs, but at the same time improving the quality of diagnostic films; for example, faster film, electronic timers, collimation, filters, cervical collars and lead aprons, tomographic equipment and automatic processors.

With reference to education and training, radiology is an integral part of the curriculums of each of the 60 dental schools in the United States. Further, providing didactic instruction, teaching radiographic techniques and providing clinical experience in dental

radiology are required for the accreditation of dental hygiene and dental assisting programs.

In dental education, radiology instruction generally spans between 2½ and 3 years of the traditional 4-year curricular sequence. A comprehensive study of dental curriculums of all U.S. dental schools in 1975 showed that the mean number of hours of radiology instruction was 88. In addition, supplementary instruction in radiology, specifically radiographic interpretation, frequently is provided in a number of other disciplines such as oral diagnosis and treatment planning. Schools provide a mean of 118.9 hours of instruction in oral diagnosis. The use and interpretation of radiographs are also an essential part of every subdiscipline of dentistry, and additional instruction in radiology, thereby, is incorporated in a study of each subdiscipline, even though this component is not specifically identified as instructional time in radiology.

More importantly, one-half of the schools reported an increased emphasis in all areas of radiology, and almost one-third of the schools reported that they had increased the number of clock hours devoted specifically to radiographic instruction.

Mr. Chairman, with your permission, I would like to make reference to the report to this committee from the Committee on Oversight and Investigations. On page 10, it states, "While we recognize that the 19-hour instruction example"—this is a range, and it is very extreme—"is extreme, it is an extreme that could not take place if there were minimum standards for instruction in radiography."

Mr. Chairman, the record was quite different from that reported in that committee's report. On page 101 of the official record of the hearings before the Subcommittee on Oversight and Investigations on July 24, and 31, 1979, it describes that this low extreme was because we were reporting one new school that was in its first year of operation, and it was a one-credit-hour course, which is absolutely reasonable. The commission on dental accreditation has paid special attention to radiography over the last several years, particularly, and in no single instance have we found an institution where we would judge the instructional time to be low.

We have also found that some schools, which have a relatively few number of hours, teach in such a way that the instructional quality is higher than some institutions that have more hours. I think what we are saying is that there is a hazard, and I think someone is coming precariously close to prescribing curriculum hours for the academic environment, and I would hope that this committee would be concerned about it.

We have some questions about H.R. 6057 that perhaps we should comment on right now. Page 5 toward the top, makes the statement that "Dental auxiliaries, including dental hygienists and assistants" and then it goes on. We know that dental hygienists and assistants expose radiographs, but we are unaware of any other dental auxiliary that might do this. This section of H.R. 6057 is unclear.

At the bottom of page 5, where it speaks to radiation protection standards for accreditation, it is very confusing whether the legislation speaks to dental education or dental auxiliary education. I

would hope the committee perhaps would look at this in terms of relieving the confusion.

The American Association of Dental Schools section on oral radiology, in cooperation with the American Academy of Dental Radiology, developed curriculum guidelines in 1973 and made them available to all dental schools. Further, that section, in 1976, developed similar guidelines for use by faculty in dental hygiene and dental assisting programs. The section on Oral Radiology has completed a further revision of these guidelines, and these will be published in the *Journal of Dental Education* in November of this year.

During accreditation site visits our commission on dental accreditation has been devoting major attention to reviewing clinical practices relating to controlling and monitoring ionizing radiation. The following areas, and I am going to skip most of them, are evaluated during the accreditation site visit. The complete list of the areas reviewed is in our formal statement. First, content, scope, depth, time devoted to teaching the subject of radiology in all subdisciplines, sequencing, faculty qualifications, and it goes on and on and on. It is a substantive list of things that we review very closely.

During these accreditation site visits, randomly selected patients records are also reviewed for the purpose of assessing, among other things, that the quality control program for radiographs is being maintained, whether there is a clear documentation of all radiographic exposures on the patients records, and whether the sequential log of exposure to ionizing radiation is recorded.

A review of the institution's quality control program for equipment is also assessed. Further, the commission evaluates the credentials of faculty teaching radiography to insure that those having this responsibility have adequate training in the area. In this regard, some believe that there is a need for additional qualified faculty in dental radiology. However, you should be aware the current Federal authority to assist in the preparation of teachers in any specific area is almost nonexistent, and the resources available to dental schools for such a purpose are extremely limited.

Until dental educational institutions have the resources to prepare qualified teachers in any area, it will be necessary for some schools to use faculty who are self-taught, or who have had continuing education courses in radiology. In our best judgment, the various pieces of proposed legislation will do very little to improve that situation.

Some have urged that a new specialty of oral radiology, similar to medical radiology, be established. The American Dental Association has opposed establishing any new dental specialties because it believes that this would not be in the best interests of the public. The soon-to-be published task force report on graduate dental education supports this position, and states: "Until there is an in-depth study of each of the dental specialties and until the relationship between the existing dental specialties and the general practice workforce is clarified, the task force does not believe any new specialty areas should be recognized."

And, to be very frank, the marketplace will not support a specialty in dental or oral radiology. The persons who are qualified basically will be performing in dental schools.

The commission has conducted, just recently, a comprehensive study of dental radiology teaching to elicit changes which have occurred since the 1976 dental curriculum study. This study includes all educational programs accredited by the commission.

The survey instrument collected the detailed and updated information on changes in the radiology curriculum since 1976, data on qualifications of faculty who provide instruction in radiology, facilities and equipment, and clinical practices related to controlling and monitoring the use of ionizing radiation. This survey has been completed, and is now in the analysis phase.

Preliminary data indicate that there are more formally trained faculty than we reported to the Oversight and Investigation Subcommittee 1 year ago. Based on these preliminary data instead of between 10 and 20 dental faculty formally trained in radiology nationally, there are 19 who reported that they had earned a certificate indicating completion of a formal program, and 30 who indicated that they had received a master's degree in radiology. This at least doubles the numbers of formally trained faculty that we reported to that subcommittee a little over 1 year ago.

The issues of formal education of dental assistants and the licensing of dental assistants have been addressed in several pieces of legislation before the Congress. Our three groups are highly supportive of formal education of dental assistants, evidenced by the fact that in 1961 there were only 26 accredited dental assisting programs in the United States. In 1980, there are 296 such programs. In 1961, there were 531 graduates of dental assisting programs. In 1978-79, this number increased to 6,036, as compared to 5,424 dental graduates.

It has been the American Dental Association's contention that the commission's accrediting program for dental assisting and the current certification process, providing that the process requires completion of an accredited program, gives the public effective protection.

Dentistry, dental hygiene, and dental education are opposed to Federal intervention in the educational process by dictating curricula, whether they be general or specific. Our associations believe that an appropriate expertise exists within the dental profession and in education to determine what course or curriculum content should be to adequately prepare the dentist, the dental hygienist, or the dental assistant for practice. Likewise, the ADA and the ADHA are strongly opposed to any Federal intervention into the licensing process. Dentistry and dental hygiene both believe strongly that all decisions relating to licensure should remain at the State level.

Finally, the ADA, ADHA, and AADS do not believe that this proposed bill is needed. The legislation would authorize governmental assumption of activity which is already being carried out through well-established private efforts and which results in well-trained and qualified radiologic personnel. The present accreditation and licensing system works very well, and follows in the traditional mode of developing quality education in this country. There is no justification for governmental usurpation or duplication of these activities such as that proposed in the various pieces of legislation.

I think, in summary, it is our very best judgment that as sympathetic as we are to the philosophy behind the legislation, we don't think the legislation will do the job. Based on our statements and what we heard this morning from previous testimony, it very clearly could be a very expensive program that really doesn't do very much.

Could I respectfully suggest, Mr. Chairman, that the subcommittee might look at alternate legislation to inspect equipment—that is a major shortfall around the country—and to develop resources to help train additional faculty, who will make the educational process even better.

Thank you very much.

[Testimony resumes on p. 70.]

[Dr. Brown's prepared statement and attachment follow:]

STATEMENT OF
THE AMERICAN DENTAL ASSOCIATION
ON
RADIATION STANDARDS
BEFORE THE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES
SEPTEMBER 5, 1980

Mr. Chairman and Members of the Subcommittee, my name is Dr. William E. Brown from Oklahoma City, Oklahoma. I am Dean at the University of Oklahoma, College of Dentistry. Currently, I also serve as Chairman of the Council on Dental Education and the Commission on Dental Accreditation of the American Dental Association (ADA). To clarify the distinction between these two ADA agencies, it should be pointed out that the Council is the policy recommending body to the Association's House of Delegates on a number of matters, including education and licensure, while the Commission, an autonomous agency of the profession, is the nationally recognized accrediting body for dental, dental auxiliary, dental specialty, general practice dental residency and general dentistry programs. The Commission is recognized by both the United States Office of Education and the Council on Postsecondary Accreditation.

Although I appear before the Subcommittee today in behalf of the American Dental Association, I am also authorized to speak on behalf of the American Association of Dental Schools (AADS) and the American Dental Hygienists' Association (ADHA). I am a member of the AADS's Council of Deans.

I am accompanied by Dr. Mario V. Santangelo, the Assistant Secretary of the Council on Dental Education and the Commission on Dental Accreditation, and by Mrs. Jocelyn D. Roman, Executive Director, University of Bridgeport, Fones School of Dental Hygiene and also the Chairman of the American Dental Hygienists' Association's Council on Consumer and Government Relations, representing ADHA. With your permission, Mrs. Roman will make a brief statement.

The American Dental Association, the American Association of Dental Schools and the American Dental Hygienists' Association are pleased to have this opportunity to present their common position on the legislation before this Subcommittee addressing radiation issues. In expressing this position, let me assure you from the outset that all segments of the dental profession are cognizant of and share the Congress' and public's concern about the use of any unnecessary ionizing radiation by the health professions, including dentists and dental auxiliary personnel. As an integral part of the profession of dentistry, the dental and auxiliary educational communities, likewise, recognize that they have not only the responsibility but also the obligation for preparing all graduates, whether they be dentists, dental

hygienists or dental assistants, competently in all aspects of radiology, including the potential hazards to patient and user. Faculty at educational institutions are not only committed to educating and training students in the judicious use of ionizing radiation, but are also equally committed to ensuring against its abuse. ADHA concurs completely with and, likewise, strongly supports these principles.

It is most important to emphasize to the Subcommittee that use of radiographic examinations for diagnostic and treatment planning purposes in dentistry is unquestionably essential for modern practice. There is no doubt whatever that radiographic examinations are an indispensable aid for diagnostic and treatment planning purposes. In recognizing the significance of radiographic examinations, the American Dental Association has consistently stated, however, that the use of x-radiation for diagnostic purposes should be made only after a careful evaluation of both the dental and the general health needs of the patient. In making any judgment on whether a radiographic examination is needed, the deciding factor is the total welfare of the patient and the risk versus the benefit to the patient. The nature and extent of diagnosis for required patient care constitute the only rational basis for determining the need or the frequency of dental radiographic examinations. The most recent statement of Association policy with respect to x-ray utilization appeared in "Recommendations in Radiographic Practices-March 1978." That stated policy follows:

Use professional judgment to determine the frequency and extent of each radiographic examination. Determine the minimum number of film exposures that will produce the desired diagnostic information.

The statement was printed in the March 1978 issue of the Journal of the American Dental Association; it is attached for your reference.

Each of our respective associations believes that formal and continuing education are key factors in assuring that an individual is and remains competent in the use of x-radiation. Our associations believe further that through such education individuals can be made to recognize the need to reduce or to eliminate unnecessary radiation in light of the potential harmful effects of low-level ionizing radiation to both patient and operator. It is in the area of education and training that I shall now focus attention.

With reference to education and training, I should emphasize that radiology is an integral part of the curriculums of each of the 60 dental schools in the United States. Further, providing didactic instruction, teaching radiographic techniques and providing clinical experiences in dental radiology are required for the accreditation of dental hygiene and dental assisting programs. In dental education, radiology instruction generally spans between two and one-half and three years of the traditional four-year educational sequence. Although comparable data

are not available for dental hygiene and dental assisting education, a comprehensive study of dental curriculums of all United States dental schools in 1975 and published in the report -- Dental Education in the United States - 1976 -- showed that 59 of the 60 dental schools (one school had not admitted its first class at the time of the study) provided from 19 to 278 clock hours of instruction in radiography. The institution reporting 19 instructional hours was a new school having only its charter class matriculated at the time the survey was conducted. The mean number of hours of radiology instruction was 88.0 hours; and the median number of instructional hours was 70.0 hours. In addition, supplementary instruction in radiology, specifically radiographic interpretation, frequently is provided in a number of other disciplines, such as oral diagnosis and treatment planning. Schools provide a mean of 118.9 hours and a median of 96.0 hours of instruction in oral diagnosis. The use and interpretation of radiographs are also an essential part of every subdiscipline of dentistry and additional instruction in radiology, thereby, is incorporated in the study of each subdiscipline, even though this component is not specifically identified as instructional time in radiology. More importantly, almost one-half of the schools reported an increased emphasis in all areas of radiology and almost one-third of the schools reported that they had increased the number of clock hours devoted specifically to radiographic instruction.

It is important to emphasize that in the section of the curriculum study report dealing with changes in curricular emphasis during the past 10 years, covering the period from 1966 to 1976, almost one-half of the 59 fully operational dental schools reported an increased emphasis in all sub-areas of instruction in dental radiology. Radiation safety and protection and interpretation of radiographs were specifically identified as the two areas which received the greatest increase in attention. It is apparent from these data that dental education has and, I am confident, will continue to recognize the need to review and to update instructional content in dental radiology as new knowledge evolves. It is, likewise, apparent that dental education is placing added and renewed emphasis on the hazards of ionizing radiation, radiation hygiene, radiation safety and protection. In short, dental education takes very seriously its obligation and responsibility of being assured that students are taught to use ionizing radiation intelligently and to base its use on professional judgment after a careful assessment of the individual patient's needs. Similar emphasis is placed on the concerns about the abuse and misuse of ionizing radiation and on the risks versus benefits to the patient.

Mr. Chairman, with that brief background, I should like at this time to give a brief review of a number of activities related to addressing the issues concerning ionizing radiation which have or are taking place within the American Association of Dental Schools, and the American Dental Association's Council on Dental Education and the Commission on Dental Accreditation. On these matters, the AADS works very closely and cooperatively with the Council and Commission.

From an historical perspective, the AADS' Section on Oral Radiology, in cooperation with the American Academy of Dental Radiology, developed curricular guidelines in 1973; and this document was made available to all dental schools for use by faculty responsible for teaching radiology to dental students. These guidelines were developed so that they could be used as course development aids. Further, that Section, in 1976, developed similar guidelines for use by faculty in dental hygiene and dental assisting programs. The Section on Oral Radiology currently is in the final process of revising these documents with a view to updating them; it is expected that the revised guidelines for dental school use will be published in the fall of 1980. These documents will then be disseminated to all educational institutions and will be published in the Journal of Dental Education.

To illustrate further the attention that radiology has received within the AADS organization, that Association's House of Delegates, at the 1979 annual meeting, adopted a position paper on "Ionizing Radiation." Officially, the AADS requested all institutions to review the procedures used in their dental clinics so as to control the use of ionizing radiation and to modify any practices that do not conform to accepted standards. In addition, the position paper urged all schools which have not established procedures to coordinate, monitor and control the use of ionizing radiation to establish such procedures. In making these suggestions, it was recognized that not all schools have clear policy dealing with these matters.

The continued commitment of AADS to deal with the issue of education and training is evidenced further by the fact that that Association's House of Delegates, at the 1980 annual meeting, adopted the following statements for inclusion in the AADS Policy Statements section on objectives. The approved Policy Statements are:

1. Dental education institutions have as a primary responsibility the preparation of qualified, competent dentists and dental auxiliaries capable of effectively without undue risk using ionizing radiation.
2. Students should be trained to critically assess the need for diagnostic radiographic information, evaluate the risk/benefit ratio for each diagnostic procedure, and establish an appropriate differential diagnosis based on clinical, laboratory and radiographic information.
3. Dental education institutions have the responsibility of minimizing to the greatest degree possible the potential risk to students, faculty, staff and the general public from any radiographic procedure.

4. Radiographic quality assurance programs should be implemented to assure the optimum quality of each diagnostic radiograph incorporating procedures that will restrict to an absolute minimum the amount of radiation received by the patient.

In addition, the following statement was added to the appropriate sections of the AADS Policy Statements dealing with dental, advanced education and auxiliary curriculums:

Radiology curricula should be based on sound, current educational philosophy and pedagogy to achieve the stated goals and objectives and reflect sensitivity to contemporary information regarding the risks and benefits to be derived from using ionizing radiation.

At this point, I should like to apprise the Subcommittee of activities concerning dental radiology with which the Commission on Dental Accreditation has been and continues to be actively involved. These activities demonstrate clearly the resolve and commitment of the Commission to deal with the issues and concerns being raised about the effectiveness of the educational process to educate users of ionizing radiation to protect patients adequately from unnecessary exposure to ionizing radiation. A major effort is devoted during accreditation site visits to reviewing and evaluating the education and training that dental and dental auxiliary students receive in all areas of radiology. The Commission, during an accreditation site visit makes a concerted effort to ensure that radiology education and training provided prepares dental and dental auxiliary graduates to be competent.

Further, site visit teams have been devoting major attention to reviewing clinical practices relating to controlling and monitoring use of ionizing radiation. The following are evaluated or reviewed during the visit:

1. Course content - depth and scope
2. Time devoted to teaching the subject of radiology in all subdisciplines
3. Sequencing of the subject in the curriculum
4. Faculty - numbers and qualifications
 - (a) Authority and responsibilities of radiology faculty
5. Technical support personnel, numbers and qualifications
6. Equipment - generators and darkroom
 - (a) Location of equipment

7. Guidelines and policies on controlling use of ionizing radiation
8. Review of institution's practices relative to:
 - (a) Use or non-use of radiographs in the patient screening process
 - (b) Use of radiographs during treatment, such as in endodontic therapy and during oral surgical procedures
 - (c) Teaching technique with use of manikins rather than live subjects
 - (d) Policy or policies in retaking radiographs
9. Quality assurance program in radiology

More specifically, the Commission requires, as a part of its accreditation review, that faculty who are responsible for providing instruction in specific subject areas complete a section of the Self-Study Manual dealing with radiology and provide detailed objectives and outlines of the course of instruction. That section of the Self-Study Manual is attached for the record. Specifically, with radiology, attention during the accreditation site visit is devoted to the depth and scope of instruction in each of the following sub-areas of radiology: radiation physics, interaction of x-radiation with matter, factors affecting radiographic image production, biological effects of ionizing radiation, radiation safety and protection, radiographic techniques and interpretation of radiographs. In addition to the review of the didactic or lecture component of the radiology course, the site visit team also devotes considerable time and effort to reviewing the preclinical and clinical component of the instructional program. The Commission also reviews the mechanisms employed by the institution to coordinate, monitor and control use of ionizing radiation to ensure the protection of the operator, the patient and the public at large.

During such visits, randomly selected patients' records are also reviewed for the purpose of assessing, among other things, if a quality control program for radiographs is being maintained, whether there is clear documentation of all radiographic exposures on the patient's record and whether the sequential log of exposure to ionizing radiation is recorded. A review of the institution's quality control program for equipment is also assessed. Further, the Commission evaluates the credentials of faculty teaching radiography to ensure that those having this responsibility have adequate training in the area. In this regard some believe that there is a need for additional qualified faculty in dental radiology. However, you should be aware that current federal authority to assist in the preparation of teachers in any specific

area is almost non-existent and the resources available to dental schools for such a purpose are extremely limited. Until dental educational institutions have the resources to prepare qualified teachers in any areas, it will be necessary for schools to use faculty who are "self-taught" or who have had continuing education courses in radiology.

To demonstrate further the Commission's concern and interest in correcting whatever problems might continue to exist in education, it adopted the following statement during its December 1979 meeting and stipulated that the statement be transmitted to all educational programs which are within its accreditation purview. The statement reads:

Strong emphasis must be given to the proper use of ionizing radiation within dental educational institutions because future dentists and dental auxiliaries will practice what they are taught in the classroom and what they observe and do in the clinics. The policies developed in dental schools must be integrated with the ionizing radiation policies and practices established within the respective health sciences centers.

The Council on Dental Education and the Commission on Dental Accreditation are giving special emphasis to the area of ionizing radiation on all site visits to dental educational institutions. It should be pointed out that the American Association of Dental Schools is in the process of developing policy statements and curricular guidelines on the teaching, use, monitoring and control of ionizing radiation. Using those and other references, the Commission on Dental Accreditation will draft statements on the critical issue of ionizing radiation to be included in accreditation guideline documents.

Schools of Dentistry can expect that more emphasis, monitoring and critical review of a school's ionizing radiation practices will be pursued with vigor in future site visits. Any deficiencies noted will be brought to the attention of the parent institution in the accreditation report.

During that same meeting, the Commission also concluded that a comprehensive study of dental radiology teaching should be conducted to elicit changes which have occurred since the 1976 dental curriculum study. This study will include, however, all educational programs accredited by the Commission. A survey instrument has been developed and field-tested in three schools to collect the detailed and updated information on changes in the radiology curriculum since 1976, data on qualifications of faculty who provide instruction in radiology, facilities and equipment, and clinical practices relating to controlling and monitoring use of ionizing radiation. The dental school questionnaire is scheduled for dissemination and data collection in mid-July 1980.

Another illustration of the desire of the Commission to focus appropriate attention to teaching of radiology to auxiliaries is the recently revised accreditation standards for dental hygiene and dental assisting. The revised standards become effective January 1, 1981 and state that: "...the curriculum must include scientific principles of radiology and practices in performing oral radiographic procedures." The standards also state:

Students must demonstrate competence in making diagnostically acceptable radiographs on manikins and must demonstrate knowledge of radiation safety measures prior to making radiographs on patients. Through scheduled instructional sessions, students must have the opportunity to develop competence in making radiographs on a variety of patients. Experience should include primary, mixed and permanent dentitions as well as edentulous or partially edentulous patients. The minimum number of acceptable radiographs of each type which each student must complete during the radiography course must be specified. Students must demonstrate minimum competence in making diagnostically acceptable radiographs on patients in the program facility prior to making radiographs during extramural clinical assignments. Faculty instruction and evaluation must be provided throughout the student's radiographic technique experience.

The program must develop and adhere to a policy on the frequency of exposing radiographs on patients and the number of permissible retakes. Radiographs must be exposed for diagnostic purposes, not solely to achieve instructional objectives. Institutions should assure that they are in compliance with state and federal laws related to radiation.

During the May 1980 meeting of the Council on Dental Education, considerable discussion centered around the need to communicate Council concerns about some alleged policies and practices of state and regional dental licensing bodies on use of radiographs in the licensing process. To call attention to the alleged practices and to protect patients from any unnecessary ionizing radiation, the Council directed that correspondence enumerating examples of problems be transmitted to the American Association of Dental Examiners (AADE) and to all state and regional dental licensing boards. In essence, the Council requested AADE, the Association representing all licensing jurisdictions, as well as each state and regional board "... to stimulate appropriate policy changes in state licensing board procedures" to preclude exposing patients unnecessarily to ionizing radiation during licensure examinations. Further, the Council suggested that AADE address the problem at the earliest possible time at both the executive and constituency levels.

It should also be noted that the Commission on Dental Accreditation, at its May 1980 meeting, concluded that each institution or program within its accreditation purview should be fully apprised of the various areas which the Commission has directed its site visit teams to review and assess during accreditation visits. In transmitting the correspondence to the administrators of dental schools and program directors of dental auxiliary and dental specialty educational programs, the Commission indicated that it "...will expect that radiology faculty will conduct an institution-wide appraisal of its dental radiographic practices to ensure that they are in compliance with accepted standards of practice."

The Commission has the mechanism in place for evaluating each program every seven years for the purpose of assessing whether institutions are complying with the accepted standards and practices. In this regard, the Commission is committed to ensuring that all students, dental and dental auxiliary, receive quality instruction in radiology and that programs use every means to control and monitor the use of radiation. Appended to our statement are some examples of the comments and recommendations made by the Commission after site visits to some education programs that relate specifically to the subject of radiology. These are comments and recommendations which were included in the accreditation reports prepared for these schools.

In view of the efforts and increased activities of the Commission on Dental Accreditation and the American Association of Dental Schools to work collaboratively in ensuring that students are provided with quality and appropriate instruction in radiology, it should demonstrate rather conclusively that the dental profession is not only interested in but has taken positive steps to ensure that the nation's public health and safety are safeguarded. Further, it should be clear that it is the intent of our respective Associations that graduates appreciate the need to minimize exposure to potentially hazardous and unnecessary radiation. Our Associations believe that they are dealing most effectively with the issues identified in the legislation before you. Our Associations believe that it is unnecessary for the federal government to develop and promulgate minimal standards and guidelines for the accreditation of educational institutions which conduct education programs in radiologic services. Our Associations believe that it is the profession's public responsibility to assure adequate protection of public health from unnecessary radiation exposure and to assure efficacious patient radiologic services. In view of the Commission's actions, there appears, in our judgment, to be little merit in having the federal government impose dictation on educational institutions when these issues are being addressed effectively and most efficiently by the Council on Dental Education, the Commission on Dental Accreditation and the AADS.

Through the years in supporting formal education, the American Dental Association has at the same time continuously reiterated its support for the licensing process, providing that the process remains with each state's licensing system. Traditionally, two members of the dental care delivery system have been licensed, the dentist and the dental hygienist. Concurrently, the ADA has voiced strong opposition either to federal licensure or to federal intervention into the state licensing system. The ADA's position on this issue and its rationale for taking this position were made clear by the 1975 House of Delegates of the ADA.

In supporting state licensure for dentists and dental hygienists to ensure that only qualified individuals provide care to the public, the profession was not convinced in the past that there was a need to license the dental assistant. It has been the profession's contention that the criterion which should determine the need to license any category of personnel should be based upon the total responsibility of that category of auxiliary in the dental care delivery system and on how that auxiliary functions in the delivery system. The profession has been steadfast in believing that it is inappropriate to license an individual to perform specific tasks or individual functions, such as making radiographic exposures. Further, the need to license the dental assistant has not been viewed as being essential since they function under the direction and supervision of the dentist in the delivery system and since the dentist assumes total responsibilities for patient care.

From an historical viewpoint, it should be called to the Subcommittee's attention that the ADA, in 1971, established a moratorium on the licensing, registration or certification of additional kinds of dental auxiliaries until more definitive information was available about the relative role of the dentist and expanded function dental auxiliaries. As noted previously, in 1971 the dentist and dental hygienist were already being licensed while a voluntary certification process was available to the traditional chairside dental assistant who completed an accredited dental assisting educational program. Perhaps it might prove helpful to the Subcommittee if background information on the reasons for the ADA's adoption and maintenance of that moratorium was provided.

In this regard, there is no question that the Association's position was influenced, in large measure, by the results of federally sponsored studies on licensure. Specifically, the June 1971 Department of Health, Education, and Welfare's Report on Licensure and Related Health Personnel Credentialing recommended that "All states are urged to observe a two-year moratorium on the enactment of legislation that would establish new categories of health personnel with statutorily-defined scopes of function." The rationale provided was that it would be unwise to

develop new statutes that define functions narrowly and establish rigid requirements for education and training at a time when education of health professionals was undergoing rapid change, when the organization of health care was being modified and when the functions of health workers in the various service settings were being revised and broadened. In the 1973 follow-up report, Developments in Health Manpower Licensure, the moratorium recommendation was subsequently extended for an additional two-year period. In June 1976, A Proposal for Credentialing Health Manpower was prepared by the Subcommittee on Health Manpower Coordinating Committee. Recommendation IV in that document suggests that:

States should entertain proposals to license additional categories of health personnel with caution and deliberation. Before enacting any legislation that would license additional categories of health manpower, states should consider the following factors:

1. In what way will the unregulated practice clearly endanger the health, safety and welfare of the public, and is the potential for harm easily recognizable and not remote or dependent on tenuous argument?
2. How will the public benefit by an assurance of initial and continuing professional competence?
3. Can the public be effectively protected by means other than licensure?
4. Why is licensure the most appropriate form of regulation?
5. How will the newly licensed category impact upon the statutory and administrative authority and scopes of practice of previously licensed categories in the state?

While the profession has reservations about other specific aspects of that document, it did concur that licensure did not appear to be the most appropriate form of regulation for dental assistants.

It should be pointed out that as recently as March 1979, in an address delivered at the Occupational Licensure Conference of the American Enterprise Institute in Washington, D.C., the Chairman of the Federal Trade Commission summarized the concern of that agency about the danger to the public of licensing occupations indiscriminately.

It should be apparent that the ADA's support of the moratorium on licensing dental assistants has been prompted by a responsiveness to federal and public concerns as well as to the concerns of the profession. The profession believes that before moving in the direction of licensing additional auxiliaries, it should be demonstrated beyond question that any new system, as proposed in this legislation, will, in fact, correct any perceived problems that exist today.

It has been the ADA's contention that the Commission's accreditation program for dental assisting and the current certification process, providing that that process requires completion of an accredited program, gives the public effective protection.

It must be emphasized that the ADA House of Delegates has during the past two decades consistently supported the formal educational process for dental assistants. Evidence of such support is demonstrated by the following House and Council actions: In 1960, the ADA House approved "Requirements for the Approval of a Certification Board for Dental Assistants" thereby giving the profession's recognition to the Certifying Board of the American Dental Assistants Association as the certifying agency for dental assistants.¹ In 1965, the House, in approving a termination of a 104-hour extension study courses as a means by which individuals became educationally eligible to take the certification examination, supported completion of a one-year formal educational program as meeting the eligibility requirement for examination by the recognized Certifying Board.² In 1969, the Council denied a request from the Certifying Board that the educational requirement be waived as a prerequisite for examination.³ In 1974, the ADA House considered two resolutions which would permit reinstatement of the 104-hour extension study course as a means for meeting the eligibility requirement for the certification examination. One of these resolutions was withdrawn while the other was postponed indefinitely, demonstrating once again the ADA's support for formal education.⁴ In 1977, the Certifying Board of the American Dental Assistants Association again requested that the Council and ADA House approve a proposal for a three-year study modifying the educational standards for certification to allow individuals who have 6,000 hours of work experience but who have not completed an accredited dental assisting program to take the examination. In its 1978 Report to the House, the Council, in recommending approval of the request, stated in its Report "...in considering this experimental eligibility change for certification, is admittedly deeply concerned about what unknown effect this may have on the continued growth and effectiveness of formal accreditation education programs. The Council and the dental profession have struggled over the years to upgrade formal education for dental assistants and still believe formal education programs are the best mechanisms for developing a capable workforce."⁵

The impact of the ADA's strong support for formal education for the dental assistant is significant. It is evidenced by the fact that in 1961 there were only 26 accredited dental assisting programs in the United States. In 1980, there are 296 such programs. In 1961 there were 531 graduates of dental assisting programs; in 1978-79 this number increased to 6,036 graduates, as compared to 5,424 dental graduates. These and other relevant data are shown on the graphs and tables which are appended to this statement. The ADA House approved the request.⁶ (A copy of that section of the Council's report to the 1978 House dealing with this matter is appended to this statement.)

It is my belief that the Council and the American Dental Association have recognized the need for and have demonstrated, during these past two decades, support for formal education for the dental assistant.

In conclusion, let me state unequivocally that dentistry, dental hygiene and dental education are opposed to federal intervention in the educational process by dictating curriculum, whether they be general or specific. Our Associations believe firmly that appropriate expertise exists within the dental profession and in education to determine what course or curriculum content should be to adequately prepare the dentist, the dental hygienist or the dental assistant for practice. Likewise, the ADA and ADHA are strongly opposed to any federal intervention into the licensing process. Dentistry and dental hygiene both believe strongly that all decisions relating to licensure should remain at the state level.

I should like to conclude by stating that the ADA, ADHA, and AADS do not believe that this proposed bill is needed. The legislation would authorize governmental assumption of an activity which is already being carried out through well-established private efforts and which results in well-trained and qualified radiologic personnel. The present accreditation and licensing system works well and follows in the traditional mode of developing quality education in this country. There is no justification for a governmental usurpation or duplication of these activities such as that proposed in the legislation before this Subcommittee.

At this time we would be pleased to attempt to answer any questions.

REFERENCES

1. American Dental Association. Transactions, 1960. Chicago: 1961, pp. 33-41, 49, 207.
2. American Dental Association. Transactions, 1965. Chicago: 1966, pp. 24-25, 44, 319-20.
3. American Dental Association. Transactions, 1969. Chicago: 1970, p. 55.
4. American Dental Association: Transactions, 1974. Chicago: 1975, pp. 671-673.
5. American Dental Association. Annual Reports and Resolutions. Chicago: 1978, p. 33, 39.
6. American Dental Association. Transactions, 1978. Chicago: 1979, p. 520.

NUMBER OF GRADUATES FROM ACCREDITED PROGRAMS FROM 1961-1979

<u>YEAR</u>	<u>DENTISTS</u>	<u>DENTAL HYGIENISTS</u>	<u>DENTAL ASSISTANTS</u>
1961	3,290	1,023	531
1962	3,207	1,219	658
1963	3,233	1,257	718
1964	3,213	1,429	895
1965	3,181	1,492	1,241
1966	3,198	1,650	1,593
1967	3,360	1,739	1,963
1968	3,457	1,834	2,302
1969	3,433	2,231	2,715
1970	3,749	2,465	2,955
1971	3,775	2,926	3,922
1972	3,961	3,516	4,814
1973	4,230	4,137	5,297
1974	4,515	4,310	5,684
1975	4,969	4,568	5,972
1976	5,336	4,616	6,208
1977	5,177	4,847	6,502
1978	5,324	5,026	6,644
1979	5,242	5,149	6,043
<u>TOTAL</u>	<u>75,850</u>	<u>55,434</u>	<u>66,657</u>

STATEMENT OF JOCELYN C. ROMAN

Mrs. ROMAN. Mr. Chairman and members of the subcommittee, my name is Jocelyn Roman, from Huntington, Conn. I am executive director of the Fones School of Dental Hygiene at the University of Bridgeport, in Bridgeport, Conn. I am also chairman of the American Dental Hygienists' Association's Council on Consumer and Government Relations.

On behalf of my association, I would like to state that we both support and endorse the record statement transmitted to you by Dr. Brown. AHDA is also opposed to H.R. 6057.

Our association firmly believes that all dental personnel assigned radiological duties and functions in a dental office, in the interest of the protection of the consumer's health, safety, and welfare, should be no less qualified than dental hygienists by virtue of education and training, and reinforced by the utilization of effective competency assurance credentialing mechanisms, such as State or regional licensure and/or certification. We believe that the best insurance against excessive radiation exposure to patients is a well-trained individual who fully understands the mechanics and physiological effects of radiography.

Dental hygiene education and testing demonstrates that hygienists are eminently qualified to expose dental radiographs. All dental hygienists must be licensed to practice in the 53 territorial jurisdictions of the United States. To be eligible for a license, applicants must be graduates of dental hygiene programs approved by the State dental board and which have also been accredited by the commission on accreditation.

In addition to each State licensing examination, most graduating hygienists take the national board examination. The national board exam contains 45 questions—or 13 percent of the total examination—on exposing and processing radiographs. The national board exam also utilizes case studies to test hygienists in their ability to use radiographs to identify physiological and pathological landmarks.

State and regional boards of dental examiners, with increasing frequency, are utilizing the clinical evaluation instrument recently developed by our association. It is a standardized, criterion-reference clinical examination to assess the competency of dental hygiene. Approximately one-fourth of this examination is devoted to radiographic technique and recognition.

I would like to cite an example. Students graduating from the Fones School of Dental Hygiene at the University of Bridgeport, where I am executive director, have completed 56 clock hours of both didactic and clinical instruction in radiography. This instruction insures that the appropriate knowledge of theory and technique for exposing and processing X-rays have been mastered.

Perhaps more important, however, is our students learn the potential hazards of unnecessarily exposing a patient to radiation. Clinical competencies are continually reinforced in order to minimize exposure of radiation. We teach our students that X-rays are taken only when they are necessary for diagnostic purposes.

The American Dental Hygienists' Association does not believe that this proposed bill, Consumer-Patient Radiation Health and Safety Act, is needed. It would authorize a Government duplication

of an activity which is already being carried out through a well-established accreditation and licensing system.

Mr. WAXMAN. Thank you very much.

Ms. Butler?

STATEMENT OF JANELLE BUTLER

Ms. BUTLER. Mr. Chairman and members of the subcommittee, I wish to thank you for this opportunity to be with you today. I am Janelle Butler, president of the American Dental Assistants Association. Accompanying me is Michael R. Lemov, of Leighton, Conklin, Lemov & Jacobs, counsel for ADAA.

We commend this subcommittee and its distinguished chairman for this demonstration of concern with the important issue of excessive patient radiation exposure. ADAA is a voluntary professional society of approximately 20,000 dental assistants nationwide. We are pleased to offer our strong endorsement for the Consumer-Patient Radiation Health and Safety Act—H.R. 6057, cosponsored by Mr. Luken and Mr. Maguire, members of this subcommittee, as well as by Mr. Lundine, who has testified so forcefully this morning.

I would also like to commend Mr. Eckhardt, chairman of the Subcommittee on Oversight and Investigation, for this persuasive and thorough report on this subject.

The devastating consequences of excessive and unnecessary X-ray usage have been of great concern to us for many years. As professionals who deal on a daily basis with radiation for diagnostic purposes, we are distressed by the estimate that 1,000 or more people lose their lives each year because of ill health due to excessive radiation exposure. In an appearance before the Oversight and Investigations Subcommittee of this committee on July 31, 1979, we urged support for legislation similar to the bill presently under consideration. Within a few months, three separate bills were introduced: H.R. 6057, H.R. 5934, and H.R. 6023. In the Senate, Senator Randolph proposed similar legislation, S. 500, in February 1979. Each of these bills has been designed to provide patient health and safety benefits by insuring that persons who administer radiological procedures have taken accredited courses and have been certified as competent by States under Federal guidelines.

We are pleased that the Senate Committee on Labor and Human Resources has approved Senator Randolph's bill offered as an amendment to the Health Professions Training and Distribution Act, S. 2375. The Randolph bill also provides for the establishment of exposure guidelines by the Department of Health and Human Services. The amendment was unanimously adopted on June 27, 1980, and that was a nice birthday present for me. We are optimistic that when the full Senate considers the bill later this summer, it will reaffirm its committee's commitment to legislation that protects the public health and safety.

As one of the groups most affected by these legislative proposals, ADAA wholeheartedly supports this timely focus upon the operators of radiologic equipment. We believe that the enactment of this legislation will represent an important step toward eliminating many of the very serious health abuses that presently result from improper and unnecessary utilization of radiation in diagnostic

medical and dental procedures. We are convinced that the Federal encouragement of State credentialing efforts envisioned in H.R. 6057 is the minimum necessary to insure the public health and safety. We applaud this subcommittee for its efforts to cure what has been for too long a very serious national health problem.

Current State laws, in most instances, include absolutely no standards controlling the education, testing, and certification of individuals who are expected to expose patients to radiation in diagnostic medical and dental procedures. This is true despite the fact that the safe operation of medical and dental X-ray equipment demands a significant degree of skill and training if the health of both the patient and the operator are not to be unnecessarily threatened. Even in the 10 States that have registry or licensure requirements for persons who expose radiographs, there are rarely adequate standards for proficiency in exposure techniques. Without initial and continuing measurements of radiographic competency, even existing State credentialing programs are inadequate to assure safety for the public.

As professionals, ADAA members are especially sensitive to the potential dangers of low-level radiation. We know that in most dental settings, it is the dental assistant who is primarily responsible for exposing and developing dental X-rays. When the dental assistant is improperly trained, untrained or unqualified, the odds are great that the amounts of radiation to which the technician and patient will be exposed over a period of time may rise to unacceptable levels. The possibility of a dental assistant or a patient suffering severe bodily harm as a result of this overexposure or improper exposure to potentially hazardous radiation is not merely speculative.

We know a dental assistant who is presently living in New Orleans, who during early years as a dental assistant, was taught to stand on one side of the chair while X-rays were being taken, and this lady at this time has no hair on the right side of her head.

Consider these statistics: This year, approximately 275 million X-rays will be performed by medical and dental X-ray operators. As already stated by Congressman Luken, this represents 90 percent of the man-made radiation—including radiation from nuclear plants—to which the general public is exposed. The Food and Drug Administration's nationwide evaluation of X-ray trends (NEXT) program found that a patient may receive more than 100 times as much radiation in one clinic as in another when undergoing the same X-ray examination.

Another indication of the severity of the problem is the final recommendation issued by the FDA on June 17, 1980. The FDA recommends that insurance carriers and other third parties refrain from requiring administrative dental X-ray examinations. This means that unless the X-ray is needed specifically for immediate dental needs, a patient should not undergo the exposure. The recommendation states in part:

Redundant radiographic procedures, whether before or after treatment, are also inappropriate because they represent an additional radiation exposure to the patient with no added benefit.

Obviously, redundant exposures due to faulty operating techniques are just as hazardous to patients as duplicate exposures required for administrative purposes.

We know that much diagnostic radiation exposure is unnecessary as well. Some of these medical and dental X-rays will be duplicative because the improper training of the operator who originally took the radiograph results in X-rays which are technically unsatisfactory.

Not too long ago, I had a young dental assistant come up to me, and she said:

You know, Janelle, I am so excited because today my dentist told me, "Lucy, on your lunch hour, since you have only been here a short time, why don't you and Mary take some X-rays of one another, and then when you come back in from lunch, I will view them, and I will let you know where you made your errors. Then you all can correct them later on during your lunch hours, since neither one of you have had any formal education in dental assisting."

In addition to the high risk that these inadequate procedures will increase patients' future ill-health costs, reexposures required by inadequate radiographic techniques inflate the estimated \$6 billion annual cost of diagnostic X-rays. In view of increasing public concern over both the high cost of medical treatment and the potential danger of low-level radiation, we believe that this subcommittee should continue without delay its responsible efforts to structure a solution for these problems.

In order to significantly reduce the amounts of unnecessary radiation to which patients and health care professionals are presently exposed, the Federal Government need take only minimal reasonable steps. One obvious step is the assurance of adequate training and qualifications for the operators of medical and dental diagnostic equipment that emits radiation. In its report of the work group on exposure reduction, issued in June 1979, the Interagency Task Force on the Health Effects of Ionizing Radiation concluded that "The improvement of user technique is an important exposure reduction effort."

The task force's report included the following recommendations:

Promote improvement in the education, training and proficiency of medical radiation technologists (e.g., X-ray, nuclear medicine and radiation therapy) by supporting the development of curricula, educational materials, testing materials, and methods of clinical competency measurement.

Develop model licensure or credentialing guidelines, including periodic retraining and certification for medical radiation technologists and provide assistance to the States in adopting and implementing them.

We believe H.R. 6057 represents a balanced approach toward alleviating unnecessary exposure due to inadequately trained or unqualified operators of medical and dental X-ray equipment. It should be noted that ADAA's attention is directed solely toward the individuals who operate the X-ray equipment and not toward the physicians and dentists who prescribe the X-rays.

Physicians and dentists are already trained and qualified. ADAA does not encourage their inclusion within the scope of the proposed legislation because we perceive no need for the Federal Government to encourage State accreditation and certification activities for those health professionals. Instead, ADAA urges that the committee focus upon the individuals who, far more often than physicians and dentists, actually are responsible for operating X-ray

equipment—the radiologic technologists, the dental assistants, and other medical and dental professionals.

Although voluntary credentialing programs for such personnel exist through private, nonprofit, independent organizations, the voluntary aspect of those programs means that not all persons who expose patients to X-rays become covered by the programs. For example, ADAA estimates that there are approximately 150,000 dental assistants who may perform radiologic procedures. At this time, ADAA's certifying board has certified approximately 55,000 assistants. However, because certification is valid for a maximum of 2 years, we estimate that 19,000 dental assistants hold valid certifications from the certifying board in any given year. Clearly, in the absence of a more effective program, only a small portion of the operators will pursue certification.

Because of the current scrutiny of any new Federal program involving regulation or expenditures, I would like to bring to your attention certain key features of the proposed legislation which pertain to these concerns. At the outset, let me state our firm belief that the provisions of H.R. 6057 will neither demand commitment by Federal or State governments to expensive programs nor burden them or any X-ray operator with an unreasonable degree of regulation.

I would like to focus upon two important aspects of H.R. 6057: First, the allocation of Federal and State responsibilities; and, second, the financing of organizations and/or programs established to perform accreditation and credentialing functions pursuant to the bill's requirements.

We believe the Federal-State allocation of responsibilities in H.R. 6057 is very sensible. The Secretary of HHS is directed to establish minimum standards in two areas: First, for the accreditation of educational programs conducted by institutions for persons who administer radiologic procedures; and second, for the certification of persons who administer radiologic procedures. In addition, the Secretary is authorized to give technical assistance to the States, including the preparation of a model law for consumer-patient radiation safety which States may adopt. Finally, the Secretary may make grants to States, educational institutions, and nonprofit organizations that are fostering the implementation of the act.

The role of the Federal Government is thus limited to promulgation of standards which will provide assistance to States and institutions. We stress that under this legislation, the Federal Government will not be authorized to engage in credentialing.

This is not to say, however, that the Federal Government will remain totally powerless to influence States to implement minimum standards. Congress has a legitimate interest in assuring the eventual establishment of minimal requirements nationwide. The current bills permit States to establish their own programs, tailored to their own needs yet assisted by Federal funds. Rather than imposing Federal standards upon States after a certain period of time, as would have been required under earlier bills, the present bills provide that 3 years from the date of enactment, the failure of a State to adopt the Federal or comparable standards will result in suspension of Federal funds targeted for services or equipment used in radiologic procedures. We believe that this provision is

calculated to allow the States the maximum degree of freedom to act responsibly in remedying a serious health hazard.

This brings me to my second topic: the expense involved in providing these health and safety benefits. There are two aspects; to this, namely, how the programs are to be financed and how much of the cost the Federal Government will bear.

Under the terms of these bills the Secretary may delegate to approved nonprofit organizations the duty to accredit education programs or to certify persons who administer radiologic procedures. In order to promote the goals of the legislation, the Secretary is authorized to make grants to educational institutions, States, and nonprofit organizations to help meet their costs for developing and operating accreditation and certification programs.

We would like to point out that some of these activities would be paid for by the fees generated by institutional applicants for accreditation or individual applicants for certification. For example, at last July's hearing before the Oversight and Investigations Subcommittee, Joseph Ward, chief of the radiologic health section of California's Department of Health Services, testified that California's certification program cost roughly \$400,000 to operate for an entire year. Thirteen persons were assigned to the program, which offered certification examinations each month at two locations in the State. About half of the cost was covered by an annual fee paid by the technologists. This seems a modest price to pay for such significant protection against cancer and other diseases. Moreover, Mr. Ward testified that California expected to save approximately \$50 million a year in future ill-health costs associated with the exposure reductions made by the program. That is a cost-benefit ratio of over 100 to 1.

Finally, certain States already have radiologic programs established, although some of these deal only with equipment inspection. Existing radiation equipment programs could be expanded to include accreditation and credentialing functions as well. At this time, we are aware of only 10 States and Puerto Rico whose programs include a licensure or certification of radiologic technologists. None of those programs, of course, follow any consistent guidelines because no minimal Federal standards yet exist.

Similarly, independent private certifying organizations need not be created from scratch, as several are already in existence. One such organization is the certifying board of ADAA which provides extensive evaluation of radiation hygiene and radiographic exposure techniques in its examination of applicants for certification. The certifying board is separate and autonomous from ADAA, and its sole responsibilities are testing, credentialing and recertifying. The certifying board currently administers seven dental-related testing programs for dental auxiliaries and one continuing education renewal program for certified dental auxiliaries.

ADAA is aware of the reluctance on the part of Congress to venture into health professional credentialing activities. Our membership believes, however, that the Federal action envisioned in H.R. 6057 is not Federal credentialing. It is only the encouragement of State credentialing according to national guidelines. It is the minimum necessary to protect the public against excessive radiation exposure. Most States have failed to act promptly in this

area. We urge this subcommittee to report H.R. 6057 favorably. Generations of unborn Americans will thank you.

We have appreciated this opportunity to present our views. We look forward to working with you, Mr. Chairman, and your able staff. We would be pleased to respond to any questions you may have.

Mr. WAXMAN. Thank you very much. Dr. Brown, I was impressed by the steps you outlined that ADA takes to insure adequate training of dentists in the use of X-rays, but FDA told us that they saw the problem primarily as a lack of supervision of those people doing the X-ray work. Do your educational and clinical requirements include supervision of anyone using radiologic procedures?

Dr. BROWN. I have to speak generally and perhaps more specifically about our school. Part of the educational program for the training of dentists, and I would assume that probably the majority of the institutions are now doing it, has to do with personnel management training; that is, retention, continuing education. This is a growing component of dental education and it comprises one of the areas that the commission on dental accreditation looks at when it makes its accreditation site visits. Of course, the dental hygienist or the dental assistant is on the premises at the time the dentist is there in providing these kinds of services; we may not be perfect, but we are headed, I think, in the appropriate direction.

Mr. WAXMAN. Dr. Villforth, from FDA, testified earlier that this bill would only affect 10 percent of the problem, because we are talking about a relatively small number, 10 percent, of X-rays that are taken by people who would be covered by this legislation. Most of the X-rays, he maintained, are in institutions that have other ways, either through accreditation or otherwise, of checking on the quality of X-ray care, and educational requirements of people getting that care. How do you respond?

Ms. BUTLER. This doesn't involve or include the dental field. Did he indicate that it did not—that 10 percent did not?

Mr. WAXMAN. I don't know that he did or not, do you plan to include the dental field?

Ms. BUTLER. I would plan to include it, but I didn't think that that 10 percent included it. It would be much higher if it was included.

Mr. WAXMAN. What percentage would you estimate?

Ms. BUTLER. I am not real sure what percentage I would estimate, Mr. Waxman. We will do some research on this and get this answer for you, if you would like. Could I ask my counselor to comment on this?

Mr. LEMOV. Mr. Chairman, I think the question you have asked is on the percentage of X-rays administered by unlicensed operators in the dental field. We will try to get you an estimate on that. It will be fairly difficult, because of the lack of detailed statistics in this area, but I think your own oversight committee estimates that 100,000 of the 150,000 operators in the dental field are unlicensed.

Mr. WAXMAN. I would like a specific response to the testimony we received from FDA, where the estimate of the impact of this legislation would be on around 10 percent of the X-rays that are taken. I might have misunderstood that testimony. I want you to look at it, and I want to hear your response to it. Yes, Dr. Brown.

[The following letter was received for the record:]

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October 2, 1980

The Honorable Henry A. Waxman, Chairman
Subcommittee on Health and the Environment
House Committee on Interstate and Foreign
Commerce
1721 Longworth House Office Building
Washington, D.C. 20515

Re: H.R. 6057

Dear Mr. Chairman:

On behalf of the American Dental Assistants Association (ADAA), we thank you for the opportunity to appear before the Subcommittee on Health and the Environment on September 5, 1980. It is a pleasure to respond to the question you raised at that public hearing.

Specifically, you requested a response to the testimony received from John Villforth, Director of the Bureau of Radiologic Health, that non-credentialed radiologists expose the public to only ten percent of the population dose of radiation received from diagnostic x-rays.

We are informed that the conclusion was based upon a compilation of NEXT (National Evaluation of X-Ray Trends) and exposure study data. We believe the use of NEXT data renders the BRH conclusion inaccurate for several reasons.

NEXT is a voluntary data gathering system. There is no guarantee of the statistical accuracy of that data or conclusions based upon that data. Further, NEXT data covers only medical x-ray equipment. There is comparable data gathering for dental x-rays through the DENT program (Dental Exposure Normalization Technique). However, the Bureau of Radiologic Health conclusion is based solely on medical x-ray data, with no explanation given for such limited data.

The omission of dental x-rays is significant. While 130,000 medical units are used for 186 million examinations annually, 172,000 dental units are used for 92 million examinations annually. Since dental x-rays account for one-third of all x-ray examinations, failure to analyze the use of credentialed and non-credentialed operators for those procedures raises serious doubts about the BRH generalization concerning population dose.

It is not possible to extend the NEXT data to account for dental procedures. The percentage of non-credentialed operators used for dental radiographs probably exceeds the percentage of non-credentialed medical operators. As Mr. Villforth stated in his testimony before the Subcommittee, BRH estimates that about 145,000 of the 200,000 dental hygienists and assistants that conduct x-ray exams are non-credentialed. Mr. Villforth further testified that about 85,000 of the 130,000-170,000 persons now operating medical x-ray equipment are certified. Therefore, the data collected from the NEXT program reflects a greater percentage of credentialed operators than would be reflected in DENT data, and the failure to include dental radiographic procedures seriously undermines the BRH assertion.

The Subcommittee on Oversight and Investigations of your Committee has noted that there is no threshold dose level for most of the carcinogenic effects of radiation:

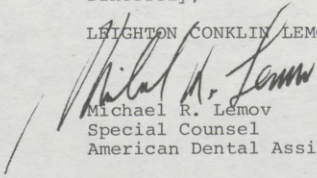
Since the late 1950's most scientists have accepted the no-threshold hypothesis, which holds that any dose of ionizing radiation can increase the risk of developing cancer in many organs and tissues of the body. Science so far has been unable to quantify exactly the correlation between radiation involved cancer and a given dose. 1/

Ninety-two million dental x-ray examinations are conducted annually. Administration by unqualified persons exposes the public to serious health hazards. The fact that large numbers of these x-ray examinations are given by uncertified personnel underscores the importance of providing the states with the tools necessary to provide a minimum accreditation procedure.

We thank you for this opportunity to respond to your concerns. If we can provide any further information to you, please let us know.

Sincerely,

LEIGHTON CONKLIN LEMOV & JACOBS


Michael R. Lemov
Special Counsel
American Dental Assistants Association

MRL/sde

1/ "Unnecessary Exposure to Radiation From Medical and Dental X-Rays", Report of the Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce, August, 1980, page 1.

Dr. BROWN. Mr. Chairman, I have some hard data that may be helpful to the committee. Since 1961, there have been 66,657 dental assistants who have been graduated from accredited programs. During that same period, there have been 55,434 dental hygienists graduated from accredited programs. Clearly we are not certain how many of those are in the current work force.

There are 50 percent, roughly, of all dentists in the United States who employ a dental hygienist, and we would assume that the entry point for patients in most of those offices would be through the dental hygienist, who in the course of her prophylaxis, her examination, her collection of diagnostic materials, would probably be the one securing the radiographs.

Now, you use those numbers and add to them the other 50 percent of the dental offices which do not have a hygienist, but may well have formally trained dental assistants, and the percentage that the FDA talked about may not be too far off.

Dr. Carter?

Mr. CARTER. Thank you, Mr. Chairman.

Dr. Brown mentioned that while the dentist was away for lunch, these two hygienists were told to X-ray one another's teeth.

Ms. BUTLER. They were assistants, Mr. Congressman.

Mr. CARTER. Thank you, ma'am; dental assistants. Were you the culprit in this case?

Dr. BROWN. I wasn't the one who said anything. It was Mrs. Butler.

Mr. CARTER. Were you the dentist?

Dr. BROWN. No, I work in Oklahoma City instead of New Orleans.

Mr. CARTER. Really, I never heard of anyone playing with X-rays in that manner. If you study the history of X-rays know that von Roentgen was the man who invented them. What happened to von Roentgen, Ms. Butler?

Ms. BUTLER. Not being a real history enthusiast, I wouldn't dare answer that question, because I promise you I would probably give you the wrong one, but I think he died a very sad and serious death.

Mr. CARTER. As I said, von Roentgen invented X-rays, and he lost his fingers, as I recall it. I thought being one who studied radiology a great deal, you would perhaps know that. And, of course, Madame Curie was the one who first isolated radium, I believe. What happened to her? You don't know that?

Ms. BUTLER. No.

Mr. CARTER. What happened to Madame Curie? She died of cancer.

Dr. BROWN. She did.

Mr. CARTER. I think that anyone who takes a course in X-rays should know the history of the people who have developed them. That is not just being a history buff. Actually, we learn that from medicine when we study about X-rays and about radium, and so on. Certainly I feel that minimum standards should be in place everywhere. I have watched this rather carefully. I come from a small town in southern Kentucky. Years ago, we developed our X-ray diagnostic plan. We conducted it in a lead-lined room, with a lead screen through which the technician could observe the patient

as he or she was being X-rayed, and it just happens we have a licensed technician, for which I am thankful. She seems to be quite good. I would hope that we could arrive at a solution to this problem by helping the States initiate their own programs without interference from the Federal Government. I have the utmost faith in most of the people to whom I have gone for X-rays. Of course, I know that X-rays can be overused, and I just can't understand that dentist who had his two technicians or technologists, play around with an X-ray machine, X-raying teeth. It is almost beyond comprehension.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Dr. Carter. Of course, the dentist who made this outrageous suggestion is already licensed. He has presumably met educational requirements that are spelled out in detail.

Dr. BROWN. Mr. Chairman, the American Dental Association board of trustees is going to be proposing to its house of delegates next month model State laws pertaining to inspection of equipment and credentialing of personnel. I don't know what is going to happen to the proposal, but it is coming from the supreme authority of the Association, and at least it indicates to you the interest that that organization has.

Mr. CARTER. I am thankful we have those laws in Kentucky, Doctor, and I believe they are very good, though perhaps not as effective as they should be.

Thank you.

Mr. WAXMAN. Mr. Maguire?

Mr. MAGUIRE. Thank you, Mr. Chairman.

Dr. Brown, people have recognized the problem for some years. Has the association decided just now to move in the way that you just described, or is this a part of a continuing effort on their part? Could you tell us whether you have done anything on this in the past, or whether what you are about to do is in any way stimulated by H.R. 6057 and similar legislative proposals?

Dr. BROWN. Frankly, I think we are way ahead of you. Over the past 10 years the ADA, has transmitted about 100,000 filters and collimators to dentists around the country. In concert with American industry, the fast films, the electronic timers, the collimators, the filters, lead aprons, the cervical collars, the automatic processors have been developed. This has been going on, frankly, long before the Congress expressed an interest in it.

The interest of the American Dental Association in radiation safety is ongoing. I think it is fair to say that it has been stimulated even further by the recent interest of the Congress. Our accrediting visits look more precisely at the radiology components of dental schools' educational programs. Resolutions presented to the house of delegates frequently speak to policy and radiation safety. We have for the record a detailed statement from our council on materials and devices on effective ways to secure high quality radiographs with maximum safety to the patient and the operator. This was published within the last 3 or 4 years and reflects an ongoing process. I don't know that Congress has increased our sensitivities to the issues. They have been there for a long time.

Mr. MAGUIRE. Ms. Butler, two of today's witnesses, with whose prepared statements I have had a chance to familiarize myself, argue that this bill is duplicative of existing authority—law. I am wondering what you make of that argument. If it is duplicative, could we expect anything more to be done than has been done in the past? If it does not duplicate, if the bill is new, can we expect anything to be done that has not been done in the past? If you believe that the legal authority is there already, what would your explanation be as to why nothing has been done in the past? I got tangled up in that. Is it clear?

Ms. BUTLER. Not really.

Mr. MAGUIRE. There are two possibilities. People argue that it is duplicative. If there is authority already the first question is, Why has nothing been done in the past? The second question is, if we are, in fact, adding something here that needs to be added, what reason would we have to believe that anything significant would be done, if nothing has been done in the past?

Ms. BUTLER. I will attempt to answer that. I don't believe that it has been duplicative. I do feel that changes have to be made. I cannot argue the fact that our educational programs aren't outstanding, because they are. They provide us with good qualified, educated dental assistants. The fact that we cannot retain these in the field, I cannot tell you. I can only let you surmise why this isn't always the case. They do leave for various reasons, or they do not enter the field.

The problem, as I see it, is that we have so many dental assistants involved in everyday work, and this isn't hearsay. I am an actively employed dental assistant and have been for 22 years. These are the dental assistants who provide services for the dentist who is a supervisor on the premises when he isn't in the room, or when he is too busy to supervise. The indication was made earlier that the patient would know when a part of the body was subjected to radiation. How would the patient know, especially if that operator didn't know how to direct the collimator, how to take the X-ray, if that uneducated operator didn't know exactly what he or she was doing to themselves. These are the changes that I see must be made. Did I help any?

Mr. MAGUIRE. Accreditation and certification standards are one of the objectives here. Right? We have no Federal standards now?

Ms. BUTLER. None.

Mr. MAGUIRE. Even though the FDA representative argued that this was duplicative of existing authority.

Doctor, would you like to comment on this?

Dr. BROWN. On the accreditation issue, the commission on dental accreditation has very precise standards for accrediting the various institutions, including dental hygiene, dental assisting and dental educational programs. They recently have been updated to make them more precise, and they are directed at the protection of the operators and the patients, and at securing good diagnostic quality films. Accreditation standards are already on line, and are being used every day.

Mr. MAGUIRE. You feel they are adequate. This would add nothing?

Dr. BROWN. They are very good. I don't see what Federal standards would do that we haven't done already. These standards have been developed in concert with literally hundreds of people, our various communities of interest who are concerned about radiation. This information on standards is in our formal statement.

Ms. BUTLER. Mr. Maguire, may I ask my counsel to speak on this. He may clarify it a lot more so.

Mr. LEMOV. Mr. Maguire, in answer to your question, we do not believe this bill is in any way duplicative of existing Federal authority. In the appendix to Mr. Villforth's statement, he lists the authority they have at the present time, and with respect to use of equipment by operators, he indicates—this is page 6 of the appendix—the bureau issues voluntary recommendations. We presume that if the bureau had authority to act in a mandatory way, they would have. Beyond that, as to the sanction, this bill provides a sanction within a period of 3 years. Congress directs that unless action is taken, certain results will occur. That is the difference between this legislation and the existing situation.

Thank you.

Mr. MAGUIRE. There is a sanction which would cut off Federal reimbursement for radiological services to States without standards as stringent as the Federal standards promulgated pursuant to this act.

Mr. LEMOV. It is a targeted sanction, too. I might point out earlier legislation was much broader in terms of the sanction, and this is very narrowly drawn to apply to a particular area, a particular subject.

Mr. MAGUIRE. Doctor, if everything is OK, then presumably you would not be worried about having the sanction.

Dr. BROWN. Let's talk about the sanction. It won't work. There is very little reimbursement for outpatient dental services. A few States have it, but very few. The sanction of withholding funds will have relatively miniscule impact. The sanction just isn't there.

Mr. LEMOV. I point out that the sanction applies to all Federal funds for radiologic procedures in the State. I think it is rather substantial, but I might comment, Mr. Maguire, I don't think the sanction will be necessary at all. It is quite clear to us with a little inducement, the States that have authorizing legislation on the books, those that have been considering it will move forward, and the sanction will probably never have to be brought into effect.

Mr. MAGUIRE. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you very much. We must move on. I want to thank you all for your testimony. You have been very helpful. I now call as a panel, Ms. Eleanor Walters, Ms. Arden C. Hyde, and Mr. John Stanton, conference of radiation control program directors, chief, bureau of environmental health.

Let me ask each of you and other witnesses who are scheduled to testify, if you have prepared written statements, which most of you do have, we will make the statements in their entirety part of the record. We would very much prefer a summary of the statement so that we can get into questions and answers. We are capable of reading the statements, and the statements will be made part of the record; so all of the views will be there as part of the written testimony to be read by others.

STATEMENTS OF ELLI WALTERS, WASHINGTON REPRESENTATIVE, ENVIRONMENTAL POLICY CENTER; ARDEN C. HYDE, EXECUTIVE DIRECTOR, NATIONAL COALITION FOR DISEASE PREVENTION AND ENVIRONMENTAL HEALTH; AND JOHN R. STANTON, ON BEHALF OF CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS

Ms. WALTERS. I have a short summary. EPC supports H.R. 6057, the Consumer Radiation Health and Safety Act, as a necessary measure to eliminate excess radiation exposures. The bill has already been described. It provides for minimum standards for accreditation of schools which train people in radiological technology, and also for certifying the competence of those technologists once they are actually working.

The Federal Government would neither be authorized to impose standards upon the State, nor authorized to engage in actual credentialing. Three years after enactment Federal funds for radiological procedures would be available to those States with programs comparable to Federal guidelines. This legislation is consistent with the recommendations made in the Subcommittee on Oversight and Investigation's report, "Unnecessary Exposure to Radiation for Medical and Dental X-Rays." States will develop licensing procedures, not the Federal Government.

Existing State programs, notably California, has shown that a radiation control program need not drain the State treasury. For example, in 1978, the California radiation program cost \$1,800,000; \$958,000 were collected through the program in inspection and licensing fees. The technologists' certification program cost \$439,000; one-half of that was supported by licensing fees alone.

That program has saved the State millions of dollars in future health care costs, and has neither significantly raised radiology service costs nor changed the rate of increased cost for services.

The Federal role in developing model standards for licensing and training X-ray technologists is not a new idea; provisions for this were deleted in the Radiation Control for Health and Safety Act of 1968, because it was believed that the FDA already had authority to develop model laws without specific authorization.

In 1973, after 2 years' study and moratorium, the Department of Health, Education, and Welfare recommended the development of national standards for selected health occupations. In 1977, the National Conference on Radiation Controls Task Force and Credentialing of Radiation-Allied Health Operators concluded that a mandatory credentialing system controlled and administered by the States should be implemented.

In March, 1979, the Food and Drug Administration announced its intent to develop voluntary national standards for the qualifications of technologists. Proposed standards should be published by the end of the year. H.R. 6057 should reflect this, and those standards could be used as the basis of the minimum standards that legislation refers to.

There are approximately 160,000 people now operating medical X-ray equipment. Only slightly more than one-half are either voluntarily credentialed or licensed. The American Dental Assistants Association estimates that as many as two-thirds of the 150,000

dental assistants in the United States who administer X-ray exams are not licensed.

At the current rate which States are enacting legislation to license X-ray technologists, it would take 40 years before all 50 States have requirements. Even in those States with procedures, there is no consistency in the licensing requirements.

The voluntary credentialing programs and the current training programs that are now in existence also differ. For example, there was an HEW-sponsored proficiency test for technologists, I believe, in the early 1970's that showed that only 1 percent of noncredentialed personnel scored 85 percent or better, and only 15 percent of the credentialed technologists scored 85 percent or better on the same exam; so credentialed operators generally do perform better than the noncredentialed operators, but if only 15 percent of the credentialed people can pass that exam, it shows there are some deficiencies in the program as it now exists.

EPC believes that mandatory credentialing of technologists and the accreditation of educational programs would assure that entry-level operators possess minimal competence. With the high cost of medical insurance for all sorts of either medical or dental X-rays, we should be getting our money's worth, and we should be having people who are trained to operate that equipment.

Obviously operator training and licensing is only one part of the wide-scale effort to reduce unnecessary exposures from medical and dental X-rays. The Bureau of Radiological Health, the State radiation protection departments, professional organizations, the medical industry, and nongovernment groups have taken steps to reduce unnecessary exposure by regulating X-ray equipment, launching public education programs, developing referral criteria for X-ray examinations, and abandoning mass X-ray screening programs.

These activities, along with successful enactment and implementation of H.R. 6057, will result in an important, well-planned Federal and State program significantly contributing to public health and safety.

[Testimony resumes on p. 92.]

[Ms. Walters' prepared statement follows:]

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Statement of
Elli Walters

before
Subcommittee on Health and the Environment
House Interstate and Foreign Commerce Committee

on
Consumer-Patient Radiation Health and Safety Act
September 5, 1980

Mr. Chairman, I am Elli Walters, Washington Representative of the Environmental Policy Center, a non-profit public interest lobbying group concerned with environmental-natural resource issues including ionizing radiation exposures. In behalf of the Center, I thank you for the opportunity to testify on H.R. 6057, the Consumer-Patient Radiation Health and Safety Act.

The scientific, regulatory, and public debate over the health effects of radiation exposure is far from over, yet, responsible parties on both sides of the issue generally agree that 1) any radiation exposure poses some risk to an individual, 2) everyone is continually exposed to radiation each day, and 3) unnecessary radiation exposures should be eliminated from the environment. Medical radiation accounts for nearly 90% of all exposures to human-made radiation sources. The expected immediate benefits from necessary medical x-rays outweigh the potential risks of cancer or other radiation-induced damage from the exposure.

Testimony presented at Congressional oversight hearings, held more than one year ago and which resulted in last month's Oversight and Investigations Subcommittee Report on X-rays, stressed that 30% or more of the 240 million

medical and dental x-rays administered in the U.S. annually are unnecessary. Many reasons including inadequate or faulty equipment, patient pressures, inappropriate clinical judgement, screening asymptomatic persons, poor user techniques and others were cited as contributors to the excess exposures. Regulating x-ray equipment, launching public education programs, developing referral criteria for x-ray examinations, abandoning mass x-ray screening programs, educating the x-ray machine operators and others were suggested last year at the hearings (as in previous and subsequent hearings and reports) as methods for reducing unnecessary exposures.

The Bureau of Radiological Health (BRH) has made important strides in several of these areas. The voluntary Dental Exposure Normalization Techniques, Breast Exposure: Nationwide Trends, and Nationwide Evaluation of X-ray Trends have dramatically reduced exposures for certain diagnostic procedures. Likewise, BRH research and development of new equipment and referral criteria will continue to lead to lower radiation exposures for patients needing diagnostic x-rays.

Reducing x-ray exposures has two cost containment benefits. First is an immediate savings if fewer medical and dental exams are ordered or if fewer repeat films are needed. The total cost for x-ray procedures is estimated to be \$6.3 billion annually. This would be reduced by \$2 million if the 30% unnecessary exams were eliminated. The second benefit is an accrued savings through the prevention of future radiation-induced health problems. California officials estimate their radiation control program, for example, saves \$50 million a year in future ill-health costs based on the 1977 Biological Effects of Ionizing Radiation (BEIR) Report projections.

Among the recent Interagency Task Force on the Health Effects of Ionizing Radiation recommendations for reducing medical radiation exposures were to:

- o Promote improvement in the education, training and proficiency medical radiation technologists (e.g., x-ray, nuclear medicine and radiation therapy) by supporting the development of curricula, educational materials, testing materials, and methods of clinical competency measurement.
- o Develop model licensure of credentialing guidelines, including periodic retraining and recertification for medical radiation technologists and provide assistance to the States in adopting and implementing them.
- o Conduct and support continuing education programs for all operators of medical radiation equipment.

Last March, the Food and Drug Administration announced its intent to develop voluntary national standards for the qualifications of technologists. Proposed standards should be published before the end of the year.

At the 9th annual National Conference on Radiation Control in 1977, the Task Force on Credentialing of Radiation Allied Health Operators concluded that:

- "1) A credentialing system shall be mandatory. A mandatory system is necessary for the protection of the public by reduction of nonproductive ionizing radiation exposure. By mandatory, the Task Force implies that at some time within a fixed period all States shall adopt a credentialing program. Currently those States possessing a credentialing program have developed such

a program in an independent manner. A degree of uniformity needs to be added so that certain concepts such as reciprocity, grandfathering, and so forth, can be accepted throughout the States.

- 2) It should be controlled and administered by the States. In order to provide a credentialing system with the necessary flexibility, the Task Force recommends that the program by State be administered and controlled. This administration by the States and local governments would allow a degree of flexibility not always available in a Federally developed program.

In a 1971 report, 'Licensure and Related Health Personnel Credentialing,' the Department of Health, Education and Welfare recommended a moratorium on State legislation which would establish health occupations with statutorily-defined scopes of functions within a particular State. This moratorium was extended in 1973 to allow the Department sufficient time to evaluate the growing number of standards and recommendations in manpower credentialing and to formulate recommendations. To facilitate these efforts, a Subcommittee on Health Manpower Credentialing was established. One of its recommendations would provide for the development of national standards for selected health occupations."

Provisions to direct HEW to develop advisory standards for licensing and training x-ray technologists was deleted in the Radiation Control for Health and Safety Act of 1968 because House-Senate conferees believed the agency

already had the authority to develop such model laws and recommend them to the States for adoption without specific authorization. Similar provisions have been deleted from other pieces of legislation in more recent Congresses as well. Also, many House and Senate Committee and independent organizations have held hearings on various aspects of the radiation health and safety issue.

There are 130,000-170,000 persons now operating medical x-ray equipment. About 85,000 are either voluntarily credentialed or licensed by one of the 12 states and territories with such programs. Thus, thousands are still performing examinations with little or no training. Last year, the American Dental Assistants Association stated that as many as 100,000 of the 150,000 dental assistants in the U.S. who administer x-ray exams are not licensed. Unless the machine operators are adequately trained and have demonstrated their competence, patient health and safety is severely compromised.

In the past, emphasis for radiation health and safety was placed on improving the machinery itself. The human element was not seriously considered. This has been a dreadful mistake which cannot be allowed to continue any longer. The high cost of medical insurance today implies that patients are getting the best medical care available; employing poorly trained or untrained people to operate the highly sophisticated, expensive equipment is "ripping-off" the patient and all consumers.

The results of a HEW-sponsored proficiency test for technologists showed that only 1% of non-credentialed personnel scored 85% or better. The BRH's Nationwide Evaluation of X-ray Trends showed that 63% of non-credentialed operators failed to properly restrict the x-ray beam to the size of film for a chest x-ray, thus unnecessarily overexposing the patient. Unfortunately, the

scores and demonstrated competence of credentialed technologists were not overwhelming--15% of credentialed technologists scored 85% or better on the proficiency exam and 43% of the credentialed operators failed to properly restrict the x-ray beam in the BRH survey.

It appears that while credentialed operators generally perform better than non-credentialed operators, deficiencies exist in operator training. The existing guidelines for educating technologists are voluntary and, generally inconsistent among the States. Likewise the existing State guidelines for credentialing technologists differ from one State to the next. Voluntary guidelines and programs, are ineffective because there are no incentives for the State or for the operators themselves. Mandatory credentialing of technologists and accreditation of educational programs would assure that entry level operators possess minimal competence.

H.R. 6057 would ensure that patients had a qualified x-ray operator. The bill directs the Department of Health and Human Services to establish minimum standards for 1) accrediting educational programs conducted for persons administering radiologic procedures and 2) certifying competence of persons administering radiologic procedures. Federal government would neither be authorized to impose standards upon the state nor authorized to engage in credentialing. Three years after enactment, federal funds for services or equipment used in radiologic procedures will be cut off in those states which have not adopted either federal or comparable standards. It would encourage state credentialing according to national guidelines. This legislation implements the recommendations made in last month's Subcommittee on Oversight and Investigations' report, Unnecessary Exposure to Radiation from Medical and Dental X-rays.

The duty to develop the two programs can be delegated to non-profit autonomous organizations such as the American Society of Radiological Technologists which conducts the voluntary credentialing programs or to others. As I stated earlier, the federal government has already allocated funds and manpower to develop national standards, therefore making the standards mandatory for federal services and as a model to States will not significantly increase federal expenditures.

The States will develop the licensing procedures, not the federal government. Existing State programs, notably California, has shown that a radiation control program need not drain the State Treasury. For example in Fiscal Year 1978, the California radiation program cost \$1,816,784 and \$958,030 was collected through the program in inspection and licensing fees. The technologist certification program cost \$439,730 of which 1/2 was supported by licensing fees alone. That program has saved the State millions of dollars in future health care costs and has neither significantly raised radiology service costs nor changed the rate of increased costs for services.

H.R. 6057 obviously will not end all unnecessary medical radiation exposures. It will, however, be an important, well-planned and hopefully implemented federal and state program contributing to public health and safety. With all the technological advancements in design and use of radiation equipment in the U.S., operators need an educational and training background.

In conclusion, the Environmental Policy Center supports H.R. 6057 as one of the many measures needed to eliminate unnecessary radiation exposures. This concludes my statement.

Mr. WAXMAN. Thank you very much.
Ms. Hyde?

STATEMENT OF ARDEN C. HYDE

Ms. HYDE. Mr. Chairman, members of the subcommittee, I am Arden Hyde, executive director of the National Coalition for Disease Prevention and Environmental Health.

We appreciate the opportunity to present our views on protection of public health and safety from unnecessary exposure to radiation.

The board of directors of the coalition applauds the members for holding these hearings. They asked me to extend to you again, Mr. Waxman, our gratitude for your keynote of our conference in the spring.

I brought with me today for you the transcripts of those hearings.

The national coalition is a nonprofit umbrella organization with more than 150 members. Its purpose is to promote a healthy environment and preventive health care as a matter of both public policy and private responsibility. The coalition coordinates, enhances, and amplifies the separate efforts of numerous groups and individuals who are active in many specific disease prevention and environmental health areas. Its concept was first proposed in 1978 by Hon. Paul G. Rogers, former chairman of the House Subcommittee on Health and the Environment, and now honorary chairman of the coalition.

The coalition is the only national organization specifically established to promote public recognition of the interrelated nature of disease prevention and environmental health. We strongly believe that disease prevention is a socially and economically desirable concept, one no less significant than the treatment of illness itself.

On June 17, 1980, our task force on the health effects of low-level radiation recommended and the board of directors of the coalition unanimously adopted a resolution including the following recommendation: "Efforts should be made by the public, industry, scientific/medical communities and Government agencies to eliminate all unnecessary sources of radiation exposure from the environment."

The national coalition supports H.R. 6057. It endorses Federal minimum standards for accreditation of radiological training programs and for certification of persons who will expose consumers to X-rays.

Everyone is exposed to radiation in some form every day. The benefits of radiation, particularly through medical usage, has revolutionized diagnosing of diseases and injuries. Radiation poses risks to humans, and it is generally assumed that persons should not be exposed to radiation unless the perceived benefits outweigh the perceived risks.

The May 1979 draft report of the National Academy of Sciences Committee on Biological Effects of Ionizing Radiation suggests that there is no safe level of exposure; any exposure poses some risks to the individual. Medical and dental radiation accounts for 90 percent of the human-made radiation exposures in the United States. Medical X-ray exposures are increasing in number although the usage patterns have changed since the 1950's.

It is estimated, however, that anywhere from 10 to 90 percent of all exposures may be unnecessary due to faulty equipment, bad clinical judgment, poor training, pressure by patients, and fear of malpractice suits.

Many types of cancer are known to result from radiation exposure; therefore, the control of radiation exposure is an effective tool for the prevention of disease.

The prevention of unnecessary exposure to radiation is important in the disease prevention quest. The current methods produce not only a greater risk to the consumer, but also to the operators of radiological equipment. The proper licensing and training of the technologists who operate the machines used for therapeutic or diagnostic purposes is critical.

Because the technologist who operates the equipment has control of the amount of radiation to all of the recipients, he is the key to proper radiation exposure. Proper licensing for training of these individuals is essential to disease prevention.

With only 11 States having licensing requirements, the qualifications and training of many technologists may be suspect. Responsibility lies in the hands of the technologists. The proper training and licensing of X-ray technicians will assure safe and proper use of equipment and result in a reduction of consumer exposure.

As high as 30 percent of the X-rays taken today are deemed unnecessary. When this is coupled with inadequately trained operators with at best minimal licensing requirements, the radiation risks to the American consumer are unnecessarily increased.

Uniform national licensing requirements would provide quality programs and professional mobility between States.

I might add I had X-rays taken 2 days ago. I have had a lot of X-rays taken in my life, by dental people and my doctors. The one 2 days ago is the first one where I have been given a lead shield. All of the people who have given me X-rays have been licensed and trained with their diplomas hanging on the wall. As I look back, it appalled me to realize that the use of such a simple piece of equipment had not been given me and therefore I feel I have had maybe not much but some unnecessary radiation exposure.

The coalition thanks you for giving us this time to present our views and hopes to work with you further on this issue.

Mr. WAXMAN. Thank you very much.

Mr. Stanton.

STATEMENT OF JOHN R. STANTON

Mr. STANTON. Mr. Chairman, members of the subcommittee, I am John Stanton, representing the Conference of Radiation Control Program Directors.

The prepared statement is brief, but I will attempt to make it briefer yet.

In general, the conference supports the intent of H.R. 6057; in particular there are several comments, most of which specifically came from our task force on credentialing of allied health operators.

These specific comments are, first, that we suggest that the term nonionizing radiation be stricken from the definition of radiation in section 104. While it is true that sources of nonionizing radiation

are used in diagnosis and therapy, we feel that this area of concern might best be addressed in separate legislation.

Second, that consideration should be given to adding physicians' assistants and persons in extern programs to the definition of medical practitioners.

Third we trust that the authors fully appreciate the enormity of the tasks outlined in sections 121 (c) and (d) and section 122 (c) and (d) and ask, should a State adopt programs to achieve the purposes of the act, whether that State would also be required to adopt the aforementioned sections verbatim.

Finally, section 136 allows the Secretary to make grants to States up to 50 per centum of the costs. We suggest that at least during the planning and development stages this percentage could be made greater, perhaps doubled, and then to revert to the lesser amount during the operation stage.

Otherwise it appears doubtful that many States would be willing to undertake the adoption and administration of the program specified in the act, notwithstanding the sanctions that are specified in the act.

Just one additional comment: The task force to which I made reference on credentialing of allied health operators has proposed a minimum standard. It is in a draft form, but should the subcommittee desire it, I would be glad to supply copies to them.

The conference appreciates this opportunity to comment on the issue.

Thank you, Mr. Chairman.

[Mr. Stanton's prepared statement follows:]

Statement of the Conference of
Radiation Control Program Directors, Inc.
on H.R. 6057

September 5, 1980

My name is John R. Stanton, representing the Conference of Radiation Control Program Directors, an organization the membership of which is comprised of the directors of radiation control programs in the 50 States, the Territories, and some larger municipal agencies. The Conference serves as a mechanism for providing a more functional means of exchanging information between State and Federal agencies, as well as among the States themselves, in areas of mutual concern or interest.

In general, the Conference supports the intent of H.R. 6057; in particular, there are several comments, most of which are specifically from our Task Force on Credentialling of Allied Health Operators. Our organization has been expressing concern about the need to reduce unnecessary and unproductive radiation exposure of the consumer public for several years. As early as 1974, the Conference went on record as favoring some form of credentialling of allied health radiation operators as a desirable mechanism to assure that operators of X-ray equipment have met a standard of education and training to qualify themselves to properly administer X-rays to humans.

Specific comments are as follows:

1. We suggest that the term "non-ionizing" be stricken from the definition of "radiation" in Sec. 104(1). While it is true that sources of non-ionizing radiation are used in diagnosis and therapy, we feel that this area of concern might best be addressed in separate legislation.
2. Consideration should be given to adding physicians' assistants and persons in extern programs to the definition of "medical practitioner" in Sec. 104(3).

3. We trust that the authors fully appreciate the enormity of the tasks outlined in Sec. 121(c) and (d) and Sec. 122(c) and (d) and ask, should a state "adopt programs to achieve the purposes of (the) Act," whether that state would also be required to adopt the aforementioned sections.
4. Sec. 136 allows the Secretary to make grants to states "up to 50 per centum of the costs....". We suggest that, at least during the planning and development stages, this percentage could be made greater, perhaps doubled, and then to revert to the lesser amount during the operation stage. Otherwise, it appears doubtful that many states would be willing to undertake the adoption and administration of the programs specified in the Act.

The Conference appreciates the opportunity to comment on the issue and offers our continued cooperation in the future development of coordinated federal-state regulatory programs.

Mr. MAGUIRE [presiding]. Thank you, Mr. Stanton.

Dr. Carter?

Mr. CARTER. No questions.

Mr. MAGUIRE. We were discussing with some of the previous witnesses about different views of accreditation and what might be helpful by way of Federal action in setting standards for accreditation and certification.

Is it your view that if we did this, we would be reducing the number of deaths that occur as a result of radiation exposures?

I address that to anyone who would like to comment on it.

Ms. WALTERS. I am not sure you could say how many deaths you would be reducing. You would be reducing excess exposure of people, which may ultimately affect whether or not they come down with some sort of cancer.

Cancer doesn't have a little red flag that says it was induced by radiation.

Mr. MAGUIRE. We have estimates that about 1 percent of the cancer deaths in the United States this year will be the result of X-ray induced cancers.

Ms. WALTERS. According to the testimony presented last year by Mr. Ward from California, they have estimated that the State of California will save approximately \$50 million a year in future health costs by having licensing and accreditation programs in the State.

Mr. MAGUIRE. Presumably that involves at least some deaths?

Ms. WALTERS. Right.

Mr. MAGUIRE. Care for people who become seriously ill and some of them die, right?

Ms. WALTERS. Right.

Mr. MAGUIRE. Why don't we say so?

Ms. WALTERS. OK. It will prevent some deaths.

Mr. MAGUIRE. Ms. Hyde, you have indicated that the board was unanimous in its resolution on this matter of exposure to radiation?

Ms. HYDE. That is correct.

Mr. MAGUIRE. I wonder if any member organizations of the coalition expressed any doubts at any point along the way?

Ms. HYDE. After our board unanimously passed the resolution, it was circulated to all our members, as well as to the appropriate Government agencies and elected officials. We have had no lack of support, none at all. In fact, it has been highly supported by our membership.

Mr. MAGUIRE. Mr. Stanton, you heard Ms. Walters' statement that the cost to California for credentialing and licensure after the fees are received amounts to something like \$1 million is that correct?

Ms. WALTERS. Yes.

Mr. MAGUIRE. Do you agree that those are roughly accurate figures, and do you think that the cost to most other States would be considerably less, given that they have smaller populations and so on?

Mr. STANTON. I just have to qualify my answer by saying that I think I heard Ms. Walters say that the entire licensing and registration program costs something in the range of \$1 million plus,

but she later clarified that to say that the annual cost for the certification program was somewhere in the vicinity of \$400,000, and, yes, I agree with that.

I have spoken with Mr. Ward personally on that. I agree that the 52 percent recovery is probably as good as they would ever consider doing.

I do have a list of several States that are certification States. Their recoveries range all the way from 38 percent to 100 percent. Yes, for a smaller State, certainly the annual cost would be considerably less.

Oregon, for instance, which has considerably less population, is only one-tenth of California's, about \$40,000.

Mr. MAGUIRE. Do you agree that the future ill-health costs that would not be incurred are many magnitudes greater than the costs of implementing a program?

Mr. STANTON. I agree.

Ms. WALTERS. Yes.

Mr. MAGUIRE. Mr. Stanton, does the conference have any additional data that would be useful to the committee on the projected costs for various States or types of States?

Mr. STANTON. I have a list of the annual costs, the amount of fees, and percent recovery, whether it goes into the general fund or a specific program for the 11 States, and I could supply that to the committee.

Mr. MAGUIRE. That would be very helpful. The committee would appreciate having that. It can be added to the record without objection.

[The following information was received for the record:]

COST OF STATE CREDENTIALING AND LICENSURE PROGRAMS

STATE	INFORMANT	ANNUAL COST	AMOUNT OF FEES	% RECOVERY	Gen. Fund or Program
Kentucky	Don Hughes FTS 351-3700	\$ 52,509 ^a	\$ 20,000	38%	GF
Arizona	Karen Armour FTS 765-4845	\$ 47,000	\$ 47,000	100%	P
California	Lee Casaleggio FTS 552-2073	\$418,119 ^b	\$217,509 ^c	52%	P
Oregon ^c	Jo Harding FTS 424-5054	\$ 40,000	\$ 40,000	100%	P
New York	Allen Cohen FTS 564-3070	\$150,000 ^d	\$ 75,000	50%	GF
New Jersey	Mary Vaey FTS 477-5586	\$ 60,000 ^e	\$ 60,000	100%	GF
West Virginia	Grady Boyer	Undet.	25,000	100%	GF
Montana	Mary Lou Crawford	Undet.	Undet.	100%	GF
Florida	Dan Cannon	\$ 60,000 ^f	Undet.	100%	P
Vermont	Ray McCandles	Undet.	\$ 2,500	Undet.	GF

- a. Includes travel and salary. Does not include data processing, printing, overhead, or duplicating. Total estimated figure \$72,000
- b. (Fiscal '79 figures given) Estimated program cost for 1980 is \$733,358. Recovery will be \$380,000 or 52%.
- c. State law requires certifying boards to be self-supporting.
- d. Does not include data processing, printing, overhead, or duplicating.
- e. \$10,000 goes to Bureau of Licensing and Collection for receiving applications and fees and preparing and mailing out certificates.
- f. Significant funds (\$200,000) have been collected from Jan. 1979 to April 1980. Majority of this fund is in reserve for production of a workbook. No testing has been done yet.

Mr. MAGUIRE. I thank you all very much for your testimony. The committee thanks you.

I now call as a panel Ms. Marilyn Holland, president, American Society of Radiologic Technologists; George W. Alexander, Jr., Society of Nuclear Medicine, associate director of training programs and chief technologist for the Society of Nuclear Medicine; and Dr. Mark Mishkin, American College of Radiology.

STATEMENTS OF MARILYN HOLLAND, PRESIDENT, AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS, ACCOMPANIED BY WARD KELLER, EXECUTIVE DIRECTOR; GEORGE W. ALEXANDER, JR., PAST PRESIDENT, TECHNOLOGIST SECTION, SOCIETY OF NUCLEAR MEDICINE, ACCOMPANIED BY MICHAEL L. CIANCI, PRESIDENT, TECHNOLOGIST SECTION; AND MARK M. MISHKIN, M.D., VICE CHAIRMAN, COMMISSION ON HUMAN RESOURCES, AMERICAN COLLEGE OF RADIOLOGY, ACCOMPANIED BY OTHO LINTON, DIRECTOR OF GOVERNMENT RELATIONS

Ms. HOLLAND. Mr. Chairman, members of the subcommittee, I am Marilyn Holland. As president of the American Society of Radiologic Technologists, I represent the Professional Association of Radiologic Technologists founded more than 50 years ago for the express purpose of enhancing through education, the proper and safe delivery of medical radiological services.

With me today is Ward Keller, executive director of the society. We welcome the opportunity to appear before you today during these hearings on H.R. 6057 and we commend the subcommittee for its attention to this very timely subject.

I will take the liberty of abbreviating my statement, hitting the high points for you. [See p. 102.]

One of our concerns is that the consumer-patient is rarely in a position to judge either the qualifications of the operator or the quality of the examination let alone the dosage that is administered.

The chest X-ray examination, when performed by an uneducated, untrained operator, has the potential to deliver 10, 20 or even 100 times the radiation dose to the patient as the same procedure performed by a properly educated technologist.

We would remind you that this medical radiation is produced solely by the action of the operator. Properly calibrated equipment and well educated technologists are primary elements in the safe delivery of this radiation. Lacking this education, the unqualified operator poses a serious threat to the consumer-patient.

From its inception, the American Society of Radiologic Technologists has recognized that formal education, coupled with moral obligation, is a controlling factor in the competence of the individual and in the reduction of unnecessary radiation to both the patient and the practitioner.

As credentialed technologists, we strive to eliminate unnecessary radiation and optimize that needed to produce a diagnostic image.

We have voluntarily submitted to examination and have met the educational standards prescribed by the profession.

The American Society of Radiologic Technologists does not believe there is an alternative to uniform national standards.

We remain firm in our opinion that without uniform national standards for qualifications of medical radiologic technologists, the public will remain unprotected and at the mercy of untrained personnel.

Because of the unique nature and inherent danger of radiation, the American Society of Radiologic Technologists believes that every patient undergoing a radiological examination has the right to have that examination properly performed and with minimal risk by a qualified practitioner.

The ASRT held its 52d annual meeting in Atlanta, Ga., from July 12 to 17, 1980. After considering H.R. 6057, the Consumer-Patient Radiation Health and Safety Act of 1979, sponsored by Congressman Luken, the society adopted a resolution urging the enactment of this legislation by the Congress.

Through a clerical error, the wrong resolution was attached, and with your permission we would like to submit the correct resolution.

We commend the subcommittee for its interest and timely concern with respect to the potential health hazards of medical and dental diagnostic X-rays resulting from the lack of proper safeguards and qualifications of persons operating ionizing radiation equipment.

We believe that this legislative area demands prompt and effective action, and we would like to respectfully point out that the Senate, on three previous occasions, has passed legislation addressing the concerns we have mentioned.

We urge this subcommittee and the full Committee on Interstate and Foreign Commerce to conduct its effort to seek a sound legislative solution to this problem which we believe is essential to protect the rights of the American public to properly performed radiological examinations and from the potential hazards of excessive and unnecessary radiation.

Thank you.

[Testimony resumes on p. 108.]

[Ms. Holland's prepared statement and attachment follow:]

STATEMENT OF
MARILYN HOLLAND, PRESIDENT
AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS
BEFORE THE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
OF THE
HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE
SEPTEMBER 5, 1980
IN SUPPORT OF
H.R. 6057
"CONSUMER-PATIENT RADIATION HEALTH
AND SAFETY ACT OF 1979"

Mr. Chairman, Members of the Subcommittee, my name is Marilyn Holland. As President of the American Society of Radiologic Technologists, I represent the professional association of radiologic technologists founded more than fifty years ago for the express purpose of enhancing through education, the proper and safe delivery of medical radiological services. With me today is Ward Keller, Executive Director of the Society. We welcome the opportunity to appear before you today during these hearings on H. R. 6057 and we commend the Subcommittee for its attention to this very timely subject.

We all have heard considerable concern regarding risks from radiation exposure, especially related to the Three Mile Island incident. And yet, less than one percent (1%) of public exposure to ionizing radiation is attributable to the normal operation of nuclear power plants. Conversely, ninety percent (90%) of public exposure to man-made ionizing radiation results from medical procedures, primarily diagnostic x-ray examinations.

Diagnostic x-rays differ from other man-made radiation inasmuch as there can be no benefit (an x-ray image) without exposure to the patient. The production of radiation as utilized in the practice of medicine is an invaluable tool in the diagnosis and treatment of disease. Even so, the utilization of radiation in medicine is not without risks and an inherent potential of biological damage to healthy tissue. As you know, any exposure to ionizing radiation, however small the dose, increases the risk of

producing biological damage. And needless to say, any unnecessary exposure therefore produces a risk without benefit to the patient.

It is with regret I inform the members of this Subcommittee that improper utilization and production of excessive and unnecessary medical radiation exposure is a widespread practice throughout these United States. Overutilization, as well as improper utilization, of radiation in the practice of medicine is a genuine and ever-increasing health hazard to the public and must be dealt with now. In most states, a physician using x-ray equipment in his practice is under no obligation to ascertain or require any credential or specific education of the person employed to operate the equipment. Literally, anyone off the street can be hired this morning and be operating this potentially dangerous equipment this afternoon. Radiation is not detected by the senses of sight, hearing, touch, smell or taste. Without sufficient knowledge of its application, the operator has the potential to produce biological damage not only to the patient but to the operator as well.

There are an estimated 130,000 to 170,000 operators of medical x-ray equipment throughout the United States. Of these, approximately 85,000 have demonstrated their competency through education and voluntary certification or state licensing examination. The remaining 45,000 to 85,000, that is, possibly one half of the total, are operating x-ray equipment and administering potentially harmful ionizing radiation to human beings without having demonstrated scientific knowledge, technical understanding, clinical competency, or professional responsibility for the practice of proper radiological procedures.

Sadly, the patient-consumer is rarely in a position to judge either the qualifications of the operator or the quality of the examination, let alone the dosage. The chest x-ray examination when performed by an uneducated, untrained operator has the potential to deliver ten (10), twenty (20), or even one hundred (100) times the radiation dose to the patient as the same procedure performed by a

properly educated technologist. We would remind you that this medical radiation is produced solely by action of the operator. Properly calibrated equipment and well educated technologists are primary elements in the safe delivery of this radiation. Lacking this education, the unqualified operator poses a serious threat to the consumer-patient.

From its inception, The American Society of Radiologic Technologists has recognized that formal education coupled with moral obligation is a controlling factor in the competence of the individual and in the reduction of unnecessary radiation to both the patient and the practitioner. As credentialed technologists, we strive to eliminate unnecessary radiation, and optimize that which is needed to produce a diagnostic image. We have voluntarily submitted to examination and have met the educational standards prescribed by the profession.

For years the American Society of Radiologic Technologists has expressed its concern regarding unnecessary medical radiation exposure to the patient-consumer of this country. In May of 1968 during consideration of H. R. 10790 (Public Law 90-602) we testified before this Committee and stated:

"We can understand the justification for regulation and improved standards if the public health is to be adequately protected . . . The American Society of Radiologic Technologists wishes to make a matter of record the firm conviction of all its members that patient exposure should be reduced to the absolute minimum."

Since the enactment of Public Law 90-602, the electronic products legislation of 1968, approved by this Committee, significant steps have been taken to protect public health through the regulation of electronic products such as x-ray equipment. However, like your car, the use and abuse of this equipment is determined by the operator. No one would permit his car, with all its safety features, to be driven by someone who has never been taught to drive. And yet, we let untrained operators

expose the patient-consumer to radiation, radiation that can affect future generations.

The Society continues to support federal legislation giving impetus to state licensure based on national standards, preferably the standards advocated by the American Registry of Radiologic Technologists (ARRT), a national voluntary certification agency.

The American Society of Radiologic Technologists does not believe there is an alternative to uniform national standards. We remain firm in our opinion, that without uniform national standards for qualifications of medical radiation technologists, the public will remain unprotected and at the mercy of untrained personnel. Because of the unique nature and inherent danger of radiation, the ASRT believes that every patient undergoing a radiological examination has the right to have that examination performed properly and with minimal risk by a qualified practitioner.

Accredited programs for the education of radiologic technologists already exist on a voluntary basis in every state. The United States Department of Education currently recognizes the Committee on Allied Health Education and Accreditation in cooperation with the Joint Review Committee on Education in Radiologic Technology as the accrediting agency for more than 800 programs. For those 45,000 to 85,000 individuals not certified by the voluntary national certifying organization, the American Registry of Radiologic Technologists, a criterion-referenced, performance-oriented examination can be utilized as a measurement tool and a prerequisite for licensure. The ARRT is currently cooperating with licensure boards in several states by offering their credentialing examination to candidates identified by the states. These considerations are offered as substantiating evidence that facilitation, implementation and costs to state government can be minimized by utilizing existing national voluntary standards.

While H. R. 6057 encompasses all technological operators of ionizing radiation equipment, it distinguishes between the types of operators and provides for licensure in a particular speciality, such as diagnostic x-ray, radiation therapy, or nuclear medicine. It also affords flexibility in providing for upward career mobility, a concern of health manpower agencies. The measure is structured to enable an orderly transition in this highly specialized field from the present situation, where the consumer must assume all operators of radiological sources are qualified, to the point where all such operators are in fact qualified. The public now assumes this to be the case. This legislation will finally make this assumption a reality and provide assurance for the entire United States.

The President of the United States has determined that the time has come for action. Responding to a joint request of the Administrator of the Environmental Protection Agency and the Secretary of Health and Human Services, he, on January 26, 1979, signed Executive Order Number 10831, which approved a number of recommendations for the guidance of federal agencies. Recommendation Number Eight states: "Operation of medical or dental x-ray equipment should be by individuals who have demonstrated proficiency to produce diagnostic quality radiographs with the minimum of exposure required; such proficiency should be assessed through national performance-oriented evaluation procedures or by didactic training and practical experience identical to, equivalent to, or greater than training programs and examination requirements of recognized credentialing organizations."

The ASRT held its 52nd Annual Meeting in Atlanta, Georgia, from July 12-17, 1980. After considering S. 500, the Consumer-Patient Radiation Health and Safety Act of 1979, sponsored by Senator Jennings Randolph, West Virginia, the Society adopted a resolution urging the enactment of this legislation by the Congress. A copy of this resolution is attached for the record.

We commend this Subcommittee, Mr. Chairman, for its interest and timely concern with respect to the potential health hazards of medical and dental diagnostic x-rays resulting from the lack of proper safeguards and qualifications of persons operating ionizing radiation equipment. We believe that this legislative area demands prompt and effective action and we would like to respectfully point out that the Senate on three previous occasions has passed legislation addressing the concerns we have mentioned. We urge this Subcommittee and the full Committee on Interstate and Foreign Commerce to continue its effort to seek a sound legislative solution to this problem which we believe is essential to protect the rights of the American public to properly performed radiological examinations and from the potential hazards of excessive and unnecessary radiation. Thank you, Mr. Chairman.

RESOLUTION IN SUPPORT OF S. 500
ADOPTED AT THE 52ND ANNUAL MEETING
of the
AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS
HELD AT ATLANTA, GEORGIA
JULY 12-17, 1980

WHEREAS, The American Society of Radiologic Technologists has since 1967 supported national legislative efforts to insure the competence of all operators of x-ray equipment and,

WHEREAS, the Society continues to believe that the establishment of uniform minimum standards of education and training are absolutely essential to protect the public health from unnecessary exposure to radiation and,

WHEREAS, the Honorable Jennings Randolph, a United States Senator from the State of West Virginia, introduced S. 500, the Consumer-Patient Radiation Health and Safety Act, in the U. S. Senate to establish minimum levels of competence for all operators of x-ray equipment, now therefore,

BE IT RESOLVED, that The American Society of Radiologic Technologists officially commends the Honorable Jennings Randolph for his leadership in Sponsoring S. 500, and urges the appropriate committees of the Senate to address this urgent national issue before the adjournment of the 96th Congress.

Ms. MEYERS. Dr. Alexander?

STATEMENT OF GEORGE W. ALEXANDER, JR.

Mr. ALEXANDER. Thank you.

Mr. Chairman, members of the subcommittee, my name is George Alexander. I appreciate the doctorate before my name but my colleagues at the university may not look upon this favorably.

It is just George Alexander. I appear before the subcommittee today representing the position of the Society of Nuclear Medicine and its 10,000 members.

With me and to my left is Michael Cianci, currently the president of the technologists section of the Society of Nuclear Medicine.

We thank you for this opportunity for the Society of Nuclear Medicine to present its comments and views on H.R. 6057 and the society commends the subcommittee for its concern and diligence in examining the question of how to properly protect patients from unnecessary exposure to medical radiation.

In order to conserve the subcommittee's time, we have a formal statement, with supporting documents, which we will submit for the record with your permission. [See p. 112.]

I will touch on the highlights of the statement; that is, the points which are most pertinent to the subcommittee.

This statement was adopted by the entire membership of the Society of Nuclear Medicine.

The Society of Nuclear Medicine is the only professional organization dedicated to all aspects of nuclear medicine. Among its 10,000 members are physicians, physicists, chemists, radiopharmacists, and nuclear medicine technologists.

This combination of disciplines within one professional organization is unique and allows viewing of the full scope of nuclear medicine practice and its contribution to the totality of quality health care for the patients who are referred to us.

The society's technologist section currently represents approximately 40 to 45 percent of the total membership of the organization.

The technologist section is the only professional organization dedicated to the discipline of nuclear medicine technology. It has always had the primary concern of assuring adequate education and competency of nuclear medicine technologists.

Nuclear medicine today encompasses two broad areas of procedures: in-vivo and in-vitro procedures, which are explained indepth in the written document.

I would like to point out that the in-vitro procedures, that is the radioimmunoassay procedures—which are one of the types of nuclear medicine procedures—constitutes almost 80 percent of all nuclear medicine procedures.

These procedures do not in any way involve a patient receiving radiation.

The role of the nuclear medicine technologist is to perform or assist in the performance of both in-vivo and in-vitro nuclear medicine procedures, with a prime consideration of skillful patient care and safety.

Over the past 10 years the Society of Nuclear Medicine has sponsored the development of voluntary national standards through the essentials of education and accreditation of the joint review committee on educational programs for nuclear medicine technologists, JRCNMT essentials, and the formation of national certification exclusively for nuclear medicine technologists, the NMTCB, which began in 1976. NMTCB functions in collaboration with the American Medical Association's committee on allied health education and accreditation, CAHEA, which accredits all health educational programs, there being approximately 140 CAHEA approved nuclear medicine technologist training programs in the United States.

NMTCB is a voluntary national certification board developed by task analysis which methodically examines all duties performed by nuclear medicine technologists.

We now feel that through development of voluntary national standards, we have a strong professional identity, job descriptions for all career levels, task analysis and the designation certified nuclear medicine technologist. Presently approximately 75 percent of all nuclear medicine technologists are professionally certified.

The Joint Commission on Accreditation of Hospitals, JCAH, accredits the hospitals, which must provide nuclear medicine services for its patient population, and, upon inspection, requires copies of each nuclear medicine technologist's certification diploma.

It further serves as a check on the safety and use of radiopharmaceuticals in the diagnosis and treatment of human diseases.

It is essential for the subcommittee to recognize that performance standards for nuclear medicine technologists already exist as a result of the society, the Joint Review Committee on Nuclear Medicine Technologists, the Committee on Allied Health Education and Accreditation, the Joint Commission on Accreditation of Hospitals, and the Nuclear Medicine Technologist Certification Board, and others as well.

The Department of HEW mandated and funded the National Committee for Health Certifying Agency to establish national standards for certifying bodies that attest to the competency of individual participants in health care delivery, and to grant recognition to certifying bodies that apply and meet the established standards.

Both the Society of Nuclear Medicine and the Nuclear Medicine Technologist Certification Board have been accepted into NCHCA as full members.

Existing Federal Government agencies such as the Nuclear Regulatory Commission and the Food and Drug Administration, maintain strict control on the safety and efficacy of use of each radiopharmaceutical which may be used in in-vitro procedures or administered to patients as in in-vivo procedures.

The subcommittee should note that retakes in nuclear medicine occur by taking additional images of an organ; that is, in-vivo procedures only, and require only initial administration of radiopharmaceutical, thus avoiding any unnecessary radiation exposure to patients.

Credentialing activities maintain the quality of practice of nuclear medicine technology. Without credentialing based upon the science of nuclear medicine, there are no standards for technologists to meet.

Credentialed technologists demonstrate an acceptable level of performance as defined by the Nuclear Medicine Technology Certification Board.

Whatever the mechanism, however, the ultimate goal of credentialing in nuclear medicine technology is to avoid unnecessary radiation exposure and to improve the quality of health care.

The Society of Nuclear Medicine is opposed to H.R. 6057 as presently written. It does not recognize the nature and scope of the medical specialty of nuclear medicine technology.

Many of the provisions of the proposed legislation are duplications of existing standards and/or regulations.

The activities of all the Federal and private sector agencies collectively serve to maintain strict control over all aspects of nuclear medicine, and thereby provide safeguards against undue radiation exposure to patients. Nuclear medicine techniques are well established with absolute controls over radiation dosage to the patient.

At the same time, we understand the pressures on the members of the subcommittee, and you may determine a real need to continue with this legislation. If you do, the Society of Nuclear Medicine recommends the following:

A. Certification and/or proficiency examination should be the central point of all licensure approaches.

B. Essentials of education, training and accreditation of programs are necessary aspects for assuring professional competency and should be incorporated into a licensure approach.

C. In any licensure approach, the practicing nuclear medicine technologist must be allowed to perform procedures for which he or she has been trained. H.R. 6057 does not recognize the scope of nuclear medicine technology.

D. There should be uniformity and consistency of licensure, regulations and reciprocity between all States.

E. On-the-job training should be evaluated and included as an acceptable criterion for licensure eligibility.

F. H.R. 6057 states that the Secretary shall consult with the Environmental Protection Agency. Since EPA has no experience with nuclear medicine application, the Society feels such consultation inappropriate.

G. If the subcommittee continues to believe that Federal minimum standards for licensure are necessary, the Society believes that the thrust of such a program must be through State licensure based upon State acceptance and adoption of national certification of the individual discipline (in our case, the Nuclear Medicine Technologist Certification Board).

H.R. 6057 also does not adequately recognize the nature and scope of the medical specialty of nuclear medicine, or that of nuclear medicine technology.

We appeal to the subcommittee to examine the information regarding our discipline.

There is no necessity to impose additional legislation on a profession that is already the most carefully regulated of the entire health care scene. We look forward to working with the subcommittee and its staff.

The Society of Nuclear Medicine greatly appreciates this opportunity to present its views, and hopes the chairman and his colleagues will feel free to look upon the society as interested in assisting with the concerns presently addressed.

[Testimony resumes on p. 138.]

[Mr. Alexander's prepared statement and attachments follow:]



THE SOCIETY OF NUCLEAR MEDICINE

470 PARK AVENUE SOUTH NEW YORK, N.Y. 10017-2499

STATEMENT
OF THE
SOCIETY OF NUCLEAR MEDICINE
ON

HR 6057 "The Consumer-Patient Radiation Health and Safety Act of 1979"

Presented to
The Subcommittee on Health and The Environment
Committee on Interstate and Foreign Commerce
United States House of Representatives

July 24, 1980

by
George W. Alexander, Jr., CNMT
Immediate Past President, Technologist Section
Society of Nuclear Medicine
and
Associate Director of Training Programs and Chief Technologist
Eugene L. Saenger Radioisotope Laboratory
University of Cincinnati Medical Center
Cincinnati, Ohio

Mr. Chairman and Members of the Subcommittee, my name is George W. Alexander, Jr. I am currently Immediate Past President of the Technologist Section of the Society of Nuclear Medicine, and I am employed as the Associate Director of Training Programs and Chief Technologist of the Eugene L. Saenger Radioisotope Laboratory of the University of Cincinnati Medical Center, Cincinnati, Ohio. I appear before the Subcommittee today representing the position of the Society of Nuclear Medicine and its 10,000 members. With me is Michael L. Cianci, President of the Technologist Section.

The Society of Nuclear Medicine is pleased to have this opportunity to present its views on HR 6057, the "Consumer-Patient Radiation Health and Safety Act of 1979", regarding the adoption of federal standards of licensure for radiologic technologists. The Society commends the Subcommittee for its concern and diligence in examining the question of how to properly protect patients from unnecessary exposure to medical radiation. We appreciate the Subcommittee's insights into the interrelationship between accreditation, certification, national standards development and licensing. All of these factors must be carefully considered since they have an important impact on the competency of both radiologic and nuclear medicine technologists and the quality of health care they provide.

SOCIETY OF NUCLEAR MEDICINE

The Society of Nuclear Medicine, founded in 1954, is the all-encompassing, inter-disciplinary organization dedicated to all aspects of the field of nuclear medicine. As a whole, the Society's purpose is to provide scientific and educational opportunities for the members of the nuclear medicine community, with principal emphasis on transferring state-of-the-art technology to contemporary, high-quality health care. Among its 10,000 members are physicians, physicists, chemists, radiopharmacists, nuclear medicine technologists, and others with career interests in the diagnostic and therapeutic use of radiopharmaceuticals for medical application. This combination of disciplines within one professional organization is unique, and allows viewing of the full scope of nuclear medicine science and practice, together with its contribution to the totality of quality health care for the patients who are referred to us.

The Society's Technologist Section was formed in 1970, and currently represents approximately 40% of the total membership of the organization. The Section is the only professional organization dedicated to the totality of nuclear medicine technology. Its purposes are to enhance the professional development of nuclear medicine technology, to stimulate and conduct continuing educational activities, to develop a forum for the exchange of ideas and information, and to represent nuclear medicine technology, in areas of socio-economic concern. It has at its foundation deep concern for assuring adequate education and competency of nuclear medicine technologists.

WHAT IS NUCLEAR MEDICINE TODAY

Nuclear medicine is the use of radiopharmaceuticals in the diagnosis and, in some instances, the treatment of disease in humans. Studies within this field of medicine are of two basic types, i.e., in vivo and in vitro procedures. In vivo studies involve administering a small amount of a radiopharmaceutical to a patient by injection or orally. The radiopharmaceutical has an affinity for a certain type of cell or tissue which we call the organ of interest. Very sophisticated instrumentation is then used to record on film a permanent image of the radiopharmaceutical within the organ of interest. In some cases, the data derived from the examination are subjected to computer analysis and the image is then reconstructed by the computer, thus improving the overall clarity of the image and the diagnostic accuracy of the study. Most major organ and tissue systems of the body and/or their functions can be examined in this manner, including the brain, lungs, liver, kidneys, bone, thyroid, pancreas and the cardiovascular system.

In vitro procedures encompass the field of radioimmunoassay. Blood samples are drawn from the patient, and serum or plasma is tagged with radioactive materials in order to be able to detect minute quantities of hormones and/or other substances in the blood. These assays are

not detectable by chemical means. These are the procedures of choice in the detection of many disease makers, pollutants and toxic materials in the human body. Special note should be made of the fact that patients for whom these examinations are being conducted receive no radioactive material.

One of the most dramatic examples of the rapid transfer of high technology nuclear medicine research into a major health problem area is in the study of coronary heart disease. During the past three years nuclear medicine has developed very sensitive procedures for identifying individuals with diseased coronary arteries. These procedures can assess the extent of damage when heart attack has occurred and are being used with increasing frequency in outpatient facilities for early detection of heart disease in men and women in certain high risk categories. It should be noted that nuclear medicine *in vivo* diagnostic procedures are non-invasive, safe and essentially painless for the patient. The only sensation the patient feels is the needle stick when the drug is administered. It will be useful to the Subcommittee to cite several examples of typical nuclear medicine procedures in order to understand this process.

Patient "A" has an annual physical examination by his family physician. On examination the physician feels the thyroid gland, and notes the presence of a rock-hard lump that should not be there. The physician suspects that the patient may have thyroid cancer. An appointment is made at a local Nuclear Medicine Department for a thyroid uptake (a thyroid function test to see if the gland is functioning normally) and a thyroid image (which maps distribution of the radiopharmaceutical within the thyroid gland). The patient comes to the Nuclear Medicine Department and is administered a radioactive iodine capsule to swallow. The capsule is tasteless and the patient feels no ill effects as a result of ingestion. The patient is asked to return to the Department 24 hours later (the time required for the miniscule radioactivity to concentrate in the thyroid gland). Upon returning, the patient is placed under a nuclear medicine instrument which measures the radiopharmaceutical present, and the thyroid uptake is performed by correlating the amount of radioiodine in the patient's neck with that of the original capsule. The result demonstrates that the patient's thyroid gland is functioning normally. Next, the patient is asked to lie down on a surface beneath a large detector (gamma-camera) and is requested to remain quiet. "Pictures" of the distribution pattern of radioiodine in the patient's neck are then made. The patient has no ill effects during or following this procedure and is perfectly comfortable throughout.

Upon completion of the procedure by the nuclear medicine technologist, the images are taken to a nuclear medicine physician for a preliminary review. Normally, the technologist takes views of the thyroid gland from three customary angles. When the physician reviews the patient's film, however, he discovers that he cannot adequately visualize the hard lump - so he requests additional views. Since the patient has an adequate quantity of radioiodine already present in his thyroid gland, no further radiopharmaceutical need be administered to obtain the additional images. Once completed, the nuclear medicine physician interprets the images and reports to the referring physician that the rock-hard lump did not take up the radioiodine, and therefore he suspects thyroid cancer. The patient is subsequently referred to a surgeon, the lump is removed, and the pathologic diagnosis of squamous cell cancer of the thyroid gland is made.

Patient "B" is a 3 year old male who has been admitted to the hospital with a red, swollen leg which is very sore to the touch. The pediatrician on the case decides that the patient either has cellulitis (an inflammation of cellular tissue of the leg) or osteomyelitis (an infection in the bone of the leg). Both diseases produce similar clinical symptoms. An x-ray of the leg bones is normal. The pediatrician orders a nuclear medicine procedure termed a bone scan. Upon entry into the Nuclear Medicine Department, a physician examines the patient and determines that pictures or images of the blood flow and blood pool to the legs should be obtained. Routinely for a bone scan a radiopharmaceutical is injected into a vein in the patient's arm, with no pain or ill feelings except the needle stick.

Normally, a patient's nurse is told to return the patient to the Department in three hours (so that the radiopharmaceutical will deposit or accumulate in the patient's bones). However, in this patient's case, the physician can glean additional information by obtaining blood flow and blood pool images of the leg plus the routine three hour post injection images, so the patient remains in the Department for a series of films. Once again, it is important to note, all films are made as a result of the initial administration of a radiopharmaceutical.

Once completed, the images are interpreted by the nuclear medicine physician. Because the additional images were obtained, the differential diagnosis of osteomyelitis is made. To the referring pediatrician this differential diagnosis is extremely important and perhaps could save the patient's leg from being amputated. The patient subsequently is administered intravenous antibiotics for two weeks. This therapy heals the infection within the bone. Had the diagnosis been cellulitis, the entire treatment would have been quite different, and not nearly so extensive.

WHAT IS THE ROLE OF THE NUCLEAR MEDICINE TECHNOLOGIST

The nuclear medicine technologist performs, or assists in the performance, of both *in vivo* and *in vitro* nuclear medicine procedures. The technologist's many duties may include preparation and administration of radiopharmaceuticals to patients; operation of highly complex and specialized detection equipment that measures or portrays distribution of radioactivity in a patient's body; radioimmunoassay procedures; calculation of test data; and, of course, delivery of skillful patient care. The Society has prepared "Position Description for Nuclear Medicine Technologists", which is provided for the further information of the Subcommittee.

ACCREDITATION OF NUCLEAR MEDICINE TECHNOLOGY

Accreditation is the process of formal approval of educational institutions or programs, as contrasted with recognition of individuals.

The Society of Nuclear Medicine has sponsored the development of voluntary national standards described in "Essentials of Education and Accreditation of the Joint Review Committee on Educational Programs for Nuclear Medicine Technology" (JRCNMT "Essentials"). We continue to sponsor JRCNMT by periodic review and update of the "Essentials" (currently underway), and through support by representation of two nuclear medicine physicians and two nuclear medicine technologists on that committee. A copy of the "Essentials" accompanies this statement for the further information of the Subcommittee.

The JRCNMT functions in collaboration with the American Medical Association's Committee on Allied Health Education and Accreditation (CAHEA), which has responsibility for accreditation of all allied health educational programs. The JRCNMT, officially formed in 1970, is responsible for the evaluation of existing nuclear medicine technology educational programs, as well as recommending new programs to CAHEA for accreditation. CAHEA routinely conducts inspections and reviews each program, there currently being approximately 140 CAHEA-approved nuclear medicine technology training programs in the United States. Since the JRCNMT "Essentials" have evolved, it is interesting to note that there has been a definite trend toward formalization of technologist training programs, rather than on-the-job training as educational background for nuclear medicine technologists.

Another accrediting agency is the Joint Commission on Accreditation of Hospitals (JCAH). JCAH requires that an accredited hospital must provide nuclear medicine services for its patient population. JCAH conducts one- to three-year inspections of each accredited institution, and thus serves as a check on the safety and use of radiopharmaceuticals in the diagnosis and treatment of human diseases. JCAH requires that all nuclear medicine technologists are qualified for the duties performed, and that both formal training and on-the-job experience of each nuclear medicine technologist shall be documented. All nuclear medicine

personnel should participate in in-service education programs according to JCAH, as well as outside workshops and professional society meetings. JCAH requires that the extent of participation in these activities of continued education shall be documented. For the last two JCAH inspections in my department, for example, copies of the certification diplomas and written evidence of continued education of each nuclear medicine technologist were required to be demonstrated. For the understanding of the Subcommittee, enclosed with this statement are the current JCAH standards for nuclear medicine.

CERTIFICATION OF NUCLEAR MEDICINE TECHNOLOGISTS

Certification is often used interchangeably with the term registration. This is a process by which a non-governmental agency or association (usually a professional organization) grants recognition to an individual meeting certain special qualifications of competency. Certification is typically voluntary and conferred upon satisfactory completion of an approved training or educational program, or following accomplishment of a given amount of work experience - in addition to acceptable performance on a qualifying examination. One who is certified is then placed on a registry.

In 1976, the Society of Nuclear Medicine evaluated existing certification processes for nuclear medicine technologists (which at that time were "spin-offs" of medical technology and radiologic technology) and made the decision that the certifying processes then in existence did not adequately meet the needs of the profession of nuclear medicine technology. In 1977, the Society initiated the formation of national certification exclusively for nuclear medicine technology: the Nuclear Medicine Technology Certification Board (NMTCB). A task analysis development project was undertaken by the NMTCB that methodically examined all duties performed by nuclear medicine technologists. A copy of this task analysis is enclosed for the review of the Subcommittee.

NMTCB is not only related to practice but reflects the full scope of practice, e.g., imaging and radioimmunoassay. Nuclear medicine technologists now have a strong professional identity, job descriptions for all career levels, the task analysis and the designation "Certified Nuclear Medicine Technologist" (CNMT). Presently approximately 75% of all nuclear medicine technologists are professionally certified, i.e., 13,400 out of 18,000 currently employed nuclear medicine technologists. It is essential for the Subcommittee to recognize that performance standards for nuclear medicine technologists already exist, as a result of the efforts of the Society, JRCNMT, CAHEA, JCAH, NMTCB - and others, as well.

NON-GOVERNMENTAL ORGANIZATIONS CONCERNED WITH THE DEVELOPMENT OF NATIONAL STANDARDS FOR ALLIED HEALTH FIELDS

The Society has also made great strides in working with non-governmental organizations concerned with the development of national standards. Its representatives serve on all major organizations concerned with allied health and national standards, such as the National Commission for Health Certifying Agencies (NCHCA) and the American Society of Allied Health Professions (ASAHP). Both the Society of Nuclear Medicine (our professional organization) and NMTCB (our certifying body) have passed the formal application process and have been accepted into NCHCA as full members. NCHCA was mandated and funded by the Department of Health, Education, and Welfare for the purpose of establishing national standards for certifying bodies that attest to the competency of individuals who participate in the health care delivery system; to grant recognition to certifying bodies that voluntarily apply and meet the established standards; and to monitor the adherence of these standards by the certifying bodies which it has recognized. With the permission of the Chairman, we wish to submit for the hearing record additional information demonstrating the significance of accreditation and certification in determining competency, in cooperation with CAHEA, ASAHP and NCHCA.

FEDERAL REGULATORY AGENCIES

WHICH AFFECT NUCLEAR MEDICINE TECHNOLOGY

In addition to the above listed agencies and/or commissions, the Food and Drug Administration (FDA) now maintains strict control of the safety, efficacy of all radiopharmaceuticals which may be administered to a patient. In addition, Nuclear Medicine has worked in concert with the Bureau of Radiological Health (BRH) of FDA in formulating and developing quality control and assurance procedures for radiopharmaceuticals and nuclear medicine instrumentation so that the dose to the patient and the operator is optimal and instrumentation operates with precision. Since radiation absorbed dose to the patient is derived from the administered dose of a radiopharmaceutical, patient safety from radiation exposure is already being strictly controlled. The Nuclear Regulatory Commission (NRC), FDA and JCAH all require that all patient doses of radiopharmaceuticals must be verified and recorded prior to administration to a patient, thus avoiding excessive radiation exposure. Retakes in nuclear medicine occur only by taking additional images of an organ without additional administration of the radiopharmaceutical.

NRC grants licenses to institutions and/or individuals to procure, possess and use radioactive materials, and maintains strict control over the radiation safety aspects of the use and handling of these radioactive materials. NRC also requires formal written documentation of any misadministration to a patient of a radioactive drug, a requirement that is only applicable to nuclear medicine. NRC regulations govern the qualification and education of the individuals who are allowed to use such radioactive materials. The NRC inspects each nuclear medicine facility on a regular basis to ascertain whether there is compliance with these regulations. Non-compliance with existing regulations may mean forfeiture of the license to use radioactive materials.

SUMMARY

Credentialing activities maintain the quality of practice of nuclear medicine technology. Without credentialing based upon the science of nuclear medicine, there are no standards for technologists to meet. Credentialing technologists demonstrate an acceptable level of performance as defined by the Nuclear Medicine Technology Certification Board. Whatever the mechanism however, the ultimate goal of credentialing in nuclear medicine technology is to avoid unnecessary radiation exposure and to improve the quality of health care.

The Society of Nuclear Medicine is opposed to HR 6057. Many of the provisions of the proposed legislation are duplications of existing standards and/or regulations. It is our firm opinion that there is no demonstrated need for duplication of currently existing regulations promulgated by the Nuclear Regulatory Commission and the Food and Drug Administration, as well as standards embodied by organizations such as the National Commission for Health Certifying Agencies and the Commission on Allied Health Education and Accreditation.

Further, there exists no scientific evidence that licensure itself has demonstrated significant changes in radiation protection practices or the recruitment and availability of radiologic technologists or nuclear medicine technologists. This finding, the product of numerous professional studies, is clearly stated, for example, by a study conducted by the American Society of Radiologic Technologists/American College of Radiology Conjoint Committee on Technology Job Descriptions and Manpower Studies. There exists no published findings to demonstrate otherwise.

HR 6057 also does not adequately recognize the full nature and scope of the medical specialty of nuclear medicine, or that of nuclear medicine technology. It does deal with that aspect of Nuclear Medicine that is performed on laboratory samples rather than humans.

The bill might even be viewed by some as an infringement upon states' rights to license occupational groups. The activities of all of the federal and private sector agencies collectively serve to maintain strict control over all aspects of the practice of nuclear medicine,

and thereby provide safeguards against undue radiation exposure to patients who benefit from nuclear medicine procedures. Nuclear medicine techniques are well established with absolute controls over radiation dosage to the patient and to technologists, as well.

If the Subcommittee deems it necessary to pursue the adoption of HR 6057, however, the Society recommends the following additional points for inclusion:

1. Certification and/or proficiency examinations should be the central point of all licensure approaches. HR 6057 should recognize specifically the adoption of the voluntary certification examinations which are available currently for nuclear medicine and radiologic technology, respectively. The Society has provided demonstrable in-depth activity and ongoing involvement in the development of voluntary certification examinations for nuclear medicine technologists, culminating in the formation of the Nuclear Medicine Technology Certification Board in June 1977, the first certification process exclusively for nuclear medicine technologists.
2. Essentials of education, training and accreditation of programs are necessary aspects for assuring professional competency and should be incorporated into a licensure approach. The JRCNMT has developed essentials and accredits training programs. HR 6057 proposes to give to the Secretary of DHEW the authority to promulgate "voluntary" minimum standards as well as authorizing professional organizations to certify such accreditation of educational programs. The proposed legislation should assure recognition of the JRCNMT as the accrediting agency for educational programs in nuclear medicine technology.
3. In any licensure approach, the practicing nuclear medicine technologist must be allowed to perform the nuclear medicine technology procedures for which he has been trained. HR 6057 ~~does not~~ adequately recognize the scope of practice of nuclear medicine technology or its diversity from other professional disciplines, particularly those nuclear medicine procedures which do not require that a radioactive drug be administered to a patient.
4. There should be uniformity and consistency of licensure, regulations and reciprocity among all states. We support the current voluntary development of national standards that is swiftly being implemented by several states. This activity supports the facts that additional legislation such as this bill is not necessary.
5. On-the-job training should be evaluated and included as an acceptable criterion for licensure eligibility. A critical manpower shortage of nuclear medicine technologists already exists. Persons who meet national standards in all other respects should not be overlooked as qualified to continue to practice. To do otherwise would create an even more critical health manpower situation.
6. HR 6057 states that the secretary shall consult with the Environmental Protection Agency, which has absolutely no experience with nuclear medicine applications. At the present time nuclear medicine practice privileges are already governed by the NRC and participating agreement states. The types, doses and radiation exposure due to radiopharmaceuticals are already controlled so that guidelines promulgated by the EPA would be redundant, superfluous and probably poorly conceived.

7. If the Subcommittee continues to believe that Federal minimum standards for licensure are necessary, the Society believes that the thrust of such a program must be through state licensure, based upon state acceptance and adoption of national certification. States implementing licensure should be encouraged to adopt national certification granted by only those certifying organizations adhering to the certification standards established by the National Commission for Health Certifying Agencies. This alternative incorporates use of national standards but still allows for state control and adaptation to fulfill local needs. National standards thusly adopted by the several states would maintain uniformity and consistency, and permit reciprocity and mobility between the states.

We appreciate the concerns of this Subcommittee, but feel strongly that these concerns are already addressed by both the profession and the federal sector, e.g. FDA, NRC, etc. The consumer public is already well protected with respect to nuclear medicine technology. The Society of Nuclear Medicine has supported the concept of a national (non-federal) certification system that would set national standards for both accreditation and certification through a collaborative effort of the federal government, professional associations and other interested parties. Establishment of the National Commission for Health Certifying Agencies has made the approach to the development of national standards a reality. The Society of Nuclear Medicine and the NMTCB are therefore actively engaged in the promulgation of national standards.

We appeal to the Subcommittee to examine the information regarding our discipline. There is no necessity to impose additional legislation on a profession that is already the most carefully regulated of the entire health care delivery system. The Society of Nuclear Medicine greatly appreciates this opportunity to present its views, and hopes the Chairman and his colleagues will feel free to look upon the Society as interested in assisting further with the concerns addressed in today's hearing.

Position Description: Nuclear Medicine Technologist

Technologist Section, Society of Nuclear Medicine

Nuclear Medicine Technologists, under the direction of physicians licensed to possess radioactive materials, utilize radionuclides and radiopharmaceuticals to perform or assist in the performance of diagnostic examinations—including radionuclidic imaging of organs and organ systems of patients, dynamic studies, assays of body fluids and tissues, and radioassays. These responsibilities require appropriate knowledge of the field of Nuclear Medicine Technology, and those aspects of chemistry, physics, mathematics, and the biomedical sciences that relate to Nuclear Medicine Technology and its growth. Technologists perform studies to evaluate and standardize new or improved methods and equipment for use in Nuclear Medicine Laboratories and Clinics. They also assist the physician in therapeutic procedures using radionuclides. Nuclear Medicine Technologists transmit findings of studies, tests, and examinations to Nuclear Medicine Physicians, who are responsible for the care of the patient. They also participate in medical research. All duties and responsibilities are assigned by Nuclear Medicine Physicians.

(Editor's note: The scope of practice of Nuclear Medicine Technology varies widely across the country. This is most probably due to the varied backgrounds of Technologists and Nuclear Medicine Physicians—and the fact that essentials for educational programs in Nuclear Medicine Technology provide for different types of structured education routes into the profession. Because of this variation, and hence some confusion, members of the Technologist Section requested the Section to develop position (or job) descriptions to define the scope of practice in a more uniform manner. These descriptions are intended to be guidelines for members and others to use and modify as they see fit for their purposes. The descriptions were written to reflect the broadest scope of practice—with knowledge of the great range of duties and the understanding that modification would be necessary in many instances.)

Level I (Staff Technologist):

(A career-entry technologist who performs either in vivo or in vitro routine tasks, or both, under close supervision)

Level II (Senior Technologist):

(A staff technologist who performs most diagnostic work in the department with limited supervision)

Level III (Chief Technologist/Technical Administrator):

(Additional levels on the Nuclear Medicine Technology

career ladder may include Educational Coordinator, Computer Technologist, etc.)

Level I (Staff Technologist)

Principal Duties and Responsibilities:

A. Dose Calculation and Administration—

1. Obtains radionuclides by eluting generator systems maintaining sterile technique.
2. Measures eluant for total activity and checks for contamination.
3. Prepares appropriate dosages of radiopharmaceuticals in preparation for diagnostic procedures.
4. Performs quality control procedures to ensure pharmaceutical quality of agents before administering to patients. This step may include such techniques as paper chromatography, pH determination, and tests for radionuclidic purity. The technologist is responsible for maintaining sterility and integrity of prepared radiopharmaceutical compounds.
5. Calculates amount and volume of activity to be administered following prescribed procedures, according to information on age, weight, and examination.
6. Administers the dose of radiopharmaceuticals to patients undergoing nuclear medicine procedures—either intravenously (where legally permitted), orally, or by inhalation.

B. Imaging Procedures—

1. Receives patients and explains procedure to them in order to obtain cooperation and allay anxieties during performance of procedure. It is the responsibility of the technologist to continually assess the immediate needs and conditions of assigned patients.
2. Visually inspects the patient in order to record any observations that may contribute additional information in the evaluation of test results, e.g., pregnancy, incontinency, surgery, interfering medications, etc.
3. Reviews and abstracts data from patient's chart.
4. Places the patient on the examination table and

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explains, as necessary, positioning and instrumentation operating characteristics, time to complete testing, etc.

5. Sets up imaging devices for studies in accordance with prescribed procedures.
 6. Performs standard nuclear medicine dynamic and static imaging procedures on patients, which includes assisting patients in assuming required anatomical body positions and positioning and adjusting the equipment to encompass the area to be studied. The technologist adjusts controls on equipment in accordance with prescribed procedures to produce information of required diagnostic quality.
 7. May consult with staff professionals to obtain information concerning the patient's physical condition, preliminary diagnosis, and care in order to take these factors into account while performing diagnostic procedures.
 8. Observes patients for a change in status and follows prescribed procedures if a change is observed, which may include taking patient's vital signs or initiating cardiopulmonary resuscitation.
 9. Evaluates needs and performs special positioning or examination techniques, certain technicalities, or additional views when necessary, or as requested by the Nuclear Medicine Physician or supervisor, or both.
 10. Checks the quality of scans in general and is responsible for the quality control of work performed.
 11. Communicates physician's written interpretation of tests, when indicated, to designated hospital personnel.
 12. Schedules patients for Nuclear Medicine examinations.
 13. Assists in maintaining current inventory of routine laboratory supplies and orders supplies in coordination with supervisor.
 14. Maintains work areas in clean and orderly condition and ensures that examination rooms are properly supplied, equipped, and operational before each examination.
- C. Instrumentation—**
1. Operates imaging equipment (scintillation cameras, rectilinear scanners, portable cameras) and related accessories (videotape, multiframing devices, xenon apparatus, computers, etc.) for routine studies.
 2. Performs quality control procedures on all instruments, including voltage and linearity checks and tests of uniformity and resolution, to ensure that all equipment is in proper working order.
 3. Records status and results of instrument checks in appropriate log books.

4. Performs minor routine preventive maintenance on instrumentation and suggests equipment repair to supervisor.

5. Acquires computer-generated data for patient studies.

6. Checks operation and calibrates survey and monitoring devices against known standards.

D. Nonimaging procedures—

1. Operates all laboratory auxiliary equipment (pipets, centrifuges, water baths, pH meters, balances, etc.) during the performance of routine laboratory procedures.

2. Prepares solutions and materials when applicable and performs serial dilutions as required.

3. Performs venipuncture at proper times, separates blood components, and stores specimens appropriately.

4. Furnishes nurses and outpatients with accurate instructions concerning urine, stool, and blood collections.

5. Prepares samples for counting in either a liquid or well scintillation detection system, or both.

6. Counts specimens in scintillation counting system, performs appropriate calculations, and records results in laboratory record books.

7. Maintains quality control program for all laboratory assays and maintains records of all quality control procedures.

8. Judges acceptability of results and decides on necessity of repetition.

E. Radiation Protection—

1. Receives and checks all radionuclide shipments for contamination according to radiation safety regulations.

2. Performs various tasks associated with receiving, processing, distributing, and storing radioactive materials.

3. Disposes of radioactivity and contaminated materials in accordance with departmental, hospital, and federal regulations, maintaining records of all disposition.

4. Using appropriate instrumentation or other devices, monitors personnel, work areas, and patient rooms where applicable to ensure that levels of radiation do not exceed those levels defined in institutional and NRC regulations. Reports all excessive radiation exposure to the proper authority.

Educational Requirements:

The basic education necessary to qualify for the Level I position in Nuclear Medicine Technology is one of the following:

1. Graduation from an approved school of Nuclear Medicine Technology or equivalent qualifications.

2. Certification in Nuclear Medicine Technology or eligibility for certification.

Supervisory Control over the Position:

The Level I Technologist is under the immediate supervision of the Level II Technologist, who, in turn, is directly responsible to the Level III Technologist. All routine duties are performed under supervision with all problems and complications reported to the Level III Technologist and the Nuclear Medicine Physician in that order.

LEVEL II (Senior Technologist)

The Level II Nuclear Medicine Technologist performs a more extensive range of nuclear medicine procedures and tasks that require an advanced level of job knowledge and skill, normally acquired through continuing education.

Principal Duties and Responsibilities:

In addition to the principal duties and responsibilities of the Level I Technologist, the Level II Technologist:

1. Plans, schedules, assigns, and coordinates the day-to-day work of technical assistants, technologists, and students.
2. Assists in the development of new computer applications in Nuclear Medicine.
3. Assists in development of new tests by performing comparison studies and clinical trials, and implements these new procedures in the absence of a Level III Technologist.
4. Assists in developing quality control procedures and instructs other technical personnel on technical aspects of their routine use.
5. Assists in clinical teaching, evaluation of students' performance, and may oversee the work of both staff and student Technologists.
6. Assists in the conduct of specialized tests and studies either in vitro or in vivo, or both.
7. Maintains regular contact with physicians and other health care personnel regarding the nature, scheduling, or results of procedures performed within the Nuclear Medicine Department.

Education Requirements

In addition to the basic educational requirements for a Level I Technologist, one or preferably two years experience in nuclear medicine technology at Level I is required for Level II Technologists, in which competence has been demonstrated in:

1. Performing all procedures with adequate quality to assist physicians in the care of patients.
2. Working with professional and other technical personnel in a unified team effort.
3. Identifying and assessing patient's needs.

Supervisory Controls over the Position:

Same as for Level I Technologist, however the Level II Technologist performs work assigned with limited super-

vision. The Level II Technologist is immediately responsible to the Level III Technologist, who is directly responsible to the Medical Director of Nuclear Medicine.

LEVEL III (Chief Technologist/Technical Administrator)

The Level III Technologist performs responsible administrative, supervisory, and advanced technical work in a Nuclear Medicine Department. In addition to all the duties and responsibilities of other Nuclear Medicine technical staff, the Level III Technologist must have the ability to recognize, anticipate, and solve problems in a prompt and efficient manner. The Level III Technologist must have the ability to supervise and guide employees and to meet and deal effectively with administrative and professional personnel of other services and divisions.

Principal Duties and Responsibilities

1. Develops short- and long-term goals for the Nuclear Medicine Department and upon approval by superiors, implements plans to accomplish these goals.
2. Develops usage of laboratory space for both existing and new equipment, and participates with hospital administration in planning or expanding a Nuclear Medicine Facility.
3. Develops and administers an operational budget for the Nuclear Medicine Department.
4. Prepares and maintains records relative to licensing requirements of the Nuclear Regulatory Commission and the Food and Drug Administration.
5. Counsels employees regarding performance, conduct, attendance, and related matters. The Level III Technologist is responsible for overall hiring, training, evaluation, discipline, and discharge of the Nuclear Medicine technical and clerical staff.
6. Communicates with various vendors of radiopharmaceuticals and equipment as to the needs of the laboratory.
7. Organizes and conducts technologist staff conferences.
8. Implements safety procedures to protect personnel and patients from radiation exposure in the event of a radioactive spill.
9. Evaluates equipment maintenance and orders repairs when needed. Evaluates new equipment available on the market and prepares budget statements, cost analysis, and justification figures.
10. Regularly reviews records of personnel radiation exposure, dose calibration, and results of assays of radionuclides purity, sterility, and pyrogen-free status and, in case of discrepancy, takes appropriate action.
11. Assesses need for and orders radiopharmaceuticals for operation of the Nuclear Medicine Department.

12. Participates in formal in-service training programs in the department and conducts in-service education programs for hospital personnel orientation to Nuclear Medicine.
13. Determines and documents duties and responsibilities of each position under his or her direction, maintaining current and accurate position descriptions.
14. Coordinates the Nuclear Medicine Technology Training Program in the absence of an Educational Coordinator. The Level III Technologist instructs interns and students, reviews student applications and selects trainees, prepares and updates program curriculum, and oversees performance of students on training assignments to ensure satisfactory completion of the program, where applicable.
15. Directs preparation and maintenance of all pertinent department records.

Educational Requirements:

To qualify for the position of Level III Nuclear Medicine Technologist, certification in Nuclear Medicine Technology is mandatory. In addition, one of the following is necessary:

1. Four years of successful nuclear medicine technology practice, in any combination of Level I or Level II experience.
2. Two years of college desired, plus adequate experience as determined by the Medical Director of the Nuclear Medicine Department.

Supervisory Control over the Position:

The Level III Technologist is directly responsible to the Medical Director of Nuclear Medicine for all clinical activities and duties performed. Assigned duties and responsibilities are performed independently within the delegated authority. Guidance and clarification are provided when necessary and as unprecedented situations arise.

Nuclear Medicine Services

Nuclear medicine services and consultation shall be conveniently available to meet the needs of the patients as determined by the medical staff. Principle

The mechanism for providing diagnostic and therapeutic nuclear medicine procedures shall be clearly defined. Standard I

The hospital shall have a mechanism for providing nuclear medicine procedures that is adequate for the scope and complexity of the hospital programs offered. When there is an organized nuclear medicine department/service, it shall be directed by a physician qualified in nuclear medicine, and staffed appropriately. When only limited procedures are performed in the hospital, as in the case of in vitro testing in the clinical laboratory, an organized nuclear medicine service shall not be deemed to exist. When nuclear medicine procedures are performed outside the hospital for hospitalized patients, the outside sources must be approved by the medical staff and must meet the requirements of these standards.

INTERPRETATION

The director of the organized nuclear medicine department/service shall be a member of the medical staff. The credentials files of the director and of all other physicians practicing diagnostic and/or therapeutic nuclear medicine in the hospital shall reflect their training, experience, and current competence in the specialty. The director shall assure that proper radiation safety principles and practices are observed and that all technical personnel are qualified for the duties performed. The formal training and on-the-job experience of each nuclear medicine technologist shall be documented. Appropriate credentials shall be required for any pharmacist involved in the preparation of radiopharmaceuticals. When limited nuclear medicine procedures are performed within the hospital, supervision shall be provided

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by a physician who is qualified in nuclear medicine and who shall assure personnel safety that is compatible with the degree of hazard and in keeping with the safety requirements outlined in this section of the *Manual*.

5 The services of a health or radiation physicist should be available, at least on a consultant basis, for educational purposes and for safety evaluations of all equipment, and storage and handling practices.

All nuclear medicine personnel should participate in in-service education programs as well as outside workshops and professional society meetings. The extent of participation shall be documented and shall be realistically related to the size of the staff and the scope and complexity of the nuclear medicine services performed. The director shall contribute to the in-service education of nuclear medicine personnel.

10 The director shall document the review and evaluation of the services provided to strive to assure the optimal degree of quality and safety, as well as to assure their appropriateness. Refer also to the Quality Assurance section of this *Manual*.

15 All nuclear medicine procedures performed in the hospital shall be in accordance with appropriate institutional or individual licensure requirements.

Standard II Nuclear medicine services, when provided within the hospital, shall have adequate space and facilities to meet, with safety, the diagnostic and therapeutic needs of the patients.

INTERPRETATION Space and facilities for the nuclear medicine department/service should include that necessary for the reception, examination, and diagnostic study of patients, as well as for related clerical work and for conferences. Adequate accommodations shall be provided for the clinical care of therapeutic patients. Facilities shall be provided for the safe preparation, storage, and disposal of radioactive materials so that radiation levels in all areas are as low as practicable and do not exceed accepted standards. The nuclear medicine service area shall be protected from sources of interfering radiation.

25 The type, quantity, and quality of equipment for the nuclear medicine procedures performed shall be adequate to conduct reliable diagnostic studies as determined by the director and the medical staff. Standards having energy radiations equivalent to those of the radionuclides used in patient studies should be utilized for routine calibration, and should be readily available.

Standard III There shall be quality control policies and procedures governing nuclear medicine activities that assure diagnostic and therapeutic reliability and safety of patients and personnel.

INTERPRETATION All radioactive materials, reagents, and standards shall be prepared, stored, and checked at a defined interval to be determined by the director, to assure accuracy, patient safety, and precision of results. All reagents must be labeled to indicate identity, date of preparation, and assay. Instrument calibration procedures sufficient to affirm proper performance shall be conducted each day the instrument is used, and the results recorded. All safety survey instruments in the hospital should be calibrated at least annually. The recommendations of the National Council on Radiation Protection and Measurements should be known and applied.

When required by federal, state, or local regulations, by licensure requirements, or by the medical staff, a radioisotope committee shall be established. At least one member of this committee must be a physician experienced in the safe handling of radioisotopes, in the measurement of radioactivity, and in determining radioisotope dosage for various patient studies or treatments. Representatives of various fields of specialization should be included on the committee, as determined by the nature of the program being conducted. In large hospitals, this committee may be absorbed into a radiation safety committee. When either of these committees exists, it shall work in cooperation with the hospital safety committee. The committee should meet as often as required, but not less than every six months, and shall maintain written minutes of each meeting. The committee concerned with nuclear medicine activities should have at least the following responsibilities:

- To review all proposals for diagnostic and therapeutic uses of unsealed radionuclides; 15
- To recommend to the medical staff those practitioners having suitable training and experience to perform nuclear medicine procedures;
- To develop regulations for the use, transport, storage, and disposal of radioactive materials used in nuclear medicine procedures; 20
- To recommend remedial action when there is failure to observe protection recommendations, rules, and regulations; and
- To establish rules to guide nursing and other individuals who are in contact with patients receiving therapeutic amounts of unsealed radionuclides; rules relating to the discharge of such patients; and rules to protect personnel involved when such patients undergo surgical procedures or autopsy. 25

Quality control procedures shall be developed to guide personnel in the standardized performance of diagnostic studies and therapeutic procedures, and to assure that the identity, strength, and integrity of all radiopharmaceutical agents are maintained. 30

Policies and procedures relating to safety within the nuclear medicine services areas shall be developed and enforced. These shall include as a minimum:

- a requirement for wearing the appropriate exposure-monitoring devices at all times when in the area; 35
- guidelines to be followed in the event of radioactive contamination of personnel, equipment, or environment;
- a requirement that there be written authority for all nonphysicians who administer radioisotopes parenterally when legally permissible; 40
- a requirement for security of all "hot" and "decay" areas in order to protect all individuals in the hospital;
- rules prohibiting oral pipetting of radionuclides and eating or drinking in the work areas;
- establishment of an effective radiation protection survey program to be performed at least every six months; and 45
- protective shielding for syringes, injection vials, and stock sources of radioactivity.

For other than radiation safety requirements, see also the Functional Safety and Sanitation section. Refer also to the Infection Control and the Pathology and Medical Laboratory Services sections of this *Manual*. 50

Standard IV Records required by federal, state, and local authorities, as well as records consistent with competent practice of nuclear medicine, shall be maintained.

- INTERPRETATION**
- 5 Nuclear medicine diagnostic and therapeutic procedures shall be performed only upon the written request of the responsible physician or a member of the house staff. Such procedures may also be provided for authorized physicians who are not members of the medical staff for their patients who are not being evaluated or treated in the hospital. Reports of nuclear medicine interpretations, consultations, and therapy shall be included in the patient's record; duplicate records should be kept on file in the nuclear medicine department/service. The patient's medical record shall also reflect the identity, date, and amount of radiopharmaceutical used, as well as any specific preparation of the patient. For further requirements relating to medical records, see the Medical Record Services section of this *Manual*.
 - 10
 - 15 Records to be maintained on radionuclides and radiopharmaceuticals should include at least the following information:
 - The dates, amounts, and methods of receipt and disposal;
 - The supplier and lot number; and
 - The use, date, amount administered, and the identity of any recipient.
 - 20 Instrument log books to be maintained shall include at least the following:
 - Calibration records of equipment and monitors showing dates, name of technologist, and sources of reference standards;
 - Maintenance and repair records, showing dates and sources of service; and
 - 25
 - The findings of federal, state, or local evaluations or those of a consultant radiation physicist, and the action taken to correct any deficiencies found.

Records shall be maintained to show the radiation exposure of all nuclear medicine personnel, as well as the results of routine radiation safety surveys.

Essentials of an Accredited Educational Program for the Nuclear Medicine Technologist

Initially adopted 1969; revised 1976

Adopted by the

AMERICAN COLLEGE OF RADIOLOGY
AMERICAN MEDICAL ASSOCIATION
AMERICAN SOCIETY FOR MEDICAL TECHNOLOGY
AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS
AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS
SOCIETY OF NUCLEAR MEDICINE

Program Review Committee

JOINT REVIEW COMMITTEE ON EDUCATIONAL PROGRAMS
IN NUCLEAR MEDICINE TECHNOLOGY

OBJECTIVE

The organizations indicated above have obvious interest and concern in the development of educational programs designed to prepare the nuclear medicine technologist. To organize their concerns and provide an orderly mechanism for both program evaluation and preparation of recommendations on accreditation status, these organizations have established a Joint Review Committee on Educational Programs in Nuclear Medicine Technology. As the agent of the five sponsoring organizations and of the Committee on Allied Health Education and Accreditation (CAHEA) in matters relating to educational programs in nuclear medicine technology, the Joint Review Committee is dedicated to the maintenance of high standards of education. Its membership is comprised of representatives from each of the sponsoring organizations.

The education and health professions cooperate in establishing and maintaining standards of appropriate quality for educational programs in nuclear medicine technology and in providing recognition for educational programs that meet or exceed the minimum standards outlined in these *Essentials*. These standards are to be used as a guide by the Joint Review Committee and program directors.

DESCRIPTION OF THE OCCUPATION

The practice of nuclear medicine includes the utilization of radioactive materials for therapeutic and diagnostic "in vivo" and "in vitro" procedures and any combination thereof. The skills of the nuclear medicine technologist shall complement those of the nuclear medicine physician and other professionals in the field.

The nuclear medicine technologist must be able to perform effectively in three major areas of responsibility:

A. Patient Care

1. Must understand and relate to the patients' concerns and fears about their illnesses and pending diagnostic procedures or therapy.

PREAMBLE

2. Must recognize emergency patient conditions and initiate life-saving first aid prior to the arrival of a physician.

B. Technical Skills

1. Prepares and manages quality control of radiopharmaceuticals to patients by intravenous, intramuscular, subcutaneous, and oral methods.
2. Understands and utilizes radiation detection devices and other laboratory equipment that measure the quantity and distribution of radionuclides deposited in the patient or a patient specimen.
3. Performs "in vivo" and "in vitro" procedures, understanding these tasks sufficiently well to supplement selected examinations and procedures for the benefit of the patient and to improve the diagnostic quality of the data produced.
4. Utilizes knowledge of radiation physics and safety regulations to practice radiation safety, thereby limiting the exposure to the patient, the public, and fellow radiation workers to acceptable, minimal levels of radiation.
5. Is aware of quality control techniques and applies them appropriately to all procedures and products in the laboratory.
6. Participates in research activities that demand a thorough knowledge of the many facets of nuclear medicine.

C. Administrative Functions

1. May supervise other nuclear medicine technologists, laboratory assistants, and other personnel.
2. Participates in the procurement of supplies and instrumentation required to operate the facility.
3. Records all operations of the laboratory including the receipt and disposition of radioactive materials, instrument and procedural quality control data, patient procedures, and medical records.

REQUIREMENTS FOR ACCREDITATION

I. SPONSORSHIP

Educational programs may be established in

- A. Junior and senior colleges, universities, and technical vocational institutes
- B. Hospitals and clinics

C. Medical schools

The institution must be accredited or otherwise acceptable to the Committee on Allied Health Education and Accreditation (CAHEA).

Colleges, universities, and technical vocational institutes without clinical facilities must have appropriate clinical affiliations.

II. INSTRUCTIONAL FACILITIES

- A. **General**—Adequate classrooms, laboratories, and clinical facilities must be provided.
- B. **Laboratory**—Appropriate modern equipment and supplies for directed experience must be available in sufficient quantities for full participation by the individual student.
- C. **Library**—A library must be readily accessible and contain an adequate supply of current reference volumes, periodicals, and other material related to the curriculum.

III. CLINICAL FACILITIES

- A. The clinical phase of the educational program must be conducted in a broad clinical setting under competent medical direction.
- B. In the clinical teaching environment, an effective ratio of students to clinical instructors must be maintained.
- C. The type and quantity of nuclear medicine procedures must be adequate for the clinical training of the student.
- D. The clinical facility must have adequate quantity and varieties of nuclear medicine instrumentation to allow for student instruction.
- E. Where classroom and clinical instruction are not provided in the same institution, accreditation will be granted to the sponsoring institution, as identified by established criteria. However, responsibility for quality of the total teaching program must be shared by both institutions involved (i.e., college and hospital).

IV. FINANCES

- A. Financial resources for continued operation of the educational program must be assured through regular budgets.
- B. The institution shall not charge excessive student fees.
- C. The sponsoring institution or its clinical affiliates must not substitute students for paid personnel to conduct the work of the clinical faculty.

V. ADMINISTRATORS AND FACULTY

- A. **Educational Directors**
The educational direction shall be assumed by a physician, nuclear medicine technologist, or other allied health personnel (i.e., physicist, professional educator).
Every program must have a qualified medical director and nuclear medicine technologist director responsible for the clinical training, and program coordination and for the organization, administration, periodic review, continued development, and general effectiveness of the program.
- B. **Medical Director**
The medical director must be a physician qualified in the use of radionuclides and a diplomate of the American Board of Nuclear Medicine, of the American Board of Radiology (in the area of nuclear radiology), or of the American Board of Pathology (in the area of radioisotopic pathology) or be otherwise acceptable to the Committee on Allied Health Education and Accreditation.
- C. **Technologist Director**
The technologist director shall devote full time to the laboratory where the educational program is conducted. The technologist must be certified in nuclear medicine technology by the American Society of Clinical Pathologists Board of Registry or the American Registry of Radiologic Technologists. This technologist must have at least three years of experience at a combination of staff and senior nuclear medicine technologist levels and shall have educa-

tion and experience embracing methods of instruction, educational psychology, and human relations.

D. Faculty Appointments

If the clinical facility is not an integral part of the institution initiating the program (i.e., university, technical vocational institution), the physician, technologist director, and instructors shall be members of the faculty or staff of the sponsoring institution.

E. Change of Director

If any of the directors of the educational program are newly appointed, immediate notification must be sent to the AMA Department of Allied Health Evaluation. The curriculum vitae of the new directors, which should include details of training, education, and experience in the field, must be submitted. If the new director's credentials are satisfactory, accreditation of the program will be continued.

F. Teaching Staff

The instructional staff must be qualified through academic preparation and experience to teach the subjects assigned. Faculty shall have adequate and appropriate training in the areas of curriculum design and teaching techniques. The staff shall include at least one instructor who is certified in nuclear medicine technology and actively engaged in the clinical practice of nuclear medicine technology. A planned program for the continued education for the faculty shall be provided.

G. Advisory Committee

For programs involving more than a single institution, an advisory committee must be appointed to assist the directors in continuous program development and evaluation, in faculty coordination, and in ensuring effective clinical relationships. Programs having minimal or no extra-institutional activities shall provide for periodic review and updating of program standards and curriculum content by the director and institutional staff.

VI. STUDENTS

- A. **Selection**—In colleges, universities, and technical vocational institutes, selection of students shall be made in accordance with the generally accepted practice of the institution. Directors of the clinical aspects of the program shall be involved in the selection. In hospital-sponsored programs, selection of students must be made by an admissions committee of individuals responsible for the program. Admissions data shall be on file at all times in colleges, universities, or hospitals sponsoring the program.
- B. **Admission Requirements**—Persons admitted into nuclear medicine technology programs shall have completed high school or its equivalent and have completed post-secondary courses in the following areas:
 1. Anatomy and physiology
 2. Basic physics
 3. Basic mathematics
 4. Medical terminology
 5. Oral & written communications
 6. General chemistry
 7. Psychology and sociology
 8. Medical ethics and jurisprudence

Under unusual circumstances some of the prerequisites may be completed during the year of nuclear medicine training.

Qualified medical technologists [MT(ASCP) or eligible], radiographers [RT (R) (ARRT) or eligible], and registered nurses [RN], are presumed to have the necessary credentials to meet the entrance requirements.

Educational institutions such as junior colleges, universities, and technical vocational institutes may provide

these prerequisite courses as part of an integrated program in nuclear medicine technology (i.e., 2 to 4 years). In these programs, educational institutions are encouraged to provide such basic elements of a general education as are necessary to qualify the students for an associate or bachelors degree.

- C. **Health**—Applicants shall be required to submit evidence of good health. Student health service shall be available for evaluation and maintenance of the student's health. When students are learning in a clinical setting or a hospital, the hospital or clinic shall provide students with the protection of the same physical examinations and immunizations as are provided to hospital employees working in the same institution.

VII. STUDENT RECORDS

Satisfactory records of student performance in the educational program shall be maintained. Monthly and annual reports of the department must be prepared and available for review. Records shall include the following:

- A. Transcripts of high school and college credits and other pre-admission credentials.
- B. Certification by a physician as to the candidate's good health upon admission.
- C. Record of class and laboratory participation and accomplishment of each student in accordance with requirements of the institution.
- D. Attendance and grades.
- E. Record of clinical performance under supervision.

VIII. PROFESSIONAL CURRICULUM

A. Length

1. General—The structure of the curriculum shall be based on not less than one calendar year of full-time study. This is to provide didactic content of appropriate scope and depth as well as clinical experience of sufficient variety to develop needed knowledge and skills.

2. Innovative Programs—Performance objectives for all phases of curriculum and for graduation shall be clearly defined in terms of measurable behavior. Therefore, the curriculum may also be structured to allow students to progress at an individual pace. This will provide an opportunity for students to meet performance standards specified for graduation in less than normal curriculum length as well as provide an opportunity for students who require more time to extend the length of their instructional program. *Students completing the program in less than one year must be advised of current requirements of national certifying bodies.*

- B. **Structure**—Instruction should follow a planned outline which includes:

1. Assignment of appropriate instructional material.
2. Classroom presentations, discussions, and demonstrations.
3. Supervised clinical experience.
4. Examinations, oral and written, for didactic and clinical aspects of the program.

C. Content

1. Patient care
2. Nuclear physics
3. Instrumentation and statistics
4. Health physics
5. Biochemistry
6. Immunology
7. Radionuclide chemistry
8. Radiopharmacy
9. Administration
10. Radiation biology

11. Clinical nuclear medicine—"in vivo" and "in vitro" studies

12. Radionuclide therapy

13. Introduction to computer application/operation or data manipulation

- D. **Records**—Complete curriculum shall be kept on file including rotation of assignments, lists of instructional aids used to augment the learning experience of the student, copies of the course outlines, and class schedules. Directed experience and teaching plans shall be kept on file and available for review. Copies of the practical and written examinations should be maintained and continually re-evaluated.

IX. EDUCATIONAL OBJECTIVES

After participation in the program, each student must be expected to have attained a certain level of knowledge and understanding that is consistent with specific performance objectives. Following is a minimal list of objectives.

- A. **Physical Science.** The technologist must demonstrate a fundamental knowledge and understanding of the following:

1. Elementary aspects of the structure of matter with special emphasis on the composition, stability, and energy levels of atomic nuclei.
2. Modes of radioactive decay with special emphasis on Beta decay, electron capture, metastable states, and internal conversion.
3. Particle and photon radiation accompanying radioactive decay with special emphasis on photon radiation.
4. Interactions of radiation with matter, with special emphasis on photoelectric and Compton interactions.
5. Radiation detectors with special emphasis on scintillation and semi-conductor detectors for photons.
6. Collimated radiation detectors with special emphasis on the characteristics of flat-field, focused, and parallel-hole diverging, and of pin-hole collimators in response to point, line, and plane sources.
7. Electronic instruments such as amplifiers, pulse-height analyzers, scalars, count-rate meters, and computers.
8. Statistics of counting random events.
9. Mathematical operations, including logarithms and exponential functions.

- B. **Radiation biology and protection.** The technologist must demonstrate a fundamental knowledge and understanding of:

1. Biologic effects of radiation exposure.
2. Administrative and technical means of reducing unnecessary radiation exposure to patients, personnel, and the environment.
3. Techniques of measuring levels of radioactive contamination and technique of decontamination.
4. Government regulations regarding exposure and material handling.

- C. **Radiopharmaceuticals.** The nuclear medicine technologist must be able to demonstrate knowledge and understanding of radiopharmaceuticals in the following specific areas:

1. Production of radionuclides by reactors and particle accelerators, the use of radionuclide generators, the concept of specific activity and the special chemical characteristics of the carrier-free state.
2. Formulation of radiopharmaceuticals, including general techniques of preparing agents used in the nuclear medicine laboratory; and quality control procedures, including tests for radiochemical purity, quantitative assay, sterility and pyrogens.

3. Operation of electronic equipment appropriate for radioassay and quality control.
4. Understanding of biochemical and physiological properties or radiopharmaceuticals including the mechanism of localization.
- D. "In vivo" procedures (imaging and "in vivo" laboratory work). The technologist must demonstrate knowledge and understanding of:
 1. Stationary and moving radionuclide imaging devices.
 2. Stationary imaging including imaging of brain, cerebral spinal fluid spaces, thyroid, lung, heart, liver, spleen, kidney, bones, and other organ systems.
 3. The use of single and multiple detectors for time-dependent studies such as cerebral blood flow, thyroid uptake, cardiac output, differential renal function.
 4. Body composition tests such as blood volume, and red blood cell volume.
 5. Erythrokinetic studies including red cell production and destruction and quantification of blood loss.
 6. Gastrointestinal absorption studies of substances such as iron and vitamin B12.
 7. Gastrointestinal loss studies such as proteins, blood.
- E. "In vitro" procedures. The technologist must demonstrate knowledge and understanding of:
 1. The hazards of working with toxic chemicals, infectious biologic materials, and radionuclides, with special awareness of proper handling and disposal of such materials.
 2. Common laboratory instruments and equipment including pipets, centrifuges, pH meters, analytical balances, calculators, and scintillation counters.
 3. The principles of saturation analysis and competitive protein binding assays in order to follow a protocol, with an appreciation of the indications for and limitations of the technique, including procedures such as principles of physiology and biochemistry pertaining to specimen collection and analyses.
 4. A good laboratory quality assurance program, including establishment of such a program and appreciation of the necessity of maintaining adequate laboratory records.
- F. Therapeutic uses of radionuclides including knowledge and understanding of:
 1. More common therapeutic applications of radionuclides, dose ranges for each indication, and proper techniques for calculating quantities of administered radiopharmaceuticals.
 2. Special problems of patient care, radiation safety, and follow-up.

3. Special problems of handling excreta from such patients.

X. ADMINISTRATION

- A. Catalog—An official publication including a description of the curriculum shall be issued at least biennially. It shall include information regarding the organization of the program, a brief description of required courses, names and academic rank of faculty, entrance requirements, tuition and fees, and information concerning hospitals and facilities used for directed experience. The catalog must also include information about the current accreditation status of the program.
- B. Accreditation—Evaluation, including survey team visits, of a program of study can be initiated only by the express invitation of the chief administrator of the sponsoring institution or his officially designated representative.
- C. Withdrawal—The institution may withdraw its request for initial accreditation at any time (even after evaluation) prior to final action. The Committee on Allied Health Education and Accreditation and collaborating organizations may withdraw accreditation whenever the educational program is not maintained in accordance with the standards outlined above, or when there are no students in the program for two consecutive years. Accreditation may be revoked only after notice in time to review and respond has been given to the chief administrative officer of the sponsoring institution and program director indicating that such action is contemplated and providing reasons therefor.
- D. Reevaluation and Review—The program director and chief administrative officer are given the opportunity to become acquainted with the factual part of the report prepared by the visiting team and to comment on its accuracy before final action is taken. At the request of the institution, a resurvey may be made. Accreditation decisions may be appealed by letter to Committee on Allied Health Education and Accreditation.
- E. Reports—An Annual Report must be made to the Committee on Allied Health Education and Accreditation and collaborating organizations through the Joint Review Committee on Educational Programs in Nuclear Medicine Technology. A report form is provided and should be completed, signed by the director of the educational program, and returned promptly.
- F. Resurvey—The AMA and collaborating organizations will periodically resurvey educational programs for consultation and evaluation.

Task Analysis

NMTCB Task Analysis of Nuclear Medicine Technology

The Nuclear Medicine Technology Certification Board

Job relatedness is the basis upon which the Nuclear Medicine Technology Certification Board developed its entry-level competence examination. In order to ensure job relatedness, this task analysis was derived by the Board with input from practicing technologists across the country. It is intended as a broad outline of the tasks that are performed in the clinical setting by a competent technologist. The examination content is based upon the tasks enumerated and the implied skill and knowledge necessary to perform those tasks. This task analysis will constantly evolve as the field of nuclear medicine continues to change. As new technologies are incorporated into routine practice, the task analysis will be modified to reflect those changes. The NMTCB always welcomes comment and input regarding the task analysis. Comments should be forwarded to the NMTCB office in Stone Mountain, GA.

I. NUCLEAR INSTRUMENTATION—QUALITY CONTROL

A. Perform routine imaging system evaluations:

1. Scintillation cameras—

- a. Perform field uniformity check—
 - 1) select radionuclide source of appropriate quantity and energy;
 - 2) check pulse height analyzer photopeak adjustment;
 - 3) obtain uniformity images using identical standardized imaging parameters, i.e., counts, information density (I.D.), intensity, etc.
- b. Analyze field uniformity images—
 - 1) compare with previous uniformity image and identify any nonuniformities;
 - 2) differentiate source of nonuniformities using proper procedures, i.e., check collimator, pulse height analyzer (PHA) peaking, detector, cathode ray tube (CRT), lenses;
 - 3) obtain service if indicated.
- c. Perform detector linearity check—

- 1) place source for uniformity check and a parallel line phantom in proper position;
 - 2) obtain two images orientated 90° to each other using standardized imaging parameters;
 - 3) identify any line distortion on the image;
 - 4) determine the source of nonlinearity, i.e., camera system, components, detector-source geometry, and arrange for service if nonlinearity is present.
- d. Perform spatial resolution checks—
 - 1) use uniformity check source;
 - 2) utilize a high resolution phantom compatible with the specified resolution of the camera;
 - 3) obtain resolution images oriented 90° to each other using standardized imaging parameters;
 - 4) compare with prior resolution images;
 - 5) obtain service if resolution degradation is observed.
 - e. Conduct sensitivity checks—
 - 1) position source with an appropriate half-life;
 - 2) assure that identical geometry and measurement parameters are used each time.
 - f. Check image recording equipment—
 - 1) perform lens focus check;
 - 2) check and adjust CRT dot focus and shape;
 - 3) assess integrity of CRT phosphor.
 - g. Maintain the required records for quality control checks.

2. Rectilinear scanners—

- a. Assess performance of NaI(Tl) scintillation spectrometer—
 - 1) calibrate with Cs-137;
 - 2) determine percent FWHM energy resolution;

- 3) conduct a sensitivity check;
 - 4) perform a 60-cycle test count if available.
 - b. Check calibration of photorecorder—
 - 1) compare three film exposures taken at three information densities for equal film density;
 - 2) assess operation of contrast enhancement and background erase using a transmission gray wedge;
 - 3) compare results with previous results to determine any changes in system operation;
 - c. Maintain required records of the quality control procedures.
- B. Scintillation counters:**
1. Calibrate with Cs-137.
 2. Determine percent FWHM energy resolution.
 3. Conduct sensitivity checks.
 4. Check background and determine cause for higher-than-normal background.
 5. Take a 60-cycle test count if possible.
 6. Conduct a chi-square evaluation.
 7. Perform an energy linearity check at installation.
 8. Perform volumetric calibration at time of installation.
 9. Maintain records of these procedures as required.
- C. Gas-filled detectors:**
1. *Survey meters (G-M tubes)*—
 - a. calibrate according to NRC specifications;
 - b. perform reference check-source test and compare with previous results;
 - c. maintain records as required.
 2. *Dose calibrator (ionization chamber)*—
 - a. ascertain linearity over entire range of radionuclide activity to be measured;
 - b. test for significant geometrical variation in activity measured as a function of sample volume or configuration and determine correction factors;
 - c. test accuracy for commonly used radionuclides that have adequate reference standards available;
 - d. check for constancy using a long-lived radionuclide standard;
 - e. maintain records of the procedures as required.

II. DOSE CALCULATION AND ADMINISTRATION

A. Dispense radiopharmaceuticals:

1. *Quantitate exact dose*—
 - a. verify label on radiopharmaceutical vial in-

- cluding concentration, specific activity, total activity, lot number, assay time, and date;
 - b. determine actual elapsed time between assay calibration and required dose calculation time;
 - c. calculate activity remaining using the appropriate decay factor for the time elapsed;
 - d. calculate activity needed for procedure;
 - e. determine volume of the radiopharmaceutical required for patient dose.
2. *Prepare dose of radioactivity*—
 - a. dispense liquid preparation—
 - 1) draw up correct volume of the radiopharmaceutical into a syringe using aseptic technique and observing proper radiation safety precautions;
 - 2) verify the dose of radioactivity using a dose calibrator;
 - 3) record patient name, examination, activity, volume, lot number, time, date, and prescription number, if appropriate.
 - b. dispense gaseous preparation—
 - 1) calibrate and dispense radioactive gas from bulk load system or unit dose system;
 - 2) load radioactive gas into administration machine if appropriate;
 - 3) maintain appropriate records.
- B. Administer dose of radiopharmaceutical:**
1. assemble the proper materials for venipuncture;
 2. determine proper method and route of administration;
 3. evaluate patient's venous anatomy and determine a suitable site for venipuncture;
 4. reassure the patient and try to relieve any apprehension;
 5. disinfect the site of puncture;
 6. administer dose with proper venipuncture techniques;
 7. observe patient for possible reactions;
 8. discard radioactive materials in appropriate waste containers.

III. IMAGING PROCEDURES

A. Provide patient care:

1. Receive patient and provide for proper nursing care during imaging procedure.
2. Provide for patient comfort, before, during, and after the procedure.
3. Maintain good communication with patient, explain procedure, answer questions, and listen to patient's comments.
4. Provide functionally safe and sanitary conditions for patient.

5. Recognize emergency conditions—
 - a. determine "vital signs" when necessary, including pulse rate, respiratory rate, temperature, and blood pressure;
 - b. administer cardiopulmonary resuscitation when necessary;
 - c. maintain intravenous fluids, oxygen, and other life-support equipment.
- B. Prepare patient:**
1. Verify patient identification and written orders for study.
 2. Check for contraindications and obtain pertinent history.
 3. Obtain formal consent when necessary.
 4. Check patient clothing and linen for objects (scars, inflamed areas, etc.) that may attenuate and contaminate.
 5. Prepare patient with premedications (Lugol's, perchlorate), instruct patient to void, etc., include any preparation necessary for the imaging procedure required.
 6. Wait appropriate length of time after administration of radiopharmaceutical to begin imaging procedure.
- C. Perform imaging procedures:**
1. *Select imaging parameters—*
 - a. select proper instrument and auxiliary equipment necessary to perform imaging procedure;
 - b. prepare instrument for procedure, i.e., select proper collimator, imaging parameters, setting, etc.;
 - c. select appropriate parameters for data acquisition using a computer;
 - d. recognize artifacts that are due to instrument malfunction.
 2. *Position patient and obtain images—*
 - a. select required positions for procedure;
 - b. place patient in correct position using supportive materials and immobilizers to obtain scintigrams for each view;
 - c. determine correct detector-to-patient distance;
 - d. indicate appropriate anatomical landmarks for each view of a procedure.
 3. *Perform data processing—*
 - a. perform any necessary data manipulations to achieve desired end product of imaging procedure;
 - b. process film according to manufacturers specifications and film processor optimum operation;

- c. review study to assure correct information is supplied and any special views required have been obtained;
 - d. analyze data acquired and report results to physicians for interpretation;
 - e. maintain quality control for all aspects of the imaging procedure.
- D. Perform administrative procedures:**
1. Maintain adequate supplies of radiopharmaceuticals and all other materials including film to ensure that patient studies may be performed whenever necessary.
 2. Schedule patient studies, ensuring that appropriate study is scheduled. Interact with hospital staff to effect proper and timely arrangements for patient study.
 3. Determine the most appropriate sequence for multiple procedures.
 4. Maintain appropriate records of patient doses, quality control procedures, patient reports, and other required records.
 5. Maintain procedure manual and update manual on a regular periodic basis.

Note: Apply the aforementioned tasks for the following types of procedures: central nervous system, endocrine, cardiopulmonary, genitourinary, gastrointestinal, and hematologic.

IV. RADIOPHARMACY

- A. Maintain radiopharmaceutical laboratory:**
1. Initiate purchase orders for supplies of radiopharmaceuticals and other supplies.
 2. Perform "wipe tests" of the exterior package on all radioactive shipments received.
 3. Log in the receipt of radioactive materials in a record book.
 4. Monitor all packaging materials and deface radiation symbols on boxes before discarding.
 5. Store radioactive materials and nonradioactive kits in the appropriate area.
 6. Determine necessity to reorder radiopharmaceuticals and kits to prevent delays.
- B. Obtain generator eluate:**
1. Assemble generator and position behind lead barriers.
 2. Elute generator using aseptic technique.
 3. Assay the eluate using a dose calibrator or whole-vial assay.
 4. Record the assay results and time in a log book.
 5. Check the eluate for radionuclidic and chemical contamination and record results.
- C. Compound radiopharmaceuticals:**

1. Review daily work schedule and prepare appropriate radiopharmaceutical compounds using [^{99m}Tc] pertechnetate to include sulfur colloid, microspheres or macroaggregated albumin, phosphates, DTPA, etc.
 2. Determine the amount of radioactivity to be added to a radiopharmaceutical kit and record the volume of generator eluate used. Be aware of any activity limits in preparation of kits.
 3. Prepare radiopharmaceutical assay form for each lot of material.
 4. Check total activity in reaction vials in dose calibrator.
 5. Calculate the concentration of radioactivity of the compound and label vial as to the date and time of preparation, lot number, the concentration and the volume.
 6. Check all preparations for proper pH, color, clarity, and particle size if appropriate and record on radiopharmaceutical assay form.
 7. Determine the radiochemical purity of the compound by chromatography or electrophoresis.
- D. Dispose of radioactive waste:**
1. Monitor all radioactive dose vials and determine if acceptable to discard.
 2. Monitor alumina columns from generators to determine if acceptable to discard.
 3. Maintain long-term storage area to allow for decay of radioactivity.
 4. Maintain log on radiopharmaceutical disposal.

V. RADIATION PROTECTION

A. Maintain local state or federal license and assure compliance with regulations:

1. Notify appropriate authority when change in safety program occurs.
2. Amend license when necessary.
3. Review regulations periodically.
4. Maintain required records.
5. Post appropriate signs in designated areas.
6. Design program to follow regulations regarding the receipt and disposition of all radionuclides.
7. Design and carry out program to follow regulations regarding therapeutic doses and follow up.
8. Recommend purchase of any protection equipment to meet regulations.
9. Package radioactive material according to regulations and keep accurate records of transfer.

B. Follow appropriate protection procedures:

1. Employ personnel monitoring devices—
 - a. review monthly personnel exposure records in regard to maximum permissible dose limits;

- b. take appropriate measures to reduce exposure when necessary;
 - c. keep exposure as low as is reasonably achievable using appropriate protection parameters continuously;
 - d. notify the NRC of excessive exposure when appropriate.
2. Select and use proper shielding to reduce radiation exposure, i.e., employ inverse square law and half-value layers.
3. Use proper methods for the storage of radioactive materials.
4. Identify and use proper procedures for those radionuclides which pose special hazards.

C. Surveys:

1. Calibrate survey instruments.
2. Set frequency and locations for surveys and follow schedule.
3. Use proper survey meters for each type and level of activity.
4. Follow regulations regarding personnel surveys and interpret results.
5. Perform wipe tests where applicable.
6. Perform leak tests on sealed sources when appropriate.
7. Record data in some standard format.

D. Perform decontamination procedures:

1. Block access to area and confine the spill.
2. Remove contamination or reduce the activity to acceptable levels.
3. Monitor the area and personnel and repeat decontamination procedure until levels of activity are acceptable.
4. Store and dispose of contaminated material following regulations.
5. Maintain adequate records concerning the clean up.

E. Dispose of radioactive waste:

1. Maintain appropriate records.
2. Dispose of waste properly according to license specifications.

F. Participate in inservice program to instruct other personnel about radiation hazards and principles of radiation safety:

1. Teach concepts including—
 - a. the biological effects of ionizing radiation;
 - b. limits of dose, exposure and radiation effect;
 - c. types of ionizing radiation.
2. Provide instruction on appropriate radiation safety measures.
3. Provide instruction on proper emergency procedures to be followed until radiation personnel arrive at the site of accident or spill.

VI. NONIMAGING PROCEDURES

A. In vivo:

1. Operate laboratory equipment—

- a. Check accuracy and operation of pipetting devices.
- b. Use microhematocrit centrifuge and determine hematocrit.
- c. Compute relative centrifugal force, operate centrifuges, and maintain routine tachometer checks.
- d. Maintain refrigerator for storage of reagents and standards.
- e. Maintain quality control records on all laboratory equipment.

2. Prepare doses and standards—

- a. Quantitate exact dose—
 - 1) determine decay constant and calculate remaining activity;
 - 2) determine volume necessary to deliver required activity;
 - 3) draw dose into syringe using appropriate materials;
 - 4) confirm calculated activity by using a dose calibrator.
- b. Prepare standard—
 - 1) choose appropriate volumetric glassware for dilution of the standard;
 - 2) add a portion of solvent to glassware and a solution to prevent sticking;
 - 3) add a dose similar to that given the patient and dilute up to calibration mark;
 - 4) dilute capsule in appropriate solvent if necessary for a standard.

3. Collect proper specimen for procedure—

- a. Blood collection—
 - 1) select proper equipment for blood collection (needles, syringes, anticoagulants, etc.);
 - 2) perform venipuncture at appropriate time intervals;
 - 3) add hemolyzing compounds when necessary;
 - 4) centrifuge blood and separate blood components;
 - 5) store aliquot of serum, plasma, or whole blood according to protocol.
- b. Urine collection—
 - 1) choose appropriate container for urine collection;
 - 2) add a small amount of preservative to container;
 - 3) instruct patient and nursing staff about the method and length of urine collection;

- 4) aliquot urine sample and measure total urine volume;
- 5) measure specific gravity of urine if required;
- 6) collect additional urine if volume collected is insufficient.

c. Stool collection—

- 1) choose appropriate container for stool collection;
- 2) instruct both patient and nursing staff as to correct method of stool collection;
- 3) homogenize stool and aliquot sample for counting; or
- 4) place sample of stool in carton for counting, maintaining same geometry.

4. Operate counting equipment—

- a. Set pulse height analyzer on scintillation detector and center the photopeak within the analyzer settings chosen for the procedure.
- b. Count in vitro samples, standards, and room background for a statistically significant number of counts, making corrections for geometrical differences if necessary.
- c. Outline organs to be counted externally and count for a statistically significant number of counts.
- d. Choose correct detector-patient distance.

5. Perform calculations—

- a. Subtract room background or patient background from all samples.
- b. Apply appropriate formulas, including conversion and dilution factors.
- c. Calculate results according to the procedure employed.
- d. Plot graph if necessary and determine $T_{1/2}$ or extrapolate to zero time.
- e. Calculate organ ratios.
- f. Report both patient calculated values and the normal range of the specific procedure used.

Apply these tasks to the following procedures where applicable: blood volumes (Cr-51 and RISA), red cell survivals, ferrokinetic studies, gastrointestinal protein loss, gastrointestinal blood loss, thyroid uptakes, and Schilling test.

B. In vitro:

1. Operate laboratory equipment—

- a. Check accuracy and operation of all pipetting devices used.
- b. Maintain constant temperatures in water baths.
- c. Compute relative centrifugal force, operate centrifuge and maintain routine tachometer checks.

- d. Calibrate and operate pH meters.
 - e. Calibrate and use laboratory scales and balances.
 - f. Operate vortex mixers and shakers maintaining constant conditions.
2. *Collect blood sample—*
 - a. Select proper equipment for blood collection (needles, syringes, etc.)
 - b. Choose proper anticoagulant for specific procedure.
 - c. Perform venipuncture at appropriate time intervals.
 - d. Collect blood sample on ice as required.
 - e. Centrifuge blood and separate blood components.
 - f. Store aliquot of patient sample as dictated by the protocol.
 3. *Perform assay—*
 - a. Allow assay components and patient specimens to equilibrate to room temperature as required.
 - b. Prepare assay reagents.
 - c. Add RIA components according to the protocol.
 - d. Incubate standards and samples in the appropriate environment for the required time.
 - e. Separate the bound from the free radioactivity using the necessary laboratory equipment.
 - f. Load samples in counter and set instrument counting.
 - g. Count all samples for the appropriate time to give a statistically significant number of counts.
 - h. Reduce data to net counts by subtracting room background and nonspecific binding counts.
 - i. Calculate the desired fraction (bound/total, bound/free, free/total, etc.) for generation of the standard curve.
 - j. Plot above fractions obtained for the standards on the appropriate graph paper.
 - k. Determine data for all patient and controls from the derived standard curve.
 - l. Transfer assay results to laboratory data record and to patient's request form.
4. *Quality control—*
 - a. Develop and maintain quality control procedures for all assays, using appropriate control sera.
 - b. Record daily results of all controls on quality control charts.
 - c. Perform periodically the appropriate control sera checks.
 - d. Maintain records of antibody binding for each assay to note any reagent deterioration.
 - e. Recognize a significant shift in assay control and take appropriate action.
 - f. Compare another laboratory's results with your own.
 5. *Assay evaluation—*
 - a. Perform all tasks necessary to assess the accuracy, precision, sensitivity, and specificity of the assay.
 - b. Develop a normal range for each assay.
 - c. Test for the biological validity of the assay.
 6. *Kit evaluation—*
 - a. Determine intra-assay and interassay variability.
 - b. Determine assay accuracy by performing recovery studies.
 - c. Choose kit with the best overall performance.

Ms. MEYERS. Dr. Mishkin?

STATEMENT OF MARK M. MISHKIN, M.D.

Dr. MISHKIN. Thank you. I appreciate this opportunity to present the views of my colleagues in the American College of Radiology. I am Dr. Mark Mishkin, chief of radiology at the St. Barnabas Medical Center, Livingston, N.J. I am a professor of radiology at the University of Pennsylvania and Cornell University. I presently serve as vice chairman of the Commission on Human Resources of the ACR, and I am a former trustee and twice president of the American Registry of Radiologic Technologists.

With me today is Mr. Otho Linton, director of government relations of the American College of Radiology, who is seated on my right.

I am here today on behalf of the ACR to present the conclusions of our review of H.R. 6057, the Consumer-Patient Radiation Health and Safety Act of 1980, and upon the topic which it and several other pending bills addresses.

In the interest of time, I will just touch upon the high points of our already submitted testimony.

The college position is as follows: With respect to the scope of H.R. 6057 and the issue of public credentialing of radiologic technologists, the college has not favored this approach to assuring the quality of performance and protecting patients. Our reasons are that we believe the existing voluntary system is working well and also that where we have studied the impact of existing State licensure, there have been no measurable benefits to the public.

The college, in cooperation with the American Society of Radiologic Technologists, has conducted a study of the impact of mandatory licensure on the practice of radiologic technology. The 1975 study reviewed the programs of New York, New Jersey, and California. The investigation was unable to demonstrate any significant difference in the levels of radiation exposure to patients between States where licensure was mandatory and comparable States where credentialing was voluntary. We offer a copy of the study for your review. [See p. 147.]

In taking this basic position, we recognize that other groups favor licensure and have attained licensure in several States. Thus, we have also attempted to define certain parameters of a licensure program which would be most supportive of good practice and least onerous upon health care practitioners. These are outlined in detail in the submitted testimony.

As we indicated above, this organization, the American Medical Association, the American Society of Radiologic Technologists and others have developed a series of voluntary programs which provide a solid basis for standards of accreditation of schools and for certification of individuals. Most of the States which have active licensure programs have adopted the standards promulgated by the American Registry of Radiologic Technologists for certification and the Joint Review Committee on Education in Radiologic Technology and the Joint Review Committee for Nuclear Medicine Technology for accreditation of schools. While we think it unwise to specify details in legislation, we would urge language in the legislative history recommending that those agencies responsible for de-

veloping programs simply adopt those which have worked so well on a voluntary basis.

We have reviewed the elements of H.R. 6057 and would offer the following general observations on the legislation. In the interest of time, I will limit my discussion here, but our written comments will contain a more detailed, section-by-section analysis of the bill.

First, we favor the exemption of physicians from the requirements of the legislation. The definition of "persons who administer radiological procedures" contained in the bill, specifically excluded physicians and dentists. The language of other sections is also careful to exempt physicians from the bill's requirements. Physicians currently receive training in the various medical uses of radiation and are licensed by the States. There is simply no need to require additional certification of physicians.

Second, we oppose the denial of Federal reimbursement for radiological procedures performed in States which fail to comply within 3 years. The withholding of medicare and medicaid payments, among other Federal funds, is not needed to achieve the legislation's purpose. It unjustly punishes hospitals and physicians for a State's failure to act. The provision would adversely impact on the delivery of vital radiological health care to patients in the State. We urge the committee to drop this provision.

Third, the legislation also requires the Secretary of Health and Human Services to provide the States with a model law. We urge the committee to require that the Secretary adopt the Bureau of Radiological Health's model State law. This model was developed in cooperation with the American College of Radiology, and has now been adopted by several States. Its adoption would eliminate duplication of effort and help reduce the costs as well.

Since the initial preparation of this testimony, we have had an opportunity to review Committee Print 96-52, the report on this subject from the Subcommittee on Oversight and Investigations. It might be gathered from the substance of our comments that we do not agree with some of its conclusions.

I will just touch upon some highlights.

At several points in the report narrative, details have been selected in a fashion which leaves an impression erroneous to the situation as we know it. For example, at page 3, the estimate by the Bureau of Radiological Health that 130,000 to 170,000 persons operate medical X-ray equipment is quoted. This is followed by a further quote from BRH that 80,000 persons are credentialed from within that number.

Dr. Shapiro, in testimony before that Subcommittee on Oversight and Investigations, pointed out that the 80,000 number is no longer valid. A telephone call to the American Registry of Radiologic Technologists on September 2 gained the information that the ARRT in 1980 has 119,959 active registrants in radiography, 7,590 in nuclear medicine technology, and 2,335 in radiation therapy technology. We have seen other BRH estimates which suggest as many as 10,000 persons licensed in a State but uncertified by the ARRT.

This adds up to approximately 140,000 credentialed operators. Further, BRH has pointed out that the uncredentialed persons

tend to be employed by low volume facilities which tend to perform only simple examinations, thus reducing the potential for harm.

One other bit of misinformation: The report correctly quotes a BRH estimate that 30 percent of all X-ray procedures are unnecessary. What the report fails to reflect is that the bureau has been unable to substantiate its estimate, despite formal demands upon it to do so. The staff paper produced at BRH in support estimates that 11 percent of the 30 percent represent retakes of all or part of an examination because of technical flaws. This is unuseful radiation but has nothing to do with medical necessity and does not add to charges. The remainder of the estimate is extrapolated from a very small segment of the literature and does not deserve the bland acceptance it has had from congressional committees and elsewhere.

We enclose a copy of the testimony presented on our behalf before the Oversight Subcommittee last year. We request that it be added to the record of this subcommittee as well.¹

If H.R. 6057 or similar legislation gains further consideration by this committee, we offer the full cooperation of the expert committees of the college to assist you in your deliberations on this matter.

Thank you.

[Testimony resumes on p. 165.]

[Dr. Mishkin's prepared statement and attachment follow:]

¹ Hearings held before Oversight and Investigations Subcommittee on July 24 and 31, 1979, entitled "Unnecessary Exposure to Radiation From Medical and Dental X-Rays" Serial No. 96-46, page 148.

Testimony before
House Committee on Interstate and Foreign Commerce
Subcommittee on Health and the Environment
on H.R. 6057
by the
American College of Radiology
presented by
Mark M. Mishkin, M.D.
September 5, 1980

Thank you, Mr. Chairman, for this opportunity to present the views of my colleagues in the American College of Radiology. I am Doctor Mark Mishkin, Chief of Radiology at St. Barnabas Hospital, Livingston, New Jersey. I am a professor of radiology at the University of Pennsylvania and Cornell University. I presently serve as vice chairman of the Commission on Human Resources of the ACR and I am a former trustee of the American Registry of Radiologic Technologists.

I am here today on behalf of the ACR to present the conclusions of our review of HR 6057, the Consumer-Patient Radiation Health and Safety Act of 1980, and upon the topic which it and several other pending bills addresses.

BACKGROUND

For those of the committee and staff who may be unfamiliar with the current practice of radiology, a brief background explanation might be helpful. Radiologists are physicians who specialize in the uses of x-rays and other forms of radiation for the diagnosis and treatment of disease.

We use visual evidence produced on x-ray films, fluoroscopic images on videotapes or movies, various kinds of computed tomography scanners, radioactive materials and ultrasound sources to make diagnoses. Our responsibilities involve both the production of images and their interpretation as well as the treatment of many diseases, primarily cancer. Radiologists are assisted in the production of images and the delivery of radiation treatments by people who work as radiologic technologists. The technologist functions under the specific direction and supervision of the physician.

THE COLLEGE POSITION

With respect to the scope of HR 6057 and the issue of public credentialing of radiologic technologists, the College has not favored this approach to assuring the quality of performance and protecting patients. Our reasons are that we believe the existing voluntary system is working well and also that where we have studied the impact of existing state licensure, there have been no measurable benefits to the public.

The College, in cooperation with the American Society of Radiologic Technologists, has conducted a study of the impact of mandatory licensure on the practice of radiologic technology. The 1975 study reviewed the programs of New York, New Jersey and California. The investigation was unable to demonstrate any significant difference in the levels of radiation exposure to patient between states where licensure was mandatory and comparable states where licensure was voluntary. We offer a copy of the study for your review.

In taking this basic position, we recognize that other groups favor licensure and have attained licensure in several states. Thus, we have also attempted to define certain parameters of a licensure program which would be most supportive of good practice and least onerous upon health care practitioners.

One of these early programs was the one enacted in California for a range of licensure, according to the tasks to be assigned to the technologist. While this had a promising logic, our impression is that it has not worked well and has caused substantial administrative and other difficulties. Thus, our current conclusion is that for the three broad areas of medical radiologic function (diagnostic radiography, nuclear medicine and radiation therapy), there should be single standards with national applicability. The single standard, for diagnostic radiography, is supported, even for the technologist working with a physician who undertakes only a few examinations. Such a technologist is likely to be isolated from his peers and to relate to a physician whose own qualifications for radiology are limited. Further, there is no reasonable way to enforce limited licensure in any practical sense.

As we indicated above, this organization, the American Medical Association, the American Society of Radiologic Technologists and others have developed a series of voluntary programs which provide a solid basis for standards of accreditation of schools and for certification of individuals. Most of the states which have active licensure programs have adopted the standards promulgated by the American Registry of Radiologic Technologists for certification and the Joint Review Committee on Education in Radiologic Technology and the Joint Review Committee for Nuclear Medicine Technology for accreditation of schools. While we think it unwise to specify details in legislation, we would urge language in the legislative history recommending that those agencies responsible for developing programs simply adopt those which have worked so well on a voluntary basis.

ELEMENTS OF H.R. 6057

We have reviewed the elements of H.R. 6057 and would offer the following general observations on the legislation. In the interest of time, I will limit my discussion here, but our written comments will contain a more detailed, section-by-section analysis of the bill.

1. We favor the exemption of physicians from the requirements of the legislation. The definition of "persons who administer radiological procedures" contained in the bill, specifically excluded physicians and dentists. The language of other sections is also careful to exempt physicians from the bill's requirements. Physicians currently receive training in the various medical uses of radiation and are licensed by the states. There is simply no need to require additional certification of physicians.

2. We oppose the denial of federal reimbursement for radiological procedures performed in states which fail to comply within 3 years. The withholding of Medicare and Medicaid payments, among other federal funds, is not needed to achieve the legislation's purpose. It unjustly punishes hospitals and physicians for a state's failure to act. The provision would adversely impact on the delivery of vital radiological health care to patients in the state. We urge the committee to drop this provision.

3. The legislation also requires the secretary of Health and Human Services to provide the states with a model law. We urge the committee to require that the secretary adopt the Bureau of Radiological Health's model state law. This model was developed in cooperation with the College and has now been adopted by several states. Its adoption would eliminate duplication of effort and help reduce the costs as well.

Since the initial preparation of this testimony, we have had an opportunity to review Committee Print 96-52, the report on this subject from the Subcommittee on Oversight and Investigations. It might be gathered from the substance of our comments that we do not agree with some of its conclusions.

In particular, we do not agree that the current situation with regard to delivery of radiologic services to Americans is one which constitutes a crisis requiring congressional action. Certainly there is no need for the federal government to develop standards for radiologic technologists, since such standards have existed for a half century and are constantly validated and updated to maintain acceptance by the medical profession. The fact that 39 states have not moved toward compulsory licensure in 15 years may reflect a clearer assessment of the situation than the 11 states which have undertaken such programs. Indeed, as Dr. Jerome Shapiro pointed out to the Oversight Subcommittee on our behalf, the ACR-ASRT study of technologist licensure failed to show any advantages to the public health from mandatory licensure over voluntary credentialing.

At several points in the report narrative, details have been selected in a fashion which leaves an impression erroneous to the situation as we know it. For example, at page 3 the estimate by the Bureau of Radiological Health that 130,000 to 170,000 persons operate medical x-ray equipment is quoted. This is followed by a further quote from BRH that 80,000 persons are credentialed from within that number. Dr. Shapiro pointed out that the 80,000 number is no longer valid. A telephone call to the American Registry of Radiologic Technologists on September 2nd gained the information that the ARRT in 1980 has 119,959 active registrants in radiography, 7590 in nuclear medicine technology and 2335 in radiation therapy technology. We have seen other BRH estimates which suggest as many as 10,000 persons licensed in a state but uncertified by the ARRT. Further, BRH has pointed out that the uncredentialed persons tend to be employed by low volume facilities which tend to perform only simple examinations, thus reducing the potential for harm.

One other bit of misinformation. The report correctly quotes a BRH estimate that 30 percent of all x-ray procedures are unnecessary. What the report fails to reflect is that the bureau has been unable to substantiate its estimate, despite formal demands upon it to do so. The staff paper produced at BRH in support estimates that 11 percent of the 30 percent represent retakes of all or part of an examination because of technical flaws. This is unuseful radiation but has nothing to do with medical necessity and does not add to charges. The remainder of the estimate is extrapolated from a very small segment of the literature and does not deserve the bland acceptance it has had from congressional committees and elsewhere.

We enclose a copy of the testimony presented on our behalf to the Oversight Subcommittee last year. We request that it be added to the record of this subcommittee as well.

If H.R. 6057 or similar legislation gains further consideration by this committee, we offer the full cooperation of the expert committees of the College to assist you in your deliberations on this matter. Thank you.

SURVEY OF THE IMPACT OF STATE
LICENSURE ON SELECTED ASPECTS
OF
RADIOLOGIC TECHNOLOGY

Conducted by

The Conjoint Committee on Technology Job
Descriptions and Manpower Studies

Thomas T. Thompson, M.D., Chairman	
Peter J. Bartolazzi, R.T.	William R. Hendee, Ph.D.
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American Society of Radiologic Technologists

American College of Radiology

August, 1976

PREFACE

In recent years radiologists and radiologic technologists and their national organizations have been concerned about the issue of mandatory state licensure of users of ionizing radiation.

Presently three states, New York, New Jersey, and California, and the Commonwealth of Puerto Rico have laws intended to protect the public from unnecessary ionizing radiation by establishing and enforcing standards of education, training, and experience for operators of radiologic equipment. Some eight additional states have plans awaiting implementation.

It has become increasingly apparent to many who work in the specialty of radiology that statewide regulation of operators of radiologic equipment may be a viable means to insure competency. Conversely, others believe that licensure imposes severe rigidity upon the practice of radiologic technology and does not necessarily raise the proficiency level of its practitioners.

Realizing these opposing viewpoints, the ACR and the ASRT directed a conjoint committee on Technology Job Descriptions and Manpower Studies to determine the impact of mandatory licensure in those states with existing active laws.

In 1974 the committee, headed by Dr. Thomas T. Thompson, began its work, the results of which are contained in this report. It is hoped that the findings will provoke careful thought and provide a useful base for those states attempting to pioneer legislation mandating the licensure of operators of radiologic equipment.

Many individuals have contributed greatly to the development and preparation of this survey. Particular recognition and thanks are extended to state health officials Howard L. Goldman of New York, O. Doc Gibbons of New Jersey, and Kenneth B. Fess of California; statisticians from the Bureau of Radiological Health; and members of the entire committee.

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SUMMARY

This study shows the effect of mandatory licensure upon the practice of radiology. The study took place in the states of New York, New Jersey, and California, where licensure laws have been in effect for several years.

The conjoint committee finds:

1. that the study was incapable of determining that mandatory licensure either enhanced or detracted from good radiation practice. Data from the NEXT surveys were used to compare radiation exposure levels in the licensure states with those in non-licensure states. Although the opinion survey demonstrated the need for radiation protection, this was not evidenced by performance data obtained from licensed and non-licensed states, which did not show any definitive differences.
2. that mandatory licensure has created no significant effect upon technology manpower in terms of recruitment, availability, and compensation in the three licensure states.
3. that the school regulation requirements in the three state licensure laws have had a strong positive effect upon the quality of radiologic technology education.
4. that the site visits and survey responses failed to indicate any significant changes in the availability of delivery of radiologic services as an observable result of the three state licensure laws.
5. that the site visits and survey responses failed to indicate any significant changes in the patterns or levels of compensation of radiologic technologists in the three states studied.

I. INTRODUCTION

A. Charge

In 1974, organizational concerns about the effect of technologist licensure on the exposure levels and quality of radiologic services led to the assignment of a conjoint committee of the American College of Radiology and the American Society of Radiologic Technologists, for the purpose of evaluating the impact of state licensure.

The charge states:

"It is proposed that a conjoint committee of the ACR and the ASRT be created to carry out the survey with support from designated staff members of both organizations. The purpose of the survey will be to determine the impact of existing licensure programs on several important parameters of radiology. This would include: patient exposure levels in license states, technology manpower (recruitment, availability, compensation), training programs, and alterations in patterns of radiologic services."

The ultimate scope of the study is seen as being useful to both its sponsoring groups in helping to guide their future policy concerning x-ray operator credentialing in states that are considering mandatory licensure.

The committee consisted of four technologists and three radiologists, with staff members representing both the ACR and the ASRT. Statisticians from the Bureau of Radiological Health consulted on the analysis of the data. Recommendations and conclusions made in this report are solely those of the committee.

B. History

New York

New York's original bill to license radiologic technologists¹ was enacted in 1964 under Article 35, Chapter 295, L. It was initiated based on state-wide evidence of abuse of radiation protection and the increasingly large number of inept graduates of commercial programs (an estimated 300 graduates a year at the time of licensure, mostly in New York City). It became apparent that many instances of excessive exposure of patients or operators to radiation could be directly attributed to the poor training of operators. Operators were often unfamiliar with radiation safety equipment and/or how to use it.

The law requires that, after October 1, 1965, only persons holding a state

1 X-ray technician (radiologic technologist) means a person, other than a licensed practitioner who uses x-ray on human beings including persons who actually handle x-ray equipment in the process of applying radiation on a human being under the supervision of a licensed practitioner.

license can apply x-rays on human beings in the practice of x-ray technology.² Further, licensed technologists can only apply x-rays while under the supervision of a professional licensed practitioner.³ The law does provide certain exemptions for students attending approved schools in the health professions.

Dental technician licensure is not required in the state. At the time the bill was passed, it was felt that dental equipment caused no significant genetic radiation exposure. Licensing is presently not required for technologists working in nuclear medicine, however, it is under consideration.

New York issues licenses in the two categories of diagnostic and therapeutic radiologic technology upon successful completion of a written examination. ARRT certification or reciprocal licensure by another state are bases for waiving the New York examination.

New York's law allows the operation of a Bureau of Radiologic Technology under the Department of Health. Power is vested in an administrative or executive officer with a nine-member advisory board. Investigative and enforcement provisions specify penalties for both employer and employee.

Programs are approved by the state health department in the case of hospitals and by the state education department in the case of colleges. Both are required to teach at least 24 hours of radiation protection.

New Jersey

New Jersey's licensure law was enacted in 1968 under Chapter 291 and closely parallels that of New York. Authority is vested in an X-ray Technician Board of Examiners with no investigative or enforcement powers provided under the statute.

New Jersey issues licenses in the two categories of diagnostic and therapeutic radiologic technology. The therapeutic license is not exclusive, so that holders of diagnostic licenses can also do therapeutic work. The law provides for issuance of chest licenses for routine thoracic work, which excludes special chest examinations (i.e., tomography, bronchography). A state examination is administered to applicants who have neither ARRT certification nor New York licenses. Individuals who are also applying for ARRT certification are not required to take the New Jersey examination. Holders of ARRT certification, New York, and/or full California licenses are given full reciprocity.

California

In 1965 a California Senate committee investigating health care services found that the state had specifications to regulate x-ray equipment, but had no oper-

² X-ray technology means the use of x-ray producing equipment on human beings for diagnostic or therapeutic purposes under the supervision of a licensed practitioner.

³ Licensed practitioner means a person licensed or otherwise authorized under the education law to practice medicine, dentistry, podiatry, osteopathy or chiropractic.

ator control. By 1970 California had enacted a licensure law to regulate radiologic technologists under Section 25668.0 of the state's health and safety code. Although the final bill excluded dentists and dental technicians working in dental offices, operators of dental radiographic equipment working in laboratories were included.

The law provides an executive administration with a nine-member advisory board. The board has the authority to inspect and approve schools, but not operators. Some investigation is done under the legal umbrella of the Department of Health and any regulation changes must be approved by the board.

Most of the educational efforts have been directed toward the limited permit programs. The state issues permits in both diagnostic and therapeutic categories. A person can hold only one permit, except in combination with a chest license. Holders of combination permits must take the examination in chest plus the appropriate examination in the other anatomical area. California also has a special one-year hardship permit given on the basis of special economic or geographical conditions; they are renewable.

Out-of-state operators can apply for a license if they have had five years experience prior to 1971 (ARRT examination not required). Applicants are required to take the written examination. The law provides full reciprocity with New York and New Jersey, ARRT and those with ARRT reciprocity (e.g., Canadian). If the ARRT was taken more than 10 years ago, the applicant must take the California exam.

II. METHOD

The Committee used three components to evaluate the effect of state licensure on radiological health care.

First, a site visit was made to each of the licensure states, New York, New Jersey, and California, to obtain information on manpower, school accreditation, inspections, and licensure examination results. The second study component was a comparison of licensure states to non-licensure states using limited data from the Nationwide Evaluation of X-ray Trends (NEXT) of the Bureau of Radiological Health. The third data base in the study was collected through a mail questionnaire. The questionnaire was designed to determine the opinions on licensure from physicians and non-practitioner x-ray equipment operators working under licensure laws that are in effect in the three states.

A. Site Visits

In October, 1975 two representatives of the committee, Dr. Thomas T. Thompson and Robert Best, traveled to New York, New Jersey, and California over a five-day period to meet with the appropriate program administrator in each state. Specific inquiries focused on length of time mandatory licensure has been in effect, changes in the original law, specific requirements of the law, educational programs, type of state examination required, and the type of program administration and its cost of operation.

The state visits indicated that similarities exist among all three state programs with New York and New Jersey having the closest parallel. The following data make comparative comments about these similarities.

1. Number of years licensure has been in effect: New York has had the most experience with 12 years, New Jersey follows with seven years, and California has the most recent program -- five years.
2. Licensed operators: At year-end 1972, New York had 7443 registered x-ray operators; in October, 1975 there were 7655 registered operators in New Jersey (4068 general, 351 limited chest, 3205 dental, and 31 therapy); in California, as of October, 1975, there were 12,317 registered operators.
3. Administration: The New York law allows the operation of the Bureau of Radiologic Technology under the auspices of the Department of Health. Operating power is vested in an administrative executive officer with a nine-member advisory board. The law outlines investigative and enforcement provisions, including administrative remedies in lieu of court. It also provides for both employer and employee penalties.

Unlike New York, New Jersey's authority is vested in an X-ray Technician Board of Examiners rather than in an executive officer. The New Jersey statute does not provide for investigative or enforcement powers under law. No apparent attempt has been made to secure investigative or enforcement powers under other legal avenues, e.g., the department of health enforcement powers.

California has an executive administration with an advisory board. Any changes in the rules and regulations must be approved by the nine-member board. Two of the nine members of the board are radiologic technologists.

4. Administration costs and support: Annual bureau operating costs in New York and California are estimated to be \$300,000 each, all expenses included. An \$18 to \$20 registration fee is collected every two years in both states, with New York charging an additional \$20 application fee. The annual operating budget for New Jersey's bureau was \$67,500 as of fiscal year 1975 including health officers, safety inspectors, and sanitation inspectors. Income from technologists alone for applications and registration totaled \$72,700. Approximately 25 percent of the operating budget is allocated for the support of the RT program. Income derived from RT's is more than the total budget for the department.

5. Examination: All three states require a written examination. Questions range from approximately 165 on the New York exam to 200 on the New Jersey and California exams. Out of those 200 questions, California's exam consists of 50 questions which deal with radiation safety and must be passed separately. In New York, a raw score of 68 percent is required to pass.

To obtain a combination permit in California, applicants must take the examination on chest and pass with a minimum of 67 percent plus take the other applicable exam dealing with the additional anatomical area. Considering all combinations, the state of California administers approximately 60 different examinations.

New York is the only state of the three surveyed not requiring dental technologists to take a state exam.

6. License limitations: New York prohibits "general" category persons from operating radiation therapy equipment; New Jersey does not. California therapy license holders are controlled for x-rays only. Sealed sources such as radium and cobalt are not covered by law.

7. Reciprocity: All three states provide reciprocity for full license holders, including those with ARRT certification. California allows reciprocity, in addition, for those with ARRT reciprocity (e.g., Canadian). If the ARRT was taken more than 10 years ago, applicants must take the California exam.

8. Grandfathering: Awarding licenses based on previous experience is basically the same among all three states. Operators can apply for a license having had at least five years experience and must pass the state examination. In New York completion of a two-year approved program is required.

9. Educational programs: Among the three states there are a total of 151 educational programs: New York has 56, New Jersey has 36 (seven collegiate and 29 hospital-based), and California has 59 limited programs. The state health department approves hospital programs and a joint committee approves college-based programs. New York's situation is similar except that the state education department approves the college programs instead of a joint committee. New Jersey's programs are approved by the X-ray Technician Board of Examiners. Both New York and California require a full-time technical director. In addition, California requires that a radiologist be in charge of clinical experience.

All three state programs require that a minimum number of curriculum hours be devoted to radiation safety: New York -- 24 hours, New Jersey -- 32 hours, and California -- 54 hours.

In New York a high percentage of failure by graduates of a school on either the state exam or the ARRT exam usually triggers a site visit by the New York State inspection team.

B. NEXT Data

The analysis of the data from the Nationwide Evaluation of X-ray Trends (NEXT) included two groups of states: California, New Jersey, and New York and Maryland, Pennsylvania, and Texas. The analysis deals with levels of patient exposure and compares the representative sample data grouped from California, New Jersey and New York to corresponding data grouped from Maryland, Pennsylvania and Texas as control states for the period January, 1973 through December, 1975.

It should be noted that this data from the six states includes all persons who operate x-ray equipment, i.e., credentialed and non-credentialed technologists, students, limited permittees, and practitioners.

Tables 1 and 2 present mean exposure at skin entrance (ESE) and mean surface exposure integral (SEI) values for selected types of examination/projections. The other seven NEXT projections were excluded from this analysis because the number of surveys performed in these groups of states was too small to permit meaningful comparisons.

Table 1. Estimated Mean Exposure at Skin Entrance (in milliroentgens) and Standard Error for Selected Groups of States, Nationwide Evaluation of X-ray Trends, January 1973 - December 1975

Type of Exam/ Projection	California, New Jersey and New York		Maryland, Pennsylvania and Texas	
	Mean	Standard Error	Mean	Standard Error
Chest (P/A)	23	4	21	2
Abdomen (KUB) (A/P)	572*	61	780*	82
Lumbo-Sacral Spine (A/P)	967	183	647	55
Dental Bitewing	555	96	540	43
Dental Periapical	593	278	635	79

* Difference between means for the two groups of States is statistically significant at the 95% confidence level.

Table 2. Estimated Mean Surface Exposure Integral (in Roentgen-square centimeters) and Standard Error for Selected Groups of States, Nationwide Evaluation of X-ray Trends, January 1973 - December 1975.

Type of Exam/ Projection	California, New Jersey and New York		Maryland, Pennsylvania and Texas	
	Mean	Standard Error	Mean	Standard Error
Chest (P/A)	47	9	53	7
Abdomen (KUB) (A/P)	464	49	616	60
Lumbo-Sacral Spine (A/P)	417	33	482	53
Dental Bitewing	19	3	18	1
Dental Periapical	23	11	20	2

* Difference between means for two groups of States is statistically significant at the 95% confidence level.

From these data it appears that exposure and collimation are similar in the two groups of states. The only significant differences were for the abdomen (KUB) study. The mean ESE and SEI values for New York, New Jersey, and California combined were significantly lower than for the group of non-credentialed states.

Table 3 shows a comparison of the percentage of radiographs for which the beam size was greater than the film size for these medical studies. Although none of the differences between the two groups of states were significantly different, facilities surveyed in California, New Jersey, and New York seemed to restrict the beam size for lumbosacral spine studies somewhat better than the other group of states. For chest and abdomen studies, the two groups were essentially equal.

Table 3. Percentage of Films for which the Beam Size was Greater than the Film Size for Selected Groups of States. Nationwide Evaluation of X-ray Trends, January 1973 - December 1975

Type of Exam/ Projection	California, New Jersey and New York	Maryland, Pennsylvania and Texas
Chest (P/A)	85%	83%
Abdomen (KUB) (A/P)	69%	67%
Lumbo-Sacral Spine (A/P)	57%	74%

C. The Survey Questionnaire

The opinion survey (see Attachment 1) contained 35 questions that could be answered yes or no. The questions were designed and approved by members of the committee. The areas of inquiry focused on the availability of personnel, delivery of services, cost of care, radiation protection, education and training of technologists, and general information on licensure. In addition to specific questions, data was also collected on the type of license held (limited or unlimited); geographical location of employment (urban, suburban, or rural); and the type of facility where employee (hospital by bed size, private office, or clinic).

The survey was mailed to a random sample of physicians and licensed non-practitioner x-ray equipment operators in licensure states along with a cover letter explaining the intent of the survey. There was no follow-up or sub-sampling of the non-respondents.

The Sample

The physician sample was randomly selected from a 1974 American Medical Association mailing list of all physicians actively practicing in the states of New York, New Jersey, and California. Physicians whose specialties were not

related to direct patient care or who probably did not use x-ray equipment in the diagnosis or treatment of patients were deleted prior to selecting a five percent sample from each state. The following describes the physician sample:

STATE	TOTAL NUMBER OF PHYSICIANS	NUMBER OF PHYSICIANS SAMPLED (five percent sample)
CALIFORNIA	27,880	1,394
NEW JERSEY	8,500	425
NEW YORK	27,020	1,351
TOTAL	63,400	3,170

A six percent sample was randomly selected from 1974 alphabetized lists of licensed non-practitioner x-ray equipment operators in the three states. The lists were supplied by the individual states participating in the study. The sample population included both employed and unemployed technologists since employment data is not collected by the states. The list supplied by the state of California included technologists who held a limited or unlimited license. The following describes the technologist sample:

STATE	TOTAL NUMBER OF LICENSED TECHNOLOGISTS	NUMBER OF LICENSED TECHNOLOGISTS SAMPLED (six percent sample)
CALIFORNIA	13,187	791
NEW JERSEY	4,683	281
NEW YORK	9,250	555
	27,120	1,627

Twenty-two percent of all questionnaires were returned. Forty-five percent were returned by the technologists and 11 percent by the physicians.

No attempt was made to survey physicians or technologists in non-licensure states. Neither was follow-up attempted on the non-respondents. Based on the fact that no information was available to compare the characteristics of the non-respondent group to the group that did respond, the assumption was made, for the purposes of this analysis, that the two groups did not differ.

It was also decided that breaking down the responses into several categories would reduce the statistical significance of any analysis. Thus, the interpretations of the data that follow go no further than to categorize as to whether the respondent was a physician or a technologist by state.

Questions which were believed to be of similar interest were grouped for these analyses. Results are generally stated for these groupings of questions with exceptions noted when appropriate.

The following describes the grouping of questions, the method of analysis, and some results.

The Groupings (refer to Attachment 1)

The first basic hypothesis to be analyzed was: were the respondents "in favor" of licensure. To arrive at a conclusion, questions 6, 20, 23, and 28 were grouped together for analysis. Thus, respondents who felt that mandatory licensure was necessary and has helped to improve radiologic technology in their states, who answered affirmatively to the questions of the effectiveness of licensure and who also felt that licensure should be mandatory in all states, were interpreted as being "in favor" of licensure.

A second analysis concerned the effect of licensure on the recruitment and retention of quality radiologic technologists. For this purpose, respondents who answered negatively to questions 2 and 33 and positively to questions 13 and 26 were grouped together.

Question 4 was isolated in order to test respondents' opinions on the effect of licensure on the availability of radiologic technologists.

The question of technologists not having a formal radiologic technology educational program was considered by analyzing responses to question 7.

In order to test the hypothesis that respondents were of the opinion that licensure has improved the delivery of health care, negative responses to questions 27 and 32 and positive responses to question 10 were grouped together.

Also looked at were opinions of respondents on the hiring of unlicensed persons to take x-rays and on whether unlicensed persons were operating radiographic equipment in their office or department (questions 17 and 34).

Questions 8 and 18 were grouped to test respondents' opinion on the effect of licensure on radiation protection awareness. Answers to questions 3, 12, 15, 16, 19, and 35 on radiation protection performance were compared with other data bases available to the Bureau of Radiological Health. To analyze respondents' opinion on licensure's influence on radiologic technology education, questions 11 and 14 were analyzed separately while questions 24 and 26 were grouped. Finally the responses to questions 5 and 22 were analyzed to determine the opinion of respondents concerning licensure's effect on the cost of patient care and technologist salaries.

All analyses were performed separately for technologists and physicians. The 95 percent level of confidence was used to determine the significance of results.

III. CONCLUSIONS AND DOCUMENTATION

A. Radiation Protection

Two types of analyses were used to determine whether mandatory technologist licensure has affected radiation exposure levels. The opinion survey was used to determine whether operators in the licensure states were more aware of radiation protection since enactment of the law. The Nationwide Evaluation of X-ray Trends Study was then used to compare radiation exposure data in the licensure states with levels in the non-licensure states of Pennsylvania, Maryland, and Texas.

For the three states (New York, New Jersey, and California) no clear opinion was stated with respect to technologist's or physician's feelings on the effect of licensure on radiation protection practices and awareness of radiation hazards. New York technologists felt most strongly (69 percent) that the effect has been a positive one while California physicians (57 percent) thought there had been no influence from licensure.

In each of the three licensure states, about 70 percent of the technologist respondents were of the opinion that licensure has influenced radiation protection in a favorable manner. Ninety-six percent answered "yes" to the question: "Do you routinely collimate to the area of clinical interest?" In response to these same questions, 70 percent of the physicians were in favor of radiation protection and 87 percent stated that they routinely collimate to the area of clinical interest.

The answers to the radiation performance questions were compared to data from the Nationwide Evaluation of X-ray Trends. The combined data from NEXT surveys in California, New Jersey and New York indicate that actual performance relative to collimation is quite different from that indicated by respondents to this survey. More than 80 percent of the operators in these states failed to limit the beam to the film size for chest radiographs, although collimation for abdominal studies was generally somewhat better. In no case did the percentage of proper collimation exceed 50 percent. NEXT does not collect data on gonadal shielding, so no comparison on this radiation protection procedure is possible.

From this analysis, the conclusion is that the study was incapable of determining that mandatory licensure either enhanced or detracted from good radiation practice.

B. Technology Manpower

1. Availability

To determine if licensure has had an adverse affect upon the availability of technologists, respondents were asked: "Has licensure contributed to a shortage of radiologic technologists in your local area?"

For the states of New York, New Jersey, and California 299 physicians responded to this question. Some 246 of these physicians were of the opinion that licensure has not contributed to a shortage of radiologic technologists in their local area. Some 648 of the technologists surveyed in the above states responded to this question. And 609 of the respondents agreed that licensure has not created a shortage of technologists.

2. Recruitment

Another objective of the survey is to determine whether or not licensure has affected the recruitment and retention of qualified radiologic technologists. Manpower data was collected on each of the site visits to the licensure states. Four questions on the opinion survey were designed to determine if physicians and technologists think that licensure has been harmful to their manpower needs.

Data from the site visits was collected to assess the number of technologists in each of the licensure states. This data shows that in New York City approximately 300 students graduating yearly from the commercial programs were lost on the job market. To offset this loss, community college programs in radiologic technology were established. There are currently 56 such programs in New York City.

At the end of 1972, the state of New York had 7443 registered radiologic technologists. In October, 1975 there were 7655 registered operators in New Jersey (4068 general, 3205 dental, 351 limited chest and 31 therapy). Data from October, 1975 shows that California registered 12,317 x-ray operators in all categories.

Both technologists and physicians in all three states felt that licensure has had a positive effect on the recruitment and retention of quality radiologic technologists. California physicians did not have a strong opinion on the question of the influence of licensure on the quality of applicants for radiologic technology educational programs.

The conclusion from the data in the study indicates that licensure has not resulted in a shortage of qualified radiologic technologists.

C. Training Programs

Another factor to be considered when determining the total impact of mandatory technologist licensure is the effect these laws have had upon the educational programs in New York, New Jersey, and California. State legislation has had more impact upon educational programs than any of the other areas studied.

In 1965, when licensure was first implemented in New York, there were 29 approved educational programs and another four commercial programs. Because of the licensure law, new programs were initiated to offset the loss of 300 new graduates per year in New York City.

Common deficits found in New York inspections of current approved educational programs included:

1. On-the-job training given rather than a solid educational opportunity.
2. Classes not scheduled or classes scheduled but not held.
3. Collegiate programs not taking full responsibility for both practical and didactic experience.
4. Lack of qualified instructors - either over or under qualified.
5. Primary academic weakness is in physics instruction.
6. The law does not specify whether the full-time educational director (required by law) is allowed other responsibilities in the x-ray department.

Site visits are usually made if a high percentage of failures on either the New York State examination or the ARRT examination are reported.

Any candidate who does not complete an approved program and pass the state examination (or approved reciprocity) cannot be employed in New York. Any program found inadequate can be closed by the state.

The licensure law in New Jersey is weak in enforcement powers. Seven programs that have not met the professional standards have been closed. The reasons many of these programs have been closed include lack of approval by the Joint Review Committee on Education in Radiologic Technology, voluntary closing, affiliation with a collegiate program, licensure requirements, or a combination of these factors.

In California, most of the state educational efforts are directed towards the limited permit programs. To obtain program approval from the state of California, a specific curriculum must be taught. Inspection procedures have reduced the number of commercial programs from 80 to 59.

The concept of the limited permit was approved to legalize what was actually being done in practice. Data from preliminary NEXT studies show that there is essentially no difference in radiation exposure in examination given by limited permit holders and fully licensed operators. The California law requires that all licensed operators, limited or fully licensed, pass a written radiation safety examination.

It is also worthwhile to note that each of the three licensure states accept reciprocity for candidates who have passed the ARRT examination. In fact, the New Jersey examination is given only to those who have failed the ARRT. Each of the three states are similar in that out-of-state operators having had five years experience prior to 1971 can apply for a license; ARRT examination usually not required. Original grandfather clauses in each of the states have expired and have not been reinstituted.

The questionnaire attempted to determine whether or not most operators felt that continuing education should be required. Results showed that California technologists who responded to the questionnaire felt that there should be mandatory continuing education to obtain license renewal; no other respondent sub-group expressed a definitive opinion on the question of mandatory continuing education.

The above information supports the premise that legislation has been the most effective for radiologic technologist educational programs in New York. Of the three states, New York has closed more commercial programs as a result of the licensure law and has the longest running program of mandatory technologist licensure. It is also significant that both technologists and physicians in New York thought that licensure legislation had a direct relationship to the quality of applicants to the new programs.

D. Alterations in Patterns of Radiologic Services

The site visits and survey responses failed to indicate any significant changes in the availability of the delivery of radiologic services as an observable result of the three state licensure laws.

E. Alterations in Levels of Compensation

The site visits and survey responses failed to indicate any significant changes in the patterns or levels of compensation of radiologic technologists in the three states studied.

IV. RESPONDENTS' COMMENTS

Many of those who responded to the mail questionnaire also took the opportunity to express some of their thoughts and ideas about technologist licensure in their respective states. The following are some of their comments.

"I have felt for a long time that there has been too much laxity as far as training is concerned with so-called partially trained technicians. I feel that any law which will eliminate inadequately trained people from taking x-rays will reduce unnecessary exposure to patients. Working in a hospital which has radiologists in charge, all the necessary protection of the patient is stressed by the radiologist himself."

R.T. - California

"I am afraid that this questionnaire will do very little to help you understand how state licensure fails. It is appalling to see how many people are licensed who don't even understand the factors they set on the machine. They are slaves to a technique chart and haven't the slightest understanding of radiation protection. All that state licensure accomplishes is added revenue to the bureaucratic coffers, at a rate of six times that of the ARRT."

R.T. - California

"I feel state licensure is very important. I also feel that a basic nurse's aide course should be included in our present 24-month course for two reasons. One, for better basic patient care within the department, and two, to upgrade the profession."

R.T. - New York

"Licensing would be great if it insured higher wages, better technical training, stricter regulations on the equipment used in doctor's offices (not only radiologists), and the removal of all unqualified persons from taking x-rays. Licensure cannot do what the ARRT has not been able to do as far as improving standards and abilities of the technicians, it can only help stop the unqualified person from acquiring a job without a limited permit. State licensure fees are high especially for what they give us in return. There are many techs who would rather there not be any C.R.T. for the little benefits that we receive."

R.T. - California

"Licensure should be mandatory by law for all x-ray technicians. A licensed technician assures patients and doctors that a qualified individual is serving them."

R.T. - New Jersey

"Personally I feel that good procedures are the result of good education and not numerous tests."

R.T.

"Our state licensing means nothing except that we pay a rather large amount of money for what we receive, which is nothing, except for a card and an 8 x 10 piece of paper that states we are C.R.T.'s, and that we can practice in this state. As far as being 'good' x-ray technicians, that can come only from good training and working with responsible, protection-conscious radiologists."

R.T.

"I am strongly in favor of licensure by the state or universities in order to give the 'profession' a legal, ethical, and economic status. The time of 'button pushers' and other unskilled help is gone and must not return under any circumstances."

R.T. - New Jersey

"I am a board-certified internist practicing alone in my private office. Radiologic examinations are restricted to chest x-rays, totalling 900-1000 per year. It would be economically impossible to hire a licensed technician to do this limited amount of work. My nurse positions the patient, sets the factors, and then I turn on the machine and take the film (to conform with state law). All films taken in this office are done in conjunction with physical examination. The quality of the films taken here compares favorably to any others taken in this area."

M.D. - New Jersey

"I have learned that real controls for patient safety must be exercised through control of x-ray machine owners, most of whom are not specialists in radiology and have less understanding of the dangers of x-rays than the technicians who operate their machines. Some provide adequate lead shields, aprons, and gloves and are aware of the cumulative effect of patient exposure, and some are not. There is little that a technician employee can do to change these conditions."

R.T. - California

Mr. MAGUIRE. Thank you. Dr. Alexander, in your statement, you accept the need for credentialing to "maintain the quality of practice of nuclear medicine technology." You have stated, as I understand it, that 75 percent of all nuclear medicine technologists are currently professionally certified. The American Dental Assistants Association and the American Society of Radiologic Technologists have both stated that at least half of the members of their professions are not certified in any way. With that as a background, do you think that professional credentialing by private groups is important to maintain qualified personnel?

Mr. ALEXANDER. Absolutely.

Mr. MAGUIRE. And you would presumably then believe that that ought to be expanded to something closer to 100 percent?

Mr. ALEXANDER. That is correct. It is very hard, if I may elaborate just a little bit—

Mr. MAGUIRE. Please do.

Mr. ALEXANDER. It is very hard for any paramedical group to come up with percentages such as this, because we have no manpower surveys. There is not a single medical professional or paramedical professional that I know of that has this manpower survey, so we really don't know what we are dealing with. Of the approved schools which are AMA accredited, we are aware of how many graduates we have, but I think the American dental assistants group related the fact that they do not know how many people drop out of the field in a year's time—how many are indeed practicing.

Mr. MAGUIRE. But if the best estimates we have are 75 percent in one category and 50 percent in another, clearly we are short of the mark in terms of the kind of professional oversight.

Mr. ALEXANDER. Yes, sir; that is true.

Mr. MAGUIRE. Of the profession that you would advocate?

Mr. ALEXANDER. That is true; yes, sir.

Mr. MAGUIRE. Then the question is, What do we do about that, in your view?

Mr. ALEXANDER. In my view, again I think that we should adopt, rather than this legislation, the national standards, which our particular profession already has in place, and I believe again that we are regulated by so many Federal regulatory agencies at this point, plus the credentialing aspect, that we have everything in place for the discipline of nuclear medicine technology. I cannot speak for the other disciplines.

Mr. MAGUIRE. What about those people who are practicing in one place or another who are not part of the professional societies involved?

Mr. ALEXANDER. This, again, is very hard to address. The Joint Commission of Accreditation of Hospitals, in my particular hospital, which is a very large one, would gig our department if every nuclear medicine technologist in our department was not certified.

Mr. MAGUIRE. Is that necessarily true in other places?

Mr. ALEXANDER. What this would mean to me is perhaps some of these other hospitals are not credentialed by JCAH, and I do not know how to address that.

Mr. MAGUIRE. Would one approach be to have national standards, but national standards which each of the professional associ-

ations help to develop or did develop for the Department of Health and Human Services? Would that be a way that might move you into the favorable column on national standards?

Mr. ALEXANDER. Yes, sir, very definitely.

Mr. MAGUIRE. Obviously, that way, bonafide members of your professional group would meet those standards.

Mr. ALEXANDER. Yes, sir.

Mr. MAGUIRE. And others outside, that is, outside of the purview of your profession, would have to meet those standards?

Mr. ALEXANDER. Yes, sir; that is correct.

Mr. MAGUIRE. Dr. Mishkin, what do you think about that?

Dr. MISHKIN. I can make several comments. Philosophically, I think that the major thrust of any solution to a problem like this must be education, not licensure.

Mr. MAGUIRE. I am glad to hear you say that. In fact, that was going to be my next question to you. I will get to it. Go ahead.

Dr. MISHKIN. If I may address the problem of national standards, I think it should be recognized and in the record that the American Registry of Radiologic Technologists as a voluntary credentialed body has been in the business for 55 years and has become truly expert during this period of time. Many, if not most, of the States with their own individual licensure laws and regulations recognize the competence of the ARRT already. This, combined with the credentialing by the various joint review committees for training programs, is a very powerful force for maintaining standards, maintaining quality rather than standards.

The American College of Radiology, working with the Bureau of Radiological Health, has already, in the past, come up with model legislation. At a recent meeting of the Commission on Human Resources of the American College of Radiology, which is a conjoint commission with the American Society of Radiologic Technologists, it was voted to introduce this month at our national meeting a resolution to the college that there be a conjoint effort between radiologic technologists through the ASRT and radiologists through the American College of Radiology, to develop a mutually agreed upon national standard for minimum licensure requirements.

Mr. MAGUIRE. Would you then support national standards if we went about it in this fashion?

Dr. MISHKIN. I already do support national standards. It is the technique that I am concerned about.

Mr. MAGUIRE. You pointed out in your statement that the study done by the college in 1975 was unable to demonstrate any significant difference in the levels of radiation exposure to patients between States where there was licensure and States where it was not mandatory.

Dr. MISHKIN. That is correct.

Mr. MAGUIRE. That rather leaves up in the air the question of whether or not the people in all of those States were getting too much radiation, does it not?

Dr. MISHKIN. Yes. The point being addressed is that licensure had no impact. What the baseline is, licensure did not.

Mr. MAGUIRE. Licensure in and of itself, then, is not a very efficient or effective way for us to deal with what presumably we

agree is a problem, although may we disagree about its magnitude. Is that a fair statement?

Dr. MISHKIN. I think that is a fair statement.

Mr. MAGUIRE. If we developed national standards, and let us say for the sake of argument that we did it the way, that Mr. Alexander and I were just discussing—and we were obviously talking about accreditation, and the educational process; certification rather than just licensure—would it be your judgment that we would make some incremental improvement in the amount of unnecessary radiation to which people are exposed?

Dr. MISHKIN. I can answer it best this way. There is already a national standard from the private sector; national standards are national standards from the private sector, through the registries both in nuclear medicine technology and in radiologic technology, and in radiation therapy technology.

There is also a national standard for each of the areas of radiology and radiologic technology through accreditation of programs in conjunction with the AMA. Mr. Alexander mentioned the Joint Commission on Accreditation of Hospitals having standards. Most hospitals, I believe, in this country are certified by the JCAH.

Is there a need for further expansion of these standards? The answer must be yes. The question that I would ask is what is the need? What is the extent of that need? Mr. Villforth this morning pointed out that 90 percent of the significant exposure—significant exposure dose, not numbers of examinations—that the American public is subjected to, if you will, is performed by people who already meet these national standards as established by the voluntary private sector. Ten percent do not meet it.

The question I would ask is, is the cost to shrink this 10 percent justified through licensure, and I suspect the cost would be very high, or would we not be better off putting whatever resources—and I would expect less resources—into a major educational effort across the country? I would strongly favor the latter.

Mr. MAGUIRE. But you are not opposed to the former. In fact, you think the former, if I understood you correctly, would have some yet-to-be-determined marginal impact.

Dr. MISHKIN. Yes.

Mr. MAGUIRE. On the amount of radiation that people are exposed to?

Dr. MISHKIN. Absolutely.

Mr. MAGUIRE. Right?

Dr. MISHKIN. Right.

Mr. MAGUIRE. Does everybody agree with that? Do you agree with that, Mr. Alexander?

Dr. MISHKIN. But we prefer to see it in the private sector, sir. I think it can respond much more appropriately and promptly to the major changes we have seen in the last 10 years in radiation technology, et cetera.

Mr. MAGUIRE. You do not think there is a crisis, and you think the 30 percent figures are exaggerated?

Dr. MISHKIN. Yes, sir.

Mr. MAGUIRE. You explain that even the staff paper estimates that 11 percent of the 30 percent represent retakes. We are only talking here, I take it, about physicians.

Dr. MISHKIN. No, sir, medical radiography.

Mr. MAGUIRE. This is overall?

Dr. MISHKIN. Yes.

Mr. MAGUIRE. Is that 11 percent of 30, or is it 11 percentage points of the 30 percentage points?

Mr. LINTON. It would be roughly one-third of the 30 percent.

Mr. MAGUIRE. Thank you. If that is true, and those are technical flaws, that radiation has nothing to do with medical necessity nor does it add to the charge, but the fact of the matter is that people are still being exposed some additional times. What is a technical flaw? Is it not to some degree something that results from somebody not doing the job properly in the first place?

Dr. MISHKIN. Sometimes. Sometimes, it is unavoidable—machine failure, processing failure, et cetera.

Mr. MAGUIRE. Or personnel?

Dr. MISHKIN. Absolutely; I could not deny that.

Mr. MAGUIRE. If one-third of that 30 percent comes from retakes alone, surely that is something that in and of itself we should try to improve. That third represents many, many additional exposures to X-rays.

Dr. MISHKIN. Absolutely, and it has been addressed and is currently being actively addressed through the FDA and the Bureau of Radiological Health with their quality assurance program, which is having a profound impact across the country in lowering that one-third.

Mr. MAGUIRE. Ms. Holland, I see that you wish to make some comments on this matter.

Ms. HOLLAND. The American Society of Radiologic Technologists, of course, is very supportive of the American Registry of Radiologic Technologists, but I think the key to this is that the American Registry of Radiologic Technologists is a voluntary certification board, and I think that our plea is that it must be mandatory to be accomplished.

Mr. MAGUIRE. Why?

Ms. HOLLAND. Because there is a certain segment who will not do it unless forced into it. I think that has been shown by the fact that we have had the registry for over 50 years, and there are still many, many technologists practicing who are not registered.

Mr. MAGUIRE. Is that true in your accredited hospital, Mr. Alexander?

Mr. ALEXANDER. No, sir.

Mr. MAGUIRE. Where is it true, then?

Ms. HOLLAND. I am from a rural State. Many doctors' offices and many small hospitals do not have accredited technologists.

Mr. MAGUIRE. Even though they may be accredited hospitals?

Ms. HOLLAND. Yes, sir. That is correct.

Mr. MAGUIRE. Accredited by the JCAH.

Ms. HOLLAND. Right; so I think that is basically the problem. Not all the radiation is being administered in large hospitals where they do hire credentialed technologists. How do you go about getting doctors' offices, small hospitals, on and on, to employ accredited technologists?

Mr. MAGUIRE. So you are saying not only that there are some unaccredited hospitals—is that what you are saying—

Ms. HOLLAND. I think there are. I think the majority of the hospitals now are JCAH.

Mr. MAGUIRE. Most of them that you are referring to would be accredited hospital where for some reasons they do not have accredited technologists.

Ms. HOLLAND. Right.

Mr. MAGUIRE. Mr. Alexander, in the particular hospital that you are talking about, do they have accredited technologists?

Mr. ALEXANDER. That is correct.

Mr. MAGUIRE. But you agree with Ms. Holland that in some other hospitals, in fact, there are no accredited technologists?

Mr. ALEXANDER. Senator Randolph, in testimony on S. 500, related the fact that there was a hospital here in Washington that is not accredited and had no accredited technologists.

Mr. MAGUIRE. Are there also hospitals which are accredited but have no accredited technologists?

Dr. MISHKIN. It is my understanding that the JCAH requirements include accredited technologists.

Mr. ALEXANDER. That is correct.

Mr. MAGUIRE. That does not mesh with what Ms. Holland has said. This must be a factual matter, and we ought to be able to ascertain the facts.

Mr. KELLER. My name is Ward Keller, executive director of ASRT. About 6 or 7 weeks ago, a hospital administrator in southern Illinois called and talked to me, and asked if I could at least give him the name of one credentialed radiology technologist, because at the present time he has three people working in radiology, none of them credentialed, and he is due for an accreditation visit by the commission. He knew at least he needed one person there, so this hospital under current accreditation has three unregistered people.

Mr. MAGUIRE. Dr. Mishkin?

Dr. MISHKIN. If I may, Ward, it does at this time, but it is responding to the pressure of the JCAH to correct that, and that, I think, is the modus operandi that I endorse.

Mr. KELLER. Not truly; asking for one rather than three?

Dr. MISHKIN. It is to meet the regulations of the JCAH. I cannot comment upon how well these regulations are enforced, but they do exist.

Mr. MAGUIRE. Does anybody have any final comments?

Thank you very much for your testimony.

The hearing is adjourned.

[The following statements and letter were received for the record:]

EXECUTIVE OFFICES

AMERICAN CHIROPRACTIC ASSOCIATION

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INTERNATIONAL CHIROPRACTORS ASSOCIATION

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Statement on H.R. 6057

Before

The Subcommittee on Health
House Committee on Interstate & Foreign
Commerce

The Nation's two national chiropractic associations, the American Chiropractic Association and the International Chiropractors Association, jointly support enactment of H. R. 6057, with several recommendations for amendments.

Protection From Unnecessary Radiation Exposure

H.R. 6057 would authorize the Secretary of HHS to promulgate radiation protection standards (1) "for the accreditation of educational programs conducted by institutions for persons who administer radiologic procedures" (§ 121), and (2) "for the certification of persons who administer radiologic procedures" (§ 122(a)). In neither case shall such standards apply to "any licensable doctor of medicine, osteopathy, chiroprody, or chiropractic" (§ 104(3), §121, 122(a)).

In other words, H.R. 6057 seeks to assure competence in the handling of health-related radiation on the part of members of the health team who may or may not have adequate training and experience. Its standards for licensure would apply to "radiologic technologists," but not to doctors of medicine, osteopathy, podiatric medicine or chiropractic, since their training and licensure by State agencies already is geared to assure such competency.

We agree with this distinction and believe it is a sound one in the public interest. We subscribe to the proposed finding in § 102(e) that

"persons who administer radiologic procedures...should be required to demonstrate competence by reason of education, experience and examination."

July 22, 1980

All of the accredited chiropractic colleges in the United States have rigorous teaching programs for their students in X-ray proficiency and safety, and insist upon supervised experience in the college clinics, prior to granting of a Doctor of chiropractic degree. And in their licensure examinations, Doctors of chiropractic are examined in radiologic procedures.

In addition, the chiropractic profession pioneered in this country in insisting on annual renewal of professional licenses being contingent on the taking of annual refresher courses accredited by the official State chiropractic licensing boards. A very substantial number of these annual courses for license renewal are in the field of X-ray and radiologic science and technique. Among the health professions, this is a unique manifestation of chiropractic's concern for assuring that the latest and safest knowledge be translated into actual practice with patients.

Recommendations

1. Accreditation and Certification Process

H.R. 6057 authorizes the Secretary of HHS to accept "as meeting the standards" for accreditation (§ 121(c)) and for certification (§ 122(c))

"existing activities...as such activities are conducted or planned to be conducted by any private, nonprofit, autonomous accrediting [or certifying] organization."

We respectfully suggest that the relevant provision in S. 500, a companion but not identical bill, is preferable. Section 131 of S. 500 relates to "the accreditation of educational institutions conducting education programs in radiologic service." We call your attention particularly, in this regard, to the second sentence of § 131(b) of S. 500 which reads as follows:

"The Secretary may authorize appropriate professional organizations to certify such accreditation as consistent with the purposes of this section if he determines that such organization will adhere (and is continuing to adhere) as a basis for certification to the minimum standards issued pursuant to this section. For the purposes of such accreditation, the Secretary shall, to the maximum extent practicable, consistent with the purposes of this Act,

utilize organizations recognized by the Commissioner of Education for such purposes..."

The Commissioner of Education has already recognized the Council on Chiropractic Education (CCE) as the accrediting agency for chiropractic colleges.

We recommend that § 131 of S. 500, replace §§ 121(c) and 122(c) of H.R. 6057, and that § 135, relative to grants to such organizations, be amended accordingly.

2. Grants to Educational Institutions

Section 134 would authorize the Secretary of HHS, under Title VII of the Public Health Service Act,

"to make grants to institutions which conduct educational programs, meeting criteria established by section 121, to carry out the purposes of this Act."

The chiropractic profession commends this subcommittee for conducting these hearings, on H.R. 6057 and for its concern with protecting the public health and safety in connection with reducing the hazards from, and assuring efficacious procedures for, health-related radiation.


AMERICAN HOSPITAL ASSOCIATION

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 WASHINGTON OFFICE

STATEMENT OF THE AMERICAN HOSPITAL ASSOCIATION
 BEFORE THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
 OF THE
 HOUSE INTERSTATE AND FOREIGN COMMERCE COMMITTEE
 ON H.R.6057, THE CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT OF 1980

September 12, 1980

The American Hospital Association, which represents more than 6,100 member hospitals and health care institutions as well as over 30,000 personal members, is pleased to have this opportunity to provide its views on H.R.6057, the Consumer-Patient Radiation Health and Safety Act of 1980.

Most hospitals in the United States provide radiological services for their patients. The complexity of the procedures performed in these institutions ranges from simple body radiographs to highly sophisticated computerized axial tomography and nuclear radiation treatments. In addition, many physicians and dentists provide x-ray services in their private offices.

The AHA believes it is important to ensure that adequate precautions are taken to protect the health and safety of the American public. In our view, however, H.R.6057 would needlessly duplicate quality controls that already exist in the private sector.

THE CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT

H.R.6057, the Consumer-Patient Radiation Health and Safety Act, introduced by Rep. Thomas Luken, seeks to minimize unnecessary patient exposure to radiation. It would

accomplish this objective by establishing minimum federal standards for the accreditation of educational programs for, and the certification of, health personnel who provide radiological procedures. Such personnel include medical radiologic technologists, dental auxiliaries, radiation therapy technologists, and nuclear medicine technologists, but, in terms of the scope of the legislation, do not include physicians and dentists.

H.R.6057 would authorize the Secretary of Health and Human Services (HHS) to approve or disapprove private accreditation programs or certifying agencies in terms of such federal standards. It would encourage state administration of accreditation and certification activities through a federal grant program. The state could administer these activities itself or delegate its authority to a private, nonprofit agency, which also would be eligible for federal funds to plan and operate accreditation and certification activities. The bill would require that any federal agency which provides grants, loans, contracts, or other financial assistance for radiologic services or equipment receive assurances that any state which receives such funds be in compliance with the minimum federal standards.

AHA COMMENTS AND CONCERNS

The AHA supports the concept of uniform standards for the credentialing of health professionals and selected allied health personnel when there is a demonstrated link between accreditation/certification and the quality or safety of the health care services being provided to patients. However, H.R.6057 is predicated upon the premise that the establishment of federal standards for operators of medical and dental x-ray equipment would reduce unnecessary patient exposure to radiation. We believe this premise to be faulty.

In remarks made upon the introduction of this bill, Rep. Luken stated, "The Bureau

of Radiologic Health estimates that 30 percent of diagnostic x rays may be unnecessary, a significant portion of which result from poor operator technique." This assertion is incorrect. In fact, the bureau reported that "surveys show that there are many unnecessary x-ray procedures being performed in this country" and that "... as many as 30 percent of the ... procedures performed last year may not have been necessary." The bureau also noted that "patients undergoing medically necessary x-ray examinations may be receiving more radiation than is needed to get a good quality film."

The bureau's comments, therefore, relate to two separate problems--one of x-ray overuse and the other of x-ray overexposure. The 30 percent figure cited relates only to overuse of x rays. Hence, it is important to note that the number of procedures performed is based on a physician's orders. Thus, there would be no decrease in overuse if licensure or certification of x-ray equipment operators were required. This is especially true because H.R.6057 specifically excludes physicians and dentists from the scope of its coverage.

As justification for the need for minimum federal accreditation and certification standards, Rep. Luken cited two Washington Post news articles. The first, published June 25, 1979, and entitled, "Anybody Can Administer X Rays," lays a substantial portion of the blame for unnecessary and excessive radiation exposure on physicians who administer radiologic procedures; yet, as we already have noted, the bill does not address this issue because it excludes physicians and dentists from its purview. The second story, published December 4, 1979, under the headline, "GAO Faults Federal, State Radiation Controls," focuses on the inability of many states to regulate and inspect radiation sources; yet H.R.6057 would neither provide assistance to states to enable them to upgrade these programs, nor would it affect equipment manufacturers, their representatives, or engineering personnel who install, maintain, and monitor the equipment. Thus, it is highly questionable whether the Consumer-Patient Radiation Health and Safety Act would in any way contribute to a reduction

in the overuse of radiologic equipment or overexposure of patients to radiation. What is certain is that this bill could unfairly penalize hospitals and other health care institutions by denying them reimbursement for radiologic services if the state in which they are located fails to comply with the minimum federal standards.

That is not to say that our Association does not believe that efforts should be undertaken to assure the competency of radiologic equipment operators. In our view, however, such programs should be conducted, with leadership from the private sector, by a consortium consisting of health professionals, health providers, educators, and public representatives. Indeed, various programs already exist. For example, the Committee on Allied Health Education and Accreditation, with the approval of the U.S. Department of Education, accredits educational programs for radiologic technologists, radiation therapy technicians, and nuclear medical technologists. Accreditation standards are developed in accordance with educational essentials prepared in collaboration with appropriate professional organizations, such as the American College of Radiology, the American Society for Medical Technology, the American Society of Clinical Pathologists, the American Society of Radiologic Technologists, and the Society of Nuclear Medicine. In addition, both the American Society of Radiologic Technologists and the Nuclear Medical Technology Certification Board have established methods to assess entry level and continuing competence for health personnel who provide radiologic procedures. And finally, the National Commission for Health Certifying Agencies, a nongovernmental organization supported by HHS, develops uniform standards for certifying agencies to promote consistent and equitable competency assessment.

Further, hospital radiology departments must comport with stringent standards for accreditation by the Joint Commission on Accreditation of Hospitals (JCAH). For example, the JCAH requires that radiology services be staffed by qualified technical personnel under the direct supervision of at least one radiologist who is

certified or eligible for examination by the American Board of Radiologists. It also calls for hospital employees to receive instruction in safety precautions for management of emergency radiation hazards and accidents. Additionally, it requires a radiology department to have written policies and procedures, including safety rules, that are reviewed annually and updated when necessary.

Moreover, hospitals are subject to a variety of governmental regulations to ensure the health and safety of patients. These include regulations issued by the Nuclear Regulatory Commission, Occupational Safety and Health Administration, HHS through Medicare conditions of participation, and individual states through hospital licensure requirements.

CONCLUSION

In summary, the AHA opposes the Consumer-Patient Radiation Health and Safety Act. We believe that mandating minimum federal standards for accreditation of educational curricula and certification of radiologic equipment operators is unnecessary since provision for accreditation and certification already exists in the private sector. Further, we believe that this legislation could unfairly penalize health care institutions due to state failure to act in compliance with the standards that would be imposed.

We appreciate the opportunity to present our views on H.R. 6057 and would be pleased to provide any further information at the request of the Subcommittee.

STATEMENT SUBMITTED BY
THE AMERICAN SOCIETY FOR MEDICAL TECHNOLOGY
to the
Subcommittee on Health and the Environment
of the
Interstate and Foreign Commerce Committee
U. S. House of Representatives
in consideration of
Consumer - Patient Radiation Health and
Safety Act of 1979
H.R. 6057
August 25, 1980

American Society for Medical Technology
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The American Society for Medical Technology (ASMT) appreciates the opportunity to present its position on radiation health and safety legislation affecting the clinical laboratory profession and consumer-patient protection.

ASMT is a national professional membership organization representing more than 25,000 health care professionals who are engaged in the delivery of clinical laboratory services. ASMT membership represents a diversity of non-physician specialists and generalists within the clinical laboratory sciences. It includes clinical laboratory administrators, supervisors, educators, technologists, technicians, assistants and such specialists as microbiologists, clinical chemists, hematologists, immunohematologists, cytotechnologists, histotechnologists and nuclear medicine technologists.

ASMT members are highly skilled laboratory scientists who perform or supervise clinical laboratory tests and assume responsibility and accountability for precise and accurate results. Consistent with our "scope of practice," our members are responsible for assuring reliable test results, which responsibility includes the integration, correlation and interpretation of test data. As generalists and specialists, we work in a wide range of governmental and non-governmental laboratories. Members' places of employment range from private or independent laboratories to physician offices, clinics, blood banks, research institutes and hospitals. Approximately

85 percent of ASMT's membership currently holds an academic degree at or above the baccalaureate level.

The Society is comprised of 50 constituent state societies in addition to the District of Columbia, which hold charters granted by the national organization. An elected House of Delegates forms the governing body of the Society and, when not in session, its functions are carried out by an elected Board of Directors. The Society is organized to afford each member the opportunity to be an active partner in the development of standards and practices enumerated in ASMT's policies, positions and publications.

The Society actively participates in accreditation and certification activities. ASMT cooperated with the American Society of Clinical Pathologists (ASCP) in establishing the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) which is an autonomous agency responsible for the accreditation of education programs for clinical laboratory personnel. The Committee on Allied Health Education and Accreditation (CAHEA) of the American Medical Association collaborates with the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) in establishing minimum standards for accrediting educational programs for clinical laboratory personnel.

The Society is currently represented in the National Certification Agency for Medical Laboratory Personnel (NCA), an independent organization which is engaged in the certification of clinical laboratory personnel through career entry-level examinations. NCA has recently announced a voluntary recertification methodology available to all clinical laboratory personnel. The Society also has a representative to the Nuclear Medical Technology Certification Board Advisory Council and, similarly, elects representatives to the Joint Review Commission for Educational Programs in Nuclear Medicine Technology.

The Society strongly supports the principle of continuing education for its members. It has developed a computerized program to record the progress of each member who participates in continuing education programs. ASMT also strongly supports the concept of maintaining and demonstrating continued competency through participation in educational programs and periodic competence evaluation.

COMMENTS ON H.R. 6057

ASMT supports, and has historically supported, a basic intent found within H.R. 6057: to promote the availability of accurate and reliable laboratory results for the diagnosis and treatment of disease. H.R. 6057 is limited to those laboratory procedures which are also included within the definition of

radiologic/nuclear medicine procedures; however, the principles involved are congruent with those more broadly embodied in clinical laboratory legislative proposals since 1975, which proposals have been vigorously supported by ASMT.

Although the most recent version of CLIA, H.R. 4894, has not yet been the subject of hearings before this Subcommittee, ASMT nevertheless welcomes this opportunity to discuss the principles embodied by CLIA in the context of H.R. 6057. ASMT strongly supports this legislation and speaks on behalf of its members who are nuclear medicine technologists.

Unlike other persons who administer radiologic procedures, nuclear medicine technologists are involved in both diagnostic and therapeutic procedures, preparing and using radionuclides in laboratory procedures, scanning-imaging, and function studies. Presently, under the guidance of a nuclear medicine physician, the technologist receives, positions and attends to patients, makes dose calculations for in vivo studies,^{*/} performs a wide variety of diagnostic tests on human beings or in vitro studies^{**/} on body fluids, and applies radioactive material in treatment procedures. Nuclear medicine technologists are responsible for the safe disposal or storage

^{*/} Diagnostic studies performed in direct contact with a patient.

^{**/} Diagnostic studies performed using materials taken from a patient (e.g., blood).

of radioactive materials and for the inventory and control of radiopharmaceuticals. Nearly all nuclear medicine technologists are employed in hospitals or clinics.

Our specific comments on H.R. 6057 are as follows:

Part 1 - Statement of Purposes

Section 102:

We are in agreement with Section 102.

One of the key findings contained in Section 102 is that it is in the public interest to have a continuing supply of all health personnel whose education has met the standards of accreditation and personally can meet the minimal entry level through certification.

When the Medicare program began in July, 1966, only six states, as well as New York City and Puerto Rico, required any form of clinical laboratory licensure. A decade later, barely half the states had any form of laboratory laws on their books; moreover, many of them remain largely ineffective. While we as a nation generally license barbers, street vendors, and even tattoo artists, fewer than a dozen states have or adequately enforce minimum standards for clinical laboratory personnel, including nuclear medicine technologists. This in essence means that personnel are literally taken from the streets in many states and employed to perform laboratory tests without any formal training or experience. Why have the states not responded to this untenable situation? The answer in part

lies in the fact that strong economic and political forces have converged in many states to block the adoption of any meaningful laboratory regulation including that for nuclear medicine. If we can judge from past history, it is highly unlikely that the majority of states will ever adopt strong legislation in the laboratory field.

The Society has historically supported the principles found in Sec. 102(e) for all health care personnel. ASMT has testified before this Subcommittee over the years that personnel should be required to demonstrate competence through appropriate combinations of education, experience, training and examination. We would suggest that this Subcommittee add, either to Sec. 102(e) or to the Committee report, language to insure that competence should be "continuing" and examinations should be "competency based."

Section 103:

The Society concurs with the intent of this section, subject to qualifications cited later in this Statement. We would prefer to see more recognition for, and appropriate definitions of the roles of, the private, nonprofit, autonomous accrediting and certifying organizations.

Section 104:

ASMT has some concerns with Section 104(5) with respect to exemptions for medical and dental practitioners. In the interest of public welfare and safety, ASMT would urge caution

in making assumptions about any group of practitioners, unless established minimum standards of education and experience with respect to administration of radiologic procedures have been met.

Also, with respect to Section 104(5), the Society believes that the intent of the Subcommittee regarding in vivo and in vitro testing deserves clarification. This is important in that many clinical pathology laboratories provide in vitro radioimmunoassay testing on body transudates and exudates, which are performed by medical technologists. If both procedures are to be covered, medical technologists should be added to the list of "persons" in this section.

ASMT believes Section 104(7) should be clarified in order to insure that the "consumer-patient" includes the person administering the radiologic procedure who may be exposed to radiation.

Part 2 - Federal Standards

Section 121(a):

As already discussed under Section 104, ASMT strongly supports the requirement for standards covering administration of radiologic procedures for all health care personnel.

ASMT also strongly supports the use of private, non-profit, autonomous organizations for the accreditation of education programs. However, there must be some level of standards and criteria developed, promulgated and enforced for radiologic programs in the area of accreditation similar to those

of the United States Department of Education. Such an approach would provide external validation of the accreditation process with recognition of those agencies meeting essential standards and criteria. These standards should require both autonomy of accreditation agencies and public representation similar to the current structure of the major accreditation mechanism for clinical laboratory personnel: the National Accreditation Agency for Clinical Laboratory Science (NAACLS).

Since accreditation should be a process which assures relevance of educational programs with respect to public well-being, standards are essential to insure that no single organization or vital interest inappropriately controls such a vital process.

The Society recommends that the Department of HHS support the establishment of a national commission responsible for the monitoring of accreditation activities with functions similar to those performed by the National Commission for Health Certifying Agencies in the area of certification.

Section 122(a):

The most crucial aspect of nuclear medicine laboratory work is the quality of the services provided. This is most reliably assured by the employment of competent practitioners. ASMT supports the principle that all health care practitioners should meet qualifications prescribed to ensure competence, and believes that any facility that receives Federal funds should be required to meet such personnel standards.

There are data demonstrating that laboratory practitioners who are specifically trained with a well integrated academic and clinical programs produce more valid test data than do individuals trained on the job. We append to our testimony a section of the Society's comments on the Notice of Proposed Rulemaking Clinical Laboratories; Personnel Standards in support of this statement.

Certification, a voluntary process, is widely utilized by many segments of society in identifying those who, on the basis of professional judgment, are determined competent to render high quality health care. Because of its widespread acceptance, certification has the potential of exerting considerable influence on both the quality and utilization of health care personnel.

Although ASMT historically has supported the concept of a uniform national certification system and therefore would agree with Section 122(a), which calls for the certification of persons who administer radiologic procedures. We recognize the need for improvements in the current certifying process as well as the chronic inability of the professions themselves, either individually or collectively, to resolve this problem. ASMT suggests that governmental intervention, to the extent necessary to reduce the impact of the vested interests which have heretofore impaired the development of such a system, is necessary.

National certification, reflecting the minimum personnel standards mandated by this bill, would be a significant step towards the identification and recognition of equivalent performance competencies of personnel and would thereby facilitate more appropriate distribution of radiologic health care professionals throughout the United States.

While supporting the recognition of private, nonprofit, autonomous certifying organizations, the Society believes that certifying organizations themselves must meet certain standards. This Society strongly recommends that the Secretary recognize and approve only those certifying organizations meeting the criteria and standards of the National Commission for Health Certifying Agencies.

This sensitive issue has been examined by the Inter-agency Task Force on the Health Effects of Ionizing Radiation, which was established in response to a May 1978 White House directive. The Task Force was chaired by HEW and included representatives from the Departments of Defense, Energy, and Labor, the Veterans' Administration, the Nuclear Regulatory Commission, and EPA. The final report of the Task Force, published in June 1979, recommended measures to be undertaken in cooperation with professional groups to improve the availability, training, and credentialing of personnel who administer radiation-related procedures. This organization offers whatever assistance is possible within the limits of our resources,

to assist this Subcommittee in working toward the goals set by the Task Force.

Part III -- Federal Activities and Grants

Section 131:

The Society strongly supports this section. ASMT has consistently testified that standards should be applied in all settings, particularly in any institution or location where federal funds are expended.

Section 133:

ASMT endorses section 133 which provides that the Secretary may delegate authority for the programs under this bill to an appropriate health agency of each state so long as it is determined that such states have implemented laws and regulations which meet or exceed Federal standards. We caution, however, that the Secretary should be sensitive to the potential for states to set unreasonably high standards beyond the Federal requirements which could negatively impact on geographic mobility and distribution of personnel.

Every effort must be made by the Secretary to develop and encourage uniform laboratory standards among states. In this regard, any funding assistance provided to states under Section 133 or 136 of the bill should assist in assuring the development of consistent and effective laboratory standards on a nationwide basis. While we agree that individual states

would be afforded the opportunity to develop a well conceived and effective state program, it would be most unfortunate to see 50 highly independent and autonomous systems developed to take the place of the current fragmented systems.

Section 135:

ASMT supports the intent of Section 135 in making available grants to private, nonprofit, autonomous organizations for accreditation or certification activities.

The Society strongly recommends that, in the health care arena, the criteria and standards developed by the National Commission for Health Certifying Agencies (NCHCA) should become the standards adopted by all certifying organizations. ASMT also recommends that the Secretary consider applying an approach similar to that utilized for the National Commission for Health Certifying Agencies as a possible model for accrediting educational programs in radiological health.

Part IV -- Administration

Section 142:

Mr. Chairman, we have read with interest comparable legislation which is presently included in the reported Senate Health Manpower legislation. That legislation would require consultation with a broad range of public and private entities -- including professional associations -- during implementation of the bill. We prefer the Senate's approach to this

matter, as the House bill authorizes the consultation with the Environmental Protection Agency and state agencies. In addition, the Society recommends the establishment of a Public Advisory Council on Radiologic Health. This Advisory Council should have the ability to provide necessary professional advice to the Secretary in the development and implementation of standards to be promulgated under the bill. Of special importance would be the Council's role in coordinating the different Federal and State radiologic health regulatory programs in order to avoid duplicate enforcement activities. Moreover, the Council would have an opportunity to insure that the standards promulgated are reasonable and workable ones and to identify additional problems which the Secretary may need to address.

ASMT believes that the composition of the Advisory Council should insure fair representation of all appropriate interests, in order to maximize the potential benefits to the public.

SUMMARY OF CONCLUSIONS AND RECOMMENDATION

In response to the proposed Consumer-Patient Radiation Health and Safety Act of 1979, HR6057, the American Society for Medical Technology:

. Recognizes the need for a continuing supply of persons whose education has met the standards of accreditation and personally can meet the minimum entry level through certification.

. Agrees that there should be national standards for accreditation and certification.

. Recommends that when possible the Secretary work through private, nonprofit, autonomous accreditation and certification organizations.

. Recommends that the accreditation and certification organization meet national criteria and standards.

. Recommends that the National Commission for Health Certifying Agencies (NCHCA) be afforded a significant role in the certification process.

. Recommends that the Secretary establish, as a counterpart to NCHCA, an organization to provide accreditation guidelines for private sector groups, such as the National Accreditation Agency for Clinical Laboratory Science, as a model for the accreditation process.

. Recommends that all health personnel, including medical and dental practitioners, meet some minimum standards before being permitted to carry out radiologic procedures.

. Recommends that standards as they apply to in vivo and in vitro testing be clarified.

. Strongly supports the concept that all education programs in radiologic health must meet national accreditation standards.

. Strongly supports the concept that all personnel who administer radiologic procedures be certified.

. Strongly recommends that these standards be applicable in all settings and institutions.

. Recommends the formation of a broadly-based public Advisory Council on Radiologic Health.

. Supports the provision of assistance to states in order to facilitate adoption and administration of the program.

. Supports grants to educational institutions, to accreditation and certification organizations, and to states to accomplish the purposes of this legislation.

ASMT is pleased to be able to assist the Subcommittee with its views on H.R. 6057. We look forward to being able to work with the Subcommittee and its staff during the evolution of this and similar legislation.



The University of Texas System Cancer Center

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Office of the President

September 5, 1980

The Honorable Henry A. Waxman
Subcommittee on Health and The Environment
2415 Longworth Office Building
Washington, D.C. 20515

Dear Congressman Waxman:

We would like to express concern about HR 6057 relating to the certification of persons administering radiologic procedures. We oppose this bill primarily because we believe the voluntary efforts of the American College of Radiology and the American Society of Radiologic Technologists to provide accreditation for various categories of radiological technologists are effective.

Eleven states, six in the last two years, have adopted the American Registry of Radiological Technologists (ARRT) examination as a means of accrediting those persons who administer radiological procedures. All but two of these states have reciprocity with other states that utilize the ARRT examination. Therefore, a radiologic technologist can move from one of these states to another without the delay, expense and loss of work time that a series of separate standards, such as those which could develop under the proposed law, would entail.

In addition, the Joint Review commission on Education and Radiologic Technology of the American College of Radiology has suggested adoption of specific education programs for those persons who administer radiologic procedures. A joint task force of the American College of Radiology and American Society of Radiologic Technologists was created this year to develop and expedite methods of establishing common standards among the various states with regard to the education of those who administer radiologic procedures.

Further, we have some doubts whether licensing makes a substantial difference in the effectiveness or ability of those who administer radiologic procedures. As a matter of fact, in 1975 the American

[Whereupon, at 12:55 p.m., the hearing adjourned.]

Society of Radiological Technologists and the American College of Radiology conducted a study of radiologic technologists in states which had both licensed and unlicensed technologists and found virtually no difference in terms of performance. More recently, we understand the United States Bureau of Radiologic Health has completed a study not yet released that reveals results similar to those shown in the 1975 survey. In our institution, we provide training for diagnostic technologists as well as a joint educational program with the University of Texas School of Allied Health.

With regard to the specific language of HR 6057, we view the penalties for failure of a state to comply with the bill excessive. The way the bill is presently written, failure of a state to adopt the model law and accreditation procedures as outlined by the Secretary of Health and Human Services would result in a withdrawal of Medicare and Medicaid funds to physicians and hospitals within that particular state. This appears an extreme punishment directed toward physicians and hospitals instead of the state governments which fail to comply.

Finally, in a period when cost effectiveness is of key importance it seems particularly inconsistent to bear the expense of creating another federal regulatory body when the results achieved by that body may be marginal and when voluntary efforts by the states are gaining momentum.

We hope these comments will be helpful and respectfully request that they be made a part of the official hearing record on HR 6057.

Sincerely yours,

Charles A. Lemaistre, M.D.
Charles A. Lemaistre, M.D.
President

cc: The Honorable Mickey Leland
The Honorable Phil Gramm
Edward N. Brandt, Jr., M.D., Ph.D.
Herman Adams
Robert M. Braden, Sr.

CLM/kj

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