HEARING
BEFORE THE
COMMITTEE ON
LABOR AND HUMAN RESOURCES
UNITED STATES SENATE
NINETY-EIGHTH CONGRESS
SECOND SESSION
ON
EXAMINING HOW LIABILITY SHOULD BE ASSESSED FOR DAMAGES CAUSED BY LOW-LEVEL RADIATION EFFECTS WHICH APPEAR AS CANCER YEARS AFTER EXPOSURE
SEPTEMBER 18, 1984

Printed for the use of the Committee on Labor and Human Resources
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(III)
RADIATION CANCER LIABILITY

TUESDAY, SEPTEMBER 18, 1984

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The committee met, pursuant to notice, at 9:40 a.m., in room SD-430, Dirksen Senate Office Building, Senator Orrin G. Hatch (chairman of the committee) presiding.
Present: Senator Hatch.

OPENING STATEMENT OF SENATOR HATCH

The CHAIRMAN. We meet this morning to consider what progress has been made toward a serviceable solution to a puzzle that has stymied legislatures, agencies, and the courts. How should liability be assessed for damages for moderate to low-level radiation, an invisible agent whose occasional effects appear years after exposure as cancers that are indistinguishable from a plague of cancers caused by other things?

Solutions, especially when they are technical and possibly tenuous, rarely gain the notice that attends the problems themselves. Still, the true work of Government and science is the search for solutions. The two scientific committees represented on our first panel have been in serious pursuit of an answer to the problem just described, and therefore, their efforts warrant the attention of the Congress and the Nation.

Over the past 18 months, Dr. Rall’s committee at the National Institutes of Health has been preparing the report and probability tables that are required by section 7(b) of the Orphan Drug Act. The promise of this project is a competent and intelligible appraisal of the causal connection between any dose of radiation and the cancer of any person who was exposed to this radiation prior to the onset of the disease. The hope is that the tables will bring coherence and fairness to the deliberations of persons who must judge whether radiation caused any particular cancer. The need is obvious since courts, workers compensation boards, and Federal agencies are befuddled by a bazaar of convoluted and conflicting testimonies. The public itself is confused. Plaintiffs do not know when to make claims, and defendants do not know when to contest them.

The use of radioepidemiology and probabilities to determine causality for radiogenic cancer claims was first proposed by me in October 1981 at a hearing that was devoted to resolving the special liability problem of those Americans who lived downwind of the Nevada nuclear test sites. The National Council for Radiation Protection and Measurement has recently established a committee to
show this radioepidemiological method. Dr. Victor Bond, who is chairman of this committee, testified at this hearing. Because of his testimony and the subsequent testimonies of other scientists, I sponsored legislation that requires the development and evaluation of the radioepidemiological method. Section 7(b) of the Orphan Drug Act resulted from this initiative.

My intention was to require the Department of Health and Human Services to attempt what the scientists at my hearings said could be done, and then to see and to let others see whether it is so. I did not and still do not endorse the method or the tables. But I am interested in the idea and hope others are interested also, because we need a reasonable means for measuring radiation liability. I have a wait-and-see attitude. This morning I have come to see.

Representatives of both the NIH committee and the original NCRP committee are present. Neither committee has published its report, but I understand that both reports should be ready soon. Since both committees are near the end of their task, it is appropriate to ask them what they think of the radioepidemiological method and their own efforts.

The task could not be easy. The time allowed was short, considering the work to be done. The data are massive, yet they are not sufficient for certainty and controversy attends their interpretation. As the witnesses know, I have had regular reports on the progress of both committees, and therefore, I know that both committees have worked long and hard and have faced serious obstacles.

I have been told repeatedly over the last 3 years that the radioepidemiological method is the best available for determining whether radiation is an improbable, possible, or probable cause of a cancer. This hearing will primarily address two further questions: (1) Even if the radioepidemiological method is the best, is it good enough? and (2) can this method be formulated in a format that will provide our people with a readily understandable standard for judging radiogenic cancer claims?

Before we turn to our witnesses, I must turn briefly to another matter involving radiation, to guidelines for the training and certification of radiation technicians who were mandated by the Omnibus Reconciliation Act of 1981 and that are being developed by the Department of Health and Human Services. Both Senator Randolph and I are concerned with the progress of this project also. We have arranged to submit interrogatories to Health and Human Services. Our questions and their answers, and perhaps some further written testimony on this subject, will be included in this hearing record without objection, and I would also include at this point a letter from Senator Jennings Randolph, dated September 18, 1984, to me.

[Material supplied follows:]
Honorabe Orrin Hatch  
Chairman  
Committee on Labor and Human Resources  
United States Senate  
Washington, D.C. 20510  

Dear Mr. Chairman:

I deeply appreciate the opportunity you so graciously afforded me to submit a series of questions to the Department of Health and Human Services during today's public hearing. As you know, it was my intention to be present today for that purpose. Unfortunately, I could not in good conscience cancel a long-standing event, in my honor, requiring me to travel to a neighboring state this morning.

Mr. Chairman, the Consumer-Patient Radiation Health and Safety Act was enacted as part of the Omnibus Budget Reconciliation Act of 1980. Public Law 97-35. The Act required the Secretary of Health and Human Services to promulgate regulations on minimum federal standards for the accreditation of educational programs and the credentialing of radiologic personnel, as well as the transmission of a model statute for adoption by the states, by August 13, 1982. Three years have elapsed since enactment, and still the minimum standards have not been published.

I know that you understand and share my concern over the fact that 39 states do nothing to deter the use of untrained, incompetent individuals in performing radiologic procedures on men, women and children in this country every day -- 30 percent of whom are being over-exposed to unnecessary and highly dangerous doses of radiation. The consequences of our not taking action now are too staggering to contemplate.

Enclosed are a number of questions for submission to the Department of Health and Human Services. Would you be so kind as to require the Department's responses be appropriate and timely so that they can become part of today's official hearing record.

With sincere thanks for your assistance in this matter, I am

[Signature]

Jennings Randolph

Enclosure
QUESTIONS SUBMITTED BY SENATOR JENNINGS RANDOLPH, TO THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES REGARDING THE STATUTORY REQUIREMENT TO PUBLI-
LISH MINIMUM STANDARDS TO PROTECT THE PUBLIC FROM POTENTIAL HAZARDS OF
UNNECESSARY OVER-EXPOSURE TO MEDICAL/DENTAL RADIATION, UNDER PL 97-35,
TITLE IX, KNOWN AS THE "CONSUMER-PATIENT RADIATION HEALTH & SAFETY ACT

August 13, 1981, (P.L. 97-35) Section 979 (a) provides as follows:

PROMULGATION OF STANDARDS

Sec. 979. (a) Within twelve months after the date of enactment of
this Act, the Secretary, in consultation with the Radiation Policy
Council, the Administrator of Veterans' Affairs, the Administrator of
the Environmental Protection Agency, appropriate agencies of the
States, and appropriate professional organizations, shall by regula-
tion promulgate minimum standards for the accreditation of educa-
tional programs to train individuals to perform radiologic proce-
dures. Such standards shall distinguish between programs for the
education of (1) medical radiologic technologists (including radio-
ographers), (2) dental auxiliaries (including dental hygienists and
assistants), (3) radiation therapy technologists, (4) nuclear medicine
technologists, and (5) such other kinds of health auxiliaries who
administer radiologic procedures as the Secretary determines appro-
priate. Such standards shall not be applicable to educational pro-
grams for practitioners.

(b) Within twelve months after the date of enactment of this Act,
the Secretary, in consultation with the Radiation Policy Council, the
Administrator of Veterans' Affairs, the Administrator of the Envi-
ronmental Protection Agency, interested agencies of the States, and
appropriate professional organizations, shall by regulation promul-
gate minimum standards for the certification of persons who admini-
ster radiologic procedures. Such standards shall distinguish between
certification of (1) medical radiologic technologists (including radio-
ographers), (2) dental auxiliaries (including dental hygienists and
assistants), (3) radiation therapy technologists, (4) nuclear medicine
technologists, and (5) such other kinds of health auxiliaries who
administer radiologic procedures as the Secretary determines appro-
priate. Such standards shall include minimum certification criteria
for individuals with regard to accredited education, practical experi-
ence, successful passage of required examinations, and such other
criteria as the Secretary deems necessary for the adequate qualifica-
tion of individuals to administer radiologic procedures. Such
standards shall not apply to practitioners.

Has the Secretary by regulation promulgated any minimum standards for the
accreditation for educational programs to train individuals to perform
radiologic procedures as required by statute?

2. Has the Secretary by regulation promulgated minimum standards for the
certification of persons to administer radiologic procedures as required by
statute?

3. If no regulations have been promulgated please explain fully why the Secretary
has ignored the requirements of this statute and also indicate when the
Secretary will comply.

**MINOR STATUTE**

Sec. 980. In order to encourage the administration of accreditation and certification programs by the States, the Secretary shall prepare and transmit to the States a model statute for radiologic procedure safety. Such model statute shall provide that—

1. it shall be unlawful in a State for individuals to perform radiologic procedures unless such individuals are certified by the State to perform such procedures; and

2. any educational requirements for certification of individuals to perform radiologic procedures shall be limited to educational programs accredited by the State.

Has the Secretary prepared and transmitted to the States a model statute for radiologic procedure safety as required by statute?

5. If model statute has been not transmitted to the States please explain fully why the Secretary has ignored the requirements of this section and also indicate when the Secretary will comply.


**COMPLIANCE**

Sec. 981. (a) The Secretary shall take all actions consistent with law to effectuate the purposes of this subtitle.

(b) A State may utilize an accreditation or certification program administered by a private entity if—

1. such State delegates the administration of the State accreditation or certification program to such private entity;

2. such program is approved by the State; and

3. such program is consistent with the minimum Federal standards promulgated under this subtitle for such program.

(c) Absent compliance by the States with the provisions of this subtitle within three years after the date of enactment of this Act, the Secretary shall report to the Congress recommendations for legislative changes considered necessary to assure the States’ compliance with this subtitle.

(d) The Secretary shall be responsible for continued monitoring of compliance by the States with the applicable provisions of this subtitle and shall report to the Senate and the House of Representatives by January 1, 1982, and January 1 of each succeeding year the status of the States’ compliance with the purposes of this subtitle.

(e) Notwithstanding any other provision of this section, in the case of a State which has, prior to the effective date of standards and guidelines promulgated pursuant to this subtitle, established standards for the accreditation of educational programs and certification of radiologic technologists, such State shall be deemed to be in compliance with the conditions of this section unless the Secretary determines, after notice and hearing, that such State standards do not meet the minimum standards prescribed by the Secretary or are inconsistent with the purposes of this subtitle.
6. Please submit for the record copies of all reports submitted to the Senate and the House of Representatives on January 1, 1982, and January 1 of each succeeding year relating to the status of the States' compliance with the statute as required by statute.

7. Please submit for the record the step by step procedures required in connection with the preparation and issuance of regulations by the Secretary of the type required by P.L. 97-35 mentioned above.

• 8. Does the Department contemplate, in future promulgation of minimum standards, to apply the burden of compliance equally to federal agencies and the armed services as would be applied on other affected entities? Or does the Department intend to exempt certain personnel? If so, what is the justification for doing so?

• 9. If final regulations/minimum standards now being considered by the Department do exempt armed services personnel from complying with minimum standards of safety in performing radiation procedures (x-ray) on members of the armed services and their dependents in order to save money, please justify placing such individuals at risk from dangerous over-exposure to radiation.

• 10. Is the Department considering exempting the armed services from compliance with minimum safety standards because of recruitment problems? If so, explain.

• 11. It is understood that the Department believes there is little support for the existing legislation because of a lack of response from members of Congress to the Department's Notice of Proposed Rulemaking.

Did it occur to the Department that a lack of response to the NPRM might have been a signal that having given the Department the authority to publish minimum standards, the Congress had every reason to expect that it would do so without further comment as to the intent of Congress in enacting the law?

If the Department believed a lack of Congressional responses to the NPRM indicated little support for the legislation, why did the Department not seek further clarification of Congressional intent in that regard?

• 12. Does the Department believe the "Statutory mandate" cannot be accommodated without creating insurmountable problems? If so, why? What are those "insurmountable problems?"

13. How many states had minimum health and safety standards on their books at the time of enactment of the Consumer-Patient Radiation Health and Safety Act? How many have passed such laws since enactment of the Consumer-Patient Radiation Health and Safety Act?
14. In 1966, the National Advisory Committee on Radiation reported to the Surgeon General that minimum federal legal standards of education, training, and clinical experience for radiologists appeared to be necessary in order to bring about an increase in effective and safe ways in which such services could be delivered to the general public.

In 1967, HEW’s Task Force on Environmental Health and Related Problems, concluded that radiation hazards, in spite of the amount of public sensitivity to the subject, were still in need of improvement in the area of safety controls, and that clearly more protections were needed for persons receiving radiologic treatments and services. It recommended that "all persons using X-ray equipment should be licensed to do so, after fulfilling written exams as to their competency to perform radiologic procedures.

In 1967, the Surgeon General’s X-Ray Advisory Committee on Public Health, in a report entitled "Public Health Considerations in Medical Diagnostic Radiation (X-rays)," observed that prime consideration should be given to the total public health interest with regard to radiologic procedures then in use, and that the stage had been reached when mandatory (emphasis added) requirements for competency examinations, training and clinical experience of operators of X-ray equipment were appropriate.

Has the Department’s personnel reviewed these previous reports to the Surgeon General in their contemplation of drafting the minimum standards to implement the Consumer-Patient Radiation Health and Safety Act of 1981?

Has the Department’s personnel reviewed the hearing record on congressional efforts to enact the Consumer-Patient Radiation Health and Safety Act of 1981 as part of their preparation in writing the minimum standards or model statute required by the Act?

If not, has something occurred over the past 18 years or so that has convinced the Department and/or the Surgeon General that the need for safety controls such as competency examinations for radiologists and accreditation of training programs no longer exists? Explain.

*Questions Numbered 8 through 12 Based on HHS Internal Memorandum Dated July 15, 1984 (Standards for the Accreditation of Education Programs for, and the Credentialing of, Radiologic Personnel - 42 CFR Part 5); Memo of Non-Concurrence in Final Regulations from Dr. Robert B. Klem to William Quinlin, Executive Secretariat.
The Honorable Orrin G. Hatch  
Chairman  
Committee on Labor and  
Human Resources  
United States Senate  
Washington, D.C. 20510

Dear Mr. Chairman:

Thank you for your letter concerning the implementation of the Consumer-Patient Radiation Health and Safety Act of 1981 (Public Law 97-35). As the enclosed answers to your 15 questions indicate, the Department has been working to ensure the issuance of standards as required by Public Law 97-35.

Since the passage of the Act, the Department has been working diligently to develop the required materials in concert with other Federal entities, the States, and the private sector. We feel that the extra time required for such coordinated efforts will pay large dividends in terms of the usefulness of these regulations to the States and in their implementation by Federal agencies.

As you know, any regulations I approve must be reviewed by the Office of Management and Budget, as provided by E.O. 12291. I expect to send rules to OMB in the near future, and hope that they can be published within 60 days.

As you requested, enclosed also are copies of the reports submitted to the Congress on the status of States' compliance as required by Public Law 97-35.

An identical letter is being sent to Senator Randolph.

Sincerely,

[Signature]
Margaret M. Heckler  
Secretary

Enclosures

1. The Consumer-Patient Radiation Health and Safety Act of 1981, enacted August 13, 1981, (P.L. 97-35) Section 979 (a) provides as follows:

Promulgation of Standards

Sec. 979. (a) Within twelve months after the date of enactment of this Act, the Secretary, in consultation with the Radiation Policy Council, the Administrator of Veterans' Affairs, the Administrator of the Environmental Protection Agency, appropriate agencies of the States, and appropriate professional organizations, shall by regulation promulgate minimum standards for the accreditation of educational programs to train individuals to perform radiologic procedures. Such standards shall distinguish between programs for the education of (1) medical radiologic technologists (including radiographers), (2) dental auxiliaries (including dental hygienists and assistants), (3) radiation therapy technologists, (4) nuclear medicine technologists, and (5) such other kinds of health auxiliaries who administer radiologic procedures as the Secretary determines appropriate. Such standards shall not be applicable to educational programs for practitioners.

(b) Within twelve months after the date of enactment of this Act, the Secretary, in consultation with the Radiation Policy Council, the Administrator of Veterans' Affairs, the Administrator of the Environmental Protection Agency, interested agencies of the States, and appropriate professional organizations, shall by regulation promulgate minimum standards for the certification of persons who administer radiologic procedures. Such standards shall distinguish between certification of (1) medical radiologic technologists (including radiographers), (2) dental auxiliaries (including dental hygienists and assistants), (3) radiation therapy technologists, (4) nuclear medicine technologists, and (5) such other kinds of health auxiliaries who administer radiologic procedures as the Secretary determines appropriate. Such standards shall include minimum certification criteria for individuals with regard to accredited education, practical experience, successful passage of required examinations, and such
other criteria as the Secretary shall deem necessary for the adequate qualification of individuals to administer radiologic procedures. Such standards shall not apply to practitioners.

Has the Secretary by regulation promulgated any minimum standards for the accreditation for educational programs to train individuals to perform radiologic procedures as required by statute?

RESPONSE: On July 12, 1983, the Department published a Notice of Proposed Rulemaking (NPRM) in the Federal Register which provided minimum standards for the accreditation of educational programs to train individuals to perform radiologic procedures. Public comments were received and appropriate changes made in the regulation. The Final Rule that will be published in the Federal Register is now under final review within the Department and will be forwarded to OMB for review under Executive Order 12291.

2. Has the Secretary by regulation promulgated minimum standards for the certification of persons to administer radiologic procedures as required by statute?

RESPONSE: The information provided in answer to question one also applies to the certification (licensure) standards, which were also included in the July 12, 1983 NPRM.
3. If no regulations have been promulgated please explain fully why the Secretary has ignored the requirements of this statute and also indicate when the Secretary will comply.

RESPONSE: The Department has not ignored the requirements of the statute. Since the enactment of the legislation, the Department has worked diligently to develop the required regulation. This process necessitated consulting with professional associations, accrediting bodies, certifying organizations, and State regulatory agencies. Many issues were raised by these organizations which required an enormous amount of staff time to resolve. However, by involving the States and the private sector in this time-consuming process, we believe the final regulations will have been improved.


Model Statute

Sec. 980. In order to encourage the administration of accreditation and certification programs by the States, the Secretary shall prepare and transmit to the States a model statute for radiologic procedure safety. Such model statute shall provide that--
(1) it shall be unlawful in a State for individuals to perform radiologic procedures unless such individuals are certified by the State to perform such procedures; and
(2) any educational requirements for certification of individuals to perform radiologic procedures shall be limited to educational programs accredited by the State.

Has the Secretary prepared and transmitted to the States a model statute for radiologic procedure safety as required by statute?
RESPONSE: A model statute has been developed by the Public Health Service (PHS) for transmittal to the States and is under final review in the Department. Because definitions and other wording in the model statute must be consistent with the standards, it was felt that the standards should be issued in the Federal Register prior to transmitting the model statute to the States.

5. If model statute has been not transmitted to the States please explain fully why the Secretary has ignored the requirements of this section and also indicate when the Secretary will comply.

RESPONSE: The requirements of the statute have not been ignored. Several drafts of a model statute have been prepared. This followed extensive review of existing State laws and model statutes and consultation with the States and professional associations. The drafts have been reviewed by many individuals and amended based upon their views. The model statute will be transmitted to the States shortly after the Final Rule on standards is published in the Federal Register.


   Compliance

   Sec. 981. (a) The Secretary shall take all actions consistent with law to effectuate the purposes of this subtitle.

   (b) A State may utilize an accreditation program administered by a private entity if--
(1) such State delegates the administration of State accreditation or certification program to such private entity;
(2) such program is approved by the State; and
(3) such program is consistent with the minimum Federal standards promulgated under this subtitle for such program.
(c) Absent compliance by the States with the provisions of this subtitle within three years after the date of enactment of this Act, the Secretary shall report to the Congress recommendations for legislative changes considered necessary to assure the States' compliance with this subtitle.
(d) The Secretary shall be responsible for continued monitoring of compliance by the States with the applicable provisions of this subtitle and shall report to the Senate and the House of Representatives by January 1, 1982, and January 1 of each succeeding year the status of the States' compliance with the purposes of this subtitle.
(e) Notwithstanding any other provision of this section, in the case of a State which has, prior to the effective date of standards and guidelines promulgated pursuant to this subtitle, established standards for the accreditation of educational programs and certification of radiologic technologists, such State shall be deemed to be in compliance with the conditions of this section unless the Secretary determines, after notice and hearing, that such State standards do not meet the minimum standards prescribed by the Secretary or are inconsistent with the purposes of this subtitle.

Please submit for the record copies of all reports submitted to the Senate and the House of Representatives on January 1, 1982, and January 1 of each succeeding year relating to the status of the State's compliance with the subtitle as required by statute.

RESPONSE: Enclosed are copies of the reports.

7. Please submit for the record the step-by-step procedures required in connection with the preparation and issuance of regulations by the Secretary of the type required by PL 97-35 mentioned above.

RESPONSE: Typically, the procedure followed by the Department in connection with the preparation and issuance of regulations by the Secretary of the type required by P.L. 97-35 is as follows:
When a decision is made to issue a regulation in the Department, the operating level, in this case the Bureau of Health Professions, develops specifications or a draft regulation and submits it to the Office of General Counsel for verification of legal sufficiency. Once there is agreement on the content, the proposed regulation is reviewed at the Agency level, in this case by the Health Resources and Services Administration (HRSA). If the Agency Administrator approves the proposed document, it is then sent to the Assistant Secretary for Health. His staff reviews it for compliance with PHS policy. Other PHS agencies that have an interest in the subject also receive copies for review and comment. After any PHS issues are resolved internally and with the initiating Agency and OGC, and the document revised to the satisfaction of the Assistant Secretary for Health, he signs the proposed regulation and sends it to the Office of the Secretary.

The proposed regulation is then examined by staff in the Office of the Secretary. Comments are obtained from key staff offices within the Department that may have a policy or operational interest in the regulation. Any issues that are identified are resolved, insofar as possible. If agreement is reached the regulation is submitted to the
Secretary for review. If any issues require her personal attention, they are resolved at that time. Once the Secretary approves the proposed regulation, it is submitted to the Office of Management and Budget (OMB) for review under the provisions of Executive Order 12291. After OMB review is completed, the regulation is sent to the Office of the Federal Register for publication, usually as a Notice of Proposed Rulemaking, with a specific period for public comment. After the close of the public comment period, the Department analyzes all responses received and prepares the Final Rule. The preamble of the Final Rule includes Department discussion of acceptance or rejection of all public comments. The process for Department review of the proposed Final Rule is similar to that for an NPRM.

The Health Resources and Services Administration of the Public Health Service undertook the following procedures with respect to the preparation and issuance of the regulation as required under Section 979. The procedures followed are presented below in outline form in their chronological sequence.

I. Three professional staff members of HRSA traveled to Chicago to consult with accrediting agencies, certifying bodies, and professional organizations
which would be directly involved and affected by the implementation of the Act.

II. A workshop with representation from each of the affected occupations was held in Arlington, VA, at which all interested organizations and individuals were invited to make presentations and/or submit written comments.

III. A Federal working group, comprised of representatives from the Department of Defense, National Institutes of Health, Environmental Protection Agency, Office of Personnel Management, Indian Health Service, Food and Drug Administration, and the Veterans Administration (VA), was formed to provide consultation.

IV. State agencies were contacted for their comments on the implementation of the Act.

V. A continuous dialogue was maintained with professional, accrediting and certifying agencies such as the American Registry of Radiological Technology, the American Society of Radiology Technology, nuclear medicine societies, and dental organizations. The comments and issues raised by these agencies were reviewed, analyzed, and taken into consideration in developing the standards.
VI. The Notice of Proposed Rulemaking was issued inviting public comments. The maximum allowable time of 120 days was provided to ensure that all interested parties would have an opportunity to respond. In addition, copies of the NPRM were sent to State licensing boards, and professional, accrediting and certifying agencies to solicit their comments. Public comments raised a number of issues which required resolution before a final rule could be drafted.

The following questions are based on Dept. of HHS internal memorandum dated July 15, 1984, entitled Standards for the Accreditation of Education Programs for, and the Credentialing of Radiologic Personnel -- 42 CFR Part 75; Memo of Non-concurrence in Final Regulations, from Dr. Robert B. Helms to Mr. William Quinlin (sic), Executive Secretariat.

8. Would regulations intended to be promulgated by the Department apply equally as to the burden of compliance on Federal agencies and the Armed Services as on other affected entities?

RESPONSE: The regulation will apply equally to all departments and agencies of the Federal government except as provided for under Section 983 of P.L. 97-35. The issue of how to apply the regulations to Federal agencies is being reviewed in response to a comment on the NPRM that a Federal agency would have problems complying with all of the requirements in that NPRM. Any provision that might be added to the final rule to address this issue would be designed to assure that health and safety is adequately protected. State law and regulation often provide to State licensing boards the kind of flexibility that would be intended by any such provision.
9. Does the Department intend to exempt certain personnel? If so, what is the justification for such exemption?

RESPONSE: The Department has proposed standards for accreditation of educational programs and the credentialing of radiographers, radiation therapy technologists, nuclear medicine technologists, dental hygienists, and dental assistants. Those standards, in general, follow existing requirements already recognized and accepted by the Committee on Allied Health Education and Accreditation of the American Medical Association, the Commission on Dental Accreditation of the American Dental Association, and private certifying agencies.

When we published that NPRM, we determined that it was not appropriate to recommend radiologic standards for other types of health personnel who may administer radiation. The Public Health Service advises that a fuller and more satisfactory base of information is necessary on existing practices, standards in the private sector, and job knowledge requirements, particularly of those occupations whose personnel have not previously been held to rigorously developed formal standards regarding their qualifications and competency to apply radiation.
The vast majority of those who administer ionizing radiation, other than doctors of medicine, osteopathy, dentistry, podiatry, and chiropractic, who have statutory exemption, fall into the five occupations for which standards were promulgated in the NPRM. The Center for Devices and Radiologic Health has testified that non-credentialed radiographic personnel account for only 10 percent of the population dose of medical ionizing radiation.

States remain free to propose additional standards for other personnel (such as nurses, medical office assistants, etc.), as they see fit, and they may do so through whatever regulatory form they consider appropriate. For example, additional State regulation of nurses might be accomplished in an entirely different manner from medical office assistants, a group not now regulated in any State. We believe States are in the best position to make informed decisions regarding the need for additional requirements and the manner in which this should be accomplished. We have in no way precluded additional State action, since any standards, although published by regulation as required by the Act, are merely advisory to States. Exclusive of licensed professionals exempted by statute
from coverage by these standards, the five occupational
groups covered by the NPRM (other than licensed doctors
of medicine, osteopathy, dentistry, podiatry, or chiro-
practic) administer the vast majority of ionizing
radiation to patients.

10. If the Armed Services are exempted by Department
regulations, please justify placing members of the Armed
Services and their families at risk from over-exposure to
radiation.

RESPONSE: The Armed Forces are not exempt from the
standards as written. Personnel utilized by the services in
the five occupations covered by the standards would be
required to comply.

11. If VA hospitals are exempted from compliance with Department
regulations on minimum safety standards, please justify
placing veterans at risk from over-exposure to radiation in
the diagnosis and treatment of such individuals.

RESPONSE: The VA is not exempt from the standards as
written. Section 983 of the Act provides that the Veterans' Administration "shall, to the maximum extent feasible"
prescribe regulations making these standards applicable
in its facilities.

12. If the Department is considering exempting the Armed
Services, VA hospitals, and the like, from compliance
requirements under regulations it may publish, is that
consideration based on claims by those entities that they
would incur recruitment problems? That it would cost too
much money to pay well-trained individuals with appropriate
credentials certifying their competency to perform
radiologic procedures?
RESPONSE: The Department is not exempting the Armed Services or the Veterans Administration or others from compliance with these standards. However, retention and recruitment problems associated with the NPRM have been raised by the Armed Services and the VA. A major issue raised is that many employees do not meet every requirement in the NPRM, and that the on-the-job experience of employees who do not meet certain formal requirements has enabled them to perform radiologic procedures without jeopardizing health and safety. The Department recognizes that implementation of formal standards proposed in the NPRM may be costly, and we are considering ways to address the issues raised by the comments in the final regulation while maintaining needed health and safety protections.

13. According to the Internal Memorandum cited above, the Department believes that lack of responses from Members of Congress to its Notice of Proposed Rule Making is an indication that there is little support for the legislation. Please explain what the Department believes the intent of Congress was in enacting the legislation, if it did not intend that regulations be published? Did the Department make any effort to further ascertain the intent of Congress if it believed there was no need for it to comply with the law because of a lack of Congressional response to the NPRM?

RESPONSE: The internal memorandum that you have cited was an expression of specific concerns of the Acting Assistant Secretary for Planning and Evaluation elicited during the
review process within the Department. In subsequent discussions with the Assistant Secretary for Health, this matter has been resolved. The Department intends to comply with the intent of the Congress and publish the required regulations.

14. According to the Internal Memorandum cited above, the Department believes it cannot accommodate the "statutory mandate" without creating insurmountable problems. Please explain.

RESPONSE: The staff memo cited above has assisted the Department by articulating some very real problems with developing regulations implementing the statute. However, it does not represent the position of the Department since no final decision has been reached. The memo did not assert that there are insurmountable problems with implementing the statute. It did assert that there are a number of serious problems, not all of which may be able to be resolved by any one regulatory approach.

15. The history of this legislation dates back more than a dozen years. It was prompted in part by the following reports to the Surgeon General:

**HEW's TASK FORCE ON ENVIRONMENTAL HEALTH AND RELATED PROBLEMS, 1967**, which found that "all persons using X-ray equipment should be licensed to do so, after fulfilling written exams as to their competency to perform radiologic procedures."
Surgeon General's X-ray Advisory Committee on Public Health, 1967 report entitled: "Public Health Considerations in Medical Diagnostic Radiation (X-rays)," finding that prime consideration should be given to the total public health interest with regard to radiologic procedures then in use, and that the stage had been reached when mandatory (emphasis added) requirements for competency examinations, training and clinical experience of operators of X-ray equipment were appropriate.

National Advisory Committee on Radiation report to the Surgeon General (1966), observing that minimum federal legal standards of education, training, and clinical experience for radiologists appeared to be necessary in order to bring about an increase in effective and safe ways in which such services could be delivered to the general public:

Has the situation improved so dramatically that, in the Department's view, there is no further truth in the above reports?

How many states required accredited education and training programs for such personnel, and competency testing for individuals performing radiologic procedures beginning in 1966, and how many now require such training and competency testing?

RESPONSE: Although complete information is not available, in 1966 few if any States regulated personnel who performed radiologic procedures (except dental hygienists who were licensed in all States). In 1984 all States still license dental hygienists, 15 States regulate radiographers, 27 States require dental assistants who make radiographs to complete specified training and/or an examination, 11 States license radiation therapy technologists, and 5 States license nuclear medicine technologists.

Clearly, therefore, the situation has not remained static since those reports were issued more than 15 years ago. It has indeed improved to the extent that State activity in this area has been effective in protecting the public.
COMPLIANCE WITH THE CONSUMER-PATIENT
RADIATION HEALTH AND SAFETY ACT OF 1981:
ANNUAL REPORT FOR 1983

Report to the Congress
Of the Secretary of Health and Human Services
As Required by Section 981(d)
Of the Consumer-Patient Radiation Health
And Safety Act of 1981

November 30, 1983

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Health Resources and Services Administration
Bureau of Health Professions
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INTRODUCTION

This is the second report on State compliance with the Consumer-Patient Radiation Health and Safety Act of 1981, Title IX of Public Law 97-35. Section 961(d) of the Act requires the Secretary of Health and Human Services to report to the Congress each January 1 on State compliance with standards for the accreditation of educational programs that train radiologic personnel and the standards for the certification of persons who perform medical and dental radiologic procedures.

The standards for accreditation and certification, and the model statute for States which is also required by P.L. 97-35, are intended to encourage adoption of uniform standards by the States, while preserving traditional State responsibilities for control of education and regulation of the professions. The Act neither prescribes nor authorizes penalties to States that do not comply with the standards published by the Department. Therefore, these standards are advisory for States. However, Section 961(c) states that in the absence of State compliance within 3 years, "the Secretary shall report to the Congress recommendations for legislative changes considered necessary to assure the States' compliance with this subtitle."

Accreditation and certification standards were issued by the Secretary as a Notice of Proposed Rulemaking on July 12, 1983, which includes standards for the five occupations specifically identified by the Act: radiographers, dental hygienists, dental assistants, radiation therapy technologists, and nuclear medicine technologists. These are the occupations responsible for the great majority of radiologic examinations and procedures, and they are occupations for which voluntary organizations have developed well-accepted standards based on careful occupational analysis. When the proposed rule becomes final, it will add a new Part 75 to Title 42 of the Code of Federal Regulations, entitled "Standards for the Accreditation of Educational Programs for and the Certification of Radiologic Personnel." The Act exempts "practitioners," defined as licensed doctors of medicine, osteopathy, dentistry, podiatry, or chiropractic, from the standards.

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1As specified by Section 978(7) of the Act, the term "State" means the several States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.
In addition, work is continuing on preparation of the model statute. The Health Resources and Services Administration of the Public Health Service has been responsible for development of the standards and the model statute. Because the Department's proposed standards have only recently been published and the model statute has not been completed, States have not had an opportunity to consider related options for legislative and administrative action.

HEALTH PROFESSIONS CREDENTIALING IN RELATION TO THE ACT

The control of educational quality and the regulation of professional practice in the health professions depend on a complex series of working relationships among voluntary (nongovernmental) organizations, and between these private organizations and their governmental counterparts. The terms accreditation, certification, and licensure, as they are applied to health professions education and practice, have taken on meanings and usages that are commonly accepted by voluntary organizations, and reflected in governmental studies of accreditation and credentialing, particularly in reports of the Department of Health, Education, and Welfare in 1971, 1974, and 1977.

Accreditation is commonly defined as the process by which an agency or organization evaluates an educational institution or a program of study as meeting certain predetermined qualifications or standards of education or service. In education, it applies to entire institutions or to specific programs of study.

The degree to which State governments involve themselves in program accreditation is variable but rather limited. Commonly, State agencies accept the accreditation standards of the voluntary agencies or establish working relationships with those agencies to jointly survey educational programs. In general, in approving programs, State governments do not seek to specify what educators must teach in detail.

Certification and licensure refer to methods of regulating personnel. Certification is commonly defined as the process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association. Thus, certification is a voluntary and nongovernmental process, yet it can be an effective means of controlling the competency of personnel to the extent that standards are rigorously developed, closely related to actual knowledge, skills, and competencies necessary for performance on the job, and accepted by employers. Certification by voluntary organizations is common in the health professions and is widely accepted by employers in the occupations discussed in this report.

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\(^2\)The Act refers to "certification" as a State function. While an occasional State may use the terms "certification" or "registration," the more commonly used term for a State authorization to practice is "licensure." When States truly "certify" personnel, they simply protect the use of a specific title but do not prohibit other individuals from working in the profession or occupation.
Licensure is commonly defined as the process by which an agency of government authorizes an individual to engage in a given occupation and use a specific title. The Federal Government does not license health professionals, since licensure of health personnel is a State prerogative.

REGULATION OF RADIOLOGIC PERSONNEL

A great range of individuals and occupations is in some way involved in the administration of radiation to patients, in the control and monitoring of radiologic equipment, or in the use and handling of radioactive materials in the health industry.

Physicians who specialize in some aspect of radiation use include radiologists, nuclear medicine physicians, radiotherapists, and clinical pathologists (particularly specialists in isotopic pathology). Other physicians and practitioners such as dentists, podiatrists, and chiropractors also carry out radiologic procedures.

A large number of professional and technical personnel administer radiologic procedures under the supervision of licensed practitioners. These include radiographers, dental hygienists, dental assistants, radiation therapy technologists, and nuclear medicine technologists. With the exception of dental auxiliaries, voluntary credentialing programs for these personnel are firmly established and widely accepted.

RADIOGRAPHERS (MEDICAL RADIOLOGIC TECHNOLOGISTS)

Radiographers are professionals who perform or may be called upon to perform a comprehensive scope of diagnostic radiographic procedures employing equipment that emits ionizing radiation, and who are delegated or exercise responsibilities for the operation of radiation-generating equipment, the shielding of patient and staff from unnecessary radiation, the appropriate exposure of radiographs, or other procedures that to any significant extent contribute to the determination of the site or dosage of the ionizing radiation to which a patient is exposed.

As the term is commonly used, radiographers are distinguished from other individuals whose use of ionizing radiation is limited to a few specific body sites or to a limited set of standard procedures. They also are distinguished from personnel in other clinical specialties who occasionally may be called upon to assist in diagnostic radiology.

Certification

Two non-governmental bodies presently certify radiographers: the American Registry of Radiologic Technologists and the American Registry of Clinical Radiologic Technologists.

Dental hygienists are licensed in all States. Voluntary certification exists for dental assistants, but only a small proportion of the work force is certified.
The larger of these — the American Registry of Radiologic Technologists (ARRT) — reported 133,743 certificate holders nationwide in November 1982. The ARRT grants certificates in radiography to individuals who successfully complete an examination and who meet prescribed educational requirements. Although the exact figures are not available, more than three-quarters of the workforce are certified.

In general, graduation from a formal educational program in radiography accredited by the American Medical Association’s Committee on Allied Health Education and Accreditation (CAHEA) is required of candidates who wish to sit for the examination. However, ARRT reviews the qualifications, on a case-by-case basis, of other applicants whose education and experience meet or exceed those of graduates from CAHEA-accredited programs. ARRT is an independent organization with four trustees appointed by the American College of Radiology and four appointed by the American Society of Radiologic Technologists.

The other certifying body — the American Registry of Clinical Radiologic Technologists (ARCRCT) — reported 13,652 certificate holders in July 1983. ARCRCT grants certificates to individuals who pass its examination and who meet prescribed combinations of education and experience. To sit for the examination, applicants must have graduated from a 24-month program in radiography accredited by CAHEA, or have completed an approved military program in radiography, or have passed a challenge examination offered by ARCRCT. The challenge examination is open to individuals who are trained on the job and who have the equivalent of 5 years of full-time clinical experience. The challenge examination was developed by ARCRCT in 1978. In addition, ARCRCT will certify individuals who hold current certificates issued by ARRT and individuals licensed in radiography by States with standards equivalent to those of ARRT.

Accreditation

CAHEA accredits educational programs for radiographers and is recognized for this purpose by the U.S. Department of Education and the Council on Postsecondary Accreditation (COPA). Virtually all educational programs for radiographers are accredited. The American College of Radiology and the American Society of Radiologic Technologists cooperate with CAHEA in the accreditation process. These organizations collaborate in developing the Essentials and Guidelines for accredited programs and appoint members to the Joint Review Committee on Education in Radiologic Technology, which evaluates programs and recommends accreditation decisions to CAHEA. Accreditation is reviewed at least every 5 years, or more frequently if circumstances warrant.

State Regulation

Licensure. Thirteen States license radiographers, all of which specify both educational and examination requirements before a license to practice is issued. There has been no change in the last year in the number of States.

ARCRCT offers a challenge examination for individuals who do not have formal preparation in the field. Individuals who pass the challenge examination become eligible to take the certification examination.
that license radiographers. Ten of these 13 States have contracted with ARRT to administer its examination as the State licensure examination. All of these will exempt ARRT certificate holders from State examination requirements. Four of these also will license individuals currently certified by ARRT if certain conditions are met by the applicant.

Three States administer their own licensure examination. One of the three will also license ARRT certificate holders if the applicant has achieved at least a score of 70 percent on the radiation protection and radiologic procedure sections of the ARRT exam. Puerto Rico requires applicants who have met its educational requirements and passed its licensure examination to serve 1 year of public service before a license is granted.

Table 1 shows the requirements of the 13 States that now regulate radiographers. It appears that these States' standards are in most respects comparable and in some cases identical to the voluntary accreditation standards of the CEREA and the voluntary certification standards of the ARRT. It is anticipated that compliance with the Department's accreditation and certification standards will not pose a problem for these 13 States.

In addition, Alaska, Delaware, Illinois, Iowa, Maine, Michigan, Minnesota, New Mexico, Rhode Island, and Tennessee have enabling legislation for the regulation of radiologic personnel. Iowa and Rhode Island set training standards for personnel functioning as operators of diagnostic X-ray equipment but do not issue licenses. Delaware, Illinois, Minnesota, and New Mexico are currently drafting regulations. Tennessee, Michigan, and Alaska have very general statutes, and have no plans to develop regulations. Maine's law was passed in July 1983.

There was considerable activity during the 1983 legislative sessions. At least 15 States considered legislation. Three new laws were passed, 1 is pending, and 11 failed. Several States will introduce proposals again next year. At least five other States have task forces and study groups in progress. Of the 50 States plus Puerto Rico and the District of Columbia, about 15 neither have a licensure program nor are considering developing one. Even though there is activity, many State legislatures and executive agencies say they have not considered or completed action because the Department's standards were just recently published and because the model statute has not yet been transmitted to the States.

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5 These States have statutes that authorize or could be cited as authority for programs to regulate radiologic personnel. They have not yet instituted licensure programs.
Table 1. State licensure requirements for radiographers, July 1983

<table>
<thead>
<tr>
<th>State</th>
<th>CANA/JRC Education program approval accepted</th>
<th>Other licensure requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arizona</td>
<td>Yes</td>
<td>ARRT, ARRT with conditions</td>
</tr>
<tr>
<td>California</td>
<td>No</td>
<td>State, ARRT with conditions</td>
</tr>
<tr>
<td>Florida</td>
<td>Yes</td>
<td>ARRT, ARRT, ARRT</td>
</tr>
<tr>
<td>Hawaii</td>
<td>No</td>
<td>State, None</td>
</tr>
<tr>
<td>Indiana</td>
<td>Yes</td>
<td>ARRT, ARRT with conditions</td>
</tr>
<tr>
<td>Kentucky</td>
<td>Yes, with joint site visit</td>
<td>ARRT, ARRT with conditions</td>
</tr>
<tr>
<td>Montana</td>
<td>Yes</td>
<td>ARRT, None</td>
</tr>
<tr>
<td>New Jersey</td>
<td>Yes, with joint site visit²</td>
<td>ARRT, ARRT</td>
</tr>
<tr>
<td>New York</td>
<td>Yes, with joint site visit</td>
<td>ARRT, ARRT</td>
</tr>
<tr>
<td>Oregon</td>
<td>Yes</td>
<td>ARRT, ARRT with conditions</td>
</tr>
<tr>
<td>Vermont</td>
<td>Yes, with joint site visit</td>
<td>ARRT, ARRT with conditions</td>
</tr>
<tr>
<td>West Virginia</td>
<td>Yes, with joint site visit</td>
<td>ARRT, ARRT</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>No</td>
<td>State &amp; 1 yr. service, None</td>
</tr>
</tbody>
</table>

NOTES: The following States have statutes that authorize or could be cited as authority for licensure programs, but have not yet instituted a licensure program: Alaska, Delaware, Illinois, Iowa, Maine, Michigan, Minnesota, New Mexico, Rhode Island, and Tennessee. No other States license radiographers.

²Information on acceptance of credentials from other States or on "grandfathering" provisions not shown.

²Planned for the future.

KEY:
- ARRT  American Registry of Radiologic Technologists
- CANA/JRC Committee on Allied Health Education and Accreditation Joint Review Committee on Education in Radiologic Technology

Accreditation. All States except California, Hawaii, and Puerto Rico accept graduation from a radiography program accredited by CAHEA as fulfillment of the State’s educational requirements. Five States cooperate with CAHEA and the Joint Review Committee on Education in Radiologic Technology to approve educational programs (or plan to in the next year).

DENTAL HYGIENISTS

Dental hygienists are oral health clinicians and educators who help patients develop and maintain good oral health. They provide preventive and therapeutic services under the supervision of dentists. Specific responsibilities vary, depending on the law of the State in which the hygienist is employed, but in all States include exposing and processing radiographs for diagnostic purposes among other duties.

Accreditation

Accreditation of educational programs in dental hygiene is conducted by the Commission on Dental Accreditation of the American Dental Association, which is recognized for this purpose by the U.S. Department of Education and COPA. Graduation from an accredited dental hygiene program is required for eligibility to sit for the licensure examination in all States except Alabama. The accreditation standards of the Commission include standards for curricula and instruction in dental radiography. Virtually all dental hygiene educational programs are accredited.

The Commission is composed of 20 members, including a representative from the American Dental Hygienists’ Association, representatives of other disciplines whose educational programs are accredited by the Commission, and public members. Recertification is conducted on a 5-year review cycle and a 10-year site visit cycle.

State Regulation

Licensure. All States require dental hygienists to successfully complete State licensing examinations in order to practice their profession. While individual States set their own licensure requirements, all require written and clinical examinations.

All States except Alabama and Delaware accept satisfactory scores on the national board examination in dental hygiene as full or partial fulfillment of the State requirement for a written examination. Additional written tests are required in all States except California, Illinois, Iowa, Massachusetts, New Jersey, New York, Puerto Rico, Rhode Island, and Utah. These additional examinations vary among jurisdictions. Alabama and Delaware require all candidates for licensure to pass an examination offered by the State, rather than the National Board. Alabama also requires a radiation safety test, which is given at the time of the licensing examination, and which must be passed in order to obtain a license.
Review of existing standards indicates that compliance with the accreditation and certification standards published by the Department does not appear to pose a problem for any State.

The national board examination in dental hygiene is conducted by the Joint Commission on National Dental Examinations of the American Dental Association and has been administered since 1962. In 1981, exposure and processing of dental radiographs, including considerations of radiation hygiene and safety, accounted for 46 items or 13 percent of the test. The examination is criterion-referenced.

State clinical examinations for dental hygiene licensure candidates include demonstration of knowledge and skills in oral inspection, dental charting, periodontal measurement, oral prophylaxis, and radiography. The weighting of these sections varies among States, but on the average, 25 percent of the examination is devoted to dental radiography.

In 1974, under a contract with the Department, the American Dental Hygienists' Association began the development of a criterion-referenced clinical examination in dental hygiene. Dental radiography accounts for 25 percent of the examination score. This test is now being used by the Central Regional Dental Testing Service (which administers examinations for 11 States), the Southern Regional Testing Agency (4 States), the Western Regional Examining Association (4 States), and State dental boards in California, Texas, Hawaii, and North Carolina.

Accreditation. Except for Alabama, all States require candidates for licensure in dental hygiene to have graduated from a formal educational program accredited by the Commission on Dental Accreditation. Alabama accepts graduates of accredited programs as eligible for the licensure examination, but also permits preceptor training of dental hygienists in the offices of designated practicing dentists. On-the-job-trained dental hygienists who complete the preceptorship program are then eligible for the licensure examination. This preceptorship program requires 2 weeks of study at the University of Alabama; 12½ hours of dental radiography are included in the course.

DENTAL ASSISTANTS

Dental assistants provide a wide range of clinical and laboratory skills and functions that aid the dentist in the delivery of oral health care. While dental assistants are permitted to assume expanded functions in some States, there are considerable differences among States in the definition of these functions. However, in all States except the District of Columbia, exposure and processing of dental radiographs for diagnostic purposes may be delegated to dental assistants.
Certification

The Dental Assisting National Board provides a voluntary national mechanism for certifying dental assistants. The Board operates under requirements adopted by the American Dental Association and is a member of the National Commission for Health Certifying Agencies. Individuals who have successfully completed an educational program in dental assisting accredited by the Commission on Dental Accreditation are eligible to sit for the certification examination. Since 1980, on-the-job-trained dental assistants have been allowed to take the national examination as part of a study to determine appropriate requirements and methods for certifying personnel trained on the job.

Accreditation

Educational programs in dental assisting are accredited by the Commission on Dental Accreditation, which includes a representative of the American Dental Assistants Association. Accreditation standards for dental assisting programs include standards for curricula and instruction in dental radiography. Reaccreditation is conducted on a 5-year review cycle and a 10-year site visit cycle. Some dental assisting programs located in proprietary schools and some military programs are not accredited by the Commission. Virtually all other educational programs in dental assisting are accredited.

State Regulation

Dental assistants are permitted to expose and process dental radiographs in all States except the District of Columbia. While no State terms its regulatory procedure "licensure," 23 require dental assistants to complete specified training and/or an examination before engaging in dental radiography under the supervision of a dentist. Sixteen of these 23 States award certificates or register dental assistants who have met their requirements in specified areas, including radiography. The remaining 27 States permit the practice of dental radiography by assistants, but have no training or examination requirements.

Training and Examinations. Of the 23 States that regulate the dental assistant's use of dental radiography, requirements vary considerably. Some require only a specified training course, others require only an examination, while still others require both training and examination.

Table 2 displays the considerable variety now existing among these State requirements. It can be anticipated that the problem faced by these States in complying with the accreditation and certification standards issued by the Department may vary accordingly.

6The National Commission for Health Certifying Agencies is a voluntary organization whose purpose is to improve the reliability, validity, and fairness of credentialing policies, procedures, and standards among voluntary agencies that certify the competence of health personnel.
Training requirements vary from graduation from a State-approved course in expanded functions for dental assistants (13 States), to graduation from a State-approved course in dental radiography alone (6), to graduation from an educational program accredited by the Commission on Dental Accreditation (1). Oregon and Georgia accept on-the-job training and New Jersey has no training requirements. Georgia requires that the dental assistant be trained by the supervising dentist and Iowa requires that the dentist certify the assistant has demonstrated clinical proficiency in dental radiography, while under his supervision for at least one month.

Five States accept certification by the Dental Assisting National Board as fulfillment of their requirements. Six States will permit dental radiography by assistants who have passed State-administered written and clinical examinations, and 10 States use written examinations only. In some States, these examinations are conducted by State dental boards or dental associations, and in others, by radiation control agencies or environmental protection agencies. The content of training courses and examinations varies among States.

RADIATION THERAPY TECHNOLOGISTS

Radiation therapy technologists, working from a prescription and with a radiotherapist, are professionals who utilise equipment that generates ionizing radiation for therapeutic purposes on human subjects. Using X-ray equipment, radionuclides, and electron beam equipment, they expose specific areas of the body to prescribed doses of ionizing radiation, assist in tumor localization and dosimetric procedures, assist in the proper operation of controlling devices, and in radiation protection for patients and clinical personnel.

Certification

ARRT provides a voluntary national system for certification of radiation therapy technologists. ARRT awards certificates to individuals who successfully complete an examination and meet prescribed educational requirements.

In general, graduation from a formal educational program in radiation therapy technology accredited by CAMEA is required of candidates who wish to sit for the examination. However, ARRT reviews the qualifications, on a case-by-case basis, of other applicants whose education and experience meet or exceed those of graduates of CAMEA-accredited programs. ARRT reported 3,289 certificate holders in November 1982. Although the exact figures are not available, about two-thirds of the work force are certified.
<table>
<thead>
<tr>
<th>State</th>
<th>Required training</th>
<th>Dental Assisting National Board</th>
<th>State Written</th>
<th>Clinical</th>
<th>Credential Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arizona</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Certificate</td>
</tr>
<tr>
<td>California</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>Colorado</td>
<td>Approved course</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>Florida</td>
<td>Approved course</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>Georgia</td>
<td>By supervising dentist</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>Indiana</td>
<td>Approved course</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>Iowa</td>
<td>Approved course</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>Kentucky</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Registration</td>
</tr>
<tr>
<td>Maryland</td>
<td>Expanded function</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>Michigan</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>Minnesota</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
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<td>Montana</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>Nebraska</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>New Hampshire</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>New Jersey</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>North Carolina</td>
<td>Accredited program</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>North Dakota</td>
<td>Accredited program</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>Oklahoma</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>Oregon</td>
<td>6 months on-the-job</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>Rhode Island</td>
<td>Approved course</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Registration</td>
</tr>
<tr>
<td>Tennessee</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Registration</td>
</tr>
<tr>
<td>Vermont</td>
<td>Expanded function</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
<tr>
<td>Virginia</td>
<td>Approved course</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Certificate</td>
</tr>
</tbody>
</table>

**NOTES:**

1. District of Columbia does not permit dental assistants to make dental radiographs.
2. Following States have statutes that authorize or could be cited as authority for licensure programs, but have not yet established a licensure program: Illinois, Rhode Island, and New Mexico.
3. All other States not listed above permit dental assistants to make dental radiographs without restriction.
4. Not required if certified by the Dental Assisting National Board.
5. Dental Assisting National Board certification accepted in lieu of State registration.
6. State provides but does not require a home-study course in dental radiography.
7. Accepted if applicant provides statement that he/she has completed training in dental radiography.
8. Supervising dentist must certify the applicant's clinical proficiency.

**KEY:**
- Certificate: Certified by a State agency
- Registration: Registered by the State dental board
- Approved course: Approved training course in dental radiography
- Accredited program: Dental assisting program accredited by the Commission on Dental Accreditation

**SOURCES:**
Commission on Dental Accreditation, Division of Educational Measurements, Legal Provisions for Delegating Expanded Functions to Dental Hygienists and Dental Assistants (Chicago: American Dental Association, January 1981).
Accreditation

As is the case for educational programs for radiographers, educational programs for radiation therapy technologists are accredited by CAHEA, with the cooperation of the American College of Radiology, the American Society of Radiologic Technologists, and the Joint Review Committee on Education in Radiologic Technology. Accreditation is reviewed every 5 years, or more frequently if circumstances warrant. Virtually all programs in radiation therapy technology are accredited.

State Regulation

Licensure. Seven States license radiation therapy technologists. In addition, Hawaii and Florida allow radiologic technologists to perform both diagnostic and therapeutic procedures, although they do not license radiation therapy technologists as a separate occupational category. Of these seven States, five have contracted with ARRT to administer its examination as the State licensure examination. California and Puerto Rico administer their own examinations. Arizona will also accept the ARRT certificate.

Table 3 displays the current status of State requirements. It does not appear that compliance with the accreditation and certification standards published by the Department will pose a problem for these seven States.

Enabling legislation exists in Alaska, Delaware, Illinois, Indiana, Iowa, Kentucky, Maine, Michigan, Minnesota, New Mexico, and Tennessee. At least four of the States are actively developing programs. Current activity by the States is more limited for radiation therapy technologists than for radiographers, although many of the States that are considering licensure of radiographers are also including radiation therapy technologists (see radiographer section).

Accreditation. Among the seven licensure States, all but California and Puerto Rico accept graduation from a CAHEA-accredited program. California also accepts training and experience other than formal education as a possible means of qualifying for the licensure examination. New York conducts joint site visits with CAHEA, and Vermont will begin to do so in the future.

NUCLEAR MEDICINE TECHNOLOGISTS

Nuclear medicine technologists are professionals who conduct in vivo or in vitro detection and measurement of radioactivity for medical purposes or who administer radiopharmaceuticals to human beings.

In vivo procedures involve the administration of radioactive tracer chemicals to the patient. In one type of procedure, the tracer is administered, and after a period of time instruments are employed to measure the radioactivity emitted from the body in the vicinity of the organ in question. To accomplish this, the tracer must emit gamma radiation powerful enough to affect recording devices, but because tracers have short half-lives, irradiation of patients' tissues continues only briefly after the recording has been completed. In another type of in vivo procedure, a tracer is administered to the patient,
Table 3. State licensure requirements for radiation therapy technologists, July 1983

<table>
<thead>
<tr>
<th>State</th>
<th>CANA/TEC educational program approval accepted</th>
<th>Exam required or Certificate accepted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arizona</td>
<td>Yes (2 year programs)</td>
<td>ARRT</td>
</tr>
<tr>
<td>California²</td>
<td>No</td>
<td>State ARRT with conditions</td>
</tr>
<tr>
<td>New Jersey</td>
<td>Yes</td>
<td>ARRT</td>
</tr>
<tr>
<td>New York</td>
<td>Yes, with joint site visit²</td>
<td>ARRT</td>
</tr>
<tr>
<td>Oregon</td>
<td>Yes</td>
<td>ARRT</td>
</tr>
<tr>
<td>Vermont</td>
<td>Yes, with joint site visit³</td>
<td>ARRT</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>No</td>
<td>State 5 yrs. service ARRT</td>
</tr>
</tbody>
</table>

NOTES: Florida and Hawaii allow radiologic technologists to perform both diagnostic and therapeutic procedures, although they do not license radiation therapy technologists as a separate occupational category. The following States have statutes that authorize or could be cited as authority for licensure programs, but have not yet instituted a licensure program: Alabama, Delaware, Illinois, Indiana, Iowa, Kentucky, Maine, Michigan, Minnesota, New Mexico, and Tennessee. No other States license radiation therapy technologists.

²Information on acceptance of credentials from other States and on “grandfathering” provisions not shown.

³Also accepts training and experience in lieu of formal education.

⁴Planned for future.

**NOTES:**
- ARRT: American Registry of Radiologic Technologists
- CANA/TEC: Committee on Allied Health Education and Accreditation/Joint Review Committee on Education in Radiologic Technology
- ARCT: American Registry of Clinical Radiologic Technologists

**SOURCE:** Council of State Governments, 1983.
and after a specified period of time a sample of body tissue or fluid is removed, and the amount of tracer in the sample is measured. In vitro procedures do not require exposure of the patient to radioactive materials. In vitro tests are performed by clinical laboratory personnel as well as nuclear medicine technologists and clinical chemists.

Certification

Three non-governmental organizations currently certify nuclear medicine technologists. The Nuclear Medicine Technology Certification Board (NMTCB) reported 7,153 certificate holders as of September 1982, when the annual exam was given. NMTCB, which was formed in the mid-70's with encouragement from the Society of Nuclear Medicine and its technologist section, is an independent agency and is a member of the National Commission for Health Certifying Agencies.

The American Society of Clinical Pathology (ASCP) reported 1,895 certificate holders in February 1983. NMTCB and ASCP are in the process of signing a merger agreement. ASCP will probably give its last examination in August 1983.

ARRT, the oldest of these bodies, reported 8,624 certificate holders as of November 1982. Their examinations are given three times a year. Since a large majority of individuals are certified by more than one organization, there are somewhat less than 10,000 certified nuclear medicine technologists. Although the exact figures are not available, more than three-quarters of the work force are certified.

All three organizations award certificates to individuals who have successfully completed an examination and meet prescribed educational requirements. In general, all three organizations require graduation from a CAHEA-accredited program, although alternative pathways exist to allow individuals with other prescribed combinations of training and experience to sit for the examination. Examinations offered by these agencies differ somewhat, and eligibility requirements for those individuals who have not graduated from accredited educational programs also differ.

Accreditation

Educational programs for nuclear medicine technologists are accredited by CAHEA. The American College of Radiology, the American Society of Medical Technology, the American Society of Clinical Pathologists, the American Society of Radiologic Technologists, and the Society of Nuclear Medicine cooperate with CAHEA in the accreditation process. The program review committee is the Joint Review Committee on Educational Programs in Nuclear Medicine Technology, which includes four members of the Society of Nuclear Medicine (two physicians, two technologists) and two members from each of the other professional associations listed above. To maintain accreditation, programs are resurveyed once every 5 years, or more frequently if indicated. Virtually all educational programs for the profession are accredited.
State Regulation

Licensure. New Jersey, Vermont, and Puerto Rico license nuclear medicine technologists. New Jersey and Vermont have contracted with ARRT for the use of its examination, and Puerto Rico administers its own examination. The two States that contract with ARRT also will license individuals who hold current certificates from ARRT, NCCTE or ASCP. Puerto Rico requires 1 year of public service, beyond State-approved training and examination, before issuing a license.

It does not appear that compliance will pose a problem for these three States.

In addition, California, Delaware, Illinois, Minnesota, and New Mexico are developing licensure programs. Alaska, Kentucky, Maine, Michigan, and Tennessee also have enabling legislation. Georgia and Virginia have task forces working on the subject. Current activity by the States is more limited for nuclear medicine technologists than for radiographers, although some of the States that are considering licensure of radiographers are also including nuclear medicine technologists (see radiographer section).

Accreditation. Of the three States that license nuclear medicine technologists, Vermont and New Jersey accept graduation from a CAHEA-accredited program as fulfilling the eligibility requirement to take the licensure examination, while Puerto Rico reserves all standard-setting and program-approval authority to a designated State agency. Both Vermont and New Jersey conduct joint site visits with CAHEA/JRC when accrediting programs.
COMPLIANCE WITH THE CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT OF 1981:
ANNUAL REPORT FOR 1982

Report to the Congress
Of the Secretary of Health and Human Services
As Required by Section 981(d)
Of the Consumer-Patient Radiation Health
And Safety Act of 1981

April 22, 1983

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Health Resources and Services Administration
Bureau of Health Professions
CONTENTS

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Appendix

COMPLIANCE WITH THE CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT:
ANNUAL REPORT FOR 1982

INTRODUCTION

This is the first report on State compliance with the Consumer-Patient Radiation Health and Safety Act of 1981, Title IX of Public Law 97-35. Section 981(d) of the Act requires the Secretary of Health and Human Services to report to the Congress each January 1 on State compliance with standards for the accreditation of educational programs that train radiologic personnel and the standards for the certification of persons who perform medical and dental radiologic procedures. The text of the Act is provided in Appendix I.

For purposes of this report, the key provisions of the Act are contained in:

-- Section 979, which requires promulgation of standards,
-- Section 980, which requires issuance of a model statute, and
-- Section 981, which addresses State compliance.

ACCREDITATION AND CERTIFICATION STANDARDS

In order to protect the public from the potential hazards of unnecessary exposure to medical and dental radiation, section 979 of the Act requires the Secretary to issue standards for the accreditation of educational programs to train individuals to perform radiologic procedures and for the certification of such individuals. Specifically, the Act requires that accreditation and certification standards distinguish between:

-- Medical radiologic technologists (radiographers);
-- Dental auxiliaries (dental hygienists and dental assistants);
-- Radiation therapy technologists;
-- Nuclear medicine technologists; and
-- Such others kinds of health auxiliaries who administer radiologic procedures as the Secretary determines appropriate.

The Act exempts "practitioners," defined as licensed doctors of medicine, osteopathy, dentistry, podiatry, or chiropractic, from the standards to be issued. The Act requires that these standards be promulgated by regulation 1 year after the enactment of P.L. 97-35.
COMPLIANCE

The Act permits States\(^1\) to utilize private accreditation or certification programs if: the State delegates administration of the program; the program is approved by the State; and the program is consistent with the standards issued by the Department.

The Act contains no penalties for States that do not comply. The standards for accreditation and certification, and the model statute, are intended to encourage adoption of uniform standards by the States, while preserving traditional State responsibilities for control of education and regulation of the professions. However, if States do not comply within 3 years, the Secretary is required to report to the Congress on recommendations for legislative changes considered necessary to assure State compliance.

CURRENT STATUS

Accreditation and certification standards were recently approved by the Secretary as a Notice of Proposed Rulemaking that would add a new Part 75 to Title 42 of the Code of Federal Regulations, entitled "Standards for the Accreditation of Educational Programs for and the Certification of Radiologic Personnel." This Notice of Proposed Rulemaking has been forwarded to the Office of Management and Budget for review. The Notice includes standards for radiographers, dental hygienists, dental assistants, radiation therapy technologists, and nuclear medicine technologists. In addition, work is nearing completion on preparation of a model statute. The Health Resources and Services Administration (HRSA) of the Public Health Service has been responsible for development of the standards and the model statute. Because the Department's standards have not yet been published, States have not had an opportunity to consider options for legislative and administrative action.

CONSULTATION AND DEVELOPMENT OF STANDARDS

Standards will be published for the five professional groups listed above. These groups are responsible for the great majority of examinations and patient exposures to ionizing radiation. They are also the professions for which voluntary agencies have undertaken considerable work to develop and refine accreditation and certification standards. These voluntary standards have wide acceptance in the professional community and among those State agencies that currently regulate radiologic personnel, and reflect the type of

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\(^1\)As specified by Section 978(7) of the Act, the term "State" means the several States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands. Information was available for this report on the 50 States, the District of Columbia, and Puerto Rico.
concern for patient protection and safety that the Act is intended to foster. As a result, the standards promulgated by the Department follow these closely in many areas.

Because the Act required that the standards be developed in consultation with appropriate Federal agencies, including the Veterans Administration and the Environmental Protection Agency, a working group was formed to give official representatives of Federal agencies that employ these personnel the opportunity to provide information and comment during the development of standards.

Agencies of States, including licensing agencies, boards that regulate health occupations, health departments, and radiation control agencies, were contacted and invited to contribute information and advice, as were appropriate professional organizations, voluntary accrediting and certifying agencies in the affected occupations, and employers.

Draft standards were then circulated to these organizations as well as to individuals with an expressed interest. A 4-day workshop was held for all interested parties to make presentations and/or submit written comments. Approximately 350 agencies, organizations, and individuals were contacted during this process.

HEALTH PROFESSIONS CREDENTIALING IN RELATION TO THE ACT

The control of educational quality and the regulation of professional practice in the health professions depends on a complex series of working relationships among voluntary (nongovernmental) organizations, and between these private organizations and their governmental counterparts. The terms accreditation, certification, and licensure, as they are applied to health professions education and practice, have taken on meanings and usages that are commonly accepted by voluntary organizations, and reflected in governmental studies of accreditation and credentialing, particularly in reports of the Department of Health and Human Services in 1971, 1974, and 1977.

Accreditation is commonly defined as the process by which an agency or organization evaluates an educational institution or a program of study as meeting certain predetermined qualifications or standards of education or service. In education, it applies to entire institutions or to specific programs of study.

In health occupations, accreditation of educational programs in a specific discipline is quite different from any permission a State might give an institution to operate within the State. Accreditation of educational programs in a specific discipline, as opposed to institutional accreditation (which may be granted by a State agency or a regional body), has been a function of voluntary organizations that draw upon the expertise of professional associations and educators in relevant disciplines.

Voluntary accrediting agencies may seek recognition from the Council on Postsecondary Accreditation (COAPA), a nongovernmental agency that reviews accrediting processes and promotes uniformity and fairness in accrediting. In addition, the U.S. Department of Education grants recognition to accrediting agencies that meet its standards. Many Federal programs that involve
financial aid to institutions or educational programs in specific disciplines require that the institution or program be accredited by an agency recognized for this purpose by the Department of Education.

Voluntary accrediting agencies set standards for curricula, program administration, instructional staff, laboratories and facilities, due process for students, and the like, to insure educational quality. Accordingly, an agency such as the American Medical Association's Committee on Allied Health Education and Accreditation (CAHEA) will adopt Essentials, which are the criteria against which programs will be measured, and Guidelines, which incorporate detailed explanatory material that will aid the program (and the reviewers from the accrediting agency) in interpreting and meeting the standards in the Essentials. (The terminology of Essentials and Guidelines is specific to CAHEA, but the principle is common.)

The degree to which State governments involve themselves in program accreditation is variable, but rather limited. Commonly, State agencies accept the accreditation standards of the voluntary agencies, or establish working relationships with those agencies to jointly survey educational programs. In general, in approving programs, State governments do not seek to specify what educators must teach in detail.

Certification and licensure refer to methods of regulating personnel. Certification is commonly defined as the process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association. Thus, certification is a voluntary and nongovernmental process, yet it can be an effective means of controlling the competency of personnel to the extent that standards are rigorously developed, closely related to actual knowledge, skills, and competencies necessary for performance on the job, and accepted by employers. Certification by voluntary organizations is common in the health professions and is widely accepted by employers in the occupations discussed in this report.

Licensure is commonly defined as the process by which an agency of government authorizes an individual to engage in a given occupation and use a specific title. The Federal Government does not license health professionals, since licensure of health personnel is a State prerogative.

The development of a certification or licensure program that has been shown to be valid and reliable and that includes requirements for eligibility, educational preparation, experience (as necessary), and credentialing examinations is a costly and time-consuming effort. Thoroughness in undertaking to develop such a program is essential for a variety of reasons: to insure that the requirements established are closely related to the knowledge and competencies

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1The Act refers to "certification" as a State function. While an occasional State may use the terms "certification" or "registration," the more commonly used term for a State authorization to practice is "licensure." When States truly "certify" personnel, they simply protect the use of a specific title, but do not prohibit other individuals from working in the profession or occupation.
necessary to perform effectively; to insure that the requirements are an 
appropriate basis for granting or denying credentials to individuals; and to 
insure that the requirements will survive legal challenge by unsuccessful 
applicants on professional, procedural, or constitutional grounds.

Development of a suitable examination is often beyond the resources of a State 
or professional association. Because of this, NRSA has for some years 
assisted professional associations in various allied health and public health 
occupations in developing credentialing programs. This assistance has 
involved three phases. Phase I, or role delineation, involves identification, 
refinement, and verification of the competencies necessary for practice. It may 
lead to development of curriculum resource guides for educational programs, self-assessment instruments for practitioners, and 
continuing competency materials. Phase II involves the development of 
criterion-referenced2 
credentia l examinations that are designed to test the 
competencies identified in the role delineation. Phase III is examination 
administration. NRSA has supported Phases I and II and encouraged 
professional associations and States to utilize these materials.

REGULATION OF RADIOLOGIC PERSONNEL

A great range of individuals and occupations is in some way involved in the 
administration of radiation to patients, in the control and monitoring of 
radiologic equipment, or in the use and handling of radioactive materials in 
the health industry.

Physicians who specialize in some aspect of radiation use include 
radiologists, nuclear medicine physicians, radiotherapists, and clinical 
pathologists (particularly specialists in isotopic pathology). Other 
physicians and practitioners such as dentists, podiatrists, and chiropractors 
also carry out radiologic procedures.

A large number of professional and technical personnel administer radiologic 
procedures under the supervision of licensed practitioners. These include 
 radiographers, dental hygienists, dental assistants, radiation therapy 
technologists, and nuclear medicine technologists. With the exception of 
dental auxiliaries, voluntary credentialing programs for these personnel are 
firmly established and widely accepted.3

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1For a fuller description, see R.M. Conant, "A Credentialing Concept," Journal 

2Criterion-referenced examinations measure examinee performance against a 
predetermined standard instead of against the performance of other persons who 
take the same examination.

3Dental hygienists are licensed in all States. Voluntary certification exists 
for dental assistants, but only a small proportion of the work force is 
certified.
RADIOGRAPHERS (MEDICAL RADIOLOGIC TECHNOLOGISTS)

Radiographers are professionals who perform or may be called upon to perform a comprehensive scope of diagnostic radiology procedures employing equipment that emits ionizing radiation, and who are delegated or exercise responsibilities for the operation of radiation-generating equipment, the shielding of patient and staff from unnecessary radiation, the appropriate exposure of radiographs, or other procedures that to any significant extent contribute to the determination of the site or dosage of the ionizing radiation to which a patient is exposed.

As the term is commonly used, radiographers are distinguished from other individuals whose use of ionizing radiation is limited to a few specific body sites or to a limited set of standard procedures. They also are distinguished from personnel in other clinical specialties who occasionally may be called upon to assist in diagnostic radiology and from assistants or technicians whose activities do not contribute in any significant degree to the determination of site or dosage of radiation.

Certification

Two nongovernmental bodies presently certify radiographers: the American Registry of Radiologic Technologists and the American Registry of Clinical Radiography Technologists.

The larger of these — the American Registry of Radiologic Technologists (ARRT) — reported 129,273 certificate holders nationwide in February 1982. The ARRT grants certificates in radiography to individuals who successfully complete an examination and who meet prescribed educational requirements. Content specifications for the ARRT certifying examination are derived from an analysis of the knowledge, skills, and competencies necessary to perform as a radiographer. The examination is criterion-referenced.

In general, graduation from a formal educational program in radiography accredited by CAHEA is required of candidates who wish to sit for the examination. However, the ARRT reviews the qualifications, on a case-by-case basis, of other applicants whose education and experience meets or exceeds those of graduates from CAHEA-accredited programs. The ARRT is an independent organization with four trustees appointed by the American College of Radiology and four appointed by the American Society of Radiologic Technologists.

The smaller certifying body — the American Registry of Clinical Radiography Technologists (ARCRT) — reported approximately 5,000 certificate holders in July 1982. The ARCRT grants certificates to individuals who pass its examination and who meet prescribed combinations of education and experience. To sit for the examination, applicants must have graduated from a 24-month program in radiography accredited by CAHEA, or have completed an approved military program in radiography, or have passed a challenge
examination\(^1\) offered by the ARCRT. The challenge examination is open to individuals who are trained on the job and who have the equivalent of 5 years of full-time clinical experience. The challenge examination was developed by the ARCRT in 1978.

In addition, the ARCRT will certify individuals who hold current certificates issued by ARRT and individuals licensed in radiography by States with standards equivalent to those of ARCRT.

Accreditation

CAHEA accredits educational programs for radiographers and is recognized for this purpose by the U.S. Department of Education and CODA. Virtually all educational programs for radiographers are accredited.

The American College of Radiology and the American Society of Radiologic Technologists cooperate with CAHEA in the accreditation process. These organizations collaborate in developing the Essentials and Guidelines for accredited programs and appoint members to the Joint Review Committee on Education in Radiologic Technology, which evaluates programs and recommends accreditation decisions to CAHEA. Accreditation is reviewed at least every 5 years, or more frequently if circumstances warrant.

State Regulation

Licensure. Thirteen States license radiographers, all of which specify both educational and examination requirements before a license to practice is issued. Ten of these 13 States have contracted with the ARRT to administer its examination as the State licensure examination. Four of these also will license individuals currently certified by the ARCRT if certain conditions are met by the applicant.

Three States administer their own licensure examination, one of which will also license ARRT certificate holders if the applicant has achieved at least a score of 70 percent on the radiation protection and radiologic procedure sections of the ARRT exam. Puerto Rico requires applicants who have met its educational requirements and passed its licensure examination to serve 1 year of public service before a license is granted. Table 1 shows the requirements of the 13 States that now regulate radiographers.

In addition, Delaware, Illinois, Iowa, Michigan, and Minnesota have enabling legislation for the regulation of radiologic personnel.\(^2\) Iowa began to implement a program on July 1, 1982, that sets standards for personnel functioning as operators of diagnostic X-ray equipment in medicine.

\(^1\)ARCRT offers a challenge examination for individuals who do not have formal preparation in the field. Individuals who pass the challenge examination become eligible to take the certification examination.

\(^2\)These States have statutes that authorize or could be cited as authority for programs to regulate radiologic personnel. They have not yet instituted licensure programs.
### Table 1. State licensure requirements for radiographers, 1982

<table>
<thead>
<tr>
<th>State</th>
<th>Education program approved by</th>
<th>Other licensure requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CAHEA/JRC or State</td>
<td>Exam required or Certificate accepted</td>
</tr>
<tr>
<td>Arizona</td>
<td>Yes</td>
<td>ARRT</td>
</tr>
<tr>
<td></td>
<td>Not at present</td>
<td>ARRT, CAHEA grade only</td>
</tr>
<tr>
<td>California</td>
<td>Yes</td>
<td>State</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>ARRT with conditions</td>
</tr>
<tr>
<td>Florida</td>
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<td>ARRT</td>
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<tr>
<td>Hawaii</td>
<td>No</td>
<td>State</td>
</tr>
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<td>None</td>
</tr>
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<td>Indiana</td>
<td>Yes</td>
<td>ARRT</td>
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<td></td>
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<td>Kentucky</td>
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</tr>
<tr>
<td></td>
<td>Not at present</td>
<td>ARRT, CAHEA grade only</td>
</tr>
<tr>
<td>Montana</td>
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<td>ARRT</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
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<td>New Jersey</td>
<td>Not at present</td>
<td>ARRT</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>None</td>
</tr>
<tr>
<td>New York</td>
<td>State with CAHEA/JRC</td>
<td>ARRT</td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td>Oregon</td>
<td>Yes</td>
<td>ARRT</td>
</tr>
<tr>
<td></td>
<td>Not at present</td>
<td>ARRT after 1974, CAHEA grade only</td>
</tr>
<tr>
<td>Vermont</td>
<td>Yes</td>
<td>ARRT</td>
</tr>
<tr>
<td></td>
<td>Not at present</td>
<td>None</td>
</tr>
<tr>
<td>West Virginia</td>
<td>State with CAHEA/JRC &amp;</td>
<td>ARRT</td>
</tr>
<tr>
<td></td>
<td>State may approve others</td>
<td>None</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>No</td>
<td>State &amp; 1 yr. service</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>None</td>
</tr>
</tbody>
</table>

**NOTES:** Iowa sets standards for operators of radiation equipment, but does not issue licenses or authorizations to practice. Enabling legislation exists in Delaware, Illinois, Michigan, and Minnesota. No other States license radiographers.

1Information on acceptance of credentials from other States, or on "grandfathering" provisions not shown.

2Also accepts training and experience in lieu of formal education.

3ARRT certificates must have scored 70 percent on the radiation protection and radiologic procedures sections of the ARRT exam.

4Agreement to cooperate with CAHEA/JRC in program approval under development by State.

**KEY:**

- ARRT: American Registry of Radiologic Technologists
- ARCRT: American Registry of Clinical Radiography Technologists
- CAHEA/JRC: Committee on Allied Health Education and Accreditation/Joint Review Committee on Education in Radiologic Technology

**SOURCES:** Information provided to the Health Resources and Services Administration by State health officers, licensing agencies, and radiation control agencies, 1982.
osteopathy, chiropractic, and podiatry. However, the Iowa State Department of Health reports that this is not a licensure program. Legislation authorizing regulation of radiologic personnel was enacted in Illinois in August 1982. Delaware, Michigan, and Minnesota have not yet put licensure programs into effect.

Accreditation. Seven of the 13 licensure States accept graduation from a radiography program accredited by CAHEA as fulfillment of the State's educational requirements. Two other States cooperate with CAHEA and the Joint Review Committee on Education in Radiologic Technology to approve educational programs. Four States approve (or reserve authority to approve) other educational programs not accredited by CAHEA. Four States do not automatically accept or recognize CAHEA accreditation, but reserve all standard-setting and approval authority to a designated State agency. Only one State accepts experience or training other than an accredited or State-approved program of formal education as a possible method of qualifying a candidate for the licensure examination.

DENTAL HYGIENISTS

Dental hygienists are oral health clinicians and educators who help patients develop and maintain good oral health. They provide preventive and therapeutic services under the supervision of dentists. Specific responsibilities vary, depending on the law of the State in which the hygienist is employed, but in all States include exposing and processing radiographs for diagnostic purposes, among other duties.

Certification

There is no national certification for dental hygienists, since these personnel are licensed in all States.

Accreditation

Accreditation of educational programs in dental hygiene is conducted by the Commission on Dental Accreditation of the American Dental Association, which is recognized for this purpose by the U.S. Department of Education and COPA. Graduation from an accredited dental hygiene program is required for eligibility to sit for the licensure examination in all States except Alabama. The accreditation standards of the Commission include standards for curricula and instruction in dental radiography. Virtually all dental hygiene educational programs are accredited.

The Commission is composed of 20 members, including a representative from the American Dental Hygienists' Association, representatives of other disciplines whose educational programs are accredited by the Commission, and public members. Reaccreditation is conducted on a 5-year review cycle and a 10-year site visit cycle.
State Regulation

Licensure. All States require dental hygienists to successfully complete state licensing examinations in order to practice their profession. While individual States set their own licensure requirements, all require written and clinical examinations.

All States except Alabama and Delaware accept satisfactory scores on the national board examination in dental hygiene as full or partial fulfillment of the State requirement for a written examination. Additional written tests are required in all States except California, Illinois, Iowa, Massachusetts, New Jersey, New York, Puerto Rico, Rhode Island, and Utah. These additional examinations vary among jurisdictions. Alabama and Delaware require all candidates for licensure to pass an examination offered by the State, rather than the National Board. Alabama also requires a radiology safety test, which is given at the time of the licensing examination, and which must be passed in order to obtain a license.

The National Board examination in dental hygiene is conducted by the Joint Commission on National Dental Examinations of the American Dental Association and has been administered since 1962. In 1981, exposure and processing of dental radiographs, including considerations of radiation hygiene and safety, accounted for 46 items or 13 percent of the test. The examination is criterion-referenced.

State clinical examinations for dental hygiene licensure candidates include demonstration of knowledge and skills in oral inspection, dental charting, periodontal measurement, oral prophylaxis, and radiography. The weighting of these sections varies among States, but on the average, 25 percent of the examination is devoted to dental radiography.

In 1974, under a contract with the Department, the American Dental Hygienists' Association began the development of a criterion-referenced clinical examination in dental hygiene. Dental radiography accounts for 25 percent of the examination score. This test is now being used by the Central Regional Dental Testing Service (which administers examinations for 11 States), the Southern Regional Testing Agency (4 States), the Western Regional Examining Association (4 States), and State dental boards in California, Texas, Hawaii, and North Carolina.

Accreditation. Except for Alabama, all States require candidates for licensure in dental hygiene to have graduated from a formal educational program accredited by the Commission on Dental Accreditation. Alabama accepts graduates of accredited programs as eligible for the licensure examination, but also permits preceptor training of dental hygienists in the offices of designated practicing dentists. On-the-job-trained dental hygienists who complete the preceptorship program are then eligible for the licensure examination. This preceptorship program requires 2 weeks of study at the University of Alabama; 12 1/2 hours of dental radiography are included in the course.
DENTAL ASSISTANTS

Dental assistants provide a wide range of clinical and laboratory skills and functions that aid the dentist in the delivery of oral health care. While dental assistants are permitted to assume expanded functions in some States, there are considerable differences among States in the definition of these functions. However, in all States except the District of Columbia and Rhode Island, exposure and processing of dental radiographs for diagnostic purposes may be delegated to dental assistants.

Certification

The Dental Assisting National Board provides a voluntary national mechanism for certifying dental assistants. The Board operates under requirements adopted by the American Dental Association and is a member of the National Commission for Health Certifying Agencies. Individuals who have successfully completed an educational program in dental assisting accredited by the Commission on Dental Accreditation are eligible to sit for the certification examination. Since 1980, on-the-job-trained dental assistants have been allowed to take the national examination as part of a study to determine appropriate requirements and methods for certifying personnel trained on the job. The certifying examination offered by the National Board is criterion-referenced.

Accreditation

Educational programs in dental assisting are accredited by the Commission on Dental Accreditation, which includes a representative of the American Dental Assistants Association. Accreditation standards for dental assisting programs include standards for curricula and instruction in dental radiography. Reaccreditation is conducted on a 5-year review cycle and a 10-year site visit cycle. Some dental assisting programs located in proprietary schools and some military programs are not accredited by the Commission. Virtually all other educational programs in dental assisting are accredited.

State Regulation

Dental assistants are permitted to expose and process dental radiographs in all States except Rhode Island and the District of Columbia. While no State terms its regulatory procedure "licensure," 21 require dental assistants to complete specified training and/or an examination before engaging in dental radiography under the supervision of a dentist. Six of these 21 States award certificates or register dental assistants who have met their requirements in specified areas, including radiography. The remaining 29 States permit the practice of dental radiography by assistants, but have no training or examination requirements.

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1 The National Commission for Health Certifying Agencies is a voluntary organization whose purpose is to improve the reliability, validity, and fairness of credentialing policies, procedures, and standards among voluntary agencies that certify the competence of health personnel.
Training and Examinations. Of the 21 States that regulate the dental assistant's use of dental radiography, requirements vary considerably. Some require only a specified training course, others require only an examination, while still others require both training and examination. Table 2 displays the considerable variety now existing among these State requirements.

Training requirements vary from graduation from a State-approved course in expanded functions for dental assistants (13 States), to graduation from a State-approved course in dental radiography alone (4), to graduation from an educational program accredited by the Commission on Dental Accreditation (1).

Five States accept certification by the Dental Assisting National Board as fulfillment of their requirements. Five states will permit dental radiography by assistants who have passed State-administered written and clinical examinations, and five States use written examinations only. In some States, these examinations are conducted by State dental boards or dental associations, and in others, by radiation control agencies or environmental protection agencies. The content of training courses and examinations varies among States.

RADIATION THERAPY TECHNOLOGISTS

Radiation therapy technologists, working from a prescription and with a radiologist, are professionals who utilize equipment that generates ionizing radiation for therapeutic purposes on human subjects. Using X-ray equipment, radionuclides, and electron beam equipment, they expose specific areas of the body to prescribed doses of ionizing radiation, assist in tumor localization and dosimetric procedures, assist in the proper operation of controlling devices and in radiation protection for patients and clinical personnel.

Certification

The ARRT provides a voluntary national system for certification of radiation therapy technologists. The ARRT awards certificates to individuals who successfully complete an examination and meet prescribed educational requirements. Content specifications for the certifying examination are derived from an analysis of the knowledge, skills, and competencies necessary to perform as a radiation therapy technologist. The examination is criterion-referenced.

In general, graduation from a formal educational program in radiation therapy technology accredited by CAHEA is required of candidates who wish to sit for the examination. However, the ARRT reviews the qualifications, on a case-by-case basis, of other applicants whose education and experience meet or exceed those of graduates of CAHEA-accredited programs. The ARRT reported 2,876 certificate holders in February 1982.

Accreditation

As is the case for educational programs for radiographers, educational programs for radiation therapy technologists are accredited by CAHEA, with the cooperation of the American College of Radiology, the American Society of Radiologic Technologists, and the Joint Review Committee on Education.
Table 2. State training, examination, and credentialing requirements for dental assistants making dental radiographs

<table>
<thead>
<tr>
<th>State</th>
<th>Required training</th>
<th>Dental Assisting National Board</th>
<th>State Written</th>
<th>Clinical Credential issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arizona</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>Yes Certificate</td>
</tr>
<tr>
<td>California</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>Yes Certificate</td>
</tr>
<tr>
<td>Florida</td>
<td>Approved course</td>
<td>No</td>
<td>No</td>
<td>Yes Certificate</td>
</tr>
<tr>
<td>Illinois</td>
<td>Approved course</td>
<td>No</td>
<td>No</td>
<td>No Certificate</td>
</tr>
<tr>
<td>Indiana</td>
<td>Approved course</td>
<td>No</td>
<td>Yes</td>
<td>No Certificate</td>
</tr>
<tr>
<td>Iowa</td>
<td>Approved course</td>
<td>No</td>
<td>Yes</td>
<td>No Certificate</td>
</tr>
<tr>
<td>Kentucky</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>Yes 1 Registration</td>
</tr>
<tr>
<td>Maryland</td>
<td>Expanded function</td>
<td>Yes</td>
<td>Yes 1</td>
<td>Registration</td>
</tr>
<tr>
<td>Michigan</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>Yes Certificate</td>
</tr>
<tr>
<td>Minnesota</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>No Certificate</td>
</tr>
<tr>
<td>Montana</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>No Certificate</td>
</tr>
<tr>
<td>Nebraska</td>
<td>Expanded function</td>
<td>No</td>
<td>No</td>
<td>No Certificate</td>
</tr>
<tr>
<td>New Hampshire</td>
<td>Expanded function</td>
<td>No</td>
<td>No</td>
<td>No Certificate</td>
</tr>
<tr>
<td>New Jersey</td>
<td>None</td>
<td>Yes 1</td>
<td>No</td>
<td>Registration</td>
</tr>
<tr>
<td>North Carolina</td>
<td>Expanded function</td>
<td>No</td>
<td>No</td>
<td>No Certificate</td>
</tr>
<tr>
<td>North Dakota</td>
<td>Accredited program</td>
<td>Yes</td>
<td>No</td>
<td>No Certificate</td>
</tr>
<tr>
<td>Oklahoma</td>
<td>Expanded function</td>
<td>No</td>
<td>Yes</td>
<td>No Certificate</td>
</tr>
<tr>
<td>Oregon</td>
<td>None</td>
<td>No</td>
<td>Yes</td>
<td>Yes Certificate</td>
</tr>
<tr>
<td>Tennessee</td>
<td>Expanded function</td>
<td>No</td>
<td>No</td>
<td>No Certificate</td>
</tr>
<tr>
<td>Vermont</td>
<td>Expanded function</td>
<td>Yes 1</td>
<td>No</td>
<td>Registration 2</td>
</tr>
<tr>
<td>Virginia</td>
<td>None 3</td>
<td>Yes 4</td>
<td>Yes 1</td>
<td>No Certificate</td>
</tr>
</tbody>
</table>

NOTES: The District of Columbia and Rhode Island do not permit dental assistants to make dental radiographs. All other States not listed above permit dental assistants to make dental radiographs without restriction.

1Not required if certified by the Dental Assisting National Board.

2Dental Assisting National Board certification accepted in lieu of State registration.

3State provides but does not require a home-study course in dental radiography.

4Accepted if applicant provides statement that he/she has completed training in dental radiography.

KEY:
- Certificate: Certified by a State agency
- Registration: Registered by the State dental board
- Approved course: Approved training course in dental radiography
- Accredited program: Dental assisting program accredited by the Commission on Dental Accreditation

SOURCES: Commission on Dental Accreditation, Division of Educational Measurements, Legal Provisions for Delegating Expanded Functions to Dental Hygienists and Dental Assistants (Chicago: American Dental Association, January 1981).


Correspondence from the Indiana State Board of Health and Virginia Department of Health Regulatory Boards, 1982.
in Radiologic Technology. Accreditation is reviewed every 5 years, or more frequently if circumstances warrant. Virtually all programs in radiation therapy technology are accredited.

State Regulation

Licensure. Seven States license radiation therapy technologists, and have educational and examination requirements for licensure. Of these seven States, five have contracted with the ARRT to administer its examination as the State licensure examination. One State administers its own examination, but also will license individuals who hold current ARRT certificates in the profession if they have scored at least 70 percent on the radiation protection and radiologic procedure sections of the ARRT examination. Puerto Rico administers its own examination, and requires 1 year of public service before issuing a license. Table 3 displays the current status of State requirements.

Two States have plans to institute licensure of radiation therapy technologists. In Hawaii, the program is under development, and in Indiana, it is scheduled to be developed at a later date. Florida does not license radiation therapy technologists, but issues a certificate to individuals who have completed a State home-study course in radiation protection; in this State, radiation therapy technologists can be trained in hospital-designed programs, but neither educational program approval nor licensure of personnel is required by the State.

Enabling legislation also exists in Delaware, Illinois, Iowa, Michigan, and Minnesota.

Accreditation. Among the seven licensure States, four accept graduation from a CAHEA-accredited program. Two of these four States also accept graduation from other educational programs approved by the State, and one State also accepts training and experience other than formal education as a possible means of qualifying one for the licensure examination. Of the three States that do not automatically accept the CAHEA accreditation process, one cooperates with CAHEA in educational program approval, and two reserve all standard-setting and program approval authority to a designated State agency.

NUCLEAR MEDICINE TECHNOLOGISTS

Nuclear medicine technologists are professionals who conduct in vivo or in vitro detection and measurement of radioactivity for medical purposes or who administer radiopharmaceuticals to human beings.

In vivo procedures involve the administration of radioactive tracer chemicals to the patient. In one type of procedure, the tracer is administered and after a period of time instruments are employed to measure the radioactivity emitted from the body in the vicinity of the organ in question. To accomplish this, the tracer must emit gamma radiation powerful enough to affect recording devices, but because tracers have short half-lives, irradiation of patients' tissues continues only briefly after the recording has been completed. In another type of in vivo procedure, a tracer is administered to the patient and, after a specified period of time, a sample of body tissue or fluid is removed, and the amount of tracer in the sample is measured.
Table 3. State licensure requirements for radiation therapy technologists, 1982\(^1\)

<table>
<thead>
<tr>
<th>State</th>
<th>Education program approved by</th>
<th>Other licensure requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CANEAR/JRC or State</td>
<td>Exam required or Certificate accepted</td>
</tr>
<tr>
<td>Arizona</td>
<td>Yes</td>
<td>ARRT, ARRT, CANEAR grade only</td>
</tr>
<tr>
<td>California</td>
<td>Yes</td>
<td>State ARRT with conditions(^2)</td>
</tr>
<tr>
<td>New Jersey</td>
<td>Not at present</td>
<td>ARRT None</td>
</tr>
<tr>
<td>New York</td>
<td>State with CANEAR/JRC</td>
<td>ARRT None</td>
</tr>
<tr>
<td>Oregon</td>
<td>Yes</td>
<td>ARRT None</td>
</tr>
<tr>
<td>Vermont</td>
<td>Yes</td>
<td>ARRT None</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>No</td>
<td>State &amp; 1 yr. service</td>
</tr>
</tbody>
</table>

NOTES: Florida does not issue licenses, but requires personnel trained in hospitals to complete a home-study course in radiation protection. Enabling legislation exists in Delaware, Hawaii, Illinois, Indiana, Michigan, and Minnesota. Hawaii is currently developing its licensure program. No other states license radiation therapy technologists.

1Information on acceptance of credentials from other States, and on "grandfathering" provisions not shown.

2Also accepts training and experience in lieu of formal education.

3ARRT certificates must have scored 70 percent on the radiation protection and radiologic procedures sections of the ARRT exam.

4Agreement for cooperation with CANEAR/JRC in approving programs under development by State.

KEY:

ARRT American Registry of Radiologic Technologists
CANEAR/JRC Committee on Allied Health Education and Accreditation/Joint Review Committee on Education in Radiologic Technology

SOURCES: Information provided to the Health Resources and Services Administration by State Health officers, licensing agencies, and radiation control agencies, 1982.
In vitro procedures do not require exposure of the patient to radioactive materials. Some in vitro tests are performed by clinical laboratory personnel as well as nuclear medicine technologists.

Certification

Three nongovernmental organizations certify nuclear medicine technologists. In 1982, the Nuclear Medicine Technology Certification Board (NMTCB) reported 13,400 certificate holders; the ARRT reported 8,273 certificate holders; and the Board of Registry of the American Society of Clinical Pathologists (ASCP) reported 1,608 certificate holders. A number of individuals are certified by more than one organization.

Initially incorporated under the sponsorship of the Society of Nuclear Medicine and its Technologist Section, the NMTCB is now an independent agency and is a member of the National Commission for Health Certifying Agencies. The ASCP was a member of the National Commission for Health Certifying Agencies until 1982.

All three organizations award certificates to individuals who have successfully completed an examination and meet prescribed educational requirements. Each agency's certifying examination is based on an analysis of the knowledge, skills, and competencies required for the profession, and is criterion-referenced. In general, all three organizations require graduation from a CAHEA-accredited program in the professions, although alternative pathways exist to allow individuals with other prescribed combinations of training and experience to sit for the examination. Examinations offered by these agencies differ somewhat, and eligibility requirements for those individuals who have not graduated from accredited formal educational programs also differ.

The existence of three certifying boards for these personnel appears to have its genesis in the relative youth of the occupation, the diverse backgrounds of the individuals who initially entered the new profession, and the specialty orientation of the practitioners who supervise these personnel. The NMTCB is more closely identified with the nuclear medicine community, the ARRT with radiology/radiologic technology, and the ASCP with clinical pathology/medical technology. All three certificates are acceptable to institutions and practitioners that employ nuclear medicine technologists.

Accreditation

Educational programs for nuclear medicine technologists are accredited by CAHEA. The American College of Radiology, the American Society of Medical Technology, the American Society of Clinical Pathologists, the American Society of Radiologic Technologists, and the Society of Nuclear Medicine cooperate with CAHEA in the accreditation process. The program review committee is the Joint Review Committee on Educational Programs in Nuclear Medicine Technology, which includes four members of the Society of Nuclear Medicine (two physicians, two technologists) and two members from each of the other professional associations listed above. To maintain accreditation, programs are resurveyed once every 5 years, or more frequently if indicated. Virtually all educational programs for the profession are accredited.
State Regulation

Licencure. New Jersey, Vermont, and Puerto Rico license nuclear medicine technologists. New Jersey and Vermont have contracted with the ARRT for the use of its examination, and Puerto Rico administers its own examination. The two States that contract with ARRT also will license individuals who hold current certificates from NMTCB or ASCP. Vermont also requires NMTCB and ASCP certificate holders to have graduated from a CAHEA-accredited program to be eligible for licensure. Puerto Rico requires 1 year of public service, beyond State-approved training and examination, before issuing a license.

In addition, California is developing a licensure program, and Indiana has plans to develop such a program at a later date. Georgia, Kentucky, and Tennessee also have enabling legislation.

Accreditation. Of the three States that license nuclear medicine technologists, Vermont accepts graduation from a CAHEA-accredited program as fulfilling the eligibility requirement to take the licensure examination, while New Jersey and Puerto Rico reserve all standard-setting and program-approval authority to a designated State agency.

SUMMARY OF STATE REGULATION

Section 981(e) of the Act, which addresses State compliance, states:

"Notwithstanding any other provisions of this section, in the case of a State which has, prior to the effective date of this subsection and guidelines promulgated pursuant to this subtitle, established standards for the accreditation of educational programs and certification of radiologic technologists, such State shall be deemed to be in compliance with the conditions of this section unless the Secretary determines, after notice and hearing, that such State standards do not meet the minimum standards prescribed by the Secretary or are inconsistent with the purposes of this subtitle."

Radiographers

Thirteen States regulate radiographers, and all 13 have standards for approval of educational programs and for personnel licensure. All 13 require specified education and examination for licensure. It appears that these States' standards are in most respects comparable and in some cases identical to the voluntary accreditation standards of CAHEA and the voluntary certification standards of ARRT. Since the accreditation and certification standards published by the Department parallel those of CAHEA and ARRT, it is anticipated that compliance will not pose a problem for these 13 States.

Dental Hygienists

Dental hygienists are licensed in all States, and all but Alabama require candidates to have graduated from an educational program accredited by the Commission on Dental Accreditation. Alabama accepts graduates from accredited
programs, and also accepts individuals who have completed a State-approved preceptorship that includes didactic and clinical training in dental radiography.

All but two States accept the results of the national board examination in dental hygiene as full or partial fulfillment of their requirements for a written licensure examination, and supplement written tests with clinical examinations. Alabama and Delaware, which do not accept the Dental Hygiene National Board examination, administer their own written and clinical examinations, which test competency in dental radiography and other areas.

Review of these existing standards indicates that compliance with the accreditation and certification standards to be published by the Department does not appear to pose a problem for any State.

Dental Assistants

Twenty-one States require dental assistants who make dental radiographs to complete specified training and/or an examination. Another 29 States permit dental assistants to make dental radiographs, under the supervision of dentists, without restriction. Rhode Island and the District of Columbia do not permit dental assistants to make dental radiographs. Among the 21 States that now regulate the dental assistant's use of dental radiography, standards of training and examination vary considerably. It can be anticipated that the problem faced by these States in complying with the accreditation and certification standards to be issued by the Department may vary accordingly.

Radiation Therapy Technologists

Seven States license radiation therapy technologists. These States have standards for educational program approval and specify educational and examination requirements for licensure. It does not appear that compliance with the accreditation and certification standards to be published by the Department will pose a problem for these seven States.

Nuclear Medicine Technologists

New Jersey, Vermont, and Puerto Rico license nuclear medicine technologists. These States have standards for educational program approval and set education and examination requirements for licensure. It does not appear that compliance will pose a problem for these States.

In addition to the States that now regulate the professions listed above and approve educational programs for these five professions, several States have legislation that could provide the statutory authority for licensure and educational program approval, and several more are now considering such statutes. Because the Department's standards have not yet been published, States have not had an opportunity to consider options for legislative and administrative action.
The Chairman. I would now like to introduce our first panel, which is comprised of representatives of the ad hoc working group to develop radioepidemiological tables, better known as the Rall committee, and representatives of the National Council for Radiation Protection and Measurement Committee, better known simply as Committee 71.

The Rall committee is represented by Dr. Ed Rall, Dr. Gilbert Beebee, and Dr. Charles Land. Committee 71 is represented by Mr. Seymour Jablon and Mr. Schaffer. Actually, Mr. Jablon has the honor, or perhaps the onus, of belonging to both committees. Mr. Schaffer has the distinction of being the only attorney on either committee.

We shall begin with Dr. Rall's testimony and then move on to Mr. Schaffer, because he is under a time constraint this morning. Bill Schaffer is not scheduled to make a formal presentation, but since he is the only lawyer involved, since these tables may have a substantial legal impact, since he has had a long experience with this issue of radiation liability, both in the Government and in private practice, and especially since we have had our differences in the past, I am most interested in hearing his perspective on the tables. After Mr. Schaffer's testimony, I shall ask him several questions so that he can keep to his schedule, but then I shall save the balance of my questions until Mr. Jablon has testified on behalf of Committee 71. Of course, Dr. Beebee and Dr. Land, you are also welcome to comment at any time, and I hope you will participate actively in the questions and answers.

As always, I would like to ask the witnesses to summarize their formal statements, so that we can have more time for discussion, but we will put all formal statements of all witnesses today in the record as though fully delivered. So summaries are certainly in order. Let's turn at this time to you, Dr. Rall, and we will proceed.

STATEMENT OF J. EDWARD RALL, DEPARTMENT DIRECTOR FOR INTRAMURAL RESEARCH, NATIONAL INSTITUTES OF HEALTH, ACCOMPANIED BY DR. GILBERT BEEBEE, CLINICAL EPIDEMIOLOGY BRANCH, NATIONAL CANCER INSTITUTE, AND CHARLES LAND, HEALTH STATISTICIAN, RADIATION EPIDEMIOLOGY BRANCH OF NCI

Dr. Rall. Mr. Chairman, I am pleased to appear before you today. The development of the radioepidemiological tables was mandated by section 7B of Public Law 97-414, enacted on January 4, 1983.

To ensure, as far as possible, that these tables represent the best scientific judgment, the Secretary of Health and Human Services established the NIH ad hoc working group, three members of which are here: Dr. Gilbert Beebee of the National Cancer Institute, Dr. Charles Land of the National Cancer Institute, and Mr. Seymour Jablon of the National Academy of Science. In addition to that, Dr. Oddvar Nygaard, director of radiation biology at Case Western Reserve; Dr. Arthur Upton, professor and chairman of the Department of Environmental Medicine at New York University; and Dr. Rosalyn Yalow at the Veterans' Administration hospital in the Bronx; and Dr. Victor Zeve, executive secretary.
I will give you some of the background underlying the preparation of the tables. I should first say that the NIH and the Assistant Secretary for Health asked the National Academy of Sciences to form an advisory committee, the so-called oversight committee, to assist the working group. This has been chaired by Dr. Frederick Mosteller, and this committee has been of great help to our committee. In addition, NRCP Committee 71, as you have noted, has been working on tables for several years, and we have benefited from their work and thoughts.

We have prepared now three draft documents. The first one in December concerned the fundamental assumptions necessary for the preparation of the tables and was submitted to the National Academy in December. We received their reply in April. We then submitted a second draft to them in July, and we have had informal communication from them since then. We are just in the process now of sending them a third draft, and we are hopeful to get a final draft, including tables, drafts and varied and assorted formulas for the calculation of probability of causation under any circumstance to the secretary early in November.

First, the working group determined it could not really review all the world’s literature on radiation as a cause of cancer, particularly since in 1980, the National Academy of Sciences’ Committee on Biologic Effects of Ionizing Radiation, the so-called BEIR III committee, prepared an exhaustive survey of the world literature up through 1979. So we have used that as a basis.

We have, however, had available to us some unpublished data and other published data which have led us to depart in significant ways from the BEIR III report. We have for example, developed a new so-called wave-function time-response model for leukemia and for bone cancer, which is different than BEIR III or any other one but which we think more accurately portrays the experimental data. We also have used different coefficients for thyroid cancer and breast cancer. We have added cancer of the salivary gland, which now appears fairly to the radiogenic. We have omitted lymphoma; it looks now as though the evidence is not sufficient to rank this as a radiation-induced cancer. And we have avoided probability-of-causation calculations for certain cancers following exposure at younger ages because we do not think there are enough data to support those calculations.

A brief history of radiation, which has been known for some 80 years now. The first indication that it might be harmful was when it was discovered that people working with radiation got a sunburn-like effect, radiation dermatitis. At that time, it was believed that there was a threshold, a certain amount of radiation below which there was no effect. This, by and large, seemed to be true for radiation dermatitis. A few rads did not produce it and 1,000 rads to the skin did produce it.

However, work on the genetic effects of radiation in the thirties and forties suggested very strongly that any dose of radiation had a certain possibility of producing a damaging effect on germ cells. Based on these findings, a 1954 report by the NCRP recommended that one could no longer assume a threshold. In the last 20 years, however, the concern has become much more over the effect of ra-
radiation on causing cancer. This is, of course, one of the reasons for the legislation enacted for the existence of this committee.

As you pointed out in your remarks, radiation causes cancer in a largely random manner. Although we can predict when a large group of people got a large amount of radiation, we can predict with a fair degree of accuracy what fraction will get cancer of the breast, leukemia, and so on, but we certainly cannot say which individual will get the cancer. When an individual has developed a cancer, we cannot say whether it was due to radiation or not, because radiation induced cancers look no different than cancers that develop for any other reason. In fact, although we know a great deal about what might cause cancer in terms of environmental factors and genetic susceptibilities, we usually cannot tell what caused any individual cancer, with the possible exception of cigarette smoking which is the cause of the vast majority of cancers of the lung and, indeed, accounts for between 30 and 40 percent of the total cancer burden in the United States.

There were a variety of assumptions that had to be made before tables could be constructed, and I might go through them rather briefly. We first had to decide what data should be used. There is a great deal of data on the induction of cancer in experimental animals, mostly rodents. There is a considerable body of data on the effect of radiation on cells in tissue culture. Unfortunately, the problem with experimental animals is the same as it is with humans in a certain sense. To observe small effects, one needs very large numbers of animals, and this is rather difficult to manage. Even more importantly, most of the animal studies have been with inbred animals, in which there are very high or very low incidences of cancers, and it would appear that the cancer in these animals is somewhat different than the cancers that develop in human beings.

Finally, the in vitro experiments on tissue culture differ so profoundly from the results when a whole individual is radiated, there being no immune response for example, that we did not feel we could use these. Hence, we used epidemiologic data derived from radiation exposure to humans.

The second thing that had to be resolved was how to estimate the risks at low doses of radiation. We have reasonably good human data on the risks of radiation for certain cancers at relatively high doses. What is the risk at low doses? We have, except for breast and thyroid, relatively little human data on radiation doses less than 100 rads.

There are basically two methods of approaching this. One is to assume that the risk is linearly proportional to the radiation. That is to say, 1 rad will produce one-hundredth of the effect of 100 rads. For thyroid cancer and breast cancer, there are data, extending down in the case of thyroid cancer, to as little as 10 rads and in the case of breast cancer to radiation doses a little bit higher than that, which support reasonably firmly the so-called linear extrapolation hypothesis. We have used that to construct the tables of probability of causation for these two cancers.

For the other cancers, the human data fit both a so-called linear quadratic formulation in which the effect of smaller doses of radiation is less per rad than the effect of larger doses of radiation.
This formulation fits perfectly well the human data for leukemia and for several other cancers. There are some radiobiologic effect reasons that make one lean toward this interpretation. Indeed, this is what the BEIR III committee felt was the most logical way to extrapolate the effects of low doses of radiation from data at higher doses. So we have used this formulation for all of the cancers except thyroid and breast.

The third assumption the group had to make was to consider the relative effectiveness of radiation delivered at different dose rates. There are no conclusive human data on this, although the differences in dose rates range from a 10,000 to 20,000 rads per minute delivered in the bombings at Hiroshima and Nagasaki to of the order of a few rads per minute delivered in fluoroscopy, where there are data for breast carcinoma. This appears to have had relatively little effect. However, there are other data which suggest that a very low dose rate may be less effective than rather high dose rates. For reasons that I do not have the time to go into, the use of the linear quadratic formulation in general resolves the problem of dose rate, particularly when we partition radiation into units no smaller than 5 rads. So we feel that this has been resolved.

A fourth problem is the relative carcinogenicity of what is called high linear energy transfer radiation. This is a radiation delivered by neutrons or alpha particles. Neutrons one will get from a reactor and alpha particles from the decay of radium, as for example with uranium miners. It is known from a variety of experimental situations that this kind of radiation is considerably more effective in causing cancer than so-called low-LET radiations, such as x rays and gamma rays. This appears to be because the ionizing events which cause the cancer are so closely spaced that they can cause two damaging events relatively easily, whereas the ionizations produced from low-LET radiation, such as gamma and x rays, tend to be much more diffusely arranged.

All of our tables except bone cancer deal with the more commonly occurring low-LET radiation, and to use the tables for high-LET radiation certain correction factors will have to be introduced. Some of these are available in the literature, and we will give some indication as to how that can be done.

Finally, a fifth assumption required for calculation of these tables has been the relationship of the numbers of cancers produced at any time after irradiation by comparison with the number normally occurring in a similar population of the same age and sex not exposed to radiation.

The BEIR III committee used two methods to do this. One was the so-called relative-risk time-projection model, the other an absolute-risk time-independent model. The absolute-risk model assumes that the added risk of developing cancer after radiation is constant after a suitable latent period. The number of cancers will be the same, irrespective of the baseline rate. The relative-risk time-projection model states that at any time after a latent period, a given dose of radiation increases the probability of developing cancer by a constant fraction, so that the fraction will be an increase of a few percent of the natural-occurring rate, and that will be constant.
even though the natural rate, as in most cancers, generally increases with age.

We have adopted the relative-risk time-projection model because the most recent data, particularly on breast and stomach cancers, quite convincingly support this model. This particularly has to do with breast carcinoma, which is quite uncommon in the twenties and thirties and then becomes very common indeed in the forties and fifties. As the experience is accumulated and the Japanese population exposed to the atom bombs at Hiroshima and Nagasaki, there is now enough experience to show that this in point of fact is exactly what happened, that there is a constant fractional increase in risk with time.

I could mention that there have been other estimates of probability of causation, or something similar, prepared by the British Nuclear Fuels, Ltd., by John Gofman and by Stewart. The British Nuclear Fuels procedure is not available to the public. Serious objections have been raised to the Gofman calculations, and the Hanford worker data used by Stewart we regard as much too fragile to provide the basis for any systematic probability of compensation table.

The draft you will see will represent a consensus of the ad hoc working group, peer reviewed by the oversight committee. I will be pleased to answer any questions that you might have at this time.

[The prepared statement of Dr. Rall follows:]
STATEMENT OF

J. E. RALL, M.D., Ph.D.
DEPUTY DIRECTOR FOR INTRAMURAL RESEARCH

NATIONAL INSTITUTES OF HEALTH
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

SEPTEMBER 18, 1984
Mr. Chairman and members of the Committee, I am pleased to appear before you today to discuss the development of the radioepidemiological tables, as mandated by Section 7B of Public Law 97-414. This law, the Orphan Drug Act, which was enacted on January 4, 1983, directed the Secretary of Health and Human Services to construct tables showing the probability that certain cancers result from prior exposure to doses of radiation.

To ensure as far as possible that the radioepidemiological tables would represent the best possible scientific judgment, the Secretary of Health and Human Services established the NIH Ad Hoc Working Group to Develop Radioepidemiological Tables. The members of this Group are Dr. Gilbert W. Bøbe, an Expert in the Clinical Epidemiology Branch of the National Cancer Institute; Dr. David G. Hoel, Director of Biometry and the Risk Assessment Program, National Institute of Environmental Health Sciences; Mr. Seymour Jablon, member of the Advisory Committee on the Radiation Effects Research Foundation of the National Academy of Sciences, Dr. Charles E. Land, Health Statistician of the Environmental Epidemiology Branch of the National Cancer Institute; Dr. Oddvar F. Nygaard, Director, Division of Radiation Biology, Department of Radiation Biology at Case Western Reserve University; Dr. Arthur C. Upton, Professor and Chairman of the Department of Environmental Medicine at the New York University Medical Center; Dr. Rosalyn S. Yalow, Senior Investigator at the Veterans Administration Medical Center, Bronx, New York, and Dr. Victor Zev, Special Assistant, Office of the Director, National Cancer Institute, and Executive Secretary of the Ad Hoc Working Group. As Chairman of the Working Group, I
will give you some of the background underlying the preparation of these tables.

The NIH and the Assistant Secretary for Health requested the National Academy of Sciences to form an advisory committee (the National Academy of Sciences Oversight Committee) to assist the Working Group. The Working Group, which has prepared a draft report, has benefited from the detailed criticisms of its preliminary material by the NAS Oversight Committee, chaired by Dr. C. Frederick Mosteller. The preliminary report is now being reviewed by the NAS Oversight Committee and by other interested Federal agencies. Our report will be made available to your Committee by the Department as soon as final review is completed and changes made as appropriate during the review process. A coordinated Federal response is currently being developed by the Committee on Interagency Radiation Research and Policy Coordination.

Limitations

In preparing the tables, the NIH Ad Hoc Working Group, as well as the Oversight Committee, identified the same set of problems involved in the calculation of probabilities of causation (PC) for cancer following exposure to ionizing radiation.

The Working Group determined that it could not attempt a new analysis of the epidemiologic data but should base many of its calculations on the third report issued in 1980 by the National Academy of Sciences Committee on the Biological Effects of Ionizing Radiation (BEIR III) (1) that itself had required more than three years to complete. The Working Group, however, did depart from the BEIR III report in several important details because of the avail-
ability of new data. These include adoption of a new "wave function" time-response model for leukemia and bone cancer, different coefficients for thyroid cancer and breast cancer, addition of cancer of the salivary gland, omission of lymphoma as a radiation-induced cancer, and avoidance of PC calculations for certain cancers following exposure at younger ages.

The problems recognized by both groups will be addressed in the future through the accumulation of more human data, and especially by new insights into the mechanisms of carcinogenesis. The Working Group interprets its mandate from the Orphan Drug Act as requiring assessment of currently available data and the exercise of its best judgment regarding the handling of the scientific uncertainties that are at present unresolved.

Relationship between Radiation Exposure and Development of Cancer

I would now like briefly to review some of the scientific issues faced by the Working Group and describe the decisions we made in order to be able to prepare the radioepidemiological tables.

Historically, not long after ionizing radiation was discovered and methods for producing and utilizing various types of radiation became available, it was demonstrated that exposure to large doses of radiation could be biologically damaging. First came the recognition that radiation to the skin could cause a serious, sunburnlike effect. Then it was learned that radiation could cause skin cancers.

In 1928 the International Congress of Radiology adopted the first international recommendation for radiation protection. At that time, it was believed that there was a threshold for the deleterious effects of radiation, that is, a dose below which there
would be no damage. Work on the genetic effects of radiation in the 1930's suggested that any dose of radiation had a certain likelihood of producing a damaging effect on germ cells, that is, sperm and egg cells. Based on these findings, a 1954 report by the National Committee on Radiation Protection recommended that a threshold could no longer be assumed. Concern over the genetic effects of radiation, so prevalent in the 1950's, has, in the last two decades, been coupled with a growing awareness of the effects of radiation, particularly the induction of cancer, on non-germ, or somatic cells of the body.

Radiation acts to cause cancers in a largely random manner. In a situation in which a large number of people have received a moderate to large amount of radiation, the numbers of specific cancers (e.g., breast cancer, leukemia, etc.) produced by that amount of radiation can be statistically estimated. We cannot, however, predict which individuals will develop cancer. Even after the cancer has developed, we cannot state with certainty whether it was caused by radiation, since it is impossible to differentiate cancers induced by irradiation from those which occur "normally" in the population.

Cancer appears to be caused by a large number of environmental factors and genetic susceptibilities although, in any individual case, it is usually not possible to be sure of the exact cause of that cancer. The events that may cause or predispose an individual to develop cancer interact in several ways, but only a few of these interactions are known and understood.

Moreover, different individuals are exposed differently to
greater or lesser carcinogenic factors as the result of cigarette smoking, alcohol consumption, viral infection, dietary habits, occupation, etc. If detailed knowledge were available about the effects of all these exposures and interactions, it would be possible theoretically to classify individuals into a large number of groups in which the probability of causation of a given cancer could be calculated with greater accuracy. For radiation carcinogenesis, however, the number of such groups is limited at present; i.e., from available data we can, with some assurance, partition populations into categories based on a few factors, including age, sex, smoking history and age at exposure to radiation. Except for these subdivisions we can calculate probabilities of causation only for aggregated groups. However, a lack of precision in partitioning has no effect on the sum of the probabilities for the entire population. Given these limitations on the validity of the radioepidemiological tables, no court should consider the tables reliable evidence that a specific individual’s cancer was caused by radiation exposure.

Attempts to estimate the probability that an observed effect resulted from one of several possible causes are not uncommon, even in the more exact physical sciences. Decay of short-lived exotic particles in physics, where only a small number of events can be observed and several potential mechanisms exist, is in some respects analogous to the problems involved in constructing radioepidemiological tables. In both cases, probabilities are calculated from a small number of events.

There is, however, an important difference. In physics a
large number of well-tested and comprehensive theories exists to guide calculations, whereas in biology and medicine there are almost no well-established general and predictive theories. This becomes particularly important for calculation of the probability that radiation caused a certain cancer when the dose of radiation was small and/or was given at a low dose rate.

Low Dose Estimates

Several government reports, such as the 1979 Report of the Work Group on Science of the Interagency Task Force on the Health Effects of Ionizing Radiation (2), the 1981 report of the Comptroller General to the U.S. Congress (3), and the 1981 report of the Interagency Radiation Research Committee (4), as well as such authoritative reports as the BEIR III report of the National Academy of Sciences (1), and the 1977 report of the United Nations Scientific Committee on the Effects of Atomic Radiation (5), testify to the uncertainty of the carcinogenic effects of very low doses of radiation. Although effects at moderate to high doses can be estimated reasonably well in large populations, the lower the dose the more uncertain any estimate becomes.

Some of these environmental and occupational doses are quite small, on the order of natural background levels to which we are all exposed (about 0.08 to 0.2 rad per year in the United States), and it might be supposed that studies of populations living in regions where background levels vary greatly would yield estimates of carcinogenic risk associated with such differentials. Several such studies have been attempted, but they have provided little information since the risks are so low that any effect is swamped by the natural
variation in cancer incidence (5,6,7). Nor can the absence of positive findings be taken as firm evidence that dose-response functions for cancer are characterized by threshold doses below which the carcinogenic effect is absent. At the present time, estimations of effects at low doses are based upon assumptions as to the mathematical form governing the dependence of effect upon dose, since we must extrapolate from the dose region where we do have reasonably stable estimates of effect, to the region where data are unavailable.

In general, the Ad Hoc Working Group utilized epidemiologic data derived from radiation exposure to humans. However, there is a large body of data on radiation effects in experimental animals, largely rodents, and additional data from in vitro studies of effects of radiation on cell cultures. The animal data on low levels of ionizing radiation are constrained, however, by the same limitations as the data on humans—the difficulty that the small effects require very large numbers of animals. Furthermore, the studies on rodents have been restricted almost entirely to highly inbred strains of animals and to types of tumors that occur with high frequency. Hence their relevance to the carcinogenic effects of low-level irradiation in the human population is uncertain. The in vitro experiments suffer, similarly, because the cells are studied under conditions that differ profoundly from those in vivo, and the experimentally induced effects of irradiation are of uncertain relevance to the carcinogenic effects of irradiation in vivo (8).

Methodology for Models

For calculations of the carcinogenic effects of low doses of
radiation, the Working Group has used the simplest dose-effect models consistent with the human epidemiologic data. For leukemia and bone cancer, the data are consistent with a so-called linear quadratic model, and this is the basis for the tables for those cancers. This model utilizes two constants and, in general, predicts that small doses of radiation have a lesser effect per rad than higher doses. There are radiologic reasons for assuming a linear-quadratic dose extrapolation generally, which are discussed both in BEIR III and in detail in Chapter III of the draft report. We have accordingly used this approach for all cancers except thyroid and breast. For carcinoma of the breast and thyroid, the data appear best described by a simple linear relationship in which the carcinogenic effect of radiation is directly proportional to the dose. Again, the tables reflect this assumption.

Although there are no conclusive human data on the health effect of radiation delivered at a very low rate relative to that delivered at a high dose-rate (atom bomb survivors, therapeutic radiation), several national and international bodies have suggested that low linear energy transfer (LET) radiation given at a low dose-rate is considerably less carcinogenic than the same amount of radiation delivered at a high rate (4,5). If a linear-quadratic model is used for extrapolation to low doses, no dose-rate correction is necessary, given a certain partitioning of protracted radiation (see Chapter V).

Another problem requiring resolution is the relative carcinogenicity of high LET radiation. This is the radiation delivered by large, highly energetic particles such as neutrons or alpha particles.
For the same total amount of energy delivered, this kind of radiation appears to be more effective in causing cancers than an identical amount of low LET radiation, such as that delivered by X rays or gamma rays. All of our tables deal with the more commonly occurring low LET radiation. To use the tables for high LET radiation, certain correction factors called "quality factors" must be used. These values will depend on the precise energy of the particles and the tissue distribution of the radiation and can best be calculated in each individual case. The alpha particle radiation received by uranium miners has usually been quantitated in working level months. How to relate this to the rad dose for LET radiation, as displayed in the tables, is discussed in Chapter III.

An additional assumption required for calculation of PC values is the relationship of the number of cancers produced at any given time after radiation in comparison with the number normally occurring in a similar population of the same age and sex not exposed to radiation. The BEIR III report utilized both a relative risk time projection model and an absolute risk time independent model. The relative risk time projection model states that, at any time after a latent period, a given dose of radiation increases the probability of developing cancer by a constant fraction. Available data, particularly on breast and stomach cancer in Japanese exposed to the atom bomb, which appeared after the preparation of BEIR III, support the relative risk time-response model even more convincingly. Therefore, the Ad Hoc Group has adopted this assumption. Chapter III of our report deals with this subject in greater detail.

Other estimates of probability of causation, or their equiva-
dent, have been prepared, to our knowledge, by British Nuclear Fuels, Limited (BNFL), by Gofman (9), and by Stewart (10), based in part on the report by Mancuso, Stewart, and Kneale (11). The BNFL procedure is not available to the public, and certain objections have been raised to the Gofman and the Mancuso-Stewart-Kneale systems of calculations (12,13,14). The present draft represents a consensus of the Ad Hoc Working Group, peer-reviewed by the Oversight Committee of the National Academy of Sciences.

**Summary of the Draft Report**

Chapter I outlines the Congressional actions that mandated its preparation, Chapter II describes briefly what is known about human cancer, and Chapter III how radiation relates to cancer. In Chapter III we also list those cancers which may be caused by radiation and for which adequate data are available to calculate probabilities of causation (PC), and discuss those for which an association with radiation is not proved. Chapter IV describes concepts involved in calculating the probability that any given amount of radiation was the cause of any particular cancer. In Chapter V, we explicitly list data sources and assumptions that are required for calculations of PC values and justify these choices. Chapter VI describes how the calculations have been performed. Chapter VII deals with the uncertainties associated with these calculations. Although we emphasize these uncertainties, in fact Lewis, more than a quarter of a century ago, calculated the radiogenic risk (absolute) for leukemia as about 2 cases per rad per 10^6 person-years (15). These values do not differ greatly from those we calculate today with better data at our disposal. Chapter VIII
discusses how these estimates may be updated and describes what new information may be available, and how it might be handled. Chapter IX gives the general form for calculating the probability of causation. Finally, Chapter X presents calculational routines and gives various examples of their usage for each radiogenic tissue. These site-specific tables and graphs are subdivided by sex and preceded by explanatory material describing any special features involved in the radiogenicity of that cancer, as well as the sources of the data. In addition to material which permits calculation of PC for any age and dose of radiation, we also have actual tables of PC for certain ages at exposure and for 1, 10 and 100 rad exposure. This arrangement has necessarily given rise to some redundancy, but the Ad Hoc Group believes that the present format permits anyone to obtain all the basic information for calculation of PC for a specific cancer in any specific case from just one part of the report.

I would be pleased to answer any questions you may have at this time.
REFERENCES


The CHAIRMAN. Thank you so much. I am going to move to Mr. Schaffer at this point because of his schedule. I will ask Mr. Schaffer questions, and then we will move to Mr. Jablon.

Mr. Schaffer.

STATEMENT OF WILLIAM SCHAFFER, ATTORNEY AT LAW, WASHINGTON, DC

Mr. SCHAFER. Thank you, Mr. Chairman. My name is William Schaffer. I am an attorney in the private practice of law in Washington, DC. From 1977 through 1980, I was Deputy Assistant Attorney General of the Civil Division of the Department of Justice, and in that capacity I chaired, in 1979 and 1980, the Interagency Task Force on Radiation Related Illnesses, which produced a naive and unsubtle variation of the methodology that is being discussed today. From 1980 to 1981, I was special litigation counsel in the Department of Justice, Civil Division, and in that capacity acted as lead counsel for the Government in the case of Allen v. United States. I am presently active in the defense of civil radiation injury cases. I am a consultant to certain injury groups. I am, as you stated earlier, a member of NCRP Committee 71, but I am not here on behalf of any client or any organization. The views which I state and the biases, if any, are solely my own.

I appreciate the invitation to appear before the committee, and I congratulate the committee chairman for the flexibility demonstrated over the years that I have been observing this issue in changing the approach to the problem and also for expending the time and effort necessary to understand and to incorporate the current scientific evidence into proposed resolutions of this problem.

I thought what I might best do to assist the committee is to give you some general observations as to the nature of the problem, to mention briefly what I see going on in the courts and the compensation boards, to express certain thoughts or perhaps recommendations concerning the use of the tables, and to make myself available for questions. I do not have a prepared statement, but I do have a paper which I have given to Mr. Preston, which it may be appropriate to incorporate into the record. It is a paper I presented in Philadelphia and covers in detail a number of the thoughts and subjects which I will only touch on.

The CHAIRMAN. We are happy to have that. Without objection, we will place that in the record as though delivered here today.

Mr. SCHAFER. Thank you, Mr. Chairman.

My concerns here go far beyond the question of who wins a particular lawsuit or even the broader question of whether a group of people or a special class of injuries is deserving of a specific kind of compensation. I think what is going on as the legislatures, both State and Federal, courts and compensation boards attempt to grapple with this issue has far broader ramifications.

First of all, the cases, as with anything nuclear, get a great deal of publicity. The publicity often misstates what is going on, but nevertheless, it is there and it affects the public. To give just one example, in the Allen case, the case involving the people who lived downwind from the Nevada testsite, the week the trial began, Newsweek magazine stated:
The case was sure to raise questions about the safety of current military and commercial nuclear programs and about the credibility of the Government agencies responsible for them.

I would submit, that case has nothing to do with current civilian nuclear power or the credibility of agencies charged with regulating nuclear power today or with military programs.

That type of publicity takes a toll, and it is for that reason that it is important, to the extent that any of us can do anything about it, that the decisions reached in the legislatures, the courts, and the compensation boards, to the extent possible, comport with good science and with good law.

We do have an energy problem in this country, and we have an ongoing debate on nuclear power. There are questions, obviously beyond the scope of this hearing, which are going to have to be answered. To the extent that we allow misinformation about the health hazards of low-level radiation to escape from this issue, to come out of these cases, we are prejudicing that debate, possibly to all of our detriment.

There are other issues where there is what I would call an adverse public education effect. I think the statistics would indicate that by far today the largest exposures to ionizing radiation are through medical exposures. Routine and nonroutine diagnostic medical procedures involve exposure to ionizing radiation, sometimes in levels higher than what we consider to be permissible in an occupational setting. With the current misunderstanding, with the current lack of knowledge, with the current credibility that, unfortunately, is being given to some of the experts who offer simplistic solutions, we could very well be getting to a point where physicians will forego valuable diagnostic x ray and other procedures for fear of lawsuits.

I think that these considerations are important. It is difficult. There are simple solutions to this, but I think this committee has already demonstrated that it is not looking for the simple solution. We owe everyone the best and clearest education we can give on the relationship between low-level ionizing radiation exposure and cancer.

There are problems for the industries who use ionizing radiation exposure. Right now, we lawyers who are involved in the issue do not know what the ground rules are. As you indicated in your opening statement, we really cannot advise our clients, nor can plaintiffs' attorneys. The result of that, I think, is that we have no way of dealing with the costs that are involved. I do not know how, perhaps Mr. Marrone will state later, the insurance company sets premiums. We really cannot, under the present system, make an evaluation of just what the risks are, what the probabilities are of winning or losing lawsuits.

Unfortunately, the returns that are coming in—at least in the cases that I am looking at, largely from the workers' comp boards but also from the courts—are not very promising. I think this area is a very apt illustration of the truism we all heard in law school that bad cases make bad law. That is what I think is happening. I think the Allen decision, which is obviously a case a lot of time and attention was put into by all parties, involved a 400-and-some-page opinion, a prodigious effort on the part of the judge, reached a
result which cannot be reconciled with traditional tort law concepts. I suppose the validity of that statement ultimately will be determined by the court of appeals.

But the broader concern there is that this decision offers no predictability, either to future claimants in that case or future claimants in other cases. Again, we have had the largest radiation injury case tried in the United States, one of which all sides expended prodigious amounts of resources, the trial judge did a very thorough job, and we really do not know what rules are to be applied or what the result is going to be in the next case. That is a serious problem.

The workers' compensation decisions, the results are even more disturbing. In part, this is because the workers' compensation boards are not geared up to deal with these problems. The cases are tremendously complex to present, if they are presented properly. There are tremendous transactional costs, which are my fees. I may be talking myself out of a job, but I think expending this kind of effort in these cases, if they begin to come in large numbers, is going to topple the system. I do not think the system can stand it. These workers' compensation boards are set up primarily to deal with occupational injuries. They are high-volume courts, designed to obtain fairly quick results.

As an example of the kind of problems that you get, I will mention one worker's compensation decision, the case of Hughes v. Berkeley Laboratories in California, which is mentioned in my paper. There, the court made the statement—which was given, unfortunately, by one of the experts—that the issue was not whether the radiation caused the cancer but how much of the cancer did the radiation cause. My medical colleagues tell me, that is absolute hogwash. The results of that from a legal point of view, if that decision is upheld in California and adopted elsewhere, is that basically you will wind up paying—the utilities and other groups which wind up with low-level radiation exposures to their employees will wind up paying for every case of cancer that is contracted by their employees. That is a form of health insurance; and if that is what we are going to do, we ought to call it that.

It is this kind of publicity, and it is this kind of misstating of the scientific evidence that I think is doing a grave disservice, really, to everyone. I think the problems are going to get worse as the volume of the cases increases. What we see happening because of the volume problem is both the courts and the compensation boards are exhibiting a tendency to give undue credence to those witnesses who offer a simple yes or no answer. Both in the Allen case and the in the Hughes case and in the other cases, we see references not to learned treaties but to a book that was put out by one of the expert witnesses, John Gofman, who appears with great frequency in these cases, published by the Sierra Club and subjected, as I understand it, to no peer review whatsoever.

With respect to the use of the tables, I do feel that there is promise in the tables. I have to leave it to others to state precisely how the tables should be used, what their limitations are, and the like. But I have, I suppose, three basic observations, which relate both to S. 921 and to how the tables might be used in future proposed legislation.
No. 1, I feel that it would be a grave mistake to legislate these tables into the tort law. The probability of causation approach has been used in tort cases. It has also been misused. I think that the courts are going to have to sort out the rules and the circumstances under which these tables or other such tables can be used or are admissible in those cases. I really do not think that in an effort to deal with the situation of the downwind people or others, we should do anything which could, even arguably, be construed as changing the tort law. We would be wreaking havoc in a general system in order to deal with a particular problem.

My recommendation would be that if the tables are to be used, they be used in connection with an administrative type of remedy that is limited to the problem at hand.

Second, I would suggest that there is a danger. I believe that the tables do have a use. I believe it is a limited use. I think we get into trouble when we try to legislate global solutions. The problems of the individuals who resided downwind from the Nevada test site are different from the problems raised by the uranium miners. It is also different from the problems raised by agent orange and Love Canal and people exposed to other toxic substances.

I think there has been an unfortunate tendency to look for the simple panacea-type solution in an attempt to design systems—and I am not necessarily speaking about this committee but other proposals that have been suggested—to try to deal with all these problems with a single stroke. I do not think it can be done, and I think there is a real danger, because of the lack of precedent in this area, that if it is not made clear when the remedies, if any, are enacted that they are designed to deal with a single situation and that situation only and are not to be construed as precedent, we are going to find that they are being construed as precedent and perhaps applied in situations where they should not be applied.

I applaud the committee in its turning to science to look for answers to these problems, but I think it is important to allow full peer review of the scientific method, and it is vitally important to understand the limitations that are inherent in these doctrines. If we use science to deal with what may well be a social problem, we should say that, we should say what the limitations are. As I say, and as Dr. Rall alluded to, there are alternatives to the tables being promulgated by Drs. Stewart, Gofman, and other people. I think it is in part incumbent upon congressional committees that turn to the tables and use the tables, unless it is made clear exactly how the tables can be used and, more importantly, what their limitations are, there is a real danger that the courts will then turn to less scientific tables or adopt these tables and use them in situations in which they were not designed to be used and should not be used.

Thank you, Mr. Chairman.

[Information supplied by Mr. Schaffer follows:]
Medical/Legal Aspects of Claims of Radiation Induced Cancer

University of Pennsylvania School of Medicine
Philadelphia, Pennsylvania

September, 1984

Claims for Illness or Injury
Arising from Exposure to Low Level Ionizing Radiation:
An Overview

by

William Gray Schaffer
Schaffer, Brown, & Cooper
Washington, D.C.

I. Background

As the anti-nuclear movement has gained strength, so has
the media attention given claims alleging injury from occupational
radiation exposures. Today issues relating to nuclear energy,
whether technical, financial, or legal, receive prominent press
coverage. Unfortunately, this coverage tends to pander to the
anti-nuclear mentality which, in many instances, is the only
reason that the events are considered newsworthy in the first
place.

Two examples illustrate the nature of this publicity:
First, in 1979, nearly one thousand residents of the states
of Utah, Arizona, and Nevada filed a lawsuit in which they claimed
that they or their deceased relatives contracted various forms
of cancer as a result of exposure to radioactive fallout from
the atmospheric weapons testing program in the 1950s. Both
the filing of the case and subsequent pre-trial developments
were widely reported in the national press. The size of the
lawsuit, as well as the historical significance of many of the
events at issue therein, did warrant media attention even in
the absence of the nuclear issues. The nuclear issues, however,
were what captured the attention of the press. In September
1982, Newsweek magazine described the impending trial as "the
litigation of the century," and stated that the case "[was]
sure to raise questions about the safety of current military
and commercial nuclear programs and about the credibility of
the government agencies responsible for them." The lawsuit
of course had nothing to do with either current military or
commercial nuclear programs. Unfortunately, however, the focus of the article illustrates the extent to which the familiar mushroom cloud still dominates the public perception of nuclear power.

The second example involves two Canadian nuclear workers who were awarded compensation for cancer under the Canadian Workers' Compensation program. A front page story in the Washington Post stressed the fact that the men's exposures were below the applicable occupational exposure limits for U.S. workers. The statement was correct but entirely misleading. The first worker had been employed in the nuclear industry for 28 years and had received a cumulative exposure of over 100 rem. The second worker had spent 31 years in the industry and had accumulated an occupational exposure of between 100 and 150 rem. Neither individual had ever been exposed to more than 5 rem per year. Thus, while the statement was technically correct, the men had each accumulated unusually high exposures which often approached the maximum permissible annual exposures, and were thus far from typical workers. The implication of the article that their cases in some way called into question the validity of the U.S. occupational protection standards was totally unwarranted.

The result of this type of publicity is to increase the number of lawsuits for two reasons: The first relates to the increasing tendency in our society to seek to blame someone for everything which happens to us. In the Utah litigation, for example, the claimants were asked during pretrial discovery whether they felt that the government was responsible for their (or their deceased relative's) cancer, and if so, why? Almost uniformly, the response was to the effect that there was no other reason why the claimant should have contracted cancer. The possibility that the illness had occurred without the intervention of a human agent was simply not considered. Publicity such as that described above is suggests to present and future cancer victims an explanation of why they contracted cancer.

The second reason relates to the legal system and to the manner in which legal services are marketed. Personal injury claims are usually brought under contingent fee arrangements, i.e., arrangements wherein the lawyer receives a fee only if his client is successful. The result of this system has generally been to deter the filing of complex lawsuits, unless the recoverable damages were substantial and there was a good likelihood of success. Most lawyers were and remain unwilling to devote several years of their practice and to advance substantial litigation costs unless the the chances of success and size of the potential payout justified the risk. Until recently, radiation injury cases were not perceived to meet these requirements, and hence few attorneys were willing to invest the time and effort necessary to effectively litigate them. The effect of the increased publicity has been to encourage the filing of suits, in that it has tended to create an impression that the cases are winners, and that there are other attorneys who are experienced in the field to
whom the neophyte can turn for assistance. In addition, the extensive media coverage of these cases provides added inducement for an attorney to accept a radiation injury claim in potential publicity for the attorney and his firm. The costs of bringing the cases are lowered, and the apparent chances of success and the potential rewards are increased.

Although it is difficult to estimate the actual number of claims pending at present, the increasing trend is demonstrated by reference to the claims experience of the nuclear insurance pools. In the first twenty years of the pools' experience, and prior to the accident involving Three Mile Island Unit Two (TMI), thirty nine incidents were reported, of which twenty eight resulted in covered claims. In the five and one half years following the TMI accident, seventy additional incidents were reported. The reporting rate thus increased from approximately one and one-half claims per year to an average of one claim per month since TMI.

It is also interesting to note that in the claims tracked by the pools, the average recorded exposure of workers filing radiation injury claims is less than three rem.

At the present time, most of the pending claims involve exposures sustained in an occupational setting. (The only significant exception is the Utah litigation mentioned earlier and described more fully below.) The experience with the occupational cases, provides guidance for medical, offsite, or other types of claims which are likely to arise in the future.

In order to understand recent developments in this area it is necessary to review briefly the two basic systems through which individuals may seek compensation for occupational injuries or illnesses. The primary means by which an injured employee seeks compensation from his employer is through workers compensation programs. Workers compensation statutes have been enacted to protect virtually all workers in the United States in the event of an injury or illness sustained in the course of their employment. The goal of these systems is to provide reasonably certain benefits, inexpensively and expeditiously. The amount of compensation provided under these statutes is set forth in published schedules, and is generally well below the amount of damages which a similar injury or condition might generate in a lawsuit; the workers compensation plans dispense with any requirement of proving negligence or fault on the part of the employer; certain defenses otherwise available to the employer are abolished; and the claims, if contested, are tried before an administrative tribunal rather than a court of law. In virtually all workers' compensation systems, the relief provided to the injured employee is the "exclusive remedy" available to the employee against his employer.

Where the employee contends that his injury or illness is the fault of someone other than his own employer, he or she
may seek damages in a common law "tort" lawsuit. Unlike the workers compensation system, the injured party (the plaintiff) in a tort suit generally must prove negligence or some other form of misconduct on the part of the party he contends is responsible for his injury (the defendant), in a court of law. Notwithstanding the stricter standards of proof, delays, and uncertainties, the tort action is deemed advantageous to the injured party because it permits him to recover far more generous damages than the benefits available to him under workers compensation. For this reason, it is not uncommon, in cases of serious occupational injuries or illness, for the injured party to seek both compensation benefits from his employer and tort damages from some third party, such as an independent contractor, a manufacturer of a component or tool in use at the place of employment, or some other entity involved in the workplace environment or the activity the plaintiff alleges to be the cause of his injuries or illness.

Common to both the workers compensation and tort systems is the requirement that the claimant demonstrate a causal relationship between his injury or illness on the one hand, and his employment, in a compensation claim, or the negligence or other misconduct of the defendant, in a tort suit, on the other. In workers' compensation this requirement is generally stated in terms of demonstrating that the injury be "work related," or that it be sustained "in the course and scope of employment." Or some similar language usually found in the statute. In a tort case, the requirement is that the plaintiff must prove that the defendant's misconduct was the "proximate cause" of the injury. "Proximate cause" is generally defined in one of two ways: The definition most commonly used is known as the "but for" test, in which the plaintiff must prove that his injury would not have occurred but for the defendant's misconduct. In the alternative, in situations in which there are multiple causes of a particular injury, proximate cause may be established by proving that the defendant's conduct was a "substantial factor" or "material factor" in causing the injury. In both systems, the burden of establishing this causal relationship is initially on the claimant or plaintiff; and if he is unable to sustain this burden, relief is denied.

Thus, although the terminology is different in the two systems, a moment's reflection makes it clear that at least in the situation with which we are presently concerned, i.e. radiation injuries, the issue is identical. Consider, for example, the situation in which a worker receives a low level radiation exposure in the course of his employment at a nuclear facility. Assume that ten years later the same individual is diagnosed as having leukemia. The individual (or his widow after his death) files a claim for workers' compensation, alleging that his leukemia was "work related." If his leukemia was in fact caused by the exposure he received while at work, it is "work related" and he should recover benefits; if his leukemia was caused by exposure to some other potential carcinogen, or if it was a "naturally occurring" leukemia (assuming that the two are different) he
should not recover.

The difficulty, of course, is that a radiation induced leukemia is clinically indistinguishable from a naturally occurring illness or one caused by exposure to another carcinogen. If the worker were able to establish that his leukemia was "work related," he would establish proximate causation in the tort sense; if he were able to prove that his leukemia was "proximately caused" by his occupational radiation exposure, he would also establish that it was "work related." Proof of causation, whether stated in the terminology of workers' compensation or of tort law, is equally impossible, and therein lies the problem.

II. Recent Developments

As radiation injury cases first began to appear before compensation boards and courts, the cases were not widely reported. The few reported judicial opinions found little difficulty with denying recovery based on the improbability of establishing causation. Workers' compensation tribunals would often sidestep the causation issue in cases they deemed sympathetic by accepting the "opinions" of medical doctors as to whether a given cancer was, or was not, related to an occupational exposure.

Recently, however, as the number of claims and the publicity which they are accorded have increased, the courts and compensation boards are being forced to confront the problem. Given the current climate of public opinion and general lack of knowledge regarding radiation risks, as well as the unfortunate juxtaposition of a cancer victim or his survivors against a perceived to be wealthy nuclear utility or insurance carrier, it is unrealistic to expect judges, jurors, and those charged with administering workers compensation programs to deny recovery based on the "technical" impossibility of proving causation. Within the past several years we have witnessed increasing efforts on the part of these institutions to stretch the law, the facts, or both, in an effort to provide compensation for individuals claiming injuries or illnesses resulting from radiation exposure. The result has been a series of decisions which cannot be reconciled with either science or legal precedent. Although the outcome of these cases is distressing, the disregard for established norms of adjudication and the resultant decline in predictability of outcome portends grave consequences, not only for the nuclear industry but also for other industries involved with potentially toxic substances.

The following four cases illustrate the lengths to which claims agencies and courts have gone to distort fact, science, and sound and well established precedent in their efforts to award compensation or damages in these cases. The first two cases are taken from the files of the Veterans Administration (V.A.), which administers benefit programs for former members of the U.S military forces. These benefit programs operate in essentially the same manner as the workers' compensation programs.
described earlier. During the weapons testing program of the 1950s and early 1960s, a number of simulated military maneuvers were conducted immediately following the detonation of nuclear weapons. In addition, military personnel were heavily involved in the testing of nuclear weapons in the Pacific Test Site. In the late 1970's, the V.A. was increasingly confronted with claims by former participants in such programs claiming that their radiation exposure during service had caused them to develop cancer and a number of other diseases. In 1981, for example, the agency reported 114 active radiation injury claims, of which over 50% involved various forms of cancer. In addition, as the number of such claims increased and became the subject of increasing pressure from constituents, a number of prominent Members of the Senate and House of Representatives began publically expressing concern with the manner in which the V.A. was handling these claims, and with what they believed to be an excessive number of claims which were being denied.

During one 1982 congressional hearing, Veterans Administration officials testified that they had awarded benefits to 16 former participants in the military weapons tests, and subsequently made public copies of its opinions in 12 of the 16 cases. Although the V.A. was being criticized for the claims it had denied, the opinions in the few cases in which it had awarded benefits were profoundly disturbing. In not one of the 12 cases did the total recorded cumulative exposure exceed 5 rem; indeed, most involved exposures of less than one rem. While the minimal exposures in these cases were disturbing, the reasoning of the Board of Veterans Appeals supporting their decisions is appalling. Two examples illustrate the point:

The first case involves a veteran (D.E.C.) who was present at the Nevada Test Site for two months during the 1957 test series. His recorded exposure was 655 mr. gamma and 84 mr. beta. In 1976, he was diagnosed as having hairy cell leukemia. In finding that his illness was "service related," the Board explained as follows:

The issues before us involves the question of whether hairy cell leukemia was caused in part by exposure to ionizing radiation in service... To this date... hairy cell leukemia has not been statistically associated with exposure to radiation... The apparent absence of this disease in the literature of radiation associated illnesses does not rule out the possibility of such relationship. It may be the case, then, that hairy cell leukemia, like some other leukemias, can be induced exclusively or in part by ionizing radiation. The appellant was exposed to an indeterminate amount of ionizing radiation during the atomic bomb testing in 1957. While participating in these tests he suffered an unexplained nose bleed and a bout of prostatitis. He was subsequently found to have a bleeding tendency on a dental examination. We may
never be able to determine with certainty what relationship, if any, the radiation bore to the leukemia. But from a legal standpoint, the circumstances of his case raise a reasonable doubt that his exposure to radiation, and such other unknown factors as may have occurred before or after service, resulted in hairy cell leukemia. We cannot exclude radiation as a reasonably probable factor.

As noted earlier, this individual's exposure records indicated a cumulative exposure of 655 mr. gamma and 84 mr. beta. For reasons which remain unclear, the Board decided to ignore the records and to characterize the exposure as "indeterminate." The Board's reasoning on causation appears to be that since radiation cannot be excluded as a possible cause of this form of leukemia (even though there is absolutely no evidence to suggest that it may be radiation related), it will be treated as if it is in fact the cause.

The second case involves a veteran (O.E.K.) who was exposed to 3.4 mr. gamma radiation while a participant in the Pacific test series. He subsequently developed malignant lymphoma. The Board's Opinion quotes extensively from the testimony of John Gofman and Alice Stewart, (who are now appearing with great regularity in our radiation injury litigation), and concludes as follows:

The experts whose opinions are of record propose various estimates of the probability that the veteran's malignancy was caused by his radiation exposure. These risk estimates range from one in three to one in one hundred.

* * * *

An assumption common to most of the opinions is that the veteran's malignancy was a lymphoma. ... It may have been a leukemia. It is generally agreed that leukemia is more susceptible to radiogenesis than lymphoma. The exact degree of difference is unknown, but radiogenic leukemias would be expected to outnumber radiogenic lymphomas by at the very least four to one. Therefore the various risk estimates should be increased by an appropriate factor.

* * * *

The expert opinions of record do not dispute the possibility that radiation caused the veteran's disease; rather it is the degree of probability that is in question. The experts' estimates of this probability vary from 1 in 100 to 1 in 3. ... From a legal standpoint, the circumstances of his case raise a reasonable doubt that his exposure to radiation was a probable factor in the development of the malignancy.
The Board thus relied heavily on the testimony of Drs. Gofman and Stewart, disregarding the reports of the other experts; ignored the film badge readings, and characterized the exposure as "indeterminate" because of the absence of data as to internal exposure; assumed that the illness was one other than that reflected in the official diagnosis; and found no significance between a 12 probability and a 33% probability, in order to reach the conclusion that radiation exposure was "a probable factor in the development of the malignancy."

After reading these two opinions, one is left with the conclusion that such reasoning would support a finding of causation in any case. Fortunately, the opinions of the Board of Veterans Appeals are not considered as precedent, even by the Board itself. Nevertheless, the V.A., because of its status as an agency of the federal government, has recourse to some of the nation's foremost scientific institutions, such as the National Academy of Sciences, the National Cancer Institute, the Armed Forces Institute of Pathology, and others, for assistance in these cases. In view of the availability of these resources, which are not as readily available, if at all, to the many state and other bodies adjudicating workers' compensation claims, the disregard of scientific evidence apparent in these V.A. opinions is all the more disturbing.

The next case is taken from the records of the Workers' Compensation Appeals Board of the State of California. In Lewis Hughes (deceased) v. Lawrence Berkeley Labs and State Compensation Insurance Fund (No. 80-53-76443), Mr. Hughes' widow claimed that his death from malignant lymphoma was caused by his exposure to ionizing radiation at the Lawrence Livermore Laboratory. Mr. Hughes had been employed at Livermore as a health physicist from 1956 through 1965. During the course of his employment, according to laboratory records, Mr. Hughes accumulated an exposure of 8.57 rem of whole body ionizing radiation. In 1978, at age fifty, and thirteen years after leaving the laboratory, Mr. Hughes was diagnosed as having malignant lymphoma, from which he died in December, 1979.

The issue was whether the illness was "work related" i.e., was his lymphoma caused by Mr. Hughes' exposure to ionizing radiation in the course of his employment at the laboratory. The principal witness for the laboratory (the employer) was Marvin Goldman, PhD, Director of the University of California Laboratory for Energy Related Health Research. Dr. Goldman testified that the probability that Mr. Hughes' illness was caused by his radiation exposure "ranged from a high of about 1% to about .1%.

The claimant's principal witness was again the ubiquitous Jon Gofman. Although Dr. Gofman used similar mathematical calculations as those used by Dr. Goldman, he managed to delete the term "probability" from his analysis, through a remarkable exercise in semantic legerdemain, so that the issue was framed
in terms of the "fraction of causation to be assigned to radiation." In a paragraph adopted in toto by the Appeals Board, Dr Gofman explained:

It is not correct to ask the question, "was this particular case caused by radiation, or was it not?" Since in any particular case, we can only know the total causal factors, spontaneous plus known carcinogens, the only correct approach is to assign fractional causations to spontaneous and to known carcinogens, if such exist in the history of the individual. Mr. Hughes was definitely exposed to ionizing radiation in the course of his employment at Livermore Lawrence (sic) National Laboratory. Therefore we must assign some fractional causation of his malignant lymphoma and death thereof to the ionizing radiation exposure received. The only question is what fraction must be so assigned.

In addition, Dr. Gofman took issue with the 8.57 rem cumulative exposure set forth in laboratory records, and testified that in his opinion the film badge readings on which the laboratory records were based were the "absolute minimum" exposure which Mr. Hughes received. Based on this exposure, Dr. Gofman calculated that "at the absolute minimum, we must say that radiation incurred in the course of occupation at Lawrence Laboratory is responsible for 7.8% of the causation of the malignant lymphoma in Mr. Hughes." Dr. Gofman also performed calculations based on the assumption that Mr. Hughes exposures were twice and three times the recorded exposure, and ultimately concluded that "the most medically probable contribution to decedent's death as a result of his radiation exposure was 35.6%." Based on this percentage, Dr. Gofman concluded that Mr. Hughes life "was shortened by 4.1 years," as a result of his occupational radiation exposure.

Although the judge who originally heard the evidence accepted the findings of Dr. Goldman, and ruled that "...the radiation exposure claimed herein is so relatively minute as to not fit the definition of proximate cause," the Appeals Board adopted the testimony of Dr. Gofman and reversed the decision. The Appeals Board reasoned as follows:

If we look for a causal connection between the employment and the injury, such connection need not be the sole cause; it is sufficient if it is a contributory cause... Reasonable probability of industrial causation is all that applicant need prove, and the causal mechanism by which decedent's lymphoma arose need not be proved in detail. ... In our view, the evidence justifies concluding that it is reasonably probable that applicant's occupational radiation exposure was a contributing cause to his developing lymphoma.

The Board's statement of the applicable law is generally correct. If the employee can establish that his employment contrib-
uted in any way to the development of an illness, the employee should recover. It would not matter whether that contribution was 35%, as estimated Dr. Gofman, or 1%, as estimated by Dr. Gold-
man, as the Board itself recognized. Dr. Gofman's further statement that Mr. Hughes' life expectancy was reduced by 4.1 years makes it clear, to the extent clarification is necessary, that the Board correctly interpreted Dr. Gofman's testimony.

Thus, through the seemingly innocuous change in terminology from probability of causation to fraction of causation, Dr. Gofman has created a situation, at least in the state of California, in which any claimant with a documented history of radiation exposure, who suffers from a cancer which has been stastically associated with radiation, will be entitled to recover workers compensation benefits. Since current cancer incidence data in the United States suggests that approximately 30% of all Americans will experience cancer during their lifetimes, adoption of the Gofman approach, by other jurisdictions, would suggest that nuclear utilities and their insurers, as well as other industries in which employees may be exposed to ionizing radiation, will be paying worker's compensation benefits for cancer to approximately 30% of their employees.

The fourth and final case is Irene H. Allen, et. al. v. the United States of America, Civil Action No. C79-0515 (United States District Court, Central District of Utah, 1984). The Allen case is the lawsuit, mentioned previously, brought by individuals who resided downwind of the Nevada Test Site during the atmospheric nuclear weapons testing, who claimed that they, or deceased family members, contracted cancer as a result of exposure to radioactive fallout from the weapons tests. The case was obviously not an occupational exposure case. It is selected for discussion, however, because the measured and calculated exposures to the downwind residents were not dissimilar from the exposures typically presented in the occupational injury cases, and therefore present similar issues of causation. In addition, because of the number of different types of cancer involved, and the careful and thorough consideration given by the trial judge to these issues, it will undoubtedly be looked to by other courts confronted with these issues.

The Allen case involved over 1,000 individual claimants. They, or the deceased relatives through whom they were claiming, each had individual medical histories, and were exposed to varying amounts of radiation, under different circumstances, over a number of years. The cases warranted individualized attention, yet it would clearly be impractical to do so. In an effort to resolve common issues of law and fact, and to provide some guidelines for the resolution of other claims, the parties agreed to select a number of "bellweather" cases, which would provide a fair representation of the diseases involved, though not necessarily the conditions of exposure, age of the individual or other relevant factors. At the time the "bellweather" cases were selected, neither the plaintiffs' attorneys nor the defendants
had investigated in any appreciable detail the medical records or other individualized information. Thus, although the cases were not selected arbitrarily, neither were they necessarily representative of anything other than the indicated diagnosis.

By the time of trial, there were twenty-four such cases, eight of which involved various forms of leukemia, and sixteen of which involved solid tumors. The calculated internal organ doses ranged from 250 mr, in the case of a woman who had died from ovarian cancer, to 31 rad, in the case of a woman who suffered from thyroid cancer. (With the exception of the thyroid cancer, the next highest dose to an internal organ was 3.7 rad to the kidney. There was also a claim for skin cancer in which the dose to the skin was calculated to be 310 rad.) The plaintiffs, not surprisingly, disputed the governments calculation of the organ doses, primarily through the testimony of Dr. Jon Gofman. With the exception of the thyroid and skin doses, however, even Dr. Gofman's calculations did not result in excessive doses, particularly since the exposures, in most instances, occurred over a number of years. Using Dr. Gofman's figures, the organ doses ranged from 8.1 rad, in the case of a child afflicted with leukemia, to 36.7 rad, which interestingly was the dose he calculated for eight of the twenty four cases, all involving different cancer sites.

The court's opinion on the causation question spans ninety pages, and is worthwhile, and indeed essential, reading for anyone involved in these claims. It is beyond the scope of this paper to summarize the court's reasoning, and to discuss the many authorities cited therein. Accordingly, the following discussion is limited to a description of the causation problem as it manifested itself in the Allen case, the rule which the court established for determining eligibility, and the application of that rule to the twenty four cases pending before it.

From the outset of the case, the trial judge made it clear that he understood the difficulties surrounding the causation issues. Moreover, since the plaintiffs' lawyers had endeavored to include most, if not all, cases of cancer among the people who resided in the downwind area during the time of the tests, and since fallout clearly would not have caused all the cancer in the area, the judge was aware from the outset that if he awarded damages to any plaintiffs, he would be required to pick and choose among them. The all or nothing solution in the typical single claimant case was clearly out of the question.

To begin, the court recognized that direct proof of causation was impossible.

The intrinsic nature of the alleged injury itself thus restricts the ability of the plaintiffs to demonstrate through evidence a direct cause-in-fact relationship between radiation from any source and their own cancers or leukemias. At least within the scope of our present
knowledge, the injury is not specifically traceable to the asserted cause on an injury by injury basis.

* * *

This does not, however, end the inquiry. That the courts cannot now peer into the damaged cells of a plaintiff to determine that the cancer or leukemia was radiation-induced does not mean (1) that the damage was not in fact caused by radiation; (2) that the radiation damage involved did not result from the defendant’s conduct; or (3) that a satisfactory factual connection can never be established between plaintiff’s injury and defendant’s conduct for purposes of determining liability. Experience and the evidence in the record indicate that indeed it can.

* * *

Following an exhaustive analysis of a number of tort cases and published workers’ compensation decisions, the court set forth the rule by which he intended to determine eligibility among the twenty-four plaintiffs:

A remedial framework can certainly be fashioned to meet the circumstances and requirements of the parties and issues not before this court in this action. To that end, this court now holds as follows:

Where a defendant who negligently creates a radiological hazard which puts an identifiable population group at increased risk, and a member of that group develops a biological condition which is consistent with having been caused by the hazard to which he has been negligently subjected, such consistency having been demonstrated by substantial, appropriate, persuasive and connecting factors, a fact finder may reasonably conclude that the hazard caused the condition absent persuasive proof to the contrary offered by the defendant.

In this case, such factors shall include among others: (1) the probability that plaintiff was exposed to ionizing radiation due to nuclear fallout from atmospheric testing at the Nevada Test Site at rates in excess of natural radiation; (2) that plaintiff’s injury is of a type consistent with those known to be caused by exposure to radiation; and (3) that plaintiff resided in geographic proximaty to the Nevada Test Site for some time between 1951 and 1962. Other factual connections may include but are not limited to such things as time and extent of exposure to fallout, radiation sensitivity factors such as age or special sensitivities of the afflicted organ or tissue, retroactive internal or external dose estimation by current researchers.
a latency period consistent with a radiation etiology, or an observed statistical incidence of the alleged injury greater than the expected incidence in the population.

Essentially, the court eliminated the requirement of proving causation in fact, and substituted therefor the requirement of demonstrating a "consistency" between the risk created by the defendant's conduct and the injury suffered by the plaintiff. Where this "consistency" is established, the burden of proof is shifted to the defendant, who then is required to rebut the inference of causation. In explaining these rather radical departures from traditional requirements of proof, the court stated:

Whether the defendant is ultimately held responsible for an injury which may likely have occurred anyway is inherently a question of policy, not of factual connection or causation.

* * * *

In cases where, as here, defendant's duty extends to protection of plaintiff from even the possibility of harm, or where, as here, defendant's wrongful conduct arguably has denied to plaintiff a potential opportunity to avoid serious or lethal injury, analysis using "but for" tests in any form falls far short of the mark.

In short, the judge in much of his opinion speaks in language which would be arguably appropriate for a legislator, whose responsibility is to create law, but not for a judge, whose responsibility is to apply existing law to the factual situations before him. The conclusions reached by the judge simply cannot be reconciled with existing legal doctrine.

In addition, even as a legislative of policy decision, the court's opinion is deficient in that it provides no basis for predicting the outcome of future cases. Of the ten cases in which the court awarded damages, four involved children, who died of leukemia, and whose highest estimated cumulative exposures ranged from 8.1 rad to 14.2 rad. Since there was nothing to distinguish these four cases from other childhood leukemia cases, one might predict that the court would be inclined to award compensation in all childhood leukemia cases. While the childhood cases are emotionally compelling, and the result is not surprising, the precedent is a disturbing one in view of the relatively low exposures. The court also awarded damages in the cases of four adults who died of leukemia, and whose highest estimated cumulative exposures were in the range of 18 rems. Again, there is nothing to distinguish these four cases in terms of causation from the numerous other claims involving adult leukemia. Particularly in view of the normal incidence of leukemia in adults, this decision, if read as an indicating
a disposition to compensate all such claims in the Allen litigation, is profoundly disturbing.

The remaining two cases in which recovery was awarded were aberrational: The first involved thyroid cancer of a woman who was exposed in early childhood and consumed large quantities of dairy milk, which was believed to contain large amounts of radioactive iodine. The second case involved a woman who was exposed during puberty, and died of breast cancer in her early thirties. Thus, the court's opinion offers little, if any guidance, to other claimants in cases involving these two tumors.

In the remaining fourteen cases, all involving solid tumors, the court denied recovery. In a number of instances, the denial was premised on the lack of a demonstrable relationship between the type of tumor and ionizing radiation. In other cases involving these tumors, the court presumably will be disposed to deny recovery as well. In others, however, the decisions may have been based on factors which were idiosyncratic to the particular "bellweather" case. As to the tumors involved in such cases, there is little guidance to other plaintiffs.

In summary, as mentioned earlier, the court decided only twenty-four cases; there are hundreds of claims in the Allen case still outstanding. The court's decision offers little, if any, guidance for those claimants, nor for claimants in future radiation injury cases. Thus, in the largest radiation injury case tried to date, the court was unable to resolve the claims within the confines of the existing law. Its efforts to establish a rational basis for deciding claims, even without regard to traditional limits of judicial authority, failed to establish a rational basis for determining eligibility for compensation in future cases.

III. Conclusion

Notwithstanding an increased number of radiation injury claims pending before workers' compensation boards and courts in the United States, there has been no satisfactory resolution of the problem of proving causation, which is inherent in every occupational injury claim alleging exposure to low level ionizing radiation. The obvious difficulty of the courts and other agencies which must decide these cases, has led them to give undue credence to those scientists and other "expert" witnesses who claim to offer simple, straightforward, and unequivocal opinions on causation, in complete disregard of the scientific evidence. The decisions which have resulted form this situation, have created a body of profoundly disturbing precedent, which compounds the already substantial burdens confronting lawyers involved in these cases.
The CHAIRMAN. Thank you, Mr. Schaffer. We appreciate your testimony. You have raised an awful lot of the issues involved here.

As an attorney who is familiar with these matters and has litigated in this area, do you think that the uncertainties that attend the science of radioepidemiology, and therefore must attend any tables that can now be developed, are sufficiently limited so that probability tables might reasonably be used as the basis for a legal determination of causality in radiogenic cancer cases?

Mr. Schaffer. I am more comfortable with that in an administrative or worker's compensation type setting than I am in the tort law, in which we are trying to answer the question of causation in fact. In worker's compensation setting, in an administrative scheme which is set up to make eligibility determinations in what is legislatively recognized to be a problem, we are, to some extent, engaged in social engineering. I think that as long as we understand what the limitations and the uncertainties are, we can tolerate them, we can deal with them.

As I stated before, I am less comfortable with that in a tort setting, because I think in a tort setting we are attempting to answer factual questions. I just do not know at this point whether the tables have that kind of accuracy.

The CHAIRMAN. There really is a real difference between workmen's compensation hearings and regular tort cases that are brought, I have to acknowledge that. But without some sort of a guide in the manner of Dr. Rall's report, do you think that the courts in tort cases, assuming that they may be utilized there—and I am not sure that is the best way to handle the downwind problems—do you think that the courts can make competent assessments of the evidence that may be presented in radiogenic cancer cases without some sort of scientific guide or guidelines like these tables may represent?

Mr. Schaffer. I think the courts can make judgments, but it is very difficult to quantify them. As you know very well, the standard in a tort case is whether it is more probable than not. We equate that to a 51-percent probability.

The CHAIRMAN. You see, I am talking about changing that from a probability of risk standard between 10 and 50 percent.

Mr. Schaffer. I have grave problems with that in a tort setting, because I think it creates far more problems than it solves and it creates problems potentially across the board because courts can and will look to these things as precedent in other areas, and there are other areas where causation is a difficult question. As I say, I have less of a problem with that—I still personally have a problem with 10 percent—but I have less of a problem with the probabilistic approach and with putting numbers in the probabilistic approach in a worker's comp setting. We are dealing there in the worker's comp setting with a high volume of cases.

The CHAIRMAN. In the case of the downwind situation, it may be, but we have to use some sort of a modified legal approach that might come close to a workmen's compensation setting. For instance, we have proposed to have a probability of risk ratio between 10 and 50 percent, but we have also proposed a limit to total exposure to liability, because we can in no way be certain who actually contracted cancer as a result of atmospheric fallout. So we
do not want the damages to go beyond that which they should be for those who really contracted cancer. On the other hand, we do not want to fail to recognize that there might be some who might not be compensated if we do not have some reasonable approach to it, and if we use the more-probable-than-not standard tort approach.

Mr. Schaffer. I testified when I was with the Government before Congressman Eckhardt's committee. The issue in those hearings was, are the courts an appropriate place to litigate these cases, particularly the cases such as the downwind cases. I think Judge Jenkins' opinion demonstrates it: the courts are not a good place to litigate issues as are presented there. I think an approach similar to that which you have just described is difficult.

The Chairman. Let me give you an illustration. The only real opportunity we have to do anything this year—and it is fast fading in the last days of this session—may be the Micronesia compact. Now, we are willing to give $150 million in a trust fund for those who suffered from atmospheric testing in the Pacific islands but nothing for people who suffered within our own country. What if we set up a similar trust fund, with a limit of liability but nevertheless a recognition that there are some things that are wrong here? Would not these radioepidemiological tables be of some benefit to us? Not a total benefit—they cannot determine everything—but would they not be of some benefit in helping to resolve those cases within the context and framework and limitation of, say, a trust fund? Would that be an intelligent way to approach this?

Mr. Schaffer. I think the tables have a great potential for making eligibility determinations within a context such as that one.

The Chairman. Then you like that context?

Mr. Schaffer. In that context, yes. In the tort context, I have reservations.

The Chairman. I see you represent the defendants in these matters, and certainly they need representation, as do plaintiffs. You look at it, perhaps, through a defense attorney's eyes, and I respect that. But you have admitted that this may be an intelligent way of approaching this problem. I appreciate that, too, because I think your testimony is going to be very helpful to us as we chat with colleagues in the Senate and see what can be done in this particular area.

Let me just ask you this. Do you see any alternative to what the Rall committee and your own committee have been attempting that might help the courts to ease their current state of confusion over radiation liability? Or do you think this is the best we can do under the circumstances?

Mr. Schaffer. I do not see alternatives. I have been looking for them. I think again the problem is more acute. We are going to have more cases, and we are having more cases, with the exception of the Allen case, in the occupational setting. No, I am not aware of a better situation. I think the tenor of my remarks, at least what I intended to say, is that the courts and the boards are not doing a good job, in part because the lawyers are not giving them a great deal to work with.
In the context of causation-in-fact, we do not have an answer. In a worker's compensation setting, the question of a work relationship—where, as Dr. Rall said, if you have a large number of people exposed to enough radiation, you can predict there is going to be an impact. I think some guidance is called for in that setting. In the tort setting, a particular injury pointing a finger at a particular defendant, more of a one-on-one situation, as I said, I do not think it would be appropriate. I think it would be more appropriate to leave that up to the courts at this point. I must say that those of us engaged in the defense of these cases are using, not Dr. Rall's tables, but are using the methodology. That is the evidence that some of us, at least, are using to say: No, it is not probable; it is highly improbable.

The Chairman. Or that it is probable under these circumstances?

Mr. Schaffer. Or that in a given situation it is probable. And in those situations, cases have been settled, and the cases are settled based on an analysis of the same kinds of factors which go into the tables: amount of exposure, age, sex, the illness, and this sort of thing.

I guess my concern with the tables is that we should not oversimplify them. We should not create the impression that they are a "cookbook." But I do think, bottom line, that the methodology, once it is subject to peer review, once the fine tuning has been done, holds great promise. In answer to your question, I do not have anything better to propose.

The Chairman. Finally, after all this time, do you think I am right in continuing to pursue a remedy for those people who lived within the shadow of the Nevada tests? If so, do you think my idea of a trust fund and an administrative remedy is the appropriate way to resolve this problem, rather than a tort remedy?

Mr. Schaffer. Let me give you several answers to that, if I might. The trust fund idea is an interesting one. I am not sure that the Micronesia precedent is totally applicable, and it is what I alluded to earlier.

The Chairman. Well, not in the sense that they have to be identical. Maybe the funds may need to be identical; I do not know. That would depend on my colleagues and everything else. But in the sense that this may be an administrative way of resolving what really are difficult problems, and resolving issues where, in fact, the court has held the Government to have been negligent.

Mr. Schaffer. I think that you are correct. If what you are saying is that the way to deal with this problem is some sort of an administrative approach in the context of a trust fund, I would agree with that. The ultimate question, the way you initially phrased it, I do not think I have any standing to answer.

The Chairman. That is a political question: How can we get this through the Congress, assuming we can. Up until now, we have not had a basis to take it through the Congress in the eyes of some of our colleagues. With these tables developing as one of the aids or tools, there may be a basis for resolving this problem, at least in a reasonable way.

Mr. Schaffer. My own feeling is that I do have problems with Judge Jenkins' opinion, though I admire the work that went into
it. Even if the opinion is upheld, I think it does not really solve the
problem except as to the 24 cases that it dealt with.

The CHAIRMAN. I agree with you. It creates more problems in the
sense that there are no definitive legal guidelines to go by in future
cases.

Mr. Schaffer. I agree with that.

The CHAIRMAN. I want to thank you, because I think that your
testimony has been very straightforward here today. I think you
have been helpful to the committee. You certainly have, I think,
helped to make a case. Whether or not these tables are subject to
criticism, they at least are an appropriate way to go to try and re-
solve these very difficult problems. Perhaps an administrative reso-
lution of these problems is better than just an ad hoc tort claims
approach that sometimes is very just and sometimes very unjust. I
want to thank you for being here. We appreciate your being with
us today.

Mr. Schaffer. Thank you.

The CHAIRMAN. We will excuse you because I know you have a
heavy schedule. We will be happy to receive into the record any
additional comments you might have after these questions. I will
be happy, if you have any additional comments or additional infor-
mation you would like to submit to us.

Mr. Schaffer. Thank you very much.

The CHAIRMAN. Thank you very much, Mr. Schaffer. We appreci-
ate your being here.

Mr. Jablon, we will now turn to you. You have been a steady de-
voted witness before this committee. We appreciate it, and I think
you have added a great deal to our knowledge through the years.
We look forward to taking your testimony now.

STATEMENT OF SEYMOUR JABLOM, DIRECTOR OF MEDICAL
FOLLOWUP AGENCY, NATIONAL RESEARCH COUNCIL, NATION-
AL ACADEMY OF SCIENCES

Mr. Jablon. Thank you, Mr. Chairman. My name is Seymour
Jablon. I am a biostatistician. I am on the staff of the National Re-
search Council, where I am responsible for the Council’s participa-
tion in the work of the Radiation Effects Research Foundation in
Hiroshima and Nagasaki, Japan. I have myself spent 6 years in
residence in Hiroshima, studying the late effects of radiation on
the Japanese survivors of the atomic bombings. You may be inter-
ested to know, Mr. Chairman, also that I am a member of the Dose
Assessment Advisory Group, which is a Department of Energy
committee with oversight over the efforts that are being made to
establish doses for the offsite residents around the Nevada test site.
I am a member of the National Council on Radiation Protection &
Measurements, which is a not-for-profit corporation chartered by
the U.S. Congress in 1964, among other things to advise on radia-
tion protection practices. I am also a member of the NIH ad hoc
working group, which is chaired by Dr. Rall, but I am testifying
today primarily on behalf of Scientific Committee 71 of the NCRP.

As you are aware, Scientific Committee 71 on radiation exposure
and potentially related injury, under the chairmanship of Victor P.
Bond, has been evaluating the probability of causation methodolo-