



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

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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.

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

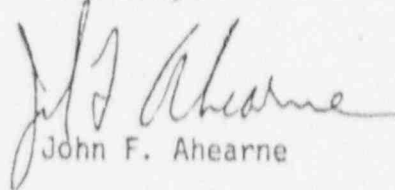
1. Section 131(a) requires the Secretary to promulgate voluntary minimum standards for the accreditation of educational institutions conducting education programs in radiologic services. Section 132(a) requires the Secretary to promulgate voluntary minimum standards for licensure of radiologic technologists. 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



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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 the Federal Radiation Council made in recent congressional evaluations and by the Federal Task Force on the Health Effects of Ionizing Radiation ("Libassi Report"). The NRC views such a change as an undesirable fragmentation of 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.
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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, NRC does not support this bill. Thank you for giving us the opportunity to comment.

Sincerely,

John F. Ahearne

96TH CONGRESS
1ST SESSION

H. R. 5934

To provide for the protection of the public health (including consumer patients)
from unnecessary exposure to radiation.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 16, 1979

Mr. LENT introduced the following bill: which was referred to the Committee on
Interstate and Foreign Commerce

A BILL

To provide for the protection of the public health (including
consumer patients) 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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FINDINGS

SEC. 102. The Congress finds that—

(a) it is in the interest of the Nation's public health and safety to minimize exposure of consumer-patients to potentially hazardous radiation;

(b) while the use of radiologic procedures is essential in modern medicine, even the most advanced procedures will not adequately protect the health and safety of either the consumer-patient subjected to radiologic procedures or the individuals performing such radiologic procedures, including their progeny, unless

1 the individuals performing such radiologic procedures
2 are fully qualified by reason of education and experi-
3 ence in the operation of radiologic equipment or in the
4 performance of radiologic procedures so as to avoid un-
5 necessary consumer-patient and operator exposure to
6 unnecessary radiation and to assure efficacious
7 consumer-patient radiologic services;

8 (c) it is in the interest of public health to have an
9 adequate and continuing supply of well-educated radio-
10 logic technologists;

11 (d) consistent with Federal radiation protection
12 guidance for diagnostic X-rays approved by the Presi-
13 dent on January 26, 1978, it is in the national interest
14 and in the interest of public health and safety to assure
15 that persons administering potentially hazardous radi-
16 ation to consumer-patients are properly qualified as has
17 been recommended by—

18 (1) the National Advisory Committee on Ra-
19 diation to the Surgeon General in 1966;

20 (2) the Secretary's Task Force on Environ-
21 mental Health and Related Problems in June
22 1967;

23 (3) the Surgeon General's Medical X-ray Ad-
24 visory Committee on Public Health Consider-

ations in Medical Diagnostic Radiology in October 1967;

(4) the 1970 report of the Secretary to the Congress pursuant to the Radiation Control for Health and Safety Act of 1968;

(5) the National Academy of Sciences-National Research Council's Advisory Committee on the Biological Effects of Ionizing Radiations in November 1972; and

(6) the Conference of Radiation Control Program Directors in May 1974.

(e) that the protection of the 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; and

(f) any person who prescribes or administers radiologic procedures to consumer-patients, including at Federal facilities, should be required to demonstrate competence by reason of education, experience, and examination.

STATEMENT OF PURPOSES

SEC. 103. The purposes of this Act, which shall be carried out consistent with the maximum protection of public

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1 health from unnecessary consumer-patient exposure to radi-
2 ation, are to—

3 (a) provide for the establishment of criteria and
4 guidelines for the credentialing or licensure of all per-
5 sonnel administering radiation to consumer-patients;

6 (b) provide for the establishment of criteria and
7 guidelines for use in accrediting programs for the edu-
8 cation of radiologic technologists;

9 (c) provide for the formulation of criteria and
10 guidelines applicable to all Federal agencies in the (1)
11 establishment and execution of consumer-patient radi-
12 ation protection programs and (2) formulation of con-
13 sumer-patient radiation protection standards;

14 (d) insure that all Federal agencies administer
15 programs carried out or funded by such agencies so as
16 to further the purposes of this Act; and

17 (e) encourage State adoption and administration of
18 programs for the accreditation of educational programs
19 for the education of radiologic technologists and for the
20 licensure of radiologic technologists.

21 DEFINITIONS

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

24 (1) "Administrator" means the Administrator of
25 the Environmental Protection Agency;

1 (2) "dental practitioners" means licensable doctors
2 of dentistry, who do or will prescribe or administer ra-
3 diation to consumer-patients;

4 (3) "medical practitioners" means licensable doc-
5 tors of medicine, osteopathy, podiatric medicine, or
6 chiropractic, who do or will prescribe or administer ra-
7 diation to consumer-patients or for specified limited
8 procedures, postgraduate physician trainees, such as
9 interns and residents;

10 (4) "radiation" means ionizing and nonionizing ra-
11 diation from such sources as consumer and commercial
12 products, medical and dental radiation (including diag-
13 nostic X-rays), and natural radiation;

14 (5) "radiologic technologist" means any person,
15 other than a medical or dental practitioner, who ad-
16 ministers radiation to consumer-patients and includes,
17 but is not limited to, medical radiologic technologists
18 (including radiographers), dental radiologic technolo-
19 gists (including dental hygienists and dental assistants),
20 radiation therapy technologists, and nuclear medicine
21 technologists; and

22 (6) "Secretary" means the Secretary of Health,
23 Education, and Welfare.

PART II—FEDERAL RADIATION PROTECTION

GUIDELINES

PROMULGATION OF RADIATION PROTECTION GUIDELINES

SEC. 121. (a)(1) The Secretary shall promulgate Federal radiation guidance with respect to consumer-patient radiation matters directly or indirectly affecting public health. Such guidance shall contain information regarding (A) the sources of consumer-patient radiation exposure and (B) techniques, procedures and methods to minimize unnecessary and nonefficacious consumer-patient radiation exposure.

(2) Pursuant to paragraph (1), the Secretary shall, in consultation with affected Federal agencies, promulgate guidelines regarding medical and dental exposure to consumer-patients. Such guidelines shall be in a form so as to (A) facilitate the establishment of optimum techniques to minimize consumer-patient exposures, (B) eliminate inconsistency and the resultant need for retakes of diagnostic radiologic procedures, (C) eliminate unproductive screening programs; and (D) obtain the optimum diagnostic information with minimum consumer-patient exposure.

(b) Within eighteen months of enactment, the Secretary shall promulgate criteria and guidelines with respect to—

(1) the application of diagnostic X-rays to consumer-patients;

1 (2) the therapeutic application of radiation to con-
2 sumer-patients; and

3 (3) the application of radiation to consumer-
4 patients in the treatment of disease, such as nuclear
5 medicine applications.

6 (c) The Secretary shall review and, as appropriate, re-
7 vise guidelines promulgated by him pursuant to this section.

8 (d) The functions of the Administrator under section
9 274(h) of the Atomic Energy Act of 1954 (42 U.S.C.
10 2021(h)) are transferred to the Secretary.

11 PART III—ESTABLISHMENT OF STATE PROGRAMS FOR
12 THE CONTROL OF RADIOLOGIC SERVICES
13 RECOMMENDED MINIMUM RADIATION PROTECTION
14 STANDARDS FOR ACCREDITATION

15 SEC. 131. (a) Not later than December 31, 1980, the
16 Secretary shall promulgate voluntary minimum standards for
17 the accreditation of educational institutions conducting edu-
18 cation programs in radiologic services. Such standards shall
19 distinguish between programs for the education of (1) radiolo-
20 gic technologists, (2) medical or dental practitioners, (3) den-
21 tal hygienists, and (4) dental assistants.

22 (b) The Secretary may authorize appropriate profession-
23 al organizations to certify such accreditation as consistent
24 with the purposes of this section if he determines that such
25 organization will adhere (and is continuing to adhere) as a

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1 basis for certification to the minimum standards issued pursu-
2 ant to this section. For the purposes of such accreditation,
3 the Secretary shall, to the maximum extent practicable, con-
4 sistent with the purposes of this Act, utilize organizations
5 recognized by the Commissioner of Education for such pur-
6 poses: *Provided, however,* That the Secretary shall find such
7 organization is not continuing to adhere to such standards.

8 (c) The Secretary shall review and, as appropriate, re-
9 vise the standards promulgated by him pursuant to this sec-
10 tion.

11 RECOMMENDED MINIMUM STANDARDS FOR LICENSURE
12 FOR RADIOLOGIC TECHNOLOGISTS

13 SEC. 132. (a) Not later than December 31, 1980, the
14 Secretary shall promulgate voluntary minimum standards for
15 licensure of radiologic technologists. The Secretary may des-
16 ignate categories of specialization or levels of competence for
17 the purpose of licensure if he finds that such categories are
18 required to assure adequate protection of public health from
19 unnecessary radiation exposure or to assure efficacious con-
20 sumer-patient radiologic services. The Secretary shall consid-
21 er for possible designation the following categories of special-
22 ization: senior radiologic technologists, medical radiologic
23 technologists (including radiographers), dental radiologic
24 technologists (including dental hygienists and dental assist-
25 ants), radiation therapy technologists, nuclear medicine tech-

1 nologists, technologist-in-training, and students in radiologic
2 technology.

3 (b)(1) The Secretary shall, within one year after promul-
4 gation of voluntary minimum standards under this section,
5 review and evaluate any voluntary certification programs or
6 State licensure programs in existence as of such date and,
7 based on such review and evaluation, determine whether
8 such programs meet such standards.

9 (2) If the Secretary is satisfied that the program meets
10 such standards he shall, within one year thereafter, certify
11 such programs as in conformance with such standards.

12 (c) The Secretary shall review and, as appropriate, re-
13 vise the standards promulgated by him pursuant to this sec-
14 tion.

15 STATE ASSISTANCE

16 SEC. 133. The Secretary shall provide the States such
17 advice and assistance as will foster establishment of appropri-
18 ate programs to achieve the purposes of this Act. Such ad-
19 vice and assistance shall include model laws and may include
20 educational curriculum and teaching aids. Such model law
21 shall provide that—

22 (a) graduation from an educational institution for
23 the education of radiologic technologists which is ac-
24 credited as in conformance with the voluntary stand-
25 ards promulgated pursuant to section 131 shall satisfy

1 the requirements for a provisional license as a tech-
2 nologists-in-training conditioned on licensure within
3 one year in one or more categories of specialization the
4 Secretary may designate;

5 (b) it shall be unlawful for an individual to apply
6 potentially hazardous radiation to consumer-patients
7 unless such individual is a medical or dental practition-
8 er or meets the standards promulgated pursuant to sec-
9 tion 132; and

10 (c) if adopted by the State any violation of the
11 model law by an individual applying potentially hazard-
12 ous radiation to consumer-patients shall be subject to a
13 civil penalty of not more than \$1,000, and any such
14 violation shall be with respect to each Act or omission
15 made unlawful by such law.

16 GRANTS TO EDUCATIONAL INSTITUTIONS

17 SEC. 134. The Secretary may, under title VII of the
18 Public Health Service Act, make grants to educational pro-
19 grams accredited pursuant to section 131 to carry out the
20 purposes of this Act.

21 GRANTS TO CERTIFICATION ORGANIZATIONS

22 SEC. 135. The Secretary may make grants to States or
23 professional organizations designated pursuant to section
24 131(b) in an amount up to 66 $\frac{2}{3}$ per centum of the cost of the
25 first year and up to 33 $\frac{1}{3}$ per centum of the cost of the sec-

1 ond, third, and fourth years for the planning, development,
2 and establishment of programs to carry out the purposes of
3 this Act.

4 STATE PROGRAM GRANTS

5 SEC. 136. (a) The Secretary may, in accordance with
6 subsections (b) and (c), make grants to State radiation protec-
7 tion agencies up to 50 per centum of the costs of programs
8 which the Secretary determines are consistent with the pur-
9 poses of this Act. Such grants shall provide for the accredita-
10 tion of educational programs and for the mandatory licensure
11 of radiologic technologists.

12 (b) Within six months of the issuance of any criteria and
13 minimum standards pursuant to section 131 for the accredita-
14 tion of educational programs, the Governor of a State may
15 file with the Secretary a letter of intent that such State will,
16 within two years of the issuance of such criteria and mini-
17 mum standards, adopt as a minimum such criteria and stand-
18 ards for the accreditation of such educational programs. If,
19 after two years, a State fails to adopt such standards, or is
20 unable to adopt such standards or more stringent standards,
21 eligibility for grants pursuant to this section shall terminate:
22 *Provided, however,* That upon application of a Governor, the
23 Secretary may grant an extension for not more than two
24 years if after review the Secretary determines that good faith
25 efforts have been made by the State and reasonable assur-

1 ance is provided that an effective accreditation program will
2 be provided by the State within the period of the extension.

3 (c)(1) Within six months of the issuance of any criteria
4 and minimum standards issued pursuant to section 132 for
5 the licensure of radiologic technologists, the Governor of a
6 State may file a letter of intent that such State will, within
7 two years of the issuance of such criteria and minimal stand-
8 ards, adopt as minimum standards for such criteria and the
9 licensure of radiologic technologists. If, after two years, a
10 Governor fails to adopt such standards, or is unable to adopt
11 such standards or more stringent standards, eligibility for
12 grants pursuant to this subsection shall terminate: *Provided,*
13 *however,* That upon application of a Governor, the Secretary
14 may grant an extension for not more than two years if after
15 review the Secretary determines that good faith efforts have
16 been made by the State and reasonable assurance is provided
17 that an effective licensure program will be provided by the
18 State within the period of the extension.

19 (d) Notwithstanding any other provision of this section,
20 in the case of a State which has, prior to the effective date of
21 standards and guidelines promulgated pursuant to this sub-
22 part, established standards for the accreditation of education-
23 al programs or licensure of radiologic technologists, such
24 State shall be deemed to be in compliance with the conditions
25 of this section unless the Secretary determines, after notice

1 and hearing, that such State standards do not meet the mini-
2 mum standards prescribed by the Secretary or are inconsis-
3 ent with the purposes of this Act.

4 PART IV—FEDERAL ACTIVITIES

5 FEDERAL AGENCY COMPLIANCE

6 SEC. 141. Each department, agency, and instrumentali-
7 ty of the executive branch of the Federal Government shall
8 comply with any minimum standards promulgated pursuant
9 to this Act.

10 FEDERAL ASSISTANCE PROGRAMS

11 SEC. 142. (a) In order to carry out the purposes of this
12 Act, the President shall, not later than one year after the
13 date of enactment, issue an Executive order requiring each
14 Federal agency which is authorized to extend Federal assist-
15 ance or reimbursement of funds by means of grants, loans,
16 contracts, or other forms of financial assistance or reimburse-
17 ment to promptly effectuate the purposes of this Act, includ-
18 ing the adoption of minimum standards promulgated pursuant
19 to this Act.

20 (b) The President may by order exempt any specific
21 grant, loan, contract, or other form of financial assistance
22 from the requirements of this subsection if he determines
23 such exemption is in the national interest. The President
24 shall notify the Congress in writing of such exemption at
25 least ninety days before it is effective.

1 PART V—ADMINISTRATION

2 SEC. 151. Guidelines and standards prescribed under
3 this Act shall be promulgated by rule in accordance with the
4 procedures set forth in section 553 of title 5, United States
5 Code.

6 CONSULTATION

7 SEC. 152. In establishing guidelines and minimum
8 standards under this Act the Secretary shall consult with the
9 Environmental Protection Agency, State health departments,
10 and appropriate professional organizations.

11 PART VI—APPROPRIATIONS AUTHORIZATION

12 SEC. 161. There is authorized to be appropriated to the
13 Secretary such sums as necessary to carry out the purposes
14 of this Act.

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